

# Deep Brain Stimulation Overview

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# Deep Brain Stimulation:

# Indications and Ethical Applications

## Deep Brain Stimulation: A Pacemaker for the Brain

- ↳ Implanted electrode
- ↳ Connected to a pacemaker in the chest
- ↳ High-frequency electrical stimulation
- ↳ Deep structures involved in the control of movement
  - ↳ Ventral intermediate nucleus of the thalamus (Vim)
  - ↳ Subthalamic nucleus (STN)
  - ↳ Globus pallidus (GPi)
- ↳ Stimulation overrides abnormal neuronal activity to bring motor controlling circuits into a more normal state of function
- ↳ Reducing movement disorder symptoms



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## Approved Indications

- ↳ **Essential Tremor**
  - ↳ FDA approved in 1997
- ↳ **Parkinson's disease**
  - ↳ FDA approved in 2002
- ↳ **Dystonia**
  - ↳ FDA approved (HDE\*) in 2003
- ↳ **Obsessive Compulsive Disorder**
  - ↳ FDA approved (HDE\*) in 2009
- ↳ **Over 200,000 patients implanted worldwide**

\*Humanitarian Device: Authorized by Federal Law for the use as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and segmental dystonia, hemidystonia, and cervical dystonia, for individuals 7 years of age and older.

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## Parkinson's Disease

- ⌘ Second most common neurodegenerative disorder, affecting more than 1 million Americans
- ⌘ Progressive neurodegenerative disorder with the cardinal features of:
  - ⌘ Bradykinesia/akinesia
  - ⌘ Tremor
  - ⌘ Rigidity
  - ⌘ Postural instability

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## Patient Selection

- ⌘ As Parkinson's disease progresses, medications may fail to provide consistent and adequate symptom control
- ⌘ Medications used at levels required for symptom control may produce adverse effects
  - ⌘ Motor complications, such as dyskinesia
  - ⌘ Cognitive and psychiatric problems
  - ⌘ Nausea, hypotension, and other systemic effects

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## When Should DBS be Considered?

- ⌘ When, despite optimized pharmacotherapy, you experience troubling motor symptoms:
  - ⌘ Wearing off – Off periods that contain troubling bradykinesia, rigidity, tremor, and/or gait difficulty
  - ⌘ Troubling dyskinesia
  - ⌘ Motor fluctuations
  - ⌘ Refractory tremor

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## Exclusion Criteria

- ⊗ Atypical (non-idiopathic) parkinsonism
  - Multi System Atrophy, PSP
- ⊗ Lack of response to levodopa
- ⊗ Frank dementia, moderate to severe dementia

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## Goal Attainment

- ⊗ DBS treats the cardinal symptoms of PD
  - Tremor
  - Rigidity
  - Bradykinesia
  - Some types of gait dysfunction
- ⊗ DBS does not treat cognitive impairment, psychiatric symptoms, axial gait dysfunction
- ⊗ DBS does not halt the progression of Parkinson's Disease
- ⊗ DBS is not a cure.
- ⊗ There is a window for DBS and PD!!!

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## Goal Attainment

- ⊗ Be sure to clearly discuss goals with your surgeon: what are you unable to do today that you would like to be able to do after DBS?
- ⊗ Be sure to clearly discuss what expectations may not be met with surgery.

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## Our Multidisciplinary Team Approach

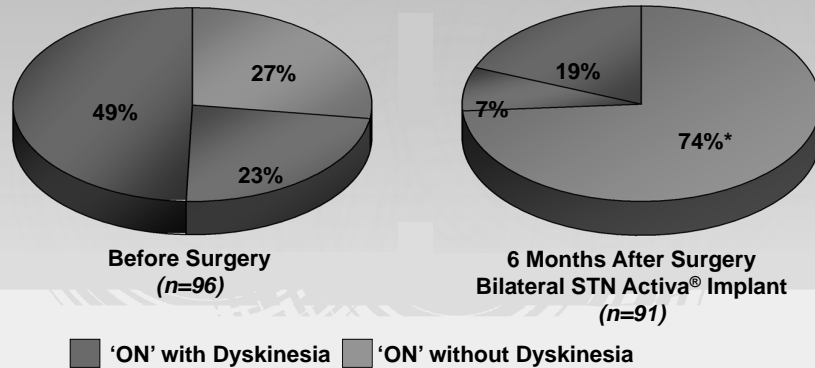
- ⊗ THE PATIENT
- ⊗ Neurology
- ⊗ Neurosurgery
- ⊗ Neuropsychology
- ⊗ Psychiatry
- ⊗ Rehab
- ⊗ “an ongoing multidisciplinary conversation around patient selection and care provides an important avenue for establishing good practice”

J Med Ethics, 2006 Feb;32(2):106-9.  
Stimulating debate: ethics in a multidisciplinary functional neurosurgery committee.

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## “ON” Time Without Dyskinesias Improves from 27% to 74% of a Patient’s Waking Day\*



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\* The Deep-Brain Stimulation for Parkinson’s Disease Study Group. Deep-brain stimulation of the subthalamic nucleus for the pars interna of the globus pallidus in Parkinson’s disease. *N Eng J Med.* 2001;345:956-63.

## Motor Symptoms Improvements Maintained After 5 Years

	OFF-Medication Motor Score Improvements*			
	6-month	1-year	3 years	5 years
Tremor	79%	75%	83%	75%
Rigidity	58%	73%	74%	71%
Akinesia	42%	63%	52%	49%

In a 5-year study, ACTIVA significantly improved OFF-medication assessments of tremor, rigidity, and akinesia/bradykinesia

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\*Results for STN

**JAMA**<sup>®</sup>

Online article and related content current as of July 10, 2009.

### Bilateral Deep Brain Stimulation vs Best Medical Therapy for Patients With Advanced Parkinson Disease: A Randomized Controlled Trial

Frances M. Weaver; Kenneth Follett; Matthew Stern; et al.

*JAMA.* 2009;301(1):63-73 (doi:10.1001/jama.2008.929)

“Conclusions: In this randomized controlled trial, deep brain stimulation was more effective than best medical therapy in alleviating disability in patients with moderate to severe PD with motor complications responsive to levodopa and no significant cognitive impairment.”

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## Motor ON/Off Periods

An additional 4.6 hours of “ON” time without dyskinesias with DBS, versus 0 hours of additional “ON” time with medications alone

**Table 2.** Patient Motor Diary Outcomes

Time	Best Medical Therapy (n = 134)			Deep Brain Stimulation (n = 124)			Best Medical Therapy Minus Deep Brain Stimulation	
	Baseline Mean (SD)	6 mo. Mean (SD)	Mean Difference (95% CI)	Baseline Mean (SD)	6 mo. Mean (SD)	Mean Difference (95% CI)	Mean Difference (95% CI)	P Value <sup>a</sup>
On, h/d <sup>b</sup>								
Without troublesome dyskinesia	7.0 (2.9)	7.1 (3.3)	0 (-0.2 to 0.5)	6.4 (2.7)	10.9 (4.2)	4.6 (3.6 to 5.3)	-4.5 (-5.4 to -3.7)	<.001
With troublesome dyskinesia	4.2 (3.1)	3.9 (3.3)	-0.3 (-0.8 to 0.3)	4.4 (3.1)	1.6 (3.0)	-2.8 (-3.3 to -2.0)	2.3 (1.5 to 3.2)	<.001
Off, h/d <sup>b</sup>	5.6 (2.9)	5.7 (2.8)	0 (-0.4 to 0.5)	5.9 (2.6)	3.4 (3.1)	-2.4 (-3.1 to -1.8)	2.5 (1.7 to 3.2)	<.001
Asleep, h/d	7.1 (1.7)	7.3 (2.0)	0.3 (0 to 0.6)	7.3 (1.6)	7.7 (2.0)	0.4 (0 to 0.7)	-0.1 (-0.6 to 0.4)	.66

Abbreviation: CI, confidence interval.

<sup>a</sup>Test for the change scores from baseline to 6 months between the best medical therapy group and the deep brain stimulation group.

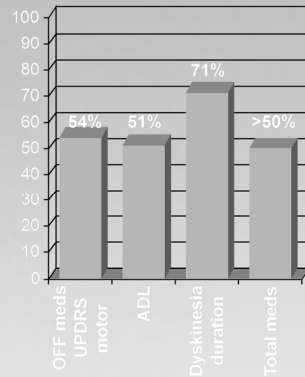
<sup>b</sup>“On” and “off” time are described in the “Study Procedures” section of the “Methods.”

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# DBS and Quality of Life

- ⌘ 5 year follow-up, prospective study
- ⌘ No significant change in neuropsychological status
- ⌘ Overall, a slight decrease in ON-medication motor subscores for akinesia, postural stability, speech, freezing of gait c/w progression of the disease

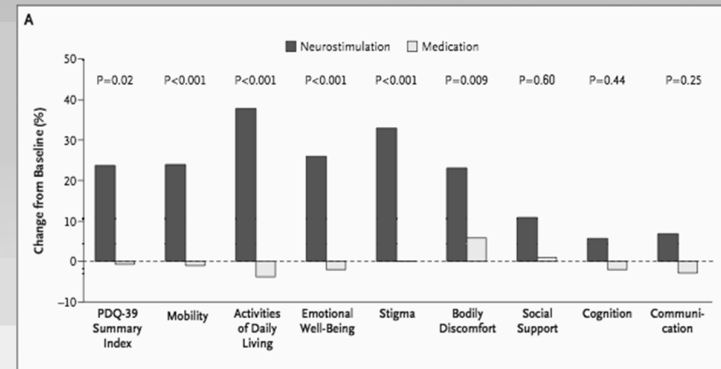


Krack et al., NEJM 2003;349:1925-34

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# Quality of Life Improvement with DBS



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# Early Stim Trial: NEJM

- ⌘ 251 patients who had just started having mild fluctuations and were still responding fairly well to drugs
- ⌘ randomly selected to be in one of two groups, one receiving medication alone and the other receiving medication plus deep brain stimulation
- ⌘ Patients in the deep brain stimulation group experienced an improvement of 26 percent in their quality of life

Gunther Deuschl, M.D., Ph.D., chairman, neurology, University Medical Center Schleswig-Holstein, Kiel, Germany; Carlos Singer, M.D., professor, neurology, and director, division of Parkinson's disease and movement disorders, University of Miami Miller School of Medicine; Feb. 14, 2013, New England Journal of Medicine

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# EarlyStim

- ⌘ mobility was also improved in the combination group
- ⌘ findings suggest that "instead of waiting for patients to have very marked fluctuations, peaks and very deep valleys, [we] move in when the peaks and valleys are not that steep," Singer
- ⌘ "The data suggest that patients can safely, and with significantly better outcome, receive neurostimulation," said Deuschl. "We expect that the international guidelines will change at this point, and the patients will be offered neurostimulation at a much earlier time."

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# Essential Tremor

- ⌘ The most common movement disorder, affecting up to 20% of the elderly
- ⌘ Produces postural tremor disorder (may also occur at rest); most commonly affects hands but can also affect head, voice, tongue, and legs

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# Essential Tremor Guidelines

- ⌘ **Guidelines published by the American Academy of Neurology (AAN) in June 2005 concluded that:**
  - ⌘ Unilateral DBS resulted in a significant (60 to 90%) reduction of contralateral limb tremor.

Zesiewicz TA, Elbe R, Louis ED, et al. **Practice Parameter: Therapies for essential tremor. Report of the Quality Standards Subcommittee of the American Academy of Neurology.** *Neurology* 2005;64:2008-2020

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# Additional Benefits of DBS

- ⌘ Bilateral, reversible, and adjustable
- ⌘ Non-destructive versus ablative procedures
- ⌘ Can be non-invasively fine-tuned to each patient's individual needs

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# DBS: Potential Complications and Risks

- ⌘ Surgery related
  - ⌘ Hemorrhage (inherent in any stereotactic procedure); may be silent or symptomatic
  - ⌘ Transient confusion
  - ⌘ Infection (typically occurs at neurostimulator site in chest when it does occur)
- ⌘ Stimulation related
  - ⌘ Usually can be minimized or eliminated by adjusting stimulation settings
  - ⌘ Reversible paresthesia, dysarthria, muscle contraction

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**Thank You!**

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