

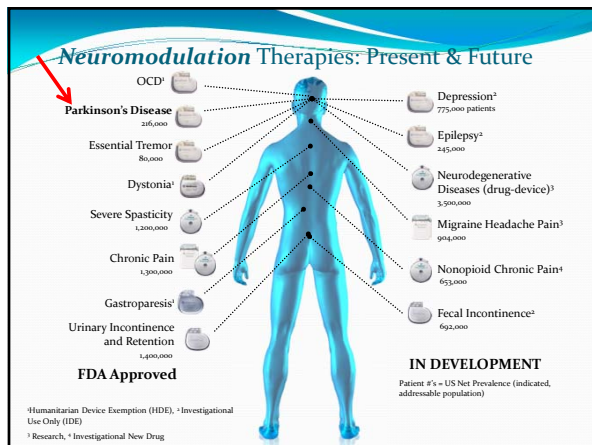
## Deep Brain Stimulation for Parkinson's Disease

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April 12, 2014

## Outline: Common Questions

- What is DBS (Deep Brain Stimulation) Therapy?
- How does DBS work?
- Is DBS Therapy considered experimental?
- When is it time to consider DBS?
- What are the benefits and how long do they last?
- Who is a good candidate?
- What can I expect from the surgical procedure?
- What are the risks of DBS?
- Is DBS covered by insurance?



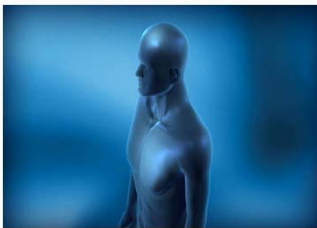
## What is Deep Brain Stimulation?

- Pacemaker-like device sends mild electrical signals to a specific area in the brain that controls movement
- Generator lasts ~ 3-5 years

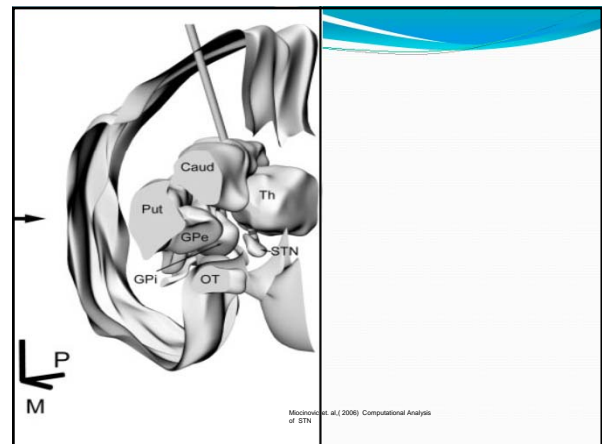


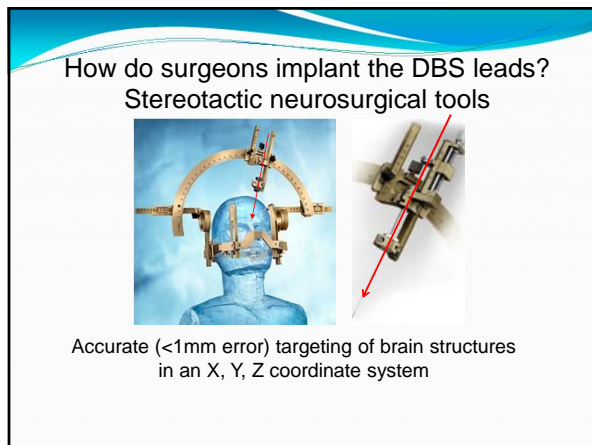
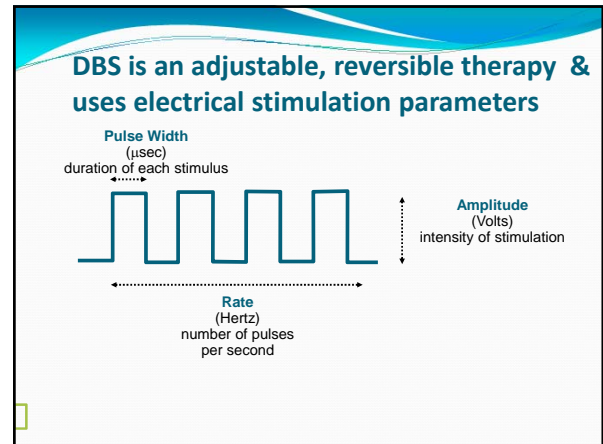
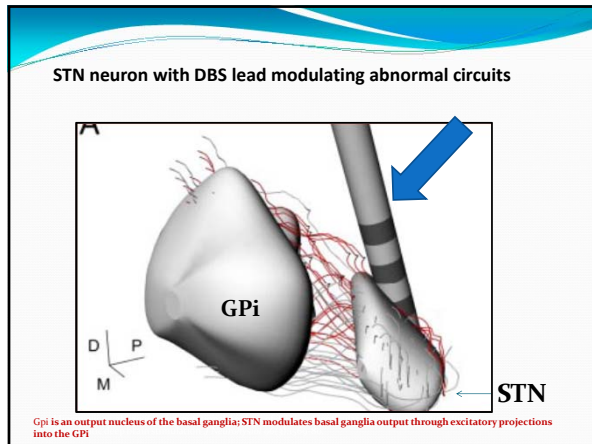
## How does DBS work?

DBS electrical stimulation *overrides abnormal neuronal activity* within specific regions of the basal ganglia: GPi or STN. This modulates abnormal motor circuits and converts them into a more normal state of function.



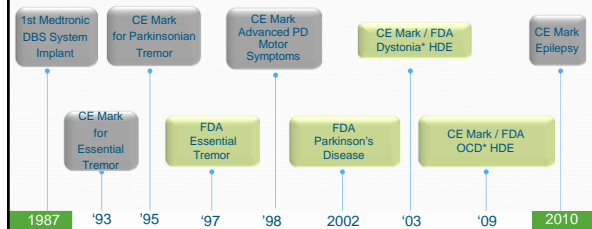
As a result people with implants experience better control over their body movements, making it easier to perform everyday tasks.





## Is DBS considered “Experimental ?”

### History of DBS in the US and Europe



\* Humanitarian Device: The effectiveness of this device for the treatment of Dystonia or Obsessive-Compulsive Disorder has not been established.

### Current US Approvals

#### Parkinson's Disease FDA Approved since 2002

- Indicated for bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) as an adjunctive therapy in **reducing some of the symptoms of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication**

>100,000+ patients worldwide have been treated with Medtronic DBS Therapy

### Randomized Clinical Trials: STN DBS vs. Best Medical Therapy

- Deuschl et al. 2006**
  - n=156, randomized to STN =78 vs. BMT =78
  - Improvement in UPDRS-III compared with BMT
  - 41% for STN and no change for BMT**
- Schuepbach et al., 2013**
  - n=251, randomized to STN=124 vs. BMT=127
  - Improvement in UPDRS motor subscores
  - 53% for STN and 4% for BMT**
- 4-5 hours per day of more 'on' time
- Not experimental, but strong evidence it works!

### What are the benefits of DBS?

Pre-op, off meds

Post-op, off meds



### Before and After STN DBS

Pre-operation

Post STN Implant

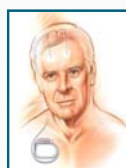




## Which Parkinson's Disease Symptoms Respond?

### Good Response to DBS

- Tremor
- Rigidity (Pain)
- Dyskinesias (avg reduction 69%)
- Bradykinesia (slowness)

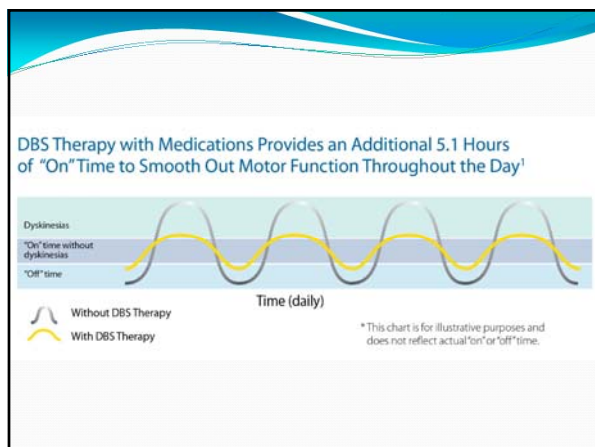


### Resistant to DBS

- Speech
- Balance
- Freezing of gait

### Not Improved by DBS

- Dementia
- Depression
- Psychosis



## Non-Motor Benefits from DBS

- Improves Quality of Life (34%)
- Pain syndromes improve
- Improves Sleep
- Improves swallowing, reduces drooling
- Reduces medications (and side effects of medications) - average reduction of l-dopa post implant 55%. (Meta analysis of STN outcomes. Kleiner-Fishman et al., 2006. Mov Disorders.)
- Reduces nocturia (urinary frequency at night) Winge and Nielsen Neurourodyn (2012.) Bladder dysfunction in advanced PD.
- Improves constipation
- Resolves off period Drenching Sweats

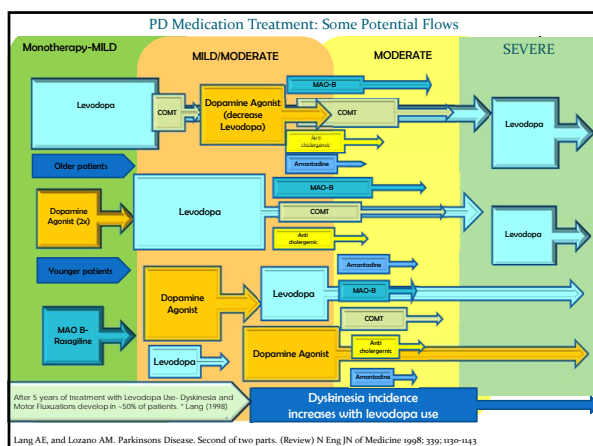


## When is it time to consider DBS?

## When DBS Therapy is a Potential Therapeutic Option

- When symptoms of idiopathic, advanced, levodopa-responsive PD are not adequately controlled with medications
- Levodopa associated dyskinesias or refractory tremor
- Unexpected off periods - motor fluctuations
  - Medication effect duration is no longer sustained





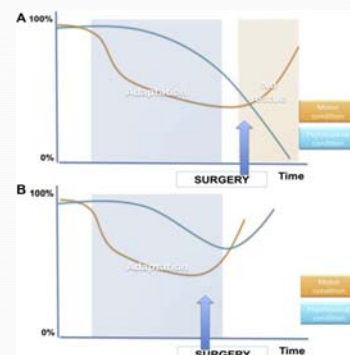
## Who is a candidate?

- PD > 5 yrs (average 7-12 yrs)
- Severe motor fluctuations (meds wearing off)
- Bad "offs"
- Still with good response to sinemet/levodopa
- Bothersome tremor, stiffness, and/or slowness
- Depression OK (treated & managed)
- Cognitively OK (don't need to be perfect)

## Recent Studies advocate for 'early' DBS

"Surgery should be performed *before* loss of adaptation develops

Current-Advanced Stage DBS Referral



(Fasano 2012)

## Original Article Neurostimulation for Parkinson's Disease with Early Motor Complications

W.M.M. Schuepbach, J. Rau, K. Knudsen, J. Volkmann, P. Krack, L. Timmermann, G. Deuschl, et al., EARLYSTIM Study Group

- In this 2-year trial involving 106 patients with Parkinson's disease and **early motor complications**, subthalamic stimulation plus medical therapy resulted in *better quality of life* and motor function as compared to medical therapy alone.
- STN stimulation was found to be superior to medical therapy in patients with 'early' Parkinson's Disease and early motor complications.

Engl J Med  
Volume 368(7):610-622  
February 14, 2013



## Baseline Characteristics of the Study Population.

Characteristic	Neurostimulation (N=124)	Medical Therapy (N=127)
Age — yr	52.9±6.6	52.2±6.1
Sex — no. (%)		
Male	94 (75.8)	85 (66.9)
Female	30 (24.2)	42 (33.1)
Duration of Parkinson's disease — yr	7.3±3.1	7.7±2.7
Dyskinesias <sup>†</sup>		
No. of patients	84	94
Duration — yr	1.4±0.8	1.5±0.8
Motor fluctuations <sup>‡</sup>		
No. of patients	121	124
Duration — yr	1.6±0.8	1.8±0.8
Treatment with levodopa		
No. of patients	111	115
Duration — yr	4.8±3.3	5.0±3.3
Treatment with dopamine agonist		
No. of patients	118	115
Duration — yr	5.9±3.0	6.1±3.0
Levodopa-equivalent daily dose — mg	918.8±412.5	966.9±416.5

<sup>a</sup> Plus-minus values are means ±SD. There were no significant between-group differences.

<sup>†</sup> The presence of dyskinesias or fluctuations for 3 years or less was an eligibility criterion.



### Stimulation of the subthalamic nucleus at an earlier disease stage of Parkinson's disease: Concept and standards of the EARLYSTIM-study

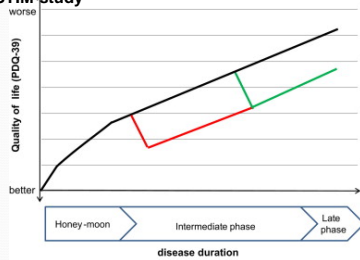


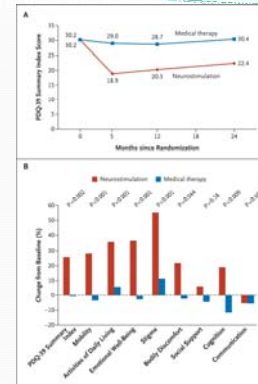
Fig. 1 The hypothesis of EARLYSTIM. Life quality is progressively worsening during the course of the disease (black line). Previous studies have shown that deep brain stimulation is successful in patients with advanced disease and can improve quality of life.

This study tested the hypothesis that this improvement can be seen much earlier in the disease when patients start to experience reductions of life quality but are still psychosocially competent (red line).

Parkinsonism & Related Disorders, Volume 19, Issue 1, 2013, 56–61

Günther Deuschl, Michael Schölpbach, Karina Knudsen, Marcus O. Pinsker, Philippe Comu, Jörn Rau, Yves Agid ...

### Quality of Life as Assessed by Means of the Parkinson's Disease Questionnaire (PDQ-39).



the NEW ENGLAND JOURNAL of MEDICINE

## Age/Co-morbidities

- Younger is safer
- But, no specific age cut-off
- General surgical risk acceptable
  - Cardiovascular (stable, no active angina)
  - Pulmonary (coughing intra-op danger)
  - Hematologic (anticoagulation: can it be stopped?)
  - Diabetes (well controlled)

## Cognitive/Behavioral

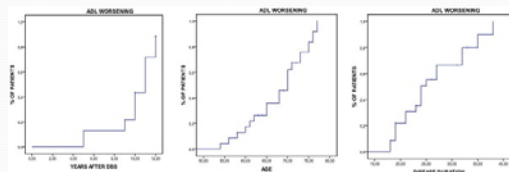
- Dementia relatively contraindicated
  - Check if medications contributing
  - Don't have to be perfect!
- Depression, anxiety
  - Treated
- Neuropsychological assessment – routine pre-operative screen

## 5. Matching Chief Complaints to DBS

- Ranking your most bothersome sx
- Good Match
  - #1 Tremor
  - #2 Rigidity
  - #3 Dyskinesia
  - #4 Wearing off too frequently
- Bad Match
  - #1 Falls/Balance
  - #2 On-Freezing
  - #3 Fatigue
  - #4 Memory
  - #5 Won't make you smarter!

## How Long do DBS benefits last?

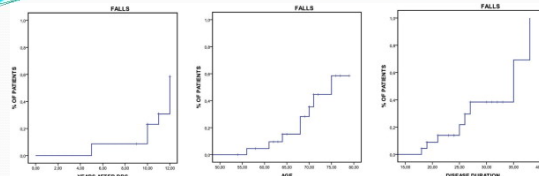
### Long-term outcome of STN DBS in Parkinson's disease: From the advanced phase towards the late stage of the disease?



MEDIAN TIME TO WORSENING IN ADL

YEARS AFTER DBS	11 YEARS	IC 95% (10.28 - 11.72 YEARS)
AGE	70 YEARS	IC 95% (65.91 - 74.11 YEARS)
DISEASE DURATION	24 YEARS	IC 95% (21.85 - 26.14 YEARS)

M.G. Rizzone, A. Fasano, A. Daniele, M. Zibetti, A. Merola, L. Rizzi, C. Piano, C. Piccinini, L.M. Rom. Parkinsonism & Related Disorders, 2014



MEDIAN TIME TO FALLS

YEARS AFTER DBS	12 YEARS	IC 95% (10.83 - 13.17 YEARS)
AGE	73 YEARS	IC 95% (63.15 - 81.84 YEARS)
DISEASE DURATION	32 YEARS	IC 95% (23.41 - 42.58 YEARS)

M.G. Rizzone, A. Fasano, A. Daniele, M. Zibetti, A. Merola, L. Rizzi, C. Piano, C. Piccinini, L.M. Rom.

Long-term outcome of subthalamic nucleus DBS in Parkinson's disease: From the advanced phase towards the late stage of the disease?

Parkinsonism & Related Disorders, 2014

<http://dx.doi.org/10.1016/j.parkreidis.2014.01.012>

### External Components: Clinician Programmer

Adjustments to stimulation parameters are made noninvasively using the clinician programmer



### DBS Patient Programmer



- Patients can adjust own therapy values within clinician-defined limits
- OK to turn off using patient controller for other surgical or medical interventions

### Risks and Adverse Events

This therapy is not for everyone.

DBS Therapy requires brain surgery which in less than 1% could have serious or even fatal complications.

Other complications can occur and may require additional surgery.

DBS Therapy may cause worsening of some symptoms.

### What are the risks of DBS?

- Infection 3-6% (usually within first month)
- Bleeding 1-3% (usually within first 12-24 hours)
- Possible device complications
- Stimulation side effects (reversible!)

## Am I a Candidate?

- Age/Co-morbidities
- Cognitive/Behavioral Status
- Clear diagnosis of PD, with clear response to dopaminergic meds
- Medications have been optimized but still suffer
  - Medications – wearing off's or fluctuations
  - Tremor
  - Rigidity/pain syndromes
  - Dyskinesias
- *Chief complaints are amenable to DBS*

## Is DBS Therapy covered by insurance?

- Yes
- Approved by Medicare
- Private insurance
  - Preauthorization from your insurance company may be required
  - Your costs will vary by benefit plan

## 16 Topics on Parkinson's Disease



*My  
Parkinson's  
Story*

[www.parkinsons.va.gov](http://www.parkinsons.va.gov)

YouTube = "My Parkinson's Story"

## Thank You!

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