

# THE FIRST REPORT

A compilation of the responses

to

## DBS/STN PATIENT SURVEY

A self-reporting questionnaire

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## **INTRODUCTION**

In late 1998 New York University Medical Center in collaboration with the Hospital for Joint Diseases began performing the first deep brain stimulation of the subthalamic nucleus (DBS/STN) operations in the United States of America. Since then this team has done over 90 operations, provided 90+ initial adjustments and is providing follow-up services for over 50 persons. This collaboration consists of a surgical team from New York University Hospital and the neurodynamic team from the Hospital for Joint Diseases.

The DBS/STN Patient Survey, was conceived and implemented in 2001. It was designed to record the reactions and feelings of the patients' to their experiences pre, during and post surgery.

The Survey consists of a Core Section, the Unified Parkinson Disease Rating Scale (UPDRS), Section 2, Activities of Daily Living and the Parkinson Disease Questionnaire (PDQ-39.)

The patient list from NYU was the source of the survey participant pool initially. The three part survey was also put on-line and people were invited to participate, but asked to observe a few rules:

Had to be patients who had bi-lateral deep brain stimulation of the subthalamic nucleus (DBS/STN) at least 6 months prior.

Ask their neurologist to provide pertinent records to the Survey administrator

Complete sections of the survey periodically (every six months.)

The First Report is the summary of the responses to the questions posed in the survey. The information presented has no constraint of standard, statistically validated double-blind random protocols. We believe that presenting the patient's unadulterated view is a novel and valuable approach from which the scientific and medical community can benefit.

Our report also contains the results of three years of following-up a select group of patients. The NYU neurology team tracked changes in scores on the UPDRS Activities of Daily Living (ADL) Section 2 and the UPDRS Motor Scale Section 3, while patients were on or off their medications, and on or off their stimulator.

## PREDICTABLE OUTCOME

It was expected that the surgery would have a measurable positive effect upon the patients' quality of life.

## METHODS OF MEASUREMENT

- The Unified Parkinson's Disease Rating Scale (UPDRS) was utilized to document variations in patient's responses to standard tasks over time. Scores were recorded each time the patient was re-evaluated.
- The answers patients provided to the questions in the DBS/STN Patient Survey represent their total DBS/STN experience. Patient response to the statements of UPDRS Sections 2 and PDQ-39 supported their recall of the feelings elicited by the incidents described in these instruments.

## DESCRIPTION OF THE SAMPLE POPULATION

Table 1 shows the demographic break-down of the population responding to our survey.

	Female	Male	TOTAL	RANGE
<b># IN SAMPLE</b>	<b>27</b>	<b>35</b>	<b>62</b>	
<b>AGE AT DX</b>	<b>47.3</b>	<b>44</b>	<b>44.7</b>	<b>31-57</b>
<b>AGE AT SURGERY</b>	<b>57.1</b>	<b>54.6</b>	<b>55.7</b>	<b>41-71</b>
<b>TIME INTERVAL in years between diagnosis and surgery</b>	<b>12.4</b>	<b>10.7</b>	<b>11.3</b>	<b>03-22</b>

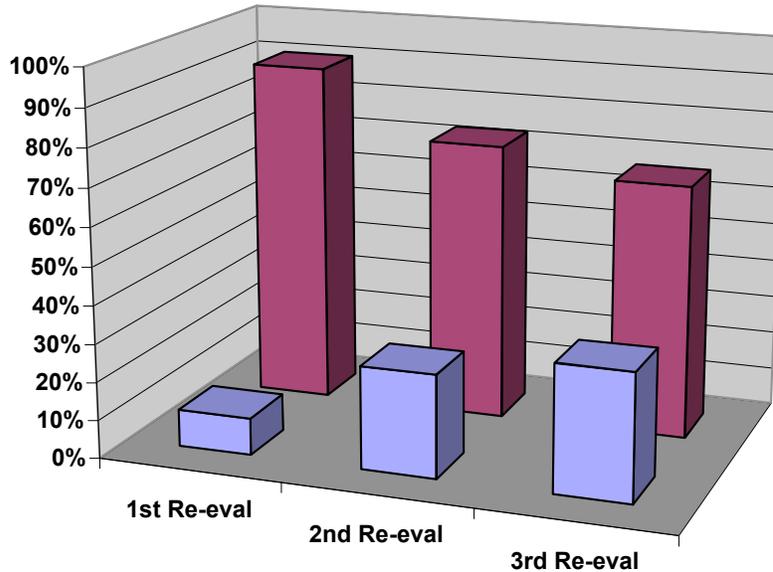
## **RE-EVALUATIONS OF THE SELECT GROUP OF PATIENTS**

Patients were evaluated by the neurology team before surgery using the UPDRS Sections 2, ADL and Section 3, Motor Scale, producing baseline scores. There are 3 different sets of conditions under which the evaluations were conducted. The patients were re-evaluated approximately 6 months after the operation (1<sup>st</sup> re-evaluation) and 2 times thereafter (the 2<sup>nd</sup> and 3<sup>rd</sup> re-evaluation). The scoring was completed by either the Neurologist or Nurse Practitioner using the UPDRS 5 point system. We then compared raw scores.

If the patient received a lower score on the re-evaluation than on the baseline evaluation, then that patient showed improvement (fewer symptoms). If he/she received a higher score, that showed that symptoms increased or their condition declined. For easier visual comparisons, we converted the numerical scores into a percentage.

# SUMMARY OF UPDRS FINDINGS FOR THE SELECT GROUP OF PATIENTS

**Chart 1  
"ON - ON"  
CHANGES BY PERCENTAGE**

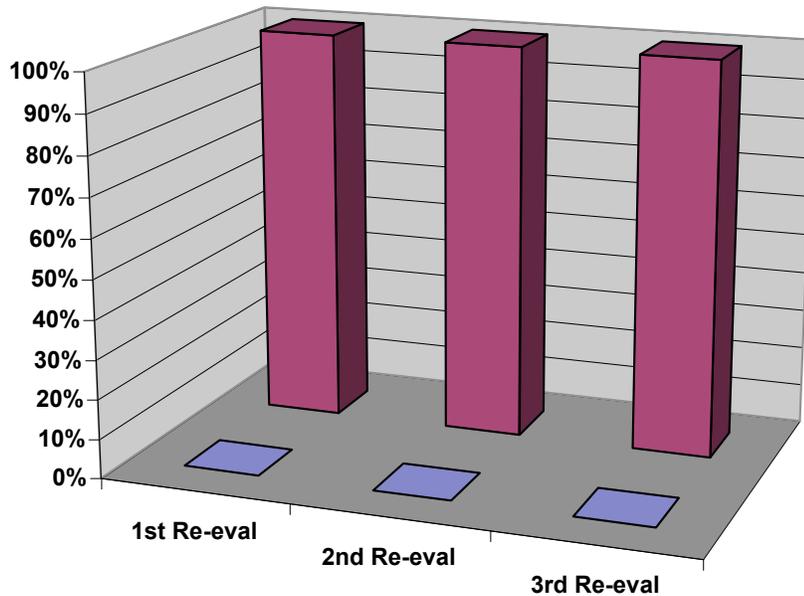


	1st Re-eval	2nd Re-eval	3rd Re-eval
Declined	10%	27%	33%
Improved	90%	73%	67%

**Chart 1 - On Stimulator and On Medication (On-On)**

Shows maximum effect of the operation by presenting the % of patients whose ADL skills and Motor functioning improved and those whose ADL skills and Motor functioning did not improve after the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> re-evaluation while On Stimulators and On Medication. 90% showed an improved score at the 1<sup>st</sup> re-evaluation, 73% after the 2<sup>nd</sup> re-evaluation, and 67% after the 3<sup>rd</sup>. The results show that, there is improvement in ADL skills and motor functioning in most patients after the operation.

**Chart 2  
"ON - OFF"  
CHANGES IN PERCENTAGE**

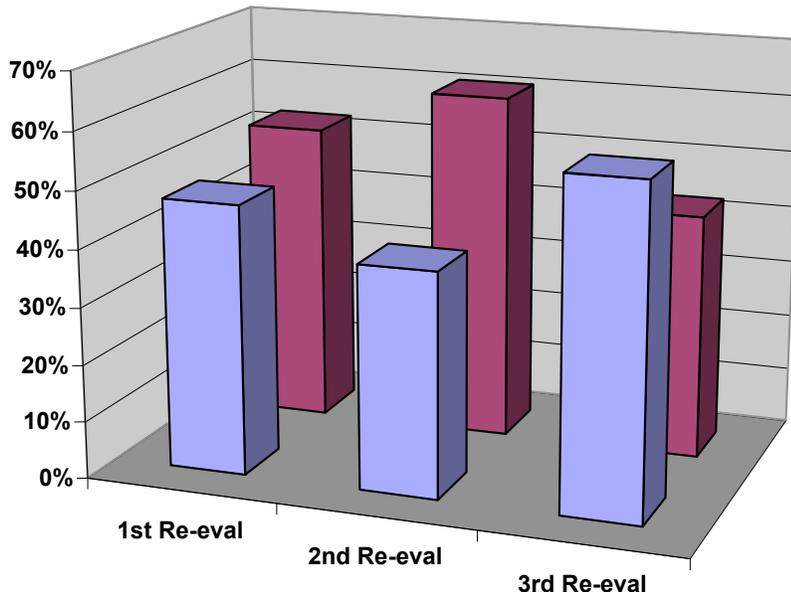


	1st Re-eval	2nd Re-eval	3rd Re-eval
<span style="color: blue;">■</span> <b>DECLINED</b>	0%	0%	0%
<span style="color: pink;">■</span> <b>IMPROVED</b>	100%	100%	100%

**Chart 2 - On Stimulators and Off Medication (On-Off)**

Numbers shows maximum effect of the stimulators alone. i.e., the % of patients whose ADL skills and Motor functioning improved and those whose ADL skills and Motor functioning did not improve after the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> re-evaluation while On Stimulators and Off Medication. As expected all patients felt improvement.

**Chart 3  
"OFF - OFF"  
CHANGES BY PERCENTAGE**



	1st Re-eval	2nd Re-eval	3rd Re-eval
DECLINED	47%	39%	57%
IMPROVED	53%	61%	43%

**CHART 3 - Off Stimulators and Off Medication (Off-Off)**

The “dreaded (Off-Off)!” Shows status of the disease without medication or stimulators. Recounts the % of patients whose ADL skills and Motor functioning improved and those whose ADL skills and Motor functioning did not improve after the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> re-evaluation while Off Stimulators and Off Medication.

Our data shows that there is improvement in ADL skills and Motor functioning in half of the patients after the operation.

The implication that neuro protection may be a result of the procedure has been suggested. Until recently studies have not had a large enough patient base and/or were not evaluated over a long enough period of time to make a valid analysis.

## **HIGHLIGHTS OF SOME OF THE RESPONSES TO OUR SURVEY**

Question: “What was your overall DNS/STN surgery effect?” 44 people had favorable responses compared to 7 negative ones.

**TABLE 2**

<b>I feel markedly better than before</b>	<b>30</b>
<b>I feel moderately better than before</b>	<b>9</b>
<b>I feel minimally better than before</b>	<b>5</b>
<b>I feel moderately worse than before</b>	<b>3</b>
<b>I feel markedly worse than before</b>	<b>4</b>

Question: “Was the relief obtained from the surgery worth the risk of potential complications and side effects?” This resulted in the following responses:

**TABLE 3**

<b>YES</b>	<b>41</b>
<b>NO</b>	<b>3</b>

Only 3 of the 4 persons who chose “markedly worse” (see Table 2) felt that the relief obtained from the surgery wasn’t worth the risk of potential complications and side effects. All others would take the risk again. This sentiment is echoed repeatedly.

Question: “Did you experience complications from the surgery?”

Out of 60 patients, 50 had no complications. Of the 10 patients who had complications there were several who had multiple problems. The types of problems can be seen in TABLE 4.

**TABLE 4**

<b>Hemorrhage</b>	<b>1</b>
<b>Seizure</b>	<b>2</b>
<b>Confusion</b>	<b>6</b>
<b>Hallucinations</b>	<b>2</b>

<b>Infection</b>	<b>4</b>
<b>Wound did not heal</b>	<b>1</b>

**Question: “What were your primary symptoms prior to surgery and post surgery?”**

**Since the variety and intensity of symptoms of the disease are the principal factors in assessing the quality of life of PD patients, Tables 5A and 5B show the positive changes experienced by the sample population**

<b>TABLE 5A</b>	
<b>PRE-SURGERY SYMPTOMS</b>	
<b>Tremor</b>	<b>58.70%</b>
<b>Freezing</b>	<b>66.60%</b>
<b>Gait</b>	<b>60.30%</b>
<b>Rigidity</b>	<b>71.40%</b>
<b>Bradykinesia</b>	<b>42.80%</b>

<b>TABLE 5B</b>	
<b>POST-SURGERY SYMPTOMS</b>	
<b>Tremor</b>	<b>21.60%</b>
<b>Freezing</b>	<b>23.80%</b>
<b>Gait</b>	<b>31.50%</b>
<b>Rigidity</b>	<b>15.50%</b>
<b>Bradykinesia</b>	<b>11.10%</b>

**Note: Freezing is when you are unable to move your feet at all  
Gait is a combination of walking difficulties, including shuffling and turning and loss of balance. Bradykinesia is slowness in initiating movement.**

**Three bits of information can be gleaned from Tables 5A and 5B.**

- The first is that the percentage of the number of respondents experiencing symptoms before and after has markedly declined. For example 50 % of the respondents reported experiencing tremors pre-surgery and less than 25% continued to have tremors after surgery.**

- The second is that the type of symptoms most commonly experienced by patients changed from rigidity 71% to Gait 31%. This does not take into consideration any new symptoms that may have appeared .**

- And thirdly, the primary symptom relieved by the surgery was rigidity which dropped from 71% to 15%. This is a very strong indication that DBS surgery deals quite effectively with rigidity.**

## **STIMULATOR SETTINGS AND LEVEL OF MEDICATIONS**

While the ideal post-surgery condition would be “medication free”, patients and their doctors seldom find that elusive state. Most of the time some medication is still needed in combination with the stimulators to create the optimum effect for each patient. Periodic adjustments are a regular part of the treatment protocol.

## **NUMBER OF ADJUSTMENTS DURING THE FIRST THREE YEARS**

Table 6 shows the average number of times the patient’s stimulators were adjusted during the 1st year, 2nd year and 3rd year. Many patients are unaware that regularly scheduled adjustment of medication and stimulators is normal and expected.

**TABLE 6**

	<b>1stYear</b>	<b>2<sup>nd</sup> Year</b>	<b>3<sup>rd</sup> Year</b>
<b>Average # Visits for adjustment</b>	<b>14</b>	<b>2</b>	<b>1</b>
<b>Highest # Visits</b>	<b>25</b>	<b>12</b>	<b>4</b>
<b>Lowest # Visits</b>	<b>5</b>	<b>1</b>	<b>1</b>

## **CHANGE IN MEDICATION DOSAGE**

One of the outcomes that was most welcomed was the reduction in the amount of medication needed by the patients after the surgery. While we

know that Sinemet was reduced by approximately 50%, we don't know of changes in other medication. This will be an area for future investigation.

## **SUMMARY**

This report does not pretend to be a scientific article. It is a review and report of patient responses to a series of questions without the statistical constraints of a double blind, random study.

It is unique to use a self reporting questionnaire and anecdotal evidence by the DBS/STN patient to support the hypothesis that demonstrates the safety and efficacy of DBS for PD. Seldom, if ever, has the patient point of view been sought and valued.

There were three questions for which we wanted to find answers at the onset of this survey:

**Does DBS/STN work?**

**Answer: Yes, indeed! There was a measurable improvement in the patient's Activities of Daily Living and therefore their quality of life.**

**How long does it's effectiveness last?**

**Answer: At least three years. As this study is continuing, the next report will update the length of time.**

**Does it have neuro-protective qualities?**

**Answer: Our data cannot support this finding. But, we are hoping.**

Journal articles published by highly esteemed neuro-surgeons and neurologists are providing scientific and statistically valid data attesting to the success of the various DBS procedures. The scientific community has yet to *prove* that stimulation of the sub thalamic nucleus has neuro-protective qualities, but this pronouncement may not be far in the future.

## **ADDENDUM**

### **INFORMAL DATA COLLECTED FROM SURVEY**

- 12 of the 62 patients lived alone.
- Most people kept the stimulators on continuously.
- Most people want to participate in a support group.
- Despite the improvement in their condition patients reported on the PDQ 39 Scale that they felt increasingly confined and were experiencing an increased amount of crying even at trivial occurrences.
- More than 50% of respondents report that they are receiving disability insurance.

### **GENERAL COMMENTS BY PATIENTS**

- This surgery has had a profound impact on my life. Just look at the before/after video tapes.
- I was happy to help. DBS sure helped me.
- (I) would like it if someone, who values this info so much had skimmed my record & filled in some of the blanks. The team was vague about likely benefits to the second implantation. I did not expect so much trouble with my speech after the second implant. Most important is (giving) accurate and complete info for patients about problem frequency and benefits.
- I have a thalamic stimulator (September of 1998) on the left side brain to control severe tremor on the right side of the body. The STN surgery has allowed me to perform tasks that were not possible two or three years ago. The placements of the electrodes in the thalamic and sub-thalamic areas of the brain have worked very well for me.
- Original surgery was bilateral and was very successful. Both wires fractured about a year later. (It) took us over a year to find anyone to replace the wiring as (the) original physician was no longer practicing.
- I am filling this out for my husband as he cannot do this. For 18 months after DBS surgery he was markedly improved but now is having tremendous balance problems and the adjustments don't seem to help. This is something that is just started to happen within the last three months.

## **ACKNOWLEDGEMENTS**

The first grateful acknowledgements go to Drs. Patrick Kelly, Aleksandar Beric, Jorge Sterio, and Christina Drafta for providing encouragement and access to patient data (always observing the regulations regarding “disclosure and privacy”), and to Patricia Taverna, Nurse Practitioner who does the adjustments and patiently continues to answer our questions about this mysterious phenomena. Carol Walton, The Executive Director of the Parkinson Alliance, has the dubious honor of being with me many, many hours each day (we work together in my home) and therefore I have the benefit of her unlimited energy, business savvy, care and concern. She is the driving force behind “marketing” the Survey, i.e., bringing attention to the success of DBS/STN. A special note of recognition and thanks for a job well done goes to Roberta Rubin, Clinical Supervisor and Head Nurse for the movement disorders surgery program at California Neuroscience Institute. Oxnard, California Roberta adroitly answers questions posed in the Forum.

Rick Kramer is brave and undaunted by the potential complications his traveling to Princeton, New Jersey from Long Island may create when he is OFF. Rick and I work well together. We both had DBS/STN and we are in synch. Rick is the creator of the super charts included in The First Report.

John Wherry, a fellow New Jersey-ite has not had DBS. We are fortunate to benefit from his awesome database knowledge. I call John after I already spent hours trying to extract information from an Excel sheet, and John just sits down and sorts, queries and makes relational wizardry And the best part is that Rick and John discovered that each is a ping-pong aficionado so they can play and relax after a long day in front of the computer.

My interest in pursuing answers regarding DBS was born out of desperation. I awoke one morning after having PD for 20+ years and decided that I was not going to crawl on my hands and knees any longer. During my personal fact finding phase about DBS I was dismayed to find so little information! I was fortunate that I “landed” at Dr. Patrick Kelly’s O.R. at NYU. After my successful bi-lateral STN, in December of 2000, I decided to “pay-back” by doing some service for the DBS/STN community.

Definitive answers are few when discussing DBS, or PD, for that matter. The excitement that follows a study that gets published with positive results –

**even with as few as 3-5 in the sample population – is electrifying. The disappointment that is felt when reading about individual patient’s problems and not being able to find a solution is devastating.**

**I am grateful to the 109 people who took time to fill out the survey and to the many care-partners who daily hold the lives of the PD patients together.**

**Margaret Tuchman, DxPD 1980, DBS/STN 2000**