Northwestern Medical Faculty Foundation
The Faculty Practice Plan of Northwestern's Feinberg School of Medicine

Patient's Guide to Deep Brain Stimulation (DBS) for Parkinson's Disease

This is intended to provide a summary of the procedure, risks, and benefits of deep brain stimulation surgery for Parkinson's disease. It does not substitute for a complete discussion of the procedure with your neurologist and neurosurgeon.

If you have questions about surgery or want to know more, please feel free to e-mail us at dbs@northwestern.edu.

History

In the 1950s, surgery for Parkinson's disease (PD) was one of the most common neurosurgical procedures performed in the United States. At that time, effective medications that we use today for relief of the symptoms of PD were nonexistent. During this time, surgery for PD consisted of creating lesions in deep parts of the brain to control tremors and rigidity. With the introduction of levodopa in the late 1960s, interest in surgical approaches decreased dramatically.

Unfortunately, clinical experience has since shown that long term medical therapy for PD has significant problems. After several years of taking medications, including levodopa (the current "gold standard" of anti-parkinsonian agents), many patients with PD experience a shortening of benefit following each dose ("wearing-off"), forcing patients to take more medication. As a result, many patients also develop drug-induced involuntary writhing and twisting movements known as dyskinesias. Moreover, the effect of the medication becomes unpredictable, leading to unexpected freezing and "off" episodes.

The modern era of deep brain stimulation (DBS) began with the first report of its use in the thalamus to treat Parkinson's disease tremor in 1987. It was approved by the U.S. Food and Drug Administration (FDA) in 1997 for the treatment of tremor. It was approved for implantation on both sides of the brain in 2002 as a treatment for the parkinsonian symptoms of rigidity, slowness of movement, and dystonia. Since its introduction, over 30,000 patients worldwide have undergone DBS surgery. Because it is FDA approved, DBS surgery for PD is covered by just about all major health insurance plans and Medicare.

Deep brain stimulation surgery involves implanting one or more small electrodes in very specific regions deep in the brain to deliver continuous high frequency electrical impulses to the brain. These impulses alleviate the symptoms of severe movement disorders, even though it does not cure them. Each electrode has four contacts at the tip. Stimulation may be performed though any combination of one or more of these contacts. In addition, the strength of stimulation, length of each pulse, and the number of pulses per second may be adjusted to individualize the stimulation

so that each patient achieves the best results possible. Each electrode is connected to an extension wire that runs under the skin behind the ear and down the neck to an implantable pulse generator ("pacemaker") which is usually placed under the skin of the upper chest.

Who is a candidate for deep brain stimulation for PD?

Patients with Parkinson's disease are candidates for surgery if they still achieve some benefit from their medication, but have significant side effects or other medication-related problems. These include freezing, rapid unpredictable on/off fluctuations, dyskinesias (uncontrolled movements), sleepiness, nausea, and early wearing-off of the medication effects. Moreover, patients need to have Parkinson's disease and not one of the other syndromes that have Parkinson-like features with other symptoms as well.

All patients must undergo an evaluation here at Northwestern prior to being deemed a surgical candidate. This includes:

1. Review of records from your current neurologist that document past treatment efforts

2. Thorough examinations by our movement disorders neurologists and neurosurgeon to determine if your symptoms will respond well to surgery. As part of this, you will have an examination both off all medications and then after your medications are taken so that we may determine the maximal difference between your most severe off state and your best on state.

3. MRI of the brain within the last year to make sure that there are no other factors that could account for the symptoms, as well as to insure there are no anatomic hindrances to surgery

4. Detailed neuropsychological evaluation to make sure there is no dementia or other cognitive disorders. It is also intended to screen for untreated anxiety or depression. These problems do not completely prevent a person from having surgery. They just need to be under treatment so that they do not interfere with the surgery or postoperative period. People with severe dementia, however, are not candidates since the operation can worsen this condition.

5. Detailed medical evaluation to medically optimize patients before surgery. This is usually performed by the Preoperative Service at Northwestern Memorial Hospital.

There is an easy questionnaire to help determine which PD patients may benefit most from DBS surgery. This questionnaire, the **Fl**orid**a** **S**urgical **Q**uestionnaire for **PD** (FLASQ-PD) may be found on our web site (www.parkinsons.nmh.org).

Good Candidate for DBS	**Poor Candidate for DBS**
Typical PD with tremor	Atypical parkinsonism
Good response to levodopa	Poor response to levodopa
Dyskinesias, freezing	Memory problems, apathy or confusion
Wearing-off spells and short "on" time	Severe depression or anxiety
Good general health	Severe medical problems
Excellent family support	No social support

Patients with these problems are not good candidates for surgery, and will likely not benefit from the procedure:

• atypical or rare forms of parkinsonism, such as progressive supranuclear palsy (PSP), multiple system atrophy (MSA), corticobasoganglionic degeneration (CBGD) or a known acquired cause of parkinsonism such as stroke or brain trauma
• failure to experience any benefit from anti-parkinsonian medications
• severe memory loss, confusion, hallucinations or apathy (these problems may actually get worse as a result of brain surgery)
• frequent falling even when medication is working its best
• a severe chronic psychiatric disorder such as psychosis, depression, bipolar disorder, alcoholism or a personality disorder
• inability to understand the potential benefits and risks of the operative procedures or to give informed consent
• significant medical problems that would unacceptably increase the surgical risk, such as cancer or serious heart disease

Note that age is not an essential criterion for surgery. An otherwise healthy older patient with PD can safely undergo and benefit from this type of surgery. Each patient is considered individually. However, the risks of surgery increase in patients over the age of 70.

Patients with other implanted electrical devices such as heart pacemakers/defibrillators are handled on a case-by-case basis.

DBS helps with:	DBS does not help with:
Tremor Rigidity Hand function Dyskinesias Unexpected wearing-off Freezing Short on time	Freezing Backwards falling Tachyphemia: rapid, soft, stuttering speech Flexed neck or posture Dementia or apathy Anxiety or depression

How is deep brain stimulation performed with a stereotactic frame?

Most of our patients undergo surgery using the stereotactic frame. We choose the technique that we feel is best for each individual patient. We will discuss with you which method we feel is best for your procedure. If you undergo surgery with the frame, this will be placed on the morning of surgery while you are in your hospital room after clipping your hair. You will go from your room to the CT scanner with Dr. Rosenow after the frame is placed. From there you will go to the operating room holding area, where your family can be with you until you go into the operating room. The stereotactic frame is attached to the patient using four pins. Local anesthesia is used to ensure that this part of the procedure does not hurt. Most people say it feels like a squeezing sensation on their head for about 15 minutes, and then they do not feel it anymore.

The CT and MRI pictures are loaded into a computer system in the operating room that allows the surgical team to merge the two pictures together. The enables the team to use the information from both scans to precisely target the correct location in the brain. The correct target is selected using a combination of direct visualization of the location on the MRI and CT and known formulas which locate the targets relative to known landmarks in the brain. The computer system also lets the team pick the entry point for the electrode on the skull and simulate the entire trajectory of the electrode. This makes sure that the electrode passes only through safe regions of the brain. The trajectory is adjusted until the optimal path is found. However, this only serves to get us close to the target. We must map the exact location in the brain to ensure the best results.

Northwestern Memorial Hospital is one of the few centers in the country offering deep brain stimulation using a new technology that avoids the use of the stereotactic frame in almost all Parkinson's patients. Dr. Rosenow, the Director of Functional Neurosurgery helped to develop and validate the accuracy of this innovative technology that makes the surgery more comfortable and speeds the start of the procedure. Instead of using a frame, the procedure uses five small markers that are attached to the skull through very small incisions. Patients usually feel almost no discomfort at all during this part of the procedure. These are placed the evening before the actual operation after the patient is admitted to the hospital. This procedure is performed in the patient's hospital room and takes about 20 minutes. Local anesthetic is used to prevent any discomfort.

Patients undergo a special preoperative DBS MRI scan up to several weeks before the surgery. Patients with Parkinson's disease are admitted to the hospital the afternoon before surgery and are taken off their Parkinson's medications starting that night at midnight. This maximizes the patient's Parkinson's disease in the operating room so benefits from stimulation can be observed.

What are the stages of surgery?

1. An MRI scan is obtained as an outpatient up to several weeks before surgery
2. The patient is admitted to the hospital the day before surgery to allow preoperative preparation and withholding of PD medications overnight before surgery.
3. The frame is placed in the morning, after which a CT scan is obtained
4. The electrode(s) is(are) placed under local anesthesia and intravenous sedation in the first operative stage. The patient is awake for part of the procedure and is off all PD medications. These are resumed immediately after surgery without changing the doses
5. **If only one wire is being placed** – the battery is placed under general anesthesia during the same trip to the operating room.
6. The patient returns to their hospital room that evening and often goes home the next day
7. **If only two wires are being placed** - The batteries are placed one week later under general anesthesia in a separate overnight hospital admission
8. Programming of the stimulators begins one month after the electrodes are placed
9. Medication doses are adjusted as programming progresses during several visits over a few months.

What happens in the operating room during DBS surgery?

In the operating room, the patient is cared for by a comprehensive surgical team. This consists of Dr. Rosenow, the neurosurgeon, and his residents, the neurosurgical anesthesiology team, the neurosurgical operating room nurses, and Dr. Alexis Kuncel, the neurophysiologist who specializes in brain mapping in Parkinson's disease.

The patient and the stereotactic frame are attached to the operating table in a position which the patient determines to be comfortable. Intravenous medication is given to allow the patient to sleep while the skin incisions are made. Generous amounts of local anesthetic are also used so that the patient feels no discomfort during the procedure. After the incision is made, a small hole (about the size of a nickel) is made in the skull according to the plan mapped out on the computer. The equipment to map the brain is then assembled.

The patient is then awakened and a very thin microelectrode is inserted into the brain to map the precise optimal location for the permanent electrode. The very fine microelectrode tip is only 5/1000 of a millimeter wide. Each location in the brain has its own characteristic patterns of nerve cell signals. The team listens to these to determine the exact location of the electrode. The patient becomes an integral part of the team at this point. The patient's arms and legs are moved

to see if this affects the firing of the nerve cells. In addition, the patient is asked to speak, look around, and relate if he or she feels any tingling or pulling in the arms, legs, or face. Each mapping track takes about 30 minutes to complete. At the end of each track, the team determines if this is the best location for the electrode or if more mapping information is needed. If another track is required, the mapping microelectrode is repositioned and another track is performed. The patient is kept informed of all of these discussions during the procedure.

Once the correct location is determined, the mapping electrode is removed and the permanent electrode is placed. This electrode is then turned on in the operating room to check the effects. The surgical team looks not only for good effects, such as decrease in tremor, rigidity and slowness, but also for unwanted side effects as well. If a satisfactory balance is found (few bad effects and many good effects), the electrode is secured at that location and the incision closed while the patient sleeps again.

If only one wire is placed in surgery, the extension wire and battery, or implantable pulse generator (IPG), is usually placed during the same trip to the operating room. This is done under general anesthesia and takes about 1 hour. One battery and extension wire are used for each side of the brain. The IPG is placed under the skin of the chest, just below the collarbone. A connecting wire runs from the electrode under the scalp behind the ear to the IPG. The battery produces a small bump on the chest, especially in very thin patients. Patients who have two electrodes placed will have two generators placed approximately one week later during a separate overnight admission to the hospital.

The patient's Parkinson's medications are restarted in the recovery room. Typically, the patient spends the night in their room again on the neurosurgical floor. Most people go home the day after the operation.

The procedure to place the electrodes (or 1 electrode and 1 battery) typically lasts until about 3 PM. However, some patients may finish earlier or later, depending on the complexity of the brain mapping portion of the procedure. Unfortunately, it is difficult to predict this preoperatively.

Sometimes symptoms are mildly improved after the DBS electrodes are in position, even though the battery has not been attached and the system has not yet been activated. This effect is usually attributed to brain swelling at the tip of the electrode. This almost always fades in the first few weeks after the electrodes are placed.

After surgery, patients have a CT scan to look for complications, such as bleeding, as well to check the general position of the electrodes. A special MRI scan is typically performed the day after surgery to obtain the exact electrode positions and compare them to the calculated ones from the operating room. This is done to ensure that the electrodes are in the optimal location for stimulation. In a few rare cases, it is necessary to return to the operating room and adjust the electrode position before the patient goes home.

After the operation, patients are typically very tired and have a mild headache. The headache usually resolves in a few days and the fatigue improves after a few weeks. Patients remain on their pre-operative medication at discharge.

Some patients with electrodes on both sides of the brain have both electrodes connected to a single, larger generator implanted on one side. Having two batteries means two protrusions, one on each side of the chest. Having one battery means a protrusion on only one side — but the battery is larger and more noticeable. In the rare case of a battery failure or infection, individuals with a single battery will lose power in both stimulators, unlike those with 2 separate batteries.

While most of our patients who have surgery for PD follow this general outline, we do treat each patient individually.

Stimulator Programming

The actual operation to implant the DBS system is only the start of a process to improve the quality of life of a patient with advanced Parkinson's disease. Optimizing the balance between the stimulation and medications takes several visits over a few months. It often requires about six months before a comfortable balance is reached and the patient can go many months between follow up appointments.

During this time, it is very important to remember that this is truly a process and that patients are not immediately at their final level of improvement once the stimulators are first activated. Some of the beneficial effects of stimulation may take hours or even a few days to become fully apparent. Along the way there may be side effects from either the stimulation or the medication (or the balance between them) that can cause the patient inconvenience until they are smoothed out. While these episodes can become disappointing at times, especially because of the hopes that surgery will lead to great improvements and the great frustration that patients with advanced PD endure, the final outcome is usually excellent.

Patients who only have one wire and battery placed will have programming of this system done as usual but at times the best outcome in terms of such things as walking and medication reduction will not occur until after the second wire and battery are placed.

Patients may check their deep brain stimulators using a hand-held device. By holding the remote over their IPG and pressing a button, patients can determine whether their stimulators are on or off. Patients may also be given control over some of the programming settings to allow them to change the stimulation themselves, within limits. The stimulator can be programmed with multiple separate programs. The patient can control which one of these is active so that they can try out several programs at home over time, reducing the number of return visits for reprogramming.

The life expectancy of the stimulator battery varies with output settings but is estimated at three to five years. As the energy in the battery becomes depleted, the efficacy of the stimulation starts to decline and PD symptoms increase. Patients can check the battery status using the hand-held device or the neurologist can do this in the office. When the battery is depleted, the implantable pulse generator (IPG) is replaced in short outpatient surgical procedure that takes about one hour. The old IPG is removed from the chest wall site by re-opening the incision. The

device is disconnected from the connecting lead, the new IPG is inserted and hooked up and the incision is again closed with stitches or staples.

Results of subthalamic deep brain stimulation for Parkinson's disease

Deep brain stimulation can greatly improve the quality of life of patients with advanced Parkinson's disease. However, it is not a cure. As far as is known, it does not speed up or slow down the progression of the disease.

In general, deep brain stimulation helps people with advanced Parkinson's disease stay in their best "on" state for two to three times as longer as before surgery, while allowing them to reduce medications on average by 50%. Moreover, because the medications are reduced, dyskinesias may be almost eliminated. The amount of useful "on" time may increase by two- or three-fold, meaning that if each dose of medication previously worked for one hour, with stimulation it may last two or three hours. In addition, fluctuations are smoothed out and are not as sharp, meaning that "off" periods are not as disabling. Moreover, these "off" periods are more predictable than without stimulation. However, it does not substantially improve the best "on" state, only keep the patient there longer without the complications caused by the medications. ..

Long term studies have shown that the effect of the stimulation continues for at least five or more years following the procedure. Some patients have continued to have steady relief as long as ten or more years after implantation with continued medication reduction. However, the duration and level of relief depends on the progression of each individual's disease.

Unfortunately, PD is a progressive condition. DBS does not prevent later complications of the disease, such as poor posture, speech impairment, gait freezing, balance problems, backwards falling or dementia. If these problems develop in a patient treated with DBS, the overall gains in quality of life after surgery may be lost even if tremor and dyskinesias remain well-controlled.

Risks of Deep Brain Stimulation

Any operation carries certain risks, and it is important to know these before undergoing the procedure. For example, some people do not get as much relief as others do. This may be due to a variety of reasons (each individual's anatomy is different, diseases progress, etc.). There is a risk of bleeding in the brain (about 1-2%) which is usually asymptomatic but can have serious consequences, such as temporary or permanent weakness, paralysis, coma or death. The risk of breakage of the device is about 1%. About 5% of patients who undergo deep brain stimulation operations get an infection of the hardware. Unfortunately, in almost all cases, it is necessary to remove the infected hardware to fully treat the infection. In patients with two separate systems (two wires, two batteries), the non-infected system continues to function. The other can be replaced about three months after the infection is treated. After bilateral STN stimulation, some patients have experienced difficulty opening their eyes. To remedy this, some may need injections of botulinum toxin, a muscle relaxant.

Most individuals tolerate brain surgery and deep brain stimulation without noticeable effects in their memory or thinking ability; in some studies, mood and behavior have improved. Unfortunately, there a very small percentage of patients experience some cognitive decline after surgery. The preoperative neuropsychological testing usually helps to identify those patients at high risk for this problem so that they may be counseled before surgery. These individuals are typically more elderly and have pre-existing dementia that may include word-finding difficulty, inability to carry out a sequence of tasks, problems with judging space and other cognitive signs. While presence of dementia at baseline is not an absolute disqualification to DBS if the patient has tremor and other symptoms that would otherwise benefit, it is important to fully understand these risks before the procedure by discussion the neuropsychological test results with the neurologist and neurosurgeon.

Some patients can experience problems due to the stimulation itself. Such stimulator-induced problems may include balance impairment, dizziness, speech difficulties or a general vague sensation of "not feeling right." There are rare reports of stimulation-induced feelings of depression or despair. Deep brain stimulation can also induce dyskinesias that resemble the dyskinesias caused by levodopa. All stimulator-induced effects are temporary and reverse promptly with a change in the stimulator output. After a programming session, it is a good idea for patients to wait at the center for an hour or so before returning home just to make sure that the new stimulator settings are well-tolerated and free of adverse effects.

Living with DBS

Patients with implanted deep brain stimulators are generally free to participate in any physical activity they choose, once the programming settings are stable. However, it is important to use common sense and not to engage in activities that could subject the device or wires to a direct physical trauma. Examples of specific activities that could potentially harm the stimulator include contact sports or chiropractic neck manipulation. Sometimes, with repeated trauma, the connecting lead or the battery erodes through the skin, requiring replacement.

Deep brain stimulators may switch off by accident if patients linger in a magnetic field, such as a store security device or theft detector. This is simply an inconvenience and carries no permanent risk to the patient or stimulator device. When the stimulator switches off, however, PD symptoms can immediately return. If this happens, the patient may re-activate the stimulator using the handheld device. Microwave ovens do not pose this risk.

There are certain procedures that DBS patients must either completely avoid or approach with caution. Patients with implanted DBS systems may have MRI scans of the brain, but only if they are performed under certain special conditions to ensure the patient’s safety. It is best to check with your neurosurgeon and neurologist at your DBS center before having an MRI. They should preferably be performed at a center that also performs DBS procedures. MRI scans of other body areas, such as the neck, back, knees, hips, etc., are not allowed under any circumstances. X-rays and CT scans are completely safe. In addition, patients should not undergo ultrasound diathermy, a treatment that involves applying a heating coil to the skin.

In case of questions about the stimulator, patients should always contact their treating neurologist, who may recommend a return visit to the medical center for a device check.

How we work with your referring physician

Once you have decided to come to Northwestern to be evaluated for DBS surgery, we will work with your neurologist or internist to ensure a smooth process. We will:

1. Request needed records from your physician
2. Try to arrange a coordinated series of visits to Northwestern
    a. Initial neurology and neurosurgery evaluations on one day, if you desire
    b. Other tests can be coordinated as well, such as:
        i. Imaging
        ii. psychological evaluation
        iii. preoperative neurologic testing
        iv. Preoperative medical evaluation
3. Maintain communication (written, email, and phone) with your physician throughout the process
4. Work with your local neurologist to coordinate care after your medications and programming are stabilized postoperatively so that they can continue most of your care locally

Why Northwestern for DBS surgery?

Northwestern Memorial Hospital Movement Disorder Surgery Program brings together the advanced resources of Northwestern Memorial Hospital and Northwestern University School of Medicine, one of the nation's premier institutions for research into movement disorders. The school was recently named by the National Institutes of Health as one of only 12 centers in the country to receive the prestigious Morris K. Udall Center grant for Parkinson's research. In addition, we team with the Rehabilitation Institute of Chicago, the nation's best rehabilitation center. We have consistently achieved the designation as a Center of Excellence by the National Parkinson's Foundation. The program provides comprehensive resources, evaluation, and treatment for patients with all types of movement disorders.

Our comprehensive team has a wealth of expertise in movement disorders surgery. Our neurologists, Drs. Simuni, Zadikoff, Melen and Malkani, have all completed fellowships in movement disorders with extensive experience in the preoperative and postoperative management of patients undergoing DBS surgery. They are national leaders in this field and have published extensively. They are continually involved in developing and testing the latest therapies for Parkinson's disease. Dr. Rosenow, director of Functional Neurosurgery at NMH and Northwestern University's Feinberg School of Medicine, completed a fellowship in stereotactic, functional and restorative neurosurgery. He was part of the team that developed and refined the frameless approach to DBS surgery. He has published widely on stereotactic surgery and movement disorders surgery and is a frequent speaker on the topic at local and national

meetings. Our center continues to bring innovations in care to patients with movement disorders in the most convenient and modern setting in the region.

Northwestern's Parkinson's Disease and Movement Disorders Center offers care in all aspects of life of patients with movement disorders. Our team consists of neurologists, neurosurgeons, psychologists, physiatrists (rehabilitation doctors), nurses, and therapists who all come together to provide total care for our patients. Pamela Palmentera, LCSW, our Center coordinator and social worker, has 25 years of expertise in caring for patients in the Chicago-land area with Parkinson's disease.