



Choosing Deep Brain Stimulation Therapy

A PRE-SURGICAL GUIDE



ST. JUDE MEDICAL™



“ Before receiving my DBS system, I did have some concerns about the system and the surgery and was very anxious about the process. But now I can say that my only regret is that I did not have this procedure sooner. It has put me back in the picture, and I intend to stay there for a long, long time. ”

MATTHEW

Father, Organic Gardener, DBS Recipient
Dallas, Texas, USA

Parkinson's: A Progressive Disorder

You and your doctor may have discussed how the symptoms of your Parkinson's will change over time. These changes require many different treatment options in different phases of treatment. It is important to understand the treatment options that can be customized to your specific symptoms and needs.

Why is my doctor recommending DBS?

At first, your treatment may have included a single medication to help improve your movement and reduce your tremor. After a while, you may have found the initial drugs to be less helpful. Next, your physician may have prescribed a levodopa formulation to help better control your PD movement symptoms. For most people, this medication level is highly effective in managing the tremor, rigidity, and slowness of motion of PD for a number of years.

But PD symptoms continue to change over time. Eventually, you may no longer be able to depend on levodopa either alone or combined with other medications to provide consistent, effective control. In addition, some side effects of the medications can be worse than your Parkinson's symptoms.

You may have noticed

- “Wearing off”: a decrease in the length of time a dose of medication lasts
- “Off periods” or “motor fluctuations”: the unexpected return of motor symptoms when a dose of medication should be working
- Dyskinesias: uncontrolled movements an hour or two after a dose of your medication

When you can no longer trust your medications to effectively manage your PD motor symptoms, you may find it difficult to complete activities of daily living, such as driving, getting in and out of a car, completing house chores, dressing, and even eating. These difficulties may even stop you from doing many things you enjoy. These changes can impact you, your family, and the people you care about.

You and your doctor may have discussed the need to explore options that may help you return to some of the activities you have not been able to participate in due to the symptoms of PD. For this reason, your doctor is recommending that you consider DBS as a treatment option.

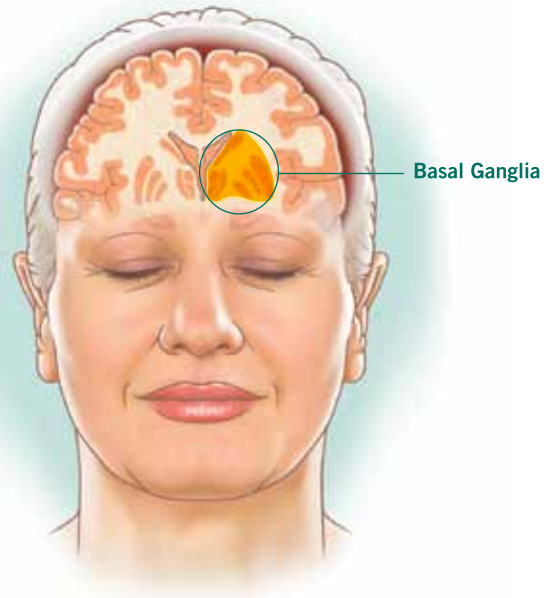
DBS: A Treatment Option for Parkinson's

DBS has been approved to manage the symptoms of Parkinson's since the mid 1990s. In addition, more than 75,000 people worldwide¹ have chosen DBS therapy.

DBS is a reversible therapy that can provide people with PD continuous control of their movement-related symptoms 24 hours a day. DBS can also be adjusted and customized to best manage an individual's specific PD motor symptoms.

How does DBS work?

Parkinson's disease is a slow, progressive brain condition that is known to particularly affect an area of the brain called the basal ganglia. One of the responsibilities of this area is to control movement. Movement is controlled by a balance of chemical and electrical signals that communicate between this area and other areas of the brain. During the early stages of PD, medication is used to help balance the chemical signals. This balance provides motor symptom relief. But as PD symptoms progress over time, medication may no longer be enough to control movement-related issues.



When medication alone is not sufficient, DBS may be an option to help restore electrical balance. DBS can help to restore normal brain communication or “signalling” by delivering mild electrical pulses to the basal ganglia. And restoring normal communication may help to reduce many motor symptoms of PD. DBS will not replace a person's need for medication, but many people can significantly reduce the amount and frequency of medication, which helps to reduce medication side effects.

How can DBS help me?

The goal with DBS is to help reduce the motor-related symptoms of PD and help improve overall quality of life. DBS can provide benefit by extending the period of time during which your symptoms are controlled. DBS may also result in the ability to decrease the total amount of medication you are taking and help to reduce medication side effects.

If you have responded well to levodopa therapy, DBS may help you with the following:

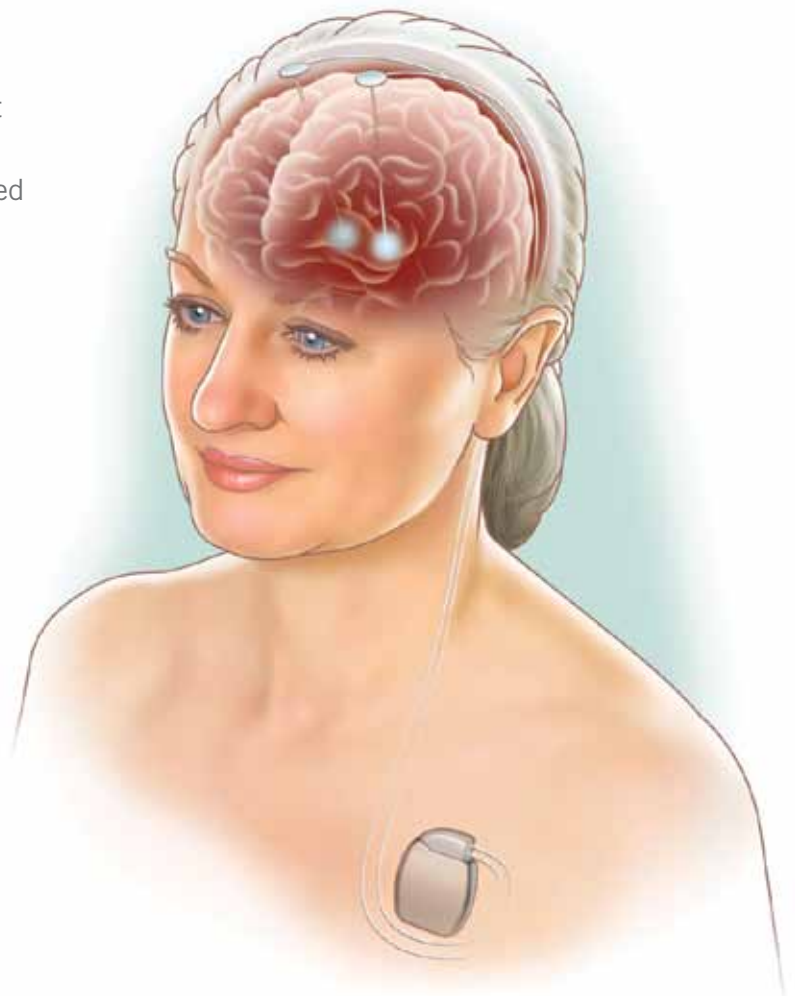
- Movement-related symptoms—With DBS, you may have more time during the day (up to 4-5 hours²) when you are not as affected by the tremor, stiffness, and slowness of Parkinson's.
- Medication—DBS may allow your doctor to lower your medication dosage. This can reduce unpleasant medication-related side effects, especially uncontrollable dyskinesias.
- Unexpected Symptoms—DBS may eliminate the unexpected return of PD symptoms, even when medication should be working.
- Quality of Life—DBS may improve your ability to move around and perform everyday, common activities such as dressing, eating, and getting in and out of a chair or car. With these improvements, many people are able to re-engage in their social life.

Is DBS a cure for Parkinson's?

It is important to note that DBS is not a cure for Parkinson's. Also, it does not manage all the symptoms of PD. But DBS can help manage movement-related symptoms that have responded well to levodopa.

In general, DBS will not help with

- Freezing and balance issues
- Non-movement symptoms of PD including depression, memory, concentration, or sleep problems
- Speech/voice issues. Some individuals receiving DBS therapy may experience a worsening of speech symptoms



What are the possible risks and complications of DBS?

As with any surgery or therapy, DBS has risks and complications. Most effects of DBS surgery are temporary and correct themselves within 30 to 90 days. However, some risks can be more serious and/or permanent. Talk with your doctor about the risks associated with placement and use of a DBS system.

Serious side effects

The risk of serious side effects from DBS is low, particularly with an experienced surgical team. The serious risks from DBS are mainly associated with bleeding occurring within the brain, possibly resulting in a stroke or seizure. This risk is low and occurs in approximately one percent to five percent of people. As with any surgery there is a risk of death, but the risk with DBS has been shown to be less than one percent.³

What are the temporary or reversible complications of DBS surgery?

Temporary or reversible complications from DBS can occur either from the surgery or from the device itself.

Possible complications⁴

- Difficulty with movement and speech—Temporary worsening of motor function (movement), increased dyskinesias, balance problems, and freezing can occur after DBS. DBS can have a temporary or a lasting impact on speech. It is especially important to discuss this issue with your doctor if your speech has already been affected by your PD.
- Infection—As with any surgery, DBS carries a risk of infection. This risk has been estimated to be three to four percent.⁵ Most infections can be managed by giving antibiotics before and after surgery. If a serious infection does develop, the entire DBS system can be removed.
- Changes in mood, memory, or thinking—For some people, DBS may worsen memory and thinking difficulty. For this reason, many people will undergo psychological testing before being approved for surgery. After surgery, some individuals may experience anxiety, depression, confusion, or hallucinations. These symptoms usually decrease within days of surgery and then completely disappear.
- Headache, dizziness, tingling of the face or limbs, or electrical jolting sensation—These temporary effects are usually directly related to the stimulation. They can be helped by adjusting the DBS system's settings. However, some people may experience these sensations because of the surgery itself.

Possible Technical Issues

In addition to the risk and complications mentioned above, you may experience other issues that impact the effectiveness of the therapy. Most issues listed below can be prevented or corrected. Discuss these issues with your doctor.

Possible technical issues can include⁵

- The lead may not be placed in the optimal area of the brain.
- The lead tip could move from the target area in the brain.
- The lead could break or disconnect from the system.
- A component of the DBS system could malfunction, including the battery.

Is DBS for Me?

You are unique. Each person with Parkinson's is unique. There are many factors that can impact a person's response to DBS. As you consider DBS as a treatment option, discuss your expectations about DBS with your doctor. This is very important to both you and your doctor. Your doctor will help you set realistic expectations about the surgery and living with a DBS system.

It is also important to discuss your expectations with your care partner. The decision to undergo DBS is significant for both of you. Open, honest discussion can help you make the transition as smooth as possible and minimize any disappointment from unrealistic expectations.

How will I respond to DBS?

Expectations to discuss with your doctor

Below you will find a list of things to consider and talk with your doctor about regarding your expectations. Use the space below to prepare for your discussion with your doctor. You will also find space to list questions of your own.

The thing that most frustrates me about having PD is _____

The side effect or problem with my medication that bothers me most is _____

After having DBS, I would really like to be able to once again _____

I would consider DBS successful if I could _____

If I had DBS, my carer would once again be able to _____

I would be disappointed if DBS did not do these things for me _____

The thing I am most concerned about regarding DBS is _____

The thing my carer is most concerned about regarding DBS is _____

Some realistic expectations for me following DBS are _____

Additional information from my doctor/other questions/notes

What Are the Components of a DBS System?

A DBS system consists of three main components: leads, a generator, and a programmer. In addition there is also a patient controller.

Leads

The lead is the wire that is inserted directly into the brain. It is less than 1.5 millimeters in diameter. The lead tip delivers mild electrical pulses from the neurostimulator to the targeted area of the brain. The wire connecting the lead to the neurostimulator is called an extension.



Neurostimulator

The neurostimulator is a pacemaker-like device that is the computer of the DBS system. When the system is turned on and the appropriate settings are set in the neurostimulator, it delivers precise electrical signals to the brain to help control movement-related symptoms of PD.



Clinician Programmer

The doctor has an external control device that is used to adjust the system's electrical signals to meet your specific motor symptom needs. The system can be adjusted as often as needed to control your symptoms.



Patient Controller

In addition, you will receive a controller that will allow you to check the status of your device and to turn it on and off if needed.



Preparing for Your DBS Surgery

Before you receive final approval to undergo DBS surgery, you will go through a number of evaluations by a multi-disciplinary team to determine if you are a good candidate. This will most likely include an evaluation by a neurologist to determine if your PD symptoms will respond to DBS. It may also include an evaluation by a psychologist or psychiatrist to determine the status of your cognitive (thinking skills) and mental health. And it may include an evaluation by a neurosurgeon to determine if you are a good surgical candidate. If you and your health care team decide you are indeed a good candidate for DBS, you will be scheduled for surgery.

Ask your doctor about possible complications associated with the procedure and the therapy, as well as restrictions you will be asked to follow during your recovery and for the long term. Also, discuss any questions and concerns with your doctor. Having questions and concerns is normal and expected. Your doctor will be able to answer your questions or provide you with additional resources. You can also find a list of additional resources at the end of this booklet.

What happens during the procedure?

Surgery for DBS does involve a hospital stay, the length of which varies from centre to centre. Also, the specific details of the implant procedure vary by centre. Ask the neurosurgeon who will be performing your procedure to explain the details of the procedure he or she uses.

The procedure generally involves the following steps:

Imaging. The day of your operation, you will undergo either a head MRI or CT scan. These help the neurosurgeon identify the exact location within your brain to place the leads. In some centres, imaging is done with a frame that is placed on the head prior to the images being taken.

Lead Placement. After the images are complete, you will be taken to the operating theatre. In most centres you will be asleep for most of the procedure. In some centres you may be semi-awake during part of the procedure. The time you are awake can be important because it can help the neurosurgeon determine if the leads are in the right place to help with your Parkinson's symptoms. You will be given a local anaesthetic to ease any pain at the scalp as well as medication to help you relax and relieve your anxiety. The brain itself does not feel pain, so there is no pain associated with the placement of the leads within the brain.

Neurostimulator Placement. The neurostimulator may be placed in your chest immediately following the lead placement or up to several weeks later. Prior to your surgery, your doctor will discuss with you when the neurostimulator will be implanted. Whether your neurostimulator is placed immediately after your leads or several weeks later, you will be under general anaesthesia (asleep) during this part of the procedure.

What happens after the procedure?

Following the operation, you will be sent to a recovery area. Then you will be transferred to a ward where you will begin your recovery process.

During the first 24 hours

- You will be closely monitored for any sign of complications.
- You will probably be able to eat a meal, get up, and move around the ward.
- Your doctor will provide medication to help control any surgical pain or headache. If headache pain becomes too severe or you notice other disturbing effects, such as blurred vision, notify your doctor or the hospital staff.
- Patients often experience exhaustion and some mild confusion after surgery. This is usually only temporary and generally subsides within 24 to 48 hours.

How long will I stay in the hospital?

The length of your hospital stay will vary depending upon the centre where your surgery is performed. Some people will be discharged within several days after surgery, while others will remain in the centre longer.



Questions to Ask Your Doctor

How many days will I be in the hospital? _____

How long will the operation take? _____

How many incisions will I have from my surgery and where will they be? _____

Will you shave all the hair from my head? _____

If so, how long will it take for my hair to grow back? _____

How should I take my PD medications the day before my operation? _____

How should I take my medications on the day of my operation? _____

Additional questions _____

Tips to Help You Prepare for Your Operation

The following check list will help you prepare for your procedure. You can also use the space at the end of the list to write down any specific instructions from your doctor.

- Check with your surgeon's office to make sure you know exactly when and where you need to be on the day of your surgery.
- Get instructions from your doctor about when to take your Parkinson's medication the night before your surgery and the day of the surgery.
- Tell your doctor about all medications and supplements you are currently taking. This includes paracetamol, aspirin, vitamins, and herbal supplements.
- Ask friends and family to help care for any pets or personal affairs while you are in the hospital. Don't be afraid to ask for help for you or your carer as you recover.
- Pack a week's supply of all of your medications in the original, labeled bottles for your hospital stay. Also, make a list of all of your medicines with dosages and times taken to provide to the hospital staff.
- Write down a list of names and phone numbers you might need, including emergency contacts.
- Pack a bag of items for your hospital stay, including personal toiletries, reading materials, and clothes to wear for your trip home. Include a shirt with buttons or a zip to make it easier to get dressed after surgery. In addition, consider packing a pair of socks to wear during surgery.

What to Expect After Surgery

The months following your DBS surgery can be an exciting time as you recover and begin to experience improvements. But the first few weeks after your procedure should be dedicated to healing and recovery.

What will my recovery be like?

Recovery is a process that involves your entire body. Allow yourself time to rest and heal. As you begin to recover, you will probably have discomfort in the area of the incisions. Over time, this pain should decrease and your energy and activity levels should increase. The most important thing during this period is to protect the incisions from infection.

In the first few weeks after your surgery, you should be able to resume a number of your normal daily activities—with some restrictions. Even if you feel great within a week or two, remember that your brain will also need time to heal. Choose activities cautiously. Trying to do more physically demanding activities too quickly could result in a potential fall or injury, for example. Also when some of the motor symptoms of PD are reduced, or go away, you may be tempted to participate in some activities that you used to do prior to the onset of PD symptoms. It is important to use caution since doing some of these activities too early can lead to an accident or harm. Talk with your doctor about what activities are acceptable during this time.

When will my DBS system be turned on?

Although doctors differ in their opinions about how soon after surgery stimulation should be turned on, most centres wait up to several weeks. Your doctor will decide when to turn on your stimulator based upon what he or she thinks is right for you and your recovery.

When will I see improvements in my symptoms?

During the first 6 to 12 months, your DBS team will work with you to adjust programming and medication to find the best possible personalised combination for your PD symptoms and lifestyle. Programming is painless and will be done using a device that can “speak” with your stimulator without the use of wires. During the programming session, the clinician will explore a range of stimulation variables to determine the optimal setting for you.

It is important to remember that there is no “perfect” response to the surgery and stimulation. Optimal benefit for your symptoms may take some time while your doctor identifies the best combination of stimulation settings and medication. You should not expect to experience a 100 percent improvement in your symptoms.

When will I be able to reduce the amount of my medication?

During the initial months with your DBS system, you and your doctor will work together to find the best combination of stimulation settings and medication to manage your PD symptoms. Make sure to discuss with your doctor what your expectations should be regarding the amount of medication you might require after DBS. Do not stop taking any of your medications unless your doctor tells you to do so.

Will I have any permanent restrictions with DBS?

People with DBS systems do have some permanent restrictions, such as the following:

- MRI— People with DBS systems should not have a total body MRI, a full-body radiofrequency (RF) coil MRI, or a head transmit coil MRI that extends over the chest.
- Diathermy—People with DBS should never undergo any form of diathermy, which is sometimes used by dentists and physical therapists for the treatment of pain. Injury can occur during diathermy whether the DBS system is turned on or off.

Ask your doctor about these and other restrictions.

Frequently Asked Questions

This section answers some commonly asked questions and also contains a list of questions you may want to ask your doctor.

Will my PD symptoms improve immediately after the operation?

Some people may experience some immediate post-surgical improvements. Most people will see improvements over several months as they recover from the operation and work with their doctor to find the best combination of stimulation and medication.

Will my head be shaved?

Most likely some of your hair will be shaved from your head. Some centres shave only around the incision area, while others shave the entire head. Talk with your doctor about his or her centre's policy.

Will I be able to drive after surgery?

Ask your doctor. You should not operate potentially dangerous machinery, power tools, or vehicles or engage in any activity that would be potentially unsafe if your symptoms were to return unexpectedly.

Will I be able to return to work?

If you were working prior to DBS surgery, it is likely you will be able to return after you recover from your procedure. If you were not able to work before surgery, discuss with your doctor what your possible outcome might be.

Will I be able to “feel” the stimulation?

Most people will not be able to feel the stimulation once appropriate settings have been determined. Some people may feel mild and painless sensations during a programming session. These sensations are almost always short-lived and disappear once stimulation settings are re-adjusted.

How often does the neurostimulator need to be replaced?

Since each person with PD has different stimulation needs, it is difficult to predict exactly how long a neurostimulator will last. After your operation, talk with your doctor about how long he or she estimates your neurostimulator may last.

Will DBS prevent my PD from progressing?

DBS is not a cure for Parkinson's. In addition, it is unlikely that it will eliminate all of your symptoms or stop them from progressing. The goal with DBS is to help improve your quality of life and provide an extended period during which your symptoms can be controlled. In addition, you may be able to reduce the amount of your PD medication and reduce medication-related side effects, such as uncontrollable dyskinesias.

How long will the benefits of DBS last?

Current data shows the motor benefits of DBS lasting for up to five years after the initial surgery.⁶ There are additional studies being done to review the longer-term benefits. Unfortunately, PD does continue to progress even after DBS, so the exact length of benefit will most likely vary on an individual basis.

What if a better treatment becomes available?

DBS is both a reversible and removable therapy, so it allows for many possible future treatment options.

Can I travel with a DBS system?

While you should always follow your doctor's advice, you will most likely not have any travel restrictions once you have recovered appropriately from your surgery. However, you will need to take special care when passing through airport security systems.

Can I exercise after having DBS?

Most people are able to return to low-impact exercise within four to six weeks after surgery. Talk with your doctor about what exercises might be appropriate for you after DBS surgery.

Information for the Carer

As the spouse or carer of someone with Parkinson's, you are very aware of how PD affects both of your lives. Because of the symptoms, you may help with the everyday activities of life, such as dressing and managing a household. You may also be experiencing increased social isolation as a result of the motor symptoms of PD or the uncontrolled dyskinesias caused by medications.

Parkinson's symptoms are probably negatively impacting you and the person with PD, so the doctor is recommending DBS as a possible therapy option. Keep in mind that the patient is most likely considering DBS as a way to potentially improve his or her life—and yours as well! The goal of this brochure is to answer some of the questions you may have about DBS therapy.

As a carer it is important for you to have all of your own questions answered and to have realistic expectations about how your life may change and what your new carer role may be like after DBS. While the idea of not having to provide so much care to your partner sounds wonderful, be aware that in reality, some people find it difficult when they are not needed as much after DBS. You may consider preparing yourself for this situation through quiet reflection, talking with a friend, or even talking with a qualified health care professional. In addition, it may be helpful to talk with the carer of someone else who has undergone DBS.

Listed on the following page are some specific questions you may want to discuss with the doctor. In addition, you may want to contact other resources for support, including online chat rooms, carer support groups, or resources available through your DBS centre.

Questions to Consider

What can we do prior to the DBS procedure to make sure we have appropriate expectations about the possible benefits of DBS therapy? _____

What will be required of me immediately following the surgery and over the next two to three months? _____

Will the patient have any special needs over the first three to six months? _____

Will the patient be able to work or drive after surgery? _____

What are the potential side effects of DBS therapy for the person I care about? _____

Sources of Additional Information*

European Parkinson's Disease Association

www.epda.org

Parkinson's Disease Society of the United Kingdom

www.parkinson.org.uk

Rewrite Tomorrow

www.rewritetomorrow.eu.com

WeMove

www.wemove.org

National Parkinson Foundation

www.parkinson.org

DBS-STN.org

www.dbs-stn.org

Life with a Battery Operated Brain:

A Patient's Guide To Deep Brain Stimulation Surgery for Parkinson's Disease

Author: Jackie Hunt Christensen, Publisher: Langdon Street Press

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- 1 Medtronic, DBS Therapy for Parkinson's Disease website. About Deep Brain Stimulation. Available at: <http://www.medtronicdbs.com/parkinsons/about/index.htm>. Accessed July 24, 2010.
- 2 Weaver, FM, et al, Bilateral Deep Brain Stimulation vs Best Medical Therapy for Patients With An Advanced Parkinson's Disease: A Randomized Controlled Trial, *JAMA*. 2009;301(1):63-73.
- 3 Voges, J, et al. Thirty Day complication rate following surgery performed for deep-brain stimulation. *Mov Disord* 2007; 22(10):1486-9.
- 4 Lyons, J., Okun, M. Parkinson's Disease: *Guide to Deep Brain Stimulation Therapy*. 2nd edition. National Parkinson Foundation; March 2007.
- 5 Lyons, KE. Surgical and hardware complications of subthalamic stimulation: a series of 160 procedures. *Neurology*. 2004;63:612-616.
- 6 Krack P, Batir A, et al. Five-year follow-up of bilateral stimulation of the subthalamic nucleus in advanced Parkinson's disease. *N Engl J Med* 2003; 349:1925-1934.



St. Jude Medical Neuromodulation Division deep brain stimulation (DBS) systems are indicated for use in unilateral or bilateral stimulation of the thalamus, internal globus pallidus (GPi), or subthalamic nucleus (STN) in patients with levodopa-responsive Parkinson's disease.

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