

Surgical Options

A Treatment Guide to Parkinson's Disease



About this book

GLOSSARY

Definitions for all words underlined in blue can be found in the glossary starting on page 60.

A comprehensive Parkinson's disease glossary can be found at [Parkinson.org/Glossary](https://www.parkinson.org/Glossary).

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An index of key words and topics can be found on page 63.

PARKINSON'S FOUNDATION RESOURCES

Certain pages include tip sheets with practical pointers. You can find more helpful tips for managing Parkinson's-related speech and swallowing changes in the books, fact sheets, videos, webinars and podcasts in our PD library at [Parkinson.org/Library](https://www.parkinson.org/Library).



The aim of this book is to describe the various types of surgical treatment that can be utilized to reduce Parkinson's disease (PD) symptoms in a subset of carefully selected individuals with a specific symptom or symptoms. This book will focus on the following potential therapies: deep brain stimulation, duopa therapy, lesion therapy, focused ultrasound.


This book was designed as a practical guide to explain the complete process required for people with Parkinson's and families considering surgical therapy. The content describes everything from the decision to have surgery, and the day of surgery, to surgical recovery. While the information contained in this book is intended to facilitate a discussion of surgical options with family, friends and healthcare team members, it is not meant to replace the advice of expert healthcare professionals involved in your care.

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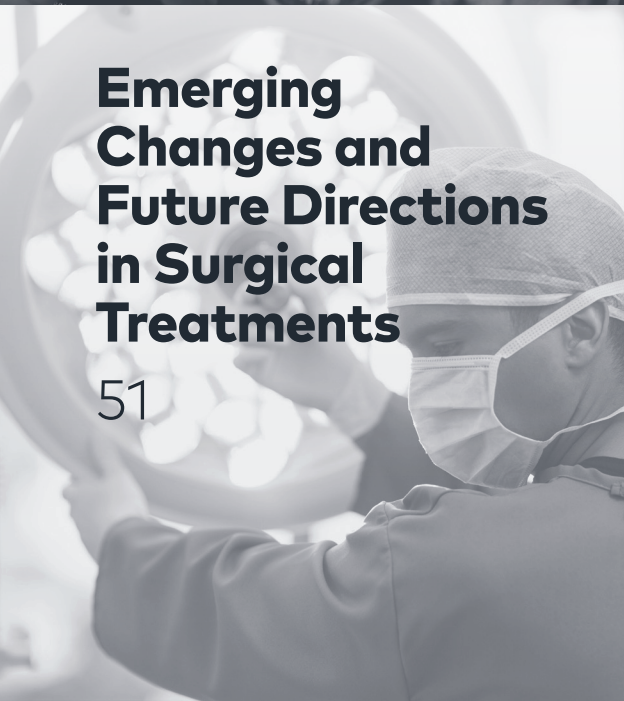
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CHAPTER ONE

About Parkinson's Disease

If you're reading this book, you are probably already familiar with Parkinson's disease, but here are some basics: Parkinson's is a progressive neurodegenerative disorder that affects about one million people in the United States and 10 million people worldwide. It is called a movement disorder because of the tremors, slow movements, stiffness, gait abnormality and muscle cramping. These symptoms are often referred to collectively as the "motor symptoms." It can also include "non-motor symptoms" such as depression, anxiety, apathy, fatigue and sexual dysfunction.

During the initial stages of PD (i.e., the first several years after a diagnosis), medications typically control symptoms in the majority of people with Parkinson's. As the disease progresses, however, individuals may need to take more medications, increase the dosages and, in many cases, take their medications more frequently. As disease duration increases, people with PD may notice that throughout a typical day they will experience good symptom control, referred to as "on time." There are also commonly periods where symptoms are much more noticeable, referred to as "off time" and periods where peak medication levels (usually an hour after taking

a medication dose) produce involuntary movements. These involuntary movements are referred to as dyskinesia. When individuals change from one of these three states to another, they are said to have "motor fluctuations."

If you are considering surgical treatment:

- **Consult with a movement disorder specialist.** A movement disorder specialist is a neurologist who has completed specialized training in PD and movement disorders, usually through a one- or two-year fellowship (make sure you ask for credentials). There are also neurologists in practice who have become experts in this area through their experience caring for many people with Parkinson's and also by completing continuing medical education courses.
- **Do your homework.** Learn all you can about the surgery you are considering. Call the centers that you may select to perform the surgery and ask questions about the care they provide. Make sure that you choose a center with an interdisciplinary team of health care professionals.

These professionals should have the training, technology and expertise required to provide specialized and expert therapy. Make sure the interdisciplinary team has a team meeting where your case will be discussed by everyone who evaluated you (prior to any surgery). This type of collaboration is considered an essential element to the success of this procedure.

- **Be prepared to invest a significant amount of time, energy and travel for both pre- and post-operative appointments, especially for DBS.** A published survey conducted by the DBS Society (Stereotactic and Functional Neurosurgery, 2005) revealed the need for a significant number of post-operative visits for both DBS programming and medication adjustments. These visits are most frequent during the first six months following implantation, and many experienced centers require monthly visits for the first six months. Undergoing DBS therapy requires a large emotional, physical and possibly financial commitment, depending on your insurance status. These are all important factors to consider before an operation. Duopa similarly requires frequent visits for device adjustments.
- **Make sure to ask who will be programming the deep brain stimulator or Duopa pump** if you are looking into one of these surgical treatments, and what kind of follow-up you can expect for any of the surgical treatments available for PD.

CHAPTER TWO

Deep Brain Stimulation (DBS) Therapy: An Overview

Deep brain stimulation (DBS) is a surgical therapy used for the treatment of Parkinson's disease (PD). During DBS surgery, a special wire, called a lead, is inserted into a specific area of the brain. The lead, which has anywhere from four to eight electrodes, delivers electrical currents to precise brain locations responsible for movement, regulating the abnormal brain cell activity that causes symptoms such as tremor and stiffness. It is important to keep in mind that DBS can only help relieve the symptoms of Parkinson's, not cure or stop its progression.

"The last five years before Sam had his brain surgery were very hard. I had to help Sam with everything, including getting dressed, getting out of bed and taking a bath. It was emotionally draining. The joy was taken out of our lives. I felt more like a nurse than a wife. We almost never socialized, as it was just too difficult. He is like a new man since having the surgery. He can do almost everything for himself now. He doesn't need his walker any more, and I only need to help him get dressed in the morning before his medication starts working. We aren't afraid to go out to dinner or shopping because he doesn't shake as badly and he doesn't get stuck or frozen. The surgery gave us both back our independence and our marriage; life is good again. We are truly blessed and grateful." — Barbara

However, DBS is not for everyone. Though people with Parkinson's like Sam have greatly benefited, the current technology has fallen short in helping most people with Parkinson's to regain walking, balance, speaking and thinking functions.

How DBS works

DBS, first approved by the U.S. Food and Drug Administration in 1997, is now considered a safe and effective treatment for carefully selected people with Parkinson's with PD based on physiological experiments performed by Mahlon DeLong at Emory University and later developed into a human therapy in 1987 by professor and neurosurgeon Dr. Alim-Louis Benabid. Though we do not currently fully grasp exactly why DBS works, we have uncovered, over the last three decades, many important clues. Understanding DBS and how it may suppress symptoms requires a basic understanding of brain function. The brain is a complex organ with billions of cells and cell connections called synapses. These cells are connected to each other by axons, or "pipes," that send messages back and forth. Communication is facilitated through a series of circuits that are organized to sort and process information. The connections in the brain circuits are similar to the electrical wiring in your house or car. If one circuit malfunctions, it can disrupt the entire system. Research has shown that in PD there are faulty signals in several brain circuits.

These faulty or disruptive signals seem related to many of the symptoms of PD (e.g., slowed movement, tremor and stiffness). When electricity is introduced into the circuit it "disrupts the disruption," restoring order and improving disabling symptoms. The electric current is thought to inhibit

cell firing, excite the axons (the pipes) and release calcium from brain cells, called astrocytes. Calcium seems to trigger a series of reactions that lead to the release of chemicals, called neurotransmitters. There are also changes in blood flow and in the natural rhythm of the brain, called neuro-oscillations. Collectively, this symphony of changes acts to combat the symptoms of PD. We believe that DBS results in changes in neurophysiology, neurochemistry, neurovascular, neuro-genesis and neuro-oscillations. We do not understand which changes underpin the improvements we see with device activation.

In PD, there is an area of the brain called the substantia nigra pars compacta (SNc) where electrical signals are not processed normally. In this region, there are more than 400,000 dopamine-producing brain cells. Over time, these brain cells can become injured and slowly die. This process reduces the natural production of dopamine, and this loss of dopamine heavily influences the appearance of PD symptoms. The SNc has connections to important areas of the brain that control both motor and non-motor functions. Two important interconnections are with the globus pallidus internus (GPi) and the subthalamic nucleus (STN). These brain areas send signals affecting the movement of arms, legs and neck, as well as other functions including thinking and mood. By placing DBS leads (wires with tiny electrodes) in either the GPi or the STN, the transmission of electrical signals through these areas can be altered and, in most cases, this results in smoother, more fluid movement. Small areas within the GPi and STN have been shown to be powerful DBS targets, especially to address the symptoms of tremor, rigidity, bradykinesia, motor fluctuations and dyskinesia.

Location of DBS target areas and substantia nigra (SN)

In DBS surgery, leads are implanted within a carefully chosen target area in the brain. Depending on the case, the target will be the STN, GPi, or ventralis intermediate nucleus of the thalamus (Vim). STN or GPi are the preferred targets for improving most PD symptoms.

DBS may be placed in many other brain locations and has been used in many other neurological disorders. Occasionally, the Vim is also targeted for treatment. A DBS lead in this area can result in an impressive reduction in arm tremor. In most cases, however, it does not improve lower extremity tremor, rigidity, bradykinesia or dyskinesia. Vim is, therefore, the preferred site for another condition known as essential tremor.

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The following table summarizes the three different sites for DBS therapy:

DBS SITE	EFFECT OF THERAPY
Thalamus (Vim)	Reduces tremor but not the other symptoms of PD
Globus pallidus (GPi)	Reduces tremor, rigidity, bradykinesia, dyskinesia; improves "on-off" fluctuations
Subthalamic nucleus (STN)	Reduces tremor, rigidity, bradykinesia, dyskinesia; improves "on-off" fluctuations

Leads may be placed on one side of the brain (unilaterally) or on both sides (bilaterally). Once the lead is placed, it is attached to a wire that runs under the scalp and just beneath the skin of the neck. It is then connected to a pulse generator, or neurostimulator. The neurostimulator, which is also called a pulse generator or implantable pulse generator (IPG), is located just below the collarbone and under the skin of the chest (or occasionally in the abdomen). Similar to a pacemaker, the pulse generator delivers electricity to the lead that is implanted in the brain. The pulse generator can be either single-chamber (connects only one lead) or dual-chamber (connects two leads). The pulse generator is turned on and off by a remote control similar to the ones used for televisions. The DBS programmer can adjust the DBS settings to one of thousands of combinations to achieve optimal symptomatic improvement.

Following DBS activation, the lead and the electricity it emits will work to normalize the brain signals in the affected circuits. Most people with DBS report experiencing a smoother response to medication, more "on" time, and improvements in dyskinesia, tremor and rigidity. When the DBS electrode is activated some side effects can occur.

Depending on the type of DBS electrode that is implanted, different strategies can be used by the DBS programmer to try to avoid these side effects.

Following DBS therapy some people with PD will require less help from their family and friends and they will achieve more independence in their daily lives. However, it is important to keep in mind that DBS does not replace the care partner. Most people are not able to return to work after DBS surgery, and it will not, in most cases, allow patients to return to complex activities, such as golfing.

DBS devices

Several components make up the DBS system. Three companies currently have FDA-approved devices: Medtronic manufactures Activa® Parkinson's Control Therapy; Abbott manufactures the Medical Infinity Directional DBS System™; and Boston Scientific manufactures the Vercise™ DBS and Vercise Cartesia Directional Lead System.

First, the DBS lead (thin wire) is implanted in, or as close as possible to the intended brain target area. The wire is just over a millimeter in diameter – about the size of a thin wire used for hanging pictures. The Medtronic lead has four electrodes and can target the STN or GPi. The Abbott and Boston Scientific devices have eight electrodes and target the STN.

Next, the connecting wire is attached to the brain electrode and then to the impulse generator battery (IPG). The IPG supplies electricity through the connecting wire to the 4–8 electrode contacts on the DBS lead. The IPG is typically placed in the chest but in rare circumstances can be placed in the abdomen.

THE CURRENTLY AVAILABLE IPGs ARE BELOW:

Activa SC

Controls one brain lead for unilateral stimulation. Patient programmer is digital and allows for up to four group settings that the patient can change between (see Chapter 6 for explanation of group settings and adjustment of stimulation). It can also allow for some patient self-adjustment within certain parameters provided by the DBS programmer.



Image courtesy of Medtronic, Inc.

Activa PC

Controls two brain leads for bilateral stimulation. Patient programmer is digital and allows for up to four group settings (see Chapter 7) that the patient can change between. It can also allow for some patient self-adjustment within certain parameters provided by the DBS programmer.



Image courtesy of Medtronic, Inc.

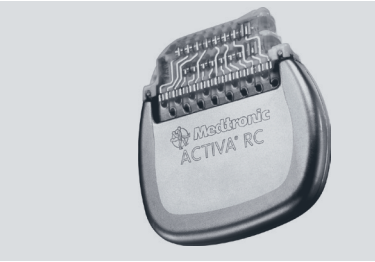


Image courtesy of Medtronic, Inc.

Activa RC

Controls two brain leads for bilateral stimulation. Patient programmer is digital and allows for up to four group settings that the patient can change between. It can also allow for some patient self-adjustment within certain parameters provided by the DBS programmer. This device is rechargeable and can last 15 years.



Image courtesy of Abbott

Infinity

Comes in two sizes and has a non-rechargeable, maintenance-free battery. The system features Bluetooth wireless connectivity. Patients are provided with an Apple iPod touch controller to allow them to turn the device on and off and change modes.

Vercise™ DBS System

A System that includes the Vercise PC or Vercise Gevia™ IPG and Vercise Cartesia™ Directional Lead(s) form the Vercise Directional System. Rechargeable battery with multiple independent current control (MICC) technology capable of bilateral stimulation and FDA-approved battery longevity of 15 years.* Patients receive a Patient Remote Control with wireless connection and the ability to switch between four program settings, check the battery level and turn the device on and off.



Image courtesy of Boston Scientific

Vercise Gevia™ DBS System

Next-generation rechargeable DBS system, compatible with the Vercise Cartesia™ Directional Lead, provides a rechargeable Directional System* for DBS.

*Battery life is dependent on the stimulation settings and conditions.

Vercise™ PC DBS System

Compatible with the Vercise Cartesia Directional Lead, Vercise PC provides a thin, contoured profile designed for patient comfort. The non-rechargeable system offers a directional primary cell with multiple sources available.



Image courtesy of Boston Scientific

Finally, the last part of the system is one that is not implanted into the body. It is the patient controller. The Activa SC, PC and RC all use the same remote. The Infinity device uses an Apple iPod touch as the patient controller; it has Bluetooth wireless connectivity. The Boston Scientific Patient Remote also connects wirelessly to the IPG. All three controllers allow the patient to turn the IPG on and off and to check the battery status. They also allow the patient to self-adjust within parameters provided by the DBS programmer.

The Medtronic IPGs are adjusted with an N'Vision or Samsung tablet programmer, devices that communicate through the use of radio waves, which can regulate the electricity delivered to the electrodes. Programming is performed by holding the programmer over the IPG (i.e., over the chest or abdomen). The Abbott device leads are programmed by providers with an iPad mini during office visits. Clinicians can do their motor skills assessments wirelessly. The Boston Scientific device is programmed by physicians using a Surface Pro 3 and the Patient Remote Control. Programming is performed by placing the remote control over the IPG.

DBS Questions and Answers

What symptoms does DBS help?

DBS can help improve the motor symptoms of PD. Typically, these are:

- Tremor or shaking in 80% of sufferers. Complete or partial tremor suppression.
- Rigidity, or stiffness.
- Bradykinesia, or slowness of movement.

DBS is a powerful therapy for addressing the motor complications of PD, which are often related to medication (e.g., Sinemet and agonists), including:

- Dyskinesia – involuntary, irregular, writhing movement. Dyskinesia can be particularly severe when medications are at peak levels.
- Dystonia – sustained, involuntary contraction of muscles – can lead to painful cramping of the feet or hands, curling toes or turning and twisting of the neck.
- "On/off" fluctuations are when a person cycles between "on" time, when the medication is working to control symptoms, and "off" time, when medication has worn off and PD symptoms return.

DBS will usually temper the degree of fluctuations experienced during "on" and "off" periods. DBS will not address dopaminergic unresponsive symptoms, such as walking, talking and thinking issues. DBS will, however, address medication-unresponsive tremor.

DBS can also improve some non-motor symptoms, including mood, energy level and general sense of well-being. As a general rule, symptoms that are helped by medication will be improved by DBS.

Is it better to have DBS on one side of the brain or both sides?

DBS on one side of the brain mainly helps symptoms on the opposite side of the body. Placing two leads can, in some cases, provide incremental improvement in motor function, especially if patients have significant symptoms on both sides of the body. Two leads may, in a few cases, improve walking, although walking will worsen over time. Some people with Parkinson's will also experience a worsening of walking particularly following implantation of two DBS leads. For individuals whose symptoms are mainly affecting one side of the body, DBS surgery on the opposite side of the brain may be sufficient. New research has suggested that one third or more of people with PD may actually do well long-term with a single-sided DBS lead (Journal of Neurosurgery, 2009). Many expert centers will

implant a single DBS lead, optimize DBS settings and medications, and in a follow-up visit re-evaluate the need for a second DBS. A single DBS lead carries half the surgical and post-surgical risk for complications.

How long do the benefits of DBS last?

Though it varies from person to person, in most cases the benefits last many years. People with PD have now been followed for 10 or more years with DBS, and the general rule has been that if the symptoms still respond to dopaminergic medications, then DBS will continue to work. DBS also will continue to work long-term against tremor and dyskinesia.

DBS settings are rarely changed much after the first year of therapy, so once settings are optimized, most of the changes will be made to the medication regimen.

Will I be able to stop taking my PD medications after I have DBS?

DBS is not a substitute for medication therapy. After the DBS system has been optimized through programming, the neurologist or nurse may attempt to gradually lower medication doses. Although most people will need to remain on medications after DBS surgery, many will be able to lower their total daily dose by 30 to 50%. Many will also be able to take their medications less frequently throughout the day. In the rare case where medications can be stopped completely, it will be added back as more symptoms emerge over time.

It is important to understand that medication reduction following DBS is not a guarantee and should not be a goal of surgery; rather, you should consider the right balance between medication usage and DBS therapy.

How do I know if I am a good candidate for DBS?

Before deciding to move forward with DBS surgery, there are lots of things to consider. Movement disorder specialists are neurologists who are experts in PD and its treatments, so you should consult a movement disorder specialist to help you determine if DBS is the right choice for you. They may be able to improve PD symptoms so that DBS is not necessary or can be delayed for several years. DBS, in general, is not helpful and could be harmful when applied to other conditions that can mimic PD, such as Lewy body dementia, progressive supranuclear palsy, multiple system atrophy and corticobasal degeneration. A movement disorder specialist is the best resource for confirming that you have PD before you have surgery.

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The best candidates for DBS therapy will meet most of the following criteria:

- You have had PD symptoms for at least five years.
- You have "on/off" fluctuations, with or without dyskinesia.
- You continue to have a good response to PD medications, especially carbidopa/levodopa (though the duration of response may be insufficient).
- You have tried different combinations of carbidopa/levodopa and dopamine agonists under the supervision of a movement disorder neurologist or specialist.
- You have tried other PD medications – such as entacapone, tolcapone, selegiline, apomorphine or amantadine – without beneficial results.
- You have PD symptoms that interfere with daily activities.

Not everyone with Parkinson's is a good candidates for DBS therapy. DBS is generally not appropriate for people who:

- Have as the main disabling symptom trouble with balance, walking or freezing that is not helped by PD medication.
- Have as the primary disabling symptom trouble with speech that is not helped with PD medications.
- Have confusion, disorientation and/or difficulties with memory and thinking on a daily basis.
- Have depression, anxiety or another psychiatric illness that has not improved or been stabilized with proper therapy, such as medication and counseling.
- Have a questionable PD diagnosis.
- Have another serious health condition, such as severe heart or lung disease.

What if DBS doesn't work?

It is possible that DBS therapy will not help; this condition has been referred to as DBS failure(s). Most reasons for DBS failures are preventable, including choosing a poor candidate for surgery, problems with the surgery (due to lead placement or hardware dysfunction), problems with programming, problems with medication management or disease progression. If you have not improved six months following your DBS surgery, ask your doctor if you need a complete workup to search for a correctable cause of the DBS failure.

Are there activities that I need to avoid following DBS therapy?

Generally, you can return to normal daily functioning within a few months of the DBS surgery. Always check with your neurologist for specific instructions. It is best to avoid neck manipulation, massage or other direct physical contact with the implanted devices. Also avoid climbing, reaching for objects above head level, and working on the roofs of houses and buildings. Swimming and sporting events are generally okay, as long as there is no contact with the device.

Can I exercise after having DBS?

Yes, most people with PD return to low-impact exercise within four to six weeks following DBS surgery. Contact sports or exercise that poses a risk of physically striking the neurostimulator or the connecting wire should be avoided. Exercise is like medication in that it should be considered an integral part of treatment for PD. We encourage all people with PD, pre- and post-DBS, to exercise daily.

Are there some electrical devices I should avoid?

Most basic household and garden electrical devices are safe to use and contact; this includes microwaves, radios and computers. Certain medical devices and possibly some high-power industrial machinery can be dangerous. Diathermy, a deep-heat treatment administered by some health care providers, is dangerous and should never be performed in patients with existing DBS. Total body coil [MRI \(magnetic resonance imaging\)](#) that is used to image the body) can be dangerous to a person with DBS; note that MRI scanning of the brain can be performed, as long as proper safety precautions have been followed. Before having any medical procedure that may interfere with the DBS device, check with your medical team or the manufacturer of your DBS equipment. Some of the newer DBS devices have been approved to be imaged by MRI scanners.

How long will the battery last? What should I do when it stops working?

The battery usually lasts between two and five years. The battery life varies depending on the settings needed to control your symptoms. We recommend that your DBS programmer check the battery life at every visit and inform you as to when the neurostimulator needs to be replaced. Handheld devices issued to you can also be used to check your battery. We generally recommend preemptive replacement of batteries before they fail usually at approximately 10%. This replacement can be done as an outpatient procedure. Once battery power is depleted, your symptoms will likely worsen and more medication than usual may be needed until the neurostimulator is replaced.

Can the DBS stop working suddenly, after working for several months or years?

Yes, malfunctions are usually a result of one of two reasons: the battery power has been depleted or the hardware in the device is malfunctioning. For example, there could be a break in the connecting wire in the neck or scalp. If your PD symptoms suddenly worsen, contact your treating neurologist or neurosurgeon immediately, as there may be a problem with the DBS system.

If a cure or new treatment for PD is found, can I have the DBS system removed?

Yes. DBS is removable and reversible. You can have the leads and neurostimulator taken out. You can try any new FDA-approved symptomatic treatment or potential cure treatment if it becomes available. Rarely over the last decade have we encountered patients wishing to have their hardware removed.

How expensive is DBS? Will my insurance cover the costs?

Each DBS surgery can cost between \$35,000 and \$50,000, and upwards of \$70,000 to \$100,000 for bilateral procedures. These estimates include the cost of the surgery, devices, anesthesia, hospital fees and physician fees. The type and amount of health insurance you have will affect the overall cost. Since DBS is approved by the Food and Drug Administration for the treatment of PD, Medicare and most private insurance carriers will cover most, if not all, of the costs of the operation. Your personal insurance policy will specify DBS coverage. If you are worried about cost, ask the neurosurgeon to meet with his or her financial counselor so that you and your family will know what to expect.

Will my neurostimulator device activate the metal detector at the airport?

Yes, it may possibly set off the alarm, and the security equipment may turn the neurostimulator off. Most airports will make special accommodations for people with medical devices and will allow them to bypass the metal detector. Bring your Parkinson's Foundation Aware in Care Kit, a free bag filled with tools to keep you safe when you travel or go to the hospital, when you travel, including your medical card explaining the neurostimulator and how it may be affected by the detector. Share this information with security personnel.

Will I feel the electricity when the stimulator is turned on?

Most people with DBS report feeling a brief tingling sensation for a few seconds after the device is turned on. You may temporarily feel a more intense electric sensation during stimulator programming or if you are near a strong magnetic field, such as a security device.

If I have a heart pacemaker can I have DBS? If I have DBS and later need a heart pacemaker, does my DBS system need to be removed?

A person can have both a brain stimulating system and a cardiac pacemaker. In order for both systems to work and not interfere with each other, they should be placed at least 10 inches apart. This might require placing the neurostimulator for the brain stimulation system under the skin of the abdomen instead of the chest wall.

What if a person needs emergency resuscitation for a heart problem, such as a cardiac arrhythmia, a change in the heart rhythm or a heart attack? Can they safely have electrical shock procedures such as cardioversion or defibrillation?

The general consensus is that if emergency cardioversion or defibrillation is needed, then it should be performed. The most likely complication is that the neurostimulator will become defective and will need to be replaced. Elective, non-emergent cardioversion for less serious arrhythmias, such as atrial fibrillation, can be performed if necessary, but the DBS system(s) should be turned off and the amplitudes/voltages set to zero before and during the cardioversion. In addition, protective shields should be placed over the neurostimulator(s) prior to elective cardioversion.

Can I use machinery and electric tools?

Some machinery and tools that produce a strong magnetic field can turn the neurostimulator off and on. Most small power tools (e.g., drills and saws) and yard tools (e.g., lawnmowers or tillers) can be used without any problems. To decrease interference with the DBS system, try to avoid any direct or close contact with the tool and the neurostimulator. Never use or be near large power machinery, power lines, arc welding equipment, electric steel furnaces, induction heaters or MRI machines.

Should I turn my stimulator off at any time, like before I go to bed?

The system should remain on at all times, even while sleeping or during times of rest. Continuous stimulation has been shown to offer the best control of PD motor symptoms. However, in the case of Vim DBS lead placement for tremor only, most patients can turn off the neurostimulator at night to save battery life. In special circumstances your doctor may recommend turning the device off at night.

CHAPTER THREE

DBS: Risks, Complications, Special Information and Warnings

Like any surgery, deep brain stimulation (DBS) carries with it a risk of complications. Problems that may occur as a result of the procedure can be serious and permanent or temporary and reversible. In addition, malfunctioning DBS devices can result in post-operative problems.

"I didn't have a very good experience with DBS. I read about it and passed all my evaluations, so the Parkinson's doctor said I could have it done. I expected it to make my Parkinson's go away or at least make it so I didn't feel like I had PD anymore. That isn't what happened. I had a seizure the day after the surgery. Luckily, my brother was with me when it happened and called 911. I don't remember anything except feeling funny and then waking up in the ambulance and feeling tired. I didn't have any more seizures. Then, about a month after the surgery, I had the system programmed, and I had less tremors and slowness. But then they came back just like before, so I had six more programming sessions over the next five months without much of a difference. I could move a little faster and my muscles weren't as stiff, but it wasn't a very big improvement. I'm now thinking about having the system taken out. The doctors explained that sometimes it just doesn't seem to work and they have to remove the electrodes and put them in a different spot. The doctors think that the electrode might have moved because of my seizure and that it is not in the spot they wanted it to be in. I haven't decided whether I want to have the surgery done again or not." – Jean

Serious or permanent complications

The risk of serious or permanent complications from DBS therapy is very low. The risk of death is less than 1%. There is a small risk of stroke from bleeding in the brain during surgery, about 2 to 3%. While most complications will have no after-effects, some people may experience lasting, stroke-like symptoms, such as weakness, numbness, problems with vision or slurred speech. People with a history of bleeding problems will have a higher risk for a stroke during DBS surgery. Hydrocephalus is a rare but possible complication of DBS, usually caused by a buildup of fluid in the brain, which leads to increased pressure. If hydrocephalus develops, a neurosurgeon may need to insert a shunt to redirect the fluid and relieve the pressure.

Temporary or reversible complications

Temporary or reversible complications may result as a side effect of the surgery or electrical stimulation. These potential complications include the following:

— **Changes in mood, memory and thinking**

DBS can worsen memory and thinking and can cause anxiety, depression, apathy, confusion, hallucinations or an overly excited mood. These psychiatric symptoms usually lessen within days or weeks of the surgery and typically disappear completely. If these symptoms persist, medication or stimulation adjustments can remedy them. People with known cognitive or psychiatric problems, such as dementia or severe depression, are at a much greater risk for these complications, and they typically do not qualify for DBS therapy. Suicidal thoughts and suicide have been reported with DBS therapy as well. These types of neurobehavioral symptoms may also occur from overly aggressive medication reduction.

— **Seizures**

A few people who undergo DBS will have a seizure. If a seizure does occur, it will usually occur during the surgery or within the first week after surgery. Seizures related to surgery will usually resolve. If seizures continue, they are more likely to be related to a stroke, brain infection or irritation of the brain by the DBS lead. In these cases, seizure medications may be prescribed.

— **Infection**

There is a risk of infection at the surgery sites in the brain, scalp or chest – about a 5-20% chance. To prevent infection, antibiotics are administered during surgery. If a serious infection develops, the electrode, connecting wire and/or neurostimulator may have to be removed.

— **Problems with movement and speech**

Dyskinesia, temporary worsening of movement, balance problems and slurred speech are all possible following DBS. Sometimes these symptoms can be improved with expert programming of the DBS. In other cases these symptoms are permanent.

— **Headache, dizziness, tingling of the face or limbs, an electrical jolting sensation**

These problems, along with worsening dyskinesia, may be improved by adjusting the stimulator settings and will likely be almost immediately improved by turning off the stimulator with the patient controller. An adjustment of the stimulation settings will most often take care of these side effects, but also in some cases such as dyskinesia medication reduction may also alleviate the issue(s).

Other risks of surgery

- **Pain, inflammation or swelling at the surgery sites.**
- **A very small risk of swelling or an allergic response to implanted materials.**
- **Malfunctioning DBS devices, associated with the DBS lead, connecting wire and neurostimulator.** These types of difficulties include lead migration (when the electrode has moved away from the optimal target site); fracture, disconnection or damage of the connecting wire; malfunction or injury to the neurostimulator; or misplacement of the brain electrode.

Many of these problems cannot be predicted or prevented. Even with the best equipment, skills and technique, there is always the possibility that the lead may not be placed in the optimal brain location. Even highly trained experts working at DBS centers may misplace electrodes. In some instances, a repeat surgery may be needed to adjust placement or correct a faulty device. Avoid twisting or pushing the implanted parts of your DBS system, such as the neurostimulator (battery). Manipulations can damage the system or cause skin erosion, and if there is damage it may require surgery.

Special Information and Warnings

Once these electrical wires (leads) have been placed in the brain, there are some strict rules you will need to follow regarding other electrical devices. Magnetic and electrical currents in the environment can cause the DBS system to malfunction and can be dangerous.

MRI and X-rays

MRI scanning uses magnetic fields and radio waves to view images of organs and other structures, including the brain. While you can have an MRI after you have DBS, it should only be done under close supervision by physicians who are familiar with procedures for people with DBS. For example, a brain MRI should only be performed with a head coil MRI, with a strength of 1.5 Tesla or less. No complications or injuries have been reported using this type of head MRI, and it is considered safe for those with DBS. The magnetic field of the head coil MRI can turn some DBS systems on and off. There are other criteria that determine the type of MRI that is safe for each individual. Prior to any MRI, you should always check with your DBS center staff to ensure the type of MRI is safe with your particular DBS system.

24 SURGICAL OPTIONS

Some DBS systems are only safe for imaging of the brain while others are safe for full-body MRI imaging. Always check with your implanting institution for the type of MRIs that are safe with your DBS system. Also, not all imaging centers are certified to do imaging in DBS patients.

CT scans, DAT/SPECT scans, common X-rays, fluoroscopy, and PET (positron emission tomography) scans are safe for people with DBS. However, scans of the brain or head will have some distortion of the picture from the DBS leads, so the quality of the image may be compromised.

Ultrasound

Ultrasound procedures, such as carotid doppler or abdominal ultrasound, can be performed safely. The amplitude/voltage of the DBS system should be turned to zero and the device turned off prior to procedures. Also, the ultrasound microphone should be placed at a distance of 6 inches or more from the neurostimulator on the chest wall. If a person has a neurostimulator placed in the left chest, they should not have an echocardiogram, or ultrasound of the heart, unless the microphone is greater than six inches from the DBS neurostimulator. After any ultrasound procedure, it is a good idea to visit your DBS center to check your device for proper function or use your remote to check to be sure the device is on and functioning. The main problem with having ultrasound procedures is that the neurostimulator may affect the ultrasound quality, so the test may not be accurate. Otherwise, there is no serious risk involved in having these procedures performed.

Cardiac pacemakers

Cardiac pacemakers can usually be placed in people who have had DBS therapy, as long as the neurostimulator and cardiac pacemaker are 10 inches apart.

Diathermy

Diathermy is a deep-heat treatment that is sometimes used by dentists and physical therapists for the treatment of pain. Diathermy should never be used in a person who has DBS leads, as it can quickly heat up the leads, resulting in stroke or even death. It can also damage the neurostimulator system.

Electrocautery

Most surgeons use electrocautery, a form of electrical heat, to stop minor bleeding during surgery. Electrocautery can be used on people with DBS, but only with the following safeguards to minimize any flow of the electrical current toward the DBS device:

- Inform the surgeon that you have DBS therapy well before the surgery; contact your neurologist to let him or her know that you are having surgery.
- Just before surgery, the leads should be turned off and the amplitude settings turned to zero.
- Bipolar electrocautery should be used to lessen transfer of electricity. Do not use a unipolar device.
- A ground lead should be placed on one of your legs. Any electrical charges that might transmit from the electrocautery device will be directed to the ground lead on your leg instead of the neurostimulator system.

Miscellaneous procedures

- Any type of medical procedure that will be performed directly over the neurostimulator device or connecting wire is not recommended. It could damage the device. Most X-rays can be performed safely.
- Do not allow your dentist to place electric drills or cleaning tools near the neurostimulator, connecting wire or implant site on the scalp. Dental X-rays are okay.
- If you have a mammogram, be sure that the pressure of the machine on the breast does not directly compress the neurostimulator or connecting wires.
- Radiation therapy for the treatment of cancer can be performed as long as it is not performed too close to the neurostimulator and a protective shield is placed over it.
- Lithotripsy, a procedure to break up kidney stones, is not recommended unless it is the only medical option, as the treatment can damage the neurostimulator. If it is the only medical option, then protective shielding should be placed over the neurostimulator, which should be turned off and amplitude/voltage set to zero.

CHAPTER FOUR

DBS: Before, During and After Surgery

If you decide to pursue deep brain stimulation therapy, the next step will be to plan and prepare for your surgery and recovery. Understand that it is important to select a center that has a staff of experts who specialize in DBS therapy for the treatment of Parkinson's disease.

"Parkinson's disease is something I have come to live with, but DBS surgery has made it so much easier. I was very scared to have it done. My doctor recommended it to me for two years before I decided to go to a DBS center for an evaluation. What I would tell someone with PD who thinks they might need DBS is to go to a good center and get a lot of information about it. The thing that really convinced me to have the DBS was talking to another person with Parkinson's who had it done. Only someone who has had it can really explain it and let you know just how scary, but also how helpful, it can be."

– Jose

Once you have been referred to a DBS center, plan to bring a family member or friend with you to your appointments. Make sure that you meet with the movement disorder specialist, [neurosurgeon](#), [neuropsychologist](#), psychiatrist and nurses who will be involved in your care. In many cases a physical therapist, occupational therapist and speech language-pathologist will be necessary members of the team. Be prepared to ask questions about DBS, and make sure that they are answered to your satisfaction before the procedure takes place. Ask the staff if there are other patients who have had the surgery performed, and if you can speak to them about their positive and negative experiences.

The following are suggested questions for the neurologist, neurosurgeon or nurse during your visit to the DBS center. We recommend that you bring this booklet with you and write down answers to each question as you ask them.

How many DBS surgeries have been performed at this center?

How many are performed each month? Most centers will do one or more surgeries per week. Larger centers may do one to five procedures per week.

Does this center use microelectrode recording? Not all neurologists and surgeons use this technique. If the center uses microelectrode recording, ask about the experience of the neurologist/physiologist who will be doing this specialized procedure. If the center is not adequately experienced in microelectrode recording, consider having the surgery at another center.

Will both sides of the brain be operated on during the same surgery, or is a separate surgery done for each side? In one third or more of cases, a second DBS lead may not be needed and it is sometimes safer to have the leads implanted in different procedures. Depending on your individual situation, both leads may be implanted in one surgery, each side may be performed as a separate surgery, or you may decide to only have the lead implanted on one side.

Will I have the neurostimulator (IPG) placed in my chest when the lead is implanted, or will that be done later? Some centers require that you return several weeks after the lead is placed to have the IPG implanted under the chest wall, while other teams will place the IPG on the same day as the brain lead(s).

Who will program my DBS system and adjust my PD medications after the surgery? For the first several months, it is best to return to the center where the surgery was done for programming and adjustments. When the programming is working and frequent adjustments aren't needed, you can, in many cases, return to your regular neurologist for care. Centers that perform the surgery should offer full post-surgery services. In many cases, monthly visits are necessary to not only change stimulation settings, but also to adjust medications and monitor for mood and thinking changes.

After surgery, how long will it be before I am able to go home? Most patients are hospitalized for one night following implantation of the brain leads. Confusion or other concerns could delay your discharge.

Pre-surgery tests and evaluations

Despite these differences, there are several important evaluations that all centers should perform prior to surgery. Some of the evaluations are specific to DBS, while others are standard tests that patients typically will undergo prior to any type of surgery.

Several visits to the DBS center may be required. The movement disorders neurologist should perform a baseline [Unified Parkinson's Disease Rating Scale](#) (UPDRS). This scale will help the neurologist evaluate the status of your PD. The neurologist will likely perform the UPDRS when you are on medications and again when you are off. This helps your neurologist gauge which symptoms DBS has the best chance of improving. You will also undergo a series of memory and thinking tests, called a [neuropsychological battery](#), to make sure that you do not have confusion, memory issues, untreated mood problems or depression. These tests should be performed by a neuropsychologist who has experience with PD. You may also be required to see a psychiatrist for treatment of depression, anxiety or other psychiatric conditions. A social worker may perform an assessment of your network of family and friends to make sure that there is someone to help you before and after surgery. It is very important that you have a full-time care partner if you undergo DBS.

Other standard, pre-operative tests may be performed by your local physician or the DBS staff. The specific tests will depend on your age and other health conditions. You may have one or more of the following:

- Magnetic resonance imaging (MRI) of the brain to make sure there are no other important issues such as brain shrinkage, strokes or tumors.
- Chest X-ray.
- EKG, which measures heart rhythm.
- Blood tests for blood counts, bleeding times, kidney function and liver function.
- Blood pregnancy test if female and of childbearing age.
- Possible type and cross-match of blood, or donation of patient's own blood.

Preparing for the surgery

As the day of surgery approaches, it is normal to be nervous or anxious as well as excited. Some people find themselves especially worried about the actual event after the evaluation and approval process is finalized and the surgery feels more real. Being nervous, scared or worried is normal and expected. Talking to other people who have had the surgery may help. Being organized, planning ahead and knowing what to expect will help prepare you for the surgery. Having a friend or family member plan to be with you before, during and after the surgery can be reassuring. Here is a checklist that can help you stay organized as you prepare for DBS.

A few weeks before surgery

- Make sure you know where to go the day of surgery. Write down the address, phone numbers and parking instructions of the center. You may wish to practice in a rehearsal trip.
- If traveling from out of town, make arrangements to arrive a day early and stay near the hospital. Check with the DBS center for recommended lodging and potential discounts.
- Confirm when to take your PD medication the night prior to and the day of surgery with the DBS staff. Most doctors will instruct you to not take PD medication the day of surgery, taking your last dose the night before.
- You will most likely be awake during surgery, so learning some relaxation techniques can help create a calm experience. Meditation, mindful breathing or listening to music may help.

Packing list for the hospital stay

Make sure that you bring the following items:

- All your medicines, along with a list of the exact medication names, dosages and times taken. Pack at least a week's worth of medication in the original, labeled bottles.
- A list of names and phone numbers that you would want contacted in case of emergency.
- Your *Aware in Care* kit. Though your care team in the hospital is trained in Parkinson's, it is always good to have it with you when you are hospitalized. If you need to order your free kit, visit Parkinson.org/AwareinCare

The night before surgery

Get a good night's sleep and follow the instructions you received from the DBS staff for the night before surgery. These will include not eating or drinking after midnight.

The Surgery

On the day of the surgery, plan to arrive at the center an hour before your operative time. From the admitting area, you will be taken to a preoperative room where you will change clothes for surgery and have your blood pressure, pulse and breathing checked. An intravenous line (IV) may be placed at this time.

In the operating room, the neurosurgeon will place the head frame onto your skull. The box-like frame is necessary to precisely guide the neurosurgeon to the target. Because application of the head frame can be uncomfortable, local anesthesia is injected to numb the areas where screws will attach to the skull to hold the head frame in place. Mild pain medication may also be offered. The head frame will remain in place for the entire surgery. After the head frame is attached, a CT scan (computed tomography) or MRI will be done. This scan helps the neurosurgeon locate the exact site in the brain where the lead will be placed. The area where the skull will be opened will be shaved or cleaned with a special shampoo. In many operating rooms it is no longer necessary to completely shave the head.

Some surgical practices will utilize a "frameless DBS system." With this procedure, you will visit the neurosurgeon a day or more before the operation. He or she will place several screws and plates in your skull in order to hold the frameless system in place. When you arrive in the operating room, he or she will attach the recording equipment to the plates and perform the surgery, essentially in an identical fashion to the frame-based system. Individual neurosurgeons will choose one method over the other based on experience and individual preference. Another approach that does not utilize microelectrode recording is done while you are **put to sleep under general anesthesia and in a MRI scanner.**

It is important to remember that any technique (frame, frameless or in the MRI) can lead to a positive outcome. The key is that your surgical team has plenty of experience with the technique and that they have quality improvement measures in place.

After the brain scan, you will be taken to the operating room. Besides the neurosurgeon, there will be nurses and a movement disorder specialists or neurophysiologist who will record the brain activity. If microelectrode recording is performed, the neurosurgeon will inject more anesthesia into your scalp and then use a drill to create a dime-sized hole in the skull to insert it.

When used, the microelectrode recording guides the neurosurgeon in placing the lead in the exact area that will offer the best possible results. This part of the surgery can take hours, depending upon the number of microelectrode passes required to pinpoint the target site. The surgery can be accomplished faster if done without microelectrode recording.

During the microelectrode recording, you may be asked to move your face, arm or leg, or the examiner may move them. You may feel twitches, pulling or tingling as electrical current is passed through the microelectrode. These are all normal and expected. The neurologist will ask you to be quiet during the recording, and he or she will move your face, arm or leg in order to pinpoint the brain activity that is responsive to movement or touch. Your patience, silence and cooperation will be necessary to ensure the best results. After the microelectrode recording locates the precise target, the neurosurgeon and neurologist will put the DBS lead in place.

After the lead is placed, the neurologist or neurosurgeon will connect it to an external generator and administer brief electrical stimulation to observe if it improves your PD symptoms; however, the extent of improvement observed in the operating room does not always reflect the amount that will ultimately be achieved. The neurologist and neurosurgeon will purposely induce side effects, such as having you see spots or feel tingling or pulling sensations. Inducing side effects helps to gauge the position of the DBS lead. When it is confirmed that the lead is correctly placed, the neurosurgeon will fasten the permanent lead into place (with a capping device) and run the connecting wire outside the brain and under the skin of the scalp. The hole in the skull is sealed with a plastic cap and stitches. At some centers, you will then be put to sleep under general anesthesia for the placement of the pulse generator, which is typically put in the chest area below the collarbone. In other centers this second procedure will be performed on a separate day.

After the surgery, you will be taken to a post-operative area and closely monitored for at least an hour. Then you will be taken to a hospital room. During the first 24 hours after the surgery, it is important to watch for any complications, such as a seizure or confusion. In some cases, you may be admitted to a special unit for close monitoring. Most patients are discharged from the hospital the next day. However, you may stay longer if you feel weak or confused, develop signs of an infection, or have an unexpected complication, such as stroke-like symptoms. Approximately 10 to 20% of patients will spend more than one post-operative night in the hospital.

The implantable pulse generator is often placed several weeks later and is performed as a separate surgery, but it may also be placed on the same day as the brain lead implantation. At that time, the connecting wire will be attached to the brain lead and the IPG. This procedure takes about 40 minutes and requires general anesthesia. Most surgeons will place the IPG and discharge the patient the same day, while others may require an overnight stay. PD medication should be continued just as before the surgery, or as directed by your neurologist. Typically, medications are adjusted after the DBS system has been programmed.

After Surgery Care

At the end of your hospital stay, the deep brain stimulation staff will provide you with discharge instructions to help you care for yourself at home. These instructions provide detailed information about how to care for your incisions (surgical cuts), the dates of follow-up appointments and dosing information for your PD medications. These instructions should also include phone numbers to call in case of emergency.

You may be issued your own hand-held magnet or patient controller device that will allow you to turn the DBS system on and off and check the battery power in your device. Sometimes these items are provided upon discharge from the hospital, but they may also be provided at follow-up clinic visits, especially if the DBS system is not activated immediately. Once you receive these items, be sure that you understand how to properly use the remote devices. You will also receive a wallet-size card in the mail that includes information about the DBS device, as well as your physician's name and phone number. You should always carry the magnet or patient controller and the information card with you, and we recommend that you keep all of this in your Aware in Care kit.

You can expect to schedule follow up appointments for the removal of sutures or staples, the placement of the neurostimulator, if it has not been implanted at the time of the brain surgery, and for your first stimulator programming session.

Complications can develop during the first few weeks or even months after surgery. You should know the signs and symptoms of infection, and you should be on the lookout for changes in mood, stroke-like symptoms and seizures.

For more guidelines around avoiding post-surgical infections, be sure to review appendix A: Avoiding Infection After Surgery on page 55.

Mood changes

Mood changes, especially depression and anxiety, should be reported to your neurologist. There are reports of people who have undergone DBS who have become severely depressed and even suicidal. If you feel depressed, tell your doctor immediately. If you have thoughts of suicide, tell a friend or family member. Have someone take you to the nearest emergency room or call 911. The depression may be related to DBS and is reversible with appropriate treatment. Here are some of the signs of depression:

- Saddened mood
- Excessive tearfulness or crying episodes
- Not feeling like doing your normal daily activities
- Wanting to be alone
- A sudden change in your sleeping habits – either sleeping too much or not enough
- Change in appetite, along with weight gain or loss
- Loss of libido or sex drive
- Feeling irritable, anxious or having feelings of panic
- Thinking and talking negatively
- Extreme loss of energy, tiredness or fatigue

Recently, it has been recognized that DBS can exacerbate impulse control disorders (e.g., inappropriate shopping, gambling, eating and/or sexual behaviors) and dopamine dysregulation syndrome (where a patient craves dopamine pills). Additionally, there are several reported cases where these types of behavioral side effects can occur following DBS surgery, including apathy. If you experience any of these behaviors, contact your doctors immediately for treatment.

Stroke-like symptoms

Signs and symptoms of a stroke or brain bleed include the following:

- Sudden severe headache, nausea and vomiting
- Suddenly becoming confused
- Numbness and weakness on one side of the body
- Difficulty talking
- Worsening of balance or falling to one side
- Thinking and memory problems
- Loss of vision

If you experience these symptoms, seek medical attention immediately. A brain scan can determine if there is bleeding or a stroke. The brain scan can also be used to check DBS lead placement.

Seizure

Seizures can occur when brain cells become irritated by head trauma, infection, blood or, in the case of DBS, from the electrode placement itself. Seizures from DBS therapy are rare and usually occur during surgery or within the first 24 hours following surgery. Seizures most often present with uncontrolled jerking of the face, arms and legs, along with loss of consciousness. They can also result in sudden confusion or abrupt numbness. If you suspect that you have had a seizure, you should call your doctor and seek immediate medical care. Anti-seizure medications may be prescribed and will likely control your symptoms. Most patients who experience a seizure during surgery or shortly after will not need medications for more than six months, and the seizures usually will not recur.

CHAPTER FIVE

DBS: Adjustment of Stimulation

Programming of the stimulator system is usually performed on an outpatient basis, although in some DBS centers the system may be activated before discharge from the hospital. Activation may also occur in a rehabilitation center, where other types of therapies are provided. Programming usually starts within a few weeks of the DBS surgery. Most centers prefer to wait two to four weeks after surgery for brain swelling to resolve around the DBS lead.

"I was diagnosed with PD 10 years ago, and I had DBS surgery after eight years. I only had one electrode put into the left side of my brain because my Parkinson's was much worse on my right side. It definitely helped. I can still move my right side much better than before the surgery, and I am taking less medicine now. I did have some trouble with tingling on the right side of my face, and my speech got slurry so they had to change the electrode settings a couple of times to make me better, but after a few programming sessions the numbness and speech were better." – Mike

During the programming process, the DBS programmer will use a small device to adjust the settings of the DBS system. He or she will hold a small wand over the neurostimulator, checking the effects of various electrode and stimulation settings.

During this process, you will be examined and questioned about how you are feeling. The programmer will be looking for improvements in your tremor, rigidity, bradykinesia and dyskinesia/dystonia, as well as side effects such as numbness, tingling, muscle cramping or pulling, electrical shock-like sensations, and possibly a worsening of PD symptoms.

Often there is an immediate improvement in some PD symptoms, and this may be followed by their return in a matter of hours or days. Some programmers will ask you to stay near the clinic for several hours after a programming session or ask that you return periodically for the first six months. You may also be admitted to a rehabilitation facility, which allows for close evaluation of your response to DBS programming and medication adjustments.

Most people with PD undergoing DBS therapy will require several programming sessions to achieve optimal symptom control. During the first six months, the average number of programming sessions reported in DBS centers throughout the United States is usually around six. Some people may be able to lower dosages of PD medication in the first few months following DBS surgery. Once the best settings and medication adjustments have been determined, you will be asked to return for routine follow-up appointments. The exact schedule will vary according to your condition and your neurologist's recommendations.

We recommend that you ask if you should take your usual medication before the appointment. Programming is typically more successful when your last medication dose before the programming session is held back the night prior, so your symptoms are more obvious and they are not confused with medication effects. Additional programming may be performed later that day, or after you have taken your PD medications. Always bring your medications to a programming session, in case you are asked to take them during or after programming.

Finding the optimal setting for a person with Parkinson's takes time due to the multiple combinations of settings, and also because many DBS leads may be activated. Each DBS electrode has four leads within it. All four electrodes are not activated. Depending on response, usually one or two

electrodes are activated. Rarely, three electrodes are activated. In addition, how these electrodes are activated determines the shape of the stimulation field. Additional settings that are adjusted include the voltage and pulse width and frequency.

Newer neurostimulators such as the Activa SC allow for even more advanced programming options with interleaving, an advanced technique that changes quickly between two settings. Often patients will ask for "higher" settings, but higher is not necessarily better. Sometimes a side effect from stimulation, such as slurred speech, is due to a setting being too high. It takes time to find the right combination of settings for each individual. Just like a combination lock can have low or high numbers to open the lock, the DBS device will require the right combination of settings to obtain optimal benefit for the patient.

When the DBS electrode is activated, the goal is to adjust the settings to affect the intended target in the brain (STN or GPi). As the settings are increased, the stimulation field can spread to other regions in the brain around the target and cause side effects, such as slurring of speech, tingling, pulling sensations, nausea, etc. With traditional DBS electrodes, the leads can be activated to try to avoid these side effects. However, as side effects are reduced, the level of benefit from the stimulation may also decrease.

The impact of benefits or side effects from a particular DBS setting may not be immediately apparent in the clinic setting. It may take several days to a couple of weeks for a patient to weigh and appreciate a side effect such as tingling or slurred speech versus the benefit of DBS. This is another reason why it can take several DBS programming visits before an optimal setting is determined.

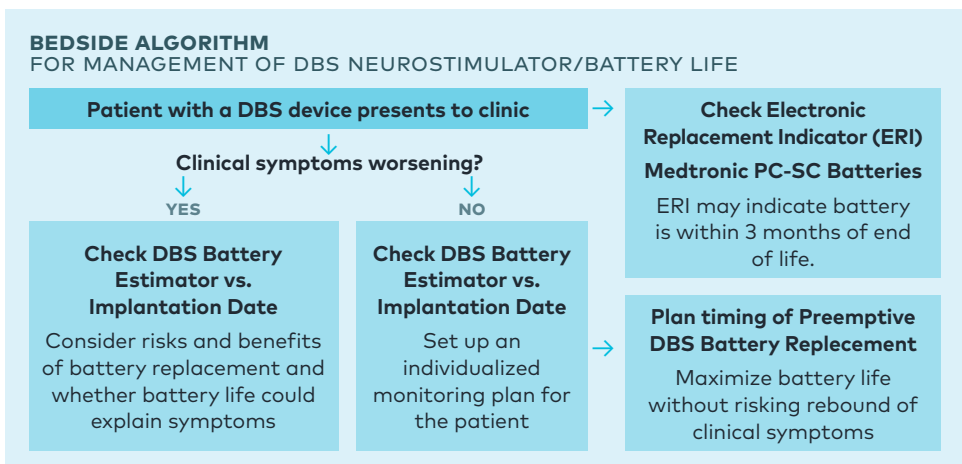
Patients with the Medtronic neurostimulators Activa SC, PC and RC have "group" setting options. This is at the discretion of the DBS programmer. Patients can have up to four groups that are lettered: Group A, Group B, Group C and Group D. Patients can be provided a different combination of settings in each group and can switch to a different group with their patient controller. This allows the patient to try alternative settings between programming visits.

Another way to use the group settings can occur when patients require higher voltage settings to control their tremor, but the high-voltage setting causes slurring of speech. You could use one group with finer tremor control but slurring of speech. Then, when you want to have a conversation without slurring, you could switch to a different group that may have only partial tremor control but minimal slurring of speech. Other types of advanced programming can

also be attempted by the DBS programmer. Another option with the newer neurostimulators is to allow the patient the ability to adjust either the voltage, also called "pulse width" or frequency within certain parameters.

Once the optimal settings have been chosen, you will be advised to NOT turn off your DBS system. If the device is turned off for some reason, you can use your hand-held magnet or patient controller device to turn it back on. Depending on the settings, the battery life of the neurostimulator should last from two to five years. Your PD motor symptoms may worsen when the battery is running low. As the battery life of the neurostimulator nears its end, your neurologist or neurosurgeon will want to schedule you to have the old neurostimulator replaced. This is a simple outpatient procedure in which an incision is made to open the area in which the neurostimulator is implanted, the DBS extensions are unplugged and a new neurostimulator is implanted and connected. The new neurostimulator can be turned on immediately after it is implanted.

It is very important that at each programming session, the programmer checks the battery life and has a plan for replacement. Sometimes the indicators of battery life can be misleading, and a battery replacement may be needed. The Parkinson's Foundation Center of Excellence at University of Florida Health Center for Movement Disorders & Neurorestoration shares a web-based DBS estimators that can be used by your DBS programmer, which can be found at movementdisorders.ufhealth.org/surgery/dbs-battery-estimator/. Also see the algorithm below, which takes into account your clinical symptoms (Montuno, Kohner, and Okun, 2012). Estimators will provide an approximate length of time that the DBS battery is expected to last. The DBS battery may need to be replaced prior to the estimated



timeframe, or it may last several months beyond the estimated timeframe. For this reason, it is important that a DBS programmer check the device regularly to help determine when the DBS battery needs to be replaced in order to avoid battery failure and loss of therapy efficacy.

A note about magnetic fields and household appliances

The neurostimulator can be turned off accidentally by any type of electromagnetic or magnetic field, including theft detection devices in department stores and security devices at airports and public buildings. Common magnets such as those placed on refrigerators, those used to close cabinet doors and those found in radios and wireless phones can also affect the neurostimulator. Though not dangerous, symptom control will be reduced if the device is accidentally turned off. The neurostimulator can be turned back on with the hand-held magnet or patient controller.

The Soletra® and Kinetra® neurostimulators are more sensitive to magnetic fields and accidental device deactivations. The newer generation Activa SC, PC and RC neurostimulators, as well as the Infinity and Vercise neurostimulators, are less sensitive to magnetic fields and are less likely to have accidental device deactivations.

Additional DBS information

After your surgery, your implanting institution should provide you with a patient remote. All companies that have DBS products provide informational booklets about their devices for your review.

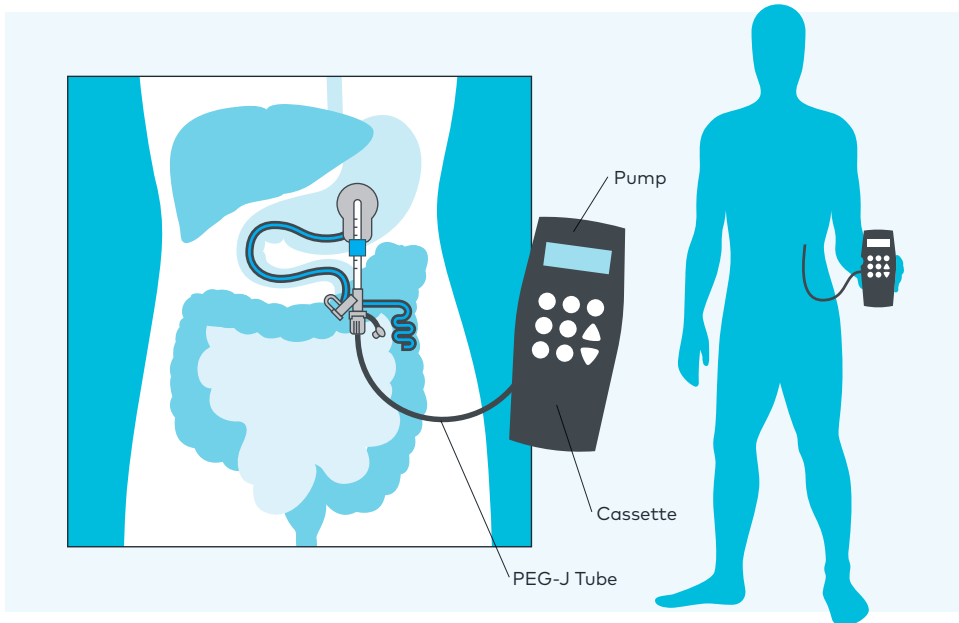
- Medtronic provides the *DBS Patient Therapy Guide*, which contains information about all DBS therapies and the *DBS Therapy-Specific Patient Booklet*, which contains DBS therapy information specific to your medical condition.
- Abbott provides the *Medical Infinity Deep Brain Stimulation (DBS) Brochure for Parkinson's Disease* and the *Medical Patient Controller Quick Reference Guide*.
- Boston Scientific provides *How It Feels to Be You Again: DBS and Parkinson's Disease. An Educational Guide for Patients*, which can be downloaded at DBSandMe.com; *Your DBS. Your Discussion*, a self-assessment for people with Parkinson's to work through symptoms and discuss best treatment options with a movement disorders specialist; and the *Vercise Charging System Quick Start Guide* and *Vercise Remote Control Quick Start Guide*, two short brochures for patients to learn how to use their IPG charging system and remote control, respectively.

CHAPTER SIX

Duopa Therapy: An Overview

DUOPA is carbidopa/levodopa in the form of a gel which is contained in a small cassette (similar to an old-fashioned music cassette tape). It is administered by a pump that delivers the medication through a Percutaneous Endoscopic Gastrostomy with Jejunal tube (PEG-J tube). The PEG-J tube passes through a hole in your abdomen, made by a doctor (called a stoma) and the end of the tube is placed into the first part of your small intestine. DUOPA is most beneficial for people who have some improvement with carbidopa/levodopa pills but also experience "on/off fluctuations" and dyskinesia. DUOPA is designed to offer a person more hours of "on" time per day. It also replaces much of the oral Parkinson's medication, and it is helpful for people who have to take their medications frequently and have difficulty maintaining their dosing schedule. Many patients will still need their Parkinson's medications at night.

The pump is “worn” outside of your body and is usually carried in a pouch or other accessory, hanging at a waist- or chest-level. Your neurologist, nurse or physician assistant (PA) will program the pump to deliver the medication at a setting specific to your needs. These settings usually include a morning dose that will be delivered when you first attach the pump, followed by medication that will be delivered at a continuous rate throughout the day for up to 16 consecutive hours. Your neurologist may also program an extra dose that can be delivered as needed if you need more medication.



DUOPA Risks, Complications, Special Information and Warnings

The most common adverse reactions after the PEG-J tube procedure are pain at the insertion site (stoma), nausea and gas pain. In most cases, these issues resolve after 24 to 72 hours. However, serious complications, including infection, bleeding and intestinal blockage can occur. Your gastrointestinal (GI) specialist and neurologist should discuss these risks with you prior to the procedure.

Side effects from DUOPA gel are similar to those from carbidopa/levodopa in pill form. These include, but are not limited to, nausea, stomach upset, low blood pressure, hallucinations, dizziness and impulsive behaviors.

For more guidelines around avoiding post-surgical infections, be sure to review appendix A: Avoiding Infection After Surgery on page 55.



CHAPTER SEVEN

Duopa: Before, During and After the Procedure

If you are determined by your neurologist to be a good candidate for DUOPA, then you will be referred to see a GI specialist.

The GI specialist will talk to you and examine you to make sure you can have the PEG-J tube procedure. If you have had certain surgeries on your abdomen, such as bariatric surgery or removal of part of your intestines, then you may not be eligible to receive DUOPA. Large scars running across your abdomen also may make it impossible to perform the PEG-J procedure. If you are deemed a good candidate by the GI specialist then the PEG-J tube procedure will be scheduled.

The procedure usually lasts about an hour, which includes your time being placed under anesthesia. The GI specialist will insert an endoscope through your mouth that goes down your throat and into your stomach. They will use the endoscope to visualize and locate the correct place for the PEG-J tube, which will be threaded through the skin of your abdomen with a needle and secured in place. In some centers this procedure is performed by a radiologist.

Most hospitals allow you to go home on the same day as the procedure. Your neurologist will calculate what your pump settings will be based on what you are currently taking in pill form. They also may bring you in for an office visit to titrate, or find the right balance for, your settings. Often your

neurologist, nurse or PA will allow your stoma to heal for a few days to a few weeks before starting to administer the gel. During this time, you will take your medications in pill form like you did before surgery.

Prior to the procedure, your neurologist, nurse or PA will arrange an educational session on how to care for your stoma and tube, as well as how to operate and maintain your pump. Shipments of DUOPA cassettes and supplies will be mailed directly to your home. Your DUOPA cassettes will need to be kept refrigerated.

It will be important to care for your stoma on a daily basis. You will be instructed on how to do this by one of your health care professionals. This will involve keeping your stoma clean and moving your tube a small amount every day.

Frequently Asked Questions

How do I know if I'm a good candidate for DUOPA Therapy?

DUOPA is approved for use in people with advanced Parkinson's disease who respond well to levodopa. You might be a good candidate for Duopa therapy if:

- You experience daily motor fluctuations (changes in the ability to move) with three or more hours of "off" time, and
- You have tried and failed to control the motor fluctuations with another class of medication, such as dopamine agonists or MAO-B inhibitors.

What does DUOPA fail to relieve?

DUOPA generally does not help any Parkinson's disease symptoms that do not improve with your best medication "on" time.

Will I still take my Parkinson's disease medications?

The pump is approved to be worn for up to 16 hours per day. Your continuous rate settings will provide most of your daily medication, and you may give yourself extra doses with the pump (if needed). Some people choose to continue their other Parkinson's medications (such as dopamine agonists or amantadine), although you often are able to stop these medications once you have the pump. At night, you can expect to take your oral medication as normal.

Can I swim/bathe with DUOPA?

You will be able to swim and bathe with DUOPA once your stoma heals, which normally takes about four to six months. Your pump cannot get wet, so you will need to remove it prior to swimming or bathing. Your

neurologist may advise you to give yourself an extra dose before you remove the pump. You may swim in a pool, but afterward make sure to wipe off the tubing to remove excess chlorinated water. You will NOT be able to go into a hot tub, lake or ocean due to potential bacterial infection. If you have any concerns, please address them with your GI specialist.

How expensive is Duopa Therapy? Will my insurance cover the costs?

The Cost of Duopa should be considered before deciding to move forward with this treatment. Though most insurance companies pay for the DUOPA therapy, because Duopa is relatively new in the United States, it is available as a name brand drug only – not generic. Out of pocket cost will differ from one insurance plan to another. Before making a decision about whether Duopa is right for you, we recommend a conversation with your doctor and your insurance provider about what you can expect to pay per month and per year. Know that “copay assistance” is not always guaranteed to continue from year to year and is different than the “free drug program” that some people with Parkinson’s are eligible for. Ask your doctor if there is a social worker, pharmacy counselor or financial counselor through their office who can help you make an informed decision.

Will my Pump activate the metal detector at the airport?

Yes, the you will need to let the TSA agent that you have a medical device and cannot go through the metal detector. Most airports will make special accommodations for people with medical devices and will allow them to bypass the metal detector. Bring your Parkinson’s Foundation Aware in Care Kit, a free bag filled with tools to keep you safe when you travel or go to the hospital, when you travel, including your medical card explaining the pump and how it may be affected by the detector. Share this information with security personnel.

Why would I pick DUOPA instead of deep brain stimulation?

Whether you choose DUOPA or DBS is a decision that should be carefully discussed with your neurologist and care team. In some cases where brain surgery is too risky, DUOPA can be a reasonable alternative. Another advantage is that the PEG-J tube procedure for DUOPA can be reversed if necessary, although you must wait a minimum of 14 days to remove the PEG-J tube after initial implantation. Some patients choose DUOPA over DBS because it reduces more of their daily pill requirement. There are some patients who have both DBS and DUOPA, so it is important to remember that having one does not rule out the other, and that the two therapies can be used in combination.

CHAPTER EIGHT

Lesion Therapy: An Overview

Pallidotomy, thalamotomy, and subthalamotomy are types of surgical procedures in which a tiny heated probe is inserted into a specific region of the brain lesion, or destroy tissue. When the region known as the globus pallidus internus is lesioned, we refer to the procedure as a pallidotomy. Similarly, when the part of the brain called the thalamus is treated, we call it a thalamotomy. And when the subthalamic nucleus is lesioned, we refer to the procedure as a subthalamotomy. Of these three procedures, pallidotomy has been the most widely applied over the last several decades to help relieve symptoms of PD.

Risks, Complications, Special Information and Warnings

Lesions in the brain can cause stroke, bleed, weakness, numbness, changes in vision or speech and/or stroke/like symptoms. Bilateral lesions can cause cognitive, voice and other effects.

A **pallidotomy** lesion has the potential to improve tremor, rigidity, bradykinesia, motor fluctuations, dyskinesia and, in a few select cases, walking and balance. Pallidotomies are in general only effective against PD symptoms that respond to carbidopa/levodopa (Sinemet®) with the exceptions of tremor and dyskinesia. Tremor and dyskinesia may potentially respond to pallidotomy even if medications are not effective. Pallidotomy has advantages over DBS; it doesn't require implanted wires, batteries or electronic programming sessions to fine-tune its parameters. There are no hardware malfunctions and, when the initial surgical procedure is done, there is no infection risk from an implanted device.

For those who might have difficulty traveling for DBS programming (from another region or country), or in cases when DBS is too expensive or not available, pallidotomy may be a good choice. Pallidotomy can be as effective as DBS in treating the symptoms of PD, but the lesion must be placed in exactly the right spot. Recent studies have revealed that the benefits of pallidotomy can be long-lasting. Unlike DBS, pallidotomy should not be performed on both sides of the brain. This is one major limitation of this surgery. Performing two pallidotomies can lead to permanent speech, swallowing and cognitive problems. Patients with an existing pallidotomy who require a second surgery will usually have DBS on the opposite side of the brain.

Subthalamotomy has been gaining popularity because it can provide the same types of benefits as pallidotomy, and many medical groups have performed the surgery safely on both sides of the brain. Subthalamotomy is the PD procedure of choice in Cuba and some other countries, and research suggests it is very effective. A few subthalamotomy patients have developed a side effect called hemiballism (uncontrollable flinging of one arm and/or leg), but in most cases it is a transient adverse effect (goes away with time).

Thalamotomy is a procedure that is rarely performed in PD because it is usually only effective for tremor. There is a Food and Drug Administration (FDA)-approved thalamotomy procedure using focused ultrasound therapy.

Focused Ultrasound: An Overview

The use of ultrasound in medicine has been primarily used for imaging. However, when these sound waves pass through tissue, their energy creates heat that is absorbed and can help to create lesions in targeted parts of the brain. High-intensity ultrasound was introduced in the 1950s as a treatment for a variety of brain disorders, but the procedure required performing a craniotomy (surgical removal of part of the bone from the skull to expose the brain) to permit the direct use of ultrasound to the brain. More recently, the use of a special helmet that allows focusing of ultrasound energy has been useful. These new systems use computer software that has eliminated the need for a craniotomy because they can adjust for ultrasound distortions caused by the skull bone. Also, new MRI imaging technology lets doctors directly observe the different brain structures and gives information about the brain tissue's temperature.

High-intensity ultrasound in the thalamus has been used for the treatment of tremor in Parkinson's disease and has revealed short-term improvement in tremor and quality of life. The procedure is performed inside of a radiology scanner using a high-intensity ultrasound machine. Brain tissue not being targeted is kept safe because less energy is absorbed in the ultrasound beam's path. The potential advantages of high-intensity ultrasound compared with other procedures, or DBS, include the ability to repeat treatments if needed with no accumulative effect, no repeat visits to replace batteries or for stimulator adjustments, and no incisions or electrodes in the brain.

Before the procedure, people with Parkinson's will typically complete a computerized tomography, or CT, scan, of the entire skull to measure skull thickness, and an MRI to define the specific area for surgery. On the treatment day, the patient's head is shaved and the scalp is inspected for scars and other lesions that could affect the course of ultrasound. Once a standard head frame is placed, a silicone plastic helmet is placed on top of the scalp to keep the skull bone temperature cool and comfortable. Vital signs are monitored during the surgery, which is performed under local anesthesia. The ultrasound helmet is attached to the patient's head and high-intensity ultrasound waves are delivered while doctors closely monitor for symptom improvement or adverse effects. The treatment ends once symptoms are better. After the procedure, a patient's neurological status is checked in the recovery room and an MRI is obtained to check the location and size of the lesion.

Risks, Complications, Special Information and Warnings

The main target for high-intensity ultrasound is the thalamus. High-intensity ultrasound was first tested in individuals with essential tremor, as tremor can be easily monitored during the procedure and tremor reduction on one side of the body can substantially improve quality of life. Tremor benefit ranges from 40-80% across studies. The most common side effects are numbness, tingling and balance problems. Procedures on both sides of the brain carry a high risk of side effects.

There is a concern about recurrence of tremor after several months, long-term benefits and potential persistent side effects. Unlike DBS, ultrasound therapy adjustments cannot be made, whether to correct problems, improve benefits or alleviate side effects. Side effects can be permanent.

Fortunately, persistent side effects are not common in larger trials. However, because this surgery is not very common, few centers have the experience required to limit complications. The most common side effects, similar to more classical thalamotomies, include face numbness, arm numbness, weakness and poor balance. The procedure has been performed in other brain targets for people with Parkinson's and, at this time, the information regarding benefit is limited but potentially encouraging. The FDA has approved the procedure for PD with tremor. Additional research is needed to establish the long-term procedure benefits and risks and to determine the best candidates.

The future applications of high-intensity ultrasound in people with Parkinson's might be limited to a more select group unable to tolerate a more classical, open procedure, including people who have bleeding disorders or are on blood thinners. Also, the procedure will be limited to one side of the brain. Performing it on two sides may result in problems with speech, swallowing and cognition. Finally, this procedure will be most useful to people with PD who have severe tremor, where tremor suppression is sufficient to improve quality of life. Good surgery candidates must have adequate control of other PD symptoms with medications alone. Finally, the procedure is not recommended for those with very thick skulls or who cannot undergo an MRI.

**CHAPTER TEN**

Emerging Changes and Future Directions in Surgical Treatments

Deep brain stimulation (DBS) is a powerful tool that can help make life easier for some people living with Parkinson's disease (PD). Scientists are continuously studying DBS to figure out ways to make it better and safer for people to manage their disease.

We have learned much from recent research that will allow scientists to think about new ways to make the surgery even better. In fact, the main reason that scientists continue to study DBS is because of the original life-changing, ground-breaking success of DBS surgery, which is now considered the gold standard. While various advances – such as better batteries, better programming/targeting that allows DBS devices to last longer on the same batteries and electrodes that deliver the best possible stimulation – have been very beneficial, the work of scientists is far from complete. Following are some innovations that will put you in the driver's seat, letting you make more choices about your Parkinson's therapy.

A new DBS approach to surgery

You have a choice between awake and asleep surgery for deep brain stimulation. DBS was originally done with patients awake because this enabled neurologists and surgeons to get feedback from patients during the surgery. Many teams continue to perform surgery this way because it is associated with good treatment outcomes. For example, patients who are awake can participate in the procedure, assisting the neurologist and the neurosurgeon in “mapping” the brain and in locating cells associated with movement or vision. Additionally, when DBS is done with patients awake and off their Parkinson’s medications for 12 hours or more, expert neurologists can identify the signals in the brain that indicate PD. This helps pinpoint the optimal location for the DBS electrode. Some groups have started using a new procedure where they use partial or full anesthesia to put patients to sleep. Many people are anxious about the surgery and feel more comfortable knowing they will be asleep. However, it is harder for the surgeon to pinpoint exactly where the electrode should go if the patient is asleep. Most of the time, the surgeon’s experience will help him or her to put the electrode in exactly the right place, but being able to verify this by having a team member listen to signals from the brain – called microelectrode recording – can help you feel more assured that the location is just right.

When you are asleep, the doctor cannot do microelectrode recording as effectively. Some doctors think that the benefits of microelectrode recording to verify proper electrode placement outweigh the challenges of managing patients’ anxiety, and others do not.

As with any surgery, it is important to see a surgeon who is experienced in the specific surgery you need. Going to a Parkinson’s Foundation Center of Excellence is a good way to ensure that you find a skilled surgeon. Visit our website, [Parkinson.org/COE](https://www.parkinson.org/COE), or call the Helpline at 1-800-4PD-INFO (473-4636) to find a Center of Excellence near you.

MRI- or CT-guided DBS versus traditional microelectrode recording

There are two approaches your neurosurgeon can use to place your DBS electrode:

1. Microelectrode recording (MER-guided): In this “gold standard” method, the surgeon plans the surgery using MRI or CT scans but then verifies that the electrode is in the right place by listening to signals from your brain cells using microelectrode recording.
2. MRI or CT scans in the operating room (imaging-guided): In this new technique, the surgeon still plans the surgery using MRI or CT scans but then uses a scanner during the surgery to watch the progress of the placement of the electrode into the brain, making sure that the electrode is correctly placed within the original target region. This method can be done with the patient asleep (under anesthesia).

The benefit of imaging-guided surgery is that the neurosurgeon can visualize the target region while they operate, then quickly adjust to any shifts or movement of the brain. However, MER is better at identifying the brain cells that will help determine a precisely located electrode. Cells don't show up on a scan. If the electrode is not in the right place, it is much harder for the neurologist to program it adequately to treat your PD. In rare cases, patients have had to go through surgery a second time to fix the placement. There is ongoing research to examine and improve the outcomes of this approach, as many patients are interested in a faster DBS procedure in which they can remain asleep. Ultimately, the most important factor in treating Parkinson's is correct electrode placement, no matter what tools your surgeon uses.

Getting DBS therapy sooner rather than later

If you are going to get DBS eventually, would it be better to go ahead and have the surgery done earlier rather than later? While the benefits of early DBS therapy are promising, most experts favor a more cautious approach when considering this important decision. A 2013 study of early DBS, called the EARLY-STIM trial, got the attention of doctors worldwide when it was featured in *The New England Journal of Medicine*. In the study, patients who were younger and in earlier stages of the disease underwent DBS.

Typical people with PD in their mid-60s and older were not included in the study, and we do not know yet how this large group will perform with earlier intervention. What we do know is that younger people with PD who have experienced motor fluctuations for approximately two years or less do seem to perform well with DBS. Most practitioners should carefully consider the merits of earlier intervention in this select group of patients. We do not have information on DBS for those who have not yet developed motor fluctuations.

On the horizon

Although we have made some big leaps forward with DBS therapy, there are many important issues that will need to be explored, and there is still much that can be improved upon. Parkinson's affects the brain in very complex ways and we have only so far scratched the surface on the best techniques and approaches for using stimulation to treat this disease. With DBS, we stimulate a "target"—a part of the brain that has been affected by PD. But there are many new targets to consider: the centromedian nucleus of the thalamus, the zona incerta, the motor cortex and the pedunculopontine nucleus. And it is possible that stimulating one of these will treat symptoms that do not currently respond well to standard DBS targets (e.g., walking, balance, talking, thinking).

Today, DBS devices pulse regularly like a clock. What if they could pulse only when your brain needed the stimulation? What if a computer could listen for signs of trouble and then respond by pulsing to bring it back to normal, like a heart pacemaker? These "adaptive DBS" devices are close to being a reality. Electrodes that can be aimed – not just put in the right place but aimed to stimulate exactly the right cells and not the wrong ones – could enable your doctor to avoid side effects and enhance your benefits. In the near future, we may be able to employ multiple leads implanted into multiple brain regions to monitor brain signals from PD and even remotely program them. We will be able to treat specific symptoms in real-time with smarter DBS devices, so you can fight back against Parkinson's where and when you need to.

APPENDIX A

Avoiding Infection After Surgery

Around the time of surgery, your doctor may prescribe antibiotics to reduce the chances of an infection at the incision sites. Other precautions that you can take to prevent an infection include the following:

- Carefully follow any instructions that were given by the surgical staff about caring for your incision.
- Wash hands frequently.
- Keep the stitches clean and dry. Clean stitches with a small amount of antibacterial soap and water, then pat dry with a clean towel or gauze. Keep stitches covered with a dry bandage or piece of gauze, especially while bathing.
- Do not go swimming or bathe in a hot tub while you have stitches.
- Never scratch, touch or put any pressure on the incision.
- Be sure pillows, sheets and bedding are clean.
- Make sure that hats and wigs are clean.
- Wash hands after handling pets.
- Return to have sutures and/or staples removed at the scheduled time. Most centers will remove sutures seven to 10 days after surgery. Some surgeons may use stitches that dissolve on their own.

Look for the signs of infection:

- Redness, swelling or warmth at the incision or around the stitches.
- A fever of 100 degrees or higher.
- Pain or tenderness at the incision
- Puss, blood or oozing at the incision.

Any signs of infection should be immediately reported to your physician, who will likely prescribe antibiotics. While an infection may mean that some or all components of the system must be removed, early detection and treatment with antibiotics can sometimes prevent this from happening.

APPENDIX B

Five Questions to Ask Before Participating in a Clinical Trial Studying Stem Cells

Stem cell treatments, which involve transplanting cells to replace the brain cells lost in PD, are being tested in clinical trials around the world. But the history of these therapies has been filled with confusion and disappointment. For people with Parkinson's disease, it can be difficult to make informed decisions about whether to participate in trials.

Experts led by Roger Barker, MD, PhD, at the University of Cambridge in England (a member of a global consortium called G-Force PD) have written guidelines, which were published in an online edition of the *Journal of Parkinson's Disease*. In this article, they lay out the following questions to ask when you hear about a new PD stem cell study:

1. What type of cells are being transplanted? How do they work?

Researchers have experimented with several sources of stem cells (e.g., taking skin cells from people who live with PD) and have had varied success in transforming them into the very specific cells needed in PD. If you're considering a clinical trial, find out whether the cells being transplanted have been proven to replace the dopamine neurons that are lost/harmed in Parkinson's disease.

2. What is the proof that a stem cell treatment is safe and effective?

Ask if the cells being transplanted in the trial been thoroughly tested in a series of laboratory studies and trials in animal models of Parkinson's disease.

3. Have the cells being used for this clinical trial been chosen for a reason besides their safety and effectiveness?

Stem cell science is difficult. Researchers may choose to experiment with certain types of cells for strategic reasons. For example, they may choose based on availability or because the cells work without having to suppress a recipient's immune system. But a cell supply should not be chosen simply for profit reasons – this is not a place for shortcuts. Researchers need to prove that transplanted cells can survive and become integrated and functional in the brains of animal models regardless of their source.

4. Is the stem cell-based therapy claiming to help better control PD symptoms or provide a cure?

Beware of claims that cell transplants can cure PD. These therapies aim to replace lost cells, restore dopamine in the brain and ultimately improve quality of life without the side effects of levodopa therapy. But they cannot prevent the build-up of alpha-synuclein protein in brain cells, which is the hallmark of PD progression. Even the best current experimental approaches for cell replacement therapy take several years to see maximal benefit and only provide symptomatic relief.

5. What is the regulatory oversight of the trial and is it guided by input from experts in the field?

In particular, find out whether a clinical trial has the independent ethical and regulatory approval of the country in which it is being done, and whether it has a follow-up period long enough for rigorous evaluation of risks and benefits, ideally several years. The data should be made publicly available. Finally, study participants should never be asked to pay for the therapy or to participate in the trial.

APPENDIX C

Going to the Hospital When You Have a Stimulator Implanted

If you have had a DBS device implanted, be sure to have your Aware in Care kit prepared before a planned or emergency trip to the hospital. The following is an excerpt from the Aware in Care Hospital Action Plan that is designed to share with your doctors. Order your free Aware in Care kit at [Parkinson.org/AwareInCare](https://www.parkinson.org/AwareInCare) or by calling our helpline at 1-800-4PD-INFO (473-4636).

I have a deep brain stimulation device.

Some people with Parkinson's disease have a deep brain stimulation (DBS) device that helps to control symptoms. A deep brain stimulator is a surgically implanted battery operated neurostimulator, and includes a pacemaker located in the chest region with a wire leading to the brain.

MRI Warning

- MRI should not be performed unless the hospital has MRI experience imaging a DBS device safely.
- MRI should never be performed if the pacemaker is placed anywhere other than the chest or abdomen.
- Under certain conditions, some DBS devices are safe for full-body MRI and do not need to be turned off. In other cases, devices should be turned to 0.0 volts and MRI should not be used to image structures of the body lower than the head, as dangerous heating of the lead could occur.
- Always check with your DBS team before having an MRI to make sure the procedure will be safe for you.

EKG and EEG Warning

- Turn off the DBS device before conducting EKG or EEG.
- Diathermy should be avoided.

If you have any questions, check with the prescribing or implanting clinicians, call the manufacturer (Medtronic: 1-800-510-6735; Abbott: 1-800-727-7846; Boston Scientific: 1-833-327-8324) or call the Parkinson's Foundation Helpline (1-800-473-4636).

APPENDIX D

Going to the Hospital When You Use a Duopa Pump

If you use a Duopa pump, be sure to have your Aware in Care kit prepared before a planned or emergency trip to the hospital. The following is an excerpt from the Aware in Care Hospital Action Plan that is designed to share with your doctors. Order your free Aware in Care kit at [Parkinson.org/AwareInCare](https://www.parkinson.org/AwareInCare) or by calling our helpline at 1-800-4PD-INFO (473-4636).

I have a Duopa Pump.

Duopa therapy is an entral gel suspension of the Parkinson's disease medication carbidopa/levodopa. The gel suspension is administered by a pump connected to the body using a percutaneous endoscopic gastrostomy with jejunal tube.

- Duopa therapy is FDA Approved for daily use of up to 16 hours.
- Patients using Duopa therapy are assigned a case manager that can be reached through Abbvie's DuoConnect at 1-844-DUO-4YOU (386-4968) to answer questions, provide education and support, and help troubleshoot problems.
- If a patient is disconnected from the duopa pump for more than two hours, the patient will likely need to be prescribed an oral form of carbidopa/levodopa.
- The Duopa pump is not waterproof.
- Do not expose the pump to therapeutic levels of ionizing radiation, ultrasound, MRI or ECG. Call DuoConnect for instructions before initiating any imaging.

Glossary

Glossary terms are identified with a blue underline the first time they appear in this book.

B Bradykinesia Slowness of movement; one of the cardinal symptoms of Parkinson's.

C Computerized Tomography (CT) Scan A medical test that use a computer linked to an x-ray machine to take pictures of the inside of the body.

D Deep Brain Stimulation A surgical treatment for Parkinson's disease. A special wire (lead) is inserted into a specific area of the brain responsible for movement. The lead is connected to a pacemaker-like device implanted into the chest region. This device creates electrical pulses, sent through the lead, which "stimulate" the brain and control abnormal brain cell activity.

Duopa Therapy A form of carbidopa/levodopa delivered in gel form – called enteral suspension – rather than a pill. It is used to treat the motor symptoms of PD.

Dyskinesia Abnormal, involuntary body movements that can appear as jerking, fidgeting, twisting and turning movements; frequently caused by dopaminergic medications to treat Parkinson's.

E Electrical Currents A movement of positive or negative electric particles (such as electrons).

Electrode A small piece of metal or other substance that is used to take an electric current to or from a source of power. These attach to the lead within a DBS system.

F Focused Ultrasound The use of ultrasound waves to create targeted lesions as they pass through tissue in the brain.

Frameless DBS System A type of DBS surgery performed by a surgeon who does not use a head frame while operating, relying instead on CT images from before the surgery and sometimes other technologies used to calculate the surgical pathway.

G General Anesthesia The use of medications that put you in a sleep-like state of unconsciousness before a medical procedure.

Globus Pallidus Internus (GPI) A section of the Globus pallidus partially responsible for sending signals affecting the movement of arms, legs and neck, as well as other functions including thinking and mood. One of three targets for Parkinson's DBS, aimed at reducing tremor, rigidity, bradykinesia, dyskinesia; improves "on-off" fluctuations.

L Lead A thin, insulated wire inserted through a small opening in the skull and implanted in the brain. The tip of the electrode is positioned within the targeted brain area.

Lesion therapy A surgical procedure in which a tiny heated probe is inserted into a specific region of the brain lesion, or destroy, tissue.

Local anesthesia Numbing of a small site where the pain or procedure will occur without a change to consciousness.

M Magnetic Resonance Imaging (MRI) A medical imaging technique that uses magnetic forces to obtain detailed images of the body. MRI is non-invasive and does not use radiation.

Motor Fluctuations Changes in the ability to move, often related to medication timing; also called "on-off" fluctuations.

Motor symptoms Parkinson's symptoms related to movement, such as slowness, tremor and stiffness.

Movement Disorder A group of neurologic conditions associated with problems with movement including Dystonia, Huntington's disease, Parkinson's disease and others.

Movement Disorder Specialist A neurologist with additional training to treat people with Parkinson's at every stage of the disease.

N Neurochemistry Structures and functions of compounds (neurochemicals) that work within the nervous system.

Neurodegenerative disorder A disease characterized by the loss of cells of the brain or spinal cord, which over time leads to dysfunction and disability.

Neuro-genesis The process in which new neurons are created in the brain.

Neuro-oscillations Repetitive patterns in the central nervous system that allow for the brain activity to coordinate in sync across brain regions.

Neurophysiology A branch of physiology and neuroscience that studies the functioning of the nervous system.

Neuropsychological battery A structured assessment of cognitive function that helps doctors assess thinking, memory, perception, problem solving and verbal ability.

Neuropsychologist A licensed psychologist with expertise in how behavior and skills are related to brain structures and systems.

Neurosurgeon A physician who specializes in surgical treatments of the central nervous system.

Neurovascular Involving nerves and blood vessels.

Non-motor symptoms Parkinson's symptoms unrelated to movement such as depression, cognitive changes, and fatigue.

P Pallidotomy A type of brain surgery in which a tiny part of the globus pallidus is lesioned.

Percutaneous Endoscopic Gastrostomy with Jejun tube (PEG-J tube) The tube used in Duopa therapy which allows medication to enter the body through the intestine.

R Rigidity In Parkinson's, stiffness of the arms or legs beyond what would result from normal aging or arthritis. Some people would call it "tightness" in their limbs.

S Substantia nigra pars compacta (SNc) A portion of the substantia nigra made up of dopamine neurons.

Subthalamic nucleus (STN) One of the three postnatal targets for DBS that is partially responsible for sending signals affecting the movement of arms, legs and neck, as well as other functions including thinking and mood. One of three targets for Parkinson's DBS, aimed at reducing tremor, rigidity, bradykinesia, dyskinesia; improves "on-off" fluctuations.

Subthalamotomy A type of brain surgery in which the subthalamus, a tiny area of the brain, is destroyed.

T Thalamotomy A type of brain surgery in which the thalamus, a tiny area of the brain, is lesioned.

U Unified Parkinson's Disease Rating Scale (UPDRS) A universal scale of PD symptoms and it was created to comprehensively assess and document the exam of the patient with PD and be able to compare it with patient's future follow up visits, or to communicate about the progression of the PD symptoms in each patient with other neurologists.

V Ventralis intermediate nucleus of the thalamus (Vim) A part of the nucleus targeted in DBS for essential tremor; a less common target of Parkinson's DBS treatment that only aims to reduce tremor.

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