

Deep Brain Stimulation Preoperative Information

Enclosed are instructions and a description of the deep brain stimulation (DBS) procedure.

DBS is unlike most other neurosurgical procedures. First of all, you may be awake for a great deal of the procedure. Also, you often see the results of the surgery immediately. Tremors arrest on the table, rigidity and dystonia can sometimes melt away during the operation. The success of DBS often depends on active participation of patient. Unlike other surgeries, DBS is done in stages or parts. All this makes DBS a very different experience for most patients. This guide is to help prepare you for the surgery. There is no way we can predict exactly how the surgery will go, we hope to prepare you for what might occur. This should help answer some questions and calm some fears. It is OK to be somewhat fearful of any operation, especially one involving your brain. Remember, your safety is the most important thing to our team. We put you first: your safety, your results and your comfort.

The Preliminary Stage –Fiducial Placement and Scanning

For frameless DBS lead insertion we need to place 4 to 6 small, skull screws prior to the surgery. This can be done anytime prior to the lead placement. There are two techniques for "framless DBS." One technique uses the Starfix platform and the other uses the NexFrame device. Both require the placement of these markers or

Fiducials to ensure accuracy.

The StarFix system uses the markers as anchor points for a custom made platform that delivers the DBS lead to the target. The Nexframe uses the markers as "waypoints" to guide the lead to the target. Dr. Levine uses the system he believes is best for your circumstance. Both have over 10 years of FDA approval.

The major difference between the two for the patient is the timing of the fiducial placement.

NexFrame

With Nexframe we like to do this the day before the surgery. We admit you the day before and the physician's assistant or resident places the screws. This will be done



Nexframe Device

with local anesthetic. The fiducials will be capped with rubber

cones. These will protect the screws from damage. We prefer to shave your head completely for this. If you prefer not we can work around it. Then we obtain a 3- dimensional MRI and CT or CAT scan is obtained. For this part there is no need to fast. The MRI takes about 30-45 minutes. Please take your medications as this will make the MRI "cleaner," without motion problems. Sometimes we have the MRI done as an outpatient before surgery. The MRI has to be specially formatted for DBS. Dr. Levine has to arrange the MRI if it is done as out patient. If this is done, please be sure to get Dr. Levine a copy of the MRI to the office at least one day before surgery and bring a CD of the MRI with you the day of Stage I (DBS implantation). Without the MRI the surgery WILL BE CANCELLED. If you cannot have an MRI for medical reasons, we can accommodate. Once the MRI and CT are completed you will go back to your room. Do not be too concerned if any of the screws fall out. We only need 4, but 5 or 6 are better. We can always place more the day of lead placement and repeat the scan that day.

StarFix

If the StarFix system is being used, the fiducials or markers are implanted



StarFix Platform

in the office. Dr. Levine or the

resident will place them. There are four screws places and they are all below the skin. Again, this is done with local anesthetic and patients usually experience no pain from this procedure. The special MR and CT are done that day in the same building as Dr. Levine's office. We will set up that appointment for you. You will be sent home after Dr. Levine has confirmed the quality of the imaging. The screws are below the skin, so are not visible to others. We send you home on antibiotics and pain medication. The custom built platform will be drafted to fit your surgery and anatomy. It is constructed using 3-D printing technology and will be shipped to the hospital for sterilization in time for your surgery. All you need to do is keep the areas clean and dry. No special care is needed. You may shower after the second day of placement and gently towel dry your hair/head. You will be admitted the day of surgery for Stage I: implantation of the DBS lead(s).

Stage I –DBS Lead placement or the "Big Surgery"

This is the day. The surgery is broken down in to phases: preparation, opening, recording, implantation and closing. The day will start with introduction to the team: the surgeon (Dr. Levine), the anesthesiologist and the anesthesia team, the scrub technician/nurse and the circulating nurse, and the electrophysiologist. We are all there to help you get through the surgery safely, comfortably, and with good results.

Preparation

Frameless surgery is usually shorter than the frame-based surgery. And most people find it more comfortable, as you able to move more freely. After introductions are

done, you will be sedated and if needed a catheter will be placed in your bladder for your comfort. All intravenous and other catheters will be placed with sedation.

We will then position you in a neck collar/brace. This is done with your help to maximize your comfort. The position you will be in for the surgery is similar to that of lying in a chez-lounge. Imagine yourself on a beach, on a cruise or wherever you would rather be while reclining in a chez-lounge. Once positioned the remainder of the preparation includes shaving, sterile washing and draping of your scalp. A total head shave is preferred, but requests for minimal head shave will be honored if possible. When using NexFrame, the preparation is completed with registering the fiducials and your head with the navigation system. This system will optically track the surgery with a pair of sophisticated cameras. For StarFix, we will mount the platform to mark the scalp.

Opening and recording

The next phase: opening, is done with local anesthetic and more sedation. The surgery in some circumstances can be done under general anesthesia while you sleep. The incision(s) and hole(s) are made to get the electrode into the brain. This should be a painless. Once the opening is completed, we will begin to localize the area of brain that needs stimulation. We will refer to this as the target. While we make the holes, you should not feel pain, but you might feel vibration. Once this phase is completed, we will allow you to wake up and participate in your surgery during recording. Sometimes the whole surgery is done under general anesthesia and in those circumstances you will remain asleep for the whole surgery.

The recording phase of the operation helps get the lead to the target. By listening to the cells in your brain we can identify where we are so that we can accurately place the lead and get the best results possible. You will hear noise that sounds like static: that's your brain. You can actually hear the cells in your brain firing! This is exciting to some patients and down-right dull to others. During the recording period we might stop and move your arms and legs. We are listening for cells that respond to movement in your body. This also

helps localize where we are in your brain. Usually, one attempt at recording is all we need, sometimes it may take more. If you get uncomfortable, tell us and we will try to get you comfortable. Once we are happy with the recording phase we move toward implantation and closing.

Implanting and Closing

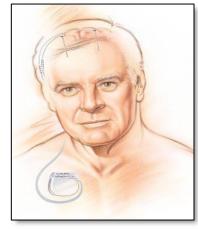
The implantation phase is the most important part. We will place the actual DBS lead and test the stimulation. Your symptoms may just melt away right in front of you. We will run you through some tests while stimulating to check for undesirable side-effects as well as expected benefit. Among these tests will be some tongue twisters to check your speech. As we turn the stimulator on you may feel some tingling or buzzing sensation in your body or face. This is not unusual and should fade away. You should tell us if you get any of these sensations when we stimulate you. You should also tell us when they stop. This helps us get you the best result possible.

Once the implant process is over for both sides we will sedate you again. We will give you more local anesthetic and begin closing. All the bone screws are removed and you are sent to the recovery room. YOU MADE IT!

A routine CAT Scan of the brain is done the next day. If there are no problems on the CAT Scan you will be discharged to home with pain medication. You should call the office (301-718-9611) and confirm your next surgery: implantation of the battery pack (or IPG).

Stage II –IPG placement

Αt this surgery you will have your battery pack or packs placed. This surgery is done under general anesthesia while or you



asleep. We place all the wires under the skin

from your head to your chest or abdomen. This operation usually takes 30 to 45 minutes. You can go home after the surgery with pain medication and sometimes we also provide a prescription for antibiotics.

The IPG(s) will not be turned on after placement until you make a programming appointment. Your referring neurologist usually does the programming. There will be some discomfort along the path of the wires, but this will go away with time. There can even be some bruising. If you have any questions please call the office and we will get back to you as soon as possible.

Follow-Up

Now that all the surgery is over, you should check your appointment with your neurologist. They will do the programming. In addition, Dr. Levine still needs to see you to check the wounds and remove any remaining staples or sutures that are not absorbable. Dr. Levine would also like to see you from time to time (once every 6 months to a year). We can make sure the battery is working. Also you should see or call Dr. Levine immediately for any of the following:

- 1. Wires sticking out of the skin/ scalp
- 2. Wounds that are oozing/red/ draining
- 3. Blow to the head near stimulator site

Final Note:

Please read all the literature and manuals from Medtronic Inc. given to you when the surgery is completed. All the appropriate warnings and information about the neurostimulator are there. Not everybody likes to read manuals, but this one is very important. This guide does not serve as a replacement to those warnings and instructions.

PLEASE CALL THE OFFICE WITH ANY QUESTIONS

Zachary T. Levine MD FAANS

Prior to admission

STOP all aspirin/ibuprofen like drugs and all blood thinners 5 days prior to admission. (please check with primary care physician prior to doing this)

Bring any preoperative MRIs or imaging of the brain

Bring all medications with you to the hospital in their bottles with labels.

Bring a list of any allergies and previous surgeries.

Bring positive thoughts and we will provide the rest.

Expectations:

Please remember DBS is NOT a cure. DBS is used to treat symptoms and most people need to continue with medical treatment as well. Hopefully, you can lower the dose you are taking. You still need to follow-up with your neurologist. DBS has been shown to dramatically improve quality of life but it is not a replacement for medicine. In two studies it has shown to be superior to medication for some movement disorders. DBS does not treat all the symptoms of any given disorder. Please speak to your neurologist to clarify.