A Frameless Approach to Deep Brain Stimulation

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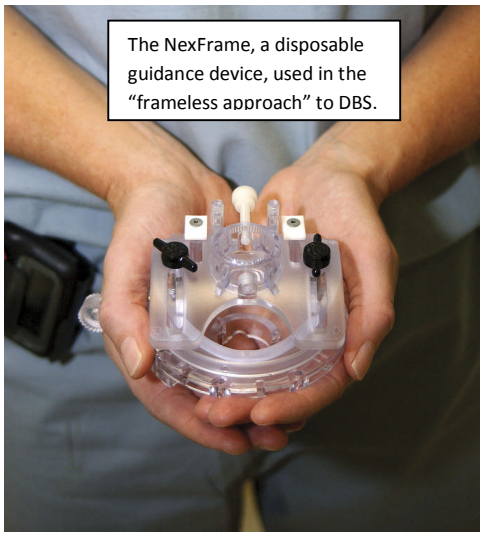

The NexFrame, a disposable guidance device, used in the "frameless approach" to DBS.

In approximately 75% of people with Parkinson's disease, the medications used to control symptoms become less effective. Some patients may experience too little or too much movement. Others may not respond at all to the medications and /or may develop neuropsychiatric complications such as hallucinations. When the regimen of existing medications and the various rehabilitation strategies become less effective in managing symptoms, surgical intervention can be considered.

Such an intervention is deep brain stimulation (DBS). This is a surgical intervention used to treat movement disorders such as essential tremor, Parkinson's disease and dystonia. It received approval from the Food and Drug Administration (FDA) to treat essential tremor and tremor in Parkinson's disease in July 1997 and for advanced motor symptoms of Parkinson's disease in January 2002. It is currently approved for the treatment of dystonia through a "humanitarian device exemption."

The subthala*mic nucleus* (STN) and the globus *pallidus* (GPi) are two locations in the brain that are targeted in the DBS procedure for the treatment of Parkinson's disease. DBS administers a well-controlled electrical current into the target area(s). This electrical current functions as an "off switch" by disrupting abnormal brain signals responsible for the abnormal physical movement. This disruption helps restore more normal activity in the brain thus enabling more controlled movement. DBS does not involve destruction of brain tissue and its effects are reversible and adjustable. It is now preferred over the *thalamotomy* or *pallidotomy*, two surgical techniques that involve the actual destruction of the brain cells that are "misfiring."

The effectiveness of the DBS procedure depends on accurate placement of the brain lead(s) or wire(s). Electrical impulses generated from on implanted battery, pass through the lead and into the target area. The target areas or nuclei are quite small, approximately the size of a grape. However, the optimal area within these structures is approximately the size of a grain of rice! Special imaging techniques and the placement of a metal, stereotactic head frame to the patient's skull help to guide the positioning of the leads. Certain areas of the brain have a characteristic sound. Microelectrode recording (MER) is conducted during surgery and involves "listening" to the brain cells to identify these specific areas. The patient is awake during this and other portions of the surgery and become an important member of the team. The patient helps in determining whether beneficial effects occur when the stimulation is applied during surgery.

DBS surgery is time consuming, usually lasting three to six hours per side of the brain being operated on. The most common complaints from patients include back and neck pain and fatigue. These complaints occasionally can become so disabling that the patient has a difficult time participating in the surgery and/or requests to have the surgery prematurely stopped. The traditional approach to DBS surgery involves attaching a large, metal halo device to the patient's skull and securing it to the surgical table. The frame's effectiveness has been proved during several decades of use. However, the negative aspects of the frame are that it creates complete immobilization of the patient's head and neck and it obscures the patient's line of vision.

In an effort to simplify the DBS procedure and enable greater patient comfort and participation during surgery, neurosurgeons at Virginia Commonwealth University, Cleveland Clinic and Tulsa, Oklahoma worked with Image Guided Neurologics Inc. (IGN) to develop a *frameless stereotaxy technique*. In this technique, the heavy frame has been replaced with five small bone screws and the NexFrame, a disposable guidance device.

This new device does not require that the head and neck be kept in a fixed position and the patient can move or adjust his/her position if needed. Importantly, the accuracy of the frameless and framed techniques has been found to be equal (J. Neurosurg/Volume 103/September 2005).

In August 2005, Medtronic Neurological, the world-wide leader in DBS therapy, acquired IGN and the *NexFrame* technology. The implications of DBS therapy are far-reaching not only in the treatment of movement disorders but for disorders such as epilepsy and depression. DBS and this new frameless option offer much promise for those suffering from Parkinson's disease that is refractory to medical therapies.

For more information about frameless deep brain stimulation, please call (804) 675-6284.