Deep-Brain Stimulation: There's Still Room for Improvement

26 May 2010. Though some 55,000 people have received deep-brain stimulation for conditions ranging from Parkinson disease to obsessive-compulsive disorder, there is still plenty of room to improve the process. Companies are working on smaller devices with longer battery life. Surgeons are seeking ways to more safely and precisely implant the electrodes that reset faulty brain signals. And people who receive DBS are hoping that researchers can improve the sometimes lengthy and cumbersome process of fine-tuning the settings on the pacemaker-like neurostimulator that controls the pulses to the electrodes.

Ever-improving imaging technology has been key to the spread of DBS, as doctors identify more brain regions that might benefit from the stimulation. For example, researchers have gone as high as seven-Tesla MR imaging, in comparison to the standard two Tesla scanners more routinely available (Cho et al., 2010). These high-resolution images help surgeons target the right spot. "Getting the electrodes in the right place is probably the most important thing to dictate clinical outcomes," said Cameron McIntyre of the Cleveland Clinic. A millimeter to the left or right, and results will be less impressive than they could be. And this placement happens some six centimeters below the skull, where surgeons cannot navigate by sight.

In the OR

To help surgeons turn the images from an MRI or CT scan into a plan of operation, McIntyre and others have developed a software package called Cicerone (Miocinovic et al., 2007). The software lines up a person's brain scans with standard neurophysiology maps and 3D brain atlases, so surgeons can identify the most promising site for stimulation and plan a route to get there. During the operation itself, the surgeon can also use the images to visualize the electrode's location, and Cicerone will predict what regions it will stimulate.

In addition to placing the electrode, better images help doctors plan a safe surgery. The location of blood vessels varies from person to person, and surgeons may nick one, causing a hemorrhage. The risk of serious bleeding, leading to brain damage or death, is between 1 and 2 percent. Neurologist Jerrold Vitek, soon to move from Ohio's Cleveland Clinic to the University of Minnesota in Minneapolis-St. Paul, said he wants to see that risk drop to 0.5 percent, so more people who might benefit from DBS will feel confident signing up for the procedure.

A person who receives DBS will likely need brain surgery once, but will also have a second surgery to implant the neurostimulator in the chest. It connects to the brain via wires under the neck's skin. That surgery is necessary every time the neurostimulator's batteries run out and require replacement—once every two to five years, depending on the voltage settings.

But Richard McEnery, a software developer and photographer in Sammamish, Washington, was burning through batteries in a year, he told ARF. DBS silenced much of his dystonia—a condition that includes involuntary muscle contraction—including the neck tremors that made him "look like a bobblehead doll," he said. Now, McEnery benefits from a relatively new improvement in DBS technology, a rechargeable battery. It doesn't last as long—perhaps a month—but he can top it off at home while watching TV. The recharger is a large plastic device connected to a

battery. Once a week, McEnery dons a harness that aligns the recharger with the neurostimulator under his skin. Over an hour or two, the device wirelessly transmits power through his skin to the neurostimulator, and he is powered up and good to go.

Post-Op

DBS is not plug-and-play; the equipment requires setting and maintenance. Neurostimulator settings include many parameters; voltage, signal length, and frequency of stimulation are just a few. A doctor or nurse works with the DBS recipient to program the neurostimulator's activity. Altogether, thousands of possible setting combinations exist, and every recipient needs a personalized one. Finding those magic numbers requires multiple office visits that can last hours. The time involved—and lack of many healthcare practitioners skilled in setting the device—is one of the biggest complaints among people who have DBS. McEnery recalls it took a year to perfect his settings.

The programming task frequently falls to nurses, neurophysiologists, and doctors still in training, who may or may not be expert in the process and in medical treatments for the condition at hand. In a 2006 study, researchers at Toronto Western Hospital examined the potential for an experienced neurologist to improve programming (Moro et al., 2006). They initiated the study when Elena Moro, an expert in DBS as well as management of Parkinson's and movement disorders, joined the clinic. She reset neurostimulators for 44 people with Parkinson's who had had DBS for an average of 3.5 years already. The result: more than half of the participants saw improvement in mobility and daily activities, and were able to reduce their anti-Parkinson's medications. Others saw no benefit; in four people, symptoms worsened. The data suggest, the authors write, that the expertise of the programmer makes a difference.

"A great deal of clinical intuition goes into the process," said McIntyre, who was not involved with the Toronto study. Yet again, he offers a computational solution. He and colleagues are developing StimExplorer, a program that integrates a patient's MR images with the position of the electrode (Butson et al., 2007). It offers users a set of theoretically optimal parameter settings. They may not be just right, but they should, hopefully, put the user in the right ballpark from which fine-tuning is easier. McIntyre has licensed much of his technology for commercial development, and hopes his software will receive FDA approval in a year or two. Something like StimExplorer could help inexperienced programmers, Moro said.

As DBS becomes more popular, more companies are developing stimulators. Medtronic, Inc., headquartered in Minneapolis, Minnesota, currently holds much of the U.S. market. St. Jude Medical, Inc., based in St. Paul in the same state, already has a DBS device approved for Parkinson's in Europe and is currently conducting a U.S. study. Competition should lead to improvements in the technology. For example, doctors hope to soon have a neurostimulator small enough to fit in the head, against the skull. This would eliminate the wires traveling through the neck, which might break. "I think you will see a lot of one-upmanship between the two players," McIntyre said.—Amber Dance.