

## DBS Gains Awareness as Therapy for Traumatic Brain Injury

*by James Cavuoto, editor*

The market potential for deep brain stimulation as a treatment for traumatic brain injury increased dramatically this month following a well publicized procedure involving a patient in a minimally conscious state and investigators at three U.S. institutions. The work, reported in the August 2 issue of *Nature*, stems from research at the Cleveland Clinic, the JFK Johnson Rehabilitation Center, and Weill Cornell Medical College.

The original concept for the DBS procedure was developed at Weill Cornell ago by Nicholas Schiff, lead author of the *Nature* article. The operation was performed at the Cleveland Clinic by neurosurgeon Ali Rezai. The patient was a 38-year-old severely brain-injured man who had been unable to communicate or eat by mouth for six years. After a six-month, double-blinded on/off "crossover" trial, with periods of thalamic DBS alternating with periods where he did not receive the therapy, the patient now has oral feeding and verbal communication abilities. This first DBS procedure is part of an FDA-approved pilot study that will include 12 patients in post-traumatic minimally conscious state.

Late recovery of this magnitude is rare in patients with chronic MCS. This state is distinct from either a persistent vegetative state or coma, in that patients show intermittent signs of awareness and may even attempt to communicate using simple words or signals. However, these glimpses of consciousness are usually rare, fleeting, and unsustainable.

Traumatic brain injury can be categorized by the degree of motor and cognitive functional loss. This functional loss can range from a simple concussion with a full functional recovery to a persistent vegetative state, where functional recovery is very rare. Experts estimate that from 100,000 to 300,000 patients with traumatic brain injury are now diagnosed as MCS. Under the current standard of care, most do not receive active rehabilitation and are cared for in long-term nursing facilities.

One of the first commercial firms to target the TBI market is [Intelect Medical](#), a Cleveland Clinic spinoff that has licensed technology from both Cleveland Clinic and Weill Cornell Medical College. Intelect's DBS therapy has been initially proposed for the treatment of patients who are in MCS or have chronic severe cognitive disability. This treatment will stimulate a specific brain target that will be selected based on neurobehavioral criteria, selected regions of hypometabolism (as determined by PET scans), and the overall pattern of cortical injuries. The applied neuromodulation therapy will be used to stimulate not only arousal, but also higher levels of functioning, such as movement and speech.

The company's neuromodulation system will consist of a proprietary implantable pulse generator capable of delivering precision stimulation through Intelect's novel DBS leads. The IPG will have unique features related to implant site, stimulation waveforms, and downloadable options. Leads and electrodes will be designed to maximize volumetric stimulation at the target site, while preventing stimulation from reaching adjacent areas to prevent undesirable side effects. Thus, the electrode sizes, shapes, and lead configurations will be customized for each of the intended stimulation sites in the brain.

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