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Non-invasive therapy significantly improves depression, researchers say

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Major depression is a common and disabling brain condition marked not only by the presence of depressed mood but also by its effects on sleep, energy, decision-making, memory and thoughts of death or of suicide.

Major depression affects 15 million adults in the U.S., and the World Health Organization projects that by 2020, it will be the largest contributor to disability in the world after heart disease.

While antidepressants have helped many to recover and resume their lives, only 30 percent of patients will experience full remission with the first medication they use. Patients typically move on to try a series of other antidepressants. A persistent problem with such drugs has been major side effects, including obesity, sexual dysfunction, fatigue, drowsiness and nausea.

Now, a unique new therapy that applies electrical stimulation to a major nerve emanating from the brain is showing promise.

In a recently completed clinical trial at UCLA, trigeminal nerve stimulation (TNS) achieved an average of a 70 percent reduction in symptom severity over an eight-week study period. The study's principal investigator, Dr. Ian A. Cook, the Miller Family Professor of Psychiatry at the Semel Institute for Neuroscience and Human Behavior at UCLA, presented the results at a recent National Institutes of Health conference on depression and other psychiatric disorders, noting that 80 percent of the subjects achieved remission, a highly significant result in this pilot

study.

TNS is not new to UCLA. It was pioneered for treatment-resistant epilepsy in humans by Dr. Christopher M. DeGiorgio, a UCLA professor of neurology. The results of a positive 12-patient feasibility trial in epilepsy were reported last year in the journal Neurology. A larger, double-blind pilot epilepsy clinical trial is underway at UCLA and the University of Southern California.

The stimulator that was used in the depression clinical trial is about the size of a large cell phone. Two wires from the stimulator are passed under the clothing and connected to electrodes attached to the forehead by adhesive. The electrodes transmit an electrical current to the nerve. All the patients in the trial used the device for approximately eight hours every night while asleep. In contrast to antidepressants, no major side effects were noted.

"The major branches of the trigeminal nerve in the face are located close to the surface of the skull and can be stimulated either with non-invasive external electrodes, as we used in this trial, or with minimally invasive subcutaneous electrodes," Cook said.

He added that some patients may prefer to have miniature subcutaneous electrodes implanted under the skin rather than applying new electrodes daily.

In describing TNS, DeGiorgio, co-principal investigator for the depression trial, explained that what is remarkable about the TNS approach is that it is possible to send signals to key structures deep in the brain without penetrating into the skull.

Cook hypothesized that electrical stimulation of the trigeminal nerve generates a cascading sequence of events in the existing neuronal

infrastructure. In essence, he said, "TNS provides a high-bandwidth pathway into the brain."

To help bring the TNS out of the laboratory and into patient care, UCLA's Office of Intellectual Property recently executed an exclusive worldwide license for the TNS with NeuroSigma, a Los Angeles-based neuromodulation company formed in 2008 to commercialize promising technologies developed at leading universities and research institutions. DeGiorgio and Cook are among UCLA's inventors of the TNS technology and are unpaid advisers to NeuroSigma. Dr. Antonio De Salles and Jack Judy, also UCLA faculty members, are co-founders of NeuroSigma and are minority shareholders. They report no role in this project.

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