

First participants in study treated using Saint neuromodulation for severe depression

By David Godkin, Staff Writer

The first participants are being treated in a clinical trial assessing a neuromodulation system developed by [Magnus Medical Inc.](#) to treat depression. The system employs the recently FDA-cleared [Saint neuromodulation technology](#) that saw remarkable results in a clinical trial for treating major depressive disorder (MDD). The new Open Label Optimization (OLO) clinical trial is evaluating the effectiveness of this platform in conjunction with the medtech's Magnus Neuromodulation System.

"We've seen 80% to 90% of people in our prior clinical trials go into remission within five days or less which means they don't have symptoms of depression anymore," Magnus co-founder and CSO Brandon Bentzley told *BioWorld*. "So to think about how that might touch their lives and their families lives is hard to put into words to be honest. But I am really excited."

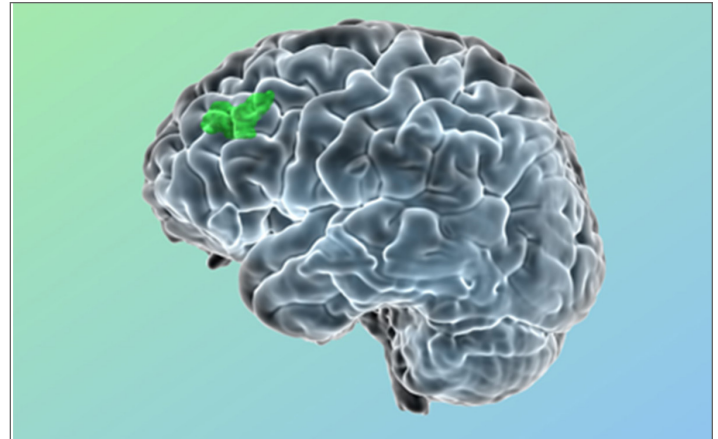
Change the only constant

MDD, also known as clinical depression, is one of the most severe forms of depression. Factors such as genetic predisposition, stress and brain chemistry increase the risk of MDD, which presents as a persistently low or depressed mood, fatigue or irritability, and a loss of interest in activities. An episodic disorder, MDD can last months or even years. Many individuals with MDD will experience multiple episodes over their lifetime.

The proportion of people who will have a diagnosis of depression in their lifetimes is stunning. An estimated 14% or about one billion people worldwide will experience the mental disease. In the U.S. the percentage affected is higher still: an estimated 20% or 60 million Americans battle depression. Said Bentzley. "Those are huge, huge numbers."

It turns out the brain's natural plasticity is responsible for both its enormous learning capability and for its ability to actually heal itself. The capacity to undergo change sits at the heart of restoring the brain's cognitive power and physical motion in patients hit by illness or physical injury – and by severe depression, Magnus Medical argues.

Current treatments, notably talk therapy and anti-depressive



Magnus Medical Inc. claims its Neuromodulation System with Saint technology is potentially a key tool for treating severe depression experienced by 60 million Americans. Credit: Magnus Medical Inc.

drugs like fluoxetine and venlafaxine, are of little or no use to the third of Americans with depression, said Bentzley. Both therapies are very slow to work, while medications "have a lot of very difficult-to-tolerate side effects, among them weight gain and a loss of sexual interest."

Setting aside controversial electroconvulsive or shock therapy radically altered to assist a small number of patients, transcranial magnetic stimulation (TMS) has increasingly been used to treat MDD, said Bentzley. TMS, he explained, employs pulse and pulse patterns to stimulate parts of the brain, altering for the better misfiring connections associated with MDD.

The problem with conventional TMS "is where to place the magnet relative to the patient's brain, because no neuroimaging is done," said Bentzley. "Instead, doctors guess."

Mapping the sweet spot

While the Magnus Neuromodulation System also transmits impulses "in an easy, non-invasive way to communicate with the brain," the platform's goal has been to eliminate the guesswork.

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“We said ‘Let’s figure out how to place pulses for each person by mapping out the brain,’” said Bentzley, “and be very careful about which pulse patterns we use to communicate with the brain.”

This is where Saint technology kicks in, he added, “mimicking many of the pulse patterns which your brain uses to make natural memories.” Ironically, is that not another form of talk therapy, Bentzley was asked. “Actually, that’s not a bad analogy,” he replied.

“We have so many ways of communicating with people, like the conversation we’re having now, through arts, literature, music and media; these are all methods for stimulating neural plasticity and communicating with the brain. We’re just being much more direct about it.”

The Magnus Neuromodulation and Saint systems target that point in the brain where natural pulse patterns strengthen the neural network, “and then use electromagnetic pulse patterns to accelerate the process,” said Bentzley. “It happens much faster and more efficiently.”

In other words, the combined systems direct a magnetic field to the precise spot of the brain requiring restoration of pulse patterns, with the technical capacity to make the right choices when replicating those patterns.

Demonstrating the Saint technology’s additive power to the Magnus Neuromodulation System falls to the OLO clinical trials at nine sites across the U.S., from small private clinics to very large medical universities. One thousand individuals struggling with MDD will participate, with the hope that OLO surpasses a previous randomized clinical trial in which fourteen participants received active neuromodulation, eleven of whom experienced remission.

“We had no idea the treatment was going to be that effective” said Bentzley. “It was more than an ‘aha’ moment; it motivated us to work really hard in other clinical trials.” In one such trial, twenty-one people were treated, with 90% going into remission over a five-day period.

Conducted at Stanford’s Department of Psychiatry and Behavioral Sciences the clinical trial was funded through grants, as well as by Charles R. Schwab, the Gordie Brookstone Fund and other supporters. What’s the endgame finally?

“At the end of the day, during these clinical trials we’re collecting very high resolution brain scans of people about their illness and very detailed information about the outcomes of treatment,” said Bentzley. “I dream of a future in which depression is no longer the number one cause of disability.”