

Magnus Medical's Saint system alters brain signals in patients with severe depression

By Meg Bryant, Staff Writer

Results from a new study suggest that treatment with [Magnus Medical Inc.](#)'s Saint neuromodulation system causes abnormal brain signals to become normal by reversing the direction brain signals flow in severely depressed individuals. The researchers also identified a new biomarker that could help doctors diagnose and treat major depressive disorder (MDD).

An estimated 280 million people worldwide suffer from MDD, according to the World Health Organization. In the U.S., about 21 million adults – 8.4% of the adult population – [experienced](#) at least one major depressive episode in 2020.

The main options for treating depression are drugs and talk therapy, both of which can be successful. But for patients with treatment-resistant depression, it's a much bigger challenge. Drugs and psychotherapy may provide little relief, or symptoms may improve, only to resurface weeks or months later. About 16% of patients with MDD contemplate suicide.

MDD also takes a significant financial toll. According to IBM's MarketScan database, 4% of U.S. adults with MDD had had a MDD-related [hospital stay](#) in 2014-15, with a mean length of stay of six days and reimbursed cost of \$8,441. Of those, 5.4% had at least one readmission for MDD within 30 days.

The Saint neuromodulation system uses structural and functional magnetic resonance imaging (MRI) to inform an algorithm that identifies the most favorable anatomic target for focused neurostimulation in people with MDD. The treatment is delivered over five days, with stimulation targeted to the unique neural mapping and connections within each patient's brain.

Based in Burlingame, Calif., Magnus received an FDA breakthrough device designation for the technology in 2021 and was granted 510(k) clearance in September 2022.

In this new study, 23 patients who received treatment with Saint and 10 patients treated with a sham were compared with 101 healthy controls. Researchers looked at the relationship between resting-state functional MRI (fMRI) brain activity, major depression

and response to Saint and found that Saint caused abnormal brain signals to reverse direction in the bilateral anterior cingulate cortex (ACC), an area in the brain that helps regulate emotions.

The study also showed that in people with depression, the ACC sent signals to the anterior insula – the opposite of normal people, whose brains signals go from the anterior insula to the ACC. This finding could serve as a biomarker for diagnosing and treating MDD, Magnus said.

The study was [published](#) in the *Proceedings of the National Academy of Sciences*.

"We now have a neural network signature that separates depression from non-depression," Brandon Bentzley, Magnus' co-founder and chief scientific officer, told *BioWorld*. "We can separate people who suffer from depression from those who do not by their neural networks, and we can also modify those neural networks successfully with personalized treatment using Saint neuromodulation."

The study builds on earlier studies with Saint, which used neuroimaging solely for the purpose of finding the right personalized target for treatment. Now, investigators are using neuroimaging and brain mapping to also identify neural network signatures associated with different neuropsychiatric diseases. This paves the way to treat a more diverse set of neuropsychiatric diseases with precision medicine, Bentzley said.

"Currently, with Saint treatment, we are looking at a map of all the roads and highways in someone's brain," he said, using an analogy. "Now, with the biomarker, or signature of neural networks, we're also seeing the traffic flow patterns on the map of roads and highways in a person's brain."

That distinction lifts precision neuromodulation to a new level, he said. "In the neurostimulation industry, we have seen the industry grow from measuring tapes and rulers to neuroimaging and brain mapping to now having the ability to have a neural network signature that will enable precision medicine."

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Despite having FDA clearance, Magnus has not yet commercialized the Saint neuromodulation system – choosing to expand clinical trials throughout the U.S.

“There is a very high demand for it,” Bentzley said, adding the company is on track to launch commercially in mid-to-late 2024.

“This new research means we can offer faster, more effective treatments with a higher probability of success, he said. “We’ll be able to make sure the right person gets the right treatment the first time.”

Other companies are also betting on brain stimulation to treat depression. In March, Helsinki-based Sooma Oy got an FDA breakthrough device [nod](#) for its Sooma Depression Therapy, which uses a mild electrical current to modulate brain activity in regions affected by the mood disorder.

And in 2022, Neuronetics Inc. launched the Neurostar transcranial magnetic stimulation system for the treatment of MDD. The noninvasive system [includes](#) the company’s FDA-cleared MT Cap technology, which speeds the selection of dose and motor threshold for each patient.