

New technique zaps major depression

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By Charlie Patton

Until the fall of 2012, Leigha Krivacek had always considered herself a happy, well-adjusted person.

At Westminster College in Pennsylvania, she was student government president and played on the softball team.

Following graduation in 2011, she moved with her family to Jacksonville and began working as a financial analyst in a bank.

Then, suddenly, depression “smacked me in the face,” said Krivacek, now 24.

The young woman who considered herself someone who could “thrive in chaos” found herself unable to get out of bed.

For three months, she was unable to go to work.

“I felt powerless,” she said. “... I had thoughts of ‘I don’t want to be here.’”

On two occasions, her depression reached such “severe intensity” that she had to be briefly hospitalized at Wekiva Springs Center, a Jacksonville psychiatric facility, said psychiatrist Nikhil Nihalani, who began treating her when she was hospitalized.

Initially Nihalani treated Krivacek with medication.

But Krivacek remained depressed. So Nihalani decided to use a new approach known as Transcranial Magnetic Stimulation (TMS).

He had acquired a NeuroStar TMS Therapy System, which was approved for treatment of depres-

sion in people for whom medication has proved ineffective by the Food & Drug Administration in October 2008.

Since then, about 12,000 patients nationally have been treated for depression with TMS.

A study reported at the American Psychiatric Association convention in May found that of 307 people treated for major depression with TMS over the course of a year, 68 percent showed symptomatic improvement and 45 percent reported complete remission.

So last February, Krivacek became Nihalani’s first patient to be treated with TMS.

For about a month she would visit his office on daily basis. She would sit in a high-tech chair while Nihalani’s nurse, Kim Peterson, positioned a magnetic coil over her head.

MRI-strength magnetic field pulses were then directed for 37 minutes at a part of the brain associated with depression.

She has proved to be one of the fortunate patients whose symptoms went into complete remission as a result of the TMS treatment.

Peterson described the transformation as “a total 360”-degree change.

“I feel like me again,” Krivacek said. “A better me ... I’m genuinely happy now.”



Photo provided by Leigha Krivacek.

Leigha Krivacek, a 24 year old Jacksonville woman, recently became the first person treated for major depression by psychiatrist Nikhil Nihalani using a technique called Transcranial Magnetic Stimulation. Unable to work or even get out of bed and hospitalized twice before undergoing the treatment, Krivacek’s symptoms are now in complete remission. The treatment involves placing a magnetic coil over the patient’s head and then zapping a targeted section of the brain with MRI strength magnetic field pulses.

And she’s become outspoken about the benefits of seeking treatment for depression, a condition that affects an estimated 20 million Americans.

“It’s always OK to ask for help,” she said. “Depression can happen to anyone.”

Meanwhile, she has a new job she loves with Deutsche Bank, she’s got a new boyfriend and she’s applying to graduate schools so she can pursue a master’s in business administration.

“I’m ready for the next level,” she said.

About NeuroStar TMS Therapy®

NeuroStar TMS Therapy indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication at or above the minimal effective dose and duration in the current episode.

The safety and efficacy of NeuroStar TMS Therapy in Major Depressive Disorder (MDD) was studied in a randomized controlled trial of patients who had failed to receive benefit from one to four prior antidepressant medications. A retrospective subgroup analysis of the overall study population demonstrated that the device was safe and effective for patients who had failed to benefit from one prior antidepressant medication of adequate dose and duration in the current episode. In this study population, patients had received a median of 4 total prior antidepressant medication attempts in the current episode, one of which achieved treatment adequacy at or above the minimal effective dose and duration.

In a controlled trial, patients treated with active NeuroStar TMS Therapy received greater than 3 times the improvement in depressive symptoms compared to placebo at four weeks (MADRS, -7.1 vs -2.1, $P=0.0006$).¹ An open-label, uncontrolled clinical study showed approximately half of the patients treated with NeuroStar TMS Therapy experienced significant improvement in their depression symptoms. About a third of the patients treated with NeuroStar TMS Therapy experienced complete symptom relief at the end of 6 weeks.¹

NeuroStar TMS Therapy should not be used (is contraindicated) in patients with implanted metallic devices or non-removable metallic objects in or around the head. NeuroStar TMS Therapy is not associated with systemic side effects reported for antidepressant medications. The most frequently reported side effect with NeuroStar TMS Therapy is scalp pain or discomfort at the treatment location. There is a rare risk of seizure with NeuroStar TMS Therapy; in post-market experience, the risk is approximately 0.1% (1 in 1000 patients). Patients undergoing treatment for Major Depressive Disorder, including NeuroStar TMS Therapy should be monitored closely for worsening symptoms and signs of suicidal behavior and/or unusual behavior.

The safety of NeuroStar TMS Therapy in the presence of concomitant antidepressant medication was evaluated in a 6-month follow-up open-label clinical trial in patients who had previously responded to acute NeuroStar TMS Therapy. The safety outcomes did not differ from those observed during acute TMS monotherapy.²

The safety and effectiveness of NeuroStar TMS Therapy has not been established in the following patient populations or clinical conditions through a controlled clinical trial: Patients who have failed to receive benefit from 2 or more antidepressant medications given at or above minimal effective dose and duration in the current episode or who have had no prior antidepressant medication failure; Patients who cannot tolerate withdrawal of antidepressant medications; Patients who have a suicide plan or have recently attempted suicide; Depression secondary to a general medical condition or substance-induced; seasonal affective disorder; Patients younger than 22 years of age or older than 70 years of age; Patients with history of substance abuse, obsessive compulsive disorder or post-traumatic stress disorder; Patients with a psychotic disorder, including schizoaffective disorder, bipolar disease, or major depression with psychotic features; Patients with neurological conditions that include history of seizures, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the CNS; Patients with metal in or around the head, including metal plates, aneurysm coils, cochlear implants, ocular implants, deep brain stimulation devices and stents; Patients with vagus nerve stimulators or implants controlled by physiologic signals, including pacemakers, and implantable cardioverter defibrillators; Patients with major depressive disorder who have failed to receive clinical benefit from ECT or VNS; Patients who are pregnant or nursing. NeuroStar TMS Therapy has not been demonstrated to be equivalent in efficacy to ECT for the treatment of major depressive disorder. Efficacy was not studied in patients using concomitant antidepressant medications or receiving psychotherapy during TMS Therapy treatments. Safety and efficacy have not been established for NeuroStar TMS Therapy beyond a 4-6 week acute course, use of treatment parameters outside the labeled protocol or for maintenance therapy.

NeuroStar TMS Therapy is available by prescription only. Patients should talk to their doctor when considering NeuroStar TMS Therapy as a treatment option. For questions regarding this article, please contact Customer Service at 1-877-600-7555. Full safety and prescribing information is available at www.NeuroStar.com.

1. Demitrack MA, Thase ME. Clinical significance of transcranial magnetic stimulation (TMS) in the treatment of pharmacoresistant depression: synthesis of recent data. *Psychopharm Bull.* 2009, 42(2): 5-38
2. Janicak P, et al. Transcranial Magnetic Stimulation (TMS) in the Treatment of Major Depression: A Comprehensive Summary of Safety Experience from Acute Exposure, Extended Exposure and During Reintroduction Treatment. *Journal of Clinical Psychiatry*, February 2008