



TMS Center of Colorado, LLC
repetitive Transcranial Magnetic Stimulation Therapy

Dear Friends,

Based on data presented at the May meeting of the Clinical TMS Society and the American Psychiatric Association in Atlanta it is becoming clear that leading researchers are now thinking of brain functioning as organized along the lines of neural networks rather than discrete structures. These networks may also be referred to as neural brain circuits. The normal functioning of these networks is mediated by complex neurochemical and electrophysiological processes.

When depression emerges there is evidence based on imaging studies (PET and fMRI) that the salience network is disrupted. Symptom emergence occurs when the combination of genetic vulnerability and bio psycho-social stressors overcomes the normal functioning of the salience network. The goal of treatment of major depression is to reverse the symptoms (hopelessness, anxiety, and others per DSM5).

A metaphor for re-regulating a disrupted salience network is like tuning a guitar that is out of tune. You have to tighten and loosen the keys precisely and follow the sound until it sounds great. Simply tightening the keys as tight as they will go will not produce the desired outcome.

Psychopharmacology and cognitive therapy are our leading tools to tune the salience network and there are numerous medication strategies including augmentation and combination therapies that are effective for most patients. Some patients have significant side effects with medication. Patients who do not respond to or cannot tolerate these treatments are referred to as treatment resistant (TRD). For these treatment resistant patients it is clear that neuromodulation with ECT (electroshock treatment) and TMS (transcranial magnetic stimulation) represents the best hope for achieving improvement and/or remission.

ECT is historically established and the most powerful neuromodulation method. It does require numerous episodes of general anesthesia and may have in some patients clinically significant, sustained neurocognitive side effects. It continues to have a major role in the treatment of resistant depression, especially in psychotic and acutely suicidal patients.

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However, the general principle in medicine is to do the least invasive/intrusive treatment first, thus in most clinical situations it is more logical to use TMS before ECT.

TMS is among the safest treatments in all of medicine. Eleven thousand (11,000) published studies and several million treatments have confirmed the safety and not revealed any neurocognitive side effects whatsoever. Seizures can occur but are extremely rare.

While no brain treatment at this point is as precise as we would like, currently TMS does give us the ability to electrically up regulate or down regulate the salience network by varying stimulation parameters and treatment location targets in the brain. This fine tuning contributes to positive results in about 75% of the patients treated in established TMS Centers, higher than seen in the studies that led to FDA clearance in 2007. A recent study presented at this year's APA meeting done in Texas showed a 76.4 response to TMS as measured by the Beck depression Inventory and PHQ 9, and remission rates of 52.5.

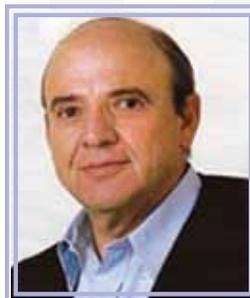
Many TMS centers, including ours, have been waiting for years to get level 1 evidence about the Theta burst TMS protocol. Level 1 evidence is obtained from sham and double blind controlled studies, the best evidence available. There are several TMS clinics in the US that only offer Theta burst protocols. Prepublication data released in Atlanta in such a study done in Toronto demonstrate that a Theta burst protocol produced virtually identical outcomes as standard TMS protocols. The advantage of Theta burst is that the entire treatment lasts only 5 to 8 minutes and may be done twice and sometimes three times a day, at least one hour apart. About 30 treatments are still required, but it may be possible to complete treatments in two weeks rather than six weeks.

This protocol has not been presented to the FDA and if used would be off label. Based on this and other evidence, the professional team at The TMS Center of Colorado has begun to offer this treatment option to our patients.

The use of TMS is increasing rapidly worldwide. There are more than 600 TMS centers in the US. There is a center in Tokyo that has 60 (yes, 60 - it is not a typo) TMS machines in use 6 days per week. In South America TMS is available and widely used in all countries. For the most part they use TMS machines made in Russia that are cheaper than those available in the US. Much of the research presented in Atlanta was done in Canada, Europe and Israel. TMS is now often seen in media as highlighted by a recent House episode and its appearance on Dr. Oz. TMS is being investigated as a treatment for several other psychiatric, neurological, and medical conditions.

Among emerging TMS technologies, the closest to receiving FDA clearance and being available for use in the US is a four channel TMS device being developed by Rio Grande Neuroscience and a TMS device being developed by NeuroSigma that delivers its impulses through the trigeminal nerve. The Rio Grande Neuroscience device will allow stimulation at four points on the brain. We are hopeful that these new devices will offer better outcomes and other advantages to our patients when available in the future.

I am pleased to say that I have never been more excited about TMS. There are so many patients suffering from treatment resistant depression (TRD) and having a tool that is able to help most of them is very encouraging.



Warm regards,

A handwritten signature in black ink, appearing to read "Ted Wirecki" with a stylized flourish at the end.

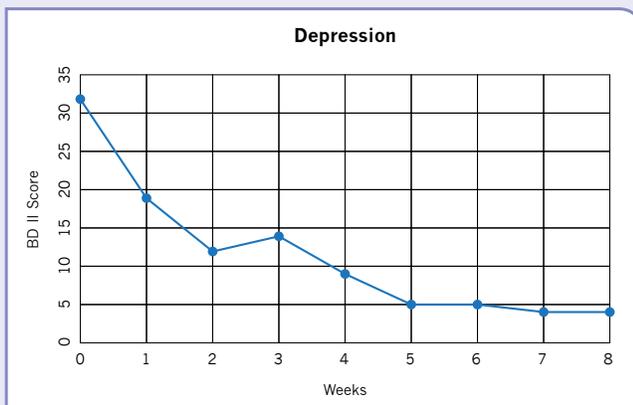
Ted Wirecki, M.D.
Medical Director
TMS Center of Colorado, LLC

A Family's Last Hope

Lexi, a 22-year-old female, was referred to TMS Center of Colorado for treatment of severe depression and anxiety by another doctor. At the time the referral was made, she was unable to attend college, had strong suicidal thoughts and was hospitalized three times in 12 months for symptoms of depression.

Lexi's medical history showed significant mental illness on both sides of her family. Suffering from depression and anxiety since age 16, she had tried eleven different prescription medications to cope with her illness, including Prozac, Cymbalta and Abilify. In addition to these psychiatric meds, she also took vitamin D, multivitamins, fish oil and exercised regularly. The drugs made little difference and often resulted in irritability and sleeplessness. Lexi had also been through many years of once-a-week counseling with several different therapists. She found the sessions helpful in a general way, but not with her depression and anxiety.

At her initial TMS evaluation, Lexi's depression test score was 31, which is in the "severe depression" category on the Beck Depression Inventory®-II index. Her anxiety test using the Beck Anxiety Inventory® was 39, which indicates severe anxiety. Based on her test results and evaluation, TMS Center of Colorado recommended and carried out a course of Brainsway® deep transcranial magnetic stimulation (dTMS) therapy over a period of eight weeks.



Beck Depression Inventory®-II (BDI®-II) scores at baseline (week 0) and through 8 weeks of dTMS treatment



Beck Anxiety Inventory® (BAI®) scores at baseline (week 0) and through 8 weeks of dTMS treatment

Lexi received a total of 35 dTMS sessions during this period. She started to see promising results with depression and anxiety within one week, and symptoms continued to improve throughout treatment. Lexi's depression score at the end of eight weeks of treatment had dropped to four, indicating a full remission of depression and normal mood disturbance. Her end-of-treatment anxiety index was 2, also a sign of full remission of anxiety.

After the dTMS sessions, Lexi's mom said that her daughter was doing "amazing" and described her progress as a "complete 180." The mom said Brainsway dTMS was the family's "last hope" due to her daughter's strong suicidal ideation and self-report that she was prepared to spend two weeks saying her final goodbyes before taking her life.

Lexi said that Brainsway dTMS, "started as a last resort, and quickly became the best decision I have ever made in my life." As her treatments came to an end, Lexi said she planned to go back to school.

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