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Poll/Question time

• "How many of you know somebody with depression?

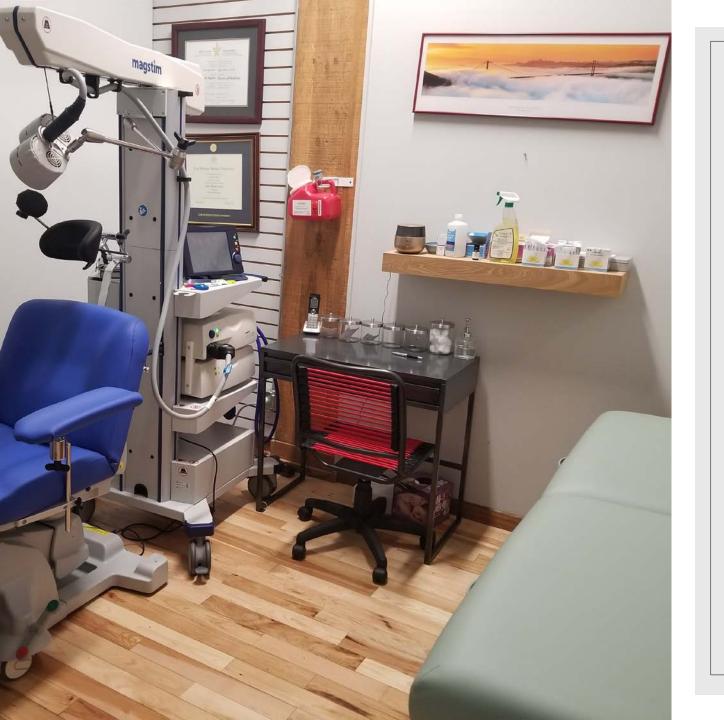
• How many of you know someone who has tried one antidepressant after another and is still suffering?

• How many of you know someone who has experienced a side effect from taking an antidepressant?

• Any of these can be reasons for starting TMS

The case of Mr. Active Duty

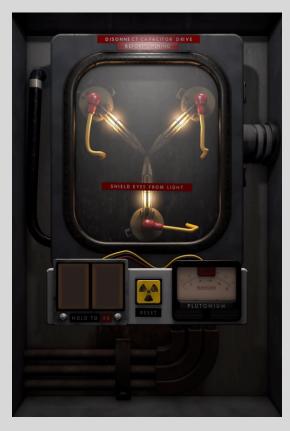
- Note: Details different than any actual patient treated, but are based on a real person treated at Strive
- 27 year old male serving in the US Navy, living in Greater Cleveland
- Depression worse over the last 2 years
- Multiple medications have been tried and not successful, causing side effects
- Went to an IOP and a residential treatment program, but remained depressed
- Came to Strive for TMS, met criteria, began a course of treatment
- By HAM-D and patient report, TMS obliterated his depression, from "Very Severe" to "None"
- Continued his request for medical discharge from the military, now starting a new chapter of his life



What is TMS?

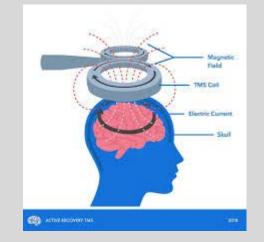
- Transcranial Magnetic Stimulation:
 - Utilizing rapid electrical discharge released from capacitors
 - Generating a pulsed magnetic field created when current passes through 2 adjacent copper coils, housed in plastic casing placed on the patient's scalp
 - Stimulating neurons of the left dorsolateral prefrontal cortex, resulting in neuroexcitation, release of neurotransmitters and subsequent antidepressant effect.

Capacitor: Remember the Flux Capacitor?

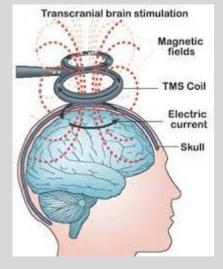


Note: The DeLorean from Back to the Future was powered by plutonium. TMS? By electricity from an outlet.

Generating a Magnetic Field







In TMS, a magnetic field is generated by passing current between 2 loops of copper coil, resulting in brain stimulation.

The history of magnets in medicine: 3 phases

- Ancient civilizations(India, Egypt, China, Greece): Discovery of benefits, use of magnets, but understanding is missing
- European scientific enlightenment(British, French, Italian, Danish, German):
 Culminating in Michael Faraday
- Modern use of magnets in medicine: MRI(diagnostics-1977), TMS(therapeutics-1985 demonstrated; approved 2008)

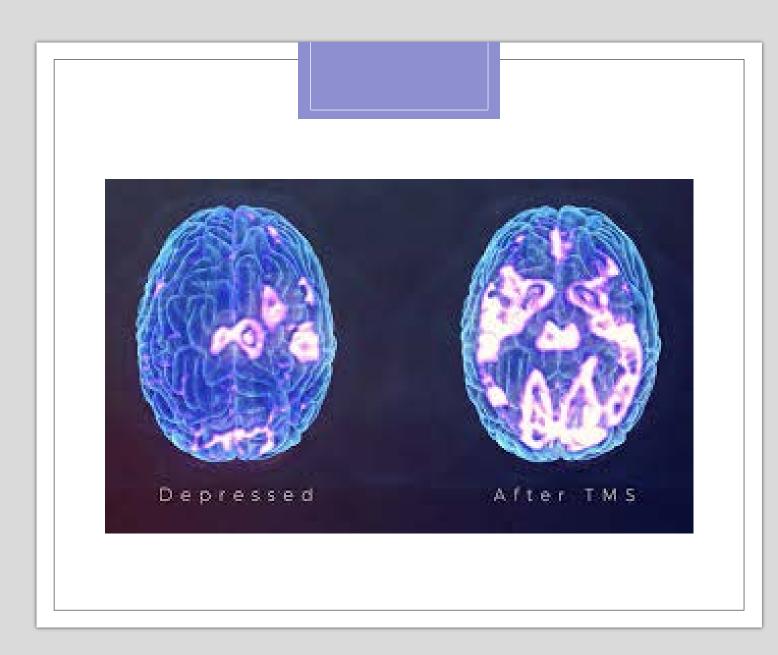
The History of TMS

- Faraday demonstrated in 1881 that pulsed electric current passed through copper coil generates a magnetic field
- Barker demonstrated in 1985 transcranial magnetic stimulation in an awake human, inducing current in the human brain to evoke a hand twitch when applied to the motor cortex on the opposite side.
- Figure 8 coil is developed in 1988
- Repetitive pulses at a consistent interval(rTMS) demonstrated to alter cortical excitability in early 90's
- Kolbinger et al demonstrates proof-of-principle study of using TMS to treat depression in 1995
- O'Rearden et al published depression study using Neurostar system in 2007
- $\circ~$ FDA approved Neurostar for TMS to treat depression in 2008





HOW DOES DEPRESSION AFFECT BRAIN ACTIVITY?



WHAT DOES TMS LOOK LIKE IN THE BRAIN?

What is TMS used for?

- FDA cleared to Treat Major Depressive Disorder that has failed at least 1 course of antidepressant therapy.
- ° Additional uses
 - ° OCD with select devices
- Investigational/Promising Uses: Depends on Location, Purpose, Stimulation vs Inhibition protocol
 - Anxiety, PTSD, ADHD, Dementia, Substance Use Disorders, Bipolar, Schizophrenia

Why does TMS matter?

- According to a SAMHSA survey, 17.3 million adults in the US, or 7.1% suffered from Major Depressive Disorder in the past year, costing American society \$210 billion per year in direct and indirect costs.
- ° An estimated 15% of the adult population will experience depression in their lifetime.
- Depression is the leading cause of disability worldwide, including in America
- Effectiveness of medication trials decreases with each subsequent trial/treatment failure
- \circ 2/3 of all suicides are depression-related
- Insurance companies may require failure of 2 to 4 medication trials/classes prior to authorization

Effectiveness of TMS vs other treatments The Goldilocks Principle

° TMS 60% response rate, 33-37% remission

• Medication 40 - 60% response rate

- ° Side effects: CNS, cardiovascular, GI, metabolic and sexual side effects
- ° Remission 27.5 45%, declines with each treatment failure
- Discontinuation of treatment increases with each medication trial.

• Recurrence up to 33% in patients being treated.

• ECT 80% response rate

- ° Requires inpatient/in-hospital service and anesthesia, driver, sick day
- ° Side effects: Memory loss, delirium, allergic reaction, respiratory complication.
- Faces historical fear and stigma.

Stigma? Or an opportunity to Strive?

- $\circ~$ 45year old male with ADHD
- Difficulty finishing standardized tests in elementary school. Structure of home helped performance in school
- Difficulty with deadlines for high school yearbook and college papers, finished by all-nighters
- Good grades in college and graduates medical school with structure and supportive environment
- Troubles completing tasks during residency in a timely manner.
- Diagnosed with ADHD at age 32, after unable to complete first residency
- Treated for ADHD, helps get through intern year in new program, but similar troubles with efficiency
- Completes 2nd year of residency but is not promoted to complete the remainder of the residency
- NEVER STOPPED BELIEVING IN HIMSELF. How do things turn out?

Stigma? Or an opportunity to Strive?

- Applied for New York medical license, granted
- Applied for Ohio medical license, granted
- Began work 6 weeks after receiving medical license
- Offered a second job 3 months later
- Took a position that allowed just having to work one job instead of 2
- Challenges with work flow remained, especially on busy days
- Decided to open own medical practice to increase professional satisfaction
- Still works in various roles as an independent contractor
- Practicing medicine past 9 years, never fired, no lawsuits. Enjoying life and career on his terms.
- How do I know?

What are the benefits of TMS?

- ° Locally directed treatment, without side effects of medications
- No anesthesia required
- No hospitalization required
- Can drive after the treatment session
- ° Can return to work the same day of treatment
- ° No adverse effect on memory. In fact, being studied as a treatment for dementia.
- Active treatment time in iTBS protocol is 3 minutes, with session lasting 15-20 minutes
 Patients can be back to work in 1 hour (including commute and treatment time)

TMS is cost-effective, improves quality of life

• rTMS was found to be more cost-effective than medication.

- Up to 40% of patients with MDD either do not respond to or tolerate medication and up to 85% of patients who do respond can be expected to relapse within 15 years; when they do, medication is less effective with each subsequent trial
- ° A course of 10 ECT sessions can cost \$25,000
- ° TMS can range from \$250 to \$500 per session, costing \$7,500 to \$15,000

What does a course of TMS look like?

- ° Initial screening consultation and prior authorization, including HAM-D
- ° Mapping session for Motor hotspot and Motor Threshold determination
- ° 36 total sessions
 - ° 30 treatment sessions, Monday through Friday
 - °6 taper sessions over 3 weeks(3 to 2 to 1)
- ° Weekly motor threshold determination and HAM-D symptom check
- ° When no response by 4th week, still 20% respond by week 6.

What does a TMS session look like?

- Brief symptom check-in
- Place treatment-marked TMS "swimcap" on head
- Insert earplugs (both patient and provider)
- Measure distance from cap edge to eyebrows to deliver treatment at consistent location
- Set TMS parameters for the session(intensity, frequency, duration)
- Line up device to target-marked location point, 5.5cm 6cm anterior from the motor hotspot
- Initiate treatment, lasting from 3 minutes to 19.5 minutes to 37.5 minutes, depending on the protocol. Real-world treatment session with 3-minute stimulation lasts 13-20 minutes in all.
- Schedule next visit

How do we create a relaxing environment?

- Cascading waterfall
- ° Smooth jazz
- °A fresh-brewed cup of tea
- ° Calming lavender essence vaporizer
- ° Deep breathing with focus on gratitude
- ° Optional complete Seinfeld series



When do you not use TMS?

- ° Epilepsy
- Metal object in the head/neck region(Foreign body, surgical hardware, medical device). Dental hardware is OK.
- ° Pregnancy
- Neurostimulator, medical infusion device, cochlear implant
- °Implanted medical device, pacemaker

What are the side effects?

- Headache, most commonly due to contraction/activation of scalp muscles
- Neck pain, due to contraction of neck muscles, maintaining a fixed neck position during treatment
- Local scalp irritation at application site due to heat (shielded, cooled, rare with device in use)
- ° Manage with ibuprofen

What are potential complications?

- Hearing loss
 - Preventable by use of ear plugs provided at each session for both patient and provider
- Seizure
 - ° Incidence on the order of 1/1000, less than some antidepressants/psychiatric medications
 - Avoid in patients who have epilepsy
 - Encourage sleep hygiene and avoid/reduce caffeine intake
 - Determine and reassess motor threshold weekly to use lowest level of stimulation that results in response
 - Protocol in place to manage an in-treatment seizure incident



Accessibility

- Strive is accepting new patients
- The last treatment cycle was completed last week
- There is now an opening for TMS!
- Only one person will be treated at a time
- Call for a free consultation

Coverage and Payment Options

- Covered by:
 - Medicaid (Buckeye, CareSource)
 - Medicare
 - Tricare
 - Commercial Insurance(Currently Strive does not accept commercial insurance)
- Able to pay with:
 - FSA (up to \$2,000)
 - HSA
- ° Payment plans are also available
 - $\circ\,$ Healthcare financing plan with 0% financing for 14 months through Advance Care
 - ° Self-pay options to pay daily, weekly, pay in full, or spread evenly over 12 months by debit or credit card

Future Directions / Offerings

• Residential TMS: Offer TMS to people living too far away to commute daily for 6 weeks, by providing:

- Local accommodations during the 6 weeks of treatment. Additional 3 weeks if a taper is approved.
- RTA pass and map
- Strive Wellness Hour pass
- A list of activities and events throughout Greater Cleveland
- Available for one person at a time

• Mobile TMS: Offer TMS to people living in nursing homes or residential treatment centers

- Customize a van with a TMS machine inside
- Bring the van to Nursing homes or Residential treatment centers or Military bases or community mental health centers
- One facility at a time.
- Provide a 6–week course of TMS treatments to eligible people who receive prior authorization
- When treatment course complete, offer treatment to another facility



TRANSCRANIAL • MAGNETIC • STIMULATION

How to schedule a TMS consultation

- Call the office at 216-752-9090
- Located at 3435 Lee Rd in Shaker Heights
- Online: strive4today.com
 - Book an appointment
 - Schedule TMS Free consultation
- Just interested in TMS?
 - We have a website for that: striveTMScenter.com
- Have a question? Secure E-mail:
 - drjeff@strive4today.com

