Methods: This double-blind randomized study offers an accelerated protocol dTMS treatment in the span of 10 treatment days. The study examined the efficacy of the dTMS accelerated protocol on suicidality indicators. This treatment was given in three arms, sham, active H1 coil and active H7 coil.

Results: 39 patients were enrolled in the study. 31 patients successfully completed 10 treatment days. Patients receiving active treatment (both H1 and H7) showed superior response (defined as > 50% improvement in depression scale) compared to sham ($p = 0.02$). Additionally, clinically close to significance improvement in suicidality intensity scales was found after 10 days of treatment in active treatment compared to placebo ($p = 0.07$). However, no significant difference was found regarding suicidality type scores. No major differences in depression and suicidality were found comparing H1 and H7 coils.

Discussion: Active suicidality is a major challenge in treating severe mental disorders, and death by suicide is still a leading cause of death among patients. However, most clinical studies in mental health still exclude patients with active suicidality, hence treatment options are limited. In this study we found deep TMS accelerated protocol (H1 and H7 coils) to be both safe and effective in decreasing suicidality intensity and depression symptoms among inpatients with severe mental disorders accompanied by suicidality.

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6

Evaluating the Safety, Feasibility, and Effectiveness of Repetitive Transcranial Magnetic Stimulation in Cancer Survivors With Depression and Anxiety: A Randomized Open-Label Pilot Trial

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Background: Cancer patients with depression and anxiety are more likely to have a long latency of anti-depressant drug action and are at an increased risk for negative drug-drug interactions. A 2018 review showed no benefit of antidepressants over placebo in patients with cancer and depression. (1)

Methods: We conducted a randomized, two-arm, open-label pilot study with twenty cancer survivors with Major Depressive Disorder who had inadequate response to their current anti-depressant treatment. A total of thirty sessions of either 10-Hz (3000 pulses per session) left dorsolateral prefrontal cortex (dLPFC) or 1-Hz right dLPFC TMS treatments were delivered at 120% of the motor threshold.

Results: Eighty three percent of the patients (10/12) reached depression remission (defined as HAMD-24 score < 10) in the right-sided group while in the left-sided group 100% (8/8) reached remission. There was no statistically significant difference between the two groups in time to remission of depression. Ninety one percent (11/12) achieved anxiety scores of < 10 on HAM-A in the right-sided group while the left-sided group had 100% (8/8) patients with scores < 10. Left-sided group achieved scores of < 10 on HAM-A at a faster rate than right-sided treatment ($p < 0.0001$). There were two dropouts in the left-sided group vs no dropouts in the right-sided group. There were no serious adverse reactions in either treatment groups on the UKU-side effect rating scale.

Discussion: Our results suggest that both low-frequency right-sided treatments and high-frequency left-sided treatments were safe, and effective in treating depression and anxiety with minimal side effects in cancer survivors.

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7

The Sensory Experience of TMS on the Scalp and Knee Characterized by Frequency and Location

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Background: While it is well known that discomfort from TMS varies at different locations over the scalp and with different stimulation frequencies, there is a lack of direct comparative data to inform research and clinical decisions. Scalp discomfort is often considered a minor confound or side-effect, even though pain research indicates peripheral sensations can have significant brain and symptom impacts.

Methods: We tested one peripheral location (knee) and six transcranial locations commonly used in research and treatments: random order of parietal cortex (P3), motor cortex, modified Beam F3 prefrontal cortex, THREE-D prefrontal cortex, orbitofrontal cortex (AF8), and medial prefrontal cortex (Fz). For each location, we tested the three most commonly used TMS frequencies in random order: 1Hz, 10 Hz and theta-burst. We conducted sensory testing by increasing the magnetic field strength to the sensory threshold (first perception of sensation), then continuing up to the annoyance threshold, then up further to the troublesome or miserable threshold where testing was stopped.

Results: We completed data collection in 18 adults (mean age 34.7 ± 21.7 years; 12 female). We found a range of tolerability across the factors of frequency and location, with theta-burst in anterior locations (AF8 and THREE-D prefrontal) poorly tolerated and 1Hz elsewhere (knee, Fz, P3) well-tolerated.

Discussion: Research and clinical approaches should consider the impact of scalp sensations on outcomes, and further research can clarify and mitigate discomfort.

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8

Deep TMS for Smoking Cessation: Outcomes From a Phase IV Registry Study of the H4 Coil

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Background: In 2020, Deep Transcranial Magnetic Stimulation (Deep TMS) gained FDA clearance for short-term smoking cessation, demonstrating efficacy comparable to pharmacotherapies with minimal side effects. This Phase IV registry study aimed to assess the real-world feasibility and efficacy of Deep TMS for smoking cessation.

Methods: Patients were prospectively enrolled from 22 clinical sites. TMS was delivered per protocol (H4 Coil, 15 sessions given 5 days per week followed by 3 sessions given 1 day per week,120% resting motor threshold, 10Hz, 60 trains, 15 sec intertrain interval,

1800 pulses). Smoking cue-exposure was given before each treatment. Exhaled carbon monoxide levels and craving levels were evaluated throughout the trial. General linear models with repeated measures were used to quantify changes in smoking and craving over time.

Results: The 68 individuals enrolled smoked an average of one pack daily for 28.5 years, with five prior quit attempts. Thirty-six individuals completed the first 15 sessions per protocol (53%), wherein 49% achieved full smoking cessation (as verified by timeline follow back and exhaled carbon monoxide) ($F = 9.5$, $p = 0.004$). There was also a significant decrease in cigarette craving across the group ($F = 6.2$, $p = 0.02$). The primary motivation of the ITT group and quitters was health concerns. A rebate incentive program increased the quit rate by 10%.

Discussion: Fifteen sessions of Deep TMS was effective for short-term smoking cessation among refractory chronic smokers. Lack of insurance coverage in the United States, however, limits access to this treatment. Addressing this obstacle is crucial to broader adoption of TMS for smoking cessation.

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9

Safety and Efficacy of Deep TMS for Adolescent Depression: A Post-Marketing Surveillance Study

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Background: Adolescent major depressive disorder (MDD) is a prevalent and serious mental health condition. Pharmacological treatments are commonly used but often have poor tolerability and severe side effects, such as suicidal ideation. Deep transcranial magnetic stimulation (TMS) is currently cleared treating MDD in individuals 22-86 years old.

Methods: This post-marketing surveillance study was designed to evaluate the safety and efficacy of using this tool as a treatment for MDD in younger patients. Data were collected from 56 sites, resulting in 1,257 patients that met inclusion criteria (e.g. 11-21 years old, H1 coil, 18Hz or iTBS, treatment-resistant MDD). Outcomes included self-reported (PHQ-9, BDI-II) and clinician-rated scales (HDRS-21, CGI-S, CGI-I). Analyses were completed using continuous change as the endpoint of interest, with response/remission as secondary endpoints.

Results: The treatment was well tolerated, with an adverse event rate comparable to adults. After 30 sessions the response/remission rates were HDRS: 58.3%/ 48.6%, PHQ9:64.4%, 25.5%. After 36 sessions the response/remission rates were HDRS: 75.0%/58.3%, PHQ9:74.6%/34.6%. The outcomes from iTBS (1800 pulses) and 18Hz were not significantly different (Fisher's exact test, $p > 0.05$). There was a significant change in PHQ-9 categorical distribution of depression severity after treatment ($p < 0.0001$, Chi-square test). Anxiety symptoms also improved in the majority of patients, wherein the response/remission rates of anxiety were 66%/40.2% (GAD-7) after 36 sessions.

Discussion: These findings suggest Deep TMS is a promising therapeutic intervention for adolescents with MDD, a vulnerable population with limited treatment options. Most patients experience improvements within 13–20 sessions, though extended treatment may benefit non-responders.

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10

rTMS Paired With Augmented Reality Training to Treat Chronic Neck Pain

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Background: Chronic neck pain (CNP) is a debilitating condition that reduces quality of life and is one of the leading causes of disability globally. We have developed a novel augmented reality sensorimotor training (ARST) task that promotes targeted goal-directed cervical movements. Repetitive transcranial magnetic stimulation (rTMS) has the potential to enhance the beneficial effects of ARST. The objective of this study is to investigate effectiveness of rTMS paired with ARST to reduce pain and improve function.

Methods: Ten participants with CNP took part in either REAL rTMS plus ARST or SHAM rTMS plus ARST for four weeks (3-5 sessions per week). Both groups received the same ARST training which required participants to make goal-directed cervical movements to track moving targets presented virtually. Clinical outcomes included pain intensity, tampa scale of kinesiophobia (TSK), neck disability index (NDI), range of motion (ROM), PROMIS-29 V2.0, and patient perceived global index of change (PGIC).

Results: There was a similar reduction in pain intensity in the REAL (21%) and SHAM (28%) groups immediately following the intervention with greater improvement seen at two-weeks post-intervention in REAL (37%) and not SHAM (24%). There was a clinically meaningful improvement in NDI in both groups at all time points and increases in ROM in all four directions.

Discussion: This is the first study to combine rTMS with augmented reality to treat patients with CNP. The results from this study suggest that rTMS promotes longer-term retention of the gains that are achieved via sensorimotor training.

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