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RESEARCH ARTICLE

A Low-Cost Custom Device to Facilitate Precise Transcranial Magnetic Stimulation

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ABSTRACT: Major Depressive Disorder (MDD) is a disease affecting over 21 million adults annually in the U.S. alone. For individuals who do not respond adequately to antidepressant medication, Transcranial Magnetic Stimulation (TMS) offers a non-invasive and clinically validated alternative. However, the therapeutic efficacy of TMS is highly sensitive to coil placement. Inconsistent coil positioning has been linked to poor treatment outcomes, primarily due to imprecise targeting of the left dorsolateral prefrontal cortex (DLPFC), the brain region implicated in MDD. Current methods present a trade-off between cost and precision. Neuronavigation systems, which offer exceptional targeting accuracy, are expensive, often exceeding $60,000. In contrast, cap-based methods are affordable but lack the required accuracy, leading to suboptimal outcomes. To address this disparity, a novel, patient-specific 3D-printed helmet has been developed to enable reproducible and accurate TMS coil placement. Validation tests show an average deviation of only 2.2 ± 0.68 mm (CPK 1.37), corresponding to a 99.998% targeting success rate. At a material cost of under $10, this solution bridges the gap between affordability and precision, offering a transformative path forward for equitable access to high-quality TMS treatment.

KEYWORDS: Engineering, Biomedical Engineering, Brain Stimulation, Transcranial Magnetic Stimulation, 3D Printing.

Introduction

MDD is a pervasive psychiatric condition characterized by persistent sadness, lack of motivation, and cognitive impairment. Its global impact is profound, as the World Health Organization estimates that by 2030, MDD will become the leading contributor to the global burden of disease.[1] In the United States alone, approximately 8.3% of adults, equating to over 21 million individuals, experience at least one major depressive episode annually.[2]

While antidepressant medications remain the first-line treatment, response rates are discouragingly low. Only 30–40% of patients achieve alleviation of their symptoms following their first course of antidepressants, with 60–70% experiencing inadequate relief.[3] Furthermore, approximately 30% of individuals with MDD go on to develop treatment-resistant depression (TRD), or the failure to respond to at least two different antidepressant trials.[3,4] Under more stringent criteria, this rate may reach as high as 55%.[5] These figures underscore the urgent need for effective, alternative treatments.

TMS, especially repetitive TMS (rTMS), has emerged as a promising, effective treatment option for MDD patients who are suffering from TRD or just unresponsive to traditional antidepressants as a whole.[6] By targeting the DLPFC, which is found to be hypoactive in MDD patients, TMS helps to normalize neural activity and alleviate symptoms through repetitive magnetic stimulation.

However, the clinical efficacy of TMS is dependent on the accurate and consistent placement of the coil over the DLPFC. As a result, small deviations can significantly reduce the induced electric field at the target, potentially rendering the treatment ineffective.[7,8] Additionally, inaccurate coil placement is not only associated with reduced therapeutic benefit but may also introduce safety concerns. Studies have demonstrated that off-target stimulation can inadvertently activate non-target cortical or subcortical regions, potentially leading to side effects such as headaches, scalp discomfort, cognitive disturbance, or induction of hypomania in vulnerable patients.[9,10] In rare cases, imprecise stimulation of motor or sensory areas has been linked to seizure risk and personality changes.[11] These risks emphasize the necessity of precise and repeatable coil positioning as a critical element in safe and effective TMS delivery.

There are two prevalent techniques for targeting the DLPFC: low-cost elastic caps and high-end neuronavigation systems. Elastic caps involve physical marking on the scalp and offer affordability (cost < $10) but suffer from poor targeting precision with an average target deviation of 10.66 mm.[12] Neuronavigation, on the other hand, uses MRI-guided 3D modeling to achieve high accuracy with an average target deviation of 0.3 mm. However, this comes for $60,000, which is financially inaccessible to some clinics.[13,14]

Thus, there is a great need for a device that combines the affordability of the elastic caps with the accuracy of neuronavigation. This project addresses such a need by introducing a customizable, 3D-printed helmet, designed to guide TMS coil placement with high precision of 99.9998% on target and repeatability at an ultra-low cost of less than $10 material cost.

Therefore, this low-cost helmet system may provide a broadly applicable solution that enables precision targeting for a wide range of TMS protocols, facilitating further research and clinical translation across multiple diseases. Future adaptations of this platform could support disease-specific coil positioning, helping optimize neuromodulation therapies well beyond depression.

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Methods

MRI or MRI/CT scans are utilized to map the patient's scalp and brain structures. From these images, the optimal treatment trajectory, defined as the shortest distance between the patient's scalp and the DLPFC, or the planned trajectory, is determined. By using the Creo 9.0 free student version by PTC Inc., a personalized helmet and a coil holder were designed so that they are precisely aligned to the scalp target. The personalized helmet and helmet positioner (Figure 1) were subsequently printed using a 3D printer (Bambu Lab X1C 3D Printer, Bambu Lab, $1149.99) and had an approximate material cost of $7.50.

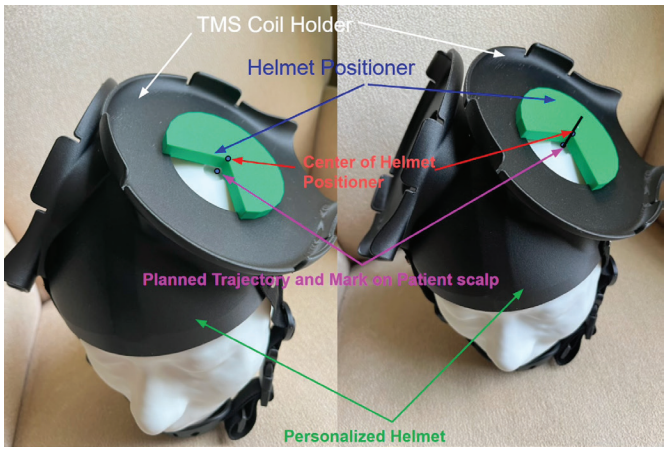


Figure 1: Photograph of a personalized 3D-printed helmet, showing: the TMS coil holder (A), the helmet positioner (B), the helmet positioner's center (C), the planned trajectory and mark on the patient's scalp (D), the personalized helmet (E), and the chinstrap (F).

It is important to note that the TMS coil holder is positioned perpendicular to the planned trajectory to ensure the shortest possible distance between the intended treatment area and the patient's scalp. The helmet positioner is designed to realign the TMS coil holder with the entry point on the scalp, according to the planned trajectory.

To verify the accuracy and repeatability of the personalized helmet, a clinically relevant experiment was designed. Two 30 mm stainless steel (SS) wires were used in the experiment. The first SS wire simulates the planned trajectory, with the distal end representing the planned treatment location. The second SS wire represents the actual treatment trajectory, with the distal end corresponding to the actual treatment location. The distance between the planned and actual treatment locations is defined as the target deviation.

It is important to note that the 30 mm length is derived from clinical studies measuring the distance between the distal end of the DLPFC and the patient's scalp surface, combined with the estimated helmet thickness and coil radius. MRI-based morphometry studies estimate the cortical thickness of the DLPFC to be approximately 2.5–3.5 mm. In comparison, the average scalp-to-cortex distance (SCD) for the left DLPFC typically ranges from 12 mm to 20 mm.[15] The helmet thickness and the estimated coil radius, totaling 6 mm, are also factored in. Therefore, the 30 mm measurement represents the distance from the DLPFC to the center of the coil.

The experimental results show that this novel method of precisely and repeatably targeting TMS treatment achieves an average stimulation target deviation of 2.2 ± 0.68 mm, with a CPK of 1.37. This corresponds to approximately 21 out of one million cases where the intended treatment target would be missed.[16]

As for the assumptions made in the project, it is assumed that:

1. A patient's MRI images accurately represent the physical shape of their skull, scalp, and brain tissue structure.
2. The location of the target treatment region has already been determined by clinicians using current practice with the MRI scan images.
3. A physician may treat the patient from both sides of the brain using up to two TMS coils, with each coil targeting a specific treatment location on one side of the patient's brain.

Procedure:

First, identify the shortest distance between the TMS coil and the intended treatment location before TMS treatment. MRI or MRI/CT scans are used to map the patient's scalp and brain structures (Figure 2). Based on these images, the optimal treatment trajectory, or the shortest path between the TMS coil and the intended target, is identified. The corresponding entry point on the scalp of the optimal treatment trajectory, or the planned trajectory, is then marked. During TMS treatment, this mark is precisely aligned with the center of the helmet positioner to ensure accurate target treatment location (Figure 2).

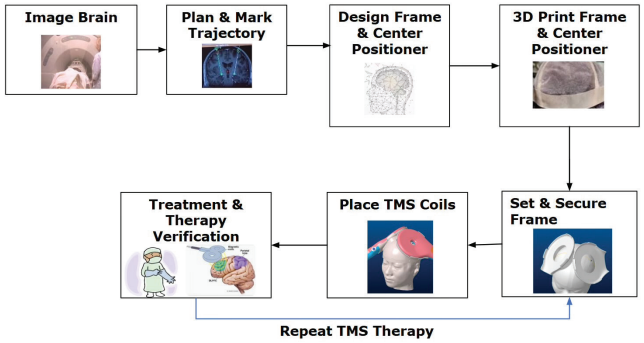


Figure 2: Workflow schematic for personalized helmet-guided TMS: MRI acquisition, scalp/cortex segmentation, and identification of the DLPFC target, as well as calculation of the planned trajectory (top row); CAD-derived helmet with an indexed coil holder mount and helmet positioner for reproducible alignment (bottom row).

Then, the TMS helmet, in which the centers of the TMS coil, the intended treatment location, and the coil holder are all aligned along the planned treatment trajectory, was created. This trajectory is oriented perpendicular to the plane of the TMS coil holder to ensure the shortest possible distance between the intended treatment location and the patient's scalp, as shown in Figure 3. The shortened distance maximizes the electric field strength at the target location produced by the TMS coil, thus minimizing dosage and side effects, which further optimizes clinical outcomes.

Additionally, chinstraps were added to improve the stability of the helmet. As for materials, about 234.53g of PETG-CF

material was used to print the helmet and its supporting structure, which took only 7 hours and 23 minutes to print. The material cost was only about $7.5 ($31.99 per kg). As a result, a more effective cap targeting treatment is created with minimal cost.

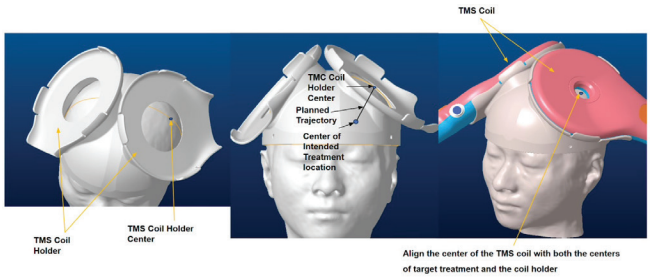
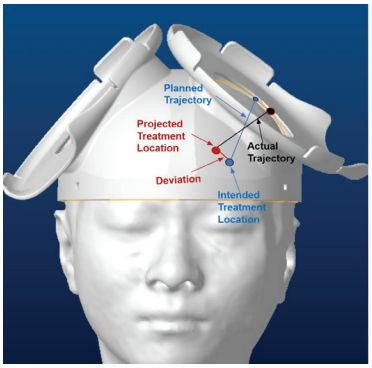


Figure 3: Demonstration of the geometric alignment of the centers of the TMS coil, the TMS coil holder, and the intended treatment location along the planned trajectory.

Then, a helmet positioner was created to ensure the precise and repeatable placement of the TMS coil (Figure 1). For depression treatment, TMS therapy typically involves sessions 5 days per week over a period of 4 to 6 weeks. This requires the personalized helmet to be removed after each session and repositioned for the next treatment. To optimize treatment outcomes for each session, the helmet positioner is used to realign the center of the TMS coil holder with the predefined marker on the patient's head, ensuring consistent precision and repeatability of the TMS coil placement.

A clinically relevant experiment was developed in Figure 4 and demonstrated in Figure 5. By utilizing 30 mm SS needles, the measurement of the deviation between the planned and the actual trajectories was made possible. The experimental results are shown in Table 1. They demonstrate that this novel method of precisely and repeatedly targeting TMS treatment can achieve an average stimulation target deviation of 2.2±0.68 mm (Figure 6).



- **Planned Trajectory: The shortest distance from the intended treatment location to the patient's scalp.**
- **Actual Trajectory: The TMS coil's center on the patient's head toward the projected treatment location.**
- **Deviation: The distance between the intended treatment location and the actual treatment location, determined by the positioning of the TMS coil.**

Figure 4: Illustration of the planned trajectory (blue), the actual trajectory (black), and the deviation (red). The planned trajectory is the shortest distance from the center of the intended treatment location to the patient's scalp. The actual trajectory goes from the center of the TMS coil on the patient's head toward the center of the projected treatment location. The deviation is the distance between the center of the intended treatment location and the center of the projected treatment location, determined by the positioning of the TMS coil.

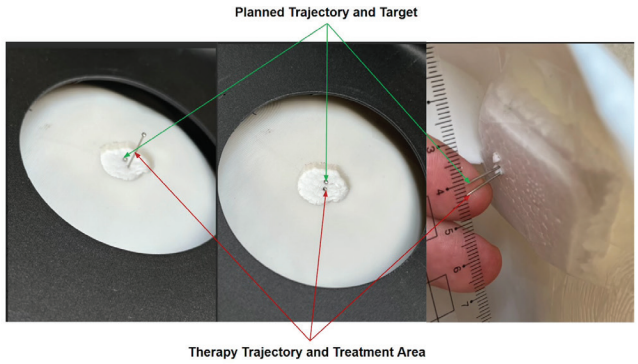


Figure 5: Demonstration of a clinically relevant experiment, measuring the deviation.

Results and Discussion

A helmet with a coil holder and a helmet positioner was developed, as shown in Figure 1. It demonstrated a targeting deviation of only 2.2 mm across 15 independent trials (shown in Table 1), thus representing a near-neuronavigation level of precision. According to industry standard process capability index values, a CPK > 1.33 reflects a six-sigma process, corresponding to fewer than 64 defects per million opportunities.[16] Since this helmet system has a CPK of 1.37, meaning an estimated targeting error of only 21 ppm, it represents a significant increase in accuracy as elastic cap systems exhibit target treatment deviations ranging from 10.66 mm to 42 mm with poor reproducibility of CPK=0.[4]

Table 1: Measurements of the target deviation, ranging from 1mm to 3mm.

Measurement Trial #	Target Deviation t (mm)
1	2
2	2
3	3
4	2
5	2
6	1
7	1
8	2
9	2
10	3
11	2
12	2
13	3
14	3
15	3

In general clinical practice, the acceptable variation in TMS coil placement, particularly when targeting the left dorsolateral prefrontal cortex (DLPFC), is generally within ±5 millimeters.[17] The location precision capability (CPK) of the cap-based TMS treatment method, which has a target deviation of 10.66 ± 11.09 mm, is nearly zero when using a 5 mm upper limit, indicating a high likelihood of missing the intended treatment location.

In contrast, the neuronavigation-based TMS method with a target deviation of 0.3 ± 0.997 mm and the same 5 mm upper limit, achieves location precision capability (CPK) of 1.57, meaning that only about 2 in one million cases would fall outside the acceptable range.

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The novel method described here demonstrates a target deviation of 2.2 ± 0.676 mm. This results in a CPK of 1.37 for the 5mm upper limit, corresponding to approximately 21 out of one million cases that would miss the intended treatment target, shown in Figure 6.

	Cap	3D-Helmet	Neuronavigation
Max Deviation (mm)	42	3	2.2
Min deviation (mm)	0.3	1	0
Ave Deviation (mm)	10.66	2.2	0.3
STDV (mm)	11.09	0.676	0.997
CPK	0	1.37	1.57
PPM (one-side)	N/A	21	2
On Target Rate	N/A	99.998%	99.9998%

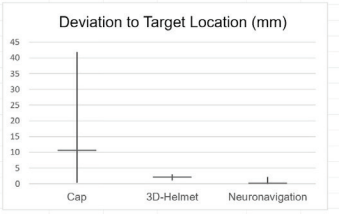

Figure 6: Comparison of different targeting methods, highlighting that the target deviation of the custom 3D-helmet approach is comparable to that of the neuronavigation method and significantly smaller than that of the cap method.

■ Conclusion

This project shows that a low-cost helmet that is customized to each patient's head shape can be made by 3D printing to facilitate the placement of the TMS coil to achieve a precisely targeted treatment location with a CPK of 1.37 (estimated 21 out of 1 million may miss the intended treatment location), compared to cap-targeting with a CPK of 0. Furthermore, placing and re-placing the TMS coil is more efficient with the guidance of the helmet positioner. Ultimately, the device allows for a neuronavigation-like level of precision without the neuronavigation level of cost.

Future Work:

This study demonstrates a low-cost, custom helmet for precise and repeatable TMS coil placement in a head model. Future developments can focus on (1) enhancing compatibility through modular or adjustable coil holders to accommodate multiple TMS systems, (2) optimizing materials by exploring medical-grade polymers (e.g., polyether ether ketone) to improve patient comfort while maintaining target precision and cost efficiency, (3) creating different helmet for other TMS coils such as "8 shaped" coils available on the market, (4) evaluating in real clinical settings to measure the system cost such as fitting and the cost to integrate such helmet into clinical workflow, (5) testing and validating with multiple MRI samples and multiple technicians who are familiar with TMS, and (6) carrying out more rigorous evaluation by adopting the measurement of the electrical field strength at the target.[18]

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