Closed-Loop Neuromodulation for MCS– Patients Using hdEEG, AI, and tFUS

ABSTRACT

Disorders of consciousness (DoC) affect thousands annually, with up to 40% of minimally conscious state minus (MCS–) patients misdiagnosed as vegetative due to limitations of behavioral assessment tools. This paper proposes ARCUS, a closed-loop neuromodulation system integrating high-density electroencephalography (hdEEG), artificial intelligence (SCORE-AI), and transcranial focused ultrasound (tFUS) to detect and stimulate neural markers of consciousness in MCS– patients. hdEEG monitors neural oscillations across 64–256 electrodes while SCORE-AI (88.3% diagnostic accuracy) classifies theta and beta brainwave patterns associated with emerging awareness. When consciousness markers are detected, tFUS delivers millimeter-precision stimulation to deep brain structures non-invasively. A proposed 14-participant, six-month pilot study using the Coma Recovery Scale–Revised (CRS-R) will evaluate the system's effectiveness in promoting consciousness recovery. ARCUS addresses critical gaps in detection accuracy, therapeutic access, and cost burden in DoC care.

KEYWORDS
brain-computer interface, closed-loop neuromodulation, disorders of consciousness, high-density EEG, minimally conscious state, transcranial focused ultrasound

INTRODUCTION

Disorders of consciousness (DoC) are a spectrum of conditions arising after severe brain injury in which a person's ability to experience and respond to the world is significantly impaired (Eapen et al., 2017). These states range from coma and vegetative state to the minimally conscious state (MCS), in which patients demonstrate some signs of awareness such as responding to stimuli (Giacino et al., 2002). Families with patients in this condition face constant uncertainty about whether their loved one will ever meaningfully interact with them again, alongside the overwhelming financial burden of long-term care; diagnostic inaccuracy in DoC is associated with $1.5–2.3 billion annually in potentially avoidable U.S. healthcare spending, and tens of billions globally.

Current diagnostic tools rely heavily on behavioral assessments, which, according to Dr. Joseph Fins, can routinely overlook covert consciousness in patients who are unable to physically communicate (Fins and Shulman, 2024). This is especially true for MCS– patients, who show only non-language-based signs of consciousness, such as eye tracking and localized pain response, and are therefore more frequently misclassified as vegetative (Schnakers et al., 2009). Moreover, there are no widely accepted treatments that directly promote neurological recovery in MCS; only 41 clinical trials focused on MCS between 2008 and 2020 (Produturi et al., 2022).

Existing technologies each address only part of this problem. Standard EEG systems use 19–32 electrodes and lack the spatial resolution to detect neural oscillation patterns associated with covert consciousness (Seeck et al., 2017). Behavioral assessments are subjective, inconsistent, and unable to detect awareness in patients who cannot physically respond. Non-invasive stimulation methods like transcranial magnetic stimulation (TMS) and transcranial direct current stimulation (tDCS) cannot target the deep brain structures, particularly the thalamus, involved in consciousness. Deep brain stimulation (DBS) can reach those structures but requires invasive surgery with significant complication risks (Monti et al., 2016). No existing device combines real-time detection and therapeutic stimulation in a single wearable system.

ARCUS was designed to address every one of these gaps simultaneously. The high-density electroencephalogram (hdEEG) offers a noninvasive yet precise method of assessing brain activity, employing 64–256 electrodes to enable far more accurate detection of neural oscillations (Seeck et al., 2017). The sheer volume of data generated by hdEEG makes manual interpretation exceedingly difficult, so EEG datasets are analyzed using SCORE-AI, an AI model that identifies patterns in neural oscillations signaling emerging consciousness with a documented diagnostic accuracy of 88.3% (Hurley, 2023). Once SCORE-AI identifies where and when to stimulate, transcranial focused ultrasound (tFUS) actively modulates neural circuits involved in consciousness using acoustic energy with millimeter-level precision: a capability not possible with TMS or tDCS, and achievable with DBS only through surgery (Yang et al., 2025). tFUS has also been shown to successfully integrate with brain-computer interfaces (Kosnoff et al., 2024). Together, these three components form a unified closed-loop system capable of detecting, classifying, and responding to markers of residual consciousness in real time.

METHODS

System Architecture

The ARCUS headset integrates hdEEG electrodes and tFUS transducers in a checkerboard pattern modeled after the Utah Array: a honeycomb-inspired electrode design that alternates EEG and tFUS components across the scalp. This arrangement ensures uniform spatial coverage so no region of neural activity goes undetected or unstimulated. By physically separating each electrode from each transducer, the design also prevents electromagnetic interference between detection and stimulation channels, preserving signal integrity in both directions. Electrode placement follows the standard 10–20 EEG coordinate system, using 10% and 20% proportional spacing between cranial landmarks to maintain relative electrode geometry across patients. TFUS transducers are positioned in inter-electrode spaces to maximize spatial coverage while minimizing signal distortion at sensing sites.

The closed-loop system operates as follows: hdEEG continuously monitors neural oscillations; SCORE-AI classifies incoming data; if a threshold is met, indicating an emergence marker, tFUS activates. Parameters, including stimulation intensity, frequency, and target location, adapt over time based on the patient's evolving neural state. SCORE-AI specifically targets increases in theta waves (3–7 Hz), which signal emerging awareness, and beta waves (15–30 Hz), which indicate cognitive processing: oscillatory patterns commonly observed in the thalamus, cerebellum, and prefrontal cortex in MCS patients (Schiff et al., 2014). In the vegetative state, power is concentrated below 1 Hz and the spectrum is largely featureless; in MCS, prominent peaks in the 3–7 Hz and 15–30 Hz ranges emerge: these are the signals ARCUS is trained to detect and reinforce.

A proof-of-concept prototype was developed to demonstrate the closed-loop logic. The prototype uses a checkerboard LED-array cap-like beanie in which pink LEDs represent EEG electrodes (continuous monitoring mode) and purple LEDs represent tFUS transducers (stimulation mode). A Raspberry Pi microcontroller mimics SCORE-AI's decision-making: the user inputs a simulated brainwave frequency, and when that frequency enters the target range, the purple LEDs activate; this makes the process of detection, analysis, and stimulation both visible and interactive.

Comparative Advantage

ARCUS (tFUS) is the only method that is simultaneously non-invasive, capable of deep brain targeting, precise at the millimeter level, and closed-loop. TMS and tDCS are non-invasive but cannot reach deep structures and lack closed-loop capability. DBS achieves deep targeting and precision but is invasive and not closed-loop. No other existing system satisfies all four criteria.

Study Design

A total of fourteen MCS– candidates will participate in the proposed six-month pilot study. Participants will be divided into Cohort A (ARCUS treatment) and Cohort B (standard care control). As participants are unable to personally provide informed consent, a legally authorized medical surrogate must be present for each candidate. Surrogates will review and sign a detailed consent form outlining the study's purpose, procedures, technology used, potential risks and benefits, and available alternatives. Surrogates may withdraw participants at any point. Each participant will undergo a baseline assessment using the Coma Recovery Scale–Revised (CRS-R), the gold standard for consciousness assessment in MCS patients. At the study conclusion, a neuropsychologist will administer a final CRS-R to each participant for comparison.

RESULTS AND DISCUSSION

As ARCUS is currently in the proposal and prototype development stage, empirical clinical results are not yet available. The following presents anticipated outcomes grounded in existing literature alongside key ethical considerations.

The primary anticipated outcome is that Cohort A (ARCUS treatment) will demonstrate significantly greater improvement in CRS-R scores than Cohort B (standard care) over six months. This hypothesis is supported by the established literature: tFUS has been shown to successfully stimulate thalamic structures non-invasively in patients with disorders of consciousness (Monti et al., 2016), and SCORE-AI has demonstrated expert-level diagnostic accuracy in interpreting EEG data (Hurley, 2023). The integration of 24/7 continuous neural monitoring with responsive stimulation in a closed-loop architecture offers a therapeutic window that current single-modality approaches cannot provide; existing clinical assessments are periodic and therefore miss transient neural activity that may represent critical recovery windows.

From a quality-of-life standpoint, more accurate detection enables earlier recognition of preserved cognition, better-targeted therapeutic interventions, and personalized treatment based on each patient's unique brainwave data. Families would gain concrete, objective evidence of recovery progress rather than relying on subjective behavioral observation. From an economic standpoint, earlier and more accurate diagnosis could reduce prolonged institutional care by 10–20%, saving hundreds of millions of dollars annually in the U.S. alone. The non-invasive design eliminates the costs associated with surgical procedures like DBS, and the scalable technology lowers long-term cost barriers across healthcare systems.

Several ethical concerns must be addressed. Informed consent is the most significant: patients cannot consent, and 74% of researchers cite this as the primary ethical challenge in brain stimulation trials (Muñoz et al., 2020). The "black-box" nature of SCORE-AI makes it difficult to explain why stimulation is triggered at any given moment, raising clinical accountability questions. The long-term effects of repeated tFUS stimulation remain under investigation (Lee et al., 2021). Additionally, access to resource-intensive closed-loop neuromodulation systems risks being unevenly distributed across healthcare settings, potentially deepening existing disparities. Mitigation strategies include surrogate consent protocols, investment in AI interpretability, ongoing safety monitoring, and open-sourcing the AI model to reduce cost barriers and promote health equity.

Regulatory next steps would involve FDA medical device submission. Given that ARCUS represents a novel device class combining EEG diagnostics and neuromodulation without a clear predicate device, a De Novo submission pathway is most applicable, as it is designed for lower-risk devices with no prior classification. Future directions include a full pilot clinical trial in ICU/rehabilitation settings, expansion of the SCORE-AI training dataset for broader consciousness classification, and development of a miniaturized wearable version for home-based monitoring.

CONCLUSIONS

ARCUS represents a novel, integrated approach to one of the most diagnostically and therapeutically underserved conditions in modern medicine. By combining hdEEG's detection resolution, SCORE-AI's classification accuracy, and tFUS's non-invasive deep-brain stimulation capability in a continuous closed-loop system, ARCUS has the potential to reduce misdiagnosis rates, actively promote neurological recovery, and lower the enormous human and economic cost of disorders of consciousness. If the proposed pilot study demonstrates that Cohort A significantly outperforms Cohort B on CRS-R improvement, this would provide meaningful proof-of-concept evidence supporting further clinical investigation and eventual deployment. This work represents a step toward a future where disorders of consciousness are met not with passive observation, but with active, intelligent, and personalized therapeutic intervention.

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