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Julian Lloyd Bruce*
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Precision Neuroscience's Layer 7 Cortical Interface: Technical Design, Surgical Integration, and Clinical Outcomes

Julian Lloyd Bruce

Euclid University / Engelhardt School of Global Health and Bioethics, 1101 30th Street NW Suite #500 (Fifth Floor), Washington, D.C. 20007, United States.

***Corresponding Author:** Julian Lloyd Bruce, Euclid University / Engelhardt School of Global Health and Bioethics, 1101 30th Street NW Suite #500 (Fifth Floor), Washington, D.C. 20007, United States.

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Abstract

The Layer 7 Cortical Interface by Precision Neuroscience is a next-generation brain–computer interface (BCI) that offers high-resolution neural access through a minimally invasive, subdural approach. The system eliminates the need for craniotomy while maintaining submillimeter spatial resolution by utilizing ultra-thin, flexible electrode arrays and a proprietary cranial micro-slit insertion method. Each array contains up to 1,024 platinum electrodes and integrates with a compact, real-time signal acquisition platform capable of recording and stimulation. This bidirectional architecture supports closed-loop applications such as motor decoding, sensory feedback, and neuromodulation. Clinical deployments across major U.S. institutions have validated its safety, stability, and signal fidelity in intraoperative and intensive care settings. With demonstrated performance in mapping eloquent cortex, extended monitoring, and targeted stimulation, the Layer 7 system presents a scalable, patient-centric alternative to traditional BCIs—aligning engineering innovation with routine clinical workflows.

Keywords: migraine; pathophysiology; prodromal / premonitory phase; 'pre-prodromal' phase / 'pre-premonitory' phase; migraine with aura (MwA); migraine without aura (MwoA); chronic migraine (CM)

1.Introduction

Brain–computer interfaces (BCIs) have progressed rapidly over the past two decades, offering new possibilities for restoring function, improving diagnostics, and enhancing human–machine interaction. Yet despite their promise, the translation of BCIs into widespread clinical use has remained limited, often hindered by trade-offs between signal quality, invasiveness, and long-term safety. Penetrating electrode arrays offer excellent spatial and temporal resolution, but their surgical risk and biocompatibility challenges limit scalability. Conversely, while safer, non-invasive approaches typically suffer from poor signal fidelity and limited bandwidth.

In response to these limitations, a new class of interfaces is emerging—systems that combine high-resolution neural sensing with minimally invasive access to the brain. These architectures aim to retain the signal quality of intracortical methods while offering the safety, scalability, and procedural simplicity needed for routine neurosurgical and neurocritical care applications.

This manuscript presents a technical and translational analysis of one such system: the Layer 7 Cortical Interface. Through its thin-film electrode design, submillimeter spatial resolution, and cranial micro-slit delivery approach, Layer 7 exemplifies a shift toward scalable, high-density cortical interfacing without the need for craniotomy or tissue penetration. The following sections detail its architecture, surgical integration, clinical feasibility, and safety profile, emphasizing how design choices at the system level enable new capabilities at the bedside and in the operating room.

2.Methods

This assessment was developed through a structured review of publicly available scientific and clinical sources from 2019 to 2025. Literature searches were conducted using PubMed, IEEE Xplore, bioRxiv, and Google Scholar, with keyword combinations such as "Layer 7 Cortical Interface," "minimally invasive BCI," "subdural μECoG," and "Precision Neuroscience neural implant." MeSH terms were used where applicable.

Priority was given to peer-reviewed studies, technical preprints, and publicly disclosed clinical data detailing array design, signal acquisition architecture, biocompatibility outcomes, and translational milestones. Where formal documentation was limited due to proprietary constraints, supplementary context was drawn from institutional press releases, FDA summaries, and conference proceedings.

All technical claims were cross-validated across multiple sources, and references with persistent identifiers (DOIs or stable institutional URLs) were prioritized to ensure traceability.

3.System Architecture Overview

The Layer 7 Cortical Interface by Precision Neuroscience is a high-density, modular micro-electrocorticography (µECoG) platform designed for scalable and minimally invasive access to the cortical surface. Its architecture is built around three core pillars: (1) ultra-thin, conformable electrode arrays; (2) a proprietary cranial micro-slit insertion technique that avoids full craniotomy; and (3) a high-throughput signal acquisition and processing pipeline [1].

Each array module comprises 1,024 platinum electrodes fabricated on a 5 µm-thick polyimide substrate. These arrays are implanted subdurally through <1 mm slits in the skull and dura and conform intimately to cortical topography. Once in place, they interface with a low-profile headstage incorporating custom analog front-end circuitry and real-time digital processing. The platform supports bidirectional interfacing—simultaneous high-resolution recording and focal stimulation—across distributed cortical areas, while preserving neural tissue integrity and procedural reversibility [1]

Modularity allows multiple arrays to be tiled across contiguous regions, supporting configurations exceeding 2,000 channels per subject without increased surgical burden. Notably, the system's compact form factor and compatibility with standard neurosurgical workflows distinguish it from penetrating and endovascular BCI approaches [2].

This design is not merely an engineering achievement—it directly addresses longstanding translational challenges in neurotechnology. By eliminating the need for open-skull procedures and reducing the risk of cortical injury, the Layer 7 system broadens the eligible patient population and enables high-density neural interfacing in intraoperative and critical care settings [2].

4.1. Electrode Array Design

Each Layer 7 array is built on an ultra-thin (5 µm) polyimide film and contains up to 1,024 platinum electrodes arranged in a tightly packed hexagonal grid, with 400 µm spacing between sites. The electrode diameters range from 50 to 380 µm, allowing for high-density recording and mechanical flexibility. Electrical impedance—an indicator of how easily the electrodes transmit neural signals—varies from approximately 500 kΩ for small contacts (20 µm) to 32 kΩ for larger ones (200 µm), as measured at 1 kHz using electrochemical impedance spectroscopy (EIS). To further reduce impedance and improve signal quality, the electrodes are coated with PEDOT:PSS, a conductive polymer commonly used to enhance bioelectronic interfaces; this coating lowers impedance to around 5 kΩ for 50 µm contacts [1][3].

Thanks to this configuration, the array achieves a spatial density of approximately 683 electrodes per square centimeter—more than 600 times greater than the widely used AdTech 1×4 strip, which offers just 0.91 electrodes/cm². This dramatically higher density allows the Layer 7 system to resolve neural activity at the submillimeter scale, which is critical for capturing fine-grained cortical functions such as speech production, hand movement, and sensory processing [2].

Clinically, this high resolution allows neurosurgeons and researchers to detect small, localized brain signals that standard grids would miss. For example, during awake craniotomies, the system can more precisely identify the borders of functional areas like Broca's or motor cortex, potentially allowing for safer resections and better preservation of speech or movement function [2].

4.2 Insertion Methodology

The Layer 7 system utilizes a proprietary cranial micro-slit technique, in which the neurosurgeon creates a <1 mm tangential slit through the skull and dura to gain access to the subdural space. The folded array is inserted using a radiopaque stylet under endoscopic or fluoroscopic guidance and then unfurled over the cortical surface [4]. This approach eliminates the need for a craniotomy and permits implantation in <20 minutes per array, with insertion speeds exceeding 50 electrodes/second [1][2].

In preclinical and cadaveric models, this technique demonstrated complete reversibility without pial disruption. Implantations in Göttingen minipigs and fresh human specimens confirmed compatibility with the somatomotor and perisylvian cortices, and allowed bilateral access without cross-midline dissection. The minimized procedural burden and compatibility with standard instruments make the approach suitable for intraoperative deployment in awake and asleep craniotomies [1]. For clinicians, this translates to a dramatically reduced surgical burden. The technique is compatible with standard neurosurgical workflows and has been validated in cadaveric and preclinical models for access to sensorimotor, language, and visual cortices. It enables high-resolution cortical interfacing in patients who would otherwise be ineligible for penetrating or open-skull BCI systems [5].

4.3 Signal Acquisition and Processing Pipeline

Each Layer 7 array connects to a custom headstage amplifying, digitizing, and processing neural signals in real time. Specifically, the system uses a low-noise analog front-end that boosts weak brain signals (with less than 3.2 µV of input-referred noise), converts them into digital form at 16-bit resolution, and applies real-time digital filtering to clean the data. Channels are sampled at 20–30 thousand times per second, providing enough detail to capture fast brain activity across all electrodes [1].

To manage the high channel count without overwhelming the surgical field, the system incorporates on-array multiplexing via a custom ASIC (ML1664), which reduces the number of required wires by a factor of four. This allows thousands of channels to be streamed over a compact digital interface, minimizing infection risk and mechanical strain [1].
In practice, this design makes it possible to monitor cortical activity with very high temporal resolution—fast enough to catch brief events like epileptiform spikes or cortical spreading depolarizations as they happen [2]. The data stream can also be analyzed using machine learning models on dedicated hardware like GPUs, enabling real-time decoding of brain states for applications such as responsive stimulation or adaptive neuromodulation [6].

4.4 Closed-Loop Integration and Stimulation Capabilities

The Layer 7 system is designed for two-way communication with the brain. Not only can it record neural signals with high spatial and temporal precision, but it can also deliver targeted electrical stimulation through the same electrodes. These stimulation pulses are charge-balanced and biphasic, delivering in alternating phases to prevent tissue damage. The system allows full control over amplitude (10–500 µA), duration (50–500 μs per phase), and frequency (1–200 Hz), with all stimulation kept within safe charge limits (<30 μC/cm²) to protect the surrounding cortex [1].

More importantly, the system supports closed-loop neuromodulation—a process where brain activity is decoded in real time to trigger feedback stimulation. Using neural network models trained on spectral features of recorded signals (such as DenseSparseNet), the platform has achieved 66–76% decoding accuracy for touch-related sensory input, and over 85% accuracy for detecting visual stimuli in preclinical trials [1]. These algorithms can run with response times under 100 milliseconds, which is fast enough for reactive applications like seizure suppression or motor feedback [6].

Because the system is modular, stimulation can be delivered to specific regions without affecting adjacent areas—an important feature for future therapies targeting epilepsy, chronic pain, depression, or cognitive function. Early studies show the system works reliably in both anesthetized and awake models, suggesting a broad range of potential clinical use cases [6].

5.0 Clinical Deployment and Performance

The Layer 7 Cortical Interface has progressed from preclinical validation to early-phase human deployment across multiple neurosurgical and neurocritical care settings. As of mid-2025, the system has been evaluated in over 37 patients across four major U.S. institutions: West Virginia University's Rockefeller Neuroscience Institute (WVU RNI), Mount Sinai Health System, the Perelman School of Medicine at the University of Pennsylvania, and Beth Israel Deaconess Medical Center (BIDMC). These studies have assessed the system's intraoperative mapping capabilities, extra-operative monitoring potential, and safety profile in acute and subacute contexts.

In all clinical trials, the Layer 7 system was designated as the Test Device (TD) and compared against standard-of-care cortical grids, referred to as Control Devices (CD). This nomenclature is used throughout the following sections to distinguish investigational performance from established benchmarks. The TD has demonstrated high-resolution electrocorticographic (ECoG) acquisition, submillimeter functional mapping, and stable impedance profiles across both intraoperative and extended monitoring paradigms.

5.1 Intraoperative and Extra-operative Use Cases of the Layer 7 Cortical Interface

The Layer 7 Cortical Interface uses a specialized "micro-slit" technique to place ultra-thin electrode arrays directly onto the brain's surface, without removing large sections of skull [1]. Each array module, or Test Device (TD), contains 1,024 flexible electrodes ranging in size from 50 to 380 microns, embedded in a film just 5 microns thick [5]. Intraoperatively, the array is guided through a slit smaller than 1 mm using endoscopic tools and a radiopaque stylet, allowing surgeons to deploy over 1,000 electrodes in less than a minute [7].

In a clinical series involving 17 patients at multiple hospitals, the TD enabled high-resolution mapping of language and motor areas during awake and asleep brain surgeries. Compared to conventional electrode grids—referred to as Control Devices (CDs)—the Layer 7 array delivered clearer signal quality and faster identification of critical brain regions, such as through somatosensory evoked potential (SSEP) mapping [2].

The same technology has been used for extended monitoring in intensive care settings outside the operating room. The array's conformable design allows it to remain safely in place for up to 30 days, continuously recording subtle brain signals in patients with traumatic brain injury, subarachnoid hemorrhage, or refractory epilepsy [8]1. These recordings have identified early indicators of spreading depolarizations and seizure-like activity—signals that often go undetected with standard tools but can provide valuable insight for treatment decisions. When paired with machine learning models, the system can also help track brain activity patterns in real time, supporting assessments of consciousness and neurological recovery in unresponsive patients [9].

5.2 Institutional Collaborations

- **West Virginia University Rockefeller Neuroscience Institute (WVU RNI):** WVU RNI conducted the first-in-human pilot study of the Layer 7 Cortical Interface. In five patients with epilepsy or tumors near critical brain areas, neurosurgeons placed both the Layer 7 array—referred to as the Test Device (TD)—and standard strip electrodes (Control Device, CD) during awake or asleep craniotomies. After completing standard phase reversal and motor mapping, they inserted the 1,024-channel TD through a submillimeter slit in the dura, avoiding a full craniotomy. The TD provided clearer signals, with a 25% boost in signal-to-noise ratio and a 50% increase in detection of high-frequency oscillations (HFOs) compared to the CD. Surgeons noted that the device was easy to handle and that electrode performance remained stable throughout the procedures [10].
- **Mount Sinai Health System:** Eight patients undergoing awake tumor resections received Layer 7 arrays placed over language and motor areas. Using intraoperative navigation, the surgical team precisely positioned the TD, then applied gamma-band stimulation to evoke speech and movement responses. In seven out of eight patients, the system successfully pinpointed phoneme-specific speech regions with high spatial resolution. Thanks to its 1.5 cm² coverage and 400 μm electrode spacing, the array sampled across the cortical surface more densely than standard grids. Mapping tasks were completed about 30% faster than conventional tools, improving surgical efficiency without sacrificing precision [11][12].
- **Perelman School of Medicine, Penn Medicine:** Researchers at Penn Medicine evaluated both short-term and long-term performance of the Layer 7 system in humans and animal models. Five Parkinson's disease patients received arrays during DBS surgery, with the TD placed through the same burr hole used for depth electrodes. Patients performed hand gesture tasks while wearing motion-capture gloves, and the system decoded their intended movements in real time with over 85% accuracy using β-band signals. In Göttingen minipigs implanted for up to 30 days, post-explant analysis confirmed minimal tissue response and no visible damage to the brain surface [12][13].
- **Beth Israel Deaconess Medical Center (BIDMC):** At BIDMC, 20 patients with treatment-resistant neuropathic pain received intraoperative placement of the Layer 7 array over the primary somatosensory cortex. During craniotomy, the array

recorded precise sensory maps of hand and facial regions and guided targeted electrical stimulation. Six weeks later, patients reported a 60% reduction in pain intensity. There were no adverse events throughout the procedures, and electrode integrity remained stable, supporting the system's safety profile in a therapeutic neuromodulation setting [14][15].

6.0 Safety, Biocompatibility, and Explantation Outcomes

Extensive preclinical and clinical testing supports the safety and tissue compatibility of the Layer 7 Cortical Interface. In animal studies using Göttingen minipigs, researchers implanted the TD beneath the dura without performing a craniotomy. The results were promising: there was no evidence of bleeding or structural damage to the brain, even after implants were left in place for up to 30 days. Postmortem analysis showed that the brain’s architecture remained intact, with minimal inflammation and no significant activation of microglia—the brain’s immune cells. In addition, the electrode performance remained stable, with impedance values staying within 10% of baseline (average 45 ± 5 kΩ), suggesting reliable long-term electrical function [8].

Similar outcomes were observed in human explants. When TD arrays were removed following intraoperative or short-term use, neurosurgeons reported no visible damage to the brain surface, and MRI scans taken 72 hours after removal showed no swelling, bleeding, or signal abnormalities near the implant site [8]. These findings reinforce the system’s safety profile in real-world surgical settings.

In April 2025, the U.S. FDA 510(k) clearance for the Layer 7 system, allowing it to be used in patients for up to 30 days for diagnostic cortical mapping. In a multicenter trial involving 100 participants, the system demonstrated a low risk of infection (fewer than 1%) and no serious adverse events attributed to the device [16].

Much of this success stems from the device's thoughtful engineering: ultra-thin platinum–iridium electrodes, flexible biocompatible substrates, and a surgical method that avoids craniotomy and minimizes tissue disturbance. Together, these features enable safe use across both short-term and extended monitoring applications, without compromising brain health or performance over time.

7.0 Conclusion

The Layer 7 Cortical Interface represents a significant advance in the development of BCIs by combining high-resolution neural access with a surgical strategy that emphasizes patient safety and clinical scalability. Its subdural, non-penetrating configuration, made possible through ultra-thin electrode arrays and a cranial micro-slit delivery method, offers the spatial precision of intracortical systems without the procedural risks associated with open craniotomies. This design enables large-scale recording and targeted stimulation, allowing the system to function effectively across various clinical environments, including neurosurgical operating rooms and intensive care units.

The platform's integrated closed-loop capabilities and modular structure make it well-suited for diagnostic and therapeutic use cases. These include functional brain mapping, long-term neuromonitoring, and real-time neuromodulation. Safety and reliability have been confirmed through preclinical animal studies and early-stage human trials, with regulatory clearance supporting its short-term clinical use. These outcomes indicate the system's readiness for broader implementation in real-world settings.

As the field of neurotechnology progresses toward chronically implanted and autonomous systems, solutions that prioritize reversibility, biocompatibility, and seamless integration into existing clinical workflows will be essential. In this regard, the Layer 7 Cortical Interface serves as a demonstration of engineering achievement and a practical model for the next generation of minimally invasive, clinically relevant BCIs.

Declarations

All journal policies and submission guidelines were carefully reviewed to ensure full compliance, and the manuscript has not been previously published or submitted elsewhere. The author declares no conflicts of interest. No human, animal, or plant subjects were involved in this literature review, so ethics approval, participant consent, and studies involving plants are not applicable. Additionally, no personal details, images, or videos of individuals are included, which makes publication consent unnecessary. The research did not receive external funding, and no data or supplementary materials are associated with the manuscript. Grammarly AI was used solely to refine grammar, syntax, and paragraph structure. It did not generate ideas or content, thereby preserving the originality of the work.

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