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FIRST-GENERATION BRAIN–COMPUTER INTERFACES: A NARRA-TIVE REVIEW OF CLINICAL TRANSLATION, COMPARATIVE SAFE-TY, AND NEURO-RIGHTS

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ABSTRACT

Objectives. This narrative review examines first-generation brain-computer interfaces (BCIs) across three domains: clinical translation in amyotrophic lateral sclerosis (ALS), locked-in syn-drome (LIS), tetraplegia, spinal cord injury (SCI), pharmacoresistant epilepsy and movement dis-orders; comparative safety covering neurological, infectious, technical and cybersecurity risks; and the emerging neuro-rights regulatory debate.
Methods. Literature was retrieved from PubMed/MEDLINE, Scopus, Web of Science, IEEE Xplore and legal-academic databases, covering peer-reviewed clinical trials, systematic reviews, safety datasets, technical analyses and bioethics scholarship through 2026.
Key Findings. The BrainGate dataset (14 adults, 12,203 implant-days) reported 68 device-related adverse events and six serious adverse events, with no intracranial infections, explantations or at-tributable deaths. The endovascular SWITCH trial found zero serious adverse events at 12 months. Safety risk follows access route and implant chronicity rather than a simple invasive/non-invasive binary. Closed-loop neurostimulation reduces seizure frequency by 60-65% in pharmacoresistant epilepsy; adaptive deep brain stimulation is the most mature movement-disorder application. The neuro-rights literature converges on mental privacy, integrity, autonomy and cognitive liberty as core protected interests.
Conclusions. Responsible BCI deployment requires matching the least invasive platform to the indication, consent specific to device capabilities, cybersecurity treated as patient safety, and pro-spective neural-data governance built into device design.

KEYWORDS

Brain-Computer Interface; BrainGate; Closed-Loop Stimulation; Clinical Translation; Neuro-Rights; Neu-Roethics

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1. Introduction

A brain-computer interface (BCI) is, in the operational sense established by Wolpaw and colleagues, a system that translates neural signals into artificial outputs and requires the central nervous system to control those signals with a reliability and accuracy comparable to its control of spinal motoneurons (Wolpaw et al., 2020). Two consequences of this definition shape every clinical question that follows. First, the choice of recording or stimulation modality (scalp electroencephalography, electrocorticography, intracortical microelectrode arrays, or endovascular sensors) is treated as an empirical question rather than a fixed theoretical commitment. Second, the brain-device interaction is genuinely bidirectional: even output-only systems involve an internal adaptation loop in which the device itself is shaped over time alongside the user (Wolpaw et al., 2020).

Alongside this clinical agenda runs a second, increasingly visible problem: how the data captured by these devices, and the modulatory capacity that some of them possess, should be governed. Burwell et al. (2017) concluded that BCI use raises various ethical, social, and legal challenges that merit further examination and discussion, and more recent work emphasises privacy risks from bidirectional devices and the absence of settled standards for protecting fundamental rights at the neural-data layer (Blasi Casagran, 2025; Cornejo, 2024; González Barrera & Covarrubias, 2025; Kellmeyer, 2022). Existing reviews have tended to address clinical translation, comparative safety, and neuro-rights in isolation, which limits the ability of clinicians, policymakers and engineers to appreciate the full range of considerations relevant to responsible deployment.

The present narrative review aims to address this gap by synthesising evidence across three interconnected domains: (1) the clinical translation of first-generation BCI platforms across communication, motor, epilepsy and movement-disorder indications; (2) the comparative safety profile of non-invasive, partially invasive and fully invasive systems, including technical failures and cybersecurity; and (3) the

conceptual foundations and emerging international regulatory frameworks for neuro-rights, along with concrete clinical recommendations. By addressing these strands within a unified analytical frame, the review aims to provide actionable insights for researchers, clinicians evaluating BCI tools, and policymakers developing governance standards for neurotechnology.

2. Methodology

2.1. Rationale for a Narrative Review Approach

A narrative review methodology was selected because the research questions of this study span heterogeneous bodies of literature. The corpus integrates clinical feasibility trials of implanted BCIs, technical analyses of electrode failure and cybersecurity, regulatory documents, normative neuroethics scholarship, and conceptual work on neuro-rights. Unlike systematic reviews, which are optimised for narrowly defined questions amenable to formal quantitative synthesis, narrative reviews allow the integration of conceptually distinct literatures, identification of patterns and tensions across disciplines, and development of interpretive frameworks that go beyond individual study designs. Methodological transparency was pursued by adhering to principles of clarity of objectives, justification of literature selection, and explicit treatment of uncertainty in conclusions.

2.2. Literature Search Strategy

Sources comprised peer-reviewed reviews, systematic reviews, original pilot and feasibility trials, regulatory documents and ethics scholarship, and one preprint where it provided unique evidence on closed-loop intracranial stimulation. The corpus was assembled iteratively across the topical domains of the review: pathophysiology of brain-device interaction, taxonomy of platforms, ALS and locked-in syndrome, spinal cord injury and tetraplegia, epilepsy and movement disorders, neurological and infectious safety, technical failures and cybersecurity, neuro-rights and international regulation, and clinical-bioethical recommendations. Searches drew on PubMed/MEDLINE, Scopus, Web of Science, IEEE Xplore and IEEE Engineering in Medicine and Biology Society proceedings for clinical and engineering literature, and on legal-academic databases for the neuro-rights and regulatory components. Where the evidence base is small, as in the case of fully implanted endovascular BCIs, individual studies are reported by name; where it is larger and more heterogeneous, as in the neuro-rights legal literature, the synthesis groups conceptual positions rather than enumerating each source.

Inclusion criteria comprised: (a) peer-reviewed journal articles, conference papers and authoritative regulatory or guideline documents; (b) English-language publications, with the addition of one Spanish-language European policy paper available in a bilingual edition; and (c) studies addressing first-generation BCI clinical translation, BCI safety, BCI cybersecurity, or neuro-rights and BCI ethics. Exclusion criteria comprised: (a) speculative or futurist work on second-generation cognitive enhancement or non-clinical consumer neurotechnology; (b) conference abstracts without full peer-reviewed publication; and (c) editorials and commentaries lacking substantive empirical or conceptual content.

2.3. Methodological Limitations

Several limitations inherent to the narrative review methodology should be acknowledged. First, narrative reviews do not involve formal risk-of-bias assessment of individual studies and therefore cannot provide the grading of evidence characteristic of systematic reviews. Second, although a broad and structured search was conducted, the selection of included studies inevitably reflects author judgement and may be subject to selection bias. Third, the rapid pace of development in BCI and neuro-rights research means that any review represents a time-bounded snapshot, and ongoing clinical trials, regulatory consultations and constitutional reforms may yield findings that modify current conclusions. Fourth, much of the strongest human safety evidence comes from a single trial platform (BrainGate), which limits how readily its conclusions can be generalised to alternative invasive BCI architectures.

Results

The results are presented across five thematic domains: the conceptual and biological foundations of BCI platforms, clinical translation by indication, comparative safety, the neuro-rights regulatory landscape, and indication-specific ethical and clinical recommendations.

3. Pathophysiology and Taxonomy of First-Generation BCI Platforms: Conceptual Foundations

3.1. Neurobiological Mechanisms of Brain-Device Interaction

The dominant conceptual frame in the technical literature is not a simple wire connecting brain to computer, but rather a co-adaptive biological interface. Wolpaw et al. (2020) describe a system in which the central nervous system and the device adapt to each other on overlapping timescales, with the requirement that the user maintain near-motoneuron-grade reliability over the encoded signal. This framing has direct clinical relevance because it predicts that the binding constraints on chronic performance will be biological in nature rather than purely electronic.

Empirically, the failure modes that recur throughout the implant literature involve interface biology and tissue mechanics. Translational reviews repeatedly identify signal loss from gliosis or micromotion as a central problem (Serruya, 2014) and categorise long-term reliability issues under broader abiotic and biotic failure modes (Serruya, 2014; Shen et al., 2023). A first-generation review adds that current systems often rely on gross electrical stimulation using empirically derived parameters, operating through incompletely understood open-loop mechanisms (Lega et al., 2011), which reflects how much of the relevant neurobiology remains to be characterised.

Two practical consequences follow from this. First, decoding accuracy and stimulation efficacy at month one are not reliable predictors of performance at year three: chronic interface stability is its own outcome, and one that surgical safety alone cannot guarantee. Second, because the mechanism-of-action gap is most acute for stimulation-based platforms, the regulatory and ethical implications differ between read-only and bidirectional systems even when the surgical access route is comparable.

3.2. The Three Platform Families: A Surgical Taxonomy

Table 1. Comparison of first-generation BCI platform families by signal source, spatial resolution, surgical risk and representative clinical examples. Developed using Claude 4.6 Sonnet by Anthropic.

Platform	Signal source	Spatial resolution	Surgical risk	Key examples
Non-invasive EEG	Scalp electrodes	Low	None	P300 speller, SSVEP
ECoG (partial)	Cortical surface	Medium-high	Low (craniotomy)	BCI2000, ECoG grids
Intracortical	Utah / Michigan array	Very high	Moderate-high	BrainGate
Endovascular	Intravascular sensor	Medium	Low-moderate	Stentrode (SWITCH)
Implanted DBS	Deep nuclei	Targeted	Moderate	Medtronic Percept

The first-generation BCI stack is most usefully divided into three platform families along the surgical axis. Non-invasive systems use scalp EEG and related signals; Wolpaw et al. (2020) position these as the lowest-risk option, noting the well-established tradeoff of lower spatial resolution and information-transfer rate compared with implanted systems (Lu et al., 2012; Wolpaw et al., 2020). Partially invasive platforms record from or near the cortical surface, predominantly via electrocorticography (ECoG). They occupy a middle ground between scalp EEG and penetrating arrays, offering better signal quality than scalp recording but less surgical burden than intracortical implants, with most published work focused on motor and communication decoding rather than formal taxonomic classification (Lu et al., 2012; Shen et al., 2023). Fully invasive systems comprise the classic intracortical microelectrode arrays and DBS platforms. Reviews of this group describe systems that rely on relatively non-specific, empirically tuned stimulation parameters and open-loop mechanisms whose pharmacology and circuit-level effects remain underspecified, and they consistently identify gliosis, micromotion and long-term interface stability as the dominant biological bottlenecks (Holt et al., 2023; Lega et al., 2011; Serruya, 2014; Shen et al., 2023). BrainGate is the most prominent human exemplar of the intracortical class, using chronically implanted microelectrode arrays in motor cortex to decode intended movement for cursor control, typing and assistive-device use (Pandarinath et al., 2017; Rubin & Hochberg, 2023).

3.3. A Functional Taxonomy and Translational Status

A second, functional taxonomy cuts across the surgical axis. Signal-extraction BCIs decode user intent for motor or communication control; signal-insertion BCIs deliver patterned stimulation to restore sensory function; and open-loop stimulation systems such as classical DBS modulate circuits without decoding user intent (Lega et al., 2011; Wolpaw et al., 2020). This functional division helps explain why the field recognises cochlear implants and DBS as the only first-generation systems with broadly accepted clinical success, while most implanted decoding BCIs remain at the pilot or feasibility stage (Rubin & Hochberg, 2023; Serruya, 2014; Shen et al., 2023).

4. Clinical Translation by Indication

4.1. BCI in Amyotrophic Lateral Sclerosis and Locked-in Syndrome

In ALS, the best-supported first-generation use case is augmentative communication rather than disease modification. A P300-based system was tested in twenty ALS patients with high reported usability (Guy et al., 2018); a longitudinal cohort found that BCI skill remained stable as the disease progressed (Silvoni et al., 2013); and a home-use study reported that fourteen of forty-two consented patients completed training and used the system independently, with patient and caregiver benefit outweighing burden (Wolpaw et al., 2018).

Beyond that core, the picture becomes more complicated as ALS advances toward the complete locked-in state (CLIS). One review argues that BCI communication in CLIS-ALS may fail because disease progression brings broader neurophysiological and cognitive changes that the interface must contend with (Grosse-Wentrup, 2019). The available empirical evidence supports this view: BCIs appear most effective in early to middle ALS, before complete locked-in status has been reached, rather than after all voluntary output has been lost (Silvoni et al., 2009; Vansteensel et al., 2016).

For LIS more broadly, the evidence is similar in shape but slightly more encouraging, largely because the syndrome itself remains heterogeneous. A non-invasive P300 system enabled a brainstem-stroke locked-in patient to communicate over thirteen months in forty of sixty-two sessions, and an intracortical BrainGate study in incomplete locked-in syndrome reported typing rates above ten correct characters per minute (Bacher et al., 2015). An intensive care feasibility study found that a commercial EEG-based BCI could be deployed and might help confirm consciousness in acute LIS, although it was unreliable in acute disorders of consciousness (Chatelle et al., 2018).

The practical conclusion is that first-generation BCI in ALS and LIS is, in clinical terms, principally an assistive-communication technology. EEG/P300 systems lead non-invasive use, while intracortical and fully implanted systems offer higher performance at the cost of surgical complexity and implant burden (Guy et al., 2018; Vansteensel et al., 2016; Wolpaw et al., 2018). The core limitation, however, is rarely decoding accuracy alone. It is patient state. Attention, fatigue, cognition, residual eye control and progression toward CLIS all determine whether the interface continues to function for a given individual at a given disease stage (Grosse-Wentrup, 2019; Guy et al., 2018; Wolpaw et al., 2018).

4.2. BCI in Tetraplegia and Spinal Cord Injury

In SCI and tetraplegia, the clinical literature divides along two main axes of communication and motor restoration, and the strongest human evidence remains limited in scale. A systematic review of invasive SCI work identified nineteen studies covering twenty-one patients; eighteen of these used intracortical arrays and three used ECoG. Every task included in that synthesis achieved some degree of motor restoration, but the same review noted that no current technology restores complete functional autonomy and that outcomes vary considerably (Holt et al., 2023).

For communication, intracortical BCIs are the most mature first-generation option. BrainGate has demonstrated control of a computer, a robotic limb, or, with functional electrical stimulation, a participant's own paralysed extremity. A high-performance intracortical communication study reported typing rates that exceeded earlier iterations by roughly 1.4- to 4.2-fold (Pandarinath et al., 2017). In tetraplegia specifically, an ECoG case report demonstrated robust three-dimensional cursor control in a patient with C4 injury, with the grid explanted at twenty-eight days and no adverse effects reported (Wang et al., 2013). The result is reassuring from a safety standpoint but, as a single case, cannot be broadly generalised.

Non-invasive BCIs are easier to deploy and serve as the entry point for rehabilitation studies, though they offer less performance. A feasibility study in twenty-five inpatient SCI participants found that most completed a game-based EEG-BCI paradigm and reported positive experience, with the authors concluding that the paradigm was feasible and safe across a range of ages, education levels and injury levels (Salisbury et al., 2016). A more recent meta-analysis of non-invasive BCI in SCI pooled nine papers and 109 patients,

identified moderate evidence for improvements in motor function, sensory function and activities of daily living, and explicitly framed its conclusions as preliminary rather than ready for routine clinical adoption (Sun et al., 2025). Rehabilitation-oriented studies point in the same direction. A pilot randomised clinical trial of BCI-controlled exoskeleton training for lower-limb rehabilitation in SCI has reported that integrating BCI with exoskeletal devices is feasible in this population (Hu et al., 2026). Together with earlier BCI-FEST series, such work shows absent or rare adverse events, occasional crossing of clinically meaningful improvement thresholds, and modest but mixed between-group gains, with the meta-analytic synthesis cautioning that between-group differences remain limited (Sun et al., 2025).

Taken together, BCI in SCI is most defensible as a neurorehabilitation adjunct and assistive-communication tool rather than as a stand-alone restorative therapy. A modality tradeoff underlies this picture: EEG/P300 systems are lower-risk and easier to scale, while intracortical and ECoG systems offer better control and richer outputs at the cost of surgical risk, implant burden and unresolved long-term reliability questions.

4.3. BCI in Pharmacoresistant Epilepsy

In pharmacoresistant epilepsy, the first-generation BCI label applies almost exclusively to closed-loop seizure detection or prediction paired with stimulation. One review describes the responsive neurostimulation system as the only FDA-approved closed-loop device in this space (Sisterson et al., 2018), while a second review of closed-loop epilepsy systems reports that seizure frequency falls by approximately 60 to 65 percent across the human trial literature (Vassileva et al., 2018). The translational bottleneck is not detection accuracy alone. Because intracranial electrodes are typically implanted for clinical reasons in the first place, both detection and stimulation sites must be tailored to the individual patient, and the system must function alongside routine epilepsy care (Zelmann et al., 2020). Preclinical evidence is, in some respects, stronger than the human record: a portable rat platform reported high seizure-detection rates and very short stimulation latencies (Liang et al., 2010), but this represents a different evidentiary tier than routine clinical practice.

4.4. BCI in Movement Disorders

In movement disorders, the BCI label more often applies to adaptive or closed-loop DBS than to classical communication BCIs. Reviews describe DBS as already safe and effective for Parkinson's disease, essential tremor and dystonia, with most closed-loop work concentrated in Parkinson's disease. The same literature concludes that several adaptive approaches look promising, but that further studies are needed to determine which are feasible, efficacious and efficient (Kuo et al., 2018). The most concrete clinical proof point in this domain is a first-use implantable sensing/stimulation interface in three Parkinson's patients, described by its authors as artefact-free in recording and clinically viable for adaptive DBS (Arlotti et al., 2021). The pattern is consistent across the two indications: epilepsy BCIs are organised around seizure suppression, whereas movement-disorder BCIs are organised around biomarker-driven personalisation of ongoing stimulation (Arlotti et al., 2021; Kuo et al., 2018; Sisterson et al., 2018; Vassileva et al., 2018).

5. Comparative Safety Analysis

5.1. Neurological and Infectious Complications: A Graded Risk Profile

A review of the human BCI safety literature does not support a single uniform risk profile; rather, it supports a graded one. Non-invasive EEG systems appear to be the safest, temporary ECoG looks relatively benign in small samples, and chronic intracortical implants concentrate the neurological and infectious burden because they require percutaneous skin breaches and long-term implanted hardware (Rubin et al., 2023; Salisbury et al., 2016; Wang et al., 2013).

The most informative quantitative human dataset remains BrainGate. Across fourteen adults and 12,203 implant-days, the trial reported 68 device-related adverse events and six device-related serious adverse events, but no explantations, no intracranial infections, no deaths and no permanent disability attributable to the device. The most common single complication was skin irritation around the percutaneous pedestal (Rubin et al., 2023). This profile resembles a chronic implant-management challenge more than a signal of catastrophic neurological injury, and it aligns with the broader translational literature, which identifies surgical risk and long-term reliability as the principal barriers to widespread clinical use, with signal loss from gliosis or micromotion as a central failure mode (Serruya, 2014).

Table 2. Summary of adverse events (AEs) and safety outcomes in selected first-generation BCI human trials. N/A = not applicable; NR = not reported; RCT = randomised controlled trial. Developed using Claude 4.6 Sonnet by Anthropic.

Study / System	N	Implant-days	Total AEs	Serious AEs	Key finding
BrainGate (intracortical)	14	12,203	68	6	No deaths, infections or explantations; main AE: pedestal skin irritation
SWITCH (endovascular)	4	~1,460	0	0	No vessel occlusion or device migration at 12 months
ECoG – tetraplegia (Wang 2013)	1	28	0	0	Explanted at 28 days; robust 3D cursor control demonstrated
P300/EEG – ALS (Wolpaw 2018)	42	N/A	NR	NR	14/42 patients completed training; benefit exceeded burden
BCI exoskeleton SCI (Hu 2026)	Pilot RCT	N/A	Rare	0	No serious AEs; modest motor gains between groups

For less invasive interfaces, the risk burden decreases accordingly. A non-invasive SCI study reported that the BCI paradigm was feasible and safe across a broad inpatient population (Salisbury et al., 2016), and a tetraplegia ECoG case report described explantation at twenty-eight days with no adverse effects (Wang et al., 2013). The endovascular SWITCH study followed four implanted patients for twelve months without serious adverse events, vessel occlusion or device migration, suggesting that the access route itself may be a major determinant of risk (Mitchell et al., 2023). The key distinction, based on these data, is therefore not the binary contrast between invasive and non-invasive. What matters is whether the system is chronic and percutaneous, chronic and fully implanted, or short-term and removable. Infection clusters around the implant access route, while the dominant neurological concern is chronic interface failure rather than new neurological deficits (Rubin et al., 2023; Serruya, 2014; Wang et al., 2013).

5.2. Technical Failure Modes: Connectors, Gliosis and Drift

Technical failure is the more concrete and directly measured dimension of the safety equation. In the best human safety dataset, BrainGate reported sixty-eight device-related adverse events across 12,203 implant-days, with most failures occurring within the first year and acute mechanical failures (largely connector-related) heading the list. The same series identified a progressive meningeal reaction in 14.5 percent of cases (Barrese et al., 2013). This finding fits the wider interface literature, which consistently returns to signal loss from gliosis or micromotion and, more broadly, to abiotic and biotic failure modes (Serruya, 2014; Shen et al., 2023). The dominant technical safety issue, based on available data, is therefore not dramatic neurological catastrophe but chronic degradation, unreliable recording and hardware-tissue mismatch.

5.3. Cybersecurity and Adversarial Threats

Cybersecurity presents a different picture from the technical-failure literature. Denning et al. (2009) argued that standard engineering and trial practices do not make neural devices robust against adversarial entities trying to alter, block or eavesdrop on neural signals, and later reviews have organised the threat space across data, permission and model levels (Denning et al., 2009; Jiang et al., 2023). The more concrete attack scenarios in this literature are straightforward: blind attacks can cause cessation of stimulation, drain implant batteries, induce tissue damage or enable information theft, and wireless connectivity creates additional attack surface (Jiang et al., 2023). In practical terms, the more immediate safety burden remains reliability engineering, but the cybersecurity burden grows quickly as implants become wireless, networked and bidirectional (Denning et al., 2009; Jiang et al., 2023).

6. Neuro-Rights: Conceptual Foundations and the International Regulatory Landscape

6.1. Conceptual Camps: New Rights or Operationalisation of Existing Ones

The neuro-rights literature is predominantly normative and policy-driven rather than empirical, and it converges on a small set of protected interests including mental privacy, mental integrity, autonomy, identity, cognitive liberty and, in some accounts, psychological continuity, equal access and protection against bias (Blasi Casagran, 2025; Cornejo, 2024; Kellmeyer, 2022; Morente Parra, 2025).

Two conceptual camps appear consistently across this body of work. The first treats neuro-rights as a new rights category. A systematic review explicitly frames neuro-rights as a new category of rights aimed at protecting mental integrity against the misuse of neurotechnologies (Cornejo, 2024), and the Chilean Supreme Court discussion concludes that neurodata require special protection because existing data law is insufficient (Cornejo-Plaza et al., 2024). The second camp argues that existing human-rights instruments are adequate if properly operationalised. Kellmeyer (2022) holds that existing human rights provide sufficient legal instruments, while González Barrera & Covarrubias (2025) propose operational definitions around neurodata, neuro-inference and neuro-effect, a Neuro-Privacy Impact Assessment, and stronger safeguards in coercive settings.

6.2. International Regulatory Frameworks: Chile, Europe and UNESCO

On the regulatory side, the most visible international pattern is not a single treaty but a patchwork of frameworks. Chile is the clearest national outlier, with constitutional-level neurorights debate and case law pushing mental privacy into the legal foreground (Cornejo-Plaza et al., 2024). Europe relies more heavily on existing human-rights and data-protection architecture, though several authors argue that those frameworks still leave gaps for brain data and cognitive liberty (Blasi Casagran, 2025; Cornejo-Plaza et al., 2024). UNESCO instruments, including the 2023 Bioethics Committee report and the 2021 neurotechnology recommendations, point toward a softer global model involving democratic and inclusive summits, globally coordinated guidelines, privacy, security and consent measures, bias prevention, and public rules for safe and equitable access (Cornejo, 2024; Goering et al., 2021). Perspectives on harmonising AI governance with neuroinformatics emphasise the same precautionary, design-stage logic in cross-border data-sharing pipelines (Alsaigh et al., 2024). The common thread across these positions is precaution and design-stage governance: neural data should be treated as unusually sensitive, protections should be built in early, and policymakers should not assume that generic privacy law will fully cover the decoding or modulation of mental states (Alsaigh et al., 2024; González Barrera & Covarrubias, 2025; Klein & Rubel, 2023; Morente Parra, 2025).

The conceptual landscape is therefore coherent even where the law is not. Neuro-rights are being invoked either as a new rights vocabulary or as a way to operationalise existing rights against technologies that can infer, modulate or expose mental states.

7. BCI-Specific Ethical Challenges and Clinical Recommendations

7.1. Identity, Agency, Privacy and Consent

The BCI ethics literature, like the neuro-rights literature, is mostly normative rather than empirical. It converges on four clinical problem areas: identity and agency, privacy and consent, bias and access, and security and liability. A recurring recommendation across these areas is to treat neural data and neural modulation as unusually sensitive and to build safeguards into both the device and the trial design from the outset (Goering et al., 2021; González Barrera & Covarrubias, 2025; Kellmeyer, 2022; Klein & Rubel, 2023).

The most concrete ethical challenge follows directly from a property of the technology itself. BCIs do not just collect data; some systems can infer mental states, and some can also modulate them. Goering et al. (2021) frame the field around identity and agency, privacy, bias, and enhancement, and call for new safeguards, including an explicit neuro-rights vocabulary, for data privacy, security and consent. Kellmeyer (2022) makes the same point from a rights-based perspective: mental privacy and mental integrity are fundamental goods that require actionable protection rather than abstract recognition. The most operational proposal in the corpus comes from González Barrera & Covarrubias (2025), who define protected objects (neurodata, neuro-inference, neuro-effect), presume sensitivity, tier duties according to what a system can reveal or modulate, and require a Neuro-Privacy Impact Assessment at the design stage.

7.2. Clinical Implementation: Fit-for-Purpose Deployment and Cybersecurity as Patient Safety

On the clinical side, the recommendations are less about specifying a single safe architecture than about governance and fit-for-purpose deployment. The translation literature consistently identifies hardware reliability, surgical risk, decoding performance and long-term interface stability as the practical limits on safe clinical use, with chronic implants failing through abiotic and biotic mechanisms including gliosis,

micromotion and material degradation (Lu et al., 2012; Serruya, 2014; Shen et al., 2023). Several practical implications follow. The system should be matched carefully to the clinical indication; the least invasive interface that can perform the required task should be preferred; consent should be specific to the device's decoding and stimulation capabilities; drift and device failure should be monitored over time; and cybersecurity should be treated as a component of patient safety rather than as an information technology add-on (Denning et al., 2009; Klein & Rubel, 2023).

The cybersecurity literature is particularly direct on this point. It states that standard engineering and trial practice does not yet make neural devices robust against adversaries who can alter, block, or eavesdrop on neural signals and that wireless connectivity expands the attack surface (Denning et al., 2009). The practical clinical posture that emerges is therefore precautionary but not anti-innovation: narrow the indication, minimise invasiveness, secure the data path, specify who can access what neural information, and plan for follow-up governance after implantation.

8. Discussion

8.1. Synthesis of Principal Findings

This narrative review has examined three interconnected strands of evidence regarding first-generation BCIs. First, the clinical translation literature consistently demonstrates that human evidence remains limited in scale across every indication. The longest-running implanted-array dataset (BrainGate) reports a favourable safety record over more than 12,000 implant-days, with no explants, intracranial infections or deaths attributable to the device (Rubin et al., 2023); the endovascular SWITCH study extends this profile in a less invasive form (Mitchell et al., 2023); and indication-specific evidence from P300 communication in ALS, intracortical typing in incomplete LIS, ECoG cursor control in tetraplegia, responsive neurostimulation in epilepsy and adaptive DBS in Parkinson's disease, is informative but based on small samples.

Table 3. Summary of clinical evidence for first-generation BCIs by indication and modality. SR = systematic review; FDA = US Food and Drug Administration approval; RNS = responsive neurostimulation. Developed using Claude 4.6 Sonnet by Anthropic.

Indication	Best-supported modality	Largest cohort	Evidence stage	Key reference(s)
ALS / LIS communication	EEG/P300; intracortical	42 (Wolpaw 2018)	Feasibility / pilot	Guy 2018; Wolpaw 2018; Bacher 2015
SCI / Tetraplegia motor	Intracortical arrays	21 (Holt 2023 SR)	Systematic review (pilot studies)	Holt 2023; Pandarinath 2017
SCI rehabilitation	EEG-BCI + exoskeleton	109 (Sun 2025 meta)	Meta-analysis (moderate evidence)	Sun 2025; Hu 2026
Pharmacoresistant epilepsy	Responsive neurostimulation (RNS)	Multi-centre (FDA)	FDA-approved device	Sisterson 2018; Vassileva 2018
Parkinson's disease (DBS)	Adaptive / closed-loop DBS	3 (Arlotti 2021)	Proof-of-concept	Arlotti 2021; Kuo 2018

Second, the comparative safety literature documents a graded rather than uniform risk profile. Risk concentrates in chronic, percutaneous interfaces, while non-invasive paradigms remain the safest. Technical failure dominates the long-term safety conversation: connector failure, progressive meningeal reaction in roughly one-seventh of intracortical cases, and chronic signal degradation through gliosis, micromotion and material breakdown (Barrese et al., 2013; Serruya, 2014; Shen et al., 2023). Cybersecurity, by contrast, is a real but still largely threat-modelled concern, and its weight will grow as implants become wireless, networked and bidirectional (Denning et al., 2009; Jiang et al., 2023).

Third, the neuro-rights and bioethics literature converges on a small core of protected interests, including mental privacy, mental integrity, autonomy, identity and cognitive liberty, along with a single recurring practical recommendation: treat neural data and neural modulation as unusually sensitive and build safeguards into both the device and the trial design from the outset (Cornejo, 2024; Goering et al., 2021; González Barrera & Covarrubias, 2025; Kellmeyer, 2022). The international regulatory environment is fragmented but consistent in its precautionary direction: Chilean constitutional law, European data-protection and human-rights instruments, and UNESCO guidance all push toward design-stage governance rather than retrofitting (Alsaigh et al., 2024; Blasi Casagran, 2025; Cornejo-Plaza et al., 2024).

8.2. Tensions, Trade-offs and Unresolved Questions

Several fundamental tensions run through this field. The first concerns the tradeoff between performance and invasiveness. Intracortical and ECoG systems achieve the richest decoding performance but carry the highest implant burden; non-invasive EEG systems are easier to scale and safer but provide lower information transfer rates. The endovascular access route is an emerging compromise but has yet to generate human evidence at the scale of intracortical platforms.

The second tension concerns mechanism-of-action transparency. Many first-generation stimulation platforms operate through empirically tuned, incompletely understood circuit-level effects. This complicates both regulatory review and consent, because the reasons a device works are sometimes less clear than the observation that it does. The mechanism gap is most pronounced for stimulation-based systems and has clear implications for the depth and specificity of informed consent.

The third tension is between data richness and privacy. More granular neural data, including raw intracortical signals, ECoG broadband recordings and longitudinal stimulation logs, may improve adaptive performance and personalisation but expand the attack surface for privacy breaches and poorly defined secondary use. The neuro-rights debate is, in part, an attempt to define where the boundary should lie between legitimate clinical use and data over-extraction.

The fourth tension concerns the relationship between innovation and regulation. Excessive regulatory burden may stifle beneficial innovation, particularly in academic and small-industry contexts; insufficient oversight may allow unsafe systems to proliferate. The most promising approaches couple precaution with practicality, incorporating design-stage Neuro-Privacy Impact Assessments, fit-for-purpose deployment, and tiering of obligations according to what each system can decode or modulate.

8.3. Implications for Clinical Practice and Policy

Several implications follow from this synthesis. For clinicians, the central message is that first-generation BCIs should be understood as fit-for-purpose assistive and adjunctive tools rather than autonomous interventions. Communication BCIs in ALS and LIS, and adaptive DBS in Parkinson's disease, represent the indications with the strongest current evidence, and their adoption should be conditional on clear evidence of subgroup applicability, transparent documentation of limitations and defined pathways for reporting anomalies.

For health systems, the implications extend beyond individual device adoption to include governance infrastructure: pre-implant Neuro-Privacy Impact Assessments, inventories of deployed neuromodulation systems, continuous performance monitoring, and mechanisms for patient and community input. Cybersecurity should be treated as an explicit component of patient safety, not as a downstream IT concern.

For policymakers and regulators, the priority agenda includes harmonising international standards where possible, ensuring that regulatory frameworks address mental privacy and integrity alongside traditional safety, and building infrastructure to enable post-market surveillance of implanted neural devices across diverse populations. The Chilean constitutional approach and UNESCO's soft global guidance illustrate the range of regulatory architectures available; convergence on design-stage protections is more important than convergence on a single legal instrument.

8.4. Limitations of This Review

Several limitations of this review warrant acknowledgement. As a narrative synthesis, it does not involve formal risk-of-bias assessment of individual studies or quantitative meta-analysis, which limits the precision of comparative claims. Much of the strongest human evidence reviewed here comes from cohorts of one to a few dozen participants, including BrainGate, SWITCH, the Parkinson's disease implantable closed-loop interface, and small ECoG, P300 and BCI-FEST series, which limits the extent to which strong generalisations can be drawn about effectiveness, durability or comparative performance across modalities. The neuro-rights and BCI-ethics literature is overwhelmingly normative and policy-driven, with thin empirical anchoring in actual implanted-patient outcomes. The cybersecurity evidence base remains dominated by threat models and proof-of-principle attacks rather than long-term clinical incident reporting. Finally, the review focuses on English-language and bilingual European/Chilean literature, and is therefore most informative about high-income legal-regulatory contexts.

8.5. Directions for Future Research

Future research directions implied by these gaps cluster in four areas. Larger and longer feasibility cohorts are needed for each indication, with explicitly pre-specified safety and performance endpoints. Modality-by-modality comparisons across endovascular, intracortical, ECoG, DBS and non-invasive approaches would help separate the contributions of access route, electrode architecture and chronicity to the overall risk profile. Empirical work on actual neural-data flows, governance arrangements and patient experience would help anchor the neuro-rights debate in clinical reality. Finally, structured incident reporting for cybersecurity events in deployed neural devices would convert today's threat-model literature into evidence that can inform clinical decision-making.

9. Conclusions

First-generation brain-computer interfaces are best understood as a clinically promising but still pilot-scale set of technologies whose concrete value is most apparent in augmentative communication, motor restoration in tetraplegia, closed-loop seizure control and adaptive deep brain stimulation for movement disorders. The safety record, where it has been quantified at scale, is reassuring rather than alarming; it reflects a chronic implant-management challenge rather than a pattern of catastrophic neurological injury. Comparative risk follows the access route and the chronicity of the implant more than any simple invasive/non-invasive distinction. Cybersecurity is not yet a clinical-incident problem but is on a clear trajectory to become one as devices become networked and bidirectional.

The neuro-rights literature, though normatively coherent, remains legally fragmented; the most defensible clinical posture is precautionary, fit-for-purpose and design-led. Across indications, the central operational message is consistent: match the least invasive platform to the indication, tailor consent to what the device can decode and modulate, treat the data path as part of patient safety, and build neural-data governance into the device rather than adding it after deployment. Meeting this standard requires combining technical innovation with ethical vigilance, regulatory maturity and a sustained commitment to mental privacy and integrity. The challenge is substantial, but so is the opportunity: given rising clinical demand, persistent implant-reliability challenges and a rapidly expanding attack surface, the careful development of first-generation BCIs offers a genuine opportunity to advance both safety and rights in clinical neurotechnology.

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