Review

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Clinical translation and accessibility of brain-computer interfaces: From technology development to clinical application

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SUMMARY: Brain-computer interface (BCI) technology establishes a direct communication pathway between neural activity and external devices. Driven by advances in neuroscience, artificial intelligence (AI), neural signal acquisition, decoding algorithms, and implantable system design, BCIs have progressed rapidly from experimental prototypes toward clinically relevant neurotechnologies. However, the translation of these technical advances into routine clinical practice and equitable real-world access remains substantially slower than technological innovation. This review summarizes the major technological pathways of BCIs and their clinical applications, and it then examines BCI development from the perspective of clinical translation and accessibility. We focus on key barriers across the translational chain, including long-term technical stability, quality of clinical evidence, evaluation standards, reimbursement mechanisms, health-economic evidence, and the feasibility of implementation in real-world healthcare settings. We argue that the central challenge in BCI development has shifted from improving technical performance alone to building the translational infrastructure required for safe, effective, affordable, and sustainable clinical integration.

Keywords: brain-computer interface, technology development, clinical application, clinical translation, accessibility

1. Introduction

Brain-computer interface (BCI) technology aims to establish a direct communication pathway between the brain and external devices by recording neural activity, decoding neural states or intentions, and converting these signals into commands for assistive, rehabilitative, or therapeutic systems (*1*). A typical BCI system includes neural signal acquisition, signal preprocessing, feature extraction, algorithmic decoding, command generation, device control, and, in closed-loop systems, sensory or neural feedback (*1,2*). Most BCIs currently in use are non-invasive and rely primarily on electroencephalography (EEG). Implantable electrode systems, including electrocorticographic and intracortical interfaces, provide higher-fidelity neural signals and have particular relevance for patients with severe motor, sensory, or communication impairments (*3,4*).

Recent advances in neuroscience, AI, flexible electronics, and computing hardware have transformed BCI signal processing, system miniaturization, and decoding performance (*5,6*). Deep learning and generative AI have expanded the scope of BCI research beyond simple motor-intention decoding toward the reconstruction of speech, handwriting, and other high-order cognitive or communicative processes (*7*). At the same time, improved non-invasive and wearable systems, including EEG-functional near-infrared spectroscopy (fNIRS) hybrid platforms, are being developed to partly address the signal-to-noise ratio, spatial-resolution, and robustness limitations of conventional EEG-based BCIs (*8,9*). Clinically, BCIs exhibit substantial potential in stroke rehabilitation, spinal cord injury, Parkinson's disease, epilepsy, disorders of consciousness, and other neurological conditions, and particularly in communication restoration, motor control, functional rehabilitation, and closed-loop neuromodulation (*10,11*).

In China, a notable milestone in BCI clinical translation was reported on March 13, 2026, when the National Medical Products Administration approved an implantable BCI medical device, the Implantable BCI Hand Motor Function Compensation System, for tetraplegia caused by cervical spinal cord injury. The system supports hand grasping through a pneumatic glove and was subsequently incorporated into Shanghai's medical service catalogue by the Shanghai Healthcare Security Administration through an expedited process

aligned with national BCI coding guidance (*12*). This case provides a useful policy and payment example for examining how BCI technologies may move from regulatory approval toward reimbursable clinical services.

Internationally, China has identified BCI as a future-industry priority, and coordinated policy, industrial, and clinical drivers are accelerating development. The United States and the European Union have also incorporated neurotechnology and BCI-related research into their strategic science and technology agendas. Despite increasing research output and investment, BCI translation continues to face multiple bottlenecks (*13*). Technical challenges include limited long-term signal stability, degradation at the electrode-tissue interface, signal non-stationarity, and low signal-to-noise ratio, all of which limit reliability in real-world use (*14,15*). Standardized clinical assessment metrics and reproducible multicenter protocols remain insufficient, limiting cross-study comparison and scalable validation (*13,16*). Regulatory and market-access pathways are also incompletely defined, and harmonized standards for BCI products have not yet been established across jurisdictions (*17*).

Contemporary BCI research is characterized by convergence across neural engineering, machine learning, materials science, clinical medicine, rehabilitation, ethics, regulation, and health economics (*18*). Although many reviews have addressed BCI signal processing, neural interfaces, and hardware development (*19*), fewer have examined the full clinical translation chain from research and development to regulatory approval, reimbursement, health technology assessment (HTA), and real-world implementation. This gap is important because promising technical performance does not automatically translate into sustainable clinical value. This review therefore adopts a clinical translation and accessibility perspective. Using recent Chinese regulatory and payment developments as an illustrative framework, we summarize major BCI technology pathways, global research landscapes, clinical applications, and translational bottlenecks. We then identify priorities for evaluation, reimbursement, policy design, and healthcare-system integration that may help accelerate responsible clinical implementation and improve access to neurorehabilitation and assistive neurotechnology.

2. Technology pathways and current translation stages of BCIs

2.1. Major technology pathways

The term BCI was introduced by Jacques Vidal in the 1970s to describe computer systems capable of extracting information from brain activity and using it for external communication or control (*20*). A typical BCI consists of six core modules: neural signal acquisition, signal preprocessing, feature extraction, algorithmic decoding, output control, and sensory or neural feedback. The acquisition module captures neural activity through electrodes or other sensors; preprocessing amplifies low-amplitude signals and reduces noise; feature extraction identifies biologically relevant neural signatures; decoding algorithms translate these signatures into interpretable intentions or states; output modules drive external devices such as robotic arms, wheelchairs, computers, or functional electrical stimulation systems; and feedback modules support closed-loop adaptation by delivering sensory, electrical, or other forms of stimulation (*21,22*) (Figure 1).

Depending to the mode and anatomical level of signal acquisition, BCIs can be broadly divided into five major pathways: non-invasive BCI, electrocorticography (ECoG)-based BCI, intracortical BCI (iBCI), endovascular BCI (EBCI), and neuromodulation-based BCI (*23,24*). These categories differ in invasiveness, signal fidelity, clinical risk, achievable bandwidth, and translational maturity.

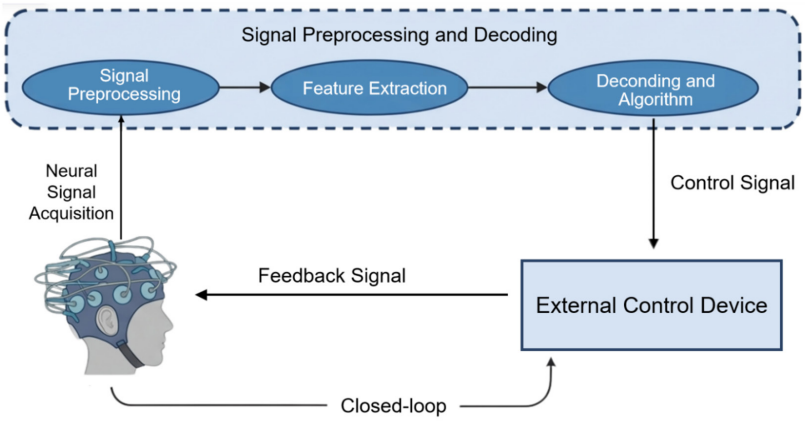

Figure 1. Schematic example of a typical BCI system. Neural signals are processed through preprocessing, feature extraction, and decoding to generate control commands for an external device. Feedback from the device forms a closed-loop system, enabling real-time interaction and control in BCI applications. *Abbreviation:* BCI, brain-computer interface.

2.1.1. Non-invasive BCI

Non-invasive BCIs are the most mature and widely deployed modality. They typically acquire EEG signals from scalp electrodes and may incorporate complementary modalities such as fNIRS or magnetoencephalography. Wet, dry, and hydrogel electrodes offer different trade-offs among signal quality, comfort, preparation time, and long-term wearability. Non-invasive BCIs are safe, relatively low-cost, scalable, and suitable for rehabilitation training, assistive communication, home monitoring, and consumer human-computer interaction. However, neural signals are attenuated by the scalp and skull and are vulnerable to motion artifacts, environmental noise, and inter-individual variability. As a result, non-invasive BCIs generally have limited spatial resolution, reduced localization precision, and lower decoding accuracy and stability than implanted interfaces (*25,26*). Improvements therefore depend on optimized experimental paradigms, robust signal processing, adaptive algorithms, and hybrid designs. EEG-fNIRS systems are an important strategy because they combine the high temporal resolution of EEG with hemodynamic information that can improve spatial and physiological interpretation (*27*).

2.1.2. ECoG BCI

ECoG BCIs use epidural or subdural electrodes placed close to cortical neural sources, often in the form of flexible cortical surface arrays. Compared to scalp EEG, ECoG provides higher spatial resolution, stronger signal-to-noise ratio, and better localization while retaining millisecond-level temporal resolution. It has clear utility in motor decoding, speech reconstruction, and epileptic focus localization (*28*). Recent high-density ECoG systems have enabled long-term spelling and speech neuroprostheses, indicating the feasibility of continuous high-performance communication. Nevertheless, ECoG requires cranial surgery and carries non-negligible risks, including bleeding, infection, tissue reaction, and device-related complications. Long-term performance may also be affected by signal decay, electrode aging, hardware failure, or the need for revision surgery (*26,29*).

2.1.3. iBCI

Intracortical BCIs use microelectrode arrays to record single-unit, multi-unit, or local field potential activity directly from the cortex. Among current BCI modalities, iBCIs offer the highest spatial resolution, signal fidelity, and information bandwidth, enabling precise real-time decoding for robotic arm control, cursor control, handwriting and typing, speech restoration, and fine motor reconstruction. Their major advantage is access to neural activity at the single-neuron or local microcircuit level, which facilitates high-dimensional decoding of motor and communicative intentions. Landmark studies have demonstrated high-performance speech and handwriting decoding in people with severe paralysis or amyotrophic lateral sclerosis (ALS), underscoring the unique value of iBCIs for high-bandwidth neuroprosthetics (*30,31*). However, iBCIs require highly invasive implantation, are vulnerable to foreign-body reactions and glial scarring, and generally sample localized cortical populations rather than distributed whole-brain activity. These limitations present challenges in terms of long-term stability, device maintenance, and broad clinical adoption (*32*).

2.1.4. EBCI

Endovascular BCIs record neural signals through stent-mounted electrode arrays deployed within cerebral blood vessels. This approach avoids conventional open-cranial implantation and therefore offers a less invasive route to implanted neural recording, while maintaining closer proximity to cortical sources than scalp EEG (*33*). Early clinical studies have suggested that endovascular BCIs can be implanted safely in selected patients with severe paralysis and can support digital control tasks such as texting, emailing, online shopping, and communication of care needs (*34*). However, EBCI remains in an early stage of clinical development. Wider translation will require stronger evidence on anatomical suitability, thrombotic and vascular complications, implant stability, long-term biocompatibility, signal quality, and long-term usability in daily environments (*35*).

2.1.5. Neuromodulation-based BCI

Neuromodulation-based BCIs integrate neural recording, state decoding, and stimulation into closed-loop systems. These systems detect neural states in real time and deliver adaptive stimulation through approaches such as closed-loop deep brain stimulation (DBS), responsive neurostimulation (RNS), BCI-functional electrical stimulation (BCI-FES), and EEG- or transcranial magnetic stimulation-based closed-loop frameworks. Compared to conventional assistive BCIs that focus primarily on external device control, neuromodulation-based BCIs aim to identify pathological or functional brain states and intervene dynamically. They have substantial potential in epilepsy, Parkinson's disease, stroke rehabilitation, chronic pain, disorders of consciousness, and functional restoration (*36,37*). Guozhen Liu's team has developed flexible, implantable electrochemical sensors capable of high-sensitivity, long-term monitoring of multiple cytokines and neurotransmitters in the brain. Validation in animal models has demonstrated the utility of this technology in tracking Parkinson's disease and neuropathic pain, offering a novel tool to aid in the diagnosis and management of neurological disorders (*38,39*). The conceptual boundary between BCI and neuromodulation

remains a subject of debate. Narrow definitions restrict BCIs to direct central nervous system signal acquisition for external device control, whereas broader definitions include closed-loop systems that decode neural activity to guide therapeutic stimulation. In this review, DBS, RNS, and related technologies are discussed within this broader BCI-related framework when they include record-decode-stimulate closed-loop functions.

2.2. From technology to the clinic: Translation stages and key transitions in BCI development

BCI development is moving from a primarily technology-driven phase toward a clinically and regulatorily oriented phase. Non-invasive BCIs have been commercialized to an extent and are increasingly used in rehabilitation and consumer settings, although their clinical value still depends on standardization, outcome evidence, and reimbursement integration. ECoG and iBCIs represent high-performance implantable pathways with clear advantages in motor decoding, speech restoration, and neuroprosthetic control, but they remain concentrated in specialized clinical trials and selected patient populations. Their broader clinical adoption is limited by invasiveness, long-term signal stability, postoperative management, their maintenance burden, and the reproducibility of outcomes across centers. EBCI offers a less invasive route of implantation, but it remains largely in the proof-of-concept and early feasibility stages. Neuromodulation-based BCIs are more mature for selected indications, and especially epilepsy and Parkinson's disease, but dissemination of adaptive closed-loop systems still depends on algorithm optimization, evidence of their long-term benefit, regulatory clarity, and reimbursement pathways.

Overall, non-invasive BCIs are closest to scalable clinical implementation, and particularly in rehabilitation and home-based training. ECoG and iBCIs provide higher performance but require more demanding surgical, ethical, and maintenance infrastructures. Endovascular systems are promising but still require longitudinal safety and effectiveness evidence. Closed-loop neuromodulation has already entered into clinical use in certain disease contexts, but its classification as BCI depends on the degree to which it incorporates neural decoding and adaptive control. Overall, the clinical translation of BCIs depends not only on their decoding performance but also on their safety, sustained reliability, usability, training burden, clinical workflow compatibility, patient selection, cost, and reimbursement (Table 1).

To indicate the logical transition from technology to clinical use, this review uses a technology-clinical-translation framework (Figure 2). Different BCI pathways occupy distinct positions along this continuum: non-invasive BCIs are in preliminary clinical use in rehabilitation and assistive communication; semi-invasive and minimally invasive systems are mostly used in early or exploratory clinical trials; and highly invasive BCIs are concentrated in carefully selected populations and specialized centers. These differences show that the clinical prospects of BCIs depend not only on signal fidelity or decoding accuracy but also on safety, long-term stability, operational complexity, patient adherence, and compatibility with existing healthcare systems.

3. Major areas of application and progress made by BCIs

3.1. Motor function restoration

BCIs are widely examined in neurorehabilitation after stroke, and especially for improving upper-limb motor function. A multicenter, randomized, open-label, controlled trial conducted across 17 centers in China showed that patients with ischemic stroke receiving BCI-based rehabilitation had significantly greater improvement in upper-limb Fugl-Meyer scores at one month than those undergoing conventional rehabilitation (*39*). Another randomized study suggested that combining BCI with functional electrical stimulation could improve post-stroke motor outcomes (*40*). A systematic review has further indicated that EEG-based neurofeedback can support motor recovery, with therapeutic benefit influenced by training intensity, feedback quality, and patient engagement (*41*). Motor-imagery BCIs combined with advanced signal processing can also detect functional changes before and after rehabilitation, providing both therapeutic and assessment value (*42*). BCIs may also restore communication and environmental control for patients with severe paralysis caused by spinal cord injury. In a first-in-human study, an endovascular BCI was implanted through the internal jugular venous route in four patients with severe bilateral upper-limb paralysis. During 12 months of follow-up, the system remained safe and stable, and participants were able to control a computer using thought-driven commands, indicating the feasibility of this less invasive approach to implantation (*33*). In addition, transcutaneous cervical spinal cord stimulation has been reported to enhance sensorimotor rhythms and accelerate BCI skill acquisition in people with spinal cord injury, suggesting a possible role for combined neuromodulation and BCI training in motor rehabilitation (*43*).

3.2. Communication restoration

BCIs provide a potential communication pathway for patients with severe speech or motor impairment caused by neurological injury or degenerative disease. Direct decoding of neural activity into text, speech, or speech-related articulatory representations has become a major clinical frontier, with rapid advances in both discrete and continuous speech decoding (*44*). For tonal languages,

Table 1. Core characteristics, translation stages, and limitations of major BCI technology pathways

Technology pathway	Signals and acquisition	Spatiotemporal resolution	Invasiveness/risk	Typical applications	Current stage	Translation potential	Key limitations
Non-invasive BCI	Scalp EEG and/or fNIRS acquisition of electrical or hemodynamic signals	Low spatial resolution; millisecond temporal resolution for EEG	Non-invasive	Rehabilitation training; disorders-of-consciousness assessment; assistive communication; consumer human-computer interaction; home monitoring	Clinical use / partial commercialization	High	Signal quality; artifact sensitivity; standardization; reimbursement integration
ECoG BCI	Epidural or subdural recording of cortical local field potentials	Intermediate to high; millisecond-level temporal resolution	Moderate; requires cranial surgery	Epilepsy localization; speech decoding; motor-intention decoding; intraoperative functional mapping; semi-implantable communication	Clinical trials / feasibility validation	Moderate	Invasiveness; long-term signal stability; postoperative management
Intracortical BCI	Microelectrode-array recording of single-unit, multi-unit, and local field potential activity	High; micrometer-scale spatial resolution and sub-millisecond to millisecond temporal resolution	High; requires intracortical implantation	Communication and typing for severe paralysis; robotic arm control; fine motor reconstruction; speech and handwriting decoding	Clinical trials / early translation	Moderate	High invasiveness; immune response; hardware lifespan; maintenance burden
Endovascular BCI	Stent-electrode recording of neural signals from cerebral vessels	Intermediate; generally below intracortical and surface interfaces but above conventional scalp recording	Lower than open-cranial implanted interfaces, but with vascular risks	Digital communication; environmental control; assistive interaction for severe paralysis	Early exploration / feasibility testing	Low to moderate	Long-term vascular safety; implant stability; limited clinical evidence
Neuromodulation-based BCI	Record-decode-stimulate systems using EEG, ECoG, local field potentials, or other neural signals	Depends on recording and stimulation modality	Depends on implementation	Epilepsy; Parkinson's disease; chronic pain; stroke rehabilitation; consciousness modulation; functional reconstruction	More mature for selected indications	Context-dependent	Conceptual boundaries; algorithm validation; reimbursement and regulatory pathways

Abbreviations: BCI, brain-computer interface; ECoG, electrocorticography; EEG, electroencephalography; fNIRS, functional near-infrared spectroscopy.

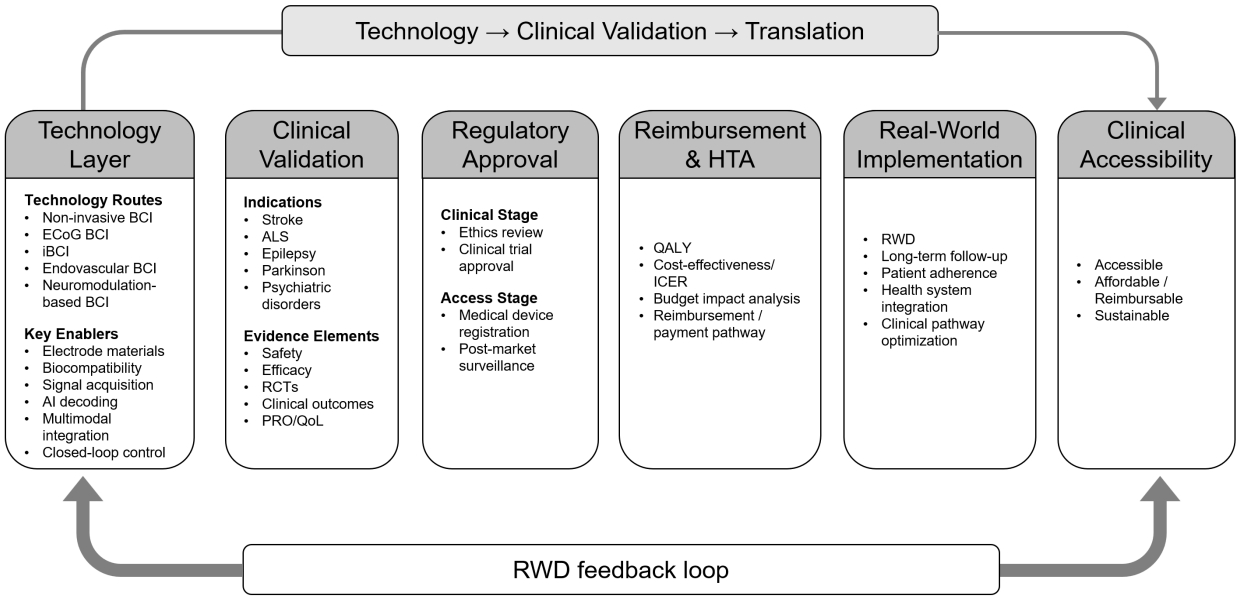

Figure 2. Framework for the clinical translation pathway of BCI. This pathway illustrates the progression of BCIs from fundamental technology development, clinical validation, regulatory approval, and health technology assessment, to real-world implementation and clinical accessibility. It emphasizes a closed-loop iterative system driven by real-world data to continuously optimize translation outcomes. *Abbreviation:* AI, artificial intelligence; ALS, amyotrophic lateral sclerosis; BCI, brain–computer interface; ECoG, electrocorticography; HTA, health technology assessment; iBCI, intracortical brain–computer interface; ICER, incremental cost-effectiveness ratio; PRO, patient-reported outcome; QALY, quality-adjusted life year; QoL, quality of life; RCT, randomized controlled trial; RWD, real-world data.

hybrid EEG-EMG BCIs have shown promise in decoding neural and muscular representations during silent and audible speech. Studies of Mandarin tone decoding have reported classification accuracies ranging from 71.22 to 91.00%, suggesting that language-specific features should be considered when developing communication BCIs for diverse patient populations (*45*).

3.3. Neuromodulation-related functional restoration

Closed-loop BCI-related neuromodulation is reshaping therapeutic strategies for neurological and neuropsychiatric disorders. In epilepsy, responsive and closed-loop systems can detect pathological activity and deliver stimulation when needed. A preclinical study in epileptic rats developed a non-invasive closed-loop acoustic BCI that showed antiepileptic efficacy superior to conventional vagus nerve stimulation, with effects eliminated by vagal pathway disruption, indicating the importance of mechanism-guided closed-loop design (*46*). In Parkinson's disease, BCI-related approaches aim to restore impaired motor or cognitive function by decoding cortical or subcortical activity and translating it into adaptive stimulation or corrective commands (*47*). In psychiatry, sensing-enabled DBS and related closed-loop neuromodulation technologies are advancing circuit-based treatment concepts. For refractory obsessive-compulsive disorder (OCD), long-term intracranial monitoring using sensing-enabled DBS has identified biomarkers associated with clinical states and treatment response, which may guide adaptive stimulation (*48*). Connectivity-guided targeting may further improve therapeutic precision in OCD and related disorders (*49*). For post-traumatic stress disorder and other conditions involving emotional dysregulation, DBS-related studies have focused on cortico-striato-thalamo-cortical circuits and transdiagnostic network targets (*50,51*). Although these approaches are not always classified as BCIs in a narrow sense, they are highly relevant to the broader BCI framework when neural signals are recorded, decoded, and used to guide closed-loop intervention.

BCI-related technologies are also being explored in disorders of consciousness, sensory dysfunction, cognitive impairment, neurodegenerative disease, sleep disorders, anesthesia monitoring, brain resuscitation, and affective-state recognition (*33*). In subacute stroke, for example, single-channel EEG-BCI systems have been used to classify selective tactile attention online, assist sensory training, and assess changes in cortical excitability (*44*). These applications illustrate a broader shift from device control alone toward neural-state monitoring, rehabilitation guidance, and adaptive therapy (Figure 3).

4. Research translation and clinical evaluation of BCIs

4.1. Research landscape and translation

BCI has become a strategic priority for several major economies, accompanied by increasing scientific output, industrial investment, and policy attention (*52*). China,

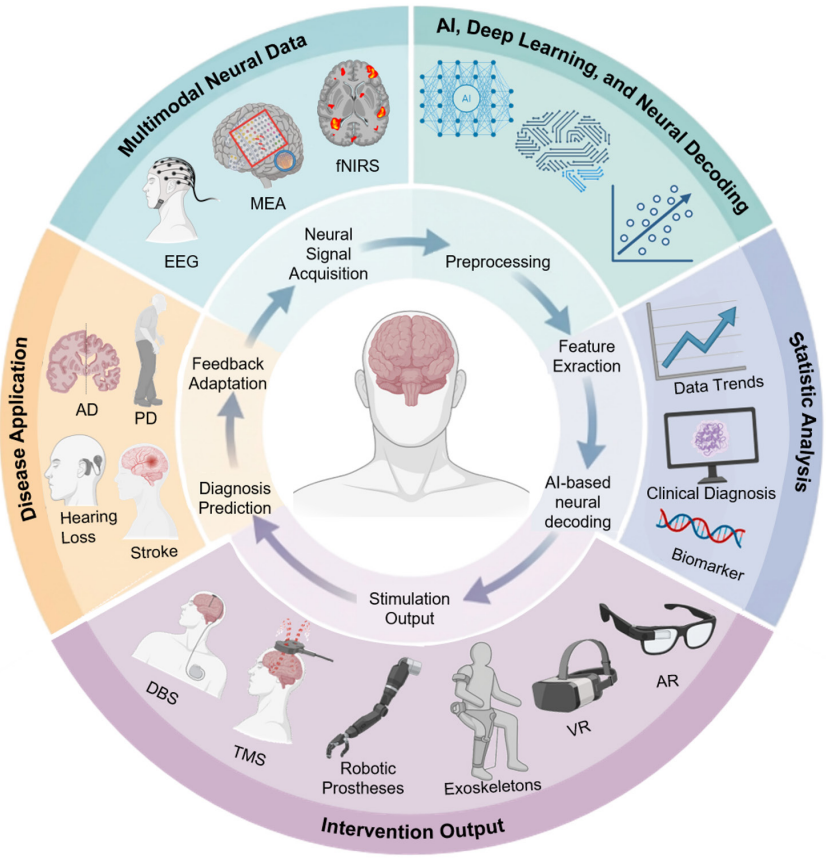

Figure 3. Main disease areas and clinical application processes for BCI-based intervention. Application scenario symbols guide related results throughout this study. Partially created with Biorender.com. *Abbreviations*: AD, Alzheimer's disease; AI, artificial intelligence; AR, augmented reality; DBS, deep brain stimulation; EEG, electroencephalography; fNIRS, functional near-infrared spectroscopy; MEA, microelectrode array; PD, Parkinson's disease; TMS, transcranial magnetic stimulation; VR, virtual reality.

the United States, the European Union, Japan, and South Korea are among the major contributors, although their development models and technical strengths differ.

China has a strong capacity in non-invasive BCI research and translation, supported by vast clinical resources, extensive EEG datasets, and a rapidly developing industrial ecosystem (*53*). National initiatives, including the China Brain Project and future-industry strategies, have elevated BCI to a priority frontier technology (*35*). China has also conducted prospective clinical testing of invasive BCIs (*54*) and is developing domestic industrial chains spanning chips, electrodes, algorithms, devices, and system integration (*55*). Rehabilitation medicine has been a major field of application, enabling the relatively rapid commercialization of non-invasive BCI systems and the accelerated development of implantable devices (*56*). The approval of an implantable BCI Class III medical device in 2026 represents an important translational milestone within this context (*57*).

The United States leads in many invasive BCI technologies, including high-channel-count neural acquisition, flexible electrodes, wireless implantable devices, and human neuroprosthetic trials (*58*). Its development model is powerfully driven by academic innovation, private capital, start-up companies, and close collaboration among engineering, industry, and clinical centers (*22*). The European Union (EU) has contributed substantially to neural coding, biocompatible materials, closed-loop neuromodulation, and hybrid brain-silicon systems designed to restore network connectivity in neurological disease (*59*). The EU also places a strong emphasis on ethical, privacy, and safety governance, with regulatory frameworks such as the AI Act and the General Data Protection Regulation shaping neurodata governance and patient protection (*60*). Large-scale infrastructures, including the Human Brain Project, have supported multicenter collaboration and public-interest translation (*61,62*), although commercialization has generally proceeded more slowly than in the United States (*63*).

Japan has integrated basic neuroscience with clinical rehabilitation, emphasizing neuroplasticity, neural decoding, and post-stroke recovery. The Hybrid Assistive Limb (HAL) in Japan has completed multiple phase III clinical trials. Randomized controlled studies in patients with neuromuscular disorders and spinal cord lesions demonstrated that HAL significantly improves walking distance and speed, alleviates limb spasticity, and enhances activities of daily living. Similar

positive rehabilitation outcomes were observed in stroke populations. The overall incidence of adverse events was below 5%, and those events were predominantly mild localized muscle soreness and minor skin discomfort, with no serious safety events reported. Long-term application appears safe and reliable. HAL is currently commercially available in Japan and covered by national health insurance (*64-66*). A study from a Japanese group has shown that BCI training combined with hybrid assistive neuromuscular stimulation can improve upper-limb function in severe post-stroke hemiplegia through induced neuroplasticity (*67*). A systematic review corroborates the role of EEG neurofeedback and motor-imagery paradigms in promoting cortical reorganization (*68*), while basic research has identified overlapping neural correlates of real and imagined movements that may contribute to BCI performance (*69*). South Korea has incorporated brain-machine interaction and digital therapeutics into its national biotechnology strategies, with investment in BCI, digital bioinnovation, neurotechnology ethics, and standardization (*70-73*) (Table 2).

Table 2. Global landscape of BCI research in selected countries and regions

Country/region	Strategic programs	Core strengths	Representative institutions	Technical focus
China	Sci-Tech Innovation 2030 - Brain Science and Brain-inspired Intelligence; future-industry policies	Vast clinical resources; non-invasive BCI deployment; industry-academia-clinical collaboration	Tianjin University; Tsinghua University; clinical rehabilitation centers	Minimally invasive BCI; non-invasive rehabilitation systems; medical translation
United States	BRAIN Initiative and related neurotechnology programs	High-performance invasive interfaces; strong commercialization capacity; extensive human trials	Stanford University; BrainGate; Neuralink and other neurotechnology companies	Invasive BCI; neuroprosthetics; speech and motor decoding; medical applications
European Union	Human Brain Project; neurotechnology and AI governance frameworks	Basic neuroscience; ethical and regulatory governance; international collaboration	Federal Polytechnic School of Lausanne; University and industry consortia	Non-invasive and hybrid systems; brain modeling; closed-loop neuromodulation
Japan	Long-term brain science and rehabilitation research programs	Neuroplasticity research; rehabilitation-oriented translation	University of Tokyo; Kyoto University; Keio University	Neural repair; motor rehabilitation; disease mechanisms
South Korea	Digital Bio Innovation Strategy	Integration of BCI with digital therapeutics and bioinnovation policy	KAIST and national research institutes	Brain-computer interaction; brain-function visualization; digital therapeutics

Abbreviations: AI, artificial intelligence; BCI, brain-computer interface; KAIST, Korea advanced institute of science and technology.

4.2. Clinical evaluation

Clinical evaluation of BCIs remains dominated by technical performance metrics, whereas frameworks centered on patient benefit, quality of life, functional independence, and long-term clinical value remain underdeveloped. Many studies use decoding accuracy, information transfer rate, task completion, or device-control performance as primary endpoints but report limited data on quality of life, the caregiver burden, long-term functional improvement, or sustained use in home settings. A systematic review of implantable BCIs found that only 17.9% of studies reported clinical outcomes, with technical metrics predominating (*74*). This imbalance is a major barrier to regulatory decision-making, payer evaluation, and routine clinical adoption.

As BCIs enter a more clinically oriented stage, evaluation should go beyond engineering metrics to include health-economic dimensions such as quality-adjusted life-years (QALYs), incremental cost-effectiveness ratios (ICERs), and budget impact. Related neuromodulation technologies provide useful precedents. A Japanese health-economic study of DBS for Parkinson's disease estimated that DBS could generate an additional 3.2 QALYs compared to conventional treatment and could be cost-effective under certain assumptions (*75*). Similarly, a cost-effectiveness analysis of responsive neurostimulation for drug-resistant focal epilepsy suggested that such systems may achieve acceptable ICERs compared to medication alone (*76*). Although these technologies are not identical to BCIs, they offer relevant methodological models for evaluating high-cost, implantable, and long-term neurotechnologies. Patient adherence, the training burden, usability, and

technological appropriateness should also be treated as core dimensions for evaluation. Evidence from a systematic review suggests that, although BCI performance may now exceed some patients' minimum expectations, prolonged training, daily-use complexity, equipment maintenance, and caregiver support requirements remain major obstacles to its sustained adoption (*77*). Clinical evaluation should therefore assess not only whether a BCI works in a controlled setting but also whether patients can learn, tolerate, maintain, and benefit from it in daily life.

5. Challenges in clinical translation and application

BCI translation faces several interconnected bottlenecks. Technical limitations include insufficient long-term stability, degradation at the electrode-tissue interface, signal non-stationarity, and a low signal-to-noise ratio, all of which constrain real-world reliability and practical utility (*78,79*). In parallel, the absence of standardized clinical outcome measures and reproducible multicenter protocols makes results difficult to compare, validate, and scale (*13,80*). Economic evidence, reimbursement mechanisms, regulatory pathways, and market-access models remain incompletely defined, while internationally harmonized standards for BCI products are still lacking (*81*).

5.1. Long-term technical safety and stability remain insufficiently validated

At the hardware level, conventional rigid electrodes can trigger foreign-body responses, causing tissue injury, glial scarring, signal attenuation, and an eventual decline in performance. Flexible electrodes, hydrogels, and biomimetic neural probes have improved mechanical matching and biocompatibility, but many remain insufficiently validated in sustained functional settings. Non-invasive EEG is safer but suffers from a low signal-to-noise ratio, artifact contamination, and limited spatial resolution; denoising algorithms can reduce but not fully eliminate these problems. Inter-individual variability further reduces robustness across users, sessions, and clinical settings (*82*). At the algorithmic level, AI and transfer learning have improved decoding accuracy but have not fully solved the problem of generalizability across individuals, devices, disease states, and real-world conditions (*83*). Long-term training and adjunctive neuromodulation may enhance neuroplasticity and improve device control, and closed-loop control has begun to show practical value in both therapeutic and assistive contexts. Nevertheless, large-scale, long-term controlled trials remain limited, and particularly in severely affected populations and home-based settings (*84*). Overall, non-invasive BCIs still face limitations in decoding accuracy and stability; iBCIs remain constrained by invasiveness and long-term device performance; and EBCIs require additional validation of long-term safety, signal stability, and vascular biocompatibility. Broader implementation will require progress in long-term stability, user adaptability, device reliability, and clinical standardization.

5.2. Monitoring systems for the effects of BCIs remain inadequate

Most BCI studies emphasize classification accuracy, hit rate, task performance, cortical activation, or functional connectivity but lack unified and clinically meaningful outcome measures that capture real patient benefit (*52,85,86*). A systematic review of 112 implantable BCI studies reported that only 17.9% assessed clinical outcomes, and the methods used to evaluate outcomes were highly heterogeneous (*74*). Standardized tools for monitoring long-term effectiveness, tolerability, quality of life, caregiver burden, and sustained use are also lacking (*87*). In patients with end-stage neurodegenerative diseases such as ALS, BCIs may support communication and daily assistance, but robust frameworks for quantifying their effects on quality of survival, autonomy, and the caregiver burden remain limited (*88*). Real-world evidence is fragmented because centers often differ in electrode layouts, sampling rates, preprocessing pipelines, experimental paradigms, methods of annotation, and outcome definitions. This heterogeneity limits cross-center comparison, compilation of evidence from multiple centers, and external validation. The lack of post-marketing real-world data and standardized follow-up frameworks further impedes the systematic assessment of BCIs' long-term effectiveness, safety, adherence, maintenance burden, and reasons for discontinued use in routine clinical and home settings (*89*).

5.3. Technical evaluation standards for algorithms and training protocols are not yet unified

Clinical translation is also hindered by the lack of standardized technical evaluation protocols. Studies differ substantially in paradigms, devices, algorithms, patient populations, calibration methods, feedback modalities, and training programs, making horizontal comparison difficult (*90*). Advanced algorithms, including Ensemble RCSSP (*91*), McRFS-IBiRNN (*92*), and OADANN (*92*), may achieve a high level of accuracy on specific datasets, but their generalizability in multicenter and real-world settings remains insufficiently demonstrated. In addition, user learning effects (*2*), differences in neuroplastic potential, fatigue, motivation, cognitive capacity, and the phenomenon often described as BCI illiteracy further complicate evaluation (*93,94*). Standardized benchmark datasets, reporting guidelines, patient-stratification criteria, and clinically meaningful performance thresholds are

needed to determine whether algorithmic improvements translate into practical benefit.

5.4. Costs are high and health-economic evidence remains insufficient

EEG-based non-invasive BCIs are often considered the most feasible route for near-term clinical translation because they are relatively low-cost, non-invasive, and easier to deploy than implanted systems (*95*). However, the overall costs of development, deployment, maintenance, training, and service delivery remain substantial (*96*). High-performance wearable EEG devices, real-time signal-processing hardware, AI-driven decoding engines, and integration with functional electrical stimulation, robotic systems, or remote monitoring platforms all require complex hardware-software co-design. Implantable BCIs provide higher signal quality but involve much higher costs for surgery, long-term device management, maintenance, and treatment of complications, all of which constrain their broad adoption (*97*). Even when novel bioelectronic materials such as conductive hydrogel electrodes improve biocompatibility and mechanical matching, clinical-grade manufacturing, quality control, sterilization, and regulatory testing remain costly (*98*). Overall, rigorous health-economic evidence for BCIs remains sparse, limiting payer confidence and reimbursement decisions.

5.5. Established reimbursement pathways are still lacking

Globally, clear and widely established reimbursement pathways for BCI technologies remain limited. Many BCI systems are still in the research or early clinical testing stage and have not been incorporated into routine fee schedules. Existing payment items often cover basic procedures or adaptation services but may not include essential costs such as device consumables, long-term maintenance, software updates, rehabilitation training, or home-use support. Payment standards vary across jurisdictions and lack harmonization (*99*). Current payment models remain largely fee-for-service and rarely incorporate value-based approaches that link reimbursement to functional outcomes, quality of life, or long-term cost offsets. Because high-quality evidence of their clinical value remains limited, the relationship between outcomes and charges is weak, yielding insufficient evidence for pricing and reimbursement adjustment (*100)*. Although several randomized controlled trials have shown that BCI-based rehabilitation can improve upper-limb motor function after stroke (*101,102*), these interventions have not yet been widely recognized by payers as standard treatment. The absence of payment mechanisms places substantial financial burdens on facilities and patients and directly limits real-world implementation.

6. Future perspectives

6.1. Accelerating the technological transition toward clinical application

BCI is undergoing a critical transition from laboratory research to real-world clinical application. This transition requires coordinated progress in technological innovation, clinical evidence, health economics, ethics, regulation, and reimbursement. Technologically, flexible electronics may improve their biocompatibility, mechanical matching, and long-term signal stability; deep learning, generative AI, and transfer learning may improve their decoding accuracy, robustness, and cross-individual generalization; and multimodal integration, closed-loop control, and adaptive design may expand their functional scope. Clinically, BCIs show great promise in stroke rehabilitation, communication support for ALS and severe paralysis, epilepsy interventions, and care for Parkinson's disease. Randomized trials substantiate the possibility of improving upper-limb function and activities of daily living, and particularly when a BCI is combined with functional electrical stimulation or robotic assistance. However, clinical research remains constrained by heterogeneous outcomes, insufficient long-term evidence, non-standardized protocols, and immature evaluation systems. Unified assessment frameworks and high-quality multicenter trials are urgently needed.

6.2. Improving HTA and reimbursement design to overcome implementation barriers

Scalable BCI implementation depends not only on technical maturity but also on HTA, reimbursement policies, ethical governance, and healthcare-system integration. Evidence on their cost-effectiveness, budget impact, payment design, and resource allocation remains insufficient. Ethical and legal questions also remain unresolved, including patient autonomy, informed consent, neurodata privacy, cybersecurity, algorithmic transparency, and risks associated with long-term neural interventions. Interdisciplinary collaboration among engineers, clinicians, rehabilitation specialists, health economists, ethicists, regulators, payers, and patient communities is necessary to develop evidence-based policies and transparent regulatory frameworks. Future BCI development should integrate neuroscience, AI, flexible electronics, clinical medicine, and implementation science to optimize hardware-software co-design, closed-loop personalized interventions, real-world robustness, and equitable access.

6.3. Aligning BCI development with clinical needs and accessible care

The next phase of BCI development should redefine their clinical goals, system architecture, and translational

logic. The field is likely to move beyond focal motor restoration toward brain-network state recognition, adaptive regulation, and precision neurorehabilitation. These advances may facilitate closed-loop interventions for epilepsy, Parkinson's disease, disorders of consciousness, psychiatric disorders, chronic pain, and other complex neurological conditions. Clinical BCI delivery will also evolve from standalone devices into integrated care systems that combine signal acquisition, intelligent decoding, closed-loop feedback, rehabilitation training, remote monitoring, device maintenance, and long-term follow-up. This systems-level model is essential for improving their real-world feasibility and sustained benefit.

The central mission of BCI development is therefore no longer simply to increase decoding speed, channel count, or spatial resolution. Rather, the goal is to match each technological pathway to appropriate clinical scenarios, patient populations, healthcare workflows, and payment models. High-quality BCI research must integrate technical optimization with evidence of their economic value, real-world effectiveness, patient adherence, usability, long-term safety, and ethical governance. Only through this integrated translational framework can BCIs move from impressive engineering achievements to accessible, affordable, and sustainable clinical neurotechnologies.

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