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Towards the Clinical Translation of Implantable Brain-Computer Interfaces for Motor Impairment: Research Trends and Outcome Measures

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Introduction: Implantable brain-computer interfaces (iBCIs) translate neural signals into motor commands, such as the movement of a device or synthesis of speech, offering potential to restore function in patients with severe motor impairments. This systematic review provides a comprehensive analysis of the evolution of implantable BCI research so far, as well as the need for robust, clinically meaningful outcome measures to enable clinical translation.

Material, Methods and Results: A sensitive search strategy was developed and applied across MEDLINE, Embase, and CINAHL databases. Studies involving iBCIs with intracranial sensing and external effector components were included. Records were screened by two independent reviewers. Data was extracted using a piloted proforma, and the risk of bias was evaluated using the Mixed Methods Appraisal Tool (MMAT). A total of 112 studies met the inclusion criteria, with a significant proportion published since 2020, accounting for 49.1% of included studies (n=55). Most research was concentrated in the United States (83.0%; n = 93), with notable contributions from Europe, Australia, and China. Over the past decade, electrocorticography (ECoG)-based devices have increasingly emerged alongside micro-electrode arrays (MEAs) as the sensing devices in iBCI studies. This coincides with a shift in focus from exclusively decoding individual neuron spiking activity to also incorporating spectral features derived from the oscillatory activity of large populations of neurons. iBCI devices are now being used to control an increasingly diverse range of effectors, including robotic prosthetic limbs and consumer digital technologies. Although most (69.6%, n = 78) studies reported outcome measures prospectively, these most commonly related to decoding (69.6%, n = 78) and task performance (62.5%, n = 70). Clinical outcomes were rarely reported, with only 20 studies (17.9%) reporting a use of clinical outcome measure. These measures were heterogenous and most often were related to robotic prosthetic upper limb functions, or the completion of activities of daily living.

Discussion and Conclusion: The clinical and engineering focus of iBCI studies has rapidly evolved since the first human studies, and fully implantable devices have now emerged which may enable clinical translation. This review highlights the dominance of U.S.-based research, the shift towards ECoG-based systems, the expanding array of controllable effectors and the predominance of engineering-related outcome measures. iBCI systems have the potential to restore functional independence at scale, however challenges remain regarding cross-subject generalisation, scalable implantation of devices, and standardisation in the reporting of clinically-meaningful outcomes. Development of novel outcome measures should involve engineers, clinicians and individuals with lived experience of motor impairment.

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