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Recalibration of implantable brain-computer interface devices to enable long-term independent use: a systematic review

Eleanor Swanson MSc[1], Esmee Dohle MA MB BChir[2], Luke Bashford PhD[3], Hugo Layard Horsfall[4], Luka Jovanovic MA MB BChir[5], Jamie F.M. Brannigan MA MBBChir[2*]

[1]University Medical Centre Utrecht, Utrecht, NL; [2]Nuffield Department of Clinical Neurosciences, University of Oxford, Oxford, UK; [3]Faculty of Medical Sciences, Newcastle University, Newcastle upon Tyne, UK; [4]Department of Neurosurgery, National Hospital for Neurology and Neurosurgery, London, UK; [5]East and North Hertfordshire NHS Trust, Lister Hospital, Stevenage, UK

*Jamie Brannigan; John Radcliffe Hospital, Headley Way, Headington, Oxford, OX3 9DU; jamie.brannigan@medsci.ox.ac.uk

Introduction: Implantable brain-computer interfaces (iBCIs) decode neural signals to generate command signals for effector devices which can restore a lost function, such as movement or speech. However, maintaining device performance over time requires recalibration of decoding algorithms due to inherent instability in neural signals. To this end, we systematically reviewed recalibration procedures in iBCIs for patients with motor impairments, focusing on the clinical implications of recalibration requirements and strategies to enable long-term, independent use.

Methods and Results: A systematic search was conducted across EMBASE, MEDLINE, and CINAHL databases to identify studies involving recalibration of iBCIs. After deduplication, 2767 studies remained which were then screened to yield 58 studies. Data on recalibration frequency, duration, staff requirements, and location were extracted and analysed, along with other outcomes like user pathology and signal stability. Penetrating arrays, i.e., microelectrode arrays (MEA) or microwires, were used in 67.2% of studies (n=39), while electrocorticography (ECoG) arrays, were used in 32.8% of studies (n=19). Recalibration practices varied widely amongst studies and were typically performed according to predetermined study protocols, rather than clinical need due to deteriorating device performance. Practices were divided into manual recalibration requiring a specialist research team (89.7% of studies; n=52), semi-automatic recalibration which could be performed by a non-specialist caregiver (3.4%; n=2), and automatic recalibration methods whereby patients did not require assistance (6.9%; n=4). In 63.8% (n=37) of the included studies, iBCIs were recalibrated before each testing session. In contrast, 36.2% (n=21) reported device use for periods >24 hours without recalibration, with an average duration of 13.8 ± 14.2 weeks (ranging from 32 hours to 61 weeks). Notably, 92.3% (n=36) of studies using intracortical (MEA-/microwire-based) iBCIs required daily or per-session recalibration. Studies employing ECoG iBCI devices generally reported less frequent recalibration, with intervals ranging from several weeks to over a year. Extended independent use was more frequently reported with ECoG-based iBCIs. Regarding the location of recalibration, 69% (n=40) took place in a lab (research) setting. Others were carried out at home (13.9%; n=8), both in the lab and at home (10.3%; n=6), not at all (1.7%; n=1), or it was unclear (5.2%; n=3). Across all studies, the most common conditions among iBCI users were spinal cord injury (42%; n=37), amyotrophic lateral sclerosis (ALS) (29.5%; n=26), and stroke (21.6%; n=19). In the subgroup with less frequent recalibration, ALS was relatively more prevalent than other conditions (48.4%; n=15), possibly reflecting the greater clinical need for reduced recalibration burden in individuals with advanced ALS.

Conclusions: Reducing recalibration frequency and/or complexity can improve patient autonomy, and optimizing recalibration strategies is crucial for enhancing the long-term independent use of iBCIs in home and clinical settings. ECoG iBCI studies typically have a low recalibration burden due to inherent signal stability. Whilst MEA iBCI studies usually involve a higher recalibration burden, recent studies have demonstrated reductions in recalibration burden, due to both latent space analysis methods, and continuously updating models during device use. Despite this progress, recalibration procedures are often not fully defined in iBCI studies, and where they are, they usually relate to the study protocol rather than the clinical meaningful requirement of recalibration due to worsening device performance. Future studies should continue to develop user-friendly recalibration procedures and outline the clinically relevant recalibration requirements where possible.

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