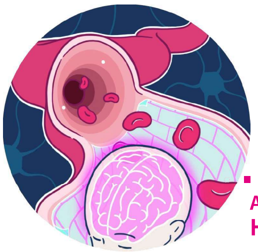
Moonshot Research and Development Program Goal 1 Kanai Project

IoB Minimally Invasive



Development of an Extremely Minimally Invasive Intravascular Brain-Machine Interface (BMI) System

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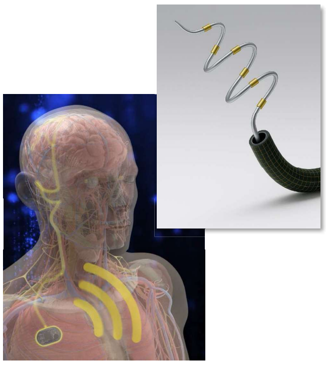
Overview

Realizing AI-assisted BMI-CA requires an interface that connects the brain and external systems bidirectionally. Based on the method used, these interfaces are categorized into “invasive BMI” and “non-invasive BMI.” Invasive BMI employs surgical techniques to implant electrodes within the skull, enabling the utilization of brainwave signals obtained from these electrodes for BMI. This approach allows for the processing of large amounts of information with low latency. However, challenges existed for human application due to the necessity of craniotomy and high costs. This research and development project aims to develop an “**extremely minimally invasive intravascular BMI system**.” This system utilizes flexible, thin-diameter intravascular electrodes that can be guided into cerebral blood vessels to detect highly accurate brainwave signals with minimal invasiveness for BMI application. This project is being pursued in close collaboration with **Takashi Yanagisawa, SPM (R&D Project 3-2-2), Takeshi Sekiya, SPM (R&D Project 5-1-1), and Takafumi Uemura, PI (R&D Project 5-1-3)**. Previous research results and future prospects are described below.



1. Can brain waves be measured from inside blood vessels?

There is no existing technology that detects brainwave signals from cortical veins (CV) running on the brain's surface and utilizes them for BMI, and its usefulness has not been proven. Therefore, we first decided to verify whether it is possible to detect brainwave signals using intravascular electrodes placed in CVs, using large animals such as pigs and sheep. The brains of large animals are significantly smaller than those of humans, and the vessels running along their surfaces are also extremely small (Figure 1). Consequently, we decided to use the large animal hybrid operating room at the Fukushima Medical Device Development Support Center, which is equipped with cerebral angiography equipment used in actual surgeries. At this facility, we guided a microcatheter from a pig's femoral vein to a cerebral surface vein (diameter 0.8 mm). Through this catheter, we placed our developed ultra-fine intravascular electrode and performed EEG measurements. To verify the accuracy of EEG measurement, we performed a craniotomy on the pig using the same invasive BMI method and compared the measured EEG signals with those obtained from sheet electrodes placed on the brain surface (Figure 2). The results of this experiment demonstrated that somatosensory evoked potentials (SEPs) could be measured with higher accuracy using the intravascular electrode than with the sheet electrode, indicating the usefulness of intravascular EEG measurement from the CV (Figure 3). Furthermore, long-term stability was confirmed by keeping pigs for extended periods with intravascular electrodes placed in the superior sagittal sinus (SSS), an intracranial vessel with a maximum diameter of approximately 2-3 mm. Successful EEG measurement was achieved even on day 49 post-implantation (the longest duration) (Figure 4).

These results suggest that an ultra-low-invasive intravascular BMI system targeting cerebral veins has the potential to provide highly accurate EEG signals over long periods with less invasiveness compared to invasive BMI using sheet electrodes.

Figure 1

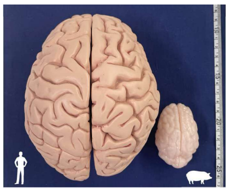


Figure 2

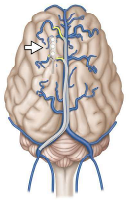


Figure 3

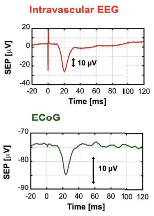
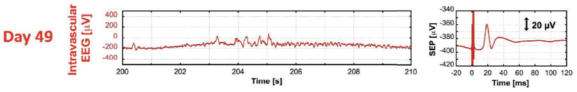


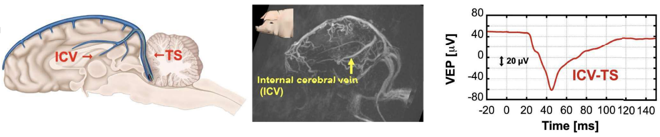
Figure 4



2. The Potential of Extremely Minimally Invasive Intravascular BMI Systems

The extremely minimally invasive intravascular BMI system is a thin and flexible device that could be placed in the internal cerebral vein (ICV), a vein running deep within the brain (Figure 5). The ICV runs near the occipital lobe and thalamus. Using an intravascular electrode placed in the ICV, we succeeded for the first time worldwide in detecting visual evoked potentials (VEP). Our ultra-thin intravascular electrodes enable measurement of brainwave signals from regions previously inaccessible with conventional methods, suggesting potential applications beyond BMI, such as epileptic focus localization and interventions for higher brain dysfunction.

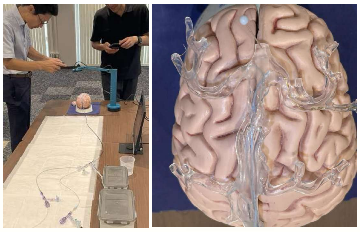
Figure 5



3. Simulation System Using 3D Printers

Experiments using pigs demonstrated the utility of the minimally invasive intravascular BMI system. However, to attempt application in humans, various device properties—such as size, flexibility, lubricity, and visibility—must be evaluated using human vascular models. In parallel with the pig experiments, we also performed device placement simulations using a 3D cerebral venous model created from human cerebral angiography data (Figure 6).

Figure 6



4. Intravascular CA Development Center@Osaka University

With support from the moonshot-type research and development initiative, the latest cerebral angiography system (Siemens ARTIS icono) was introduced to the animal research facility at Osaka University's Faculty of Medicine in fiscal year 2025. Utilizing this system is expected to accelerate the development of a extremely minimally invasive intravascular BMI system and bring us closer to its implementation in society.

Future Prospects

This study demonstrated the utility and future potential of the minimally invasive intravascular BMI system. Moving forward, we plan to verify the device's long-term safety while preparing for preclinical trials. We have also established a placement simulation system using human 3D models and will strive to enhance the safety of placement procedures. We are fully committed to realizing the societal implementation of this system in collaboration with the IoB Minimally Invasive Team.

Hajime Nakamura

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Vice Director, Stroke Center, Osaka University Hospital

I serve as the head of the Cerebrovascular Disease Treatment Team at Osaka University Hospital. I strive to develop gentle yet effective treatment strategies for patients by combining craniotomy with endovascular procedures. In this research project, I will dedicate myself to developing an ultra-minimally invasive endovascular BMI system, maximizing the utilization of neurosurgical techniques.

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Internet of Brains

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