RESEARCH PROJECT:

INTERFACCIA WIRELESS ENCEFALO-MUSCOLARE

(BRAIN-MUSCLE WIRELESS INTERFACE)

Background

To date, the regeneration or the substitution of a damaged nervous system is considered impossible. This results in a severe motor disability for the person and in important costs for the healthcare system in her management.
Every year between 250 and 500 thousand people suffer a spinal cord injury, with an incidence of 40-90 per million. Males are twice more hit than females and the average age is 42 years. Traumas account for the 91% of causes (road accidents 38%, falls 30%, violence 14%, sport 9%) and iatrogenic and non-traumatic damages (tumours, infections, congenital defect, ischemic lesions) for the remaining 9%.
A lesion to the spinal cord injury can result in different clinical presentations depending on the site of the damage. These range from low motor disability to most dramatic cases of paraplegia, in which both inferior limbs receive no motor impulse, and tetraplegia, where all four limbs cannot be spontaneously moved.
What is proposed to these patients are supportive measures directed to treat indirect complications of immobilization (e.g., deep vein thrombosis, pressure ulcers, cardio-pulmonary complications…) and physiotherapy programs aimed to restore as much function as possible. All these measures and rehospitalization of patients produce a cost per patients between 68.000 and 184.000 dollars every year.
Despite this, no solution for regenerating and substituting the impaired nervous system is known. To date, just the 1% of patients has a complete recovery of function after a spinal cord injury.
We therefore decided to study if it’s possible to restore motor function bypassing the impaired nervous system through wireless. This would be possible by creating a neural interface composed by an epidural sensor that recognizes the activation of the cerebral motor cortex. This central sensor is wirelessly coupled with the intramuscular functional electrical stimulators implanted in the muscles. When the intramuscular stimulator is activated produces the contraction of the muscles and the movement is restored.

To date, neuro-muscular interfaces are not used in a clinical setting due to the unavailability of a suitable implantable devices. Despite this, modern exoskeletons use wireless technology for connecting epidural EcoG sensors of cerebral motor cortex activation and the prosthetic actuators. This allows the movement of the exoskeleton by the patient simply by thinking to move. This technology is nowadays used in spinal cord injured patients, allowing them to move again. On the other hand, other devices as functional electrical stimulators are used to restore movement in paraplegic patients by manually activating them through a cabled circuit providing muscle contraction bypassing nerves.

We therefore decided to match these two technologies by developing a neuromuscular interface using wireless communication between the cerebral motor cortex sensor and the functional electrical stimulators. To date, the EcoG signal is processed by an external device. As the aim of the project is to create an interface suitable to be implanted and useful in the everyday life, the switch from a PC decoder to a wearable device will be one of our objectives. Moreover, despite the nowadays used functional stimulators, our functional electrical stimulators will be wirelessly activated. In both central sensors and functional electrical stimulators, the battery is wirelessly recharged, so that the devices can be recharged by an external source.

This device is very similar to one that recently allowed a paraplegic man to walk again. Actually, in May 2023, an article published in Nature showed how a paraplegic man was able to walk again using a wireless brain-spinal cord interface (Walking naturally after spinal cord injury using a brain–spine interface, Lorach et al, Nature 2023). The ECoG sensor presented in the paper is the same as ours; as well, the processing of the brain motor cortex signal was based on a deep open supervised machine learning; the difference, was that the Authors of the study implanted the functional electrical stimulator on the spinal cord. In our project, we will implant it directly in the muscles. This provides two advantages: first of all, the surgical procedure is less invasive; second, the device would work also if the peripheral nervous system is damaged as it is completely bypassed by wireless (often, these patients had serious trauma and the functionality of peripheral nerves of usually impaired).

Objective

The goal of the present project is to develop a wireless brain – muscle interface to bypass spinal cord injuries to potentially treat paraplegic and tetraplegic patients.

Development phases

The project will unfold through phases of fundamental and industrial research and experimental development. The innovation lies not in the hardware devices to be used, but in the wireless connection between them, specifically between the ECoG sensor that recognizes brain cortex activity and the muscle functional electrical stimulator. For this reason, ECoG sensors and implantable functional electrical stimulators already available on the market and proven to function efficiently in a clinical setting will be procured. These will be connected to the intramuscular wireless functional electrical stimulator through fundamental and industrial research activities, utilizing the machine learning software of the Host Institution VIBRE.

The experimental development phase, on the other hand, will be conducted with the support of Neurosurgeons and Orthopaedic surgeons to optimize the surgical implantation process. In the initial stage, 10 paraplegic patients will be selected for surgery with the implantation of two sensors (commercially known as WIMAGINE) for recognition of motor cortex activation using electrocorticographic (ECoG) signals. These sensors consist of an electrode with 64 platinum-iridium microarrays. They will be implanted in the subdural space on the motor cortical area of both cerebral hemispheres, one on the right and the other on the left.
Subsequently, the extracted signal will be processed in a laboratory setting through an deep open supervised machine learning algorithm by an external device to associate that specific signal with the patient's intent to move a particular muscle. Once the artificial intelligence training is complete, the project envisions the wireless connection of the machine learning device with the wireless functional electrical stimulators to test their functionality. After verifying the association between the patient's will to perform a specific movement and the coupled functional electrical stimulator activation, the implantation phase of the functional electrical stimulator into the patients' musculature will commence. The following muscles will be targeted for implantation through a surgical procedure

performed by the orthopaedic surgeon: gluteus maximus, gluteus medius, femoral quadricep, and femoral bicep. Activation of these muscles would indeed enable the patients to independently walking, utilizing the support of two crutches and ankle braces to stabilize ankles.

In the fundamental development phase, external electroencephalography (EEG) sensors and external functional electrical stimulators will also be used to study motor cortex activation patterns and potential wireless connectivity in a less invasive manner compared to implantable devices.

All these steps will enable the brain of the patients to reestablish a connection with muscles, being potentially able to walk again.