Integration of a BCI system for the control of the T-FLEX Ankle Exoskeleton

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Undergraduate Project

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Abstract

Stroke is one of the leading causes of motor and cognitive disability in the world. Despite the existence of various conventional therapies that seek to maximize the recovery of patients, Brain-Computer Interfaces (BCI) are tools to integrate the central nervous system in the rehabilitation process to empower the recovery. Technologies based on the acquisition of EEG signals seeking to complement existing therapies with exoskeletons present enormous potential. The T-FLEX is an active ankle orthosis that has shown efficiency in recovering patients with disabilities in the lower limb. This project presents the preliminary integration of T-FLEX and a BCI system based on EEG signals with validation in post-stroke patients.

Initially, a theoretical framework based on Motor Imagination (MI) principles were implemented, specifically in the Event-Related Synchronization (ERS) of the beta frequency band in the central zone of the cerebral cortex. In this sense, a local server was designed, which worked as a communication bridge between the designed BCI and the T-FLEX device using different data sending protocols.

In the experimental study, the BCI system was analyzed with five post-stroke patients with external stimuli facilitating the MI generation. These were visual and visual with tactile stimuli. Significant differences were found in the accuracy, which concluded greater accuracy in the ability of the BCI to detect MI with visual and tactile stimulation with an increase of 13.3% to 20%.

Significant differences were found in the Power Spectral Density (PSD) related to the tests performed with visual and tactile stimulation in the Cz, C2 and Cpz channels vs. the therapy mode of the T-FLEX device, in which the patient was not required to generate MI. In the same way, the subjective perception of the patients was evaluated through a QUEST 2.0 questionnaire. The results showed that the preliminary integration of this technology is viable for future studies in the medium and long term.

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Chapter 1

INTRODUCTION

This first chapter presents the general motivation of the work presented in this project. This work's motivation includes world statistics of stroke, advantages of using robotics in conventional therapy, a brief description of Brain-Computer Interface systems, and its purpose and needs in the rehabilitation field. The project is articulated with the T-FLEX exoskeleton that frames the study for ankle rehabilitation. From this, the study's objectives are presented in addition to the contributions and document organization.

1.1 Motivation

A stroke occurs when blood circulation is blocked or the blood vessels involved burst [1]. About 15 million people around the world suffer a stroke each year [2]. Therefore, stroke is one of the leading causes of a physical disability that directly affects the quality of life. The above is the motivation to develop technologies that improve interaction spaces, daily activities, and social relationships for this population [2].

Post-stroke rehabilitation is a patient-centered process to maximize patients' functional independence who have suffered a series of disabilities associated with the episode [3]. Post-stroke rehabilitation therapy is more effective if performed with a multidisciplinary team made up of different health professionals working together to achieve the patient's goal [3]. These fields' participation aims to meet small specific objectives such as neuromotor recovery, correct posture, cognitive rehabilitation, and even language recovery in seizures. Regarding motor recovery, this interdisciplinary team has included the engineering sciences to improve the scope of physical therapy using assistive technologies [4].

Assistive technologies for motor rehabilitation include exoskeletons and robotic orthoses, which may provide high motor intensity, repeatability, and precision [5]. These essential characteristics of robotics in rehabilitation make this field a proper research object in medical applications. However, one of the most critical problems that must be solved for the clinical implementation of these developments is their control systems. Conventional control includes tools as inertial sensors, direct contact operation, and external transducers. However, despite the effectiveness of conventional control systems, some authors insist that these methods ignore the patient's involvement with the system in terms of neurofeedback progression [6]. Thus, robotics-based rehabilitation becomes a process that does not fully exploit the patient's ability to generate neuroplasticity progressively, since neurological intend is not directly implicated [6].

In this way, given the rise of the Brain-Computer Interfaces (BCI) paradigm, many developments have focused their applications on motor rehabilitation and language assistance [7]. BCI-based control of exoskeletons and orthoses have been extensively studied. Some research affirms that physical therapies involving BCI in patients with neuromotor conditions may improve their neuroplasticity more effectively [8]. Therefore, the recent development of BCIs proposes the opening to a line of research that promises practical applications in physical therapy.

However, in this subject there is less research focused on the lower limb comparing to the upper-limb development, motivating to deepen its development [9].

There are many paradigms and modalities of BCI used in research; one, of the most approached is Motion Imagery (MI) analysis, which is based on the electrical activity of the motor cortex that occurs when there is an intention to the movement of the subject [8]. This strategy seeks to improve the patient's interaction with the therapeutic mechanisms that pursuit an evolution of the neuroplasticity, adequately including the use of the neuromotor abilities through the BCI system in the rehabilitation process [10]. Following the above, this study proposes integrating a control system for the T-FLEX exoskeleton, based on the analysis of Electroencephalography (EEG) signals and their involvement in the locomotor system.

1.2 Related Project

This project is part of the research project 'Development of an Adaptable Robotic Platform for Gait Rehabilitation and Assistance' (AGoRA project) supported by *Ministerio de Ciencia y Tecnología* and internal funding from the Colombian School of Engineering Julio Garavito (ECIJG). The AGoRA project's primary goal consists of deploying and validating a robotic platform for gait rehabilitation and assistance. Therefore, this robotic platform will be divided into two devices: (1) a stiff exoskeleton to support the knee and hip joints, and (2) a soft exoskeleton to assist the ankle, known as T-FLEX.

The T-FLEX device (Figure 1.1) is an Active Ankle-Foot Orthosis (AAFO) system based on servomotors located in the anterior and posterior part of the lower limb; through a system that includes an inertial sensor, specific algorithms can detect the phases of gait in real-time. In this way, T-FLEX presents advances for the robotic-assisted rehabilitation line focused on the dorsiplantar flexion of the foot [11]. There are two types of modalities in the use of the T-FLEX device. The first modality is the *Therapy Mode* and the second is the *Assistance Mode* [12]. Regarding the Therapy Mode, it consists of the execution of repetitive dorsi-plantarflexion movements. This modality also might be named Stationary Therapy. Rehabilitation programs apply this sort of mode in patients who present spasticity. Likewise, the second sort of execution, the Assistive Mode, intends to use the device during gait and other daily living activities [12].

Nevertheless, independently of the specific exoskeleton task and the patient affection, one of the most crucial features of this sort of technology is the control. As most of the exoskeletons' current paradigm, T-FLEX uses inertial sensors to involve the patient with the operational processes. The sensor integrated into T-FLEX may estimate user movement intention on the paretic foot, replacing the automatic movement in its use.

This project is part of an international collaboration associated with the research group of the Corporación de Rehabilitación Club de Leones Cruz del Sur in Chile. This group will have active participation in the research project, especially in the EEG signals acquisition necessary for the system and, consequently, with the execution of protocols for the validation stage with the test subject.

Figure 1.1: T-FLEX system. The figure illustrates the main components: the actuators that work in conjunction with the transmission elements to generate movement assistance, the electronic control system and the inertial sensor that detects the motion intention [13].

1.3 Objectives

Considering the motivation stated before, the objectives of this project are defined.

1.3.1 General objective

To integrate a motor imagery-based BCI system that controls the exoskeleton T-FLEX in stationary therapy in post-stroke patients and perform a technical evaluation of this technology.

1.3.2 Specific objectives

- To perform state of the art about BCI and exoskeletons in clinical and rehabilitation application in lower-limb.
- To detect and integrate ankle movement imagination EEG signals to control the movement of the T-FLEX exoskeleton in stationary therapy.
- To analyze the feasibility, in terms of classification accuracy, of the integrated use of the BCI system in the T-FLEX device, evaluating correct detection rate.
- To evaluate the effect of the BCI system on the cortical activation of the frequency band associated with MI in three different states: (1) stationary therapy, (2) detection of Motor Imagery with Visual stimulation, and (3) detection of motor imagination with Visual and Tactile stimulation.

- Analyze the user's perception of the use of assistive technology proposed in this study, considering subjective variables proposed in the QUEST 2.0 test, in terms of user satisfaction.

1.4 Contributions

The development of this undergraduate project made the following contributions regarding the integration of a BCI control system in the rehabilitation field:

- An application to the T-FLEX device, opening a line of research focused on brain-machine interaction that seeks to improve the rehabilitation process.
- Characterization of the design of the BCI system in terms of accuracy and user satisfaction.
- Preliminary validation of the application of BCI strategies integrated to the T-FLEX exoskeleton by assessing its functionality in post-stroke patients, observing significant differences in their brain activity within different states.

1.5 Document organization

This document contains six chapters divided into Introduction, Literature Review, Methodology, Results, Discussion, Conclusions, and Recommendations and Future Works.

The second chapter presents the Literature Review. Initially, it is shown the theoretical framework by which this study is supported. This chapter considers concepts such as ankle anatomy and biomechanics, BCI systems (i.e., definition, modalities, and design strategies), and related works in the rehabilitation field associated with lower-limb and the final section is explicitly related Foot-Ankle Complex.

The third chapter presents the methodology used in this project. First, the BCI's methodology is established according to the strategies reviewed in the literature, including the protocol communication with T-FLEX. On the other hand, the experimentation methodology with post-stroke patients is also exposed, explaining the implemented set up and the equipment. Finally, the methodology for the treatment of data obtained from the experimentation is presented, including monitoring EEG signals.

Then the results are set out in the fourth chapter. This section includes the characterization of the BCI, where the accuracy of the patients is evaluated. The results obtained from the EEG signals extracted according to the exposed processing methodology, and, finally, the results of the QUEST 2.0 satisfaction tests are described and analyzed. In the same way, the fifth chapter corresponds to the discussion section which is divided into two main parts: The discussion related to the quantitative results and the discussion related to the qualitative QUEST test.

Finally, the sixth chapter describes the conclusions based on the objectives set previously. Then, the seventh chapter proposes some recommendations to carry out the study more efficiently and future works in the medium and long term are described.

Chapter 2

STATE OF ART

This chapter presents the state of art proposed in the objectives of this study. First, the functionality and need for rehabilitation of the foot-ankle complex will be presented in anatomical and biomechanical terms. Then, the T-FLEX project, its technical details, and its most relevant results so far will be described. Likewise, the concept of BCI will be described and, its elementary design process and current paradigms. Similarly, a review of the literature on clinical trials performed with exoskeletons and BCI will continue. In this way, the state of art will be finalized with a section of works with BCI focused on the foot-ankle complex.

2.1 The ankle

The ankle is a shortened way to refer specifically to the tibiotalar joint. Its functions are always considered a complementary process between the foot and the ankle, generally named foot-ankle complex [14]. This complex comprises the lower leg and the foot and forms a joint that allows the lower limb to contact the ground. Therefore, the ankle is a crucial part of gait and other human life activities [15]. The ankle generally is named a synovial hinge joint with a joint capsule and associated ligaments. The foot-ankle complex's main features allow both stability and mobility depending on the lower limb current conditions [16].

2.1.1 Anatomy of the ankle

As mentioned earlier, the ankle is not considered a single part of the human anatomy; it is interdependent with other lower limb functions [15]. Accordingly, the foot-ankle complex comprises thirty-three joints, including the related long-bones of the lower limb—further, the ankle joint spans several articulations surfaces, which provides mobility to the foot. The tibial, fibular distal epiphyses, and the talus are some of these surfaces. The talus grasps firmly between both malleoli; this gripping system forms a hinge-type synovial joint with only one movement axis called the bimalleolar axis, allowing foot dorsiflexion and plantar flexion in the sagittal plane [17]. The above is part of the foot-ankle complex biomechanics, and it will be treated in the next section.

In the literature, it is possible to find some references related to other joints. For instance, the subtalar joint articulates between the talus superiorly and the calcaneus and navicular inferiorly [18]. This joint is responsible for the foot eversion-inversion and abduction-adduction movement. Nevertheless, it is necessary to clarify that this joint is essentially different from

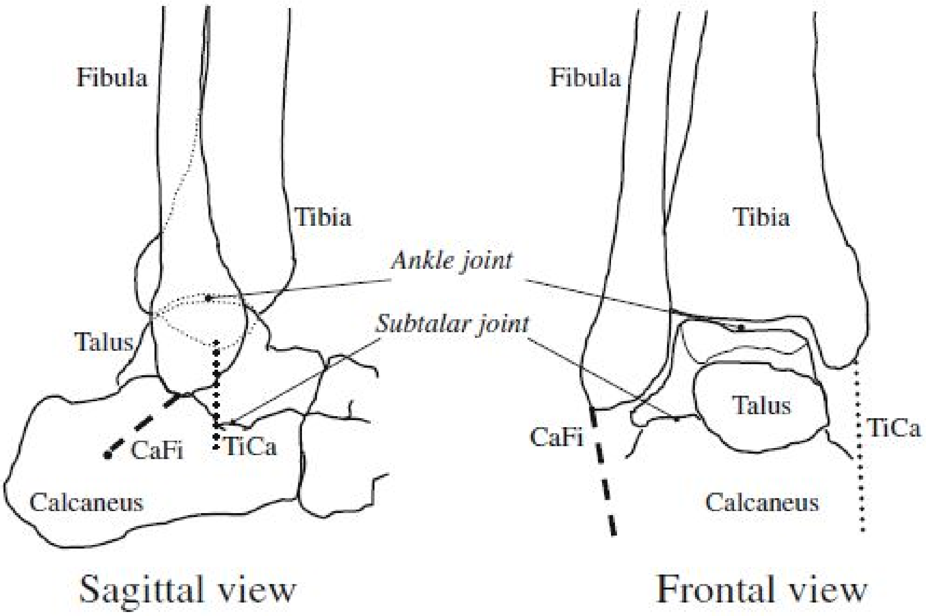

Figure 2.1: Ankle and subtalar joint anatomic difference: Sagittal and frontal views show the location of the ankle joint and the subtalar joint.
[16]

the ankle joint, even though it is part of the foot-ankle complex [19]. Figure 2.1 shows the anatomic difference between the ankle and subtalar joint.

2.1.2 Ankle biomechanics in gait

The primary motions allowed by the ankle joint are dorsiflexion and plantarflexion. The range of motion (ROM) commonly found in the literature is 20° for dorsiflexion and 50° for plantarflexion. However, there may be significant differences among individuals related to the measurement techniques and the subject characteristics.

Regarding the gait cycle, the ankle might be related to the stance phase looking closely at some of its events. In the *heel-strike* event, the ankle is in a slight plantar flexion position until the end of this segment, when the foot is completely flat over the ground. Before the *foot-flat* event, the ankle moves from the plantarflexion to dorsiflexion, during which the tibia and fibula rotate forward around the ankle, allowing the progression of the cycle. Finally, a new plantarflexion happens until getting the maximum flexion (14° to 20° approximately); this movement is related to the *heel-off* event and the beginning *toe-off* event [20],[15].

In terms of the swing phase, the foot dorsiflexion enables the foot to clean the ground, and this can avoid stumbling/tripping before the slight plantarflexion that drives to the heel-strike contact. The subtalar joint can complement this motion with an eversion/inversion rotation. Eversion movement is helpful in the midstance event and might allow the heel-off and the push-off stance phase final event [15]. .

Other ankle functions include behaving like a power dissipator, bearing approximately five times the body weight in normal walking. The ankle can also actuate as a torque generator to carry propulsion tasks out [12].

2.1.3 Neurological pathologies in the ankle

This review's main objective is to gather information about ankle rehabilitation; however, many types and causes could affect this joint. This review will focalize on neurological affection, putting special attention on those caused by a stroke. Next, some of these related ankle issues will be treated.

2.1.3.1 Spasticity

Inside all neurological episodes, spasticity is one of the most known pathologies. This affection can be caused mainly by stroke and spinal cord injury (SCI). Spasticity is defined as a pathology that includes involuntary muscle activity manifested with spams, hyperreflexia, and clonus [21]. According to Singari et al. [22], more than 60% of the population that suffers some neurological problem related to SCI and stroke could show spasticity symptoms.

Regarding the ankle and the gait cycle, it is possible to find anatomic issues in this joint. Some researchers have found spasticity problems in the ankle, such as an increased in passive ankle-related muscle stiffnes. The peak reflex torque of the ankle associated with the dorsi- and plantar flexion was more considerable in this sort of patient [21]. According to other reports, ankle spasticity contributes to increasing the swing phase and double-leg support time [23]. Therefore, this may alter the human velocity and mobility gait.

Spasticity may lead to an affliction known as *Equinovarus Deformity.* This spasticity-related pathology contracts and twists the foot inwards and laterally [24]. Anatomically, the equinovarus foot is characterized by the development of ankle dorsiflexion reduction and is often accompanied by forefoot inversion [25]. Regarding the gait cycle, the main problem of these affections is the beginning of the heel strike. In these patients, the first contact with the ground begins with the forefoot or the toes instead of the heel. This deformity also disturbs the support and the cycle balance [26].

2.1.3.2 Foot-drop

According to some reports, 20% of stroke survivors may have foot-drop after recovering [27]. Foot-drop is caused by a combination of weak dorsiflexors and an increased plantar flexor stiffness (that could be caused by neurological spasticity). In addition to affecting the gait velocity, this pathology also affects the energy expenditure of the cycle events [28]. One of the typical observations in a foot-drop patient is the stepping gait produced by a patient's intention to prevent dragging the foot [27].

2.2 Conventional gait rehabilitation therapy concepts

The rehabilitation objective is to restore the patient's physical, neurological, and psychological capacities. Supporting the affected person is one of the therapist's responsibilities due to the deficits which may not be managed clinically [29]. However, in terms of gait, the specific aim is to walk independently and perform daily life activities related to the lower limbs. Therefore, rehabilitation programs for stroke patients and other neurological issues focus mainly on walking special attention to sub-acute patients [30].

Nevertheless, rehabilitation treatments require much work, especially for lower limb recovery. These therapies often need more than three therapists to support manually patient legs and the torso to performing the training exercises. Moreover, according to Belda et al. [30], there are two crucial concepts therapists aim to apply in rehabilitation therapy. These concepts are *Motor adaptation* and *Learning*. Adaptation is defined as the modification of a movement from trail-to-trail based on error feedback. Thus, learning is the primary mechanism of behavioral adaptation. According to the last, some essential learning and motor adaptation processes are the intensity of movement demands repetitively and recognizing the discrepancy between actual and expected outcomes [30].

In this way, in literature, there is substantial evidence that patients benefit from the training programs in which functional tasks are performed directly and intensely [31]. Thus, training task-oriented can aid in natural functional recovery patterns, so adaptive strategies are needed to compensate for deteriorated body functions.

Hence, a demand to develop new techniques and methods for therapy assistance may help patients improve their daily life gait skills and recover the lost movement control due to a neurological pathology. Moreover, these techniques associated with the recent technology advances may help therapists support intensive training with this user [31].

2.3 Exoskeletons

In this section, some essential definitions regarding the development of exoskeletons will be described. The T-FLEX robotic orthosis will be mentioned as a research object in this project and its most significant advances. The control mechanisms used and the importance of complementing them will also be introduced.

2.3.1 Lower-limb Exoskeleton

As presented above, new technologies and technical strategies may help to enhance the fundamental processes in rehabilitation. In that way, exoskeleton robotic devices, also named wearable devices, have been developed as complementary tools in therapies [32]. An exoskeleton is a comprehensive technology that integrates sensing, control, and computer science to provide a wearable mechanical device [33]. According to Zhang et al., these robots are divided into four basic types: treadmill-based, orthoses, platform-based end-effector, and footplate-based end-effector exoskeletons [34]. Treadmill based exoskeleton robots are usually composed of a weight support system and runs on a treadmill through the lower-limb exoskeleton frame. Platform-based end-effector are devices that, instead of having a joint based architecture as exoskeletons, the device uses a footplate to move the leg by simulating foot movements [35]. According to Vaida et al., footplate-based end-effector devices are robotic systems that use a solution similar to that of a footplate, the difference is that these devices are generally made to exercise the different motions of the ankle joint, instead of simulating a walking pattern like footplate based structures [35].

Every exoskeleton classification has a role on a concrete pathology related to the lower limb and its selected strategy to treat it [34]. For instance, the T-FLEX device [11], the exoskeleton objective in this study, is an Active Ankle-Foot Orthosis; this classification is in the Orthesis Exoskeleton domain since this device is a technical auxiliary and therapeutic element whose primary function is to reconstruct, substitute, and correct impaired functions related to the human body biomechanics [11]. A more in-depth description will be mentioned in the next section.

2.3.2 T-FLEX device

T-FLEX is a wearable ankle exoskeleton whose main objective is to assist patients with impairment in the foot-ankle complex [11]. Some specific targets of this device are related to the pathologies discussed in section 2.1 and may be summarized in the following four items [12]:

1. Provide stability to the user.
2. Correct the pathological ankle posture.
3. Assist the dorsi-plantarflexion movements.
4. Allow the ankle motions in other planes.

As a general description of the robot hardware, it can be described from its essential characteristics. T-FLEX incorporated two fundamental pillars in its design: Bio-inspired actuation using composite tendons and the non-restriction of the ankle's movement along the other planes of motion, through a soft structure. T-FLEX owns two Dynamixel MX106-T servomotors (Robotics, Korea). Each of these motors is located in the posterior and anterior parts of the affected limb. The actuators are characterized by a torque of 1 Nm and have an ARM CORTEX-M3 microcontroller (72 MHz, 32 Bits) to connect the motors to an external device. In addition, the sensing system is made up of an Inertial Measurement Unit (IMU) BNO055 (Bosch, Germany) located in the foot tip; with this sensing system, it is possible to detect the gait phases in the Assistive mode. In addition, the robot has a Raspberry Pi 3 processing card so that the computer acquires information from the sensor, executes the control algorithms and sends the control commands to the actuators.

There are two types of modalities in the use of the T-FLEX device. The first modality is the *Therapy Mode*, and the second is the *Assistance Mode* [12]. Regarding the Therapy Mode, it consists of the execution of repetitive dorsi-plantarflexion movements, this modality also might be named Stationary Therapy. Rehabilitation programs apply this sort of mode in patients who present spasticity. Likewise, the second sort of execution, the Assistive Mode, intends to use the device during gait and other daily living activities [12].

In this study it is essential to explain the technical fundamentals for the Stationary Therapy mode. T-FLEX uses stiff filaments combined with the tendons to assist the user's dorsi-plantarflexion movements.

This device has a bidirectional system of rigid filaments that, in addition to assisting the dorsiplantar flexion movement of the ankle, allows correcting any internal or external rotation that the user presents, this without restricting the natural movement in the other planes. T-FLEX uses stiff filaments combined with tendons made of flexible materials to assist the user's dorsi-plantarflexion movements. This tendons are attached from the frontal and posterior actuators to the foot-tip and the heel, respectively. Likewise, T-FLEX includes stiff filaments to integrate both motors in the ankle movements' execution. Those elements attach the opposite actuator with the corresponding foot part. Thus, the posterior actuator aids the dorsiflexion, and the frontal actuator contributes to the plantarflexion [12]. Figure 2.2 presents graphically the T-FLEX actuation for Stationary Therapy Mode.

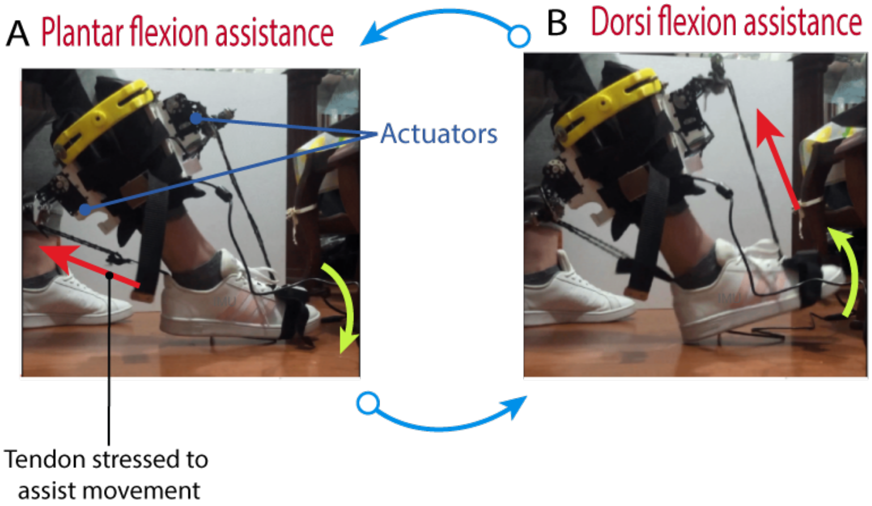

Figure 2.2: Functioning of T-FLEX in Stationary Therapy. A) The direction in which the tendon is stressed by the actuator to assist plantar flexion is shown and B) The direction in which the tendon is stressed by the actuator to assist dorsi flexion is shown. Both types of movement are performed repetitively in succession.

Regarding the results found on the use of this device, it has been observed that it improves parameters associated with the kinematics and the spatio-temporal characteristics of the patients with disabilities in the foot-ankle complex. T-FLEX has been observed to reduce dorsiflexion time in the swing phase, which improves motor control [12]. Likewise, the cadence and speed of the patients' gait have improved substantially. In addition, it was found that muscle activity increases with therapy associated with the T-FLEX device [12]. Regarding Therapy Mode findings, researches showed an improvement of motor recovery and reduced spasticity. However, despite the multiple benefits of rehabilitation with the T-FLEX orthosis, there was a lack of interaction with the rehabilitation program [11]. Therefore, it is important to develop strategies to involve the patient in the use of the device, specifically in this related mode [11].

Nevertheless, independently of the specific exoskeleton task and the patient affection, one of the most crucial features of this sort of technology is the control. As most of the exoskeletons' current paradigm, T-FLEX uses inertial sensors to involve the patient with the operational processes. The sensor integrated into T-FLEX may estimate user movement intention on the paretic foot, replacing the automatic movement in its utilization [13].

2.4 Brain-Computer Interfaces (BCI)

Brain-computer interface (BCI) is considered a relatively novel communication method between a user and a machine. This communication may work as a control system in which thoughts of the human mind are translated into real-world interactions. Some recent studies have shown a significant role in future technologies for assisting people with disabilities independently of the pathology's nature [36], [37]. In rehabilitation and assistance technologies, the ideal BCI system is when a device may be controlled as naturally as using a human body limb [38].

During the last 20 years, much research has been performed to improve the current BCI techniques available [36]. Many approaches have motivated these studies: optimization, accuracy, low-cost implementation, accessibility, among others. According to He et al. [6], there are four primary stages to construct a universal BCI system. The first one is the signal acquisition from the brain. The second one is the pre-processing stage of the signal mentioned above. The third stage refers to the processing, which includes feature extraction and decoding or translation. Finally, the last stage is the execution stage that puts the device into operation according to the human brain's intent.

However, all the previous stages have many kinds of research, set ups and configurations. In this way, the following sections will consider the most significant advances on the BCI system focused on rehabilitation and assistance, whose utility is the main object of this study.

2.4.1 Electroencephalography (EEG)

Many neurons are strongly interconnected in the brain's cortex to accomplish different tasks related to the Central Nervous System (CNS). This communication among neuronal cells implies releasing action potentials throughout receiving and processing sensory inputs from other neurons or external stimuli. EEG is the summation of all these action potentials measured at the skull surface [39].

The EEG technology may accurately measure brainwave activity [40]. The way to access this physiological data is through sensitive electrodes attached to the scalp. Usually, the collected signals are amplified to give a graph of electric potential versus time. The most common recording technique is the application of 21 electrodes and an equal number of channels. Other techniques include 256 electrodes and a number up to 64 channels [39], [40].

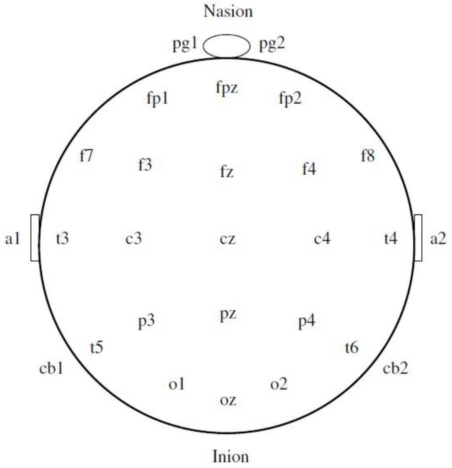

Figure 2.3: 10/20 international standardized mounting: F refers to the frontal part, C refers to the motor cortex, P refers to the parietal area, and O refers to the occipital area. [40]

Moreover, the most common EEG set-ups for measurements are performed in a standardized mounting named 10/20 system [40]; this allows the reproducibility of experiments for advances in general human brain studies. The system has the electrodes at 20° angles with each other across the middle of the skull in the hemispherical matrix and approximately 10° above the eyes [41]. Figure 2.3 shows the positioning of EEG electrodes according to the international 10/20 system. The letters F, T, C, P, and O represent the brain's anatomical region, respectively, Frontal, Temporal, Central, Parietal and Occipital.

EEG rhythm	**Frequency Band (Hz)**	**Expression**
Delta (δ)	0.5–4	• Adult slow-wave sleep. • Present in babies. • Continuous attention tasks.
Theta (θ)	4–8	• Present in parietal and temporal in young.
Alpha (α)	8–13	• Awake adults • Primarily found in the occipital region
Beta (β)	13–30	• These waves are typically identified in the frontal and central regions. • Related to movement and motor activity.
Gamma (γ)	>30	• It is the higher rhythms that have frequencies more than 30 Hz.

Table 2.1: Frequency ranges of the EEG signal with the most common expressions associated with each one [40]

Even when there are other methods for extracting the brain activity, for instance, electrocorticograms (ECoGs) [42], magnetoencephalograms (MEGs) [43], functional magnetic resonance imaging (fMRI) [44], and near-infrared spectroscopy (fNIRS) [45]; the popularity of EEG makes it widely used due to its non-invasive action, compatibility, portable and its high temporal resolution in comparison with the mentioned methods above. Nevertheless, the EEG has a weak signal and is prone to several artifacts and relatively low spatial resolution [39]. This type of signal is generally in the order of microvolts (μV) range. Moreover, many investigations have categorized the EEG signals in the frequency domain, and until now, these ranges are divided into four main categories. Table 2.1 summarized each frequency interval, which consists of alpha (α), beta (β), delta (δ), theta (θ), and gamma (γ).

2.4.2 BCI basic system

Every BCI system has a basic structure. It is necessary to clarify each notion specifically to develop an effective control system. Figure 2.4 shows the fundamentals stages mentioned above. It is essential to add that this basic diagram could change in some aspects, for instance, depending on the system design. Choi et al. [46] have decided to attach other resources to make the BCI control more effective, accessible, and optimal. Some signals could be added as hybrid BCI (h-BCI) systems or feedback sources to improve rehabilitation or assistance aspects. The following subsections will describe the general objective of each stage. Other sections below will name the most used methods and algorithms related to each phase found in the literature [47], [48].

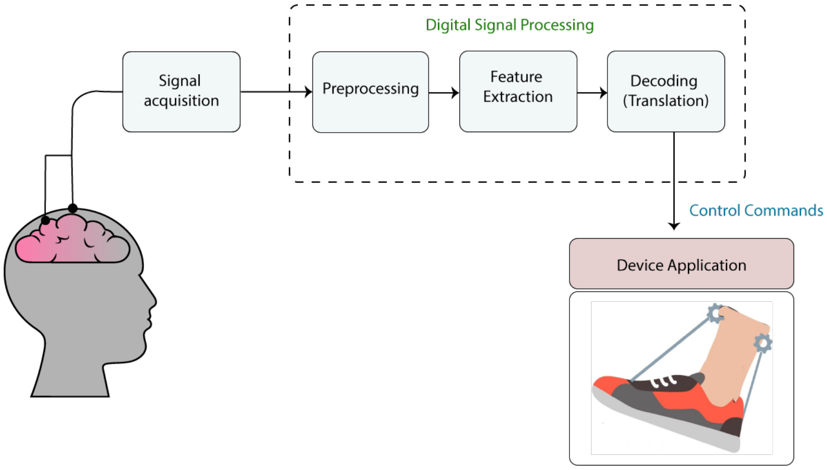

Figure 2.4: BCI basic system diagram: As a starting point we have the acquisition of signals through hardware and then the signal processing that includes pre-processing, feature extraction and decoding.

Inspired by [47]

2.4.3 Signal acquisition

As was mentioned above, EEG is the preferred tool to extract brain activity from the user. However, the signal acquisition process may be executed in numerous ways depending on the suitable BCI *modality*. These modalities could be classified into two categories exogenous and endogenous [31]. The acquisition system could not only capture brain signals with a particular electrode mounting, but it also may use external instruments as the Steady-State Visual Evoked Potential (SSVEP) to excite brain signals and perform the BCI more effectively [49]. Modalities as SSVEP and others will be described in other sections.

2.4.3.1 Endogenous modalities

An endogenous BCI system refers to a modality classification. EEG acquisition is produced independently from an external stimulation; meanly, it may entirely be managed voluntarily by the user. This modality is mainly applied to subjects who have neurological issues [31]. In

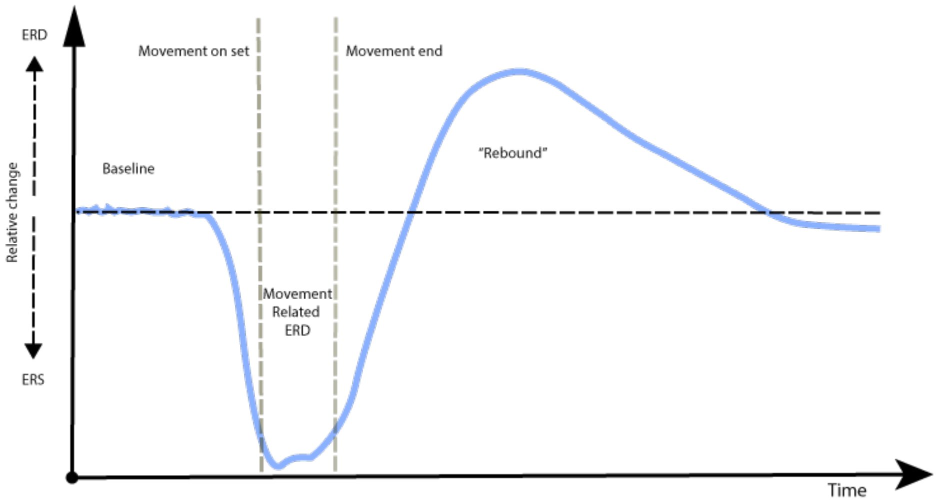

Figure 2.5: ERD/ERS power behavior
Inspired by [55]

this manner, the BCI could offer a more natural and spontaneous way of interaction. Neuroplasticity, for instance, is a fundamental feature that may be improved with an endogenous modality [50]. According to Cramer et al. [51] neuroplasticity is defined as the ability of the nervous system to respond to intrinsic or extrinsic stimuli by reorganizing its structure, function and connections. Endogenous systems may generate an improvement on this feature by a BCI training [52].

- **Event-Related Desynchronization/Synchronization (ERD/ERS)**

The ERD/ERS modality works based on the behavior of brain signals and motor intent. Frequency bands may show a power increasing or decreasing when a subject imagines or executes a lower movement. The signal amplitude is proportional to the number of active neurons; it is believed that the increasing/decreasing power EEG register is caused by desynchronization and synchronization of the neuron population [8]. to detect the ERD/ERS process, the EEG signal has to be analyzed in the frequency domain, focusing on those bands associated with the movement: μ (8-12 Hz), β (16-24 Hz), and γ (>30 Hz) [8].

It has been observed that in the study of the power of the beta signal there is a phenomenon of 'rebound' [53] , which is a considerable and abrupt increase in the power of the signal just when the movement of the lower limb ends. This behavior can be contrasted with the imagination of movement which behaves similarly way. Therefore, the methods to detect lower limb MI with ERD / ERS usually focus on the power of the beta band of the EEG cortical zone, where this mentioned increase in power would indicate MI [54].

Even with the extensive evidence about the differences that make possible the MI modality, some authors as Duan et al. [48] remark there are still some issues with this strategy that is necessary to improve. One of them is the large intersubject variability concerning the characteristics of the EEG signals. Another problem found in the literature is regular use; namely, some subjects cannot execute this modality [56]. Moreover, Emami et al. [57] have made findings of the significant role of the distractor factors on BCI performance. Therefore, an extensive training process is imperative, and this a high cost in terms of effectiveness in therapy.

Nevertheless, the ERD/ERS modality is a suitable alternative that could improve with some aggregates. Some studies [58] reinforce this idea by including other signals, feedback systems, and even other modalities. In the following sections, h-BCI, a combination of modalities systems, and their advances will be described according to the literature.

- **Movement-Related Cortical Potentials (MRCPs)**

The MRCP modality is based on a set of power variations in the cortical activity before and after the movement execution. Its registration is performed in the time domain. There are two crucial components for the MRCP study, the Bereitschaft Potentials (BP) and Motor Potentials (MP) [59]. Likewise, BPs are classified into two types: early potentials and late potentials. They generally appear between 1 and 2 s before the movement's beginning in terms of early potentials [59]. These potentials are bilateral, symmetric, and may reach a maximum amplitude over the vertex (Cz). Alfonso et al. [50] remark that there are no significant differences between the early potentials when the subject performs a movement and imagery motion. On the other hand, late BP potentials usually start before 500 ms of the movement's beginning [50]. Moreover, the MP component is associated with the motion execution, and its region is predominantly found in the primary contralateral motor area [59].

2.4.3.2 Exogenous modalities

Likewise, an exogenous BCI refers to the generation of external stimuli to add more effectiveness. There are many types of stimuli; in the literature, the most common are auditory and visual [31]. Other advantages imply simple training strategies compared with the endogenous modalities, necessary for the subject to drive suitably the BCI system. Other authors have named these alternatives as reactive systems. Nevertheless, one issue found is that the subject cannot manage the entire device by himself and is dependent on external conditions.

- **Steady-State Visual Evoked Potential (SSVEP)**

The SSVEP is an exogenous system based on a set of multiple visual stimuli, such as LEDs or figures on a computer screen [60]. The main characteristic of these stimuli is a significant frequency variation capacity. It has to be a concentration state from part of the subject on the object that elicits the stimulation frequency in the EEG. When the retina is excited by the system between the suitable frequency range (3.5-75 Hz), the brain generates electrical activity approximately at the same interval of frequency [61]. Figure 2.6 shows this system clearly.

- **Event-Related Potential: P300**

This exogenous system is a specific type of Event-Related Potential (ERP). Generally, P300 is a positive deflection in the EEG signal, which appears approximately 300 ms after presenting an attended stimulus. P300 has numerous and vital components as amplitude, energy, latency, among others. Every component could reflect different features: attention, speed stimuli reception, error awareness, and memory performance [62]. For instance, psychic

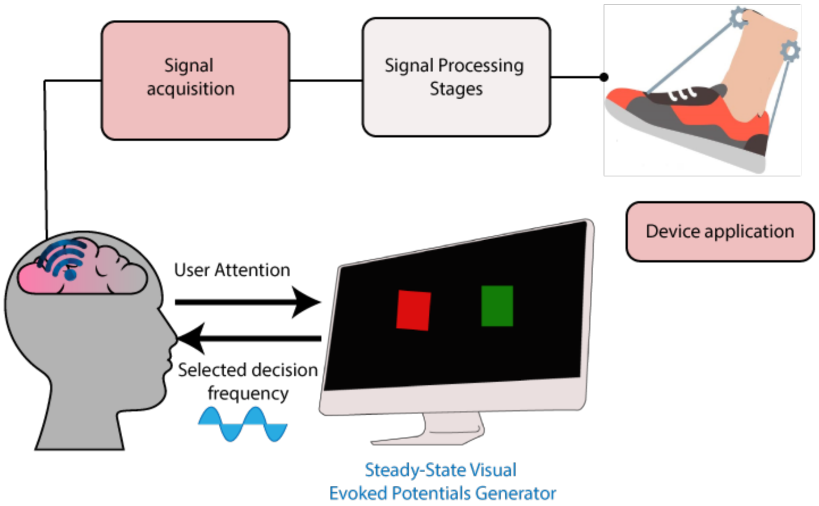

Figure 2.6: SSVEP basic system: In addition to the basic system explained above, the emission of signals at a specific frequency is added as visual stimulation.
Inspired by [60]

health is associated with the P300 amplitude [63]. In BCI applications, a set of stimuli is presented to the subject similar to the SSVEP. Usually, some selection objects are delivered on a screen; the subject has to focus on the selected item and ignore the rest.

2.4.3.3 Hybrid modalities (h-BCI)

Between h-BCI modalities, there are two categories, system hybrid and signal hybrid modality. The process could be sequentially or simultaneously. According to Hong et al., there are three objectives for implementing an h-BCI [64]. The first one is to enhance classification accuracy. The second is to increase the number of brain commands for control application. Finally, the third objective is to achieve a shortened brain-command detection time.

- **EMG-EEG BCI**

EMG signals indicate muscles' electrical activity, which changes when a voluntary or not voluntary contraction appears. Therefore, EMG signal confirms a detection system for muscular movement [64]. The incorporation of EMG with EEG signals depends on the task the subject performs. For instance, Rohm [65] combined an EMG acquisition with a conventional BCI to manage a neuro-prosthetic arm. Some research found an increase of accuracy in an IM-based BCI by EMG [64]. In any case, EMG control is used as an additional control system in terms of biomechanical action. For instance, the detection of laterality could be reliable with an EMG-based h-BCI modality [64]. Balasubramanian et al. [66] also add other advantages as detecting biomechanical freedom degrees, which could be quite complicated with only an EEG-based system.

This system has been proposed for tetraplegic patients. Even when a slow response defined these experiments' results, they affirm that the h-BCI with EMG is a promising alternative for rehabilitation therapies [67]. Other authors carried some studies that conclude that stroke patients have optimal conditions to use devices controlled by this type of h-BCI system [66].

- **ERD/ERS-SSVEP BCI**

As mentioned above, one part of the population is not eligible for using an ERD/ERS-based BCI. Some authors, like Ko et al., suggest that this problem, even when it is related to an inability or insufficiency in technological terms, other issues are linked with the intrinsic characteristics of the user [68]. Therefore, to enhance this structure but conserve the user's implication, an h-BCI could combine both ERD/ERS and SSVEP modalities. Bunner et al. have achieved a high accuracy system carrying this proposal out [69]. Other authors have done experiments with this implementation, concluding that this modality does not need an exhaustive training process. Moreover, according to some studies, this modality could reduce the non-legible population by 20% [70].

2.4.4 Pre-processing

Once a set of signals are obtained, it is necessary to consider that this set is entirely raw and full of artifacts depending on the technology used for this objective, the environment, and the user's physical conditions [71]. Therefore, denoising and cleaning the data is a widely studied process that already has numerous advances.

Noise related to the hardware is generally presented due to instrument degradation, electrode wear, interference, among others. According to Tariq et al. [56], most of these problems could be managed through digital filters as a notch filter. Another concern in the pre-processing stage is physiological activities such as skin impedance fluctuations, other electrical activities as Electrooculogram (EOG), EMG, and Electrocardiogram (EKG) supposes a problem in the EEG signal acquisition. An effective way to eliminate these artifacts is still the use of frequency filtering. However, according to the literature, some other methods have been tested, such as Filter Bank Common Spatial Patterns (FBCSP), independent component analysis (ICA), principal component analysis (PCA), non-linear adaptive filtering, and dipole analysis.

2.4.5 Feature extraction

After the signal pre-processing, this stage oversees classifying as many features as the BCI system requires. Some BCIs are based on Motor Imagery (MI) [8]; this modality is related to specific frequency bands. Therefore, its use depends on the suitable method to characterize these specific ranges for future decoding to build a set of commands necessary to control the target device [72].

Numerous feature extraction methods have been studied in BCI systems. However, these strategies depend on the modality structure. According to Medina et al. [73] and Lotte et al. [74], the extraction methods could divide into three categories: (i) Time-domain analysis, (ii) Frequency-domain analysis, (iii) Time-frequency domain analysis, and (iv) Spatial complimentary analysis.

One of the most used methods is instantaneous statistics and autoregressive methods (AA) in a time-domain analysis. For its part, AA may be categorized in two methods: Autoregressive Adaptative models (AAR) and multivariable models (MVAR) [73]. Likewise, frequency-domain methods include Fourier Fast Transform analysis, Short Time Fourier Transform

(STFT), and Power Spectral analysis [73]. Frequency-time techniques, for their part, may span Wavelet Transform and Hibert-Huang Transform (HHT). The fourth classification is the Common Spatial Patterns and has been widely used according to Medina et al. [73].

2.4.6 Decoding

The feature extraction layer formed a set of classification that the decoding stage uses to identify the intent brain signals, namely, manipulate the robotic device via machine-understandable commands for interfacing. This last processing stage implies another classification in terms of execution. Some of them are extensively studied due to the lack of efficacy for some tasks [31]. Methods as Support Vector Machine (SMV) or Linear Discriminant Analysis (LDA) will be generally described in the following sections.

Among the decoding, classification algorithms have been used according to Tariq et al.[56]. Previous to the BCI use itself, these algorithms could be calibrated via supervised or unsupervised learning during the training stage, prior to the BCI use. The system generally works by making a weighted class estimate, presented by a feature vector for mapping the desired driving application command. Some of these strategies are Linear Discriminant Analysis (LDA), Support Vector Machine (SVM), Gaussian Mixture Model (GMM), and Artificial Neural Network (ANN).

2.5 Related Works

Twelve papers related to a lower-limb exoskeleton controlled by a BCI system were found according to the literature review process proposed below (see Figure 2.7). The information gathered here was extracted from databases such as Pubmed, Google Scholar, and IEEE Xplore. Moreover, the selected criteria were mainly at least one clinical assessment in patients with lower-limb impairment and specific exposition of signal processing stages. It was also considered that the publications were updated in the last ten years (from 2011). Given the interest of this study to develop a BCI integrated into an Ankle-Foot device, the studies found related in any way to this subject will be included. Table 2.2 summarizes the principal data found in the research for each exoskeleton with a BCI integrated system.

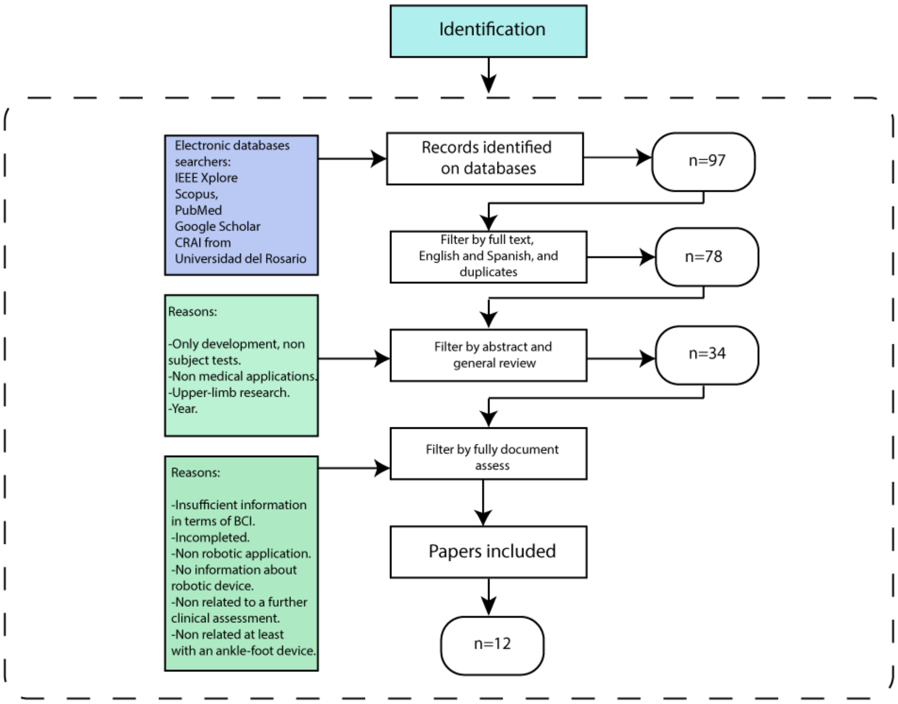

Figure 2.7: Literature review flow chart of articles on BCI system development with medical applications criteria

2.5.1 Lokomat

Lokomat is a robotic treadmill exoskeleton to automate locomotion training for spinal cord injured and stroke patients [75]. BCI system in Lokomat device was researched with a motivation based on the subject participation. Initially, this orthosis worked in a training mode where the device influenced the subject's motion with a fixed gait pattern [75], [76]. Even when some reports conclude this causes greater coordination of the muscles and the neuromotor system, BCI became an alternative to improving the device.

Donatti et al. shows some clinical assessments [77]. Eight (8) chronic spinal cord injury (SCI) paraplegics were subjected to long-term training with a multi-stage BCI-based gait neurorehabilitation paradigm aimed at restoring locomotion. The BCI system modality was the MRCP. For preprocessing stage, the Common Average Patterns method was used, including conventional digital filters for denoising. Moreover, the decoding process was based on LDA methods.

The methodology of these authors was composed of six parts. They decided to familiarize the BCI with a tactile feedback system while the patient is in a wheelchair (i). Then this same familiarization continued in an orthostatic position supported by a stand-in table (ii). Without using a BCI, they began conventional training with the Lokomat device, which includes body weight support (BWS) in the treadmill (iii). Then a BWS training was continued without Lokomat's joint support (iv). Finally, in sections (v) and (vi), the BCI was integrated into the gait training system supported by the tactile feedback system (on treadmill and overground, respectively). Figure 2.8 shows the set up included in steps (v) and (vi).

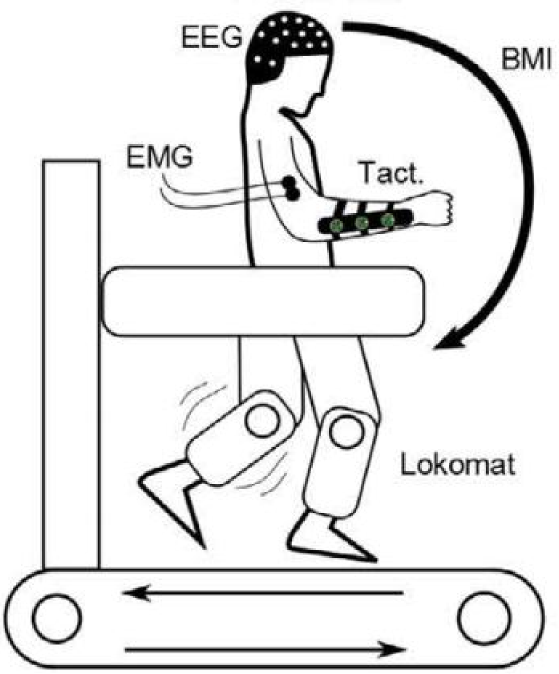

Figure 2.8: BCI system set up to control Lokomat device [77]

After one year of training in the Lokomat BCI system, all eight subjects improved neurological motion and somatic sensation as pain and proprioceptive sensing. In terms of neuroplasticity, the research showed no significant differences between a desynchronization and synchronization of the beta wave from an event-related potential analysis at the onset of the training therapy period. However, after ten months of therapy this synchronization differences were observed in all patients. In terms of anatomic improvements, all patients exhibited a complete ROM of the joints and a maximal grade of lower limb spasticity of 2 on the Ashworth scale. Furthermore, a test provided by Lokomat developers known as L-stiff was used. This test is in charge of quantifying the spasticity of hip and knee muscles for flexors and extensors. Thus, on average, all patients exhibited a reduced spasticity level by the end of 12 months.

2.5.2 RoGo

RoGo is a robotic gait orthosis addressed to Spinal Cord Injury (SCI) patients and developed at the University of California in the United States [78]. This orthosis has been studied mainly with the BCI system control [78]–[80]. The BCI modality used in the investigation includes ERD/ERS induced by the kinaesthetic motor imagination of the left hand, right hand, and feet. The preprocessing method is briefly described by Wang et al. and includes an EEG prediction model that excludes those EEG channels with excessive artifacts [80]. Two states were defined in the feature extraction method, Idling and Walking states. Then this data was transformed in the domain frequency and their Power Spectral Densities. Moreover, a PCA algorithm was applied to reduce the data dimension. Finally, the researchers use the AIDA method to classify the commands to RoGo. Serious games have been implemented before a complete integration to the rehabilitation device. For instance, one experiment proposed to drive an avatar that expects to stop with a specific indication. The results gathered all the correct and wrong attempts and showed an 85% accuracy.

This system was assessed in a study by Do et al. [78] with a clinical assessment where patients with SCI impairments and one healthy subject were compared. The performance of this system was assessed by calculating the cross-correlation and latency between the computerized cues and BCI-RoGO response and, the omission and false alarm rates. The methodological protocol consisted of three divisions: active walking (subject voluntarily walks while the RoGO servos are turned off); cooperative walking (subject walks synergistically with the RoGO); and passive walking (the subject is fully relaxed while the RoGO makes walking movements). Those different training stages were helpful in set baseline values for EMG and EEG. Furthermore, instructional cues were indicated on an eye-level monitor. Figure 2.9 shows the experimental set up of this study. Finally, the accuracy of the EEG prediction model averaged 86.30% across both subjects. The cross-correlation between instructional cues and the BCI-RoGO walking epochs averaged across all subjects, and all sessions were 0.812. Also, there were, on average, 0.8 false alarms per session and no omissions.

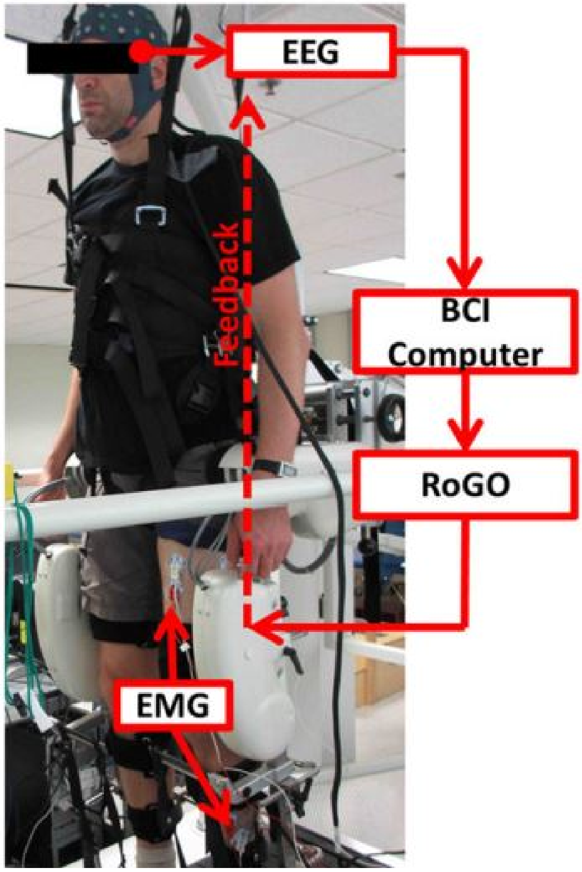
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Figure 2.9: BCI system set up to control and evaluate RoGo device [78]

2.5.3 H2

H2 exoskeleton was developed in Spain and is addressed to stroke patients with gait impairments [81]. This device is aimed to assist and rehabilitate patients with suitable walking in a natural environment. According to the researchers, the exoskeleton has six joints, including the hip, knee, and ankle. Moreover, H2 presents an open architecture that allows modifications in the control system. This advantage is supposed to improve the device; thus, researchers have implemented a BCI control system [82], [83]. Lopez-Laraz et al. [84] implemented this paradigm with ERD/ERS-MRCP hybrid modality. Preprocessing methods are based on an automated procedure based on z-scores to eliminate the trials containing artifacts and conventional denoising filters. In terms of feature extraction, on the one hand, the ERD features were calculated after applying a small Laplacian filter to the frontocentral, central, and centroparietal EEG channels. On the other hand, the Common Average Referencing method was used for the MRCP modality. For the decoding process, a strategy named Sparse Discriminant Analysis (SDA) was used.

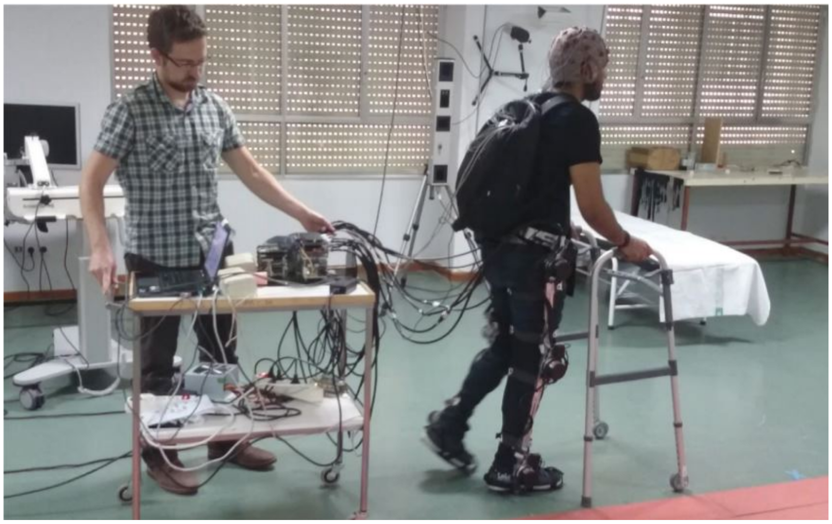


Figure 2.10: BCI system set up to control and evaluate H2 device [84]

López-Laraz et al. [84]. published an article with a clinical assessment in 2016. Three (3) healthy subjects and four (4) SCI patients were tested. The basic system uses the BCI described above to trigger exoskeletons' assistive motion. Figure 2.10 shows the set up performed by the authors. Factors as fatigue and exertion level was assessed, usability, and user satisfaction. Results concluded for healthy subjects with approximately 84% of accuracy, and SCI subjects 77%. On average, 55% and 40% of the trials (for healthy subjects and patients, respectively) have suffered unexpected activations without the proposed control strategy.

2.5.4 REX

Rex is an exoskeleton produced in New Zealand. This device's main aim is to assist rehabilitation and mobility for those with neurological and spinal injuries [85]. Rex has been developed for private users that can now perform tasks that are not possible when sitting in a wheelchair. Specifically, the exoskeleton aids the patient to improve git patterns and movement for standing and sitting [86]. A joystick system initially drove Rex, but to include this device in the rehabilitation field, some BCI systems were designed [87] .

Zhang et al.[87] made an investigation with MRCP-based BCI implemented on the REX exoskeleton. The authors included a filter in the 0.1–2 Hz range in terms of the pre-processing stage using a second-order Butterworth filter and standardized z-score method. In the feature extraction stage, isolation of the delta band was carried out. For the classification stage, a Multiple Kernel Learning (MKL) was used and compared with the SMV algorithm, where they conclude MKL was more suitable for the system. A clinical assessment was performed in this paper. Two (2) subjects tested the system, one healthy subject and one with SCI impairment. Results conclude that the frontal/fronto-central regions were the most critical regions for classifying gait states of the tested subjects, consistent with the brain regions hypothesized to control lower-limb movements. Moreover, the classification accuracy increased, and the findings suggest cortical plasticity triggered by the BCI use. Figure 2.11 shows the set up used for this study.

Figure 2.11: BCI system set up to control and evaluate REX device [87]

2.6 Ankle-Foot related works

In this section recent works on developing BCI systems focused on the Foot-Ankle complex will be described. The papers found that focus exclusively on the ankle-foot complex were the works of Xu et al. and Do et al., which are explained in the following sections.

Robotic Technology with BCI	Joints Implicated	Modality /Paradigm	Pre-processing Methods	Feature Extraction Methods	Decoding Methods	Participants	Main Results
Lokomat [75]–[77]	-Hip -Knee -Ankle	MRCP	-Common Average Patterns -Temporal Filters	N/I*	-LDA	8 SCI patients	-Neuroplasticity generation observed from significant beta wave De/Synchronization. -The patients exhibit complete ROM joint safter therapy. -Spasticity reduced
RoGO [78]–[80]	-Hip -Knee -Ankle	ERD/ERS -Serious games for feedback	-Own Prediction Channels Method	-Frequency analysis -PSD -PDA	-AIDA	-1 healthy subject and 1 SCI patients	- 85% BCI commands accuracy - 0.812 correlation between natural movement and BCI MI detection. -Average of 0.8 false alarms in BCI commands. -No omissions in BCI commands
H2 [81], [82], [84]	-Hip -Knee -Ankle	h-BCI: -ERD/ERS -MRCP	-Z-scores method -Temporal filters	-Laplacian spatial filter -Common Average Patterns	-SDA	-3 healthy subjects and 4 SCI subjects	- 84% accuracy commands for healthy subject. - 77% accuracy for SCI patient -55% false alarms commands or healthy subjects -40% false alarms command for SCI patients. -No omissions in any case
Rex [85]–[87]	-Hip -Knee -Ankle	MRCP	Z-scoresmethod. -Temporalfilters	-Own method for isolation of delta wave.	-MKL	-1 healthy subject and 1 SCI patient	-A rise of accuracy BCI commands from 60% to 90%
MAFO [88]	-Ankle	MRCP	-Spatial Filters -Temporal Filters	-Local Preserving Projection	-LDA	-10 Healthy subjects	-73% accuracy reported. -Feasible Plasticity Induction
H2 Ankle Orthosis [89]	-Ankle	ERS/ERD FES feedback	-Temporal Filters	-PSD	-Own Classification Method	-5 Healthy subjects	100% BCI-FES response (no omissions) -Only one subject had 1 false alarm

Table 2.2: Comparison of the paradigms, characteristics and results of the BCI systems applied to exoskeletons found in the literature review.

2.6.1 MAFO

This study was carried out by Xu et al. [88] where a BCI system was applied to the MAFO Foot-Ankle orthosis. The mentioned orthosis allows the assistance of the ankle dorsiflexion movement. The objective of this research was focused on the evaluation of the functionality of the BCI system commands and the verification of an increase in neuroplasticity in the subject. The paradigm chosen by the researchers was MRCP. Spatial filters and temporal filters were used as pre-processing. The processing means were defined by a Locality Preserving Projection (LPP) method in conjunction with the LDA decoding method.

The set up used included two EEG acquisitions (see Figure 2.12). One related to the monitoring of the activity of the motor cortex and another related to the classification of commands that were subsequently interpreted by the orthosis control system. The BCI system was evaluated through the manifestation of the subject on possible false commands or omissions. The rate of accurate detections was measured along with the rate of false commands per minute. In addition, subject monitoring was evaluated to verify her motor activity concerning MI. The results yielded 73% accuracy in the general system, weighting the values described. In terms of the induced plasticity, it was determined that there were significant differences before and after the tests that demonstrated induction of neuroplasticity in the subjects' cortical zone.

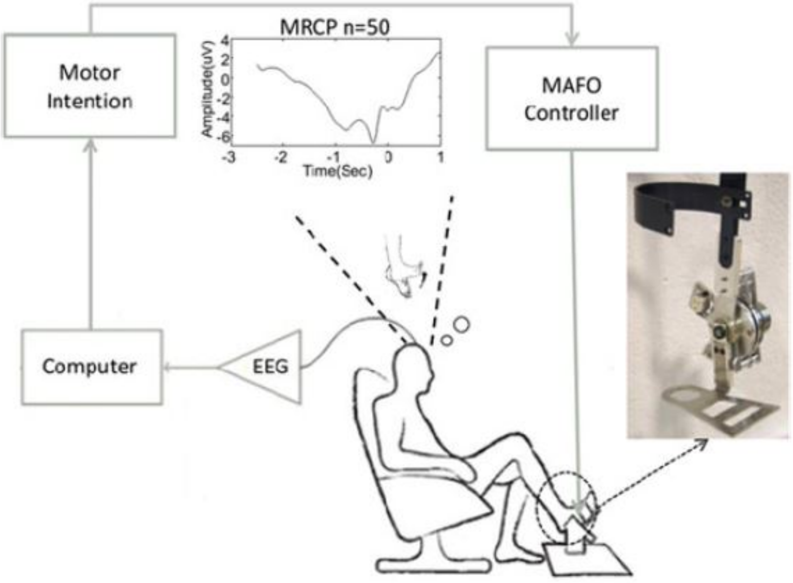


Figure 2.12: BCI system set up to control and evaluate MAFO device [88]

2.6.2 H2 Foot-Ankle Orthosis

This research led by Do et al. [89] does not include a robotic orthosis directly, but it is part of the research project that wants to improve the H2 orthosis mentioned above. However, according to the research carried out, reports of this integration has not yet been carried out. Thus, a BCI system was integrated into a functional electrical stimulation (FES) system, which potentially allows a robotic orthosis to be controlled in its dorsiflexion movement and, therefore, act like one. The details of the set-up are shown in Figure 2.13. The digital processing of the signals was not described in detail, so they were limited to showing the acquisition process and the tests with the subject.

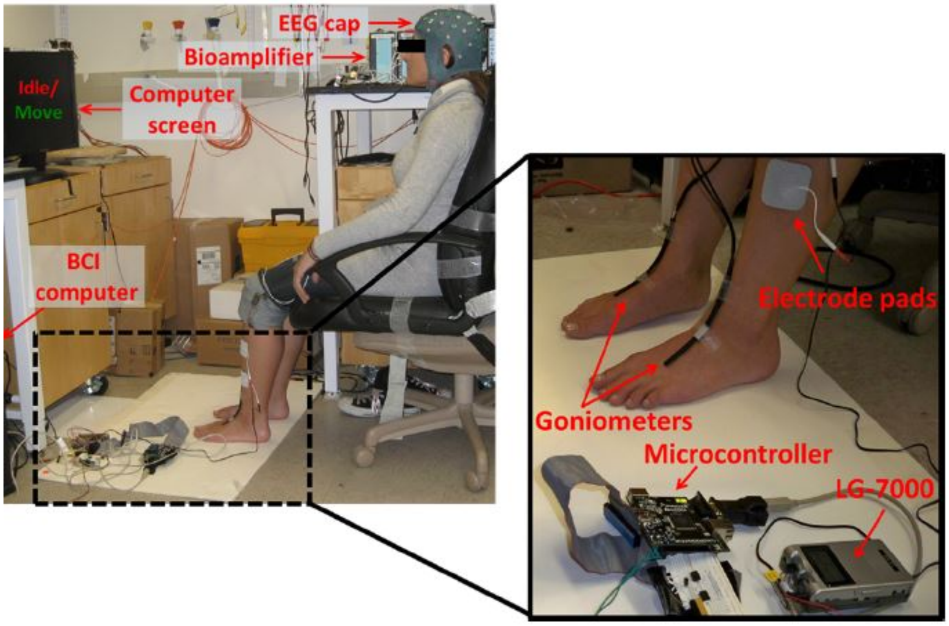


Figure 2.13: BCI system set up to control and evaluate Do et al. FES system. At the right FES system equipment. At the left the complete experiment set-up [89].

Five healthy subjects were evaluated, executing ten repetitions interspersed between dorsiflexion and relaxation. The BCI commands were intended to trigger the assistance caused by the FES system. The subject received signals to perform MI or remain at rest, with which the results of the system's functionality were observed. The results showed a correlation between the commands and the signals given to the subject of 0.77. Latencies were measured between the ranges of 1.4 s to 3.1 s. Furthermore, no omissions were evidenced and only one subject had one false alarm.

Chapter 3

METHODOLOGY

This chapter will present the different procedures carried out for the integration of the BCI system with T-FLEX. To achieve this objective the project was divided into four main phases. The first is the design of the BCI system (BCI Design) based on methodologies consulted in the literature applied to OpenVibe software. The second phase of the complete integration is the communication of the system with the T-FLEX device, whose operation will be linked through the commands produced by the BCI acquisition structure. The final stages are the characterization tests of the system with subjects who were patients with neurological lesions that affect mobility in lower limbs, and, finally, the characteristics related to the operation of the BCI system and its involvement with the user in terms of their subjective experience when interacting with it will be presented. Figure 3.1 represents the general methodology for this project.

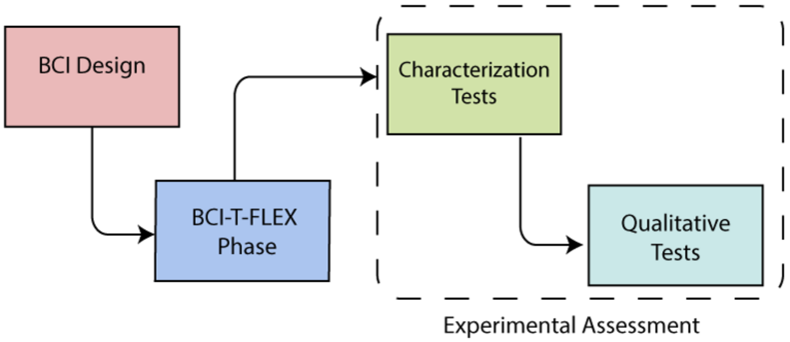


Figure 3.1: Main phases selected for carrying out a suitable and functional BCI system integration.

3.1 BCI Design

In this first methodological section, the design of the BCI is presented, which was carried out through the steps outlined in state of the art. This process was divided into pre-processing, feature extraction, and decoding, and was done through the OpenVibe software (Inria Rennes, France).

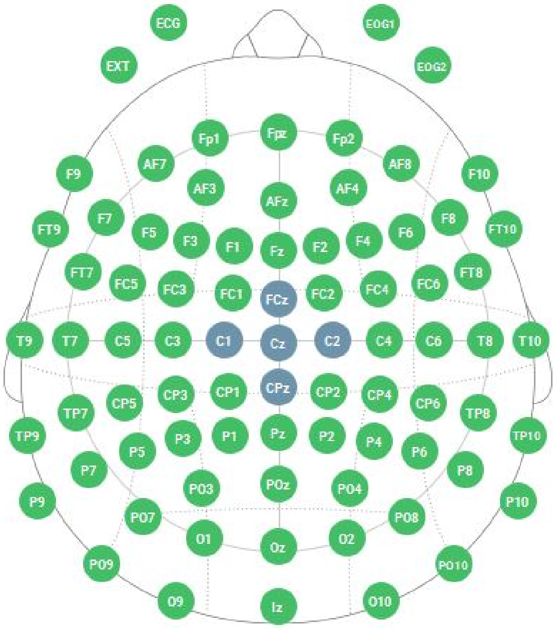


Figure 3.2: Laplacian was montage selected for performing the EEG signal acquisition. In blue the electrodes were chosen according to the methodology described above. In green electrodes are not used.

3.1.1 EEG signal acquisition

To adequately expose the EEG acquisition process, it is necessary to start from the modality in which the system will perform. In this project it was essential to send commands to an external application with MI. This objective was achieved from the extraction of characteristics located in the activity of the beta power, whose frequency range in this application is from 16 to 24 Hz according to Clerc et al. [54]. Therefore, the modality chosen was the beta ERS, paying particular attention to the beta rebound. According to the referenced authors, during foot movement there is an inhibition of this frequency band power. However, at the end of this movement there is an abrupt and considerable increase in power, followed by a short latency period to return to the initial power level.

The acquisition system was achieved through *Enobio 20* hardware (Neroelectrics, Spain). This hardware was linked through the *NIC 2.0* software tool from the same developer. The union of these tools allowed the motor cortex recording. The montage established in the software was a Laplacian type. This type of set up uses multiple electrodes at once as a reference. A single output channel can be the neighbor electrode average of a specific electrode. These montages are widely used for highly focused analysis and emphasize waveforms by filtering out the surrounding activity [90]. In this case, the acquisition protocol took as reference the Cz electrode of the international system 10-20. In this way, the output was the average of the acquisition channels C1, C2, FCz, and CPz, which will help to improve the Cz signal. The assembly is shown in Figure 3.2.

Once the raw signal is acquired through the software, it is connected to a local server capable of transferring this data to the pre-processing, feature extraction, and decoding system. OpenVibe (Inria Rennes, France) is an open-use program that allows the implementation of different BCI modalities and exogenous and endogenous origin paradigms. According to the creators, the interfaces in OpenVibe reach a speed of up to 1 selection per 5 seconds with a selection accuracy of up to 70% in MI [91]. However, the developers emphasize that this data is general so that, the results may vary depending on each user. In addition, OpenVibe has developed external neurofeedback applications that make possible the potential of this tool for a medical environment [91].

The OpenVibe software uses a system of 'boxes' within specific environments, also called scenarios. These scenarios can be modifiable both online and offline. Functions such as digital filters, operators, and the definition of thresholds are applicable in this box system. It is possible to digitally process a raw signal such as the one obtained from the EEG from Neuroelectrics equipment.

As mentioned, preliminary signals for the development of the BCI were obtained through an acquisition server. The data obtained could be remotely analyzed with a box called 'Generic Writer' capable of recording the signal and simulating it in other scenarios. As indicated, the acquisition and its protocols were carried out in Chile, therefore, it was necessary to use the Generic Writer function to be able to use real signals remotely and to design the experimental protocols.

3.1.2 Pre-processing

The pre-processing method was divided into two stages. The first one is applying of a Laplacian filter, and the second one is based on a temporal filter. These implementations are described in more detail below.

3.1.2.1 Laplacian Spatial Filter

This spatial filter calculates the second derivative of the instantaneous spatial voltage distribution for each electrode, and therefore focuses the activity originating from radial sources immediately below the electrode [92]. This tool highlights localized activity and reduces poorly defined activity. This filter can create the best possible linear combination of the electrodes used to obtain a signal with less noise and maximized utility in the data [93]. In this case, the OpenVibe box multiplies the input signals by spatial filters represented by a matrix (parameter spatial filter coefficient of the box). This matrix represents the weights to be given to each input sensor. Here, the weights -1 are applied to Fcz, C1, C2 and Cpz and 4 to Cz to perform a Laplacian filter

3.1.2.2 Temporal Filter

This filter was applied conventionally as a Butterworth-type band-pass filter, order 100 and with a 0.5 dB band ripple, according to the recommendations of Clerc et al. [54]. Consequently, with the frequency range of the beta wave, whose behavior is essential for applying the ERS/ERD paradigm, the lower and upper cutoff frequencies were 16 and 24 Hz [54], respectively.

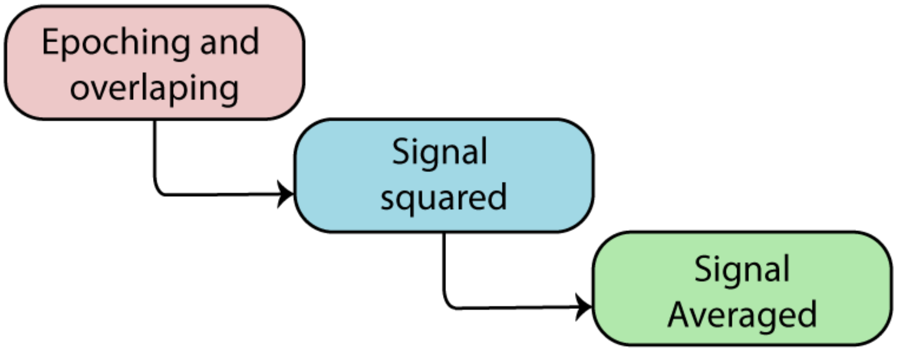


Figure 3.3: General scheme for the feature extraction necessary for the design of the BCI proposal

3.1.3 Feature extraction

For the extraction of characteristics, it is necessary to remember that what is required to obtain is a signal as straightforward as possible, representing the behavior of the beta wave in its periods of motor synchronization and desynchronization.

Following the methodology proposed by Clerc et al. [54] the signal strength was obtained in three steps (see Figure 3.3). All the digital processing methodology was done with the functions available in OpenVibe. The first one (i) consisted of decomposing the filtered signal into 1 s long epochs with an overlap of 100 ms between two consecutive epochs. The second step (ii) was the signal square operation. The third step (iii) consisted of calculating the signal's average over the input epoch. The average of the signal was calculated for each interval of 1 s received from the previous step.

3.1.4 Decoding

For the decoding process, it was decided to crop the signal to a minimum value. The minimum value was obtained after a calibration period of 5 minutes and from which the average plus three times the standard deviation is taken as indicated in the Equation 3.1, where $\overline{x}$ is the average of the signal and σ is the standard deviation of the signal over the specified interval [54]. In addition to this crop, it was decided to remove the offset of the signal by subtracting the minimum value obtained. Then the signal was referenced to this threshold value, so that the potentials detected below the said value are taken as zero, while those that exceed it would be considered potentials of motion intend; this was achieved by subtracting the calculated threshold power from the cut signal. Consequently, there is a proportionality between the intensity of movement and the potential magnitude generated by the beta rebound.

It is important to highlight that some authors conclude limitations in the threshold decoding system, Bauer and Gharabaghi [94] affirm that this classification method can be susceptible to a lack of functionality on the part of some users, this is an inability to generate electrical activity necessary to operate a BCI. On the other hand, Pfurtscheller [95] has stated that the thresholding of the beta rebound may have limitations in the reaction time for the applications, that is, the data transfer speed with which certain applications are carried out may be insufficient with this methodology.

$$Th_{min} = \overline{x} + 3\sqrt{\sigma^2} \tag{3.1}$$

3.2 BCI-T-FLEX

The tools used to communicate the designed interface with the robotic orthosis are based on the same threshold crossing associated with the application tested on OpenVibe. Once these MI thresholds are exceeded, OpenVibe will send command instructions to the robotic device. However, this communication is carried out differently and requires two sections. (i) An output of the OpenVibe software to a local server and (ii) a delivery of data from the local server to the external server of the robot controller. Figure 3.4 shows a graphical representation of this communication. To explain this process in more detail, it is necessary to clarify the operation of the robotic orthosis.

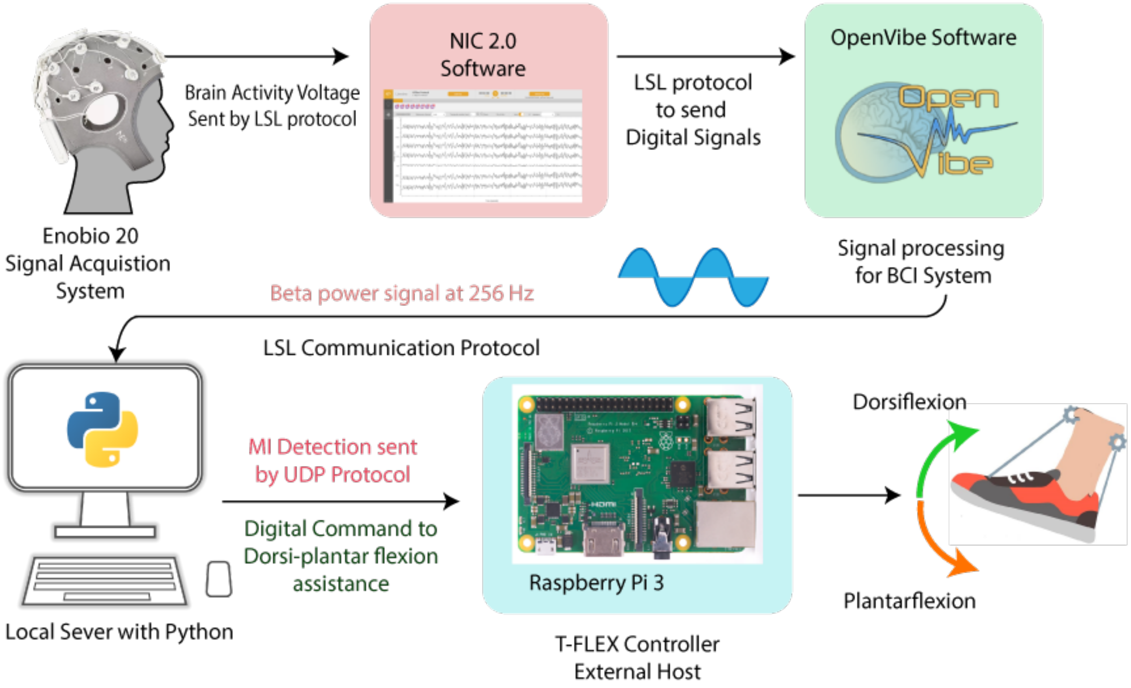


Figure 3.4: Diagram that ilustrates the communication protocol involved into the integration to the BCI-TFLEX system

The general fundamentals for the T-FLEX device as a tool for the rehabilitation field have already been explained in previous sections. In this case, technical details are essential to carry out the objectives of this project properly. Thus, in this specific project the control by IMU will be disabled, so that the reading of the movement intention is obtained through the BCI system. This system will send data continuously to the Raspberry Pi 3, with which the orthosis will have a control reference that will start the actuation system. In terms of the software, the implemented system is based on the Robot Operative System (ROS) architecture. Within this framework, the controllers, algorithms, and sensor acquisitions were deployed and implemented.

3.2.1 OpenVibe to Local Server Connection

This communication section is essential not only to carry out communication from the BCI to the robot. Still, it will also be the control base for the Stationary Therapy mediated by this system. The local server is intended to act as a mediator interface between the user and the robot. The details of this component will be explained in the Section 3.3. For this data extraction, the Lab Streaming Layer (LSL) protocol is used. OpenVibe uses a native LSL system, in which it is necessary to specify a name of a transmission channel and the type of signal to be sent. Once this channel was configured in the OpenVibe box system, a local server was created in Python, whose objective was to receive the transmission channel. In turn, a data *inlet* receiver is built, specifying the name of the sender channel. When compiling the code, the program receives an array of variables for each sample of the EEG signal, which includes sample number, time in seconds, channel, encoding type, and magnitude. These data will be used to process the signal on the local server and continue with the second communication section to the Raspberry Pi 3.

3.2.2 Local Server to T-FLEX Controller

Once the data arrives continuously through the LSL channel which has a sampling frequency of 256 Hz, this data will be processed to detect the exceeding of the previously defined threshold. This implies that the calibration process must be appropriately associated with the local server created in Python. In this way, every time a threshold is exceeded, the data will be sent as a logical ‘1’ to the Raspberry Pi 3. This will cause an action equivalent to the dorsiflexion assisted by the robot. However, once a drop below the beta rebound signal threshold is detected, the local server will send a logical ‘0’ to the controller and it will remain in plantarflexion. This commands will be sent per epoch equivalent to 10 seconds.

The communication protocol used to send this data was the User Datagram Protocol (UDP) connection that uses the IP address data of both parties to carry out a data exchange. In this case, it is an open-loop system that only sends unidirectional data to the T-FLEX. This procedure is continuous and its performance will be evaluated through the local server and the interface created within it.

3.2.3 Cues System

For the use of BCI in patients, one of the recommendations used in the literature is visual and tactile stimulation [9]. In this case, two feedback systems will be used that will be compared: The Visual and Visual and Tactile stimulation system.

3.2.3.1 Visual Cue System

For this system it was necessary to use the local server designed in Python as a command center. In this case, the local server was configured to control an image interface that allowed the user to generate a brain stimulus that facilitated the generation of MI. Therefore, the Local Server was programmed in such a way that it would show three types of images: (1) 'Wait', (2) 'Idle' and (3) 'Move your feet'. The Wait image needs to be differentiated from the 'Idle' image, since the main objective of this image is a waiting period to eliminate noise from the acquisition of EEG signals. On the other hand, 'Idle' and 'Move your Feet', will give an explicit indication to the user to stay in a state of relaxation and a state of MI generation, respectively. In this way the local server will be willing to receive MI to send commands to T-FLEX or omit any command in the idle periods.

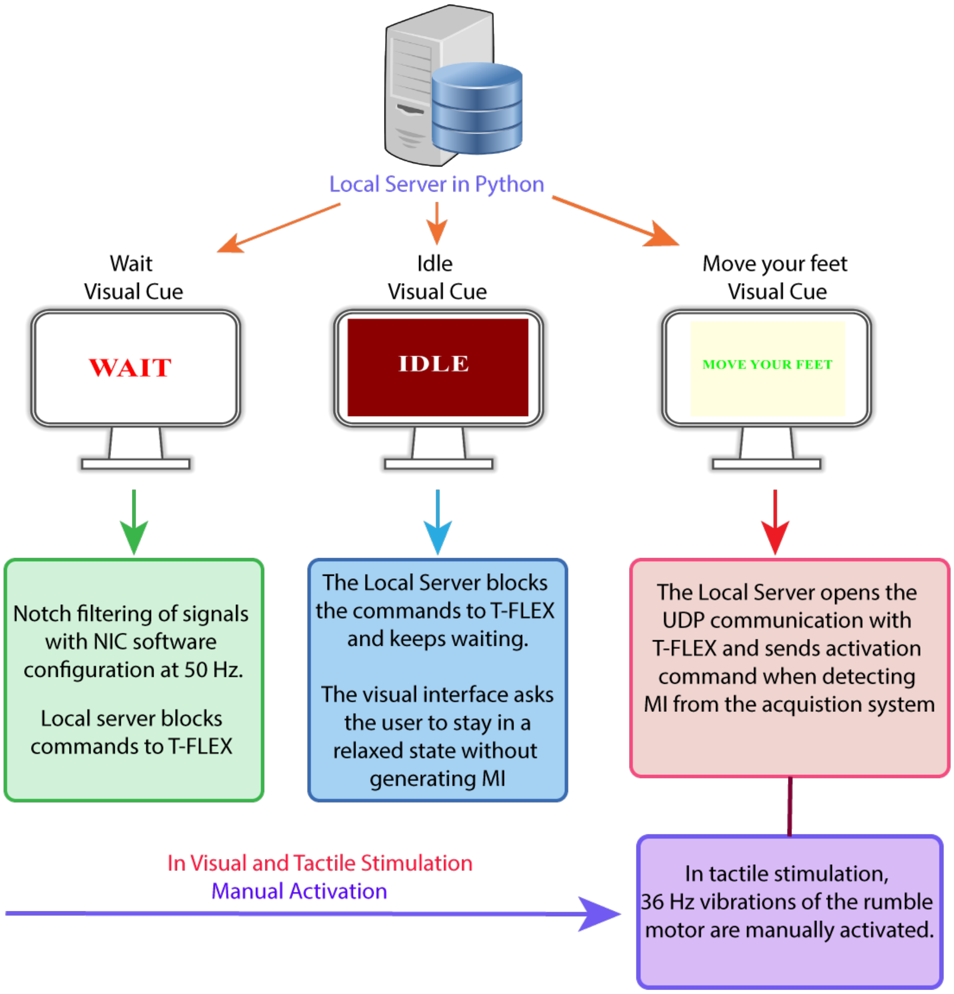


Figure 3.5: Functions designed for the visual feedback system. The images shown are the same as those that appear for the patients in the evaluated experimental conditions (See Section 3.3.3)

3.2.3.2 Visual and Tactile Cues System

The cue system with Visual and Tactile stimulation works in a similar way to the visual system. However, the tactile system is added in sync with the 'Move your Feet' periods manually (activated by the clinician in charge). This system was implemented through the SunniMix rumble vibration motor (SM SunniMix, USA). This motor works with a direct supply of 0.7 to 5 V, in this case it was activated with two AA batteries (3 V). The frequency of the vibration obtained from this energization is in a range between 36 and 40 Hz (2200 to 2500 r/min). To attach the mentioned motor to the system, a construction made of Ethylene Vinyl Acetate (EVA) was built, where the motor was coated by a box made of ABS material. Adherence was achieved through velcro material to the anterior tibialis muscle area. This tactile system structure is shown in the Figure 3.6.

As explained previously, this system is activated simultaneously in the periods of 'Move your Feet' to assist the patient in the generation of MI. Figure 3.5 shows the Local Server's main functions while the visual and tactile interface is working.

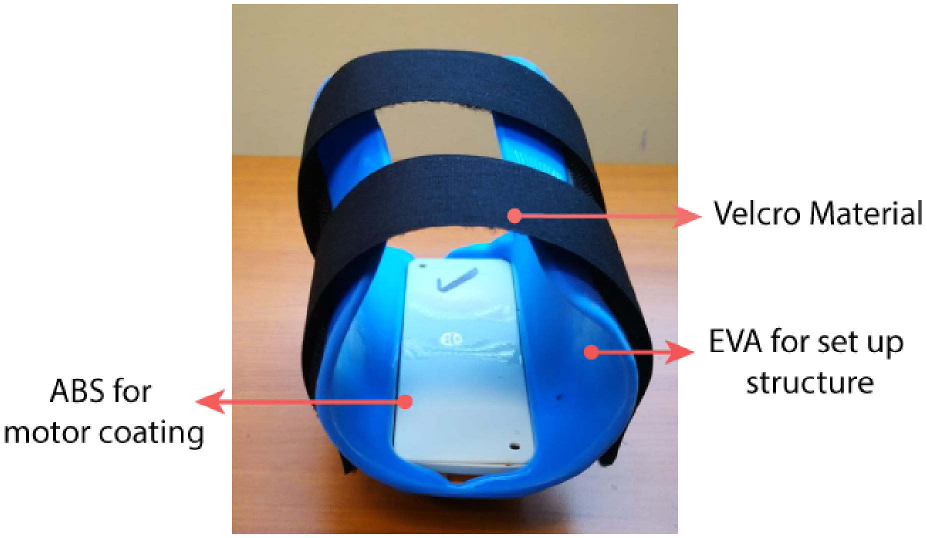


Figure 3.6: Structure of the tactile cues system used in the experimental procedures (see Section 3.3).

3.3 Experimental Assessment

The experimental assessment was proposed in two main sections: the BCI operation characterization and the validation of viability in clinical applications for patients with lower limb impairment. Therefore, this section exposes the different experimental procedures, the materials used, the participants, the evaluated variables and the evaluation procedures. The experimental protocol for this study is attached at the end of this document (see Appendix A).

3.3.1 Participants

In this protocol, five post-stroke patients were included, who presented disability in the lower limb. The age of the patients was in a range of 56,24 ± 3,26 years, the weight of the patients was 84,94 ± 9,93 kg. A height in a range of 166,40 ± 4,02 cm. Patients P2 and P5 had left hemiparesis laterality due to stroke, while the others suffered from right laterality, as is shown in Table 3.1.

Patient	**Age (years)**	**Stroke Laterality**	**Weight (Kg)**	**Height (cm)**	**Stroke Year**
P1	55	Right Hemiparesis	84	173	2018
P2	62	Left Hemiparesis	96	168	2016
P3	63	Right Hemiparesis	79	161	2018
P4	56	Right Hemiparesis	94	164	2013
P5	61	Left Hemiparesis	69	166	2006

Table 3.1: Data from the volunteer patients who performed the proposed experimental procedure

3.3.1.1 Inclusion criteria

The patients must have some pathology associated with the foot-ankle complex due to a neurological injury. Patients must have partial independence to mobilize. Also, they must be between the ages range of 18 to 70 years.

3.3.1.2 Exclusion criteria

Candidates will be excluded from the study if they present any of the following conditions:

- Uncontrolled hypertension.
- Uncontrolled epilepsy.
- Pain in the lower limbs or the spine prevents walking.
- Severe ankle-foot spasticity (Level 4 of the Ashworth scale).
- The presence of wound or pressure ulcers makes it nonfeasible to use the device.
- The user has not to count with affiliation to the general health social security system.

3.3.2 Materials and Equipment

- T-FLEX robotic ankle orthosis (support and actuation system).
- The hardware of the Enobio 2.0 EEG acquisition system from *Neuroelectrics* (Spain).
- NIC 2.0 acquisition system software from *Neuroelectrics* (Spain).
- Vibration rumble motor for vibration stimuli (SM SunniMix, USA).

3.3.3 Experimental Procedure

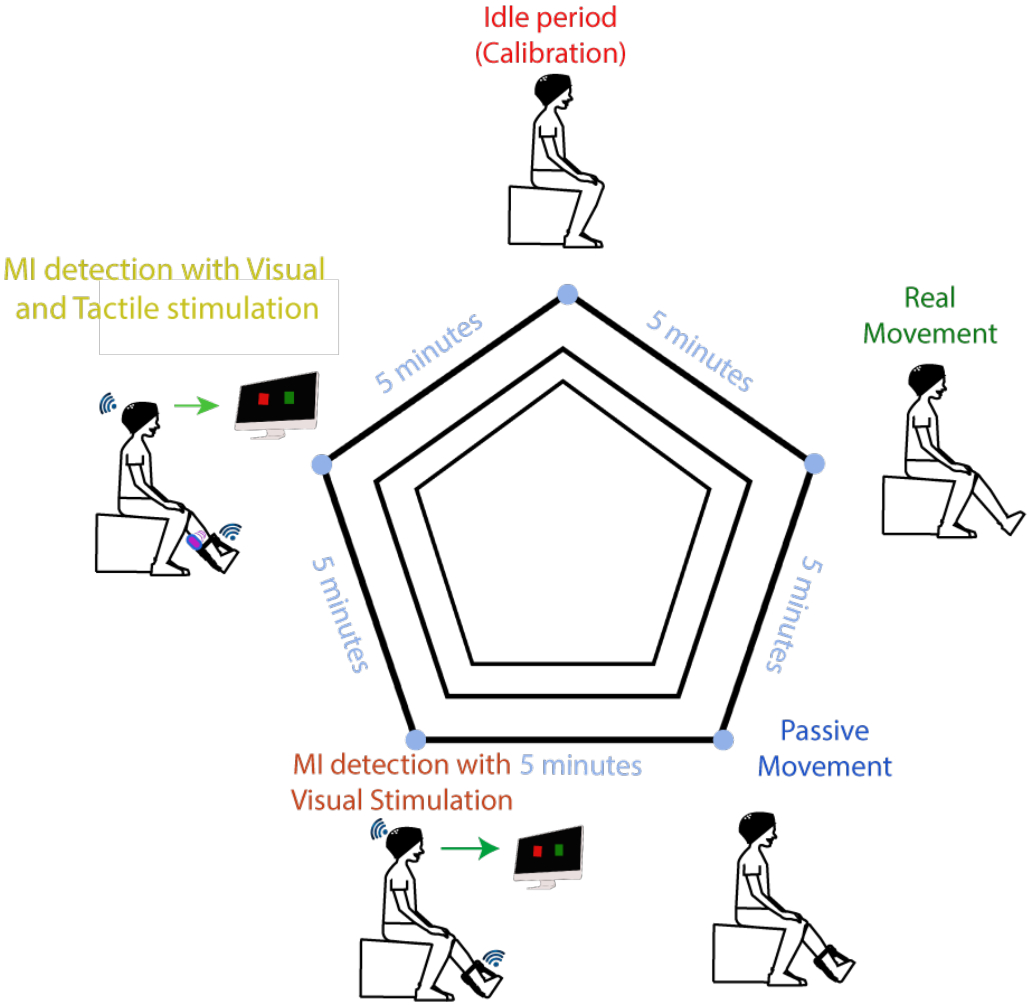


Figure 3.7: Experimental procedure BCI T-FLEX system in post-stroke patients with lower-limb impairment.

In this section, the experimental procedure carried out with the participants will be exposed. Figure 3.7 shows the experimental procedure graphically. The implemented protocol is based on experimental designs found in the literature [96] [88] [97]. Each experimental condition will consist of observation by the patient of a visual interface with full-screen text instructions indicating: (1) “Wait” text for 30 seconds; (2) Text "Idle" for 10 seconds; (3) Text “Move your feet” for 10 seconds. **Instructions 2 and 3 are repeated continuously until completing 5 minutes of the session.** In this sense, the patient had a maximum of 10 seconds to be able to generate MI to activate the T-FLEX device, therefore this period will be counted as an attempt to execute the instructions presented in each experimental condition. Following this period, the patient will be asked to remain at rest and so on until completing 5 minutes of each experimental condition, this equivalent to a total of 15 attempts for each of the tests that include MI. This session (that is, the performance of the four experimental conditions that will be described) was carried out only once per patient (see Figure 3.8)

- **Idle-Calibration**

In this first part, the user will be asked to sit comfortably in a chair with a 90 ° knee flexion. This part lasts approximately 5 minutes. The user will remain statically while the acquisition system will carry out the calibration process. After this calculation, the threshold to detect MI will be defined. For this, the following succession of procedures will be followed:

- **Experimental Condition 1: Real Movement**

EEG is recorded while the patient performs alternating dorsi-plantarflexion movements for 10 seconds. It alternates with ten second-periods of rest until reaching a 5-minute test.

- **Experimental Condition 2: Stationary Therapy (ST)**

EEG is recorded while the patient receives alternating dorsi-plantar flexion motion for 10 seconds using the T-FLEX robotic orthosis. It alternates with ten second-periods of rest until reaching a 5-minute test.

- **Experimental Condition 3: MI with Visual Stimulation (MIV)**

EEG is recorded while the patient imagines alternating dorsi-plantar flexion movement for 10 seconds while observing an image showing the desired command (See Section 3.3). Thus, the patient has a maximum of 10 seconds to generate MI, when the activation is detected in the BCI system, the subject receives active movement through the T-FLEX robotic orthosis. It alternates with ten second-periods of rest until reaching a 5-minute test. As shown in Figure 3.10, visual stimulation is produced employing a screen at the visual level of the patients.

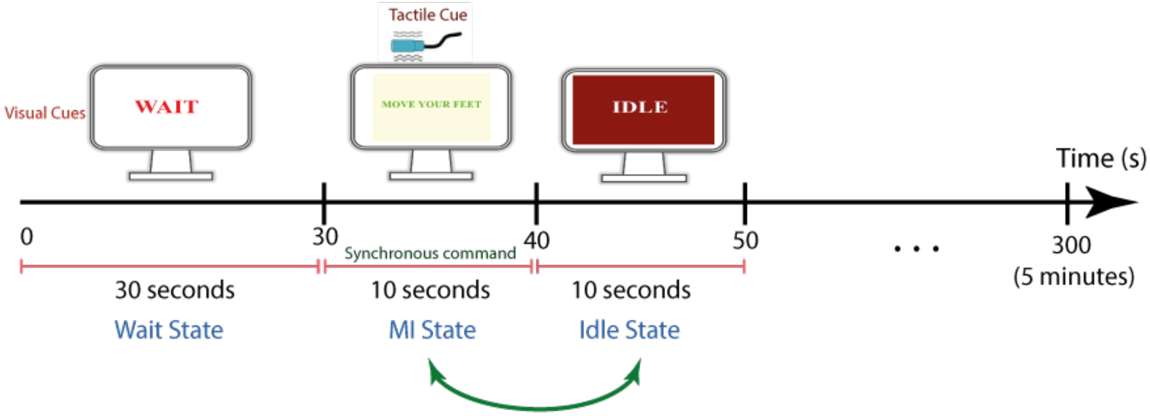


Figure 3.8: Timeline illustrating the procedure applied in MI experimental conditions. The Idle and MI ('Move yur feet') states are repeated cyclically until the completion of 5 minutes, at which time the experimental condition described is completed.

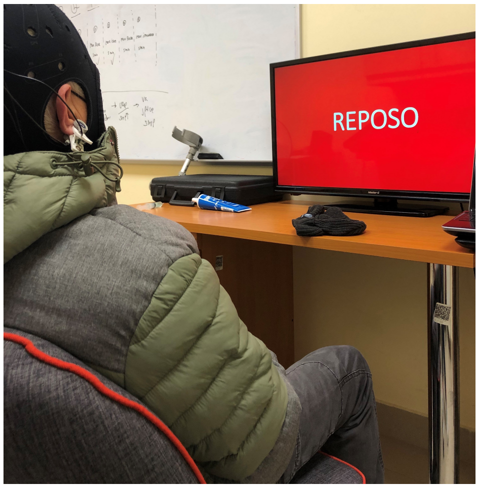


Figure 3.9: Visual stimulation through the interface designed for the experimental procedure. *In spanish 'Reposo' is the equivalent of the state 'Idle'*

- **Experimental Condition 4: MI with Tactile Stimulation (MIVT)**

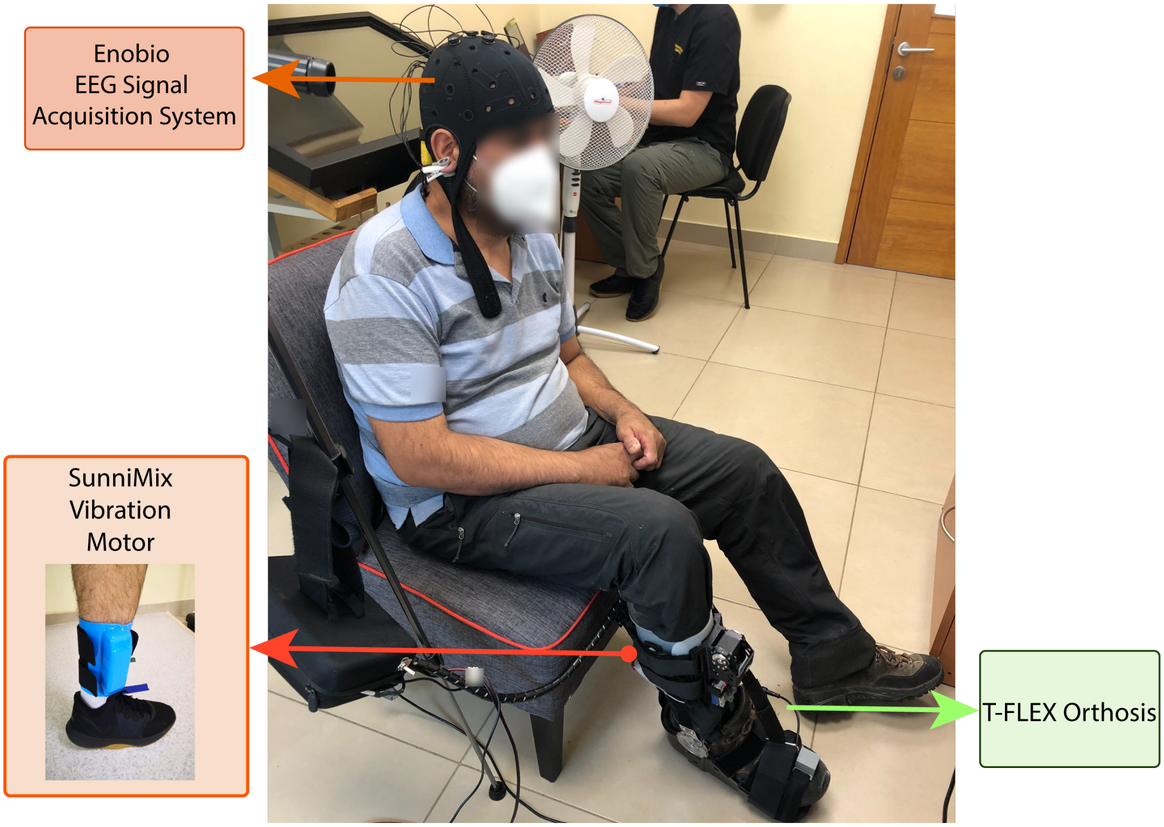


Figure 3.10: Visual and Tactile stimulation through the interface designed for the experimental procedure.

EEG is recorded while the patient imagines alternate dorsi-plantar flexion movement for 10 seconds while receiving vibratory stimulation in the anterior tibialis muscle. Thus, the patient has a maximum of 10 seconds to generate MI, when the activation is detected in the BCI system, the subject receives active movement through the T-FLEX robotic orthosis. It alternates with 10 second-periods of rest until reaching a 5-minute test. As seen in Figure 3.10, the set up used for the patients in this test adheres to the tactile stimulation system composed of the rumble vibration motor with velcro material in the anterior tibialis muscle.

It is essential to highlight that the four experimental conditions (Captures 2,3,4 and 5) will be under a comparative analysis in terms of brain activation of the MI frequency band (8-32 Hz). Therefore, each capture will have EEG records that will be subjected to later studies.To perform visual and tactile feedback, the commands to the patient are generated from the local server created in Python, which is also waiting for an MI generation and sends commands to T-FLEX depending on the test to be performed.

3.3.4 Quantitative characterization of the BCI system

- **Accuracy rate:** In this variable, the data associated with the MI attempts correctly detected by the BCI will be collected in the 10-second periods in which the patient is asked to imagine movement. In this sense, it was possible to elucidate the rate of omissions associated with BCI, that is, the number of unsuccessful attempts to perform an MI detection within 10 seconds of detection.

  In addition, statistical analyses will be carried out to compare this accuracy to verify significant differences between visual stimulation and visual and tactile stimulation. To do this, it will be defined whether to use parametric tests or non-parametric tests with a Shapiro Wilk normality test.

- **Acquisition of EEG signals from the cortical zone:** Continuous signals will be acquired at each test interval from the cortical zone, using channels Fcz, C1, Cz, C2 and Cpz the International System. In this way, signal processing will be carried out to compare and conclude if there are significant differences in the brain-motor activity of the patient when using the T-FLEX device integrated into the BCI system and in its absence. To conclude in this regard, an analysis of PSD will be used, which will be presented in more detail in the next section.

3.3.5 EEG Analysis

To show the effect of integrating the BCI system on the volunteer patients, the acquisition of EEG signals was performed throughout the experiment. The acquisition had two objectives: On the one hand, it is the central structure of the implemented BCI , from which a Laplacian Surface referencing was used. On the other hand, the channels Fcz, C1, Cz, C2 and Cpz were recorded with a Common Mode Sense (CMS) which consists of placing electrodes provided by the manufacturer in the mastoid area [98]. This second acquisition was used to analyze the brain activity of the patients through PSD activation.

Through the methodology used by Duan et al. [97], in which similar tests were evaluated, the signals average PSD associated with the active periods of each channel were obtained. This methodology is presented in Figure 3.11.

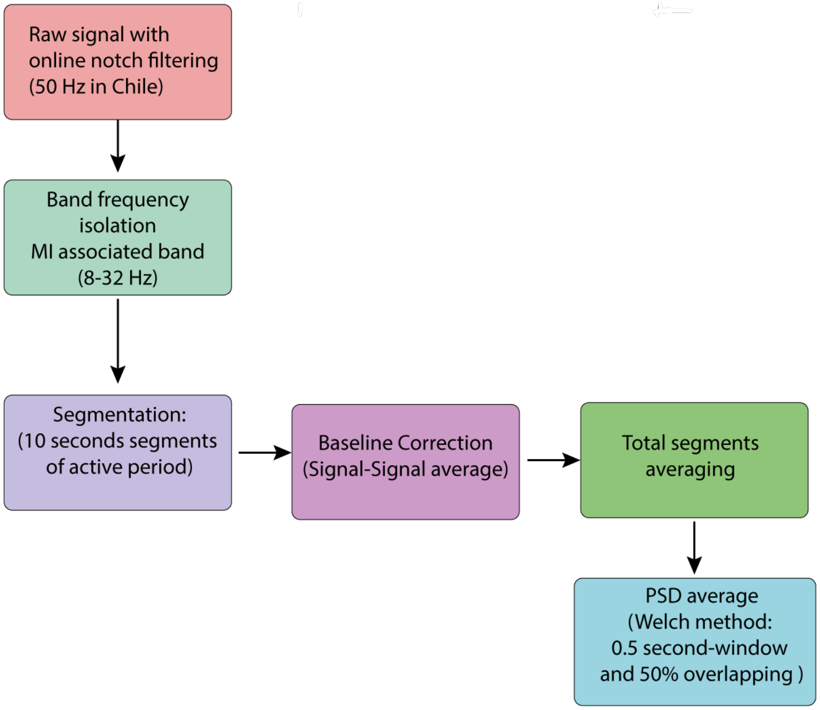


Figure 3.11: Signal processing used to obtain the PSDs associated to each channel in each patient.

3.3.5.1 Raw Signal extraction

As indicated, the signals were acquired through the tools provided by Neuroelectrics. These signals were filtered with a Notch-type filter at 50 Hz to eliminate noise. produced by the line noise.

3.3.5.2 Segmentation, Frequency Band Isolation, and Baseline correction

In this step, the frequency band associated with the MI (8-32 Hz) was isolated through a band-pass Butterworth filter of order 100 according to the methods presented by Clerc et al. [54]. On the other hand, it was decided to segment the continuous signal of each test (equivalent to 5 minutes) into 10-second segments, corresponding to the 10-second active period described in the experimental protocol. The **active period** refers to the time intervals in which there is either movement by T-FLEX or MI detection, where the device waits for detection to perform an active movement. That is, these active periods exclude idle intervals. Then, a baseline correction was carried out, subtracting the average of the signal from each segment.

3.3.5.3 Average signal calculation

Subsequently, the average of the signals for each window is calculated through the equation x, where S is the signal for each 10-second window and n is the total number of windows for a specific test.

$$Average_{channel} = \frac{1}{n}\sum_{i=1}^{n} S_i \tag{3.2}$$

3.3.5.4 PSD calculation

Finally, from this resulting signal the average Power Spectral Density (PSD) was obtained, ensuring that the values belong to the isolated frequency band in the previous steps. To carry out the above, the Welch method was used, with a window of 0.5 seconds and an overlap of 50%, following the methodologies mentioned above.

Thus, each channel was compared in two paired tests: average PSD in Stationary Therapy with periods of MI detection with visual stimulation, and in Stationary Therapy with periods of MI detection with visual and tactile stimulation. The periods of Stationary Therapy (Passive Movement) will be taken as the control samples, since no type of MI-related activity was requested to the patient. In addition, brain activity in the MIV and MIVT tests will also be compared to verify, in a similar way, if there are significant differences in the expression of the patients for each stimulation paradigm.

3.3.6 Qualitative characterization of the BCI system

The variables measured in this section will be taken at the end of the experiment. The Quebec User Evaluation of Satisfaction with Assistive Technology **QUEST** survey [99] test will be performed to determine the level of patient satisfaction with the device. This information will be used as feedback from the user regarding the operation and structure of the proposed system (See Appendix B for more details).

Chapter 4

RESULTS

This section will be presented in three main parts: The first part refers to the characterization of a BCI, where the results are associated with the accuracy that the system had with the users. The second part refers to the analysis of the EEG signals acquired in the active intervals, comparing the captures of Stationary Therapy (ST), detection of MI with Visual stimulation (MIV), and detection of MI with Visual and Tactile stimulation (MIVT). Finally, the results collected in the QUEST survey will be presented from the scores associated with said test. Thus, as the results are presented, they will be discussed consistently throughout the section.

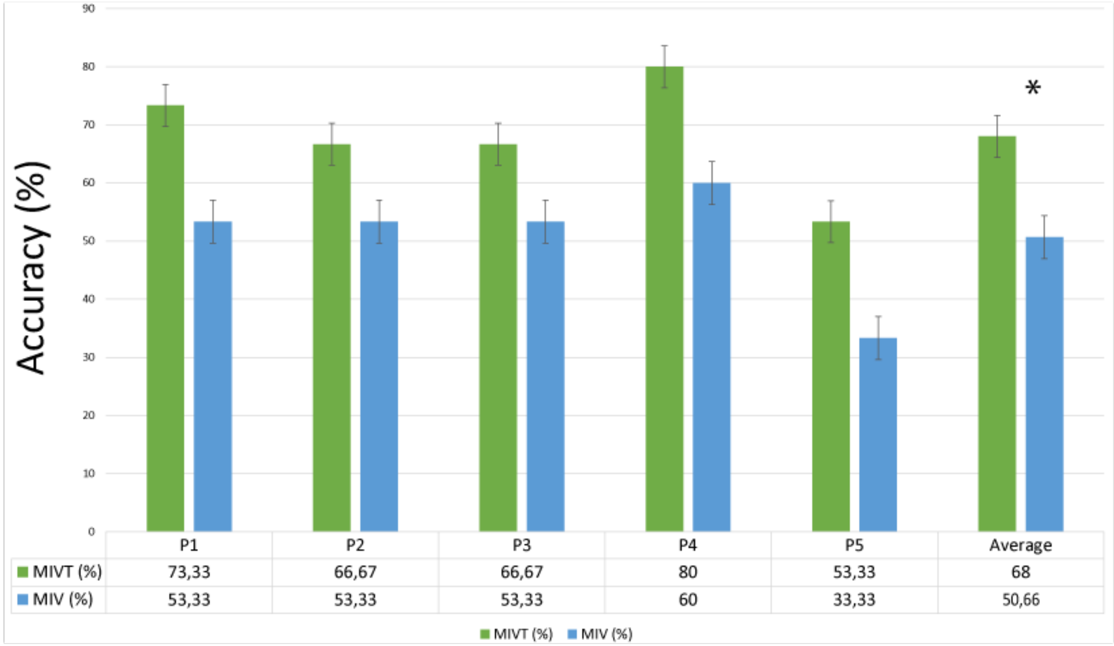
4.1 BCI Characterization

This section will present the results of the characterization of the BCI, which includes the level of accuracy of the system, followed by the behavior of the brain electrical activity of the patients in the related tests, where the PSD average for each channel was analyzed.

4.1.1 Accuracy

To give an adequate notion about the results of the BCI, a percentage of accuracy was obtained for each patient. This percentage of accuracy is taken from the relative frequency of the total number of hits for each active period. As mentioned in the methodological section, each patient had a maximum of 10 seconds to generate MI with sufficient beta rebound activation to generate the dorsi-plantar flexion movement of the T-FLEX device. The system's accuracy was measured from its ability to detect MI in these active periods, for which the data were collected for both MI detection with Visual stimulation (MIV) and MI detection with Visual and Tactile stimulation (MIVT). Figure 4.1 shows the compiled results in a bar graph grouped by the patient. In green the accuracy calculated for the MIVT test and, in blue,the accuracy calculated for the MIV test can be seen.

To obtain an adequate notion of the results shown, it was decided to carry out a statistical comparison involving all patients. For this, a Shapiro-Wilk type normality test was carried out since it was a sample of an order less than 30. Table 4.1 shows the results. When obtaining a significance value less than 0.05 to distribute the accuracy in the MITV test, a medians comparison test was carried out through the Wilcoxon signed-rank test.



	P1	P2	P3	P4	P5	Average
🟩 MIVT (%)	73,33	66,67	66,67	80	53,33	68
🟦 MIV (%)	53,33	53,33	53,33	60	33,33	50,66

Figure 4.1: Accuracy of MI detection for each patient in the MIV (In blue) and MIVT (In green) tests. *Means a p-value<0,05

Normality test	
MI TEST	p-Value.
MIV	0,777
MIVT	0,044

Table 4.1: Results of the normality test of the Shapiro-Wilk type to demonstrate whether or not there is normality in distributing of the data of the accuracy.

Considering the results obtained in Figure 4.1, the Wilcoxon test performed showed a 0.038 p-value ($p<0.05$). Therefore, it can be concluded that all patients had better performance with the BCI system when both a visual and tactile stimulation system was applied. In this case, the null hypothesis is rejected, which held that there were no significant differences in the medians of the accuracies of each of the tests with the patients evaluated. Therefore, it is concluded that for the designed BCI system and the sample of patients with neurological lesions there is greater utility when the patient is stimulated visually and tactilely.

4.1.2 EEG Analysis

As explained in the methodological section, the methodology of Duan et al. was used to observe significant differences in the patient's brain activity in the frequency band associated with MI through PSD. In Figure 4.2 the first stage of the proposed processing is shown, where the raw signal can be observed, this signal is without the noise from the electrical network since its harmonic at 50 Hz was eliminated through the NIC 2.0 software.

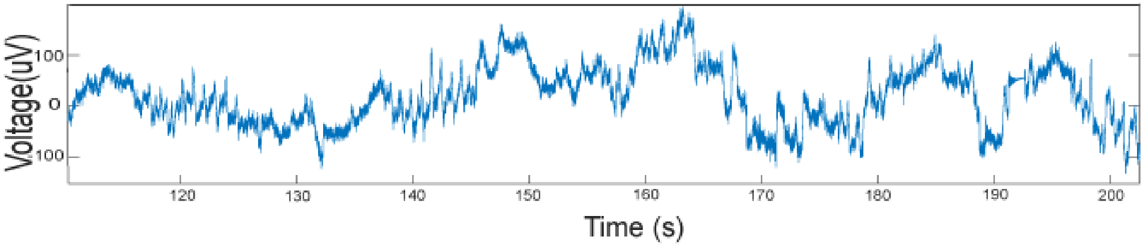


Figure 4.2: Raw signal of Cz channel with Notch filter at 50 Hz from patient P1 in Motion Imagination detection state with Visual and Tactile stimulation

On the other hand, the application of the Butterworth band-pass filter to isolate the frequency band had the temporal response of Figure 4.3. The correction was also made to eliminate the offset, which allowed the signal to be referenced to the zero level. In this sense, we proceeded to carry out the segmentation of active periods, for which Figure 4.3 shows a window in an interval of 10 seconds.

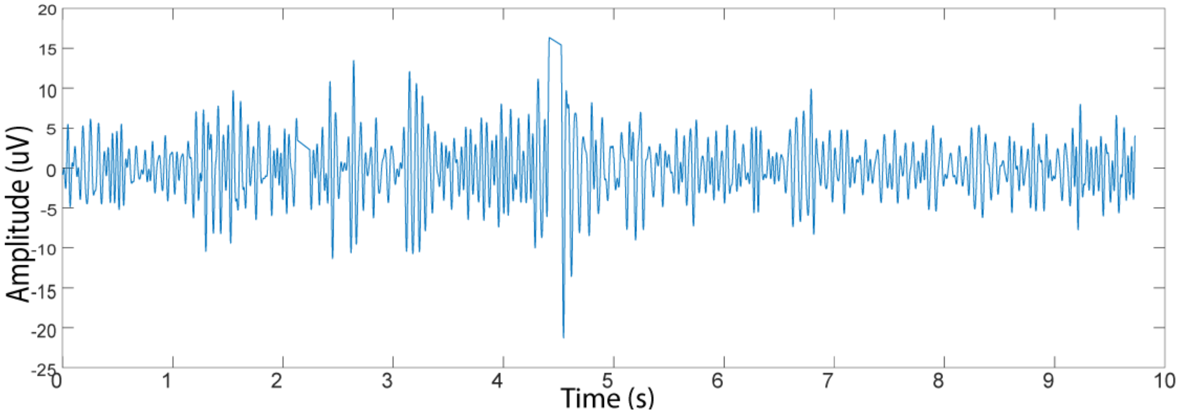


Figure 4.3: Filtered signal of Cz channel on the band 8-32 Hz from patient P1 in Motion Imagination detection state with Visual and Tactile stimulation

The signal obtained by applying Equation 3.2 is shown in Figure 4.4 . This single signal is the average signal associated with the Cz channel of patient P1 in visual and tactile stimulation.

Given the above, the PSD of the mentioned signal is obtained from which an average value is obtained only in the isolated frequency band. Figure 4.5 shows the magnitude obtained from the average signal associated to the channel Cz of the patient P1 in visual and tactile stimulation test.

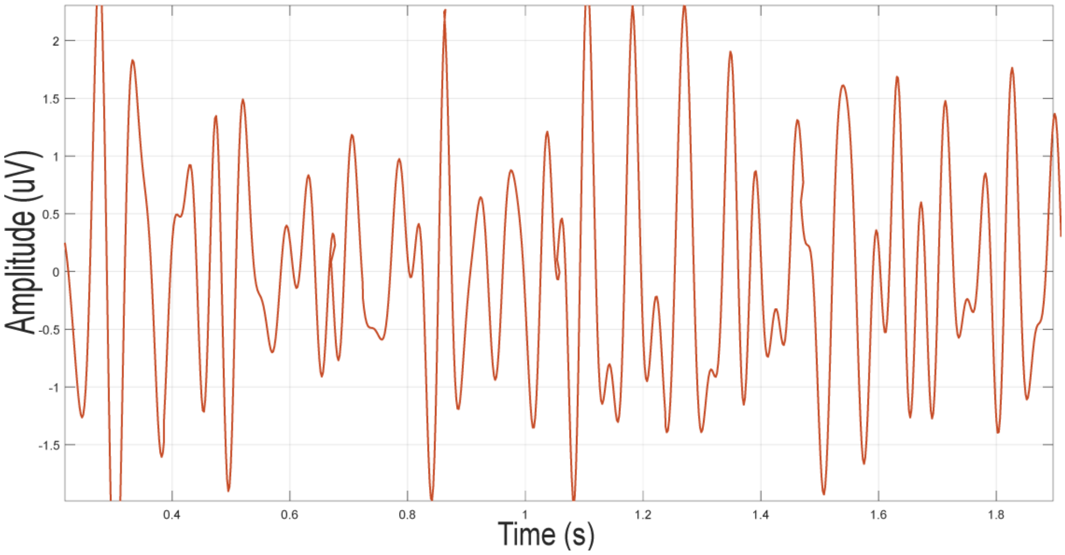


Figure 4.4: Average signal associated with the CZ channel of patient P1 obtained through the processing methodology

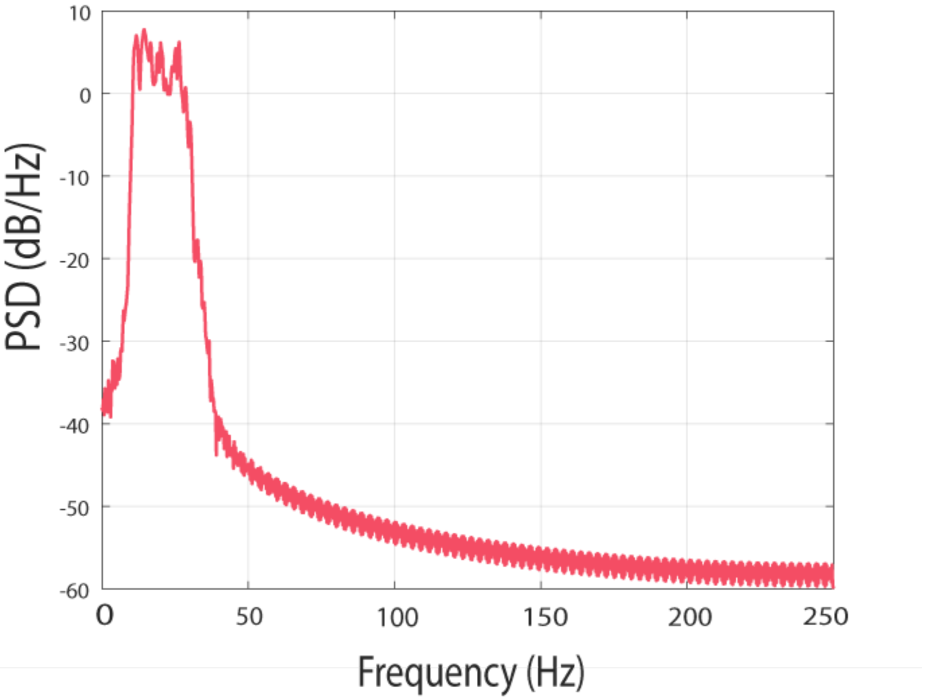


Figure 4.5: PSD associated with the CZ channel of patient P1 obtained through the processing methodology

Table 4.2 show the average PSD obtained for the 8-32 Hz frequency band. Each table corresponds to a given test. As indicated in the methodology, each of the channels will be compared in two pairs of tests: ST with MIV, and ST with MIVT. As indicated in the description of Table 4.2, the Cpz channel of Patient 4 was discarded due to its low quality, for which it was impossible to recover useful characteristics considered in the analysis.

To better illustrate the characteristics associated with the PSDs of the channels of each subject, it was proposed to carry out topographies, which are based on the information collected in Table 4.2. These topographies were constructed through the MATLAB software and can be seen in Figure 4.6. Visually all the patients had differences in the PSD associated with the MIVT test. On the left side of each topography, the color map can be seen, keeping the scale constant for a given patient. As mentioned in previous annotations, it is necessary to clarify that the PSD of the Cpz channels for patient P4 was not taken into account. Therefore a shallow contrast of PSD will be observed in the topographies of this patient given that the MATLAB function that performed the topographies did not accept less than 5 EEG channels.

To better understand the significance of these results,a statistical analysis was performed to check whether there are significant differences in the PSDs of patients the ST and MIV states, and in the ST and MIVT states. Therefore, it was decided to compare each channel with the PSD values collected by the tests of the patients. Thus, it can be demonstrated which channels may have significant differences and contrast them with the methodologies found in the literature.

	TEST: ST PSD (dB/Hz)				
Patient	Fcz	C1	Cz	C2	Cpz
1	6,81	6,46	6,84	7,60	6,30
2	8,49	8,69	9,15	9,35	9,04
3	4,90	5,07	4,66	6,19	4,50
4	5,54	5,76	6,23	8,22	NA*
5	5,21	6,38	5,57	4,90	4,77
	TEST: MIV PSD (dB/Hz)				
1	7,75	7,66	7,61	8,83	7,19
2	8,30	8,32	8,97	9,36	8,66
3	2,50	3,245	2,42	2,23	2,51
4	4,87	6,34	5,65	6,33	NA*
5	5,87	7,36	6,37	5,59	5,91
	TEST: MIVT PSD (dB/Hz)				
1	8,54	8,94	8,62	9,28	8,62
2	8,81	8,55	9,44	10,46	9,74
3	3,83	3,42	6,69	7,74	5,25
4	7,49	7,54	8,22	9,32	NA*
5	7,73	8,22	7,54	7,68	7,11

** Not Applied: the Cpz channel Of the Patient 4 did not have the necessary signal quality to be included in the studies.*

Table 4.2: PSD associated with each channel for each of the patients evaluated for the ST, MIV, and MIVT test.

Normality tests	
	Shapiro-Wilk
	p-Value
Fcz-ST	0,318
Fcz-MIV	0,739
Fcz-MIVT	0,068
C1-ST	0,388
C1-MIV	0,198
C1-MIVT	0,055
Cz-ST	0,700
Cz-MIV	0,803
Cz-MIVT	0,994
C2-ST	0,938
C2-MIV	0,615
C2-MIVT	0,352
Cpz-ST	0,052
Cpz-MIV	0,641
Cpz-MIVT	0,056

Table 4.3: Shapiro-Wilk normality tests for each of the channels associated with a given test.

To make a suitable statistical analysis, a Shapiro-Wilk normality test was proposed, since the sample for each channel is less than 30. According to the previous test results presented in Table 4.3, all channels present a normal distribution, so the comparison analysis is parametric. In this case, a t-Student test for comparing means was chosen, paying particular attention to the p-value (Significance). It is essential to clarify that the t-Student test was applied for each channel, comparing three pairs of states. On the one hand, the means between the ST and MIV tests were compared, followed by the ST and MIVT tests and finally the means of the MIV and MIVT tests. These paired tests were carried out since it is sought to compare two states (MIV and MIVT) with a reference state (ST), where it is desired to observe if there is greater brain activity in MI states than in conventional therapy.

p-Values of t-Student Tests					
	Fcz	C1	Cz	C2	Cpz
ST-MIV	0,601	0,848	0,635	0,459	0,914
ST-MIVT	0,169	0,323	**0,008**	**0,006**	**0,046**
MIV-MIVT	0,200	**0,032**	**0,049**	0,051	**0,025**

Table 4.4: P-values of the comparison of means between the ST-MIV and ST-MIVT tests for each evaluated channel.

Table 4.4 shows the t-Student test of comparison of means for each channel in the comparisons mentioned above. As can be seen, according to a significance value of 0.05 of the test, the Cz, C2 and Cpz channels in the MIVT test have a higher associated power spectral density when compared to the ST tests. On the other hand, a similar comparison was performed between the test MIV and MIVT. Results show significant differences in the PSD

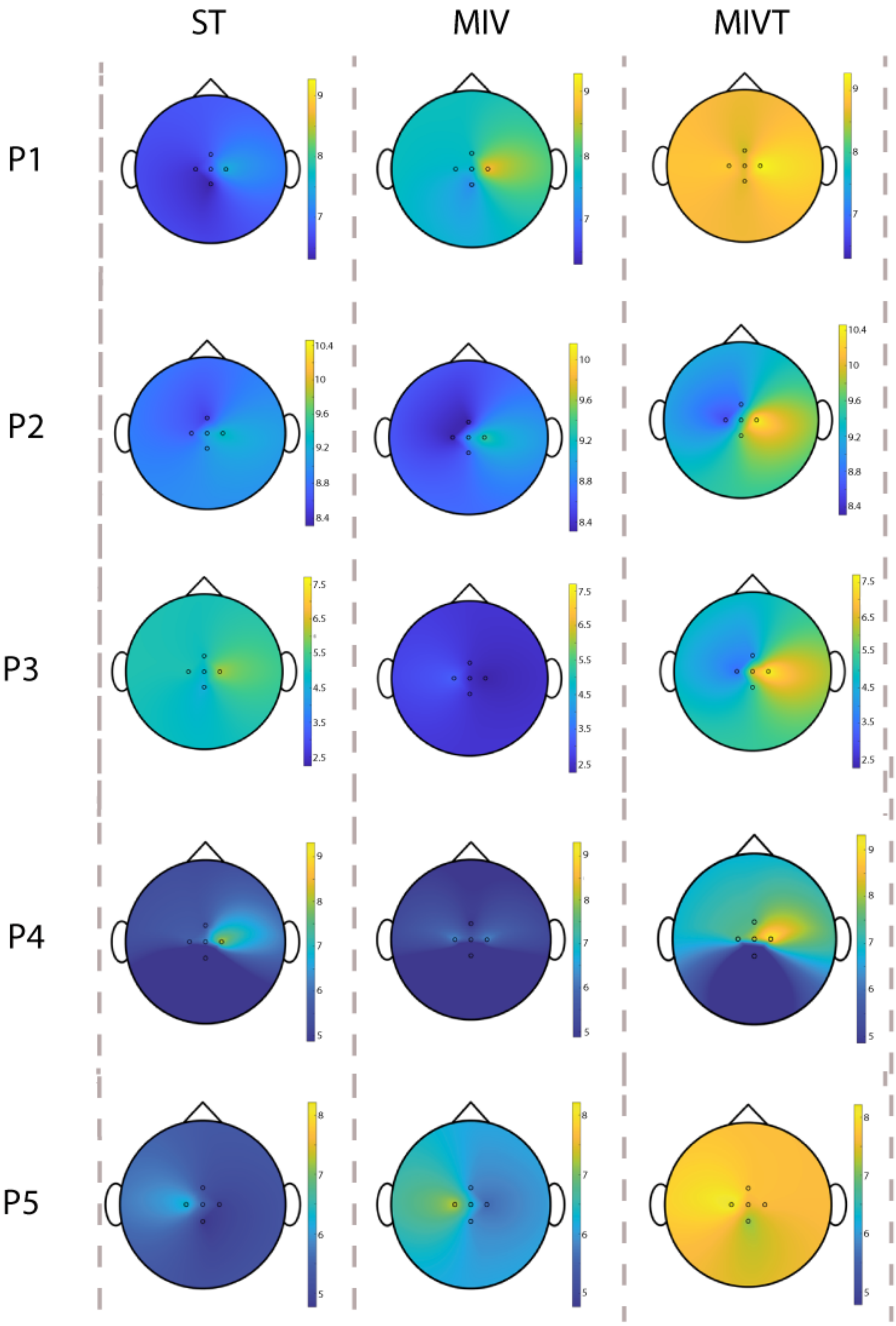


Figure 4.6: PSD topographies of the ST, MIV and MIVT tests of Patients.

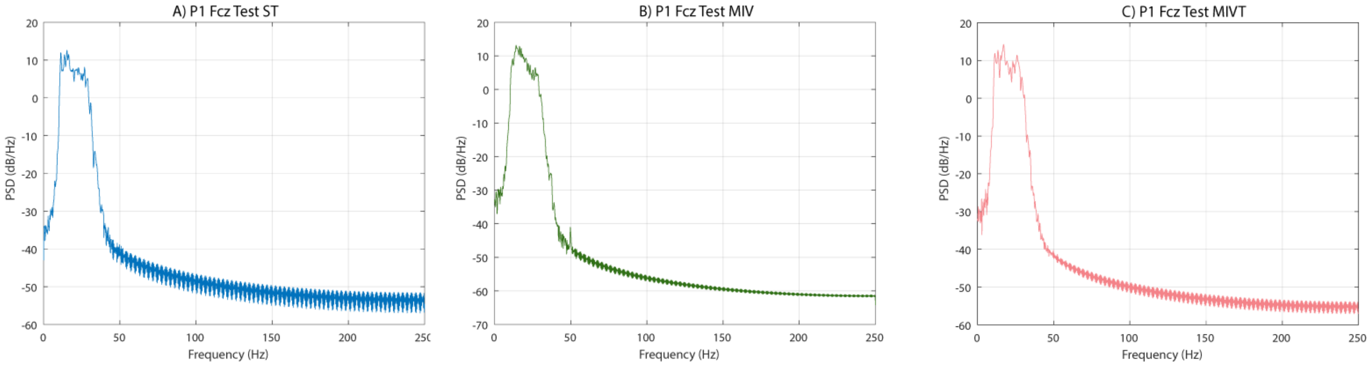


Figure 4.7: Power spectral density curves for patient P1 in the C1 channel. A) PSD corresponding to the ST test. B) PSD corresponding to the MIV test. C) PSD corresponding to the MIVT test.

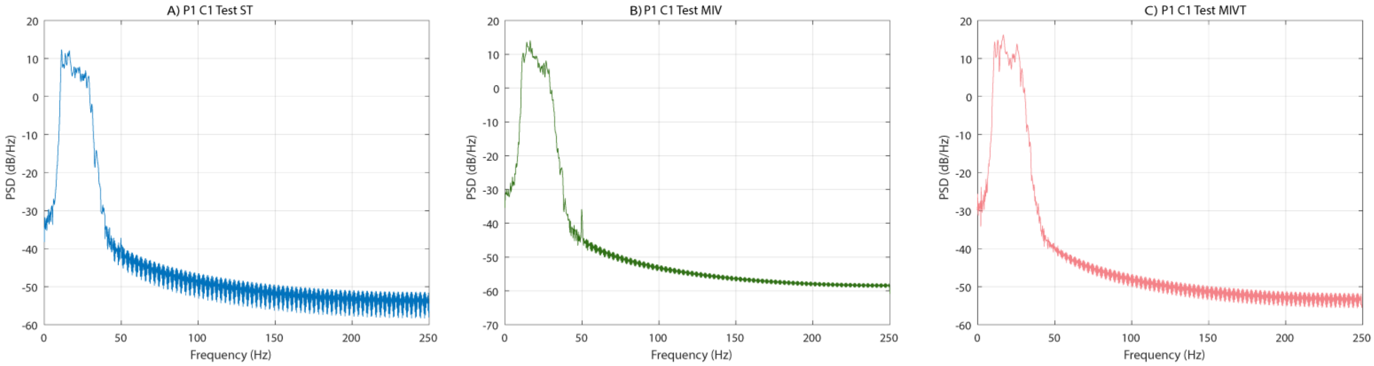


Figure 4.8: Power spectral density curves for patient P1 in the C1 channel. A) PSD corresponding to the ST test. B) PSD corresponding to the MIV test. C) PSD corresponding to the MIVT test.

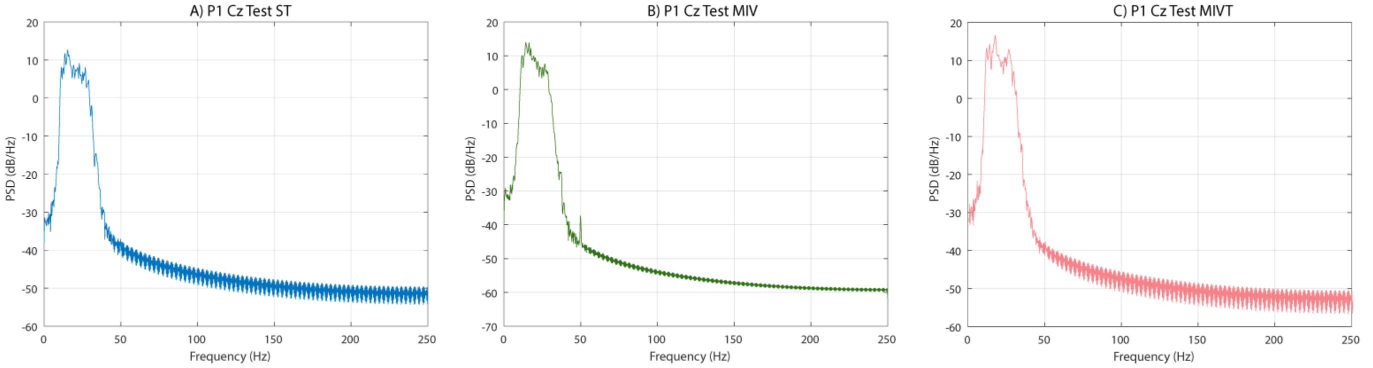


Figure 4.9: Power spectral density curves for patient P1 in the Cz channel. A) PSD corresponding to the ST test. B) PSD corresponding to the MIV test. C) PSD corresponding to the MIVT test.

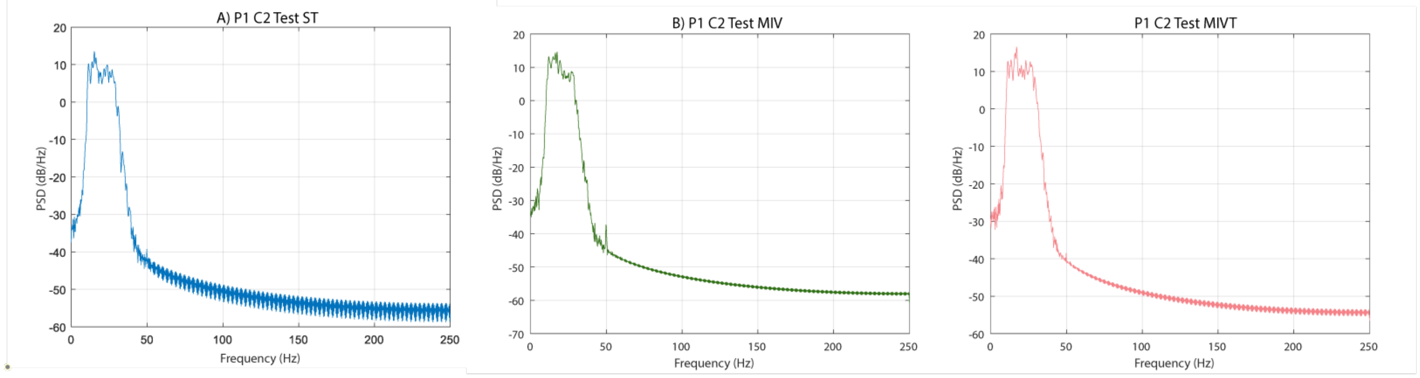


Figure 4.10: Power spectral density curves for patient P1 in the C2 channel. A) PSD corresponding to the ST test. B) PSD corresponding to the MIV test. C) PSD corresponding to the MIVT test.

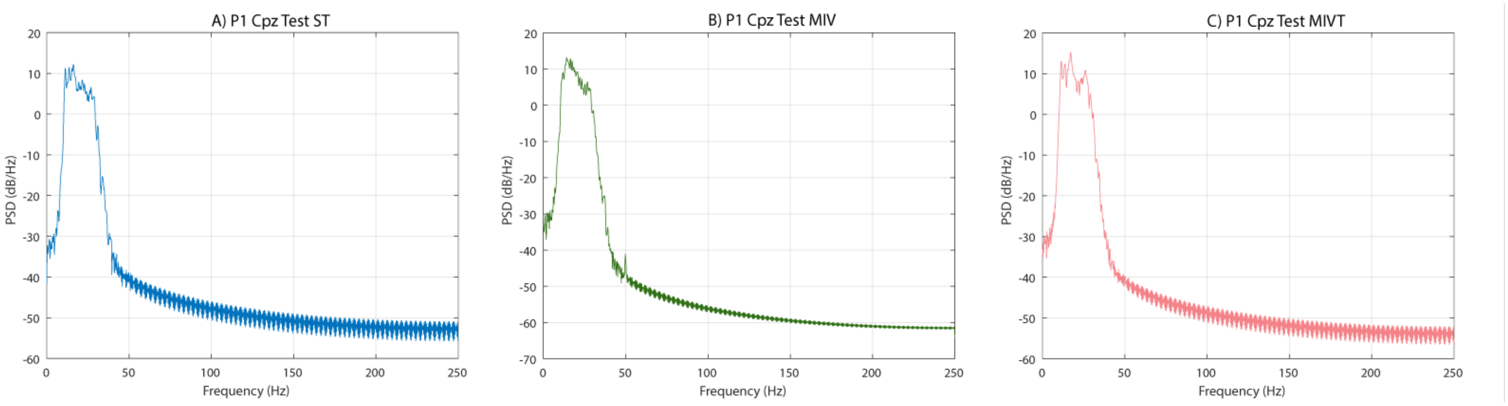


Figure 4.11: Power spectral density curves for patient P1 in the Cpz channel. A) PSD corresponding to the ST test. B) PSD corresponding to the MIV test. C) PSD corresponding to the MIVT test.

values on C1, CZ and Cpz channels.

Figures 4.7, 4.8, 4.9, 4.10, and 4.11 show the power spectral density curves for the particular case of patient P1 in the ST, MIV and MIVT states in the channels involved. A trend can be observed in MIVT being of greater amplitude in the isolated frequency band.

4.2 User Survey Results

As mentioned in the methodological section, it was decided to perform a QUEST test in this study. For each of the categories related to this standard survey, scores were collected for each subject evaluated. This was done to know the perception of the designed BCI system. Following the above, Table 4.5 summarizes the results obtained for each of the users. To know the general results, the final results of each patient were averaged.

	Extended QUEST 2.0					
Criteria	P1	P2	P3	P4	P5	Average
Dimensions	4,00	5,00	3,00	4,00	5,00	4,20
Weight	5,00	5,00	5,00	5,00	5,00	5,00
Adjustment	5,00	5,00	4,00	5,00	5,00	4,75
Safety	5,00	5,00	4,00	5,00	5,00	4,75
Ease of use	5,00	5,00	5,00	4,00	5,00	4,75
Effectiveness	5,00	5,00	5,00	4,00	5,00	4,75
Information/Instuctions	5,00	5,00	5,00	5,00	5,00	5,00
QUEST total score	**4,85**	**5,00**	**4,42**	**4,57**	**5,00**	**4,76**
Reliability	5,00	5,00	4,00	5,00	5,00	4,75
Speed	4,00	4,00	4,00	4,00	4,00	4,00
Learning	4,00	5,00	5,00	5,00	5,00	4,75
Aesthetic design	4,00	5,00	4,00	5,00	5,00	4,25
Added items total score	**4,25**	**4,75**	**4,25**	**4,75**	**4,75**	**4,55**

Table 4.5: Collecting QUEST 2.0 test results and extending additional criteria

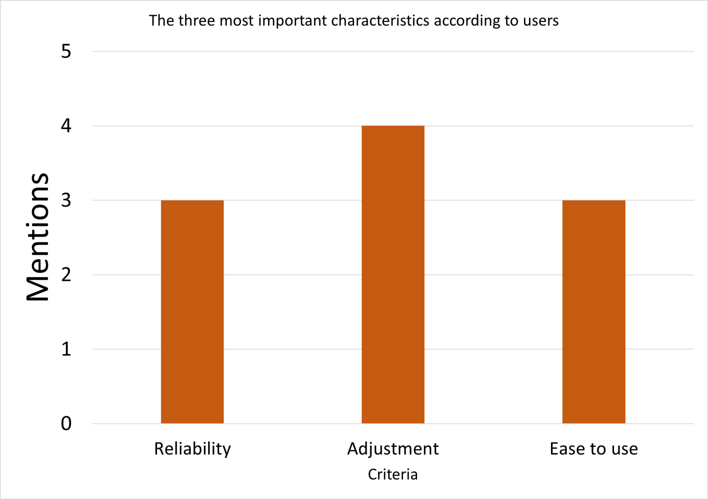


Figure 4.12: Results of the three most important characteristics considered by the patients.

In addition, the survey also included three of the essential characteristics that can describe the technology used. According to the results, the three characteristics most mentioned by the entire sample were shown in Figure 4.12. Adjustment, ease of use and reliability criteria had the highest positions of frequency of mentions. These results, as already mentioned, are beneficial to be able to have a vision of the usability and feasibility of the integration of the system.

Chapter 5

DISCUSSION

In this chapter the most relevant results of the proposed study will be discussed. To do this, it was decided to divide this chapter into two main sections: discussing of the results of the characterization of the BCI and the discussion associated with the qualitative tests obtained from the extended QUEST test. In the characterization part, the results of the measured precision level and the PSD results associated with the tests carried out will be taken into account. Likewise, the displayed results of the qualitative results will be discussed.

5.1 BCI Characterization Discussion

5.1.1 Accuracy

In terms of the level of accuracy of the BCI presented in the previous section, the most relevant results of this section show a level of accuracy for the MIV test between 33.3% and 60%, which compared to the level of precision in the MIVT status, which obtained a percentage between 53.3% and 80%, is relatively low. This can be contrasted with the results obtained by Duan et al. [97] where the level of precision of the integrated BCI for lower limb exoskeleton was compared and significant differences were found in both tests, where it was concluded that there is greater precision in MI tests that involve both visual and tactile cues. This may be beneficial as MI detection is found to be low when using visual-only stimulation. The literature shows that BCIs tend to have more deficient precision levels when additional stimulation to visual stimulation is not used [100] [9], this agrees with this study and is consistent with the conclusions in the literature that determine greater BCI functionality with vibratory stimulation. Therefore, the operation of the BCI should be guided by accompanying it with additional stimulation to visual cues.

5.1.2 EEG Analysis

Despite the low relative powers in ST for all patients, no substantial increase in spectral density can be observed between ST and MIV tests. For Patient P3, a greater activation occurs according to the topography in ST than in MIV, which seems to be atypical. The characteristics of the topographies may be oriented to an increase in brain activity on visual and tactile stimulation tests (MIVT). This can be contrasted with the results of Duan et al. [97] who performed similar tests for a BCI system involving the activation of a lower limb exoskeleton. In this study, EEG activations during visual stimulation and visual and haptic stimulation were compared. The results showed greater activation in the frequency band associated with MI when visual and haptic stimulation in the C3 and C4 channels. Therefore, in this study it is intended not only to compare both paradigms but also to contrast them with the absence of BCI, only in TS, which is one of the operating modes of the T-FLEX device. Finding significant differences in brain activity between these tests may indicate that there is a difference in the conventional therapy mode and the use of integrated BCI. Therefore, these results are helpful since they show a preliminary added utility in the proposed integration concerning the conventional use of T-FLEX.

In this case, the laterality of the movement was not taken into account. Thus, according to other literature consultations [95] [101], the PSD of lower limb MI is challenging to differentiate in its laterality. However, a considerable increase in the power of the beta wave has been observed for the Cz channel, which agrees with the results of this study. However, it should be noted that the PSD did not have significant differences in the MIV state, concerning the ST state.

The above can be observed according to other results obtained in the characterization of the BCI, specifically in the level of accuracy. It has already been concluded that there are differences between the accuracies provided by the MIVT tests in contrast to those provided by the MIV test. Therefore, a greater activation of the MI band in these results is consistent with what was obtained in the previous section. These results are important because they show that to generate a significant difference in MI-related brain activity, the most viable paradigm for future research must include both visual and tactile stimulation.

It is essential to mention that these results are partially beneficial for generating neuroplasticity in post-stroke patients [102] [103]. However, this single-session test does not prove that neuroplasticity was generated or induced in the patient using this interface. According to long-term research, this can be demonstrated in therapies with BCI systems and exoskeletons lasting between 10 to 12 months with a weekly intensity session [77]. Therefore, this research is limited to achieving immediate results related to partially beneficial brain activity as consulted in the literature.

5.2 Qualitative Tests Discussion

According to the results presented in Table 4.5, a favorable result can be concluded regarding user perception. Within the evaluation, it is possible to highlight similar results for the non-extended QUEST test, having the weight of the rehabilitation technology and the instructions at the time of use. According to Zickler et al. [104], this result is helpful for the study in general, since this designed technology is aimed at rehabilitation. Therefore, it is conclusive that the technology complies with a sufficient design for the use of patients. These results are favorable given that the average of this non-extended test is between the values of 4 to 5, according to the QUEST test this value indicates a classification of *high satisfaction* [105] on the part of the patients who used the technology.

In the case of the extended QUEST test, favorable results were also obtained. In this test, particular attention is paid to reliability and the learning process, which were optimal according to the patients' perception. The latter was beneficial since one of the most encountered problems in current BCI systems used with patients is the learning system [56]. This survey does not eliminate the shortcomings in precision that were presented in previous sections, but it does contribute to subjective patient satisfaction, which may benefit possible long-term studies

Chapter 6

CONCLUSIONS

State of the art carried out in this project made it possible to compile the basic concepts of BCI systems applied to exoskeletons aimed at rehabilitation and allowed to apply one of the paradigms designing these systems. Despite the various modalities found in the literature, there are few advances in BCI oriented to the lower-limb than the studies performed for upper limb applications. However, this review concludes the long-term advantages using these systems in rehabilitation therapy in terms of induction of neuroplasticity. It was found that stimulation methods are essential to induce patients to generate movement imagination in BCI systems, which that were applied in this work. Furthermore, some conclusions found in the literature could be contrasted in this study given the compatibility of the data analysis.

The present work aimed to integrate a BCI system to the T-FLEX lower-limb exoskeleton aimed at the rehabilitation of patients with neurological injuries. Some concepts like ERD / ERS of EEG analysis was applied to carry out the detection of Motor Imagination. This was possible thanks to the free-to-use applications developed by OpenVibe. In addition, an interface located on a local server was developed, which through two communication protocols could process the data to send orders to T-FLEX immediately by using the BCI paradigms described. Thus, a low computational cost BCI system was integrated to test its possible applications in the rehabilitation field.

The integration of these systems could be tested in post-stroke patients with lower-limb movement deficiencies. One of the objectives set was to perform a characterization in terms of the accuracy of the BCI system. In this sense, data were obtained on successful Motor Imagination detections. In this way, it was obtained that the BCI system ranged in its accuracy between 33.33% to 60% for visual stimulation and ranged between 53.33% to 80% with visual and tactile stimulation. Statistical analysis was performed to ensure a significance between the two IM stimulation paradigms, a statistical analysis was performed that involved the Wilcoxon median test. In this case, significant differences were found between the paradigm of visual stimulation and tactile stimulation, where more precision was found in the system when there was visual and tactile stimulation.

On the other hand, one of the proposed objectives was to analyze the patients' brain activity when the BCI was used and in its absence. The analysis was carried out from PSDs, where it focused on the active periods of both the stationary therapy tests and the two Motor Imagination paradigms. According to the methodologies consulted, the average power spectral density found in the channels used for each patient was observed. It was found that there were significant differences in the activation of the zones and the frequency associated with Motor Imagination when there was visual and tactile stimulation concerning stationary therapy. On the other hand, no differences were found between stationary therapy and the detection of Motor Imagination with only visual stimulation. These results could be contrasted with those on which the analysis methodology was based, finding similar results. In this way, a more significant MI activity induced by the BCI system with the proposed stimulation was validated, which leads to a possible integration in rehabilitation settings. According to several sources, the proper induction of Motor Imagination can be beneficial for patients in their rehabilitation process. However, these findings are not conclusive in the clinical sense. To obtain results on the BCI where neuroplasticity is induced as the main objective, it is known that this is only possible with deeper analyzes and obtained in the long term, observing correlations between muscle activity and brain activity as in studies cited in the literary review.

Finally, a good acceptance of the patient towards the integrated technology was demonstrated in this study. As noted in the previous section, the results were favorable. This is very beneficial since one of the main concerns of rehabilitation technology is the acceptance by patients who use them. Therefore, this study shows that the implemented BCI system is viable, in terms of the user's subjective perception.

Chapter 7

RECOMMENDATIONS AND FUTURE WORKS

7.1 Recommendations

To benefit studies of the operation of the BCI system with visual stimulation, an improvement of the visual interface is recommended that more effectively projects a motivation to improve MI. In addition, since the tactile system was low-cost, it is possible that other research related to T-FLEX could carry out the integration of haptic interfaces. It is recommended these systems be included in the BCI technically and with specifications found in the literature. This can improve the performance and expression of the patient concerning the BCI system.

7.2 Future Works

Regarding future work, two investigations are proposed, the first in the medium term and the second in the long term.

In the medium term, implementing the visual feedback system made for T-FLEX *Jumping Guy* is proposed, which is a serious game that works with motion-intended detection through inertial sensors (IMU) [106]. Therefore, the intention is to integrate the BCI interface to this project, in such a way that the user can make use of the serious game through the MI principles applied in this study. The integration of these two systems in the T-FLEX exoskeleton may prove beneficial for a therapeutic process focused on the foot-ankle complex.

In the long term, a more advanced clinical study with post-stroke patients is proposed. This in order to show an increase in neuroplasticity after the implementation of long-term sessions. As mentioned in previous sections, definitive therapies can include several weekly sessions over a 10-12 month term of BCI therapy. The correlation between muscle activity measured by EMG and brain activity associated with ERD in patients can conclude the feasibility of BCI integrated into T-FLEX. Thus, future studies propose long-term therapy with rigorous measures that allow evidence of neuroplasticity in patients with lower limb deficiencies.

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Appendix A

ASSESSMENT OF THE T-FLEX DEVICE CONTROL THROUGH A BRAIN-COMPUTER INTERFACE IN HEALTHY ADULTS AND PATIENTS WITH NEUROLOGICAL INJURIES

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1 Problem Statement

The number of people with gait disabilities due to neurological problems and traumatic accidents worldwide has increased in recent years. Pathological episodes, such as stroke, are among the most frequent causes of mobility impairments in adults, especially those over 45 years of age [1]. In this sense, different studies affirm that approximately 80 % of patients recovered from stroke have residual mobility limitations [2], [3].

One of the most fundamental , taken as an object of improvement, is the acquired dysfunction of the joints. The ankle, as a specific case, is essential for gait locomotion. Therefore, technologies have been developed to complement the conventional therapy process. In this sense, the T-FLEX device is a robotic orthosis that can assist the patient in its mobility, providing support for the dorsiflexion movement in the foot-ankle complex [4]. However, despite the existence of these devices, their operation is executed through physical manipulators, as well as commands through buttons, variations in body weight or by generating desynchronized impulses of the patient's will [5]. These types of therapeutic strategies, although effective, intervene in the fluidity, intuition and naturalness of locomotion. Therefore, these robotic systems might be improved by using the Brain-Machine Interface (BCI) paradigm [5], [6].

BCIs have been broadly defined as systems capable of controlling external devices using bioelectric signals obtained from the cerebral cortex as a channel, which are generally derived from electrodes with non-invasive implementation [6]. One of the most used strategies to decode brain activity following BCIs is the Motor Imagery (MI) study [7].

This protocol is proposed to evaluate the operation of a BCI control system for the T-FLEX exoskeleton and its effect on healthy subjects and patients with neurological injuries.

2 Objectives

2.1 General

To evaluate the functionality of a BCI system integrated into the T-FLEX device and its graphical feedback system in terms of time synchronization, command precision, the effect of cerebral cortex activation, and subjective perception of the user.

Appendix A

2.2 Specific

- To analyze the feasibility, in terms of time synchronization and command accuracy, of the integrated use of the BCI system in serious gaming, evaluating variables such as response time, latency time, false command rate, and command skipping rate.
- To analyze the feasibility, in terms of time synchronization and command precision, of the integrated use of the BCI system in the T-FLEX device, evaluating variables such as response time, latency time, false command rate, and command skipping rate.
- To assess the effect of the subject on the use with and without the T-FLEX device, in terms of its cortical activation, using EEG analysis.
- To assess whether there are significant differences in cortical activation between Motion Imagination detection and the stationary therapy mode of the T-FLEX device.
- To analyze the user's perception of assistive technology proposed in this protocol, taking into account subjective variables proposed in the QUEST, Adaptability and Operability test.

3 Methodology

For the development of this protocol, an EEG signal acquisition system from the company *Neuroelectrics* will be used, including the Enobio 2.0 hardware (electrode system) and the NIC 2.0 software (Neuroelectrics, Spain). In addition, the OpenVibe (Inria Rennes, France) platform will be used, which aims to perform the preprocessing of the acquired signals, the extraction, processing of characteristics and the issuance of commands to the T-FLEX device. The study will be guided by five captures (Calibration and four Experimental Conditions) with a duration of 5 minutes for each one (see Section 3.3). The tests will be carried out in a single session per subject, lasting approximately 30 to 40 min.

3.1 Inclusion criteria

The inclusion criteria will be divided into two types: healthy subjects and patients with physical limitations due to neurological injuries:

Concerning healthy users, they must have a complete absence of pathologies associated with the foot-ankle complex due to a neurological injury). These subjects must have complete independence to mobilize. Also, candidates must be between the ages range of 18 to 70 years.

With regard to patients, they must have the presence of some pathology associated with the foot-ankle complex due to a neurological injury. Patients must have partial independence to mobilize. Also, they must be between the age range of 18 to 70 years.

3.2 Exclusion criteria

Candidates will be excluded from the study if they present any of the following conditions:

- Uncontrolled hypertension.

Appendix A

- Uncontrolled epilepsy.
- Pain in the lower limbs or the spine prevents walking.
- Severe spasticity (Level 4 of the Ashworth scale).
- The presence of wound or pressure ulcers makes it nonfeasible to use the device.
- The user no count with an affiliation to the general health social security system.

3.3 Assigned intervention

The procedure of this protocol is divided into five captures. The first capture, *Idle*, refers to a calibration period in which the MI threshold is defined. The second and third captures refer to an experimentation period that will allow the user to become familiar with the BCI system. The last two captures are considered as the MI stage, where tests will be carried out that only imply the performance of the interface without real movement. In these captures the patient will be stimulated visually and tactilely, respectively. It is important to highlight that the 4 experimental conditions (Captures 2,3,4 and 5) will be under a comparative analysis in terms of brain activation of the beta wave, therefore, each capture will have EEG records that will be subjected to later studies.

Each experimental condition will consist of observation by the patient of a visual interface with full-screen text instructions indicating: (1) “Wait” text for 30 seconds; (2) Text ”Idle” for 10 seconds; (3) Text “Move your feet” for 10 seconds. **Instructions 2 and 3 are repeated continuously until completing 5 minutes of session.**

Idle-Calibration

In this first part, the user will be asked to sit comfortably in a chair with a 90 ° knee flexion. This part lasts approximately 5 minutes. The user will remain static while the acquisition system will calculate the mean by adding three times the standard deviation of the acquired signal at rest. After this calculation, the threshold above which MI will be detected will be defined. For this, the following succession of procedures will be followed:

1. Location of EEG signal acquisition system: Montage with Fcz, Cz , C1, C2 y Cpz electrodes from Enobio Acquisition system (Neuroelectrics, Spain).
2. Verification of connections and reading of sensors.
3. Execution of Sleep-Calibration capture in OpenVibe.

Experimental Condition 1: Real Movement

EEG recording during alternating active real movement of feet. The patient must perform alternating dorsi-plantar flexion movements for 10 seconds. It alternates with 10 second-periods of rest until reaching a 5-minute test.

1. Instruction to user on Experimental Condition 1 (Real Movement)
2. Beginning of Experimental Condition 1 (Real Movement)
3. Execution of repetitions of dorsi-plantar flexion (10 seconds)
4. Rest position (10 seconds)

Appendix A

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5. Alternate items 3. and 4. until completing 5 minutes.
6. Verification of stored EEG data.

Experimental Condition 2: Passive Movement

EEG recording during alternating passive movement of the foot assisted by T-FLEX. The patient receives alternating passive dorsi-plantar flexion motion for 10 seconds using the T-FLEX robotic orthosis. It alternates with 10 second-periods of rest until reaching a 5-minute test.

1. Instruction to the user on Experimental Condition 2 (Passive Movement).
2. Beginning of Experimental Condition 2 (Passive Movement).
3. Execution of assisted dorsi-plantar flexion repetitions (10 seconds)
4. Rest position (10 seconds)
5. Alternate items 3. and 4. until completing 5 minutes.
6. Verification of stored EEG data.

Experimental Condition 3: Motor Imagery with Visual Stimulation

EEG recording during Motor Imagery. The patient imagines alternating dorsi-plantar flexion movement for 10 seconds while observing a photograph of a moving foot and when the activation is detected in the BCI system, the subject receives passive movement through the T-FLEX robotic orthosis. It alternates with 10 second-periods of rest until reaching a 5-minute test.

1. Instruction to the user on Experimental Condition 3 (Motor Imagery with Visual Stimulation).
2. Beginning of Experimental Condition 3 (Motor Imagery with Visual Stimulation).
3. Execution of assisted dorsi-plantar flexion repetitions (10 seconds)
4. Rest position (10 seconds)
5. Alternate items 3. and 4. until completing 5 minutes.
6. Verification of stored EEG data.

Experimental Condition 4: Motor Imagery with Tactile Stimulation

EEG recording during Motor Imagery. The patient imagines alternate dorsi-plantar flexion movement for 10 seconds while receiving vibratory stimulation in the tibialis anterior muscle and, when the activation is detected in the BCI system, the subject receives passive movement through the T-FLEX robotic orthosis. It alternates with 10 second-periods of rest until reaching a 5-minute test.

1. Instruction to the user on Experimental Condition 2 (Motor Imagery with Tactile Stimulation)
2. Beginning of Experimental Condition 2 (Motor Imagery with Tactile Stimulation).

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3. Execution of assisted dorsi-plantar flexion repetitions (10 seconds)
4. Rest position (10 seconds)
5. Alternate items 3. and 4. until completing 5 minutes.
6. Verification of stored EEG data.

4 Confidentiality

In this project the information will be linked, that is, the information can be related or connected with the person to whom it refers. However, this information will be recorded anonymously, in this case it can be linked to the person to whom it refers except through a code or other means known only to the owner of the information. In this way, the personal information of the participating subjects is protected. Your identity will never be revealed or published.

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Appendix B

Satisfaction QUEST BCI-T-FLEX System

How satisfied are you with…?

1	2	3	4	5
Strongly Dissatisfied	Dissatisfied	Neutral	Satisfied	Strongly Satisfied

Ítem	1	2	3	4	5	Comentarios adicionales
System Dimensions: Width, Length, Height)						
System weight						
Adaptation: (Is the system adequately adapted to your context?)						
Security: (Do you consider the system to be safe for your context?)						
Ease of use: (Do you think the system is easy to use?)						
Effectiveness: (Is the system effective according to the objective set?)						
The information for its use is clear and concise:						
Total Score:						
Consideraciones adicionales QUEST						
Reliability: (Would you trust the BCI system for rehabilitation applications)						
Velocity: (How fast do you perceive the use of the system according to your context?)						
Learning: (Is it easy to learn to use the system?)						
Aesthetics:						
Total Score:						

Appendix B

- Which of the following items do you think are the most important to the rehabilitation technology you used?

Select 3 important items with an 'x'

1. Dimensions (width, size, length, etc.)
2. Weight
3. Physical adaptation
4. Security
5. Ease of use
6. Effectiveness
7. Information
8. Reliability
9. Velocity
10. Learning
11. Aesthetics

Participant Name: ________________________________

Signature: _______________________

Professional Name: ______________________________

Signature: ___________________________