NEUROPROSTHESES CONTROL INTERFACES BASED ON BODY MOTION IN PERSONS WITH SPINAL CORD INJURY

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Abstract

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Spinal cord injury (SCI) is a serious medical condition that often leads to severe motor disabilities. Persons with SCI may have paraplegia or tetraplegia, greatly decreasing their ability to perform basic tasks such as locomotion, feeding and hygiene. It affects hundreds of thousands of people in Brazil alone and very few people totally recover from it. Traditional recovery treatments such as physiotherapy typically have limited results.

A person with SCI may not be able to control their upper or lower limbs, but often the local structures, such as muscles and motoneurons, are preserved. Therefore functional electrical stimulation (FES) can be used to induce contraction on these muscles and generate movement in paralyzed limbs. However, due to their own motor disabilities, patients usually find it hard in their daily lives to operate FES assistive devices. This limits their performance and usability.

In this work, I developed a framework of techniques for user interfaces that explore residual motor capabilities that users with SCI may still possess to control neuroprostheses. In order to acquire movement information I use inertial measurement units (IMUs). I developed and evaluated algorithms for detection and classification of movements by users with paraplegia and tetraplegia. They use their own residual movements, depending on their injury levels, to activate different commands in assistive devices. I applied the developed techniques in three application scenarios with persons with SCI.

First I performed an experiment in which three users with paraplegia activated an FES device to aid in sitting pivot transfers (SPT). I analyzed their trunk kinematics to investigate the feasibility of using that information to activate the FES on their lower limbs during the SPT.

Then I developed an interface with which nine users with tetraplegia used shoulder movements to control a robotic hand, which simulated an upper limb grasping assisted device. In this case, I used accelerometer and gyroscope data along a threshold technique to detect movements, and a principal component analysis (PCA) to classify them. I then mapped these movements into different commands on the robotic hand.

Next I developed an interface that uses upper limb kinematics to properly activate an FES neuroprosthesis on lower limbs of persons with paraplegia during FES-rowing. I used a finite state machine and linear discriminant analysis (LDA) to constantly classify every upper limbs movement from the user into three different rowing phases commands. I evaluated it with one participant and an adapted rowing machine for rowers with SCI.

On the transfer experiment, each participant moved their trunk in a similar way across trials, with angles standard deviations less than 5°, which means I can use it to automate the FES activation. Using the upper limb grasping simulation interface, participants were able to successfully control the robotic hand, correctly performing 91% of the robotic hand commands I instructed them to. Finally, the rowing protocol participant was capable of rowing with the developed interface with only their upper limbs movements. The system activated his lower limbs neuroprosthesis in sync with the upper limbs rowing motion. Also, he could start and control the FES by stopping or moving his arms.

These results show that persons with SCI are successful in using residual motor capabilities to control assistive devices under the observed conditions.

Keywords: Spinal Cord Injury. Functional Electrical Stimulation. Motion analysis. Machine Learning.

Resumo

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A lesão medular (LM) é uma condição médica que frequentemente leva a deficiências motoras severas. Pessoas com LM podem ter paraplegia ou tetraplegia, e perder suas habilidades de realizar tarefas básicas como locomoção, alimentação e higiene. Ela afeta centenas de milhares de pessoas apenas no Brasil e muito poucos se recuperam totalmente. Tratamentos tradicionais como fisioterapia normalmente têm resultados limitados.

Uma pessoa com LM pode não conseguir controlar seus membros superiores e inferiores, mas normalmente as estruturas locais, como músculos e neurônios motores, são preservados. Portanto estimulação elétrica funcional (EEF) pode ser usada para induzir contração nesses músculos e gerar movimento em membros paralisados.

Neste trabalho eu desenvolvi uma plataforma de técnicas para interfaces de usuário que explora capacidades motoras residuais que usuários com LM podem ainda ter para controlar neuropróteses. Para obter informações de movimento, uso unidades de medida inercial (UMI). Eu desenvolvi e avaliei algoritmos para detecção e classificação de movimentos de usuários com paraplegia e tetraplegia. O objetivo é que os usuários possam usar seus próprios movimentos residuais, dependendo do seu nível de lesão, para ativar diferentes comandos de dispositivos assistivos. Eu usei as técnicas desenvolvidas em três cenários de aplicações com pessoas com LM.

Primeiro eu executei um experimento em que três participantes com paraplegia ativaram um dispositivo ativado por EEF para auxílio em transferências sentado-pivô (TSP). Eu analisei dados cinemáticos dos troncos para investigar a viabilidade de usar essa informação para ativar a EEF nos seus membros inferiores durante a TSP.

Depois eu desenvolvi uma interface com a qual nove participantes com tetraplegia usaram movimentos de ombro para controlar uma mão robótica simulando um dispositivo de auxílio de preensão manual. Eu usei dados de acelerômetros e giroscópios e uma análise de componente principal para classificá-los. Então eu mapeei esses movimentos em três comandos na mão robótica.

Em seguida eu desenvolvi uma interface que usa dados cinemáticos de membros superiores para ativar uma neuroprótese acionada por EEF em membros inferiores de pessoas com paraplegia durante remo assistido por EEF. Eu usei uma máquina de estados finitos e análise discriminante linear para classificar todos os movimentos de membro superior do usuário em três comandos de fases diferentes no remo. Eu avaliei esse sistema com um participante e um remo ergômetro adaptado para remadores com LM.

No experimento de transferência, cada participante moveu seu tronco de uma forma similar em todas as repetições, com desvios padrão de ângulos menores que 5°, o que significa que eu posso usar essa técnica para automatizar a ativação da EEF. Os participantes que utilizaram a interface de simulação de preensão manual conseguiram controlar a mão robótica com sucesso, corretamente executando 91% dos comandos solicitados. Por fim, o participante do protocolo de remo foi capaz de remar com a interface desenvolvida utilizando apenas os movimentos de membros superiores. O sistema ativou a neuroprótese em seus membros inferiores em sincronia com os seus membros superiores.

Esses resultados mostram que pessoas com LM conseguem usar seus movimentos residuais para controlar dispositivos assistivos nas condições observadas.

Keywords: Lesão medular. Estimulação elétrica funcional. Análise de movimento. Aprendizado de máquina.

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List of Acronyms

ACC accelerometer

ADL activity of daily living

CNS central nervous system

C-SVC C-Support Vectors Classification

EEG electroencephalography

EMG electromyography

FES functional electrical stimulation

IMU inertial measurement unit

LDA linear discriminant analysis

PCA principal component analysis

PNS peripheral nervous system

SCI spinal cord injury

SPT sitting pivot transfer

STS sitting to stand

SVM support vector machine

1 Introduction

1.1 Motivation

The nervous system is responsible for controlling many functions in the human body, such as motor functions. Electrical signals travel the nervous system carrying information from and to other systems. One example of such signal is the one associated with information of touch, detected by nervous terminations on the skin, and sent to the brain. The brain can, then, process that information, and decide to activate muscles to perform some action. If something disturbs that path of information, such as a spinal cord injury (SCI), both ascending and descending signals might not reach their destination. Considering the example above, the person might not be able to feel the touch, nor to contract his/her muscles.

If that happens, the communication between the brain and body parts below the injury may be totally or partially interrupted. There are currently 282,000 persons living with SCI in the US, and there are approximately 12,000 new cases each year [1]. In Brazil, there are no precise data [116], however it is estimated that there are over 10,000 new cases each year [81].

When the lesion is below the cervical vertebrae, it may cause paraplegia, which refers to the condition in which the patient loses sensory and/or motor skills on their lower limbs. If the lesion is at a cervical level, it is a tetraplegia, which refers to the condition in which the patient loses sensory and/or motor skills on their upper limbs as well. The injury can be incomplete or complete. As a consequence of the former, some motor or sensory capability is retained, and on the later both are lost. Out of all persons living with SCI in the US, about 45% are diagnosed with incomplete tetraplegia [1].

Often, such disabilities can hinder people from working, socializing, and performing basic activities of daily living (ADLs), like feeding, maintaining personal hygiene, or using the restroom. An SCI may lead to grave consequences, both physically and psychologically. For instance, patients may also have bladder and bowel malfunction, impotence, and even breathing difficulties. There are also associated secondary effects, such as pressure sores due to the lack of movement, overweight, heart diseases, loss of bone density, depression, social isolation, and suicide [21].

Every case must be treated accordingly. There are surgeries and medicines that may be sometimes indicated. However, it usually results in loss of some sensorimotor capability, which requires rehabilitation. The rehabilitation of the nervous system, or neurorehabilitation, is mainly based on its capacity for neural plasticity, which is its ability of adaptation to changes in the environment. Through this mechanism, neurons are able to modify their shape or function. This is usually addressed through rehabilitation by repetitive tasks that aim at inducing neural plasticity. This process, however, is not always successful. In fact, among all SCI cases in the US, less than 1% fully recover [1].

There are numerous assistive devices for movement restoration or function replacement, such as wheelchairs. A wheelchair does not help patients recover their movements, nor helps them walk again, but it provides them with locomotion capability. It is probably the most used piece of assistive technology among persons with paraplegia or tetraplegia. Particularly in case of paraplegia, users can sometimes enjoy high levels of quality of life, including social and labor activities [8], greatly thanks to wheelchairs. There are also technologies that focus on other important aspects of one's life, such as communication and access to information. Devices that help persons with disabilities to use computers or communication aid systems are examples of technologies that can also greatly improve the lives of individuals by enabling them to interact with other people. Such tools usually explore the users residual motor capabilities as replacement for the ones they lost. Users are, however, dependent on these technologies for as long as they have the disability, which is usually forever. Moreover, there are devices developed to aid in the rehabilitation process, such as weight support systems. These devices are supposed to be used until the original function is recovered. There are also the ones that can be used both for rehabilitation and assistive purposes, such as walking aids and orthoses.

Although natural commands may no longer reach targeted muscles after a complete SCI, the muscles located below the lesion may have preserved motoneurons; this allows their activation via functional electrical stimulation (FES). FES can induce muscle contraction [111] and functional movements in paralyzed limbs [71, 102]. In this work, FES-based assistive devices will be called neuroprosthesis.

1.2 Problem Definition

One major issue users with SCI face when using FES devices – or other technologies for restoring human motor skills – is controlling movements through an interface capable of interpreting user intent. Typical solutions such as buttons [4, 87] present a challenge for persons with physical disabilities, particularly tetraplegia, because their very ability to activate these buttons might be compromised. Other methods have been proposed, such as devices controlled by muscular electrical activity through electromyography (EMG) [113], implanted mechanical sensors [63], brain signals decoding [53], eye movement [128] and voice commands [35]. But they are either not practical, or do not have acceptable performance. Proper EMG signals, that are well controlled and repeatable by the subject, are hard to acquire. Also, electrode positioning and skin conditions, such as levels of sweat, make EMG signals unreliable [13]. Implanted equipment require surgery and attentive maintenance. The use of brain signals present a very attractive solution because it is very close to natural commands. However, there are difficult challenges related to low signal-to-noise ratio and high rates of false positives and false negatives. Also, less invasive techniques such as electroencephalography (EEG) require long set-up times [53]. Eye-movements based interfaces work by capturing electrical signals from ocular muscles. This can generate clean, useful signals. However, dimensionality is limited. Also, it might interfere with mundane activities, which require complex command patterns for safe use [128]. Voice commands can be useful for controlling assistive devices.

[35] presented good speech recognition results, but they are highly dependent on controlled environments, since they are very susceptible to surrounding noises.

Persons with SCI often retain some motor skill. Even persons with tetraplegia can often move their shoulders or their heads. Considering these movements are well controlled by the user, they may be better suited for controlling assistive devices because they do not interfere with other activities as much as eye tracking or voice commands, and are easier to acquire than brain signals or muscle electrical activity. Current inertial sensors are precise enough to capture subtle movements and are cheap, small, lightweight and accessible. Thus this work explores the hypothesis that these **residual motor capabilities in persons with SCI can be captured by inertial sensors, and these movements can be detected and classified to predict user intent for neuroprostheses control**. I use different techniques to develop user interfaces that interpret motion from the able body parts of participants with paraplegia and tetraplegia. Finally, by predicting the user intent, I map different voluntary movements into commands to control assistive devices, such as FES neuroprostheses.

Depending on the specific activity, the optimal scenario would be that the user simply tries to perform the movement, without any or with very low concern for how the system works. Whereas the system, based on previous learning or set up, must be able to recognize the movements performed by the user, and to activate the neuroprosthesis. This is called in this work a "transparent" control method.

Perhaps the most important feature is the capability of starting and stopping the system. For instance, consider a walking system based on a hybrid actuated neuroprosthesis, where there is an underactuated exoskeleton assisted by FES. This system is being piloted by a user with paraplegia. According to the hypothesis, the upper body movements are correlated with the lower part movements. Let us say that the arms swing can be correlated with the steps. If all that is true, when the user swing their arms, the system can perform steps accordingly. If the user stops swinging their arms, the steps can also stop. Another feature would be the control of the speed of actuation. Still considering the walking example, can we correlate the arm swing cadence with the stepping speed? If so, the user could control the walking speed.

Note that all of this may feel transparent to the user, at least in situations concerning the system control. They would simply swing their arms as if they would normally walk, and the pre-configured system would actuate the lower body as intended. Nevertheless, more important than being transparent, the system must be functional. Individuals with tetraplegia might not have sufficient motor capabilities to control such a transparent interface. Thus, the system must be able to work even with non natural, intentional movements that can be learned by the user and by the system.

1.3 Objectives

In order to investigate the aforementioned hypothesis, the main objective of this work is:

- To develop a framework of techniques for assistive devices interfaces that enable persons with SCI to operate these devices with their residual motor skills to perform functional activities. These interfaces must be customized to the users specific capabilities, and they must be able to operate them in a "transparent"or intuitive manner.

In order to accomplish that goal, specific objectives must be completed:

- Develop a user interface to control neuroprostheses based on inertial measurement units (IMUs) that is light, small, wireless, and have low power consumption.
- Develop a control system with which the interfaces are capable of automatically learn users specific motor requirements and commands.
- Test the system feasibility in a sitting pivot transfer scenario with persons with paraplegia by evaluating if there is enough kinematic information to reliably control the neuroprosthesis.
- Develop an interface for upper limb grasping for persons with tetraplegia in which the neuroprosthesis is controlled by arbitrary shoulder movements.
- Develop a FES-rowing user control interface with which persons with paraplegia can row only by moving their upper limbs in a regular rowing motion, and the neuroprosthesis activates their lower limbs accordingly.

1.4 Thesis Outline

In Chapter 2 the basic theoretical fundamentals are presented. Relevant human physiology concepts are presented. The process of an SCI is explained, and its consequences in loss of sensorimotor capabilities are described. FES and some of its applications are briefly presented.

Chapter 3 describes several techniques used to control different assistive devices. Common approaches such as EMG are discussed. Some commercially available solutions are presented. Finally, the main works related to body motion based control interfaces are listed and discussed.

The material and methods used in this work are explained in Chapter 4. The general interface design is presented. Three scenarios are described where each is used to investigate a different feature or capability of the interface. In each scenario, a different part of the interface is detailed and developed through a practical experiment with persons with paraplegia or tetraplegia as a consequence of SCI.

The results from the applications described in chapter 4 are shown in Chapter 5. Chapter 6 discusses the results presented in chapter 5. These discussions are contextualized according to each application, and also their role in the whole interface. Finally, chapter 7 presents the conclusions of the present work. Also, next steps are proposed for future works.

2 Theoretical Basis

An SCI can be extremely disabling, and requires intense rehabilitation treatments that often do not result in complete recovery of sensorimotor capabilities. Many research groups work to improve this condition and the patients quality of life. These works have different methods, such as tissue regeneration, motor learning or complete function replacement (e.g. exoskeletons).

In this chapter, I present the basic concepts of the nervous system. SCI is explained, and different recovery approaches are discussed. Particularly, FES is explored as a mean to assist persons with disabilities.

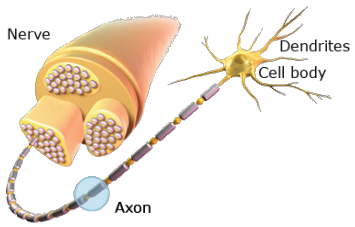
2.1 Neurophysiology of Movement

The nervous system is very important in controlling many functions on the human body. One of these is the motor function. Subsection 2.1.1 presents the nervous system and its elements. Subsection 2.1.2 describes the influence the nervous system has over the musculoskeletal system.

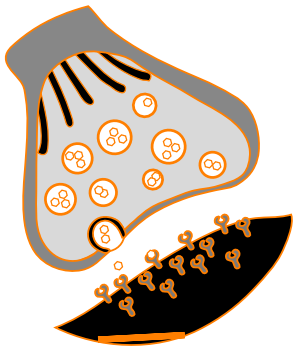
2.1.1 Nervous System, Neurons and Nerves

The human nervous system can be divided in two parts: the central nervous system (CNS) and the peripheral nervous system (PNS). The CNS is formed by all structures inside the skull and also the spinal cord. It is in the CNS where most of the neurons are. The mains elements of the PNS are nerves. Nerves are long fillets that, when grouped together, form nervous fibers. These fillets are parts of neurons, which can have their main body located in different locations. Nerves connect the spinal cord or the brain to organs. They transport information, by means of electric pulses, from one point to the other. This information may be efferent, in cases in which they leave the CNS, or afferent, in cases in which they enter the CNS [74].

Neurons are cells capable of transmitting and processing electrical signals. They have a cellular body, where the core is; dendrites, small elongations around the body; and a bigger elongation called axon, that can be longer than one meter in humans. an illustration of such structure can be seen in in Figure 2.1a. Neurons communicate with each other through synapses. Synapses can transmit, block or modify messages. Figure 2.1b shows the illustration of a synapse happening. Inside a neuron, information is transmitted as nervous pulses by means of action potentials, which is caused by ionic trades between tissues. By the end of the axon, the nervous pulse triggers a synapse, which is the emission of neurotransmitters to other cell or cells. Since nervous pulses have this ionic nature, they can be seen as electrical charges and can be measured using electrodes, such as in EMG or EEG.



(a) Illustration of a neuron with dendrites, cell body and axon. The axon goes in a nerve [93].



(b) Illustration of a synapse. Hexagons represent neurotransmitters that transport information [101].

Figure 2.1: Illustrations of a neuron and a synapse.

2.1.2 The Nervous System and the Musculoskeletal System

Skeletal muscles are connected to bones by tendons and form the musculoskeletal system. These muscles are structures that generate force and promote movement. In order to do that, they contract and shrink. By relaxing, they elongate. When a muscle contracts and shrinks, it pulls the tendon and, by consequence, the bone to which it is connected. By doing so, the musculoskeletal system can move the body. Muscles respond to action potential coming from nerves reach them, and this is how the nervous system activates their contraction. Since electrical stimulation can cause nerve depolarization, and trigger an action potential, muscles are highly responsive to it [74, 104].

The link between the nervous system and a muscle is called neuromuscular junction. Nerves enter muscles with the main artery and are divided until they reach all muscle fibers. The neuron that connects to a muscle fiber is called motoneuron. A motoneuron and the muscle fibers to which it is connected are called a motor unity. Some motor units have many muscle fibers, and other have few, depending on the muscle size and function. Muscles responsible for fine movements, like eyes movements, may have as few as five fibers. On the other hand, big muscles such as the gastrocnemius can have over 2000 fibers [74, 104].

2.2 Spinal Cord Injury

An SCI is a syndrome that can cause sensory, motor, and autonomic dysfunctions [75, 104], and that is often caused by trauma [1]. Its consequences may be severe for patients in several aspects, affecting their quality of life. This section describes what is an SCI, how it is classified and possible recovery approaches.

2.2.1 The Lesion

The spinal cord is located inside the vertebrae, which serve as a mechanical protection. If damaged, some nervous system functions may be affected. The spinal cord transmits signals from the superior CNS to upper and lower limbs, and also organs. The PNS nerves that take

the signals to these destinations are originated in different points of the spinal cord. If it is interrupted at any point, descending signals that travel through nerves originating on that point or below will not reach their destination [37].

Besides trauma, other situations can also result in SCI. Blood cloths or lack of oxygen can cause cell death and, as a consequence, lesions in the spinal cord. Multiple sclerosis and infections, such as HIV, tuberculosis, meningitis and syphilis too [109, 121, 114].

The motor disabilities caused by SCI result in higher dependency on other individuals. Some conditions that may arise from the lack of mobility are thrombosis, osteoporosis, muscle atrophy or pressure sores. SCI often also cause spasm and chronic pain [104].

Also, there are serious secondary consequences such as bladder and bowel malfunction, respiratory disability, overweight, cardiovascular complications, sexual dysfunction and psychological issues such as depression, sometimes leading to suicide [104, 90, 115, 70, 65, 54]. After the lesion, many patients report being less active socially and not having a job [8].

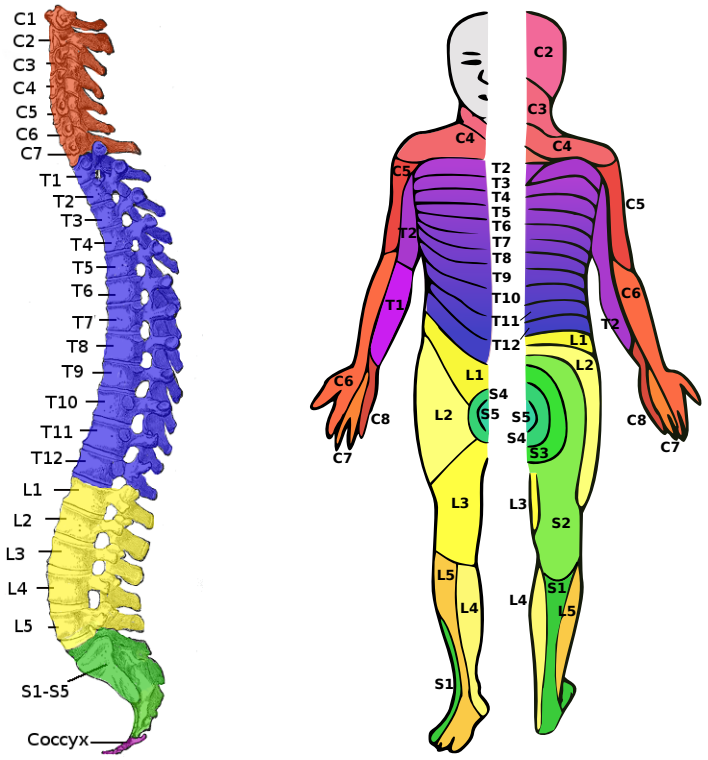
2.2.2 Classification

According to the American Spinal Injury Association (ASIA), the traumatic SCI can be classified, based on its functional consequences, in tetraplegia or paraplegia. In cases in which the SCI causes a total interruption of the neural tissue, in a way that there are no more functional action potentials being generated and thus information flowing through that region, it is called a complete lesion. All other cases, in which functional information can still be detected through the lesion area, are incomplete lesions. The ASIA scale for SCI is classified, then, from A for complete lesion (total lack of motor or sensory functions below the lesion level) to E (normal functions are preserved), with intermediary levels B, C and D [58].

The height at which the lesions happens is also important and is typically associated to the vertebra at the same height. For instance, the C1 SCI level is at the same height as the vertebra C1. Lesion levels are grouped in cervical, thoracic, lumbar, and sacral. Each level name is formed by the first letter of its group and a number that represents its height, from top to bottom. So, for instance, the third lumbar level is called L3. Figure 2.2a illustrate these levels. Each SCI level affect an area of the body. Lower levels will typically affect lower parts of the body, such as weakness or lack of control in the lower limbs, urinary, bowel and erectile dysfunction. Higher levels affect higher parts, as upper limbs, trunk balance capability, cardiovascular dysfunction due to alterations on the autonomic system, and even possibly the diaphragm [78]. Figure 2.2 shows an illustration that indicates the body area affected by different SCI classification levels. A person with SCI at the thoracic area or below may have paraplegia. A person with SCI at the cervical area may have tetraplegia [68, 82, 37].

2.2.3 Possible recovery approaches

The process of recovering from a neural lesion is called neurological rehabilitation, or neurorehabilitation [10]. It regards all the affected aspects of the life on someone with



(a) Illustration of the spinal cord and its lesion classification levels [126].

(b) Illustration of the body part affected by SPI in each classification level [126].

Figure 2.2: Illustrations of SCI classification levels.

disabilities, such as health, work, family and leisure. It can be done by restoring loss function, or by replacing it with some different strategy or assistive device.

An SCI is considered a syndrome, a condition characterized by a group of symptoms which occur together. Therefore there are different recovery approaches. Some of them rely on neuroregeneration, which is the technique of restoring damaged neural tissue [104]. This is done mainly with physioterapy, but can also be induced with neural tissue implantation [25], or with the aid of Shwann cells [22, 95]. Also, it has been shown that electric fields can directly affect the orientation and regeneration of axons [51]. The nervous system capability to change its own structure and function is called neural plasticity [79].

Regardless of the chosen recovery approach, it is important for patients to be able to perform key functional activities with minimal dependency on others. Notably, they must learn to empty their bladder and bowel, avoid pressure sores caused by immobility and perform transfers between the wheelchair and other locations [99, 96, 78]. Moreover, there is evidence that learning to and using assistive technologies can increase the quality of life after the lesion, including psychological aspects [8, 9]. Finally, many people learn to perform all kinds of activities to live a satisfactory life, such as sports, sex, social activities, and work [76, 38, 46, 48, 16, 117].

In this work, I call neuroprosthesis devices that are used to restore a lost function, and

that have an interface with the nervous system. These interfaces rely on the electrical signals elicited by the nervous system action potentials, either to act on it or to extract information from it.

2.3 Functional Electrical Stimulation

Functional electrical stimulation (FES) is the stimulation of neurons with superficial or implanted electrodes [104] to restore lost functions after a lesion to the nervous system. Superficial stimulation is convenient because it does not require surgery. However, the selectivity of specific fibers is a challenge, since it is hard to control the path of the current inside the body. FES is widely used in neurorehabilitation, both in clinical use and research. Differently than typical physiotherapy methods such as passive manipulation and repetitive motor learning exercises[52], FES stimulates both afferent and efferent neural pathways, which is believed to better enhance neural plasticity [104, 122, 17, 20].

FES can be used in several scenarios. Besides post-SCI neurorehabilitation, patients of stroke, cerebral palsy, and multiple sclerosis can benefit from it. The two most known applications are pacemakers and cochlear implants. The first is a FES system which is implanted in users chests and control their heart rates. The second is a partially implanted FES device that encode sound into electrical signals and then stimulates the cochlea, which results in the user hearing an aproximation of the original sound.

Specifically in SCI treatment, the two most complete FES applications are cycling and rowing. On the former, lower limbs are stimulated to power a cycling motion. On the latter, lower limbs are stimulated to flex and stretch in synchrony with upper limbs in persons with paraplegia. Both applications have been shown to produce good results in SCI treatment, improving bone density, muscle mass, and cardiorespiratory function [12, 73, 125, 7, 46, 41, 59, 30].

2.4 Machine learning

Computers are valuable tools to perform tasks often difficult for humans. Particularly in cases in which these tasks are repetitive and well defined, machines can many times execute them faster, better and safer than people. For instance, building thousands of identical vehicles, or billions of electronic components. In cases such as these, machines can be programmed with specific instructions.

There are tasks, however, that cannot be defined as a set of immutable instructions. For example, it is difficult to program a computer to recognize someone in a picture. It is even hard to describe how humans do it.

Machine learning is a subset of artificial intelligence that studies techniques used by computers to accomplish tasks without explicit instructed to [69]. It is useful in cases in which there is enough know data to train the system to accomplish the desired task. In the example aforementioned, if one has a certain number of pictures of different people, and it is possible

to train the computer with information of which ones are of which people, machine learning techniques may be used to recognize these people in new pictures

In this work I used two machine learning techniques: principal component analysis (PCA) and linear discriminant analysis (LDA). The next subsections briefly explain these two techniques.

2.4.1 Principal component analysis (PCA)

Principal component analysis is the mathematical method of applying a transformation to a data set in order to obtain a new data set composed by its principal components. The original data set may be formed by n observations of an event. Each observation may contain p features that are possibly correlated. The PCA transformation outputs a new data set with p new features that are orthogonal to each other. Also, each new feature has its own variance. The greater the variance, the greater its influence in the original data set. Therefore, the new feature with the greatest variance is the first principal component. The feature with the second greatest variance is the second principal component, and so on. In other words, PCA is an orthogonal linear transformation that outputs a new coordinate system, in which the components have decreasing variance magnitude.

In many cases, systems with multiple dimensions retain most of its information in a few principal components. Therefore, PCA is often used for dimension reduction and feature extraction.

Consider a data matrix $\boldsymbol{X}$ with p columns and n rows. To perform the PCA of $\boldsymbol{X}$ is to find the matrix of weights $\boldsymbol{W}$ such that

$$\boldsymbol{T} = \boldsymbol{X}\boldsymbol{W}, \tag{2.1}$$

where the $\boldsymbol{T}$ matrix contain the same data points as $\boldsymbol{X}$, but rotated into the new coordinate system. In order to do that, the first component is given by the weight vector $\boldsymbol{w}_1$, which must maximize the variance of $\boldsymbol{t}_1$. So it is calculated by solving

$$\boldsymbol{w}_k = \arg\max_{\|\boldsymbol{w}\|=1} \left\{ \sum_i (\boldsymbol{x}_i \cdot \boldsymbol{w})^2 \right\} \tag{2.2}$$

for $k = 1$. And any other component k is then calculated by subtracting all the previous components:

$$\hat{\boldsymbol{X}}_k = \boldsymbol{X} - \sum_{s=1}^{k-1} \boldsymbol{X}\boldsymbol{w}_s\boldsymbol{w}_s^{\mathrm{T}} \tag{2.3}$$

and using Eq. 2.2 again.

2.4.2 Linear discriminant analysis (LDA)

Linear discriminant analysis works similarly to PCA in a way that it tries to describe the system with a combination of independent variables. The conceptual main difference between the two is that, while PCA looks for the most variance among all training data set for the first component, the LDA searches for the most variance between data elements in different classes. In other words, the first component in PCA will contain the information with the greatest variance considering all data elements, and the first component in an LDA system will contain information that maximizes the difference between classes [84]. Therefore, LDA requires class labeling and is a supervised machine learn method. Moreover, LDA is more suitable to classification problems in which classes are know during the training phase.

Hence, LDA is often used in problems such as face recognition and medical diagnosis suggestion, applications in which there is abundant previously known data to train an LDA system to classify new cases.

Consider an observation $\boldsymbol{x}$ containing all the relevant features. The LDA approaches the classification problem by calculating the probabilities of $\boldsymbol{x}$ belonging to a class y: $p(\boldsymbol{x} \mid y = 0)$ and $p(\boldsymbol{x} \mid y = 1)$. It is assumed that both probability density functions have normal distributions with means $\boldsymbol{\mu}_0$ and $\boldsymbol{\mu}_1$ and the same covariance Σ. These parameters are all calculated from the training set.

The LDA classifies $\boldsymbol{x}$ as belonging to class $y = 1$ if

$$\Sigma^{-1}(\boldsymbol{\mu}_1 - \boldsymbol{\mu}_0) \cdot \boldsymbol{x} > \frac{1}{2}(T - \boldsymbol{\mu}_0^T \Sigma_0^{-1} \boldsymbol{\mu}_0 + \boldsymbol{\mu}_1^T \Sigma_1^{-1} \boldsymbol{\mu}_1). \tag{2.4}$$

Therefore T can be found through a linear combination of all the known observations from the training data set.

Geometrically speaking, the LDA calculates one axis on which to project all observations, and then defines a plane perpendicular to that axis which separates the original multidimensional-space into two classes. The classification of new observations is performed by projecting the new data onto this axis and checking at which side of the plane it is.

3 State of the Art

Many sensor modalities have been proposed so far in the literature for neuroprostheses control interfaces. In this chapter I discuss some of the these methods, particularly motion-based interfaces, which are the ones used in this research.

3.1 Alternative Sensor Modalities

Several non-invasive interfaces have been developed in the past, notably EEG-based Brain Computer Interfaces (BCIs), where surface electrodes are used on the head to read brain signals and decode them into commands. The most common goal is to identify thought commands into two classes: stand and walk. It has been used for instance to control exoskeletons[53]. At this time, more work is needed to improve their accuracy and reliability [83, 107]. Mechanomyography (MMG) has been used to read muscle vibrations with accelerometers, which can in turn serve to control devices by estimating isometric muscle contraction [6]. However, this method is highly sensitive to limb movement artifacts, and therefore not reliable in real life situations [105]. Electro-oculographic potential (i.e., tracking two-dimensional eye movements) has also been used to control a robotic arm [128]. Three-dimensional gaze-tracking would likely expand the control possibilities of this method, but its development remains challenging [89]. Voice commands have been used to control upper-extremity prostheses with relative success [35]. Nevertheless, this method's accuracy drops dramatically in noisy environments, which can lead to possible issues regarding user acceptance [127].

A common control method of choice is based on surface EMG signals [113]. In the past, several authors have proposed using surface EMG from the contralateral arm deltoid muscle to control a device which stimulated hand muscles [64, 67]. In [119], the EMG signal from the ipsilateral wrist extensor muscles was used to control a hand neuroprosthesis. EMG signals have also been used to control an upper limb exoskeleton in [33]. EMG-based control may be very intuitive for the user, since they often control devices functions the same way they would otherwise control their own limbs. Also, proportional force control is straightforward, as more force from the device can be controlled by more force from the user. However, EMG-based solutions do have important drawbacks. Electrode placement is usually very sensitive, which makes day-to-day use complicated. Also, persisted contraction may be very fatiguing for users, particularly the ones with disabilities.

Invasive approaches to control arm and hand muscles with FES, such as head and neck-implanted EMG [85] or invasive BCIs [3, 18], have recently been proposed. However, non invasive approaches remain more common. Indeed, they require less complex technology and no surgery, although they often require donning and doffing each time the system is used.

3.2 Body Motion-Based Interfaces

Body movement are used in both active and body-powered prostheses. The latter ones are mechanical devices that link functional end actuators or other joints of a prosthesis to the contralateral shoulder, which users move for control [113]. Table 3.1 presents a summary of relevant works that explored body motion to control active devices. Since EMG is a popular first choice, sometimes IMUs are used to improve an EMG-based device. Many works have relied on machine learning techniques to classify user movements, such as PCA, LDA or support vector machine (SVM). These are useful in cases in which similar movements are intended to be classified as different classes. Others used linear functions between the volitional body movement and the device activation, which can be used in proportional control, such as force. Very few tested their systems with subjects with disabilities, and most of the works that did had only one subject. Performance comparison between works is hard because there is no standard test, since many applications are very specific.

To control active devices, body motion was used in [49, 88] with camera-based systems and IMUs, respectively. In [63], contra-lateral shoulder motions were related to hand muscle stimulation by an external shoulder position transducer. In [61], the kinematic data in a sitting pivot transfer movement in able subjects was analyzed in order to develop an FES assistive device for that application. Later, in [60], a similar approach was tested in SCI patients for sitting to stand movements, resulting in less upper limb effort. In this thesis, this modality of body motion-based sensor is explored in the development of a intuitive and practical interface for controlling assistive devices.

Nevertheless, many applications still rely on basic user interfaces. Modern FES-assisted rowing machines work with simple, manual buttons [45], even though there has been an attempt of developing an automatic body motion based system long before, with good reported results from a sole subject [27]. One of the most known commercially available FES assistive device was the Freehand, by NeuroControl (Fig 3.1). It was an implanted FES system for upper limb function that was activated by body motion [63]. Unfortunately, the company stopped manufacturing the system in 2001 and, by 2010, the system was completely out of official support [11]. However, there are some FES assistive devices commercially available for customers today, such as the H200 by Bioness (United States) [4, 87], also controlled by buttons (Fig. 3.2).

Many companies are currently developing and commercializing FES assistive devices for a lower limb situation known as drop foot. It is a common consequence of conditions related to the sciatic nerve or strokes in which patients lose the ability to lift their feet while walking, causing it to drag. These devices typically benefited from mechanical foot switches in the past, but currently employ a more advanced control method based on IMUs for identifying walking phases and automatically triggering the FES on the tibialis anterior muscle for ankle dorsiflexion. The devices are small and portable, suitable for everyday use [94, 19, 124, 66]. Examples of commercial devices can be seen on Fig. 3.3.

At this developmental stage, movement or force-based sensors seem to offer the most

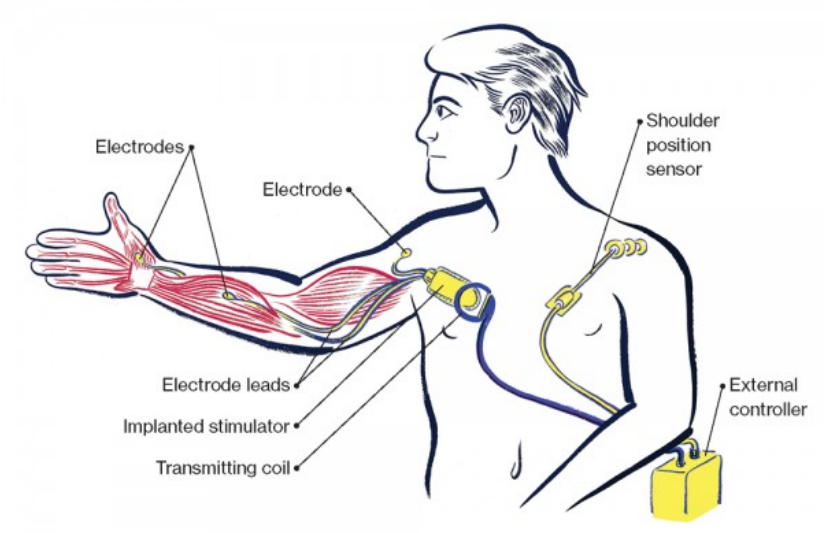


Figure 3.1: Diagram of the Freehand system by Neurocontrol [11].

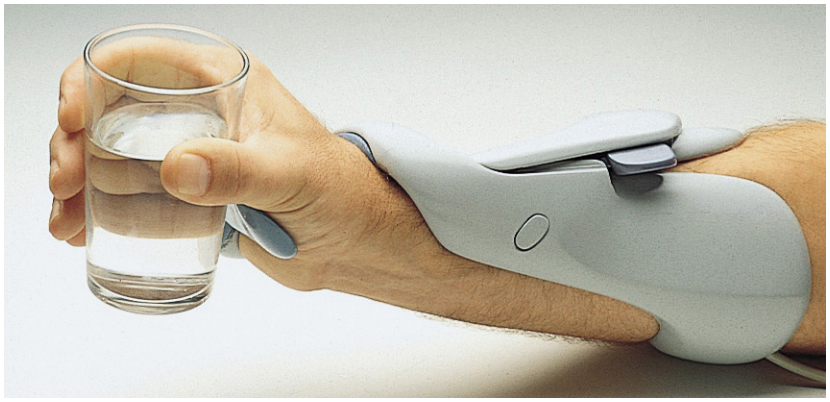


Figure 3.2: Upper limb assistive device H200 (Bioness, USA) [14].

realistic approach for user-intention recognition. However, these interfaces present challenges in conditions in which motor skills are severely limited, such as in cervical-level SCI patients. Therefore, the use of these devices is usually limited to rehabilitation purposes [77].

Table 3.1: Selection of works that used body movement to control active assistive devices. On the *Mathematical technique* column, *linear relation* means a direct proportional relation between variable extracted from the input movement and the output device activation, *threshold* means that a device function is activated when a specific input movement variable is higher or lower than a predefined threshold. On the *Type of control* column, *discrete* means a preset action is triggered on the device, and *continuous* means the device actuation has a continuous range of input and output values. Percentage results refer to classification test accuracy. Each work reported their results in a different manner, so the *Reported results* column cannot be used for a direct comparison between them.

Reference	Main sensor	Number of sensors	Other sensors	Validation subjects	Number of subjects	Mathematical technique	Number of classes	Type of control (discrete/continuum)	Body part controlling the system	Actuation	Proposed application	Reported results
[23, 63]	Mechanical transducer	2	EMG	Tetraplegia	1	Thresholds and linear functions	3	Discrete/Continuous	Shoulder, neck, any controllable muscle	FES	Grasping/ADLs	Success
[88]	IMU	2	-	Healthy	1	Thresholds	2	Discrete	Leg	Spring-based actuators	Lower limb orthosis	Success
[103]	Mechanical transducer	1	-	Tetraplegia	12	Linear functions	1	Continuous	Wrist	FES	Grasping/ADLs	Better tests scores
[36]	IMU	2	EMG, force	Multiple Sclerosis	1	SVM and C-SVC	3	Discrete	Lower limbs	-	Lower limb exoskeleton, but can be used in other lower limb applications	98,73%
[112]	IMU	2	-	Healthy	9	LDA	11	Discrete	Wrists	-	Identify emergency situations	96%
[106]	ACC	2	EMG	Healthy	10	LDA	8	Discrete	Forearm and arm	-	Improve EMG classification for upper limb prosthesis control	Long training period
[2]	IMU	4	-	Healthy	9	Discrete Wavelet Transform and Random Forest Classifier	6	Discrete/Continuous (offline)	Lower limbs	-	Analyze sport performance	98%
[60]	IMU	1	-	Paraplegia + Tetraplegia	5 + 1	Maximum acceleration detection	4	Discrete	Trunk	FES	Automatic FES triggering for STS transfer	Best trunk movement related moment to trigger FES
[118]	IMU	4	-	Tetraplegia	3	PCA	2	Continuous	Shoulders	Powered wheelchair	Control a powered wheelchair with shoulder movements	Slower than joystick, but improved with training
[86]	IMU	1+	-	Transhumeral amputees	1	Generic upper limb coordination model	1	Continuous	Upper arm residual motion	Powered elbow prosthesis	Grasping with a powered elbow prosthesis	Worse performance than with myoeletric-based control, but with less compensation
[72]	IMU	12	EMG	Healthy + transradial amputees	31 + 3	LDA	40 offline + 6 online	Discrete	Residual upper limb	Powered upper limb prosthesis	Improve upper limb powered prosthesis operation by correctly identifying numerous activities	Approximately 80% accuracy with 4-6 multi-modal sensors
[110]	IMU	6	EMG	Healthy + Stroke	3 + 1	Threshold and state machine	3	Discrete	Forearm and fingers	FES	Grasp and release	Success in a subject by subject basis
[34]	IMU	up to 6	EMG	Healthy	10	Linear functions and thresholds	6	Discrete/Continuous	Head and shoulders	Robot arm	Robot arm mounted on wheelchair for persons with tetraplegia	Slightly worse performance when compared to simple joystick. Improvement with training.

(a) Bioness L300 [15]. (b) Walkaide [123].

Figure 3.3: Example of commercially available FES drop foot systems.

4 Materials and Methods

The base hypothesis of this work is that there are links between movements of different parts of the body, and that it is possible to explore those links by acquiring kinematic information to predict the movement of one part based on another, and use this prediction to control neuroprostheses. This chapter describes the development of a framework of techniques that use this concept to control neuroprostheses for persons with motor disabilities. Also, it presents how I used interfaces developed with this framework to test that hypothesis in three different application scenarios with persons with SCI.

4.1 Framework for control interfaces

The aim of the control interfaces developed in this work is to allow the user to control a neuroprosthesis with their residual movements. To do that, the system captures kinematic information from some body part the user still has control over, and translates that information into commands. Movement signals are acquired by IMUs, and the neuroprosthesis will often act on the user own paralyzed body parts.

In order to work with user with different disabilities, the interface must either be easily customizable or flexible enough to adapt to these differences. Therefore, before the user can fully operate it, there is a learning phase in which the system learns the movements that will be used as commands during the operation phase. Hence, the learning phase is the stage in which the system acquires the necessary knowledge to decode users intent from their residual motor commands with inertial sensors. Next, the operation phase is the stage in which the system uses the previously learned knowledge to activate a neuroprosthesis based on the users intention.

4.1.1 Learning phase

In the learning phase, the system obtains features for an algorithm that translates the voluntary movements from one part of the body to the intended movements from the paralyzed part of the body. To do that, the system is presented with both user intent, in the form of body motion, and the desired activation of the paralyzed body part. It then calculates relations between these by classifying each movement to trigger the correct activation. That activation can be the actual limb movement by FES, or a simulation or representation of that command.

The voluntary movements are captured by an IMU placed on the able body part, and the desired movement is captured by a second IMU, or by other feedback method, depending on the application. The signals from the IMUs or other methods are analyzed and features are extracted from both movements and the **Movement Knowledge** is formed. The Movement Knowledge contains information which enables the system to construct a desired movement on

the paralyzed body part based on the actual movement of the able body part. The diagrams on Fig. 4.1 illustrate this learning process both with and without the execution of the actual desired movement.

In cases in which the system is presented with the actual desired movement of the paralyzed limb there might be a challenge, since the system cannot yet activate these parts automatically. Consider a person with total paraplegia, who cannot move his/her lower limbs. Consider also a FES system connected to this person's quadriceps, set to induce knee extension, and controlled by a button. Finally, consider a situation in which one wishes to train the system to activate the FES based on head movements.

One option is the manual activation of the assistive device by the users themselves or by an assistant. In this example, the user or an assistant can activate the button at the same time as the user moves their head. This is the case illustrated in Fig. 4.1a.

Another option is an open loop preset activation. In this case, the FES would be preset to activate in a certain pattern, and the user would know that pattern and would move their head at the same time. This is the case illustrated in Fig. 4.1b

It is also possible to set the interface to activate another device or simulation that represents the desired movement. In the example, instead of a FES system actually acting on the user lower limb, there could be a computer screen showing a simulation of a leg reacting to the interface command. This is the case illustrated in Fig. 4.1c

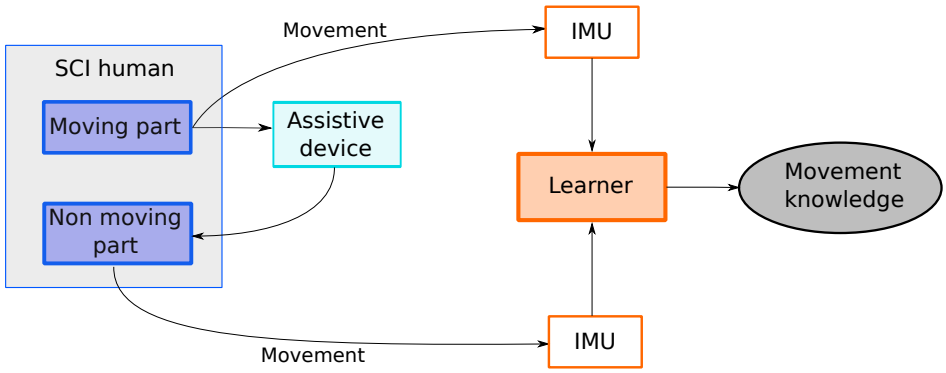
Finally, in some cases the learning phase can be performed by an higid person, who is capable of executing both able and disabled body parts movements. In the example above, the user could be an higid person who would move their head while extending their own knee. This case is illustrated by Fig. 4.1d.

Regardless of the chosen method, the framework uses the resulting movement (or representation of that movement) to label the data and learn to classify it from the able body part movements.

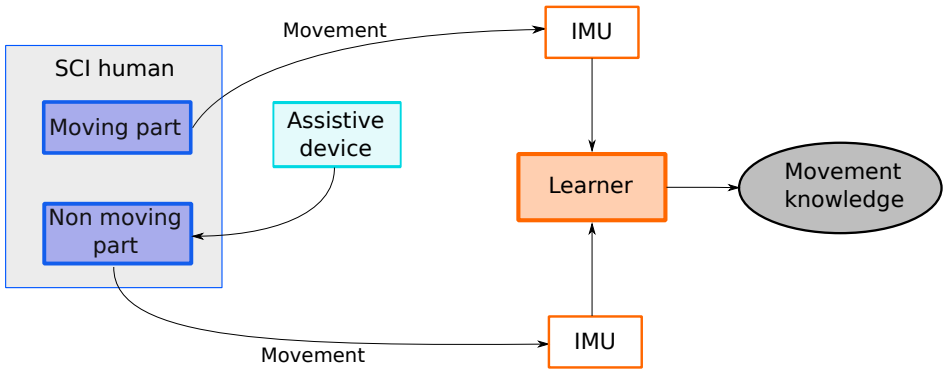
4.1.2 Operation phase

After the learning phase the system can be used in operation mode. At this phase, the user simply executes the voluntary movement. This movement is captured by an IMU. The IMU signal is used by the interface that, with the Movement Knowledge learned in the previous phase, calculates the Expected Movement to be performed by the paralyzed body part. The activation of the paralyzed body part is solely commanded by the interface in response to the users voluntary movement. Different from the learning phase, in which that movement was triggered by some other method and the interface would learn from it, here it is the interface that activates it.

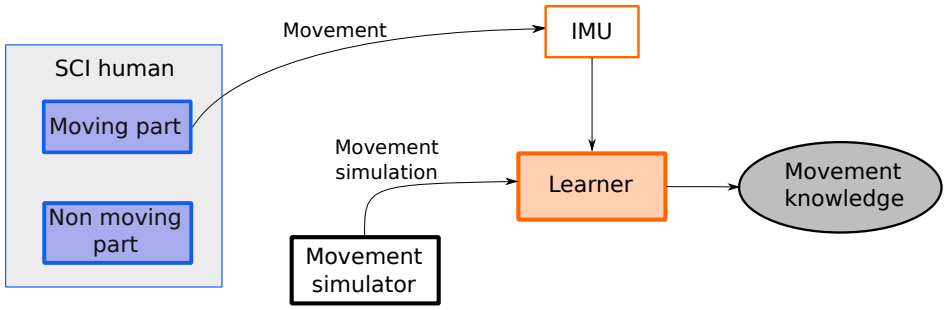
A second IMU may be placed on the paralyzed body part which is used to monitor and control its movements. This would enable a lower level control to compare the two movements (expected and actual) and actuate by activating the neuroprosthesis accordingly. Alternatively, the assistive device activation can be pre-configured and only triggered by



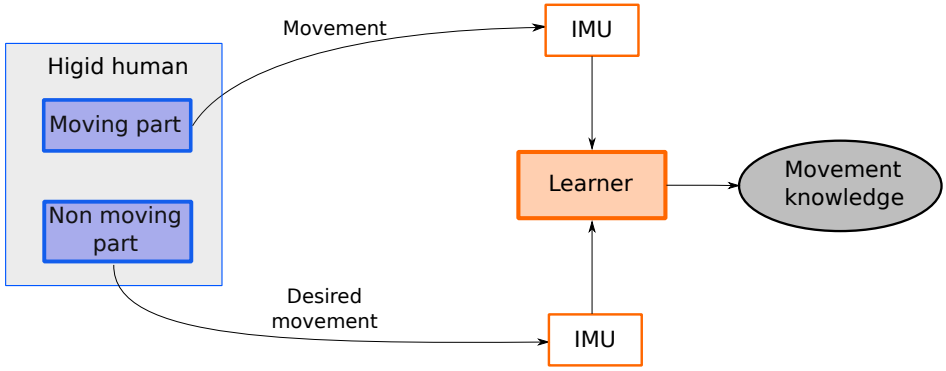
(a) Learning phase with desired movement performed by the user.



(b) Learning phase with desired movement performed by the user in an preset, open loop activation by the assistive device.

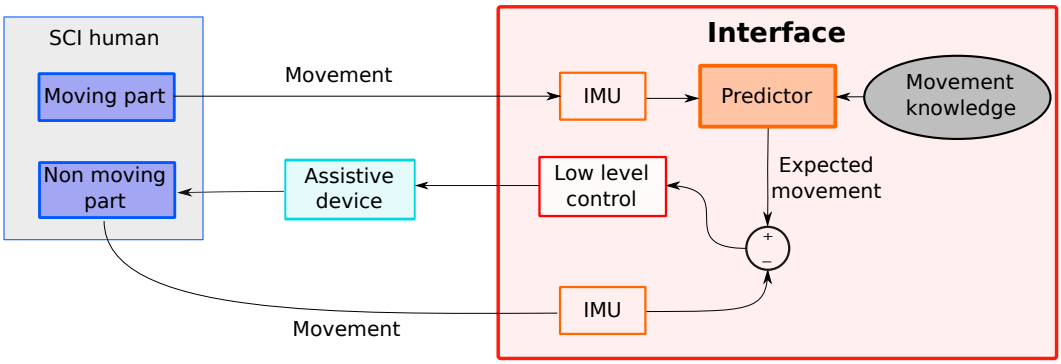


(c) Learning phase with simulated desired movement.

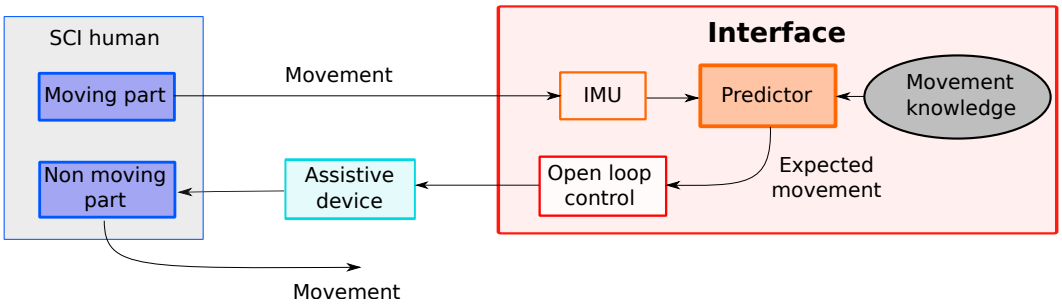


(d) Learning phase being performed by an higid person.

Figure 4.1: Block diagrams of the system's learning phase. The Movement Knowledge is formed by the Learner from the able body part movement and the desired movement or its simulation.



(a) Operation phase with low level control of the disabled body part movement.



(b) Operation phase with preset activation of assistive device for disabled body part movement.

Figure 4.2: Block diagrams for the system's operation phase. The predictor uses the Movement Knowledge and the able body part movement information to predict the expected movement.

the interface, which would not require a low level control. This process is illustrated by the diagrams on Fig. 4.2.

4.1.3 Continuous learning

After the learning phase is completed, the system can optionally continue to learn and improve during the operation phase. In this case the system asks the user to perform a certain movement in a certain manner with the paralyzed body part. The system is run in operation mode and the user tries to execute what is requested, and, knowing that, the system adjusts the desired output to that particular input.

4.2 Application scenarios and evaluation

In order to develop and test each aspect of the proposed interface, this work was divided into three steps, each with an increased complexity level. In every step a different aspect of the interface is implemented in a specific experimental application with participants with SCI.

In each application, I present the proposed scenario in a structured framework. First, the participants and setup are described. Then all materials used in that application are presented. The specific control system developed for that scenario is described next. Finally, the experimental protocol is defined, followed by the method used to analyze the resulting data.

The following subsections present three application scenarios, and detail the developed interface features in these scenarios. Subsection 4.2.1 presents an application in which a pressure sensor based interface was used to evaluate the feasibility of an IMU-based solution for functional transfers by participants with paraplegia. Subsection 4.2.2 describes a scenario in which participants with tetraplegia used an interface developed in this work to control a hand grasping assistive device with residual shoulder movements. Subsection 4.2.4 presents an application in which a participant with paraplegia used the final version of the interface to practice FES-rowing by controlling the lower limbs stimulation with upper limb movements.

4.2.1 Transfer

Transfer from/to wheelchair by persons with SCI is a key ability to gain mobility and independence, allowing greater interaction with the environment, social participation and improvements of the quality of life [80, 120, 44, 62]. The most commonly performed type of transfer by paraplegic subjects is sitting pivot transfer [42]. They do it by sitting down sideways to where they want to transfer to, and then lifting their trunk with their arms at the same time as moving their hips to land on the destination. In most cases, they can perform this task independently. The sitting pivot transfer (SPT) is executed on average 15 to 20 times a day. This large number of transfers contributes to the development or perpetuation of secondary upper limbs musculoskeletal impairments over time. It is known that, after SCI, individuals have great risks of pain and injury in the upper limb due to joint overloads during activities of daily living [96, 32, 43].

FES can be used as a potential technological resource to assist these people during transfers. The goal is to activate lower limbs muscles at a precise timing to lower the weight load over the upper limbs during the SPT, somewhat similar to how able persons would perform the same transfer [78, 91, 61, 60]. However, how the user activates the stimulation poses a problem. Since they use both upper limbs during the transfer, any strategy that requires manual activating at the time of stimulation, such as buttons, is not practical. The interface proposed in this work can automate the moment of the stimulation onset in order to free the user's upper limbs.

We hypothesized that kinematic information could be used to trigger the stimulation with minimal user training, as proposed by [60]. A system for FES-assisted SPT can work as follows: the user has some kind of interface, like a switch, that they use to enter a "SPT mode" when they are already in the starting position. Then they place their hand wherever they wish and perform the transfer. The IMU, placed over the C7 vertebra, captures the trunk angle and triggers the lower limbs stimulation according to the relative angle threshold previously set to that user. A similar test was performed with able-bodied subjects in [78] with manual stimulation triggering.

We performed an experiment based on the aforementioned possible FES-assisted SPT motivated by the following question:

- Can an IMU collect kinematic information capable of reliably trigger FES for SPT

assist on paraplegic subjects?

In order to do that we captured kinematic data from SCI subjects performing numerous SPTs with two different systems simultaneously; an IMU and a motion capture system. In addition, we developed a glove that allowed the subject to activate the stimulation as intended during the transfer by simply pressing down on any surface.

4.2.1.1 Participants and setup

Participants were recruited from the SARAH Network Quality Control Center database that were in treatment at the Brasília (Brazil) unit between 2015 and 2016. During recruitment process, candidates were evaluated according to inclusion and exclusion criteria that can be seen on Table 4.2. Particularly, the most relevant aspects were related to general health, bone density, transfer independence, adequate response to electrical stimulation and presence of pain.

Five patients were finally recruited for a broader project[1] [78]. Out of those, three patients underwent the experiment related to this work: 2 men and 1 woman aging between 34 and 49 years old, all with AIS A (American Spinal Injury Association Impairment Scale) lesions between T2 and T11 (Table 4.1 describes all subjects in more detail). They signed the Consent Form, which, along with this work, was approved by the Research and Ethics Committee from the SARAH Network (CAAE: 54748116.9.0000.0022). The ethics committee approval and the consent agreement are available as Appendixes A and B.

Table 4.1: Transfer protocol participants characteristics.

Subject	Sex	Age	Lesion Level	Lesion Chronicity
p1	F	34	T6 - AIS A	14 years
p2	M	49	T11 - AIS A	9 years
p3	M	40	T2 - AIS A	22 years

The patients took part in two sessions. The first one took place at the hospital, where a physiotherapist applied a physical exam to make sure they were able to perform the task of SPT. The second session was the experiment in the laboratory. Two benches were placed next to each other, with a 10° angle between them. The patient's feet were positioned in front of the benches, and equidistantly to both of them. There were specific places for positioning the hands, which were kept unchanged during the whole work for the sake of comparability. The experimental set-up can be seen on Fig. 4.3.

In order to collect accurate kinematic data, a golden standard motion capture system was used. Also, an IMU collected data for the purpose of this work. Finally, pressure sensors on the hands provided readings related to the pressure applied by the hand on the support.

[1] This project, led by a physiotherapist, aimed to study not only technical aspects of user interfaces, but also clinical implications of FES-assisted SPT. She also works at the SARAH Network, which is where the recruitment and initial assessment of participants took place.

Table 4.2: Transfer protocol inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Individuals with traumatic SCI being treated at the SARAH Network Brasília unit	Clinical instability, such as infections
Living at Brasília	Osteoporosis diagnosis
SCI AIS A or B, T2-T11	Post SCI lower limb fracture
Between 25 and 45 years old	Complaints of upper limbs pain or lesions in the last 6 months
Lesion chronicity greater than 6 months	Spasticity, clonus, or major spasms that could interfere with the SPT
Capable of independent transfer between wheelchair and same height bed	Flaccidity in the lower limbs
Capable of using wheelchair for at least 6 hours a day without posture hypotension	Pressure sores on the pelvis or lower limbs
Completed at least one full rehabilitation program phase at the SARAH Network	Reduced range of motion in the upper or lower limbs
Must have electronic records citing clearance for orthostatism with orthoses	Pregnancy
Time availability and interest to participate in the research and be comfortable with electrical stimulation	Metal implants on the lower limbs
Adequate response do FES on the quadriceps femoral: 4- (beats gravity, maintain weak resistance), according to the Manual Muscle Test [39]	Cardiac pace-maker
	Neoplasm
	Refusal to sign the Consent Agreement

4.2.1.2 Materials

Electrical stimulation The stimulator was a Rehastim (Hasomed, Germany). Two channels were used, one for each leg on the quadriceps muscle group. An emergency stop button was positioned on the metal structure, easily accessible by both patient and supervising physiotherapist. Stimulation was applied at 50 Hz and 450 μs. The current was determined on the day of the experiment, based on each subject's individual response to achieve leg extension for 10 s.

Inertial measurement unit (IMU) One IMU (Yost Labs, EUA) was positioned over the participant's C7 vertebrae. This positioning was chosen to match a marker location of the motion capture system. It communicated wirelessly with the computer and sampled orientation data at about 170 Hz. In order to simulate real applications, IMUs readings were performed with respect to the initial position, i.e. angle data was always set to 0 at the start of each trial. Indeed, for everyday use, a helpful feature is the possibility of using the device without any initialization, such as positioning in vertical orientation for providing an absolute reference. In our case, this is done by the IMU firmware after the sensor is tared the start of

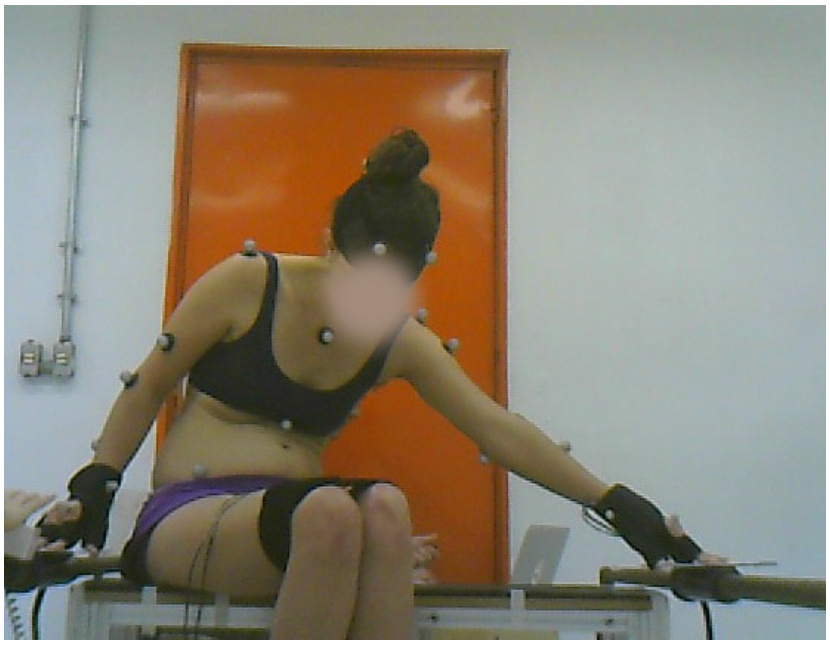


Figure 4.3: Transfer experimental set-up. The gloves embed pressure sensors. It is possible to see the markers over the subject body, whose 3D positions are captured by the motion capture system. The benches are next to each other, with a 10° angle between them. The legs are constrained to keep them for falling sideways.

the process.

Hands pressure sensors A pair of hand pressure sensing gloves were custom-made. Each glove embeds three FlexiForce sensors (Tekscan, EUA), which were connected to a micro controller. The resistive sensors are placed on specific palm areas to maximize the force application. A microcontroller sampled data at 1 kHz and forwarded it to a computer at 20 Hz.

Motion capture system Qualisys QTM (Qualisys, Sweden) was used to capture motion data, as well as data from the force plates. It was all sampled at 200 Hz and recorded on a local computer. The upper body marker protocol[2] was used with 31 markers. The C7 marker, which is usually positioned over the C7 vertebrae, was instead positioned over the IMU.

4.2.1.3 Assistive device activation control

The hand pressure sensors gave the subjects the control over when to activate the stimulation. They could prepare themselves for the transfer and activate the stimulation when they supported their weight on their upper limbs, in a intuitive way.

The lift pivot phase is defined between the moment the subject supports his weight on the upper limbs and the moment he reaches the target seat, and it lasts on average 1 second, according to [44]. Therefore, after starting, the stimulation remains activated for 1 second during the lift pivot phase.

[2] Plug-in Gait Full-Body (C-Motion, available in: https://c- motion.com/v3dwiki/index.php?title=Tutorial:_Plug-In_Gait_Full-Body)

4.2.1.4 Experimental protocol

At the beginning of each trial, the subject was either on one bench or the other, already prepared to execute the transfer. Their hand would be placed on the predefined places, but they were asked not to apply weight on it to prevent the stimulation activation ahead of time.

The system would start collecting data, and a researcher would tell the subject they could do the transfer whenever they wanted. The subject would do it, and when they supported their weight on their upper limbs, the stimulation would be activated and cause the lower limb muscles to contract, assisting with the transfer. After the stimulation was over, and the transfer was finished, the trial was concluded.

Each subject underwent 12 transfers, 6 in each direction (left and right). Out of the total 12, 6 were performed with stimulation and 6 without it. Before the 12 transfers in which data was collected for this work, there were 6 transfers with the purpose of familiarizing the user with the system, particularly the stimulation activation method.

4.2.1.5 Data analysis

After the trunk angles were recorded from both the motion capture system and the IMU, intra-subject trials correlation of trunk angle on the sagittal plane was calculated. An analysis of trunk angle could determine if it was consistent across several SPTs for each participant. Then the trunk angle was analyzed at the moment in which the stimulation was activated by the subject. The same was done with the trunk angle first derivative, second derivative and standard deviation along a moving window of $0.1s$. Since this work aims at developing technologies which must ultimately work in real time, no offline non causal filters were used.

This result is used to analyze the link between the trunk angle and the stimulation onset timing. That information is the Movement Knowledge that can be used on the operation phase to predict when the user intends to activate the stimulation. By studying that in this scenario, we could evaluate if the wireless IMU provided kinematic data that is consistent intra-subject with the user intended stimulation activation timing. This was the first step to further develop the interface based in a simpler and more flexible measurement system which are inertial based sensors, instead of sensorized gloves or camera based motion capture systems.

4.2.2 Upper limb grasping

One of the most basic function lost by persons with tetraplegia is the ability to grasp objects. Without it, it is hard to perform ADLs such as self hygiene, feeding and using a phone. Therefore, the restoration of upper limb function is often said to be the highest priority for such users [5]. This subsection describes how the framework developed in this work can be used to assist these persons to control assistive devices with residual discrete movements. These are quick movements that start and end in the same, static pose. In this

Table 4.3: Upper limb grasping protocol inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Signed written consent agreement	Refusal to participate in this study
Beneficiary of social security or equivalent	Being unable to consent
Not currently prohibited of participating because of other protocol	Lack of liberty rights (according to local justice and administrative systems)
Must have liberty rights (according to local justice and administrative systems)	Be younger than 18 years old
Must be between 18 and 65 years old	Not beneficiary of social security or equivalent
SCI AIS A or B, C7 or higher	Pregnant woman
Clinically stable	Unstable epilepsy
Able to remain at a wheelchair for 2h	Unstable cardiopathologies
	Pacemaker users
	Dermatological problems that contraindicates surface electrical stimulation

case, a non natural movement was chosen by the participant to control the system, based on their residual motor capabilities and comfort.

We performed an experiment in which participants with tetraplegia used an interface based on the framework developed in this work to control either FES on their arm or a robotic hand. The system classified the users shoulder movements into two classes. With these two movement classes, users were able to execute three different commands, which are further explained below.

4.2.2.1 Subjects and Setup

All participants gave their informed written consent to participate. The study approval by the Ethical Committee (Comité de Protection des Personnes #2016-A00711-50, Sud Méditerranée IV, Montpellier, France) can be seen on Appendix C and its Written Consent Agreement on Appendix D. Inclusion and exclusion criteria can be seen on Table 4.3. A group of participants with ASIA A or B tetraplegia were recruited from the Propara Neurological Rehabilitation Center in Montpellier, France. The group was composed by 9 male subjects with lesions between C4 and C7 (Table 4.4). Aiming to evaluate both the classification system and the FES muscle activation, two actuation modalities were used during the experiments: a robotic hand and electrical stimulation. However, FES was only used on participants that experienced no pain or discomfort from it.

4.2.2.2 Materials

Electrical Stimulation We used a wireless electrical stimulator (Phenix© Neo USB, Vivaltis, France) to activate the subjects forearm muscles. We used 2 channels to induce hand flexion and extension. Since our aim was not to study functional grasping, we optimized the resulting movement so as to provide visual feedback for the participant. We thus placed electrodes and set stimulation parameters to obtain a sufficient contraction to elicit a clearly visible movement of the fingers or the wrist. Therefore, electrode placement and FES parameters varied from participant to participant. We used auto-adhesive 5x5 cm surface electrodes and set the stimulation parameters as follows: frequency, $25Hz$; pulse width, $300\mu s$; current intensity was adjusted for each muscle and for each subject. The waveform was rectangular, biphasic and balanced.

Robotic hand In order to standardize the visual activation, we chose to use a robotic hand for validation, training and feedback because it would produce the same output for all users. Thus, users were able to monitor the outcome of their movements and the algorithm's activation of the robotic hand responses. We used the Shadow Dexterous Hand (Shadow Robot Company, UK) and configured three different hand gestures: the **at-rest (RS)** position featured a natural hand at-rest position; the **opened (HO)** position consisted in having all fingers fully extended; and the **closed (HC)** position consisted in flexing the fingers into a key grip position. The robotic hand was placed in front of the users so they could see it and observe its response to their commands. This placement is shown in Fig. 4.10.

Inertial measurement units (IMUs) The IMU used in this work (Hikob, France) is, as usual, comprised of three different sensors in one unit: accelerometer, gyroscope and magnetometer. Each of them measure their signals in all 3 axes, which makes possible to acquire the sensor's orientation relative to both gravity and the magnetic field. However, in this work we only used the accelerometer and gyroscope data. We avoided using the magnetometer because calibration and sensitivity may vary with the environment - a potential limitation, especially in a possible implanted future version of the system. The sample frequency may vary depending on data processing or data communication limitations. In this work the mini-

Table 4.4: Upper limb grasping participants characteristics. The FES column indicates which subjects used FES during the experiment.

Subject	Sex	Age	Lesion Level	Lesion Chronicity	FES
s1	M	25	C6 - AIS B	3 years	x
s2	M	63	C7 - AIS A	34 years	x
s3	M	44	C5 - AIS A	$<$ 1 year	x
s4	M	40	C5 - AIS A	3 years	
s5	M	56	C5 - AIS A	3 years	x
s6	M	51	C4 - AIS A	33 years	x
s7	M	65	C7 - AIS B	47 years	
s8	M	25	C6 - AIS A	3 years	x
s9	M	19	C5 - AIS B	$<$ 1 year	x

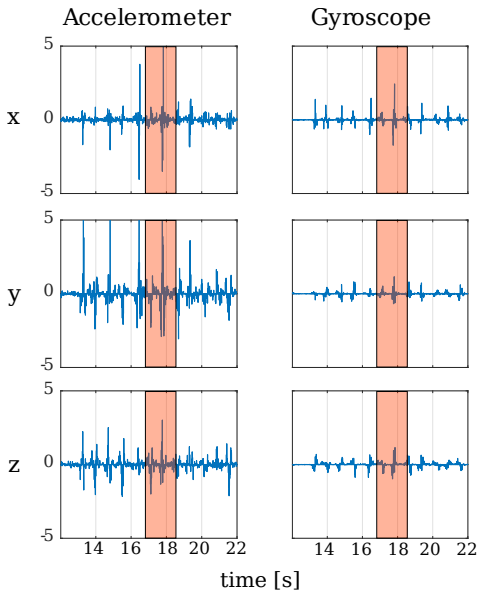


Figure 4.4: Example snippet of raw data from the three axes of the accelerometer and the gyroscope. The highlighted rectangles represent the 1 second window considered for this method's calculations.

mum accepted frequency was 45Hz. The IMU has an onboard microprocessor that processes the sensors raw data and delivers Euler angles, quaternions, or rotation matrices. During that procedure, the signals are filtered with Kalman filters.

4.2.2.3 Assistive device activation control

For the upper limb grasping experiment, I developed a system that recognizes users intention based on movements that are captured by the sensor or sensors and are mapped to desired motor activation with a classification algorithm, which I implemented in Matlab (Mathworks, USA). As explained in section 4.1, this algorithm is comprised of the learning and operation phases

Learning Phase First we ask the participant to perform various movements with the body part on which the IMU is placed. We requested the execution of each movement multiple times for 10 seconds, with 1-second intervals between each repetition. We carried out this procedure for each different calibrated movement in order to acquire reference signals. The data is differentiated using the backwards euler method, thereby providing a vector $\mathbf{x}$, in which each element x_i refers to one axis of an individual sensor (i.e., accelerometer or gyroscope), and resulting in six elements (three axes for each of the two sensors). Then, thresholds are empirically calculated using

$$\alpha_i = \frac{max(x_i)}{2}, \tag{4.1}$$

which was defined after observation of raw data collected before the experiments. An example snippet of such data can be seen in Fig. 4.4.

Next α is used to find movements performed during the initial calibration phase. At any instant k, whenever there is at least one i such that $x_{i,k} > \alpha_i$, $1 \leq i \leq a$, where a is the total number of axes considering all sensors being used, a feature vector θ is calculated by extracting the root mean square for the last second of signal acquisition:

$$\theta_i = \sqrt{\frac{1}{N} \sum_{j=k-N/2}^{k+N/2} x_{i,j}^2}, \tag{4.2}$$

where $N = 1/f$, and f is the average signal frequency during the last second. Therefore, θ contains the information of the movement performed on that last second. With that method, feature extraction is only performed after a movement is detected, and not constantly. This procedure can be adapted to different features depending on the signal, such as peak value, mean, signal energy, wavelet features, etc.

Next, I calculate the PCA with all movements, which are treated as six dimensions points, resulting in the PCA matrix $\boldsymbol{W}$. For this calculation, I used the Statistics and Machine Learning Toolbox in Matlab (Mathworks, USA). Then, n principal components are considered, where $2 \leq n \leq 6$. Later, the centroids for each class of movement are calculated as the average coordinates of all points in each class, as described in Eq. 4.3

$$c_{i,k} = \frac{1}{t} \sum_{j=0}^{t-1} \boldsymbol{W}\boldsymbol{\theta}_j, \tag{4.3}$$

where $c_{i,k}$ is the centroid coordinate for class i considering the component k, t is the total number of points labeled to class i, and j is the point index. $\boldsymbol{W}\boldsymbol{\theta}_j$) outputs the PCA transformation of the original point $\boldsymbol{\theta}_j$ into one in the new PCA coordinate system. Eq. 4.3 is calculated for each component being considered. In the particular case in which two components are considered, the result can be visualized in a plot such as the example in Fig. 4.5.

In case there were more than two different movements trained in the learning phase, the system analyzes every combination of two movements individually, and chooses the one with the two most easily classifiable movements. It does that by scoring each combination according to Eq. 4.4.

$$s_{a,b} = \frac{d_{a,b}}{\sigma_a + \sigma_b}, \tag{4.4}$$

where $s_{a,b}$ is the score for combination a and b, $d_{a,b}$ is the distance between centroids from classes a and b, and σ_a is the standard deviation of the distances of all points of class a to that class centroid. The combination with the higher score s is chosen.

This learning phase is performed for each user, so that the Movement Knowledge learn by the system is customized for that user, sensor placement and choice of movements.

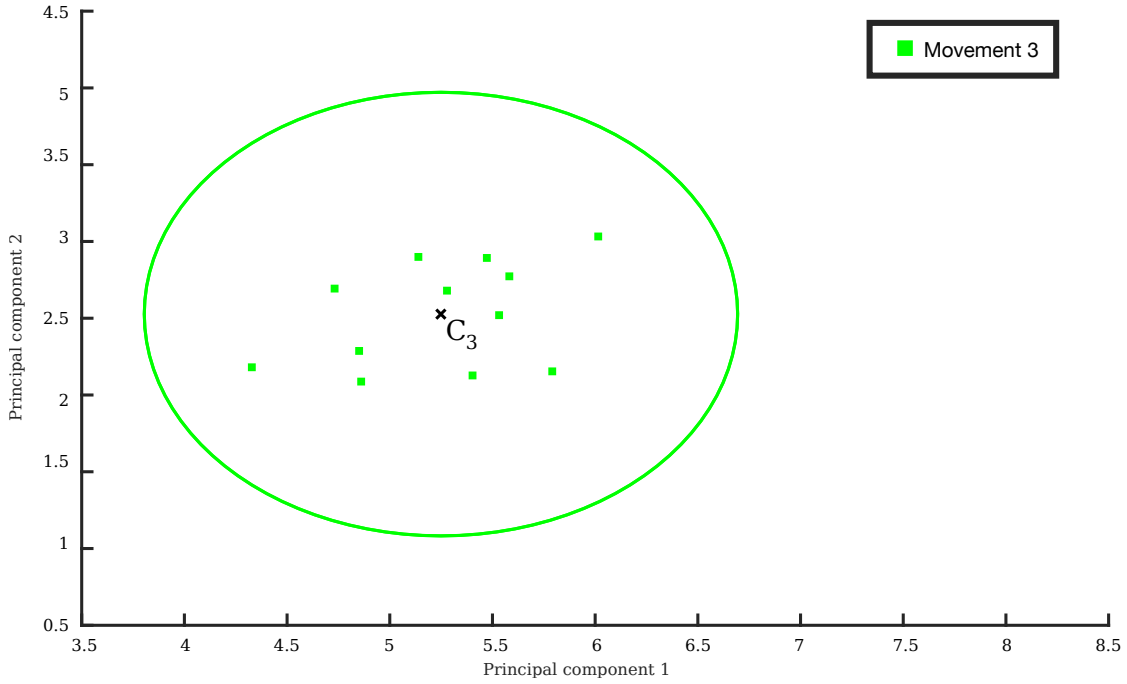


Figure 4.5: Example visualization of one class after PCA calculation with two principal components. Green squares indicate the location of each point. The black x represents the class centroid. The ellipse illustrates three standard deviations of the points distances from the centroid.

Operation Phase After the learning phase I use the aforementioned process to find a new point for each new movement using the pre-calculated PCA matrix $\boldsymbol{W}$, as in

$$\boldsymbol{Y}_{new} = \boldsymbol{W}\boldsymbol{\theta}_{new}, \tag{4.5}$$

where $\boldsymbol{Y}_{new}$ is the new point coordinates on the PCA new coordinate system and $\boldsymbol{\theta}_{new}$ is the new point six-dimensional representation matrix before the PCA rotation.

The classification algorithm is based on minimum distance. Therefore, I calculated the new point distance to each centroid and, based on the shortest one, that point is classified and associated with a movement represented by that centroid. I called this the **basic learning** algorithm. I implemented two other algorithms as follows.

On the **assisted learning** algorithm the user performs the previously calibrated movements while I observe each new point as the two-dimensional plot representing the two main components of the PCA is updated in real time as each movement is performed and processed, resulting is figures such as Fig. 4.6.

If the new points seemed to appear far from the initially calibrated ones, I recalibrate the system with them, and without the old ones. It is also possible to arbitrarily choose each centroid location on the 2-dimensional space. With these tools I am able to manually tune the learning process until the users feels the system can reliably classify their movements.

On the **adaptive learning** algorithm, this process of improving the calibration is automated. After every new movement during the operation phase, the system is recalibrated

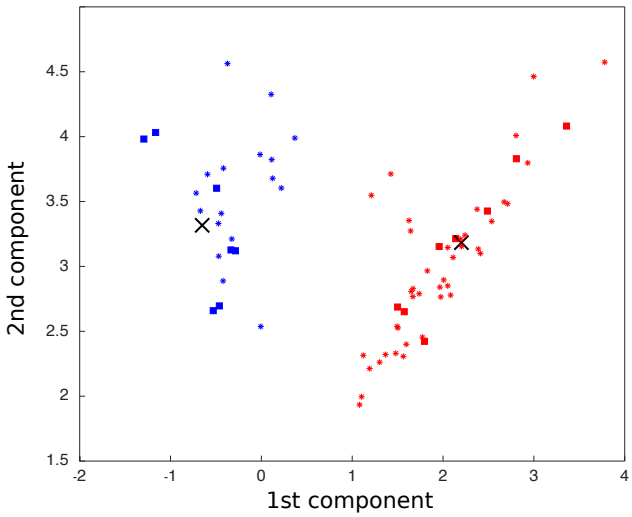


Figure 4.6: Representative example of movement classification with the IMU. Squares represent the movements used for calibration whereas stars are the movements classified online. The big "X" are the classes centroids. At every new movement by the user, a new point is plotted, and it is possible to see it being classified by the system according to its distance to each centroid.

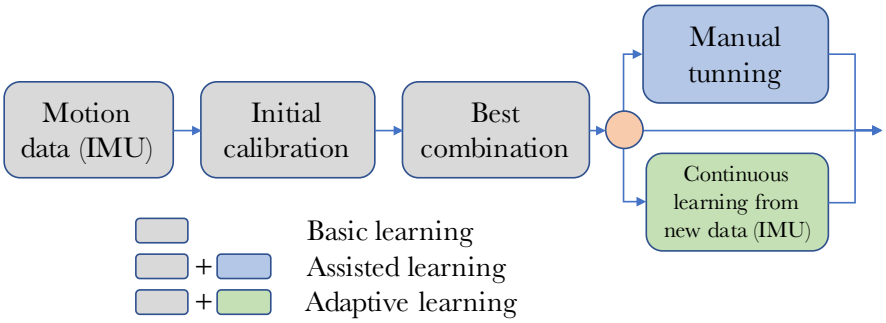


Figure 4.7: Learning processes block diagram.

using the new point, removing the oldest one. Note that, differently from the basic and the assistive learning algorithms, this one is completely automatic.

The three systems are summarized in Fig. 4.7.

4.2.2.4 Experimental Protocol

Each subject participated in one session. At the beginning of each session, we first assessed the possibility of activating wrist or finger flexors and extensors with FES. We then equipped the opposite arm with one IMU, avoiding that the elicited movement itself interfered with the voluntary movement classification in cases in which FES was used. The IMU was placed on different locations of the shoulder or upper arm, depending on the participants ability to perform repeatable movements.

A calibration phase was performed as described in section (4.2.2.3). Here, the learning phase follows the diagram on Fig. 4.1c, in which the desired movement is the robotic hand

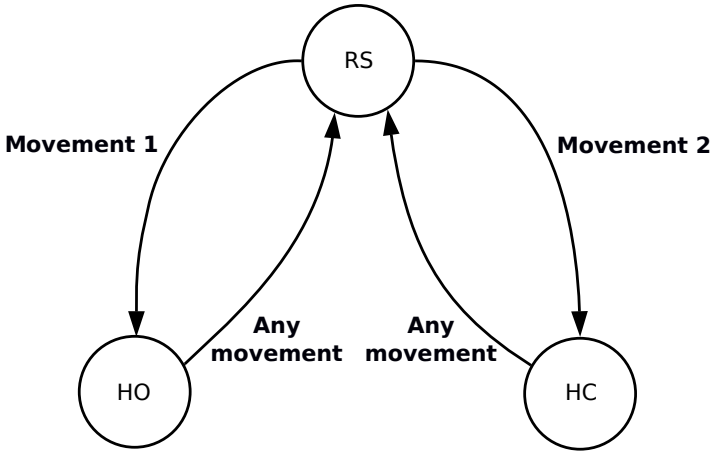


Figure 4.8: Finite state machine used to map 2 movements to 3 commands: Hand Open (HO), Hand Close (HC), Rest state (RS).

or FES activation. As for the movements, we instructed the subject to move the shoulder up, forward and backward. If they had any difficulties doing so, if they felt tired, or if their movements seemed too slow (more than 1 s) or not very consistent (every repetition looking different), we asked them to move their upper arm forward, backward and outward. If the results still seemed inadequate, we asked them to move their forearm upward and inward. The calibration phase lasted about 10 min for each subject and was performed once. Each time, two movements were calibrated. All subsequent movements were then classified into one of the two classes. However, three postures were set on the robotic hand. In order to map the two movements into the three postures, we employed the finite-state depicted on Fig. 4.8.

Once the calibration procedure was completed, participants were encouraged to freely operate the system for a period of 5 minutes by performing the two movements, and to observe the induced robotic hand open, close and at-rest gestures. These movements were used to improve the classifier using the assisted learning algorithm, as described in 4.2.2.3. All data was recorded to later simulate the two other algorithms.

Finally, we performed a validation phase with the robotic hand, illustrated in Fig. 4.9. An experimenter sat in front of the participant and moved his own hand to indicate to the participant which hand gesture to execute on the robotic hand (Fig. 4.10). The sequence was generated randomly and included 5 transitions from RS to HO, 5 transitions from RS to HC, 5 transitions from HO to RS and 5 transitions from HC to RS. This represents a total of 20 shoulder movements, since users had to perform one movement to open/close the hand and a second movement to return it to the neutral position.

4.2.3 Questionnaire

At the end of each trial, participants answered an oral questionnaire to evaluate effort, fatigue and comfort in completing the exercise, as well as their perception of the device overall operation. This questionnaire can be seen on Appendix E. A numeric scale from 1 to 7 was provided; the higher the number, the higher the perception of the system's ease of operation.

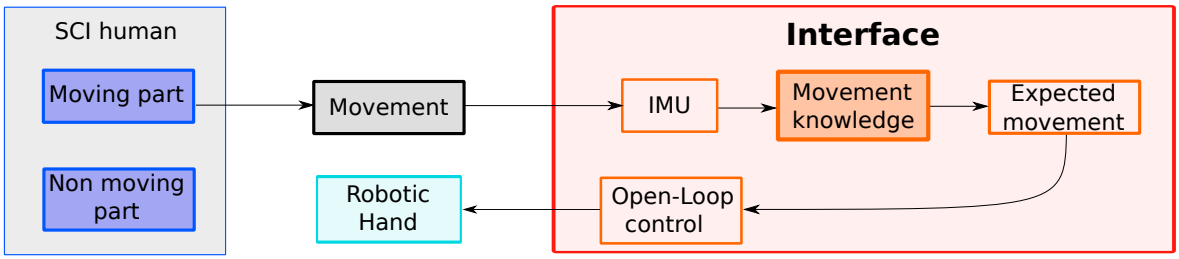


Figure 4.9: Operation phase of the Upper Limb Grasping experiment with a robotic hand. During the operation phase, the interface activates pre configured gestures on the robotic hand.

4.2.3.1 Data analysis

This experiment tested both the subject's ability to correctly choose the required action to activate the desired robotic hand gesture and the overall system ability to correctly identify the subject action.

Accuracy was calculated as a percentage according to Eq. 4.6.

$$r = \frac{u_p}{u_i} \cdot 100, \tag{4.6}$$

where r is the resulting accuracy, u_p is the number of correctly performed hand gesture by the robotic hand and u_i is the total number of indicated gestures.

The entire robotic hand procedure was repeated for the subjects who participated in the FES actuation modality session of the protocol. These subject are indicated on Table 4.4. Figure 4.10 shows the experiment setup.

4.2.4 Rowing

Physical therapy and exercise have been demonstrated as a potential alternative for reducing the negative effects of SCI [31]. Although regular upper body resistance exercise is essential for guaranteeing independence, its limited peak oxygen uptake does not provide a significant contribution to cardiovascular health [57]. An option of aerobic exercise is Arm Crank Ergometry (ACE), in which users with paraplegia or tetraplegia must use their upper limbs to rotate a crank set that features varying load. Nevertheless, this form of exercise also has not demonstrated the capability of generating sufficient exercise volume to meet recommended levels [50].

An additional alternative is to employ FES to contract lower limb muscles, and thus potentially increasing the oxygen consumption of the exercise. Indeed, a system that applies low-level electrical stimuli to enable lower limb exercise was demonstrated several decades ago [100], when FES-cycling for individuals with SCI was evaluated for the first time. However, regardless of recent efforts from research groups worldwide [16], FES-cycling has also failed to induce a satisfactory level of exercise [56].

In this scenario, the combination of FES-produced lower limb and upper limb movements may constitute an ideal exercise in terms of prolonged peak oxygen consumption.

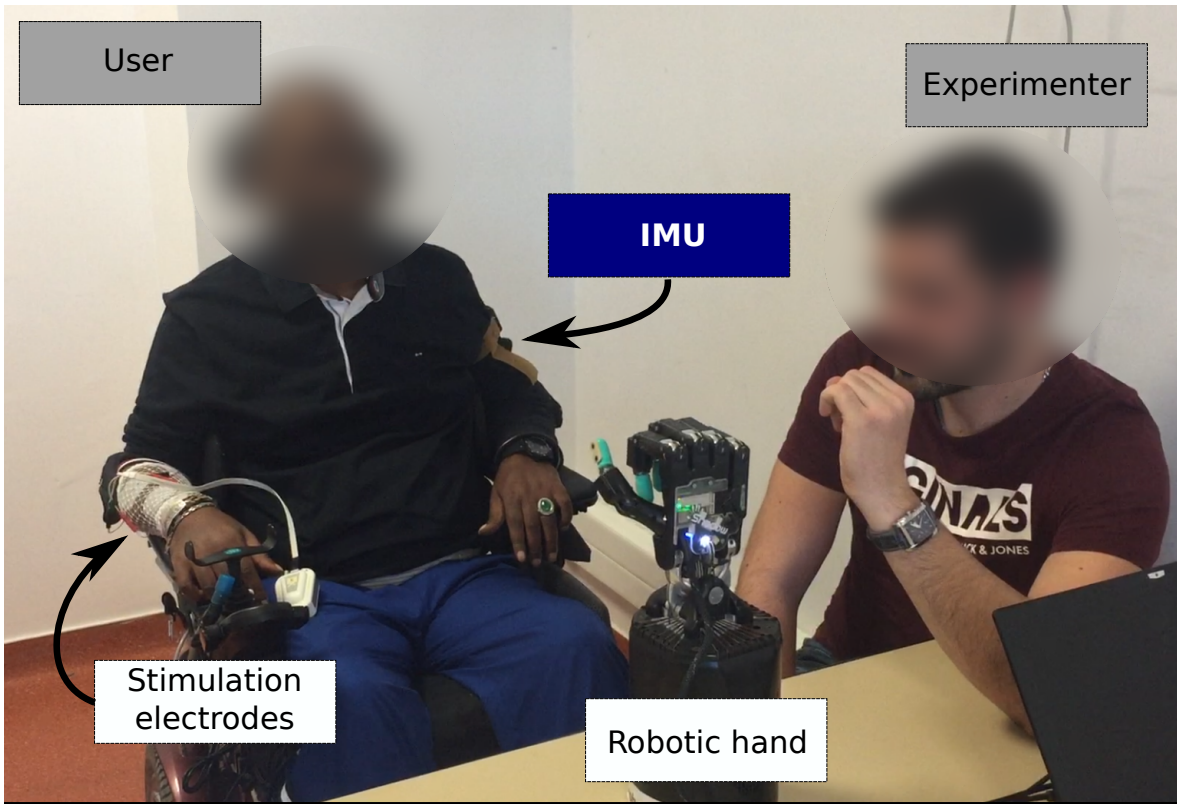


Figure 4.10: Setup for the experimental sessions. In the validation phase, an experimenter showed the subject which gesture the robotic hand should be commanded to execute.

Clinical investigations have shown that FES-rowing exceeds the minimum advised metabolic cost for lowering the relative risk of coronary heart disease in SCI users [56, 55].

Rowing is also a convenient platform to test the system developed in this work. It can be easily adapted to users with SCI and upper limb movements seem to be closely correlated to lower limb movements. In this section, I describe the development of a novel platform for FES-rowing. I propose a mechanical design to ensure safe movement in the sagittal plane, as well as a control interface, which engages the user to synchronize upper and lower limbs motion. I use the platform for analysis of FES-rowing when the user with SCI controls the stimulation onset, and for evaluation of the FES automated control based on upper limb movements by the interface proposed in this work.

4.2.4.1 Participant and setup

The development of the rowing interface is part of a broader project that aims at studying different rehabilitation techniques, including FES-rowing. The Ethical Committee approval can be seen in Appendix F (Comitê de Ética em Pesquisa da Faculdade de Ciências da Saúde, Universidade de Brasília, CAAE: 11717119.3.0000.0030), along the Written Consent Agreement on Appendix G. Participants on that project undergo initial exams that evaluate their overall health, particularly bone density and response to FES (see Table 4.5 for inclusion and exclusion criteria).

I recruited one participant from that project to take part in the rowing experiments

Table 4.5: Rowing protocol inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Persons with SCI between T1 and T12 (paraplegia) and chronicity over 12 months	Adequate response do FES on the quadriceps femoral: 2 (beats gravity, maintain weak resistance), according to the Manual Muscle Test [39]
Persons with SCI classified as AIS A, B or C	Severe spasticity and contractures
Persons whose neurologic rehabilitation has stalled with stardard treatments	Body weight over 100 Kg
Must be between 18 and 60 years old	Ostheoporosis diagnosed from bone density exam
Stable health without musculoskeletal comorbidities	High risk of cardiovascular event
Persons without cognitive impairments that would prevent the understanding or execution of the demanded tasks	Pregnant woman
	Persons with epilepsy
	Persons with dysreflexia not under control
	Users of pacemaker or other active implanted devices
	Dermatological problems that contraindicates surface electrical stimulation
	Persons with phobia of electricity
	Persons who feel discomfort with electrical stimulation
	Persons with blocked joints on upper or lower limbs
	Persons with other health issues that may affect mobility in upper or lower limbs

and test the user interface. He was a male, 39 years old and with an SCI classified as AIS A level T9 for 5 years by the time of the experiments. Thus, he had complete paraplegia, but also complete upper limb function and good trunk control.

4.2.4.2 Materials

Electrical stimulation An 8-channel commercial electrical stimulator (Hasomed Rehastim, Germany) is used to generate the FES signals. It is controlled in real time by the control module. Stimulation is applied through self-adhesive 5x10 cm electrodes. During the lower limb extension phase, stimulation can be applied to quadriceps and gastrocnemius muscle groups for knee extension and ankle plantar flexion, respectively; and, during the lower limb flexion phase, to hamstrings and tibialis anterior for knee flexion and ankle dorsiflexion, respectively. The signal waveform is biphasic, square and balanced at 30 Hz. Pulse width and current amplitude shall be set according to each muscle and individual user in order to generate at least force level 4 according to the Manual Muscle Test. Both legs are assumed similar, therefore the parameter set for the two are the same. When the control system activates the extension phase, all muscle groups involved are activated simultaneously, with the appropriate precalibrated parameter set. Similarly, during flexion, the other muscles are activated.

Inertial measurements units (IMUs) For the rowing protocol I used the same IMUs as in the transfer. However this time I used two sensors (3-Space Wireless, Yost Labs, USA) positioned on the same side arm and forearm of the participant (see Fig. 4.11). Since both sensors communicate simultaneously with the dongle connected to the computer, the final sample rate is lower than with a single IMU, being at approximately 100Hz.

Adapted rowing platform We have built the rowing platform on top of a established rowing machine. We worked on mechanical changes, added electronic equipment and a FES stimulator, as well as a control software.

The main needs of a rower with paraplegia are related to trunk and lower limbs stabilization. As for the trunk, we replaced the regular rowing seat with a custom one, similar to a chair, with a broad seat area and a back part to which the user is constrained. The new seat runs free on the regular track, just as the original seat.

An important safety feature in any device that uses FES for knee extension on SCI users is a way to avoid hyperextension. We installed safety adjustable straps connecting the adapted seat to the feet base. The straps limit the seat range of motion so that the legs are never fully extended.

As the user's lower limbs lack natural stabilization, we built a device that holds the legs on the same sagittal plane while letting them free in that plane. As a result, extension and flexion are permitted, but no adduction or abduction. In addition, the feet are firmly fixed to the platform. The legs stabilizing device holds both legs with protective material, such as foam, and an axis that allows the rowing motion on that plane only. A soft contact between

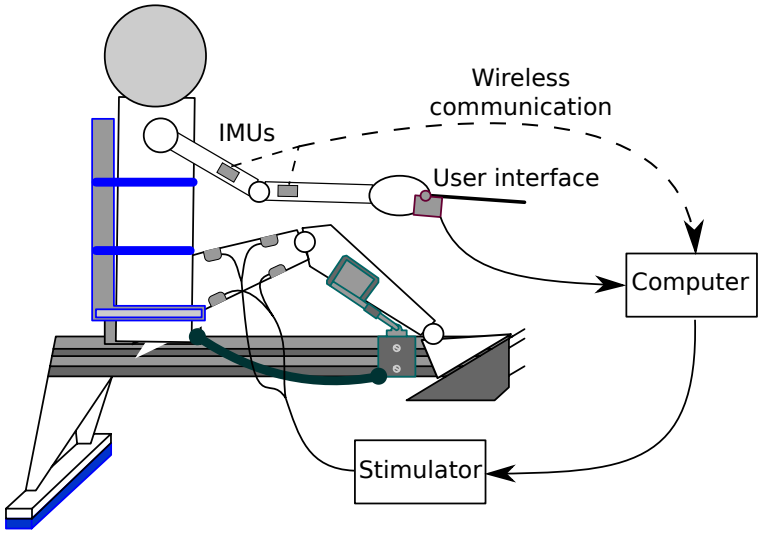


Figure 4.11: Detail of the proposed mechanical adaptations to a regular rowing machine.

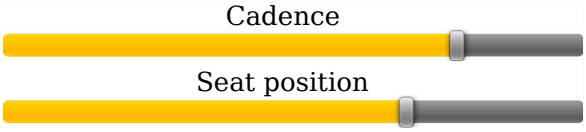


Figure 4.12: Visual feedback to aid the rower to correctly sync their movements with the open loop stimulation pattern. Both bars move from side to side, indicating to the rower at which position their hands and seat must be at all times.

the device and an SCI user's legs is of great importance because, since sensory capabilities are usually weak or nonexistent, pressure points can harm the blood flow. Considering the user's distance to the pivot point changes during the activity, there is a telescope mechanism, which shortens the axis when the legs are flexed, and lengthens it when the legs are stretched.

To aid during the lower limbs flexing phase, we rose the rowing machine posterior part to create a slope of approximately 5°. This and the aforementioned adaptations are illustrated on Fig. 4.11.

Manual activation interface The user can control the FES system with a device attached to the handle bar, the user interface, shown on Fig. 4.11. This device is positioned in a way that its three buttons can be operated with the thumbs while the regular rowing movement is performed. As both legs movements are the same, each button activates the same FES signal for both legs, on the corresponding muscle group.

Open loop activation interface The user can also be aided by FES while rowing in an open loop manner. We preset the duration of all phases of the rowing motion, and a screen positioned in front of the rower shows them the movement progress. The rower then has to synchronize their own movements to those preset parameters. Figure 4.12 illustrates such feedback.

4.2.4.3 Assistive device activation control

Data synchronization The rowing system is based on inertial sensors. In this work, I used two wireless sensors that streamed data simultaneously. However not only the sensors do not have a constant sample rate, they are not synchronized with each other. In order to calculate time based values, such as moving window averages, it was necessary to address these inconsistencies. Therefore every time I used IMU data, I downsampled and fitted it in an artificially generated timestamp vector corresponding to $50Hz$. At each point of the vector, the closest data point in time is considered. The process results in fixed sample rate sensor data vectors perfectly synched that are approximations of the original data vectors.

Learning phase The complete rowing movement can be divided into 4 steps: *a*) lower body drive (legs extension), *b*) upper body drive (trunk extension and arms flexion), *c*) upper body recovery (trunk flexion and arms extension), and *d*) lower body recovery (legs flexion). These four steps can be performed in sequence, one after the other. Regarding the stimulation, the legs muscles must be activated for extension during step *a* and also *b*, otherwise, when the rower pulls on the handle bar, the seat will slide forward. Stimulation may be off during step *c*, and it must activate leg flexion for step *d*. Hence, there are three different situations for FES actuation regarding the lower limbs: *extension*, *off*, and *flexion*. So I designed the FES-rowing control problem as a finite state machine with these three states (extension, off and flexion).

Differently from the Upper Limb Grasping method described in subsection 4.2.2, in which the system identifies the events and only then classify them, in this case the system continuously classifies the upper limb movements as corresponding to FES extension, off or flexion. In this case, the system needs to start each rowing step at the correct moment.

There are two ways the user can execute the system's learning phase. One is using the manual control system (Subsubsection 4.2.4.2) to activate the stimulation whenever desired. In that case, the Movement Knowledge is formed using the movements the FES activation induce in the lower limbs, as illustrated by the diagram in Fig. 4.13. By doing so, the user can execute the whole rowing motion, while the system learns both volitional and intended movements. The other way is by activating the stimulation in a open loop, rhythmic manner, as illustrated in Fig. 4.14. The user must then synchronize their upper body movement to the stimulation pattern. An audio or visual cue can be used to aid them. Either way the system learns when to activate the FES based on the upper and lower limbs movements.

I developed two machine learning algorithms for the rowing control. Both of them are based on LDA supervised learning methods, and I call them **Single LDA** and **Multi LDA**. For mathematical calculations, I used the Scikit-learn machine learning library for python [98].

On both methods, the LDAs are fed with the following features from the IMU signals: joint angle, joint angle differentiation, and the specific force from the three accelerometers. The joint angle is calculated from the quaternions obtained from the two IMUs placed on the

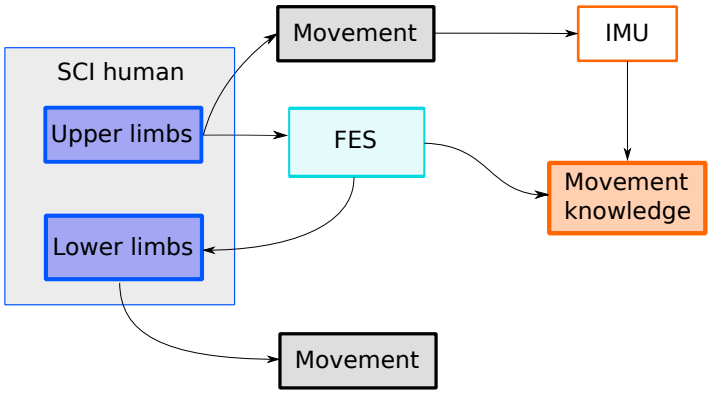


Figure 4.13: Learning phase used in the rowing experiment with manual FES activation. The Movement Knowledge is formed from the user able body movement and the lower limbs movements induced by the manual FES activation.

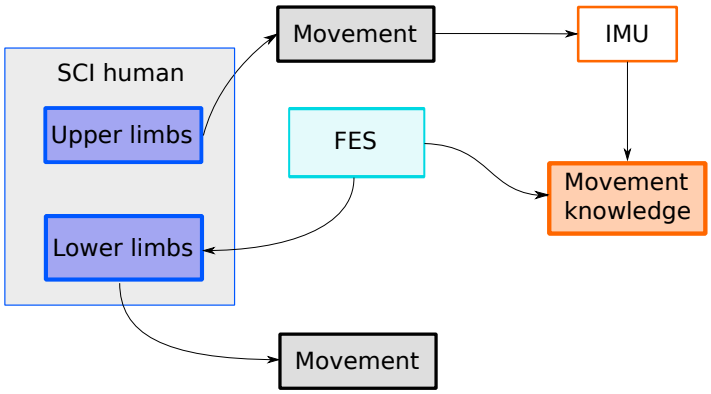


Figure 4.14: Learning phase used in the rowing experiment with open loop FES activation. The Movement Knowledge is formed from the user able body voluntary movement and the lower limbs movements induced by the FES activation, which is preset and works in open-loop.

participant's forearm and arm, as described by Eq. 4.7:

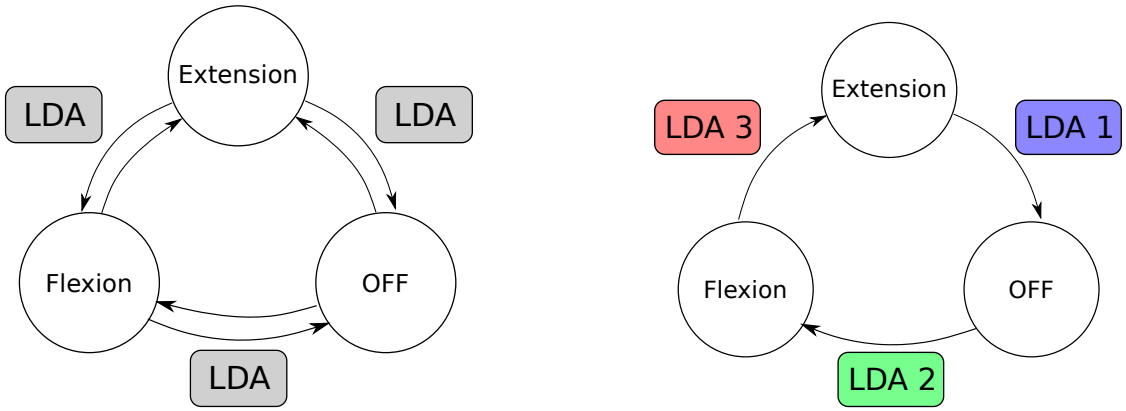
$$q = q_1 \cdot q_2^* \tag{4.7}$$

$$\theta = 2 \cdot arccos(q) \cdot 180/\pi \tag{4.8}$$

Eq. 4.7 outputs the distance between quaternions q_1 and q_2 in the hypersphere. Therefore, Eq. 4.8 gives us the smallest positive joint angle between the arm and forearm.

The learning data is, then:

$$\begin{cases} x = \begin{bmatrix} \overline{\theta} \\ \overline{\frac{d\theta}{dt}} \\ \overline{f(a,s)} \end{bmatrix} \\ y = u \end{cases}, \tag{4.9}$$



(a) Single LDA. (b) Multi LDA.

Figure 4.15: FES-Rowing control finite state machine.

where x is the input data vector to be learned by the LDA, $f(a)$ is the median filter of a with size s, y is the labels vector, based on the FES activation u, and a is the accelerometer data from both IMUs in all three axes. Accelerometer data is always filtered with a median filter of size 3 to reduce high frequency noise. All features are calculated as an average of a moving window of 0.5 seconds. Eq. 4.9 is calculated for every data point collected during the learning phase, and used to train the LDA.

Operation phase On the operation phase, the system uses the previously acquired movement knowledge to classify the desired movement based on the able body part movement. This is the stage in which the user can row by performing the upper limbs rowing movements and the system must follow them by correctly activating the lower limb muscles.

The same finite state machine described in the learning phase is used here. It works differently depending on the choice of using the Single LDA or the Multi LDA paradigm. On the Single LDA paradigm, the trained LDA continuously classify the current state based on the upper limb kinematic data. Any transition is possible. On the Multi LDA paradigm, there is an LDA for each transition.

During the learning phase, the system automatically creates a new LDA for each transition according to the labels presented by the data. In this case, there are three possible transitions: from extension to off, from off to flexion, and from flexion to off. Therefore there are three LDAs. Each one is trained only with data from the two classes regarding its transition, so it is a binary classifier specialized on that transition. In each state, only the LDA responsible for the next transition is active. Once it detects a transition, it is deactivated and the next LDA is started. Fig. 4.15 illustrates how each paradigm drives the FES-rowing control finite state machine.

The control system diagram can be seen on Fig. 4.16.

Experimental protocol After the participant is safely positioned on the rowing machine, the learning phase is initiated. When using the manual activation interface, we asked the participant to maintain a steady rowing cadence between 10 and 20 strokes per minute.

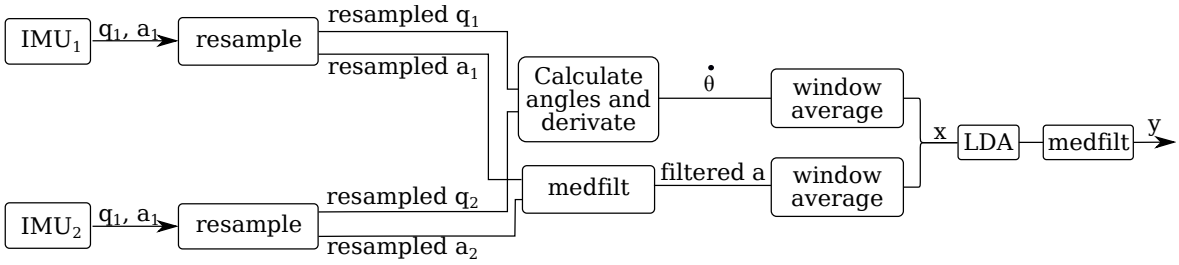


Figure 4.16: FES-rowing control diagram. q is the angle as quaternions. a is the accelerometer data. *resample* is the process described in 4.2.4.3. *Calculate angles* is the process described by Eqs. 4.7 and 4.8. *medfilt* is the median filter of size 3. *window average* is the average of a moving window of size $0.5s$. x represents all LDA input data. y is the estimated state classified by the LDA.

When using the open loop activation interface, we set its cadence to 15 strokes per minute. In this work, I collected data for the learning phase with the recruited participant with SCI and also with an higid, experienced rower [3].

At the end of the learning phase, the movement knowledge is saved in a file that is later loaded for the operation phase. Hence, the operation phase can be performed right after the learning phase, or in a different time. The experimental protocol for this work was divided in two days. On the first, only the learning phase was performed. On the second, both learning and operation phases were performed.

Data analysis After the LDA was trained, I evaluate it by simulating it with that same data it was used to train it. I calculate a point-by-point accuracy, comparing each prediction of the simulation with the actual command. This result is given in percentage.

In order to avoid rapid switching in the border areas between two classes due to incorrect classifications, besides evaluating the LDAs with the standard 0.5 confidence level, I also tested them with the higher confidence level of 0.85. This value was arbitrarily chosen to compare the differences between the two, and represents the system's classification certainty. The purpose of this method is to work similarly to a hysteresis.

Once in operation mode and successfully rowing, I asked the participant to perform the following tasks to evaluate the system: stop rowing, hold the position for a while, and resume rowing; try to accelerate or slow down the overall rowing cadence; try to row with the Movement Knowledge acquired in a different day; and try to row with the Movement Knowledge acquired from another rower.

[3] The higid participant was a member of the research team

5 Results

The three application scenarios described in Chapter 4 served as experiments for different user interfaces based on the framework of techniques developed in this work. The following sections present the individual results of each of those scenarios, highlighting their contribution for the development of the overall framework.

5.1 Transfer

Figure 5.1 shows the trunk angle on the sagittal plane on all 12 trials for one subject with the motion capture system (Fig. 5.1a) and the IMU (Fig. 5.1b). From the moment the subject was told he could do the transfer, there were no instructions for specific timing on when he should start it. Therefore, for visualization purposes, all trials were centralized by the peak trunk angle and plotted on top of each other. Also, the data was trimmed to show only the 5 seconds around the peak trunk angle. This is why not all trials start at exactly 0^o on Fig. 5.1b, even though the IMU angles are set to 0^o at the beginning.

The trunk angle correlation between all trials in each subject presented correlation greater than 0.75, where 1 indicates complete similarity, both with the motion capture system and the IMU data.

Figure 5.2 shows the angles on which the stimulation was activated by one subject related to the initial angle position. Since the angles are relative to the initial position, it was expected that the activating angles would be low. Table 5.1 summarizes these relative angle means and standard deviations for the IMU data.

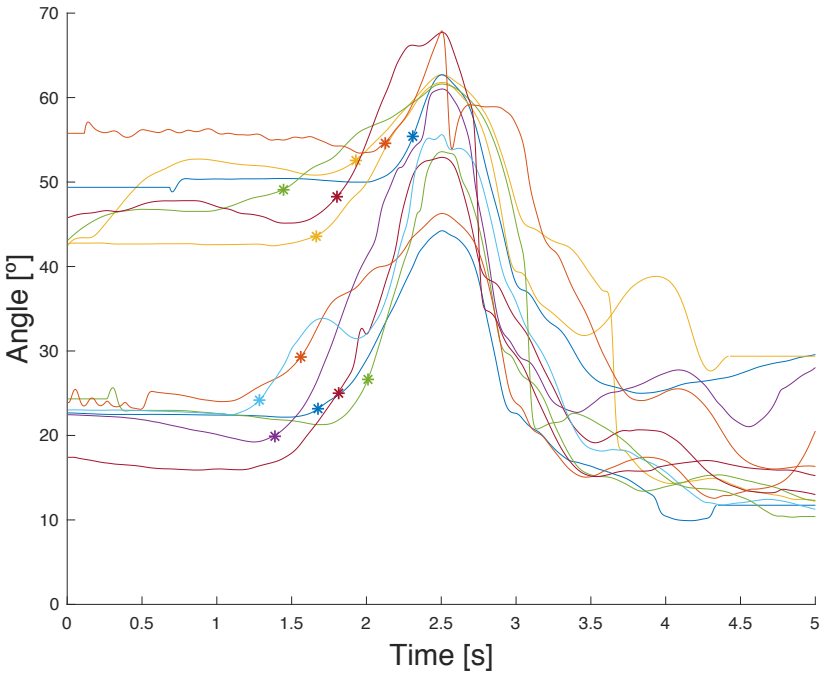
5.2 Upper Limb Grasping

5.2.1 Learning phase

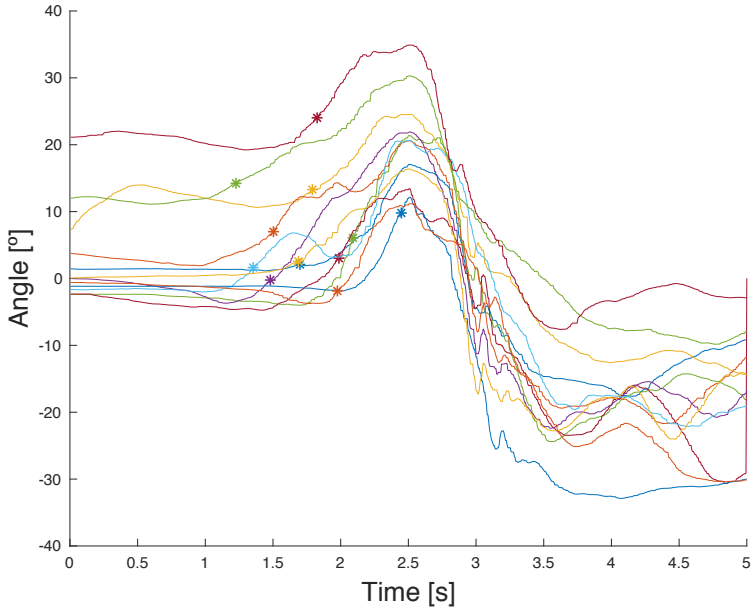
After each learning phase, I could see the results as 2D plots such as the ones in Figs. 5.3 and 5.4. On the first case, the system found the two movements to be less separable when compared to the second one. In this example all these movements were performed by the same participant and the second combination was automatically chosen for the operation phase according to the Eq. 4.4.

Table 5.1: Mean and standard deviation of relative trunk angle position from the IMU data.

Subject	Mean [°]	Standard deviation [°]
A	7,74	2,06
B	4,11	3,78
C	5,28	3,31

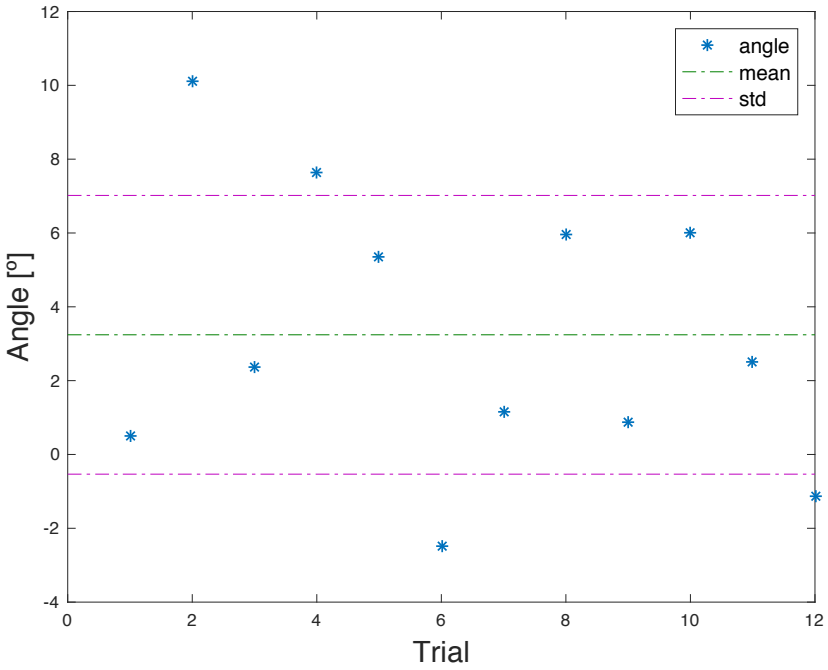


(a) Trunk angles from the motion capture system.

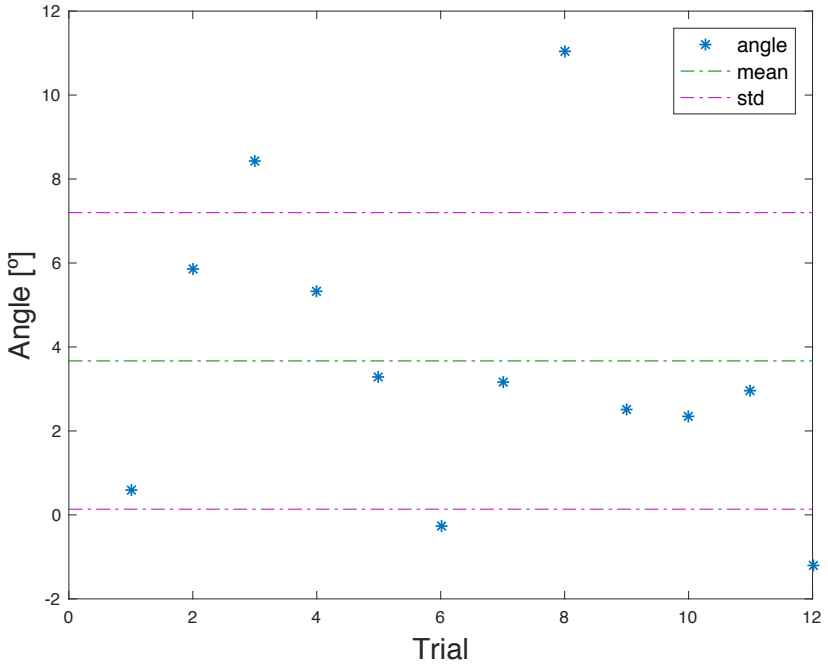


(b) Trunk angles from the IMU.

Figure 5.1: Trunk angles for all trials of subject B. The * marker indicates the moment the stimulation was activated by the subject in each trial.



(a) Relative trunk angle from the motion capture system.



(b) Relative trunk angle from the IMU.

Figure 5.2: Trunk angle for all trials of subject B related to the initial angle position. Each point represents one trial. The green dashed line is the average of all measurements, and the pink dashed lines represent one standard deviation up and down.

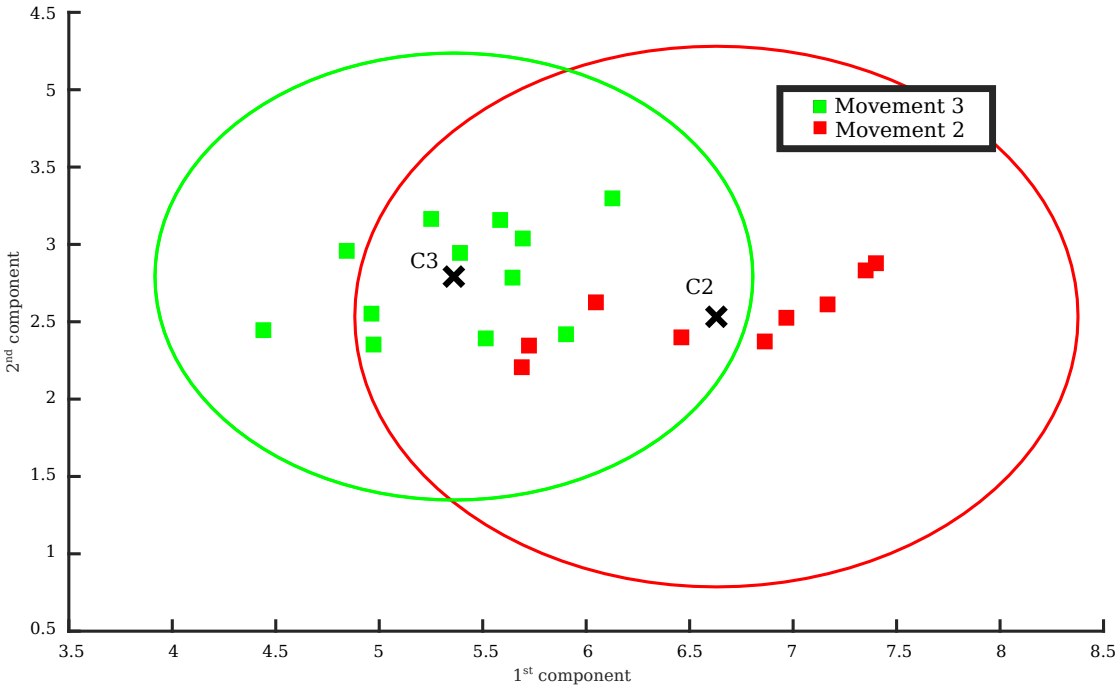


Figure 5.3: PCA space example after the learning phase in which two movements are hard to classify in the upper limb grasping experiment. Each square represents a movement, and the ellipse indicates three standard deviations of the distances of each movement to their respective class centroid.

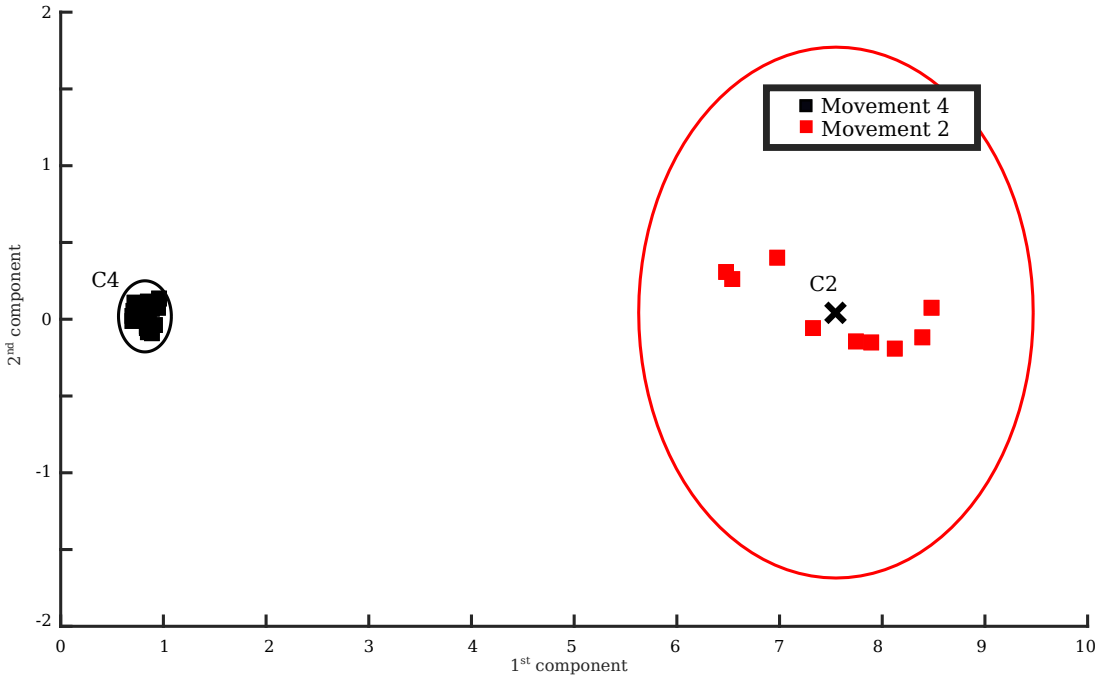


Figure 5.4: PCA space example after the learning phase in which two movements are easy to classify in the upper limb grasping experiment. Each square represents a movement, and the ellipse indicates three standard deviations of the distances of each movement to their respective class centroid.

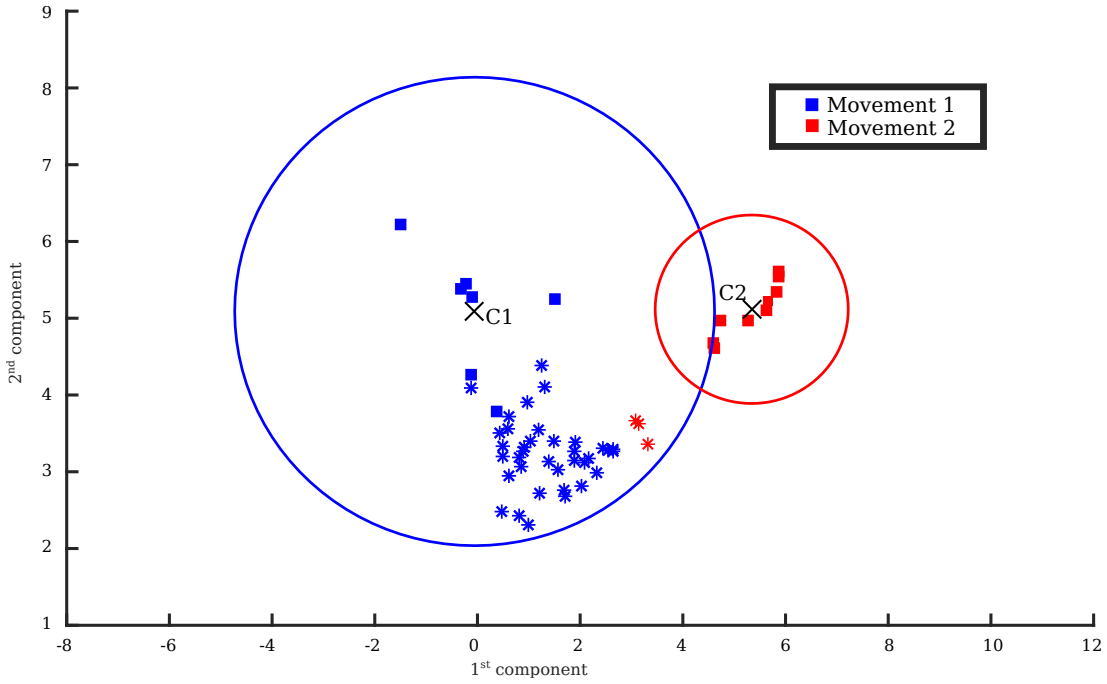


Figure 5.5: PCA space example after the learning and operation phase in which most movements were incorrectly classified in the upper limb grasping experiment. Each square represents a learning phase movement, the ellipse indicates three standard deviations of the distances of each movement to their respective class centroid, and stars represent operation phase movements.

Fig. 5.5 shows the results of one trial of the basic learning algorithm. Note how the initial movements, illustrated by the squares and ellipses, seemed easy to classify. However the operation phase movements, the stars, were all in a different area, further away from both centroids than the initial movements. Therefore I applied the assistive learning algorithm and chose these new movements as learning movements. Fig. 5.6 shows the result of that process, in which all movements in the operation phase, the stars, were correctly classified.

5.2.2 Operation phase

All participants were able to complete the task of controlling two movements which were classified and associated with specific actions. Figure 5.7 shows the accuracy achieved with the assistive learning algorithm and assessed in the robotic hand modality. The average outcome was 91($\pm$8)%.

These results were achieved using two components from the PCA. Simulations were performed using up to all 6 components and the final results changed less than 1%. Furthermore, the movement detection algorithm had no false negatives or positives, indicating that the threshold automatic calculation was appropriate.

The robotic hand served as a feedback tool for the users. They performed the movements and watched as the hand activated accordingly. The participants involved in the FES modality tests were also able to pilot their hand opening/closing. However, since the exact grasping movement of each participant was different, there was no standard performance

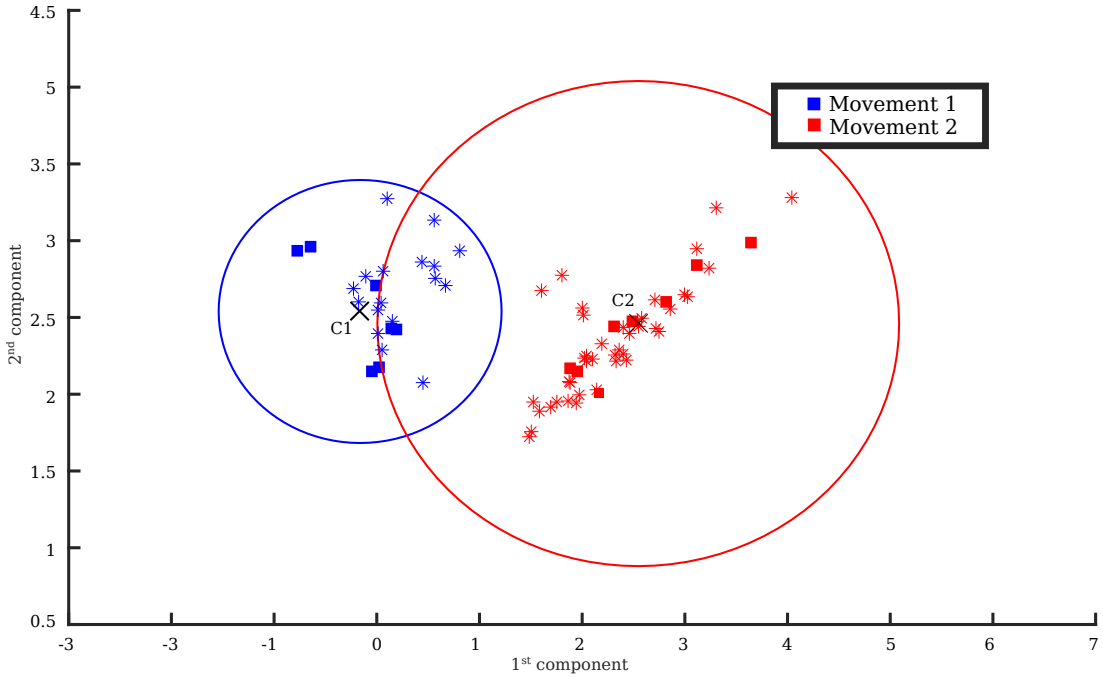


Figure 5.6: PCA space example after the learning and operation phase in which all movements were correctly classified in the upper limb grasping experiment. Each square represents a learning phase movement, the ellipse indicates three standard deviations of the distances of each movement to their respective class centroid, and stars represent operation phase movements.

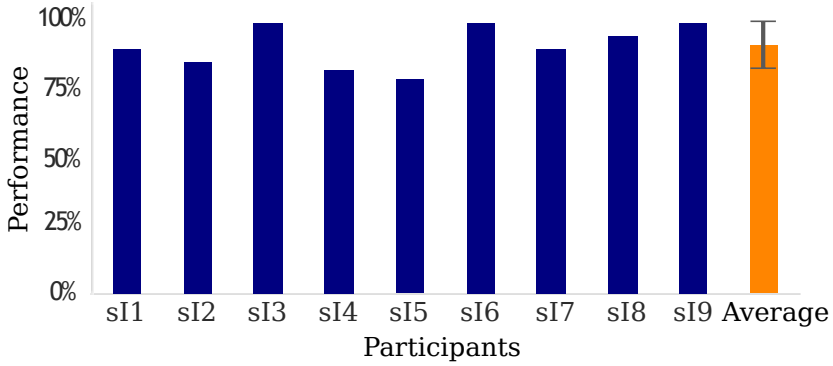


Figure 5.7: Accuracy results with the assisted learning algorithm in the upper limb grasping experiment. Vertical bars represent one standard deviation.

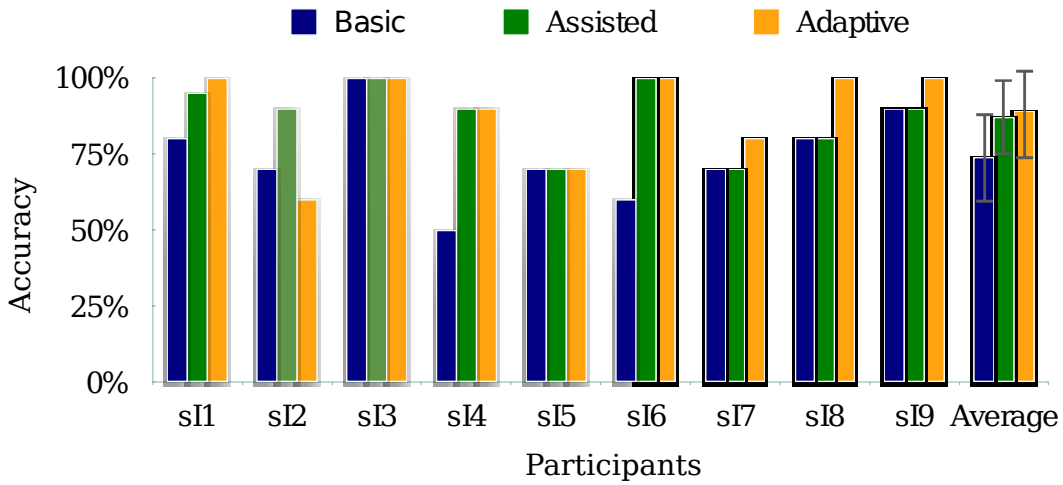


Figure 5.8: Simulation accuracy results with the three proposed algorithms in the upper limb grasping experiment. Vertical bars represent one standard deviation.

measurement.

Using the data acquired in the assisted learning algorithm experiment, I ran simulations to predict the accuracy of the basic and adaptive learning algorithms. These results can be seen in Fig. 5.8. The basic learning system had an inferior result when compared to the assisted one. The adaptive system, however, had a similar accuracy to the assisted algorithm.

5.2.3 Questionnaire

Responses to the questionnaire applied during the upper limb grasping protocol were averaged and are shown in Figure 5.9. Arm, shoulder and elbow fatigue were perceived to be low ($6,46 \pm 0,33$). Overall system operation seemed satisfactory ($6,31 \pm 0,44$). The physical effort required was perceived as moderate ($5,96 \pm 0,76$). The attention effort required was significant ($5,23 \pm 0,73$), implying the system required a certain level of attention from the user. Finally, overall comfort seemed adequate ($6,38 \pm 0,34$).

5.3 Rowing

In accordance to the method described in chapter 4, a comparison between a regular rowing machine and the one adapted by us can be seen on Fig. 5.10. The new seat, although bigger, slides on the track as easily as the original one. It is also more stable. The safety straps can successfully limit the seat range of motion, however it has an abrupt stop at the end. The legs stabilization device fits well on a regular size adult, with minimal resistance to the rowing movement.

The SCI participant in this work can be seen on Fig. 5.11 using the system. Hamstrings activation did not elicit enough force to flex the legs and pull the seat forward. Therefore a member of the research team assisted on that phase by pushing the seat forward when the hamstrings were stimulated. This could be seen both directly on the participants legs and also on the computer screen.

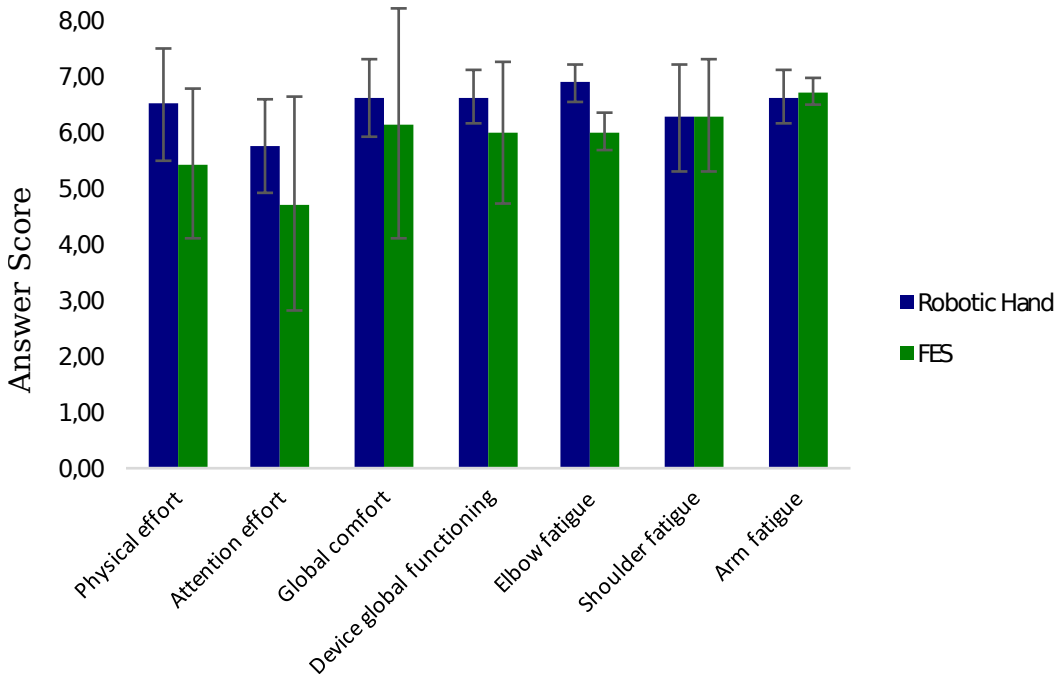


Figure 5.9: Questionnaire results for the robotic hand control task. The higher the value, the more positive the subject's perception. The maximum score is always 7.

Figure 5.10: Comparison between the adapted rowing machine and a standard one. Note the seat for trunk stabilization, the custom device for legs stabilization, and the safety straps.

Figure 5.11: SCI participant in the final FES-rowing experimental setup. Both IMUs are highlighted in orange.

5.3.1 Learning phase

Data was collected from the participant with SCI and an higid one. The results regarding the higid participant can be seen on Appendix H.1.

Here we can see results of the SCI participant learning phase. Fig. 5.12 shows a snippet of elbow joint angle and the z axis accelerometer specific force data. These are some of the data used to feed the LDA, along with angle differentiation and the specific force from the other axes and sensor.

Figure 5.14 illustrates how the angle data is labeled according to the FES commands. Each data point is fed into the LDA with that label for the supervised training.

Figure 5.14 is a plot showing the two first components of the single LDA trained for the SCI participant. The centroids are well separated, and, although there are many points which are difficult to correctly classify, most of them are actually close to their respective centroids, as we can see by the relative small standard deviation indicated by the ellipses. It is important to note that, since there are three classes being trained here, I have only two available components, as the maximum number of components is equal to the number of classes minus one.

Figures 5.15a and 5.15b show the evaluation of the single LDA trained for the SCI participant with the standard confidence level of 0.5.

We can see by Fig. 5.15 that there was no fast switching. In other words, the LDA did not quickly switch between classes. This is a favorable result because it could cause unwanted muscle contractions. However, this is a risk and it actually happened for the higid participant,

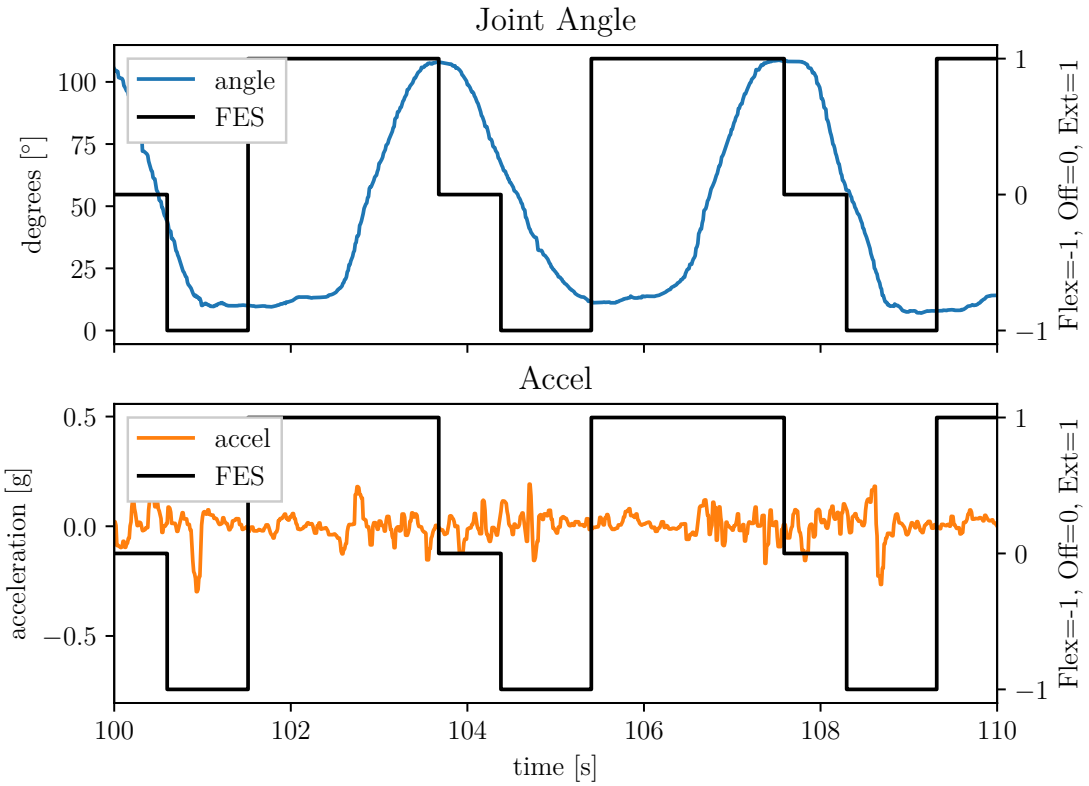


Figure 5.12: Example snippet of data with the elbow joint angle and one axis of the accelerometer during 10 seconds of the learning phase with an SCI participant.

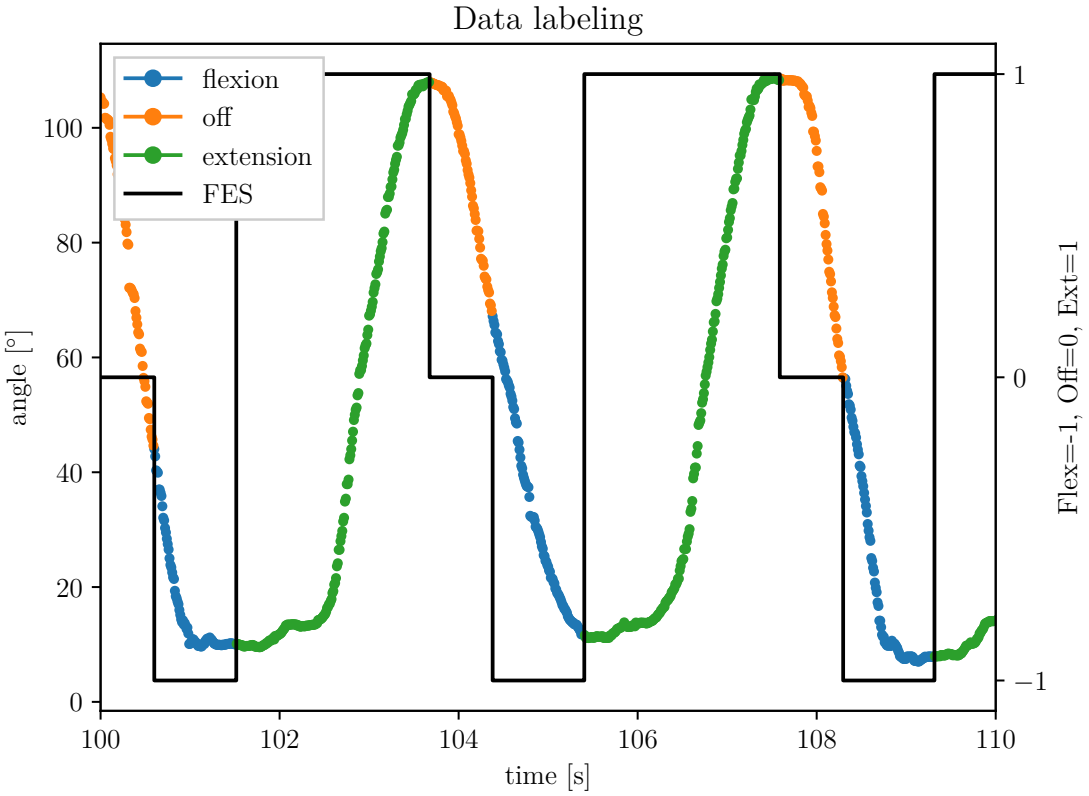


Figure 5.13: Data labeling example snippet for the SCI participant. Data is labeled according to the FES command.

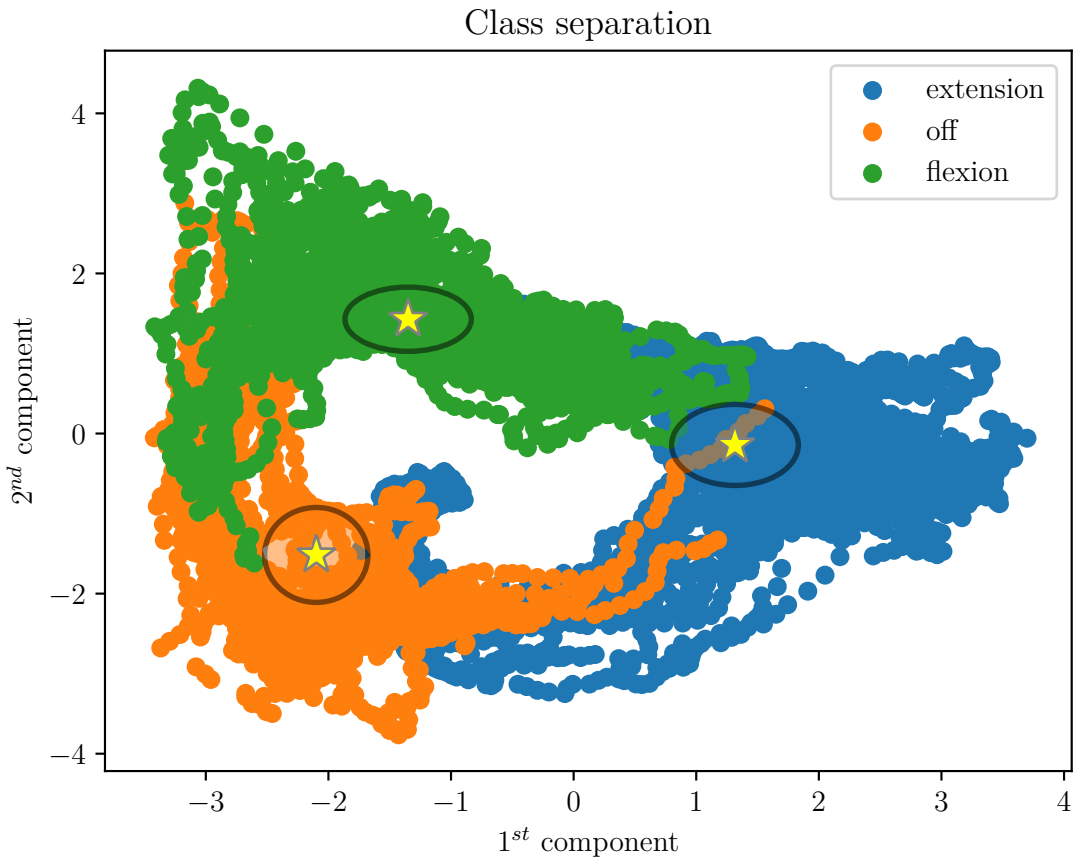


Figure 5.14: Class separation visualization for the SCI participant with a single LDA. Stars indicate the centroid of each class. The ellipses represent one standard variation in the two axis.

as can be seen in Figs. H.4 and H.5 in the Appendix H.1.

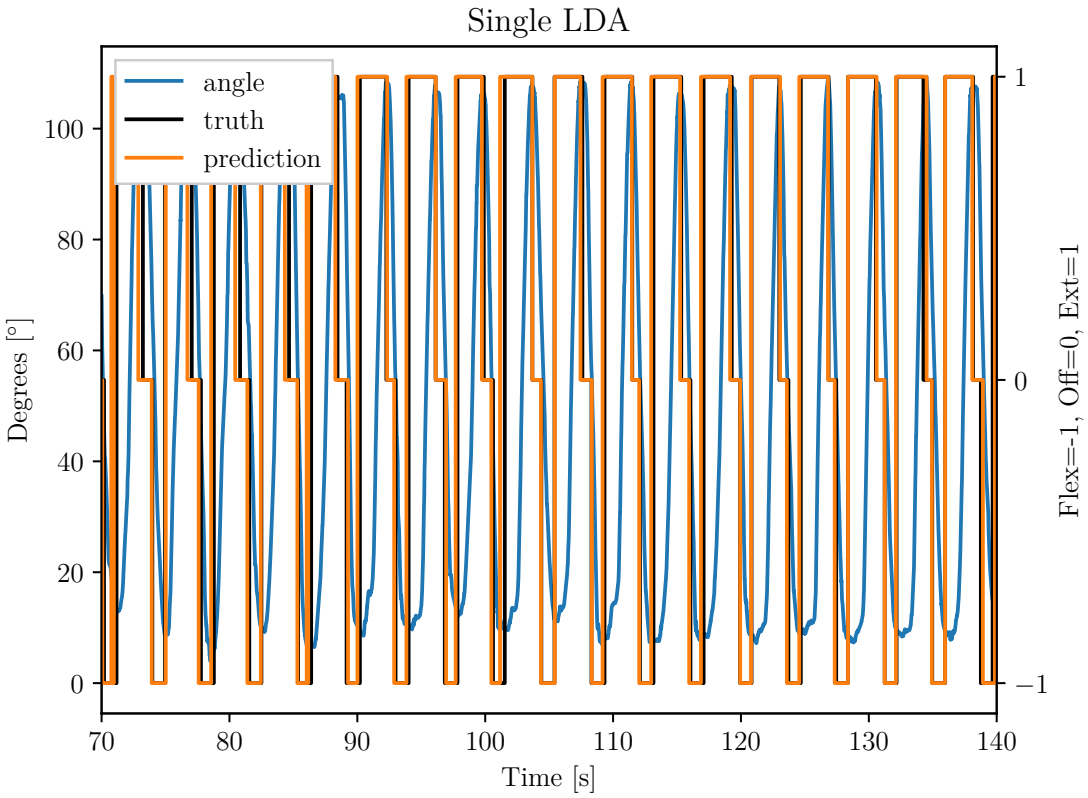
Figures 5.16a and 5.16b show the same data pieces as the previous two figures, but now with the confidence level of 0.85. It is possible to see the transitions are delayed due to the more conservative nature of this method.

The Multi LDA method had the goal of improving the classification between every two classes. Since each LDA was trained with only their respective two classes, there is only one component to be evaluated. Fig. 5.17 shows the resulting learning data for the SCI participant with Multi LDA. Again, even though there are data points difficult to classify, particularly between the flexion phase and the extension phase (LDA 2), most points are close to their respective centroids.

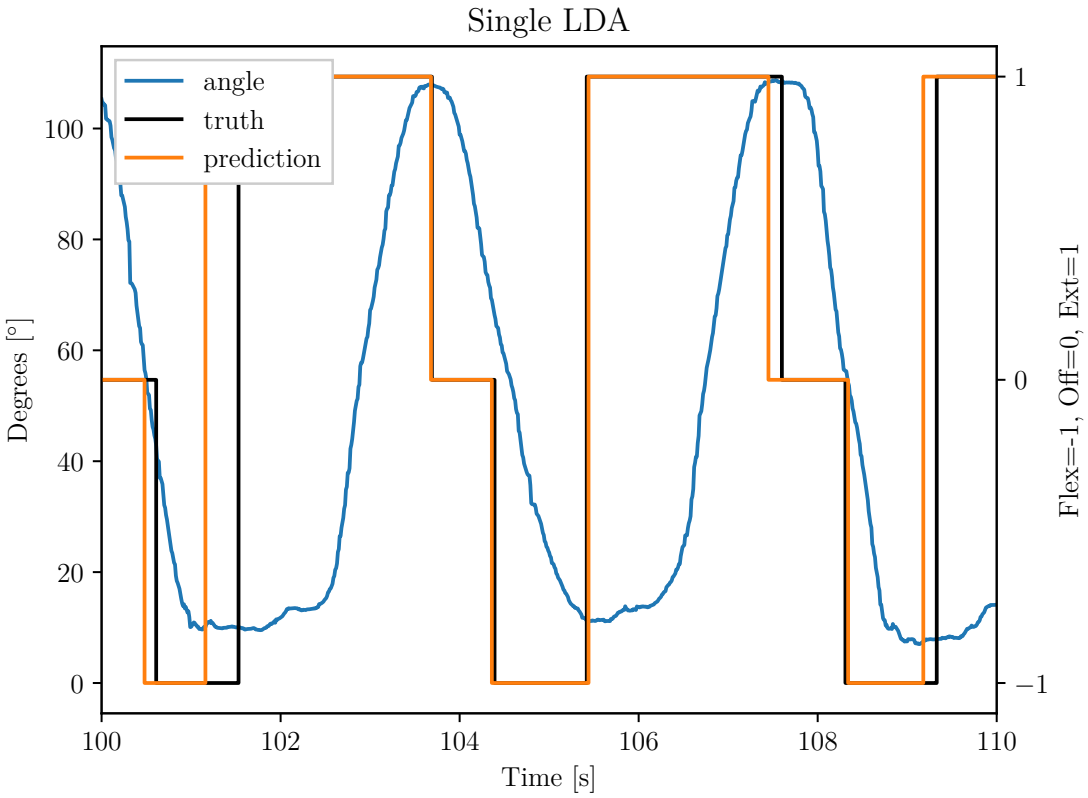
Figure 5.18 shows the simulation result as if each of the three trained LDAs was the only one classifying the input data. As expected, each LDA only outputs the two known class to it. Each seems to have a good result classifying the transitions it was trained to.

Finally, Figs. 5.19a and 5.19b show the simulation result of the Multi LDA method in the learning phase with the SCI participant.

Table 5.2 shows the point-by-point accuracy of all LDAs trained for both partici-

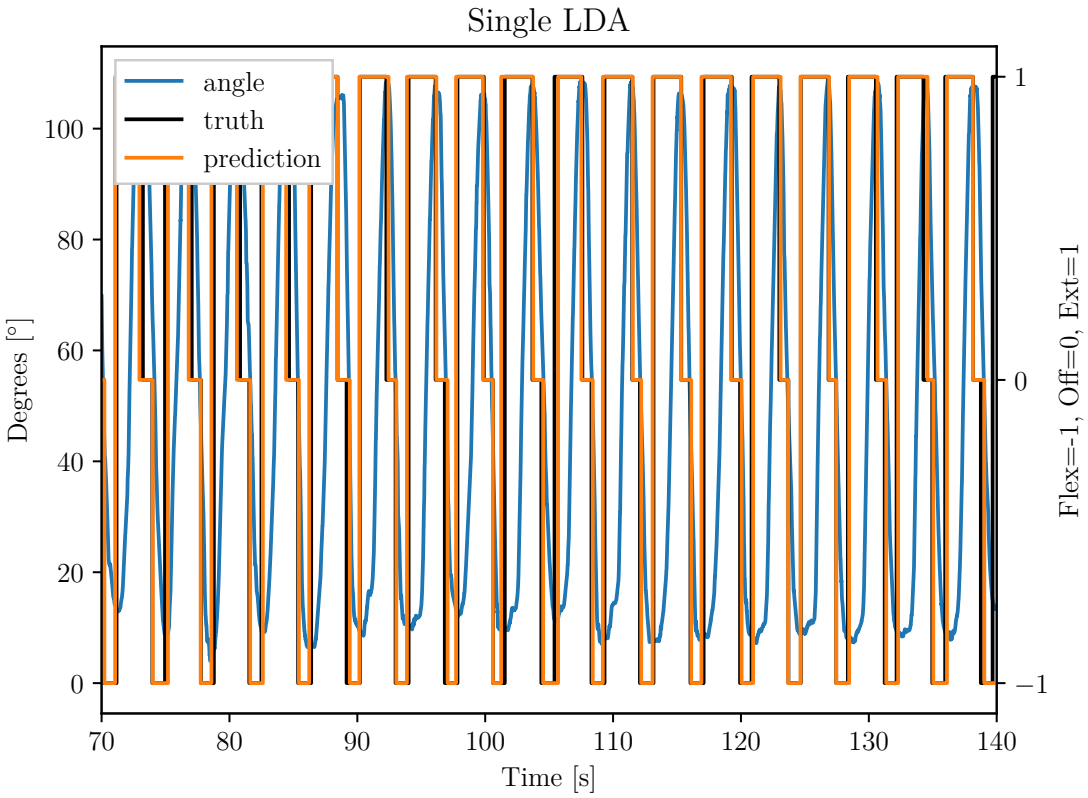


(a) Full simulation.

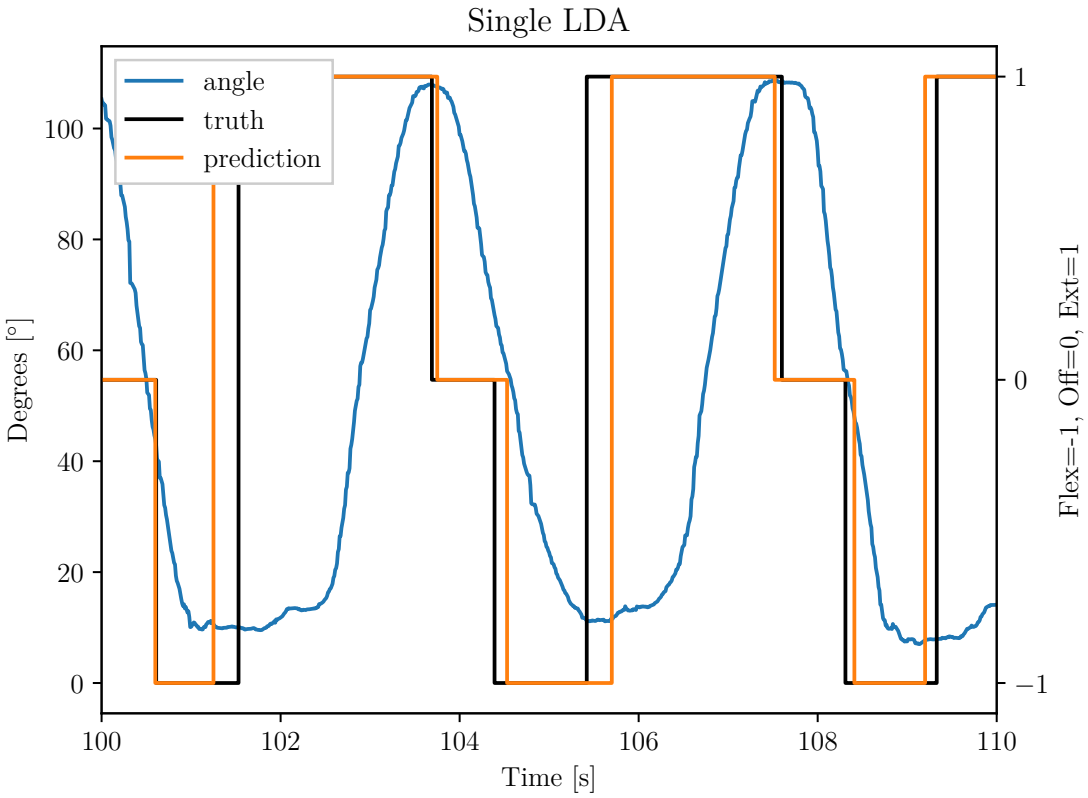


(b) Detail snippet of the simulation.

Figure 5.15: Simulation of trained LDA with the same data used for training. SCI participant and a single LDA with the standard confidence level of 0.5.



(a) Full simulation.



(b) Detail snippet of the simulation.

Figure 5.16: Simulation of trained LDA with the same data used for training. SCI participant and a single LDA with the confidence level of 0.85.

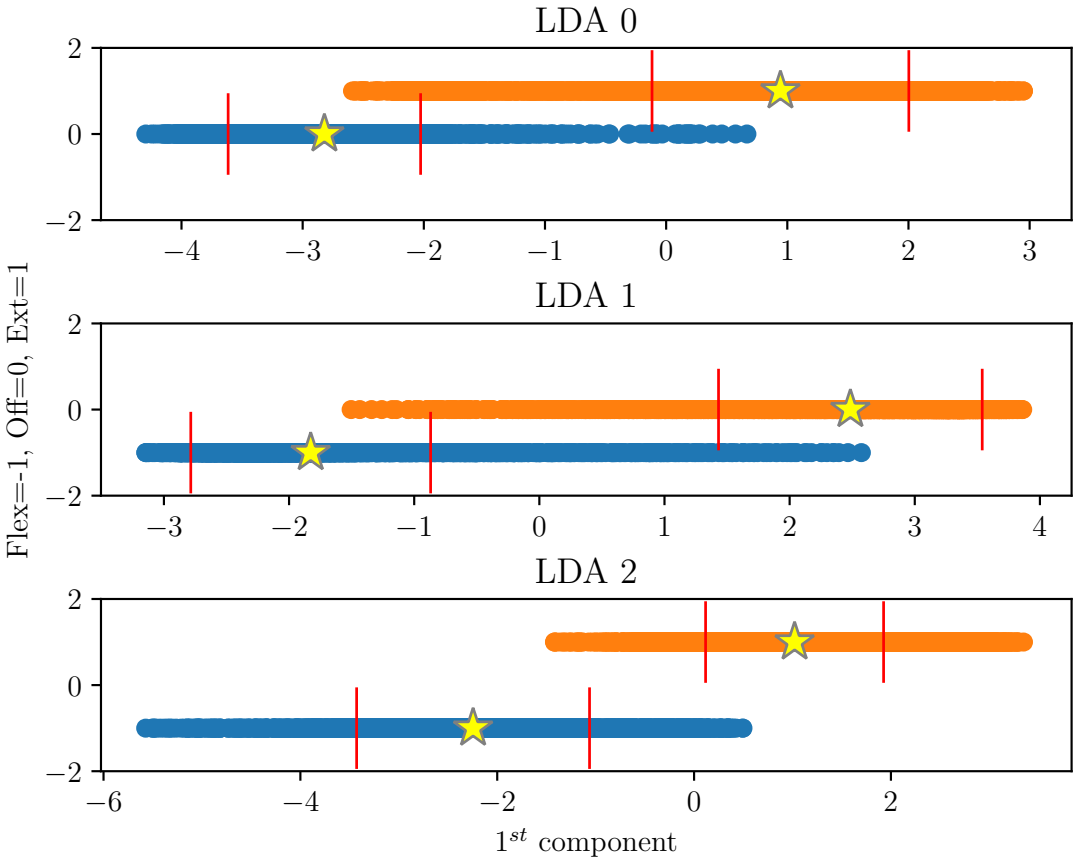


Figure 5.17: Class separation visualization for the SCI participant with three LDAs. Stars indicate the centroid of each class. Red bars represent one standard variation for each side.

Table 5.2: Point-by-point accuracy of the learning phase. CL means *confidence level*. Each value refers to one trained LDA system and simulation.

Participant	Single LDA (CL = 0.5)	Single LDA (CL = 0.85)	Multi LDA
Higid	83.7%	66.0%	85.8%
SCI	88.2%	88.4%	88.8%

pants. All results are calculated from simulations performed with the same data used for training. Note that a higher confidence level may decrease the accuracy, as was the higid participant's case. However, the Multi LDA method seems to be equivalent or superior in all cases. Therefore it was the method I chose to perform the operation phase.

5.3.2 Operation phase

During the operation phase, the SCI participant tried to row in different scenarios. In all cases, I asked him to try to row in different cadences and to try to stop rowing, wait a couple seconds, and then resume the movement.

Figures 5.20a and 5.20b show the SCI participant rowing with the Multi LDA trained with the higid participant data (available at Appendix H.1). We can see that the participant was able to stop rowing twice by the end of the experiment. However, there was an evident

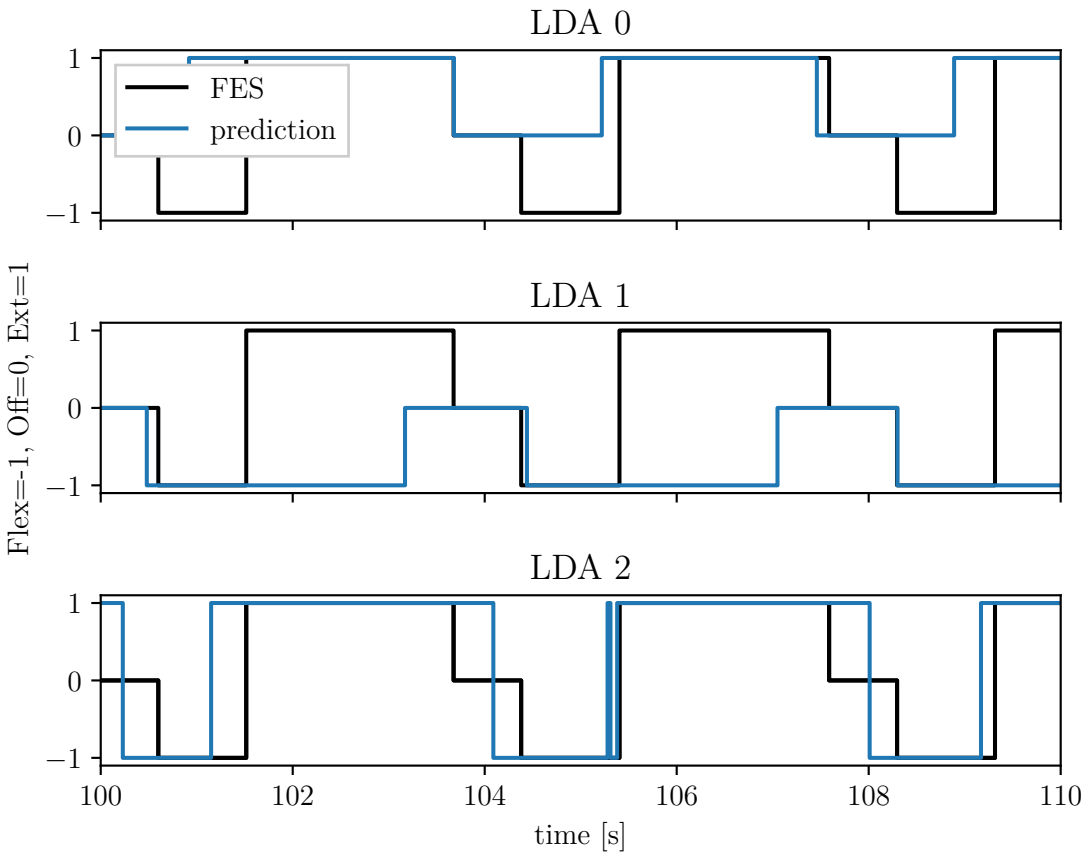


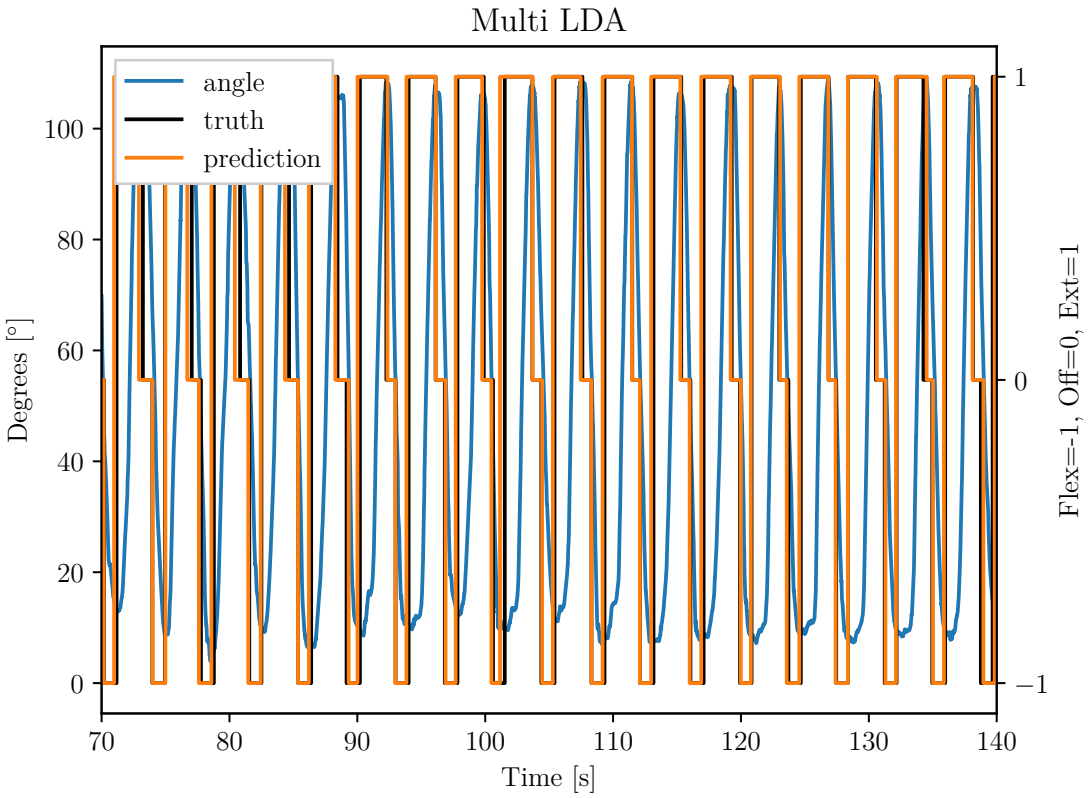
Figure 5.18: Detail snippet of individual LDA classification of the same data used for training. In this case, LDA 0 was trained to classify *Extension* and *Off* classes, LDA 1 was trained to classify *Off* and *Flexion* classes, and LDA 2 was trained to classify *Flexion* and *Extension* classes.

bias in the angle data that increased over time.

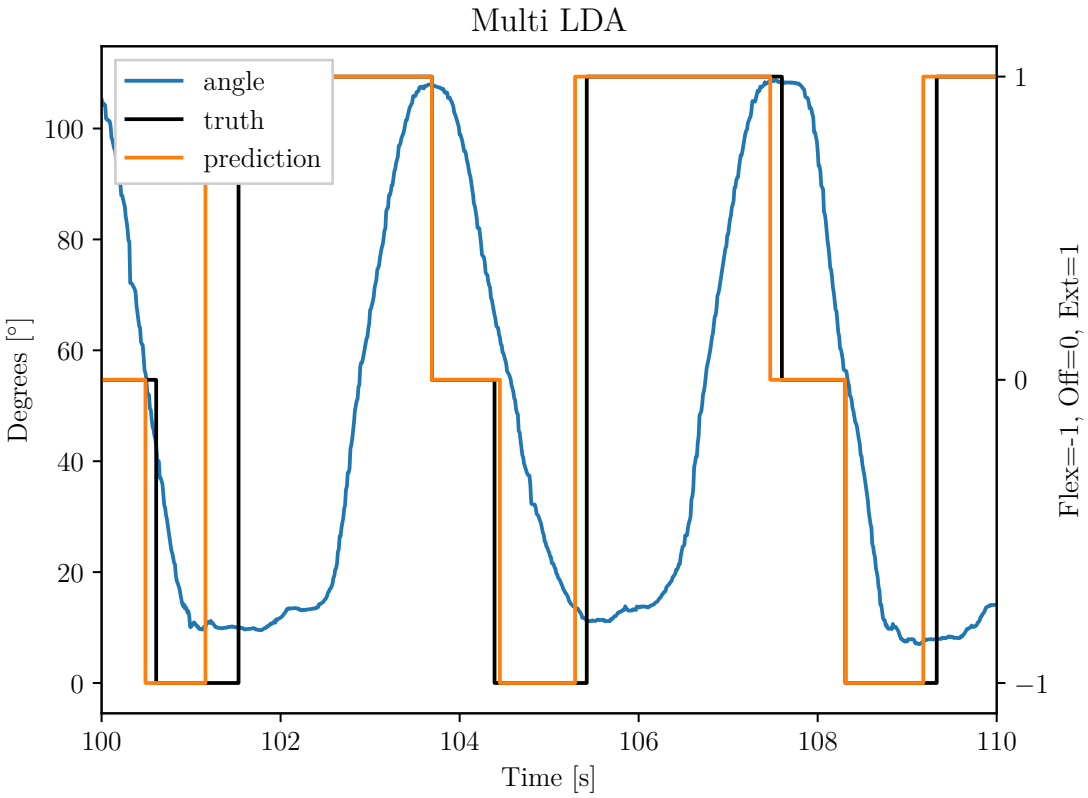
Figures 5.21 show the result of the SCI participant trying to row with a Multi LDA trained with his own data, but from a different day. This is the Multi LDA depicted in Subsection 5.3.1. He was not able to row, as the output command was almost constantly *Extension* with brief changes to the other classes. This figure show the whole experiment, which was interrupted as soon as it became evident it was not working.

Due to the unsuccessful experiment with the Multi LDA trained with the SCI participant's own data, a new Multi LDA was trained and tested immediately. Figs. 5.22a and 5.22b show the results of that test.

We can now see a superior accuracy, as the participant not only was able to row for almost 5 minutes, but also could do the stop and resume maneuver with ease. Again we can see some bias in the angle data, however smaller than that on Fig. 5.20a. In all cases the participant was not able to successfully and consistently row in different cadences.

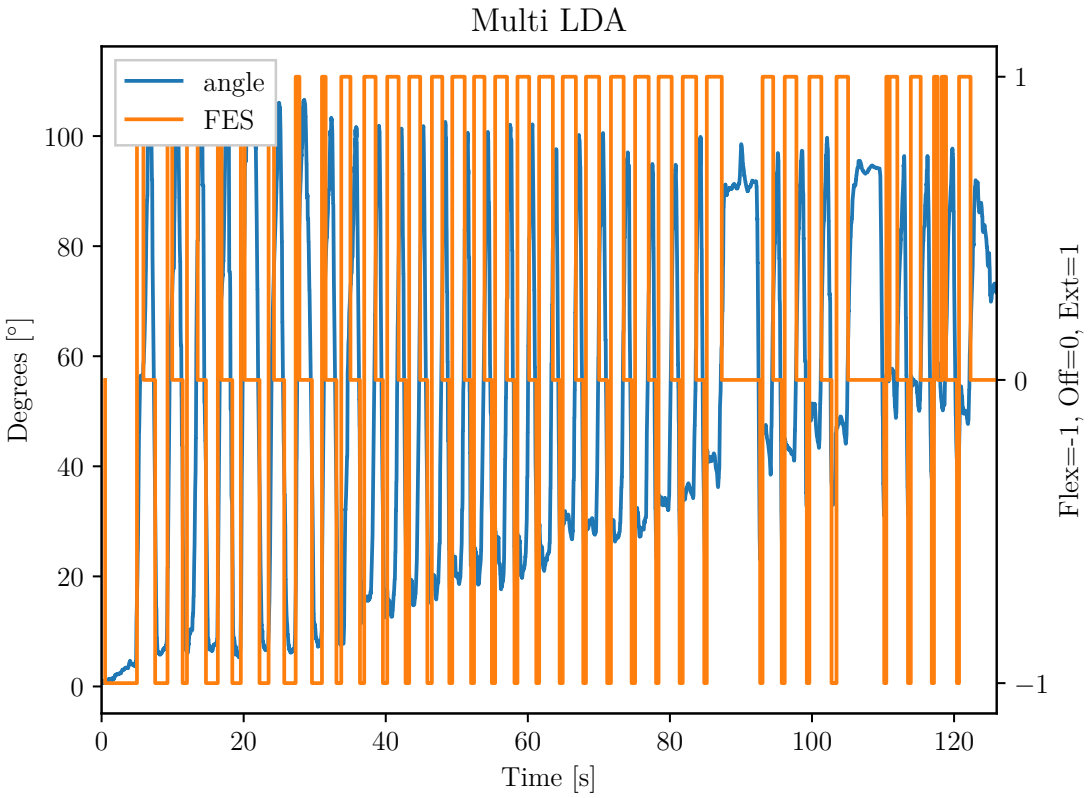


(a) Full simulation.

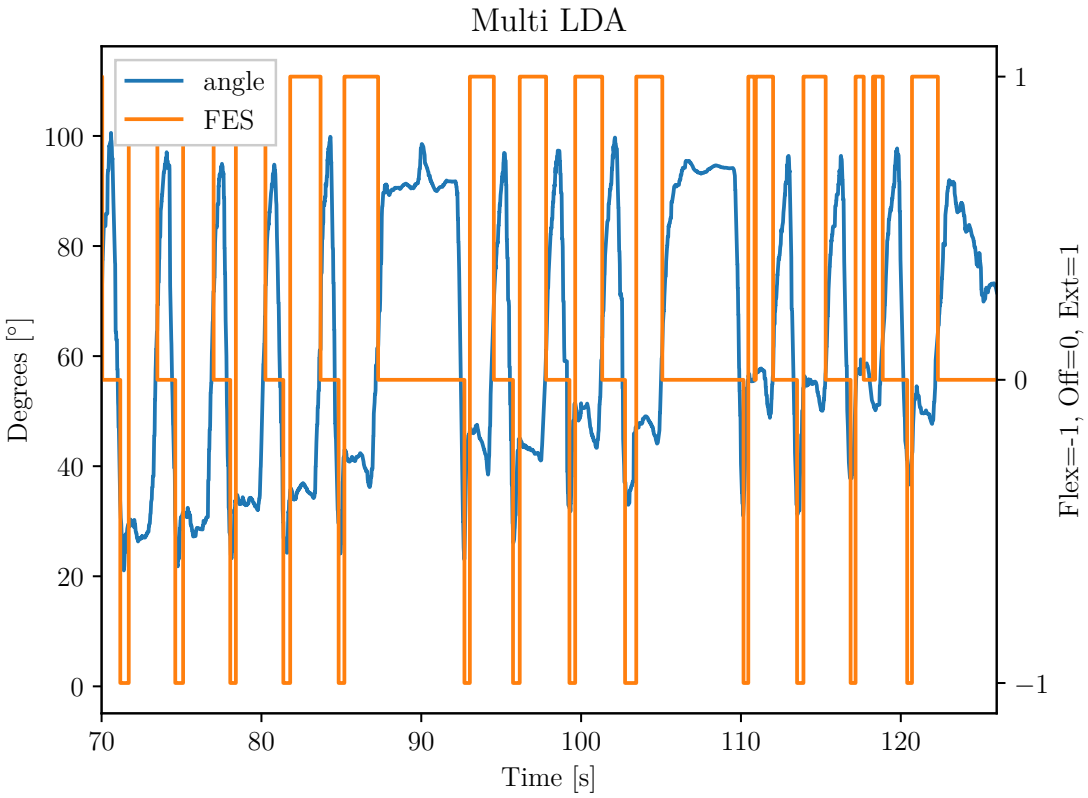


(b) Detail snippet of simulation.

Figure 5.19: Simulation of trained LDAs with the same data used for training. SCI participant and three LDAs.



(a) Full test result.



(b) Detail snippet of test result.

Figure 5.20: Test result with SCI participant rowing with LDA trained with data from the higid participant.

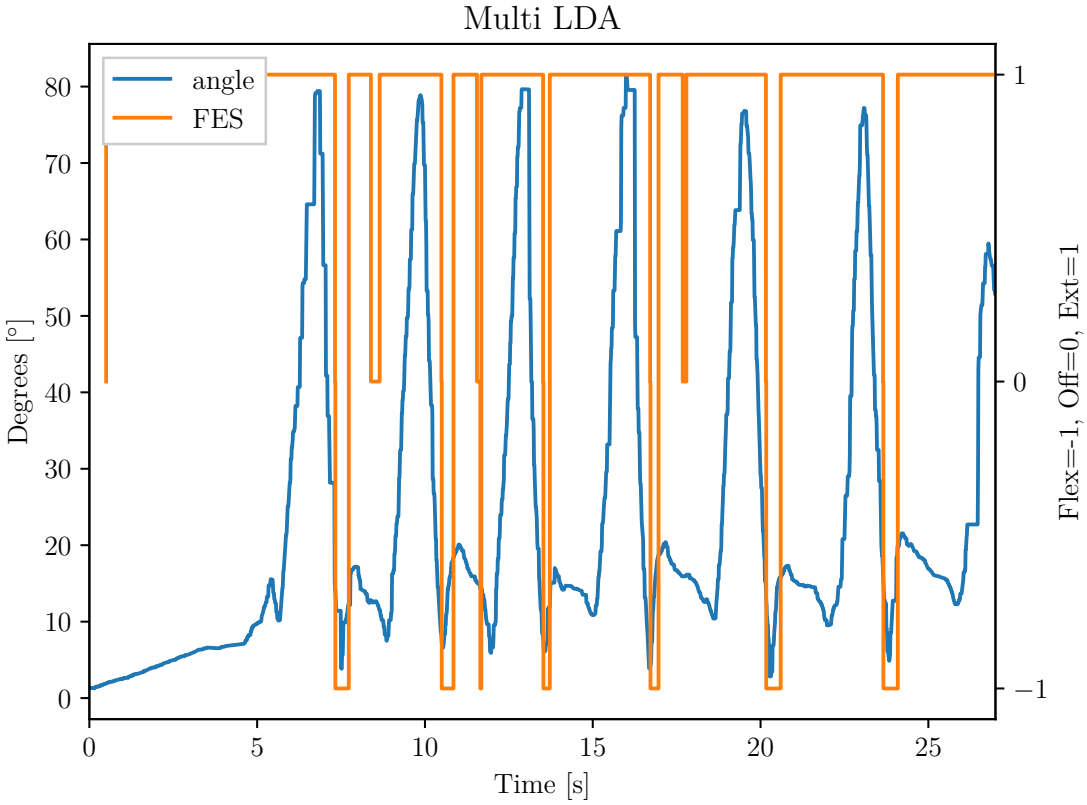
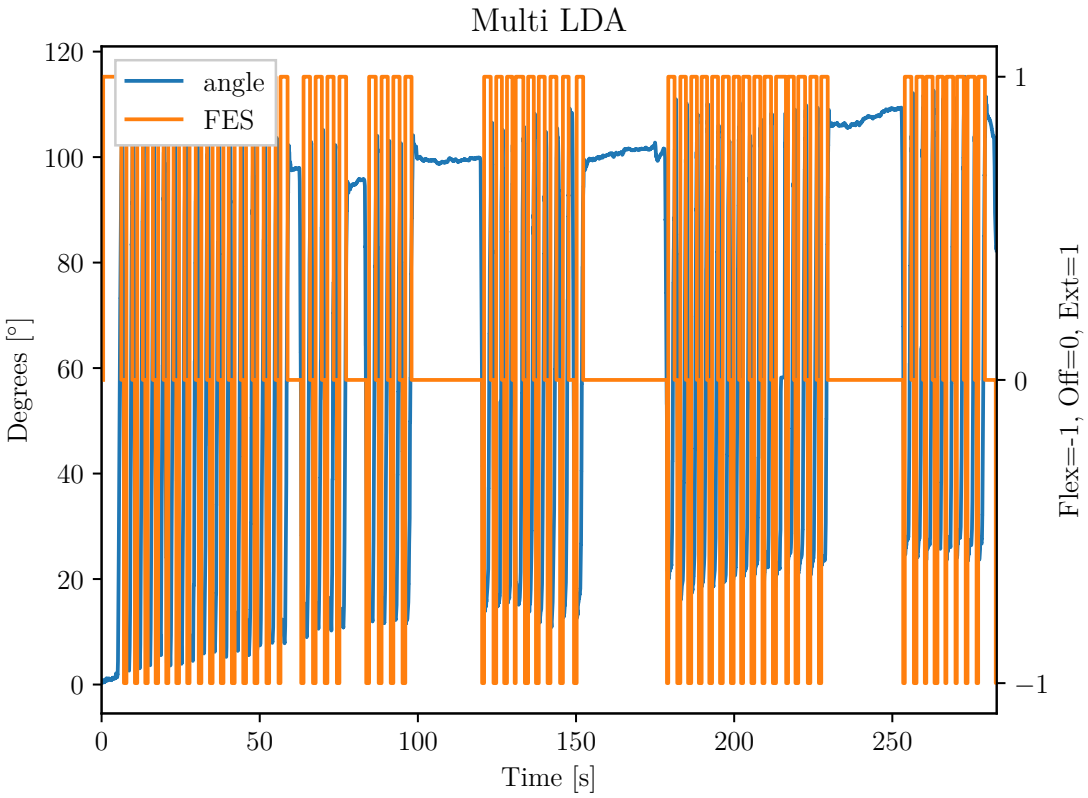
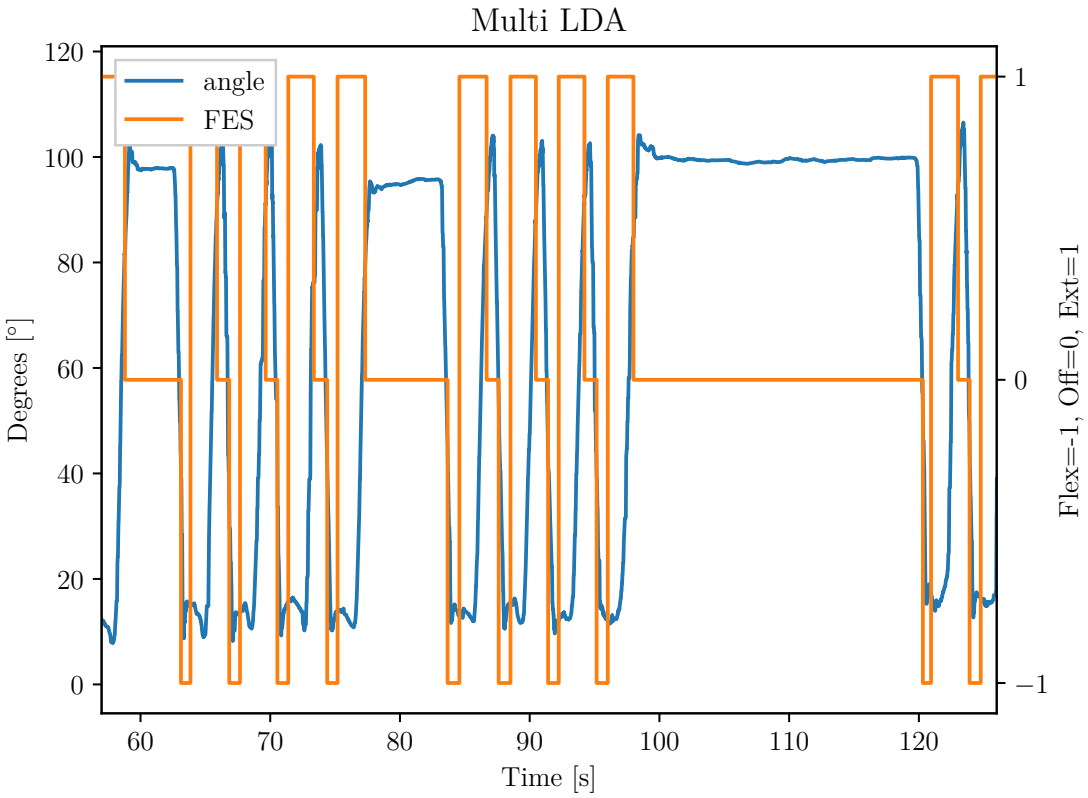


Figure 5.21: Test result with SCI participant rowing with LDA trained with data from the same participant, but in a different day.



(a) Full test result.



(b) Detail snippet of test result.

Figure 5.22: Test result with SCI participant rowing with LDA trained with data from the same participant in the same day.

6 Discussion

The three application scenarios proposed in this work show the potential of the developed interface. It demonstrates the feasibility of individuals with SCI controlling assistive devices with residual motor skills and inertial sensors. The next sections discuss each of the applications scenarios, and how they contribute to this work.

6.1 Transfer

We analyzed the kinematics of a participant during SPT when compared to their own volitional triggering of FES as an assistive device on that task. The differences between the angles captured by the motion capture system, Fig. 5.1a, and the IMU, Fig. 5.1b, are due to two reasons. First, the procedure on which the IMU angles are set to 0^{o} on the beginning of each trial. Also, the two systems do not measure the exact same body segment. The trunk angle from the motion capture system is based on the trunk body segment, which was built using the shoulders and hips markers. Therefore, it does not capture the curvature along the trunk. The IMU, however, was placed over the C7 vertebra. As a result, the IMU captures the upper trunk orientation, which may also be affected by the neck, but ignores the lower trunk movement, close to the hips.

We can see on Fig. 5.1a that the absolute angle varies substantially between trials of the same subject, which also makes it unsuitable to be used as trigger for the stimulation. However, the relative angle between the starting position and the moment of activation is more consistent, as can be seen on Fig. 5.2. Note that, despite the differences aforementioned between the two systems used, the relative angle seems similar between the two.

Having a high trunk angle correlation between trials on each subject is a strong indication that a device to automate the stimulation trigger is feasible. Table 5.1 shows low standard deviations for the angles in which the stimulation was activated. It suggests that these angles collected by the IMU can be used to set a trigger, which must be calibrated for each individual to activate the stimulation without the need of hand sensors or any other method.

It is important to point out that the transfers performed in this work were done without prior training, and the system performed reliably with all users. A real life application, however, would profit from some practicing, which we believe would further narrow the angle deviation. In addition, the relative angle would probably pose an easier learning curve for the user than something like the acceleration (second derivative), which would be harder to understand. Still, the good results without training indicate this system can be considered a transparent control interface, which users can operate the same way they would without it.

Note that, in this case, the system is responsible for detecting an event, but it does not need to classify it. It might be possible, however, to expand the system to different appli-

cations, in which a correct classification on events would become necessary. Also, actuation was pre-configured and only triggered by the systems. This means there was no closed-loop control of the desired movement and, as such, no need for the feedback sensor as described in Fig. 4.2b.

This experiment has shown that inertial measurements can be used for an application such as FES activation for transference. It is a practical application in which the activation would be very intuitive. Also, the FES activation is a simple one, in open-loop. More complex tasks will require the low level control as illustrated in Fig. 4.2.

6.2 Upper Limb Grasping

We investigated the capability of individuals with tetraplegia to control either a robotic hand or their own hand through different discrete shoulder movements. The IMU-based control tested in this experiment required only one sensor to control the transitions between actions. Using a unique sensor requires a classification method to identify the various movements associated with the participant's commands, and that classifier needs to be trained. The IMU placement did not need an accurate placement because it could be quickly calibrated.

This work did not evaluate day-to-day performance or functionality, but, in any case, electrode or sensor positioning is important. However, the calibration or training process would take no more than 2 minutes for a trained subject, which would not affect the system usability. The trials were successful (more than 90% of correct movements). Improving individual fit can be achieved, but custom-fitting depends on individual residual capacities for movements.

The assisted learning algorithm accuracy was better than the simulated result of the basic learning system, as expected, since there is the classification manual improvement step. The accuracy of the adaptive system was close to the assisted one. This was also expected because the improvement step is similar in both case. Nevertheless, the adaptive system if fully automated after the first calibration, which represents an important advantage for the final user.

The IMU method studied here successfully classified two movements. These movements can be mapped as desired to perform different tasks on an assistive device, and also be expanded to more than two or three tasks if sequences of movements are considered. Also, it can be improved to classify more movements, as in [112]. Since the IMU data is differentiated, the calibrated movements can be performed regardless the user initial position, but the design choice of classifying any detected movement as command 1 or 2 is a drawback. Although it did not happened in this work controlled situation, movements that differ from the two calibrated ones would still be classified as one of the two calibrated classes. Real life applications must consider a "do nothing" command to be classified in cases in which a movement is neither one calibrated. It is important so that the user can do different movements and even move from one place to another, or from/to the wheelchair, without activating the device.

It is important to note that this system is highly sensitive to any movement because the threshold was calculated from a static posture. Therefore, as it is, users with involuntary movements would find it challenging to operate it. To solve that, the method to detect movements can be changed in a way that the user's involuntary movements are learned by the system, and not seen as intended movements, a similar approach as done in [47]. One solution would be to also use machine learning for that purpose. Theoretically, a PCA system such as the one developed in this work would still be able to classify movements if the involuntary ones are not too intense.

In our study, the visual feedback provided by the robotic hand or, to a lesser extent, by the subject's own hand, was valuable to them; however, they could only see if the commands were in fact the desired ones or not. More precise biofeedback could therefore be provided to further enhance user performance. By watching the real time PCA plot in the IMU approach, on the computer screen, we could not only tell if every new movement was similar to the calibrated ones, but by how much. Sometimes the user movements would get increasingly different over time, and the classification would get harder. If the users had access to that information, they could probably adjust their movements accordingly. This could be used during a training period.

Whenever FES was used, users were able to control their own hand with the system's assistance. In several participants, we found it somewhat difficult to identify the motor points upon which to place the electrodes which would enable them to perform grasping movements. However, in most cases, we were able to activate wrist extension or lower arm rotation muscles. Several subjects had never experienced FES before. They were often in awe of their own limbs' movements. This would sometimes distract them from the visual or auditory cues (e.g., movements to perform) given by the experimenters.

During the development phase, our subjects stressed the importance of low system latency, requesting that the delay between their muscle contraction or limb movement and the reaction of the robotic hand or the electrical stimulation be as short as possible. For instance, the RMS was calculated at the end of a 1s-window around each movement. Since the movement was in the center of this time window, the system's response delay was approximately 0.5s. One of the subjects reported that this delay still felt too long.

The questionnaire results showed that several subjects reported scores below 4 in *attention effort* to control the device: these subjects needed to remain deeply concentrated on the task. We believe this was mostly due to the fact that they did not have any prior training. Remotely controlling a robot can be a highly unusual experience, and even more so when attempting to move a paralyzed hand. These subjects would have most likely been able to complete the task more confidently and with more ease after a couple of days of training (as did several other subjects with just minutes of practice). Similarly, we assume the overall performance would also increase with further training.

Our proposed finite-state machine control process implies that users can activate predefined prosthesis actions such as closed hand, or open hand. Therefore, it does not allow any force control, or any other continuous control. This approach could also be adapted to

allow proportional control, as proposed in [118]. We can even imagine an algorithm that can enter in a "fine control mode", which could link the shoulder angle to the grasping force, for example, if the user had such skill.

One future possibility is to implant these systems, since we only used accelerometer and gyroscope, small low energy sensors. The Freehand device, commercialized until 2001 [97], used contralateral shoulder movement to control a hand FES neuroprosthesis for grasping by users with tetraplegia.

All these possibilities allow researchers to customize solutions to users depending on their individual capabilities and limitations.

This is a more complex application than the transfer, discussed in section 6.1. In this experiment, users used a non intuitive movement to trigger the assistive device. Also, the FES activation for a grasping movement is a complex one, involving multiple muscles and controls. This work did not focus on that control, but on its activation. It has shown that both natural and non natural movement can be used to control assistive devices. Different situations may be better assessed by different strategies. Most likely, a real life application would require a combination of the two.

The fact that persons with tetraplegia were able to successfully operate the system is a strong indicator that persons with other disabilities would do the same. Users with hemiplegia certainly could pilot the interface with their able side, and patients with multiple sclerosis might be able to do it depending on the stage of their disability.

6.3 Rowing

The device is a flexible FES-rowing machine that will be used as a test platform for this work. The stimulation parameters can be customized and the user can develop a system operation strategy to achieve the best results. We have previously found that users may enjoy such manual control better than a more automated strategy [16]. Figure 5.10 is a comparison between the adapted rowing machine and an untouched original one. Note the seat for trunk stabilization, the custom device for legs stabilization, and the safety straps.

During the Learning Phase (4.1.1) the assistive device must be activated without the automated, final system. One option is to allow a manual activation by the users themselves. This, however, must be done in a way that they can perform the same movements they would if the final system were working. This is why we mounted the activating user interface on the handle bar, allowing minimum physical effort to use it.

Although the interface module is attached to the handle bar, the user has to move the thumbs from their regular position, below the bar, to push the buttons. That might be undesirable during the Learning Phase because it can slightly change the user normal position. In order to overcome this, we are planning to build a custom handle bar which will embed the interface module as a single unit. That way the buttons can be much closer to the thumbs natural position. The battery and data access will be made through the handle's

extremities, facilitating maintenance. In addition, it will be mechanically more robust.

We have assumed that the user's legs have similar muscular strength and endurance between the two, and that the electrodes are positioned the same way contra-laterally. In fact, that is not always true. Therefore, the same FES parameters should not be applied to both legs. But even if each muscle is individually assessed, the fixed configuration of the feet and the identical movement of legs makes it difficult to observe eventual differences between their performances. That problem has also been identified on FES cycling systems [24]. As proposed by [108], individual force sensors such as the one developed by [92] could help the system adapt the FES parameters automatically during runtime.

The adjustable straps that limit the seat range of motion are not elastic, which can cause an abrupt stop at the end of extension, and even a backlash caused by a rebound motion. Therefore elastic straps would be more suitable for this situation, reducing the end of course speed while keeping the intended safety. Another possibility is the proportional break proposed by [29], which damps the terminal stop, and also releases the energy on the next, opposite movement requiring less overall stimulation.

Even though a second person is required to aid on electrode placement and seat belt adjustments, the transfer from the wheelchair to the rowing machine seat can be performed by the user alone, which is not always true on FES cycling devices.

The applied stimulation is directly controlled by the buttons on the interface module, which are regular push buttons, or by the open loop activation interface, which works by sending precofigured on/off signals to the stimulator. Therefore, there is no proportional control, and the stimulation only works in a on/off strategy, which delivers enough activation to sustain the rowing motion, but certainly results in excess torque during parts of the movement. As a possible solution, a low level high frequency controller must be applied by the control module, ultimately aiming on lower muscle fatigue and smoother motion [26]. That low level control can follow a predetermined activation curve or follow a reference seat speed. Either way, it would work as the diagram in Fig. 4.2a illustrates. A similar approach was done in [28], with a finite state machine, as in this work, and a fuzzy logic control in a lower level. In that work, the authors found that the lower level control scheme enabled two paraplegic participants to row spending less muscle energy and to produce smoother rowing movements when compared to the finite state machine alone.

This rowing platform seems to be a good option for this work. It is safe and the lower limbs have only two movements: knee flexing and extending, which can be accomplished with only two channels per leg. These activation should be directly modulated by the upper limbs movements features such as speed and amplitude. The FES activation during the Learning Phase is really intuitive and should require little effort from the user beyond the typical rowing movement.

The participant was able to successfully row using the interface developed in this work. Although he could not consistently change cadence, he could keep rowing for several minutes and could stop and resume whenever he wished.

Lower limb automatic control of FES-rowing has been shown to have important benefits, such as users reporting it to be more convenient, and easier to operate since it requires less concentration by not having to push buttons or following an open loop pattern [27]. The participant in this work reported similar benefits. Also, it makes it possible for persons with limited or no hand function to row in a controlled manner.

Differently from the Upper Limb Grasping method, in which there is a threshold based movement detection phase and only then the movement is calibrated, here all movements are constantly being classified between all possible ones. Therefore, although it was not the case in this work, users with involuntary movements could theoretically still operate this system, as long as it is trained considering their particular movement patterns.

One important key point was the participant's ability to row using a system that was trained by a different person. Particularly, it was trained by an experienced rower. Moreover, it indicates that this trained system may be used with other SCI rowers as well. This is useful because it can be difficult to train the system with as SCI rower, even using the manual or the open loop interfaces developed for this work. Also, it means faster preparation for a rowing session.

Besides being able to row with a system trained by someone else, he could also row with a system trained by himself. This makes possible the customization of each participant's rowing patter, which can be different from one another, allowing them to row in their own fashion if desired [29]. However, the use of a pre-trained system may be useful in cases in which one wishes to practice a particular rowing pattern.

In [29], SCI participants extended their upper limbs faster than their lower limbs. The authors suggested they seemed to to that expecting to accelerate the slow recovery phase (when the lower limbs flex), which did not happen with their control method. It, however caused a jerkier motion on the handle bar. In this work, on the other hand, any movement may be relevant for the FES control. A faster recovery on the upper limbs will result in a sooner response on the lower limbs.

Although the participant could control the onset of the stimulation from his upper limbs movements, the main reason for his lack of ability to change cadence was that the FES intensity remained unchanged. Therefore, even though he could gain some time during the upper limbs phases, the lower limbs extension and flexion phases were virtually constant. This could be addressed by varying the FES intensity, inside a preset range, according to the upper limbs movements. Depending either on the velocity in which the arms move, or the length of time the upper limbs movements are performed, the FES intensity could be adjusted ate every stroke.

One other challenge to complete control over cadence is the difficulty of the participant to independently flex their own legs with hamstrings stimulation. When he wanted to increase the cadence he had to ask the assistant to push him faster. This was an inconsistent method that made the cadence control evaluation even more challenging. This scenario seems to happen for two reasons. One, the rower posture bio-mechanic puts the legs' weight

in favor of stretching them, adding weight against the flexion motion. Two, torque elicited from hamstring stimulation seems to be much weaker than that of the quadriceps, with the same FES intensity. We have inclined the entire rowing machine to try to take advantage of gravity during the flexion phase, with little success [40]. Another possibility is to use elastic bands or strings pulling the seat and assisting the legs flexion movement.

The Multi LDA method seemed more robust since it is a binary more specialized classifier than the Single LDA. The confidence level tuning present in the Single LDA method was not necessary when using the Multi LDA because the finite state machine prevented a transition to the previous state once the new state is active. Still, one can set the confidence level if desired in case transitions triggering is too sensitive.

Even though the test in which the participant rowed using a system trained by an higid rower was successful for about two minutes, it stopped responding correctly after that. This certainly happened because of the evident angle bias seen in Fig. 5.20a. In order to avoid unforeseeable electromagnetic interference, I deactivate the IMU's magnetometer sensor. This removes the IMU onboard capability for correcting itself over time and preventing biases such as this. Therefore, I need to frequently calibrate the gyroscope to remove such bias. The best way to do this is by placing the sensors on a stable surface and acquire the signal offset. One other way is asking the user to hold still while I do that acquisition. This, however, is highly susceptible to small movements by the user, which can cause an even worse bias than before, and was probably what cause the bias seen in this experiment. In any case, such calibration could also be done with the magnetometer active, taking into consideration the magnetic field where the experiment or practice is to be performed.

Since the participant was able to row with a system trained by the higid rower, it was unexpected that he could not with a system trained with his own data from a different day (see Fig. 5.21). One reason that may have caused this is the seemingly low signal-to-noise ratio in the accelerometer data used for that training, which can be seen in the Fig. 5.12. However, most likely it was due to the difference in angle range between the training data and the signal output during the experiment. Figure 5.13 shows that the angle varied between about 10° and 110°. On the other hand, during the experiment (Fig. 5.21), elbow joint angles were measured between 10° and 80°.

The ability the participant had to stop and resume the rowing activity, both with the system trained by the higid participant as with his own data, as seen in Figs. 5.20a and 5.22a, gives him greater confidence than an open loop system, while avoiding the need to push buttons. This way he can concentrate solely on the rowing upper limb movements.

Finally, since I can save a system trained by someone and use it with someone else, it is possible to simulate different scenarios. For instance, I can use the kinematic data saved from the higid participant, from the session in which he trained the system, and simulate him rowing with the system trained by the SCI participant. The result can be seen in Fig. 6.1.

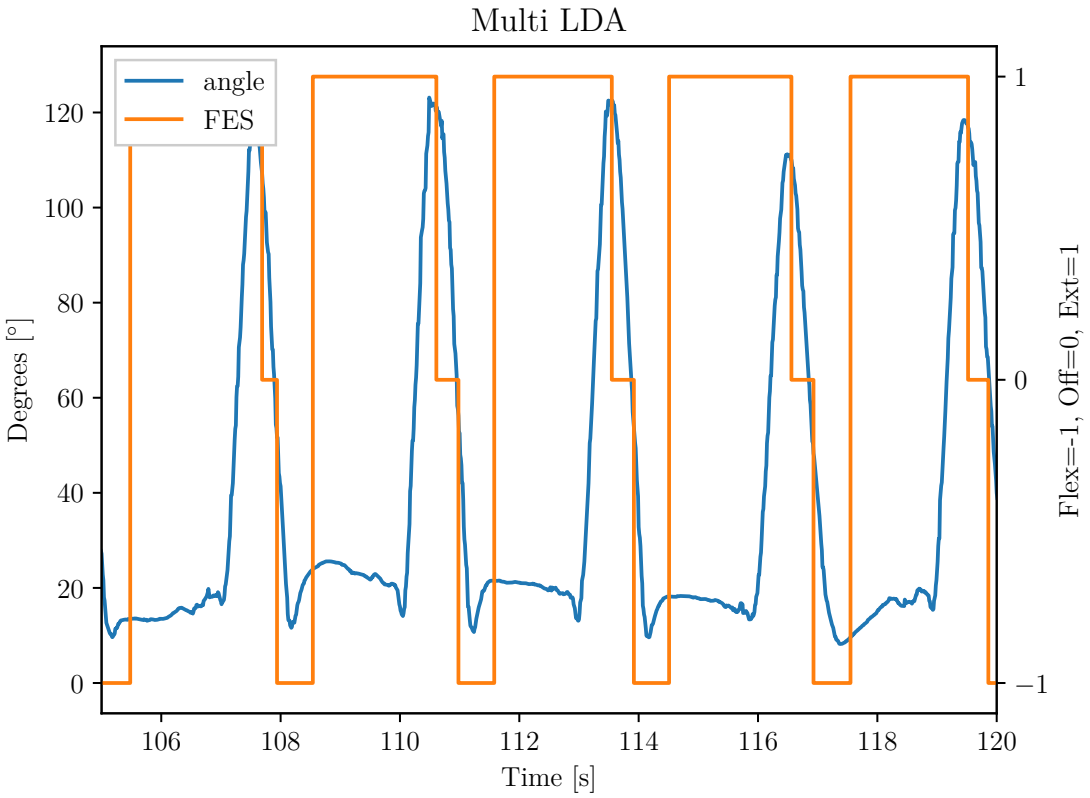


Figure 6.1: Simulation result with higid participant rowing with LDA trained with data from the SCI participant.

7 Conclusion

All three application scenarios explored in this work served as stepping stones to develop a framework of techniques upon which user interfaces can be built to enable persons with SCI to operate assistive devices.

In the transfer protocol, we learned that trunk angle can provide intra-user reliable kinematic information to activate lower limb FES to decrease upper limb load during SPTs. Moreover, users have precise control over the stimulation onset timing. In that scenario, one specific movement was detected with a threshold-based technique.

Next, I used a similar technique to detect shoulder movements on persons with tetraplegia in the upper limb grasping application. On top of that, instead of only detecting one movement, a second technique was developed to classify that movement. Therefore users could now not only choose when to activate the assistive device, but also command it in different ways.

Finally, in the rowing application scenario, the technique was upgraded to maximize class separation. Also, it was improved by a finite state machine that allowed the developed interface to have multiple and separated learning systems, each specialized in a specific state transition.

7.1 Final Remarks

Transfers are performed many times everyday by persons with paraplegia, and upper limb overload may lead to serious and debilitating situations. The developed FES-assisted SPT technique may prevent that, and the standard deviations of less than 5° in the trunk angle for FES activation is a promising result for a practical, functioning device.

Persons with tetraplegia have a great level of dependency on others. Recovering upper limb grasping abilities, even in a very basic fashion, can have a big impact on their lives. The 91% average accuracy outcome in the upper limb grasping experiment indicate an interface such as this could be used in a daily basis by persons with tetraplegia. These persons are suitable users of the technology developed in this work because their motor skills are very limited, but they often remain some residual movements capabilities. The high level of customization that the developed framework allows is paramount for this population, for each person's motor skill may be very specific, particularly in cases in which the SCI happened many years ago.

The interface developed for the rowing application is the most complete technique in this framework. Not only it became clear it can be used for FES-rowing, which is a good exercise for persons with SCI, but it is also flexible enough that it can probably be used in different scenarios. The ability to stop, resume and synchronize the FES onset with only able body parts might prove useful in other situations.

Each of the applications described in this work is relevant in different aspects for persons with SCI. In all cases users were able to operate the system with little to no training and the final goal was achieved.

Methods to control assistive devices must be developed with the specific requirements of persons with SCI and other disabilities. Still, this work's results indicate the developed system could be operated not only by persons with SCI, but also possibly by users with others disabilities such as those caused by stroke, multiple sclerosis, and other conditions. As long as there are well-controlled residual movements and the paralyzed target limbs responds to FES, the systems developed in this work might be used as neuroprostheses interfaces.

Regardless of the specific technique used, or in which application, devices that increase the independence of persons with motor disabilities may have a great impact on their quality of life, including improved physical and mental health, work capability and social integration.

7.2 Future work

Considering the practical use in the proposed scenarios, the developed interfaces can be improved to be more easily operated by the users themselves or an assistant. For instance, the FES systems can be embedded in clothes, as could the inertial sensor, making most of the system wearable. The control unit, which in this work was always a computer, could also be a smaller device, such as an embedded computer or microcontroller, although the computing performance should be tested in that case.

In all cases, implanted electrodes could be considered. Implanted FES use much lower stimulation intensities, is more selective and induce less fatigue, which are important characteristics for long term use in the proposed applications.

A key difference between the rowing application and the other two is that the former is done in a specific situation, while the other ones would be performed as ADLs. On these cases, the system may easily be accidentally activated in undesired moments. Therefore, for a real life use of these techniques, it would be important do implement ways to activate and deactivate the system, or to switch between mode. For example, one must be able to engage in "SPT mode"whenever, and only then, one desires.

7.3 Published contributions

During the development of this work, a number of papers were published. They are listed on Appendix I.

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A Transfer protocol - Ethics committee approval

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Eletroestimulação como recurso tecnológico para favorecer a transferência em pivô sentado em indivíduos com lesão medular

Pesquisador: Ana Claudia Garcia Lopes

Área Temática:

Versão: 1

CAAE: 54748116.9.0000.0022

Instituição Proponente: ASSOCIACAO DAS PIONEIRAS SOCIAIS

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.579.124

Apresentação do Projeto:

A transferência é uma habilidade chave para o ganho de mobilidade, independência e melhora da qualidade de vida dos indivíduos com lesão medular, já que permite maior interação com ambiente e participação social. A grande maioria dos indivíduos com lesão medular nível motor C6 (cervical 6) são dependente para as transferências. Paraplégicos apresentam grande risco de dor e lesão em membros superiores devido às sobrecargas articulares durante as atividades da vida diária. A eletroestimulação neuromuscular pode ser utilizada como um recurso tecnológico em potencial para auxiliar essas populações. Objetivos: o presente estudo tem como objetivo testar diferentes sistemas de controles que coordenem o recrutamento motor voluntário e artificial (via eletroestimulação) de grupos musculares envolvidos na transferência em pivô sentado, identificando o arranjo mais conveniente para eliminar sobrecargas articulares em membros superiores em pessoas com paraplegia e possibilitar a transferência em pessoas com tetraplegia; em seguida será desenvolvido o protótipo do sistema para avaliar as variáveis cinéticas e cinemáticas do mesmo usuário com e sem uso da tecnologia assistiva em Laboratório de Movimento. Material e Métodos: o tetraplégico terá nível motor C6 e os paraplégicos terão lesão torácica alta. Os participantes serão submetidos a entrevistas individuais e treinamento com eletroestimulação para estabelecimento da musculatura eletroestimulada durante a transferência

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em pivô sentado. Uma equipe de engenheiros desenvolverá o protótipo do sistema com supervisão da equipe clínica e, ao final, variáveis cinética, cinemática e tempo total de execução da transferência com e sem uso da tecnologia serão analisadas.

Hipótese: a EENM de tríceps braquial e/ou grande dorsal de indivíduo com lesão medular com nível motor C6, sem contração muscular ativa de tríceps braquial, possibilitará a transferência em pivô sentado da cadeira de rodas para superfície de mesma altura, com uso de tábua de transferência, apenas com supervisão. A EENM de membros inferiores de paraplégicos diminuirá a sobrecarga de membros superiores durante a transferência em pivô sentado.

Objetivo da Pesquisa:

Objetivo Primário:

O presente projeto propõe verificar as possibilidades e os limites da eletroestimulação neuromuscular ser utilizada como uma tecnologia assistiva que favoreça a execução da transferência em pivô a partir da postura em sedestação em indivíduos com lesão medular traumática. Como se trata de uma proposta de pesquisa associada ao desenvolvimento tecnológico, para alcançar o objetivo geral, os objetivos específicos foram definidos,

iniciando-se por aqueles relacionados ao desenvolvimento da tecnologia, seguidos pelos relacionados à produção de conhecimento em pesquisa na seguinte ordem: 1.Testar diferentes arranjos de automatismo de sistemas de controle que coordenem o recrutamento motor voluntário e artificial (via eletroestimulação) dos grupos musculares envolvidos na transferência em pivô sentado, identificando o arranjo mais conveniente para eliminar

sobrecargas articulares em membros superiores em pessoas com paraplegia e possibilitar a transferência em pessoas com tetraplegia. 2.Desenvolver um protótipo do sistema de controle que atenda aos requisitos de arranjos eletromecânicos previamente definidos em conformidade com as características funcionais apreendidas das percepções dos usuários e de seus cuidadores. 3.Comparar o comportamento das variáveis cinemáticas e cinéticas no mesmo usuário, com e sem o uso da tecnologia, durante a transferência estudada para as diferentes populações de pessoas com lesão medular (paraplegia e tetraplegia).

Avaliação dos Riscos e Benefícios:

Riscos:

Riscos e benefícios serão ponderados, tanto aqueles conhecidos como potenciais, individuais ou coletivos. Comprometemo-nos com o máximo de benefícios e o mínimo de danos e riscos. É

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garantido aos participantes que danos e desconfortos previsíveis serão evitados. Os possíveis riscos da pesquisa estão envolvidos com a segurança dos indivíduos durante a transferência e a EENM. Para evitar o risco de queda durante a transferência sempre haverá um profissional fisioterapeuta experiente e capacitado ao lado do indivíduo. Os riscos da eletroestimulação serão controlados pela adequada seleção dos participantes através dos critérios de inclusão e exclusão do estudo e pela experiência do pesquisador principal envolvido no atendimento do indivíduo com lesão medular. Vale ressaltar que devido à alteração de sensibilidade que esses indivíduos apresentam abaixo do nível da lesão, serão utilizadas frequências, largura de pulso e intensidade de corrente adequadas para que não acarrete nenhum tipo de lesão. Deve-se destacar que todas as condições serão ajustadas de forma a proporcionar o uso seguro e confortável das interfaces em estudo.

Benefícios:
Trata-se de um projeto interdisciplinar em reabilitação, em que a fisioterapia atua em sinergia com o desenvolvimento de tecnologias assistivas para proporcionar ou ampliar habilidades funcionais de pessoas com deficiência e consequentemente promover vida independente e inclusão. Os possíveis benefícios: a eletroestimulação funcional poderá ser utilizada como um recurso de tecnologia assistiva para a prevenção de sobrecarga em membros superiores em indivíduos paraplégicos e recurso funcional para favorecer a transferência com tábua em indivíduos tetraplégicos. Indivíduos que não realizam transferência da cama para cadeira de rodas, permanecem mais tempo imóveis, acamados e tem menor possibilidade de participação ocupacional, social e de qualidade de vida. Favorecer a transferência tem impacto significativo na vida sujeito e do seu cuidador. A possibilidade de participação do tetraplégico durante a transferência com a órtese e/ou a eletroestimulação podem ser alternativas de recursos de tecnologia utilizados em uma fase de treinamento durante a reabilitação, como um pré-treino antes de cirurgia de neurotização ou transposição muscular para ganho de extensão de cotovelo, ou mesmo recurso para uso a longo prazo. A sobrecarga em MMSS durante as transferências nos paraplégicos estão associadas a alta prevalência de dor ou lesão, que limita a participação social e reduz a qualidade de vida. Um novo recurso para diminuir essa sobrecarga tem impacto significativo em sua vida.

Comentários e Considerações sobre a Pesquisa:
Trabalho importante por favorecer as transferências dos pacientes com lesão medular incompleta e com isso melhorar a qualidade de vida dos pacientes e cuidadores.

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Considerações sobre os Termos de apresentação obrigatória:

A autora apresentou a folha de rosto assinada, as informações básicas do projeto, o projeto de pesquisa final e o termo de consentimento livre e esclarecido.

Recomendações:

1) Na pagina 7 do projeto final, no final do segundo parágrafo, retirar ou substituir o termo "assistência integral gratuita".

2) No termo de consentimento livre e esclarecido, no último parágrafo, retirar a última linha que diz "a sua participação é muito importante....".

3) No parágrafo anterior, o termo "Dou meu consentimento de livre e ....", ficou mal localizado. Considerar colocá-lo em um parágrafo separado.

Conclusões ou Pendências e Lista de Inadequações:

Recomendamos realizar as adequações relatadas no item recomendações.

Considerações Finais a critério do CEP:

Tendo em vista a legislação vigente (Resolução CNS 466/12), o CEP-APS recomenda aos Pesquisadores:

Comunicar toda e qualquer alteração do projeto e do termo de consentimento via emenda na Plataforma Brasil,

Informar imediatamente qualquer evento adverso ocorrido durante o desenvolvimento da pesquisa (via documental encaminhada em papel), apresentar na forma de notificação relatórios parciais do andamento do mesmo a cada 06 (seis) meses e ao término da pesquisa encaminhar a este Comitê um sumário dos resultados do projeto (relatório final).

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_684192.pdf	24/03/2016 17:18:52		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Termo_Consentimento_Livre_Esclarecido.docx	24/03/2016 17:16:43	Ana Claudia Garcia Lopes	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_pesquisa_para_ComiteCientificoeEticaSARAH_finalcomajusteComiteEtica.pdf	24/03/2016 17:13:48	Ana Claudia Garcia Lopes	Aceito

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Folha de Rosto	Documento_folhaderostoplataforma.pdf	24/03/2016 17:11:28	Ana Claudia Garcia Lopes	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BRASILIA, 07 de Junho de 2016

Assinado por:
Mauren Alexandra Sampaio
(Coordenador)

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B Transfer protocol - Consent agreement

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO - TCLE

Convidamos o(a) senhor(a) a participar do projeto de pesquisa "Eletroestimulação para favorecer a transferência em pivô sentado em indivíduos com lesão medular", sob a responsabilidade da pesquisadora Ana Claudia Garcia Lopes.

O objetivo desta pesquisa é avaliar se a eletroestimulação pode ser utilizada como um recurso em potencial para favorecer a transferência em pivô sentado. Em indivíduos tetraplégicos a eletroestimulação possivelmente será utiliza em membros superiores e/ou tronco com objetivo de possibilitar a transferência da cadeira de rodas para superfície de mesma altura. Em indivíduos paraplégicos será realizada eletroestimulação em membros inferiores e/ou tronco com objetivo de verificar a possível diminuição de sobrecarga em membros superiores durante a transferência da cadeira de rodas para superfície de mesma altura.

Será realizada avaliação inicial para verificar o tipo de transferência que realiza da cadeira de rodas para cama e avaliação da resposta a eletroestimulação na coxa no Hospital SARAH no Programa de Neurorreabilitação em Lesão Medular, no Setor Hospitalar Sul. Em Ceilândia será realizada a documentação da transferência em Laboratório de Análise de Movimento, no CEM 4 ao lado da estação de metrô Guariroba, no Laboratório de Movimento da UnB.

Os desconfortos relatados pela eletroestimulação são: fadiga muscular e discreta vermelhidão da pele no local onde o eletrodo foi posicionado, que desaparece geralmente de forma espontânea, em alguns minutos. Os riscos decorrentes de sua participação na pesquisa são quedas durante a transferência, que será minimizada pela presença de um profissional fisioterapeuta ao seu lado durante toda a execução.

O (a) senhor (a) receberá todos os esclarecimentos necessários antes e no decorrer da pesquisa e lhe asseguramos que seu nome não aparecerá, além do mais rigoroso sigilo pela omissão total de quaisquer informações que permitam identificá-lo (a). As informações obtidas nesse estudo serão confidenciais, sendo assegurado o sigilo sobre sua participação, quando da apresentação dos resultados em publicação científica ou educativa.

O (a) senhor (a) pode se recusar a participar de qualquer procedimento ou responder qualquer questão que lhe traga constrangimento, podendo desistir de participar da pesquisa em qualquer momento sem nenhum prejuízo para o(a) senhor(a). Sua participação é voluntária, isto é, não há pagamento por sua colaboração. Todas as despesas que você tiver relacionadas diretamente ao projeto de pesquisa (tais como, passagem de transporte público para o local da pesquisa e alimentação no local da pesquisa) serão cobertas pelo pesquisador responsável. Caso haja algum dano direto ou indireto decorrente de sua participação na pesquisa, você poderá ser indenizado, obedecendo-se as disposições legais vigentes no Brasil.

Os resultados da pesquisa serão divulgados na Universidade de Brasília podendo ser publicados posteriormente. Os dados e materiais serão utilizados somente para esta pesquisa e ficarão sob a guarda do pesquisador por um período de cinco anos, após isso serão destruídos.

Se o (a) senhor (a) tiver qualquer dúvida em relação à pesquisa, por favor, telefone com Ana Claudia Garcia Lopes ou Emerson Fachin na Universidade de Brasília, Campus Ceilândia no telefone (61) 8118-5886 ou fixo 3376-0252 no horário de 13:00 – 17:00 de segunda a sexta.

Este projeto foi Aprovado pelo Comitê de Ética em Pesquisa (CEP) da Rede SARAH de Hospitais de Reabilitação. O CEP é composto por profissionais de diferentes áreas cuja função é defender os interesses dos participantes da pesquisa em sua integridade e dignidade e contribuir no desenvolvimento da pesquisa dentro de padrões éticos. Qualquer dúvida com relação à assinatura do TCLE ou os direitos do participante da pesquisa podem ser esclarecidos pelo telefone (61) 3319-1515 ou do e-mail comiteeticapesquisa@sarah.br. O CEP/FS se localiza SMHS Quadra 301 Bloco B Número 45 - 3º andar - Asa Sul - Brasília/DF - 70.330-150.

Este documento foi elaborado em duas vias, uma ficará com o pesquisador responsável e a outra com o senhor (a). Dou meu consentimento de livre e espontânea vontade para participar deste estudo.
Sua participação é muito importante. Obrigada por sua colaboração.

Brasília, ___ de _____de _____.

_____ _____

Nome completo e assinatura do participante Ana Claudia Garcia Lopes - Pesquisador responsável

C Upper limb protocol - Ethics committee approval

COMITE DE PROTECTION DES PERSONNES
SUD MEDITERRANEE IV

Président : Pr. Jean-Marc DAVY

Montpellier, le 5 juillet 2016

Référence CPP : 16 05 03

N° ID-RCB : 2016-A00711-50

Le Comité de Protection des Personnes Sud Méditerranée IV a été saisi le 25 avril 2016 d'une demande d'avis sur le projet de recherche biomédicale intitulé :

Ancien titre : Contrôle ergonomique d'une neuroprothèse dédiée à la préhension chez le patient tétraplégique.

Nouveau titre : **Evaluation de la capacité à utiliser l'enregistrement de l'activité des muscles sus lésionnels et/ou des mouvements d'épaule chez des patients tétraplégiques en vue de piloter une neuroprothèse de préhension : étude de faisabilité.**

Autorisation ANSM/DEDIM : ND

Promoteur :	Investigateur-coordonnateur
Clinique Mutualiste Neurologique PROPARA 263 rue du Caducée – 34090 Montpellier	**Dr Anthony GELIS** Clinique Mutualiste Propara 263 rue du Caducée – 34090 Montpellier
Contact : Docteur Anthony GELIS (tél : 04 67 04 67 04 – courriel : a.gelis@propara.fr) – dossier suivi par : Mme Wafa Tigra – INRIA – 860 rue de St priest – 34095 Montpellier cedex 5 (tél : 04 67 14 96 04 – courriel : tigra@lirmm.fr)	

Le comité a examiné les informations relatives à ce projet lors de sa séance du 8 mars 2016 et a été amené à formuler une demande de modifications complémentaires.

Prennent part au vote les membres titulaires et les membres suppléants en cas d'absence du titulaire.
Ont participé à la séance du jeudi 16 juin 2016, Mesdames et Messieurs :

	Titulaires	Suppléants
Catégorie I	JM. DAVY, J. DE VOS	S. THEZENAS
Catégorie II	J. RIBSTEIN	
Catégorie III		
Catégorie IV		
Catégorie V		
Catégorie VI		D. BERTHON
Catégorie VII		
Catégorie VIII	V. RAGE ANDRIEU	
Catégorie IX		A. PILON

Documents du dossier	
Formulaire de demande d'avis : 20 avril 2016	Document additionnel : 20 avril 2016
Protocole : v.2 du 23 mai 2016	Résumé : v. 2 du 23 mai 2016
Note d'information : v.3 du 15 juin 2016	Consentement éclairé : v.3 du 15 juin 2016
Liste investigateur : v.1 du 2 mars 2016	Assurance InterMutuellesEntreprises n°340 1090 01995 M 38 daté du 6 juin 2016

Référence CPP : 16 05 03

N° ID-RCB : 2016-A00711-50

Suite du dossier	
Questionnaire d'évaluation du confort et de l'utilisabilité du dispositif	Brochure Investigateur v.1 du 2 mars 2016 Dispositif d'électrostimulation fonctionnel Vivaltis PODstim/Bio (marquage CE daté du 4 juillet 2012
Cahier d'observation : v.1 du 2 mars 2016	Document « réponses » reçu le 13 juin 2016 et celui reçu le 7 juillet 2016

Les renseignements fournis par le promoteur répondant de façon satisfaisante aux demandes d'informations et de modifications, le Comité donne un avis favorable à la réalisation de la recherche, avis rendu sur l'appréciation du respect des dispositions de l'article L 1121-2 et sur la validité de la recherche selon les dispositions de l'article L 1123-7

Le Président de Séance
Professeur Jean-Marc DAVY

Arrêtés spécifiques : Dès que le promoteur dispose de l'avis favorable du CPP et de l'autorisation de l'Autorité Compétente, il transmet à l'un et à l'autre la version définitive du protocole et de la brochure pour l'investigateur lorsque des modifications ont été apportées à la demande de l'un ou de l'autre.
Art. R. 1123-32. –(…) «La décision de l'autorité compétente est transmise pour information par le promoteur au comité de protection des personnes concerné.
Art. R. 1123-28. –Si, dans le délai d'un an suivant l'avis du comité de protection des personnes, la recherche biomédicale n'a pas débuté, cet avis devient caduc. Toutefois, sur justification produite avant l'expiration dudit délai, celui-ci peut être prorogé par le comité concerné.
Art. R. 1123-34. –Le promoteur informe sans délai l'autorité compétente et le comité de protection des personnes de la date effective de commencement de la recherche, correspondant à la date de la signature du consentement par la première personne qui se prête à la recherche en France.

Adresser la correspondance à : CPP SUD MEDITERRANEE IV- Hôpital St. Eloi, 34295 MONTPELLIER CEDEX 5
Téléphone : 04.67.33.78.07 — Fax : 04.67.63.52.54 - courriel:cppsudmed4@orange.fr
site : http://www.cpp-sudmed4.fr/

D Upper limb protocol - Consent agreement

CONSENTEMENT ECLAIRE

Je soussigné (e) :
Prénom et Nom :……
Adresse :……

Accepte par la présente de participer à la recherche biomédicale intitulée : *Evaluation de la capacité à utiliser l'enregistrement de l'activité des muscles sus lésionnels et/ou des mouvements d'épaule chez des patients tétraplégiques en vue de piloter une neuroprothèse de préhension : étude de faisabilité*, dont le promoteur est le Centre Mutualiste Neurologique Propara. Le Dr Gélis est l'investigateur-coordonnateur pour cette recherche.

J'ai lu ce jour la note d'information réservée au patient (Version N°4 du 28 juin 2016). J'ai bien pris connaissance de l'objectif et de la durée de l'étude, des bénéfices attendus, des contraintes et des risques prévisibles, des éventuelles alternatives médicales et des modalités de prise en charge médicale prévues en fin ou en cas d'arrêt ou d'exclusion de la recherche. Les conditions de sa réalisation m'ont été clairement expliquées par le Docteur Gelis.

J'ai bénéficié d'un temps de réflexion suffisant entre ces informations et le présent consentement.

J'ai bien compris que j'ai le droit de refuser de participer à cette recherche biomédicale et je connais la possibilité qui m'est réservée à tout moment d'interrompre ma participation sans en fournir la raison et sans que cela ne me porte préjudice, ni que cela porte atteinte aux soins qui continueront à m'être prodigués.

J'accepte qu'un enregistrement vidéo soit effectué à condition qu'aucune caractéristique permettant de me reconnaitre n'apparaisse.

Je certifie sur l'honneur être affilié à un régime de Sécurité Sociale ou bénéficiaire d'un tel régime.

J'ai bien noté que cette étude a reçu l'autorisation de l'Agence Nationale de Sécurité du Médicaments et des produits de Santé et l'avis favorable du Comité de Protection des Personnes Sud Méditerranée IV.

J'ai compris que les données de cette étude resteront strictement confidentielles. Je n'autorise leur consultation que par les personnes qui collaborent à la recherche, désignées par le promoteur.

En application de la loi « Informatique et Liberté » du 6 janvier 1978, modifiée par les lois n°94-548 du 1er juillet 1994, n° 2002-303 du 4 mars 2002 et n° 2004-801 du 6 aout 2004, j'accepte que les données enregistrées à l'occasion de cette étude puissent faire l'objet d'un traitement informatisé par le promoteur ou pour son compte. J'ai bien noté que le droit d'accès (article 39) et de rectification (article 40), que m'ouvrent les textes susvisés, pourra s'exercer à tout moment auprès du Dr. Anthony Gelis et que les données me concernant pourront m'être communiquées directement ou par l'intermédiaire d'un médecin de mon choix.

J'ai bien noté que j'ai le droit d'être informé des résultats globaux de cette recherche selon les modalités qui m'ont été précisées dans la note d'information. J'accepte que les données soient réutilisées à d'autres fins de recherche dans le cadre d'études ultérieures portant sur les neuroprothèses de stimulation des muscles de la main. J'ai été informé(e) de la possibilité de vérifier l'exactitude des données me concernant et leur destruction ultérieure.

J'ai lu et reçu un exemplaire de la note d'information et j'ai toutes les informations nécessaires à la prise de ma décision. J'ai lu et reçu un exemplaire de ce formulaire de consentement et j'accepte de participer à cette recherche biomédicale. En retour de ma participation, j'ai été avisé que je ne recevrai aucune indemnité.

Fait à ……, le……

Signature du patient Signature du médecin-investigateur

E Upper limb protocol - Questionnaire

QUESTIONNAIRE

Ce questionnaire inspiré de la norme ISO 9241-9 (Exigences ergonomiques pour travail de bureau avec terminaux à écrans de visualisation (TEV)-Partie 9: dispositifs d'entrée autres que les claviers) vise à évaluer le confort et l'utilisabilité du dispositif d'entrée. Ce questionnaire sera à remplir à la fin de chaque test (série de 5 tests correspondant à 5 modes de commandes différents).

1. Efforts physiques requis par l´utilisation du dispositif
(1 = Très importants, 7 = Très faibles)

1.....2.....3.....4.....5.....6.....7

2. Efforts attentionnels requis par l´utilisation du dispositif
(1 = Très importants, 7 = Très faibles)

1.....2.....3.....4.....5.....6.....7

3. Confort global (1 = Très inconfortable, 7 = Très confortable)

1.....2.....3.....4.....5.....6.....7

4. Fonctionnement global du dispositif
(1 = Utilisation très laborieuse, 7 = Utilisation très facile)

1.....2.....3.....4.....5.....6.....7

5. Fatigue du cou (1 = Très importante, 7 = Aucune)

1.....2.....3.....4.....5.....6.....7

6. Fatigue de l´épaule (1 = Très importante, 7 = Aucune)

1.....2.....3.....4.....5.....6.....7

7. Fatigue du bras (1 = Très importante, 7 = Aucune)

1.....2.....3.....4.....5.....6.....7

F Rowing protocol - Ethics committee approval

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Reabilitação de função sensório-motora em pessoas com lesão medular usando estimulação elétrica superficial

Pesquisador: Antonio Padilha Lanari Bo

Área Temática:

Versão: 2

CAAE: 11717119.3.0000.0030

Instituição Proponente: UnB - Faculdade de Tecnologia

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.365.667

Apresentação do Projeto:

Segundo os pesquisadores:

"Resumo:

Uma Lesao Medular (LM), seja completa ou incompleta, pode causar perda de sensibilidade e motricidade, bem como afetar outras funcoes fisiologicas, muitas vezes provocando uma drastica reducao na qualidade de vida. Em especial, a paraplegia completa e caracterizada pela perda de sensibilidade e controle de movimento dos membros inferiores. Para individuos nessa condicao, muito embora algumas funcoes possam ser restabelecidas, seja por meio de recuperacao espontanea ou alguns procedimentos clinicos especificos, na maioria dos casos nao ha restauracao das funcoes perdidas. A Estimulacao Eletrica Funcional, ou, do ingles, Functional Electrical Stimulation (FES), tem mostrado efeitos comprovadamente beneficos e seguros no processo de reabilitacao, pois possibilita exercicios fisicos em membros paralisados e possivelmente auxilia na inducao da plasticidade do sistema nervoso. Este trabalho propoe um sistema de reabilitacao baseado na sinergia entre FES e outras tecnologias, como ergometros e realidade virtual. Espera-se que, apos a intervencao, os participantes apresentem melhoras mensuraveis em termos da funcao sensorio-motora.

Introducao:

Pessoas com lesao medular (LM) enfrentam muitas vezes limitacao para controle voluntario de musculos esqueleticos, perda de sensacao proveniente de membros afetados, bem como outras

complicacoes, Alem disso, infelizmente as perspectivas de recuperacao sao limitadas. Aqueles com lesoes completas e cronicas normalmente enfrentam a menor probabilidade de melhoria. Na maioria desses pacientes nao ha restauracao da funcao, embora varios tipos de terapias tenham sido propostos.Entre as abordagens apresentadas para melhorar a qualidade de vida de individuos com LM, a reparacao e regeneracao neural e uma das mais atraentes. No entanto, apesar de resultados positivos (muito embora modestos) terem sido obtidos ate agora usando esta abordagem, as estrategias baseadas em novos medicamentos, celulas-tronco, imunoterapia e terapia genetica potencialmente devem proporcionar melhores resultados quando aplicados de forma sinergica com outros tratamentos (revisados em [25, 22, 30]). Alem do tempo apropriado de intervencao terapeutica, nosso conhecimento atual apoia a ideia de que a combinacao de metodos complementares sera essencial para maximizar a recuperacao e o beneficio funcional. Neste projeto, nos concentramos em paradigmas inovadores voltados para a reabilitacao de LM com base em recursos tecnologicos nao-invasivos integrados com principios de plasticidade dependente de atividade.De fato, muito tem sido investido no desenvolvimento de tecnologias que permitem reduzir o efeitos de uma LM. Nas interfaces cerebro-maquina (ICM), por exemplo, a atividade neural do cortex motor e decodificada para permitir o controle em tempo real de dispositivos externos, como bracos roboticos [8, 36]. Alem da interacao com objetos e, portanto, da restauracao de alguma funcao, as ICMs tambem ajudaram a investigar o sistema nervoso. Por exemplo, experimentos em modelo animal demonstraram que a decodificacao do cortex pre-motor para gerar estimulacao para o cortex somatossensorial poderia promover a recuperacao apos lesao no cortex motor, aumentando a conectividade entre essas areas [17].Tais ICMs foram aplicadas nao so para fornecer interface com dispositivos externos, mas tambem para fornecer controle do movimento do corpo [5, 24]. Na verdade, diferentes tecnologias estao disponiveis para gerar movimento de membros. O movimento artificial pode ser conseguido usando, por exemplo, orteses externas embarcadas com atuadores. Entre as desvantagens desses exoesqueletos, dois aspectos importantes sao a sua estrutura incomoda e a necessidade de ajustar o dispositivo para as dimensoes especificas do individuo. Alternativamente, pode-se usar Estimulacao Eletrica Funcional (em ingles, FES), em que impulsos eletricos sao aplicados ao corpo para restaurar funcoes neuromusculares perdidas. Essa tecnologia esta disponivel em sistemas comerciais ha 20 anos para restaurar a caminhada em LM [16]. No entanto, os sistemas FES tambem apresentam limitacoes significativas, como o inicio acelerado da fadiga. Por essa razao, alguns pesquisadores tem investigado o uso combinado de exoesqueletos e sistemas para marcha auxiliados por FES [9] na tentativa de combinar as vantagens de ambas as tecnologias. Outra limitacao importante da FES

diz respeito a estabilidade e a seletividade muscular, que motivou investigacoes sobre sistemas de estimulacao implantada [18].Os sistemas FES baseados em eletrodos de superficie foram utilizados para atingir outro problema enfrentado por individuos com LM. Estudos descobriram que a pratica do exercicio dos membros superiores, como a ergometria de membro superior, e insuficiente para produzir saude cardiovascular sustentavel [23]. Diante deste contexto, a FES tem sido usada por mais de 30 anos em associacao com cicloergometros [33] e remo ergometros [26] como alternativa para o exercicio fisico para individuos com paraplegia.A restauracao da funcao motora dos membros inferiores usando estimulacao eletrica tambem pode ser obtida por meio da estimulacao dos circuitos neurais lombossacrais usando a estimulacao direta da medula (em ingles, SCS). De fato, estudos em modelos animais e humanos demonstraram a geracao de movimentos semelhantes a uma caminhada usando interfaces superficiais e invasivas (revisados em [34, 32]). No que diz respeito aos estudos em modelos animais, a estimulacao intraespinhal demonstrou induzir uma atividade motora controlada prolongada [27]. No entanto, o requisito para o posicionamento preciso dos eletrodos foi visto como uma desvantagem dessa tecnica. Em outra abordagem, o uso de agonistas de receptores de serotonina junto com SCS peridural permitiu a geracao de marcha em ratos [35]. Com base em um implante menos invasivo quando comparado a estimulacao intraespinhal, os autores deste trabalho tambem alcancaram controle de altura de passo, mas usando modulacao de frequencia. O esforco experimental deste grupo incluiu recentemente ensaios em primatas nao humanos, onde uma interface cerebro-medula foi usada para controlar a SCS [6].Ensaios humanos usando SCS relatando restauracao parcial da funcao motora tambem foram realizados. Sistemas SCS peridurais disponiveis no mercado (utilizados em geral para o tratamento da dor cronica) tem sido empregados em varias investigacoes que visam a reabilitacao de pessoas com LM. Em um desses estudos, os padroes de marcha de individuos com LM incompleta melhoraram durante a aplicacao de SCS tonica [7]. A amplitude de estimulacao foi estabelecida abaixo do limiar do motor, sugerindo que a SCS facilita a atividade locomotora que perdeu sua estimulacao corticospinal. Curiosamente, um resultado semelhante foi obtido em um estudo onde SCS transcutanea tonica foi aplicada a tres individuos com LM incompleta caminhando com suporte de peso corporal em uma esteira [21]. O mesmo paradigma de estimulacao foi avaliado em uma instalacao envolvendo um treinador robotico e quatro individuos com LM completa. Neste caso, os ensaios com SCS transcutanea tonica suprimiram o clonus e aumentaram a atividade muscular ritmica, mesmo sem feedback periferico especifico do passo [31].Os estudos acima mencionados alcancaram melhora na funcao locomotora durante a aplicacao da estimulacao eletrica. Apesar da aplicacao potencial de tais intervencoes, uma vez que a estimulacao era

desligada em tais intervencoes o efeito positivo sobre a capacidade motora foi drasticamente reduzido, muitas vezes ate o mesmo nivel antes dos estimulos. No entanto, outros estudos relataram recuperacao de funcao real apos lesoes neurologicas. Novamente usando SCS, com base em estimulacao epidural [19, 2] ou transcutanea [15] (neste caso tambem combinada com agonista serotoninergico), individuos com LM clinicamente classificados na escala de comprometimento da American Spinal Injury Association (ASIA) como A ou B foram submetidos a protocolos que duraram entre 5 e 22 meses e todos os individuos obtiveram recuperacao motora que persistiram quando a estimulacao foi removida. Em outro estudo usando estimulacao eletrica, mas com foco no ciclismo auxiliado por FES e terapia complementares, um unico caso de recuperacao de funcao de um individuo com tetraplegia foi relatado [29]. No entanto, nenhum outro estudo conseguiu replicar esses resultados.Finalmente, um relato recente de estudo realizado no Brasil descreveu recuperacao de funcao em individuos com LM completa [11]. O protocolo realizado envolve longa duracao (cerca de ano) e exercicios baseados em ICM, feedback proprioceptivo no membro superior, treinamento de marcha robotizada e realidade virtual. Nesse estudo, todos participantes obtiveram melhorias em exames clinicos realizados de acordo com protocolo ASIA. Entretanto, e essencial reconhecer que, embora a recuperacao tenha sido relatada, o nivel de melhoria foi limitado. Na verdade, os autores concluiram que e necessario um maior estudo para avaliar todo o potencial das estrategias aplicadas para a reabilitacao de pessoas com LM.Na sequencia desses relatorios, ocorreu extenso debate sobre a explicacao fisiologica para tal recuperacao. De fato, os mecanismos atraves dos quais a ativacao voluntaria dos musculos afetados e alcancada mesmo em lesoes completas sao desconhecidos. Uma alternativa e que pode haver surgimento neuronal espontaneo cujas conexoes sao otimizadas devido a estimulacao e a atividade locomotora. Outra explicacao, e possivelmente a mais popular na literatura, considera a existencia de caminhos neurais que nao sao perdidos na ocasiao da lesao, mas que permanecem em silencio desde entao. De fato, se de uma perspectiva funcional uma lesao completa e caracterizada pela falta de sensacao e movimento voluntario, um estudo recente foi capaz de detectar atividade eletromiografica voluntaria (EMG) em 66% dos individuos clinicamente diagnosticados com LM completa que participaram do estudo [20].Em resumo, essas descobertas sugerem que uma parte significativa do controle da locomocao ainda pode ocorrer no nivel da coluna vertebral apos a lesao, mas a excitabilidade sustentavel desses circuitos e comprometida. O desafio atual e encontrar os metodos mais adequados para aumentar essa excitabilidade e facilitar a plasticidade para promover a recuperacao e, possivelmente, permitir a traducao para a pratica clinica."

Objetivo da Pesquisa:

Segundo os pesquisadores:

"Objetivo Primario:

O objetivo primario deste trabalho e avaliar a recuperacao de funcoes sensorio-motoras em individuos com lesao medular apos protocolo de reabilitacao de longa duracao e em regime intensivo envolvendo ferramentas tecnologicas, em especial ciclismo e remo assistidos por estimulacao eletrica superficial, bem como exercicios isometricos e exercicios de verticalizacao e marcha simulada envolvendo realidade virtual.

Objetivo Secundario:

Sao estabelecidos dois objetivos secundarios:- Avaliar o nivel de restauracao de funcao em termos de ativacao muscular voluntaria, funcao sensorial e funcao do sistema nervoso autonomo.- Desenvolver interfaces e estrategias de controle para as diferentes tecnologias utilizadas no estudo, buscando sempre a maior participacao do individuo."

Avaliação dos Riscos e Benefícios:

Segundo os pesquisadores:

"O protocolo experimental é composto por atividades projetadas para pessoas com LM que, quando executadas de forma segura, produzem benefícios de natureza cardiorespiratória e metabólica ao participante.

Os principais riscos decorrentes da participação na pesquisa são fraturas durante a atividade ou transferências da cadeira de rodas para os equipamentos. Tal risco é minimizado pela avaliação da densidade óssea realizada previamente à participação no protocolo, bem como pela utilização de medidas adicionais de segurança, como fixação dos pés e pernas no cicloergômetros de forma segura, e botões de parada de emergência sempre ao alcance dos sujeitos e profissionais.

A equipe de pesquisa é composta por pesquisadores com experiência em pesquisa com estimulação elétrica em humanos. Antônio Padilha L. Bo, Miguel Paredes, Juliana Guimarães e Lucas Fonseca têm, cada um, mais de 4 anos de experiência. A responsável clínica, Juliana Guimarães, acumula experiência clínica e acadêmica no assunto.

Caso tais medidas se mostrem insuficientes e o participante sofra entorse nas condições descritas no projeto, será realizada imobilização e recursos não-farmacológicos serão empregados para reduzir edema e dor. Em seguida, o participante será levado para o hospital mais próximo e receberá atendimento apropriado. Esse atendimento será gratuito para o participante.

Existe o risco de descompensação relacionada ao esforço, como elevação de pressão arterial de

forma súbita e outros problemas cardíacos. Este risco será minimizado pela avaliação de um cardiologista antes do início do protocolo e pelo regular controle da frequência cardíaca e pressão arterial durante as atividades. Caso ocorram intercorrências cardíacas ou qualquer outra complicação do quadro de saúde durante os treinos, o participante será imediatamente conduzido para o hospital mais próximo e receberá atendimento apropriado. Esse atendimento será gratuito para o participante..

Em relação à estimulação elétrica em si, o risco é mínimo para o paciente, pois é uma técnica consolidada de fisioterapia. Os riscos de lesões por queimadura por parte da estimulação elétrica são minimizados com duas estratégias adicionais:

Controle intrínseco do estimulador. Antes de cada pulso de estimulação, um sinal de teste é usado para verificar as características elétricas do tecido, certificando-se que o pulso não causará lesão.

Controle adicional por software. O algoritmo responsável por acionar os pulsos elétricos conterá uma camada de segurança, com máxima prioridade, que impedirá que um pulso com características nocivas seja gerado.

Os benefícios envolvidos dizem respeito aos resultados científicos e também à qualidade de vida e saúde dos participantes. No primeiro caso, esta pesquisa pode gerar conhecimento importante para a melhoria das terapias de reabilitação de LM, o que poderia impactar positivamente milhões de pessoas todos os anos. No segundo caso, a literatura indica que os participantes devem obter melhorias relativas às funções cardiorespiratória e metabólica. Além disso, podem ser observados também outros benefícios em termos de capacidade motora e funções autonômicas, o que resultaria em ganhos diretos para a saúde e qualidade de vida.

Por fim, a participação dos pacientes no estudo poderá ser cancelada imediatamente mediante solicitação. Além disso, todo o material coletado que permita identificar os participantes tera um tratamento de forma a garantir o anonimato no caso de qualquer publicacao."

Comentários e Considerações sobre a Pesquisa:

Trata-se de um projeto de pesquisa coordenado pelo Prof. Dr. Antonio Padilha Lanari Bó envolvendo outros pesquisadores engenheiros e fisioterapeutas. O projeto contará com 14 participantes com lesão medular, e estes serão acompanhados por uma fisioterapeuta e irão participar de um protocolo experimental que visa a recuperação sensório-motora dos pacientes. O desenho experimental é quasi-experimental, e todos participantes serão submetidos aos mesmos procedimentos.

Todos pesquisadores envolvidos no projeto tem experiencia compativel e adequada a execucao da pesquisa. O estudo apresenta beneficios diretos aos participantes. O TCLE apresenta os potenciais riscos do projeto, assim como os potenciais beneficios, em linguagem adequada.

O recrutamento esta previsto para iniciar em 01/06/2019, e a ultima etapa com os participantes esta prevista para 31/05/2021.

O orcamento do projeto, de financiamento proprio, preve o gasto de R$ 7.660,00 para transporte dos participantes e aquisicao de eletrodos descartaveis de estimulacao eletrica.

"7.1 Criterios de inclusao
Os criterios de inclusao para participacao no estudo sao relacionados a seguir:
Pessoas com lesao medular completa ha mais de 12 meses e comprometimento motor tipo paraplegia com nivel neurologico de lesao entre T1 e T12;
Pessoas cuja LM e classificada como ASIA A, B ou C.
Pessoas cuja recuperacao neurologica esteja estagnada, ou seja, que nao esteja mais apresentando melhora decorrente de tratamento tradicional prescrito.
Pessoas com idade minima de 18 anos e maxima de 60 anos;
Pessoas com quadro de saude estavel e sem outras comorbidades musculo-esqueleticas;
Pessoas sem deficit cognitivo que possa prejudicar o entendimento da tarefa e a concentracao durante a realizacao das atividades.
7.2 Criterios de exclusao
Os criterios de exclusao para participacao no estudo sao relacionados a seguir:
Nao apresentar contracao muscular de grau 2 (de acordo com escala de avaliacao de forca muscular do Medical Research Council) em resposta a estimulacao eletrica funcional;
Pessoas que apresentem peso corporal maior de 100 Kg;
Mulheres gravidas;
Pessoas que apresentem osteoporose detectada por meio de exame de densitometria ossea; Pessoas que apresentem historico de fratura por fragilidade;
Pessoas com alto risco de evento cardiovascular;
Usuarios de marcapasso ou outros dispositivos ativos implantaveis;
Pessoas que apresentem epilepsia;

Pessoas que apresentem disrreflexia autonomica nao controlada; Pessoas que apresentem reacoes cutaneas exacerbadas devido a corrente eletrica; Pessoas que possuam fobia a eletricidade;
Pessoas que apresentem desconforto com a estimulacao eletrica;
Pessoas que apresentem severa espasticidade e contraturas;
Pessoas que apresentem bloqueios articulares em membro inferior ou superior;
Pessoas com outras condicoes de saude adversas que possam influenciar a mobilidade do membro inferior ou superior."

"A equipe de pesquisa e formada pelos seguintes pesquisadores:
Antonio Padilha Lanari Bo, engenheiro de controle e automacao e professor adjunto do Departamento de Engenharia Eletrica (ENE) da Faculdade de Tecnologia (FT) da Universidade de Brasilia (UnB);
Funcao: Pesquisador responsavel e coordenador da equipe. Apoio tecnico em tecnicas de controle e analise dos dados.
Juliana Araujo Guimaraes, fisioterapeuta e mestre em Ciencias e Tecnologias da Saude pela UnB;
Funcao: Protocolo clinico, seguranca dos participantes, e acompanhamento das variaveis clinicas durante a pesquisa.
Roberto de Souza Baptista, engenheiro de controle e automacao e doutor em engenharia de sistemas eletronicos e de automacao. Membro do Laboratorio de Automacao e Robotica, vinculado ao ENE/FT/UnB;
Funcao: Responsavel tecnico dos assuntos relacionados a algoritmos de identificacao e estimacao necessarios para o correto controle dos equipamentos durante os experimentos.
Ana Carolina Cardoso de Sousa, engenheira de controle e automacao e doutoranda do Programa de Pos-Graduacao em Engenharia de Sistemas Eletronicos e de Automacao (PGEA), vinculado ao ENE/FT/UnB;
Funcao: Responsavel tecnico dos assuntos relacionados ao funcionamento dos sensores utilizados no protocolo experimental, sobretudo na aquisicao e processamento de dados e tecnicas de controle dos atuadores.
Lucas Oliveira da Fonseca, engenheiro de controle e automacao e doutorando do Programa de Pos-Graduacao em Engenharia de Sistemas Eletronicos e de Automacao (PGEA), vinculado ao ENE/FT/UnB;
Funcao: Responsavel tecnico dos assuntos relacionados a sinergia de todos os sistemas, sincronismo dos sensores, atuadores e controladores usados nos experimentos, processamento

dos dados adquiridos, e tecnicas de controle dos atuadores.
Miguel Eduardo Gutierrez Paredes, engenheiro biomedico e doutorando do Programa de Pos-Graduacao em Engenharia de Sistemas Eletronicos e de Automacao (PGEA), vinculado ao ENE/FT/UnB.
Funcao: Responsavel tecnico pelos assuntos relacionados aos equipamentos mecanicos usados nos experimentos, bem como o estimulador eletrico, placas eletronicas e microcontroladores.

9.3 Amostra
Está prevista uma amostra de 14 individuos para participacao no estudo. Todos participantes seguirao o mesmo protocolo experimental. A amostra foi calculada a partir da avaliacao da diferenca entre as medias, levando-se em consideracao um poder estatistico de, pelo menos, 95% e um tamanho de efeito de 1,41, baseado na variavel de desfecho secundaria (nivel de contracao voluntaria em musculos afetados) considerando um nivel de significancia de 0,05. A amostra foi ajustada para compensar perda de sujeitos durante a pesquisa (10%). Para a determinacao do tamanho da amostra foi utilizado o software G*Power.

9.4 Protocolo experimental
Apos selecao e avaliacao do participante frente aos criterios de inclusao e exclusao, sera iniciado o protocolo experimental de reabilitacao, que pode ser subdivido nas seguintes etapas:
A0: avaliacao inicial;
TC1: terapia de controle;
A1: primeira avaliacao intermediaria; TP1: terapia principal;
A2: segunda avaliacao intermediaria; TP2: terapia principal;
A3: terceira avaliacao intermediaria; TC3: terapia de controle;
A4: avaliacao final."

Considerações sobre os Termos de apresentação obrigatória:
Documentos analisados para emissão deste parecer:
1. Informações Básicas do Projeto ATUALIZADO - "PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1282302.pdf", postado em 17/05/2019.
2. Carta resposta às pendências apontadas no Parecer Consubstanciado No. 3.317.013 - "Carta_resposta_parecer.doc e Carta_resposta_parecer.pdf", postadas em 14/05/2019.
3. Cronograma de execução do projeto de pesquisa ATUALIZADO - "Cronograma.doc", postado em 14/05/2019.

4. Projeto Detalhado ATUALIZADO - "ProjetoPesquisa.docx", postado em 14/05/2019.

Recomendações:

Não se aplicam.

Conclusões ou Pendências e Lista de Inadequações:

Análise das respostas às pendências apontadas no Parecer Consubstanciado No. 3.317.013:

1. No projeto da Plataforma, item "Riscos", e projeto detalhado, item "8 Riscos e Beneficios Envolvidos na Execucao da Pesquisa", le-se: "Em seguida, o participante sera acompanhado ao Hospital da Universidade de Brasilia. Se o participante sofrer fratura durante os procedimentos, o pesquisador mantera o individuo imovel e imediatamente acionara o SAMU (Servico de Atendimento Movel de Urgencias) pelo numero 192. [...] Caso ocorram intercorrencias cardiacas ou qualquer outra complicacao do quadro de saude durante os treinos, o participante sera imediatamente conduzido ao Hospital da Universidade de Brasilia.". Nao e eticamente adequado consumir os recursos publicos do SUS para cobrir as despesas de estudos experimentais de projetos de pesquisa. Solicita-se que o pesquisador altere o texto retirando a informacao sobre o medico ligado ao SUS, garantindo ele mesmo juntamente com a instituicao proponente a assistencia integral e gratuita ao participante de pesquisa ou no caso de manter o encaminhamento para o HUB ou SAMU, este devera apresentar anuencia por meio de declaracao de gestor institucional autorizando a realizacao desses atendimentos.
RESPOSTA: O texto foi alterado conforme a recomendação, em especial na página 8 do documento ProjetoPesquisa.docx, ao fim dos parágrafos iniciados com “Caso tais medidas..” e “Existe o risco..”. Assim, não está previsto uso de recursos do SUS nos casos mencionados no projeto de pesquisa.
ANÁLISE: As mudanças efetuadas atendem à pendência apresentada. PENDÊNCIA ATENDIDA

2. Solicita-se o ajuste do Cronograma de Execucao do experimento para que este se inicie apenas apos a aprovacao pelo CEP/FS. Esta modificacao deve ser efetuada no documento "Cronograma.doc" e na Plataforma Brasil.
RESPOSTA: 2. As alterações no cronograma foram realizadas tanto na Plataforma Brasil como no documento Cronograma.doc. No documento Cronograma.doc, acrescentou-se informação de que as atividades iniciarão “apenas apos a aprovaçao pelo CEP/FS”. Visto que na Plataforma Brasil não é possível indicar o início das atividades “apos a aprovaçao pelo CEP/FS”, foi escolhida a data inicial de 01/06/2019 e alteradas todas datas subsequentes.

ANÁLISE: As mudanças efetuadas atendem à pendência apresentada. PENDÊNCIA ATENDIDA

Todas as pendências foram atendidas.

Não há óbices éticos para a realização do presente protocolo de pesquisa.

Considerações Finais a critério do CEP:

Conforme a Resolução CNS 466/2012, itens X.1.- 3.b. e XI.2.d, os pesquisadores responsáveis deverão apresentar relatórios parcial semestral e final do projeto de pesquisa, contados a partir da data de aprovação do protocolo de pesquisa.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1282302.pdf	17/05/2019 16:37:45		Aceito
Outros	Carta_resposta_parecer.doc	17/05/2019 16:37:22	Antonio Padilha Lanari Bo	Aceito
Outros	Carta_resposta_parecer.pdf	14/05/2019 19:32:51	Antonio Padilha Lanari Bo	Aceito
Cronograma	Cronograma.doc	14/05/2019 19:25:59	Antonio Padilha Lanari Bo	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoPesquisa.docx	14/05/2019 19:25:43	Antonio Padilha Lanari Bo	Aceito
Folha de Rosto	FolhaRosto.pdf	11/04/2019 15:38:20	Antonio Padilha Lanari Bo	Aceito
Outros	CartaEncaminhamento.docx	06/03/2019 14:27:21	Antonio Padilha Lanari Bo	Aceito
Outros	CartaEncaminhamento.pdf	06/03/2019 14:25:35	Antonio Padilha Lanari Bo	Aceito
Outros	Antonio_Bo.pdf	19/02/2019 16:20:43	Antonio Padilha Lanari Bo	Aceito
Outros	Roberto_Baptista.pdf	19/02/2019 16:20:19	Antonio Padilha Lanari Bo	Aceito
Outros	Miguel_Paredes.pdf	19/02/2019 16:19:46	Antonio Padilha Lanari Bo	Aceito
Outros	Lucas_Fonseca.pdf	19/02/2019 16:19:32	Antonio Padilha Lanari Bo	Aceito
Outros	Juliana_Guimaraes.pdf	19/02/2019 16:19:10	Antonio Padilha Lanari Bo	Aceito
Outros	Ana_Carolina_de_Sousa.pdf	19/02/2019 16:18:28	Antonio Padilha Lanari Bo	Aceito

Outros	lattes.pdf	21/01/2019 00:20:05	Antonio Padilha Lanari Bo	Aceito
Outros	TermoResponsabilidadeCompromisso.pdf	21/01/2019 00:03:04	Antonio Padilha Lanari Bo	Aceito
Outros	TermoResponsabilidadeCompromisso.doc	20/01/2019 23:59:27	Antonio Padilha Lanari Bo	Aceito
Outros	TermoAutorizacaoImagemSom.doc	20/01/2019 23:58:12	Antonio Padilha Lanari Bo	Aceito
Declaração de Instituição e Infraestrutura	TermoConcordancia_CapitalRemo.pdf	20/01/2019 23:56:31	Antonio Padilha Lanari Bo	Aceito
Declaração de Instituição e Infraestrutura	TermoConcordancia_CapitalRemo.doc	20/01/2019 23:56:17	Antonio Padilha Lanari Bo	Aceito
Declaração de Instituição e Infraestrutura	TermoConcordancia_FT.pdf	20/01/2019 23:55:12	Antonio Padilha Lanari Bo	Aceito
Declaração de Instituição e Infraestrutura	TermoConcordancia_FT.doc	20/01/2019 23:54:56	Antonio Padilha Lanari Bo	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.doc	20/01/2019 23:47:25	Antonio Padilha Lanari Bo	Aceito
Orçamento	Orcamento.doc	20/01/2019 23:47:14	Antonio Padilha Lanari Bo	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BRASILIA, 03 de Junho de 2019

Assinado por:
Marie Togashi
(Coordenador(a))

G Rowing protocol - Consent agreement

Termo de Consentimento Livre e Esclarecido - TCLE

Convidamos o(a) Senhor(a) a participar voluntariamente do projeto de pesquisa Reabilitação de função sensório-motora em pessoas com lesão medular usando estimulação elétrica superficial, sob a responsabilidade do pesquisador Antônio Padilha Lanari Bó. O projeto busca investigar novas técnicas de terapia para lesão medular utilizadas em conjunto, e usando tecnologias inovadoras. Será utilizado estimulação elétrica superficial nos membros afetados nas atividades de ciclismo e remo, além de exercícios em posição verticalizada em que você utilizará óculos de realidade virtual e tentará controlar um boneco virtual caminhando. Nenhuma dessas atividades deve gerar dor ou desconforto, entretanto algumas podem ser cansativas. Você será sempre acompanhado por um profissional responsável pela sua segurança na atividade, e é importante seguir rigorosamente as instruções dele(a).

O objetivo desta pesquisa é justamente avaliar a recuperação de funções sensório-motoras em indivíduos com lesão medular após protocolo de reabilitação de longa duração envolvendo ferramentas tecnológicas, em especial ciclismo e remo assistidos por estimulação elétrica superficial, bem como exercícios envolvendo realidade virtual.

O(a) senhor(a) receberá todos os esclarecimentos necessários antes e no decorrer da pesquisa e lhe asseguramos que seu nome não aparecerá em lugar algum, sendo mantido o mais rigoroso sigilo pela omissão total de quaisquer informações que permitam identificá-lo(a).

A sua participação se dará por meio de sessões de fisioterapia e exames clínicos não-invasivos realizados no Departamento de Engenharia Elétrica da Faculdade de Tecnologia da Universidade de Brasília, bem como no centro de treinamento Capital do Remo. O estudo terá duração de um ano, em que serão realizadas três sessões por semana (datas específicas a combinar). O tempo estimado para a realização de cada sessão é de uma hora.

Os riscos decorrentes de sua participação na pesquisa são fraturas durante a atividade ou transferências da cadeira de rodas para os equipamentos. Esse risco é minimizado pela avaliação de composição corporal realizada previamente à participação no protocolo, além da utilização de medidas adicionais de segurança, como fixação dos pés e pernas no cicloergômetros, e botões de parada de emergência sempre ao alcance. Existe também o risco de descompensação relacionada ao esforço, como elevação de pressão arterial de forma súbita e outros problemas cardíacos. Este risco será minimizado pela avaliação de um cardiologista antes do início do protocolo e pelo regular controle da frequência cardíaca e pressão arterial durante as atividades.

Se o(a) senhor(a) aceitar participar, estará contribuindo para a geração de conhecimento científico importante para a melhoria das terapias de reabilitação de lesão medular, o que poderia impactar positivamente milhões de pessoas todos os anos. Além disso, é possível que você tenha melhorias em sua capacidade motora e funções autonômicas, o que resultaria em ganhos diretos para sua saúde e qualidade de vida.

O(a) Senhor(a) pode se recusar a responder (ou participar de qualquer procedimento) qualquer questão que lhe traga constrangimento, podendo desistir de participar da pesquisa em qualquer momento sem nenhum prejuízo para o(a) senhor(a). Sua participação é voluntária, isto é, não há pagamento por sua colaboração.

Todas as despesas que o(a) senhor(a) e seu(ua) acompanhante tiver(em) relacionadas diretamente ao projeto de pesquisa (tais como passagem para o local da pesquisa, alimentação no local da pesquisa ou exames para realização da pesquisa) serão cobertas pelo pesquisador responsável.

Caso haja algum dano direto ou indireto decorrente de sua participação na pesquisa, o(a) senhor(a) deverá buscar ser indenizado, obedecendo-se as disposições legais vigentes no Brasil.

Os resultados da pesquisa serão divulgados na Universidade de Brasília, podendo ser publicados posteriormente. Os dados e materiais serão utilizados somente para esta pesquisa e ficarão sob a guarda do pesquisador por um período de cinco anos, após isso serão destruídos.

Se o(a) Senhor(a) tiver qualquer dúvida em relação à pesquisa, por favor telefone para: Prof. Antônio Padilha Lanari Bó no Departamento de Engenharia Elétrica da Faculdade de Tecnologia da Universidade de Brasília nos telefones 061 31071040 e 061 981698477, disponível inclusive para ligação a cobrar, bem como no email antonio.plb@lara.unb.br.

Este projeto foi aprovado pelo Comitê de Ética em Pesquisa da Faculdade de Ciências da Saúde (CEP/FS) da Universidade de Brasília. O CEP é composto por profissionais de diferentes áreas cuja função é defender os interesses dos participantes da pesquisa em sua integridade e dignidade e contribuir no

desenvolvimento da pesquisa dentro de padrões éticos. As dúvidas com relação à assinatura do TCLE ou os direitos do participante da pesquisa podem ser esclarecidos pelo telefone (61) 3107-1947 ou do e-mail cepfs@unb.br ou cepfsunb@gmail.com, horário de atendimento de 10:00hs às 12:00hs e de 13:30hs às 15:30hs, de segunda a sexta-feira. O CEP/FS se localiza na Faculdade de Ciências da Saúde, Campus Universitário Darcy Ribeiro, Universidade de Brasília, Asa Norte.

Caso concorde em participar, pedimos que assine este documento que foi elaborado em duas vias, uma ficará com o pesquisador responsável e a outra com o(a) Senhor(a).

_____
Nome e assinatura do Participante de Pesquisa

_____
Nome e assinatura do Pesquisador Responsável

Brasília, ___ de _____de _____.

H Rowing protocol - Additional results

H.1 Learning phase results for the higid participant

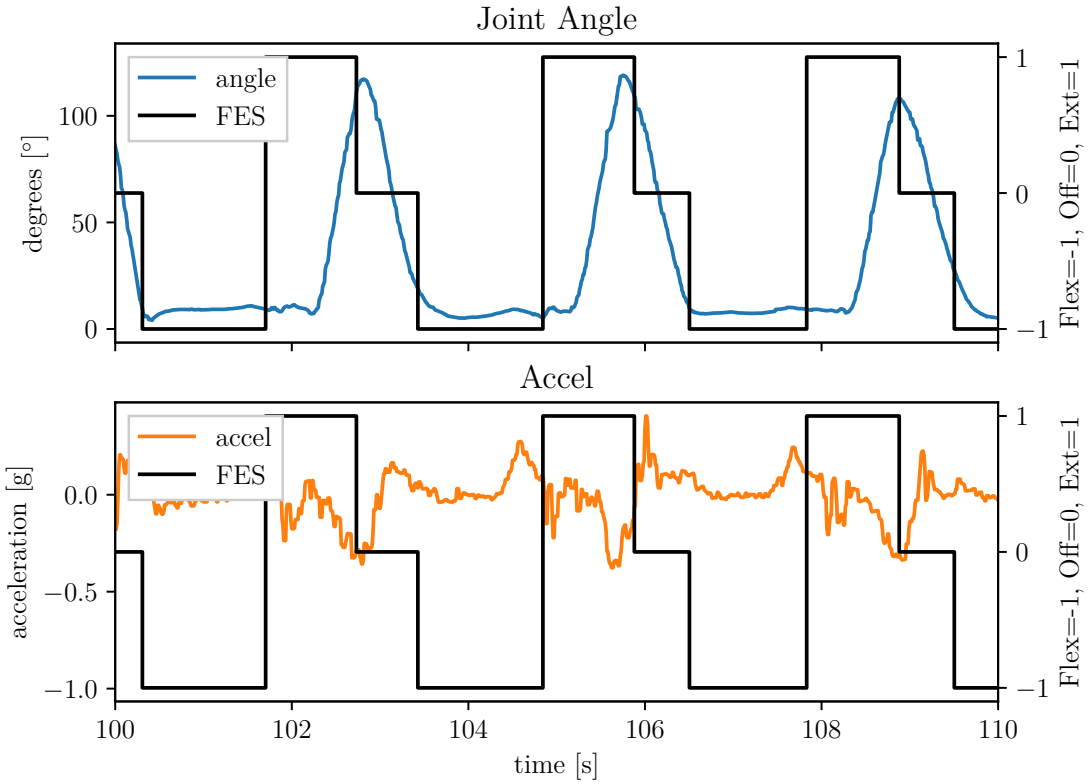

Figure H.1: Example snippet of data with joint angle and one axis of the accelerometer during 10 seconds of the learning phase with an higid participant.

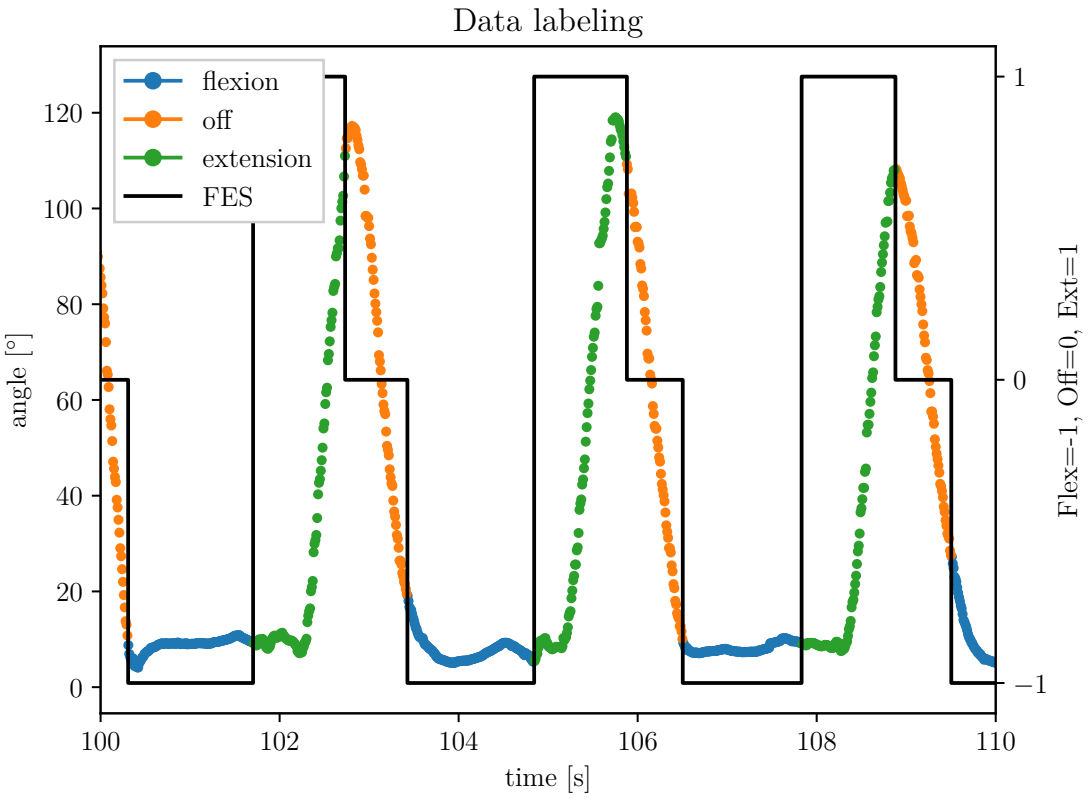

Figure H.2: Data labeling example snippet for the higid participant. Data is labeled according to the FES command.

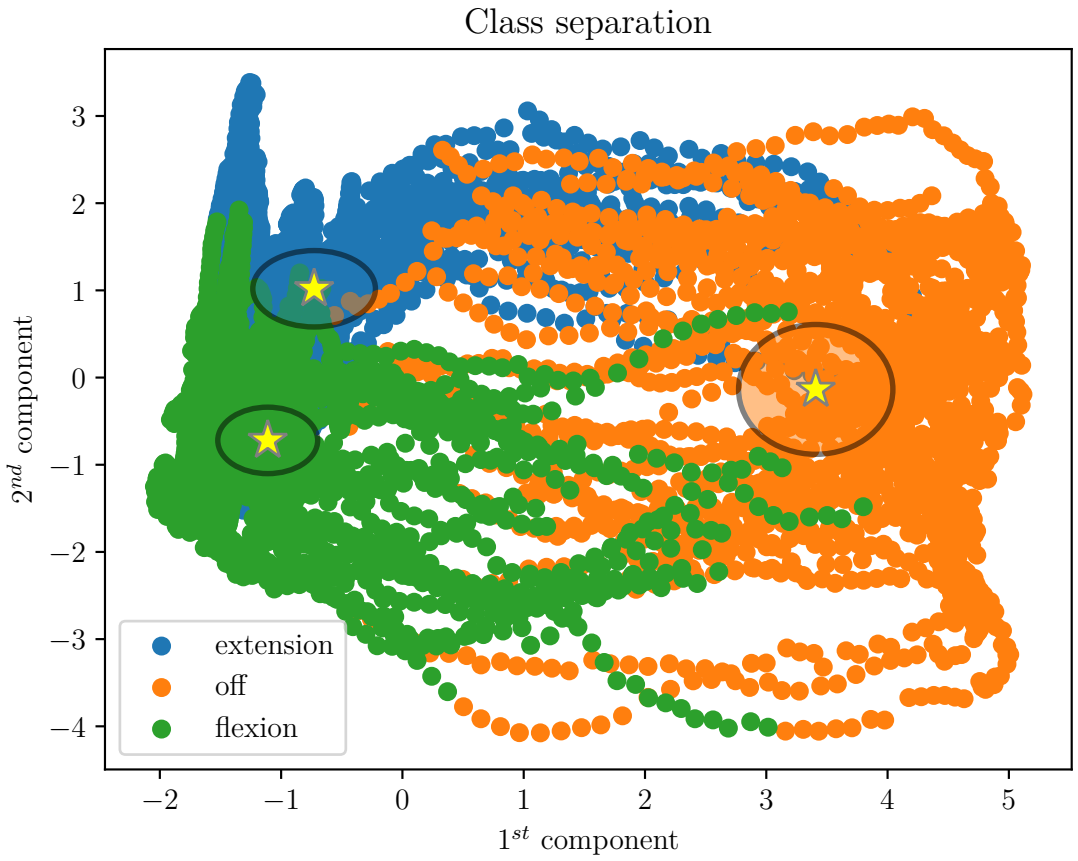

Figure H.3: Class separation visualization for the higid participant with a single LDA. Stars indicate the centroid of each class. The ellipses represent one standard variation in the two axis.

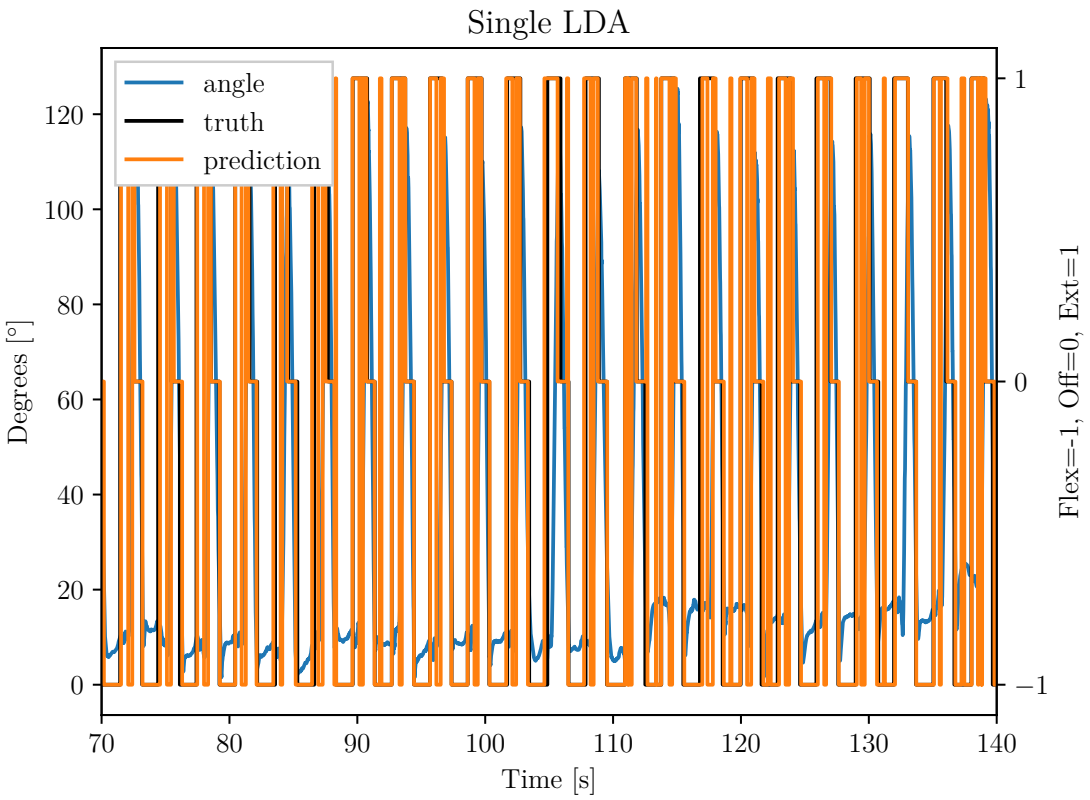

Figure H.4: Simulation of trained LDA with the same data used for training. Higid participant and a single LDA with the standard tolerance level of 0.5.

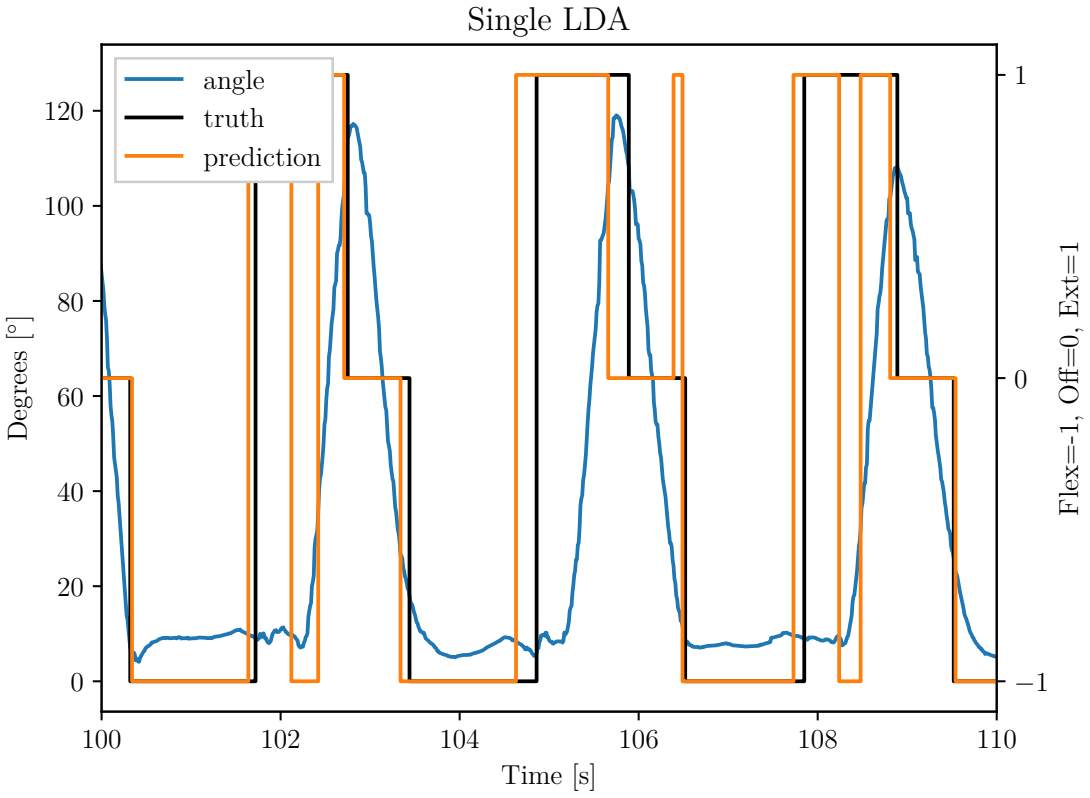

Figure H.5: Detail snippet of the simulation of a trained LDA with the same data used for training. Higid participant and a single LDA with the standard tolerance level of 0.5.

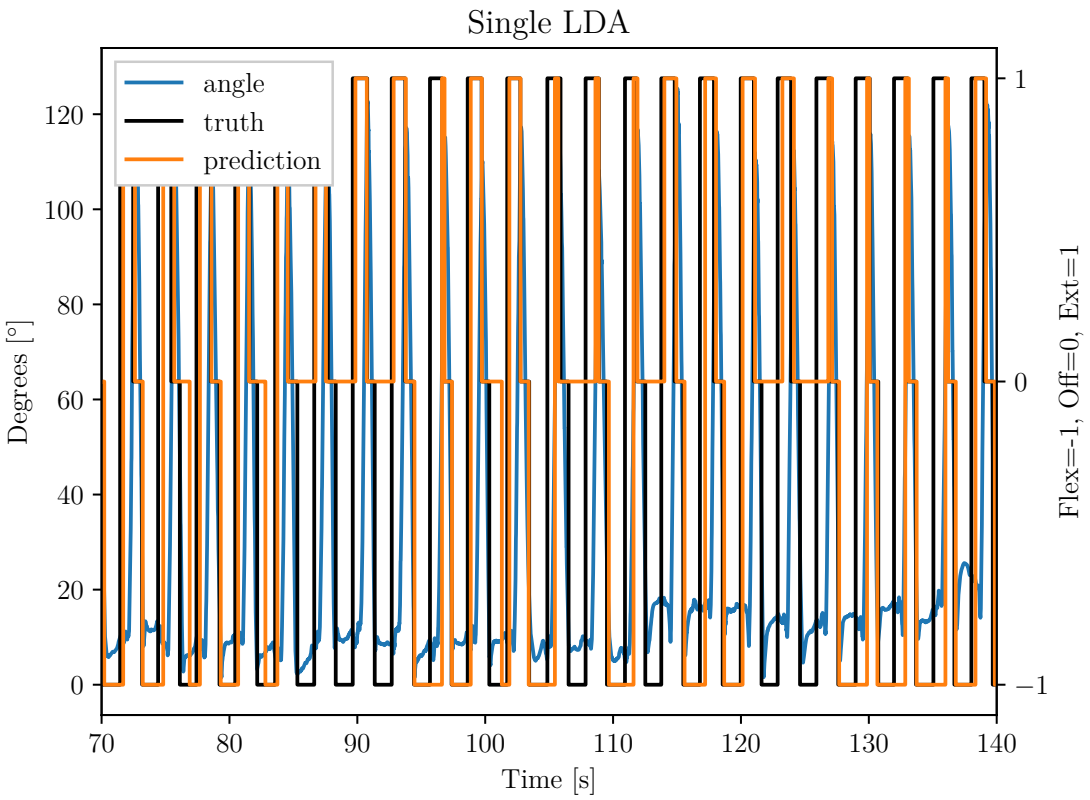

Figure H.6: Simulation of trained LDA with the same data used for training. Higid participant and a single LDA with the standard tolerance level of 0.85.

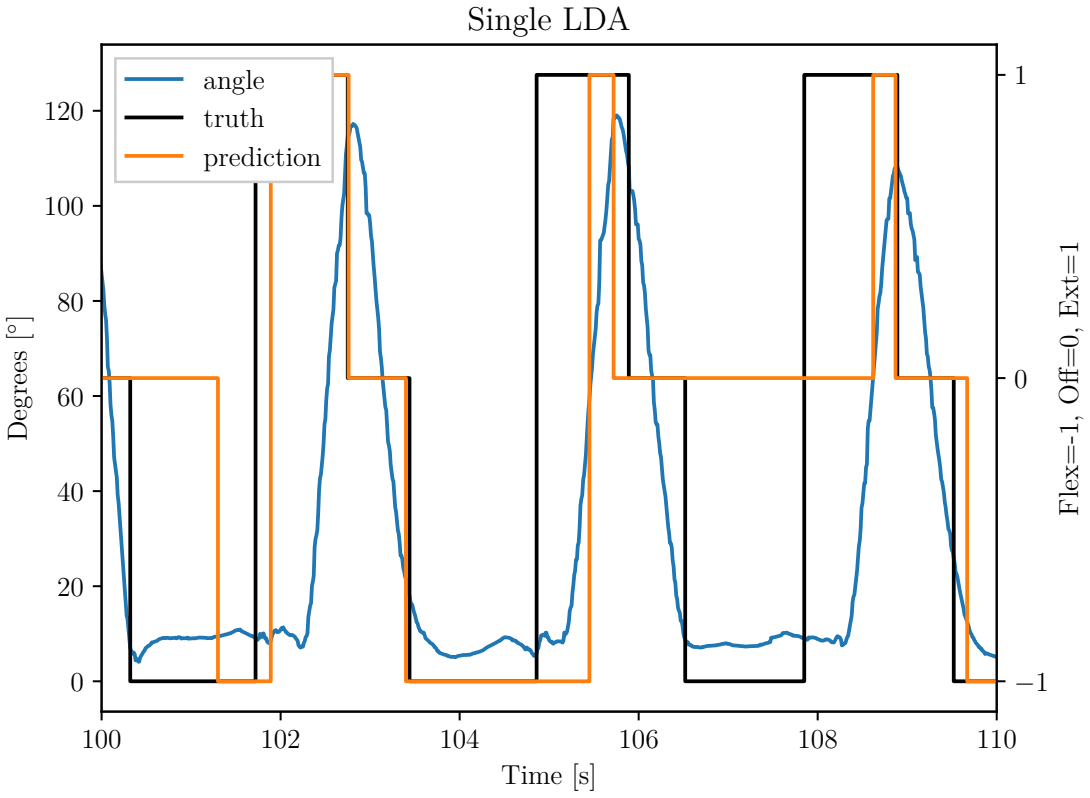

Figure H.7: Detail snippet of the simulation of a trained LDA with the same data used for training. Higid participant and a single LDA with the standard tolerance level of 0.85.

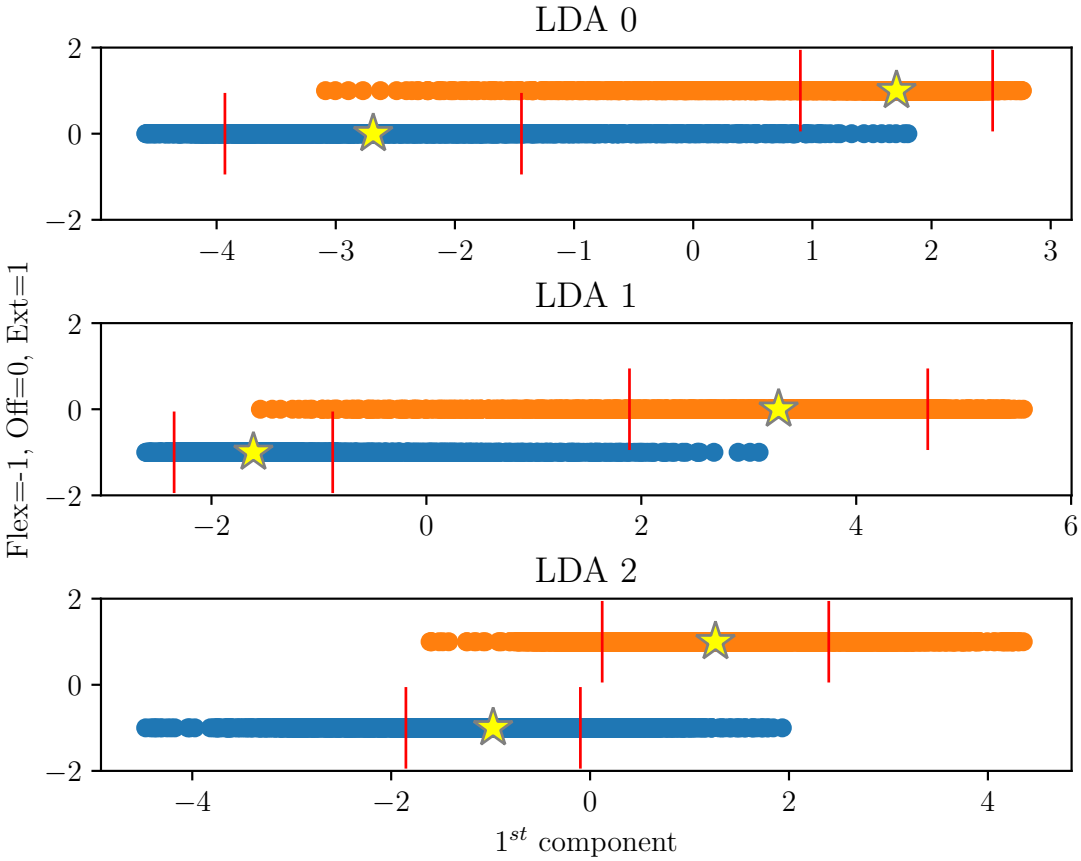

Figure H.8: Class separation visualization for the higid participant with three LDAs. Stars indicate the centroid of each class. Red bars represent one standard variation for each side.

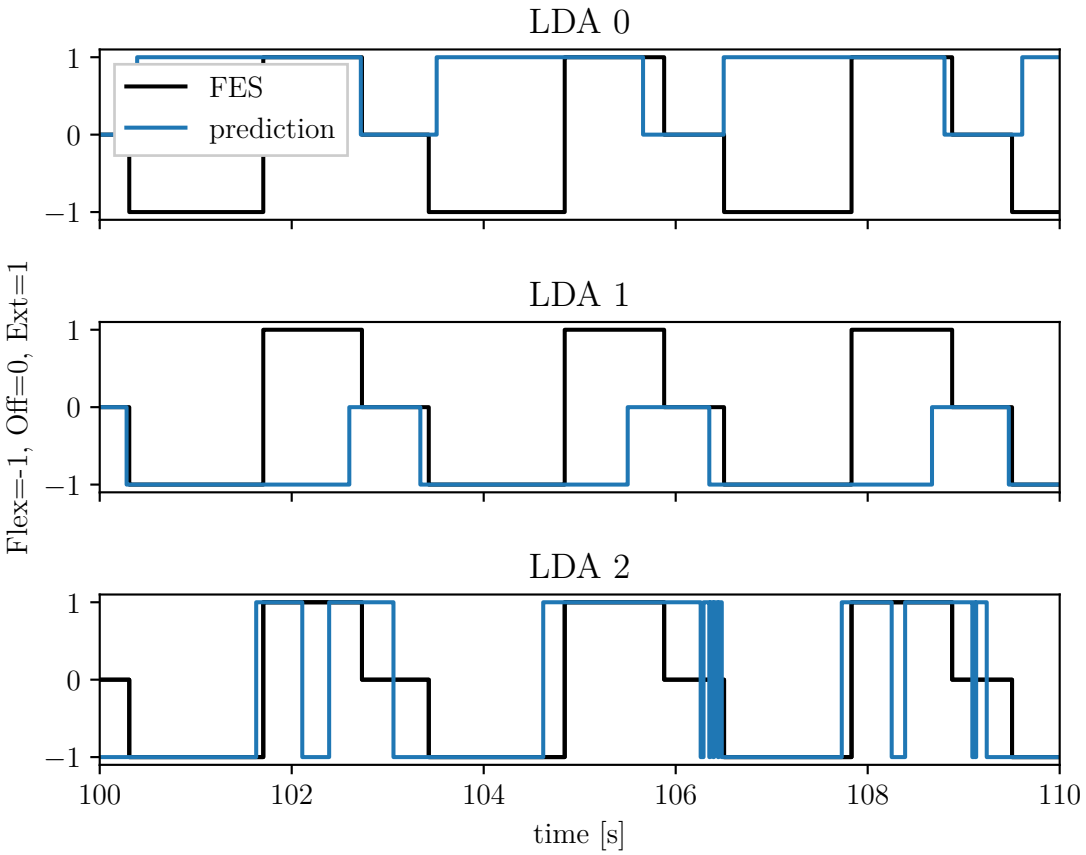

Figure H.9: Detail snippet of individual LDA classification of the same data used for training. On this case, LDA 0 was trained to classify *Extension* and *Off* classes, LDA 1 was trained to classify *Off* and *Flexion* classes, and LDA 2 was trained to classify *Flexion* and *Extension* classes.

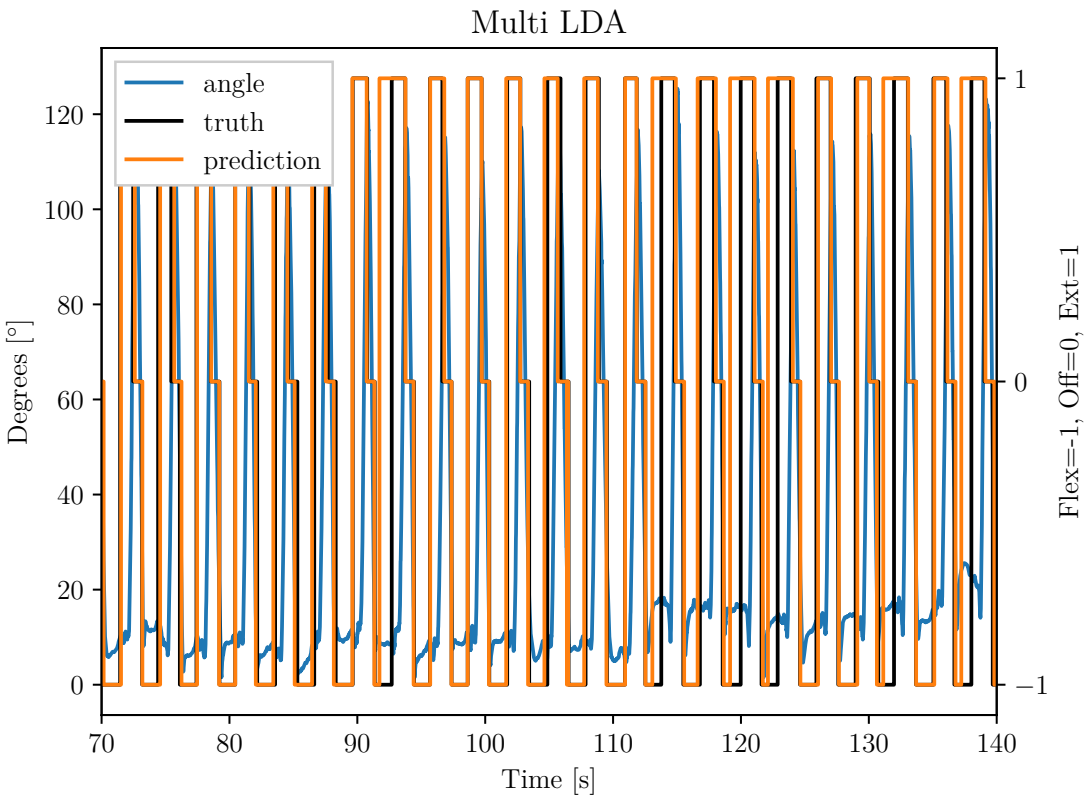

Figure H.10: Simulation of trained LDAs with the same data used for training. Higid participant and three LDAs.

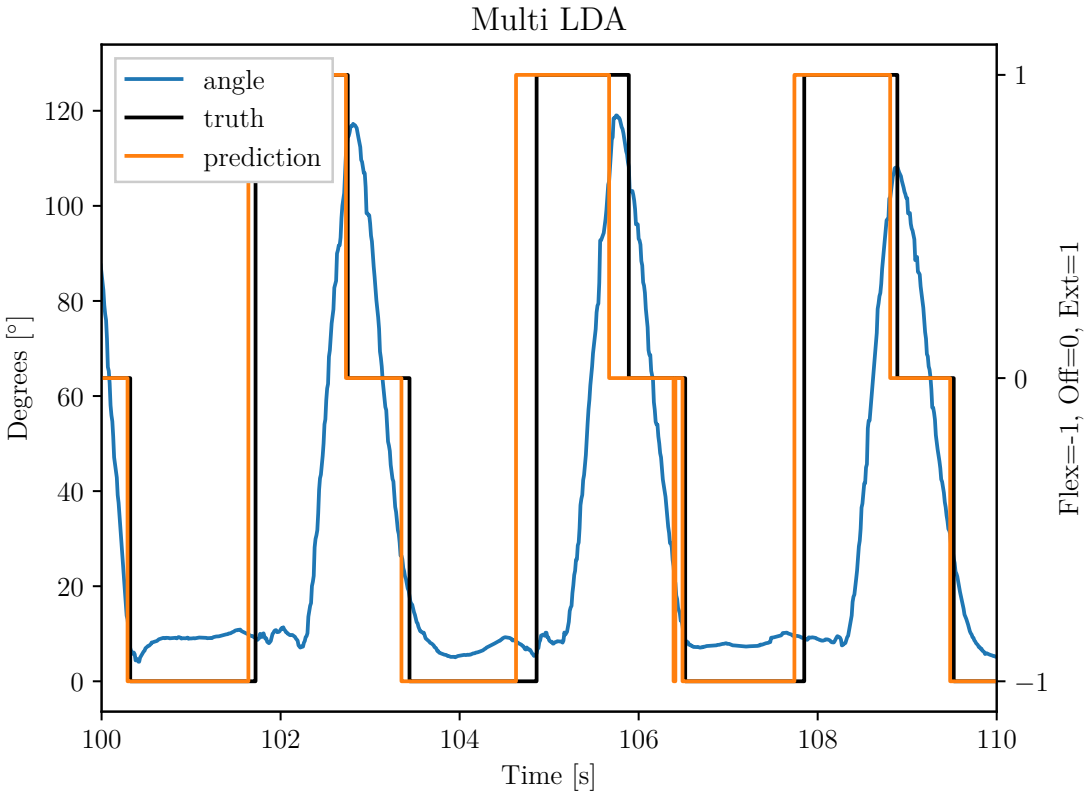

Figure H.11: Detail snippet of simulation of trained LDAs with the same data used for training. Higid participant and three LDAs.

H.2 Learning phase results from the same day as the test with the SCI participant

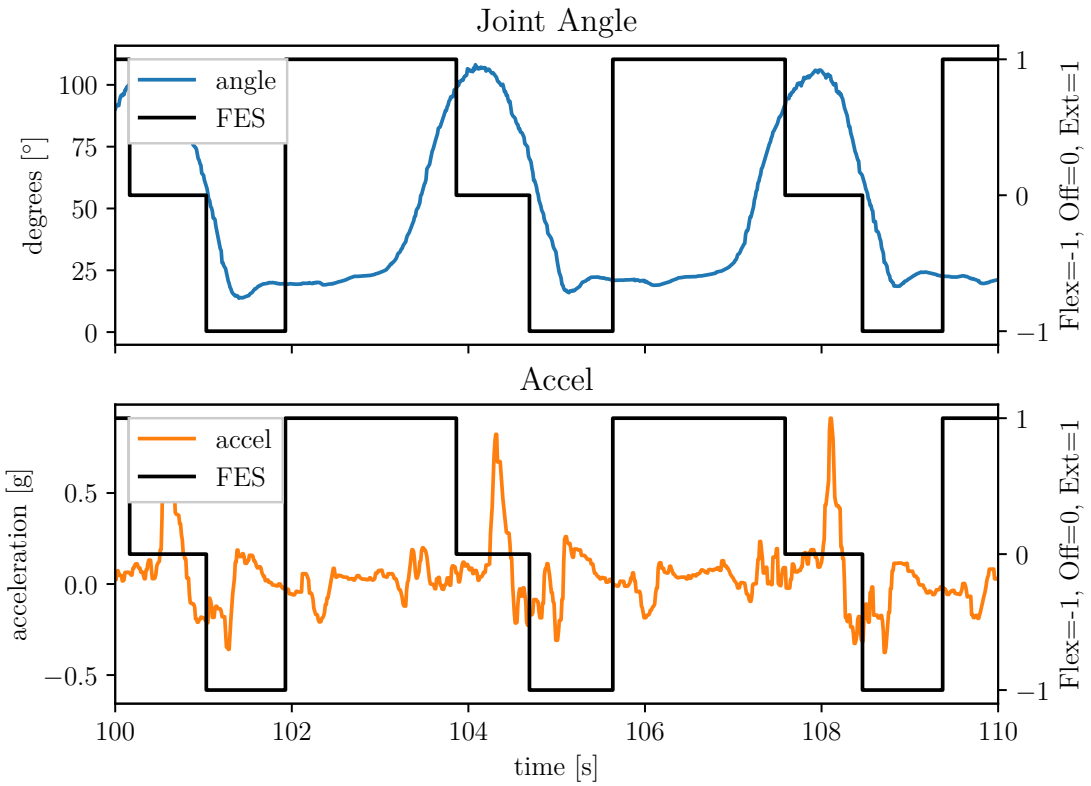

Figure H.12: Example snippet of data with the elbow joint angle and one axis of the accelerometer of a new learning phase with an SCI participant.

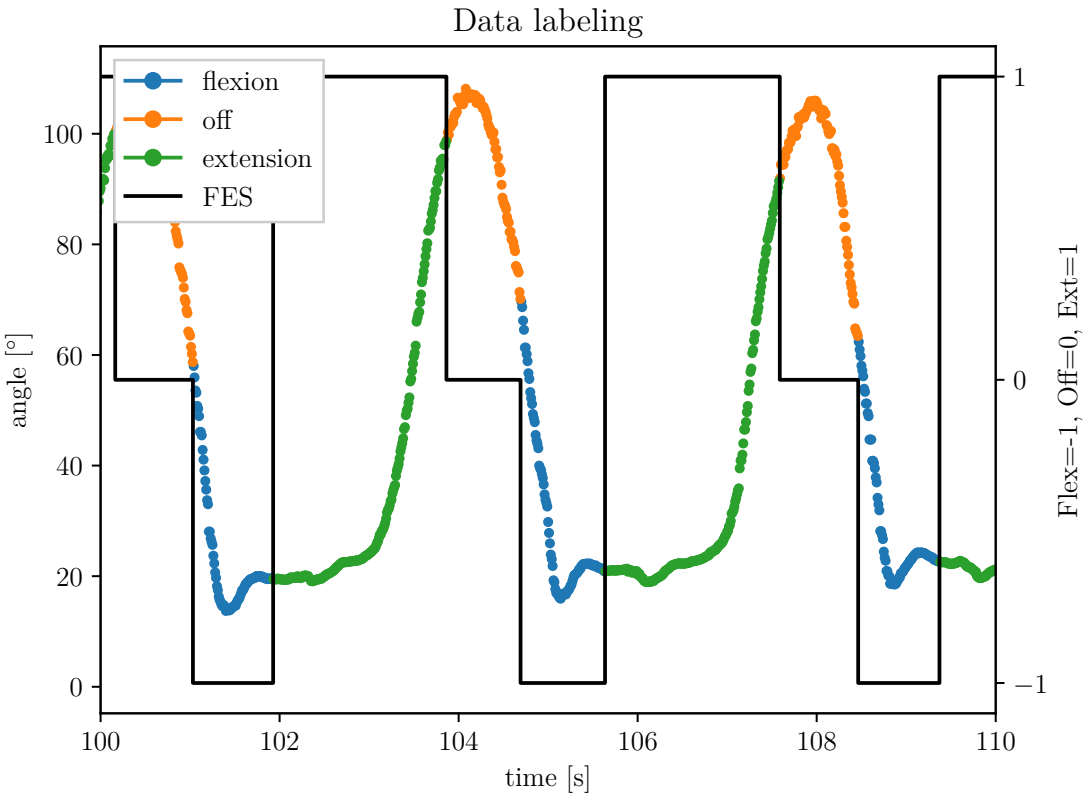

Figure H.13: Data labeling example snippet for the SCI participant in a new learning phase. Data is labeled according to the FES command.

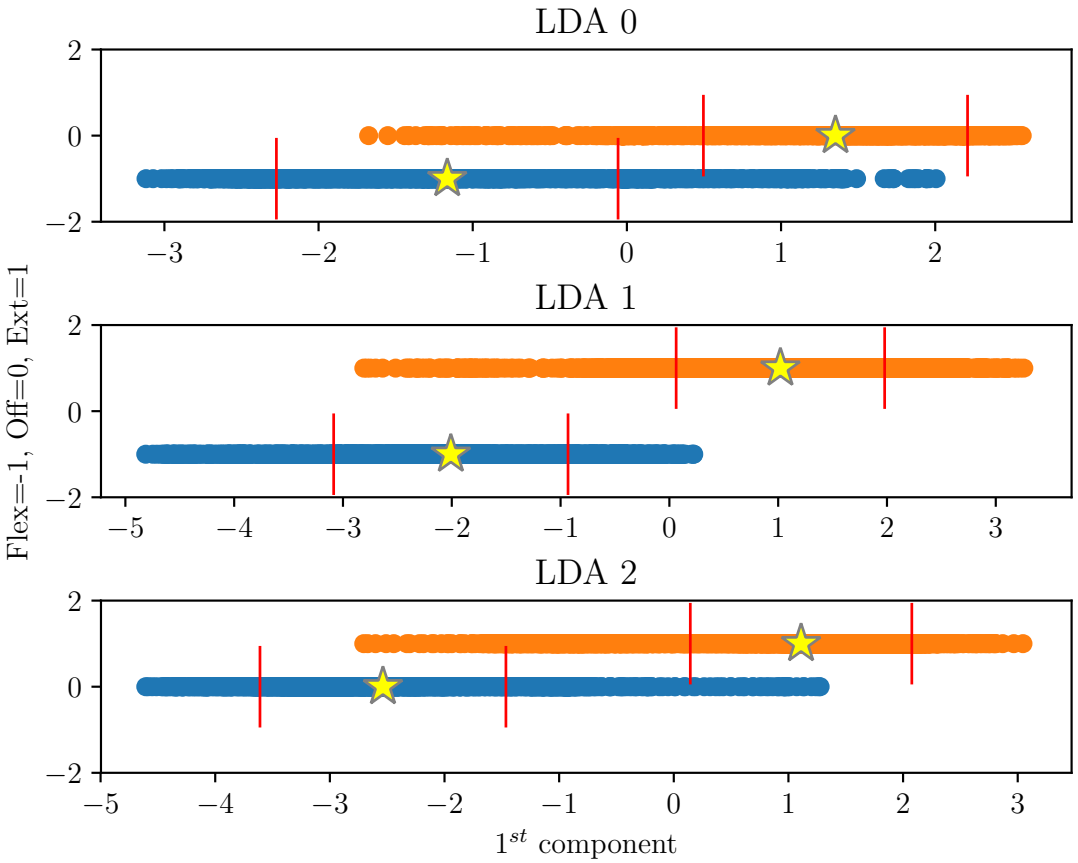

Figure H.14: Class separation visualization for the SCI participant with three LDAs in a new learning phase. Stars indicate the centroid of each class. Red bars represent one standard variation for each side.

I Published contributions

During the development of this work, the following contributions were published:

- M. Caramenti, V. Bartenbach, L. Gasperotti, L. Oliveira da Fonseca, T. W. Berger, and J. L. Pons, "Challenges in Neurorehabilitation and Neural Engineering," in Emerging Therapies in Neurorehabilitation II, vol. 10, J. L. Pons, R. Raya, and J. González, Eds. Cham: Springer International Publishing, 2016, pp. 1–27.
- J. Araujo Guimarães, L. O. Fonseca, C. Paz, A. Bó, C. Fattal, C. Azevedo-coste, E. Fachin-Martins, "Towards parameters and protocols to recommend FES-Cycling in cases of paraplegia: a preliminary report," in IFESS, 2016, vol. 26, no. 3.
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J Resumo Espandido em Português

J.1 Introdução

A lesão medular (LM) é uma condição médica que frequentemente leva a deficiências motoras severas. Pessoas com LM podem ter paraplegia ou tetraplegia, e perder suas habilidades de realizar tarefas básicas como locomoção, alimentação e higiene [75, 104]. Ela afeta centenas de milhares de pessoas apenas no Brasil e muito poucos se recuperam totalmente [81]. Tratamentos tradicionais como fisioterapia normalmente têm resultados limitados [1].

Uma pessoa com LM pode não conseguir controlar seus membros superiores e inferiores, mas normalmente as estruturas locais, como músculos e neurônios motores, são preservados. Portanto estimulação elétrica funcional (EEF) pode ser usada para induzir contração nesses músculos e gerar movimento em membros paralisados [111, 71, 102].

J.2 Materiais e Métodos

Neste trabalho eu desenvolvi uma plataforma de técnicas para interfaces de usuário que explora capacidades motoras residuais que usuários com LM podem ainda ter para controlar neuropróteses. Para obter informações de movimento, uso unidades de medida inercial (UMI), que são sensores pequenos, leves, sem fios e relativamente baratos. Eu desenvolvi e avaliei algoritmos para detecção e classificação de movimentos de usuários com paraplegia e tetraplegia. O objetivo é que os usuários possam usar seus próprios movimentos residuais, dependendo do seu nível de lesão, como movimentos de ombro ou tronco, para ativar diferentes comandos de dispositivos assistivos. Eu usei as técnicas desenvolvidas em três cenários de aplicações com pessoas com LM.

Primeiro eu executei um experimento em que três participantes com paraplegia ativaram um dispositivo ativado por EEF para auxílio em transferências sentado-pivô (TSP). Eu analisei dados cinemáticos dos troncos para investigar a viabilidade de usar essa informação para ativar a EEF nos seus membros inferiores durante a TSP. A Fig. J.1 mostra uma participante posicionada para realizar uma TSP no set-up experimental construído para esse cenário.

Depois eu desenvolvi uma interface com a qual nove participantes com tetraplegia usaram movimentos de ombro para controlar uma mão robótica simulando um dispositivo de auxílio de preensão manual. Eu usei dados de acelerômetros e giroscópios, além de uma técnica de limiar para detectar movimentos, e uma análise de componente principal (ACP) para classificá-los. Então eu mapeei esses movimentos em três comandos na mão robótica. A Fig. J.2 mostra um participante durante o experimento de preensão manual.

Em seguida eu desenvolvi uma interface que usa dados cinemáticos de membros superiores para ativar uma neuroprótese acionada por EEF em membros inferiores de pessoas com

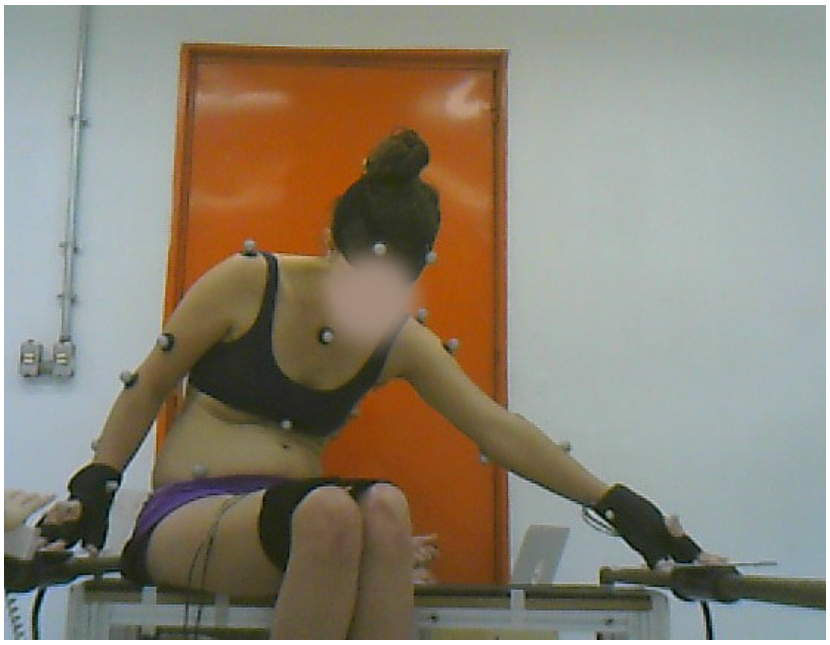

Figura J.1: Set-up experimental para transferências.

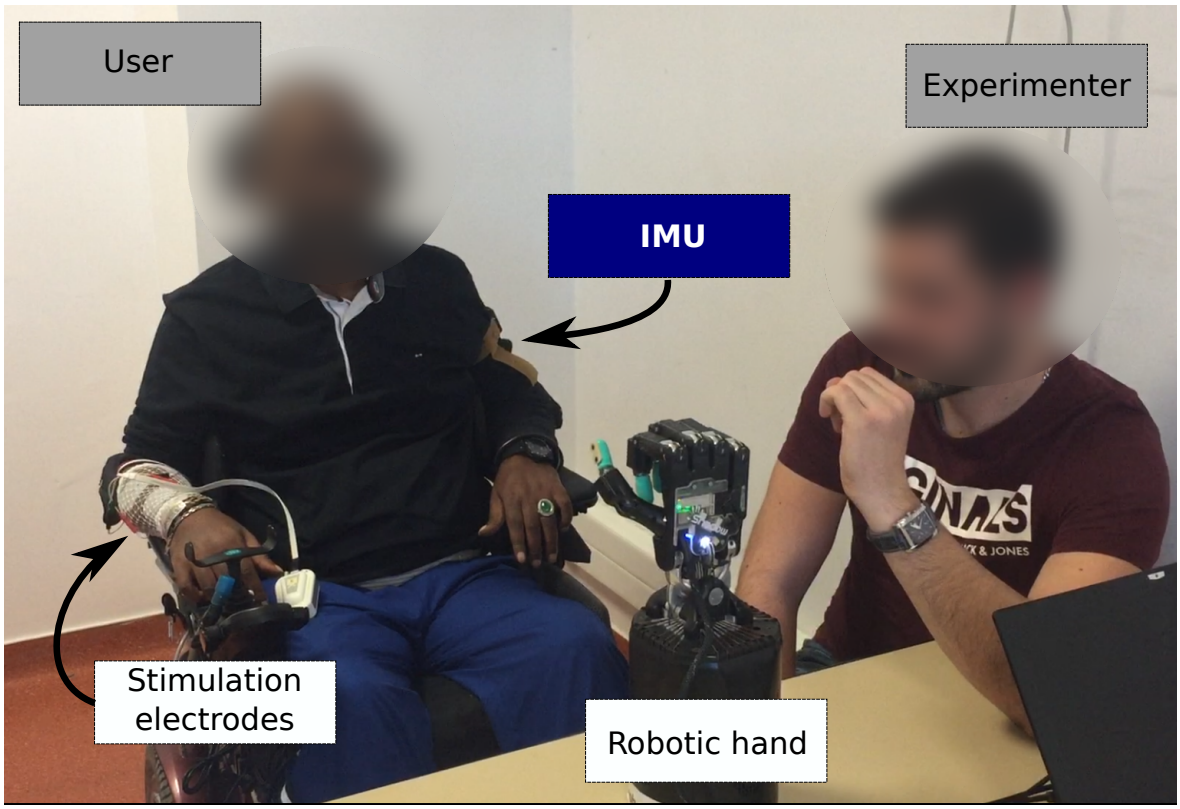

Figura J.2: Set-up do experimento de preensão manual.

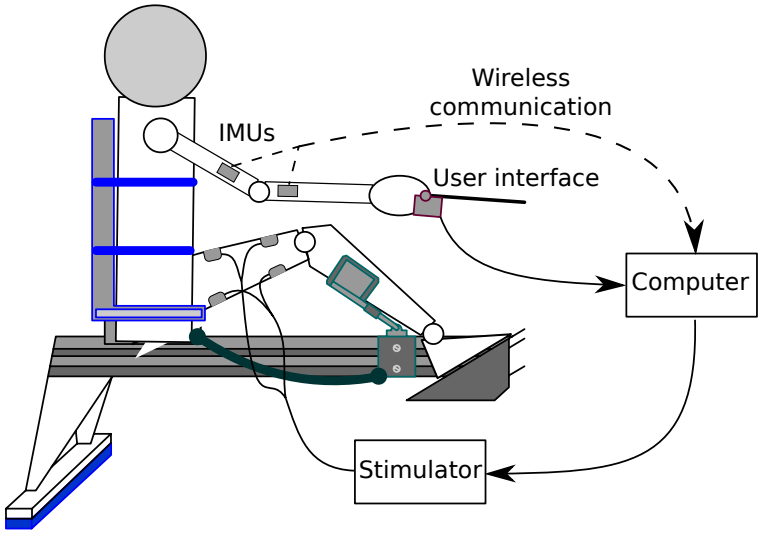

Figura J.3: Detalhamento das adaptações mecânicas propostas em um remo ergômetro regular.

paraplegia durante remo assistido por EEF. Eu usei uma máquina de estados finitos e análise discriminante linear (ADL) para constantemente classificar todo e qualquer movimento de membro superior do usuário em três comandos de fases diferentes no remo. Eu avaliei esse sistema com um participante e um remo ergômetro adaptado para remadores com LM. A Fig. J.3 mostra as adaptações propostas em um remo ergômetro regular para a realização deste experimento.

J.3 Resultados e Discussão

No experimento de transferência, cada participante moveu seu tronco de uma forma similar em todas as repetições, com desvios padrão de ângulos menores que 5°. A Fig. J.4 mostra esses resultados. Isso significa que eu posso usar essa técnica para automatizar a ativação da EEF a partir do movimento do tronco durante a TSP.

Os participantes que utilizaram a interface de simulação de preensão manual conseguiram controlar a mão robótica com sucesso, corretamente executando 91% dos comandos solicitados. A Fig. J.5 mostra a acurácia de cada participante com cada um dos três algoritmos propostos ao tentar controlar a mão robótica para execuar os comandos solicitados.

Por fim, o participante do protocolo de remo foi capaz de remar com a interface desenvolvida utilizando apenas os movimentos de membros superiores. O sistema ativou a neuroprótese em seus membros inferiores em sincronia com os seus membros superiores. Ele também conseguiu parar e controlar a EEF ao parar de mover seus braços. A Fig. J.6 mostra o resultado de um teste onde o participante realizou três paradas e depois retomou a remada. É possível ver que o sistema respondeu aos comandos, corretamente estimulando os membros inferiores.

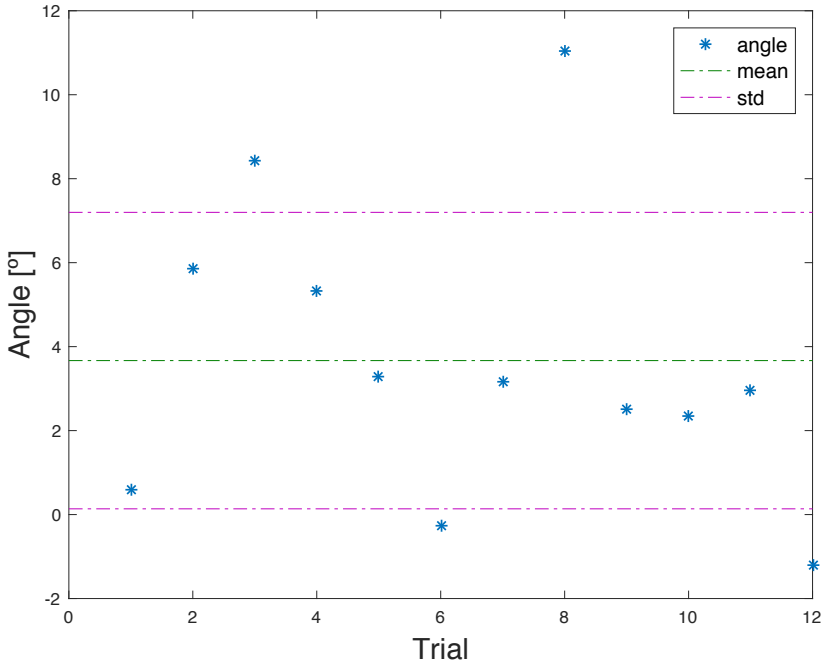

Figura J.4: Ângulo do tronco em todas as repetições de um participante capturado com a IMU no experimento de tansferência. Cada asterisco representa o ângulo relativo do tronco em que a EEF foi ativada em uma transferência. A linha verde é a média e as linhas roxas representam um desvio padrão para cima e para baixo.

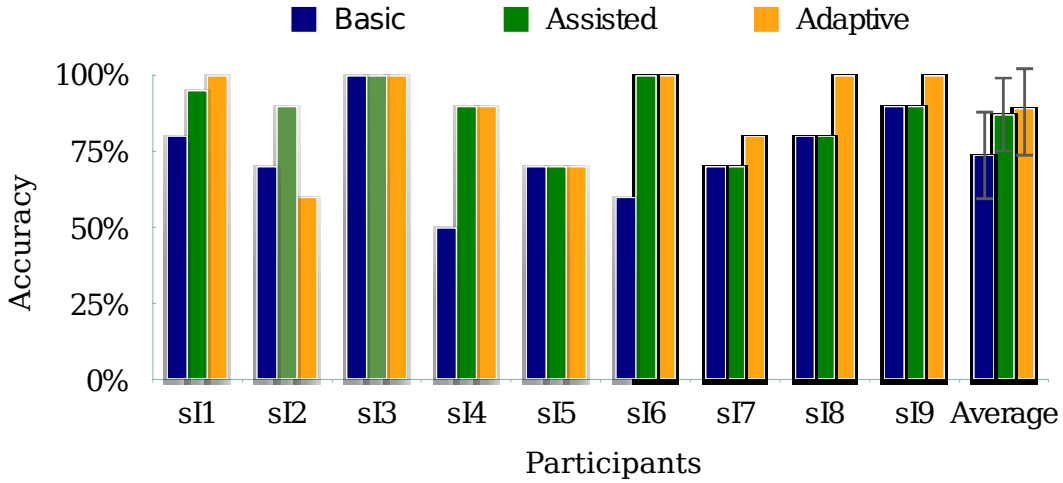

Figura J.5: Resultados de acurácia simulados com os três algoritmos propostos no experimento de preensão manual.

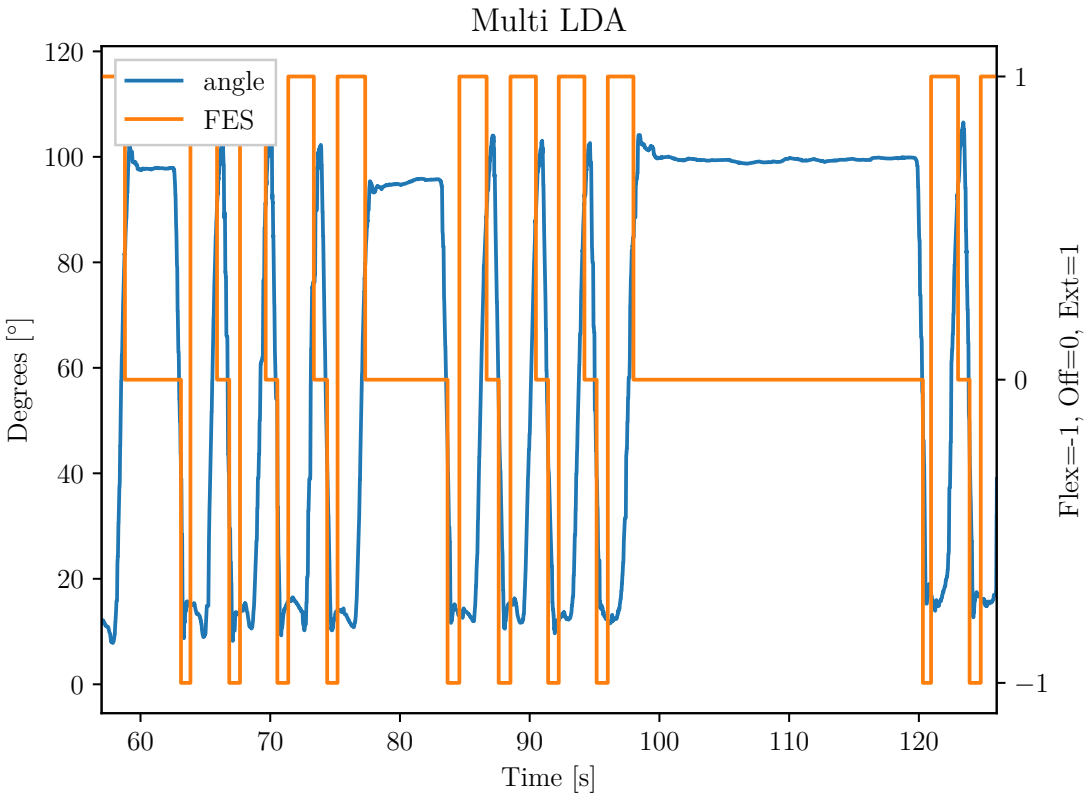

Figura J.6: Resultado do teste de remo com o participante com LM remando com uma ADL treinada por ele mesmo no mesmo dia. A linha azul representa o ângulo do cotovelo, e a linha laranja representa a ativação da EEF nas três fases do remo definidas neste trabalho.

J.4 Conclusão

Esses resultados mostram que pessoas com LM conseguem usar seus movimentos residuais para controlar dispositivos assistivos nas condições observadas. Além disso, a aceitação por parte deles parece ser alta, pois normalmente conseguem operar os sistemas sem nenhum ou com pouco treinamento ou desconforto.