Development of an Interface for Rehabilitation Based on the EMG Signal for the Control of the Ankle Exoskeleton T-FLEX

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Undergraduate Project

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ABSTRACT

Stroke is the second leading cause of death and third of disability, and 75% of individuals who sustain a stroke each year experience limitations in mobility-related to walking. Strategies involving robotic devices, such as exoskeletons and orthoses, have been considered to improve stroke rehabilitation. Some of them have included the implementation of Electromyography (EMG) signals either for muscle activation analysis or movement intention detection. The latter has been involved in the activation process of robotic devices to handle the device's assistance by the subject's intention to perform a specific movement. This would allow the subject to get involved in his/her therapy. Hence, this project introduces an EMG interface for the control of the ankle exoskeleton T-FLEX.

Some studies where EMG signals have been included in control and therapy processes were reviewed, and algorithms with different threshold methods calculation were analyzed. Considering the information from those studies, a threshold-based algorithm for movement intention detection was developed. The algorithm consisted in two main stages, the threshold calculation and the movement intention detection. The first stage consisted on the threshold establishment through statistical features extraction (MEAN, standard deviation (STD), variance (VAR), MEAN + 3*STD and Root Mean Square value (RMS)) from the EMG signal. The second consisted of comparing the signal with the reference value (threshold).

To test the algorithm, two sessions were planned. In the first session, ten healthy subjects participated and their EMG signal was acquired from the Tibialis Anterior muscle through a Myoware muscle sensor. Additionally, an Inertial Measurement Unit (IMU) sensor was placed on each participant's foot tip to acquire the angular velocity when the ankle's dorsiflexion was performed. The output signals from both sensors were recorded and the processing with the algorithm was done offline. The second session was carried out with the ankle exoskeleton T-FLEX and a Serious Game, implementing the algorithm in real-time with a statistical feature selected from the first session as the threshold. The detection from the EMG algorithm was evaluated. The algorithm that T-FLEX already had for the movement intention detection with the IMU sensor also was evaluated.

The results from the first session showed that the MEAN feature worked for the threshold establishment with the IMU sensor, and for the EMG sensor was the (VAR), presenting and error of less than 10% in the amount of False Positive (FP) and False Negative (FN) values. With this, the second session was carried out, showing that there was more precision handling the game using the IMU sensor than the EMG sensor. With the EMG sensor the maximum precision achieved was 89,7% and with the IMU sensor was 94.1%.

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Chapter 1

INTRODUCTION

This chapter presents the general motivation and the theoretical framework of the work presented in this thesis. This work's motivation includes world statistics of stroke, advantages of using robotics in therapy, some robotic devices that have been considered, signals for control strategies and the need for feedback. The project is articulated with the T-FLEX exoskeleton that frames the study for ankle rehabilitation. From this, the study's objectives are presented in addition to the contributions and the document organization.

1.1 Motivation

Stroke is the second leading cause of death and the third leading cause of disability. It happens due to a blockage or rupture of an artery to the brain, provoking the lack of oxygen in some brain cells causing a disturbance in brain function [1]. This affects approximately 16.9 million people worldwide and can be classified into two types: hemorrhagic and ischemic stroke. The latter covers around 80% of the cases [2]. The complications of a post-stroke vary depending on the lesion location as well as its critical state. The consequences of stroke usually are impairments of strength, sensory processing, coordination and balance, affecting walking ability. Immediately post-stroke, only 37% of stroke survivors can walk. Among the patients with initial paralysis post-stroke, only 10% recover independence and for those who are not paralyzed, 75% can use their affected limb and walk [3].

Some studies showed that stroke is more likely to appear in males and increases exponentially with age. In Latin America, this disease has an incidence of about 1/1000 persons [4]. In Colombia, this disease was the first cause of death responsible for 23.47% of deaths between 2005 and 2014 [5]. The risk factors that have been identified are arterial hypertension, sedentary lifestyle, arterial fibrillation, congestive heart failure, diabetes, and ischemic heart disease [4], [6].

It is possible to deduce that stroke can lead to low levels of physical fitness such as severe disability, partial paralysis, and even death. This implies the existence of a significant long-term participation restriction. Post-stroke patients usually suffer from gait dysfunction, which involves the hyperextension of the knee during the support phase and the reduction of ankle dorsiflexion during heel contact [7]. The ankle flexor and extensor muscles are crucial to provide vertical support and forward progression of the body. Therefore, the lack of ankle functionality represents a significant limitation for walking and many other human activities [8].

A comprehensive rehabilitation approach requires therapy from the earliest time of the disease to achieve a meaningful recovery of lost functions and help people return to their lives and fulfill roles and engage in meaningful life activities [9]. Understanding neuroplasticity, many rehabilitation opportunities can be available at different post-stroke periods and even other neurological diseases. Repetitive training is the base of neuroplasticity, which can be defined as the brain's ability to change, remodel, and reorganize to adapt to new situations. While one activity, such as a sequence of movements, is practiced repeatedly, neuronal circuits are being formed, leading to a better ability to perform the practiced task with less waste of energy. That is why neuroplasticity is considered to lead to many occurrences, even the recovery following brain injury [10]. Therefore, task-oriented, high-repetition movements can improve muscular strength, motor control, and movement coordination in the patients [11].

Thus, repetitive exercise training is an essential factor in enhancing motor recovery after stroke. For low-speed walking, the behavior of a healthy ankle can be satisfactorily achieved through passive orthoses. However, for standard and fast walking speeds, the ankle provides additional energy for propulsion at the plantar flexion phase. The lack of energy source in passive orthoses can lead to gait deficiencies and higher metabolic energy consumption [8]. Moreover, it is crucial to consider that if gait rehabilitation is performed, for instance, with insufficient or incorrect repetition of the push-off motion, patients may learn compensatory instead of normal gait [12].

Several lower-limb exoskeletons are commercially available to assist walking, such as the Lokomat (Movard, Spain) and the G-EO (Reha Technology, Swiss) systems (Figure 1.1) [13]. They induce upright walking movements at variable speeds and improve the patient's walking ability. However, it is challenging for some patients to maintain an upright position for training in the early period after injury, due to orthostatic hypotension and significant weakness of their core and lower extremity muscles [14]. Thereby, active and semiactive ankle devices have been developed to help impaired individuals walk [8].

The Ankle-foot orthosis is considered in stroke rehabilitation because it can stabilize the ankle joint and compensate for insufficient ankle dorsiflexion and mediolateral instability of the subtalar joint, increasing balance ability [17],[18]. Active orthoses might involve user motion intention recognition to activate the device, engaging the user in its control [19]. Their objective is to safely facilitate the restoration of mobility, providing task-oriented and repetitive gait training [20]. The generation of control signals to activate these devices can be addressed using different sources of information. The main categories are biomechanical signals, electromyography (EMG) signals, peripheral nervous system signals, and central nervous system signals, predominating mechanical and EMG interfaces [8].

Formerly, the rehabilitation had been done passively. That is, the professional therapist mobilizes the patient, or a device is programmed by a computer externally to the patient, so that the movements would be done, but the patient will not be encouraged to do them by him/herself [21]. Some strategies were established to approach human-device close-loop inter-

Figure 1.1: a) Lokomat system. A stationary system which influences on the patient's walking trajectory, rather than producing movements volitionally [15]. b) G-EO system. Robotic therapy aid for plegic or paretic limb movements that may help the functionality recovery recovery simulate gait and other more complex gait standards of gait such as the steps on stair [16], [13].

action, such as Electromyography (EMG) [22]. The latter has been involved in the control of robotic devices since the assessment of the movements of the patients would be more precise with the EMG signals due to the possibility of detecting whether the person is activating a muscle to do a specific movement, besides the advantage of the time delay between the activation and the actual movement, which is around 25ms - 130ms [23], [19]. The inclusion of the EMG signals analysis in the activation of the device would allow knowing if the patient intends to move, and the device would help him/her get the task done. Hence, the development of an acquisition system of EMG signals would create an active rehabilitation system that can be used to obtain better results in patient rehabilitation [23].

On the one hand, robot-aided therapy can provide early, intensive, task-specific, and interactive treatment of the impaired limb and monitor the patient's motor progress objectively [24]. On the other hand, therapy with a games-based interface has been considered due to the engagement and motivation that generates in the patients, offering motor re-learning and motivating active movement training with sufficient repetitions to improve mobility, balance and locomotion [24]. Therefore, the inclusion of an interface in the robot-aided therapy can deliver engaging high-intensity intervention and guidance to the patients via real-time audiovisual feedback, which can contribute to the participant's attention, competence and self-improvement [24],[25],[26].

Considering the previous information, this study aims to present an EMG signal-based interface for detecting movement intention by acquiring signals from a specific muscle relevant to the human's gait to activate the ankle exoskeleton T-FLEX. The current T-FLEX's method of movement intention detection would be compared with the EMG-based method in the handling of the serious game *"Jumping Guy: Ankle Rehabilitation Therapy with T-FLEX"* and the results will be discussed to see the performance of each method and the behavior that can have in the therapy of post-stroke patients.

1.2 Related project

T-FLEX (Figure 1.2) is a wearable and portable Active Ankle-Foot Orthosis (AAFO) for rehabilitation and assistance of people with ankle dysfunctions, which is part of the AGoRA platform (Grant 801-2017, Minciencias Colombia) [27]. It incorporates concepts of bioinspiration in the actuation and control systems and can be manually adjustable for both limbs [28]. This device has two servo motors, MX106 (Dynamixel, Korea), located on the anterior and posterior parts of the shank. The orthosis integrates an inertial sensor BNO055 (Bosch,Germany) on the foot tip and has two modes of operation, the gait mode and the therapy mode [29]. The gait mode consists of a statistical algorithm to estimate the user gait phase and assist the dorsi-plantarflexion on the ankle according to the gait phase detected in real-time [28]. The therapy mode consists of repetitive flexion and extension movements on the ankle, enabling the user to train the flexo-extension motions [28], [29].

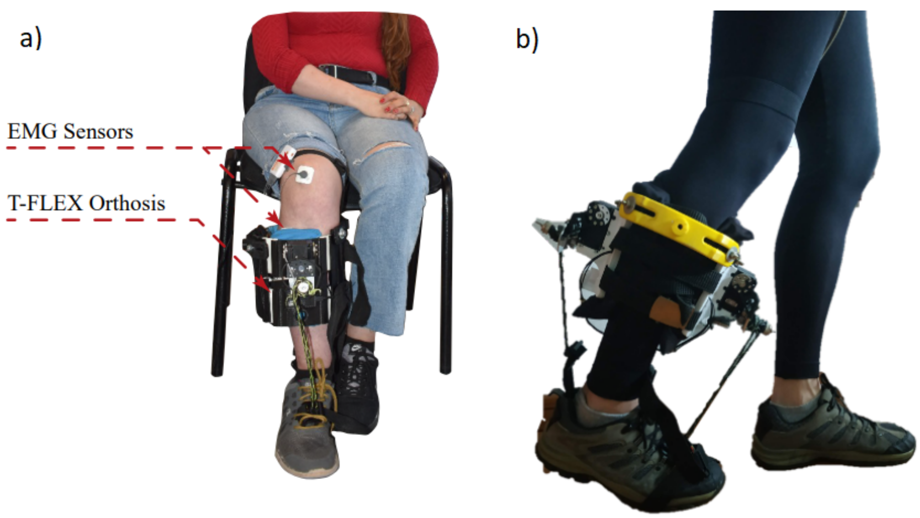

Figure 1.2: a) Ankle exoskeleton T-FLEX in the stationary therapy setup [29]. b) Ankle exoskeleton T-FLEX in the gait therapy setup [29]

In a previous study with T-FLEX in the therapy mode, in which T-FLEX is calibrated taking into account participant's maximum dorsi-plantarflexion movements and execute the values acquired to assist the dorsi-plantarflexion [29], a decrease in spasticity was presented as well as increased muscle activity [29], [30]. However, as early as the muscle overcame the adaptation period, the same training did not produce enough effort to generate high electrical activity [29]. Hence, a variable rehabilitation program with T-FLEX orthosis, where the requirement and the effort increase over time, could provide better results. Likewise, some studies proposed that Electromyography as a control signal would perform better results in spasticity [29]. Considering the information mentioned above, including the electrical activity of the muscles could lead to better assistance in training and improve the actuation of T-FLEX in the rehabilitation of the patients.

1.3 Objectives

1.3.1 General objective

Development of an electromyography (EMG)-based movement detection system for the T-FLEX control and Serious Game.

1.3.2 Specific objectives

1. Integration of an EMG sensor for the ankle exoskeleton T-FLEX's command in stationary therapy based on a Serious Game.
2. Evaluate non-pathologic user's detection of movement intention with inertial measurement unit (IMU) and EMG sensors in the ankle's dorsiflexion therapy independently.
3. Evaluate in non-pathologic users the adaption and performance of each detection method in one therapy session with the serious game.

1.4 Contributions

The development of this undergraduate project made the following contributions regarding the integration of an EMG-based interface in the robotic rehabilitation field:

- The main criteria and considerations for EMG signal processing and threshold establishment.
- A movement intention detection algorithm for the activation of T-FLEX exoskeleton through an EMG sensor, adding the motivational stage implementing a Serious Game to increase the concentration and motor recovery.
- Experimental protocol to validate the performance of the sensors with the device and the participant's experience, adaptability, and satisfaction level with the interface.

1.5 Document organization

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

The first chapter presents the motivation of this study and the related project. The second chapter presents the Literature Review. Initially, it is presented the theoretical framework by which this study is focused on. This chapter considers concepts such as ankle anatomy description, motor relearning, conventional ankle rehabilitation, detection of movement intention, serious games in rehabilitation, and EMG. Finally, it presents a literature review studies related to ankle rehabilitation using robotic devices and serious games controlled by EMG to motivate physical therapy.

The third chapter presents the methodology used in this project. First, the EMG signal's acquisition and the statistical features selected to the threshold establishment according to the methods reviewed in the literature. Then is carried out the setup diagram, describing the process and tools used. After this, the hardware and software considered for this project are shown, including the integration method with the T-FLEX exoskeleton and the Serious Game.

The fourth chapter shows the results of the data obtained after following the methodology. There are the results from both sessions and the statistical analysis. Following, chapter fifth presents the discussion of the results obtained.

The sixth chapter includes the conclusions and the fulfillment of the objectives initially set. Moreover, the last chapter of this document has the recommendations and future works.

Chapter 2

LITERATURE REVIEW

This chapter presents the literature review considered for the development of this work, following these next topics: ankle anatomy, motor relearning and neuroplasticity, inertial measurement unit (IMU) sensors in the movement intention detection, Electromyography (EMG) sensors in the movement intention detection, rehabilitation with robotic devices and serious games, and some threshold-based algorithms considered for EMG signals in some studies.

2.1 Anatomic description of the ankle

The ankle joint complex comprises the lower leg and the foot, which allows the lower limb to interact with the ground. All of its movements are related to the maintenance of gait and other activities of daily living [31], [32]. Gait refers to the movement and balance of the human body when walking upright, which is the primary movement mode of the lower limbs and is carried out by the joint action of muscles, joints, and bones [33]. The gait in a walking cycle can be divided into support/stance and swing phases [33]. The stance phase represents 60% of the gait cycle and can be subdivided into double-limb stance and single-limb stance subphases. In double-limb stance, both feet make contact with the ground, but in single-limb stance, only one foot contacts the ground [34].

The angular ankle positions, ankle moment of force peak (AMP), and ankle power peak (APP) have been considered important kinematic and kinetic parameters for measuring foot function during the gait stance phase [35]. The majority of motion within the foot and ankle is produced by the twelve extrinsic muscles, which originate within the leg and insert within the foot (Figure 2.1). These muscles are contained within four groups. The anterior group, the lateral group, the posterior group, and the deep posterior group [31].

The anterior group consists of four muscles: the Tibialis Anterior, the Extensor Digitorum Longus, the Extensor Hallucis Longus, and the Peroneus Tertius. The Tibialis Anterior and the Extensor Hallucis Longus produce dorsiflexion and inversion of the foot. The second group comprises two muscles: the Peroneus Longus and the Peroneus Brevis, which produce plantar flexion and eversion of the foot. The third group consists of three muscles: the Gastrocnemius, the Soleus, and the Plantaris, which contribute to the plantarflexion of the foot. And the last group is composed of three muscles: the Tibialis Posterior, the flexor Digitorum Longus, and the Flexor Hallucis Longus, which produces plantarflexion and inversion of the foot [31].

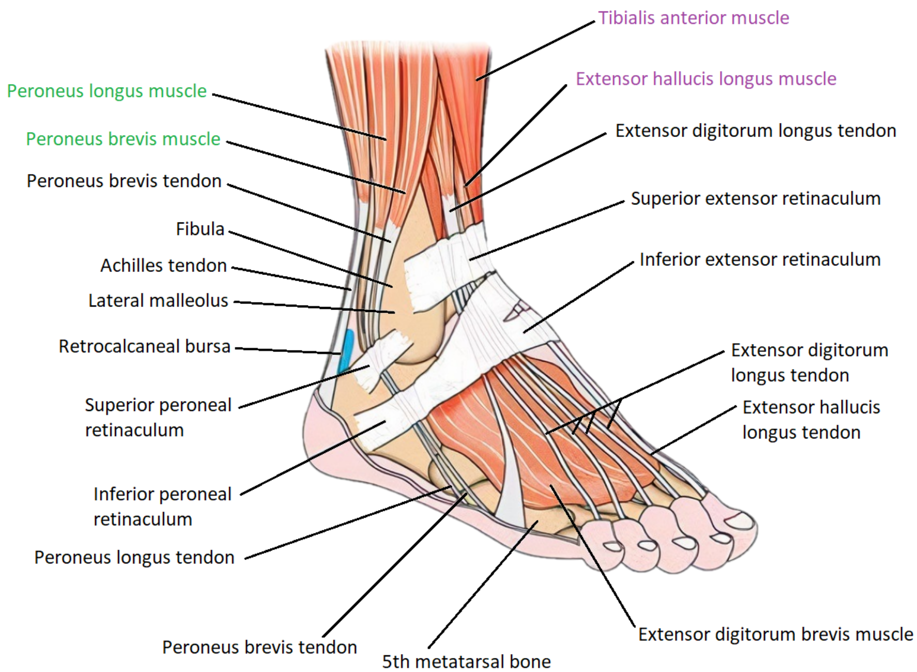

Figure 2.1: Muscles involved in ankle movements [36]. The muscles that appear in purple contribute to the dorsiflexion movement. The muscles that appear in green contribute to the plantarflexion movement.

Some studies reported that as the ankle strength reduces, the elderly experience loss of balance, and increasing Tibialis Anterior muscle strength can lead to the recovery from injuries of the lower extremities and reduce the risk of falling [37]. To walk, sufficient strength needs to be regained in the muscles that extend the lower limb so that a net extensor moment at the hip, knee, and ankle joints supports the body in stance [38].

Muscular strength has also been strongly related to walking speed, mainly the ankle dorsiflexors, which can provide more stability [38]. Since the features of stroke gait are identified by stiff-legged gait (reduced range of knee motion) and drop foot (lack of ankle dorsiflexion during the swing) leading to the raised hip during the swing, in rehabilitation programs it is advisable to treat the flexor muscles with peroneal nerve stimulators, functional electrical stimulation (FES) or solid ankle-foot orthosis (AFO), to achieve foot clearance during the swing and controlled dorsiflexion at initial contact, as well as extensors during loading response [39], [40], [41].

Thus, the ankle is the site of significant biomechanical contributions to normal gait and the sensorimotor control of balance [42]. Therefore, it is targeted for any alteration, for instance, a neurological disease that can characterize it as paretic ankle [42].

2.2 Motor relearning for movement recovery

Motor relearning is defined as the recovery of previously learned motor skills lost following localized damage in the central nervous system [43]. Learning to improve muscle behavior occurs in an ever-changing environment. It Involves the interplay of intrinsic and extrinsic factors associated with performing a movement and a functional task, in the same way, using the same body parts as that used pre-injury [44]. Active participation and self-reliance help in motor learning of movement patterns [45]. To facilitate motor recovery following brain injury, therapeutic training has been taken into account, showing results especially during the acute and sub-acute stages of heightened neuroplasticity [24].

Evidence of reorganization has emerged from studies on focal brain damage. The system-level reorganization has been shown to reflect molecular, synaptic, and cellular events and constitutes post-injury brain plasticity [46]. Studies on brain plasticity have shown that the ability to adapt to environmental changes or learn motor skills preserves by repetitively executing actual movements [46]. Hence, neuroplasticity can be defined as the brain's ability to change, remodel and reorganize for a better ability to adapt to new situations. Thus, task-oriented and high-repetition movements can improve muscular strength, motor control, and movement coordination in the patients [10], [11]. Neuroplasticity also makes it possible to alleviate muscle atrophy and promote nerve recovery through exercise therapy in stroke rehabilitation [47].

2.3 Conventional ankle rehabilitation

Limited ankle range of motion (ROM) is a typical impairment in patients with stroke, whose ankle dorsiflexion passive ROM (DF-PROM) is, on average, only half respect healthy subjects [48]. Conventional gait rehabilitation often involved intensive, repetitive, and task-specific gait practices. Various interventions, including ankle stretching, ankle joint mobilization, and ankle mobilization with movement (MWM), have been used to improve DF-PROM, gait function, and balance ability in individual patients with stroke [49], [48]. The rehabilitation is intended to increase motion and strength, and aiming to evoke brain plasticity to regain the lost functions of the brain through physical therapy proves to be the effective primary treatment for stroke patients [50].

The therapist manually holds the affected ankle to carry out exercises, such as internal/external rotation, dorsiflexion/plantarflexion, and inversion/eversion motion during ankle rehabilitation [51]. However, conventional manually assisted gait training is labor-intensive and physically demanding for therapists. The availability, consistency, duration, and frequency of training sessions are often limited, leaving many stroke patients with permanent disabilities untreated. To overcome the significant limitations of traditional manual therapy rehabilitation, robots have been introduced into the earlier recovery phases after stroke [50], as well as devices that can assess accurately the patient progress in his/her rehabilitation and not be limited to the experience of the therapist [17].

2.4 Ankle rehabilitation with robotic devices

Some mobility problems following a stroke can be improved by an externally applied ankle–foot orthosis (AFO) to modify the structural and functional characteristics of the neuromuscular and skeletal systems through principles of motor learning, including high volumes of repetition, which can provide indirect knee/hip control during the stance phase of gait by controlling the alignment and motion of the ankle–foot [52], [47].

Some studies suggest that early, intensive, multisensory and task-related training could help facilitate neuroplasticity and improve motor control ability. Ankle rehabilitation devices are broadly divided into two major categories: rehabilitation platforms for various ankle rehabilitation exercises without walking (Figure 2.2) and wearable rehabilitation robot (also known as an AFO), which can be prefabricated or custom-made and further subdivided into passive (PAFO) for correcting deformities, and active (AAFO) for a wide range of rehabilitation exercises including walking [47].

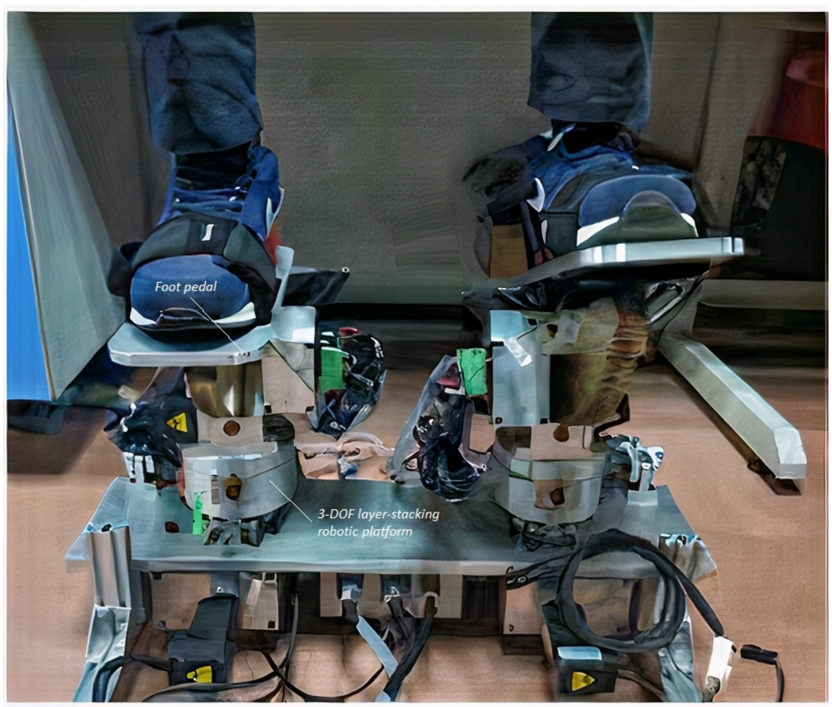

Figure 2.2: Rehabilitation platform. A 3-DOF robotic platform was proposed to assist the ankle in achieving inversion/eversion, dorsiflexion/plantarflexion, and internal/external rotation. [51].

Unlike rehabilitation platforms for exercising an ankle in a fixed place, AFO-based exercises help improve gait functions [47]. When the patient can hardly move, passive range-of-motion (ROM) exercises can be accompanied by position control that drives the injured foot/ankle along a trajectory with motion parameters specified by a physiotherapist. When the patient is capable of initiating the motion but unable to deliver sufficient torques to complete the exercise trajectory, additional torque needed is monitored by a force/torque (F/T) sensor that detects and provides information to a controller to supply mechanical assistance to complete a patient's intended motion, which reduces a total reliance on robotic assistance to complete prescribed movements and including some strategies, such as feedback via a video game-based format and goal setting (Figure 2.3), increases contributions in walking and balance control [52],[47].

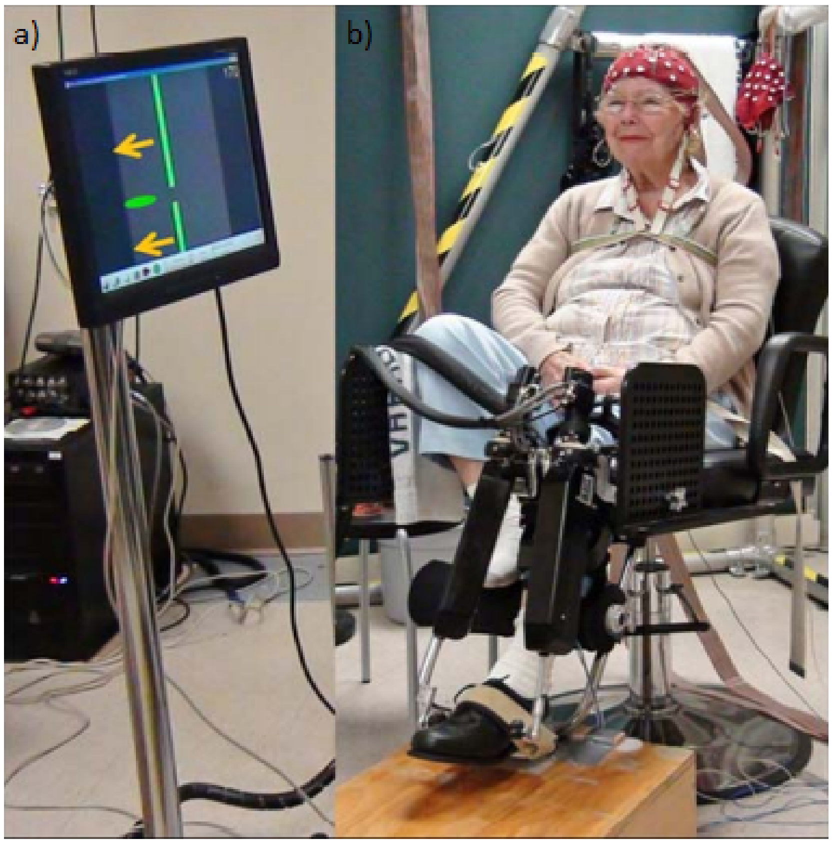

Figure 2.3: a) video game-based feedback. The participant is seated and plays the videogame by moving the ankle in dorsiflexion (DF) and plantarfelxion (PF) ranges to control a cursor that moves across the screen through gates at different vertical levels. b) Ankle–foot orthosis (AFO) was used [52].

The active ankle-foot orthosis (AAFO) T-FLEX's design (See Figure 1.2) mainly intends to provide stability to the user, correct the pathological ankle posture, assist the dorsi-plantarflexion movements, and allow the ankle motions in other planes. The stability and posture are kept within the minimum requirements of both robotic devices and passive orthotic structures prescribed to the ankle treatment. The principal interest lies in dorsi-plantarflexion assistance to improve the gait pattern. This way, other joint compensatory movements (in the hip and knee joints) can be reduced. Moreover, permanent damage's risk and metabolic costs to the locomotor system would be avoided through changes in the user's kinematics. Additionally, considering the robotic advantages, interactive sessions can be carried out, recording and displaying session data, and interconnecting with other robotic systems [26].

2.5 Detection of movement intention

Human movement intention, that is, the intention that a person must execute a specific movement with any part of his/her body, is highly significant for an effective assistive system. It is in the case of the ankle for successful gait rehabilitation [53]. It is critical to detect the movement intention as early as possible to provide the system with enough time to adapt to the requirement of the individual [53]. The movement intention has been employed as an indicator to quantitatively measure the willingness and movement of patients participating in training. It demonstrates a statistical difference between rest and movement and between different types of movement [54]. Detecting movement intention could provide effective rehabilitation of motor-impaired persons, also providing them with necessary motor capabilities [53].

Movement intention can represent an interaction between the user and the device through a control interface used to operate active movement-assistive devices [55]. To detect the movement intention, some studies have used a wide variety of sensors; for instance, in the case of grasp intention detection from a hand, force sensors have been used [56]. Some examples of signals that are implicit signals related to the motion intention are the neural signals from the central nervous system, neural activation of the muscles, muscle contraction forces, and small movements and forces of the human. Motion intention can also be derived from explicit commands of the user, for example, by pressing command switches through speech, and head, tongue, or eye movements [55].

2.5.1 Inertial sensors in movement detection

An interface used is based on the human body movement, which occurs due to the interaction between the forces generated by the muscles and the configuration of the skeletal system. Measurements of relative joint rotations and motion of body segments concerning a fixed reference have been used to detect motion intention [55]. several sensors have been used to detect gait initiation like gyroscopes and accelerometers [57]. Thus, a low-cost nine-axis IMU sensor (3-axis accelerometers, 3-axis gyroscopes, and 3-axis magnetometer sensors [58]) has been used because it can determine, for instance, a subject's toe movement collecting acceleration, angular velocity, and geomagnetic output values, so that the gait would be monitored [59]. Such wearable sensors have already been used in general gait analysis and activity recognition. They can detect falls or events during cyclic gait [60].

The inertial sensors express their data (angular speed, acceleration, and magnetic field [58]) in the sensor coordinate system ($\vec{S_s}$), and a rotational matrix ($\vec{R}$) is used to get the data in the body coordinate system ($\vec{S_b}$), where $\vec{S_b} = \vec{R} * \vec{S_s}$, which would represent the axes of the limb that is being evaluated. The use of inertial sensors for motion detection is relatively easy and requires low computational levels and low sampling frequencies (around 100 Hz[61]) [62]. The data has to be filtered and then analyzed. The goal is to use such technology to control devices for lower limb motion assistance or replacements such as robotized orthoses and prostheses [60], [57].

However, inertial sensors have been used to capture overall movements and might not differentiate tiny motion that can be related to a movement different from the one being evaluated as some other strategies like the implementation of EMG sensors can. The latter has been used to identify the difference in the muscular activity of the intended movements [63].

2.5.2 Electromyography sensors in movement detection

Electromyography (EMG)-based control interfaces are widely used because of their easy access and generation and their direct correlation to the movement intention [55]. This is because EMG signals represent a straightforward way to decode the human motor intent. With control strategies, it is possible to encode them into high-level input signals for controlling rehabilitation devices, such as wearable powered ankle-foot orthosis, and assist in flexion and extension [64], [65].

EMG consists of measuring and recording the electrical potential generated by the activation of muscle fibers when performing voluntary or involuntary movements [66]. With EMG sensors is possible to detect the movement onset before starting the actual movement [67],[62]. Although these sensors require a higher sampling frequency (around 1000 Hz - 2000 Hz [68]) than inertial sensors, they can be beneficial for gait initiation detection with a consistent and earlier detection [62]. An EMG-based interface requires significant signal processing before it can be used as a control signal due to its broad bandwidth and low-voltage amplitude [55]; therefore, it is essential to apply the appropriate filters to analyze the data.

The movement intention can be detected through two steps: features extraction and classification. The features of the signal can be found by analyzing the time domain or frequency domain. In the time domain, the mean absolute value (MAV), wavelength (WL), the amplitude, variance (VAR), standard deviation (STD), root mean square value (RMS), among others, are some features that have been taken into account [69]. The procedure of feature extraction and classification brings some disadvantages, such as low speed in the processing stage. Hence, dividing the signal in windows has been presented as a solution. The action classification is performed by judging the steady-state data in each window rather than processing the whole data. Thus, action recognition is achieved by analyzing the steady-state data of small windows (from 30 [70] to 100 samples [68]) in EMG signals, reducing the response time and providing the possibility that the biosignals could be well combined for control in real-time [71].

EMG signals have been used in the assessment during gait in robotic exoskeletons to identify any alteration in any gait cycle event, such as heel-strike and toe-off. These signals are from the unaffected limb and the affected limb to verify the device's assistance and ensure an appropriate rehabilitation [72], [73].

As was previously mentioned, detecting and assisting from patient's movement intention seeing the voluntary activity, the execution of a task, and feedback of a movement to retrain the ability to move quickly in response to a real-world perturbation is ideal for leading neuroplasticity. This method implies repetitive exercises. With the EMG signals, there is the possibility to monitor the movement intention of the patient and ensure neuroplasticity in the desired movement execution [74], [75].

It is possible to see that the EMG signal has had an essential role in rehabilitation. It is helpful in the assessment of movements and their detection and classification [76]. Hence, it is critical to know how the detection is done. There is a wide variety of algorithms that have been used, from low to high complexity. However, complex algorithms require more computational cost, so low complexity algorithms such as threshold-based algorithms have mainly been implemented [77].

Overall, threshold algorithms are based on statistical methods used to analyze the data and carry out the features extraction to identify irregularities and changes [78]. There are several ways to establish a threshold, for instance, using the sum of statistical features. Its comparison with the current data would represent a fact in the results of the study. The threshold can be established as the sum of the mean of the samples from the EMG signal presented in an established window and three times their STD so that the intention would be identified when the actual signal exceeds the threshold [79].

The combination of EMG with rehabilitation devices aims to assist the movement of the subject, for instance, the one from the leg, in a coordinate way through an intended movement detector based on pattern recognition, such as Artificial Neural Networks (ANN), for processing EMG signals that allow sending control/activation signals to the device [70].

An ANN consists of three fundamental layers, input layer, hidden layer and output layer. The artificial neurons are connected, and this connection represents a weight. The input transfers from the input layer to the output layer through the hidden layer, and the error transfers from the output layer to the input layer through the hidden layer. When the network is active, the node (which receives and sends data to several nodes in the layers that are beneath it and above it) receives a different data item (different number) over each of its connections and multiplies it by a weight yielding a single number [80]. During the transfer, the value of the neurons in each layer only directly affects that in the next layer [71]. After being transmitted to the output layer, the result is compared with the expectation. The weights and thresholds of each layer are constantly modified because the training does not stop until the error is reduced below the preset. The number of nodes in the output layer is related to the actions that are being evaluated. The classifier learns eigenvalues of different actions, in this case from the EMG signal, and carries out the classification.

For training, the movement intention annotations are given as ANN Target. The ANN will perform a sample-to-sample training according to the inputs and the target [70]. After the training is completed, the samples are tested to predict whether these samples can meet the expectation [71]. To get the detection, the EMG signals corresponding to the desired muscles are considered and randomly divided, for instance, into the following sets: 70% for training, 15% for validation, and 15% for evaluation. The ratio of events detected for each muscle demonstrated that it is possible to detect the movement intention, with an algorithm with a high level of complexity [70].

Other studies have established different statistical features like RMS value, MAV, STD, WL, simple square integral (SSI), and integrated EMG as the threshold. These features were analyzed independently in the algorithm to use seven different algorithms with the same logic. The operations from the features can be applied in the first 500 samples without movement, and then the threshold establishment is carried out. The signal processing can be offline, and then the feature can be proved with real-time data [81].

Adaptative thresholds have been used either, in which some statistical features, such as mean, window length, STD, and a percentage of sensibility, are taken into account to establish the threshold. The latter can be expressed in the equation (2.1), where T(t) is the threshold, $\bar{x}$ is the mean value, $\bar{\mu}$ is the STD, N is the window length for the mean and STD, and p the sensitivity factor of the threshold. The results are analyzed taking into account the preprocessing stage (Figure 2.4), which consists of applying the VAR, STD, and Teager Kaiser Energy operator (TKEO) to the signal. The formula for the TKEO is given in equation (2.2), where x(t) is the current EMG sample [82].

$$T(t) = \bar{x}N + p\mu(t)N \tag{2.1}$$

$$\psi = x(t)^2 - (x(t-1)x(t+1)) \tag{2.2}$$

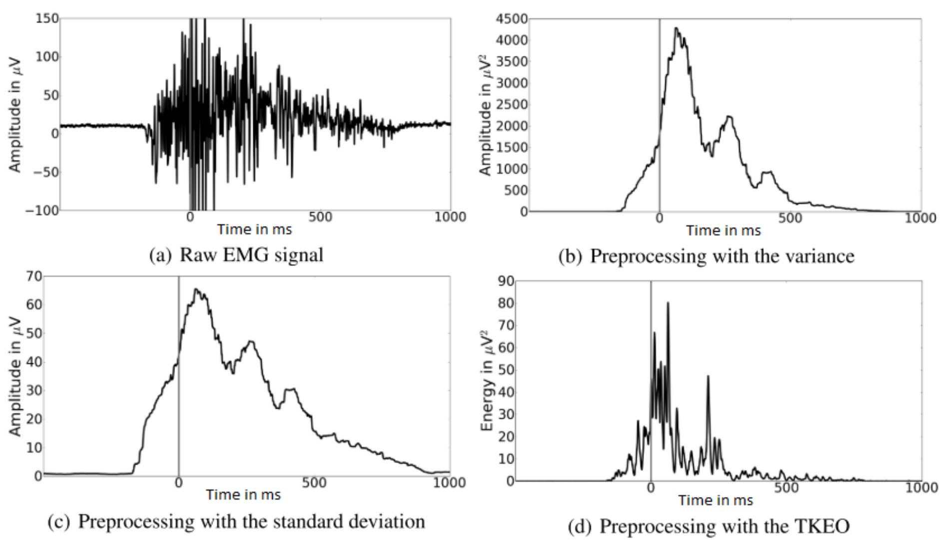

Figure 2.4: This figure shows the different EMG signal pre-processing methods applied to the signal before the threshold-based movement detection [82].

Some studies have considered using a double-threshold technique, where statistical features, such as mean and STD, are considered to establish the threshold. The first threshold corresponds to the mean of the first twelve peaks of the signal's envelope and, the second corresponds to the STD of those peaks; the onset would be determined once the signal exceeds both thresholds. To ensure the detection, the RMS value of the following samples after the detection (the amount established by the user) is analyzed and its quasi-linear relation with the magnitude [83].

Complexity in the threshold methods has been seen either, as in the constant false alarm rate (CFAR) threshold. It is necessary to establish several training samples R, several guard samples G, and a sensitivity parameter S_o. The adaptive threshold for an event is calculated by computing the average for the reference samples and multiplying it with a sensitivity parameter. The samples adjacent to the test sample are excluded as guard samples and the ones next to these are the reference samples (See Figure 2.5). In other words, based on the number of R and G, the algorithm creates a low-pass filtered reference signal (moving average of the rectified signal) for the onset detection, which, when multiplied with S_o, the adaptive CFAR threshold is determined [84].

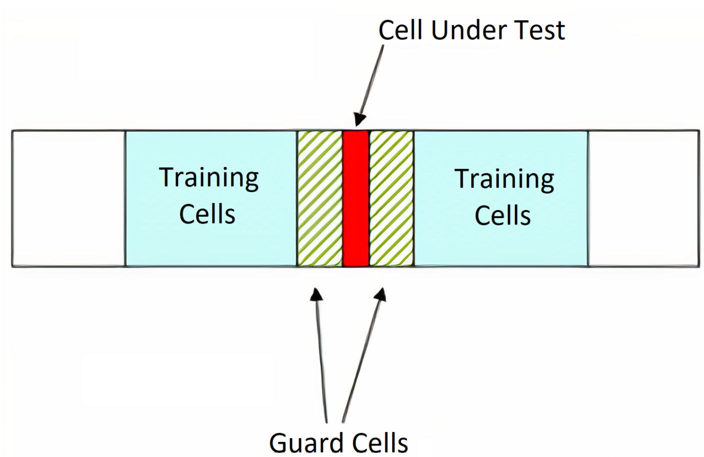

Figure 2.5: Graphic diagram of the base of CFAR threshold.

2.6 Serious games

In long-term rehabilitation processes, it is expected that the users lose motivation because of the repetitive exercises that need to be performed in each session. This can lead to a loss of effectiveness in the therapy [25]. Some studies have shown that serious games help in the patient's motivation in the rehabilitation process due to the cognitive and motor activities required for the games, which motivate the user's attention [25].

2.6.1 Rehabilitation with Serious Games

Recent studies have attempted to associate the rehabilitation equipment used to improve or treat physical abilities with serious games, applying game elements such as motivation and challenge. These programs are considered to increase the patient's motivation to rehabilitate and effectively recover the physical abilities by reducing the rejection or disinterest of treatment that patients may have (Figure 2.6) [85]. Patients who have impaired balance ability

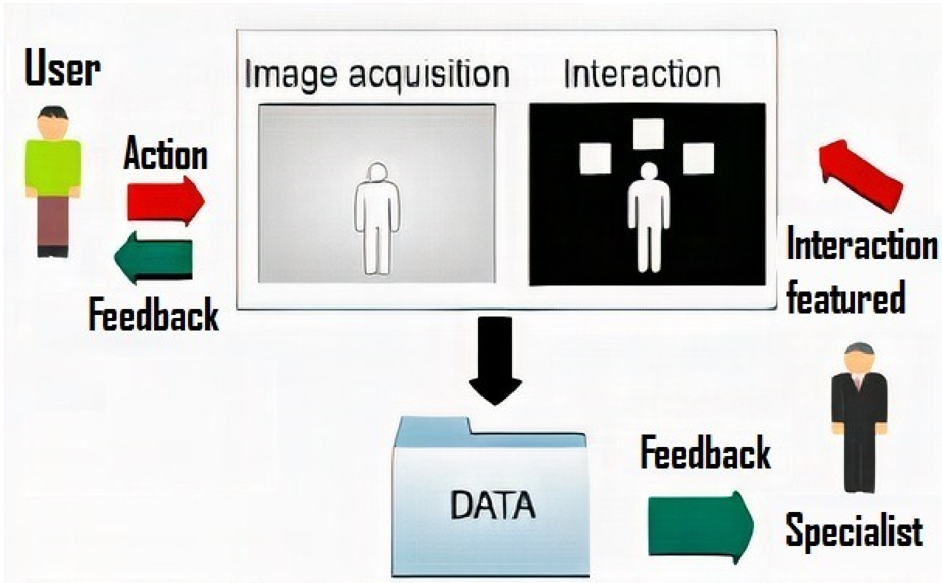

Figure 2.6: Serious game system, representing how the data is being analyzed and the feedback acquired [25].

need diverse training, such as visual feedback, and efficient interventions utilize visual feedback in conjunction with exercise for the ankle joint, likely because visual feedback enables physical self-control through continuous visual information that activated the brain's motor areas, resulting in the improvement of balance ability [86].

2.6.2 Serious games and Electromyography

Regaining muscle strength and coordination is a cognitively exhausting and repetitive process, during which the proper execution of movements is reestablished using surface EMG feedback. Transferring traditional EMG rehabilitation protocols to a virtual setting, and incorporating video games into the training process can increase the patient's engagement and perseverance. These rehabilitation games are prevalent in older adults, patients affected by stroke and Parkinson's disease [87].

Video games provide greater accessibility and allow patients to set up the games at home quickly. Games can be chosen to motivate the players and maintain engagement over a more extended period. An example of a commercially available video game for upper limb rehabilitation that has been interfaced using EMG signals is Guitar Hero (See figure 2.7) [87], which is based on rhythm and speed and requires a fast reaction from the player and direct transmission of the processed EMG signals to the gaming system. Similarly, a rehabilitation concept for stroke patients using a modified version of the WiiMote control is used for rehab purposes of the upper limb, in which EMG signals are matched to the keys of the WiiMote [87] for games similar to the classic Pong arcade, in which the user's muscle activity is mapped into a paddle motion that hits a ball into their opponent's court [87].

Some studies have implemented racing games, such as Super Tux Kart, dexterity games,

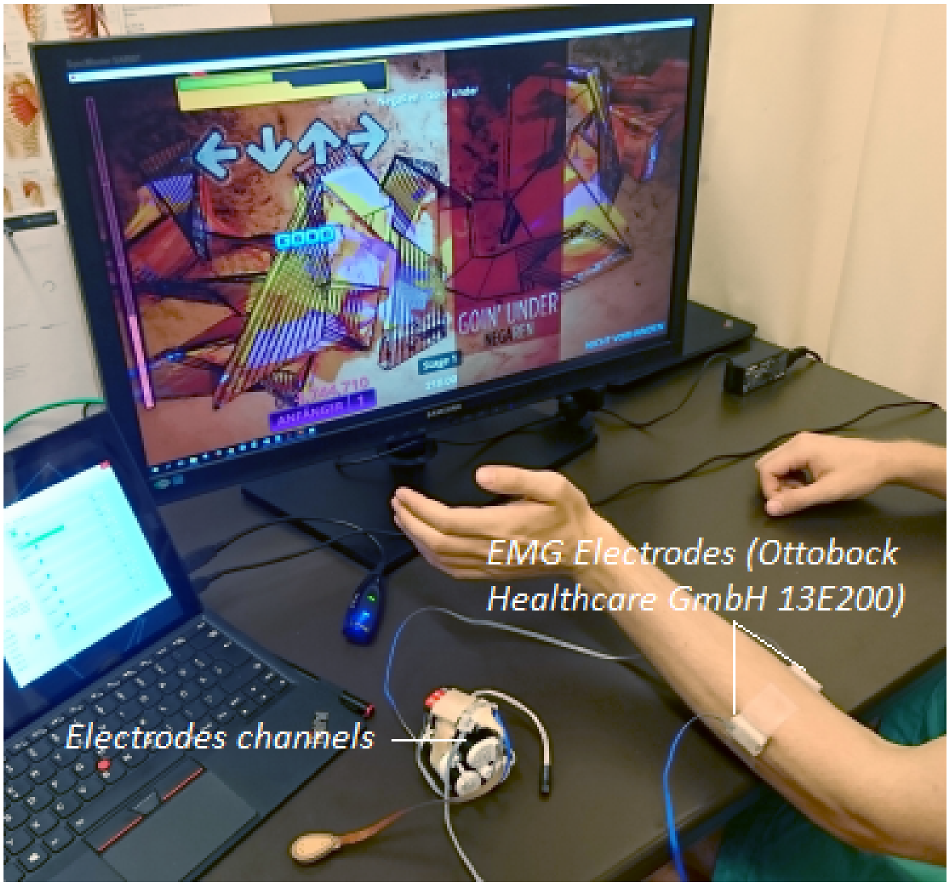

Figure 2.7: Experimental setup with Guitar hero and EMG signal acquisition from the top of the wrist's prominent flexor and extensor muscles on the participant's non-dominant side [87].

such as Pospos [87], and rhythm games like Step Mania 5 [87] (Figure 2.8). Required EMG activations were quick contractions, sustained contractions over a specific period, and co-contractions. Participants not only conducted repetitive flexor and extensor muscle activation, but also sustained contractions over varying periods, performed precisely timed contractions, and executed simultaneous contractions of flexor and extensor wrist muscles [87]. These actions can be seen in the control of games like Myo-Pong (Figure 2.9) [88], a table tennis game that demonstrates the gaming capabilities of a myoelectric real-time system. These games are a valuable graphical tool for motor rehabilitation and are controlled similarly to how patients handle an actual robotic device [87], [88].

Figure 2.8: Some Games that have been handled with EMG signals [87].

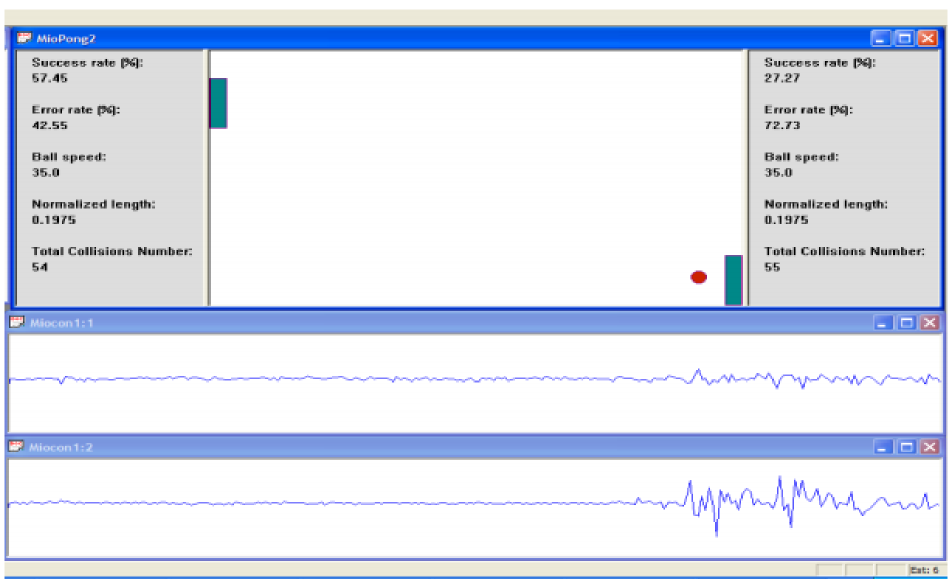

Figure 2.9: Table-tennis game (Myo-Pong) resembles a popular game of the seventies applied to myoelectric control. It is integrated into the custom UVa Neuromuscular Training System (UVa-NTS) real-time platform, developed at the University of Valladolid [88].

Every serious game includes elements of visual feedback recommended to boost the rehabilitation. The therapeutic objective is to improve the precision and smoothness in the patient's upper limb movement and recover fine motor control. The current generation of myogames typically has similarities with the activities in daily life. The configuration of the game attributes is essential to fit the games according to the needs of each patient concerning the functional capabilities [89], [90].

For lower limb rehabilitation, the combination of robotic devices and video games has been implemented to improve rehabilitative gait therapy in adults and children. These games have been developed focusing on therapeutic goals and combine all necessary elements for successful motor learning, namely repetition, augmented feedback, and motivation. In the case of the children undergoing rehabilitation often act motivation-driven rather than rationally, so it is necessary to have an appropriate graphical design and exciting theme [91].

A serious game that has been used for gait rehabilitation is *Gabarello*, which consists of collecting flowers on the surface of a planet with a little astronaut. Participants control the avatar by modulating the activity of their legs during the swing phase. The level design of the game thereby encourages deliberate increases and decreases in the exertion of the patient. Thus, the game addresses a crucial therapeutic goal [91]. This game has been used with Lokomat. The results indicate that the Gabarello can purposefully enhance and reduce the activation pattern of the patients, which is essential for a modulation of the gait pattern in response to environmental changes [91].

Other techniques based on serious games for lower limb rehabilitation are the visual-evoked routines that relate the position of a cursor on the screen with the angular position of the ankle. During the game, a sequence of targets appears alternately on two vertical levels of the screen. The subjects are asked to reach the targets and hold in them with the lowest error possible wearing an anklebot. To impose an additional challenge to the patient, a constant torque is added in the opposite direction of the targets. However, EMG signals do not get involved in the game control, just in the analyzing stage for muscles activity involved in the ankle's movement, such as tibialis anterior, peroneus longus, soleus, medial and lateral gastrocnemius, showing which one stands out the most in some specific movements [92].

2.7 Related works

The literature review related to algorithms included 27 records from the electronic databases searchers (IEEE Xplore, Scopus, PubMed, ResearchGate, and CRAI from Universidad del Rosario) using combinations of the following terms: Movement intention detection, Electromyography, Algorithm, signal, and threshold (Figure 2.10).

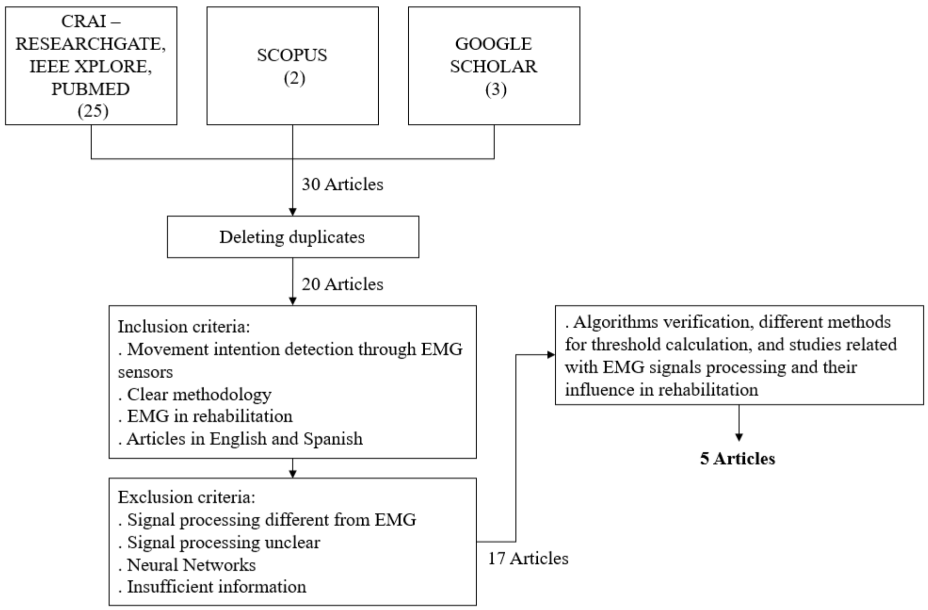

Figure 2.10: Literature review diagram for the selection of the articles considered.

In the eligibility criteria, articles in English and Spanish related to EMG in robotic rehabilitation and recovery for stroke survivors were included. On the other hand, within the exclusion terms, the quality of the information provided and the signals involved in the study, insufficient information about signal processing or the outcomes of the study were considered. Following this, five articles based on different methods for threshold calculation were selected. The results of the algorithm's detection and some other specifications from the five articles selected can be seen in Table 2.1.

Work	**Muscle**	**Sample frequency**	**Features extracted**	**Threshold type**	**Results**
J. Mickelborough *et al.* 2004 [79]	Tibialis anterior and medial gastrocnemius	500 Hz	Mean, STD	Sum of features	Efficiency of onset detection 91% - 95%
C. Lersviriyanantakul *et al.* 2016 [81]	Flexor carpi radialis and extensor carpi radialislongus	1000 Hz	STD, RMS, MAV, WL, SSI, IEMG	Feature	Maximum error in the detection of 15% using SSI as the threshold (offline)
M. Tabie *et al.* 2013 [82]	Brachioradialis, biceps brachii, triceps brachii, and deltoideus	5000 Hz	Mean, STD, WL, VAR	Adaptative threshold	VAR as the preprocessing operator and accuracy of

					78% and 85% for detection of slow and fast movements respectively
A. Avila *et al.* 2014 [83]	Deltoid	1000 Hz	Mean, STD, RMS	Double threshold	80% - 100% success in detection
A. Kontunen *et al.* 2018 [84]	orbicularis oculi	1024 Hz, 2048 Hz, 10000 Hz	Mean	CFAR threshold	Detection success 93% - 97%

Table 2.1: Results from previous works that have included EMG signal processing and movement intention detection algorithms.

One of the studies, presented in Table 2.1, aimed to describe the phasic activity of the primary muscles required to complete the task of gait initiation in normal older people to provide a baseline against which to compare the abnormal patterns of gait initiation muscle activity in elderly patients with gait initiation and balance disorders [79]. The muscle patterns were acquired through EMG signals, and it was shown that the tibialis anterior muscle was consistently active at or within 10% of gait initiation onset. However, a failure of medial gastrocnemius to be consistently inhibited at gait initiation onset is more common in older people. Moreover, it was possible to see that the tendency for muscle activity to be more variable in the preparatory phase than the stepping phase suggests that the initial phase may be a particular source of difficulty in patients with high-level gait disorders [79].

As can be seen, the study presented was focused on describing gait initiation through the analysis of the EMG signal from some muscles involved in the gait performance. Nevertheless, some other studies are focused mainly on the signal processing and detection of movement intention, such as *EMG onset Detection Comparison of different methods for a movement prediction task based on EMG.* This study aims to compare other processing methods to choose a method that can perform the detection and the earliness, in this case, of EMG activity (See Figure 2.11). The results (Table 2.1) showed that the selected method was able to detect either fast or slow movements and some facts, such as computational cost, were taken into account [82].

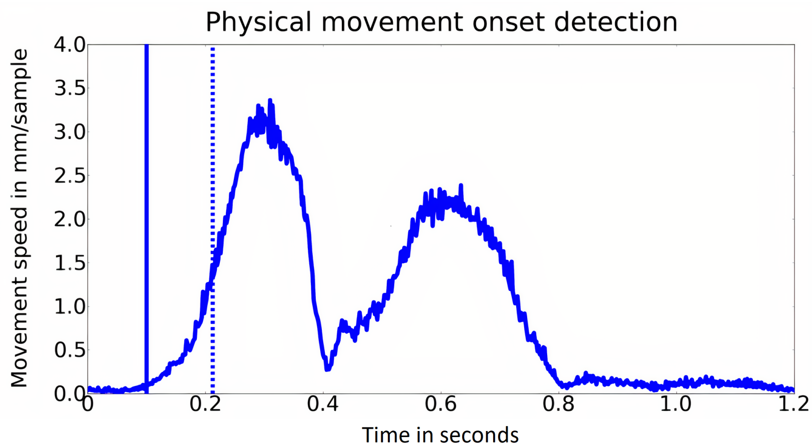

Figure 2.11: Physical movement onset detection. The dashed vertical line indicates the position of the marker from the flat board and the solid one the detected physical movement onset [82].

Other work-related with the EMG signal processing can be seen as the second study in Table 2.1), where six statistic equations were taken into account for the smoothing and threshold calculation to detect the onset times of the surface Electromyography (sEMG) signals recorded and perform them in real-time through the NY myRIO platform. The results showed that using the Simple Square Integral SSI-SSI as the smoothing-threshold equation can appropriately detect the onset time in real-time (See Figure 2.12) [81].

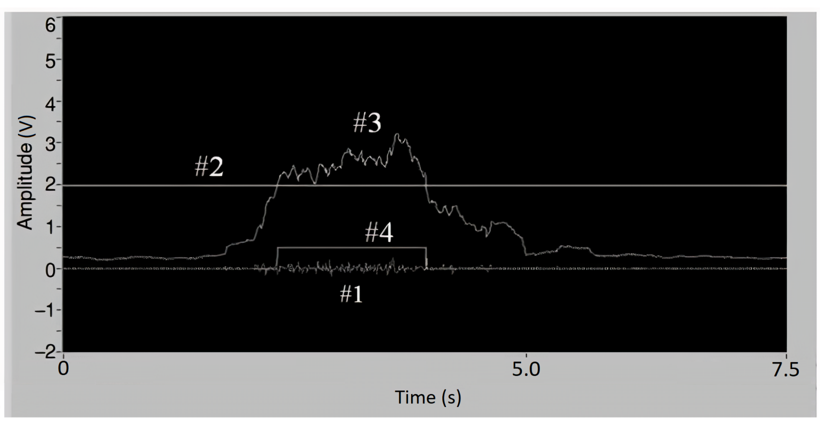

Figure 2.12: The onset time detection result. Single movement in the real-time detection simulation. The numbers #1, #2, #3, and #4 represent the raw sEMG signal, the threshold value, the smoothed graph, and the sEMG detection starting at the onset time detection [81].

In the study named *EMG Onset Detection and upper limb movements identification algorithm* was possible to see that the EMG signals have been used not only for the movement detection but also to differentiate (identify) among five different movements of the upper limb; abduction (AB), adduction (AD), flexion of the upper limb (FUL), extension of the upper limb (EUL) and AB followed by the arm to the front (ABF). It was focused on a single muscle performing different movements, and initial implementation of an algorithm for the movement intention detection was carried out. The features taken into account for the movement intention detection were the mean, and for the pattern recognition, the RMS was considered. The detection and pattern recognition can be seen in Figure 2.13.

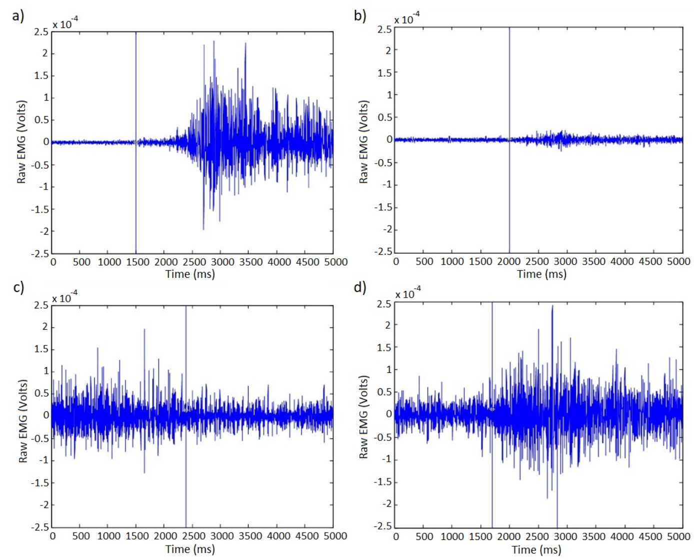

Figure 2.13: Onset detection and EMG signals of the movements performed by one person [83]. a) Signal of Middle Part Deltoid (MD) CH1 for extension of the upper limb (EUL). b) Signal of Anterior Part Deltoid (AD) CH2 for EUL. c) Signal of MD CH1 for abduction followed by the arm to the front (ABF). d) Signal of AD CH2 for abduction followed by the ABF.

In the previous study from Table 2.1, it can be seen that besides the onset detection of a movement, its termination can also be detected (See Figure 2.14). The adaptive CFAR threshold was established for the signal processing setting the parameters as R = Fs/4 and G = Fs/10, where Fs is the sampling frequency. Second threshold parameters for the M-out-of-N detectors (additional M-out-of-N sliding window applied to the binary signal to make the final onset detection) were Mo = 4 and No = 5 for onset detection, and Mt = 32 and Nt = 40 for termination detection. EMG data was gathered from 15 healthy participants. The experiment started with a one-minute-long resting task, after which the participants were asked to perform three facial movements: smiling, lip-puckering and frowning. Each movement lasted 6 seconds, and ten repetitions were instructed to be performed in random order. This study aimed to introduce an algorithm for onset and termination detection, which would be tested in physical applications [84].

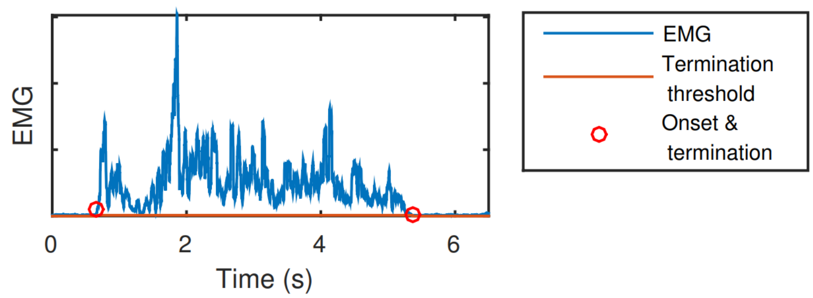

Figure 2.14: An EMG signal measured from the corrugator supercilii muscle with the termination threshold value, and detected onset and terminations points [84].

EMG signals are used in some areas besides detecting a muscle's activation, such as diagnostics, since evaluating the muscles activated in some task would allow knowing if there is a neural injury or a pathological movement [93]. The EMG signal acquisition has been involved in several rehabilitation processes. Among these, it is possible to find cases such as self-myostimulation, which has been tested in the rehabilitation of the upper limb, exerting electrical stimulation with current in the paretic limb by detecting movement intention from a healthy upper limb EMG signal. This is a process that the patient controls since he/she decides, with the healthy limb contraction, the stimulation in the other and its relaxation to increase muscle strength, decrease spasticity, maintain muscle trophism and improve the peripheral circulation [94].

Besides the rehabilitation with electrical stimulation, some other strategies have been implemented, such as controlling robotic devices based on the human's motion intent. However, after stroke, in some cases, people may have an abnormal coactivation [95], affecting detecting a specific movement. That is why analyzing movements, for instance, those made by the hand, like opening and closing in a patient post-stroke through EMG, would let know how much coactivation affects the detection of a specific movement. This process has been considered in various scenarios, like having the arm resting or raising the shoulder in its 25% maximum abduction capacity [95]. The EMG signal has been considered to classify and recognize different movements despite an inappropriate muscle co-activation. Thereby, the detection and classification of activities exerted by a patient post-stroke can be feasible [76].

In the case of robotic devices, such as robotic arm composed of exoskeleton concept, data acquisition and processing in the term of EMG and IMU sensor to the physiological concept and online data monitoring data had been developed which allow operating with both the virtual and real environment. The EMG and IMU sensors are placed in the healthy arm, and the signal from the healthy arm would be used to move the exoskeleton, which is attached to rehabilitating arm. The IMU is used to calculate the angle of the movement and the EMG sensor to acquire muscular activity. In this way, the exoskeleton system can adapt to the user [22].

It can be seen that robotic devices are being controlled through EMG signals and can improve the rehabilitation process. It is essential to establish a straightforward method for movement intention detection, so that the device that is being controlled can behave appropriately considering the patient's needs.

Chapter 3

METHODOLOGY

In this chapter, the construction procedure of the algorithm for movement intention detection would be explained. Moreover, the comparison procedure of the Electromyography (EMG) algorithm and the current movement intention detection algorithm, which T-FLEX operates, will be carried out. The strategies for obtaining, processing, and analyzing the information of the sensors are presented.

3.1 Sensors

Table 3.1: Technical information of the sensors implemented in this project.

	EMG	**IMU**
Reference	Myoware Muscle Sensor (AT-04-001)	Inertial Measurement Units (BNO055)
Supply	+2.7 V to +5.7 V	+2.4 V to 3.6 V
Output	EMG envelope, raw EMG	Accelerometer, gyroscope and magnetometer signal.
Output range	0 V - Vs	Accelerometer: $\pm 2g/\pm 4g/\pm 8g/\pm 16g$ Gyroscope switchable from $\pm 125°/s$ to $\pm 2000°/s$ Magnetometer: $\pm 1300\mu T$ (x-,y-axis) and $\pm 2700\mu$ T (z-axis)
Filters	High-pass filter 0.4 Hz	Low-pass filter Accelerometer: 1 kHz-<8 Hz Gyroscope: 523 Hz-12 Hz
Other parameters	Common Mode Rejection Ratio (CMRR)-110	Sensibility Accelerometer: 1 LSB/mg Gyroscope: 16 LSB/°/s
Applications	Videogames, robotics, Medical Devices, Wearable/Mobile Electronics, Prosthetics/Orthotics	Navigation, robotics, fitness and well-being, augmented reality, context awareness, tablets and ultra-books

The sensors used in this project can be seen in Table 3.1. In the table is shown the reference, the supply voltage requirements, the output that each sensor has, the output range in terms of voltage for the EMG sensor, and the output range in terms of acceleration for the accelerometer, angular velocity for the gyroscope, and magnetic field for the magnetometer; the filters for each sensor, the applications, and some other parameters that have been considered. The documents related to the information presented in Table 3.1 can be seen in references [96], [97], and [98].

3.2 EMG-based algorithm

This section contains a description of the EMG signal acquisition procedure, the processing to calculate the threshold, and finally, the explanation of how the movement intention detection was done.

3.2.1 Signal acquisition

A MyoWare Muscle Sensor AT-04-001 (Pololu, United States) was placed with Ag/AgCl electrodes in the tibialis anterior. The EMG signal was acquired at a sampling frequency of 1000 Hz and digitalized by Arduino Uno (10 bit resolution) (Figure 3.1); the sensor provided the signal filtered and rectified so that the output was the envelope.

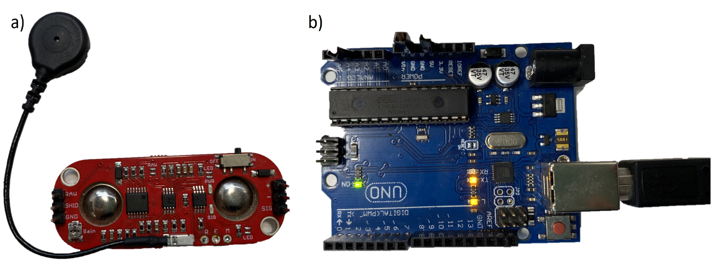

Figure 3.1: a) Myoware muscle sensor. b) Arduino Uno.

3.2.2 Data processing

Based on previous work (See reference [81]), the first 500 samples of the EMG signal (the participant did not perform any movement) were considered to get the threshold. The latter was established considering the features of variance (VAR), standard deviation (STD), Root Mean Square RMS, MEAN plus three times STD, and the MEAN of the signal, considering that in most of the previous works, these features remained selected in the feature's extraction stage. Each of these features were a different threshold. Hence, there were five methods in consideration for the detection of movement intention.

Considering the window lengths that have been taken into account in a previous study (See reference [66]), the signal was analyzed considering a window's length of 30 samples. These samples were operated and compared with the established threshold with the respective feature being evaluated. Whether the threshold was obtained with the VAR, then the signal samples were operated to get the equivalent feature and then compared with the reference value.

The variance method is then expressed in equation (3.1).

$$T = \frac{1}{N}\sum_{i=1}^{N}(x_i - \bar{X})^2 \tag{3.1}$$

The formula for the standard deviation can be seen in equation (3.2).

$$T = \sqrt{\frac{1}{N}\sum_{i=1}^{N}(x_i - \bar{X})^2} \tag{3.2}$$

In the case of the mean, is expressed by equation (3.3).

$$T = \frac{1}{N}\sum_{i=1}^{N} x_i \tag{3.3}$$

For the method based on the mean and three times the standard deviation, the formula is expressed by equation (3.4).

$$T = \frac{1}{N}\sum_{i=1}^{N} x_i + 3 * \sqrt{\frac{1}{N}\sum_{i=1}^{N}(x_i - \bar{X})^2} \tag{3.4}$$

The expression for RMS can be seen in the equation (3.5)

$$T = \sqrt{\frac{1}{N}\sum_{i=1}^{N}(x_i)^2} \tag{3.5}$$

Where T is the threshold (the reference value), N is the number of samples, x_i the value that is being analyzed and $\bar{X}$ the mean of the samples. The same expressions are used with the smaller amount of samples established for the signal analysis.

Detection procedure

The detection was based on verifying when the VAR, STD, MEAN, MEAN + 3STD or RMS of the window of 30 samples exceeds the threshold, which depends on the chosen feature in the trial (VAR, STD, MEAN, MEAN + 3STD or RMS).

3.3 T-FLEX's IMU-based algorithm review

When T-FLEX is in therapy mode, the inertial sensor placed in the foot tip and integrated into T-FLEX can estimate the user movement intention on the paretic foot, replacing the automatic movement in its control. A 4th-order Butterworth low-pass filter with a cutoff of 6 Hz removed the noise from the measured angular velocity along the sagittal plane [99]. The data was acquired at a sampling frequency of 100 Hz and subsequently, the filtered data was compared in real-time with the threshold value calculated in the calibration stage. The latter involved the same statistical features considered for the EMG algorithm as operators to establish the threshold. When the angular velocity exceeds the threshold, T-FLEX assists the dorsi-plantarflexion.

3.4 Serious Game - Jumping Guy: Ankle Rehabilitation Therapy with T-FLEX

The virtual environment and functionalities were performed with Unity software in version 2.3.1 and Windows 10. This game engine was selected because of its 3D and 2D environments and the intuitive game programming process. The sprites, sounds, and graphic resources were taken from a free retro-type game called "Jumping Guy". A pre-game calibration task was included to evaluate the ankle's range of motion. In this case, the person was asked to perform five dorsiflexion movements with the ankle and consider each one's maximum ability. This information allowed the set of thresholds that the user must exceed to perform movements with the character.

The evaluation of the user's progress during the game was based on the number of jumps and misses avoiding the enemies, the percentage of precision during the entire session, and the type of response in front of each enemy. An ideal skip was counted as one in which the avatar passes without approaching the enemy. From this, the anticipated or a delayed time response were those in which the enemy was gently closer in his back or front, respectively. "Early" was classified as a jump 0.15 s before the ideal jump, and "Late" was a jump 0.34 s after the ideal [26], [100].

3.5 Integration with T-FLEX

The integration processes of the critical components between the exoskeleton and the platform are developed. These components correspond to T-FLEX Ankle Exoskeleton, graphic Interface, IMU, and EMG sensors. Based on this and the strategies for detecting motion intention, the user would actively participate in the game. The main idea is to reflect the ankle movements parallel with the avatar movement when the dorsiflexion movement exceeds the threshold. For that purpose, the setup with T-FLEX can be seen in Figure 3.2.

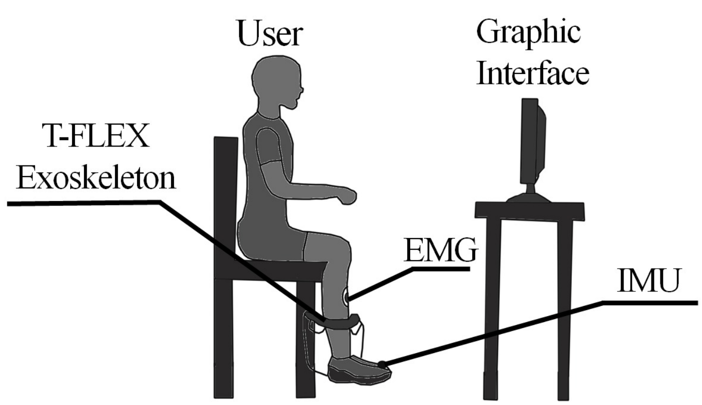

Figure 3.2: Set-up of all the critical components that makes up the present work.

As seen in Figure 3.2, the participant must be seated in a chair with ninety-degree knee flexion. The lower member where the device was located must be raised avoiding contact with the ground. Moreover, the orthosis must be used in its therapy mode.

3.6 Evaluation procedure

To evaluate the EMG algorithm and the IMU algorithm some sessions were arranged with two types of tests. The first one was a sound-pulses-based test. The second one involved implementing T-FLEX and the Serious Game *Jumping Guy: Ankle Rehabilitation Therapy with T-FLEX* (Figure 3.3).

Figure 3.3: Jumping Guy: Ankle Rehabilitation Therapy with T-FLEX.

3.6.1 Hardware

The Myoware muscle sensor AT-04-001 (Polulu, United States) was placed on the participant's Tibialis Anterior muscle (from the dominant limb) with Ag/AgCl electrodes and its signal was acquired at a sampling frequency of 1 kHz. The sensor was connected to the analog serial port A3 from Arduino UNO, and the Arduino was connected to a Raspberry Pi 4 board through its USB port.

The IMU sensor BNO055 (Bosch, Germany) was placed on the participant's foot tip, its signal being acquired at a sampling frequency of 100 Hz. The sensor was connected to the Raspberry Pi 4 I2C port. Additionally, for the first session, some headphones were also connected to the audio port from the Raspberry Pi 4. Thus, the latter ran the acquisition and the sound commands production algorithms to begin the session. The sensors' information was recorded (See Figure 3.4).

For the second session, T-FLEX was placed on the user's dominant limb (where all the sensors were placed). Another computer was facing the participant, where the Serious Game *Jumping Guy: Ankle Rehabilitation Therapy with T-FLEX* was running.

The Raspberry Pi 4 board was used for the processing. Thus, it acquires the sensors information, runs the movement intention detector algorithm, runs the control algorithms, and sends the control commands to the T-FLEX's actuators. The sensors' information and some levels of the session were recorded.

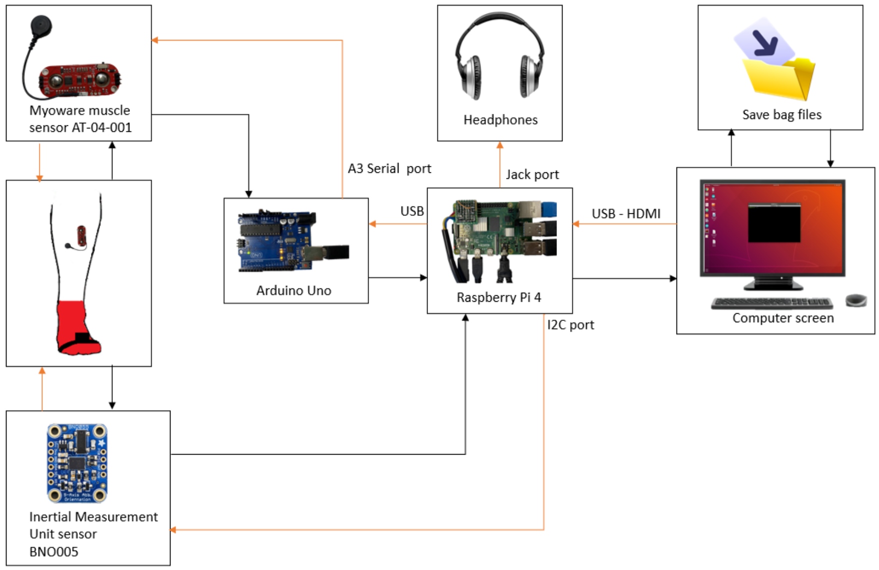

Figure 3.4: Hardware diagram for the first session of this project. The orange arrows represent the physical connection of the system and the black arrows represent the information.

3.6.2 Software

Since this project aims to use T-FLEX, the software implemented is based on the Robot Operative System (ROS) architecture. The latter is a Linux-based meta-operative system used in the robotics field. This system provides modularity to incorporate sensors and actuators already supported, operability to communicate with multiple processes, robustness against unexpected events, and quickly developed modules replicability [26].

3.6.2.1 First session

The signals acquisition and the sound commands production algorithms were deployed. The signals acquired from the EMG and IMU sensors were recorded in a .bag file to later reproduce them and implement the motion intent detection algorithm to carry out the offline processing. The outcome of the movement intention detection algorithm was the time where each contraction was done. The times were recorded in a .bag file that was processed in Matlab to visualize the signals and the detection. Moreover, the information allowed to verify and see graphically whether False Positive (FP) or False Negative (FN) values were performed.

3.6.2.2 Second session

Considering T-FLEX, the controllers, algorithms, sensor acquisitions, and the Serious Game (from a different screen) were deployed and implemented. T-FLEX has a public repository with the device's functionalities and controllers available at https://github.com/GummiExo/t_flex. This repository details the procedures to configure the actuators and the device's computer, install required libraries for proper operation and connect the device for using it. The libraries for actuators' communication and control are based on the Dynamixel Workbench package supported by Robotis (Seoul, Korea).

3.6.3 Experimental procedure

All the subjects agreed to participate in this project, followed the steps from the biosafety protocol, and signed the informed consent presented in the protocol for this project (See Annexes), which the ethics committee previously accepted. All of them were aware of the risks either from the project or related to the current situation of the pandemic.

3.6.3.1 First session

First, the subject was asked to sit in a chair, leaving the knee flexed 90 degrees making sure that the foot does not touch the floor (See Figure 3.5). The EMG sensor was placed in the tibialis anterior and the IMU sensor in the tiptoe. After arranging the sensors, the test started. Ten healthy subjects, from 20 to 30 years old, were asked to execute dorsiflexion when the sound pulses were performed, increasing their frequency from every 3 to 2 and 1.5 seconds in approximately ten minutes. The data was recorded and used to test each statistical feature that was being evaluated. This session lasted about 20 minutes, considering the arrangement stage and the test stage.

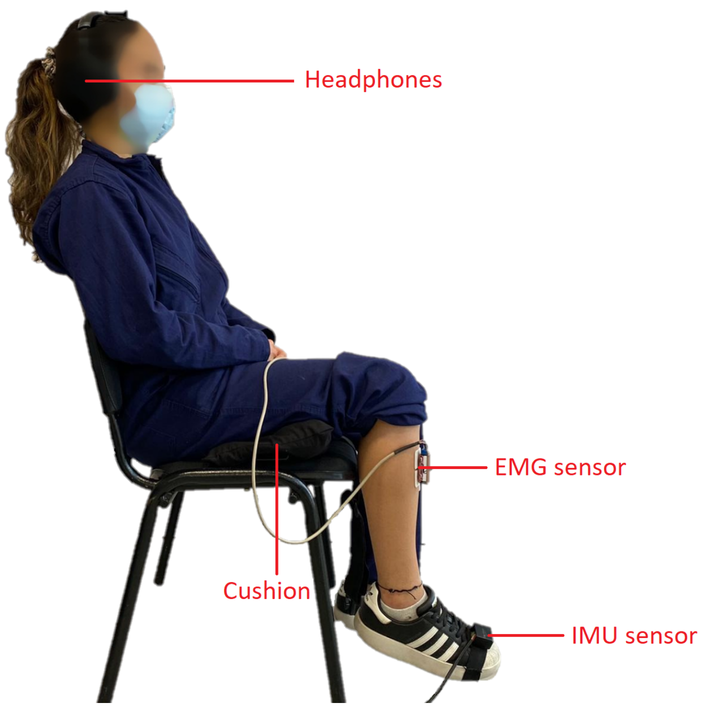

Figure 3.5: Participant in the established setup for the first session.

The data was processed offline, and a specific statistical feature, in which each algorithm performed the best detection, was selected. Both sensors were active simultaneously.

3.6.3.2 Second session

In this session, the statistical features selected in the first session were considered and the movement intention detection algorithms through the EMG sensor and the IMU sensor were tested independently using T-FLEX and the serious game as the visual feedback (See Figure 3.6). The subject followed the same instructions related to the body posture from the first session. The EMG sensor was placed in the Tibialis Anterior muscle and the IMU sensor in the tiptoe (in this case, despite the presence of both sensors, if the movement intention detection algorithm for the EMG sensor was being tested, the IMU algorithm was not running. This was fulfilled in the same way for the IMU sensor.). The serious game ran and the test began. This test lasted about 20 minutes with the EMG sensor and then the test was repeated using the IMU sensor as the movement intention detector after 5 minutes of rest, leading the duration of the session to be approximately one hour. The data was processed, and a comparison of the EMG and IMU results was carried out.

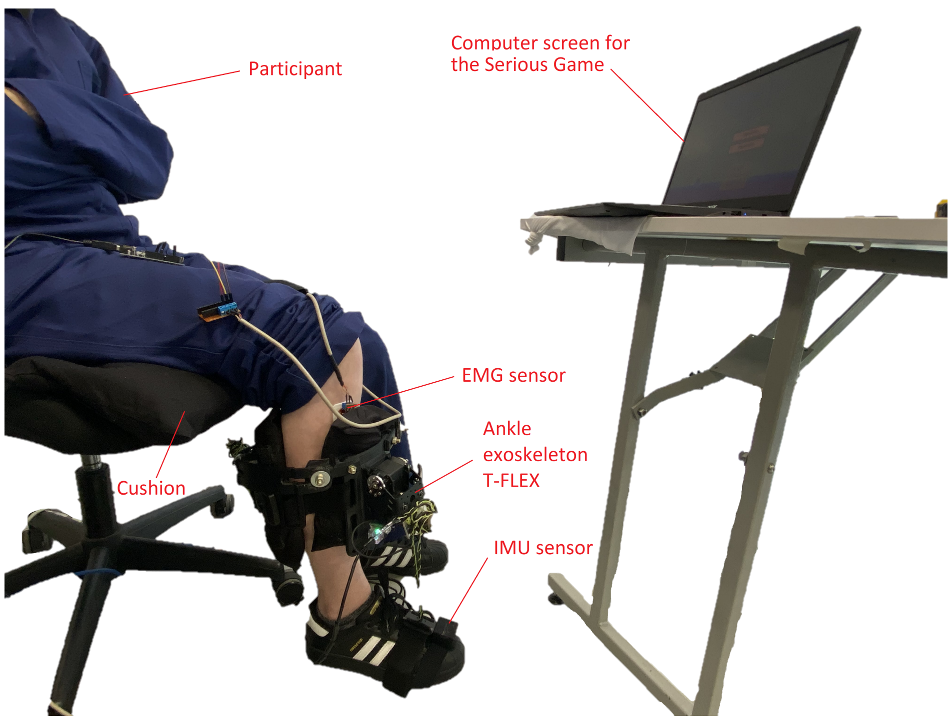

Figure 3.6: Participant in the established setup for the second session with T-FLEX and the serious game.

3.7 Data analysis and Validation

The main parameters evaluated were the detection time (DT) and the False Positive (FP) and False Negative (FN) values. In the first session, the time in which the sound pulse was generated was taken into account to see how close or how far the EMG and IMU algorithms detected the movement intention. This evaluation was carried out with all the statistical features (MEAN, STD, VAR, MEAN + 3STD, and RMS). The statistical feature that allowed each sensor to perform a low amount of FP and FN values was selected.

The statistical tests Shapiro-Wilk, Friedman and Wilcoxon were carried out to analyze the data. The first test was done to verify whether the data had normal distribution. With the results was possible to see that the data had not normal distribution, so the Friedman was implemented to see the significant differences in the parameters (FP, FN, and DT) that could exist among all the statistical features considered for the threshold establishment.

The statistical features were organized from the lowest values performed in FP and FN to the highest. This way, the features would be in the order that could perform a more accurate detection. They were analyzed by pairs implementing the Wilcoxon test to the parameters that had significant differences considering the results from the Friedman test, and this way, verify the significant differences that may have the selection of a specific feature for the threshold establishment. Finally, with the selected feature for each sensor, the Wilcoxon test was carried out to see whether significant differences in the movement intention detection with each sensor exist.

For the second session, considering the specific features selected for each sensor, the parameters of Precision, Hits, Mistakes, Ideal Jumps (IJ), Early Jumps (EJ), and Late Jumps (LJ) were evaluated. The IJ represented the jumps of the avatar that completely avoided the enemy; EJ represented the jumps performed 0.15 s before the ideal jump, and LP represents a jump 0.34 s after the ideal. The results from the EMG detection method were compared with the results from the IMU method. Some levels and the scenery of the session were recorded to analyze how the movements were done.

3.8 Satisfaction evaluation

At the end of the second session, the participant filled out two surveys (See Annexes), expressing how does he/she felt in the test considering the ankle exoskeleton T-FLEX, the detection carried out with both sensors, and the Serious Game as the visual feedback.

Chapter 4

RESULTS

This section presents the results of the experimental sessions, where there are some figures that show the acquired signals and the detection of the algorithms of both sensors, some Tables showing the performance of each sensor, and the results of the questionnaires. The latter involves a qualitative evaluation of the virtual environment and the detection of movement intention system carried out with T-FLEX.

4.1 First session

The signals recorded in the .bag file from each subject were displayed in ROS with PlotJuggler (See Figure 4.1), so that it was possible to see the data that was being acquired from the Electromyography (EMG) sensor and the Inertial Measurement Unit (IMU) sensor.

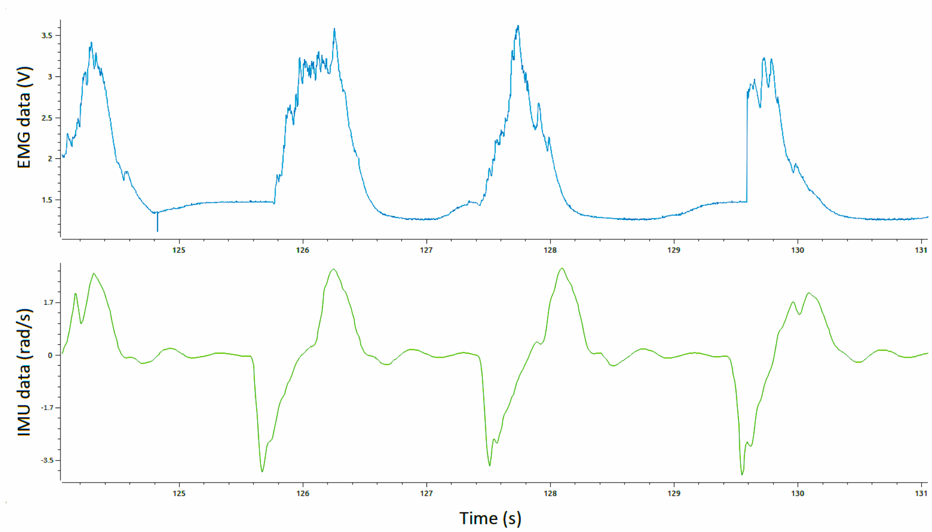

Figure 4.1: Signals acquired from the Myoware muscle sensor and the inertial sensor. At the top of the graph, it is possible to see the signal of the Tibialis Anterior muscle, and in the bottom, it is possible to see the angular velocity from the Gyroscope in the y axis.

Matlab was used to extract the data from the bag files. The data corresponded to the time when the sound pulses were performed, the time when the algorithm detected the movement intention from the sensors, the time in which each sample of the IMU and EMG data was acquired, the IMU data in rad/s, and EMG data in voltage (V).

This information was saved in a csv file. The information was used to see in a graph when the detection occurred, the time when the sound pulses performed and the signal from the participant that was being evaluated. Moreover, other calculations were carried out, such as the difference of time between the pulse and the detection to know the time that the algorithm took to detect the movement intention, and the number of False Positive (FP) (times that the algorithm detected a movement intention when the movement was not performed) and False Negative (FN) (times that the algorithm did not detect a movement intention when the movement was performed) values obtained from the sensors. An example of the detection carried out by the algorithm can be seen in Figure 4.2.

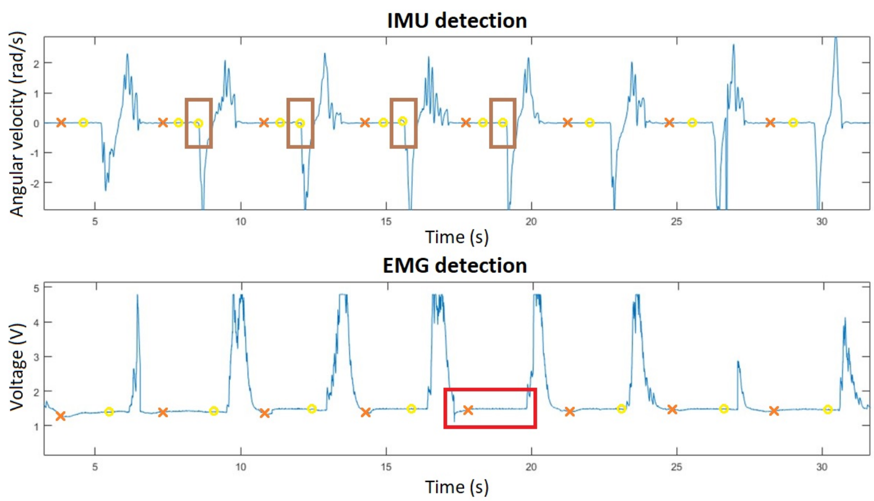

Figure 4.2: Signals acquired from the IMU and EMG sensors. An orange "x" represents the sound pulse, and the algorithm's detection is represented by a yellow "o". The brown boxes show an example of how the FP values were performed, and the red box shows an example of the FN values.

The information extracted from the csv files from each person, considering the IMU sensor performance, can be seen in Table 4.1. It is possible to see that the detection time varies the most from each participant with the features of STD, VAR, MEAN + 3STD and RMS, while with the MEAN, the detection time remained close to one another. Moreover, the MEAN feature had fewer FN values, comparing it with the other features.

Table 4.1: Results of the algorithm for detection of movement intention with the IMU sensor, where STD is Standard deviation, VAR is the Variance, RMS is the Root Mean Square value, FP corresponds to False Positives, FN to False Negatives, and DT to Detection Time (difference of time between pulse and detection in seconds).

	STD			**VAR**			**MEAN + 3STD**			**RMS**			**MEAN**		
	FP	**FN**	**DT**	**FP**	**FN**	**DT**	**FP**	**FN**	**DT**	**FP**	**FN**	**DT**	**FP**	**FN**	**DT**
P1	0	189	2,067	0	182	2,059	0	117	1,853	50	0	0,885	7	0	0,630
P2	0	218	2,601	53	0	0,962	0	189	2,281	0	177	2,216	6	0	1,247
P3	0	57	1,552	0	191	2,088	0	195	2,366	50	0	0,886	14	0	1,403
P4	0	92	1,694	0	0	1,266	50	0	0,885	50	0	0,885	6	0	1,640
P5	49	0	0,887	49	0	1,230	50	0	0,886	0	165	2,327	67	0	1,401
P6	0	11	0,784	0	226	2,610	0	31	1,216	50	0	0,886	0	1	1,119
P7	374	0	0,709	0	235	0,250	0	10	1,539	50	0	1,229	1	0	1,128
P8	0	94	2,061	0	225	2,606	0	29	1,164	0	234	2,699	7	0	1,129
P9	0	87	2,058	0	215	2,414	0	13	0,804	0	222	2,486	1	0	1,136
P10	0	160	2,007	232	0	2,549	0	9	1,593	0	235	1,005	14	0	1,405

The information extracted from the csv files from each person, considering the EMG sensor performance, can be seen in Table 4.2. It is possible to see that the detection time varies the most from each participant with the features of MEAN, MEAN + 3STD, and RMS, while with the STD and VAR, the detection time remained close to one another. However, the VAR feature had fewer FP and FN values, comparing it with the other features.

Table 4.2: Results of the algorithm for detection of movement intention with the EMG sensor, where STD is Standard deviation, VAR is the Variance, RMS is the Root Mean Square value, FP corresponds to False Positives, FN to False Negatives, and DT to Detection Time (difference of time between pulse and detection in seconds).

	STD			**VAR**			**MEAN + 3STD**			**RMS**			**MEAN**		
	FP	**FN**	**DT**	**FP**	**FN**	**DT**	**FP**	**FN**	**DT**	**FP**	**FN**	**DT**	**FP**	**FN**	**DT**
P1	0	8	1,441	2	0	1,369	4	0	1,359	116	0	0,893	0	46	1,033
P2	19	0	0,475	22	0	0,461	40	0	0,527	0	102	1,616	33	0	0,507
P3	32	0	0,605	0	8	1,258	64	0	0,543	11	0	1,450	72	0	0,569
P4	0	7	1,193	0	2	1,423	116	0	0,888	116	0	0,893	0	3	1,384
P5	0	1	1,361	2	0	1,347	2	0	1,346	0	46	1,064	0	51	1,467
P6	0	56	1,090	0	11	0,910	0	34	0.920	31	0	1,313	0	56	1,426
P7	65	0	0,796	4	0	1,509	26	0	0,627	10	0	1,286	68	0	0,594
P8	0	46	1,080	0	23	1,573	0	32	0,963	0	44	1,011	0	37	1,364
P9	0	43	1,613	2	0	1,515	50	0	1,827	71	0	1,224	76	0	0,663
P10	0	7	1,838	31	0	0,488	24	0	0,677	10	0	1,593	70	0	0,619

The data was statistically analyzed (See Table 4.3). The Shapiro-Wilk test was used to see the normality of the data. The p-value less than 0,05 indicate that the data distribution is not normal. Hence, considering that the data are paired, the Friedman test was used (See Table 4.4), and it gave a p-value greater than 0.05, except for the FN parameter for both sensors. The latter indicates that there are significant differences in the FN values performed in the detection among the statistical features for each sensor.

Table 4.3: Statistical analysis with the Shapiro-Wilk test to determine whether the data has a normal distribution. The data highlighted in blue represents the most suitable values of FP and FN, considering each sensor's statistical features. In bold, it can be seen the values of FP and FN from the features that would be the following to be considered.

Sensor	Feature	Parameter	Mean±Std	p-value Shapiro-Wilk
IMU	MEAN	FP	12,3±19,83	p<0,01
		FN	0,1±0,31	p<0,01
		DT	1,2±0,26	0,23
	STD	FP	42,3±117,56	p<0,01
		FN	90,8±77,91	0,33
		DT	1,6±0,64	0,17
	VAR	FP	33,4±72,93	p<0,01
		FN	127,4±110,77	p<0,01
		DT	1,8±0,82	0,13
	MEAN+3STD	FP	**10,0±21,08**	p<0,01
		FN	**59,3 ±77,76**	p<0,05
		DT	1,4±0,56	0,20

	RMS	FP	25,0±26,35	p<0,01
		FN	97,3±108,27	p<0,01
		DT	1,5±0,76	p<0,01
EMG	MEAN	FP	31,9±35,58	p<0,01
		FN	19,3±24,73	p<0,01
		DT	0,9±0,41	p<0,05
	STD	FP	**11,6±21,76**	p<0,01
		FN	**16,8±22,21**	p<0,01
		DT	1,1±0,43	0,94
	VAR	FP	6,3±10,934	p<0,01
		FN	4,4±7,63	p<0,01
		DT	1,1±0,417	p<0,05
	MEAN+3STD	FP	32,6±36,96	0,06
		FN	6,6±13,92	p<0,01
		DT	0,9±0,42	0,20
	RMS	FP	36,5±47,03	p<0,01
		FN	19,2±34,59	p<0,01
		DT	1,2±0,26	0,44

Table 4.4: Statistical analysis with Friedman test considering all the statistical features for the threshold establishment and the parameters for each sensor.

Sensor	**Parameter**	**Friedman (p-value)**
EMG	FP	0,12
	FN	**p<0,01**
	DT	0,19
IMU	FP	0,07
	FN	**p<0,05**
	DT	0,65

Table 4.3 shows the average and standard deviation of the FP and FN values in both sensors, where the lowest values (highlighted in blue) are presented with the MEAN feature and the VAR feature for the IMU and EMG sensors, respectively. Hence, a second feature was selected depending on the FP and FN values performed to verify between one another the existence of significant difference. To select the second feature, the data was organized from the lowest to the highest FP and FN values to see the order of the features that could work in the detection. The FP and FN values from the second feature for each sensor can be seen in bold, where for the EMG sensor is the STD feature, and for the IMU sensor is the MEAN+3STD.

Wilcoxon test was implemented per sensor with those two features and the two following features beginning from the second previously analyzed until the last feature is compared.

The p-value was fewer than 0.05 considering the first two features for the IMU sensor (The most suitable among all the features), indicating that there was significant difference (See Table 4.5). With the EMG was possible to see that the statistical analysis (in pairs) of the organized features gave a p-value greater than 0.05, indicating that there was not significant differences.

Table 4.5: Statistical analysis with Wilcoxon test considering two features. The features were organized from the lowest to the highest in terms of FN values. This order was considered to analyze each feature with the following and verify whether significant differences exist.

Sensor	**Features**	**Wilcoxon p-value**
IMU	MEAN vs MEAN+3STD	**0,01**
	MEAN+3STD vs STD	0,19
	STD vs RMS	0,90
	RMS vs VAR	0,68
EMG	VAR vs STD	0,06
	STD vs MEAN+3STD	**0,02**
	MEAN+3STD vs MEAN	0,06
	MEAN vs RMS	0.83

The fact that for the IMU sensor the first two features (the most suitable for the detection in terms of FP and FN values) presented significant differences, led to choosing the MEAN as the operator to establish the threshold, taking into account that the subject would have more control with T-FLEX activation and the Serious Game progression. On the other hand, since the first two features for the EMG sensor did not present significant differences, the selection of the feature was based on the FP and FN performed, considering the one that could allow the subject to have control in T-FLEX activation and the Serious Game, which corresponds to VAR.

Table 4.6 shows the results of Wilcoxon test, which was implemented to see whether the detection with both sensors and the statistical feature selected for the threshold establishment had significant differences in the parameters. This Table shows that there are not significant differences.

Table 4.6: Statistical analysis with Wilcoxon test considering the features selected for each sensor (MEAN for IMU and VAR for EMG).

Parameter	**IMU (MEAN)**	**EMG (VAR)**	**Wilcoxon p-value**
FP	12,3±19,83	6,3±10,934	0,6
FN	0,1±0,31	4,4±7,63	0,1
DT	1,2±0,26	1,1±0,417	0,9

4.2 Second session

Since the features for the IMU and EMG sensors were chosen, the second session took place with the Ankle exoskeleton T-FLEX and the Serious Game *Jumping Guy: Ankle Rehabilitation Therapy with T-FLEX*. The Second session was carried out as a study case, where two subjects participated and tested the Serious Game with the IMU and EMG sensors as the activation command for T-FLEX. The performance of the subjects in the Game with T-FLEX can be seen in Table (4.7. In this table can be seen the parameters of Precision, Hits, Mistakes, Ideal Jumps (IJ), Early Jumps (EJ) and Late Jumps (LJ). The precision expresses in percentage the hits achieved concerning the expected total; the hits represent all the enemies avoided by jumping over them; the mistakes represent all the enemies that were missed; IJ represents the jumps of the avatar that completely avoided the enemy; EJ represents the jumps performed 0.15 s before the ideal jump, and LP represents a jump 0.34 s after the ideal.

Table 4.7: Results from the second session using T-FLEX and the Serious game. In bold can be seen the greatest precision percentage performed among the sensors in each level of the Serious Game, and in red can be seen the minimum percentage of precision that each sensor achieved.

Participant	*Level*	*Sensor*	*Precision*	*Hits*	*Mistakes*	*IJ*	*EJ*	*LJ*
P1	1	*IMU*	89.5%	102	12	71	16	15
		EMG	**89.7%**	104	12	59	7	38
	2	*IMU*	**79.9%**	83	3	76	6	49
		EMG	78.9%	138	37	76	4	58
	3	*IMU*	**91.7%**	209	19	77	3	129
		EMG	85.9%	195	32	107	12	76
P2	1	*IMU*	**94.1%**	112	7	68	13	31
		EMG	74.1%	83	29	41	3	39
	2	*IMU*	72.7%	128	48	75	19	34
		EMG	**82.9%**	136	28	75	21	40
	3	*IMU*	**84.3%**	194	36	121	31	42
		EMG	78.4%	178	49	89	25	64

The performance of the participants in the game can be seen graphically in Figure 4.3 considering the IMU and EMG sensor. Graphs a) and b) correspond to the performance of both participants with the IMU sensor in the Serious Game. Graphs c) and d) correspond to the performance of both participants with the EMG sensor in the Serious Game. It possible to see that with the EMG sensor, the amount of late jumps and failures were higher than with the IMU sensor. However, the amount of IJ prevailed respect to EJ, LJ and failures in both cases.

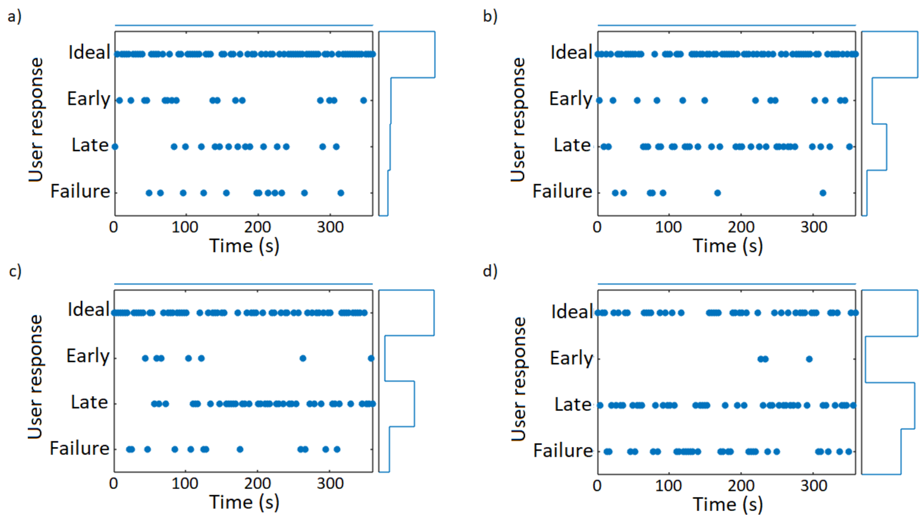

Figure 4.3: Visualization of the participants' performance in the first level of the Serious Game. a) The performance of the first participant in the first level with the IMU sensor. b) The performance of the second participant in the first level with the IMU sensor. c) The performance of the first participant in the first level with the EMG sensor. d) The performance of the second participant in the first level with the EMG sensor.

4.3 Questionnaires

After the second session, the participants from the study case were asked to answer two questionnaires (See annexes). The results from the device satisfaction questionnaire can be seen in Table 4.8. It can be seen that the device received a 5,0 points score in the criteria of *Ease of use* and *Effectiveness*, showing that the participants were satisfied with everything related to the device function. The other criteria received a similar score, giving as a result, an overall score of 4,18 (considering the average of the evaluation of both participants) for the satisfaction with T-FLEX.

Table 4.8: Results from the participants in the study case with the experience with T-FLEX. In red can be seen the criteria that received the lowest score respect to the given scores. In green is possible to see the criteria that received a maximum score from the participants.

Criteria	Total evaluation P1	Total evaluation P2
Dimension	4,0	4,0
Weight	3,0	4,0
Ease of implementation	4,0	3,0
Posture	4,0	5,0
Ease of use	5,0	5,0
Effectiveness	5,0	5,0
Comfort	4,0	4,0
Security	4,0	4,0
Device satisfaction	**4,1**	**4,2**

The results from the second questionnaire can be seen in Table 4.9. This Table shows the participant's experience in the session, mainly considering the visual feedback and the experience with the sensors in the Serious Game progress. The *Learning* item refers to understanding all the game's dynamic and its potential in ankle therapy. The *Operability* item is about handling the game (speed, reaction time with the sensors over the avatar, interface, and game duration). The *Attractiveness* item is about the aesthetic part of the game. The *Communication* item refers to the explanation of the game methodology and the messages that it provides. The *Satisfaction* item verifies the goals, feedback performance and opinion about the implementation in therapy. The last item, the *motivational model*, refers to the motivation and fun that the game can provide.

The overall results were the same for both participants. However, in the items of *Attractiveness*, *Communication*, *Operability* and *Learning*, the participants experience was slightly different.

Table 4.9: Results from the participants in the study case with the methodology carried out in the session.

QUEST item	Total evaluation P1	Total evaluation P2
Learning	4,5	4,6
Operability	3,9	3,7
Attractiveness	4,6	4,4
Communication	4,3	4,6
Satisfaction	4,2	4,2
Motivation model	4,0	4,0
Session experience	**4,3**	**4,3**

Chapter 5

DISCUSSION

This study aimed to develop and Electromyography (EMG) interface based on movement intention detection for the activation of the ankle exoskeleton T-FLEX. Therefore, a threshold-based algorithm for the Tibialis Anterior EMG signal (muscle involved in the ankle dorsiflexion) was proposed. The algorithm considered the statistical features extraction for the threshold establishment. These features corresponded to the MEAN, standard deviation (STD), variance (VAR), MEAN + 3STD, and the Root Mean Square value (RMS).

The movement intention detection system with which T-FLEX have already worked is with an Inertial Measurement Unit (IMU) sensor placed on the foot tip. The algorithm for this sensor was based on the threshold establishment through the extraction of the statistical feature MEAN. Hence, the movement intention detection with the EMG and IMU algorithms were evaluated, considering the same statistical features proposed for the threshold establishment for the EMG, to see whether the performance of the EMG algorithm is accurate with a specific feature and if the IMU algorithm enhance its performance with a different statistical feature. The algorithms were tested with each statistical feature independently and the experimental procedure to evaluate the statistical features in the detection of movement intention was divided into two sessions.

In the first session, the EMG and IMU algorithms were running simultaneously and the participants had to do a dorsiflexion movement at the moment when they hear the sound pulse. The total number of sound pulses in the ten minutes of the session was approximately 237, so the participant had to do the same number of movements. Ideally, the algorithms would have to detect the same amount. However, as can be seen in Table 4.1 and Table 4.2, with the features used for the threshold establishment the algorithms presented False Positive (FP) and False Negative (FN) values, showing that the detection was not completely accurate.

In order to avoid an uncomfortable experience in the second session, the main criteria to the establishment of the statistical features as the threshold operators was based on allowing the subject to have the control of T-FLEX and the Serious Game, which could be achieved by avoiding a high amount of FP and FN values. This way, the FP and FN values performed by each feature were analyzed. The average of the FP and FN values presented in all the features can be seen in Table 4.3, and it is possible to notice that some features did not perform a high amount of FP and FN values respect to the others, which would mean that the detection was more accurate.

Statistical tests, such as Shapiro-Wilk, Friedman and Wilcoxon, were carried out (see Table 4.3, Table 4.4 and Table 4.5). The p-value from the Shapiro-Wilk test showed that the data had not a normal distribution. This led to applying the Friedman test, considering that the data were paired, obtaining a p-value lower than 0.05 for the FN parameter in the EMG sensor and IMU sensor, showing that there were significant differences between the detection carried out with all the statistical features considering that parameter.

Considering the results presented in Table 4.3, it was possible to see that among all the features, MEAN was the most suitable in terms of FP and FN values for the movement intention detection using the IMU sensor and for the EMG sensor, VAR was the most suitable. These features presented an error below 10% in the detection. The average of the detection time (DT) of each feature can be seen in Table 4.3 and it is possible to see that the DT remained approximately 300 ms lower with the EMG sensor than with the IMU sensor. However, among the statistical features that had the lower amount of FP and FN values for each sensor, the DT remained close ($\pm$ 100 ms).

To analyze the data from Table 4.3, as was previously mentioned, the Friedman test was implemented, and the results demonstrated that the parameters of FP and DT did not have significant differences. However, each sensor presented significant differences in the detection considering the FN parameter (See Table 4.4). In Table 4.3 was possible to see that the FP and FN values presented were close in the MEAN and MEAN+3STD features considering the IMU algorithm. Hence, each feature was organized from the one that performed the lowest FP and FN values to the highest and verify whether the selection of the following feature can affect the results in the detection. The Wilcoxon test was applied to those features by pairs considering the FN parameter from each feature due to the results given in Table 4.4 and see if they had significant differences. Table 4.5 shows that significant differences exist between choosing MEAN or MEAN + 3STD as the threshold operators for the IMU sensor, despite that the MEAN + 3STD was the second feature to perform the lowest FP and FN values. Therefore, the MEAN feature was selected due to the test results and having the lower amount of FP and FN values among all the statistical features.

The FP and FN values were close in the STD and VAR features considering the EMG algorithm. The features were organized from the one that performed the lowest FP and FN values to the highest and the Wilcoxon test was applied to those features by pairs to see whether they have significant differences. In Table 4.5 it is possible to see that there was not significant difference, and considering that the subject would have more control with T-FLEX activation and the Serious Game progression with few FP and FN values, the VAR was selected.

The first two features mentioned above for the EMG algorithm have already been evaluated in a previous study (See reference [82]) for the preprocessing stage of the EMG signal. The latter study evaluates how early is done the movement prediction considering the statistical feature used for the preprocessing. With these features a fast prediction was achieved, and for this reason they say that modifying the threshold with these features would improve the detection, mainly with VAR, due to its low computational cost with respect to STD.

On the other hand, in Table 4.3 was possible to see that, with the EMG algorithm, the MEAN performed six times more FP values respect to the VAR, and this fact was also presented with the feature MEAN + 3STD. The error presented with the latter feature in the detection was over 13%, while in a previous study (See reference [79]) the error considering this feature was from 5% to 9%. However, analyzing the MEAN and STD features separately, the error achieved was about the 13% and the 5% for the MEAN and STD, respectively. These features have been used for the establishment of a double threshold (See reference [83]), where the error in the detection was about 20%. This shows that considering a double threshold for the algorithm used in this project would perform a more accurate detection respect to the study mentioned.

To analyze the features selected for each sensor for the threshold establishment, the Wilcoxon test was implemented (See Table 4.6). It was possible to see that the p-value in all the parameters indicate that there were not significant differences between the EMG and IMU performance. This way, the statistical results show that each algorithm could not stand out more than the other in the detection.

It is crucial to know that, at the moment of implement the algorithms in real-time, the reaction time could be affected by the FP and FN values presented. These values can be presented because of the way that the threshold is calculated with the statistical features or external factors. The latter can be explained by the fact that some subjects manifested tiredness in the final part of the test. About 60% of the participants felt sleepy, and some others found the cushion that kept the leg above the floor uncomfortable. These events could have affected the results of the detection carried out by the algorithms. That is, the presence of stages where muscle activity was not seen despite the order made by the sound commands, movements related to getting into the seat for more comfort, or early movement performance when the participant thought the sound pulse would sound.

For this reason, considering the second session, the algorithms for detecting movement intention were evaluated for each sensor in real-time to verify their performance. Some adjustments were carried out, such as increasing samples for the threshold calculation to ensure that a high amount of FP values would be avoided. The latter was done to prevent FP values as activation commands for T-FLEX and ensure that the subject has control of the orthosis in the longest possible time of the test. However, when the participants were doing the test, some FP values appeared, making it challenging to handle the orthosis in some parts of the game.

The participants expressed that the difficulty was more significant when the FP values appeared when the EMG sensor was being tested. This happened because, even though at the beginning, the EMG sensor and algorithm received some changes to enhance the results, when the exoskeleton T-FLEX was placed, the sensor received increase pressure to the muscle. The signal that was being received arrived with more noise, affecting the stage of the threshold calculation and, thus, the movement intention detection. The pressure over the sensor was giving the sense of muscular activity, and the algorithm was detecting a high amount of FP values, activating the exoskeleton even when the participant was not performing any movement. This situation led to adding some delays in the algorithm so that there would be enough time to detect the first movement (intended from the participant) and then wait some time without detecting anything.

When the session started, with all the changes made to enhance the ankle exoskeleton T-FLEX, with the EMG signal, it was possible to see that the detection was slow, comparing it with the person's moment doing the dorsiflexion movement. When the game started, the participants expressed that the detection from EMG was slow (It can be seen in Figure 4.3), expressed in the parameter "Late".), and when some FP value appeared, it was difficult to handle it. On the other hand, the participants expressed that the detection of movement intention from the IMU sensor was faster, according to when the dorsiflexion movement was performed, and although there were more FP values than with EMG, the participants expressed that those moments did not bother the rest of the test.

The results from Table 4.7 showed the results after finishing all levels of the Serious Game, in which a higher precision was achieved with the IMU sensor. With the IMU sensor, the amount of "Hits" (enemies overcome) was higher than the EMG sensor, except for the second level. The minimum precision obtained from the system based on movement intention detection from the IMU sensor was 72,7% and with the EMG sensor was 74,1%. The maximum precision of the system considering the IMU sensor was 94,1%, while it was about 89,7% for the EMG sensor. It was possible to see that the participants had the lowest precision percentage in the second level. This could have happened because this level was a transition where the FP values started to affect in both participants performance, showing this values without having the same period of time as in the first level to avoid failures. This FP values were close to the real movement, so the performance and precision of both participants improved in the last level, where the frequency of the enemies increased and the FP values appeared close to the movement and did not let the avatar fall right over an enemy.

Considering a previous study, which involves the movement intention detection with EMG in the lower limb (See reference [84]), the minimum precision achieved was 93% and the maximum was 97%, while in Table (4.7) is possible to see that the minimum was 74,1% and the maximum was 89,7%. Although the signal in the previous study and in this study corresponded to the lower limb, the previous study used a threshold with more complexity in its calculation. This way, more accuracy in the detection could be achieved.

Two questionnaires were done to know the participants perspective in the second session study case. Table 4.8 shows the score given by the participants considering their experience with T-FLEX, which according to the score, their experiences were similar. The 87.5% of the criteria established in the questionnaire received a score of 4,0 and 5,0. It could be seen that the *Ease of use* and *Effectiveness* were parameters in the criteria that both participants agreed and scored with five points. However, in the *Weight* and *Ease of implementation* parameters, the participants alternated a 3,0 score (lowest considering all the already given scores), showing that the experience considering those parameters from the criteria was regular. However, the general score shows a high level of adaptability of the user to T-FLEX. Moreover, the participants expressed as the three most important aspects the *Ease of use*, *Device effectiveness*, and *Device security*.

On the other hand, in Table 4.9, the participants' experience with the Serious Game and its handling with the sensors were the same in terms of score. The lowest score can be seen in the *Operability* item, which contains the game performance and the movement intention detection performance with the sensors. Due to the difficulty handling the EMG sensor and the FP values to progress in the Game, this sensor received a lower score than the IMU sensor. Despite the performance with the sensors, the overall score represents that the participants did not have a bad experience.

All the information mentioned above suggests that it is necessary to fix some parameters considering external factors to improve the movement intention detection algorithms. Moreover, taking into account that in this study, the IMU sensor presented a faster reaction and that the EMG sensor presented fewer FP values than the IMU sensor, a combination of both strategies could lead to an algorithm that can give a more accurate performance.

Chapter 6

CONCLUSIONS

Games controlled by Electromyography (EMG) can be handled by quick contractions, prolonged contractions, or simultaneous contraction of the flexor and extensor muscles. They have shown to be a graphical tool for control training for robotic devices, since the actions are similar to how subjects would control a real device. Also, they are considered as a tool for motor rehabilitation and have shown more outstanding results than using just EMG assessment.

It is necessary to know the functionality of the muscles involved in specific movements for rehabilitation. The lower limb does not require delicate motor control tasks, so it is not needed to recruit multiple muscles to analyze a particular movement. Thus, EMG signals have been considered to evaluate, for instance, gait performance and motor learning, centering in some muscles (those who contribute more).

The EMG has been considered to assist movements by detecting motion intention and control of robotic rehabilitation systems, such as exoskeletons, to assist flexion and extension exercises. Thus, EMG is a potential tool for the implementation of robot-assisted rehabilitation.

Studies have shown different methods for detecting the movement intention from the EMG signal. They can be based on features extraction, such as mean, standard deviation (STD), variance (VAR), Root Mean Square (RMS), to establish a threshold, or more complex processes involving Neural Networks. However, an appropriate detection has been achieved with statistical features as the threshold, as is in the case with VAR. Hence, it is possible to predict the movement simply and efficiently.

The ankle exoskeleton T-FLEX has two modes of operation, gait mode and therapy mode, and for this study, the therapy mode was considered. T-FLEX already had an algorithm for movement intention detection considering an Inertial Measurement Unit (IMU) sensor. Thereby, this study aimed to develop a threshold-based EMG algorithm to detect the movement intention detection. It was compared the movement intention detection through an EMG sensor and the IMU sensor to control of T-FLEX. This comparison was made considering the statistical features MEAN, VAR, STD, MEAN + 3STD, and RMS as operators for the threshold establishment.

Each statistical feature was evaluated to figure out which one could fit more for the movement detection for each sensor. The best feature, considering the False Positive (FP) and False Negative (FN) values performed, was selected. This process was carried out in a session that lasted about 10 minutes. A second session was carried out with the features selected for each sensor, where the movement intention detection would be evaluated with T-FLEX and a Serious Game.

The results showed that it was possible to develop an EMG-based interface for the control of T-FLEX. The best performance of the detection with the EMG sensor was with the feature of VAR, and with the IMU sensor was the feature of MEAN. After the second session, the participants manifested that the control of the serious game and the ankle exoskeleton T-FLEX was better using the IMU sensor. According to the participant's movement, the reaction was faster with this sensor than with the EMG sensor.

According to the EMG signal, some changes were established in the algorithm before starting the test to enhance the T-FLEX behavior. However, the time for the detection was affected. The FP values that appeared in the test with the IMU sensor did not significantly affect the participant's performance in the Serious Game. Besides, the precision with the IMU sensor in the study case was higher than with the EMG sensor.

The slow reaction time from the EMG sensor was not expected. This could happen due to the changes made to the algorithm, mainly because of external factors, such as the pressure from T-FLEX over the EMG sensor. This could affect the detection because of the noise added to the signal. For this reason, it is advisable to consider a trial with the EMG signal that results from the muscular activity with the ankle exoskeleton T-FLEX so that the appropriate management of the signal will be carried out and the signal of the desired muscle will not be affected.

Chapter 7

RECOMMENDATIONS AND FUTURE WORKS

Other techniques for the threshold calculation can be some options to enhance the algorithm's detection. Some studies proposed to use the combination of the statistical features, like variance (VAR) and standard deviation (STD) to establish the threshold due to the velocity and performance that those features have had in the detection of movement intention. Also, the implementation of some additional features can be considered.

On the one hand, an adjustment in the EMG sensor's setup, so the sensor avoids the pressure, can be considered to fix the external factors that could have affected the movement intention detection. On the other hand, some strategies involving a more complex threshold calculation could bring better results in movement detection, such as an adaptive threshold, or even apply a constant false alarm rate (CFAR) threshold.

For future works, in the short term, it is the enhancement of the connections to avoid repeating tests due to sudden disconnections of the EMG sensor. Also, the establishment of additional filters to the signal so that the performance with T-FLEX would not require delays and would show a faster reaction in the participant's perspective and better results in the Serious Game.

In the medium term, the adjustment of parameters in the movement intention detection algorithm would detect the minimum intention of movement. This way, the system would be considered for rehabilitating post-stroke patients with a limited range of movement in the lower limb. Moreover, the combination of the IMU sensor detection can be considered.

In the long term, some concepts involving Neural Netwoks can be considered to get better results. The signals recorded for the first session and some others can be targeted and used for the training model, and analyzing some other works can lead to a movement intention detection algorithm. Also, adding the EMG signal from the Gastrocnemius to the movement intention detection system could better detect the movement, detecting not only dorsiflexion but plantarflexion, and can be linked to how T-FLEX works.

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ANNEXES

DETECTION OF ANKLE FLEXION MOVEMENT INTENTION BY ELECTROMYOGRAPHY AND INERTIAL SENSORS IN HEALTHY SUBJECTS

Experimental Protocol

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1 Abstract

This document presents an experimental protocol that compares two detection methods of ankle flexion movement intention through two sensors: one Electromyography (EMG) sensor and one inertial sensor. It is expected to evaluate the performance of both sensors independently and integrated into the T-FLEX ankle orthosis in order to control the level of assistance if the device along with a serious game.

2 Statement of the problem

The World Health Organization defines disability as a general term covering deficiencies, limitation of activities and participation restrictions. Physical disability, which affects mobility, is generated mainly by Strokes,cerebral palsy and spinal cord injuries. Acute stroke is a frequent neurological emergency, with 17 million annual cases.This, makes it the leading case of disability [1], [2].

Like other accidents, Strokes also present side effects. Among, these is the partial or complete loss of motor functions(hemiplegia), debility (hemiparesis) localized. These effects are counteracted by seeking to improve the motor capacity of patients, through rehabilitation processes based on physical therapy. [3]. Nevertheless, these processes tend to require much effort by the rehabilitator [4]. That is why these robotic devices have been implemented in physical therapy as tools to speed up the rehabilitation process, recover motor functions and improve people's quality of life [5].

Despite the advantages of using robotic devices, distal joints,as the ankle, represent a challenge in these rehabilitation processes. Different active orthoses have been designed to assist ankle movement in the sagittal plane, restricting natural movement in frontal and transverse planes [6]. This is done to provide the patient stability and lift the foot during the swing phase [7]. However, this restriction can lead to abnormal movements in other joints, inappropriate for a patient in a relearning stage during his/her rehabilitation.

Ankle exoskeleton (T-FLEX) has been developed to counteract these deficiencies. T-FLEX is part of the AGoRA robotic platform (Minciencias grant 801-2017). T-FLEX is an active wearable ankle orthosis based on the variable stiffness principle [8]. This device counts with a flexible filaments bidirectional system that besides assisting the dorsi-plantar movement of the ankle flexion, allows correcting the internal or external rotation that the user presents, without restricting the natural movement in the other planes. Also, T-FLEX allows increasing the system's rigidity, through the tension of bio-inspired tendons composed of a flexible element (Filaflex) and rigid filaments. This device counts with two operation modalities: (1) Therapy used to generate repetitive movements in the user and (2) Assistance used to provide support in the stance phase and provide the user dorsi-plantarflexion movements.

The therapy modality of the orthosis (T-FLEX) only generates programmed movements. That, there is no interaction between the subject and the orthosis. Ankle movement intent detection alongside serious game *Jumping Guy*, looks for generating a different response to repetitive movement. In other words, it seeks to involve the subject more so that he has decision control over the moment of action.*Jumping Guy: Ankle Rehabilitation Therapy with T-FLEX* is a serious game that involves audiovisual feedback to motivate the rehabilitation process and vary its intensity.Its objective is to generate the jump of an avatar, by detecting of the plantar and dorsal flexion movements of the ankle, to evade the enemies and advance in the game.

This protocol is proposed to evaluate the best method to detect the intention of ankle dorsiflexion movement, that is, the strategy that, with minor delay and greater precision, allows to capture the voluntary movements of the users, about the variation of the given intensity during the different sessions of the serious game.

3 Justification and use of the results

The purpose is to verify the performance of the movement intention detection algorithms through EMG and IMU sensors and the variation of the assistance with T-FLEX presented with the serious game on the user.

4 Objective

4.1 General Objective

To analyze two methods of motion intention detection, using EMG and IMU sensors, in the activation of the T-FLEX ankle exoskeleton.

4.2 Specific Objectives

- To determine the statistical characteristic between average, variance, and standard deviation, each sensor better detects movement intention.
- To analyze movement intention detection using an EMG sensor in the tibialis anterior and an inertial sensor in the tip of the foot in the use of the T-FLEX ankle exoskeleton.
- To analyze the usability of a serious game independently using two movement intention detection methods for the activation of the T-FLEX ankle orthosis
- To determine if there is a possibility to combine the two methods of motion intent detection as a new method with which better results are obtained.

5 Methodology

For the development of this protocol, Myoware electromyography sensors (AT-04-001 (Pololu, United States)) will be used to acquire EMG signals in the tibialis anterior and in addition to this, an inertial sensor (BNO055 (Bosch , Germany)).

Ten healthy subjects will participate and the experiment will take place at the Julio Garavito Colombian School of Engineering, which will consist of two stages. The first, a session of approximately 30 min to choose one of the three statistical methods (Average, standard deviation and variance) on which the algorithm for detecting movement intention through EMG and IMU sensors is based. The second stage consists of another session, a week after the first session, of approximately 1 hour to test the detection of movement intention of EMG and that of the inertial sensor in the three levels of the serious game with the T-FLEX ankle orthosis (Figure 1) considering the highlighted statistic in the previous session.

Figure 1: Ankle Exoskeleton T-FLEX.

5.1 Operational variables definition

The evaluation of the two different movement intention detection methods, is expected to analyze the variables acquired in two main groups: variables acquired in the first session and variables acquired in the second session. The variables related to surveys are subjective and subject to the perception of the participant.

5.1.1 First Session

The variables measured in this section will be taken during the experiment.

- **Muscular Activity:** Muscle activity will be measured by calculating the average, variance and standard deviation of the signal given by the electromyography sensor in the tibialis anterior.
- **Angular Velocity:** The angular velocity (rad / s) will be measured along the sagittal plane through the inertial sensor.
- **Articular Range:** The Euler angles (°) will be measured through the inertial sensor to estimate the joint range that the ankle has when dorsiflexed.
- **Video Recordings:** The dorsiflexion movements will be recorded in a synchronized way with the progressive sounds of activation of the movement to have in another way the time in which the movements are carried out.

5.1.2 Second Session

The variables measured in this section will be taken during and at the end of the experiment.

- **Muscular Activity:** Muscle activity will be measured by calculating the average, variance and standard deviation of the signal given by the electromyography sensor in the tibialis anterior.

- **Angular Velocity:** The angular velocity (rad / s) will be measured along the sagittal plane through the inertial sensor.
- **Articular Range:** The Euler angles (°) will be measured through the inertial sensor to estimate the joint range that the ankle has when dorsiflexed.
- **Serious Game Results:** Each of the data reported by the game will be stored. This includes: the number of hits, number of mistakes, percentage of accuracy and type of response to the enemy (Ideal, Early or Late).
- **Video Recordings:** Dorsiflexion movements will be recorded with the device and sensors during the serious game test as another way of keeping track of the time the movements are performed.
- **QUEST:** The QUEST test will be carried out to know the level of user satisfaction with the device. This information will be used as feedback from the user regarding the operation and structure of the system. This questionnaire can be seen in Section 7.1.
- **Serious Game Survey:** A survey will be carried out within the framework of the Likert scale to evaluate the experience and level of adaptability to serious play and each of the control strategies proposed. This questionnaire can be seen in Section 7.2.

5.2 Study type and general design

The study presented in this protocol is longitudinal, observational, prospective and open. On the other hand, regarding the general design, the experiment will handle the repetitive measures method.

5.3 Inclusion criteria

Healthy users between the age range of 18 to 70 years. The participants' height must be between 150 and 190 cm, taking into account T-FLEX's anthropometric design.

5.4 Exclusion criteria

Under the influence of alcohol, drugs, or any type of hallucinogen, users suffer from some type of cognitive disability that prevents them from volunteering, reading, understanding and signing informed consent.

Additionally, candidates will be excluded from the study if they present any of the following conditions:

- Any pathology associated with the ankle.
- Uncontrolled hypertension.
- Uncontrolled epilepsy.
- Pain in the lower limbs or the spine.
- Severe spasticity (Level 4 of the Ashworth scale).
- The presence of wound or pressure ulcers make it impossible to use the device.
- The user does not have affiliation to the general health social security system (EPS or EPSS).

5.5 Equipment and facilities

- Robotic Ankle Orthosis (Support and Actuation System) T-FLEX.
- EMG Sensor Myoware (AT-04-001).
- Inertial Sensor Bosch BNO055.
- Disposable Electrodes for EMG.
- Serious game executables: *Jumping Guy: Ankle Rehabilitation Therapy with T-FLEX*
- Camera

5.6 Costume Condition

The user must wear a lower garment to be lifted to expose from the knee area or shorts.

5.7 Pre and post-test procedure

5.7.1 Entering and leaving the facilities

Before entering the facilities, the volunteer will be asked to fill out a form present in section (6.0.1) related to the Julio Garavito Colombian School of Engineering's biosafety measures. The user must carry the basic biosecurity implements (mask, mask, alcohol, and anti-fluid suit). The volunteer will go through a disinfection area, and the temperature will be taken. When leaving, the person will go through this last procedure again.

5.7.2 Disinfection of laboratory implements

The research environment and all the implements used during the test will be previously disinfected to minimize the risk of contagion of COVID-19. This process will be repeated once the test is finished.

5.8 Test procedure

The procedure that will be carried out during the execution of this experiment is divided into two main sessions adjusted to a visual feedback strategy with a serious game and dorsiflexion movements of the ankle. The intervention to which the subject will be subjected involves two main stages in each session: location of the necessary muscles or another specific area of the lower limb to correctly locate the EMG and IMU sensors (instrumentation phase) and the performance of repetitive movements during the session.

The instrumentation of the inertial sensor corresponds to the third metatarsal of the foot with the z-axis in opposition to the gravity vector and the x-axis towards the back of the body. For the EMG sensor the electrodes will be in the corresponding muscle (Tibialis anterior).

To position the electrodes and the EMG sensor, the recommendations are given in SENIAM will be followed. However, some modifications were made considering the dimensions of the sensor and the length of its reference cable, which will later be used with T-FLEX. According to SENIAM, the recommendations are to follow the direction of the line drawn between the fibula and the tip of the middle malleolus and place the sensor at 1/3, having as a reference some area of the ankle. Considering what the T-FLEX covers, it is proposed to place the sensor at 2/3 of the distance, ensuring that the signal being captured remains that of the tibialis anterior. Considering the reference wire's length, the reference would be in the lower part of the tibia (figura 5.8).

On the other hand, to perform repeated movements, the person will be sitting with a 90 degree knee flexion; the member where the measurements are made must not make contact with the ground.

Participant with electrode  and Myoware sensor in the corresponding places.

First Session

This stage consists of choosing the algorithm for the detection of movement intention through sensors EMG and IMU. This procedure will be performed without the orthosis, where the participant will be subjected to a test with sound pulses that progressively increase in frequency for approximately 10 minutes. The volunteer must perform dorsiflexion movements when a sound is played, which will appear every 3, 2 and 1.5 seconds within the established time. For the detection of movement intention, three statistics will be taken into account. Each one will be evaluated separately in an offline manner considering the previous test. Through the results the statistical characteristic with which each algorithm performs a better detection will be chosen.

In this way, the sequence of activities is given by:

1. User instrumentation.
    - EMG surface electrode placement in the areas to be treated (tibialis anterior muscle).
    - Inertial sensor location on the tip of the foot.
2. Verification of connections and reading of sensors.
3. Instruction to the user about the test.
4. Start test.
5. Verification of stored data.
6. Cleaning and disinfection of equipment and instrumentation.

Second Session

During this stage, in addition to using both sensors, the T-FLEX ankle orthosis will be used in therapy mode and serious game *Jumping Guy: Ankle Rehabilitation Therapy with T-FLEX*. The experiment consists of 2 tests of 20 minutes that involve the three levels of the game in two conditions: (1) with the EMG sensor and (2) with the IMU sensor. During the test, the participant must generate the avatar's jump to avoid colliding with the enemy through plantar and dorsal flexion movements assisted by the orthosis. The first level of play induces a dorsal-plantar flexion every 3 s, the second every 2 s, and the third every 1.5 s. The participant will execute each level with both conditions considering a 5-minute break between tests. In this case, each sensor's motion intention detection method will consider the best statistic found in the previous stage.

In this way, the sequence of activities is given by:

1. Installation of the clamping system and actuation of the robotic orthosis.
    - Insole adjustment on the wearer's shoe.
    - Placement and adjustment of the orthosis to the leg.
    - Securing tendons and hemp to motor mounts.
    - Adjust electronic wiring.
    - Verification of the functioning of the orthosis in therapy mode.
2. User instrumentation
    - EMG surface electrode placement in the areas to be treated (tibialis anterior muscle).
    - Inertial sensor location on the toe.
3. Verification of connections and reading of sensors.
4. Running the serious game program: *Jumping Guy: Ankle Rehabilitation Therapy with T-Flex.*
5. Instruction to the user about the test.
6. Start test.
7. Verification of stored data.
8. Completion of the surveys (once the sessions have been completed).
9. Cleaning and disinfection of equipment and instrumentation.

Finally, an evaluation will be carried out with the variables indicated in section 5.1.2, to quantify the participant's progress during the experiment.

5.9 Information gathering and methods for data quality and control

The collected data will be stored in a special folder where each participant will have their folder with their information. Connection verification and data reading must be carried out before starting the test regarding the sensors used.

6 Informed consent

This section of informed consent is directed to the people who are invited to participate voluntarily in the research, which is divided into two parts:

- Information about the study
- Consent form to sign if the volunteer agrees to participate

Part I: Information

Introduction

These informed consent sheets may contain words that you do not understand. Please ask the main investigator or anyone in the study to explain any words or information that you do not clearly understand. You will be given a copy of the complete informed consent document.

Purpose

Mobility disability has become a significant problem in Colombia as in the whole world. Regarding mobility disability associated with the ankle, there is little development of devices in the Colombian health system that assist the patient during the march and improve their pattern recovery.

For this reason, an ankle exoskeleton (T-FLEX) has been developed, that is, a wearable robotic ankle orthosis that allows to assist the movement of dorsi-plantar flexion of the ankle and correct an internal or external rotation that the user presents. The above is achieved through two modes of operation that the device has, the first is the therapy modality to generate repetitive movements to the patient helping in their rehabilitation, and the second is the assistance modality in order to provide support in the stance phase and provide the patient with dorsi-plantar flexion movement.

Given the above, this study seeks to verify the performance of the ankle movement intention detection algorithms through EMG and IMU sensors and the variation in the assistance that T-FLEX presents on the user for their participation in the serious game.

Type of Research Intervention

This investigation will include a protocol of non-invasive measurements during repetitive flexion movements.

Selection of participants

In this project, a non-random sample will be used based on people willing to participate voluntarily in the project. These will be selected taking into account their state of health and physical conditions

Inclusion criteria

Healthy volunteers between 18 and 70 years of age who are between 150 and 190 cm tall, considering T-FLEX's metric design, aware of the risks and inconveniences that the experiment may cause.

Exclusion criteria

Under the influence of alcohol, drugs, or any type of hallucinogen. Users who suffer from some type of cognitive disability that prevents them from volunteering, reading, understanding, and signing informed consent.

In addition, candidates will be excluded from the study if they present any of the following conditions:

- Any pathology associated with the ankle.
- Uncontrolled hypertension.
- Uncontrolled epilepsy.
- Pain in the lower limbs or the spine.
- Severe spasticity (Level 4 of the Ashworth scale).
- Presence of wounds or pressure ulcers that make it impossible to use the device.
- Not having affiliation to the general health social security system (EPS or EPSS)

Participation in this research is entirely voluntary. You can choose to participate or not. Whether you choose to participate or not, all the services you receive at this facility will continue, and nothing will change. You can change your mind later and stop participating even if you have agreed earlier.

Procedures and Protocol

In the methodological procedure, 10 healthy volunteers will be taken into account. Each participant must carry out a total of **two** sessions.

Duration

This procedure will have 2 sessions. The first with a duration of approximately 30 minutes and the second, a week later, with approximately 1 hour. The first part of each session will have 5 to 15 minutes for instrumentation and putting on the device. In the remaining time, the seated participant will perform the dorsi-flexion and relaxation movements.

Methodology

During the execution of the experiment, in both sessions there will be an instrumentation phase where the tibialis anterior is identified and the appropriate position to place the inertial sensor on the limb where the measurement will be made. Once this muscle has been identified, it will be proceeded to identify the nearby areas that will correspond to the reference of the sensor that will be positioned in the muscle, fulfilling that they are bone, and in this way make the appropriate adjustments so that the sensor is positioned in the corresponding muscle with your reference. Once the aforementioned is completed, the electrodes will be adjusted on the sensor and placed on the volunteer, preparing them to acquire electromyography (EMG) signals, which refer to electrical signals produced during muscle contraction.

To position the electrodes and the EMG sensor, the recommendations given in SENIAM were followed. However, some modifications were made considering the dimensions of the sensor and the length of its reference cable, which will later be used with T-FLEX. These modifications are:

- Tibialis anterior: For this muscle, the recommendations are to follow the direction of the line drawn between the fibula and the tip of the medial malleolus and place the sensor at 1/3, having as a reference some area of the ankle. Considering what the T-FLEX covers, it is proposed to place the sensor at 2/3 of the distance, ensuring that the signal being captured remains that of the tibialis anterior. Considering the length of the reference wire, the reference would be in the lower part of the tibia.

To position the inertial sensor, the third metatarsal of the foot is considered with the z-axis in opposition to the gravity vector and the x-axis towards the back of the body.

First Session

The participant will be sitting on a chair performing a 90 degree knee flexion; likewise, the participant's lower limb must be elevated in such a way that it does not contact the ground. When the conditions are set, the test will start. The participant will perform dorsi-flexion and relaxation. Each of these is interspersed, to obtain a result such as: DF (dorsi-flexion) - Relaxation - DF (dorsi-flexion) - Relaxation. These movements will depend on the sound pulses set for the test.

Second session

The participant will be sitting on a chair performing a 90 degree knee flexion; likewise, the participant's lower limb must be elevated in such a way that it does not touch the ground. When the conditions are set, the test will start. The participant will perform dorsi-flexion and relaxation with the device. Each of these is interspersed, to obtain a result such as: DF (dorsi-flexion) - Relaxation - DF (dorsi-flexion) - Relaxation, in order to advance in the game.

For the second session there will be a 5-minute rest period between the test for each sensor.
Figure 2 shows an example of the two proposed movements is observed (A. dorsi-flexion, B. relaxation).

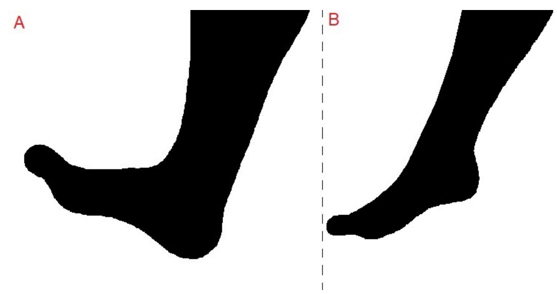

Figure 2: proposed movements for the protocol. A) Dorsi-flexion. B) Relaxation.

Validation: At the time of the test, the information from the inertial sensor corresponding to the Euler angles will be used to estimate the joint angle exerted by the ankle at the moment in which the intention of dorsiflexion movement is detected. In addition to this, the leg will be recorded in the sagittal plane to record the entire process of the person performing the test. This applies to both sessions.

Dress conditions

Light shorts at the knee or pants that can show the muscles necessary for the placement of the electrodes.

Risks

By participating in this research, you may expose yourself to feeling fatigued or pain due to the repetitive movements performed, you may experience cramps or a slight numbness in the limb with which the test is being performed due to the posture required for the test or you may feel a tingling in the area where the electromyography sensor is placed. If this occurs, immediately notify the Investigator-in-charge to pause, adjust the items, and see if it is feasible to continue the test.

COVID-19 Considerations

Suppose you have an acute respiratory infection, cough, fever, nasal congestion, generalized muscle pain, headache or sore throat, chest pain or shortness of breath, and other symptoms related to COVID-19, which may affect your participation in the test. In that case, you should withdraw from it for your safety and that of the researchers involved who will be interacting with you, notifying the research center staff of your current health condition.

Aches or pains

When participating in this research, you may experience discomfort from the use of electrodes placed on your body.

Benefits

Your participation in the development of this project could benefit the health of people who require this means of therapy, helping them in their rehabilitation process. Likewise, their participation will contribute to fulfilling the purpose of the research, and future generations probably benefit from the results.

Incentives

No money, gifts, or incentives will be given to you for taking part in this research.

6.0.1 Facility entry form

To enter the educational institution Escuela Colombiana de Ingeniería Julio Garavito you must fill out a form found in the link below:

https://form.jotform.com/EscuelaingEncuestaSalud/reporte-obligatorio-salud

You will be asked to choose the modality you will enter, which you must choose as "In-person (to apply to the campus)". Once the modality has been chosen, you will be asked to enter your data, these being: full name, exact age, cell number, email, and your relationship with the institution.

Additionally, you will be shown a list of symptoms related to COVID-19, which you must indicate if you have presented them in the last seven days. Later there is another section where you are asked for your health history that has been diagnosed in the last five years, and then you will be asked to sign to confirm that your answers are true.

Finally, a photo of your identification document and the date of admission to the institution will be requested. Once the terms have been accepted and the form has been sent, you will receive a QR code to the previously entered email, which you must present at the entrance to be able to enter the institution.

Confidentiality

In this project, the information will be linked. In other words, the information can be related or connected with the person to whom it refers. However, this information will be recorded anonymously. In this case, it can be linked to the person to whom it refers except through a code or other means known only to the owner of the information. In this way, the personal information of the participating subjects is protected. Your identity will never be revealed or published. The recordings of the test will be made so that the movement of the ankle and the participant's posture can be appreciated without revealing their face. This information will be used to show the space and how the test was carried out.

Sharing the results

During the study, the participants will know the status of the research project and the preliminary results at all times. The disclosure of the final results obtained from this research will be sought so that other interested people can learn. Confidential information will not be shared.

Right to refuse or withdraw

You do not have to take part in this research if you do not want to. You can stop participating in the research at any time you want. It is your choice and all your rights will be respected.

If you have chronic diseases such as cancer, diabetes, hypertension, among other conditions that may affect your immune response due to complications from Covid-19, or if you consider that participating in the test is a potential risk to your health, taking into account the health emergency , you have the right to deny your participation or to withdraw at any time you wish.

Who contact to

If you have any questions, you can ask them later, even after the study started. If you have questions later, you can contact any of the following:

Marcela Munera 310 273 4857
Daniel Gomez 321 360 2314
Angie Pino 301 487 1663
Camila Castellanos 312 443 3027

Part II: Consent Form

I, ____,
identified with the citizenship card number ____________________________________, declare that I have read and understood this document and that my questions about the tests for this research have been answered satisfactorily; I, therefore, give my informed consent to participate in the research called "Ankle flexion movement intention detection by electromyography and inertial sensors in healthy subjects". I agree that my name, age, and other anthropometric data are stored, and I am aware that I will be recorded throughout the sessions. I know that I can withdraw from the experiment at any time. In addition, I understand that despite preventive care such as social distancing, hand washing, disinfection of laboratory implements, there is a risk of the possibility of contagion by Covid-19.

I certify that during the last 15 days I have not had contact with people diagnosed with COVID-19 and that in case of presenting any symptoms related to those exposed in the **COVID-19 Considerations** section, I will immediately notify the researchers to Maintain the necessary preventive isolation measures established by the District Health Secretariat and the National Health Ministry and I will notify if I will be ordered to take the antigen or PCR for COVID-19. In such a case, I will report the result.

Participant Subject:

Name: ____________________________________

Address:____________________________________

Cellphone:____________________________________

Signature:____________________________________ ID: ____________________________________

Investigator statement

I certify that I have explained the nature and purpose of the investigation to this person and that this person understands what their participation consists of, the possible risks and benefits involved. All the questions this person has asked have been answered appropriately. Likewise, I have read and adequately explained the parts of the informed consent. I certify with my signature.

Investigator:

Name: ____________________________________ ID: ____________________________________

Investigator Signature:____________________________________

Date (Year/month/day):____________________________________

Thank you for your collaboration.

7 Questionnaires

7.1 QUEST

Name: ____________________
Evaluation Date: ____________________
Age: __________ Genre: __________
Pathology: ____________________

The purpose of this survey is to assess your satisfaction with the device. The survey consists of 8 questions.

- For each of the questions, rate your level of satisfaction (how pleased you are with the device) using the following scale from 1 to 5.

1	**2**	**3**	**4**	**5**
Not Satisfied at all	Not Satisfied	More or less Satisfied	Satisfied	Very Satisfied

- Leave no questions unanswered
- In each question, you declare that you are not very satisfied, please write it in the comments section.

Thank you for your collaboration.

How satisfied are you with:?	**1**	**2**	**3**	**4**	**5**	**Comments**
The dimensions of the system (tight, width, length)?						
The device's weight						
The ease of the implementation of the device?						
The ease to wear (have it on) the device?						
Usability of the device?						
The device's effectiveness according to its functionality?						
The comfort of the device?						
The security of the device and the possibility that the system does not harm you?						

Below you will find the list of the same 8 satisfaction questions. Please select the THREE questions that are most important to you, mark them with an x in the THREE boxes of your choice:

1. Dimensions.
2. Weight.
3. Ease of implementation.
4. Ease of use of the device.
5. Device usability.
6. Device effectiveness.
7. Device comfort.
8. Device security.

7.2 Serious Game Survey

This survey aims to know the experience between the user and the serious game. Mark on the scale from 1 to 5 according to your perception, where 1 totally disagrees and 5 totally agrees.

1	**2**	**3**	**4**	**5**
Totally disagree	Disagree	Neither agrees or disagrees	Agree	Totally Agree

Criteria	**Statement**	**1**	**2**	**3**	**4**	**5**	**Comments**
Learning	It was easy to play						
	It was not hard to understand the game dynamic						
	The video game is familiar						
	The tutorial gave the necessary instructions to know the game operation						
	It is easy to read the statements						
	The video game is helpful to achieve a therapeutic goal						
Operability	The speed of the game was continuous						
	Options are visible, and easy to identify						
	Game duration is appropriate						
	The interface is easy to use						
	Interface functions are understandable						
	It is easy to keep up with the levels in the game						
	It is easy to correct an action to continue playing						
	Detection of errors is clear						
	Response time of the EMG sensor was appropriated for progress in the game						
	Response time of the IMU sensor was appropriated for progress in the game						
Attractiveness	The video game is aesthetically pleasing						
	Text combination and graphs were enough						
	Color combinations were visually pleasing						
	Interface elements fit your profile						
	The video game DOES NOT generate eye discomfort or any type of headache						
Communication	The explanation is clear about the video game input and output requirements						
	The language used is simple and clear						
	The density of the texts are appropriate						
Satisfaction	Goals are achieved						

	comfortably and safely						
	Feedback from your performance was clear						
	You feel improvement in ankle function thanks to the video game						
	You would use the video game as a therapy modality						
Motivation Model	You felt motivated while playing						
	You find the video game fun						

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