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Adaptive Hybrid FES-Force Controller for Elbow Exosuit

Tesi di Laurea Magistrale in
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Alla mia famiglia,
senza la quale non sarei l'uomo che sono.
Siete esempio e aspirazione di vita.
Grazie.

Abstract

Patients impaired by neuromuscular diseases experience motor disabilities which hinder their independence during activities of daily living. Robotic devices and Functional Electrical Stimulation (FES) proved their capability to assist and restore lost functionalities of patients. However, their independent assistance has limitations. Merging together FES and robots in Hybrid Robotic Rehabilitation Systems overcomes these drawbacks. Currently, the possibility of including soft wearable robots (exosuits) in hybrid systems was investigated by only two studies in the literature, but none of these implemented a balanced assistance between the exosuit and FES. To the best of the author's knowledge, no hybrid system comprising FES and exosuit for assisting the elbow was proposed in the literature. Would exosuits be a feasible alternative to rigid exoskeletons in elbow Hybrid Systems? To address this question an innovative hybrid controller involving FES and an exosuit was implemented to assist elbow flexion and extension. This controller cooperatively manages the assistance of the two systems and adaptively varies the assistance allocation based on the muscle fatigue estimated. The designed hybrid controller was tested on six healthy participants. The results obtained showed how the hybrid controller significantly overwhelmed the performance of FES alone, not only improving movements precision but decreasing muscle fatigue during the trials of about 63% and delaying its onset, potentially allowing longer-lasting therapy sessions. Concurrently, the hybrid controller allowed the wearers to perform movements with no significant worsening of accuracy and precision with respect to the exosuit alone, but with a significant shrink of the motor energy consumption of about 72%. Finally, the implemented EMG-based intention detection method successfully decoded the participants' intention with an accuracy of about 70%. The results obtained clearly revealed the potentiality of using the proposed hybrid controller in exosuits hybrid systems and reasonably suggest their application in rehabilitation treatments.

Keywords: Functional Electrical Stimulation, Exosuits, Soft Wearable Robot, Hybrid Robotic Rehabilitation Systems

Abstract in lingua italiana

I pazienti affetti da malattie neuromuscolari mostrano disabilità motorie che ostacolano la loro indipendenza durante le attività della vita quotidiana. Dispositivi robotici e la stimolazione elettrica funzionale (FES) hanno dimostrato la loro capacità di assistere e ripristinare le funzionalità motorie dei pazienti. Tuttavia, la loro assistenza autonoma presenta dei limiti. Unendo FES e robot in Sistemi Robotici Riabilitativi Ibridi permette di superare queste limitazioni. Attualmente, la possibilità di includere robot indossabili (exosuits) in sistemi ibridi è stata indagata solo da due studi in letteratura, ma nessuno di questi ha implementato un'assistenza coordinata tra exosuit e FES. Al meglio delle conoscenze dell'autore, non è mai stato sviluppato un sistema ibrido che comprenda un exosuit del gomito. Possono gli exosuits essere un'idonea alternativa agli esoscheletri rigidi nei sistemi ibridi per assistere il gomito? Per rispondere a questa domanda un controllo ibrido che comprende la FES e un exosuit è stato sviluppato per assistere flessione ed estensione del gomito. Questo controllo gestisce in modo cooperativo l'assistenza dei due sistemi, variandone l'allocazione in base all'affaticamento muscolare. Il controllo ibrido è stato testato su sei partecipanti sani. Dai risultati ottenuti è emerso come il controllo ibrido abbia surclassato significativamente le prestazioni della sola FES, non solo in termini di precisione dei movimenti ma anche diminuendo la fatica del 63% e ritardandone notevolmente l'insorgenza. Al contempo, il sistema ibrido ha permesso ai soggetti di muoversi senza un significativo peggioramento della precisione rispetto al solo exosuit, ma rispetto a questo riducendo significativamente del 72% il consumo energetico del motore. Infine, il metodo di detenzione dell'intenzione dei soggetti basato sull'EMG ha permesso di decodificare con successo la loro volontà riguardo al movimento da compiere con un'accuratezza circa del 70%. I risultati ottenuti hanno chiaramente rivelato le potenzialità dell'uso del controllo ibrido proposto in sistemi ibridi con exosuit e suggeriscono ragionevolmente la loro applicazione riabilitativa.

Parole chiave: Stimolazione Elettrica Funzionale, Exosuit, Robot Indossabili, Sistemi Robotici Riabilitativi Ibridi

Executive Summary

Introduction

Neuromuscular diseases, such as spinal cord injury or stroke, can lead to motor disabilities and loss of strength, hindering affected patients in producing functional movements and execution of activities of daily living. Robotic devices and Functional Electrical Stimulation (FES) proved their capabilities to assist and restore motor functions. Despite rigid exoskeletons allow adaptable training intensity and higher accuracy and repeatability of movements, they are generally bulky, expensive, and they require the perfect alignment between the user and device joints. Contrarily, soft robotic suits (or exosuits) do not present this necessity, thus they hinder movements less, they are lightweight, cheaper and more comfortable. However, in case of patients with high level of impairment the rehabilitation effect of robotic devices is limited to only passively guide the task, without inducing the activation of patients' muscles.

On the other hand, Functional Electrical Stimulation (FES) actively stimulates muscles fibers by delivering short electrical stimuli to motor neurons reactivating paretic muscles, achieving functional tasks and restoring lost motor skills. Nonetheless, due to its working principle, the application of FES leads to muscle fatigue earlier in time and the highly non-linear muscle response to the stimulation could generate inaccurate movements.

Merging FES and robotic systems in Hybrid Robotic Rehabilitation Systems allows to exploit advantages of both systems and overcome their limitations. In particular, the assistance from robots improves the precision and the accuracy of FES-induced movements and postpones muscular fatigue. On the other hand, the inclusion of FES boosts the rehabilitative benefits and reduces the motor torque requirement. In order to achieve these goals the two systems must work in synergy, actuating cooperatively the same joint. Therefore, active robots are more suitable for this application since their assistance can be more finely modulated.

In the literature, the majority of hybrid systems composed by active robots and FES assisting the same joint involve rigid exoskeletons and are designed for lower-limb. Indeed, only few studies developed active exoskeleton hybrid system to assist the elbow and

Figure 1: FES-exosuit Hybrid System.

none of these managed a balanced and coordinated actuation between FES and robot contribution. Moreover, these systems did not account for the FES-induced muscle fatigue. Concerning exosuits, only two studies have explored the possibility of combining them with FES [1, 2]. Nonetheless, these studies shared the same limitations of the elbow active exoskeleton hybrid systems and none of them assisted the elbow. Guided by these literature limitations, this study designed for the first time in the literature a hybrid system integrating FES within an elbow exosuit. The goal of the system is to aid subjects in performing elbow flexion and extension, exploiting the rehabilitation benefits of FES, while assuring kinematics precision and accuracy provided by the elbow exosuit. In order to accomplish these goals, a coordinated and cooperative controller was developed, able to vary FES and robot assistance in order to limit, manage and postpone the FES-induced muscle fatigue.

Hybrid System design

Active elbow exosuit

The soft exosuit used in this work is a fully-embedded system built by ARIES Lab (ZITI, Heidelberg, Germany) [3], able to assist elbow movements (Fig.1). It comprises a textile harness that connects arm and forearm, made starting from a passive orthosis. The actuation stage aids elbow flexion/extension through a brushless motor (T-Motor, AK60-6, 24V, 6:1 planetary gear-head reduction, Cube Mars actuator, TMOTOR, China) which drives the pulley (35mm) around which the artificial tendon is wound (Black Braided Kevlar Fiber, KT5703-06, 2:2 kN max load). On the textile harness two anchor points are suited both on the distal and proximal side of the elbow and they are linked to the motor pulley via a Bowden cable (Shimano SLR, 5mm, Sakai, Japan). A force sensor (ZNLBM-1, 20 kg max load, China) is placed in between the connection of the cable with the distal anchor point and it measures the cable tension. Two Inertial Measurement Units (IMU, Bosch, BNO055, Germany) detect the arm kinematics and orientation. The actuation unit and the power supply (Tattu, 14.8V, 3700mAh, 45C) are screwed on the back protector. The control unit is driven by a microprocessor (Arduino MKR 1010 WiFi,Arduino, Ivrea, Italy) that receives sensors measuraments via wireless protocol and sends the signals to the actuation stage via CAN-bus [3]. Moreover, a Bluetooth Low-Energy interface was developed to allow the Arduino to control the electrical stimulator.

Electrical stimulator

The electrical stimulator (KT motion, Medel, Hamburg, Germany) was used to stimulate the biceps inducing elbow flexion by means of two electrodes (Krauth+Timmermann, 4x6 cm area) placed over the muscle belly. When the stimulation is off, the EMG activity of the same muscle is measured. Biphasic electrial pulses at a frequency of 40 Hz were delivered to induce muscle contraction. The current amplitude was tuned for each subject as described in Section *Calibration Procedure* and kept constant, whereas the pulse width (PW) was modulated during the movement.

Real time Control

The implemented real-time control consists in a hybrid approach that coordinates the assistance from the exosuit and from FES. Three main layers are interconnected in a close loop system (Fig.2): (i) *Hybrid Controller* that detects the subject's intention and computes the assistance for both the devices, (ii) *Exosuit Controller* which modulates the motor actuation, and (iii) *FES Controller* that manages the stimulation.
The functionality of these layers is controlled by a state machine (Fig.3), which defines the role of the robot and FES according to the state. In particular, during the *Break* phase the exosuit compensates for the gravity and the *Hybrid controller* identifies the intention of the subject. The *Flexion* state manages the flexion movement coordinating

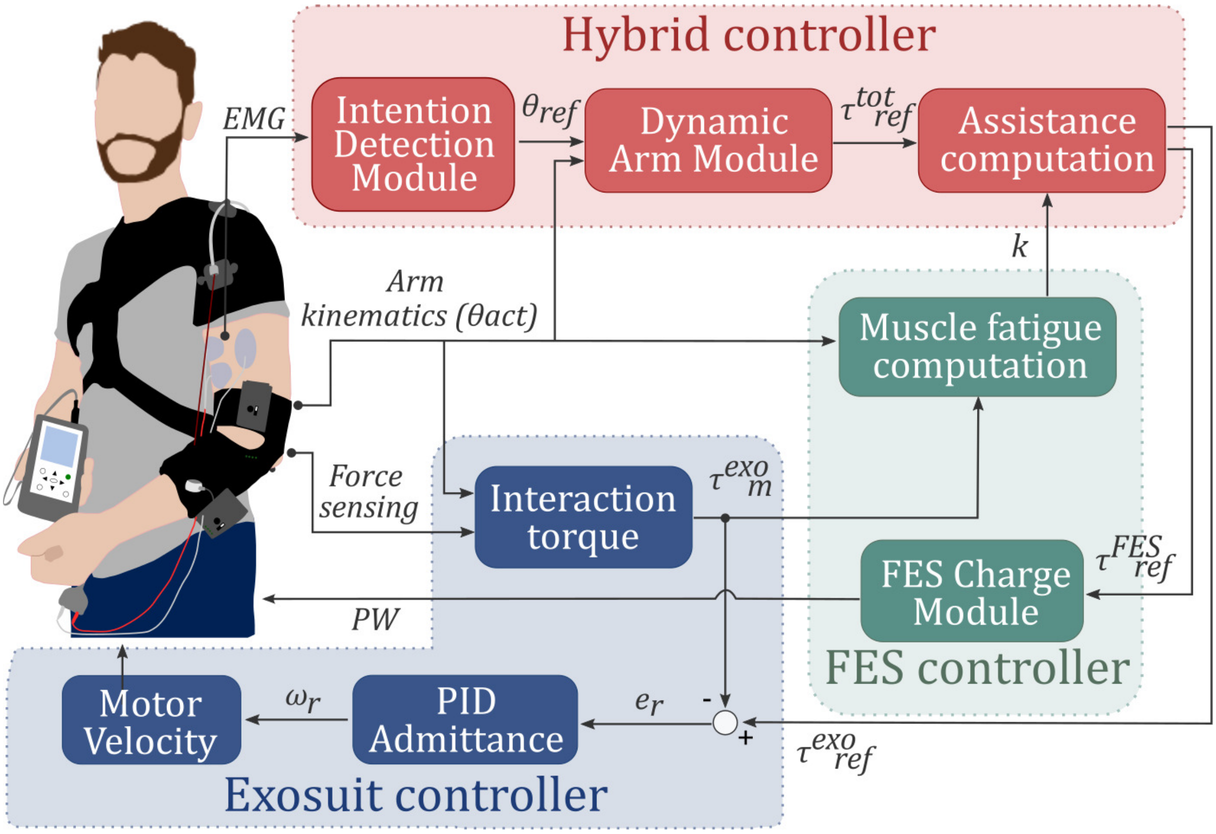


Figure 2: Real time control framework.

the exosuit and FES assistance. The *Compensation* phase accounts for the occurrence of muscle fatigue. Lastly, the *Extension* state is in charge of controlling the extension of the arm.

Hybrid controller

The *Hybrid controller* is the layer responsible of estimating the assistance needed to achieve the task. In the *Intention Detection Module* two thresholds are computed as 1.2 and 1.7 times the mean EMG value, which is calculated over a time window of 2 seconds in the *Break* phase. To each threshold a value of elbow flexion is associated: 60° and 90° respectively. The subject is asked to perform an isometric biceps contraction and once the EMG overcomes a threshold and the current EMG sample value is lower than the previous one, i.e. the EMG shows a downward trend, the subject's intention is mapped to a desired angle θ_{ref}, which is fed as input to the *Dynamic Arm Module*. This module computes the total elbow torque τ_{ref}^{tot} through an inverse dynamics approach, considering the subject's anthropometry, as described in [3]. Similarly to [4], the *Assistance computation* module splits τ_{ref}^{tot} into the reference torques of the exosuit (τ_{ref}^{exo}) and of the stimulator (τ_{ref}^{FES}) as follows

$$\begin{aligned}\tau_{ref}^{FES} &= \tau_{ref}^{tot} \cdot GainFES \\ \tau_{ref}^{exo} &= \tau_{ref}^{tot} \cdot GainEXO\end{aligned} \tag{1}$$

$GainFES$ and $GainEXO$ have values between 0 and 1 and $GainEXO = 1 - GainFES$. Their modulation is performed as explained in Section *FES controller*.

Exosuit controller

In order to deliver the motor command to the exosuit, the *Exosuit controller* estimates the error between the reference torque τ_{ref}^{exo} and the interaction torque between the wearer and the device (τ_m^{exo}), which is computed multiplying the force sensed by the load cell by the moment arm as described in [3]. The PID-admittance maps this error into the reference velocity w_r, which enters into the velocity loop of the motor, whose output is the mechanical actuation provided to the user.

FES controller

The *FES controller* involves two modules aimed at (i) modulating the pulse width according to the reference torque τ_{ref}^{FES}, and (ii) estimating the fatigue over time in order to adjust $GainFES$ and $GainEXO$.
The *FES Charge Module* defines the PW corresponding to τ_{ref}^{FES}, as follows:

$$PW = -\frac{\log(\frac{a}{\tau_{ref}^{FES}} - c)}{b} + \frac{PW_{off} \cdot \tau_{ref}^{FES}}{\tau_{max}^{FES}} \tag{2}$$

where a,b,c are subject-specific parameters tuned after a calibration procedure, PW_{off} is the term that accounts for the variation of this equation due to fatigue and τ_{max}^{FES} is the FES-induced torque at the maximum PW (500 µs). The *Muscle fatigue computation* estimates the actual torque provided by FES(τ_m^{FES}) through the torque balance equation

$$\tau_m^{FES} = \tau_m^{tot} - \tau_m^{exo} \tag{3}$$

with τ_m^{tot} being the actual elbow torque, computed using the arm kinematics. Subsequently, the FES-induced muscle fatigue k over the task is determined as follows

$$k = 1 - \frac{\tau_m^{FES}}{\tau_{ref}^{FES}} \tag{4}$$

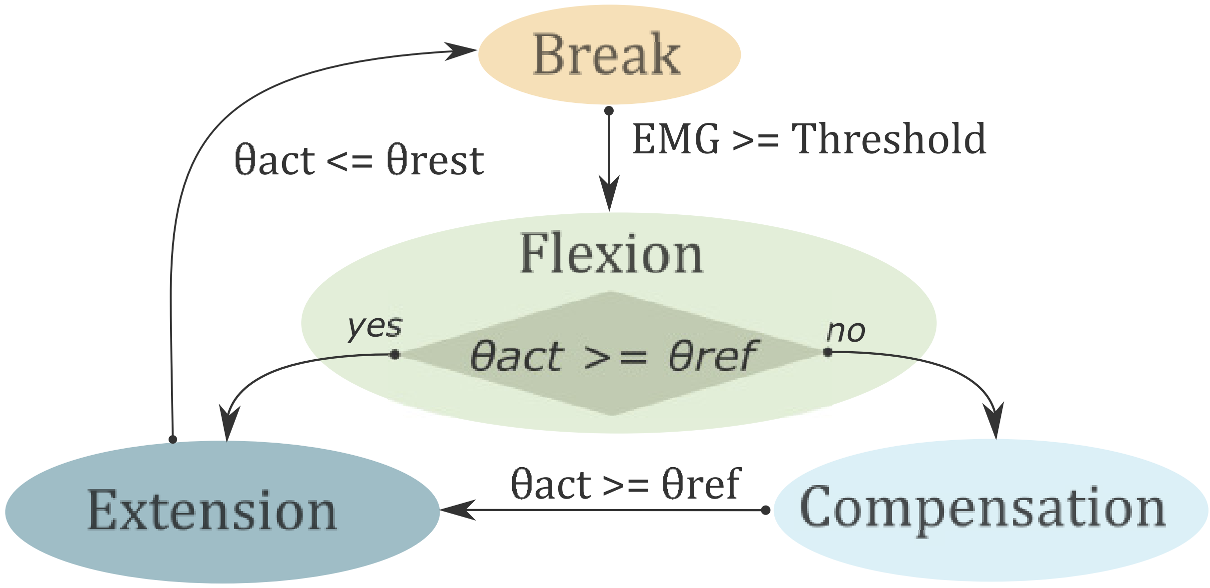


Figure 3: Illustration of the state machine.

Based on k, $GainFES$ and $GainEXO$ are tuned for the next movement as follows

$$\begin{aligned} GainFES(n) &= (1-k)\cdot GainFES(n-1) \\ GainEXO(n) &= 1 - GainFES(n) \end{aligned} \tag{5}$$

State Machine

The functionality of the hybrid system is coordinated by a state machine, which involves four main states: Break, Flexion, Extension and Compensation (Fig.3).

Break phase The *Break phase* is the phase in which FES does not provide stimulation ($GainFES$=0) and the assistance is delivered only by the exosuit ($GainEXO$=1). The input to the *Dynamic Arm Module* is the arm kinematics, used to compute the torque τ_{ref}^{exo} necessary to compensate for the gravity. The biceps EMG activity is acquired and its mean value is computed: when it reaches one of the two thresholds, the subject's movement intention is detected and the state machine switches to the *Flexion phase*.

Flexion Phase In this phase the elbow movement is totally driven by the hybrid system to get to the desired angle θ_{ref}, following a minimum-jerk trajectory of 3 seconds. The *GainFES* and *GainEXO* values define the two systems assistance levels. If at the end of the trajectory the desired angle is reached, the state machine switches to the *Extension phase*. Otherwise, the state machine enters into the *Compensation phase*.

Compensation Phase The state machine enters into the *Compensation phase* when FES is incapable of providing the required torque, due to muscle fatigue. Hence, the *Muscle fatigue computation* module determines the fatigue level and updates the gains for the next stimulation. Lastly, ramping up the PW, the system tries to get to θ_{ref}. The difference between the final PW value which allows to accomplish the task and the initial PW value (i.e. the one at the beginning of the *Compensation phase*) corresponds to the value of PW_{off} that appears in Eq. 2. Nevertheless, in case during the increase of the PW its maximum value (500 µs) is achieved, the exosuit compensates. When θ_{ref} is reached, the state machine moves into the *Extension phase*.

Extension Phase During the *Extension phase* the stimulation is gradually reduced and the Bowden cable tension is progressively released in order to extend the patient's elbow till a rest angle θ_{rest}. Ultimately, the state machine switches back to the *Break phase*.

Calibration Procedure

The calibration procedure was carried out for each participant before every trial in order to estimate the parameters of Eq.2 of *FES charge Module*. During this procedure, the exosuit was not used and the voluntaries wore only the IMUs in order to record the arm kinematics. As first step, the current amplitude able to flex the elbow at 90° with a value of PW of 250 µs was selected and kept fixed. The wearer was then stimulated in sequential trials, with increasing PW values, from 20 µs to 500 µs, in steps of 20 µs. For each PW value, the initial position of the subject's arm was the resting one. Based on the arm kinematics, the elbow torque for each value of PW was estimated by means of the *Dynamic Arm Module* output τ_{ref}^{tot}. Finally, the data were used to find the subject-specific coefficients *a,b,c* in Eq.2. The whole calibration procedure lasts around two minutes.

Experiments

Six healthy participants with no evidence or known history of musculoskeletal or neurological diseases, exhibiting normal joint range of motion and muscle strength, were enrolled in the experiment (four males/two females, age 27±2.53 years, mean±SD, body weight 83±21.16kg, and height 180.83±11.90cm). All experimental procedures were carried out in accordance with the declaration of Helsinki on research involving human subjects, and were approved by the IRB of Heidelberg University (Nr. S-311/2020). All subjects provided explicit written consent to participate in the study. The study consisted in repetitions of tracking trajectory tasks, performed in three different conditions: (i) *Exo*,

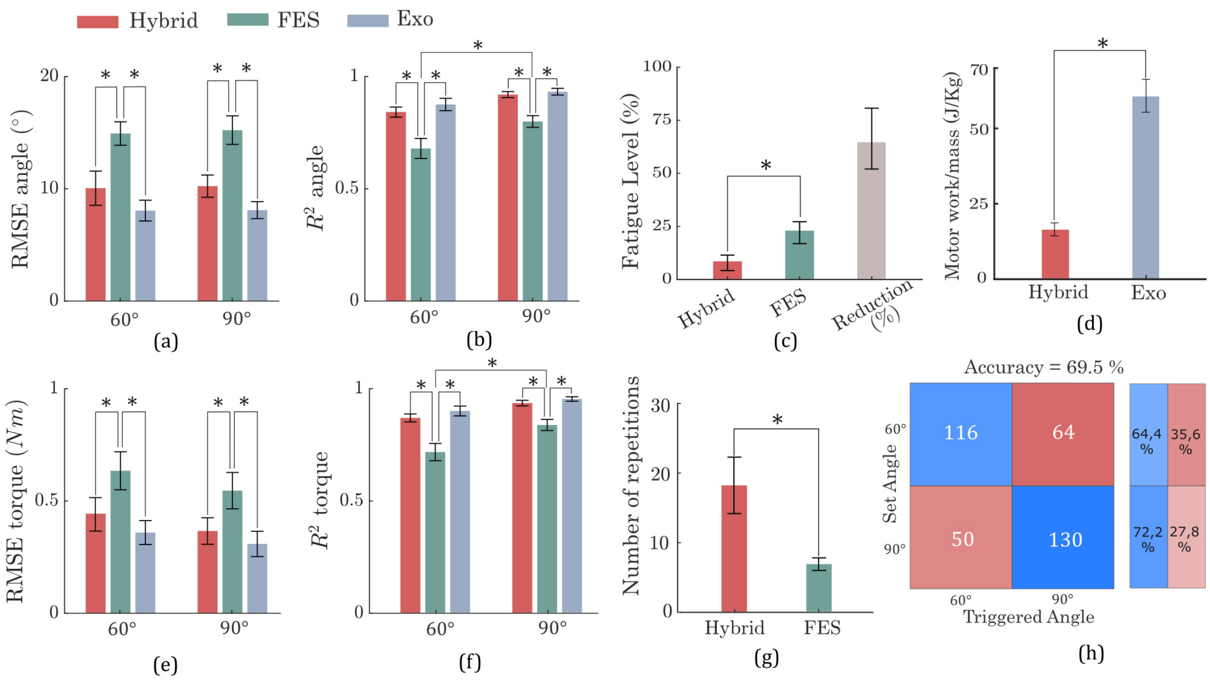


Figure 4: *Hybrid controller results.* RMSE and R^2 for elbow angle(a-b) and torque(e-f). (c)Fatigue level and percentage reduction of *Hybrid* fatigue compared to *FES*. (g)Fatigue onset (first repetition that displayed fatigue). (d)Motor work per unit of mass. (h)Intention detection confusion matrix.

where the movement was entirely guided by the exosuit (*GainEXO=1, GainFES=0*), (ii) *FES* in which only FES provided assistance (GainEXO=0, GainFES=1) and (iii) *Hybrid* during which both the systems worked cooperatively to provide assistance. For each condition, a total of thirty repetitions of elbow flexion with amplitude of 60° and 90° in equal number were performed. Both the order of the conditions and the sequence of the angles repetitions were randomized between subjects to avoid biased behaviours. To avoid fatigue, subjects rested for at least two hours between conditions. For each repetition, the supervisor asked the subjects to reach a specific threshold, i.e. the one corresponding to the pre-set angle for that repetition (60° or 90°), performing a biceps isometric contraction. Despite the threshold triggered by the subject, the variable θ_{ref} was set equal to the pre-set angle, so that the accuracy of the intention detection method was assessed comparing the requested and triggered angles, while ensuring the same amount of repetitions with both angles. Subsequently, they had to remain completely relaxed throughout the elbow flexion to avoid any voluntary compensation. For the *Hybrid* condition, the initial *GainFES* was set equal to 0.8.

Data Analysis

For every conditions the coefficient of determination R^2 and the Root Mean Square Error (RMSE) were computed considering all the trajectories of one subject, between the target and the actual elbow angle and between the target and the actual total torque provided by the systems . The FES-induced fatigue was assessed for *FES* and *Hybrid* as the ratio between torques after and before the trial, generated by stimulation (same current amplitude, PW=500 µs) and obtained mapping the elbow angle into the torque through the *Dynamic Arm Module*. This index was subtracted to 1 and express in percentage, i.e. percentage reduction of the FES torque due to fatigue. Moreover, the fatigue onset was evaluated as the first repetition of the trial that required an increase of PW in the *Compensation phase*. For *Hybrid* and *Exo* conditions the motor power, computed as product between the motor velocity and motor torque, was normalized by the subject's mass and integrated in time, obtaining the motor energy per unit of mass. Lastly, comparing the pre-set angle and the one actually triggered by the user, the accuracy of the intention detection method was evaluated, creating a confusion matrix. The statistical analysis was performed with MiniTab. Data normality distribution was validated using Shapiro-Wilk test. Assistance indexes, which resulted to be normally distributed, were tested with a two-way ANOVA using the three conditions as the first factor and the two angles (60°, 90°) as second one. A two-samples T-test was used to compare both *Hybrid* and *FES* for the fatigue indexes and *Exo* and *Hybrid* for the motor energy index. When the ANOVA results were significant, a Fisher's LSD test was carried out to assess pairwise differences. For all the tests, the level of statistical significance was set to 0.05. Reported values and measurements are presented as mean ± standard error (SE). Significant differences in the results were highlighted with the symbol * in all figures.

Results

In Figure 4 the results obtained are reported. The RMSE and R^2 of the trajectory angle and torque showed significant dependency on the three conditions ($p < 0.003$). Furthermore, the R^2 of *FES* condition had significant difference ($p < 0.007$) between the two angles, for both the kinematics and torque. For all the assistance indexes, the *Hybrid* condition did not show any significant difference ($p > 0.25$) with respect to the *Exo*. On the other hand, a significance difference ($p < 0.05$) was present for all the indexes between *FES* and *Hybrid* and between *FES* and *Exo*.

For what concerns the fatigue level a significant difference ($p = 0.001$) was highlighted between the *Hybrid* (6.89 ± 2.90 %) and *FES* (22.37 ± 4.17 %). Moreover, the *Hybrid*

condition significantly ($p = 0.008$) delayed the fatigue onset (14.50 $\pm$ 3.22 repetition number) with respect to *FES* (5.50 $\pm$ 0.72 repetition number).
The motor work per unit of mass was significantly ($p = 0.005$) related to the conditions *Hybrid*(16.56 $\pm$2.10 J/Kg) and *Exo* (60.83 $\pm$5.45 J/Kg).
Lastly, the intention detection module showed an accuracy of 69.5%, highlighting how the 90° threshold was more accurately triggered (72.2%) compared to the 60° one (64.4%).

Discussion

The maximum outcomes of patients rehabilitation in neuromuscular pathologies are obtained with active, intensive, repetitive and long-lasting rehabilitative sessions. Hybrid Robotic Rehabilitation Systems demonstrated their ability to fulfil these requirements, merging the rehabilitation benefits of FES with the precision, repeatability and adaptive intensity of robotic devices. Even thought exosuits seem to be a promising alternative to exoskeletons, few studies have explored the possibility of combining exosuits with FES. Would exosuits be a feasible option in hybrid systems? To address this question, an innovative hybrid system composed by FES and an elbow exosuit was proposed and its functionality was analyzed in terms of kinematics, FES-induced fatigue and motor torque requirement.
As expected, the results highlighted how the solely use of FES produced both the highest torque and angle trajectory errors. Contrarily, the exosuit by itself was able to perform flexion movements with the lowest angular and torque error. No significant differences were found for these metrics between the exosuit and hybrid system, whereas the hybrid system significantly outperformed FES alone. This means that the hybrid controller was able to counterbalance the low precision and accuracy of FES, while preserving the assistance performances of the exosuit. Moreover, since the metrics were not significantly dependent on the amplitude of the movement angle, we can state that the hybrid controller performed with no significant difference with respect to the exosuit independently by the range of motion.
Decreasing and delaying FES-induce muscle fatigue was one of the crucial goal of this study, since it is currently the biggest FES drawback. Comparing the torque generated by FES at the beginning and after the trials, a significant reduction of about 63$\pm$11.6% of the fatigue with the hybrid controller with respect to FES alone was obtained. This result is the direct consequence of the adaptive allocation of the assistance between the exosuit and FES in the hybrid system, according to the estimated fatigue. Moreover, with the hybrid controller the subjects were able to perform more repetitions before experiencing fatigue with respect to FES alone. This is a consequence of assisting the movement by

both the exosuit and FES since the beginning of it, hence reducing the amount of stimulation required by FES and resulting in delayed onset of fatigue.
Regarding the motor work for the *Hybrid*, the results showed a significant reduction of about 71.70±5.44% compared to *Exo*. These outcomes suggest the capability of the developed hybrid system to lower the energy and torque required by the motor, therefore enabling the system to include smaller actuators, hence increasing the portability of the system.
Lastly, the data analysis carried out on the intention detection showed that the method had a satisfactory accuracy of about 69.5%, hence being suitable to recognize subjects' intention.
Notwithstanding, this work presents some limitations. First of all, the control of FES is not implemented in a close loop, but it relies on the subject specific relationship between the FES-induced torque and PW. Even thought a modality to vary this relation accounting for the fatigue was proposed, due to the highly variability of FES outcomes a closed loop regulation of the stimulation would be more appropriate to manage its assistance. Secondly, the controller required the subjects to be completely relaxed throughout the movement. This requisite was necessarily introduced because the controller was tested on healthy subjects and without measuring continuously the biceps EMG signal, it was not possible to detect the subject's voluntary effort. Lastly, the developed controller was tested only on healthy subjects.
In future studies another FES controller approach, either close-loop or EMG-proportional, should be implemented for this exosuit hybrid system. Moreover, further analysis should be conducted to validate the different outcomes between exoskeletons and exosuits in hybrid systems and their long-term rehabilitation achievements.

Conclusions

This study integrated for the first time in the literature FES with an elbow exosuit to investigate the possibility of using exosuits in hybrid systems. The results demonstrated that the hybrid controller managed cooperatively the assistance provided by the two systems, resulting in accurate and precise movements. Moreover, the proposed adaptive assistance allocation was able to detect and manage muscle fatigue, culminating in lower and delayed in time fatigue, decreasing also the motor torque requirement. These results reasonably suggest the feasibility of using exosuits in hybrid rehabilitation treatments of neuromuscular diseases in order to promote motion recovery.

Contents

1 | Introduction and Background

1.1. Functional Electrical Stimulation

1.1.1. FES principles

Functional electrical stimulation (FES) is a technique that consists in delivering short electrical pulses of current to intact lower motor neurons in order to elicit artificially induced muscle contractions [5, 6]. In general, whatever system or device that activate the nervous system using FES is called *neuroprosthesis* and it presents two main functions: functional assistance role to enhance or aid a functional task, and therapeutic role. The application of FES is particularly indicated in those clinical situations in which subjects present partial or complete paralysis of the muscles. Indeed, delivering coordinated stimulation pulses to muscles associated with a joint, results in generation of torques about the joint and therefore to its actuation. Two pathologies for which FES is mostly used are spinal cord injury (SCI) and stroke.

SCI is a pathological condition caused by the disruption or damage of spinal cord tissue, due to diseases or traumatic injuries. SCI is associated with partial or complete alteration of strength, autonomic nervous system functionality and muscular paralysis in the body parts below the injured site. Despite most of the time SCI disabilities are permanent, with the help of rehabilitation is possible to help the SCI patients to restore motor functions. On the other hand, stroke occurs when some parts of the brain do not receive enough nutrients and oxygen, due to the lack of blood supply to those brain areas. This is provoked by either a blood vessel rupture or a blood clot. As a consequence, stroke patients might present either hemiparesis of one side of the body, for which the patient experience weakness or loss of strength, or hemiplegia, i.e. partial or complete paralysis. Moreover, other common symptoms are deficit of sensorial information, muscular spasticity, lack of coordination and muscle atrophy.

For both these categories of patients, FES is a great tool to regain motor functionality, both for assistive and rehabilitation applications [5, 7]. Indeed, the main advantages of exploting FES in these conditions are: motor relearning, reduction of spasticity, strength-

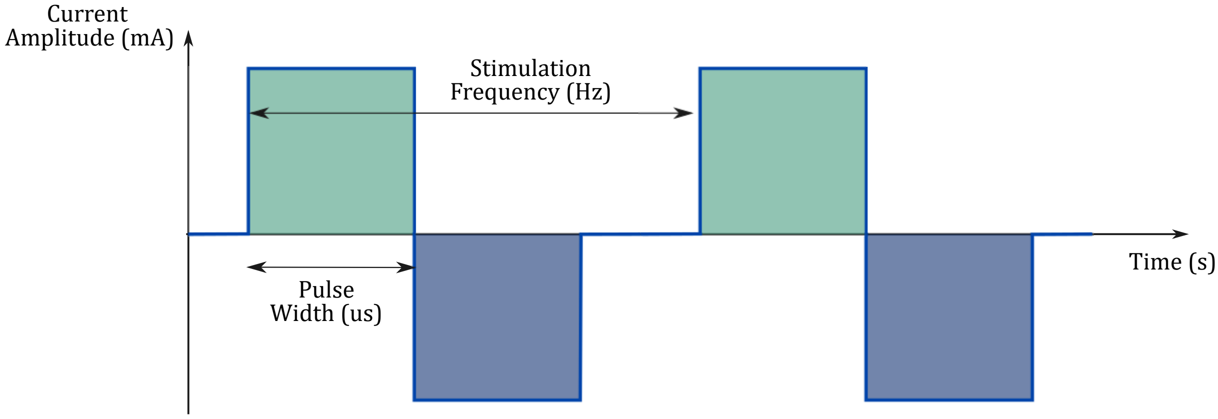


Figure 1.1: *Symmetrical biphasic stimulation waveform.* Typical biphasic stimulation waveform, defined by the current amplitude (mA), the pulse width (us) and the stimulation frequency(Hz). The areas under the curves represent the charge transferred into (green one) and out of (blu one) the tissues. These areas are equal, since a biphasic waveform provokes a balanced charge transfer toward and from the tissues.

ening of muscles, bone remineralization and recovery of sensorial awareness. The delivery of the stimulation pulses is carried out thanks to electrodes. Based on the type of electrodes, two main categories of FES systems can be highlighted: implanted (percutaneous, epimysial, epineural, intraneural and cuff) and transcutaneous (electrodes are put on the skin surface). The transcutaneous stimulation presents the advantage of being non-invasive but less selective than the implanted one, since it is not able to selectively stimulate a specific motor unit. It makes use of two electrodes place in either monopolar or bipolar configuration. The latter is the most common since it restricts the electrical field in a narrow area between the electrodes, thus having a greater selectivity with respect to the monopolar configuration.

When muscles are stimulated by FES, they receive a train of short electrical pulses which are characterized by four parameters: current amplitude, pulse width, frequency of stimulation and stimulation waveform (Figure 1.1). The product between the stimulation current amplitude (measured in mA) and the pulse width (measured in us), defined the charge delivered to the neuromuscular system. The higher the charge is, the higher the number and deeper the amount of muscle fibers stimulated. The frequency of stimulation (measured in Hz) determines the rate of the stimulation pulses; the higher the frequency is, the higher the tension generated, but the earlier the occurrence of muscle fatigue. All of these parameters influence the stimulation intensity and consequently the tension produced by the stimulated muscle [5, 6]. The stimulation parameters need to be tuned for each subject depending on the desired task and whenever the electrodes position is change.

For what concerns the stimulation waveform, different stimulation patterns can be adopted, such as monophasic, triangular, symmetrical biphasic, asymmetrical biphasic. The one most commonly used is the biphasic (asymmetrical or symmetrical), since the charge that is sent into the body tissues is the same that is removed from the biological tissues, i.e. the charge in the positive cycles is the same of the negative ones. This hinders galvanic processes that could eventually cause biological tissue damage [8].

The artificial electrical stimulation of a motor nerve originates two action potentials in two opposite directions. The first one is in orthodromic direction and it goes towards the neuromuscular junction of the corresponding motor unit; it is the one responsible of causing muscle contraction. Conversely, the one that travels in the opposite direction, the antidromic potential, goes towards the anterior horn cell. These potentials are indistinguishable from the physiological ones, so they present the "all or none" characteristic and the "stimulation threshold", which can be defined as the lowest magnitude of electrical charge able to elicit an action potential. Nevertheless, the FES-induced muscles activation and the physiological one present several differences.

Physiology of muscle contraction Physiologically, when a subject wants to perform a specific task, the brain regulates the force elicited by the muscles varying the number of motor units activated and the motor neurons firing frequency. Motor units are defined as the systems composed by a single motor neuron and the muscle fibers innervated by it. The amount of motor unit per muscle depends on the muscle function: the higher the level of accuracy of the movement required by a muscle, the higher the number of its motor units and the lower the muscle fibers innervated per motor unit. Muscle fibers can be distinguished in two main categories [9]: type I and type II. The first ones are "slow-twitch" (type I) muscle fibers, which use mainly oxidative metabolism and therefore they are fatigue resistant, they have slower reactivity with respect to type II fibers but they are able to produce a constant and long-lasting force. On the other hand, "fast-twitch" (type II) muscle fibers, whose energetic metabolism is mainly glycolytic, undergo to fatigue much faster than type I ones and provide a fast, high magnitude and short force twitch. Type II fibers possess long recovery periods, thus show fast muscle fatigue. The muscle fibers composition are plastic in time, since they are able to adapt to changing demands varying the size and the type of muscle fibers [9, 10]. This phenomenon can be observed in subject with pathological situation like SCI and strokes; indeed, following a long period of inactivity, their muscles suffer from atrophy and their fibers composition shifts towards a greater percentage of fast twitch type II fibers. Consequently, pathological patients are incapable of withstanding muscle fatigue as healthy subjects.
Every time a motor neuron fires, the corresponding muscle fibers momentarily contracts.

In order to achieve a constant contraction of the muscle fibers, i.e. the muscle exerts a constant force in time, the associated motor neuron must deliver a sequence of impulses. This goal is physiologically achieved with a stimulation frequency that varies from 6 to 8 Hz [5]. In addition, adjacent motor units deliver contraction stimuli to their muscle fibers asynchronously, i.e. when one motor unit fires, the adjacent ones are resting. This phenomenon, which is called asynchronous recruitment, is necessary to prevent the early onset of fatigue.

FES artificially induced contraction As stated before, the FES-induced contraction of muscle fibers presents some dissimilarity with respect to the physiological one. First of all, the FES-induced fibers recruitment is non physiological, since type II muscle fibers, which are the ones with less resistance to fatigue, are recruited prior to type I fibers. This is due to the fact that type II fibers have larger diameter axons, hence they have a lower activation threshold. Secondly, there is no turn-over between the muscle fibers activated by FES, since only the fibers included in the stimulated muscle volume (space between the two electrodes) will be activated. This activation happens synchronously, i.e. all the muscle fibers inside the stimulated volume with activation threshold lower than the charge delivered are recruited. Consequently, the only way to obtain a constant contraction is to increase the frequency of stimulation at least above 20 Hz, which is more than twice the physiological one. All these aspects lead to an earlier onset of muscle fatigue and they hinder the possibility of finely modulating the contraction.
How muscles respond to FES presents some criticalities. Firstly, muscle response is non-linear, since it requires a minimum level of charge in order to elicit a muscular activation and after a certain amount of charge the response is constant, i.e. the muscular system goes into saturation. Secondly, due to muscle fatigue, the output of a stimulation is time varying, thus same level of stimulation will elicit different muscular contraction in different time instant.

1.1.2. FES for motor relearning

Motor relearning can be defined as restoring motor skills lost due to central nervous system damage [6]. Motor relearning is possible thanks to neuroplasticity, i.e. the "ability of the nervous system to respond to intrinsic or extrinsic stimuli by reorganizing its structure, function and connections" [7]. It has been shown that active (i.e. with the subject involvement), repetitive, high intensity and goal-oriented movements during rehabilitation lead to greater extent of neuroplasticity [6, 11]. Moreover, if these movements are mediated by the combining action of FES and the subject's residual voluntary capability, motor

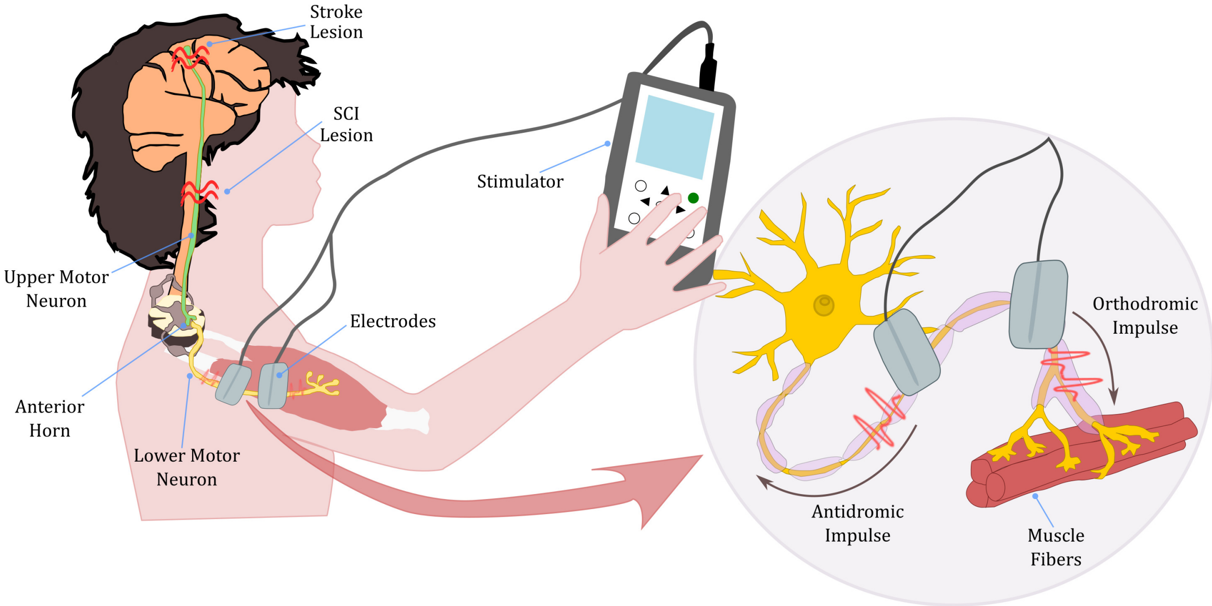


Figure 1.2: *FES principles.* Due to either a lesion of the spinal cord (SPI) or a cortical injury (stroke), subjects experience partial or complete loss of motor control. Exploiting Functional Electrical Stimulation is possible to artificially activate lower motor neuron, hence eliciting muscle contraction. In particular, two types of impulses are elicited. The antidromic one runs towards the anterior horn cell whereas the orthodromic one goes towards the muscle fibers, resulting in muscle contraction. The synchronous occurrence at the anterior horn of the antidromic impulse and the voluntary impulse coming from the cortical cortex leads to synaptic potentiation, boosting the rehabilitation outcomes (Rushton's theory).

relearning is enhanced also via spinal mechanisms. This hypothesis was first proposed by Rushton [12]. Rushton's idea relies on the hypothesis that the synaptic connections between the anterior horn cells and the pyramidal tract axons can be consider a Hebb-type synapse. A synapse is called Hebb-type if it follows Hebb's rule [13]: if pre-synaptic and post-synaptic firings coincide or the latter presents a short delay with respect to the pre-synaptic one, the synaptic connection is strengthened, otherwise the synapse is weakened. Because of a partial lesion of the spinal cord or following a stroke event, some of the pyramidal track population are impaired and just a small percentage of anterior horn cells present an efficient and complete innervation by the pyramidal track, leading to activity decorrelation and low synaptic strength. As described before, when FES is delivered to the neuromuscular system, two electrical impulses are generated: orthodromic and antidromic. The antidromic one goes in the direction of the anterior horn cell, activating it. Therefore, if the triggering of anterior horn cell by FES is simultaneous with the activation of the residual pyramidal track, due to the voluntary effort of the subject, it will boost the synchronization of the presynaptic and postsynaptic activity in the anterior horn cells, leading to a potentiation of the synaptic connection (Hebb's rule) and a higher rehabilitation outcome (Figure 1.2).

1.1.3. FES control strategies

In order to achieve accurate, precise, smooth and robust movements, FES should be controlled efficiently modulating the stimulation parameters. To obtain such fine modulation, some considerations should be taken into consideration [14]. Firstly, as stated earlier, the muscle response to FES is nonlinear and it changes in time when muscle fibers are fatiguing. Secondly, a significant delay of about 50 ms between the stimulation and the muscle contraction is always present, which represents the time required by biochemical mechanisms to transform electrical stimulation charge into muscle tension. Thirdly, many muscles are biarticular, hence they actuate multiple joints at the same time, hence the dynamic of the movement could be affected by this aspect. Lastly, in case of SCI patients, there could be some spasticity symptoms and unpredictable movements, due to preserved spinal cord reflexes below the level of injury, that can be seen as internal disturbances. As shown in Figure 1.3, the simplest designs of FES controllers can be implemented in open loop (Figure 1.3a), in close loop (Figure 1.3b) or in feedforward-feedback configuration (Figure 1.3c). The input to all these configurations is usually either a reference angle or torque at the actuated joint, whereas the output is commonly the current amplitude or the pulse width (PW).
The open-loop modality requires the creation of an *Inverse Model* able to map the input desired variable into the stimulation parameter. In this configuration there is not feedback by sensors and most of the inverse models are not updated accounting for the time-variability of FES. In addition, this mapping is not straightforward since it needs to be tuned on each subject and it is influenced by several aspects, for example the position of the electrodes.

Contrarily, a close loop architecture comprises a *Control System*, usually a Proportional Integrative Derivative (PID) controller, able to convert the error (err) between an input reference variable and the actual variable, measured by a sensor, into the stimulation parameters level (PW), as shown by Equation 1.1.

$$PW(t) = K_p \cdot err(t) + K_i \cdot \int_0^t err(t)dt + K_d \cdot \frac{derr(t)}{dt} \tag{1.1}$$

where K_p, K_i and K_d being the proportional, integrative and derivative gains respectively.

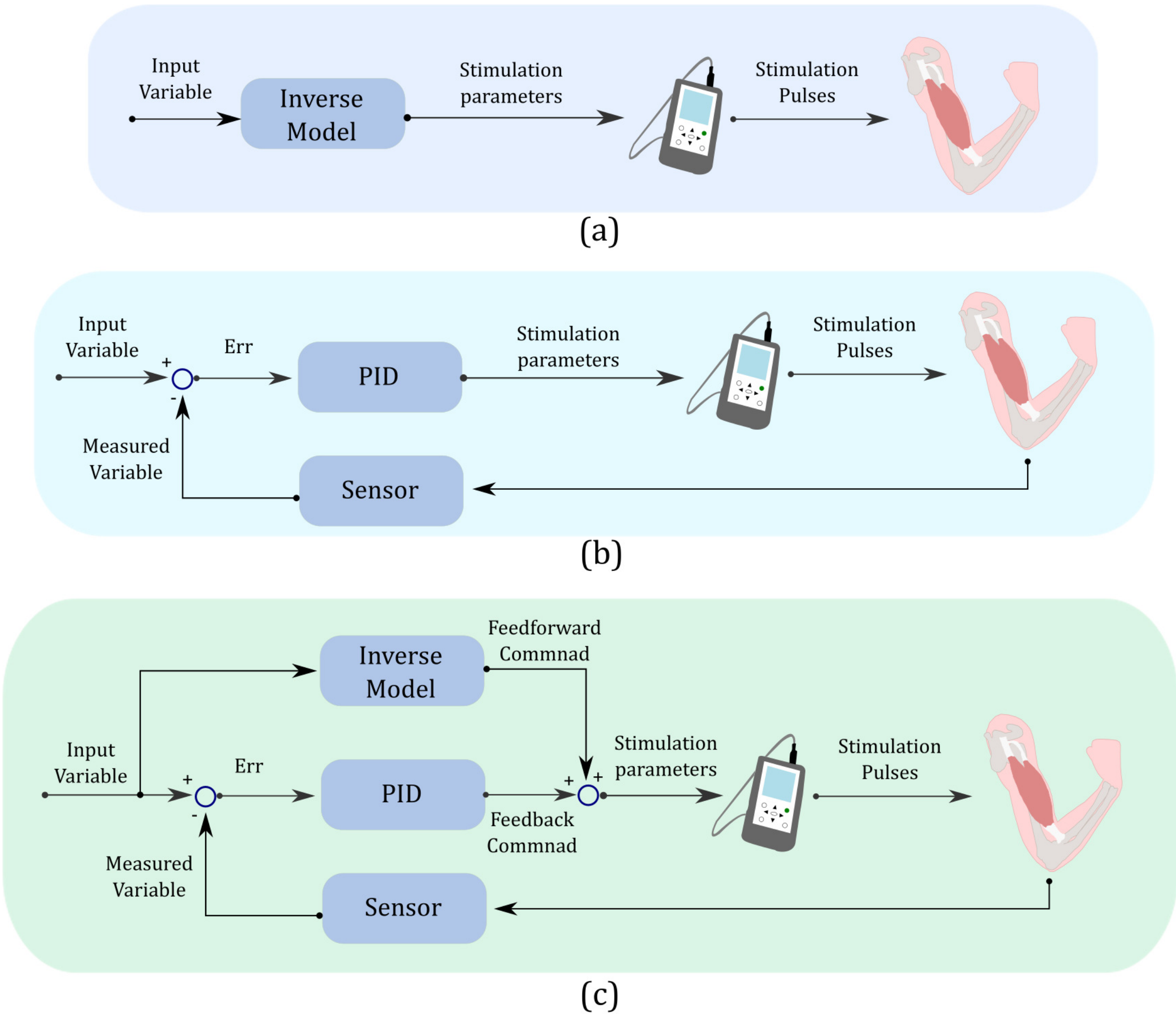


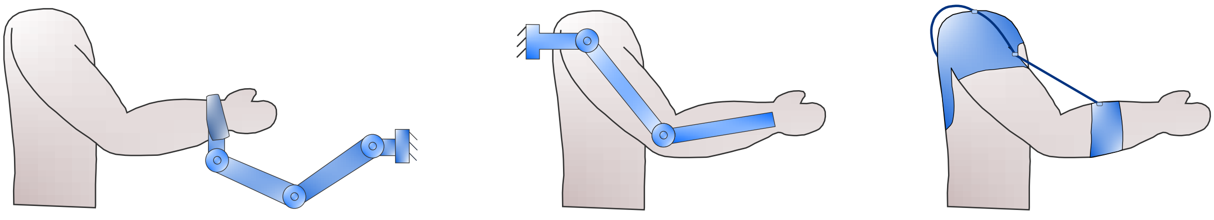
Figure 1.3: *Generic FES control systems.* (a)Open-loop configuration. (b)Closed-loop (feedback) configuration. (c)Feedfroward-feedback configuration. Figure adapted from [5].

The advantages of controlling the stimulation in closed loop are the possibility of accounting for unpredictable external and internal (i.e. spasms) disturbances and avoiding relying on predefined stimulation patterns or on predefined relationship as open-loop FES controller. Nevertheless, it requires the tuning of the PID constants, which are subject-specific, and they are not able to manage the non linearity and time variability of FES stimulated muscle system. For example, in case of muscle fatigue, the input *err* variable would be higher since the feedback variable would differ from the reference one, leading to an increase of the stimulation parameter, which would eventually end up in higher fatigue, creating a vicious circle.

Lastly, a feedforward-feedback controller combines the predicted stimulation parameter by the inverse model (feedforward loop) and the ouput of the PID controller (feedback loop). The advantages of this control system is to overcome the open-loop limitations thanks to the feedback term, concurrently reducing the time-lag introduced by the feedback loop, thanks to the feedforward component.

1.2. Robotic devices for rehabilitation

Robotic devices have gained more and more attention in the rehabilitation field, since they are capable of increasing patients access to therapies and serve as additional cooperative tools for therapists, thanks to their movement controllability and measurements reliability [15–17]. Rehabilitation of impaired limbs and the resulting restoration of functional movements are maximized when patients are trained with intensive, goal-oriented and active repetitive movements [18, 19]. Rehabilitation robots have shown to be suitable in providing such therapies requirements, increasing training frequency, intensity and reducing the need physiotherapists' supervision. A general classification of rehabilitation robots can be done between *End-effector* and *Exoskeleton* [15].
End-effector systems (Figure 1.4a) interact with the patient distally on one single site; the patient holds a manipulandum which senses forces exerted by the robot [17]. Since the only interaction with the subject is on the attachment point, the others not actuated joints, for example the shoulder and elbow, could perform several unrestrained rotations, resulting in a potentially harmful joints configurations and hindering the correct movement re-learning. Moreover, end-effector robots primarily allow planar reaching [19].
On the other hand, rigid exoskeleton robotic systems (Figure 1.4b) completely define the joints' axes, since they enclose patient's limbs, aligning with the patient's joints. Along the assisted limb, exoskeletons exert distributed forces, giving reliable joints' measurements independently at each joint [17, 18]. There exists two subdivisions of exoskeleton devices (Figure 1.5): *external force exoskeletons*, which transfer forces towards an external based, and not grounded *internal force exoskeletons* in which forces are transmitted directly to the subject.
Multiple studies have shown the ability of exoskeletons in providing both assistance during functional movements, reducing the metabolic consumption [20], strengthening human capabilities [21], supporting post-stroke rehabilitation [22–24] and paraplegic patients [25]. Nonetheless, due to their high production costs, most of the exoskeleton devices are bounded to few specialized medical centers, such as research laboratories or elite rehabilitation facilities. Furthermore, such devices are bulky, heavy and require the perfect alignment between the user and device joints. Indeed, joints misalignment would lead to unrestrained forces exerted to patients, causing their discomfort, hindering the correct



(a) (b) (c)

Figure 1.4: *Illustration of types of robotic devices.* (a)End-effector. (b)Rigid exoskeleton. (c)Soft wearable robots (Exosuit).

motor rehabilitation and potentially being dangerous [26].
Such limitations open up new possible scenarios for soft wearable robotic technologies (Figure 1.4c), given their less restricted and more compliant structure. These devices are made of textiles and elastomers materials, allowing them to be wore without hampering the subject's biomechanics, being more conform to the human anatomy. In the past decade, soft wearable robots have been addressed with different titles, such as *exomuscles*, *soft exoskeletons* and *exosuits* [27].

1.2.1. Exosuits: soft wearable robots

Soft robotics suits, or exosuits, are clothing-like wearable robotic devices made of soft materials, that wrap around subjects' body part, working along side with their muscles [27]. The materials adopted in these devices, such as silicone elastomers or fabrics, are defined "soft" due to their compliance under the application of external forces and their ability to conform to different geometries [28]. As Thalman *et al.* [28] found out in their meta-analysis regarding soft wearable robotics publications over the time period from 2009 to 2019, 57% of these publications were conducted between the 2017 and 2019, pointing out the great spreading these devices are experiencing. This fast rise is mostly the consequence of the capabilities of soft robotics in overcoming exoskeletons drawbacks. In particular, compared to rigid exoskeletons, exosuits do not require the perfect alignment between the robotic device joints and the subject ones, preventing possible interference during the execution of movements. Furthermore, they are light-weight and less cumbersome, hence they are safer, cheaper and with higher comfort for the wearer [19, 28, 29].

1.2.2. Exosuits taxonomy and actuation

In Figure 1.5 is shown a general classification of wearable robotic devices [27]. The first classification of wearable robots is done based on the loads bearing modality. Rigid ex-

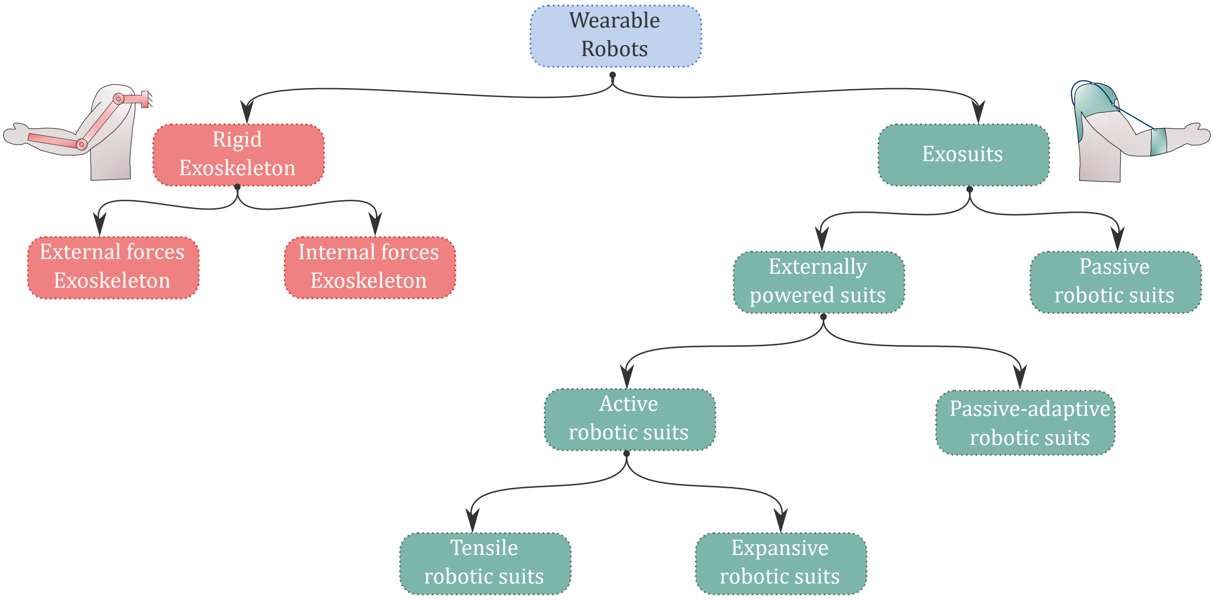


Figure 1.5: *Taxonomy of wearable robots.*The first classification is between *Rigid Exoskeleton* and soft wearable robotics (*Exosuits*): the latter rely entirely on human skeleton to bear forces. Exosuits are further classified depending on the presence of an external source of power (*Externally powered* or *Passive*), on the transmission of the power (*Active* or *Passive-adaptive*) and on the modality of power transmission (*Tensile* or *Expansive*). Figure adapted from [27]

oskeletons possess harsh structures that allow them to sustain compressing loads alongside with the human skeleton. Contrarily, soft robotic suits do not have a load-bearing frame, but they exploit human body structure to dissipate reaction forces among body segments. Further distinction can be done for soft suits that are powered, *Externally powered suits*, or not powered, *Passive robotic suits*. *Externally powered suits* can be divided in the ones that have actuators that directly produce mechanical power or the ones that change their mechanical properties using the extenal power source (*Passive-adaptive soft robotic suits*). Lastly, the actuation can be accomplished putting under tension a functional element (*Tensile robotic suits*) or inducing the expansion of a folded bladder containing a fluid (*Expansive robotic suits*). The functionality of *Tensile robotic suits* recalls the physiological process of skeletal muscles that are in charge of generating forces which are transmitted to the exoskeleton tensioning tendons associated to those muscles. Similarly, *Tensile robotic suits* present a functional element able to contract and transmit tensile forces to the skeletal system. Based on the type of the functional element and on the actuators, four subgroups of *Tensile robotic suits* can be identified [27, 28]: Pneumatic artificial muscles (McKibben PAMs), Twisted strings actuators, Shape-memory alloys and Electric motor-tendon unit.

1. Pneumatic artificial muscles (McKibben PAMs): actuators which use compressed air into an elastic bladder to produce uni-axial contraction forces. They are a feasible solution for joints that need high torques due to their high power-to-weight ratio, compliance and durability. Nevertheless, their are in general bulky, limiting the wearer mobility.

2. Twisted strings actuators: made of multiple tendons twisted around each other, able to transform rotatory to linear power and deliver high linear forces.

3. Shape-memory alloys: materials, such as NiTi alloys, that under the action of an external stimulus are able to vary their shape and coming back to the original configuration when the stimulus is no longer present. Their contraction and extension are in general slow.

4. Electric motor-tendon unit: comprise a cable (tendon) connecting two anchor points, able to deliver forces to a target joint mimicking the human musculoskeletal system. Since the mechanical power is transmitted by these cables, the motor can be placed far from the target joint, for example in a place where it can be better sustained by the subject. These tendons are light-weight and display high flexibility, such as Bowden cables. Given the well known knowledge about electric motors, this type of actuators are currently the most used for exosuits. Nonetheless, the major drawbacks of cable-driven exosuits with respect to others actuators are: (1) the compliance of the Bowden sheaths and the high friction produced between Bowden cable and the sleeve, which drastically decreases the mechanical efficiency; (2) higher weight due to the presence of the motor; (3) possible displacement of the anchor points ; (4) the wearer's skin is subjected to strong shear stresses.

1.2.3. Field of application of Exosuits

The dominant employments of exosuits are augmentation of human capabilities and strength, assistance or rehabilitation [28]. The assistance provided by exosuits mainly focuses on aiding subjects in accomplish ADLs and functional movements. The level of assistance delivered to the subject depends on the number of joints that are actuated and aided. Multiple examples of assistive exosuits can be found in literature, both for lower limb and upper limb, as shown in Figure 1.6. Lower-limb exosuits aim at supporting subjects during locomotion delivering timed assistance, reducing their metabolic consumption and not hindering their natural kinematic. Indeed, a common goal to all exosuits, and in general to all robotic devices, is to be transparent to wearers, i.e. preventing the application of torques when not requested and do not hampering their kinematics.

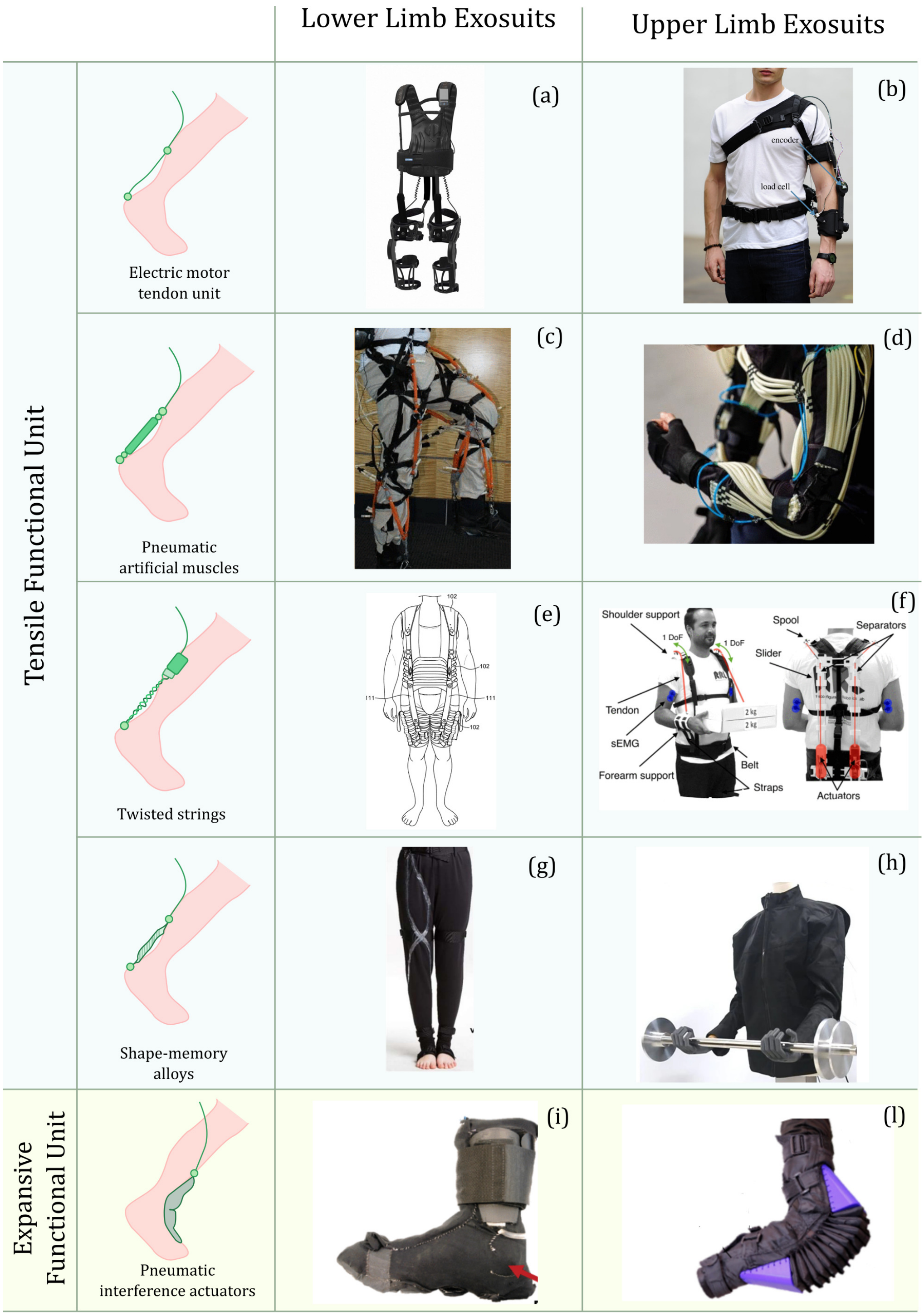


Figure 1.6: *Classification and examples of exosuits.* Examples of exosuits for lower-limb and upper-limb categorized based on the type of functional unit: Tensile (a-h) and Expansive(i-l) . Moreover, *Tensile robotic suits* are further subdivided based on the type of actuation. Figure adapted from [27]. Reference of the images: (a) [30], (b) [31], (c) [32], (d) [33], (e) [34], (f) [35], (g) [36], (h) [37], (i)[38], (l)[39]

Regarding upper-limb exosuits, the principal objective is assisting the degree of freedoms (DOFs) of the actuated joints, aiding them in performing ADLs, such as drinking or grasping. These joints present higher complexity with respect to lower-limb ones, both in terms of DOFs and their necessity to be not over-stressed with high-weight components. Moreover, upper-limb joints movements do not follow cycling pattern as lower-limb ones, hence the actuation control has to deal with more intricate problems.
Another promising use of exosuits is in the rehabilitation field [40], which it has been poorly investigated yet. Impaired patients who lack the necessary muscle strength to perform a functional movement, would benefit from the help of exosuits, since these ones work in parallel with patients' muscles, hence proving the additional torques necessary to accomplish a task. Nevertheless, most of impaired subjects require the rehabilitation systems to be robust in term of delivered assistance, which is one of the greatest limitation of exosuits compered to rigid exoskeletons.

1.3. Hybrid Rehabilitation Robotic Systems

Rehabilitation of impaired limbs and the resulting restoration of functional movements are the key targets of rehabilitation techniques, which are maximized when patients are trained with intensive, goal-oriented, frequent and active movements. As presented in previous sections, both robotic devices and FES have proved their suitability to be rehabilitation tools, despite both of them present limitations. Robotic devices assure adaptable, high frequency and high intensive training, with high precision and accuracy of movements. However, the rehabilitation effect of robotic devices is limited to only passively guide the task, without comprising the activation of patients' muscles. Contrary, FES is able to elicit musculoskeletal system activation and ultimately inducing activity-dependent plasticity on the Central Nervous System [41]. Nonetheless, the precision of movements elicited by FES is affected by several aspects: non-linearity, time-variability and unpredictability of muscle response to artificial stimulation and muscle physiological electro-mechanical delay. Additionally, muscle fatigue arises early in time with respect to physiological muscle contraction, worsening even more movements accuracy and precision and preventing the application of the stimulation for long period of time.

It is evident that the drawbacks of robots are the advantages of FES and vice-versa, hence is reasonable to join them together. In other words, merging FES and robotic systems together, with the development of Hybrid Robotic Rehabilitation Systems, allows to exploit advantages of both systems and overcome their limitations, resulting in a more

effective rehabilitation therapy and better assistance in ADLs [42, 43].
In particular, the assistance from robotic devices is able to improve both the precision and the accuracy of movements and to shrink muscle fatigue magnitude. On the other hand, the inclusion of FES in the control loop allows to make use of the rehabilitative benefits by eliciting the musculoskeletal system activation, reducing the motor torque requirement, the robots motor energy consumption, the actuators dimensions and consequently the weight and size of the total system [44].
With hybrid devices we refer to whatever system configuration that comprises Functional Electrical Stimulation and a robotic device. Therefore, in literature there exits studies in which the two systems assist the same joint synchronously, and others in which the systems actuate different joints. Nonetheless, in order to achieve all the benefits listed above, the two systems must work in concert, in such a way they can provide a coordinated actuation on the same joint. Consequently, the hybrid system configuration opens up new problems regarding the complex coordination of the systems and the strategy according to which the assistance is delivered.
In the following sections, the current state of art of hybrid system and their control strategies are presented. In particular, the focus of the discussion would be on those studies regarding upper-limb exoskeleton hybrid systems which actuate concurrently the elbow joint and that comprises only stimulation mediated by surface electrodes.

1.3.1. Intention detection and user interface

One common element in hybrid systems is inferring the subject willingness and exploit it to guide and manage the system functionality, either to trigger the onset of the hybrid system actuation or to continuously control it. There are several modalities through which is possible to detect and decode the intention of subjects, such as electromyography, brain-machine interfaces, eye-tracking and voice commands.
The most commonly implemented are electromyography and brain-machine interface (Figure 1.7).

Electromyography (EMG) Electromyography signal is the summation of all the action potentials of the muscle in the sensed electrodes volume. It can be obtained either with surface or with implanted electrodes; the former is the most common due to its low invasiveness. Exploiting EMG signal in hybrid system requires a residual degree of volitional control of the target muscle, for example in case of incomplete SCI or stroke patients.
The EMG signal can be exploited to control the stimulation in two main modalities:

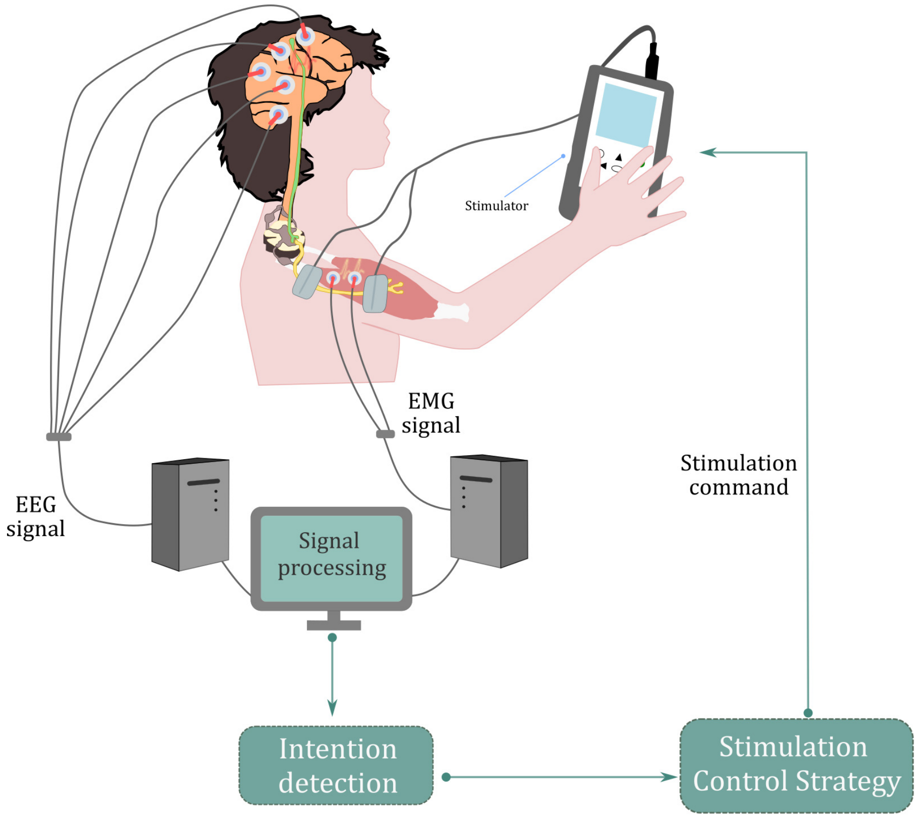


Figure 1.7: *Illustration of two common architectures for subjects' intention detection.* The most common modalities for subjects' intention detection consist in recording either the electroencephalography (EEG) signal (Brain Computer Interfaces) or the Electromyography (EMG) signal. Commonly, these signals are acquired placing electrodes on the scalp (EEG) or on the skin (surface EMG). The measured signals are then processed and analyzed in order to decode the intention of the patient; then the willing of the subject is used to manage the stimulation according to the implemented control strategy.

1. EMG-triggered FES: the EMG activity is recorded and when its value is greater than a specific level (threshold), a predefined stimulation sequence is provided. In this way, the EMG is not used to close the loop of FES.

2. EMG-proportional FES: the amount of stimulation provided is proportional to the EMG activity recorded, which is measured continuously. This modality promotes a more active participation of the subject during the task but it introduces a new problem: the stimulation artifact, which is an electrical spike induced by the stimulation, is superimposed to the EMG signal. Consequently, hardware or/and software solutions must be applied in order to differentiate between these two signals. An example of this implementation was proposed in [23].

Exploiting the EMG signal to detect the user-intention, amplifying it to drive the assistance of the hybrid system is the best option is case of incomplete spinal cord injury or stroke subjects.

Brain-machine interfaces An alternative modality to infer subjects' volitional intention is recording his/her brain activity, for example by means of electroencephalography (EEG). This technique consists in placing electrodes on the scalp and analysing the EEG the subject's intention can be decoded. With respect to EMG, this signal does not present the stimulation artifact, but it requires a higher number of electrodes, longer time for the set-up and training, and more complex signal analysis. An example of application of brain-computer interface was presented in [45]. Brain computer interfaces are better options to interface with patients in case of complete or very severe spinal cord injuries, even though they require long calibration procedure for each subject.

The reasons behind decoding subjects' intention is the inclusion of them into the control loop. This is a critical aspect since entails three main benefits:

1. It allows subjects to perceive the robotic device as less extraneous, achieving the embodiment with the device. This has been proved to lead to higher acceptability [46].
2. It boosts the active involvement of the subject during the therapy, which as stated previously is a fundamental requirement in order to increase rehabilitation outcomes.
3. Lastly, as explained in Section 1.1.2, in case of EMG based intention detection, when the stimulation is combined with active volitional signals from the patient, the neuroplasticity elicited at CNS is amplified.

1.3.2. Hybrid Systems shared control strategies

The functionality of hybrid systems is regulated by a coordinated control of FES and exoskeleton. Depending on the role of the robots, the hybrid control varies its logic; commonly, in upper-limb hybrid configurations, the task of exoskeleton can be [19]:

1. Immobilize a single joint, through passive devices like arm braces.
2. Stabilize a target limb, thanks to supporting orthosis.
3. Compensate for the gravity forces of the target limb. In this case the robotic device does not need to be active, i.e. to be actuated by a motor, but it can also passively support gravity through passive elastic components or weights.

4. Actively guide the movement of the arm over its range of motion to perform a task, thanks to the actuation of motors.

The last two roles, gravity-compensation and active movement support are by far the most common applications of exoskeleton in hybrid configurations. Since active robotic devices are capable of providing active assistance to the patient, the benefit they can bring to the hybrid system is predominant with respect to passive exoskeleton: the assistance of active robots can be varied and updated based on the desired control strategy, spanning from being transparent to completely guiding the movement. For this reason, in the following review I have focused on hybrid controllers managing active exoskeletons.

Hybrid controllers can be divided in two subsystems: High-level controller and Low-level controller. High-level controller mainly comprises the intention detection of subjects, carry out in different modalities as described in Section 1.3.1 and the logic behind the allocation of the assistance between the stimulator and the exoskeleton. On the other hand, the low-level controller is in charge of defining the amount of muscle stimulation by FES and the motor torque managing.

Low-level Controller Multiple approaches have been proposed to control the low-level of the stimulation. The basic one is to manually set the stimulation parameters with a predefined profile and update them iteratively till the desired outcome is obtained. Clearly this method is time-consuming, requires the constant intervention of an operator and does not take into account time-varying behaviors.
In case of lower-limb application, FES open-loop control is often implemented; indeed, since walking can be considered a cyclic event, it is possible to map the necessary stimulation to a specific gait phase. However, this methodology is not able to react to different FES-induced muscle response and does not vary the allocation dynamically.
Another approach is to control FES in closed-loop. Basically the stimulation charge is either increased up to the level that allow the desired movement to be accomplished [23], or it is varied according to the error between a reference torque (or angle) and the measured one. Nevertheless, as described in Section 1.1.3, this control is not able to manage the non linearity and time variability of the FES stimulated muscle system and eventually increasing the stimulation parameters to account for fatigue would lead to higher and longer-lasting fatigue. Moreover, it requires the estimation of either the FES interaction torque, i.e. the torque generated by FES, or the actual angle. In case of passive robotic devices, this measures are not difficult to obtain but with robots that actively provide torques, it is not trivial to distinguish the actual torque provided by FES from the one provided by the exoskeleton; likewise, discriminate the contribution of the two systems

regarding the angle measures is not feasible. This is the reason why most of the close-loop application of FES in hybrid systems are used with passive robotic devices.
Other studies implemented a FES control based on a subject-specific arm's inverse dynamics, able to define the joints torque necessary to perform a specific movement [47]. Alternatively, a more sophisticate model comprises patient-specific muscle dynamics which is able to solve an optimization problem determining the contributions of each muscle, accounting for their activation dynamic and transform this into the desired stimulation profile. Nonetheless, it is complicated to build a musculoskeletal model that accurately predicts muscle responses to FES, which as state before, is time-varying, non-linear and it needs to be updated every time the electrodes are placed.

For what concerns the low-level control of exoskeletons, the most exploited controls are based on different type of PID position control. The input to the PID controller is the difference between the desired angle trajectory and the measured one, i.e. the position error. Besides the feed-back PID controller, another stage of feed-forward can also be introduced in order to correct for friction effects and other undesired gravity effects [31, 48]. Alternatively, PID controller can also be based on torques [31]. More sophisticated models based on Neuromusculoskeletal have also been proposed [49, 50]. These computational models comprise subject-specific EMG-driven musculoskeletal models and they showed better response time with respect to traditional force controllers, but longer settling time [51]. Moreover, these models require long calibration procedures for each subject in order to create his musculoskeletal model.

High-level Controller With hybrid high-level controller we refer to the strategies to allocate the assistance needed between the robot and FES. In case of active robots, their function is not solely stabilizing or supporting the limb, but they actively provide torques in concert with FES. Since FES is included in the control, the hybrid strategy has to take into account the low repeatability of the FES-induced motion and the time-variable behavior of FES-elicited muscle contraction. A possible scheme of the hybrid control strategy is shown in Figure 1.8. In this type of strategy, the torque necessary to perform a specific movement, defined by the intention of the subject, is estimated thanks to an inverse dynamic model; subsequently, the assistance of the two systems is estimated splitting this torque into the two contributions of FES and the motor, similarly to [4]. The allocation of the two assistance is usually performed by an optimization problem; if this strategy is time-varying and not fixed in time, it will be able to take into consideration the fatigue induced by FES and therefore allowing a longer therapy application. Finally, the loop is closed on a specific variable, usually the angle or the torque at the joint.

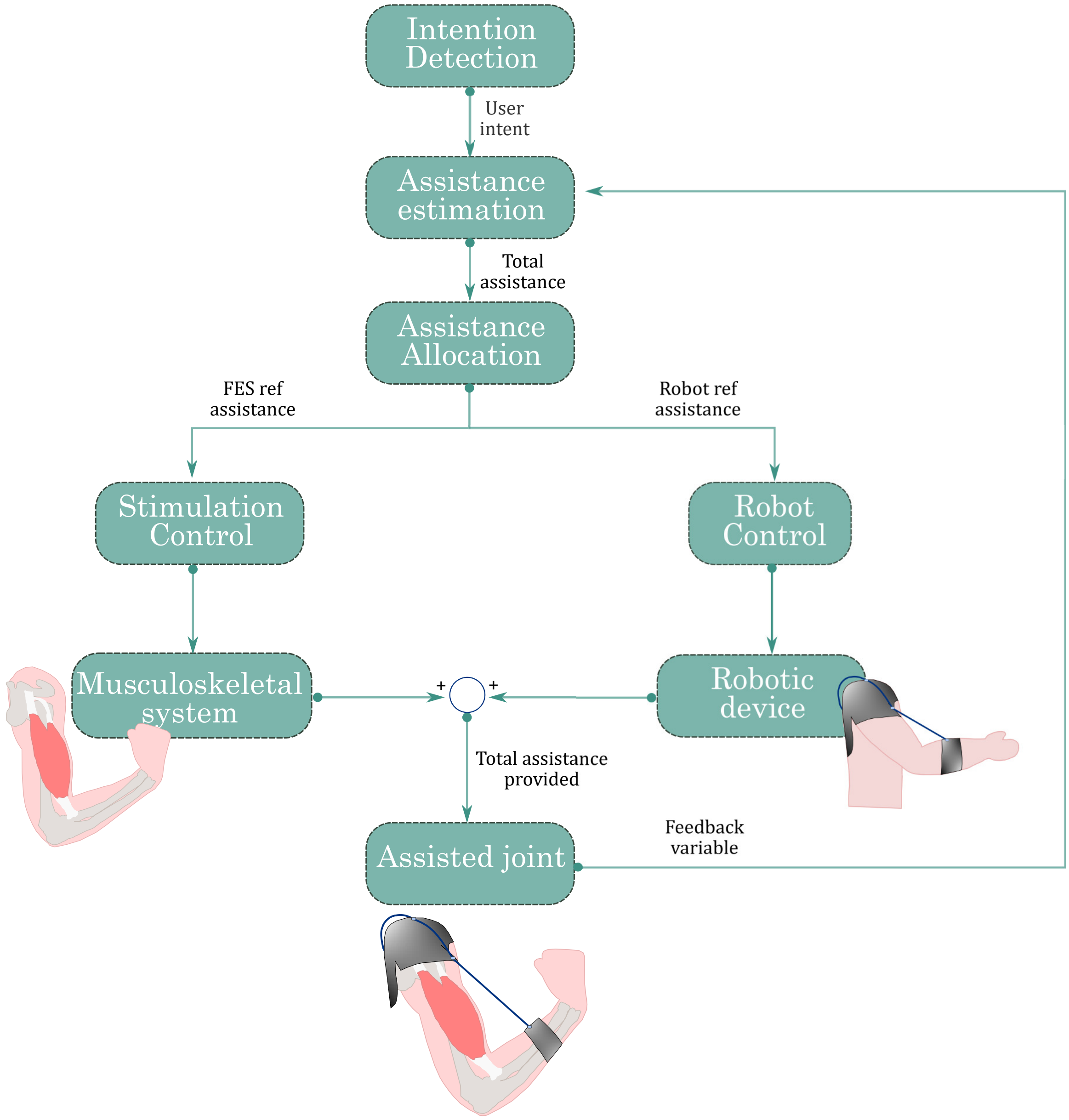


Figure 1.8: *Possible architecture for a high-level hybrid control strategy.* In figure a generic strategy to allocate the assistance needed between the robotic device and FES is represented. The starting point is the computation of the total reference assistance based on the measured subject's intention. This assistance is then split into the contributions of the two system, according to the hybrid allocation strategy implemented. Both FES and the robotic device are managed by their controllers, which define the torque provided to the musculoskeletal system (FES) and to the robot structure. The concurrent actuation of the two systems results into the actual assistance provided to the limb, which is usually measured by sensors and used as feedback signal to the controller. Figure adapted from [42].

Examples of cooperative Hybrid strategies In this paragraph, few hybrid control strategies will be discussed. All of the following studies are for lower-limb since there is not evidence in the literature of any balanced and accurate control strategies for upper-limb.

In [52] del Ama *et al.* developed a knee joint cooperative control for a knee-ankle-foot exoskeleton. The interaction torque between the patient and the robotic device was measured in order to adjust the stiffness controller of the electric motor. On the other hand FES was controlled with a closed-loop modality and the fatigue was estimated as torque-time integral.

Ha *et al.* created in [53] a lower-limb exoskeleton hybrid system in which the system prioritized the FES assistance, which was updated every cycle in order to minimise the torque of the motor. The torque induced by the stimulation was computed as the difference between the measured torque during the walking with and without the stimulation. Hence a calibration trial was necessary to estimate the torque without FES. The FES parameters were increased until the torque required was achieved.

Both these works tried to minimized the motor torque but as pointed out by Kirsch *et al.* in [44] they do not allocate FES and motor assistance in an optimal way since they did not implemented a muscle fatigue model.

Therefore in [44] Kirsch*et al.* developed a muscle fatigue model and based on the fatigue level they allocated the assistance between the motor and FES. Their work presented some drawbacks: the fatigue model was based on approximation of the muscle activation and fixed time constants, hence it was not able to take into consideration the variability in time and the non-linearity of the muscle response.

Lastly, Zhang *et al.* designed in [4] a hybrid control comprising a FES feedforward control and a lower limb exoskeleton feedback control, able to regulate the assistance of the two systems in real time. The hybrid strategy consisted in splitting the total torque into the reference torque of FES and of the motor. The allocation of the assistance was varied based on the estimated fatigue level, estimated through kinematics parameters. The FES feedforward control comprised a Hill-type inverse muscle model that represents the activation and contraction dynamics of the muscles and it is able to compute the pulse width that produce the reference torque. Even though, Hill-type inverse muscle model is commonly used in literature, it is inadequate since it requires the estimation of many subject's specific parameters and it does not account for muscle time-variability.

1.3.3. Exoskeleton Hybrid Systems for Elbow joint

The main applications of hybrid devices for upper limb aim to assist the movements of one or multiple target joints throughout their range of motions and/or recover lost functions. Regarding the elbow joint, the degree of freedom assisted is the elbow flexion extension, which normally ranges from 0° in full extension to 145° degrees when flexed, with a significant variation between subjects. In Figure 1.9 are reported some example of hybrid systems with passive (1.9a) and active (1.9b) exoskeleton, which assist the elbow joint.

An example of passive gravity compensation exoskeletons in hybrid systems was proposed by Ambrosini *et al.* in [54], Figure (1.9a). This system, called RETRAINER-ARM, was implemented for arm rehabilitation of post-stroke patients. In their work, the action of FES was triggered when the ElectroMyoGraphic (EMG) signal of the patient overcame a patient specific threshold. EMG signal was continuously recorded to assess patients' active involvement during the task. All the stroke patients involved in the study showed improvement of their motor capabilities in terms of speed, smoothness and range of motion.

Active exoskeleton for elbow Hybrid Systems In the literature, there are few studies published regarding hybrid systems comprising active exoskeleton that actuate the elbow joint concurrently with FES.

In [55, 56] a hybrid exoskeleton called EXOSLIM was developed to assist elbow flexion and extension and shoulder movement over three axes. The exoskeleton was constituted by four DC motors, one for each DoF assisted. The same DoFs were also assisted by FES during reaching task movements following a predefined trajectories. The subject's intention about moving the left or right arm was detected by a BCI based on motor imagery, but it was used only to trigger FES and actuators assistance and not to continuously manage it. Therefore, the patient's voluntary effort was not included inside the control loop. The FES control was implemented using a simple Hill muscle model, that relates the reference elbow angle to the pulse width stimulation parameter. The authors pointed out however that the muscle model was a feasible approximation of the muscle system response only for isometric contraction and it was not able to take into consideration any time-varying muscle behaviors, such as muscle fatigue. Lastly, even though both the systems actuated the elbow joint concurrently, they did not described how and if their actuation was balanced.

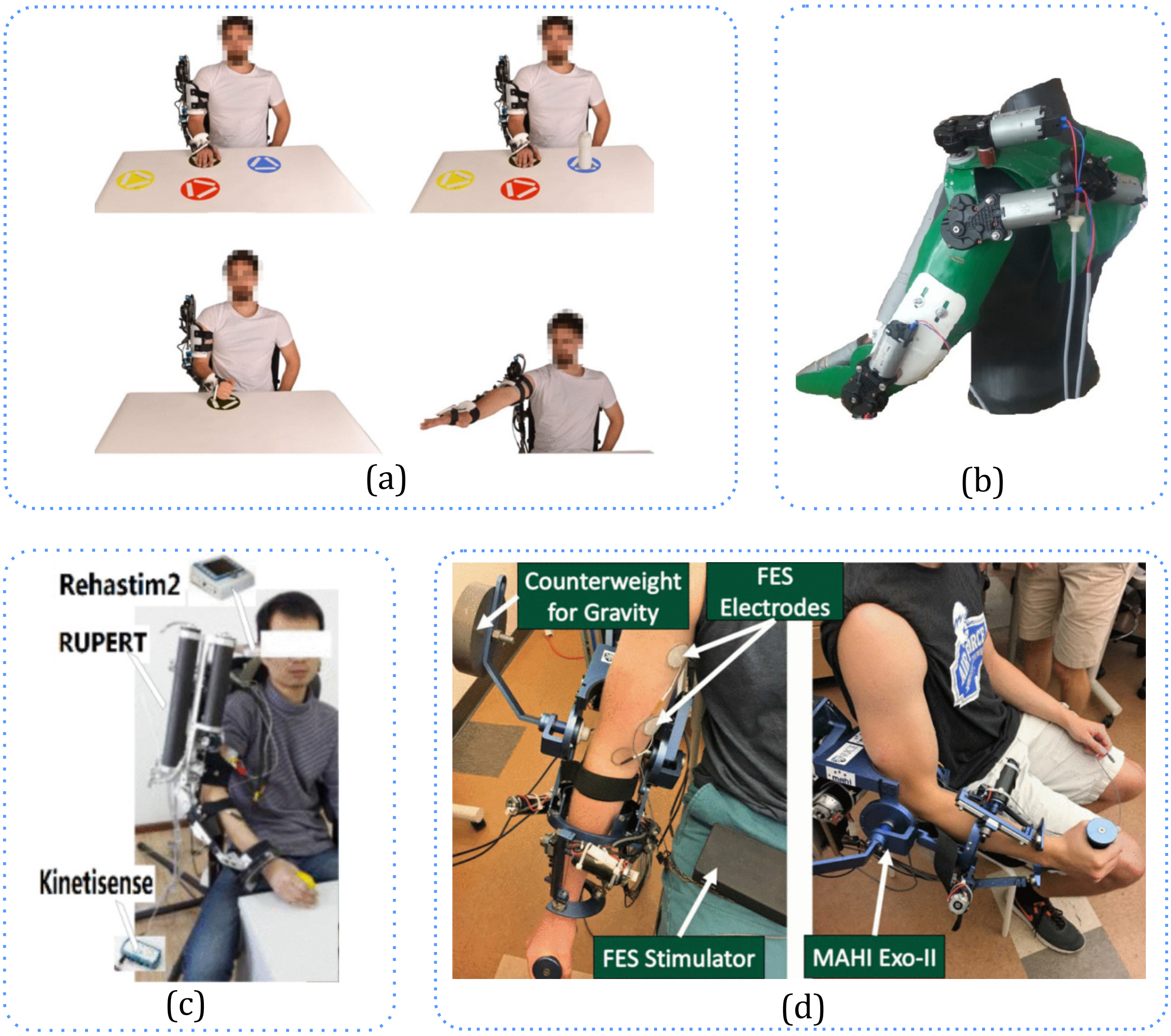


Figure 1.9: *State of art of elbow Hybrid Systems.* In figure hybrid devices with passive (a) and active(b-d) exoskeletons for the elbow assistance are displayed. (a) Passive exoskeleton hybrid device developed presented in [54] for arm rehabilitation, (b) EXOSLIM [55, 56] exoskeleton which assist both elbow and shoulder, (c) RUPERT [57] hybrid device able to assist elbow flexion and extension, (d) hybrid system developed by Wolf *et al.* in [43] to assist the elbow DOFs.

RUPERT upper limb rehabilitation robot was integrated in [57] with FES to assist in concert the elbow joint. Nonetheless, the actuation of the stimulation worked in opposite direction with respect to the pneumatic motors: the stimulation of the biceps induced elbow flexion, whereas the pneumatic motor led to elbow extension. The motor was controlled with a classical PID. Nevertheless, is not clearly specified how the stimulation parameters were adjust and the control did not consider fatigue effects.

Wolf *et al.* investigated in [43] the effect of their elbow hybrid system on trajectory error and on the exoskeleton control effort. The biceps of the patient was stimulated concurrently with the actuation of the exoskeleton; however, a coordinated assistance and a cooperative control between the exoskeleton and the stimulator were missing, therefore, as pointed out by the authors, they may had interfered against each other during the trials.

Lastly, Bardi et al. in [58] developed a control that defines the contributions of FES and the motor, which is varied in based on the estimated fatigue as in [4]. Moreover, the trajectory errors were corrected by the motor, giving it an additional torque to provide, computed with an impedance loop. Nevertheless, they only tested the functionality of the controller in simulation environment reproducing elbow flexion/extension movements with a exoskeleton model and simulated FES.

1.3.4. Exosuits-based Hybrid Systems

As previously discussed in Section 1.2.1, exoskeletons are rigid and require the perfect alignment between the robot and subject's joints; hence, they might alter FES-induced movement, leading to higher trajectory errors [19]. Replacing rigid exoskeleton with soft wearable exosuits would limit the interference between the robotic device and FES actuation, thus obtaining a smoother and more natural joint movement since they are less constraining. However, most of the exosuits are composed by smaller actuators with respect to rigid exoskeletons, therefore they are capable of delivering limited torques. Hence, in order to be used in assistive hybrid device, soft wearable suits must be capable of proving the required torques for the target movement. Investigating the suitability of exosuits in hybrid systems would also shift the use of these devices from specialized center to home-based therapies, enhancing the patients' independence.
In spite of these promising advantages, the integration of exosuits with FES hasn't been thoroughly investigated yet. To the best of the author's knowledge only two studies have integrated FES and a soft wearable suit to actuate the same joints, as shown in Figure 1.10.

Regarding lower limb applications, Ana de Sousa *et al.* merged in [1] FES with a hip exosuit. Their control architecture was composed by two main PID controllers: one able to command the active orthosis and one guiding FES action. Nonetheless, it is not specify how and if the assistance was balanced between the two system. Furthermore, even though the authors referred to their device as exosuit, their orthosis was composed by rigid components, therefore it cannot be considered an exosuit. Moreover, they tested

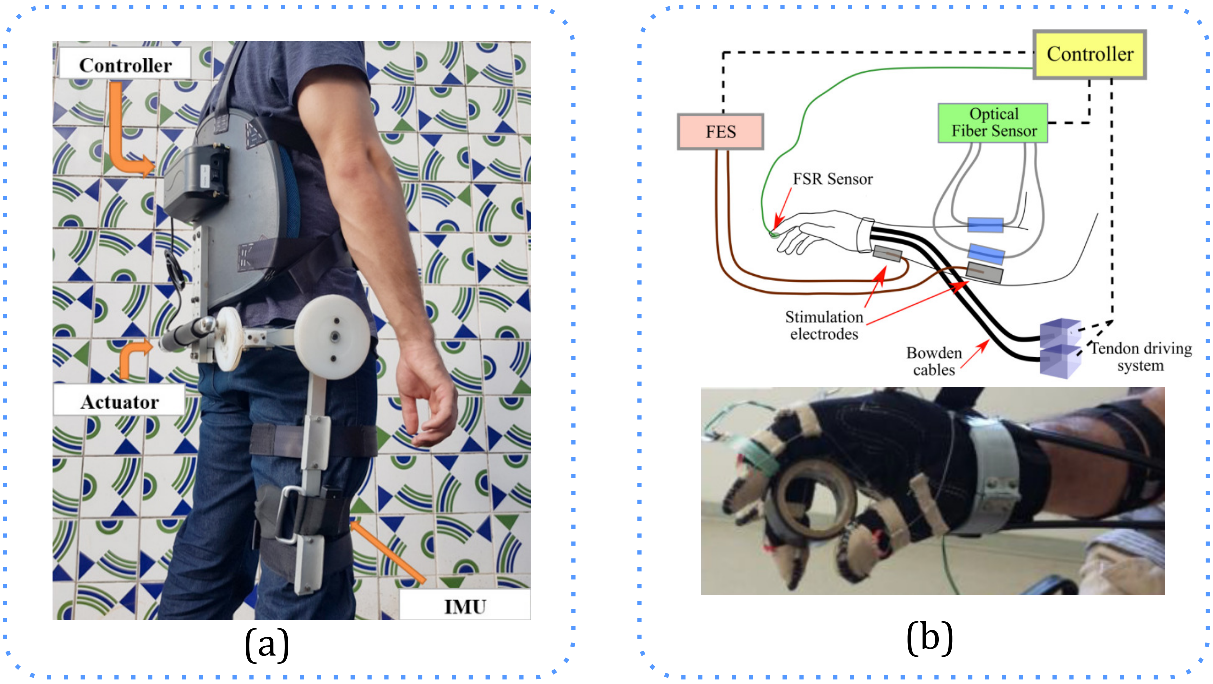


Figure 1.10: *State of art of exosuits Hybrid Systems.* In figure the only two examples of hybrid devices comprising soft wearable exosuits are displayed. (a) lower-limb hybrid system developed by Ana de Sousa *et al.* in [1] for gait assistance. (b) Glove-like orthosis developed by Neto *et al.* in [2] for grasp assistance. Their controller managed the action of FES and the motor, including the forcemyography (FMG) signal of the forearm in the loop.

their control only in a simulating environment, modelling the stimulation with OpenSim Excitation Editor.

The second exosuit-based hybrid system was implemented by Neto *et al.* in [2]. They proposed a glove-like orthosis with forcemyography (FMG) control and FES-motor hybrid actuation to assist grasp actions. The FMG allowed to detect the patients' intention without being affected by the stimulation artifact, contrary to EMG signal. Both FES and the tendon driven orthosis aided hand movements. Nonetheless, they did not develop a strategy to subdivide the actuation between the motor and FES and they did not account for and manage the fatigue.

To the best of the author's knowledge, no Hybrid Systems comprising FES and exosuit to assist the elbow have ever been proposed in the literature.

1.4. Motivation and goals of the thesis

In the previous sections the state of art of hybrid systems was described. As we can infer from the literature review, there are several under-investigated problems and current limitations:

1. In Section 1.3.3 active exoskeleton-based hybrid systems for the elbow joint assistance have been presented. Only three of the reviewed devices [43, 55, 57] have been actually developed and tested, whereas the other one [58] was entirely simulated. None of the developed hybrid systems implemented a balance hybrid strategy between the motor and FES actuation. We can therefore state that in the literature there is not evidence of any elbow hybrid device based on active exoskeleton able to cooperatively manage the actuation of motors and stimulation.

2. Concerning lower-limb hybrid systems, both the studies [52] and [53] did not optimize the assistance allocation between FES and motor. Moreover, all the lower-limb hybrid devices reviewed controlled FES with a muscle model that did not take into account muscle time-variability response to the stimulation.

3. For what concerns the use of exosuits in hybrid systems, only two studies have addressed this possibility so far [1, 2]. Moreover, these two studies share the same control limitations of active elbow exoskeleton hybrid systems. No hybrid systems including elbow exosuit have been developed yet.

4. Most of the reviewed devices did not include the patient's intention detection inside the loop and the input to the controller was generally a predefined trajectory.

5. Most of FES controls implemented are quite elementary, since they did not take into consideration the time-variability and the non-linearity of the muscle response to FES, therefore they are not optimized for a long lasting therapy and for an optimal hybrid allocation strategy. Moreover, some FES close-loop controllers tend to increase the stimulation parameters in case of increasing errors of the input variable (either angle or torque). Nonetheless, this type of control, without a simultaneous updating of the allocation between the motor and the stimulator, would lead to further increase of longer-lasting fatigue, reducing the duration of the therapy.

Taking into account all these literature limitations, this study proposes the first elbow Hybrid System, including FES and a soft wearable elbow suit, which aims at assisting the subject in performing elbow flexion and extension. This thesis is the result of a collaboration between the NearLab of Politecnico of Milan and the ARIES lab (ZITI

Institute, Heidelberg University, Germany). In particular, I merged the knowledge and experience about FES of the NearLab with the elbow exosuit designed and provided by the ARIES lab.
The key aspects of this work are the followings:

1. The two systems, i.e. motor and FES, must work cooperatively: it is therefore necessary a balance between their actuation.
2. The hybrid controller should be able to reduce the low accuracy and repeatability of FES-elicited movements.
3. The hybrid controller should limit, manage and postpone as much as possible the FES-induced fatigue; therefore, it should be capable of estimating the muscle fatigue.
4. The FES actuation should be prioritized since it possesses the highest rehabilitation power.
5. The hybrid system should decrease the requirement of the motor torque over time (decrease the motor power and work), since the actuation is partially supplied by FES.
6. The subject's intention regarding the extent of flexion movement he/she wants to perform should be detected and used to guide the system functionality.

2 | Methods: Hybrid System and Hybrid Controller

2.1. Hybrid System Design

The developed hybrid system is composed by two main devices: the soft wearable exosuit for the elbow joint and the electrical stimulator. In this section their main components and their functionality are described.

2.1.1. Active elbow exosuit

The soft exosuit I used in my work is a fully-embedded prototype built by the ARIES Lab (ZITI, Heidelberg, Germany) able to assist elbow movements (Fig. 2.1). It is an updated version of the elbow exosuit presented in [59]; with respect to this one, the actuation stage, the battery case and the IMUs sensor cases are smaller, thus the total system is more compact. The exosuit comprises a textile harness that connects arm and forearm, made starting from a passive orthosis (Sporlastic Neurolux II, Nürtingen, Germany). The actuation stage aids elbow flexion/extension through a brushless motor (T-Motor, AK60-6, 24V, 6:1 planetary gear-head reduction, Cube Mars actuator, TMOTOR, Nanchang, Jiangxi, China) which drives the pulley (35mm) around which the artificial tendon is wound (Black Braided Kevlar Fiber, KT5703-06, 2:2 kN max load, Loma Linda CA, USA). On the textile harness two anchor points are suited both on the distal and proximal side of the elbow and they are linked to the motor pulley via a Bowden cable (Shimano SLR, 5mm, Sakai, Ōsaka, Japan) that acts like an artificial tendon. The exosuit comprises two different kinds of sensors. A force sensor (ZNLBM-1, 20 kg max load, Bengbu Zhongnuo Sensor, China), placed in between the connection of the cable with the distal anchor point, measures the interaction between the exosuit and the user's arm. Two Inertial Measurement Units (IMU, Bosch, BNO055, Gerlingen, Germany) detect the arm kinematics and orientation. Each IMU communicates with a Feather nRF52 Bluefruit (Adafruit Industries, New York City, USA) responsible of receiving the quaternions re-

Figure 2.1: FES-exosuit Hybrid System for elbow flexion and extension: back view on the left and front view on the right.

garding the arm posture and the cable tension measures from the load cell, which is send via Bluetooth Low Energy serial protocol (BLE UART, Nordic Semiconductors, Trondheim, Norway) to another receiving Feather board in the control stage, as described in [3].

The actuation unit is encased in a 3D printed structure which is screwed on the back protector (Zandoná, Treviso, Italy) next to the power supply (Tattu, 14.8V, 3700mAh, 45C). The control unit is driven by a microprocessor (Arduino MKR 1010 WiFi, Arduino, Ivrea, Italy) that sends the signals to the actuation stage via CAN-bus and controls the electrical stimulator by using a Bluetooth Low-Energy protocol. Moreover, the Arduino communicates via I2C with the Feather that receives from the other Feather boards the buffered kinematics data coming from the IMUs.

2.1.2. Electrical Stimulator

The Electrical stimulator used in this study is KT Motion by Medel, Hamburg (Germany), shown in Figure 2.2. This device comprises four channels of stimulation, with the possibility of recording the EMG signal over 2 channels when the stimulation is off. Around three seconds after the stimulation is turned off, the stimulator starts to measure

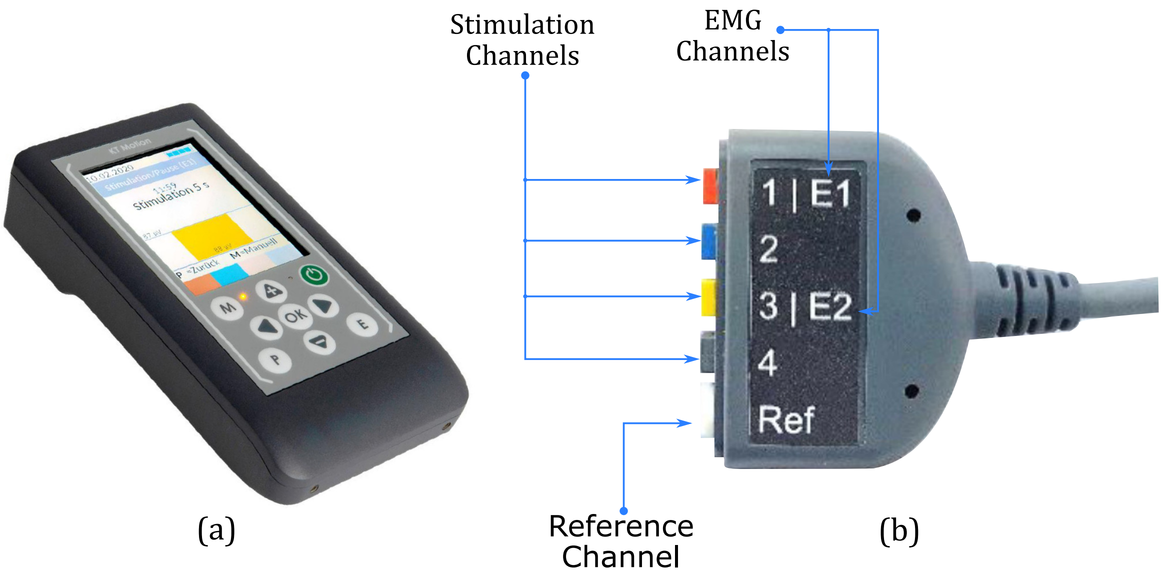


Figure 2.2: *Stimulator* (a) FES stimulator, KT Motion; (b) The stimulator presents four stimulation channels, two of which are capable of proving the EMG signal when the stimulation is off, measured with respect to a reference electrode connected to the reference channel.

the EMG signal. Since in this work the aim was to assist elbow flexion and extension, just one channel (Channel 1|E1 in Figure 2.2b) was used to stimulate the biceps and recording the EMG activity of the same muscle group. The stimulation was carried out using two oval electrodes (Krauth+Timmermann, 4x6 cm area) put on the subject's biceps. The stimulator communicates via BLE (Bluetooth Low Energy) protocol with the Ardunino in the control stage. In particular, this communication is bidirectional: the EMG signal, already processed by the stimulator, is sent to the Arduino when the stimulation is off and the Arduino controls in real time the stimulator functionality and the FES parameters. In order to establish this bidirectional transmission, I developed a Bluetooth interface program able of managing the communication between these two systems.
Regarding the stimulation settings, the subjects were stimulated with biphasic pulses whose frequency was set constant at 40 Hz, the current amplitude was tuned for each subject as describe later in Section 2.2.5 and kept constant, whereas the pulse width was the only parameter updated during the movement, as presented in Section 2.2.

2.2. Real Time Hybrid Control

The developed Hybrid real-time control framework is a new hybrid approach able to combine and cooperatively manage the assistance from the exosuit and FES. In this section the main functional blocks of the real time controller and the state machine that coordinates the system functionality are described.

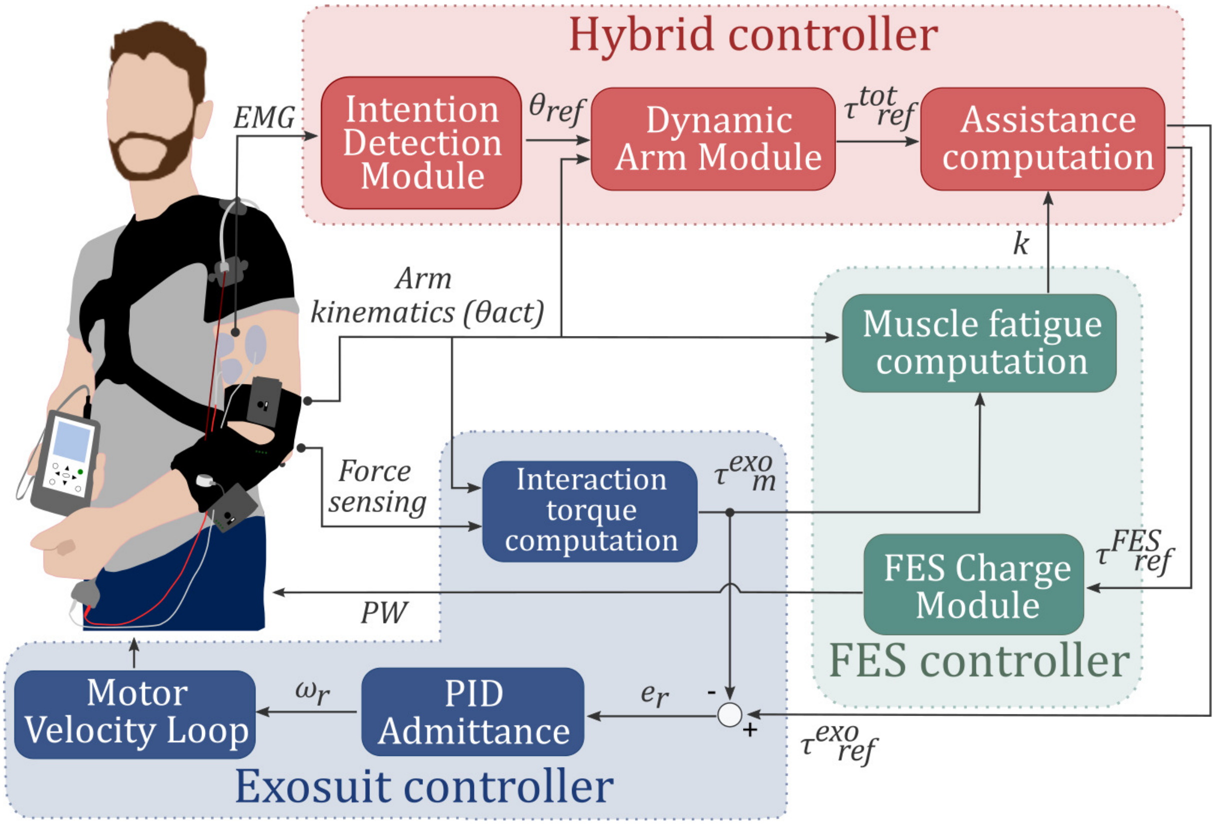


Figure 2.3: *Real-time control framework.* The real-time control framework presents three main controllers. The *Hybrid controller* splits τ_{ref}^{tot}, which is the torque required to achieve a specific angle θ_{ref}, into the reference torques of FES (τ_{ref}^{FES}) and exosuit(τ_{ref}^{exo}). The *Exosuit controller* converts the difference between the input τ_{ref}^{exo} and the interaction torque τ_{m}^{exo} into an error e_r which regulates the assistance of the exosuit. The *FES controller* transform the input τ_{ref}^{FES} into the FES Pulse Width *PW*. Moreover, the *Muscle fatigue computation* module estimates the fatigue level k that is used to tune the assistance allocation between the two systems for the next stimulation, updating $GainFES$ and $GainExo$.

Three main layers are interconnected in a close loop system 2.3 : (i) the *Hybrid controller* that estimates the user's intention and computes, updates and coordinates the assistance of both the devices, (ii) the *Exosuit controller* which modulates the motor actuation and (iii) the *FES controller* able to regulate the stimulation pulse width according to the desired assistance. The functionality of these layers is controlled by a state machine (Figure 2.9), which defines the role of the robot and FES according to the state.

In particular, during the *Break* phase the exosuit compensates for the gravity and the *Hybrid controller* identifies the intention of the subject. The *Flexion* state manages the flexion movement coordinating the exosuit and FES assistance. The *Compensation* phase accounts for the occurrence of muscle fatigue. Lastly the *Extension* state is in charge of controlling the extension of the arm.

2.2.1. Hybrid controller

The *Hybrid controller* is the layer responsible of estimating and regulating the assistance needed to accomplish the task. It can be subdivided in three main functional blocks: *Intention Detection Module*, *Dynamic Arm Module* and *Assistance computation*.

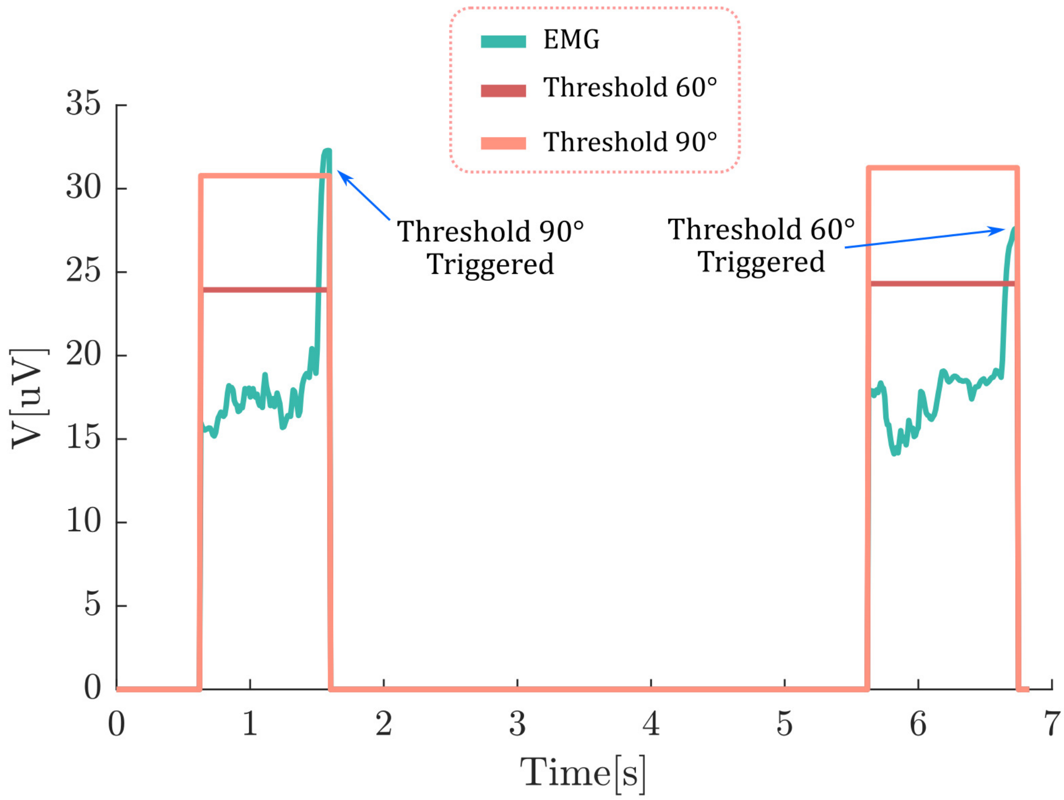


Figure 2.4: *Intention detection example.* In the figure the biceps EMG signal and the two thresholds (60° and 90°) of a representative subject during one trial are shown. The intention of the subject is recognized when the EMG signal overcomes one of the two thresholds.

Intention Detection Module The aim of this block is to detect the intention of the subject, i.e. the amplitude of the flexion angle he/she wants to achieve. As described in Section 1.3.1 there are several ways to infer the willingness of the patient. The stimulator

adopted in this study is able to record the EMG signal of the biceps exploiting the same electrodes, i.e. same channel, used for the stimulation. Since recording the EMG signal is a non-invasive procedure and its analysis could be easily performed, an intention detection method involving the electromyography of the subject was implemented. Hence, a correspondence between the EMG value and the desired elbow angle was necessary. Obviously, exploiting the EMG signal leads to a limitation regarding patients who could benefit from the system, since it requires a residual functional capability.
The designed approach is based on two thresholds, defined as follows:

$$\begin{aligned} Thr_{60} &= EMG_{mean} \cdot 1.2 \\ Thr_{90} &= EMG_{mean} \cdot 1.7 \end{aligned} \tag{2.1}$$

where EMG_{mean} is the mean value of the EMG computed over a time window of 2 s, Thr_{60} and Thr_{90} are the thresholds for 60° and 90° of the elbow angle respectively. With the arm extended, the subject isometrically contracts the biceps trying to reach one of the two thresholds depending on his/her intention. Once the EMG overcomes one of the two thresholds and the current EMG sample value is lower than the previous one, i.e. the EMG shows a downward trend, the subject's intention is mapped to the desired angle θ_{ref}, as shown in Figure 2.4. The two constants values 1.2 and 1.7 used to compute the thresholds are experimentally set and they correspond to a mild and a more intense isometric biceps contraction.

Dynamic Arm Module The *Dynamic Arm Module* takes as input an angle and it computes in real-time the torque at the elbow joint, i.e. the reference torque τ_{ref}^{tot}, necessary to counterbalance the gravity torque corresponding to that angle. This torque is calculated through an inverse dynamics approach, considering the subject's anthropometry as described in [59]:

$$\tau_{ref}^{tot}(\theta) = I\ddot{\theta} + mgl_c sin(\theta) \tag{2.2}$$

with I being the elbow moment of inertial, θ and $\ddot{\theta}$ the elbow angle and acceleration respectively, m the combined forearm and hand mass, g the gravitational acceleration, l_c the distance of the center of gravity of the forearm and hand from the center of rotation of the elbow joint. Note that θ is either the actual elbow angle θ_{act} or the desired angle θ_{ref} depending on the current state of the state machine, as describe later in section 2.2.4.

Assistance computation The last functional block of the *Hybrid controller* is the *Assistance computation*, which is in charge of allocating the assistance between the motor and FES. As described in Section 1.3.2, a viable solution to perform the allocation consists in splitting the total torque required to perform a movement, i.e. τ_{ref}^{tot}. Therefore, τ_{ref}^{tot} is subdivided into the reference torques of the exosuit (τ_{ref}^{exo}) and of the stimulator (τ_{ref}^{FES}) using two gains as follows

$$\begin{aligned} \tau_{ref}^{FES} &= \tau_{ref}^{tot} \cdot GainFES \\ \tau_{ref}^{exo} &= \tau_{ref}^{tot} \cdot GainEXO \\ 0 < GainFES &< 1 \\ GainEXO &= 1 - GainFES \end{aligned} \tag{2.3}$$

where $GainFES$ and $GainEXO$ have values between 0 and 1, therefore τ_{ref}^{exo} and τ_{ref}^{FES} represent the complementary percentage of τ_{ref}^{tot} allocated to each system respectively. The modulation of the allocation is performed by the state machine varying the two gains, as explained in Section 2.2.4.

2.2.2. Exosuit controller

The *Exosuit controller* is the layer in charge of managing the exosuit assistance, i.e. the low-level controller of the exosuit. I decided to keep unchanged the low-level controller previously developed by the ARIES laboratory, as presented by Lotti *et al.* in [51, 59], for two reasons: firstly it is an already tested efficient architecture and secondly so that the results obtained could only be attributed to the High-level strategy implemented.
The input to the layer is the reference torque of the exosuit τ_{ref}^{exo} and its output is the mechanical power delivered by the motor to the subject. The conversion of the input into the output is done by three functional blocks: *Interaction torque computation*, *PID Admittance* and *Motor Velocity Loop*.

Interaction torque computation The *Interaction torque computation* block is able to estimate the interaction torque between the exosuit and the wearer τ_{m}^{exo}. To do so, the tension measured by the load cell sensor f is multiplied by the moment arm $P(\theta)$, computed as described in [60]

$$\tau_{m}^{exo} = P(\theta) \cdot f \tag{2.4}$$

PID Admittance The *PID Admittance* takes as input the exosuit torque error e_r, which is the difference between the reference torque τ_{ref}^{exo} and the interaction torque τ_m^{exo} and it transforms e_r into the reference velocity command w_r to the motor through a PID-like admittance block, whose transfer function is

$$Y(s) = \frac{w_r}{e_r} = \frac{K_p + K_i \cdot \frac{1}{s}}{1 + K_d \cdot s} \tag{2.5}$$

with K_p, K_i and K_d being the proportional, integrative and derivative gains. These constants were experimentally tuned, using the Ziegler-Nichols heuristic method, before starting the study and kept fixed for all the participants [60].

Motor Velocity Loop An inner velocity loop of the motor was included to compensate the intrinsic non linearity of the exosuit dynamics, such as backlash and friction [60].

With respect to the previous studies of the ARIES lab [3, 59, 60], whose low-level controller had the same architeture of the *Exosuit Controller*, a consideration regarding τ_m^{exo} should be done. τ_m^{exo} identifies the assistance torque provided by the exosuit, which corresponds to the torque the motor provides only if the Bowden cable is in tension. Indeed, if the artificial tendon is slack, the measure from the force sensor f is not representative of the torque the motor is providing. In case of hybrid system with simultaneous actuation by the motor and FES, which work in the same direction flexing the elbow, the output of the load cell is an underestimated measure of the cable tension. This happens because the stimulation-induced torque flexes the arm, therefore partly reducing the tension of the Bowden cable. Nonetheless, from the point of view of the exosuit low-lowel control, this is not a issue: the underestimation of f would decrease τ_m^{exo}, which in turn increases the input error to the *PID Admittance*, leading to a higher velocity command to the motor. Therefore, the close-loop of the exosuit would compensate for the underestimation of the interaction torque. This is true only if the speed of the flexion movement is not too rapid, allowing the motor to counteract the torque error. In conclusion, τ_m^{exo} can be considered a reliable indicator of the exosuit interaction torque even in case of concurrent actuation of the motor and FES, only when the movement is slow or when the arm is stationary at a specific angle.

2.2.3. FES controller

The FES controller involves two modules which aim at (i) modulating the pulse width according to the reference torque τ_{ref}^{FES}, done by the *FES Charge Module*, and (ii) estimating the fatigue over time in order to shape $GainFES$ and $GainEXO$, through the block *Muscle fatigue computation*.

FES Charge Module The control of the stimulation is performed by the *FES Charge Module*, which is able to map in open-loop a reference FES torque τ_{ref}^{FES} into the pulse width PW, i.e. it represents the low-level controller of FES. This model should be as accurate as possible, in order to obtain a precise and independent managing of FES, increasing the balance control between the motor and FES. As described in Section 1.3.2, even though there have been investigated different modalities to model this correspondence, the critical point of most of the solutions was the incapability to both account for the non-linearity and time-varying behavior of the muscle response. Moreover, some studies defined their models based on isometric contraction experiments, therefore they are not suitable to precisely represent the FES PW-torque relationship during dynamic movements. In other words, the relationship between τ_{ref}^{FES} and the PW should be adaptable and time-varying, otherwise it would not be a feasible option to perform the mapping. Another important aspect to consider is that all FES models are subject-specific, thus they require to be tuned for every subject and every time the electrodes are detached from the skin. Indeed, the torque produced by FES is dependant on the number and the types of fibers activated by FES in the stimulated neuromuscular volume, which depends on the electrodes position. Therefore, the ideal tuning process, i.e. the calibration of the relationship on the patient-specific data, should be easy, take as little time as possible and reducing as much as possible the measuring devices exploited during the procedure [61].

The relationship between the stimulation charge, identified by the PW, and the torque elicited by FES has been already analyzed in literature [61, 62]. This relation can be approximated with a sigmoidal curve, characterized by three main elements:

1. PW threshold: minimum level of pulse width, i.e. charge, able to elicit a torque at the elbow joint.
2. quasi-linear trend: increase of FES torque almost linearly with increasing of PW.
3. Saturation: not significant increase of the torque after a certain level of PW.

In preliminary tests, I carried out some experiments in order to implement and test a FES PW-torque characteristic curve. In Figure 2.5a, the characteristic FES PW-torque curve of one subject (Male, 24 years old, Mass 85 Kg, Height 1.83, Healthy) was obtained stimulating the biceps of the subject with a fixed current level and increasing level of PW, starting from 20 µs up to 500 µs with an increasing of 20 µs for each stimulation. Before

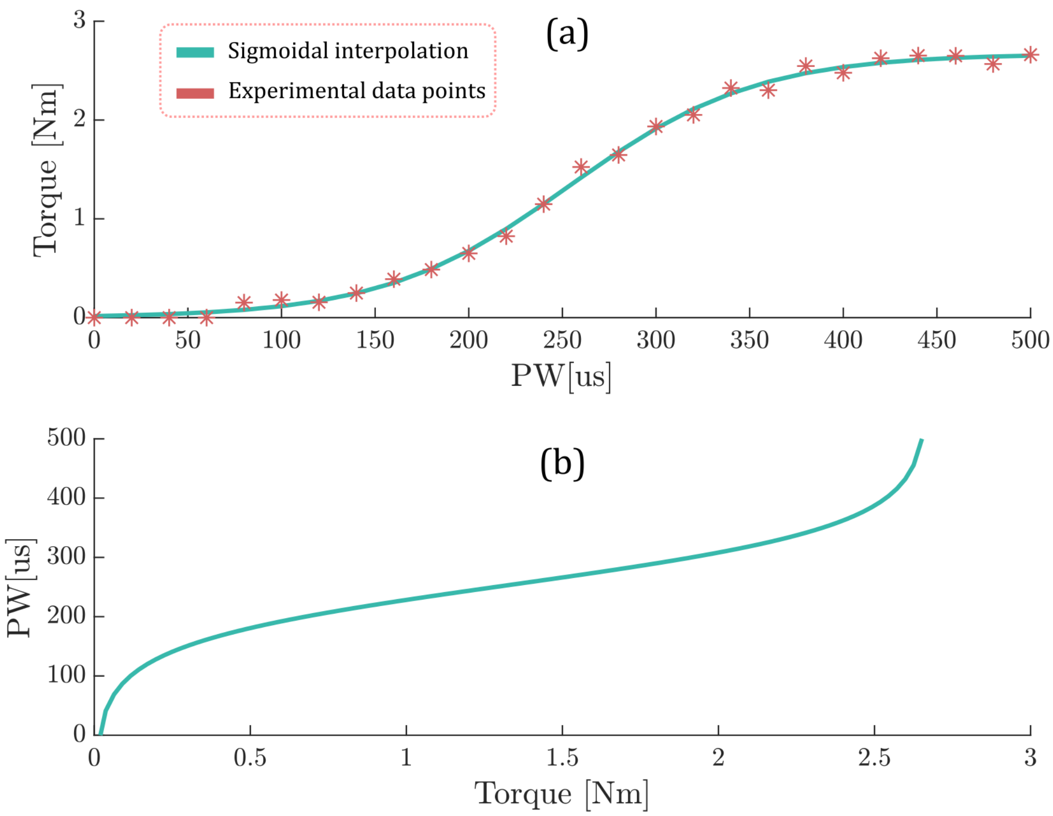


Figure 2.5: *FES characteristic curves.* (a) The experimental data points, obtained estimating the maximum torques elicited by train of stimulations with different PW, were interpolated with a sigmoidal curve, obtaining the subject specific coefficients of the curve. (b) The experimentally derived curve is inverted, obtaining a function that relates the PW in function of the torque, therefore allowing to estimate the PW necessary to produce a specific torque.

stimulating the subject, his arm position was the resting one (elbow extended) and the measured angle data coming from the IMUs were converted into the elbow torque by means of the *Dynamic Arm Module*, Equation 2.2. The data points obtained were then imported into Matlab and interpolated with a sigmoidal curve whose expression is

$$\tau_{ref}^{FES}(PW) = \frac{a}{c + \exp(-PW \cdot b)} \tag{2.6}$$

where a,b,c are subject-specific parameters, outputs of the interpolation.

As we can infer from Figure 2.5a, this relationship is able to correctly approximate the experimental data and we can identify the PW-threshold, the quasi-linear region and the saturation behavior.

Once the *a,b,c* parameters have been estimated, the curve can be inverted obtaining an equation that is able to relate the input FES torque to the output PW parameter (Figure 2.5b). Thus, the PW value able to provide a desired reference FES torque τ_{ref}^{FES} can be estimated. The inverted equation takes the expression of a logarithmic function

$$PW(\tau_{ref}^{FES}) = -\frac{\log(\frac{a}{\tau_{ref}^{FES}} - c)}{b} \tag{2.7}$$

In order to understand if Equation 2.6 was suitable for different amplitudes of current and different stimulation frequencies, eight other tests were carried out on the same subject with the same procedure described before. Four tests, were performed with a fixed stimulation frequency of 30 Hz but four different current amplitudes (8mA, 10mA, 12mA and 14mA). On the contrary, the remaining four tests were done with a fixed current of 13 mA and four different frequencies values (20 Hz, 30 Hz, 40 Hz and 50 Hz).

The curves obtained are reported in Figure 2.6. Qualitatively evaluating the curves acquired, it is clearly visible that both increasing the current amplitude and the stimulation frequency leads to a shift of the characteristic curves, even tough this shift is not homogeneously distributed throughout the range of the independent variable. We can interpret this shift as follows: for the same level of PW, stimulating the subject with higher current amplitude and higher frequency generates higher torque at the elbow. This is coherent with the functionality principle of FES, since both these stimulation parameters influence the intensity of the stimulation; moreover, similar results were found for FES actuation of the knee in [61].

As stated earlier, the PW-torque relationship should account for time-variability due to the stimulation induced muscle fatigue. This means that Equation 2.7 should be updated based on the estimated muscle fatigue.

To investigate how the fatigue influenced the implemented FES characteristic curve, I carried out a further test on the same subject. This test consisted in performing the same calibration procedure described before, to obtain FES PW-torque curves. The calibration was done twice: in between the two calibrations, the subject was stimulated for 5 minutes, divided in 10 seconds of stimulation and 5 seconds of rest, to induce muscle fatigue. The resulting characteristic curves are shown in Figure 2.7.

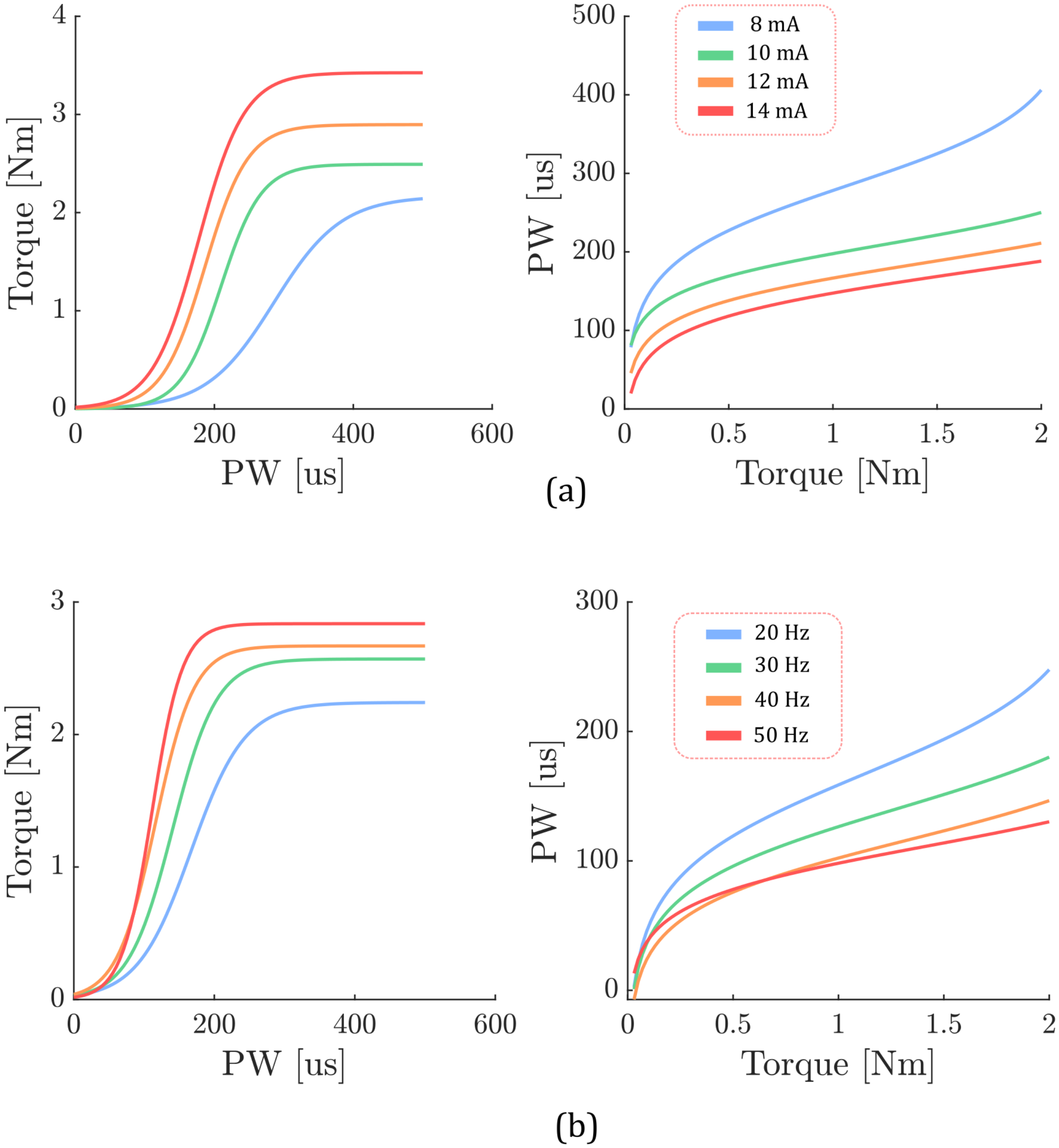


Figure 2.6: *PW-torque curves for different currents and frequencies.* The influence that different currents (a) and different stimulation frequencies (b) have on the FES PW-torque curves is shown in figure. In particular, varying these two stimulation parameters the characteristic curves are shifted, since they both influence the stimulation intensity and therefore the contraction of the target muscle fibers.

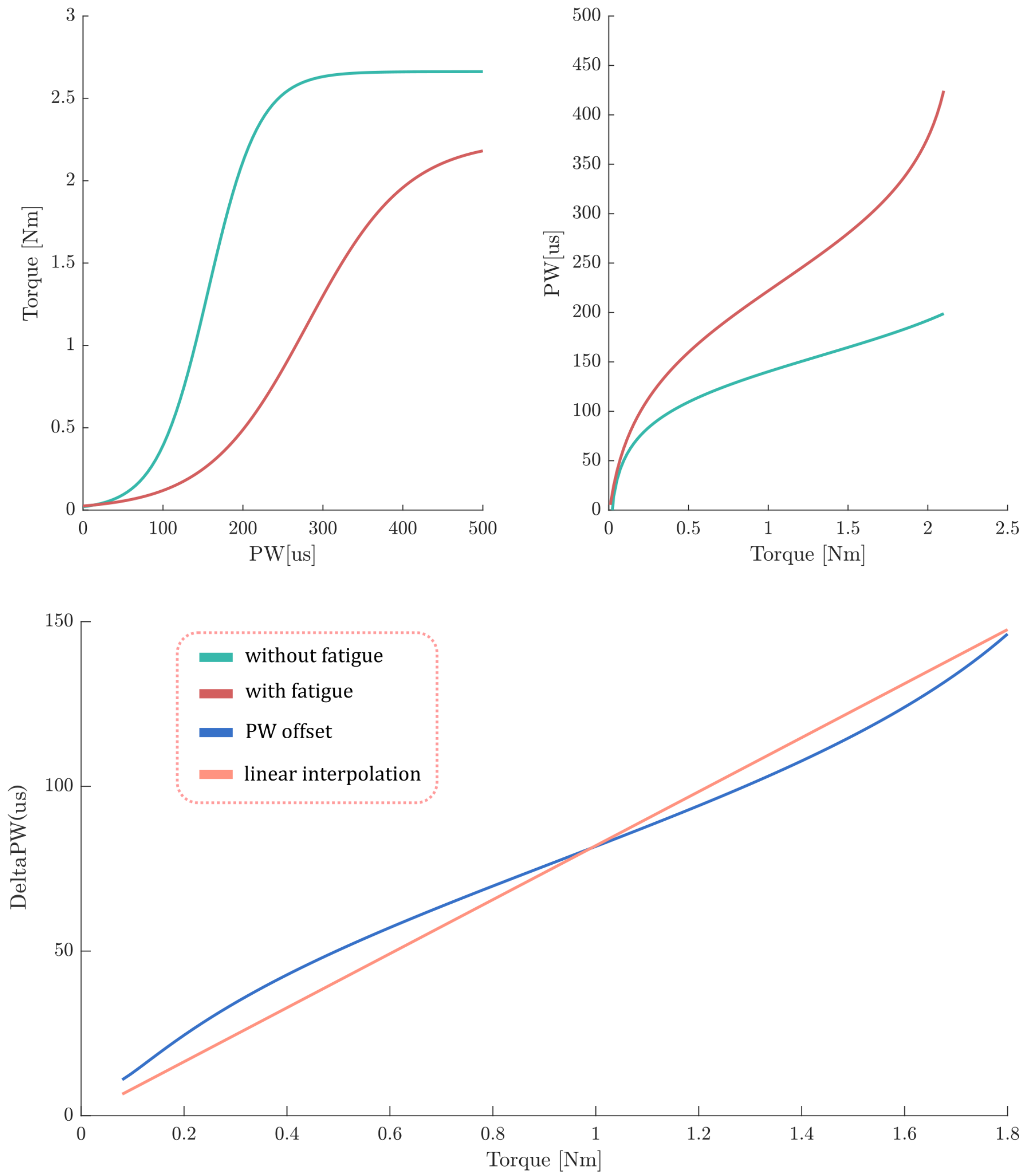


Figure 2.7: *FES characteristic curves in presence of muscle fatigue.* The subject characteristic curves are shown in figure, analyzed before the test (without fatigue) and after it (with fatigue). The PW difference (*DeltaPW*) between the *PW(Torque)* curve with and without fatigue is plotted in function of the torque. As we can see it approximately follows a linear trend, i.e. *DeltaPW* increases linearly with the torque.

As we can notice from the subject's characteristic curves, in presence of muscle fatigue they result in a shifted version of the ones without fatigue. This behavior is reasonable: the more the muscle is fatiguing, the more the electrical charge to deliver (PW) should be higher to obtain the same output torque. The additional PW that needs to be injected

to elicit the torque can be seen as a delta PW ($DeltaPW$). Focusing on the curve of the PW in function of the torque, i.e. the one displayed on the right side of the figure, what can be noticed is that this $DeltaPW$ is not constant, but it increases with the increase of the torque. Plotting $DeltaPW$ in function of the torque showed how this curve is almost linear; indeed, as shown in Figures 2.7, it can be well approximated ($R^2 = 98.8$ %), by a linear regression line. In other words, the variation of the FES characteristic curve can be approximated with a $DeltaPW$ which varies linearly in function of the torque.
Therefore, Equation 2.7 was updated introducing a variable PW_{offset} in order to account for time-variability due to muscle fatigue, obtaining the final characteristic function between the input τ_{ref}^{FES} and the required PW:

$$PW(\tau_{ref}^{FES}) = -\frac{\log(\frac{a}{\tau_{ref}^{FES}} - c)}{b} + PW_{offset} \cdot \frac{\tau_{ref}^{FES}}{\tau_{max}^{FES}} \tag{2.8}$$

where a,b,c are subject-specific parameters, PW_{offset} is the offset of the pulse width, i.e. the term that accounts for the variation of this equation due to fatigue. PW_{offset} is $DeltaPW$ evaluated at the maximum FES-induced torque τ_{max}^{FES}, i.e. the torque provided by Equation 2.7 at the maximum PW (500 µs). In other words, the second term added in Equation 2.8 takes PW_{offset} at the maximum FES torque τ_{max}^{FES} and maps it at the desired τ_{ref}^{FES}.

Muscle fatigue computation The *Muscle fatigue computation* block estimates the actual torque provided by FES (τ_m^{FES}) through the torque balance equation. During elbow flexion movements in the sagittal plane, the main torques acting on the elbow are: the gravity torque $\tau^{gravity}$, the voluntary torque $\tau^{voluntary}$ exerted by the subject, the FES-induced torque τ^{FES} and the torque produced by the exosuit motor τ^{exo} (Figure 2.8).

$$I\ddot{\theta}_{act} = \tau^{voluntary} + \tau_m^{exo} + \tau_m^{FES} - mgl_c sin(\theta_{act}) \tag{2.9}$$

with I being the elbow moment of inertial, θ_{act} and $\ddot{\theta}_{act}$ the actual elbow angle and actual angle acceleration respectively, m the combined forearm and hand mass, g the gravitational acceleration, l_c the distance of the center of gravity of the forearm and hand from the center of rotation of the elbow joint, $I\ddot{\theta}_{act}$ being the inertial term and $mgl_c sin(\theta_{act})$ the gravitational torque $\tau^{gravity}$.

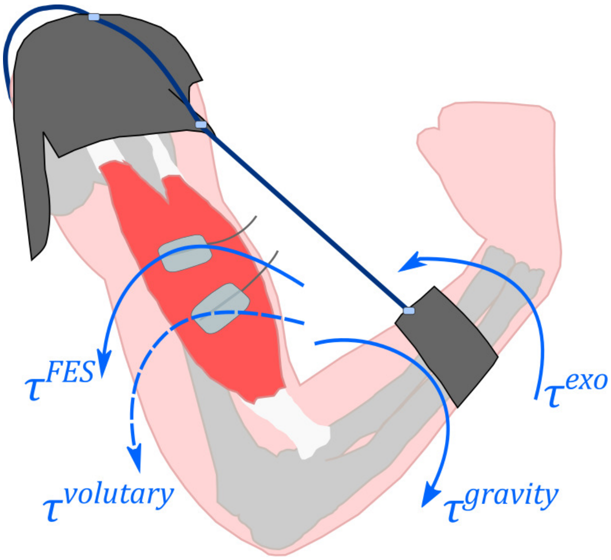


Figure 2.8: *Elbow joint torques.* Illustration of the main torques acting on the elbow joint during a flexion movement.

As explained before in Section 2.2.2, during the flexion movement τ_m^{exo} cannot be considered the real torque provided by the exosuit motor, due to the synchronous actuation of FES and the motor; hence, the Equation 2.9 cannot be used to compute τ_m^{FES} during dynamic movements. Nonetheless, in quasi-stationary conditions the Bowden cable is tensioned and τ_m^{exo} is a reliable estimation of the torque delivered by the exosuit. In addition, assuming that the subject voluntary contribution to the flexion movement is null, thus $\tau^{voluntary}$ is zero, τ_m^{FES} can be calculated as

$$\tau_m^{FES} = mgl_c sin(\theta_{act}) - \tau_m^{exo} \tag{2.10}$$

with $mgl_c sin(\theta_{act})$ being the measured total elbow torque, computed using the arm kinematics, i.e. the actual angle θ_{act}. Note that since it is a quasi-static condition, the angular velocity $\ddot{\theta}$ is almost null and therefore in the equation the inertial component is null.
The hypothesis of null voluntary torque from the subject, $\tau^{voluntary}$ equal to zero, is valid in case of impaired subjects with no residual motor capability, whereas for healthy subjects or for patients with remaining motor control is applicable only if the subject is asked to be completely relaxed during the movement. Nevertheless, it is worthy to point out that for these categories of subjects their contribution would never be completely null.

Lastly, *Muscle Fatigue Computation* is in charge of computing the FES-induced muscle fatigue k over the task. As shown in Figure 2.7, when stimulated muscle fibers are fatiguing, the torque they are able to elicit is lower than the one without fatigue. This implies that muscle fatigue can be estimated in function of the torque provided by FES. Therefore, I decided to estimate the fatigue as:

$$k = 1 - \frac{\tau_m^{FES}}{\tau_{ref}^{FES}} \tag{2.11}$$

where k represents the fatigue index. When τ_m^{FES} is close to τ_{ref}^{FES}, hence muscle fibers are not fatiguing excessively, the index is close to 0; contrarily, when the stimulated muscle fibers are in fatigue, τ_m^{FES} is much lower than τ_{ref}^{FES} and k is close to 1.

Based on k, the *Assistance computation* block of the *Hybrid controller* layer updates the new gains $GainFES$ and $GainEXO$ for the next flexion movement

$$\begin{gathered} GainFES(n) = \frac{\tau_m^{FES}}{\tau_{ref}^{tot}} = \frac{\tau_m^{FES}}{\tau_{ref}^{FES}} \cdot \frac{\tau_{ref}^{FES}}{\tau_{ref}^{tot}} = (1-k) * GainFES(n-1) \\ GainEXO(n) = 1 - GainFES(n) \end{gathered} \tag{2.12}$$

where n represents the following movement and $n-1$ is previous one. Note that $GainFES(n)$ is always lower or equal than $GainFES(n-1)$.

A clarification should be done regarding the choice of controlling FES in open-loop. Even though as explained in Section 1.1.3 a close-loop feedback control is more suitable to account for external disturbances and errors, this control requires a feedback variable to be compared with the input reference variable (i.e. either the elbow angle or the elbow torque). Nevertheless, in this work the actuation of FES and the motor act simultaneously, as better explained in Section 2.2.4; hence, the actual elbow angle cannot be used as feedback variable since it is influenced by both the actuation of the motor and the stimulator. In other words, the elbow error is the result of both the actuation errors of FES and the exosuit motor. Moreover, the input reference variable to the *FES controller* is τ_{ref}^{FES}, thus the close-loop control should consider the error on the FES-induced torque. FES measured torque τ_m^{FES} can be theoretically computed knowing at each time instant the real interaction torque of the exosuit τ_m^{exo}. Nonetheless, as described in Section 2.2.2, during the flexion movement τ_m^{exo} measure is dependant both on the action of the motor and FES, without being able to distinguish their relative actuation. Consequently, τ_m^{exo} cannot be used to estimate τ_m^{FES} during the movement, but only when the arm position is stationary at a specific angle; thus, a close-loop based on FES torque could not be implemented. The other feasible option to implement a fine control of FES, would have been using the electromyography signal from the biceps and implement a EMG-proportional control of the stimulation (Section 1.3.1). Nonetheless, even though this method would have allow to include the subject's active involvement throughout the movement, the stimulator used in this work was able to provide the biceps EMG only when the stimulation was off, hence this modality was not applicable without adding further EMG electrodes and implementing software and/or hardware solutions to eliminate the stimulation artifact.

2.2.4. State Machine

The functionality of the hybrid system is coordinated by a state machine, which modulates the gains $GainFES$ and $GainEXO$ to vary the assistance. The state machine involves four main states (Figures 2.9 and 2.13): *Break*, *Flexion*, *Extension* and *Compensation*.

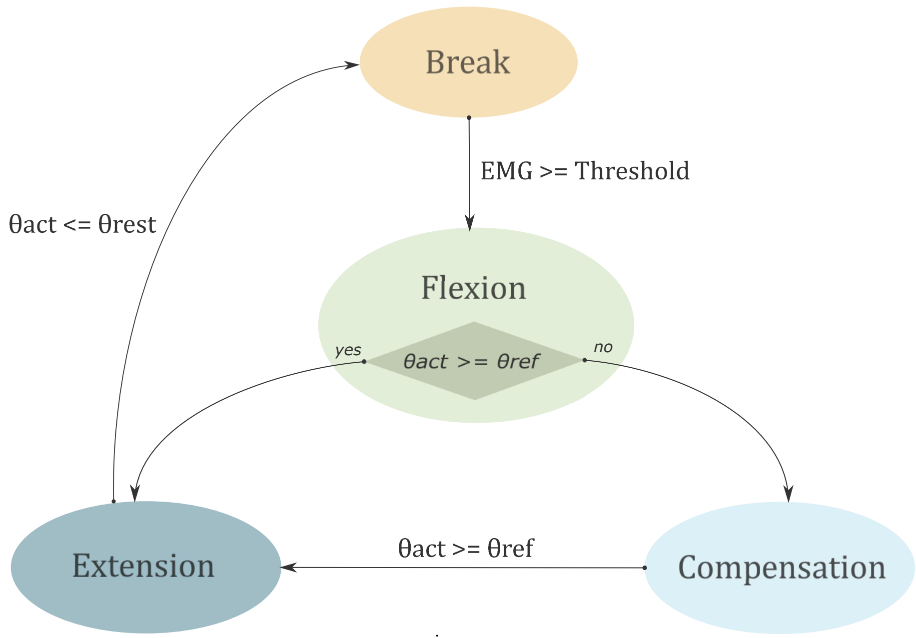


Figure 2.9: *State Machine*. The state machine is composed by four states. In the *Break* phase only the exosuit is providing assistance compensating for the gravity. When the EMG overcomes a predefined threshold, the state machine enters into the *Flexion phase*, where both the systems work cooperatively to flex the elbow. If after 1 second from the end of the flexion trajectory, which lasts 3 seconds, the desired angle is not reached, the *Compensation* phase is selected and the PW is increased to get to θ_{ref}. Whenever the actual angle θ_{act} overcomes θ_{ref}, the state machine enters into the *Extension* phase where the the subject's elbow is passively extended till the rest angle θ_{rest} reducing the torque of the motor and/or decreasing the stimulation. Ultimately, the state machine comes back to the *Break* phase and a new flexion movement can start.

Break phase

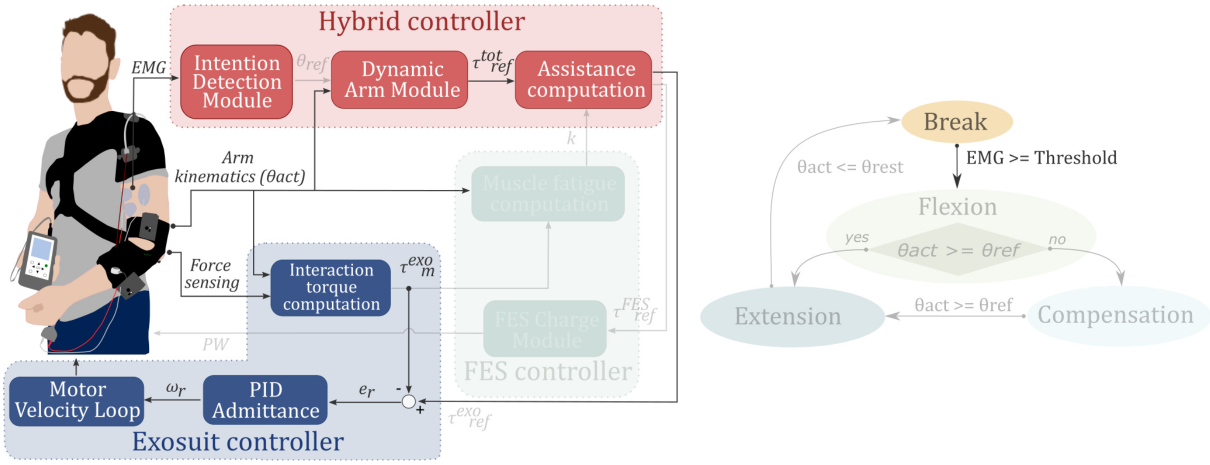


Figure 2.10: *Break Phase.* In the figure the main functional blocks of the three layers involved during the *Break* phase are highlighted.

The *Break phase* (Figure 2.10) is the phase in which FES does not provide stimulation ($GainFES = 0$) and the assistance is delivered only by the exosuit ($GainEXO = 1$). In this state, the assistance of the exosuit is tuned to compensate for the gravity at the elbow joint.
The input to the *Dynamic Arm Module* is the arm kinematics, used to compute the torque τ^{exo}_{ref} necessary to compensate for the gravity, using Equation 2.2. The biceps EMG activity is acquired by the stimulator and sent to the micro-controller, which computes the EMG mean value over a time window of 2 s. Consequently, the two thresholds used for the intention detection are calculated as described by Equation 2.1. The subject receives a visual feedback on a monitor regarding his/her real-time EMG signal and the two thresholds level. Performing a biceps isometric contraction, he/she tries to reach one of the two thresholds, according to the angle he/she wants to achieve. When the EMG signal overcomes one of the two thresholds, the subject's movement intention is decoded into the desired angle θ_{ref} and the state machine switches to the *Flexion phase*. In other words, the EMG signal is used both to decode the subjects' intent and to trigger the flexion movement.

Flexion Phase

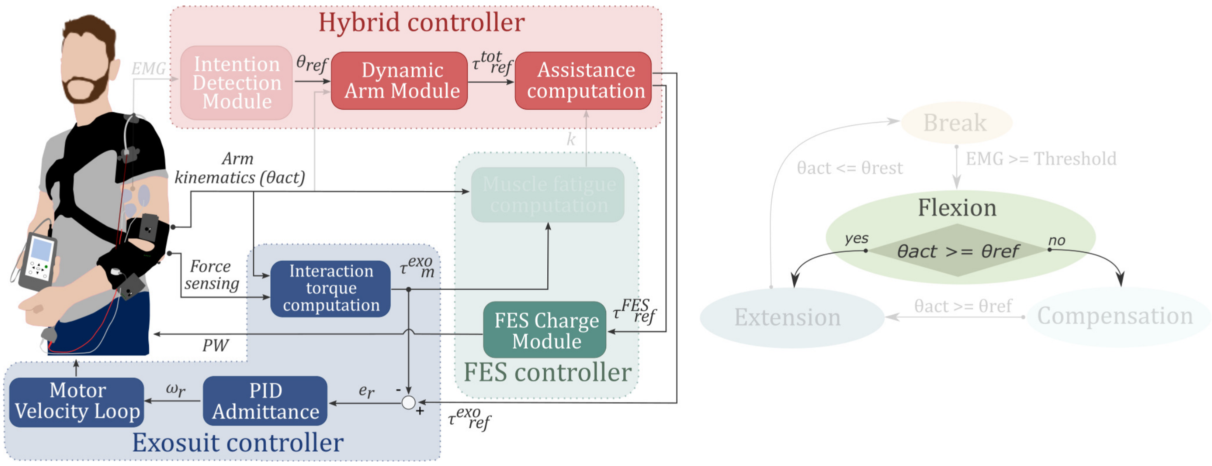


Figure 2.11: *Flexion Phase.* In the figure the main functional blocks of the three layers involved during the *Flexion* phase are highlighted.

In this phase (Figure 2.11) the elbow movement is totally driven by the hybrid system from the initial angle (i.e. the elbow angle at the end of the *Break phase*) to the desired one (θ_{ref}), following a minimum-jerk trajectory of 3 seconds. This trajectory follows the mathematical expression described by R. Shadmehr and S. P. Wise in [63]

$$\theta(t) = \theta_i + (\theta_f - \theta_i) \cdot (10 \cdot (\frac{t}{d^3})^3 - 15 \cdot (\frac{t}{d})^4 + 6 \cdot (\frac{t}{d})^5) \tag{2.13}$$

where $\theta(t)$ represent the minimum jerk trajectory in one dimension, θ_i being the initial angle, θ_f the final angle (θ_{ref}), d the duration of the trajectory (3 seconds) and t the time.

It is worth to mention that during this phase the subject should not perform voluntary elbow flexion, since the movement is completely guided by FES and motor. The extent of the assistance of the systems depends on the set values of $GainFES$ and $GainEXO$. If at the end of the trajectory the desired angle is reached, the state machine switches to the *Extension phase*. Otherwise, if the task is not accomplished after 1 second from the end of the trajectory, the state machine enters into the *Compensation phase*. This 1-second wait was included in order to account for the delay of two systems actuation.

Compensation Phase

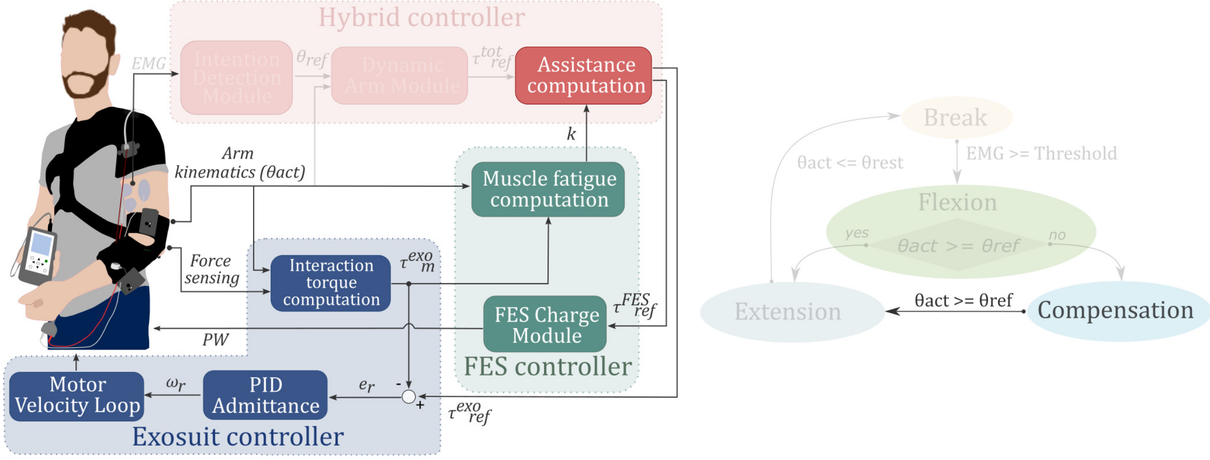


Figure 2.12: *Compensation Phase.* In the figure the main functional blocks of the three layers involved during the *Compensation* phase are highlighted.

The state machine enters into the *Compensation phase* (Figure 2.12) when FES is incapable of providing the required torque, due to muscle fatigue. The tasks of this phase are: (1) estimate muscle fibers fatigue level; (2) adjust the balanced action of the motor and FES for the next stimulation; (3) accomplish the task reaching the desired angle. As explained in Section 2.2.3, the *Muscle fatigue computation* module determines the fatigue level based on the actual FES torque τ_m^{FES} using Equation 2.11. According to the estimated fatigue, the gains must be updated for the next flexion movement, using Equation 2.12. If the state machines goes directly into the *Extension* phase without passing by the *Compensation* phase, the gains for the next movement are left unchanged, since no muscle fatigue was detected. On the contrary, when the gains are updated using Equation 2.12, the new gain for FES $GainFES(n)$ is always lower than the previous one $GainFES(n-1)$, since when the state machine is into the *Compensation phase* the fatigue k is always greater than 0. Consequently, the new $GainEXO$ is increased by the same amount as the decrease of $GainFES$.
Lastly, the desired angle θ_{ref} is reached ramping up the PW. The difference between the final PW value that succeed in the task and the initial PW value (i.e. the one at the beginning of the *Compensation phase*) gives $DeltaPW$, which is used to compute the PW offset (PW_{offset}) in order to update the relationship in Equation 2.8. Indeed, as explained before in Section 2.2.3, the relationship between the required FES torque and the PW level varies in time due to fatigue, hence it has to be modified accounting for that, otherwise the control would always end up into the *Compensation phase*. Note that PW_{offset} can be seen as the increase of the charge needed in order to obtained the

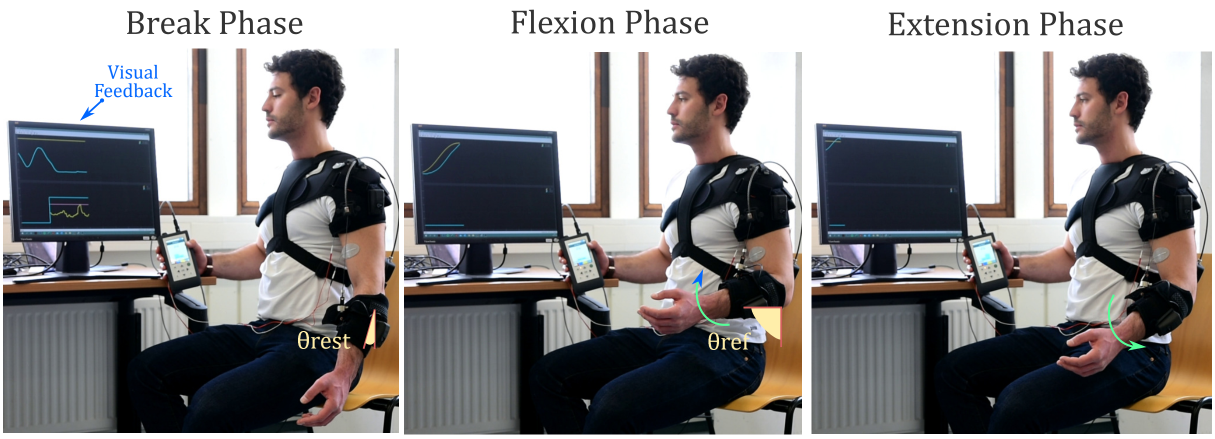


Figure 2.13: *Phases of the State Machine.* Example of one subject using the hybrid device. The Break, Flexion and Extension phases are shown. On the monitor of the computer the EMG signal and the two thresholds are shown to the subject in other to give to him a visual feedback regarding the extent of muscle contraction necessary to get to a threshold.

maximum reference FES torque τ_{max}^{FES} at the elbow, whereas $DeltaPW$ is the delta PW at τ_{ref}^{FES} for the current stimulation cycle. As explained in Section 2.2.3, the delta PW can be approximated as linearly dependent on the reference FES torque. Therefore, $DeltaPW$ is linearly mapped into PW_{offset}, i.e. the offset at τ_{max}^{FES}:

$$PW_{offset} = DeltaPW \cdot \frac{\tau_{max}^{FES}}{\tau_{ref}^{FES}} \tag{2.14}$$

Nevertheless, in case during the increase of the PW its maximum value (500 µs) is achieved, the compensation is further carried out by the exosuit, increasing its reference torque. When θ_{ref} is reached, the state machine moves into the *Extension phase*.

Extension Phase

During the *Extension phase* the stimulation is gradually reduced ramping down the PW and the Bowden cable tension is progressively released in order to extend the patient's elbow till a rest angle θ_{rest} (i.e. the most comfortable angle for each subject with the arm extended). Therefore, the extension of the arm is carried out passively since the exosuit does not comprise a tendon for elbow extension and simultaneously the stimulation of the triceps was not implemented.

Ultimately, the state machine switches back to the *Break phase* and another flexion movement cycle begins.

2.2.5. Calibration procedure

The calibration procedure was carried out for each participant before every trial in order to customize the relationship in Equation 2.8 of the *FES charge Module*.

During this procedure, the exosuit was not involved and the subjects wore only the IMUs in order to record the arm kinematics. As first step, the amplitude of current able to flex the elbow at 90° with the PW equal to 250 µs was selected. The wearer was then stimulated in sequential trials, all performed at a fixed value of current (i.e. the just calibrated value) and with an increasing value of PW, from 20 µs to 500 µs, in steps of 20 µs. For each PW value, the initial position of the subject's arm was the resting one. Based on the arm kinematics, the elbow torque for each PW was estimated by means of the *Dynamic Arm Module* output τ_{ref}^{tot}. Finally, the data were used to find the subject-specific coefficients *a,b and c* in Equation 2.8, as explained in Section 2.2.3.
Throughout the calibration time the subjects were asked to remain relaxed, so that the voluntary torque was approximately zero and the measured one could be completely associated to FES and/or to the motor actuation. The whole calibration procedure, which is completely automatic, lasted around two minutes.

3 | Experiments and Data Analysis

3.1. Experimental Procedure

Six healthy participants (four males/two females, age 27 ± 2.53 years, mean ± SD, body weight 83±21.16 kg, and height 180.83±11.90cm) were enrolled in the experiments, Table 3.1. Inclusion criteria were based on no evidence or known history of musculoskeletal or neurological diseases, and exhibiting normal joint range of motion and muscle strength. All experimental procedures were carried out in accordance with the declaration of Helsinki on research involving human subjects, and were approved by the IRB of Heidelberg University (Nr. S-311/2020). All subjects provided explicit written consent to participate in the study.

	Sex	Age	Body mass (Kg)	Heigth (m)	Current (mA)
Subject 1	Male	24	110	1.91	24
Subject 2	Male	27	92	1.93	27
Subject 3	Female	28	53	1.63	18
Subject 4	Female	29	62	1.70	18
Subject 5	Male	30	95	1.85	18
Subject 6	Male	24	85	1.83	14

Table 3.1: Data of the subjects involved in the trial. The frequency was set for every subject equal to 40 Hz, whereas the current amplitude was tuned for each subject as described in Section 2.2.5.

The study consisted in repetitions of tracking trajectory tasks, performed in three different conditions: (i) *Exo* Condition, where the movement was entirely guided by the exosuit and no stimulation was delivered (*GainEXO = 1 , GainFES = 0*), (ii) *FES* Condition in which only FES provided assistance (GainEXO = 0, GainFES = 1) and the exosuit cable was slack and the motor turned off, (iii) *Hybrid* Condition during which both the systems worked cooperatively to provide assistance. For each condition, a total of thirty repetitions of elbow flexion movements with amplitude of 60° and 90° in equal number were performed. Both the order of the conditions and the sequence of the angles repetitions were randomized between subjects to avoid biased behaviours. To avoid fatigue, subjects rested for at least two hours between conditions.

At the beginning of each repetition, the supervisor asked the subjects to reach a specific threshold, i.e. the one corresponding to the pre-set angle for that repetition (either 60° or 90°), performing a biceps isometric contraction. To receive a visual feedback regarding the extent of the contraction they were performing, the EMG signal and the two thresholds were plotted in real-time on a monitor. Despite the threshold triggered by the subject, the variable θ_{ref} was set equal to the predefined angle, i.e. the one the supervisor asked to trigger. This was done in order to assess if the developed intention detection methodology based on EMG-thresholds was a feasible solution to trigger the system and allow the subjects to decide the movement to perform. At the same time, this assured the same amount of repetitions with both angles. Once the movement was triggered by the subjects, they had to remain completely relaxed throughout the elbow flexion movement to avoid any voluntary compensation.
Before the experiment, a familiarisation phase allowed the participants to experience the assistance of the hybrid device, FES stimulation and the extent of biceps contraction required to trigger the movement.
The two thresholds were set as defined in the Equation 2.1 and left unchanged for every subjects since they resulted to be suitable for everyone.
For the *Hybrid* condition, the initial $GainFES$ was set equal to 0.8. This was done according to the hypothesis for which starting since the beginning of the trial with a hybrid coordinated assistance would lead to a delayed onset of fatigue; at the same time, allocating 80% of the assistance to FES, assures the stimulation priority to the assistance.
The frequency of stimulation was kept at a constant value of 40 Hz for all the subjects. This frequency value is a common setting in FES application, since it is not too high to lead to premature fatigue but at the same time it prevents unpleasant stimulation sensation to the user.
Lastly, the current amplitude was tuned and kept constant for each subjects as described

in the *Calibration Procedure*, Section 2.2.5.

3.2. Data Analysis Indexes

The performance of the developed Hybrid Controller was assessed in terms of assistance provided, effect on reducing and delaying FES-induced fatigue, effect on the exosuit motor torque and work, and accuracy of the detection method implemented.

3.2.1. Assistance assessment

For every conditions (*Hybrid*, *FES* and *Exo*) the coefficient of determination R^2 and the Root Mean Square Error (RMSE) were computed considering all minimum-jerk trajectories of one subject, between the target and the actual elbow angle and between the target and the actual total torque provided by the systems

$$\begin{aligned} RMSE &= \sqrt{\sum_{i=1}^{N} \frac{(y_{ref} - y_m)^2}{N}} \\ R^2 &= corrcoef(y_{ref}, y_m)^2 \end{aligned} \tag{3.1}$$

where y_{ref} being the reference angle or torque, y_m being the actual angle and torque, N the total number of repetition, $RMSE$ the root mean square error, R^2 the coefficient of determination which is equal to the square of the correlation coefficients $corrcoef$.

The angle trajectories indexes were used to evaluate the tracking accuracy during the flexion movement, whereas the torque indexes assessed the ability of the hybrid controller to coordinate the system in producing the required torque.

3.2.2. Fatigue assessment

The FES-induced fatigue was assessed just for *FES* and *Hybrid* conditions. During, the trials the fatigue level was computed as $k = 1 - \frac{\tau_m^{FES}}{\tau_{ref}^{FES}}$ (Equation 2.11) and it was used to update the assistance gains (in case of *Hybrid* condition). Therefore, a possible solution to estimate the total FES induced muscle fatigue over the trial could have been computing the integral of this coefficient over the trial window time, both for the *Hybrid* and *FES* conditions. Nevertheless, this coefficient presents at the denominator the reference torque of FES (τ_{ref}^{FES}), which is almost constant in case of the *FES* condition since the assistance is entirely allocated to FES, whereas it varies in the *Hybrid* condition according to the gain value. Therefore, comparing the two conditions in terms of fatigue level adopting

the k fatigue coefficient could have lead to misleading conclusions.
In the literature an example of fatigue estimation computed based on torques was proposed by Nguyen *et al.* in [64]. They defined a fatigue index as the ratio between the FES-induced torque at the end of the stimulation divided by the maximum torque before the stimulation. Inspired by this method, I decided to evaluate the fatigue induced by the *Hybrid* and *FES* trials as the ratio between torques after (τ_{post}^{FES}) and before (τ_{pre}^{FES}) the trial, generated by stimulation with the same level current, PW equal to 500 µs and obtained mapping the elbow angle into the torque through the *Dynamic Arm Module*. This index was subtracted to 1 and express in percentage, giving the percentage reduction of the FES-induced torque due to fatigue

$$Fatigue = 1 - \frac{\tau_{post}^{FES}}{\tau_{pre}^{FES}} \tag{3.2}$$

Note that τ_{pre}^{FES} was the FES-induced torque obtained during the calibration procedure with PW equal to 500 µs, therefore it did not require further stimulation. On the other hand, τ_{post}^{FES} was obtained immediately after the trial.

One of the goal of the hybrid system developed was to be capable of delaying the onset of fatigue. To assess this capability, I decided to identify the onset of the fatigue as the first repetition of the trial that required an increase of PW, i.e. the first time the state machine entered into the *Compensation phase*. Indeed, the entering of the state machine into the *Compensation phase* implies that FES was not able to provide the required torque, due to FES-induced muscle fatigue.

3.2.3. Motor work assessment

One of the advantages of the introduction of FES in hybrid system lies on the possibility of adopting smaller motor, since it reduces the motor torque requirement. In order to assess this aspect, during the trajectories time window the motor mechanical power was computed for the *Hybrid* and *Exo* conditions as follows

$$P_m = \frac{\tau_m \cdot w_m}{m} \tag{3.3}$$

where P_m is the motor mechanical power per unit of mass (W/Kg), m is the mass of the subject (Kg), τ_m is the torque delivered by the motor (Nm) and w_m is the angular velocity of the motor (rad/s). Both τ_m and w_m were sent via CAN-bus from the motor to the Arduino. Consequently, the mechanical power per unit of mass was integrated in time obtaining the motor energy (work) per kilogram. Note that the division of the power by the mass of the subject was carried out in order to normalize the index allowing a comparison between subjects.

3.2.4. Intention detection assessment

During the trials the subjects were asked to try to reach a specific threshold, the one corresponding to the pre-selected angle. Therefore, comparing the pre-set angle and the one actually triggered by the user, the accuracy of the implemented intention detection method was evaluated. A confusion matrix was created to perform a pair-wise comparison between the two angles of 60° and 90° performances.

3.3. Statistical Analysis

The statistical analysis was performed with MiniTab (Minitab, State College, PA, USA). Data normality distribution was assessed using Shapiro-Wilk test. Assistance indexes, which resulted to be normally distributed, were tested with a two-way ANOVA using the three conditions (*Hybrid*, *FES* and *Exo*) as the first factor and the two angles (60° and 90°) as second one. For the fatigue indexes, the two conditions (*Hybrid* and *FES*) were compared with two-samples T-test. Similarly, the two-samples T-test was also used to check the significance between the *Exo* and *Hybrid* conditions regarding the motor energy. When the ANOVA results were significant, I performed a post-hoc analysis applying the Fisher's LSD test to evaluate the significant pairwise differences between each type of assistance based on the distribution of the data. For all the tests, the level of statistical significance was set to 0.05. Reported values and measurements are presented as mean ± standard error (SE). Significant differences in the results were highlighted with the symbol * in all the figures.

4 | Results

In this chapter I present the results of the statistical analysis performed. In case of Fisher pairwise comparisons, only the significant ($Pvalue < 0.05$) comparisons are shown.

4.1. Assistance results

In the Table 4.1 and in Figure 4.1 the mean ± standard error (SE) for each assistance index is shown, distinguishing for condition and for angle amplitude.

	Hybrid		**FES**		**Exo**	
	60°	90°	60°	90°	60°	90°
RMSE angle	10.05 ±1.52	10.23 ±0.99	14.92 ±1.04	15.22 ±1.27	8.05 ±0.92	8.09 ±0.75
RMSE torque	0.44 ±0.08	0.36 ±0.06	0.63 ±0.087	0.55 ±0.08	0.36 ±0.05	0.27 ±0.05
R^2 **angle**	0.84 ±0.02	0.91 ±0.01	0.68 ±0.04	0.79 ±0.03	0.87 ±0.03	0.93 ±0.01
R^2 **torque**	0.86 ±0.01	0.93 ±0.01	0.71 ±0.04	0.83 ±0.02	0.90 ±0.02	0.95 ±0.01

Table 4.1: Assistance indexes mean ± standard error (SE). RMSE angle measured in (°) and RMSE torque in (Nm).

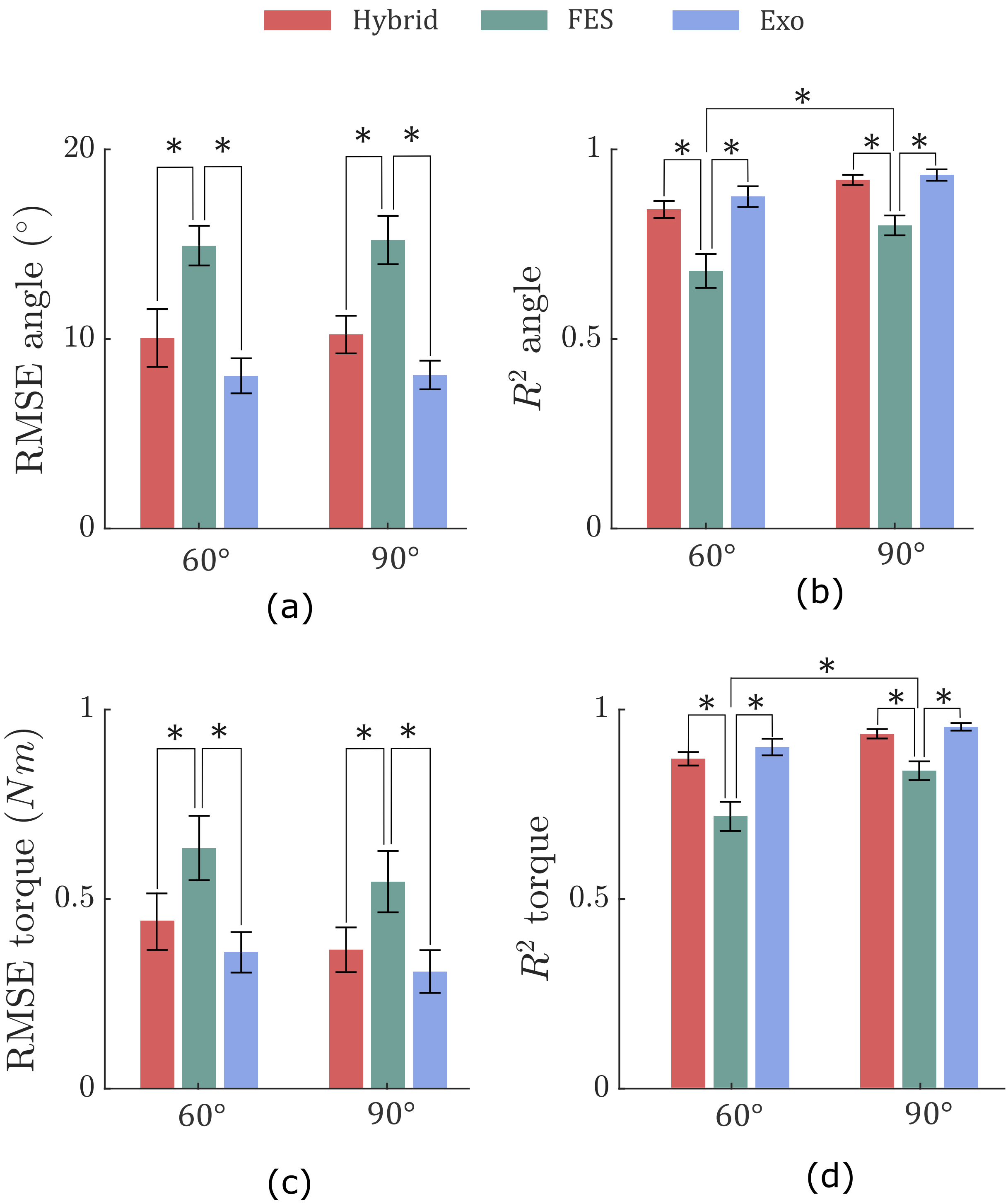


Figure 4.1: *Assistance results.* RMSE and R^2 between the reference trajectory and the elbow angle(a-b), and between the reference torque and the elbow torque (c-d).

RMSE angle

	F-Value	P-Value
Conditions	17,35	<0,000
Angle Amplitudes	0,03	0,862

Table 4.2: Analysis of variance for RMSE angle.

Comparison between levels	T-Value	P-Value
(60 FES) - (60 Exo)	3,98	<0,000
(60 Hybrid) - (60 FES)	-2,82	0,008
(90 FES) - (90 Exo)	4,13	<0,000
(90 Hybrid) - (90 FES)	-2,89	0,007

Table 4.3: Fisher Pairwise Comparisons for RMSE angle.

As reported in Table 4.2, the RMSE of the angle showed significance dependency only on the three conditions ($p < 0.000$). In particular the Fisher pairwise comparisons (Table 4.3) pointed out how both the *Hybrid* and *Exo* conditions are significantly different ($p < 0.007$) from *FES* condition, regardless of the angles amplitude. Lastly, there is no significant (p >0.05) evidence of differences between *Hybrid* and *Exo* conditions.

RMSE torque

	F-Value	P-Value
Conditions	6,93	0,003
Angle Amplitudes	1,57	0,220

Table 4.4: Analysis of variance for RMSE torque.

Comparison between levels	T-Value	P-Value
(60 FES) - (60 Exo)	2,63	0,013
(60 Hybrid) - (60 FES)	-2,07	0,047
(90 FES) - (90 Exo)	2,27	0,031
(90 Hybrid) - (90 FES)	-2,06	0,048

Table 4.5: Fisher Pairwise Comparisons for RMSE torque.

For what concerns the torque RMSE, there is a significant dependency on the three conditions ($p = 0.003$) but not on the angle amplitudes ($p = 0.220$), as shown in Table 4.4. Moreover, as displayed in Table 4.5, for both the angle amplitudes of 60° and 90°, the *FES* condition is significantly different ($p < 0.048$) from the other two. On the contrary, the comparison between *Hybrid* and *Exo* is not statistically significant ($p > 0.05$).

R^2 angle

	F-Value	P-Value
Conditions	18,21	<0,000
Angle Amplitudes	12,48	0,001

Table 4.6: Analysis of variance for R^2 angle.

Comparison between levels	T-Value	P-Value
(60 FES) - (60 Exo)	-4,70	<0,000
(60 Hybrid) - (60 FES)	3,89	0,001
(90 FES) - (90 Exo)	-3,19	0,003
(90 Hybrid) - (90 FES)	2,88	0,007
(90 FES) - (60 FES)	2,88	0,007

Table 4.7: Fisher Pairwise Comparisons for R^2 angle.

The R^2 of the angle is significantly dependent both on the conditions ($p < 0.000$) and on angle amplitudes ($p = 0.001$), as displayed in Table 4.6. Nevertheless, the significant ($p = 0.007$) dependency on the amplitude of the angles concerns only the *FES* condition. Moreover, the *FES* condition showed to be significantly ($p < 0.007$) different from both the *Hybrid* and *Exo* conditions. Even for this index *Hybrid* and *Exo* conditions are not significantly ($p > 0.05$) different (Table 4.7).

R^2 **torque**

	F-Value	P-Value
Conditions	20,49	<0,000
Angle Amplitudes	15,33	<0,000

Table 4.8: Analysis of variance for R^2 torque.

Comparison between levels	T-Value	P-Value
(60 FES) - (60 Exo)	-5,17	<0,000
(60 Hybrid) - (60 FES)	4,30	<0,000
(90 FES) - (90 Exo)	-3,27	0,003
(90 Hybrid) - (90 FES)	2,75	0,010
(90 FES) - (60 FES)	3,41	0,002

Table 4.9: Fisher Pairwise Comparisons for R^2 torque.

Similarly to the angle R^2 , also the torque R^2 resulted to be significantly related on both on the conditions ($p < 0.000$) and on angle amplitudes ($p < 0.000$), as shown in table 4.8. Even in this case, the dependency on the angle amplitude is significant ($p = 0.002$) only in case of the *FES* condition. The comparisons between the three conditions are significant ($p < 0.01$) only between *FES* and *Hybrid* and between *FES* and *Exo* conditions (Table 4.9).

4.2. Fatigue results

The statistical analysis of the fatigue indexes results were analyzed with two-sample T-tests and the results are displayed in Figure 4.2.

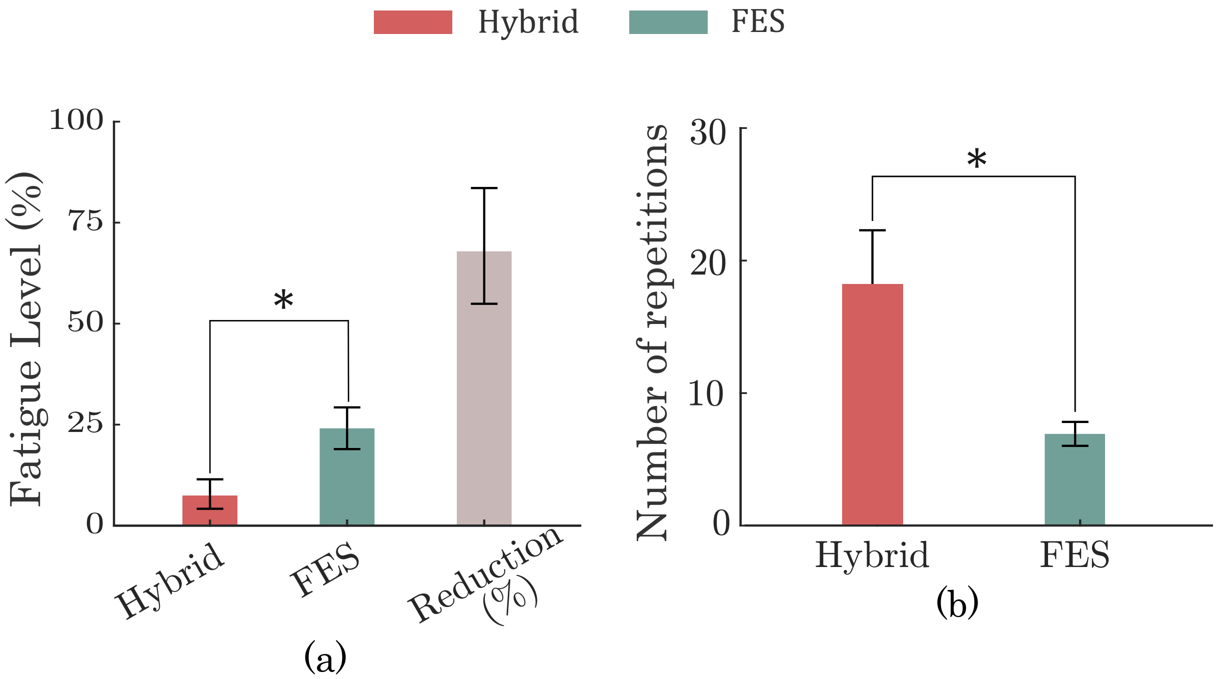


Figure 4.2: *Fatigue results.* (a)Fatigue level post trial for the *FES* and *Hybrid* conditions. The percentage reduction of the *Hybrid* fatigue with respect to *FES* is shown. (b)Fatigue onset results, indicated as the first repetition during which the state machine entered inside the *Compensation* phase.

Post-trial Fatigue level

	T-Value	P-Value
Conditions	2,77	0,024

Table 4.10: Results of the two-sample T-test on the post-trial fatigue.

Table 4.10 shows how the dependency of the post-trial fatigue on the two conditions (*Hybrid* and *FES*) is statistically significant ($p = 0.024$). In particular, the mean ±

Standard error (SE) of the *Hybrid* and *FES* conditions are respectively: 6.89 ± 2.90 % and 22.37 ± 4.17 %.

Regarding the fatigue onset, the *Hybrid* condition significantly ($p = 0.041$) delayed the fatigue onset (14.50 ± 3.22 repetition number) with respect to *FES* (5.50 ± 0.72 repetition number), as shown in Table 4.11. Note that higher repetition number means that the fatigue occurs delayed in time.

Fatigue onset

	T-Value	P-Value
Conditions	-2,73	0,041

Table 4.11: Results of the two-sample T-test on the fatigue onset.

4.3. Motor work results

The motor work per unit of mass was significantly related to the conditions *Hybrid* and *Exo*, with a p value equal to 0.005 (Table 4.12). Specifically, the mean value ± standard error was 16.56 ±2.10 J/Kg for the *Hybrid* condition and 60.83 ±5.45 J/Kg for the *Exo* condition. This results are displayed in graph 4.3.

Motor Work

	T-Value	P-Value
Conditions	7,57	0,005

Table 4.12: Results of the two-sample T-test on the motor work.

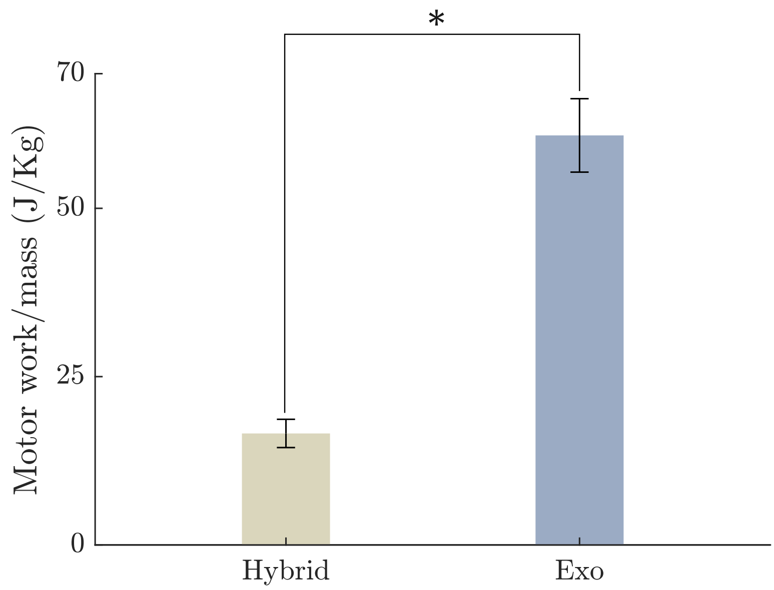


Figure 4.3: *Motor work results.* The bar plots show the mean and standard error of the motor work normalized by the mass, for the *Hybrid* and *Exo* conditions.

4.4. Intention detection results

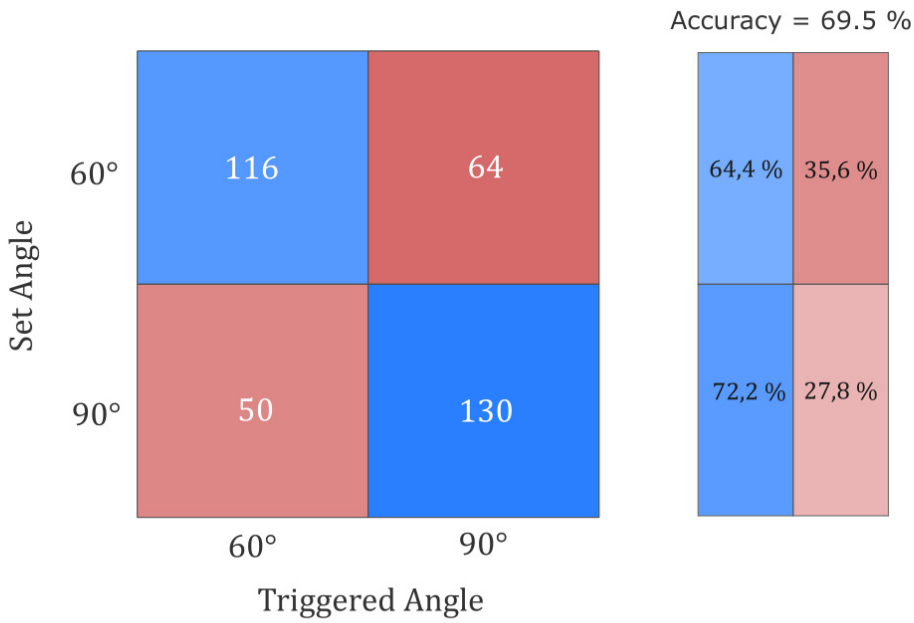


Figure 4.4: *Intention detection confusion matrix.* On the left the confusion matrix is displayed with the rows label being the set angles, i.e. the ones the subjects is asked to reach, whereas on the column the triggered angles. On the right the rate of correct and incorrect triggered angles.

In Figure 4.4 the confusion matrix regarding the intention detection results is displayed. Each row of the matrix represents the a priori set angle, whereas each column represents the intentional triggered angle. The total accuracy was equal to 69,5 %. In particular, when the subjects were asked to reach the 60° threshold, only 64.4 % of the times they succeeded, whereas when the request was to try to trigger the 90° threshold, a succession rate was around 72.2%.

5 | Discussion

Maximum rehabilitation outcomes of patients suffering from neuromuscular pathologies are obtained through intensive, repetitive, long-lasting rehabilitative sessions, involving the active involvement of patients and their active muscle contraction. Hybrid Robotic Rehabilitation Systems demonstrated their ability to fulfil these requirements, merging the rehabilitation benefits of FES with the precision, repeatability and adaptive intensity of robotic devices.

From the literature review performed, a clear lack of elbow hybrid systems based on active exoskeletons [43, 55, 57] able to manage a balanced and coordinated actuation between FES and the robotic device emerged . Moreover, these devices did not account for the FES-induced muscle fatigue, completely neglecting this problematic. Lastly, most of the reviewed devices did not included in the control loop the intention of subjects, which as stated before is critical to achieve the highest rehabilitative results.

Even thought exosuits have shown their capabilities in reducing muscular effort and keeping unaltered the wearer's kinematics, only few studies have explored the possibility of combining exosuits with FES [1, 2]. Nonetheless, these studies showed the same limitations of the active exoskeleton hybrid systems previously explained and none of them assisted the elbow joint.

Would exosuits be a feasible alternative to rigid exoskeleton in hybrid systems to assist elbow movement? To address this question, I proposed for the first time in literature a Hybrid Controller capable of cooperatively managing the Hybrid System composed by FES and a soft wearable elbow exosuit. I analyzed its functionality in terms of assistance provided, FES-induced fatigue, motor torque requirement and the feasibility of using the developed intention detection method as human-exosuit interface. Moreover, a comparison between the hybrid system controller and the solely actuation of the exosuit and FES was performed.

5.1. Hybrid System performance

5.1.1. Assistance

The assistance for all the three conditions was evaluated computing the RMSE error and R^2 on the angle and on the torque following a minimum-jerk trajectory.

As expected, the results highlighted how the solely use of FES produced both the highest torque and angle trajectory errors. Contrarily, the exosuit by itself was able to perform flexion movements with the lowest angular and torque error. The functionality of the hybrid system in terms of torque and angle errors turned out to be significantly lower than the solely stimulation, thanks to the higher precision and accuracy of the exosuit. What it is interesting to notice is the lack of statistically significance for all the assistance indexes between the exosuit and the hybrid system. These outcomes imply that the developed hybrid controller was able to counterbalance the low robustness of FES, while preserving the assistance performances of the exosuit.
In addition, all the assistance metrics for both the Hybrid System and exosuit were not significantly dependant on the amplitude of the movement angle. Hence, we can state that the hybrid controller performed with no significant difference with respect to the exosuit independently by the range of motion; in other words, the assistance provided by the Hybrid System is as precise and as accurate as the solely actuation of the exosuit regardless the amplitude of the performed flexion movement.

As a matter of example, in Figure 5.1 six trajectories for the angle and the torque of a representative subject are reported. As we can notice, while the *Exosuit* and *Hybrid* curves have a quite constant trend, due to their higher precision, the *FES* curves exhibit inconsistent trend, sometimes overshooting and sometimes being incapable of delivering the required assistance.

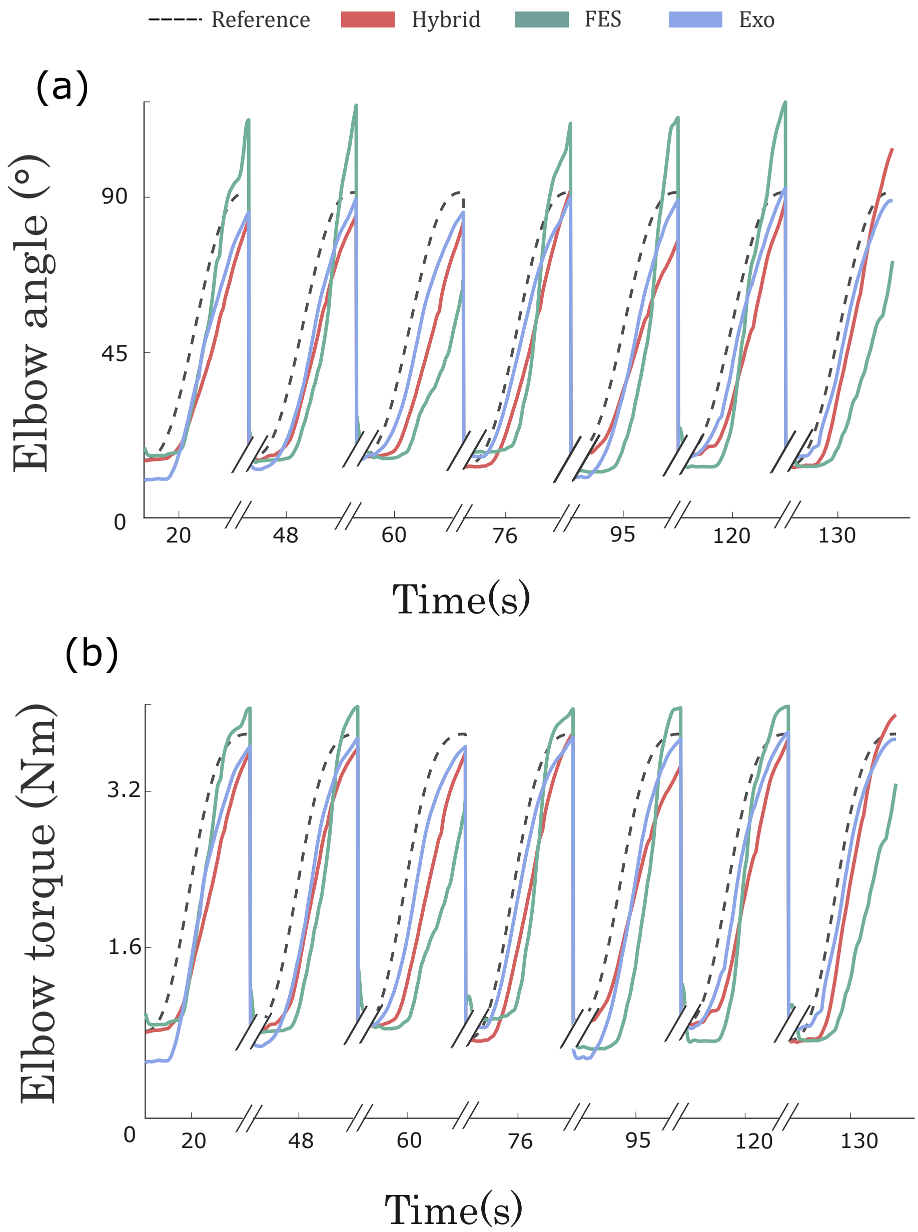


Figure 5.1: *Tracking trajectory examples.* Example of six trajectories of 90° for the angle (a) and torque (b) of a representative subject. It is clearly visible how the solely FES tends to overshoot and to not provide the required assistance, with respect to the other two conditions.

5.1.2. Fatigue managing

The biggest drawback of eliciting muscle contractions by means of FES is the induced muscle fatigue, which arises earlier in time with respect to physiological muscle activation, thus hindering long-lasting rehabilitative therapy. For this reason, decreasing and delaying the fatigue was one of the crucial goal of my study. To accomplish this, I hypothesised that measuring the fatigue during the trials and accounting for that balancing the allocation of the required assistance towards the exosuit, could culminate in lower fatigue at the end of the trial.

Comparing the torque at the elbow generated by FES at the beginning and after the trials, a significant reduction of about 63±11.6% of the fatigue with the implemented hybrid controller with respect to FES alone emerged. In particular, all six subjects presented lower fatigue with the hybrid controller.

This achievement is the direct consequence of the adaptive allocation of the assistance between the exosuit and FES in the hybrid system, according to the estimated fatigue. Indeed, without updating the reference torque assigned to FES, the fatigue would imply higher injection of charge, i.e. higher PW, to the muscle to fulfil the torque requisite. However, as discussed in Section 1.3.2, increasing the current or PW parameters to compensate for the fatigue will lead to a vicious cycle for which the fatigue would continue to rise and potentially it might last longer in time.
In Figure 5.2 can be seen the variation of the allocation ($GainFES$) and the increasing of PW_{offset} for the six subjects in function of the number of repetitions. As we can appreciate, in correspondence of the repetition number in which PW_{offset} increased, i.e. when the state machine was in the *Compensation* phase and so the muscle fibers were fatiguing, $GainFES$ was decreased, reallocating the assistance towards the exosuits.

Regarding the onset of fatigue, the data analysis highlighted how the hybrid controller allowed the participants to perform a higher number of elbow flexion repetitions before experiencing muscle fatigue, with respect to only FES assistance. This is due to the fact that in the hybrid system the assistance is provided by both the exosuit and FES since the beginning of the movement, hence reducing the amount of stimulation required by FES and resulting in delayed onset of the fatigue. In particular, the initial $GainFES$ was set equal to 0.8, hence at the beginning FES accounts for the 80% of the require total elbow torque, whereas in the FES only condition the stimulation was required to provide entirely the total reference torque. Probably, further reducing the initial $GainFES$ could bring to even more delayed onset of fatigue.

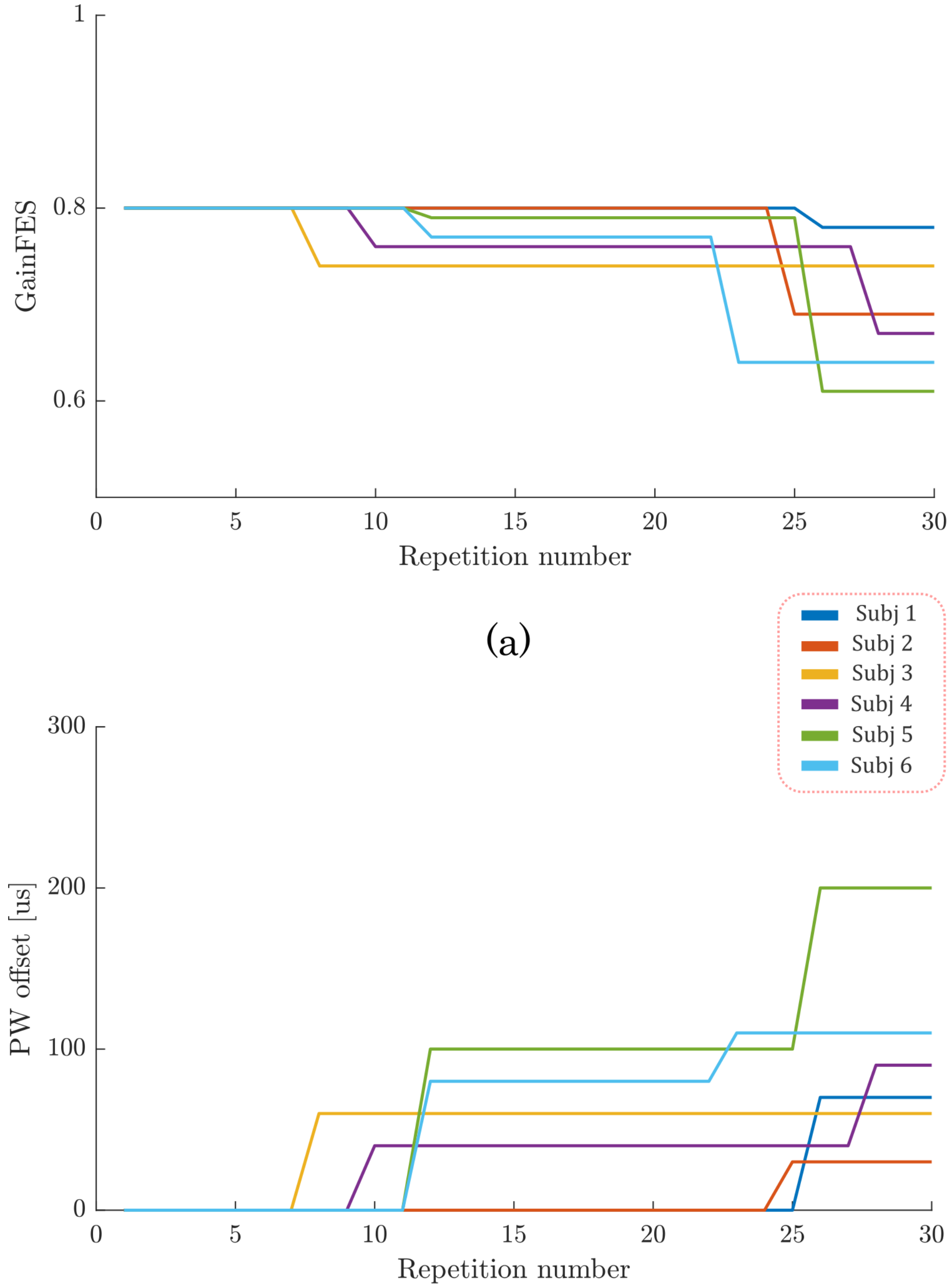


Figure 5.2: *Reallocation of the assistance.* In the figure the updating of $GainFES$ (a) and PW_{offset} (b) during the *Hybrid* trial for the six subjects are plotted. Whenever the subject was fatiguing, PW_{offset} was increased and consequently $GainFES$ was decreased for the following stimulation.

5.1.3. Motor torque requirement

One aspect that has been rarely analyzed in the literature studies regarding active robots hybrid systems, is the potentiality of minimizing the motor torque requirement thanks to the inclusion of FES.
The motor torque requisite is directly proportional to the assistance allocation to the exosuit. Thus, since the hybrid system developed varies the allocation over time based on the estimated fatigue level, I decided to analyzed the motor power (product between the motor torque and its velocity) over time, which represent the motor energy or work. This measure was normalized by the mass of the subjects so that this metric could have been compared inter-subjects.
The results obtained, showed a significant reduction of about 71.70 ±5.44 % in the motor work of the *Hybrid* compared to *Exo* conditions. These outcomes suggest the capability of the developed hybrid system to lower the energy and torque required by the motor, therefore enabling the system to include smaller actuators, hence increasing the portability of the system.
In Figure 5.3 an example motor torque and power for a representative subject during six non-consecutive repetitions have been plotted; as we can notice, the motor torque and power during the *Hybrid* condition is noticeable lower than the *Exo* one.

Nevertheless, this conclusion depends on the functionality of the system regarding long-lasting therapy session. Indeed, the longer the therapy session time is, the higher will be the fatigue, hence the assistance balance between the motor and FES would tend to shift towards the exosuit as the duration of therapy progresses. Hence, as state earlier, the motor torque requirement increase with the time of the session, until the assistance is completely allocated to the motor of the exosuit. Indeed, when FES is not even able to provide 20% of the total torque, i.e. muscle fatigue is detected with $GainFES$ equal to 0.2, the hybrid controller set $GainFES = 0$ for the following flexion movement, to prevent long-lasting fatigue. When this situation arises, the motor should be able to autonomously assist the movement, hence the motor requirement does not vary with respect to the solely *Exo* condition; notwithstanding, what really changes is the energy consumption.
In this study, the participants were asked to performed 30 repetitions of a flexion movements for each trial, but since the starting of the movement was triggered by the subject, the duration of the trials was different between the conditions and inter-subject, with a mean $\pm$ standard error of 6.57 ±0.17 minutes. During this time windows the lowest value of the $GainFES$ detected between all the subjects was 0.61, as shown in Figure

5.2, hence the limit situation of $GainFES$ equal to 0.2 was not reached. Consequently, it can be stated that for this study the hybrid system was able to decrease the demand of high torque motor and concurrently reducing the energy consumption.

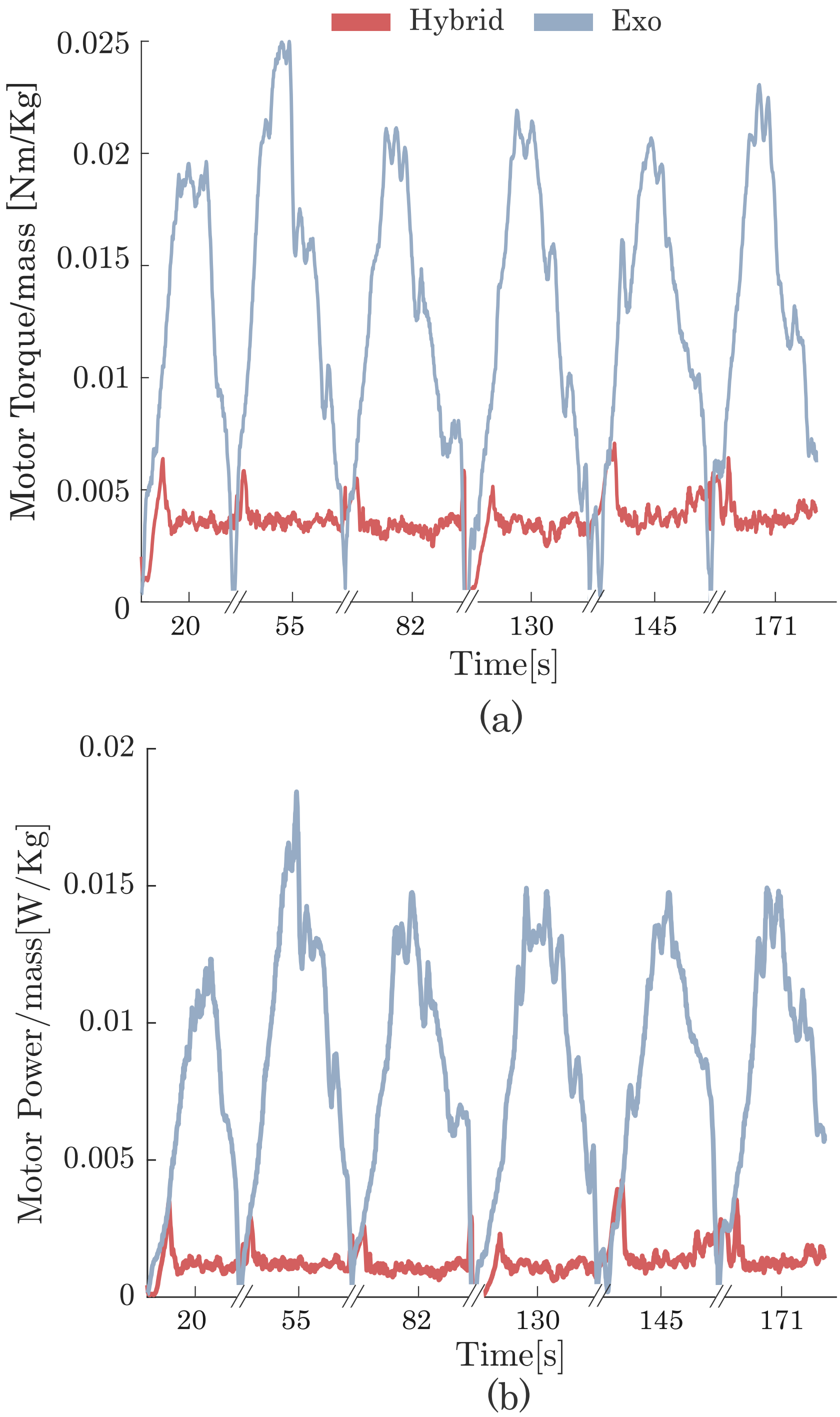


Figure 5.3: *Motor torque and power example.* Example of motor torque (a) power (b) over six trajectories of a representative subject.

5.1.4. Intention Recognition

Including the patient into the control loop, understanding the willing of starting the movement and/or to continuously control it, opens up the possibility to boost the active participation of the subject, increasing the device embodiment and the neuroplasticity, in case of FES combined with EMG.

In this work, an intention detection method based on EMG signal was implemented to trigger the movement of elbow flexion. This method is commonly used to trigger the stimulation; however, an innovative methodology was implemented in which based on two different thresholds, the user can not only start the movement but also decide the amplitude of the elbow flexion angle he/she wants to execute.

The data analysis carried out showed that this method had a satisfactory accuracy of about 69.5%. In particular, it seemed that the participants could successfully trigger the threshold corresponding to 90° more precisely (72.5%) than the one corresponding to 60° (64.4%). This could be due to the fact that the 90° threshold could be triggered with higher probability since any contraction associated with an EMG level higher than the threshold would set off the movement. On the contrary, for the lower threshold only a narrower range of EMG values could trigger it. Moreover, it should be taken into consideration that even though the subjects were allow to experience the intention recognition method prior to the trial, no long training phase were performed, which would have allowed the participants to better exploit the threshold system.

Increasing the number of thresholds, i.e. dividing the range of motion of the movement in higher number of discrete angles, would allow the user to execute distinct flexion movements, depending on the task to be performed. Nonetheless, I would speculate that it might increase the difficulty of fine triggering the desire threshold, since it is not straightforward to understand the level of contraction that would elicit the required EMG activation.

5.2. Limitations and Future Developments

The performance analysis demonstrated how the implemented Hybrid Controller successfully accomplished all the initial goals. Nonetheless, my work presents several limitations.

Limitations The first limitation concerns the control of FES. This study involved an open loop FES controller that relies on the subject specific relationship between the FES-induced torque and PW. Even thought a strategy was implemented to vary this

relation considering the FES-induced muscle fatigue, due to the highly variability of the stimulation outcomes, a closed loop regulation would be more appropriate to manage its assistance. Nonetheless, a close-loop feedback control requires a feedback variable to be compared with the desired one. Since the reference input variable to FES controller is the desired FES torque τ_{ref}^{FES}, the feedback variable should be the actual torque elicited by the stimulation. Nonetheless, as discuss in Section 2.2.3, τ_m^{FES} is representative of the actual FES torque only when the arm position is stationary at a specific angle, thus closing the loop in torque was not applicable.
Alternatively, the control of the stimulation could have been implemented exploiting the EMG signal, creating an EMG-proportional managing of the stimulation. To develop this, a distinct system to record the muscle electrical activity has to be implemented, which needs to be able to distinguish the EMG activity from the stimulation artifacts. The reasons why I decided to neglect this option are two. First of all, I wanted to reduce as much as possible the complexity of the entire system, exploiting the potentiality of the stimulator which was capable of proving the electromyography activity only when the stimulation was off. Secondly, the two additional electrodes necessary to record the signal would have to be placed between the stimulation electrodes; however, the shoulder harness of the exosuit limits the space on the biceps available for placement of these electrodes, considering also the need of the electrodes to not touch each other during movements.

The second limitation of my study relies on the requirement of the subject to be completely relaxed throughout elbow flexion. This requisite was necessarily introduced because the controller was tested only on healthy subjects, therefore able to perform movements autonomously; moreover, without measuring continuously the EMG signal coming from the biceps I could not detect the subject's voluntary effort. This voluntary torque could be seen as external disturbance to the system, which should not be consider null even if subjects are asked to remain relaxed, especially for those participants that are not used to electrical induced contraction, who tend to either co contract the antagonist muscle to oppose the movement or further contract the stimulated muscle.

Lastly, the developed controller was tested only on healthy subjects, preventing the possibility of measuring the rehabilitation outcomes of the patients. Nonetheless, the application of the implemented controller results to be viable also for impaired subjects with remaining motor functionality. For example, the impaired patient could try to autonomously start the movement during the *Break phase*, aided by the gravity compensation provided by the exosuit, and trigger the stimulation when the residual motor capabilities do not allow any further movement.

Future research Being aware of the presented exosuit hybrid system limitations, I reckon future studies should investigate the feasibility of including in a hybrid system comprising exosuit a more efficient modality of controlling FES, either with a close loop or with a proportional control based on the EMG. Moreover, including the EMG would also allow to estimate the voluntary effort of the subject, hence allowing the control to boost his/her involvement during the task, estimating the residual motor capabilities in case of impaired subjects and to achieve a more robust control system. As described previously, the assistance was initially allocated to FES in order to account for the 80% of the total torque ($GainFES = 0.8$) and this led to delayed onset of fatigue; it would be interesting to investigate the influence that the initial $GainFES$ has on the onset and on the magnitude of the fatigue, i.e. find the optimal value of the gain that minimize the fatigue and that maximally delay the fatigue onset.

In addition, no studies in literature have tested neither the use of exosuit in a rehabilitation environment nor exosuit hybrid system. It should be necessary therefore to prove their efficacy in rehabilitative contest and compare their long-term rehabilitation achievements with the rigid exoskeletons.

6 | Conclusion

This study integrated for the first time in the literature FES with an elbow exosuit to investigate the possibility of using exosuits in hybrid systems. The motivation of this work was guided by the lack in the literature of any study which attempted to include a soft wearable suit for the elbow in a hybrid system. Indeed, the existing hybrid systems for the elbow joint are composed by rigid exoskeletons, hence they share their disadvantages: they are generally bulky, heavy and in order to deliver the assistance in a safe way, they require the perfect alignment between the user and device joints. Contrarily, exosuits do not present this necessity, therefore they potentially could lead to smoother and more natural movements when combined with FES, reducing the size and cost of the device and eventually approaching a home-based rehabilitation therapy.

The functionality of the hybrid system was regulated by an innovative hybrid controller, which harmoniously allocate the assistance between FES and the exosuit. During the trial the FES-induced fatigue was monitored estimating the torque generated by the stimulation and comparing it with the reference one. Based on the fatigue, the assistance allocation was updated in order to account for the muscle fatigue. The controller proved to be capable of managing cooperatively the two systems, balancing harmoniously their assistance and resulting in accurate and precise movements. In addition, the hybrid system substantially decreased the magnitude of muscle fatigue and concurrently delayed its onset with respect to the solely assistance by FES, potentially allowing its application for long-lasting therapy sessions. Concerning the performance of the exosuit, it was proved that the hybrid system remarkably shrank the motor energy (work) consumption and its torque requirement. Lastly, thanks to an intention detection module based on the EMG signal of the subject, his/her willing to initiate the movement and the amplitude of movement to perform was recognized accurately.

The main scientific question of this work was to investigate the feasibility of combining exosuits with FES to assist the elbow joint movements. The results obtained clearly revealed the potentiality of soft wearable suit to be integrated in Hybrid Robotic Rehabilitation Systems and reasonably suggest their application in rehabilitation treatments of neuromuscular diseases in order to promote motor function recovery.

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Variable	Description	SI unit
$\boldsymbol{PW}$	Stimulation Pulse Width	us
$\boldsymbol{EMG}$	Electromyography signal	uV
$\boldsymbol{EMG_{mean}}$	Mean EMG signal	uV
$\boldsymbol{Thr_{60}}$	EMG threshold for 60° elbow angle	uV
$\boldsymbol{Thr_{90}}$	EMG threshold for 90° elbow angle	uV
$\boldsymbol{\theta_{ref}}$	Reference angle	°
$\boldsymbol{\theta_{act}}$	Actual (measured) angle	°
$\boldsymbol{\theta_{rest}}$	Rest angle (elbow extended)	°
$\boldsymbol{\tau_{ref}^{tot}}$	Total reference torque	Nm
$\boldsymbol{\tau_{ref}^{exo}}$	Exosuit reference torque	Nm
$\boldsymbol{\tau_{ref}^{FES}}$	FES reference torque	Nm
$\boldsymbol{\tau_{m}^{tot}}$	Total measured torque	Nm
$\boldsymbol{\tau_{m}^{exo}}$	Exosuit measured torque	Nm
$\boldsymbol{\tau_{m}^{FES}}$	FES measured torque	Nm
$\boldsymbol{\tau_{max}^{FES}}$	FES maximum torque at 500us PW	Nm
$\boldsymbol{\tau^{voluntary}}$	Voluntary torque	Nm
$\boldsymbol{I}$	Elbow moment of inertial	Kg$\cdot m^2$
$\boldsymbol{\ddot{\theta}_{act}}$	Actual angle acceleration	$\frac{rad}{s}$
$\boldsymbol{m}$	Combined forearm and hand mass	Kg
$\boldsymbol{g}$	Gravitational acceleration	$\frac{m}{s^2}$
$\boldsymbol{l_c}$	Distance forearm and hand COG from elbow rotation center	m
$\boldsymbol{k}$	Fatigue coefficient	
$\boldsymbol{GainFES}$	FES Gain parameter	
$\boldsymbol{GainEXO}$	Exosuit Gain parameter	

Variable	Description	SI unit
$\boldsymbol{PW_{offset}}$	Delta PW at τ_{max}^{FES}	us
$\boldsymbol{e_r}$	Error between τ_{ref}^{exo} and τ_m^{exo}	Nm
$\boldsymbol{w_r}$	Refernce velocity command exosuit	$\frac{rad}{s}$
$\boldsymbol{Y(s)}$	PID admittance transfer function	$\frac{rad \cdot Nm}{s}$
$\boldsymbol{Kp}$	PID admittance proportional gain	
$\boldsymbol{Ki}$	PID admittance integrative gain	
$\boldsymbol{Kd}$	PID admittance derivative gain	
$\boldsymbol{a, b, c}$	Sigmoid parameters	
$\boldsymbol{P}$	Elbow moment arm	m
$\boldsymbol{\tau_{post}^{FES}}$	Measured FES torque post trial	Nm
$\boldsymbol{\tau_{pre}^{FES}}$	Measured FES torque pre trial	Nm
$\boldsymbol{Fatigue}$	Measured fatigue index	
$\boldsymbol{P_m}$	Motor mechanical power per unit of mass	$\frac{W}{Kg}$
$\boldsymbol{\tau_m}$	Motor torque feedback variable	Nm
$\boldsymbol{W_m}$	Motor velocity feedback variable	$\frac{rad}{s}$

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