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Executive Summary of the Thesis

A graphical user interface for a hybrid FES robotic exoskeleton for walking: design and usability evaluation

Laurea Magistrale in Biomedical Engineering - Ingegneria Biomedica

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1. Introduction

Spinal Cord Injury (SCI) is a disease mainly caused by a trauma which provokes the interruption of the efferent nerves of the Central Nervous System (CNS), compromising the conduction of electrical signals to the Peripheral Nervous System (PNS). As a consequence, SCI strongly disables social life and Activities of Daily Living (ADLs) for affected subjects. For this reason, the development of rehabilitative treatments is fundamental for delaying secondary consequences, such as muscular atrophy, spasticity and pressure sores related to the immobility of patients, and to favour the reorganization of neural connections, namely the neural plasticity process.

Conventional therapies applied to SCI people consists in mobility exercises calibrated on the deficit level of the patient and focused on maintaining the joints range of motion and the muscular mass. However, during these treatments the patient plays a passive role and it represents a big disadvantage that lowers the therapy-related benefits.

In the last years, robotic rehabilitation has been proposed as an alternative to standard therapy as its aim is to develop robotic devices to assist the therapist or the caregiver during the rehabilitation session of patients affected by movement impairments. According to Cheng and Lai [3], robotic devices can be divided in two groups: end-effectors and exoskeletons. Focusing on exoskeletons, one of their advantages is to provide longer rehabilitation sessions that enhance the neural plasticity process, maximizing the benefits for the patient. As drawbacks, when used in rehabilitative sessions they can induce the 'slacking effect', namely the passive role of the patient that is completely moved by the robot during the movement.

Functional Electrical Stimulation (FES) in an alternative rehabilitative method, which can be combined with robotic devices. It consists in delivering low-energy electrical pulses to peripheral nerves that innervate paralysed muscles, inducing their contraction and, consequently, a functional movement. Both the muscle-skeletal and the cardiovascular system take advantage from the FES application: muscle tone is increased, spasticity and osteoporosis are reduced and the risk of veins thrombosis decreases. However, this technology is associated with 2 main drawbacks, namely the non linear relation between stimulation parameters and induced contraction and

the early appearance of muscle fatigue that limits the duration of the rehabilitation session.
In recent years, these two technologies have been joined together in those that are called hybrid systems to overcome their individual disadvantages. Hybrid FES-robotic devices provide stability and motor assistance to the user, allowing to prolong the duration of rehabilitative sessions since the supported of the exoskeleton delays muscle fatigue.
However, the development of a cooperative control strategy that balances the contribution of robotic motors and FES-induced movements is still a challenging task because of the difficult management of actuators redundancy.
In literature, examples of hybrid systems are present such as Kinesis ([5] and [4]), Vanderbilt ([6]) and FEXO Knee ([7]).
Considering the significant amount of data that hybrid systems deal with, it is fundamental to develop a Graphical User Interface (GUI) to support users in handling the system. Considering the clinical use of the system, the GUI should be user-friendly, intuitive and safe in order to properly guide the rehabilitation session without threatening the security of the patient. To this aim, all human-related error should be managed by avoiding their occurrence with warning messages.
The aim of this work was to develop a GUI to calibrate and control a rehabilitative session during which a hybrid FES-robotic device is used to support walking in people with SCI. The hybrid device used in this work consists of a lower-limb motorized exoskeleton (called Twin) combined with a 8-muscle lower limb neuroprosthesis. The starting point of the work was the user interface of the Twin exoskeleton, used alone and not in combination with FES. In particular, the main features that were added regard the possibility to perform a session in the hybrid modality and the development of an automatic FES calibration procedure. Moreover, other additional features were included to improve the general user experience, such as the possibility to save FES parameters and rehabilitation session set-up and performance (i.e. control modality, number of step performed and stimulated muscles)

2. Materials and Methods

2.1. Twin-FES

Twin Twin is an active lower-limb exoskeleton manufactured by the Italian Institute of Technology (IIT) of Genova. It has been developed to assist people with motor impairments, such as SCI or stroke, within a clinical context. Twin's structure is composed by two active joints at the hip and knee level and a passive Ankle-Foot Orthosis (AFO). Ankle joint stiffness can be adjusted by loosening the spring embedded within the AFO, which determines the maximum plantar-flexion and dorsi-flexion allowed. The three joints are connected by modular rigid links, mimicking the tibial and femoral segments. Finally, the movement is transmitted from motors to the limbs through fabric braces in correspondence of the pelvis and the shank and thigh of each leg. All these elements are available in different sizes to adapt to different patient's anthropometries.

FES Twin has been embedded with two RehaMove3 stimulators to integrate FES in the structure. In this work, we will refer to TwinFES to indicate the hybrid FES-robotic system used in this work. Target muscles that can be stimulated are: quadriceps, hamstrings, gastrocnemius and tibialis anterior, both for the right and left side. Electrical pulses are delivered to the muscles through surface electrodes, positioned over the muscle belly in a bipolar configuration (one anode and one cathode). The pulses have a biphasic rectangular waveform, whose parameters can be defined, specifically: pulsewidth, frequency and amplitude. In particular, frequency and pulsewidth are kept constant while amplitude is modulated over time during the rehabilitative session. Hence, before starting the rehabilitative session, a calibration phase is required to set the current amplitude range for the specific patient and muscle. The calibration process consists in delivering to the patient a ramp of increasing amplitude defining three current thresholds, namely the sensory threshold, the movement one and the maximum value. The first value refers to the lower current level that the patient can perceive (in case of residual sensitivity) or an arbitrary low value (e.g., 4 mA), otherwise. The second value, the movement threshold, is the current amplitude at which the body segment starts to move. Finally, the maxi-

mum value corresponds either to the current amplitude that allows to perform the complete limb movement or to the maximum FES amplitude tolerated by the patient.

Control Modalities Twin-FES allows two different control modalities: the proprioceptive modality and the hybrid modality. These modalities define the reference trajectories that each joint has to follow based on the set of walking parameters (i.e. clearance, step length and duration, range of motion (ROM) and offset of hip and knee and the active/passive ankle option).
The proprioceptive modality is based on a position-driven control. Indeed, for each joint the predefined reference trajectory is rigidly followed during the movement. In this case, the patient is passive and any active contribution to the movement is not possible. Nevertheless, FES is enabled also in this modality but always below the movement threshold. Consequently, the aim of FES is not to produce a functional movement but to provide a proprioceptive feedback. Electrical pulses are delivered by biphasic rectangular waveform, having constant pulsewidth and frequency and amplitude is modulated with a shape that mimics muscles activation during walking but always below motor threshold.
Differently, the hybrid modality allows a compliant tracking of the reference trajectory. Indeed, a first order impedance controller (Proportional-Derivative) computed the torque to be generated by motors at the joints level. The impedance mechanical model is given by:

$$I(s) = K_s + sK_d \tag{1}$$

where K_s is the stiffness gain that, multiplied by the position error, forces the trajectory toward the desired one; a higher K_s determined a more rigid tracking of the reference trajectory. K_d is the damping coefficient and, multiplied by the velocity error, stabilizes the movement, avoiding velocity oscillations.
In contrast to the position-driven controller of the proprioceptive modality, here the compliance of the PD controller allows deviations from the target trajectory and thus a participation of the subject to the movement. In fact, FES is here applied above movement threshold as the aim is to have functional FES-induced muscle contractions which "cooperate" to the motor to achieve the walking movement. Especially, FES induces muscle contraction only during the flexion/extension of the swing knee while other joints are controlled in position. Stimulation pattern is tuned step by step by an Iterative Learning Controller (ILC) based on the position error of the previous iteration (i.e. step) in order to maximize the contribution given by FES-induced contractions to the movement. In particular, the implemented ILC maintains constant frequency and pulsewidth while it varies amplitude according to the position error between the reference trajectory and the actual one during the previous iteration.

2.2. Application

A Tablet application, called *TwinFES*, has been developed in order to remotely control the hybrid device and handle the execution of the training session. In particular, the application allows the setting of the training parameters, user data (i.e. FES calibration and previous rehabilitation sessions) and the selection of the control modality.

Requirements The application has to satisfy some technical requirements to guarantee a safe and correct use of the hybrid system. The identified requirements have been divided in three groups:

1. **Always On Functions**: essential conditions to guarantee a safe therapy;
2. **Assistance throughout the therapy**: features that aim to reduce the human errors and to provide an adequate feedback to the therapist about the ongoing training;
3. **Data Management**: the capacity to store data about the specific patient during each session. In particular, it aims to speed up repetitive procedure and to monitor the patient over time.

Always on Functions regards the connection and communication between TwinFES and the application. In particular, the connection has to be stable for the whole session duration and both systems need to correctly receive and send messages. Furthermore, user needs a constant feedback about how the therapy is being performed, which is provided by dialog windows.

Assistance throughout the therapy deals with the management of human-related errors. In particular, this achievement is carried out by controlling the flow of the therapy through enabling/disabling button functions and highlighting the missing actions to be performed to pursue a correct therapy.
Finally, *Data Management* concerns the storage of patient-related data; in particular, it tracks the previous rehabilitation treatments and stores FES calibration data. The former helps the therapist in taking therapy-related decisions, the latter reduces the waste of time for repetitive actions, permitting the re-use of an already existent calibration.

2.2.1 Guidelines for application use

Once the application is launched, the connection between TwinFES and the application is set automatically. Afterwards the user is selected and the session begins with the appearance of the main control panel.
As first step, the user should perform FES calibration through the 'FES panel'. In particular, frequency, pulsewidth and current range (minimum and maximum values that current amplitude can assume) are set. Then, all muscles to be calibrated are selected and calibration is performed one muscle at a time. When the process starts, a ramp of increasing current is delivered to the muscle and the three thresholds are defined (see section 2.1). To enhance usability, the current amplitude is displayed in real-time during the ramp-up phase.
Secondly, walking parameters (i.e. clearance, step length and duration, range of motion (ROM) and offset of hip and knee and the active/passive ankle option) are set. From these data, reference trajectories for hips and knees are computed.
Afterwards, one of the two control modalities can be enabled. Their panels have common features. On top right corner there is a miniature of the patient wearing the exoskeleton and its colour changes accordingly to batteries' level and joints connection status. Furthermore, four icons depict the state of the exoskeleton; possible ones are: seated, standing, walking or no control. Once the control is enabled, a panel with the saved calibration values is displayed and the therapist can either keep them or modify them through 'FES Panel' (as explained in section 2.1). Successively, the user can select the muscles to be stimulated during the session. The activation of a muscle is permitted only if a calibration for that muscle is present both for the right and left side. Finally, the modality can be activated and several steps can be executed by triggering each of them one by one.
At the end of the session, when the control is disabled, a dialog window displays a summary of the training with the current used for each stimulated muscle and the number of steps performed. If saved, the training will be stored within the 'Training Panel'.
In the 'Training Panel', all previous training sessions are listed, identified by the hour and the date in which they were performed. By selecting one of them, more detailed information are available, in particular: the used modality, the number of steps performed and the FES parameters used (pulsewidth, frequency and amplitude levels) for the stimulated muscles.

2.2.2 Usability Evaluation

In this work, the usability of the *TwinFes* application has been evaluated by 10 biomedical engineers and 7 therapists of the Villa Beretta rehabilitation center. The tests were divided in three parts:

1. Application Training: the participant is instructed on the app functioning, particularly to the features regarding FES calibration, setting of walking parameters, activation of hybrid modality and saving of the training session data;
2. Application use: the user carries out on its own all the steps that were previously showed to him;
3. Usability Evaluation: each user assesses the app usability by filling two questionnaires: the System Usability Scale (SUS) and an *ad hoc* questionnaire.

System Usability Scale The System Usability Scale (SUS) is a 10-item questionnaire related to the usability of a device. According to [2], it has been created as a tool that allows the direct comparison between different systems. SUS is compiled by the user soon after having tried the system by answering to questions with a score from 1 to 5. The overall score is given by

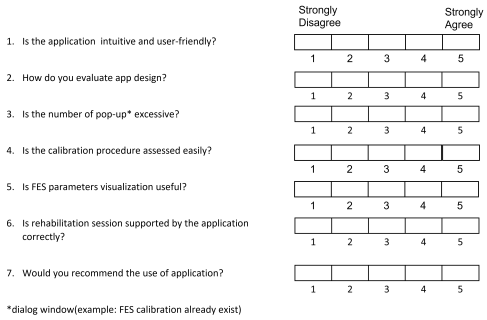


Figure 1: Template of *ad hoc* questionnaire.

summing up all scores and multiplying it by 2.5. Doing this, the overall score will vary between 0 and 100. If the obtained score is above 68, the system is considered as above average [1].
The limitation of SUS is that questions are general and not system-specific. Therefore, an *ad hoc* questionnaire with specific questions was needed to the usability evaluation.

***Ad hoc* questionnaire** Since usability depends on three features, user, task and context, an *ad hoc* questionnaire is essential to evaluate the real application of the system. This questionnaire is composed by seven closed questions, three open questions related to positive, negative and general notes and three images of app panels where the user can indicate improvements for the app design by directly annotating them on the image. Then, the scores of each question are summed up and the result is multiplied by 3.5, thus the total score can vary between 0 and 100. A template of the *ad hoc* questionnaire is shown in *Figure 1.*

3. Results

Results have been divided in two parts: requirements validation and questionnaires scores analysis.

3.1. Requirements Validation

All requirements (see section 2.2) have been validated by empirical laboratory tests.
Regarding *Always On Functions*, they were achieved by checking if the connection between TwinFES and the application was stable and if messages were correctly sent and received by both systems, and by implementing graphical tools and dialog windows to inform the therapist about the ongoing of the therapy.

The *assistance throughout the therapy* has been assessed by controlling the flow of the rehabilitation session. The principal developed features consist in enabling/disabling button functionalities depending on what the therapist should or should not do and highlighting the actions that still need to be achieved. In this way, the flow control allows to reduce human-related errors.
Finally, *Data Management* and their correct loading at each session has been verified. In particular, the storage of FES calibration parameters and the saving of training data were checked.

3.2. Questionnaires Scores Analysis

In this section, results of both questionnaires are presented considering firstly the overall results and then biomedical engineers and therapists separately.

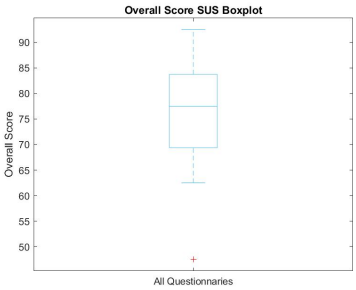
Frequencies Response Considering both groups together, the SUS question that obtained the lowest score is #4 (i.e. 'I think that I would need the support of a technical person to be able to use this system') with a median of 2, while the one with the maximum score is question #7 (i.e.'I would imagine that most people would learn to use this system very quickly') with a median of 4.
On the other hand, considering the *ad hoc* questionnaire, it presents a lower distance between the lowest and highest score with respect to the SUS. Indeed, the median of the lowest-rated question (i.e. Question #3) is 3 while the one of the best-rated question (i.e. Question #4) is 4.
By analysing SUS results of the two groups separately, both of them gave the lowest rate to question #4 ('i.e. 'I think that I would need the support of a technical person to be able to use

this system': median for engineers: 2, median for therapists: 2) and the higher rate to question #7 (i.e.'I would imagine that most people would learn to use this system very quickly': median for engineers: 4, median of scores for therapist: 3). So, there is complete agreement between the two groups.
For what concerns *ad hoc* questionnaire, the lowest-rated question is different between the two groups: for engineers it was question #2 (i.e. 'How do you evaluate app design?') with a median of 3 while for therapists it was question #1 (i.e. Is the application sufficiently intuitive and user-friendly?') with a median of 3. Another different opinion regards the aspect that mostly satisfied the two categories. Therapists were more impressed by the fast calibration allowed by the application, in fact, they gave a median of 4 to question #4 (i.e. 'The application allows a fast FES calibration phase'). On the other hand, biomedical engineers particularly appreciated the intuitive design and the facility in learning it, scoring question #1 (i.e. Is the application sufficiently intuitive and user-friendly?') with a median of 4.

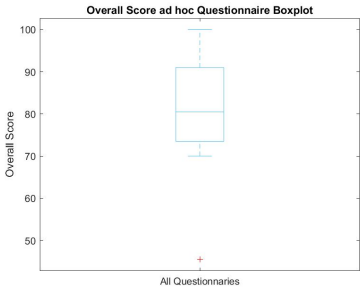
Total Scores The total scores for both questionnaires have been analysed and depicted in *Figure 2*. Overall, SUS obtained a median equal to 77.5 while *ad hoc* questionnaire obtained a median equal to 80.5.
Regarding each group, the total scores were analysed by looking at their distribution (see *Figure 3*). For SUS questionnaire, therapists had a median equal of 77.5 whilst engineers had a median equal to 76.2. Instead, *ad hoc* questionnaire recorded a median equal to 80.5 both for biomedical engineers and therapists .
Furthermore, a statistical analysis has been done on the overall scores of both questionnaires to see if any statistical difference is present. Since the number of samples is reduced, a Mann-Withney U test has been performed. This test did not arise any significant difference between the opinions of therapists and engineers regarding both questionnaires.

4. Conclusions

Both questionnaires obtained satisfactory results, certifying the good usability of the application. Moreover, even if it was evaluated by two different groups with different backgrounds, no statistical differences arose.
However, two main points emerged from the results analysis. The first one is relative to the disagreement recorded between the two groups in the identification of the worst and best aspects of the application. As highlighted in section 3.2, for engineers the worst aspect was the app design (Question #2) while for therapists the fact that it is not enough user-friendly (Question #1). On the other hand, the best feature identified by engineers was the intuitive design and the ease to learn it, while for therapists it was the fast FES calibration procedure enabled (Question #4). The cause of these disagreements can be identified in the difference in both average age and clinical experience of the users. In fact, the age ranges of the two groups are very different: biomedical engineers range between 21 and 30 years old while therapists between 30 and 60 years old. Hence, this could explain why therapists found the system more complicated to use. Nevertheless, therapists had a more practical vision of how the robotic rehabilitation is carried out, indeed, they rewarded the functional aspect of the application such as the reduced time-cost for FES calibration.
The second point regards the results obtained about the question with the minimum and the maximum score. Indeed, many users felt the necessity of a technical person beside them to guide the rehabilitation treatment but, at the same time, they found the application very easy to use. This contradiction can be explained with the hypothesis that initially people are not very confident on how to use the GUI but, at the same time, they think that they could handle it easily with more practice. Probably, multiple training sessions on how to use application are to be considered to accelerate the learning process and increase the confidence of the users. Overall, the obtained usability results are satisfactory as the median of total scores of both questionnaires are above 75. In particular, SUS median score is over 68 points which means that the application is considered above average [1].
Despite these results, the necessity to extend the number of involved participants is crucial to collect more opinions about application usability and get hints on how to improve it. Moreover, an intensive use of the application can reveal

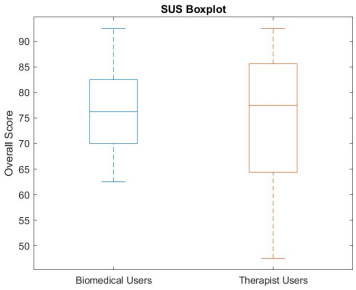


SUS scores Boxplot.

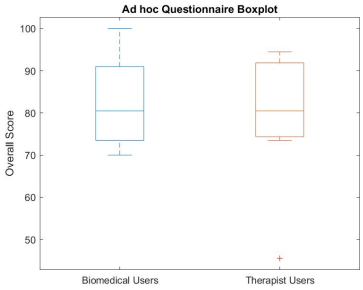


ad hoc scores Boxplot.

Figure 2: SUS and *ad hoc* questionnaires total scores distribution considering groups together.



SUS scores Boxplot.



ad hoc scores Boxplot.

Figure 3: SUS and *ad hoc* questionnaires total scores distribution divided in groups.

malfunctioning that have not been detected yet. Finally, the real efficiency and functioning of Twin-Fes will be achieved when it will be used in clinical contexts to guide rehabilitation sessions.

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