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Executive Summary of the Thesis

Feasibility tests of a hybrid FES-robotic lower limb exoskeleton to support locomotion in neurological patients

Laurea Magistrale in Biomedical Engineering - Ingegneria Biomedica

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1. Introduction

Spinal Cord Injury (SCI) is caused by either traumatic or non-traumatic damage to the neurological tissue of the spinal cord, resulting in a partial or total loss of sensory and/or motor functions below the injury level. A stroke, instead, is a brain damage with two possible causes: the closure of a cerebral blood vessel causing the lack of oxygen and nutrients to the relative brain area, or the rupture of a cerebral blood vessel creating high-pressure areas that damage brain cells. Both injuries result in functional problems with a significant impact on patients' quality of life, as they affect their functions and social participation [5].

Various assistive technologies for motor rehabilitation are available, such as Functional Electrical Stimulation (FES) and robotic exoskeletons. FES consists of delivering low-energy electrical pulses to muscles to induce functional movements. However, this technique exploits a non-physiological activation of muscle fibers, which leads to the early appearance of muscular fatigue. Moreover, it exhibits a non-linear relation between the injected current and the resulting movement, causing poor control of joint trajectories. On the other hand, exoskeletons are motorized robotic structures ideal for delivering intensive, task-oriented and repetitive training, representing crucial aspects of motor recovery. Nevertheless, these devices present several drawbacks associated with energy management, portability, weight and discomfort [1]. The combination of FES with an exoskeleton, referred to as Hybrid Robotic Rehabilitation System, has emerged as a promising approach, aiding gait restoration and providing a safer, more robust and more efficient neurological rehabilitation. Their aim is to achieve motor recovery or compensate for motor function, by combining the torque coming from electrically stimulated muscles with the one coming from motors. Hybrid devices emphasize the advantages of both components while mitigating their drawbacks: the addition of FES may allow the development of lighter exoskeletons, while the presence of the robotic component may delay the appearance of muscle fatigue, prolonging the training duration [2]. However, in most literature cases, these two technologies are simply overlapped without demonstrating their complete integration [3]. The FESleg project, conducted in collaboration with the INAIL (Istituto Nazionale per l'assicurazione contro gli Infortuni sul La-

voro, Italy) Prosthetic Center, aims to overcome some limitations of current approaches by developing a hybrid walking device, named TwinFES, that integrates FES into a motorized exoskeleton, establishing a cooperation between the two. In particular, a cooperative joint control is defined, that reduces the overall motor torque demand and includes the FES-induced patient participation in the loop.
The project's first objective is to verify TwinFES performances on healthy subjects and to observe the behavior of the hybrid system with respect to fatigue, performing both single joint and walking tests. The second objective is to validate the usability, acceptability, user experience, human-exoskeleton interaction and safety of the TwinFES prototype on two SCI subjects. In particular, the potential advantages coming from the stimulation addition are studied by comparing TwinFES with the use of the sole exoskeleton.

2. Materials and methods

Twin is a motorized lower limb exoskeleton developed by the Rehab Technologies Lab of the Italian Institute of Technology (IIT). The structure (shown in Figure 1) consists of four motor modules positioned at the hip and knee joints of both legs, five rigid connecting links, five ergonomic fabric interfaces and two AFO (Ankle Foot Orthosis) [4].

Figure 1: TwinFES prototype consisting of the Twin exoskeleton and two electrical stimulators

At the trunk level, the exoskeleton is equipped with a backpack containing batteries (Lithium batteries), IMUs, the emergency button and the Central Control Unit (CCU). This latter is the motherboard, referred to as SMEx (Scheda Madre Exo), which consists of an ARM Cortex-M4 microcontroller based on Linux operating system and programmed in C++. The device is used in conjunction with walking aids, such as crutches or walkers, since it is not self-balancing and thus the patients are required to use their upper limbs to maintain stability. Additionally, a therapist walks behind the patients to support them in the movement. Twin is only intended for rehabilitative use and is confined to rehabilitation sessions within dedicated facilities, under close supervision of healthcare professionals.
Within the FESleg project, the research team at Politecnico di Milano integrates two neuromuscular stimulators (RehaMove3, Hasomed, Germany) into the Twin exoskeleton's control system. Their control is directly integrated into the exoskeleton software, which is accordingly modified to work in conjunction with the stimulation. Both stimulators, used one per leg, have 4 stimulation channels, enabling the simultaneous stimulation of Quadriceps, Hamstring, Gastrocnemius, and Tibialis Anterior of both sides. The stimulation waveform is rectangular and biphasic, fully balanced in terms of charge. Frequency and pulse width remain constant ($f = 40$ Hz, $PW = 400\ \mu s$), while the amplitude is modulated over time. Before starting a session with the device, every patient has to undergo a calibration phase to define two subject-specific intensity levels:

- Level 1 (L1 - movement threshold): the value that produces a first visible movement;
- Level 2 (L2 - maximum threshold): the minimum value between the one producing a full joint movement and the maximum tolerated one.

2.1. Control mode

The hip joints in the stance and swing phase and the knee one in the stance phase employ a rigid position control, to produce a physiological gait pattern without patient involvement and to ensure subject stability. For the Quadriceps, Hamstring, Gastrocnemius and Tibialis Anterior of the stance leg and for the Gastrocnemius and Tibialis Anterior of the swing leg, FES is applied with a biomimetic activation timing, trying to mimic natural muscle activations. Its intensity is defined as *proprioceptive*, meaning that it is able to reach proprioceptive sensory fibers, but it is not strong enough to activate motor fibers and thus induce movements.

The knee joint during the swing phase, the same used for flexion-extension of single joint test, instead, adopts a cooperative control, with both the motor and FES components on the Quadriceps and Hamstrings actively contributing to swing movements. A first-order implicit impedance control is implemented, promoting a more compliant behavior compared to rigid position control, allowing deviations from the equilibrium point when external forces induced by FES are applied. The proposed impedance control architecture includes two nested loops: an internal torque loop, responsible for calculating the total torque sent to the motor to support motor/FES compliance, and an external position-feedback loop, that corrects trajectory-tracking errors. The torque control is defined as implicit since the system is not equipped with a torque sensor at the joint level and so, it is impossible to directly measure the actual torque generated at the joint's output shaft. The total torque sent to the motor is divided into two components: feedforward torque (τ_{FF}) and feedback torque (τ_{FB}). The former is the motor contribution needed to support the movement, computed as the sum of inertia and gravity contributions from both the exoskeleton and the subject's shank. The exoskeleton's weight is always fully compensated, while the patient one is compensated up to a certain percentage, $\alpha \in [0,1]$, depending on the patient's needs and on the fatigue induced by FES, following an assist-as-needed paradigm. The latter, instead, is a corrective torque, realized as a Proportional-Derivative controller, which adjusts the torque sent to the motors, trying to reduce position and velocity errors.

The stimulation amplitude of Quadriceps and Hamstrings is modulated through an Iterative Learning Controller (ILC). This approach involves iterative adjustments of the input variable to minimize a cost function evaluated at the previous step [6]. Thus, the signal is updated only at the end of a complete iteration, making this approach well-suited for repetitive movements like walking. In this specific case, the input variable is the current amplitude and the goal is to minimize the trajectory tracking error from the previous step. The range of motion for FES amplitude is determined by user-specific thresholds L1 and L2 established during the calibration phase.

2.2. Protocol

Testing protocol on healthy subjects At first, the developed prototype was tested on healthy individuals. In particular, three conditions with a different degree of knee motor assistance (α) and with or without stimulation were compared:

1. EXO100: this served as the baseline condition, where maximum motor support was provided (α = 100%) and stimulation was turned off. In this scenario, the entire movement was carried out solely by the exoskeleton's motors.
2. FES0: in this condition, the feedforward contribution of the motor was reduced (α = 0%) and stimulation was introduced with the aim of providing the additional torque necessary to execute the correct trajectory.
3. EXO0: here α was set to 0% and no stimulation was added. Consequently, this condition was expected to result in suboptimal performances, as the provided input was insufficient to accomplish the complete movement. It was introduced as a proof-of-concept condition to validate the advantages of incorporating FES when the motor contribution was reduced.

The first tests involved single-joint movements, in particular knee flexion-extension from a seated position. FES integration occurred only during extension (anti-gravity movement) and thus only involved the Quadriceps. Six healthy participants performed 50 repetitions in the three conditions. Subsequently, 15 subjects performed walking tests in the same modalities, trying to remain as passive as possible to minimize interferences with the FES-motor control. For EXO100 and EXO0 20 strides were executed, while for FES0 50 strides were performed to evaluate muscle fatigue appearance over time. The Ethical Committee of Politecnico di Milano (Nr 13/2021) approved this study and all subjects provided their written informed consent before starting the acquisition. An ID number was assigned to each one of them, to maintain anonymity during the following phases of data analysis.

Testing protocol on patients Before the start of the training, some anamnestic/anthropometric data and previous experience with FES and/or lower limb exoskeleton use were collected and a baseline assessment was conducted. Specifically, this evaluation included the assessment of the Autonomic Nervous System (ANS), the osteoporosis degree, the bladder and bowel functionality, the spasticity and pain level, the global well-being and the muscle response to electrical stimulation. Also the type and level of injury, time since the injury and the ASIA scale were recorded.
If the subjects met all assessment criteria, they started the familiarization phase with Twin in EXO100 mode, for a maximum of 10 sessions. Simultaneously, they underwent FES familiarization sessions of 30 minutes each, where all leg muscles were stimulated. These were conducted outside the exoskeleton to let the patient familiarize with the stimulation in a simpler context. Afterwards, the testing phase of the TwinFES cooperative control was carried out, with a maximum of 4 sessions in the FES0 mode. For safety reasons, the EXO0 condition was not tested since it might threaten patients' safety, as the provided input was not sufficient to complete the movement. Acceptability, usability, user experience and interaction with the system were evaluated for EXO100 and FES0. Patients were also administered some questionnaires: Technological Acceptance Measure 3 (TAM-3), System Usability Scale (SUS) and User Experience Questionnaire (UEQ). The Ethical Committee (Nr 03_14/10/2022 session of the 14/10/2022) approved this study and all patients provided their written informed consent before starting the acquisition.

2.3. Data analysis

Data elaboration was performed in the MatLab 2022b environment (MathWorks). For the single joint, each movement was divided into extension and flexion phases, while for the walking tests, both for healthy subjects and patients, each step was divided into swing and stance phases. For each of these phases, except for flexion in the single joint movement, which was not considered in the analysis, the following data were considered:

- Real and target position (θ_{real} and θ_{target})
- Motor current (I_{MOT})
- Total theoretical torque given to the motors (τ_{TOT})
- Current amplitude of Channel 0 (Quadriceps) and Channel 1 (Hamstrings).

From these, the following metrics were calculated:

- Root Mean Square Error of the position (RMSE)
- Motor current integral (I_{MOT} integral)
- Total torque integral (τ_{TOT} integral)
- Current integral of Channels 0 (Quadriceps) and 1 (Hamstrings), normalized to the maximum current value recorded during calibration (L2).

Subsequently, the median, 25th, and 75th percentiles of all data and metrics were calculated for the performed flexion-extension movements or steps, to obtain the median movement in the 3 conditions (EXO0, EXO100, and FES0). For the FES0 condition, we also decided to divide the data of the healthy subjects into groups of 5 successive repetitions and calculate the same metrics to visualize the presence of any fatigue induced by the stimulation. Considering that the two patients performed many tests inside a session, the median value of all tests in a single session was calculated. Results were compared between the last session in EXO100 modality and the last one in FES0 modality.
Considering statistics, for healthy subjects, both in single joint and walking trials, a three-fold analysis was conducted to compare the outcomes of interest in the 3 modes (EXO100, EXO0, and FES0); for patients, instead, a double-fold statistical analysis was carried out between the two modes (EXO100 and FES0) on different training sessions. The statistical analysis was performed using the IBM SPSS software. Specifically, the generalized linear model was used and the Fisher's exact test, because of the small sample size. Pairwise comparisons between conditions were executed and differences were considered significant in case of p-value < 0.05.

3. Results and discussion

3.1. Healthy subjects

Single joint Figure 2 reports the single-joint tests metrics for all 6 recruited subjects (2 males and 4 females, with an average age of 24.3 ± 2.4 years). The RMSE is smaller and similar for EXO100 and FES0, indicating a small difference between the real and target trajectories in these cases; instead, it takes on much larger values for EXO0, significantly different from the previous ones. This larger error is caused by the fact that the reduced motor input ($\alpha = 0\%$) is not able to accomplish the complete trajectory. As the same is not observed in the FES0 case, it is possible to conclude that the stimulation addition is able to compensate for reduced motor contribution. Considering the integral of the motor current and the one of the total torque, as expected, they are always significantly greater for the EXO100 condition than for the other two. In particular, when $\alpha = 100\%$, the feedforward torque is computed as the sum of inertia and gravity contributions from both the exoskeleton and the subject's shank, and not only for the exoskeleton, as when $\alpha = 0\%$. The higher values showed by the EXO0 condition, with respect to the FES0 ones, are due to a greater feedback component (considering that the feedforward one is identical), given by the higher trajectory error of the only-exo condition.

Walking Figure 3 contains the boxplots of the walking test metrics for all 15 subjects (3 males and 12 females, with an average age of 25.1 ± 4.4 years). Taking into account the RMSE, it assumes very low values for the hip and knee in the stance phase and for the hip in the swing one, which is expected considering that these limbs implement a rigid position control, not allowing deviations from the target trajectory. Differently, it is higher for the swing knee; in detail, a lower RMSE is registered for the EXO100 and FES0 modes (values of about 6°), while it is higher for the EXO0 (values of about 10°). The same considerations can be done for the integral of the motor current, which shows similar values for the three joints with rigid position control and significant differences among the three conditions for the knee during swing. As seen for the single-joint tests, the total torque integral shows significantly greater values for the EXO100 and, again, the integral for FES0 is slightly lower than that of EXO0.

3.2. Patients

Two patients were involved in the usability testing and completed the protocol: one complete and one incomplete SCI.
Figure 4 shows the metrics of patient P1, a complete SCI subject, with lesion level T7 and ASIA impairment scale of grade A. He underwent 8 sessions using Twin: the first 5 in EXO100 mode and the subsequent 3 in FES0 mode. Considering the RMSE of the knee in swing, it has the same order of magnitude as the one recorded on healthy subjects. Comparing the FES0 and EXO0 conditions, we observe a slightly higher RMSE for the former case. The total torque integral is much lower for the FES0 condition, as before. Therefore, the stimulation addition allows to depower the motor, while maintaining the same performance in terms of walking. The

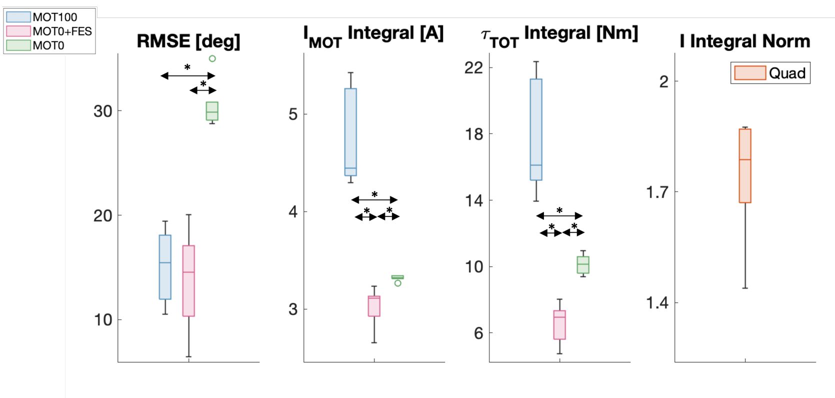

Figure 2: Motor and current metrics for the single joint tests of all subjects (differences between conditions were considered significant in case of p-value < 0.05 and marked with an asterisk).

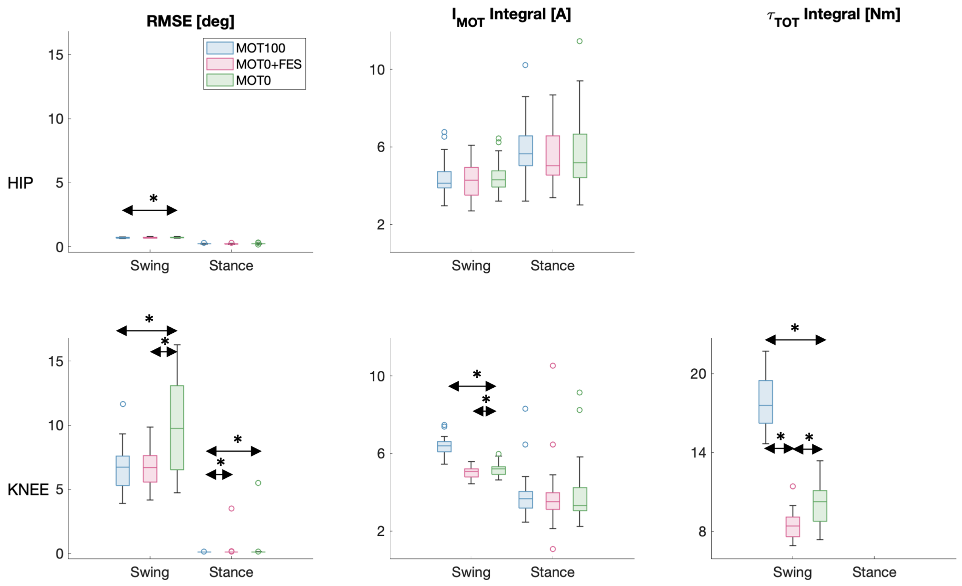

Figure 3: Motor metrics for the walking tests of all subjects (differences between conditions were considered significant in case of p-value < 0.05 and marked with an asterisk).

value of the motor current integral is maintained at slightly lower values for the FES0 condition. Patient 2, an incomplete SCI subject, with lesion level L3 and ASIA impairment scale of grade D, underwent 6 sessions using Twin (3 in EXO100 and 3 in FES0 mode) and achieved similar results to the first patient.
Finally, the analysis of the questionnaires administered to the patients is done. SUS analysis shows a higher value for the TwinFES device than for the sole Twin exoskeleton for both patients, but with generally low values of grade D (poor). In particular, Patient 1 scores went from 52.5 to 60, while patient 2 scores went from 50 to 57.5. Regarding the UEQ analysis, for patient 1 the scale values increase slightly when stimulation is added, but with bad and below-average results for all parameters except *novelty*. On the other hand, for patient 2, the addition of stimulation achieves the grade *excellent* for *attractiveness* and *stimulation*, never reached for the case without stimulation.

4. Conclusions

In this study, a new cooperative control system is tested, which integrates the motor and the FES components: the idea is to get the walking movement by reducing the motor-generated power and exploiting the one produced by FES-stimulated muscles. The tests conducted on healthy subjects demonstrate that the integration of stimulation into a depowered exoskeleton is feasible and yields comparable results, in terms of movement performance, to using solely the exoskeleton. The same is not observed when depowering the exoskeleton but without the FES integration. Additionally, the presence of FES carries significant physiological advantages for spinal-injured patients as it engages their paralyzed muscles in the activity, inducing their contraction that would be otherwise unfeasible. Furthermore, enabling the reduction of the exoskeleton motor power, while maintaining the proper movement execution, it reduces the overall system energy consumption. This conclusion is promising in view of developing novel systems with lower encumbrance and weight, easing their usability. Regarding the early onset of muscle fatigue, which is one of the main problems when using FES as a rehabilitation technique, the support given by the exoskeleton allows to reduce it. Indeed, from our tests, we do not notice significant performance worsening over time, meaning that patients' muscles are not fatigued. Beyond the above-listed promising results, some limitations have been identified. Among them: the limited number of SCI patients tested, the lack of information about the effect on stroke

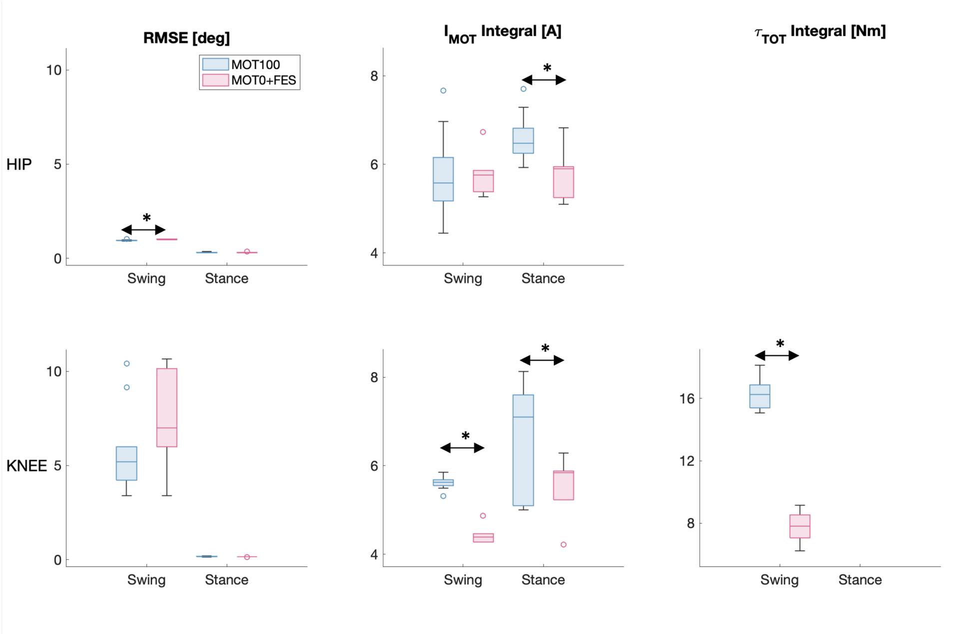

Figure 4: Motor metrics for P1 in the two conditions.

patients, the repeatability of the FES electrode placement and the complexity of the single-step triggering. Moreover, the questionnaires completed by the two SCI patients revealed poor usability of the system, which is still too complex and unsuitable for rehabilitation sessions. Despite these limitations, the proposed TwinFES prototype is innovative and high-performing, as demonstrated by the results. It therefore represents a significant starting point in the attempt to realize new hybrid robotic neurorehabilitation systems.

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