Sanna *et al. Journal of NeuroEngineering and Rehabilitation* (2025) 22:55
https://doi.org/10.1186/s12984-025-01585-0

Journal of NeuroEngineering
and Rehabilitation

RESEARCH **Open Access**

Evaluating the health and fitness benefits of a 6-month FES-cycling program on a recumbent trike for individuals with motor complete SCI: a pilot study

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Abstract

Background Spinal cord injury (SCI) severely affects physical function, leading to muscle atrophy and reduced bone density. Sport-therapy, incorporating recreational and competitive activities, has shown promise in enhancing recovery for individuals with SCI. Functional Electrical Stimulation (FES)-cycling combines exercise benefits with stimulation advantages, and recent integration with mobile recumbent trikes adds further potential. This study aimed to evaluate the effects of a 6-month FES-cycling sport therapy using a recumbent trike on individuals with motor complete SCI.

Methods Five participants engaged in bi-weekly FES-cycling sessions using an instrumented recumbent trike. A comprehensive assessment was conducted before training, at 3 and 6 months of training, and at 1-month follow-up. Outcome measures included maximal muscle Cross-Sectional Area (maxCSA) from Magnetic Resonance Images, bone mineral density, clinical scales, and questionnaires on spasticity, pain, bowel dysfunction, psychological well-being, and sport motivation. Additionally, maximal power output and cycling endurance were assessed.

Results The FES-cycling program led to a significant increase in muscle mass of 34% after 6 months of training, correlated to an improved cycling performance (maxCSA versus peak power). A slight decrease of muscle mass was observed as expected at follow-up. Participants reported high well-being and strong motivation throughout the training program. Bone health, spasticity, bowel dysfunction, and pain levels did not significantly change overall.

Conclusions FES-cycling on a recumbent trike shows potential as a therapeutic and recreational activity for individuals with SCI. It significantly improved muscle mass and physical performance while positively impacting psychological well-being and motivation. Further research with larger cohorts is necessary to confirm these benefits and optimize protocols, establishing FES-cycling as a valuable sport-therapy model for SCI.

Trial registration The study protocol was retrospectively registered on clinicaltrials.gov (NCT06321172).

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Keywords Cycling, Pedalling, Functional electrical stimulation, Neuromuscular electrical stimulation, Recumbent trike, FES-cycling, Spinal cord injury, Sport-therapy, Rehabilitation, Cybathlon

Background

According to the World Health Organization (WHO), more than 15 million people worldwide suffer from Spinal Cord Injury (SCI), with an annual incidence of 40 to 80 new cases per million [1]. The most common causes are trauma from falls or vehicle accidents, leading to severe physical and social impacts [2]. Depending on the injury's severity and location, SCI can result in total or partial loss of motor and sensory functions, paralysis, and muscle atrophy. Moreover, individuals with SCI often face multiple comorbidities such as neuropathic pain, spasticity, neurogenic bladder and bowel, bone density loss, cardiovascular issues, and sexual dysfunction [3].

Functional Electrical Stimulation (FES) is a widely used rehabilitation technique for SCI patients, where electrical pulses stimulate paralyzed muscles to enable activities like grasping, standing, or cycling. Specifically, FES-cycling is a well-established therapeutic technique due to its feasibility and lower risk of falls [4, 5]. Over the last 40 years, several research groups have focused on studying the effects of FES-cycling on health and fitness-related outcomes. In a systematic review, van der Scheer et al. [6] reported the use of FES-cycling on stationary motorized cycle ergometers in 97 studies from 1984 to 2021, examining outcomes such as aerobic fitness, power output, muscle strength, muscle quality, fat mass, cardiovascular and metabolic factors, bone health, other secondary health conditions (e.g., edema, spasticity), subjective well-being, and functional and neurological outcomes. The authors concluded that FES-cycling in SCI patients can provide substantial benefits, including enhanced neurological and functional performance, increased muscle size and force-generation potential, reduced spasticity, and improved quality of life. Positive effects on the cardiorespiratory system, blood circulation, and bone health have also been demonstrated [7–12].

The impact of SCI extends beyond physical health, affecting the psychological and social well-being [13]. Adequate rehabilitation procedures are essential, but engaging subjects with SCI in physical exercise and sport is also crucial. Sport can greatly improve the quality of life of people with SCI [14]. Physical exercise is fundamental in mitigating the effects of a sedentary lifestyle and enhancing cardiometabolic health in this population [15].

Accordingly, FES-cycling has recently evolved from a rehabilitation exercise to a form of sport, enhancing its recreational aspect. Combining rehabilitative exercise with sporting activity makes it enjoyable, social and engaging, fostering the spirit and physical efficiency necessary for complete social reintegration. Competitions like Cybathlon have brought interest in FES-cycling, contributing to a shift in perspective [16, 17]. Cybathlon, first held in 2016, is an international competition where individuals with physical disabilities compete using advanced assistive technologies. The event aims to promote the development and use of these technologies, demonstrating how they can improve daily life, fostering social inclusion, and integrating sport with therapy.

Before the Cybathlon competition, FES-cycling was primarily viewed as a rehabilitation exercise performed using stationary and often motorized cycle ergometers in clinical settings, with few using mobile FES-cycling systems. Among the 97 studies cited by van der Scheer [6], less than 10 employed devices suitable for outdoor training [18–22] and their focus remained primarily on clinical outcomes (i.e. aerobic fitness, power output, muscle strength and quality, fat mass and bone health). The growth of the Sport-Therapy approach has significantly impacted the rehabilitation and perceived well-being of people with SCI. Consequently, several research groups have developed new FES-cycling systems adapted for sports activities [22–34]. While some studies focused on the functionality, effectiveness, and usability of these devices by developing specific training programs [25–27, 29, 31–34], others evaluated health and fitness-related outcomes [24, 35, 36] such as aerobic fitness, bone and muscle health, edema, power output, and subjective well-being. Despite adopting a new approach to investigate FES-cycling as a Sport-Therapy model, all these studies were limited to single-subject investigations, except for McDaniel et al. [24] who involved five participants with motor-complete SCI preparing for the Cybathlon competition, focusing on technological advancements, bike design, and the development of a specialized training program. Therefore, none of these works has been comprehensively evaluated physiological and functional health outcomes in a longitudinal, multi-subject study. To address this gap, we involved five participants with complete SCI in a FES-cycling training program on a recumbent trike for six months [23]. Our study aims to investigate the effects of consistent training on performance improvement, bone and muscle health, bowel function, and autonomic nervous system. Additionally, it assesses the overall well-being and motivation to engage in such a training.

Methods

Participants

In 2023, five subjects were enrolled from the Valduce Hospital – Villa Beretta Rehabilitation Center (Costa Masnaga, Italy) and the INAIL network (Istituto Nazionale Assicurazioni Infortuni sul Lavoro, National Institute for Industrial Accidents Insurance, Italy). All participants provided written informed consent. The research protocol was approved by the ethics committee of IRCCS Medea (Prot.N. 14/22 -CE, approved on February 17, 2022). The study protocol was retrospectively registered on clinicaltrials.gov (NCT06321172).

The recruitment followed health and safety criteria to ensure proper and safe use of the FES-cycling device.

Inclusion criteria

- Age between 18 and 65 years.
- Paraplegia resulting from a SCI (both traumatic and non-traumatic) that occurred less than five years prior to the study to facilitate muscle conditioning.
- Complete loss of motor function in the lower limbs (level ≤ T3, ASIA A or B) with residual trunk control.
- Sufficient muscle contraction using FES with surface electrodes to effectively use the device.

Exclusion criteria

- Severe osteoporosis with an elevated fracture risk as assessed by an expert clinician.
- Severe spasticity and pain preventing device use.
- Skin lesions in areas interfacing with the trike.
- Dysfunction of the autonomic nervous system.
- Psychopathological comorbidities.

Equipment

The device used in this study is a prototype developed by Politecnico di Milano, based on a commercial recumbent trike (ICE VTX, 2017), and specifically adapted for FES-cycling for individuals with reduced mobility [23] (see Fig. 1A).

The system uses two battery-operated four-channel stimulators (RehaMove3, Hasomed GmbH) to activate four muscles in each leg through surface self-adhesive electrodes (Pals® from Axelgaard Manufacturing Co. Ltd.). The stimulators deliver balanced biphasic current pulses to the gluteus, quadriceps, hamstrings, and gastrocnemius muscles in both legs. Pulse duration is set at 400–500 µs, frequency at 40 Hz, and current amplitude up to 130 mA, individually calibrated for each participant. The stimulation parameters are selected based on their widespread use in literature for FES applications

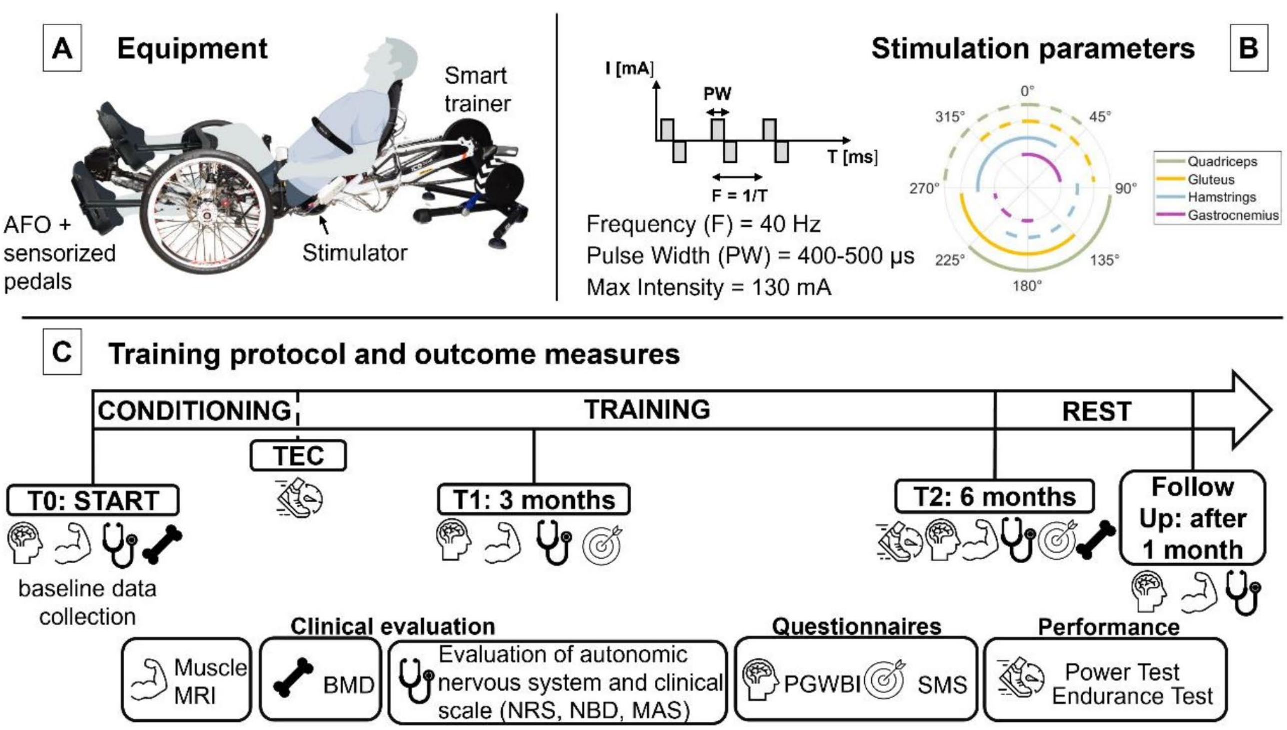

Fig. 1 Description of the equipment and stimulation strategy used during the study. (**A**) Schematic representation of the set-up (composed on BioRender.com) while (**B**) definition of the stimulation parameters used during the training protocol. In (**C**) the training protocol followed in the study is presented together with the outcome measures. Definition of acronyms: Ankle-Foot Orthosis (AFO), time at the end of the conditioning phase (TEC), Magnetic Resonance Imaging (MRI), Bone Mineral Density (BMD), Numerical Rating Scale (NRS) Neurogenic Bowel Dysfunction (NBD), Modified Ashworth Scale (MAS), Psychological General Well-Being Index (PGWBI) and Sport Motivation Scale (SMS)

[6]. The stimulation amplitude is automatically adjusted using a Proportional-Integral (PI) controller to maintain a consistent cadence [30]. A magnetic absolute rotative encoder (AS5047P, ams OSRAM) measures the crank angle, allowing for the sequential activation of muscles during specific angular ranges of the cycling motion (see Fig. 1B).

Users interact with the system through four buttons and a 7-inch touchscreen display, which also provides information on stimulation settings and training sessions.

The system includes custom-made ankle foot orthoses (AFOs) to stabilize leg movement. These are attached to two commercial sensorized pedals (X-Power, SRM GmbH) integrated into the system, which measure power output during exercise.

This setup is suitable for both outdoor and indoor use. For indoor training sessions, the back wheel is replaced with a KICKR smart trainer.

Protocol and outcome measures

At the beginning of the study, baseline data were collected, including demographic information (age, gender, height, weight), injury-related details (level of injury, time since injury, American Spinal Injury Association scale - ASIA), and prior experience with FES and/or cycling/trike use post-injury. The outcome measures were collected at different time-points (see Fig. 1C):

- T0: start of the study.
- TEC: end of the conditioning phase.
- T1: 3 months from the beginning of the study.
- T2: 6 months from the beginning, at the end of the training.
- Follow up: 1 month after the end of the training.

The primary outcome was the **Cross-Sectional Area (CSA) of thigh muscles**, assessed using Magnetic Resonance Imaging (MRI) at T0, T1, T2, and follow-up. The secondary outcome measures are detailed below:

- **Dual-energy X-ray absorptiometry (DXA)** for measuring bone mineral density (BMD) and assessing bone health. **Timepoints**: T0 and T2.
- **Blood pressure (BP)**, **heart rate (HR) and hemodynamic parameters** for evaluating the autonomic nervous system. **Timepoints**: T0, T1, T2 and follow up.
- **Modified Ashworth Scale (MAS)** [37] to assess spasticity of the lower limbs. **Timepoints**: T0, T1, T2 and follow up.
- **Neurogenic Bowel Dysfunction (NBD) score** [38] to evaluate intestinal function. **Timepoints**: T0, T1, T2 and follow up.
- **Numerical Rating Scale (NRS)** [39] to quantify subjective evaluation of perceived pain levels. **Timepoints**: T0, T1, T2 and follow up.
- **Psychological General Well-Being Index (PGWBI)** [40] questionnaire to evaluate the impact of continuous FES-cycling on participants' well-being. **Timepoints**: T0, T1, T2 and follow up.
- **Sport Motivation Scale (SMS)** [41] to assess drivers' motivation for participating in sports. **Timepoints**: T1 and T2.
- **Power produced while cycling at maximum current amplitude** to evaluate maximal power output. **Timepoints**: TEC and at T2.
- **Maximum distance traveled in six minutes** to assess endurance. **Timepoints**: TEC and at T2.

Pilots were asked to achieve a minimum compliance rate with the protocol, which required them to attend at least 75% of the training sessions in the six months.

Muscle evaluation using MRI

Four out of five volunteers were scanned using a Philips Achieva dStream 3T MRI scanner with a torso coil, utilizing a T1-weighted (T1-w) turbo spin echo sequence (pixel size: 1×1 mm2; slice thickness 6 mm, no gap; number of slices: 50; Matrix: 256×256; Echo Time: 15ms; Repetition Time: 600ms; flip angle: 90°; SENSE: 2; Number of averages: 2). Due to a spinal cord implant not compatible with MRI scans at 3T, one volunteer was scanned using a General Electric 1.5T MRI scanner with an 8-channel body FullFOV coil. A T1-w fast spin echo sequence was performed (pixel size: 1×1 mm2; slice thickness 6 mm; number of slices: 50; Matrix: 256×256; gap: 9 mm; Echo Time: 13.3 ms; Repetition Time: 600ms; flip angle: 90°; Number of averages: 1). All sequences were acquired on one thigh, with the field of view extending to the middle of the femoral head.

To derive CSA, regions of interest (ROIs) were delineated for specific thigh muscles, including the vastus lateralis, vastus medialis, vastus intermedius, rectus femoris, sartorius, gracilis, adductor magnus, semimembranosus, semitendinosus, biceps femoris caput longum, biceps femoris caput breve, and adductor longus. The segmentation was guided by a reference range, from the beginning of the semimembranosus to the last available slice of the rectus femoris. Consistency was maintained in the ROIs across all longitudinal scans for each participant [42]. ROIs were semi-automatically traced on T1-w images using the Dafne tool (Deep Anatomical Federated Network), which is accessible at https://dafne.network/ [43]. This process entailed an initial automated outline, which was then meticulously refined by users via an interactive interface. The maximal CSA (maxCSA) was determined by identifying the slice showing the largest muscle cross-sectional area.

Bone health evaluation using DXA

BMD measurements were performed using the HOLOGIC QDR 4500 system (Hologic, Inc, USA) to assess osteoporosis and derive T-score parameters. The T-score classifies bone condition, with values above − 1 indicating normal bone density, between − 1 and − 2.5 indicating osteopenia, and below − 2.5 indicating osteoporosis. Standard protocols were used for the column and femoral neck, resulting in 2 T-score values. The Toronto Rehab Protocol [44] was applied to the distal femur and proximal tibia, yielding 8 T-score values per leg, for a total of 18 T-scores per subject.

Evaluations of the autonomic nervous system

The autonomic nervous system was evaluated using the Task Force® Monitor (CNSystems Medizintechnik GmbH, Austria), which provides continuous recording of systolic and diastolic blood pressure (sBP and dBP), HR and the total peripheral resistance index (TPRI).

The assessment involved a series of tests commonly employed in clinical practice to simulate the stress conditions typically experienced by the cardiovascular system during daily activities. The tests included:

- Supine position evaluation for 3 min, which is considered as the rest condition.
- Tilt-up test: passive verticalization by tilting the bed from a flat position to 60°, held for 5 min.
- Stepping in place with an automatic step induction system (Erigo, Hocoma) at a cadence of 60 steps per minute for 5 min.
- Passive cycling for 5 min using the LAMBDA system (Lambda Health System, Switzerland) to assess the impact of cycling on the autonomic nervous system. The LAMBDA System is a parallel robot that may be used for mobilization of the lower extremities, simulating different motor tasks, including cycling. This device was chosen because it can resemble the task performed by participants during the training sessions.

The mean values of HR, dBP, sBP and TPRI were computed for each pilot during each specific test (Rest, Tilt-up, Stepping and Lambda).

Clinical scales

Clinical evaluations of the level of spasticity of the lower limbs, intestinal function and a subjective assessment of the level of pain perceived by the subject were carried out. In particular:

- The MAS was used to evaluate the severity of spasticity, measuring the velocity-dependent resistance of a muscle to passive stretch. The scale ranges from 0 to 4, where 0 indicates no increase in muscle tone and 4 denotes a rigid joint limb.
- The NBD score was used to evaluate symptoms related to bowel management and function, including constipation, incontinence, and the impact on daily life. The NBD tool consists of 10 questions, each assigned specific point values. The maximum possible score is 47, where a score above 14 indicates severe bowel dysfunction.
- The NRS was used to measure the intensity of general pain experienced by the pilots in their daily lives, with 0 indicating no pain and 10 representing high pain.

Well-being evaluation

PGWBI is a self-report questionnaire designed to assess overall psychological well-being. It is composed by 22 items that investigate 6 different dimensions: Anxiety, Vitality, Depression, Self-control, Positivity and Vitality. Each question is scored on a scale from 0 to 5, with a total score ranging from 0 (indicating maximum distress) to 110 (indicating maximum well-being). The PGWBI questionnaire was administered to assess the impact of continuous FES-cycling activity on participants' well-being.

Evaluation of the sport motivation

SMS is a tool used to evaluate an individual's motivation for participating in a sport activity. It measures different types of motivation, including intrinsic (enjoyment and personal satisfaction) and extrinsic (rewards and recognition) factors, as well as amotivation (lack of motivation). The SMS consists of 28 questions divided into seven subscales, each reflecting a different type of motivation: Intrinsic Motivation to Know, Intrinsic Motivation to Accomplish, Intrinsic Motivation to Experience Stimulation, Identified Regulation, Introjected Regulation, External Regulation and Amotivation. Each question is rated on a 7-point Likert scale, where 1 corresponds to strongly disagree, while 7 strongly agree. Participants were asked to focus on FES-cycling on a recumbent trike when answering the questions to assess their perception of the training as sport-therapy.

Performance evaluation

Two tests were conducted on the recumbent trike to assess the impact of the training on performance: a maximal power test and a cycling endurance test. In the maximal power test, the sensorized pedals measured the peak of power output produced by the pilots while providing them with the maximal current amplitude for 2 min. In the cycling endurance test, the maximum distance traveled in 6 min was computed. During the endurance test, the stimulation intensity was automatically adjusted by the PI controller.

Training modalities

Over six months, each participant engaged in biweekly FES-cycling training sessions, lasting up to 30 min of stimulation. The training period was mainly conducted indoors at the Politecnico di Milano, under the supervision of clinical staff from the IRCCS Medea, using the KICKR smart trainer set to 10% resistance. The experimental protocol began with a conditioning phase where stimulation and trike parameters were tailored to each participant's individual needs. This phase aimed to train the leg muscles to enable independent pedaling for at least six minutes, assisted solely by FES. If participants were unable to complete a training session during the conditioning phase, operators provided manual assistance. The duration of the conditioning phase varied depending on individual progress, ensuring participants were adequately prepared for the required effort during training. Once the conditioning phase was successfully completed, the main training period commenced. Each training session included a 3-minute warm-up, four sets of 6-minute pedaling intervals, and a 3-minute cooldown, with a pedaling cadence maintained between 20 and 50 RPM, with no manual assistance from the operator, relying solely on FES-supported pedaling.

To incorporate a recreational aspect, participants also engaged in occasional outdoor cycling sessions. These sessions aimed to foster the enjoyment and motivational benefits of cycling in a non-clinical setting. Furthermore, some participants had the opportunity to participate in parallel events such as the Lyon Cyber Days and the Cybathlon Challenges 2024, highlighting the integration of sportive and community-based activities alongside structured training program.

Statistical analysis

The sample size of five subjects was chosen due to the pilot nature of the study and the 6-month protocol, deemed sufficient to provide preliminary evidence of the muscle-level efficacy of FES-bike training. The data were analyzed using IBM SPSS Statistics v21 and MATLAB (R2023a), with a significance level set at 5%. Descriptive statistics were used for demographic data analysis.

For all outcome measures but DXA assessments, the Wilcoxon test was applied for comparisons between two timepoints, while the Friedman test was used for comparisons across multiple timepoints. If significant differences were detected, post-hoc analysis using Bonferroni correction for significance. For DXA assessments, an intrasubject Wilcoxon test compared T0 and T2 assessments using the 18 T-scores per subject.

Changes in the primary outcome (muscle maxCSA) after 6 months were correlated with performance outcomes (peak power and distance travelled) using Spearman's Rho.

All outcome measures were reported as median values with interquartile ranges.

Results

Participants

Table 1 shows demographic data of participants. We enrolled 5 male pilots with a level of injury between T3 and T12. The median age was 29 years and the median time after injury was 2 years. All pilots but one had previous experience with FES, while only 2 had no experience with cycling/trike use after the injury. The pilots' compliance with the protocol showed a median value equal to 92% with all participants exceeding the imposed threshold of 75%. The number of conditioning sessions performed by the pilots was different according to their performances, from 6 to 17 sessions with a median value equal to 7. All pilots completed the assessments at T0, TEC, T1 and T2.

S05 did not undergo the follow up assessment since he had to continue his training for Cybathlon Challenge

Table 1 Demographic data of the enrolled pilots definition of acronyms: identification code for each subject (ID), functional electrical stimulation (FES), American spinal injury association (ASIA)

ID	Age [years]	Height [cm]	Weight [kg]	Time after injury [years]	Lesion level (ASIA)	Previous experience with FES	Previous experience with cycling after the injury	Total sessions (conditioning sessions)
S01	64	175	72	2.7	T12 (A)	Yes	Yes	52 (17)
S02	23	178	80	2.0	T10 (A)	No	No	48 (7)
S03	41	175	75	3.8	T5 (A)	Yes	Yes	55 (10)
S04	27	191	80	1.8	T12 (B)	Yes	Yes	40 (6)
S05	29	173	62	1.1	T3 (A)	Yes	No	46 (7)

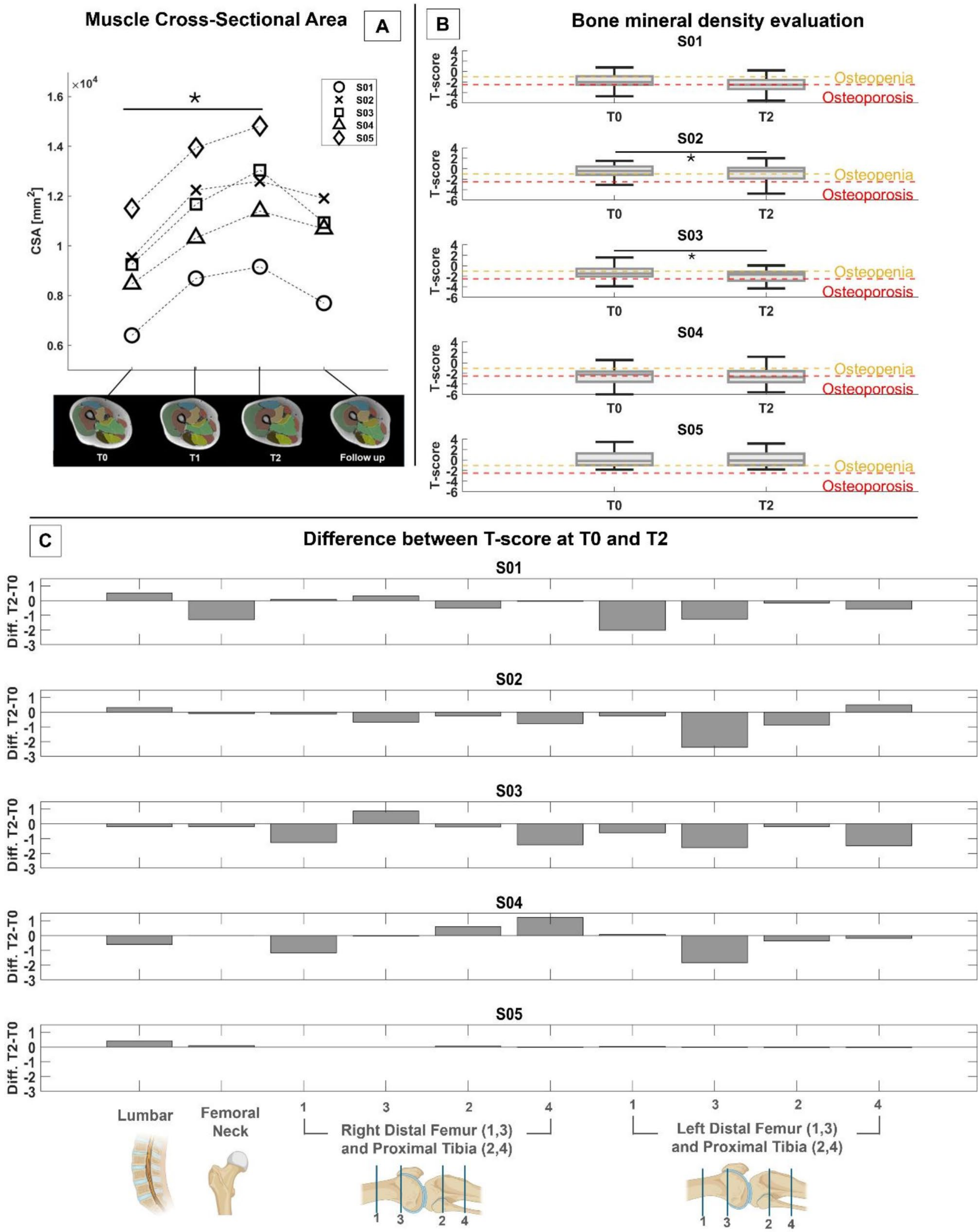

Fig. 2 (See legend on next page.)

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Fig. 2 Results of Magnetic Resonance Imaging (MRI) and Dual-energy X-ray absorptiometry (DXA) are presented (**A**) Top: the evolution of the maximal Cross-Sectional Area (maxCSA) for each pilot is shown. In the bottom part of the figure a representative image shows the evolution of maxCSA for one pilot (S03). (**B**) The boxplots related to T-scores for each pilot are reported together with the threshold value of osteoporosis. In (**C**) the difference between the T-score at T0 and T2 are plotted for the lumbar site, femoral neck, and sites of distal femur and proximal tibia for both legs (to improve the readability of the figure, only 4 sites of distal femur and proximal tibia were plotted for each leg, the images of the different bone site are from BioRender.com). The number reported in brackets refers to specific sites according to the Toronto Rehab Protocol. Positive differences correspond to improvements of the bone density while negative ones to a decrease

2024. S04 took part in Lyon Cyber Days. Both performed 2 sessions outdoors.

Outcome measures

Muscle evaluation using MRI

Considering the primary outcome of the study, the maxCSA demonstrated consistent patterns throughout the study, as highlighted by the Friedman test's p-value which is equal to 0.011. In particular, the data at T0 were significantly different from data at T2 (p-value after Bonferroni correction equal to 0.006). Initially, at T0, the maxCSA was established at a median value (inter-quartile range) across subjects of 9252 (1057) mm². This metric rose significantly by roughly 26% to 11,667 (1924) mm² at T1, and then increased further by approximately 34% to 12,594 (1647) mm² at T2 with respect to baseline. A slight decrease was noted at follow up, yet the maxCSA remained elevated by about 22% in comparison to the baseline, registering at 10,811 (1239) mm². For graphical details of these results, please see Fig. 2A.

Bone health evaluation using DXA

The value derived from bone health evaluation using DXA are reported in terms of T-score in Fig. 2B. There is a significant reduction of T score median values between T0 and T2 for S02 and S03 (p-values from the Wilcoxon test are 0.022 and 0.011, respectively), indicating a progression of bone demineralization, although their scores remained above the critical threshold. On the contrary, the other subjects did not present a significant difference between T0 and T2 (p-value for S01, S04 and S05 are respectively 0.058, 0.381 and 0.729). Figure 2C shows the differences between T2 and T0 for the lumbar site, the femoral neck, and sites of distal femur and proximal tibia for both legs. To improve the readability of the figure, only 4 sites of distal femur and proximal tibia were plotted for each leg, which were selected as the sites most affected by fractures. There was no homogeneous variation between the different districts.

Evaluations of the autonomic nervous system

No significant difference was obtained between different timepoints for any of the indices considered (all p-values > 0.212, Friedman Test). Figure 3A shows rest condition (left) and the difference between Lambda test and rest condition (right) for HR, sBP, dBP, and TPRI. Differences between the rest condition and the Tilt-up test and the stepping test are reported in Figure S1 (see supplementary material). The adaptation trends observed between rest and the other conditions of the four indices were different among pilots but limited to safe ranges (e.g. HR increases < 40 bpm and sBP increases < 20 mmHg during Lambda test).

Clinical scales

No severe spasticity was assessed at T0 for all participants according to the MAS. Furthermore, no changes in MAS were observed (Table S2). No significant difference was identified in NBD scores among the four timepoints (p-value equal to 0.543, Friedman test). Interestingly, the score of S02, who was the only one with an NBD value at T0 higher than 14, decreased after 3 months and this beneficial effect persisted at the follow up, suggesting a lasting positive impact of the training (Fig. 3B). Considering the NRS scale, no significant difference was found in the pain level between the four timepoints (p-value of the Friedman test equal to 0.942, Fig. 3C).

Well-being and sport motivation evaluation

In general, all the pilots had a good well-being from the start of the study as the PGWBI dimensions highlighted at T0 (Fig. 4A) with low level of anxiety and depression and high levels in the other dimensions, like self-control. The well-being was maintained during the whole protocol. There is an interesting trend concerning depression that slightly increased after the interruption of the study, but no significant differences were found in any dimension (all p-values > 0.084, Friedman Test).

The SMS highlighted the strong motivation of all the pilots during the study with low values of amotivation in the specific item (Fig. 4B). No significant differences were found between T1 and T2 (all p-values > 0.102).

Performance evaluation

Figure 5 shows the results of tests performed on the trike to assess pilots' performance. Figure 5A reports the peak of power output expressed during the test. All the pilots improved their power output significantly at T2 (p-value = 0.043). Four pilots increased their endurance after the training, while S04 showed a decreasing trend. The median value of kilometres performed in 6 min had an increasing trend although no significant difference was found between TEC and T2 (p-value = 0.138).

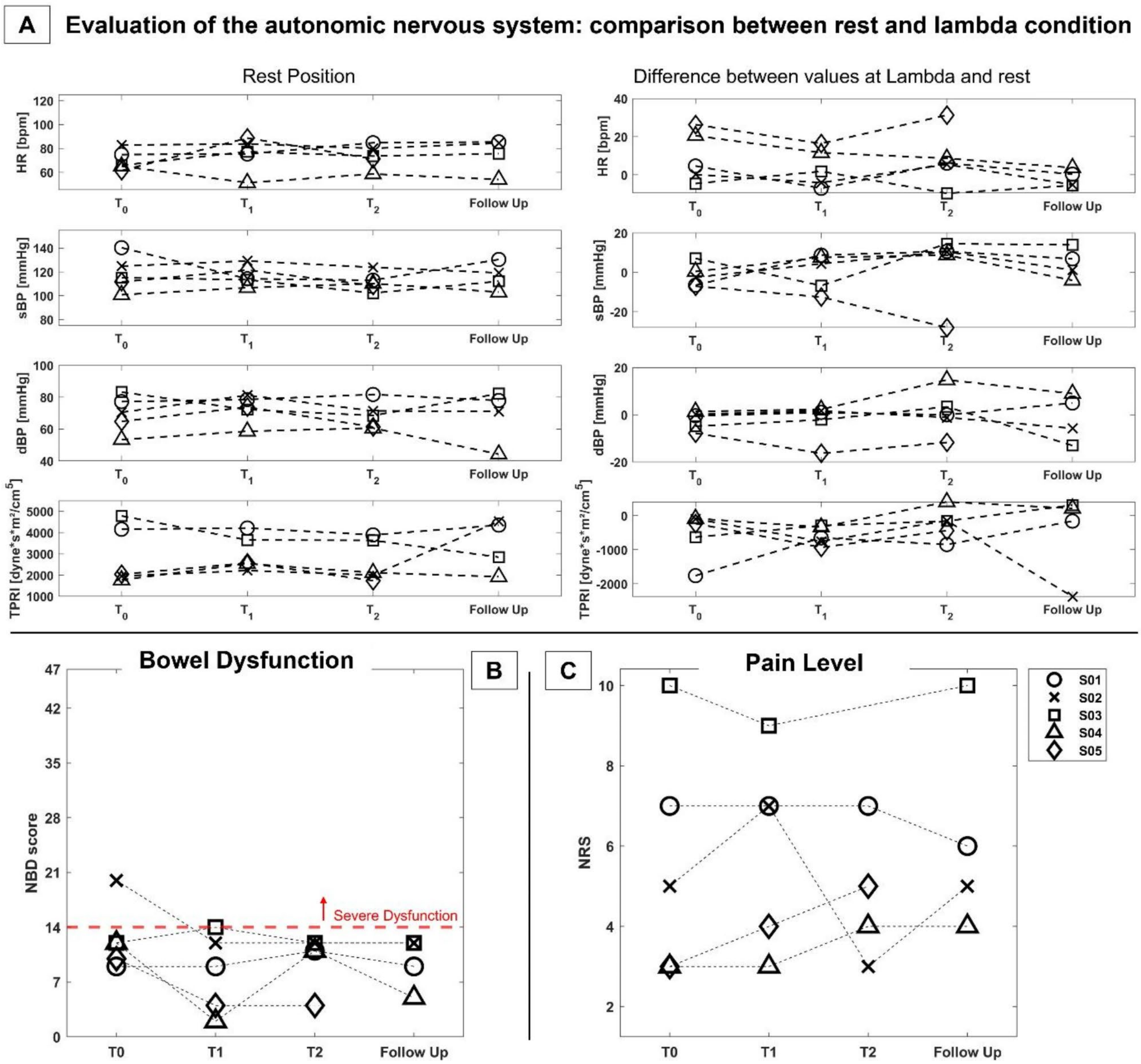

Fig. 3 Evaluation of the autonomic nervous system, the bowel functions and the pain level. (**A**) On the left the mean value of Heart Rate (HR), systolic and diastolic blood pressure (sBP and dBP) and total peripheral resistance index (TPRI) for each subject at rest condition are reported, while on the right the difference between Lambda condition and rest are shown. (**B**) Results for each pilot of NBD (Neurogenic Bowel Dysfunction) score are reported. It is also indicated the threshold value that suggests a severe dysfunction. (**C**) Results of Numerical Rating Scale (NRS) are provided

Correlations between muscle changes and performance improvements

There is a positive correlation between the increment of power output and the increment of maxCSA between T0 and T2 (p-value equal to 0.037, rho equal to 0.9, Fig. 5C). Instead, no significant correlation was found between changes of endurance and changes of maxCSA.

Discussion

This study investigated health and fitness benefits of a 6-month FES-Cycling program on a recumbent trike on five male individuals with motor complete SCI. We selected participants within five years post-injury to ensure a more homogenous sample with comparable baseline physical conditions, enhancing the reliability of our results. Additionally, individuals with more chronic injuries often face greater challenges in conditioning and sustaining prolonged FES-cycling sessions, especially if they lack prior experience with FES.

The primary outcome, muscle mass, showed significant improvement after six months of training. MRI scans revealed substantial increases in cross-sectional muscle area (maxCSA) from the start of the study (T0) to three months (T1) and six months (T2), with a decrease

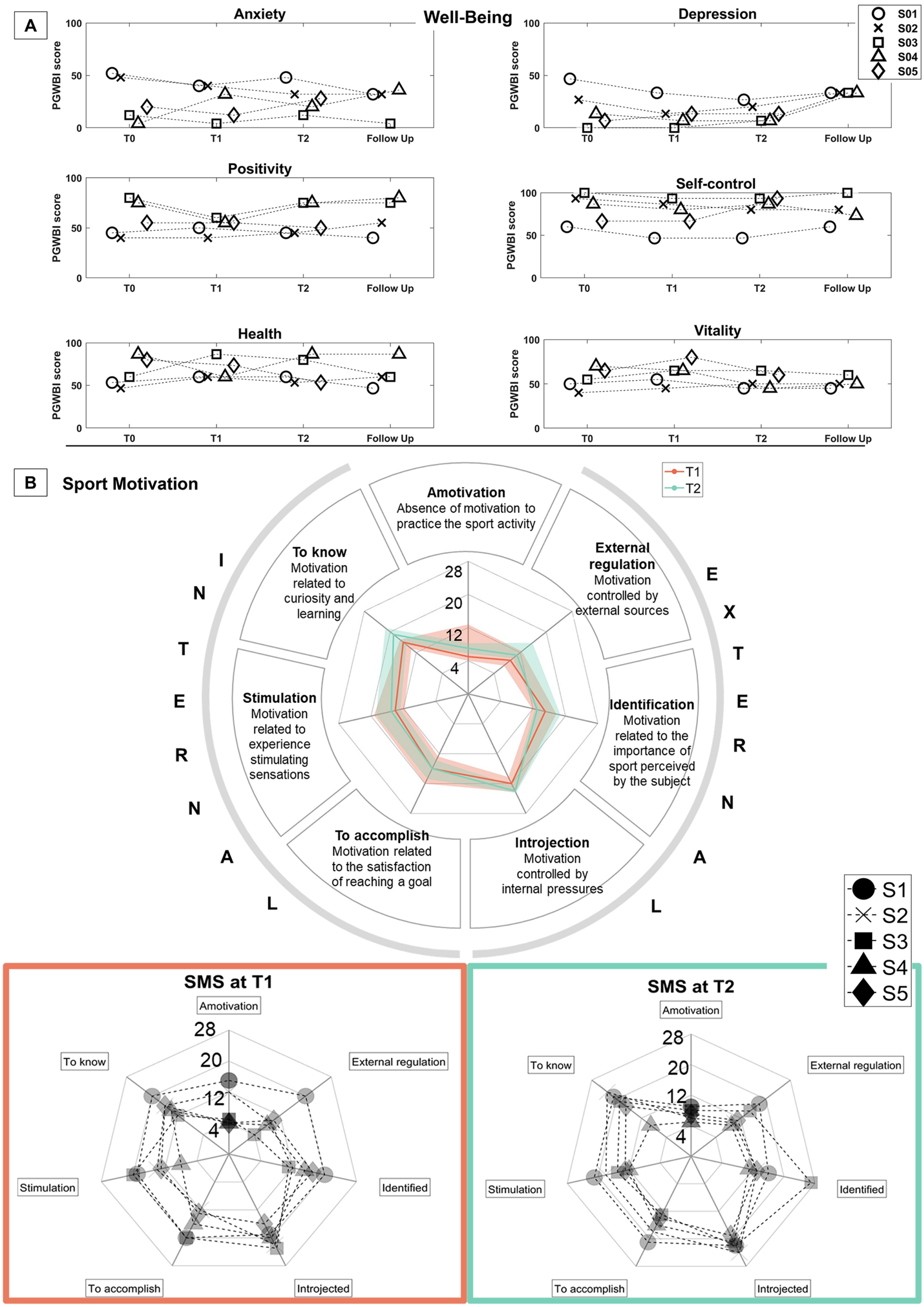

Fig. 4 (See legend on next page.)

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Fig. 4 Overall well-being and motivation to practice FES-cycling on a recumbent trike as a sport activity (**A**) The score of each pilot for each Psychological General Well-Being Index (PGWBI) item is presented. The data are presented as a percentage of the maximum achievable score. (**B**) On the center-top, the median trend of Sport Motivation Scale (SMS) is shown for T1 and T2; at the bottom, the score for each type of motivation for each pilot is reported at T1 (left, red) and at T2 (right, green). Sport activity is referred to FES-cycling on a recumbent trike. Higher scores of the PGWBI items indicate higher levels of that item, also for SMS, higher values in specific motivation suggest that motivation is stronger

at follow-up after one month of no activity. This result aligns with Tong et al.'s [35] findings, which qualitatively observed reductions in muscle atrophy in a single pilot participant by visual inspection of the leg, attributed to improved blood circulation following training with a recumbent mobile trike. Similarly, Fattal et al. [36] observed improvements in muscle volume in one participant with SCI after training with a recumbent trike, as deduced from measurements of the leg circumference. Additionally, this trend is consistent with previous studies using static, often motorized, cycle ergometers, which have highlighted the benefits of FES-cycling on muscle strength and volume [6]. The observed reduction in CSA following the end of the training program is both anticipated and physiologically consistent considering the physical inactivity [45, 46]. The changes are particularly rapid in SCI patients due to the interplay of inactivity and systemic inflammation and metabolic disturbances [47].

Bone density, assessed through DXA scans, showed mixed results. Three participants maintained stable bone density, while two experienced significant decreases (S02 and S03), though these declines did not cross critical thresholds (S02 remained in the normal range and S03 in the osteopenic range). This outcome is consistent with the general trend in SCI patients, where bone quality tends to deteriorate over time regardless of interventions like FES-cycling [48]. Bone loss in individuals with SCI is most pronounced within the first few years post-injury, particularly in the lower extremities. Therefore, individuals in the early stages of SCI, like those included in our study, could be more susceptible to rapid bone loss than individuals with more chronic SCI [49]. Similar findings were reported in a pilot study by Fattal et al. [36], where no significant improvement in bone density was observed after a 4-month FES-cycling program on a recumbent trike, conducted 1–3 times per week. This finding is further supported by the review conducted by van der Scheer et al. [6], which reported similar outcomes using static motorized cycle ergometers. Moreover, the studies that reported improvements in preventing bone loss had longer duration or more sessions per week. These results suggest that FES-cycling might offer limited benefits for bone health in individuals with SCI, further supported by the review of Soleyman-Jahi et al. [48, 50].

The autonomic nervous system of people with SCI can undergo different changes according to level and the severity of the injury but only in recent years has the scientific community started to use specific procedures to assess its functioning [51]. In this study, the autonomic nervous system was evaluated by means of non-invasive and repeatable tests that monitored the physical fitness of the pilots throughout the duration of the study. The adaptive transitional changes induced by the different conditions with respect to rest were found to be in the norm. No trend in the modification of the response of the autonomic system induced by training resulted from an analysis of the different timepoints. This result confirmed that FES-cycling can be safely practiced by people with SCI.

The Modified Ashworth scores revealed no significant changes in terms of spasticity across the four timepoints, consistent with previous research indicating no alterations in spasticity levels after training with mobile FES-cycling systems [36, 52]. Similarly, the NRS results showed no significant differences in general perceived pain during daily life across the four time points, which aligns with previous research [53]. However, it is important to note that NRS scores varied widely among participants, reflecting the highly subjective and individual nature of pain perception. This variability underscores the challenge of capturing consistent pain metrics across different individuals, particularly since the reported pain was general and not specifically related to the training sessions. The NBD scores showed no significant differences in bowel dysfunction across the timepoints, although one subject did show improvement. In a previous study, Sadowsky et al. [54] observed significantly better mean bowel function scores in the FES group compared to controls who did not perform FES training. Their higher effects could be attributed to the more intensive training regimen, which consisted of 3 sessions per week, each lasting 45–60 min, over an average duration of 33.7 ± 33.4 months.

Overall well-being remained high from the start, and training did not significantly affect it. Our findings on well-being and motivation provide further evidence to support the positive impact of FES-cycling on the quality of life corroborating Fattal et al.'s results [36], who observed improvements in their pilot trained with a recumbent mobile trike. Interestingly, depression appeared to increase after the training period ended, suggesting that the cessation of regular physical activity might negatively affect mental health. The observed trends of increased depression and decreased CSA at follow-up underscore the critical importance of maintaining consistent physical activity to preserve the benefits

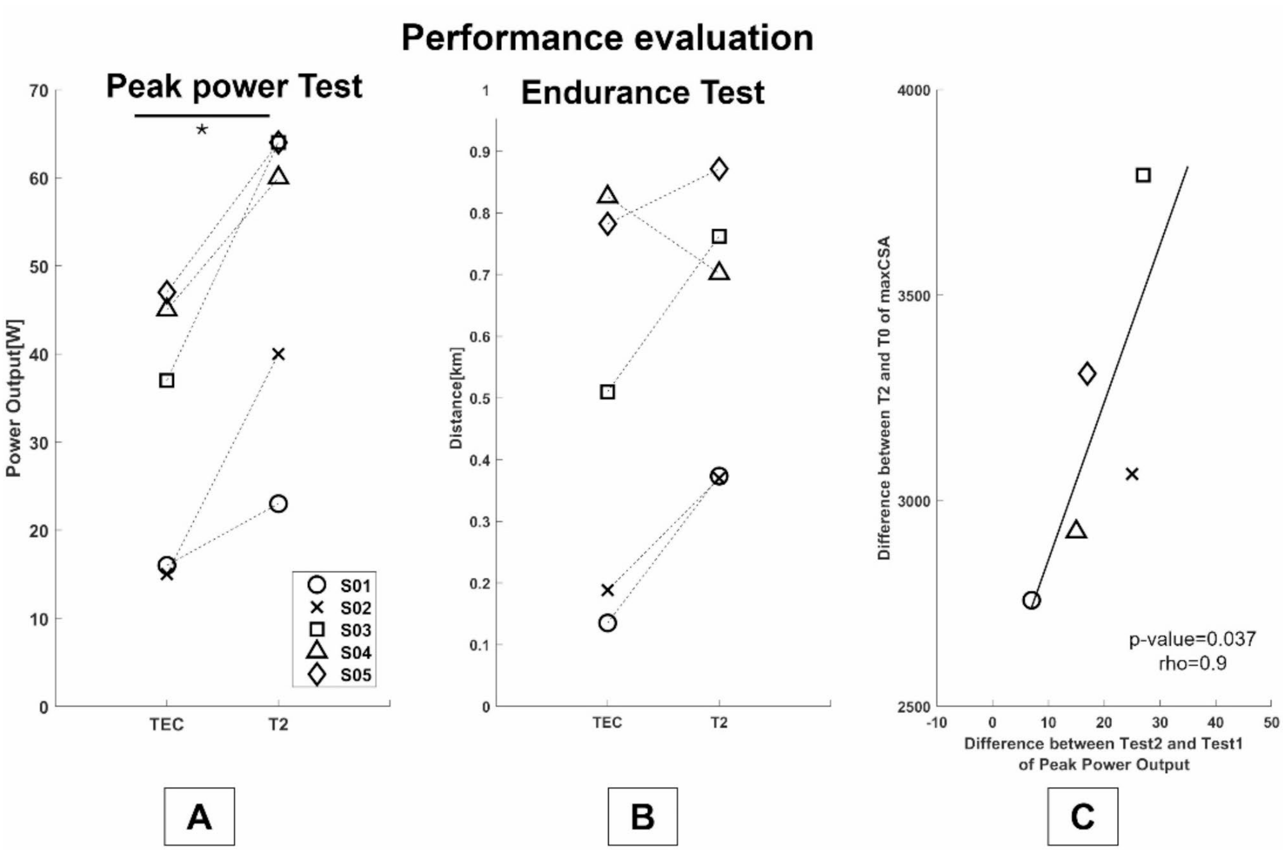

Fig. 5 Performance assessment and correlation with maximal Cross-Sectional Area (maxCSA) changes (**A**) Peak of power output; (**B**) km covered in 6 min during the endurance test; (**C**) relationship between the power output improvement and the thigh maxCSA change

of FES-cycling. These results are consistent with previous research, which has demonstrated that interruptions or reductions in physical activity among individuals with SCI can lead to declines in both physical outcomes, such as muscle mass and bone density, and psychological health, including elevated levels of depression and reduced quality of life [55, 56]. Incorporating FES-cycling into a broader lifestyle can boost adherence by making physical activity part of daily routines and helping counter these negative trends. Moreover, a more recreational oriented approach may reduce the drop-off often observed in rehabilitation setting.

The SMS results indicated strong motivation among participants, with low levels of amotivation. Ferri-Caruana's findings [57] suggest that motivation in people with SCI to engage in physical activity is closely linked to the type of exercise performed. Combined with our results, this suggests that FES-cycling was perceived as engaging, serving as a therapeutic and recreational activity. High compliance to the study, consistent with findings from van der Scheer [6], further confirmed the SMS findings, reflecting participants' continuous effort and commitment.

Participants exhibited high scores in both Introjected Regulation and Intrinsic Motivation to Know. Introjected Regulation indicates that the participants were driven by internal pressures to meet personal standards and maintain a positive self-image, motivating them to persist in their training. This is consistent with Watson et al.'s findings [58] on common motives for physical activity among people with SCI, such as health management and self-worth. Intrinsic Motivation to Know reflects the participants' curiosity about how FES-cycling would affect their physical abilities and health. Their desire to master the technique and see measurable improvements, such as increased muscle mass and endurance, further fueled their motivation. This is in line with Machida et al.'s research [59] on how sports foster resilience and with Gernigon et al.'s [60] findings that physical activity enhances self-worth and global self-esteem in individuals with SCI.

All participants improved their power output, and all but one showed enhanced endurance, highlighting the effectiveness of FES-cycling in increasing functional capacity and physical fitness in individuals with SCI. The correlation between increased thigh CSA and peak power output suggests a link between muscle volume and strength. These results are consistent with Sijobert et al. [61], who reported enhanced speed, endurance, and maximum covered distance in a pilot trained with a recumbent mobile trike. Additionally, this aligns with findings from other studies on static, often motorized, cycle ergometers that have demonstrated FES-cycling's benefits in improving aerobic fitness, muscle strength, and endurance [6, 8].

The study's limitations include a small sample size, which affects the generalizability of the findings. However, unlike some research on FES-cycling as sport-therapy [27, 35, 36], our study involved more than one participant, offering a broader perspective on its effects. Additionally, the study achieved a high number of training sessions, reflecting strong adherence to the program. Despite this, the intensity of the training regimen was lower compared to some existing literature [50], due to logistical constraints and the fact that the training was not home-based, coupled with participants' varying proximity to the training facility.

The observed decrease in BMD in two participants during the six-month study period highlights another limitation of our investigation. While literature suggests that BMD decline is a natural and often inevitable process following SCI, particularly in the early years post-injury [49], our study design did not include a control group of non-cycling participants to definitively attribute these changes to normal physiological progression rather than potential limitations of the FES-cycling intervention. This distinction is crucial to fully understand whether FES-cycling may help mitigate bone loss or if its effects on bone health are negligible. Future research should address this limitation by incorporating control groups and longer follow-up periods to better assess the relation between FES-cycling and bone health in individuals with SCI. We opted against a short-term follow-up for safety reasons, reducing radiation exposure.

A further limitation arises from potential self-selection bias. All subjects showed a good well-being already at baseline, which might have favored their decision to volunteer for the study. As a result, this might have limited the observed benefits due to a potential ceiling effect. Future studies could benefit from targeting populations with more varied baseline characteristics, including those with higher levels of anxiety, depression, or less motivation to participate. This would allow for a better understanding of benefits and challenges associated with FES-cycling.

Despite the abovementioned limitations, this study demonstrates some strengths, particularly in achieving significant physical improvements among participants. Gains in muscle mass and physical performance, coupled with high levels of compliance and motivation, underscore the effectiveness of the FES-cycling protocol. While larger sample sizes are necessary to validate these physical outcomes and assess their long-term impact, the results are promising and warrant further investigation. In addition to the physical benefits, this study highlights the broader potential of FES-cycling by incorporating recreational and sport-related elements. Participants engaged in outdoor cycling sessions and took part in events such as the Lyon Cyber Days and Cybathlon Challenge, showcasing the capacity of FES-cycling to transcend the clinical environment. These experiences enriched participants' involvement and underscored the potential for FES-cycling as a bridge between therapy and recreation. However, the sporadic nature of these recreational opportunities reflects a broader challenge in integrating clinical rehabilitation with community-based sport-therapy programs. Sustained engagement is critical to maintain the benefits of rehabilitation, yet barriers such as accessibility and lack of structured programs often hinder long-term participation. Addressing this gap requires a more integrated healthcare model, one that seamlessly connects clinical care with accessible, community-focused sport-therapy initiatives. Solutions could include combining home-based [18, 19, 21–23] training protocols with organized community events, ensuring continuity of care while fostering motivation and well-being. Such programs would not only enhance the therapeutic and recreational value of FES-cycling but also establish it as a cornerstone of holistic healthcare for individuals with SCI.

Conclusion

The six-month FES-cycling training program on a recumbent trike proposed in this study demonstrated notable benefits for individuals with SCI, particularly in terms of increasing muscle mass and enhancing physical performance. Additionally, the participants maintained high levels of overall well-being and motivation throughout the study.

FES-cycling on a recumbent trike not only offers physical exercise but also may integrate engaging, enjoyable activities, which contribute to a positive and sustained commitment from participants. Incorporating sport-therapy programs that are integrated with clinical care is a gap that should be addressed considering the potentiality.

Abbreviations

WHO	World Health Organization
SCI	Spinal Cord Injury
FES	Functional Electrical Stimulation
INAIL	Istituto Nazionale Assicurazioni Infortuni sul Lavoro
IRCCS	Istituto di Ricovero e Cura a Carattere Scientifico
ASIA	American Spinal Injury Association
PI	Proportional Integral
AFO	Ankle Foot Orthosis
CSA	Cross-Sectional Area
DXA	Dual-energy X-ray Absorptiometry

BMD	Bone Mineral Density
dBP	Diastolic Blood Pressure
sBP	Systolic Blood Pressure
HR	Heart rate
MAS	Modified Ashworth Scale
NBD	Neurogenic Bowel Dysfunction
NRS	Numerical Rating Scale
PGWBI	Psychological General Well-Being Index
SMS	Sport Motivation Scale
ROI	Regions of Interests
TPRI	Total Peripheral Resistance Index

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12984-025-01585-0.

Supplementary Material 1

Supplementary Material 2

Acknowledgements
We thank Mattia Colella for his help in training and assessments and Mattia Chiappini for the interpretation of the SMS questionnaire. We thank all the participants for their availability and constant participation.

Author contributions
NS drafted the protocol, assisted pilots during their training, handled data curation and formal analysis, and contributed to drafting the article. RN drafted the protocol, assisted pilots during their training, managed data curation, and co-drafted the article. EB was responsible for conceptualizing the project, drafting the protocol, providing assistance to pilots throughout their training sessions, securing funding, overseeing project administration and supervision, and reviewing the article. EG contributed to develop the protocol, performed clinical evaluations to the pilots and reviewed the article. ED contributed to develop the protocol, performed clinical evaluations to the pilots and reviewed the article. SF was responsible for conceptualizing the project, securing funding, and reviewing the article. FM was responsible for conceptualizing the project, securing funding, overseeing project administration and supervision, and reviewing the article. DP defined the MR acquisition protocol, acquired the MR images, and reviewed the article. CN analyzed MRI data and reviewed the article. AM drafted the protocol, analyzed MRI data and reviewed the article. GR was responsible for overseeing project administration and supervision and reviewing the article. MT was responsible for conceptualizing the project, securing funding, overseeing project supervision and reviewing the article. AP was responsible for conceptualizing the project, securing funding, overseeing project administration and supervision, and reviewing the article. EA was responsible for conceptualizing the project, drafting the protocol, securing funding, overseeing project administration and supervision, and reviewing the article.

Funding
This work was supported by INAIL (Istituto Nazionale Assicurazione contro gli Infortuni sul Lavoro) within the FESleg project (PR19-RR-P5). This work was also partially supported by the Italian Ministry of Health (Ricerca Corrente 2022/2025 to E. Biffi).

Data availability
The datasets used and/or analysed during the current study are available from the corresponding author on request.

Declarations

Ethical approval and consent to participate
All participants provided written informed consent. The research protocol was approved by the ethics committee of IRCCS Medea (Prot.N. 14/22 -CE, approved on February 17, 2022).

Consent for publication
The participant signed consent for publication.

Competing interests
The authors declare no competing interests.

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Received: 19 September 2024 / Accepted: 20 February 2025
Published online: 10 March 2025

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