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ORIGINAL RESEARCH ARTICLE

Usability of Myosuit exosuit and effects of device-mediated rehabilitation on chronic stroke survivors: a non-randomized pilot study

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ABSTRACT

Objectives: The aim of this study is to assess the usability of the Myosuit within a chronic stroke survivors' rehabilitation program and to explore its therapeutic and assistive role on gait, stair negotiation, sit-to-stand transfers, and balance.
Methods: Ten chronic stroke survivors with gait impairments were enrolled. The System Usability Scale (SUS) was the primary outcome of the study; secondary outcomes were the Stroke Self-efficacy Questionnaire (SSEQ), the Short Physical Performance Battery, the 10-meter Walking Test (10mWT), the 2-minute Walking Test (2minWT), and the Stair Climbing Test. Tests were carried out before (T0) and after (T1) the training sessions, with and without the exoskeleton.
Results: The SUS rated poor-to-ok in 30% of the participants, good in 40%, and excellent to best imaginable in 30%. Comparing T1 vs T0, all the functional tests, except stair descending, showed statistically significant improvements without the exoskeleton, and SSEQ did not change significantly. T1 vs T0 comparisons with the exoskeleton showed improvements in all functional tasks, statistically significant for all, except for 2minWT and 10mWT.
Conclusions: This study confirmed the feasibility of a Myosuit-mediated treatment in a sample of chronic stroke survivors. Despite the usability of the wearable robot being generally positively perceived, it varied among users. Furthermore, the Myosuit exhibited both therapeutic and assistive potential in the sample.

Keywords: Exoskeleton, Exosuit, Neurorehabilitation, Stroke, Usability

What is already known?

- *Previous studies have demonstrated the potential of exoskeletons to improve mobility and function in individuals with gait impairments, including chronic stroke survivors. The System Usability Scale (SUS) is widely used to assess the usability of such devices, with prior research exploring both the therapeutic and assistive benefits of exoskeletons. While exoskeletons can provide immediate support during activities, their long-term impact on functional recovery has been an ongoing area of investigation.*

What this manuscript adds?

- *This study specifically evaluated the usability and role of the Myosuit, a soft wearable exoskeleton, in a rehabilitation program for chronic stroke survivors' therapy and assistance. It found that while the Myosuit had varied usability ratings, it demonstrated both therapeutic and assistive benefits. Participants showed significant functional improvements in walking, balance, and transfers after training, even without the exoskeleton, confirming its therapeutic potential. When using the Myosuit, most tasks also improved, though not all gains were statistically significant.*

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Introduction

Stroke can affect motor abilities and performance in Activities of Daily Living (ADL) in individuals who survive the acute event (1–3). Physical consequences of stroke often include reduced mobility and balance, asymmetry of gait, spasticity, and muscle weakness in the more affected side (4).

It is estimated that at 3 months after stroke, about 70% of affected individuals walk at reduced speed and capacity (5). These factors contribute to reduced long-term physical activity and increased dependence on caregivers (4). In addition, the increased risk of falls and the energy cost of walking negatively affect mobility, participation, and, in the most severe cases, even the perception of personal identity (6, 7). Also, self-efficacy, i.e., the individual's confidence in enacting actions to achieve results (8), is positively associated with objective measures of mobility (9,10). Thus, it is possible to hypothesize that the use of an assistive robot, possibly improving ambulation performance, would also improve participants' self-efficacy concerning such activities.

Rehabilitation plays a key role in restoring autonomy in movement, helping participants reintegrate into society (10), and improving perceived self-efficacy (12). In this context, task-oriented and intensive programs have proven effective in motor recovery (13,14). In particular, robotic devices have been introduced into clinical practice to expand therapeutic approaches and support therapists in rehabilitation programs, showing promising results (15). Among robots designed for gait training, exoskeletons can assist participants during walking by transmitting mechanical power from body-worn actuators to the users' lower limbs (16,17). Some subtypes of such devices, such as exosuits, have been developed to provide the necessary assistance for a functional gait while stimulating users' active participation (16,18). Compared to rigid exoskeletons, exosuits are lightweight, minimally bulky, and do not impose biomechanical constraints. Because of these features, they are often considered both rehabilitative and assistive devices, i.e., they can be used for therapeutic purposes in clinical settings, and for assistive purposes in community settings (19,20).

Among lower limb exosuits, the Myosuit (MyoSwiss AG, Zürich) is designed to augment the motor performance of people with lower limb disability during walking, sit-to-stand and stand-to-sit transitions, and stairs negotiation (20). A previous study has shown Myosuit-mediated training to be safe and well-tolerated by a small, mixed population of subjects with lower limb motor disorders (19). Additionally, preliminary positive effects were observed on gait performance, increasing the average walking speed and endurance. However, although previous studies have shown promising results on the use of the device, they used heterogeneous methodologies and involved multiple clinical conditions (19,21), thereby warranting further investigation on stroke survivors in particular, to validate the usability and self-efficacy on a comprehensive set of mobility tasks. Additionally, no previous studies have evaluated the clinical outcomes of participants using the Myosuit for both rehabilitative and assistive purposes.

In light of these considerations, the primary objective of this trial was to verify the usability of the Myosuit in rehabilitation programs for a specific population: chronic (>6 months) stroke survivors. The secondary objectives of the study were to investigate potential changes in self-efficacy and to preliminarily explore the therapeutic and assistive role of the Myosuit on all motor tasks involving the lower limbs (i.e., walking, sit-to-stand and stand-to-sit transitions, stair ascent and descent, balance control), which have never been explored before. These preliminary results will constitute a determining element for the assessment of the feasibility of such a protocol for rehabilitative or assistive purposes.

Methods

Study design and setting

This study is a non-profit, non-controlled, interventional usability trial. The enrollment was carried out in the Neuromotor Rehabilitation Unit of the IRCCS Fondazione Don Carlo Gnocchi Onlus, Firenze, between May 2022 and September 2023. The study received approval from the local Ethics Committee under the number 20946_SPE in April 2022 and was registered on ClinicalTrails.gov under the number NCT05579197. The CONSORT reporting guidelines for pilot and feasibility trials were followed for this study reporting (22).

Participants

According to the eligibility criteria, researchers consecutively enrolled 10 individuals with chronic stroke at the outpatient neurorehabilitation clinic. Participants were informed of the study by a researcher, who provided their willingness to participate by signing the written informed consent form.

The inclusion criteria were the following:

- Chronic stroke (time from event >6 months);
- Age ≥18 years;
- Clinical stability was assessed by the administration of the Modified Early Warning Score scale (MEWS) (23);
- Being able to stand up from a chair without bending more than 45° to the right or left during movement;
- Being able to walk over 10 meters without assistance (the use of conventional aids other than knee orthoses was allowed, e.g., cane/ ankle-foot orthoses);
- Height between 150 cm and 195 cm;
- Weight between 45 kg and 110 kg;
- Functional Ambulation Category (FAC) ≥3 (24);
- Modified Ashworth Scale (MAS) ≤2 (25);
- Hospital Anxiety and Depression Scale (HADS) in the normal range (>10/21 for each subscale) (26);
- Montreal Cognitive Assessment (MoCA) >1 (using the equivalent score by Italian normative adjustments from Santangelo et al. (27));
- Signed informed consent.

The exclusion criteria were:

- Neurological and psychiatric conditions preceding the vascular event, active or with outcomes;
- Severe bilateral hearing loss or severe visual impairment;
- Functional Reach Test <15.24 cm, following normative value and user manual contraindication (28);
- Non-reducible retraction in flexion of the hip or knee greater than 10°;
- Varus or valgus of the knee greater than 10° (criteria required by the user manual of the device);
- Pregnancy;
- Previous stroke.

The device

The robotic device used was the Myosuit (20), a CE-marked medical exosuit to improve motor functions of the lower limbs in individuals affected by various neuromotor conditions (MyoSwiss AG, Zürich). The Myosuit resembles an exo-muscle providing active assistance to both hip and knee extension and supporting hip flexion via passive components. Its assistance is based on the analysis of inertial measurement units (IMUs)-derived kinetic and kinematic data to identify the synergistic sequences involved in supporting the body against gravity in ADL.

Specifically, through cables powered by two mechanical actuators located in the backpack, the Myosuit provides active assistance for hip and knee extension during the stance phase of gait. Additionally, two passive elastic bands located anteriorly to the hip support hip flexion in the swing phase. The overall weight of the system is 4.6 kg.

In this study, two assistive modes were used to tune the assistive profile of the hip and knee extension provided by the robot: the concentric and isometric modes. In both, the level of support could be adjusted for each leg independently on a 6-point scale, each level corresponding to a portion of the maximum available assistance (230 N), ranging from 0% to 100%, and with 20% intervals. The concentric mode assists the user when moving against gravity. For this mode, the user's locomotion data obtained from the IMUs is embedded in the device, where the support is synchronized with the kinematic profile of the task. The isometric mode provides a selected level of support by keeping the tension of the Myosuit cables constant, simulating an isotonic muscle contraction. Thus, the concentric mode is advised and was used for walking and stair climbing, while the isometric mode is for balance and stair descending. For sit-to-stand transitions, both modalities are contemplated and were tested in this study.

Lastly, the robot is equipped with strings connecting the middle third of the tibia to the toe to correct the foot drop. This feature was used according to a visual clinical assessment of the gait and the users' preferences.

Experimental protocol

Before starting the study, the interdisciplinary team conducted a series of unstructured tests on both healthy and post-stroke participants. These preliminary tests aimed to further train clinicians in using the device, ensure careful attention to wearability, and align the familiarization and tuning phases for selecting assistive parameters and modalities across different tasks.

During the experiments, the study participants underwent one *enrollment*, one *baseline assessment* (T0), seven *treatments*, and one *final assessment* (T1) session, for a total of 10 sessions for each participant (Figure 1). In the following subsections, details for each session are provided.

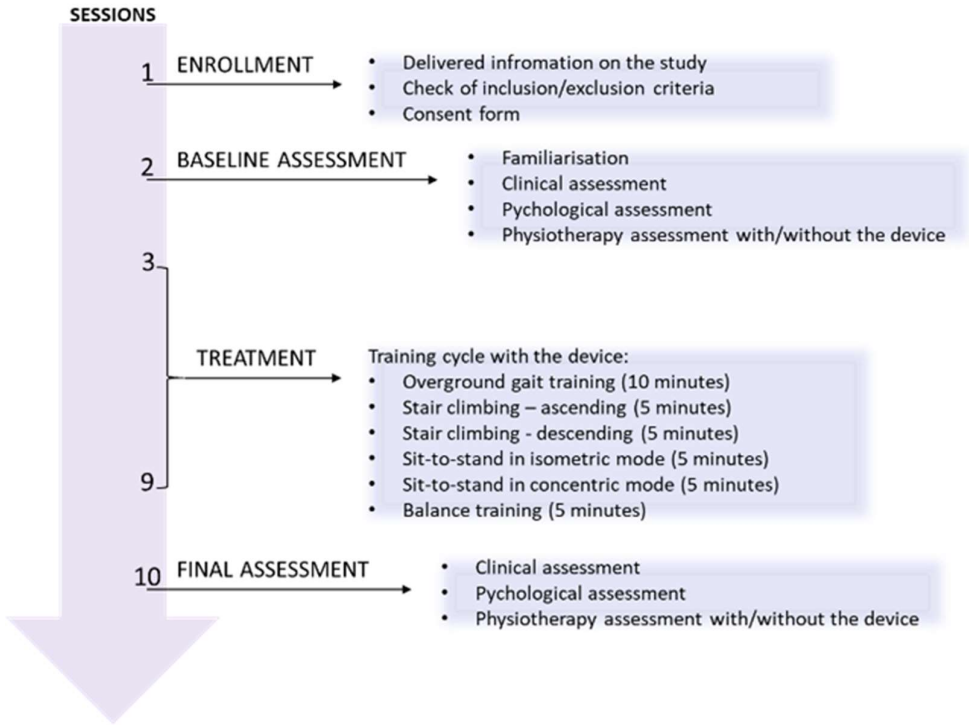

FIGURE 1 - Timeline of experiments. Details on the assessments are displayed in blue squares, and the treatment is in purple.

Session 1. Enrollment

In the enrollment session, a multidisciplinary team consisting of a physiatrist, a psychologist, and a physical therapist provided the study participants with all information on the investigation objectives and methods, verified that the eligibility criteria were met, and collected the signed consent form.

Both baseline and final assessment sessions were characterized by a comprehensive assessment of the participants, including physiotherapy, psychological, and clinical assessments.

The following tests were administered for the physiotherapy assessment (T0 and T1):

- Short Physical Performance Battery (SPPB) (29), a short lower-limb performance assessment composed of:
  - A Balance Test (BT) where a rater assesses the person's ability to stand unassisted without the use of a cane or walker in different conditions (i.e., Side-by-side, semi-tandem, and tandem stand);
  - The 4-meter Walking Test (4mWT) is used to assess the self-selected walking speed in meters per second over a short distance.
  - The 5-times Sit to Stand (5-tStS) test measures the time required to stand up and sit on a chair to quantify functional lower extremity strength during transitional movements.
- 10-meter Walking Test (10mWT) (30), to assess the maximal walking speed in meters per second over a short distance;
- 2-minute Walking Test (2minWT) (31), a measurement of endurance that assesses walking distance over two minutes;
- Stair Climbing Test (SCT) (32), a measure of the ability to ascend and descend a flight of stairs.

The following scales were administered for the psychological assessment:

- Stroke Self-Efficacy Questionnaire (8, 33), to assess stroke survivors' self-efficacy, intended as how confident the patient believes him/herself capable of organizing and executing the courses of action required to attain 13 tasks related to Activities of Daily Living despite the stroke (8);
- HADS, for the assessment of the depression and anxiety levels of hospitalized patients.
- MoCA, only at T0, is used to screen the global cognitive status of patients.

Lastly, both in T0 and T1, to complete the verification of eligibility criteria and to conduct a comprehensive multidimensional assessment, the clinical assessment included the following measures:

- MEWS is designed to identify early deteriorating patients with a composite score of physiological parameters to aid decision-making for escalating patient care;
- FAC, a 6-point assessment tool for functional walking, assessing the ambulation capacity of individuals by gauging the degree of human assistance needed during ambulation, regardless of whether they use a personal assistive device;
- MAS (34), to evaluate the level of spasticity of patients' lower limb muscle groups;
- MRC (35), to clinically assess the muscle strength on a 0-5 rating scale;
- Numerical Rating Scale (NRS) (36), to evaluate pain on a 0-10 analog scale;
- Modified Barthel Index (mBI) (37), for the assessment of the functional status of the patients;
- National Institutes of Health Stroke Society (NIHSS) (38), for an assessment of stroke severity.

At T0, after the assessment battery without the exoskeleton was completed and before carrying out the tests with the exoskeleton, each participant underwent 20 minutes of familiarization with the device.

This sub-session aimed to set the most appropriate torque profile for each of the motor tasks to be carried out in the protocol. Also, familiarization helped participants gain confidence with the robot and understand how to use it. This phase was carried out using a standardized approach developed by the clinical team. The intensity level of both concentric and isometric modalities of the robot was tuned, starting from symmetric configurations between the two legs and eventually switching to asymmetric ones based on the clinical features and comfort level of the users.

Sessions 3 to 9. Treatment

After the initial assessment, each participant performed seven circuit training sessions, wearing the Myosuit, 3 times per week. Each session was composed as follows: 10 minutes of overground gait training, 5 minutes of stair climbing, 5 minutes of stair descent, 5 minutes of sit-to-stand in isometric mode, 5 minutes of sit-to-stand in concentric mode, and 5 minutes of balance training. Moreover, a 5-minute break was taken between tasks to ensure the patient received the necessary rest, for a total of approximately 1 hour per session.

To avoid consistently training the same functions at the end of the session and introducing a potential bias from intra-session fatigue, the sequence of tasks was kept constant across the seven training sessions, but with a rotation: the first task in one session moved to the end in the following session (e.g., session one began with walking, session 2 with stair climbing, while walking was performed last). This procedure allowed each participant to train each motor task at different times during the training session. Finally, between tasks, participants could rest as much as needed based on subjective perception of exertion fatigue, generally around 5 minutes (Fig. 2).

Given participants' motor changes throughout the rehabilitation sessions, physical therapists were fine-tuning the levels of support based on visual analysis of motor tasks and users' feedback.

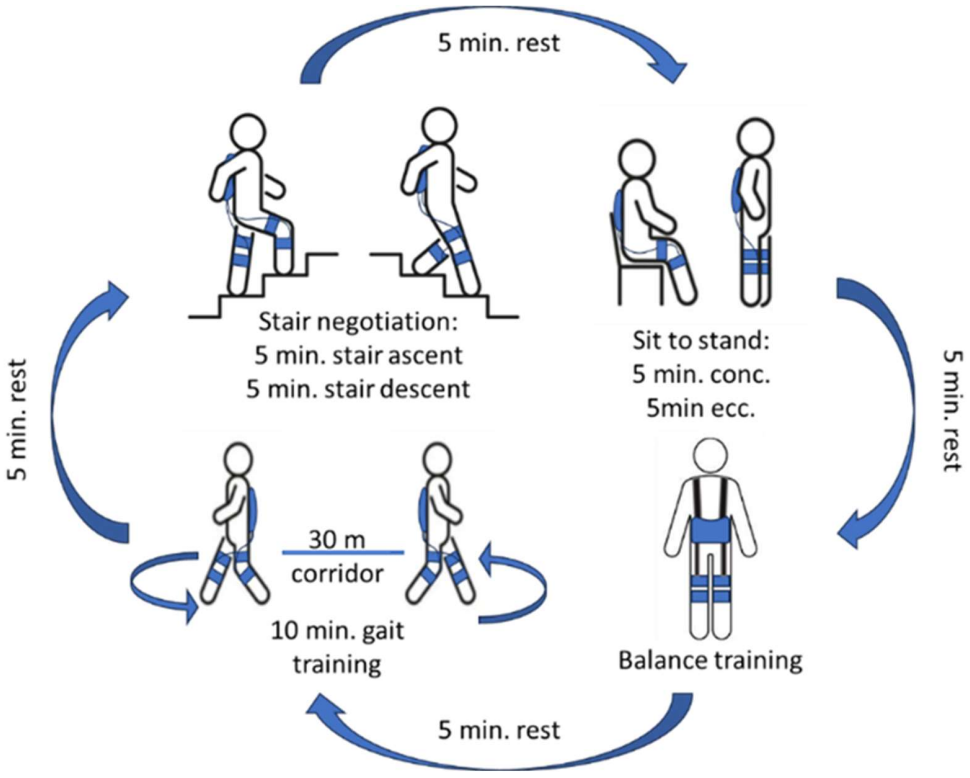

FIGURE 2 - Representation of the circuit performed in the training sessions.

Outcomes

The primary outcome was the System Usability Scale (SUS) (39), administered at T1, for the evaluation of the usability of the device once the protocol was completed. The SUS score ranges from 0 (worst) to 100 (best), and using such a score, we obtained the usability categories. These consisted of 6 different levels corresponding to different total score ranges of the SUS, namely: worst imaginable, SUS between 0 and 25; poor, SUS between 25.1 and 39; ok, SUS between 39.1 and 52; good, SUS between 52.1 and 73; excellent, SUS between 73.1 and 85; best imaginable, SUS between 85.1 and 100 rating (40). Secondary outcomes included the SSEQ, the SPPB score, the 2minWT (m), 10mWT (s), and the SCT (s).

Additionally, researchers recorded qualitative clinical notes regarding potential adverse events occurring during the trial. An adverse event was defined as any undesirable effect (e.g., red skin, muscle soreness) observed during or immediately after the treatment that appears to be caused by the device.

Data analysis

Statistical analyses were conducted using SPSS Statistics (IBM Corp. Released in 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp).

Concerning the primary objective, both the total score and the usability categories (40) were evaluated at T1 for the SUS. Furthermore, the median values of each SUS item were graphically investigated both overall and among subgroups generated by positive (SUS total score between 52.1 and 100) and negative (SUS total score between 0 and 52) SUS usability categories.

Concerning the secondary objectives, the measures of outcome considered were the SSEQ, the SPPB, the 10mWT, the 2mWT, and the descend and ascend SCT. For SPPB, the analysis was performed on both its total score and the score of each exercise. Additionally, metrics were obtained for the SPPB measures acquired with the device on, both in concentric and isometric modes.

Statistical analyses were focused on the description of the sample and comparison of both before/after the treatment and with/without the device for the main measures involved.

Descriptive statistics were performed through median (interquartile range, IQR) or absolute and percentage frequencies for continuous and categorical variables, respectively. Paired associations were performed using the Wilcoxon and McNemar tests for continuous and categorical variables, respectively. For all the tests, a p-value <0.05 was considered statistically significant. Given the numerosity of the sample, non-parametric tests were selected for analysis without checking for normality of the distributions.

Lastly, additional analyses involved the association between usability and baseline participants' characteristics. Specifically, Spearman's correlations were performed to investigate the linear association between baseline participants' characteristics and the SUS total score. Additionally, Mann-Whitney tests were conducted to investigate differences in baseline characteristics in the two groups determined by positive or negative SUS usability categories.

Results

Participants

During the trial, 24 outpatients with chronic stroke were consecutively screened for eligibility in the study. A total of 10 people were not enrolled in the study. Specifically, one refused to participate in the study. And the remaining nine did not fit the inclusion criteria. Of the remaining, four dropped out. Specifically, one was affected by a stable aortic dissection and showed signs of hypoperfusion and altered blood pressure response to physical exercise, even without the Myosuit, so clinicians decided to interrupt the protocol; one could not attend three weekly sessions because no family member could accompany him, and two withdrew consent for personal reasons unrelated to the intervention itself.

Participants were seven males and three females; six had an ischemic and four had a hemorrhagic stroke; six had a right-sided lesion, and four had a left-sided lesion; the median age (median (IQR)) was 61.5 (20.5); the median (IQR) time from the event was 36.5 (61) months.

Besides occasional discomfort, corrected by wearability adjustments, no side effects were experienced during the treatment. A description of the clinical, psychological, and physiotherapy characteristics of the sample is presented in Table 1.

Primary objective

Concerning the primary objective, the median (IQR) SUS total score was 55 (36.3). Its usability categories resulted in poor to ok by 30% of the participants, good by 40%, and excellent to best imaginable by 30%. By dividing patients into two groups with negative and positive SUS usability categories, two sub-samples of 3 and 7 participants were obtained,

TABLE 1 - Description and paired association (T0-T1) of the main clinical, psychological, and physiotherapy characteristics of the sample

Variables	Baseline assessmentsession (T0)		Final assessmentsession (T1)		p-value
	Median (IQR) or Frequency (%)	N	Median (IQR) or Frequency (%)	N	
Demographics and stroke history					
Age	61.5 (20.5)	10	–	–	–
Time from event (months)	36.5 (61.0)	10	–	–	–
Sex	Male: 7 (70%) Female: 3 (30%)	10	–	–	–
Education (years)	9.0 (8.0)	10	–	–	–
Aetiology	Ischaemic: 6 (60%) Hemorrhagic: 4 (40%)	10	–	–	–
Side of the lesion	Right: 6 (60%) Left: 4 (40%) Bilateral: 0 (0%)	10	–	–	–
Clinical assessment					
NIHSS	3.0 (4.0)	10	3.0 (3.0)	10	0.279
mBI	96.0 (7.0)	10	98.0 (5.0)	10	0.168
MAS_ LL	3.0 (3.0)	8	2.5 (2.0)	10	0.221
FAC	5.0 (1.0)	8	4.0 (1.0)	10	0.564
NRS	0.0 (0.0)	8	0.0 (2.0)	10	0.180
MoCA (adjusted score)	25.5 (2.4)	10	–	–	–
HADS_ depression	2.5 (4.0)	10	2.5 (5.0)	10	0.582
HADS_ anxiety	3.0 (7.0)	10	4.0 (6.0)	10	0.359
SSEQ	28.0 (10.0)	10	29.5 (17.0)	10	0.592
SUS	–	–	55 (36.3)	10	–
SUS usability categories	–	–	Worst imaginable: 0 (0%) Poor. 1 (10%) Ok: 2 (20%) Good: 4 (40%) Excellent: 2 (20%) Best imaginable: 1 (10%)	10	–

Abbreviations: FAC: Functional Ambulation Category, HADS: Hospital Anxiety Depression Scale, IQR: Interquartile Range, MAS_LL: Modified Ashworth Scale_ Lower Limbs, mBI: Modified Barthel Index, MoCA: Montreal Cognitive Assessment, NIHSS: National Institute of Health Stroke Scale, NRS: Numerical Rating Scale, SSEQ: Stroke Self-Efficacy Questionnaire, SUS: System Usability Scale.

respectively. Figure 3 reports the median SUS item values over the 10 participants and the two subsamples of 7 with positive ratings and 3 with negative ratings. Item 9, "*I felt very confident using the system*", revealed very positive ratings from both groups and thus overall. On the contrary, item 4, "*I think I would need the support of a technical person to be able to use this system,*" received overall negative ratings. Conflicting ratings were especially encountered for items 1, "*I think that I would like to use the system frequently*", and 10, "*I needed to learn a lot of things before I could get going with this system*", with positive results for the group with positive SUS usability categories.

Secondary objectives

Clinical assessment demonstrated no statistically significant changes when comparing T1 vs T0 without the exoskeleton; on the other hand, all the functional tests, except stair descending, showed statistically significant improvements. The stair descending component of the SCT showed a statistically significant longer time after the training (median (IQR); 7.6 s (6.7) to 8.0 s (5.8); p = 0.022). Also, T1 vs T0 comparisons with the exoskeleton showed statistically significant differences in all functional tasks, except for the 2minWT and the 10mWT. In detail, the SPPB in concentric mode increased from 8.0 (3.0) to 9.5 (4.0), p = 0.037; the SPPB in isometric mode from 8.0 (3.0) to 9.5 (4.0), p = 0.024; the 2minWT (m) from 99 (65.8) to 109 (65.1), p = 0.028; the 10mWT (s) from 10.8 (8.9) to 10.9 (8.5), p = 0.028; the SCT up from 8.3 (5.4) to 7.6 (3.3), p = 0.028; the SCT down from 8.3 (7.6) to 7.3 (5.3), p = 0.022. The assistive effect is not supported by statistically significant changes when comparing with and without the exoskeleton, both in T0 and T1. All changes across conditions and evaluation time points in functional tasks are reported in Table 2.

Correlation analyses between participants' usability and baseline characteristics resulted in non-significant associations for all the variables (Table 3).

Discussion

In the current study, we showed that an exosuit-mediated treatment for chronic stroke survivors, specifically using the Myosuit device, was usable in an outpatient rehabilitation setting, with no reported adverse events. Despite mostly positive usability scores, the exosuit was found to be differently usable from one user to another, ranging from poor to best imaginable across study participants. In detail, seven participants rated the Myosuit higher than the usability threshold of 68 points. These values are in line with the results of a previous study investigating the usability of the Myosuit, where five out of seven participants scored in the SUS questionnaire more than the good usability threshold (41). In their study, Basla et al. discussed the possibility of a selection bias favoring a positive outcome on the SUS due to the high interest in the technology of the sample. This bias is less impactful in the current study, where, out of 10 participants, only two were previously included in robotics trials. Furthermore, the participants in our study did not purchase the exoskeleton directly but were contacted by the research team and involved in the

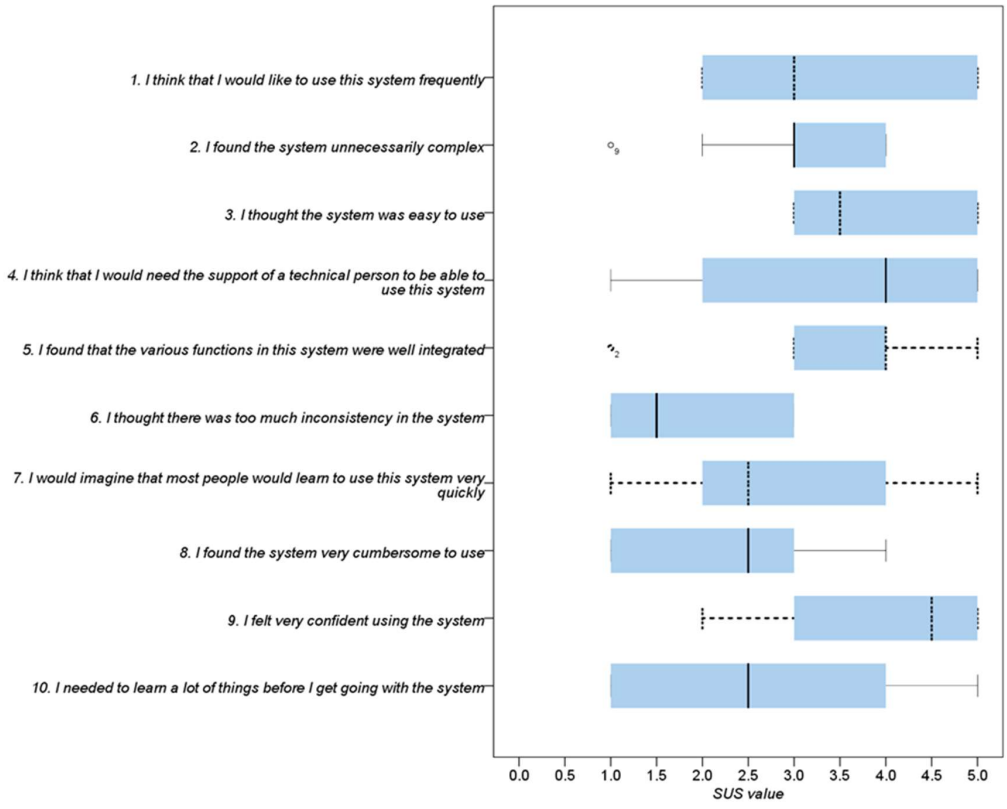

FIGURE 3 - Median scores of individual items on the System Usability Scale (SUS).

TABLE 2 - Functional task scores in T0 and T1, without and with the exoskeleton

Variables	Baseline assessment session (T0)			Final assessment session (T1)			p-value without (T0/T1)	p-value with (T0/T1)
	Without device	With device	p-value baseline (with/without)	Without device	With device	p-value final (with/without)		
SPPB _ concentric mode	7.0 (2.0)	7.5 (3.0)	0.655	8.5 (4.0)	9.0 (4.0)	0.317	**0.016**	**0.037**
SPPB _ isometric mode	7.0 (2.0)	8.0 (3.0)	0.317	8.5 (4.0)	9.5 (4.0)	0.458	**0.016**	**0.024**
BT	0: 0 (0%) 1: 0 (0%) 2: 2 (20%) 3: 4 (40%) 4: 4 (40%)	0: 0 (0%) 1: 0 (0%) 2: 2 (20%) 3: 3 (30%) 4: 5 (50%)	0.317	0: 0 (0%) 1: 0 (0%) 2: 1 (10%) 3: 3 (30%) 4: 6 (60%)	0: 0 (0%) 1: 0 (0%) 2: 0 (0%) 3: 2 (20%) 4: 8 (80%)	0.083	0.257	0.102
4mWT	0: 0 (0%) 1: 2 (20%) 2: 1 (10%) 3: 5 (50%) 4: 2 (20%)	0: 0 (0%) 1: 2 (20%) 2: 1 (10%) 3: 4 (40%) 4: 3 (30%)	0.564	0: 0 (0%) 1: 2(20%) 2: 1 (10%) 3: 4 (40%) 4: 3 (30%)	0: 0 (0%) 1: 2 (20%) 2: 1 (10%) 3: 2 (20%) 4: 5 (50%)	0.317	0.314	0.157
5-tStS _isometric mode	0: 0 (0%) 1: 6 (60%) 2: 3 (30%) 3: 1 (10%) 4: 0 (0%)	0: 0 (0%) 1: 6 (60%) 2: 2 (20%) 3: 2 (20%) 4: 0 (0%)	0.655	0: 0 (0%) 1: 2 (20%) 2: 2 (20%) 3: 6 (60%) 4: 0 (0%)	0: 0 (0%) 1: 4 (40%) 2: 2 (20%) 3: 3 (30%) 4: 1 (10%)	0.180	**0.014**	0.129
5-tStS _ concentric mode	0: 0 (0%) 1: 6 (60%) 2: 3 (30%) 3: 1 (10%) 4: 0 (0%)	0: 0 (0%) 1: 7 (70%) 2: 2 (20%) 3: 1 (10%) 4: 0 (0%)	0.655	0: 0 (0%) 1: 2 (20%) 2: 2 (20%) 3: 6 (60%) 4: 0 (0%)	0: 0 (0%) 1: 6 (60%) 2: 2 (20%) 3: 2 (20%) 4: 0 (0%)	**0.023**	**0.014**	0.480
2minWT (m)	100 (59.7)	99 (65.8)	0.508	111 (56.7)	109 (65.1)	0.683	**0.028**	0.203
10mWT (s)	10.9 (6.8)	10.8 (8.9)	0.799	10.1 (6.1)	10.9 (8.5)	0.114	**0.028**	0.074
SCT_up	8.4 (4.7)	8.3 (5.4)	0.359	8.2 (3.7)	7.6 (3.3)	0.646	**0.028**	**0.028**
SCT_down	7.6 (6.7)	8.3 (7.6)	0.508	8.0 (5.8)	7.3 (5.3)	0.878	**0.022**	**0.037**

Abbreviations: 10mWT: Ten Meters Walking Test, 2minWT: Two Minutes Walking Test, 4mWT: Four Meters Walking Test, 5-tStS: 5-times Sit to Stand, BT: Balance Test, SCT: Stair Climb Test, SPPB: Short Physical Performance Battery.

project. A difference to be highlighted between the study by Basla et al. and ours concerns the eligibility criteria; in the previous study, they were broader, including individuals with a variety of diseases with functional gait limitations, whereas our results are focused on a relatively larger sample of chronic stroke survivors.

In our study, the median SUS score was found to be 55, which corresponds to good usability categories overall, indicating that the system is usable, though it can possibly be improved to reach better usability rates. The item that received the most negative feedback was item 6, '*I thought there was too much inconsistency in the system*,' which had a median score of 1.5 (Figure 3). The low score for this item indicates that users perceive a lack of consistency in the Myosuit system, which may cause frustration and reduced trust in the device. To improve this, efforts could be focused on enhancing the user interface to provide clearer feedback and more predictable responses. Streamlining the transition between different modes of assistance and reducing the variability in system behavior could help users feel more in control and ultimately increase the overall usability and user satisfaction in this aspect. One notable aspect is the IQR of 36.3, reflecting high variability in the responses. While some participants found the device usable, others encountered difficulties. This disparity is further highlighted by the substantial difference between the minimum (37.5) and maximum scores (92.5), underscoring the varying perceptions of usability among the participants.

In our sample, the correlation analysis did not show any significant association between participants' features and the SUS total score. Although descriptive differences were noted among patients—specifically, the three participants who provided an overall positive SUS score were older, more

TABLE 3 - Correlation analysis between SUS total score and baseline participants' characteristics

Variables	Correlation coefficient	p-value
Age	0.298	0.404
Time from the event (months)	0.262	0.464
Education (years)	0.440	0.203
MoCA (adjusted score)	−0.189	0.601
SSEQ- (T0)	−0.328	0.355
NIHSS	−0.227	0.528
mBI	−0.040	0.912
SPPB_ without device	−0.032	0.931
SPPB_with device_isometric mode	0.032	0.931
SPPB_with device_concentric mode	−0.056	0.879
2minWT_without device (m)	0.250	0.486
2minWT_with device (m)	0.354	0.316
10mWT_without device (s)	−0.140	0.699
10mWT_with device (s)	−0.213	0.554

Abbreviations: 10mWT: Ten Meters Walking Test, 2minWT: Two Minutes Walking Test, mBI: modified Barthel index, SSEQ: Stroke Self Efficacy Questionnaire, MoCA: Montreal Cognitive Assessment, NIHSS: National Institute of Stroke Society, SPPB: Short Physical Performance Battery, SUS: System Usability Scale.

educated, and presented a lower SSEQ compared to those with negative ratings—these observations were not subjected to statistical analyses. Given the limited literature on the relationship between SUS scores and patient characteristics, as well as the limited sample size of this pilot study, we encourage future studies with larger samples to rigorously investigate these potential relationships. The association between psychological and social factors and functional performance following stroke has been confirmed in previous studies (42), and the role of self-efficacy as a movement recovery moderator is acknowledged (43). In our study, overall self-efficacy was very low compared to a previous study by Jones et al. (8); even if we excluded persons experiencing moderate to severe depressive symptoms, differences both in participants' psychological profiles and objective performances may explain this discrepancy. Unfortunately, in the previous article, the functional profile of the participants was not assessed, thus impeding an in-depth comparison with our results. Assessing self-efficacy is also relevant in rehabilitation studies to verify whether the clinical benefit is directly due to the experimental treatment (44) or whether self-efficacy changes play a relevant role in the outcome. In this pilot, we did not see a statistically significant improvement in the SSEQ after the treatment. This is well explained by the size of the reported functional improvements, which are significant but small and have little impact on the tasks explored by the SSEQ, particularly mobility. On the other hand, this result suggests a direct effect of the Myosuit training on measured functional outcomes, independent from potential changes in patient motivation or self-confidence.

Concerning secondary outcomes, comparing T1 vs T0, we observed an increase in performance in almost all functional tasks conducted without the device (Table 2), suggesting a therapeutic effect of the rehabilitation training with Myosuit. The SPPB increased after the treatment without the exoskeleton by a mean (standard deviation, std) of 1.3 (1.1) points. This improvement, despite its relatively large dispersion, exceeded most of the values of the Standard Error of Measurement (SEM = 0.68-1.42), the Minimal Detectable Change (MDC = 0.54-2.9), and the Minimal Clinically Important Difference (MCID = 1) reported in previous studies (45,46). However, the significance of our findings remains to be clarified, given the limited sample size and the fact that the psychometric properties of SPPB are not validated on a population of stroke survivors but on community-dwelling older adults (46,47). Moreover, it is worth mentioning that when looking at the differences between the SPPB items, only the sit-to-stand and stand-to-sit show statistically significant improvements, meaning that the improvement in the total test score is dependent on the changes observed in the 5-tStS and not on the 4mWT and BT. Regarding the 2minWT, our study shows a statistically significant increase with a mean (std) of 9.0 (10.0) meters in the T1-T0 comparison without the exoskeleton, getting very close to the MDC95% for the 2minWT, found by Hiengkaew et al. in 2012 in 61 chronic stroke survivors, equal to 13.4 m or 23% change from baseline (48). These results need insights into the future, adequately powered randomized controlled studies, to determine if the recorded positive changes can be attributed to this device specifically.

When considering the therapeutic effects in the 10mWT, our results showed a mean (std) improvement of 0.09 (0.12) m/s without the exosuit at T1 compared to T0. This improvement is lower than the substantial meaningful changes reported by Perera et al., 2006 (47) (0.14 m/s) and by Tilson et al, 2010 (49) (0.16 m/s). One aspect that has potentially affected the motor recovery of training is the limited number of treatment sessions, as literature proposes longer treatments for chronic stroke (50).

Descending stairs was the only ambulatory task that did not show a statistically significant improvement at T1 without the exoskeleton. This could be due to the device applying constant torque throughout the entire task of descending the stairs. Doing so provided support in bearing the weight of the body during the stance phase but restricted the movements of the wearer during the swing phase. A dedicated modality for stair descending was not available on the device (the isometric modality is currently used), but it could be desirable.

Regarding the comparison of T1 vs T0 with the exoskeleton, significant differences were observed in SPPB scores in both concentric and isometric modes, as well as in SCT_up and SCT_down. In all these tasks, the observed effect size remains borderline in terms of clinical significance. The other tasks that without exoskeleton showed a difference between times, the 5-tStS (both isometric and concentric), the 2minWT, and the 10mWT, do not show statistical significance with the exoskeleton. This could be attributable to the weight of the device masking the induced rehabilitation

effects. Regarding assistive effects, the baseline comparison between conditions (exo vs no-exo) shows no statistically significant difference. However, at the post-treatment evaluation, a significant difference appears in the 5-tStS concentric mode, likely due to the improved human-machine interaction over time.

In relation to these results, it is worth highlighting that the current study was a usability study, with a limited sample size and no control group. However, the positive preliminary results we found on some secondary outcomes, particularly walking speed, seem promising and deserve to be investigated in future power-sized controlled clinical trials. Although our sample included only chronic stroke individuals with inclusion criteria limiting clinical variability, we cannot ensure the exclusion of strokes (e.g., certain pontine or midbrain strokes) that may cause lower limb weakness and balance impairment as separate dysfunctions. Furthermore, the order of execution of the functional tests might lead to some limitations. Indeed, these were always carried out without the exoskeleton before, potentially introducing a fatigue bias in the advantage of the without-exosuit condition. Also, we tested the Myosuit only in an outpatient-like research setting. Although our protocol tried to emulate everyday life scenarios, testing the device in a laboratory environment is a major limitation to an ecological investigation of the robot's assistive potential. Lastly, this study lacks T1 data for dropouts, potentially introducing a selection bias and limiting longitudinal analyses, both for the SUS and clinical effects. Even if more details are missing, future clinical trial designs should consider the dropout rate obtained in this pilot trial.

In light of these limitations, we can conclude that the Myosuit device, in the selected cohort of post-stroke individuals, showed encouraging results in terms of potential therapeutic applicability. These results are promising for the potential further applicability of this device since previous studies have primarily highlighted its assistive benefits.

Conclusions

The results of this study support the usability and feasibility of a Myosuit-mediated rehabilitation program and present no factors that would hinder the repeatability of the treatment on a larger sample of stroke survivors. Also, the Myosuit has shown preliminary evidence of effectiveness, but the extent of the observed clinical improvement remains uncertain.

Future investigations should then consider the inclusion of a larger sample and a controlled study design to demonstrate the role of the experimental treatment against evidence-supported therapy. Ultimately, as the study did not include subacute stroke survivors, exploring the usability of the Myosuit in an inpatient setting at an earlier stage of the disease remains a priority for understanding the rehabilitation potential of the robot.

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Disclosures

Conflict of interest: RR is the author of the European patent application 16207252.4 filed by ETH Zürich and licensed by MyoSwiss AG and is a minor shareholder at MyoSwiss AG. All other authors have no competing interests.

Ethics approval and consent to participate: The study was approved by the local Ethics Committee (20946_SPE, April 2022) and registered on ClinicalTrails.gov (NCT05579197). Written informed consent was obtained from all subjects before the study.

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Authors' contributions: FC, RR, SC, AM, SD, and CB were involved in the study design; TB and EG contributed to the clinical protocol design; SD, TC, and MP participated in the physiotherapy protocol design; CP and SM were involved in the psychological protocol design; SC performed statistical analyses; SD edited the manuscript. All authors were involved in the revision of the manuscript.

Data availability statement: Pseudonymized data will be available, upon request to the corresponding author, for research purposes.

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