Preliminary Evaluation of a Soft Wearable Robot for Shoulder Movement Assistance

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***Abstract*—Spinal cord injuries (SCI) often lead to upper limb impairment, necessitating innovative solutions for daily assistance beyond traditional rigid robotics due to their impractical weight and size. Despite still preliminary, soft wearables are arising as a possible solution to fill this gap. Here, we demonstrated an enhanced version of a soft inflatable robot that assists the shoulder against gravity, previously tested with different neurological conditions. Noteworthy improvements include a single-layer actuator, simplifying manufacturing, a built-in bending angle and a nylon hammock, for better armpit conformity. We characterized the actuator (approximately $8Nm$ at $90°$ at $70kPa$) and demonstrated its good transparency, both from a kinematic and a muscular standpoint. Then, on 11 healthy individuals, we showed reductions in shoulder muscle activity (both at the anterior and middle deltoid) while performing a lift and hold task, ranging from 16% to almost 60% of the maximum voluntary contraction. More importantly, we confirmed these effects on two SCI individuals SCI, at two different stages of recovery. While preliminary, considering the limited exploration of soft wearable robots for the shoulder in SCI cases, this is a significant advancement playing an important role in the development of future soft technology for SCI assistance.**

***Index Terms*—Soft Wearable Robotics, Rehabilitation Robotics, Spinal Cord Injury.**

I. Introduction

THE spinal cord is a fundamental two-way pathway that, along with peripheral nerves, allows communication between brain and body. An injury to this communication channel is often critical for proper neuromuscular control and sensory feedback, causing impairments at different levels. Yearly, the global estimated incidence of spinal cord injury (SCI) is 40-80 cases per million population, 90% of which have traumatic origins [1]. Statistics reveal that in the United States, 38% of the new SCI cases are due to vehicle collision, 30% from falls, 9% from sports injuries, and 5% from medical and surgical causes [2].

Thanks to better road safety and the increasing median age of the population, a common trend in Western countries is that falls (mostly on the same level and from a low level) are becoming a leading cause of traumatic SCI [3]. This epidemiological data implies that, due to the mechanism of injury [4], there is an increasing percentage of cervical SCI, often incomplete. Among other effects, cervical SCI partially or completely impairs upper limb movements [5]. When targeting shoulder rehabilitation, passive range of motion (ROM) exercises with the support of the therapist help to relax the pain and to maintain any residual functional capabilities [6]. These capabilities can also be partially improved if patients use any residual volitional movement to practice these exercises actively, thus active ROM. In the last few decades, robotics has been introduced to make the therapy more intense, less heavy on the therapist, and thus potentially more effective, with the target of shortening the time required for the patient to recover any functional abilities [7], [8].

While traditional rigid robots or exoskeletons have been demonstrated as a potential solution for rehabilitation robotics [9], a recent trend in the field is the use of soft materials and lighter actuation strategies [10]. Exoskeletons are indeed generally limited to a few high-technological clinics and hospitals, mostly due to high costs and high requirements in terms of both facility space and clinicians' experience with technology, as it is often required to run these robots under the direct supervision of an expert operator [11]. Soft robots have, instead, the potential to become a cheaper, simpler to use, and more portable option for patients who need to extend the therapy out of the clinical environment [12], [13].

In the last 10 years, it has been possible to observe several new designs of soft wearables [13], [14], using cable-driven, fluidic, shape memory alloy, or electroactive polymer-based actuation, targeting one or more joints of the upper limbs. Focusing on the shoulder joint, several studies demonstrated the feasibility and performance of soft wearable robots in assisting this complex portion of the human body. In particular, researchers showcased reduced muscle activity in healthy individuals engaged in weightlifting [15]–[18], reduced heart rate activity in individuals with upper extremity impairments performing weightlifting [19], delayed onset of muscular fatigue during a static hold in individuals with SCI and muscular dystrophy [20], improved passive ROM in stroke survivors [21], [22], improved active ROM, along with reduced muscular

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Fig. 1. A) Overview of our soft wearable robot for shoulder assistance. It consists of a single-layer inflatable actuator, a custom harness (total weight of harness and actuator, $265g$), a portable ($2.1kg$) benchtop control box, and a graphical user interface. The shoulder device is unilateral but can be mounted on either side of the body. (B) A close-up of the actuator and its characteristic Y-shape for improved comfort. (C) Demonstration of the built-in 45 degrees bending angle of the soft actuator. This angle is meant for better fitting under the armpit and thus improved torque transferring.

activity, and improved performance of activities of daily living in individuals with amyotrophic lateral sclerosis (ALS) [23].

However, it is important to notice that the cumulative testing size across these studies is relatively small, involving approximately 50 healthy individuals and around 30 individuals with various clinical conditions, predominantly stroke survivors. When compared to traditional rigid exoskeletons, even when considering only studies involving impaired populations, nine studies have evaluated exoskeletons or end-effector efficacy with over 50 impaired individuals in each study [9]. This discrepancy is particularly significant in the context of SCI treatment, where currently, only one individual with SCI has been documented testing a soft wearable robot [20]. Therefore, additional demonstrations validating the efficacy of a soft wearable approach are of paramount interest to both the research and the clinical communities.

In this work, we leverage our prior experience in supporting individuals with ALS [23] through the implementation of a shoulder soft robot. Our objective is to investigate the potential efficacy of such assistance in a distinct neurological condition, specifically SCI. Similar to ALS, cervical SCI manifests both upper and lower motor neuron symptoms in the upper limbs. However, it is essential to note that the development of an assistive device for ALS does not guarantee its suitability for individuals with SCI due to the inherent differences between these two conditions. A primary distinction is the diminished or absent perception of tactile and painful stimuli exclusively experienced by individuals with SCI. This presents a significant challenge in preventing skin or musculoskeletal lesions when utilizing an assistive device. Moreover, another critical differentiator is the higher prevalence and increased severity of spasticity in SCI compared to ALS. Spasticity, characterized by increased muscle tone and exaggerated reflexes, is almost twice as frequent and tends to be more severe in SCI than in ALS [24], [25]. This further complicates the design and implementation of assistive devices, necessitating ad-hoc adaptive mechanisms to accommodate this unique challenge.

From a technological standpoint, compared to our previous work [23] we introduced some elements of novelty in the design of the soft actuators with a non negligible impact on the

manufacturing process, see Figure 1. In particular, the inflatable robot now features a single-layer material (thermoplastic polyurethane, TPU, coated nylon) actuation unit. Compared to our previous solution employing a TPU bladder into a textile-based shell, the use of a single material simplifies the manufacture and potentially improves the robustness of the actuator. Moreover, we designed the actuator with a model-based built-in bending angle that increases the contact with the armpit and thus the comfort with respect to a straight structure. Finally, the extremities of the y-shaped actuator have been kept together by a nylon hammock for improved sustain and comfort.

In the rest of the paper, we first introduce these new design elements and provide the new actuator mechanical characterization using a universal material tester. Then we demonstrate its performance in reducing muscle activity in eleven healthy individuals. This is a mandatory step to validate the assistance of the soft wearables before applying it to individuals with physical impairments. Finally, as a proof-of-concept, we focused on measuring immediate improvements attributable to the direct effects of the robot on two individuals with SCI.

II. Materials and Methods

A. Actuation unit

A single-layer inflatable actuator was designed by using a TPU-coated nylon sheet (Ariatex, *DD Global Store*, Italy, thickness 0.3 mm, weight 268 g/m^2, tear strength 2.5 kg warp, 1.5 kg weft). The actuator manufacturing process is shown in Figure 2. The actuator measures about $1l$ of volume. By following similar design principles as in our most recent previous work [23], the actuator has a y-shape to best accommodate the arm in terms of comfort and support. However, in contrast with previous works, the y extremities of the actuator have been kept together by a nylon hammock, which both improves sustain and comfort. When inflating, a straight actuator tends to push away from the armpit, potentially causing a reduction in on-body torque production, discomfort, and making the anchoring to the human body more complex [28], [29]. To address these issues, here we imposed by design a built-in bending angle to the actuator. We derived a simplified model (Equation 1), which was used to estimate the length of a single crease that was then manufactured in one of the layers forming the inflation chamber of the actuator. Multiple shorter creases could be modelled in theory, but for a matter of reducing the difficulty of manufacturing the actuator, we designed a single crease. The simplified model is the following:

$$\Delta l = d \cdot \alpha \cdot c \tag{1}$$

where Δl is the amount of additional material, that is the length of the crease, d is the actuator diameter, α the desired bending angle, and c an empirical coefficient to take care of the material elasticity and the effect of self-folding of the actuator on the opposite side of the bending. In particular, we designed an $\alpha = 45$ degree bending angle that was used throughout this work ($d = 6.4cm, c = 0.7, \Delta l = 3.9cm$). The actuator is anchored to the body through a custom harness in neoprene (Cubic, *DD Global Store*, Italy), with two buckles on the torso and a velcro-based strap on the arm to adjust and fit the wearable to the body. The actuator can be mounted on either the left or the right shoulder. To avoid rupture of the actuator, the maximum pressure for the experiment was set to $70kPa$.

B. Control and sensing

The actuator is automatically controlled in pressure by a custom control box (Figure 3), including two air pumps (SP 622 EC-BL-DUp-DV, *Schwarzer Precision GmbH*, Germany), a miniature 2/2 normally closed solenoid valve for the actuator exhaust (G068A319S1V00F3 ASCO, *Emerson Electric Co.*, USA), a miniature 2/2 normally closed solenoid valve for the pump exhaust (LVM10R3, *SMC Corporation*, Japan), a microcontroller (Feather M4 Express, *Adafruit*, USA), and custom electronics. The portable benchtop control box weighs $2.1kg$, measures $22cm \times 14cm \times 30cm$, and is wall-powered. The actuator is connected to the control box via a 2 m air hose. The microcontroller runs a low-level pressure control loop (bang-bang with hysteresis, acceptable error range $\pm 3.5kPa$) at $200Hz$, measuring the pressure in the actuator via a pressure sensor (ABPDANV060PGAA5, *Honeywell International Inc.*, USA). The pressure set-point is manually set by a researcher via a custom graphical user interface, displaying pressure and data from on-body sensors in real time. The user is equipped with two electromyographic sensors (EMG, SEN0240, *OYMotion Technologies Co.*, Ltd, China) placed on the middle and anterior deltoid, and two inertial measurement units (IMU, BNO055, *Bosch Sensortec GmbH*, Germany) placed on the upper limb and on the torso, to estimate the shoulder elevation angle with respect to the torso and compensating for any torso bending. Data was sampled at $60Hz$.

C. Mechanical characterization protocol

Before human subject testing, we characterized the soft actuator mechanically. In particular, we used a universal material tester (Instron 5965, *Instron Corporation*, USA) with a $1kN$ load cell inline to measure the force profiles at different pressure levels and different actuator angles. In particular, at fixed actuator angles, the pressure was ramped up from $0kPa$ to $77kPa$, at steps of $7kPa$. Angles were changed only when the previous test was finished and ranged between 30 and 120 degrees at a step of 15 degrees. Measurements were taken 3 times per condition, and data averages and standard deviations were presented in the results.

D. Testing population

Eleven healthy individuals (8 M, 3 F, 28.7 ± 3.0 years age, $176.3 \pm 7.2cm$ height, $71.6 \pm 11.5kg$ weight) and two individuals with C4 SCI (1 M, 1 F) participated in the study. One participant had SCI 1 year before the study, the other about 1 month before the study. Detailed information on the testing population is available in Table I. All individuals volunteered to participate in the study and gave informed consent before participating. The study was approved by the Scuola Superiore

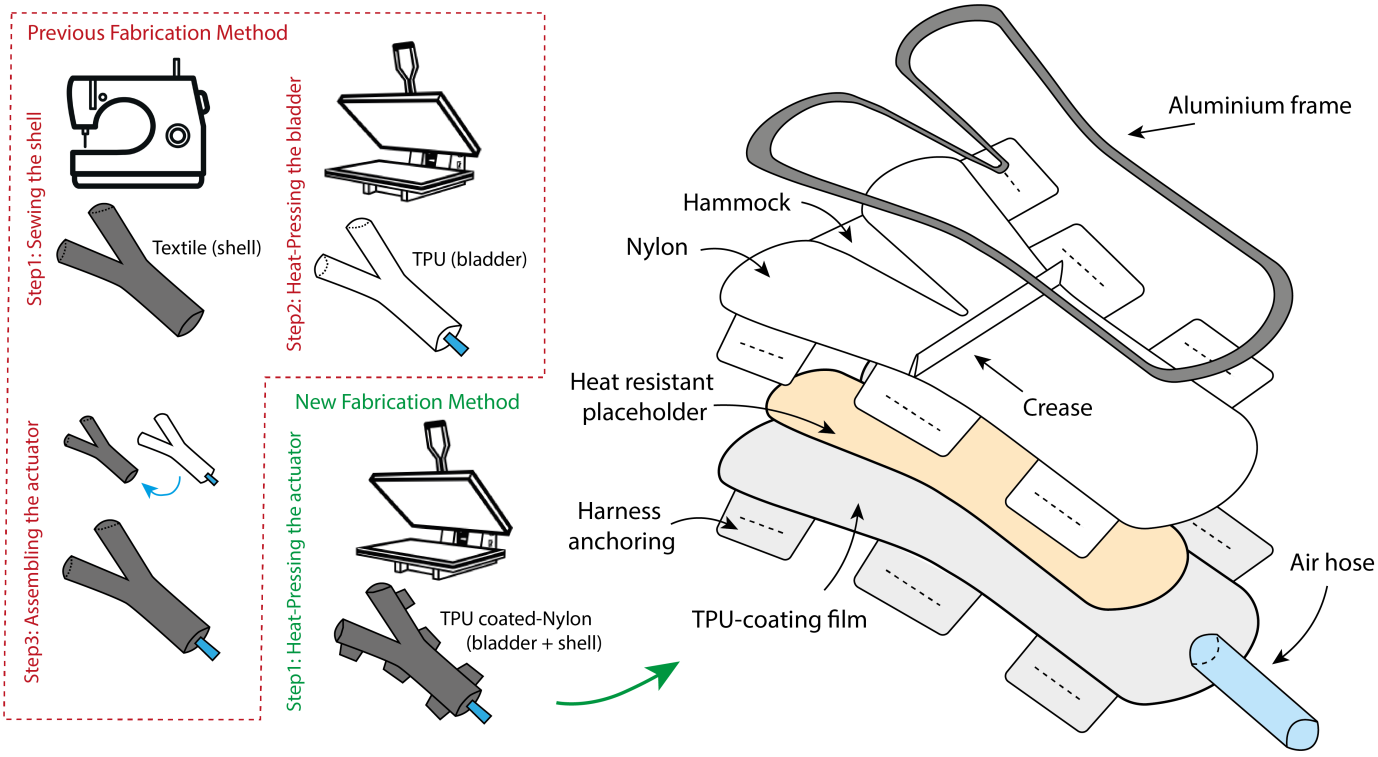

Fig. 2. Soft actuator fabrication process. Compared to the previous method [23], the new method consists of a single heat-press of the new TPU-coated nylon material. This simplifies the fabrication, as it is faster and does not require a skilled sewing machine operator. Moreover, it potentially improves robustness since fewer manufacturing steps mean fewer potential sources of error. On the right, assembly of the soft actuator before the heat press is shown (temperature 170°C, duration 160 s). The aluminum frame (10 mm thick, 5 mm height) helped in controlling the transfer of heat only to the edges of the actuator and was removed at the end of the process. The aluminum frame was placed only on the aligned layers and pressed with the heat press. A heat-resistant placeholder was included to prevent the chamber from melting due to the heat. The crease for bending the actuator was created with a preliminary local heat press step. The air hose was inserted in the chamber once this had cooled down, and it was sealed with a hot air gun that melted and glued the inner TPU coating of the nylon fabric to the hose. Flaps were cut along the dashed line to insert the harness and anchor the actuator to the body.

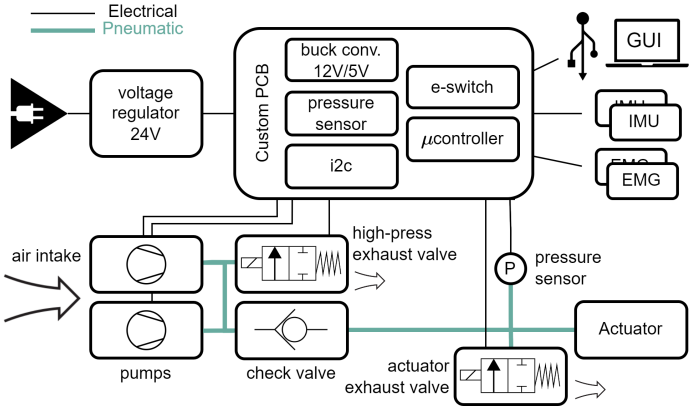

Fig. 3. Electro-mechanical schematic of the control box, supplying pressurized air to the soft actuator and running a low-level pressure control loop. The pressure set-point was manually set by a researcher via a custom graphical user interface, displaying in real-time pressure and data from on-body sensors.

TABLE I
TESTING POPULATION CHARACTERISTICS

	Sex	Age $[years]$	Height $[cm]$	Weight $[kg]$	SCI level	Time from injury $[m]$
P1	M	35	183	95	-	-
P2	M	26	185	71	-	-
P3	M	27	175	75	-	-
P4	F	24	183	65	-	-
P5	M	32	178	80	-	-
P6	F	28	162	53	-	-
P7	M	29	175	70	-	-
P8	M	27	180	70	-	-
P9	M	31	177	76	-	-
P10	M	27	178	80	-	-
P11	F	30	163	53	-	-
P12	F	71	159	45	C4	1
P13	M	25	180	70	C4	12

Sant'Anna Institutional Review Board (IRB) under protocol n. 30/2023, and by the Politecnico of Milan IRB under protocol n. 35/2022. Tests with SCI participants took place at the Spinal Cord Unit, Careggi University Hospital in Florence, Italy.

E. Human subject testing protocol

The testing protocol consisted of 6 consecutive major phases, shown in Figure 4. First, on-body sensors (EMG and

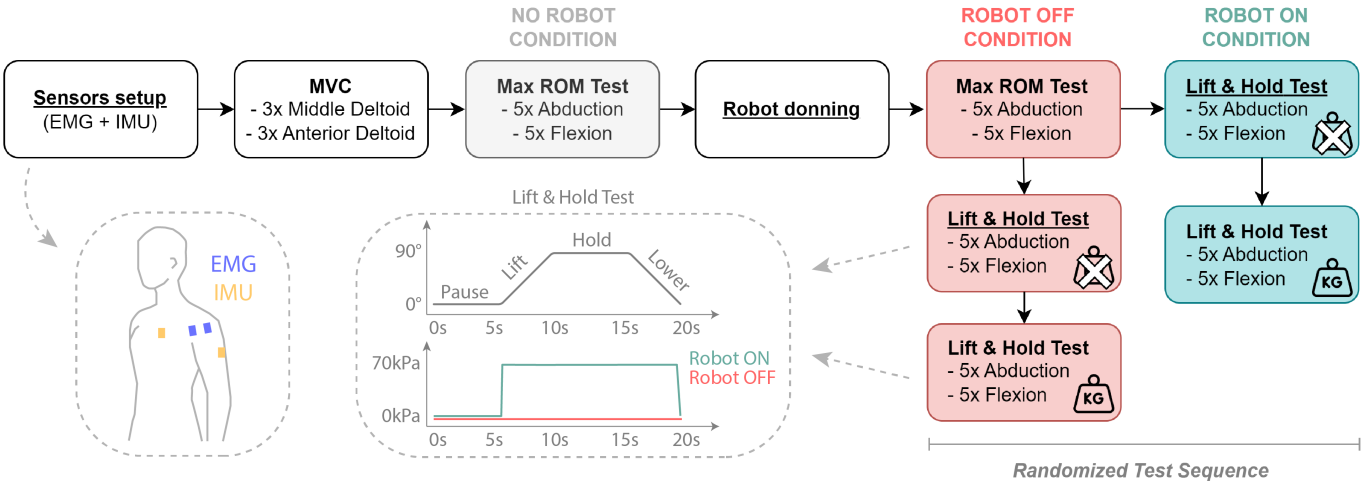

Fig. 4. Human subject testing protocol. The lift and hold test was performed lifting nothing or $2kg$ weight. Participants with SCI only performed blocks of tests indicated by underlined names. MVC = maximum voluntary contraction, EMG = electromyographic sensor, IMU = inertial measurement unit.

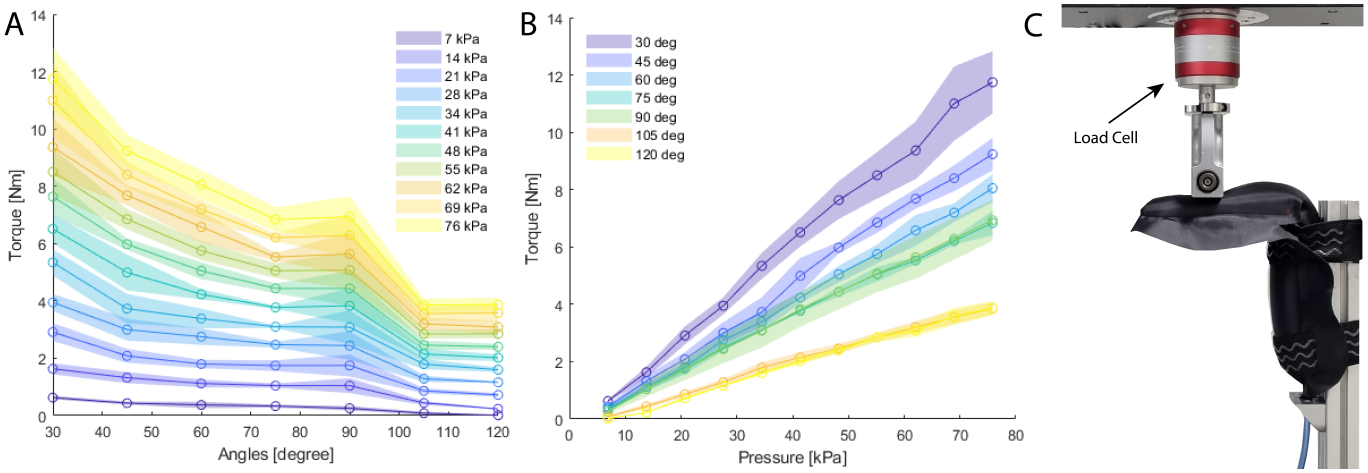

Fig. 5. Soft actuator characterization. As expected, the torque generated by the actuator decreased non-linearly with the angles (A), and increased linearly with the pressure (B). The shaded area represents the standard deviation of the three repetitions. (C) Setup for the measures, with the universal material tester and a $1kN$ load cell.

IMU) were placed and calibrated. Then, a maximum voluntary contraction (MVC) test was performed three times for both the anterior and the middle deltoid. The third phase consisted of a maximum ROM test to assess the robot's transparency. Participants were asked to perform five shoulder abductions and five shoulder flexions to their maximum extent from a rest pose (arm along the body). Then, the robot was donned, while keeping the sensors in place. The fifth phase consisted of the robot off condition. In particular, the maximum ROM test was repeated to compare with the previous condition. Then, a lift and hold test was performed twice while lifting no weight, and while lifting a $2kg$ weight. Participants were asked to perform five shoulder abductions and five shoulder flexions from a rest pose (arm along the body) to 90 degrees. These movements were controlled in time: participants were asked to raise the arm in 5s, hold the 90 degrees position for 5s, lower the arm in 5s, and rest for 5s, in a cycle. Finally, the robot was turned on and manually controlled by a research team member, and the lift and hold tests were repeated. The target pressure of the actuator was set to 70 kPa when inflated. At the end of the procedure, the robot was doffed and feedback from the participants was collected.

F. Data processing

EMG data was processed with standard filtering methodologies: $20Hz - 150Hz$ bass-pass filtering, $50Hz$ notch filtering, rectification (squared), and exponential filtering ($\alpha = 0.03$). For the MVC, the average maximum values for the three repetitions were used. The MVC was used to normalize all the other EMG data, to allow for intra-subject comparison. For the lift and hold test, we segmented sections of the exercise (raise, hold, lower, pause) by using the IMU kinematic data, and gathered dynamic and static phases together. For the static phases, the mean activation over the whole hold phase was considered. For the dynamic phases, the integral of the EMG was instead computed. For the maximum active ROM task, being a dynamic task, we repeated the same processing as before, thus the integral of the EMG. Statistical analysis was

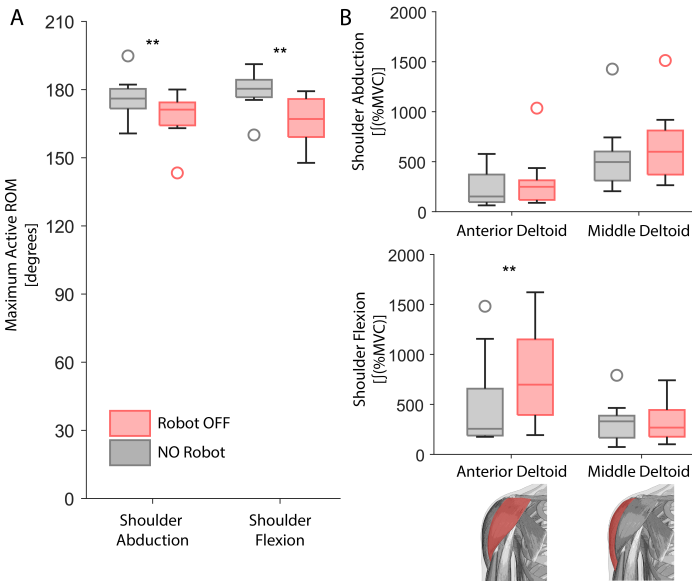

Fig. 6. Transparency tests for the 11 healthy participants. (A) The robot reduced the active ROM (**, $p < 0.01$) only at limit angles, *i.e.* above 170 degrees, while allowing full reachability of the workspace needed for performing common ADLs [30], [31]. (B) When considering the impact of the device on the muscle activity, we observed a significant increase (**, $p < 0.01$) only for the anterior deltoid during shoulder flexion.

carried out to investigate the results' significance. Given the small sample size, a Wilcoxon signed-rank test was used to compare the three conditions. The significance level was reported when exceeding standard p values of significance ($p < 0.05$, marked with a single asterisk *, $p < 0.01$, marked with two asterisks **).

III. Results

Figure 5 shows the characterization curves for the soft actuator after the measures using the universal material tester. In particular, as expected from similar devices in literature [23], [29], we observed a linear relationship between pressure and torque, and a non-linear one between actuator angle and torque, with the latter reducing with the increase of the angle. The values of produced torque are also in line with the literature, with the presented actuator able to produce a maximum of approximately $8Nm$ at 90 degrees and $76kPa$, and over $12Nm$ at 30 degrees.

Regarding the test of robot transparency, the results are shown in Figure 6. In particular, we demonstrated good kinematic transparency (Figure 6.A) with the robot slightly restricting ($p < 0.01$) the maximum ROM for angles only above 170 degrees. From an exertion point of view, in Figure 6.B we only observed a statistically significant increase of muscle activation for the anterior deltoid during shoulder flexion when the robot was worn *vs* when the robot was not worn.

Figure 7 and Figure 8 show the aggregated results for the 11 healthy participants performing the lift and hold test, in the four combinations of weight ($0kg$ *vs* $2kg$), and assistance (robot OFF *vs* robot ON), 5 repetitions per condition. Importantly, Figure 7 presents only the static phases of the test (hold portion), while Figure 8, the dynamic ones (lift and lower). What comes to light is that almost in any condition the support by the robot was able to significantly reduce the muscular activity of the shoulder, at both the anterior and middle deltoid. Results are more marked in the weighted test (46% reduction with respect to the MVC of the middle deltoid during abduction, 41% of the anterior deltoid during flexion, thanks to the robot anti-gravity support), given that for any healthy individual the task of raising their arm is quite low-demanding from a muscular standpoint.

Importantly, the effectiveness of the robot was confirmed when the lift and hold tests were performed by two individuals with SCI. Figure 9 shows the average data and standard error for the five repetitions of tasks for both participants. Interestingly, we observed two distinct effects of the robot assistance for the two participants. For the chronic one (P13) who had good residual control of the limb, it is clearer how the robot reduced the exert (respectively, -45% and -55% of middle deltoid and anterior deltoid activity) while allowing the participant to reach the same shoulder abduction and a slightly higher flexion (+25%). This effect was more similar to the case of healthy individuals and is likely due to the 12 months of rehabilitation and therapy this participant underwent before the test. For the more acute one (P12) who just injured, we did not observe a large muscle activity reduction (actually, an increase of almost 90% was observed for the anterior deltoid) but we did observe the benefit in terms of kinematics, with +79% and +176% increase of ROM for the shoulder abduction and flexion respectively. Given the limited amount of participants, no statistical analysis was performed in this case. Footage of the SCI participants performing the lifting task is available in the Supplementary Material (Video S1).

Considering the dynamics of the actuator which directly impact the performance of the assistance, we measured the inflation and venting times of the robot while assisting the two SCI participants. For the lighter participant (P12), the robot needed $t_{infl} = 4.89s \pm 0.24s$ to inflate, and $t_{vent} = 3.76s \pm 0.75s$ to vent, ranging between 0 kPa and 70 kPa of pressure. For the heavier participant (P13), instead, we reported $t_{infl} = 5.17s \pm 0.44s$ to inflate, and $t_{vent} = 3.55s \pm 0.33s$ to vent.

IV. Discussion

This work demonstrates a soft inflatable robot for assisting the shoulder of individuals with physical impairments due to SCI. Building on our prior experience in supporting individuals with ALS [23], the possibility to assist a distinct neurological condition was not granted due to the inherent differences between these two conditions, among which the different perception of tactile and painful stimuli, and the higher prevalence and increased severity of spasticity in SCI compared to ALS. Moreover, to the authors' knowledge, only Georgarakis *et al.* [20] tested a soft wearable robot for the shoulder for SCI individuals on a single patient. Therefore, this preliminary work represents an important confirmation that a soft approach can be useful for people with this condition too.

We demonstrated that our robot is highly transparent, allowing almost the full natural range of motion while marginally

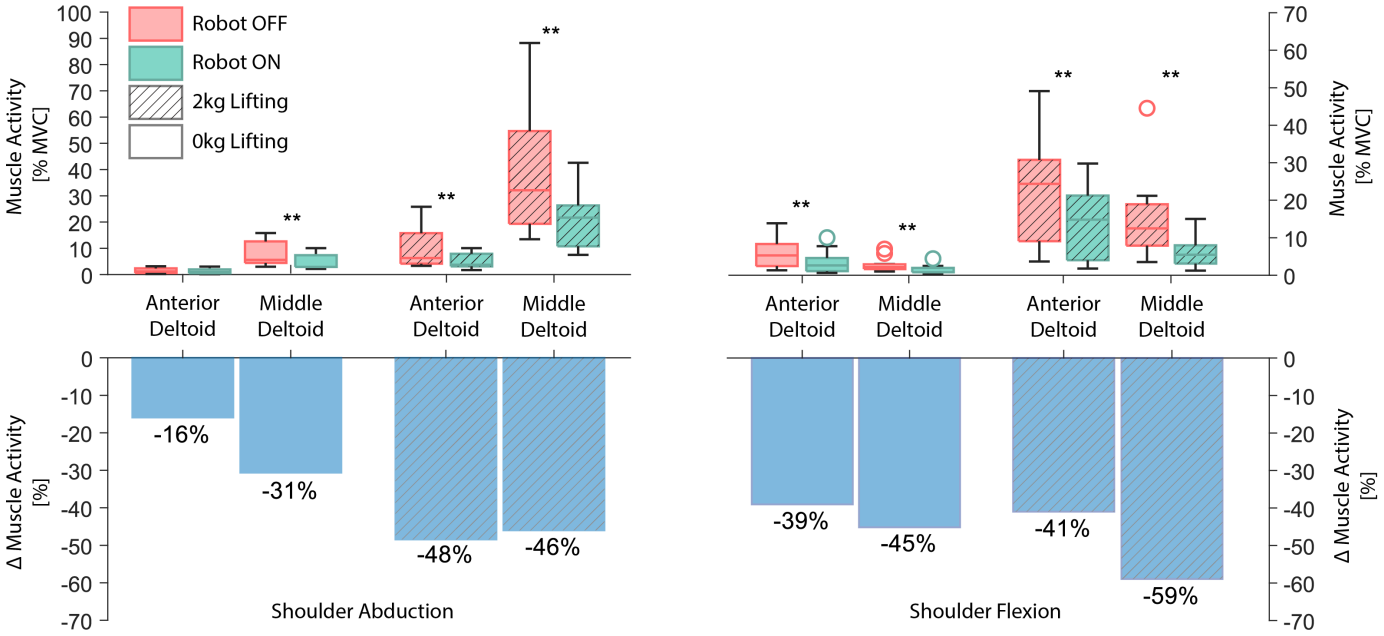

Fig. 7. Lift and hold test for the 11 healthy participants, static phases only. The support by the robot significantly reduced the deltoid activity in any condition but for the anterior deltoid in the offloaded abduction test (**, $p < 0.01$). Top, the boxplot central mark indicates the median, and the bottom and top edges the 25th and 75th percentiles, respectively, for the absolute muscle activity as normalized by the percentage of MVC. Bottom, delta muscle activities (negative values indicate higher reduced activity when the robot was ON *vs* when the robot was OFF) are comparisons between averaged data.

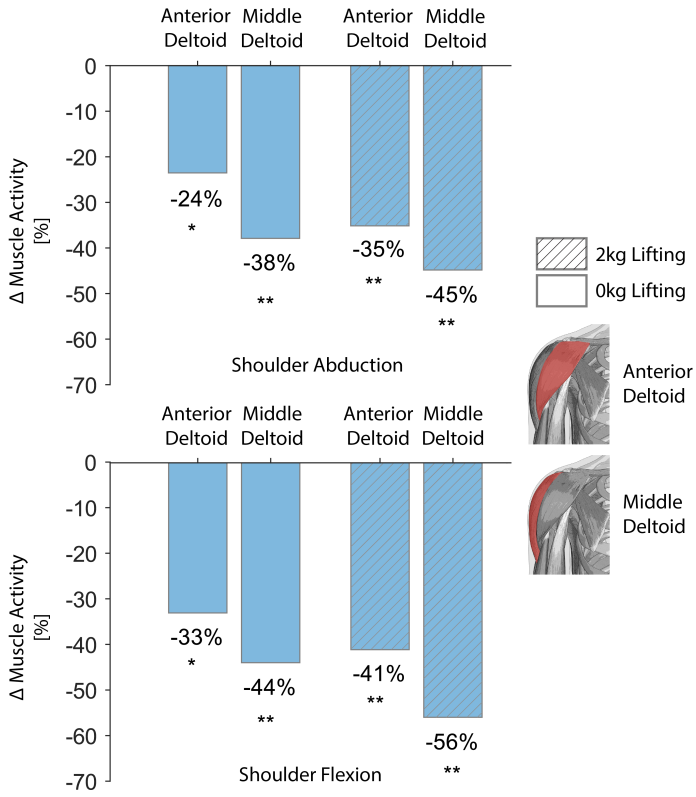

Fig. 8. Lift and hold test for the 11 healthy participants, dynamic phases only. The support by the robot significantly reduced the deltoid activity in all conditions (*, $p < 0.05$, **, $p < 0.01$). Delta muscle activities (negative values indicate higher reduced activity when the robot was ON *vs* when the robot was OFF) are comparisons between averaged data.

increasing the activity of the shoulder (only the anterior deltoid during shoulder flexion was negatively affected). Importantly, it allows full reachability of the workspace needed for performing common ADLs, found to be within 120-130 degrees of elevation [30], [31]. This was possible thanks to the use of soft materials (neoprene for the harness, and coated-TPU nylon for the actuator), mounted on a simplified harness that weighs only 265 grams on the upper body of the user, including the sensors. Interestingly, from qualitative feedback by the participants, the main reason behind the perceived slight limitation to the natural movement was due to the wiring of the sensors around the shoulder (2x IMUs, 2x EMG). If this was confirmed, an easy fix could be done by adopting wireless sensors which will be investigated in future iterations.

The presented new actuator featured three main elements of novelty with respect to our previous and more recent work [23]. 1) We used a new material (TPU-coated nylon) that simplified the manufacturing process of the actuator (no sewing of external textile was needed, thus not requiring an expert sew machine operator, but just a single heat-press process). This in theory could improve the robustness of the actuator as well, given that fewer steps of manufacturing are needed, and thus fewer potential sources of error. 2) We modelled and implemented a crease in one of the two layers of the air chamber to build in a bending angle of 45 degrees. This improved comfort and fit to the armpit. 3) We left a nylon hammock connecting the y extremities of the actuator, again for improved comfort. Despite these modifications, we demonstrated that the actuator was still able to produce approximately $8Nm$ of torque at 90 degrees of angle and about $76kPa$ of pressure in a benchtop test. This value is in line with other measurements of torque available in the literature for actuators of similar volume, using a TPU

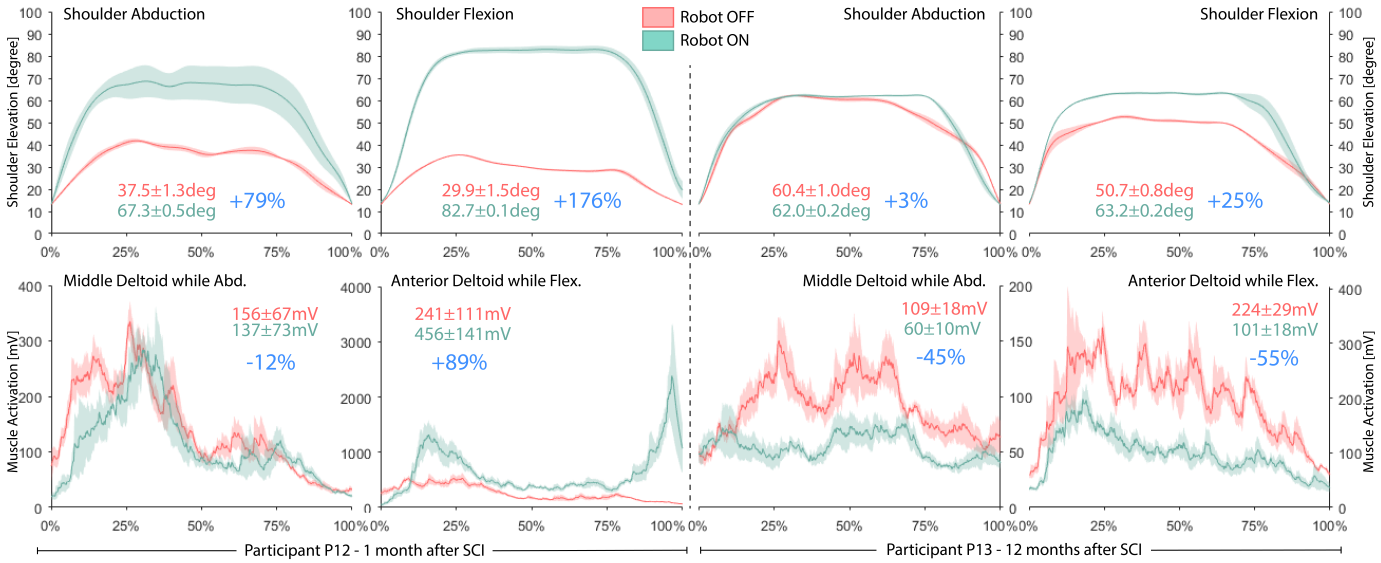

Fig. 9. Lift and hold test for the 2 SCI participants. On the left, participant P12, after only 1 month from the SCI; on the right, participant P13, one year after the SCI. Average raw data over the five repetitions and standard error as shaded area are shown. Generally, we can observe large muscle activity reduction for the chronic participant, in line with the results of the healthy individuals, and larger kinematics improvement for the acute participant, with +79% and +176% increase of ROM in shoulder abduction and flexion respectively.

bladder and a textile shell, with no bending angles, at the same actuator angle and air pressure [23], [29]. The pneumatic actuator required approximately 5 seconds to inflate and 3.6 seconds to vent, as measured on the two SCI participants, with minimal impact from differences in body shape and weight. These dynamics, which may seem slow for healthy individuals, are adequate to assist those with physical impairments, such as SCI. In this population, faster movements may even trigger velocity-dependent spastic reactions, which have, of course, to be avoided. None of the participants reported discomfort while wearing and using the device at the end of the experimentation. However, they interacted with the pneumatic actuator for a limited amount of time. Only after extended use of the robot and the administration of a usability survey, we will be able to properly assess comfort and usability.

While benchtop torque data may differ from on-body measurements [28], the available thrust from the actuator allowed the robot to significantly reduce muscular activity – in particular, of the middle deltoid and the anterior deltoid – during the simple exercise of lifting and holding the arm at 90 degrees of shoulder flexion and shoulder abduction. The reductions reached almost 50% and 60% of the MVC for the anterior deltoid during weighted abduction and the middle deltoid during weighted flexion, respectively. This was demonstrated in 11 healthy individuals and, more importantly, confirmed in 2 individuals with SCI.

Interestingly, we were able to observe two different effects of the anti-gravity action by the robot on the two SCI participants. In particular, the chronic participant who underwent one full year of therapy and regained good control of their limb, showed results similar to the healthy individuals, with large muscle activity reduction. From a ROM point of view, we observed a similar range for shoulder abduction and a +25% in flexion. Instead, the more acute participant, who was injured only one month before the experiment, showed almost no improvement from a muscle activity standpoint, but large positive effects on the kinematics of the shoulder. This is very clear when observing pictures of the test (Figure 10). The difference in maximum assisted shoulder elevation between the two participants (with P12 reaching higher angles than P13) could be attributed to the use of a set pressure for all the participants (70 kPa) and the smaller weight of participant P12. Adjusting the pressure to the specific characteristics of each participant could have increased the level of assistance and will be validated in future work. More interestingly, the improved workspace allowed the participant to perform a simulated drinking task, a simple activity of daily living (Figure 10), a movement that, as stated by the participant, was hardly possible without the support of the soft wearable. While we focused on and assessed the residual shoulder function of the two SCI participants (robot off condition), we did not perform a comprehensive assessment of arm functions, including other joints such as the elbow, or a condition without the robot. Given the results on healthy, the transparency of the robot was not validated on the SCI participants to reduce the burden of experimentation on these fragile individuals. However, positive effects on distal joints (e.g., the elbow flexing with a good range of motion as shown in Figure 10) may have been overlooked in our analysis and will be further investigated in the future.

The difference in the effects of the robot on the two participants and their recovery status should be pointed out. It could open to the use of such a technology, not only to actively support but also to monitor the recovery and tune the therapy accordingly. When compared to traditional rigid robots, on one side soft wearables are limited in the maximum assistance that they can provide. However, on the other side, their key advantages are that of being lightweight and transparent

Fig. 10. Participant P12 performing the lift and hold test in the two conditions, robot OFF *vs* robot ON (top pics). The improved workspace allowed the same participant to drink from a bottle, a task not achievable without the robot (bottom pics).

on-demand [9], [12]. In this preliminary demonstration, we showcased such potential. Looking ahead, we envision these devices evolving into a complementary solution to traditional robotics. This evolution could enable unsupervised therapy beyond clinical settings and facilitate remote monitoring of the therapy itself, thereby significantly impacting the current rehabilitation landscape.

While a large number of investigations on wearable robotics targeted SCI assistance, most of them concerned the support of the lower limb for walking. For this, there already exist studies performed outside of a clinical environment, in the community, as well as commercial solutions [32], [33]. For the upper limb, a recent review found a limited number of studies on active exoskeletons enrolling individuals with SCI [34], while most of the available literature is for stroke rehabilitation [9]. In addition, the authors found the usefulness of current solutions questionable and suggested further research on the long-term effects [34]. Clearly, our promising outcomes are only preliminary and must be confirmed on a larger sample of individuals with SCI, and the limited sample size of SCI participants easily represents the main limitation of the study. The rehabilitative purposes, such as shoulder pain reduction and maintenance or even improvement of residual functional capabilities, were not within the scope of this preliminary study. The aim was to demonstrate the feasibility of using this approach with SCI individuals. Future work will need to investigate and discuss the continuous working capability of our soft wearable solution in the context of longitudinal therapy.

Another limitation of the current setup is the control. All the tests shown in this work were performed with one team member manually and timely triggering the inflation or venting of the robot. The pressure set-point was then automatically tracked by a low-level pressure control loop. Timing the exercise limited the possibility that the researcher affected the rigor of the analysis. However, for future investigation and to target more functional tests (*e.g.*, simulated ADLs or clinical assessment like a box-and-block test), an automatic control strategy, capable of predicting the user intention of movement, will be needed and investigated.

V. Conclusion

This work demonstrates a soft inflatable robot for assisting the shoulder of individuals with physical impairments due to SCI. First, we described the new manufacturing process that resulted from an evolution of our previous experience and could lead to improved robustness. Then, we mechanically characterized our soft actuator, reaching approximately $8Nm$ of torque at 90 degrees at $76kPa$. Third, we showed significant mechanical transparency for the robot, both kinematically and at the muscle level. Then, we demonstrated that such active assistance was able to reduce muscle activity (both at the anterior and the middle deltoid) in 11 healthy individuals during a lift-and-hold task. The promising effects, both from a muscle standpoint and from a kinematics one, were finally confirmed on 2 individuals with SCI and a different recovery

status, an important result given the limited number of SCI individuals who tested a soft robot for the shoulder. Future work will target validation on a larger set of individuals and the implementation of an automatic control strategy to allow for more functional testing. While very preliminary, these results play an important role in the development of future soft wearable technology for assisting individuals who suffered an injury to their spinal cord.

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AUTHOR DISCLOSURE STATEMENT

C.W. is an inventor on U.S. patent application US2022047444A1 filed by Harvard University that describes the inflatable soft robotic components tested in this study.

AUTHORS CONTRIBUTION

Conceptualization: TP, SM, GDP, MG, GR. Software & Hardware: LC, TP. Formal Analysis: LC, TP. Investigation: LC, GD, GS, GR. Writing – Original Draft: TP. Writing – Review & Editing: All. Supervision: TP, SM. Funding Acquisition: SM.

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