Inflatable Soft Wearable Robot for Reducing Therapist Fatigue During Upper Extremity Rehabilitation in Severe Stroke

Ciarán O'Neill, Tommaso Proietti, Kristin Nuckols, Megan E. Clarke, Cameron J. Hohimer, Alison Cloutier, David J. Lin, and Conor J. Walsh

***Abstract*—Intense therapy is a key factor to improve rehabilitation outcomes. However, when performing rehabilitative stretching with the upper limb of stroke survivors, therapist fatigue is often the limiting factor for the number of repetitions per session. In this work we present an inflatable soft wearable robot aimed at improving severe stroke rehabilitation by reducing therapist fatigue during upper extremity stretching. The device consists of a textile-based inflatable actuator anchored to the torso and arm via functional apparel. Upon inflation, the device creates a moment of force about the glenohumeral joint to counteract effects of gravity and assist in elevating the arm. During a device-assisted (i.e. inflated) standard stretching protocol with a therapist, we showed increased range of motion across five stroke survivors, and reduced muscular activity and cardiac effort by the therapist, when comparing to a vented device condition. Our results demonstrate the potential for this technology to assist a therapist during upper extremity rehabilitation exercises and future studies will explore its impact on increasing dose and intensity of therapy delivered in a given session, with the goal of improving rehabilitation outcomes.**

***Index Terms*—Soft robot applications, rehabilitation robotics, wearable robotics.**

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I. Introduction

APPROXIMATELY 800,000 people suffer a stroke each year in the United States, equivalent to a stroke every 40 seconds [1]. This high frequency rate together with the negative effects of stroke on the human body are among the reasons why stroke is also one of the leading causes of serious acquired long-term disability [2]. There are over 7 million stroke survivors in the United States at present, and two-thirds of this population are currently disabled with projections showing that by 2030 an additional 3.4 million US adults aged $\geq$18 years will have survived a stroke [3].

Rehabilitation robotics is, therefore, an emerging field of research using robots to help caregivers during rehabilitation therapy in hospitals and rehabilitation centers. The key features of rehabilitation robots are their ability to impose high intensity, measurable and repeatable motions to humans, to present real-time biofeedback to the user, therapist, or caregiver, and the capability of improving engagement through virtual reality or gaming applications [4]. However, the provisional idea of improving current outcomes of traditional rehabilitation by introducing this technology into clinics is still under discussion [5]. One theory for the limited outcome of previously studied rehabilitation robotics is the insufficient time spent doing robot-assisted therapy [6].

Up to two thirds of stroke survivors have difficulty using their arm in everyday life [7], but when evaluating robots developed to assist post-stroke upper extremity disability, we observe that:

- most of the available prototypes and commercial products are rigid exoskeletons [8],
- there has been, in general poor clinical evaluation of these devices ($<30\%$ of prototypes was tested on stroke patients) [9],
- available technology is limited to large scale clinical settings, not capable of at-home or out-patient assistance [8].

The last issue is particularly crucial since easily portable devices could open the field of robot assisted therapy to out-patient clinics and allow for at-home rehabilitation followed by a caregiver, considerably increasing the dose of therapy provided and realizing the potential of traditional rehabilitation through robotics. Soft wearable robots may be well suited for this task as they are normally lightweight, inherently compliant, and relatively inexpensive to manufacture. Recently some examples of assistive soft wearable robot prototypes for the shoulder, mostly cable-driven, appeared in the literature [10]–[13]. To date, the primary outcome of these studies was a decrease of selected muscle activity on healthy participants when performing activities assisted by the robots. None of these shoulder devices have yet published results evaluating their robots when assisting stroke survivors, though several soft robotic devices targeting hand rehabilitation have been evaluated in clinical populations (e.g. in spinal muscular atrophy [14], in stroke survivors [15], in spinal cord injuries [16]).

Apart from their portability enabling at-home rehabilitation, soft wearable robots have other inherent features that may be desirable for clinical or at-home rehabilitation. For example, due to their apparel-based design, a therapist, caregiver or the stroke survivor themselves can directly manipulate the device and adjust its placement on the arm to improve the device/limb coupling. The natural lightweight and compliant characteristics of these devices allow for their use with a wide range of environments and patients (with or without wheelchair or any other additional external devices). Finally, soft robots cannot achieve full-passive control of the human limb due to their under-actuated nature and intrinsic flexibility: however this is actually desirable for rehabilitation as engagement and active participation of the stroke survivor are key factors for improving functional outcomes [17].

During upper-extremity rehabilitation sessions aimed at motor restoration, stroke survivors are performing roughly 30 movement repetitions per hour, most likely due to real or perceived fatigue by the patient or the clinician [18]. While there are clearly differences between human and animal neurological recovery, in animals studies investigating how motor skill learning alters cortical representation, several hundreds repetitions were required per hour to effect change [18]. As such, it is well accepted that intense therapy is a key factor and has been shown to improve rehabilitation outcomes [19]. By reducing the fatigue of the clinician or a caregiver we aim to augment the intensity and number of repetitions provided during a session, resulting in improved rehabilitation of stroke survivors [6]. Another critical component of rehabilitation is stretching of the paretic limb. Stretching has multiple benefits, from increasing the range-of-motion of the target joints, to reducing tone and spasticity of the limbs and the possibility of reducing pain. When stretching more distal paretic joints, therapists must support more proximal joints to maximize the effects of the stretching and to counter any flexor synergy. This limb management is challenging and fatiguing as a therapist must compensate for the weight of the limb and any inherent tone, while still stretching the target joint. Therapists typically utilize support surfaces (hard ones like tables or soft ones like pillow or beds) while stretching patients to reduce their fatigue.

To address this problem, we work with an updated version of a shoulder-assisting inflatable soft wearable robot, originally presented in [20], that is now aimed at improving severe stroke rehabilitation by reducing therapist fatigue during upper extremity stretching. The robotic device consists of a textile-based inflatable actuator anchored to the torso and arm via functional apparel. Upon inflation, the device creates a moment of force about the glenohumeral joint to counteract the effects of gravity and assist in elevating the arm. Our hypothesis is that by reducing the primary load on the paretic arm, (1) the same number of arm repetitions can be achieved with reduced effort from the therapist and/or caregiver as measured by muscle activity and heart rate, and (2) the arm can be stretched more effectively. Indeed stretching can be more focused on the distal joints, which are generally more difficult to stretch sufficiently as the therapist has to actively support the weight of the upper arm with one hand, while performing the stretch with the other. Moreover, the benefits of a wearable device to aide in shoulder movement over the current standard of care include increased flexibility and scope of therapy that can be provided (i.e. not limited to lying supine bolstered with pillows or seated with the arm laying on table), promotion of natural movement patterns, and the option to transition to home-based activities to increase repetition and carryover of therapeutic treatments.

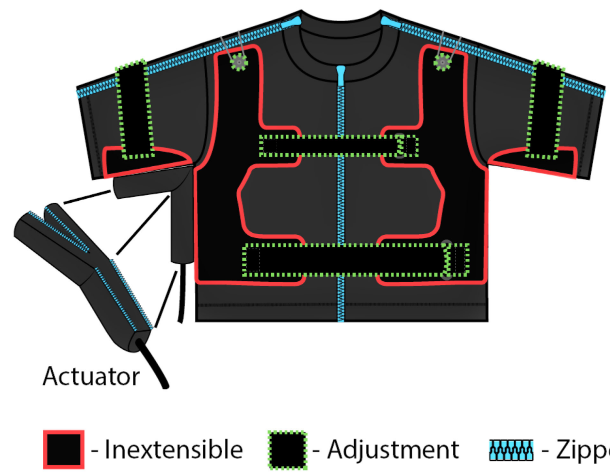

Fig. 1. Principle elements of the soft wearable robot and inflatable bifurcated actuator. The actuator can be anchored in either armpit using the zippers integrated into the functional apparel. Inextensible elements in the apparel are used for actuator anchoring and force transmission around the torso. Zippers along the top of the sleeves help with donning the robot around the paretic limb.

II. Device Design

A textile-based wearable robot was designed and fabricated to provide assistance to motions against gravity of the paretic upper limb of a stroke survivor. Fig. 1 shows the wearable robot which consists of a pneumatically powered inflatable textile-based actuator, coupled to functional apparel for anchoring to the body using select inextensible elements and zippers.

The inextensible components of the functional apparel distribute the forces of actuation around both shoulders, securing the actuator tightly to the axilla. The single inflatable actuator can be zipped to either side of the wearer, allowing for assistance of the paretic limb of the stroke survivor. This method allowed us to reduce the number of garments fabricated in the lab for testing purposes. Moreover the inextensible elements are mounted on an extensible base layer which minimize restriction to a wearer's range of motion and improve the comfort of the device when compared to our previous work [20].

The addition of zippers along the top of both sleeves aids in donning of the robot, in particular on the paretic limb of

Fig. 2. Soft wearable robot worn by a person. The bifurcated actuator cradles the anterior and posterior of the arm, distributing the forces and stably locating the arm between both chambers.

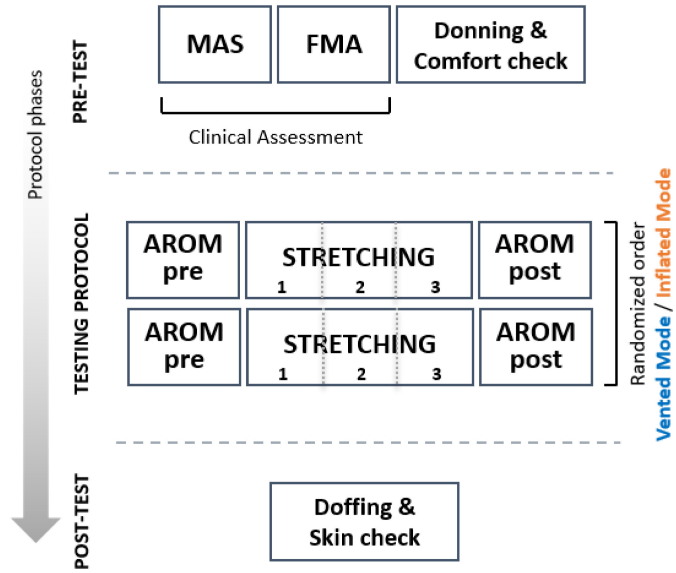

Fig. 3. Protocol phases. The two test conditions (inflated and vented device) were randomized among subjects. MAS = Modified Ashworth Scale, FMA = Fugl-Meyer Assessment, AROM = Active Range Of Motion (Shoulder Abduction and Shoulder Flexion), Stretching = 3×8 cycles of 45 s of stretching followed by 15 s of rest (Str. #1 = Shoulder Flexion, Str. #2 = Elbow Extension, Str. #3 = Wrist and Finger Extension). Donning time is about 90 s.

stroke survivors, and a single zipper is included along the front. Once the robot is donned, the fit of the device can be adjusted at six locations across the shoulder, arm, back and torso through some velcro-based inextensible elements, to align the actuator with the shoulder joint and upper arm. Due to the limits of adjustment, multiple wearable devices were created to ensure the best fit over the range of participant sizes. Starting with a size medium device, extra-small, small and large versions of the functional apparel were graded using standard industrial methods. Additional zippers (#5, YKK, Japan) are sewn onto the inextensible elements to couple the actuator to the wearer.

The inflatable actuator provides the necessary forces for shoulder gravity compensation, pushing the arm up against gravity. The end of the actuator that contacts the upper arm is bifurcated, forming a cradle which the arm rests in, see Fig. 2. This increases the comfort and stability of the arm on the actuator over our previous version which balanced the arm atop a cylindrical actuator. The bifurcated actuator was designed to generate a maximum of 16 Nm at 90 degrees of shoulder abduction and 136 kPa. This allows the actuator to provide complete gravity compensation(10–14 Nm based on size) [21] at 90 degrees of shoulder abduction, however during this study that magnitude of gravity compensation was set to 50%.

The device is externally powered and controlled by a manual pneumatic supply. The supply is connected to a compressor or shop air, and is comprised of a pressure regulator (4963K32, McMaster-Carr, USA) and several 3-2 manual valves (62475K41, McMaster-Carr, USA). For the current version of the device, inflation and deflation were manually controlled by a research team member in time with the therapist's movements.

III. Methodology

A. Protocol Description

In order to evaluate the potential of the device to assist in rehabilitation, we performed a study consisting of two separate visits, spaced one to two weeks apart. Participants with self-reported severe motor deficits and a minimum of 6 months post stroke were contacted, screened and subsequently enrolled if suitable. This study was approved by the Harvard Medical School Institutional Review Board under protocol IRB13-3418.

An initial study visit allowed for a secondary screening of participants post-enrollment and familiarization with the device and the various phases of the protocol. On the second visit, instead, the formal protocol was conducted. A schematic diagram of the several consecutive phases of the protocol is presented in Fig. 3. Upon arrival, informed consent was obtained before the spasticity of the participant was assessed using the Modified Ashworth Scale (MAS) by a certified Occupational Therapist (OT) in our team, with score of $>= 3$ disqualifying the participant from the study, as a score of 4 indicates severe rigidity or immobility of the limb. Spasticity was assessed at the shoulder (abductors, flexors, int./ext. rotation), elbow (flexors and extensors) and at wrist and finger extensors. The Upper Extremity Fugl-Meyer Assessment (FMA-UE) was performed to characterize the severity of the motor impairment (reflexes were excluded, maximum score = 60). FMA-UE scores lower than 31 were characterized as severe and enrolled in the study. Stroke survivors with a Fugl-Meyer score higher than 31 are likely to have better control of the proximal arm and instead possess challenges with distal arm function (wrist, hand, finger control) or coordination. Once participant eligibility had been determined, they donned an appropriately-sized robot (donning time of about 90 s). The alignment of the robot and the comfort for the participant was then fine-tuned and secured as necessary.

The pressure required to provide 50% gravity compensation at 90 degrees of shoulder abduction was determined using a simple calibration procedure. The paretic arm of the participant was supported with a dynamometer (MircoFET 2, Hoggan Scientific Inc., USA) on a tripod to measure the effective mass of the arm. The actuator was slowly pressurized until the mass of the arm

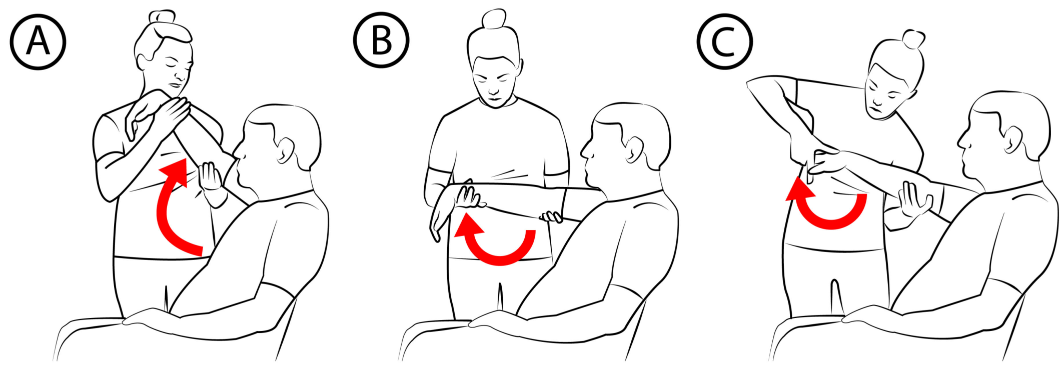

Fig. 4. The three stretching exercises: A) Shoulder Flexion, B) Elbow Extension, C) Wrist and Finger Extension. The stretching exercises build upon one another, continuing to stretch more proximal joints if they are present, i.e. the OT is performing partial shoulder flexion while extending the elbow (B), and the OT is performing both partial shoulder flexion and elbow extension while stretching the wrist and finger extensors (C). To provide these partial stretches, the OT must use their proximal arm, with the distal arm focused on the distal joint stretching.

registered on the dynamometer was reduced by half, and this pressure was used throughout the visit.

The testing protocol consisted of several steps under two separate conditions (vented mode and inflated mode), with the order of conditions randomized for each visit. Before stretching began, the participant's shoulder Active Range Of Motion (AROM) was assessed, both on the paretic and non-paretic sides to determine a baseline ROM. The participant was first instructed to maximally abduct their upper arm and hold for 3 seconds, repeating 5 times. The static hold instruction was given to avoid ballistic artifacts in the measurement of the ROM itself. The participant was then instructed to repeat this test with maximal shoulder flexion. The therapist did not assist the stroke individual during ROM.

The stretching phase of the protocol was comprised of three different bouts of stretches, each building upon the previous and targeting a more distal joint, as seen in Fig. 4. Participants were instructed to remain passive and allow the therapist to administer the stretching. During each bout, the stretch was held 8 times for 45 s with a 15 s rest between stretches before moving onto the next bout. The first stretch of the first bout targeted shoulder elevation, the second bout targeted elbow extension in addition to shoulder elevation, while the third bout added stretching of the extension of wrist and fingers. A 60s rest was allowed between bouts. Upon completion of the stretching phase, a second ROM assessment was performed (ROM-post). Again, the therapist did not assist the stroke individual during ROM assessment. Following a 5 minute break, the testing was repeated under the alternative test condition. Finally, after doffing the device, a check for skin redness was carried out. For the second study visit, the order of the test conditions was reversed, with all phases of the protocol repeated and metrics recorded for analysis.

B. Metrics & Expected Outcomes

To measure the effect of the participant arm partial gravity compensation on the therapist, the muscular activity of the therapist was measured at 2 kHz using surface ElectroMyoGraphy (sEMG) sensors (Trigno Avanti, Delsys, USA). Five muscles were measured on each side of the therapist: Trapezius Descendens, Biceps Brachii, Deltoideus Medius, Erector Spinae and Finger Flexors. Sensor placement was determined

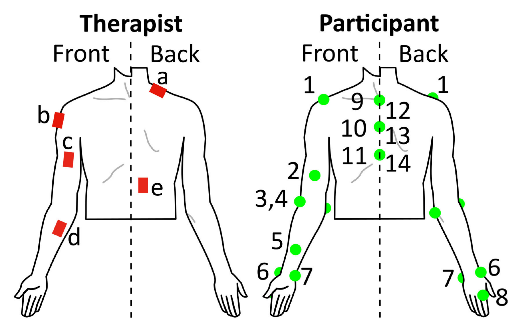

Fig. 5. sEMG sensor (red) placement on therapist and tracking marker (green) placement on participant per Table I.

according to SENIAM recommendations for each of the targeted muscles [22]. Muscle activation of the targeted muscles was expected to decrease when assistance was provided.

As a proxy for the metabolic savings provided by the participant partial arm support during therapist administered exercises, the heart rate of the therapist was measured using a heart rate monitor (OH1+, Polar, Finland). The mean cardiac activity was additionally expressed in an amount of calories saved during the testing protocol by using equations in [23]. It was expected that average heart rate would decrease when assistance was provided, which is correlated with lower energy expenditure [24].

Finally, the participant's shoulder range of motion was measured at 100 Hz using motion capture (Qualsys, Sweden). 22 tracking markers were placed on across the torso and upper limbs of the participant as depicted in Fig. 5. When assisted by the inflatable device, the shoulder ROM of the wearer in both abduction and flexion was expected to increase with respect to the baseline condition (vented mode), and slightly increase further after stretching.

Table I describes sEMG sensors placement on the therapist as well as motion capture markers position on the stroke participant body.

C. Data Processing

Motion capture data is processed in Visual 3D (C-Motion Inc., USA), with raw marker locations filtered with a 6 Hz, zero-lag, 4th order Butterworth low pass filter before joint angles and rotations are calculated according to the ISB recommendations

TABLE I
MOCAP MARKER (1–14) AND sEMG SENSORS (A–E) PLACEMENT

	ID #	Anatomical Location	ID #	Anatomical Location
Participant	1*	Acromion	8*	Index MCP
	2*	Mid-Biceps	9	Clavicular Notch
	3*	Lateral Epicondyle	10	Mid-Sternum
	4*	Medial Epicondyle	11	Xiphoid Process
	5*	Mid-Forearm	12	C7
	6*	Radial Styloid	13	Mid C7-T10
	7*	Ulnar Styloid	14	T10
OT	a*	Trapezius Descendens	d*	Finger Flexors
	b*	Deltoideus Medius	e*	Erector Spinae
	c*	Biceps Brachii		

*denotes usage on both sides.

for joint orientations and rotation order [25]. The resulting joint angle and velocity data were exported and further processed in MATLAB (Mathworks, USA). The EMG data was first bandpass filtered (4th order, 10–400Hz), then rectified before passing through a final low pass filter (4th order, 10 Hz) [26]. Shoulder ROM was measured as the greatest ROM sustained for 2 seconds of the target 3 second hold, during each condition (inflated and vented) and compared to contralateral measurement.

Stroke participant upper limb elevation was used to segment sEMG data into the active and rest periods of the stretching. The mean muscle activation of the therapist for each active stretch was calculated and aggregated to determine the mean activation for each bout of stretching. Muscle activation during rest was not included as the device provides no assistance. These muscle activations were normalized by the peak activation (maximum 100 ms mean of muscle activation) observed during testing for each individual muscle to allow for comparison between visits.

Therapist heart rate was first normalized using their resting heart rate (2 minutes seated) and the estimated Maximum Heart Rate (MHR $=$ 208 BPM $-$ 0.7 $\times$ age, [27]) before averaging over each bout of stretching. Both active and rest periods were included to reflect how a normal therapy session would be conducted. The well-studied relationship between heart rate and calorie consumption [23] allowed for calculation of the calories consumed through each bout of stretching.

A paired-samples t-test was conducted to compare the specific metrics (therapist muscular activity and heart rate, stroke participant shoulder ROM) in vented mode and inflated mode conditions. Significance level is reported when exceeding standard p values of significance ($p < 0.05$, marked with single asterisk *) and high significance ($p < 0.01$, double asterisk **), after a post-hoc power analysis (required power $= 0.80$, effect size using Cohen's criteria).

IV. RESULTS

A. Participant Population

Five ambulatory stroke survivors (4 male, 1 female) with severe arm impairments were enrolled in this study, with an average modified FMA-UE (excluding reflexes) of 17.2 ± 5.8 and an average MAS of 1.7 ± 0.85 during the second visit. The average age of the participants was 54 ± 14.4 years, with an average time post stroke of 4.6 ± 3.4 years. Three participants had right-side hemiparesis. Average participant weight was 83.0 ± 19.4 kg.

B. Metrics Outcome: Muscular Activity

Fig. 6 shows the comparative results of the stretching exercises performed in the two testing conditions (vented and inflated), averaged over the 5 participants. Generally, the presence of assistance from the device reduced the activity of muscles on both the distal and proximal arm of the therapist (where proximal indicates the closest arm of the therapist to the impaired shoulder of the participant, and distal the farthest), over all 5 selected muscles. After paired-samples t-test on individual participant data (statistical analysis of each stretching, 8 cycles per stretching), 64% of the vented-inflated comparison displayed statistically significant EMG reductions in inflated condition (49% $p < 0.01$). However, when applying paired-sample t-test on averaged data from the 5 participants, the reduction during the inflated condition with respect to vented condition was statistically significant in fewer cases (20%, marked with asterisks in Fig. 6).

C. Metrics Outcome: Heart Rate

When considering metabolic savings and heart rate, general reduction in cardiac activity was observed among the three stretching exercises. Fig. 7 shows the average delta in heart rate of the therapist between vented and inflated conditions, normalized as explained in section III-C, over the entire testing population. During stretch #3, in particular, almost 9% heart rate reduction was achieved (Vented $= 85.0 \pm 4.7$ bpm, Inflated $= 74.4 \pm 4.4$ bpm), due to the ability of the device to support the paretic limb in place of the therapist. Fig. 7 also shows the mean power savings (in $\mathrm{cal/kg/min}$) measured during the 3 stretching sessions over the 5 stroke participants. When considering a 50 kg female therapist (as in our case), the amount of energy saved during 8 minutes of stretching #3 was over 10 kCal which would extrapolate to a savings of over 275 kCal per day, based on 20–30 minutes of stretching per session, 8–10 sessions per day.

D. Metrics Outcome: ROM

Fig. 8 shows stroke participants averaged shoulder abduction and shoulder flexion ROM in two phases of the protocol (pre- and post-stretching) and in several conditions (contralateral – i.e. the non-affected side–vented mode and inflated mode). As noted in Section III-A, the therapist did not assist the stroke individual during ROM. As expected, the immediate effect of using the robotic device with 50% gravity compensation is that we can provide more than 10 degrees of improvement in ROM on both abduction and flexion, in the absence of training effects or learning by the stroke subject. Due to the severe condition of the sample stroke population, however, we are still far from the reaching non-affected arm capability and the effect of stretching is negligible in both inflated and vented conditions, when comparing pre- and post-ROM, which is expected for a single stretching session.

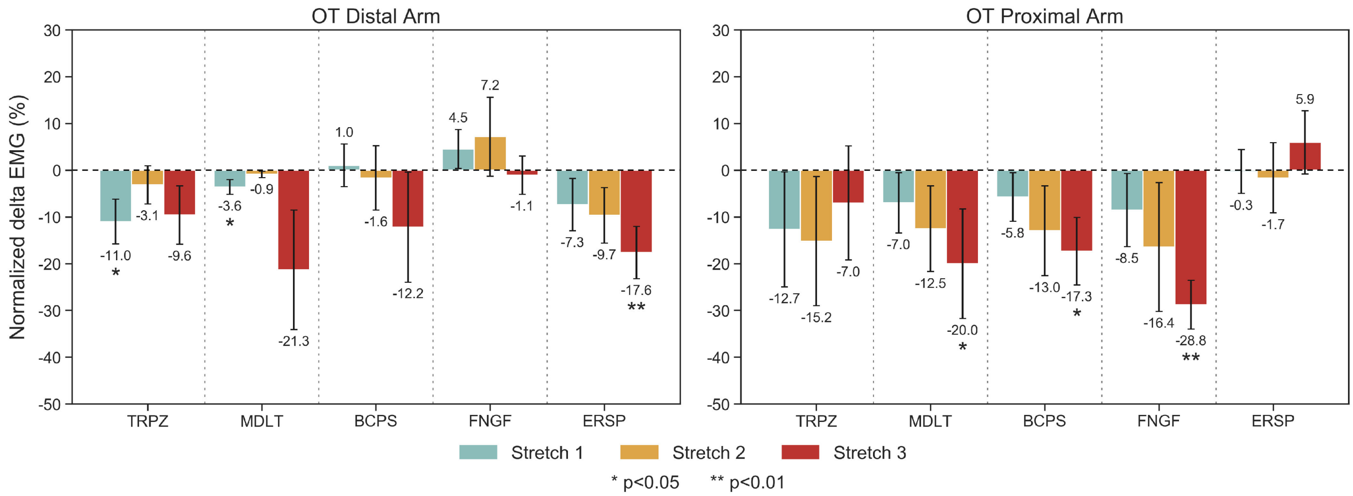

Fig. 6. Change in normalized therapist muscular activity with and without the assistance by the robotic device, averaged over the testing population. Negative values indicates reduction of muscular activity with the inflated device versus the vented device. Error bars represent standard deviations. Numbers are the mean value of the bar plot. TRPZ = Trapezius Descendens, MDLT = Deltoideus Medius, BCPS = Biceps Brachii, FNGF = Finger Flexors, ERSP = Erector Spinae.

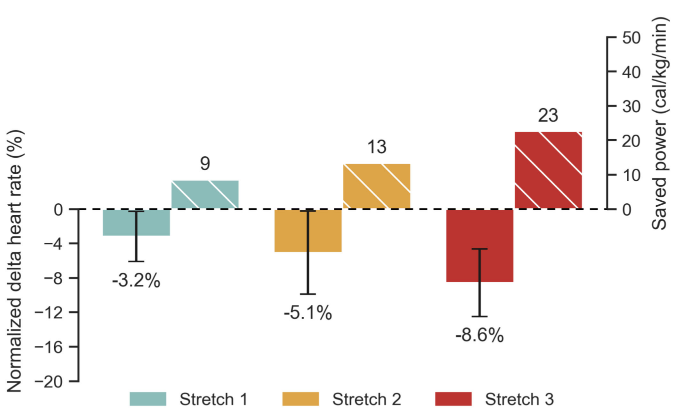

Fig. 7. Left axis: normalized therapist heart rate comparison with and without the assistance by the robotic device, averaged over the 5 stroke participants. Negative values indicates reduction of heart rate in inflated versus vented. Right axis: saved power in calories/kg/min corresponding to normalized mean delta heart rate.

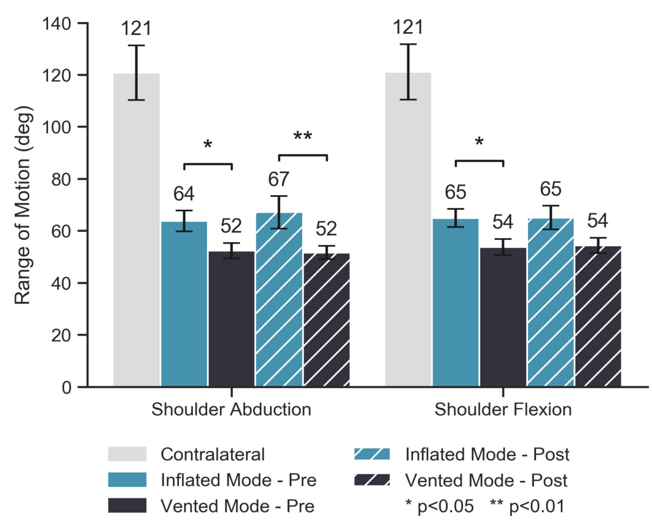

Fig. 8. Shoulder ROM results in three conditions – inflated, vented and contralateral (the non-affected side) – in two phases of the protocol (pre- and post-stretching). Results are averaged over the five stroke participants.

E. Comfort Considerations

Participants did not report or exhibit any signs of discomfort or pain during the testing protocol due to the worn device, and no test visits were interrupted due to discomfort or device failure. After doffing the device, no redness of the participant's skin was found by the therapist.

V. Discussion

We present an inflatable wearable robot to assist with therapist-performed stretching exercises on stroke survivors by supporting the paretic upper arm against gravity, and evaluate the robot impact on both the participant ROM and the therapist fatigue (through heart rate and sEMG measurements) in a study with five stroke survivors.

As hypothesized at the beginning of the study, we were able to show reduced muscular activity and heart rate of the therapist when the stretching was assisted by the device. Widespread significance was observed when assessing multiple repetitions of the individual stroke participants between both conditions (inflated versus vented). However, statistical significance was not met when averaging results over the entire sample population, in our opinion mainly due to the small size of this population (only 5 sample subjects) combined with the large variability in spasticity ($\pm$0.85 for MAS) and in weight ($\pm$19.4 kg) of our sample population.

Interestingly, we observed that, when using the device to support upper limb elevation, the therapist naturally modified the way they provided the stretching as shown in Fig. 9 for the wrist/finger extension stretching exercise (stretch #3). The distal arm was less involved in support of the paretic limb but rather assisting with the stretching of the distal joint, limiting

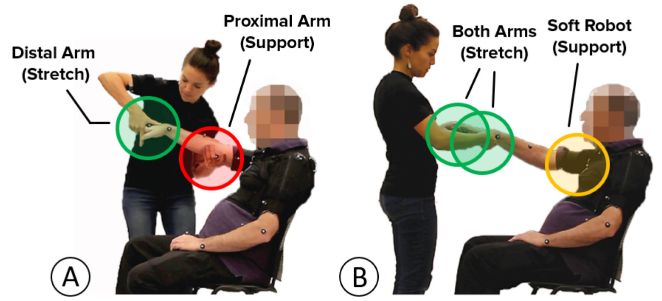

Fig. 9. Example of stretch #3, comparing vented to inflated. When assistance by the robotic device was off, the therapist used her left hand to support the paretic arm against gravity (A). Only the right hand was involved in performing distal joint stretching. Instead, when assisted by the device (B), the therapist was able to provide a different and more distal joint focused stretching with both hands, leaving the whole limb support effort to the robot.

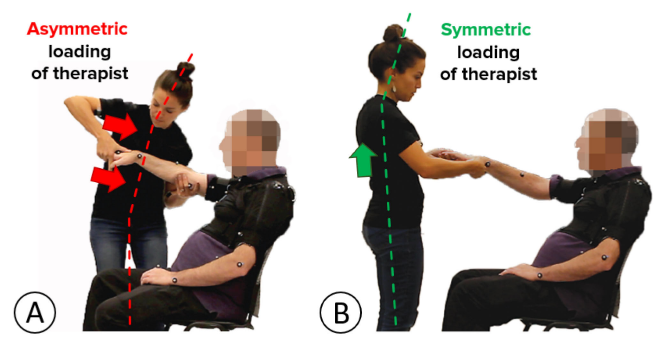

Fig. 10. Example of stretch #3, comparing vented to inflated. When assistance by the robotic device was off, the therapist leant towards the paretic limb to support the weight of the limb (A). This action results in an increase in muscular activity in the distal Erector Spinae, which contracts to balance the lean. When assisted, the therapist no longer leant towards the paretic limb, more uniformly loading the Erector Spinae on both sides (B).

the benefit to this arm from the presence of the robot. The assistance from the device helped the therapist focus more on the distal stretching by releasing her from providing upper arm gravity support, which is represented as higher activity of the Biceps Brachii and Finger Flexors on the OT distal arm, as shown in Fig. 6. The response of the Erector Spinae on both sides is also indicative of the change in approach to stretching by the therapist. Without assistance, the therapist leans towards the paretic limb to support the weight of the limb, as shown in Fig. 10. This action results in an increase in muscular activity in the distal Erector Spinae, which contracts to balance the lean. When assisted, the therapist no longer leans towards the paretic limb, more uniformly loading the Erector Spinae on both sides, which manifests itself as an increase in the proximal side which was formerly not activated. This improved symmetry of loading when assisted may further help reduce the fatigue of therapist during therapy sessions more than an overall reduction in activation. Both the change in the way the stretching was provided and the immediate effects to the participants were hard to quantify (a video of this specific exercise – stretch #3 – is available in the supplementary material). However, this change could improve stretching outcomes given additional training sessions as the therapist may apply the therapy with both hands, leaving the gravity compensation support of the arm to the robot. Future work will need to assess if wrist and fingers ROM may also benefit from this condition with respect to the traditional "one-handed" therapy.

Heart rate reduction could be expressed in terms of energy saving as potentially 275 kCal on an average work day for our therapist (female, 50 kg). This reduction, together with the decrease in muscular activity, indicates that for the same therapist effort, the outcome of the rehabilitation itself could be improved. This would be due to increased intensity of therapy and number of repetition possible during a standard therapy session when assisted by our soft wearable device, as suggested by [18]. In the future, we will need to confirm this possibility on a longer training session and by involving multiple therapists to confirm these promising outcomes. Indeed, one limitation of our study is that results come all from a single therapist in our team.

Stroke participants range of motion was also improved by the immediate use of the device, resulting in >10 degrees improvements on both shoulder abduction and flexion. These improvements could be magnified by increasing the level of gravity compensation by increasing air pressure in the actuator (for this study it was set to provide a 50% shoulder gravity compensation). We were unable to observe significant pre- vs. post-stretching improvement in ROM but this was expected due to the severity of the condition of our participants and the length of the total stretching. Again, a future investigation will involve a training study on multiple days to observe learning effect and could yield improved results.

VI. Conclusion

We presented one of the first evaluations of an inflatable soft wearable robot on a clinical population and the effects the device had on the therapy provided. With assistance from the wearable device, 5 stroke survivors immediately improved their shoulder ROM and a therapist providing rehabilitative stretching expended less muscular and cardiac effort, showing the potential to reduce fatigue in a session or even enabling an increase in the dose of therapy delivered in a given session. With repeated, consistent use in an acute stroke population, the increased intensity of rehabilitation enabled by such a device may improve the outcomes of rehabilitation. Furthermore the simple stretching routine demonstrated in this research study could be used as the precursor to movement facilitation by the therapist to the subject, followed by attempts at real-life activities with the paretic arm. This is an advantage of this technology compared to standard care because if the subject has to be seated with the arm propped up on a table for support (as usually occurring during rehabilitation therapy), the options for attempts at motor recovery and real-life task training are very limited. A wearable device providing gravity compensation could allow the therapist to use his or her hands to facilitate movement, gesture or provide balance support while the subject reaches into a cabinet, closes a door, or turns on a light switch using the paretic arm.

Future work will focus on expansion of the existing protocol to include multiple therapists and a larger cohort of stroke survivors, in both lab and clinical settings, to further validate our hypotheses. If this validation is successful, the use of our wearable device could also be expanded to higher functioning chronic stroke survivors to assist in functional motions during rehabilitation. This shoulder assistance device was designed to be part of a larger suite of wearable devices that, in future works, would assist additional joints of the arm, including the elbow and hand, appropriate for stroke survivors with very little active movement. Methods of on-board, automatic control of inflation and deflation will also be investigated in future works, for both individual device control and coordination between joints.

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