User-Driven Functional Movement Training with a Wearable Hand Robot after Stroke

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Abstract—We studied the performance of a robotic orthosis designed to assist the paretic hand after stroke. This orthosis is designed to be wearable and fully user-controlled, allowing it to serve two possible roles: as a rehabilitation device, designed to be integrated in device-mediated rehabilitation exercises to improve performance of the affected upper limb without device assistance; or as an assistive device, designed to be integrated into daily wear to improve performance of the affected limb with grasping tasks. We present the clinical outcomes of a study designed as a feasibility test for these hypotheses. 11 participants with chronic stroke engaged in a month-long training protocol using the orthosis. Individuals were evaluated using standard outcome measures, both with and without orthosis assistance. Fugl-Meyer scores (unassisted) showed improvement focused specifically at the distal joints of the upper limb, and Action Research Arm Test (ARAT) scores (unassisted) also showed a positive trend. These results suggest the possibility of using our orthosis as a rehabilitative device for the hand. Assisted ARAT and Box and Block Test scores showed that the device can function in an assistive role for participants with minimal functional use of their hand at baseline. We believe these results highlight the potential for wearable and user-driven robotic hand orthoses to extend the use and training of the affected upper limb after stroke.

Index Terms—Wearable Robotics, Rehabilitation Robotics, Hand Orthosis, Stroke Rehabilitation, Intent Detection.

I. INTRODUCTION

STROKE is the leading cause of physical disability in the United States [1], and hemiparesis of the upper limb (UL) is a common and debilitating complication after stroke [2]. Outcomes are frequently poor despite conventional rehabilitation treatment: about half of stroke patients with UL hemiparesis regain functional use [3]. There is growing evidence demonstrating that high quality, highly repetitive, and task-specific training is beneficial in UL recovery after stroke [4], [5], [6]. However, there are a number of practical barriers that impede many chronic stroke patients from receiving this type of rehabilitation program, for reasons that include logistical and geographical barriers of visiting therapy clinics, insurance and reimbursement limitations, and insufficient availability of therapists with specialized training [7].

This work was supported in part by the National Science Foundation under grant IIS-1526960 (part of the National Robotics Initiative).

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Aiming to help address this need, we have designed and built a wearable hand orthosis which enables grasp patterns by providing mechanical assistance for finger extension. To

A number of robotic devices have been designed to address the need for increased UL repetitions for post-stroke rehabilitation [8]. However, these largely focus on proximal segments of the UL (i.e. shoulder and elbow), and produce improved functional gains mostly in the proximal joints [9], [10], [11]. This disparity of motor recovery between proximal and distal joints (i.e. wrist and fingers) can lead to undesirable compensatory grasp patterns which make long-term rehabilitation more complicated and often ineffective [12]. In contrast, recent work has found that distal joints outcomes are improved more when subjects receive robotic support directly to the distal joints rather than to the proximal joints [13]. However, wearable active assistance for the hand is complicated by the limited space available for the necessary motor and transmission components, and by the complex anatomy and kinesiology of the hand. These difficulties have led to the current lack of functional prototypes for wearable hand robots used and assessed with clinical outcomes [14].

Fig. 1. Top : Exotendon device and EMG armband. Bottom : Functional movement training with a wearable hand orthosis.
address many practical and anatomical challenges of hand robot designs, the device utilizes underactuation mechanisms through tendon networks, which require few and small anchoring structures for wearability [13]. The anchoring structures are designed to provide effective force transmission, in order to overcome hand spasticity while using low motor forces [16]. This design allows functional hand movement using a small actuator while also preventing distal migration, an undesirable phenomenon where the motor components of the device slide down the forearm towards the hand due to the applied forces.

An important goal of our work is to enable user-driven operation: our device is designed to infer the intent of the patient, and provide active assistance for finger extension only when the intent to open the hand is detected. Similarly, the device releases and allows the fingers to flex when the intent to close the hand is detected. To achieve this, we rely on two different methods to infer user intent, each based on a different sensing modality. The first approach uses forearm Electromyography (EMG). The patient simply attempts to open the affected hand; this intent is detected based on EMG data processed through a pattern recognition algorithm [17], and used to trigger extension assistance. Our algorithm enables the use of a consumer-grade commodity EMG armband and does not require exact placement of the sensors. Our second intent inferral method introduced in this study is intended for subjects where the EMG-based method described above does not prove reliable enough for long-term operation. In such cases, we utilize unaffected shoulder movements to trigger motor commands. The patient can signal the intent to open the affected hand via contralateral shoulder depression, which we detect via a stretch sensor mounted on a shoulder harness.

Our previous studies have established the basic operation principles of the device: in limited case series with stroke survivors, we have shown that our exotendon network can enable finger flexion and extension [15], that we can provide this assistance via small, wearable motors relying on effective force transmission mechanisms [16], and that, for a subset of patients, we can infer the intent to open and close the hand when the orthosis is used in conjunction with a commodity EMG armband [17]. However, the clinical performance of this device, and the importance of training effects over longer-term use have not been investigated to date.

In this study, we focus on the performance of our active hand orthosis as a rehabilitation device and as an assistive device. We present clinical outcomes from a 12-session training program for each participant, consisting of 3 sessions per week for 4 weeks. Each session lasted one hour and involved 30 minutes of active training time in which participants practiced a variety of grasp and release tasks with everyday objects to simulate Activities of Daily Living (ADLs). Eleven subjects with chronic stroke completed the protocol and were evaluated with a battery of clinical assessments pre and post-intervention: Fugl Meyer (FM) - UL, Action Research Arm Test (ARAT), and Box and Block Test (BBT).

In order to determine the efficacy of the orthosis as a rehabilitative device, we compare clinical outcomes both pre- and post-intervention without the device assistance. To distinguish between recovery throughout the entire UL and more localized improvement of the distal segments, we subdivide FM into shoulder/elbow (FM-proximal) and wrist/hand (FM-distal). To determine efficacy when used as an assistive device, we compare baseline performance pre-intervention against post-intervention performance while wearing the device. Our goal is to determine if increased competence in using the device, due to a month-long training program, leads to increased performance in tasks requiring grasp, transport, and release of objects while wearing the orthosis. We examine the assistive capability through ARAT and BBT scores measured while the users are wearing the robot. Finally, we compare performance for our two intent inferral methods, namely EMG and shoulder harness controls, used to drive the hand device during both training and post-testing.

Overall, the main contributions of this paper are:

- To the best of our knowledge, it is the first time an active wearable hand robot has been employed to support user-driven functional hand exercises for chronic stroke patients interacting with real-world objects.
- FM subsection scores suggest that intensive hand functional exercises using our robot improve motor function in distal segments on the UL.
- Scores of BBT and subsection of ARAT highlight the potential for the assistive capability of the device for stroke patients with lower functional use of their UL.

Our overall aim for this work is to provide fully wearable, user-driven assistance for the stroke-affected hand, and to investigate its effects on both rehabilitation and functional performance. These are steps towards our directional goal of user-operated active orthoses used outside of a clinical setting, for rehabilitation or home-assistance, with the potential to significantly increase the number of motor repetitions and the intensity of training.

II. RELATED WORK

In the past, the main focus of numerous robotic UL rehabilitation devices has been on the shoulder and elbow. This type of device provides repetitive UL exercises through large exoskeletal workstations. The Armeo Power by Hocoma, Inc., perhaps the most advanced off-the-shelf UL training tool, allows gravity and weight offset support to enable training using games and functional movement in a simulated environment. A study with 35 enrolled ischemic stroke patients showed improvement of motor function after 40, hour-long training sessions [11]. The MIT-MANUS robotic system is another example of commercially available training tool for UL motor recovery [9]. In extensive randomized, controlled clinical trials involving 127 chronic stroke patients, robot-assisted therapy outperforms human-delivered usual care and provides similar benefit with intensive treatment by therapist for motor performance after 36 weeks of training. A wrist module has been attached to the robot in addition to the original shoulder and elbow support, and showed promising clinical outcomes [18]. Even though these studies offer some support that a robotic rehabilitative treatment can be effective in motor recovery of the UL, improvement is only reported for proximal segments. Therefore these subjects may still
experience functional limitations as it is difficult to complete most ADLs without improvement in the UL distal segments.

Due to the highly complex movements of the hand as well as broad spectrum of possible impairment patterns seen in stroke patients, it is only recently that robotic devices for hand rehabilitation have been proposed [14]. The Amadeo is one of the very few robotic workstations for hand rehabilitation on the market [19]. Results of a randomized controlled trial found superior outcomes in subacute stage stroke rehabilitation after 40 session with at least 300 repetitions per training session [20]. However, workstation devices are often bulky, costly, and tethered to a clinical setup, requiring extensive supervision by health care providers. Wearable robots, by contrast, promise to enable use outside the hospital which would in turn provide a greater number of repetitions of functional tasks in context. Therefore, this type of robot has become a focus of recent research in robot-assisted rehabilitation [21]. To facilitate these benefits, we focus on wearable hand devices in this work, though in this early pilot stage, the device is utilized in a clinical environment with staff supervision.

Traditional wearable hand robots in the early stage are mostly exoskeleton comprised of rigid links [22]. However, such devices are difficult to align axes of biological and robotic joints. A soft pneumatic actuator based orthosis can be an alternative as it provides safe human-robotic interaction thanks to natural compliance and flexibility. Polygerinos et al. have developed a pneumatic powered glove that are inexpensive, low-profile, and well adapted to complex finger movement [23] although untethering from air pressure sources can be challenging for complete portability. A wearable hand device can also take the form of supernumerary robotic finger to provide assistive benefits for practical use of the affected UL [24].

For intuitive and user-driven control of a wearable hand device, there have been research works to develop wearable sensors. Multichannel EMG with wireless communication can be built within a wearable package [25], and this type of sensor allows intuitive control using a pattern recognition algorithm [17]. A low-profile and portable glove with various sensors, such as DAGLOVE [26], can also allow use of a pattern recognition utilizing multimodal sensor data. Multimodal intent detection can provide better accuracy for stroke patients compared to the performance of the algorithm that uses a single modality, such as EMG [27].

Among many hand rehabilitation tools [22], [28], [14], a subset have been supported by clinical evidence for chronic stroke patients. The PneuGlove facilitates manipulation activities in virtual reality (VR) and with real-world objects [29]. In a VR mode, the virtual object determines the level of extension for each finger and a therapist controls the device in the real environment. In a pilot study of 14 subjects (7 robot and 7 control), significant improvements were observed in FM, BBT, and grip strength. Hand of Hope has also demonstrated the efficacy of robot-assisted training through a pilot study with 19 stroke patients [30]. Both robot and control group improved significantly in ARAT, FM-proximal, and Wolf Motor Function Test (WMFT) after 20 session training. In particular, improvements in robot group were superior to the control group on the WMFT functional tasks sub-scale. A number of passive devices have also been proposed and validated [31], [32], [33], with the advantage of being simpler to operate for unsupervised therapy. However, given that patients with hemiparesis may exhibit severe muscle weakness in grip strength [34], even lower level of mechanical interference with finger flexion via passive mechanisms can adversely affect hand functionality.

While the majority of devices aim to demonstrate clinical effectiveness as a rehabilitative training tool, some others aim to develop an assistive device for immediate assisted functional gains. Yurkewich et al. have designed a glove based hand orthosis iteratively with occupational therapists and stroke survivors [35]. The device uses either an inertial measurement unit on the forearm or a simple button to control. Three chronic and two acute stroke patients achieved improvements in modified BBT, range of motion of the fingers, and a water bottle task in CAHAI. The other device is the Myomo which is a portable elbow-wrist-hand orthosis controlled by EMG. With the Myomo, 18 chronic stroke survivors achieved immediate and significant UL improvements as confirmed by FM, BBT, and a battery of functional tasks [36]. In terms of intent detection for assistive robots, a mathematical formulation and algorithm can potentially help improve functionality of users with motor impairment [37]. However, these devices have not been tested for long-term use for ADLs. We believe it is important for wearable devices to demonstrate their robustness such that users can complete clinical sessions, and eventually use the device unsupervised at home. In this work, we investigate the feasibility of our hand robot through a clinical protocol to evaluate its strengths and limitations, both as a rehabilitative intervention and as an assistive device.

III. An Active Hand Orthosis for Stroke Patients

One of the most common impairment patterns after stroke is a combination of weakness, spasticity, and poor coordination in the hand, which often results in a flexor synergy pattern and functional disuse. Many stroke survivors may be able to actively flex their fingers in order to form a gross grasp, but are unable to volitionally extend their fingers to release the grasp. After months or years with an involuntary flexed resting hand position, patients may develop more spasticity or even muscular shortening, making finger extension and functional use of the hand even more difficult to achieve.
A. Exotendon Device

In order to address these limitations and provide finger extension for manipulation tasks, we have developed an exotendon device (Fig. 1 - top). The device consists of a rigid forearm splint on which an actuator is mounted, along with 3D printed distal components for the fingers. The splint constrains wrist movement, thus allowing motor force to be transmitted through cable routes to the fingers. The 3D printed fingertip components (Fig. 2 - right) are secured on the dorsal side with Velcro strapped around each finger. The main role of these components is to increase the tendon moment arms around the proximal interphalangeal (PIP) joints throughout the entire range of motion, so that the motor force is more effectively applied to the digits. Also, this component mechanically prevents hyper-extension of the distal interphalangeal (DIP) joint to avoid any injury. Similarly, the distal portion of the fingertip component creates a mechanical block that prevents hyper-extension at the metacarpophalangeal (MCP) joints.

The main role of the orthosis is to provide assistance for finger extension (hand opening). As size and weight are of critical importance for building a wearable device, we rely on a heavily underactuated design: a single motor provides assistance for extending all the digits except the thumb. When we detect the wearer’s intent to open the hand (as detailed in the next subsection), the actuator retracts, applying extension torques to the digit joints via the exotendon network. Conversely, when we detect the intent to close the hand, the motor extends and relaxes the forces in the tendon network, allowing the digits to flex. We rely on the patient being able to generate sufficient finger flexion torques, which is common for the impairment pattern we focus on. Throughout this study, we use a PID position control to drive the motor, and the range of motion is determined at the beginning of protocol depending on the size of the user’s hand. Extension or retraction of the motor takes approximately 1.8 seconds.

The natural movements of the thumb are complex and distinct from the other digits [38]. In addition to flexion/extension and abduction/adduction, the thumb moves in opposition to the other digits, which is a critically important motion for grasping and pinching. In order to ensure that the thumb is in an approximation of opposition, we use two passive cable routes, one for extension-flexion and another for abduction-adduction (Fig. 2 - left). The tensions of these two cables are calibrated at the beginning of each session and are fixed for the duration of the session. The thumb is thus not actively assisted by the orthosis, but rather statically splinted into opposition for the duration of the protocol, as seen previously in the literature [59]. We have found this procedure to enable grasping while reducing the load on the actuator, which must only assist the remaining digits. For future designs, we plan to also investigate the addition of one or more actuators in order to provide independent thumb actuation.

B. Intent Detection

Our goal for this robotic device is for the patient to initiate robotic assistance, by signaling the intent to open the hand (at which point the motor retracts providing assistance for finger extension), or to close (at which point the motor extends, allowing the fingers to flex). We provide two methods for detecting the intent of the patient, and compare them here.

1) Intent Detection via Ipsilateral EMG Signals: The first method utilizes ipsilateral forearm surface EMG signals to detect the patient’s intent as the patient attempts to close the affected hand. If such a method can be realized, it has appealing characteristics: it is highly intuitive (the patient simply attempts to open/close the hand as needed for the task), and could facilitate neuroplasticity as it closes sensorimotor loop on the impaired UL. In this study, we use an EMG-based intent inferral method that we have introduced previously [17], [27], and shown to be able to assist hand opening and closing. This approach relies on a pattern recognition algorithm to detect user intention based on data collected by commercial armband (Myo by Thalmic Labs) equipped with eight EMG sensors, and does not require precise sensor placement.

While previous work has shown that intuitive control is indeed possible, it has also highlighted a number of challenges. EMG signals are inherently abnormal in patients with hemiparesis and can be distorted by spasticity and fatigue [40], [41]. As a result, when working with stroke patients while engaged in functional tasks, we found our current EMG-based intent detection method to be effective only for a subset of patients.

2) Intent Detection via Contralateral Shoulder Movement: To account for this phenomenon, we introduce here a second intent inferral method, using contralateral shoulder movement. This approach, often used for body powered UL prostheses [42], provides a more robust control compared to EMG, as it relies on the unaffected side. Additionally, compared to other non-EMG control methods, such as a button switch [43], it enables bimanual tasks since the unaffected hand is free. However, this approach has the disadvantage of requiring the patient to engage in additional movement (elevating the contralateral shoulder) with the only purpose of providing a signal for our device. Such movement can be unintuitive, and of limited rehabilitative value.

In our work, a shoulder harness is worn on the unimpaired UL and used to detect shoulder movement. When shoulder depression is detected, the device retracts to trigger hand opening through finger extension (Fig. 3). Conversely, when shoulder elevation (shrug) is detected, the device extends to allow hand closure via finger flexion. A load cell (Futek, FSH00097) is installed in series with a suspender to measure the tension in the harness, and an extension spring which eases discomfort caused by the tension connects a belt and the suspender. Two different thresholds on the load cell signal are used to detect shoulder elevation and depression in order to prevent unnecessary motor oscillation. The thresholds are manually calibrated at the beginning of each session. In the rest of this study, we will refer to this intent inferral method as SH, shorthand for shoulder harness.

The main advantage of the contralateral SH intent inferral method over EMG is its robustness to differences in impairment patterns, since it relies exclusively on the unimpaired side. Still, we believe that the potential advantages of ipsilateral EMG control (more intuitive motor commands, closing the loop on the affected side) outweigh the SH robustness.
advantage, as long as EMG control is applicable. In consequence, we chose not to randomly assign intent detection methods for clinical intervention. Instead, users are assigned to use EMG method as long as it can correctly detect intention during a control screening, which we describe in section IV-C. Otherwise, users are assigned to the SH group.

IV. CLINICAL INTERVENTION

In order to evaluate our active hand orthosis, we performed a clinical study aiming to quantify its performance as either a rehabilitative or assistive device. The three main characteristics of the study included the following. First, each training session consisted of user-controlled functional interaction with everyday objects and simulated ADLs. This is intended to emulate use of the impaired UL outside of clinical settings, which is our directional goal for the project. Second, each patient underwent 12 one-hour training sessions, distributed over the course of one month. The relatively large number of sessions (compared to our previous feasibility studies) was required both to study rehabilitative effects, and to allow patients to develop familiarity with the device and its controls, in order to quantify performance as an assistive device. Third, our outcome measures post-intervention included clinical assessments performed both assisted (with the device on, in order to study assistive performance) and unassisted (without the device, in order to study rehabilitation effects). Results were compared to baseline measures without using the device. We present the details of our clinical intervention next.

A. Participants

Total twelve community-dwelling individuals with chronic stroke volunteered to participate in the study and met inclusion criteria. Inclusion criteria were:

- Stroke diagnosis at least 6 months prior to start of study
- Passive range of motion: Wrist to neutral, Digits within normal limits
- Moderate muscle tone, i.e., Modified Ashworth Scale (MAS) <2 in digits, wrist, and elbow
- Active Range of Motion: At least 30 degrees shoulder flexion, 20 degrees shoulder abduction, 20 degrees elbow flexion, finger flexion within functional limits
- Strength: At least trace finger extension
- Able to successfully flex the fingers to form a grasp
- Unable to extend the fingers fully without assistance
- Intact cognition to provide informed consent

Exclusion criteria were:

- Concurrent participation in another study
- Comorbid orthopedic condition/pain limiting functional use of the impaired upper extremity
- History or neurological disorder other than stroke
- Excessive spasticity (Greater than 2 on the MAS)
- Recent Botox injection to the affected limb (< 13 weeks)

Some participants had prior experience with the exotendon device in varying capacities, but not within 6 months before start of the protocol. All subjects gave informed consent to participate and the protocol was approved by the Columbia University-Irving Medical Center Institutional Review Board. The trial was registered on ClinicalTrials.gov (NCT03767894). All training and testing sessions were performed under the supervision of an occupational or physical therapist.

B. Outcome Measures

All clinical assessments were performed by an occupational therapist who was not involved in the training protocol, though blinding was not possible in this study design. For all testing sessions, the MAS was performed first since other measurement tools can cause fatigue, which can impact muscle tone and spasticity. After the MAS, the FM, ARAT, and BBT, were administered in a randomized order to limit order effect. FM is an impairment level measure of body structures that evaluates reflexes, motor function, and joint range of motion of the UL [44]. ARAT is an activity level assessment that involves specific grasp, grip, pinch, and gross motor tasks for the UL [45], and BBT is an activity level assessment that tests unilateral pinch and manual dexterity in a timed manner [46].

Participants completed two days for post-testing after completing the 12 training sessions to evaluate both rehabilitative and assistive effects of the device. One post-testing session involved administration of the FM, ARAT, and BBT without robotic-assistance, while the other session involved administration of the ARAT and BBT with robotic assistance. The order
of post-testing days was also randomized. The FM was only performed at post-testing without robotic assistance because the FM assesses capacity of the arm primarily through gross motor tasks, and comparatively few grasping and pinching tasks. We thus presumed that robotic assistance would have minimal influence on FM scores.

Post-testing without the device assesses motor recovery after robot-assisted training whereas post-testing with robotic-assistance evaluates the assistive aspects of the device. We assumed that the proposed intent detection methods, particularly EMG-based, will take time for users to learn, so the clinical assessments are performed after 12 training sessions in order to allow competent use of the device.

FM and ARAT can be sub-scaled. The FM has two sub-scales: FM-proximal evaluates the shoulder and elbow, while FM-distal evaluates the wrist and hand. The ARAT has 4 sub-scales: grasp, grip, pinch, and gross movement. In addition to total scores, we were interested in evaluating grasp components as those are our targeted areas of intervention. To determine statistical significance, we provided p-values for gains from the paired sample t-test between baseline and post-testing scores, in both conditions as applicable. Statistical significance was determined at \( p < 0.05 \).

C. Protocol

After participating in the informed consent process, all participants were screened for inclusion. Those who were included then performed baseline measurements during pre-testing as described previously. During the next screening visit, each participant was fitted with the exotendon device and was screened with the EMG classifier to determine which control method they would use for the duration of the study. During the control screening, the user was trained with the EMG method and was asked to open, relax, and close their hand three times each, with the forearm on and off the table. If our EMG method was able to classify the user intention correctly under all conditions, the user was assigned to the EMG group. Otherwise, the participant was assigned to the SH group.

We allowed the use of a mobile arm support for participants who were clinically observed to have significant difficulty performing the training protocol even with frequent rest. Criteria for use of the mobile arm support included weakness (2-/5 to 3-/5 muscle grades for elbow flexion and shoulder flexion, abduction, and rotation) and significant fatigue limiting functional performance as observed by the therapist. The participants that met these criteria used the arm support for the duration of training sessions at a set level of support.

Next, each participant completed 12 training sessions, three times per week for four weeks. Each training session was between 60-90 minutes including time for set up, system classification, donning/doffing the device, and rest breaks as needed. Participants completed 30 minutes of active training during each visit. Training followed a protocol that involved massed practice of pick and place tasks with a variety of everyday objects of different shapes and sizes to encourage varied grasp and pinch patterns (Fig. 4). Simulated ADLs included tasks that required bimanual manipulation and/or sustained grasp. If participants completed the full protocol in less than 30 minutes, they participated in higher level free play tasks to continue practicing for the duration of the session. After the 12 sessions, participants completed two days of post-testing as described above as well as a questionnaire for subjective feedback on their experience.

V. Results

Among twelve enrolled individuals, eleven subjects completed the training and evaluations. One participant dropped out prior to the first training session due to a medical issue unrelated to the study, therefore all analysis is of eleven subjects. Six participants were screened to use EMG method and five subjects were assigned in SH group. Note that the subjects screened to the EMG group tended to have more functional use of their impaired UL at baseline, as noted by pre-testing scores compared to those assigned to the SH group (Table I). We examine the difference in clinical outcome between the two groups in this section as well. Finally, one subject used the arm support for training.

A. Fugl-Meyer Upper Extremity Scale

The complete results for FM are shown in Table III. We note that, at baseline, ten subjects had ‘no to poor’ UE capacity (<31) and one subject had ‘limited capacity’ (between 32 and 47) as defined in [47] on the FM. After the treatment, most of the subjects showed improvement except for subject 2 and subject 7 (EMG control), and subject 6 (SH control); per-subject results are shown in Fig. 5. Overall, the participants achieved statistically significant improvement with a mean gain of 2.64 points (p-value = 0.026). EMG group had a mean gain of 2.67 points (p-value = 0.114) and SH group improved by 2.6 points (p-value = 0.076), though statistical significance was not observed in either groups.

To further understand the implications of the results, we analyze the FM into two subtests, FM-distal and FM-proximal. FM-distal, hand and wrist segments, improved significantly with a mean gain of 2.27 points (p-value = 0.001) while significant improvement was not achieved in FM-proximal, shoulder and elbow segments (Table III). 86% of the total mean gain (2.64 points) was attributed from the FM-distal. This is particularly notable given that the overall FM is more heavily weighted proximally, with more items in the FM-proximal compared to FM-distal.

B. Action Research Arm Test

Complete ARAT results are shown in Table IV. Positive mean gains of 1.33 points (p-value = 0.111) in EMG group...
TABLE II
SUBJECT DEMOGRAPHICS

| Subject | Age | Sex | Type of stroke | Time since stroke | Affected side | Baseline handedness | Intent detection | Mobile arm support |
|---------|-----|-----|----------------|-------------------|---------------|---------------------|-----------------|-------------------|
| 1       | 62  | F   | Ischemic       | 6 years           | L             | R                   | EMG             | N                 |
| 2       | 37  | F   | Ischemic       | 4 years           | L             | R                   | EMG             | N                 |
| 3       | 48  | F   | Ischemic       | 14 years          | R             | R                   | EMG             | N                 |
| 4       | 68  | M   | Unknown        | 13 years          | R             | R                   | EMG             | N                 |
| 5       | 41  | M   | Ischemic       | 6 years           | R             | R                   | SH              | N                 |
| 6       | 32  | M   | Hemorrogic     | 22 years          | R             | L                   | EMG             | Y                 |
| 7       | 84  | F   | Ischemic       | 14 years          | R             | R                   | EMG             | N                 |
| 8       | 44  | M   | Ischemic       | 12 years          | R             | R                   | SH              | N                 |
| 9       | 44  | M   | Ischemic       | 5 years           | L             | R                   | SH              | N                 |
| 10      | 80  | F   | Ischemic       | 3 years           | L             | R                   | EMG             | N                 |
| 11      | 65  | F   | Ischemic       | 10 years          | R             | R                   | SH              | N                 |
| 12      | 50  | M   | Ischemic       | 2 years           | R             | R                   | SH              | N                 |

EMG group: EMG, SH group: SH, All subjects: N

TABLE III
MEAN GAINS (P-VALUES) WITHOUT ROBOTIC ASSISTANCE FROM FM POST-INTERVENTION. BOLD DATA ARE STATISTICALLY SIGNIFICANT (P<0.05).

| Category   | EMG group | SH group | All subjects |
|------------|-----------|----------|--------------|
|            | (n=6)     | (n=5)    | (n=11)       |
| Distal     | 3 (0.007) | 1.4 (0.026)| 2.27 (0.001)|
| Proximal   | -0.33 (0.415)| 1.2 (0.258)| 0.36 (0.372)|
| FM-Total   | 2.67 (0.011)| 2.6 (0.076)| 2.64 (0.026)|

and 1.4 points (p-value = 0.286) in SH group were achieved without statistical significance when ARAT was tested without robotic assistance post treatment. For post-testing with robotic assistance, the EMG group showed mean gain of -2.5 points (p-value = 0.083) whereas the SH group slightly improved with gain of 2.2 points (p-value = 0.07) approaching statistical significance (Table IV). The most notable improvement in a subcategory was observed in the Grasp category, with mean gain of 2.4 points (p-value = 0.026) in the SH group and 1.16 points (p-value = 0.055) in the EMG group. Mean gains were negative in all other categories (Table IV).

C. Box and Block Test

BBT results are shown in Table V. At baseline, seven participants scored 0 points, while four subjects scored between 4 to 23 points. The seven participants without any baseline function were able to improve with mean gains of 2 points (p-value = 0.014) when assisted by the robot, but more functional subjects performed worse both with and without the device. For the subjects without the ability to pick up any blocks at baseline, the robot served as an assistive device to improve function. BBT scores decreased in the EMG group both with (-4.3 points) and without (-1.8 points) robotic assistance, while SH group slightly improved when assisted (0.6 points).

D. Survey

In subjective feedback recorded after post testing, participants generally reported enjoyment, functional improvements, and a desire to continue using the device. “It encourages me to use my hand more. It gave me the feeling of freedom to use my hand again.” “I am able to fold and wring out a washcloth.” “If I could, I would wear it at home for most of the day for everything.” Participants also offered feedback for device improvements such as reduced wiring, less bulk around finger tips, increased training intensity (time and duration), and actuation of the thumb tendon for powered pinch.

VI. DISCUSSION

Overall, we identified trends in the data that suggest this device might serve two distinct purposes for different subsets of the stroke population - namely as a rehabilitation or assistive device. However, these results also highlight limitations of the current device, and point towards possible areas for future improvements.
TABLE V
MEAN GAINS (P-VALUES) FROM BBT POST-INTERVENTION. BOLD DATA ARE STATISTICALLY SIGNIFICANT (P<0.05).

| Group                  | Unassisted  | Assisted  |
|------------------------|-------------|-----------|
| Non functional (n=7)   | 0.286 (0.178) | 2 (0.014) |
| Functional (n=4)       | -3.5 (0.125) | -9.25 (0.053) |
| EMG group (n=6)        | -1.8 (0.1173) | -4.33 (0.156) |
| SH group (n=5)         | -0.2 (0.407) | 0.6 (0.311) |

A. An Active Hand Orthosis as a Rehabilitation Device

From a rehabilitation perspective, we discuss here results obtained post-intervention without using the device, and compared to baseline performance. Positive gains noted on the FM suggest that training with the device can serve as a rehabilitative tool to remediate some functional use in the affected UL, especially for participants with some degree of baseline functionality. The gains were largely attained in the FM-distal subtest, indicating that our customized robotic treatment was effective in improving hand functionality as intended. For future interventions, we can consider modifying the training program to involve more proximal movements.

Based on the observation of a positive trend on the ARAT score, we posit that increasing the intensity and duration of the intervention in future studies may lead to increased gains quantified using this measure. For example, small gains that were captured on the FM (e.g. ability to actively flex or extend the fingers) may not be captured on the ARAT because the improvement in range of motion was not sufficient to translate into increased functional ability (e.g. ability to pick up a small object). However, we expect the trend of improvement would continue with further treatment and eventually lead to a statistically and clinically significant outcome.

B. An Active Hand Orthosis as an Assistive Device

We focus here on performance measured post-intervention with the participants actively using the device, and compare against baseline. ARAT and BBT results suggest that for participants with minimal to no UL baseline capacity, using the robot as an assistive device for long term compensation to increase functionality in daily life may be feasible.

In the case of ARAT results, the improvement from both the EMG and SH groups was expected as the device specifically assists grasping tasks. We speculate that the differences between groups is related to baseline differences in hand functioning. EMG group participants tended to have more residual functioning at baseline, often employing compensatory patterns to achieve grasp and/or pinch, whereas when wearing the robotic device, the bulky finger components may have impaired their performance by making it more difficult to pick up and place objects in tight spaces. In contrast, those in the SH group had less functionality at baseline, and therefore the device assisted their ability to pick up objects, though they still had similar difficulty placing objects in tight spaces.

The most encouraging improvement in BBT was observed in participants with no functionality at baseline. We speculate that the negative gain by participants with non-zero baseline functionality occurred because these participants were employing functional compensatory pinch patterns at baseline. Based on our qualitative observations, however, training with the device discouraged compensatory patterns and forced users to grasp and pinch with typical patterns (e.g. finger pad to finger pad pinching), leading to poorer performance as participants did not master the new pinch pattern in this timeframe. We believe additional training time may help, however it is important to understand that some patients may be satisfied with their compensatory patterns if they are able to participate in their meaningful daily tasks.

The outcome measures highlighted a few limitations of the device. Improvement in Grasp category of the ARAT and negative mean gains in all other categories implies that the device facilitated grasping of mid-size objects, but not small objects which require pinching. We speculate this was because the thumb was splinted into an opposition pose against the other digits. This had the advantage of reducing actuator load, and we found this pose to be effective when grasping mid-size objects. However, a static thumb also made it difficult for subjects to stably hold small objects in a pinching pattern. This behavior likely affected the results in both the ARAT and BBT tests. We are planning to address this issue in future studies by designing an actuated thumb component which enables assisted pinch in addition to enveloping larger objects.

Another limitation was poor performance of the EMG method due to abnormal muscle synergy in unregistered UL postures. The BBT score drop in the EMG group with robotic assistance was likely because of unstable EMG classification when the user had to lift the arm higher than the partition and height of the box. We note that the training sessions contained no action item that involved lifting an object higher than the height of the partition (15.2 cm), thus the participants did not get an opportunity to practice their proximal muscles or learn to control the device while lifting the arm high in our protocol.

C. Limitations

It is important to point out a number of limitations related to study design in this pilot case series. In particular, we did not use a control group consisting of patient receiving treatment of similar intensity and duration, but without the use of robotic assistance. However, we note that meaningful motor recovery with traditional physical therapy for chronic stroke patients with moderate to severe motor impairments is considered rare [48], [49]. In addition, our robotic-assistance enabled training tasks that were not possible for most of the participants otherwise, and thus can not be replicated with traditional therapy. Furthermore, our study did not comprise a follow up assessment to observe the durability of gains. We plan to address both of these limitations in the future.

We also note that assignments between the EMG and SH groups was not performed in randomized fashion, but rather based on the ability of our intent inferal algorithm to classify EMG signals. As a result, we noticed systematic differences between the groups, with SH participants generally having lower baseline functionality. This limits our ability to interpret differences in the results obtained by the two groups.
Finally, we note that rehabilitation studies strive to assess progress using outcome measures that are at the participation-level, observing and rating how participants perform tasks in real-life environments. However, the FM measure, considered as the gold-standard in stroke research due to well established psychometric properties and minimal clinically important difference [50], only assesses body structures at the impairment level, focusing on the capacity of the UL to move. ARAT and BBT are activity-level assessments that involve observing and scoring participants performing simulated functional tasks that are far shorter in duration and more highly scripted compared to ADLs. We believe that customized outcome measures that capture higher task variation and allow longer completion times might be better suited for capturing progress when using robotic devices in an assistive fashion.

VII. CONCLUSION

In this work, we presented clinical outcomes for a study using a wearable robotic hand orthosis. Our robotic device is designed to assist the paretic hand after stroke, focusing primarily on an impairment pattern characterized by difficulty with active finger extension. The robotic orthosis uses a network of exotendons connected to a motor that retracts to assist hand opening (digit extension), or extends to allow the hand to close (via digit flexion). Two main design goals for our device are wearability and user-driven operation: we use two different methods to infer the intent of the user, and thus to determine when to provide assistance. The first method (EMG) relies on ipsilateral surface electromyographic signals, while the second one (SH) uses contralateral shoulder movement detected via an instrumented shoulder harness.

A wearable, user-driven hand orthosis could fulfill two roles: a rehabilitation device, designed to improve performance of the unassisted UL by providing assisted exercise, or an assistive device, designed to improve performance of the assisted UL. In this work, we have presented the clinical outcomes of a clinical intervention designed as an early feasibility test of both of these hypotheses. In our study, eleven chronic stroke participants engaged in a month-long training protocol in which they trained with our orthosis. The subjects were assigned to either an EMG or an SH group for intent inferral based on a control screening, and they all used the exotendon device which assisted with finger extension for functional grasp activities during training. Participants were evaluated with the FM (unassisted only) and the ARAT and BBT (both assisted and unassisted) to study the utility of the robot as a rehabilitative training device and/or an assistive device.

Post-intervention FM sub-scores suggest the grasp exercises helped improve distal movements of UL whereas it did not have a significant impact on proximal segments. Unassisted ARAT scores also had a positive trend. These results suggest the possibility for using our orthosis as a rehabilitative device for the hand. Assisted ARAT and BBT scores show that the device can indeed function in an assistive role for participants with minimal functional use of their hand at baseline. We noted no significant differences between the EMG and SH groups. This is, to the best of our knowledge, the first time that either assistive or rehabilitative effects were shown via clinical outcome measures by using a wearable, fully user-driven robotic hand orthosis.

Our study also underscored a number of limitations of the device. In particular, the device disrupts compensatory grasp patterns developed by stroke survivors, leading to an immediate decrease in functionality when the device is removed. It is likely that the 12-sessions were not long enough to enable learning of new grasp patterns for participants. Furthermore, our current design relies on a static, passively splinted thumb, which enables gross grasps but is not suited for pinching smaller objects. Our clinical intervention did not include a control group receiving traditional therapy instead of robotic assistance, or a follow-up assessment.

Nevertheless, we believe that this work can highlight the potential and feasibility for wearable and user-driven robotic hand orthoses. Such devices may enable robotic based-hand rehabilitation during daily activities (as opposed to isolated hand exercises with limited UL engagement) and over extended periods of time, even in a patient’s home environment. Numerous challenges must still be overcome in order to achieve this vision, related to design (compact devices with easier donning/doffing), control (robust yet intuitive intent inferral), and effectiveness (improved functionality in a wider range of metrics). However, if these challenges can be addressed, wearable robotic devices have the potential to greatly extend the use and training of the affected UL after stroke, and help improve the quality of life for a large patient population.

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