

Improvements in Functional Dexterity, Quality of Life, and Motor Control After Using an Upper-Limb Myoelectric Orthosis: A Six-Week Pilot Study with Chronic Hemiparetic Stroke Survivors

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Abstract—Wearable myoelectric orthoses can assist stroke survivors with chronic upper-limb hemiparesis in completing activities of daily living and therapeutic activities. Prior work has shown that using an assistive myoelectric orthosis in therapy and at home can improve functional dexterity, patient-reported quality of life, and even motor function outcomes. However, these past studies have mostly explored each of these outcomes in isolation, using extensive non-conventional therapy programs often tailored to support the primary outcome. In this pilot study, we explored whether structured, goal-oriented therapy with a myoelectric orthosis could improve motor control, functional dexterity, and patient-reported quality of life. Four stroke survivors used the Myomo MyoPro® myoelectric orthosis both in clinic and at home over the span of 6 weeks. Personalized patient-centered goals were selected using the Canadian Occupational Performance Measure (COPM). Occupational Therapy (OT) was delivered twice a week for 50 minutes, consistent with the standard of care. Standardized clinical assessments were performed at baseline without the myoelectric orthosis and at follow-up (6 weeks) with and without the myoelectric orthosis. Stroke survivors showed improvements in all three domains: motor control, functional dexterity, and quality of life. We also found that some outcomes were more sensitive than others, at least within the short-term 6-week duration explored in this pilot study. Importantly, even in this short-term four-person pilot study, we found preliminary evidence of significant and clinically meaningful gains in motor control (Fugl-Meyer Assessment for the Upper Extremity [FMA-UE]), functional dexterity (Chedoke Arm and Hand Activity Inventory [CAHAI]), and quality of life (COPM). To our knowledge, this is the first assessment of conventional goal-oriented therapy used in conjunction with a myoelectric orthosis, and the first demonstration of improved patient-reported perceived performance and satisfaction of functional outcomes. These results add to the growing body of literature showing that myoelectric orthoses may support improvements in functional outcomes for stroke survivors. Moreover, this work sets the stage for future randomized controlled clinical trials by identifying the most appropriate outcome measures for myoelectric orthoses across multiple domains when using traditional standard-of-care therapy. We recommend that future trials use the CAHAI as a primary outcome, and the COPM and FMA-UE as secondary outcomes.

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I. INTRODUCTION

Stroke is the leading cause of disability in the United States, with over 795,000 people suffering a stroke annually [1]. Approximately 80% of stroke survivors experience motor deficits resulting in upper-limb hemiparesis [1], [2]. Hemiparesis presents as a weakness or paralysis to one side of the body and often significantly limits the ability to perform Activities of Daily Living (ADLs) [2]. Chronic loss of upper-limb function is strongly associated with less independence and reduced quality of life (QoL) [3].

Even during the chronic stages of hemiparesis, stroke patients retain the ability to modulate their muscle activity [4], [5]. This muscle activity can be recorded noninvasively through surface electromyography (sEMG) to estimate a patient's intended hand motion [4], [6]. Importantly, this is true even in cases where the patient has no overt physical movement [4], [5]. Because sEMG signals are intuitively linked to intended motion and provide a robust noninvasive control signal, they have become a popular choice for controlling assistive devices [7]. Although patients impacted by hemiparesis tend to have poorer sEMG signal quality compared to healthy individuals, most still retain enough residual activity to control multiple degrees of freedom [4], [8]. This factor makes myoelectric control via sEMG, a useful control strategy for assistive orthoses that support and augment paretic arm function during ADLs.

Conventional occupational therapy (OT) can improve patient autonomy by addressing specific functional activities that are made difficult or impossible by hemiparesis. However, many stroke survivors remain unable to accomplish desired ADLs independently despite standard-of-care rehabilitation [2], [9]. A recent systematic review demonstrated that myoelectric orthoses are highly effective as a compensatory tool for performing ADLs [7], consistent with American Heart Association guidelines recommending functional task training integrated into ADLs [10]. These devices are particularly relevant to chronic stroke survivors who have plateaued in their recovery through conventional therapy but still retain latent muscular activity that can be used as an intuitive control signal for wearable powered orthoses.

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Within the OT framework, myoelectric orthoses controlled by sEMG are used to assist the patient with functional tasks and therapeutic activities. The impact of these myoelectric orthoses has been studied through two primary lenses: rehabilitative effects and compensatory assistance. Early landmark studies focused predominantly on rehabilitative gains in upper-extremity motor control, demonstrating that use of a myoelectric orthosis significantly improves outcomes on the Fugl-Meyer Assessment (FMA-UE) [11]. Assistive use of a myoelectric orthosis has also been shown to improve performance on standard dexterity tasks (e.g., Box and Blocks Task) and select activities of daily living when compared to performance of the paretic limb alone [12]. More recent research has demonstrated that long-term assistive use in the clinic and at home improves self-reported disability scores [3].

Indeed, there is a growing body of literature documenting the efficacy of myoelectric orthoses as both rehabilitative and assistive tools, leading to short-term and long-term gains in motor function and recovery. However, there is limited documentation on patient-reported outcomes and quality of life, which are often primary drivers for reimbursement.

A key challenge for future randomized controlled trials (RCTs) is that primary outcome measures do not necessarily capture the value and utility of current myoelectric orthoses. For example, many conventional upper-limb assessments focus on either fine motor function (e.g., Purdue Pegboard Test; PPT) or gross motor function involving the shoulder (e.g., Action Research Arm Test; ARAT). Commercially available myoelectric orthoses predominantly focus on gross function at the hand and elbow. In other words, because of their inherent design, it is unlikely that the use of a myoelectric orthosis would improve scores of tasks like the PPT or ARAT. Thus, an important next step is to identify motor assessments that are appropriate for current myoelectric orthoses.

It is also critical to understand how these ideal motor assessments interact with broader patient-reported outcomes and QoL measures that are likely to drive device adoption and reimbursement. Prior work has shown improvements in motor control, QoL, and functional dexterity. Still, these studies have mostly explored these outcomes in isolation, under specific therapy protocols optimized for that outcome. Thus, the key knowledge gap concerns the question of whether one therapy program can simultaneously improve outcomes across all domains.

Here, we explore this question with a pilot cohort of four chronic stroke survivors with upper-limb hemiparesis using the Myomo MyoPro® myoelectric orthosis both in clinic and at home over the span of 6 weeks. Therapy was delivered twice weekly for 50 minutes, consistent with standard care, and was structured around personalized patient-specific functional goals. Patients performed a battery of assessments at baseline (without the orthosis) and at 6-week follow-up (with and without the orthosis) to evaluate rehabilitative and assistive effects across motor, functional, and quality-of-life outcomes.

II. METHODS

A. Participants

For this pilot study, we recruited four chronic stroke survivors with unilateral stroke-induced hemiparesis in their upper limb. All participants had Modified Ashworth Scale scores between 0-2 for the shoulder, elbow, wrist, and fingers.

Inclusion criteria required all participants to be between 18-80 years old, have had a radiologically confirmed ischemic or hemorrhagic stroke with residual hemiparesis of the upper limb more than six months ago, and have detectable trace voluntary activation in elbow and wrist flexors and extensors on manual muscle testing ($>1/5$). Additionally, participants showed sufficient surface electromyography (sEMG) signals in the paretic biceps and forearm muscles to allow for the myoelectric orthosis to be controlled. Participants were also required to demonstrate a passive range of motion with a 5° terminal range for wrist flexion and extension, and for finger opening and closing, as well as active shoulder flexion and abduction of at least 30°, and elbow flexion of at least 20°. Lastly, participants were required to perform functional tasks for 20 minutes, with intermittent rest, without excessive fatigue. All participants self-reported that they ambulate independently or with minimal assistance and spent more than half of their waking day out of a wheelchair.

Informed consent and experimental protocols were carried out in accordance with the University of Utah's Institutional Review Board and the Declaration of Helsinki guidelines. All patients were required to be able to understand and provide informed consent, as well as demonstrate a willingness to comply with study procedures.

Prior to the study, participants' demographic and clinical histories were obtained, including age, sex, time since stroke, and affected side (Table 1). Physical measurements of participants' arms were taken to allow the manufacture of each custom-fabricated myoelectric orthosis, as is standard in clinical care.

TABLE I: Patient Demographics

Participant	Age	Sex	Baseline FMA-UE	Type of stroke	Years since stroke
1	46	M	22	Ischemic	3
2	47	M	14	Ischemic	5
3	43	F	34	Hemorrhagic	3
4	66	M	10	Hemorrhagic	3
Average	50.5	75% M	20		3.5

B. Hardware

Participants were fitted with a commercially available powered myoelectric orthosis (MyoPro®; Myomo Inc., Burlington, MA; Fig. 1). This device is designed to support elbow flexion and extension, as well as hand-closing and hand-opening movements, for the paretic upper limb. The device consists of a rigid frame encompassing the upper arm, forearm, and hand, with powered joints at the elbow and hand. sEMG electrodes embedded in the device measure muscle activity at the biceps, triceps, and forearm flexors and extensors, allowing for powered augmentation of attempted movements in response to residual muscle activity [4], [9].

The MyoPro® uses detected sEMG to drive joint motion in an assistive manner during voluntary, attempted movements. The device uses a threshold to activate the motorized assistance; if muscle activity exceeds a threshold, the motors activate accordingly. These thresholds, along with other participant-specific parameters, were adjusted for each





Figure 1: The MyoPro®, a commercial myoelectric orthosis manufactured by Myomo, Inc. The device assists hemiparetic patients with hand and elbow function. Each device is custom fabricated to the patient. Two motors are controlled by two pairs of surface electromyography electrodes. The elbow motor controls elbow flexion or extension. The hand motor controls opening and closing the hand. The device is battery powered, and can be used in therapy, at home, or out in the community.

participant during an initial fitting session to ensure reliable control and minimize unintended activations. Parameters were modified as needed by OTs as participants continued to learn to use the device more effectively and for new activities.

C. Occupational Therapy

Participants participated in regular in-clinic OT sessions with their myoelectric orthosis. Sessions occurred twice a week for 6 weeks. Each session lasted 50 minutes (standard clinical practice) and focused on performing functional activities set by the patient and their therapist [13], [14]. Therapists who carried out therapy protocols were separate from OT staff who performed assessments. All therapists were licensed and trained occupational therapists. In-clinic therapy sessions and at-home therapy programs included both conventional upper-limb rehabilitation and activity-specific training, both involving the myoelectric orthosis.

D. At Home Use

Participants took their myoelectric orthosis home with them between in-clinic OT sessions, where they used it unsupervised to support them with their ADLs as a home therapy program. Participants were taught to don and doff the device independently. Participants were not required to use the myoelectric orthotic for any specific amount of time at home as a part of this study, although therapists did assign at-home therapy programs with their device, as is standard clinical practice for OT. Compliance with these at-home programs was not directly measured. However, participants received a weekly phone call to ensure there were no new concerns or technical issues since their last appointment.

E. Assessments

We evaluated upper-limb function using a battery of standardized assessments targeting functional dexterity, patient-reported outcomes, and motor control. Assessments were performed by a separate OT, who evaluated the patient's function and identified individual goals aligned with the

capabilities of existing myoelectric orthoses. These assessments were first conducted at baseline without the myoelectric orthosis. The assessments were then conducted again after 6 weeks of therapy and home use. The functional dexterity follow-up assessments were performed both with and without the use of myoelectric orthosis to quantify assistive and rehabilitative effects, respectively. All assessments were administered by a separate, trained occupational therapist, distinct from the one who provided therapy to the patients.

1) Functional Dexterity Assessments

a) Chedoke Arm and Hand Activity Inventory (CAHAI)

The CAHAI-13 assesses the functional ability to perform bimanual ADLs [15]. Performance is assessed on a 7-point scale (1 = unable; 7 = normal performance; maximum score is 91 points). The CAHAI has been validated with the stroke population, and the minimum detectable change (MDC) is 6.3 points for the stroke population [16]. Scores on the CAHAI have previously been shown to improve with the use of a myoelectric orthosis [17]. As is standard for the CAHAI-13, patients completed 13 ADL-relevant functional mobility tasks, including tasks such as mixing with utensils or lifting a container bimanually. The task was completed with and without the myoelectric orthosis.

b) Box and Blocks Test (BBT)

The BBT assesses unilateral gross manual dexterity [12]. Performance is assessed by the number of wooden blocks transferred from one side of a container to the other within 60 seconds. The BBT has been validated in the stroke population, and the minimum detectable change (MDC) is 5.5 blocks/minute for the stroke population [18], [19]. Scores on the BBT have previously been shown to improve with the use of a myoelectric orthosis [12]. The task was completed with the paretic limb, with and without the myoelectric orthosis.

c) Select ADLs

We also evaluated participants on six select ADLs, which have been shown to be used with the myoelectric orthosis [9]. These six tasks included: 1) moving an object to the mouth, 2) holding an object in space, 3) stabilizing an object, 4) moving an object to a new location, 5) opening an object, and 6) lifting and transferring an object. Together, these tasks represent motor function necessary for numerous ADLs (Table 2). These tasks have not been validated in the stroke population, and there are no minimum clinically important difference (MCID) or MDC values. However, these tasks have been previously reported in literature and have been shown to improve with the use of a myoelectric orthosis [9]. The first four tasks, along with the exact objects and protocols for administering and assessing, were originally reported by Chang et al. in 2023. The last two tasks were previously used by Peters et al. in 2017 without a formal protocol for administering or assessing. Therefore, we applied the protocol for administering and assessing the first four tasks to the last two tasks to provide more standardized scoring. Performance is assessed at key subcomponents within each task on a binary scale (able to complete or not) and then summed across all subcomponents. Each task consists of 4 subcomponents (maximum score of 4), except for moving an object to the mouth, which has 5 subcomponents (maximum score of 5). Each task is also timed, and participants are allowed a maximum of 45 seconds per subcomponent before it is determined that they are unable to



complete the task. Participants unable to complete the task are assigned the maximum allowable time (45 seconds) for the remaining uncompleted subcomponents. All six tasks were completed with and without the myoelectric orthosis.

TABLE II: Select ADLs

Task	Objective	Related ADLs
Move object to mouth	Hold a plastic cucumber with the affected limb and simulate cutting it with a plastic knife in the non-affected limb for two seconds. Then, using the affected limb, bring the cucumber to the mouth for two seconds before lowering it back to the table	Meal preparation, feeding, drinking, brushing teeth, wiping nose, washing face
Hold object in space	Using both hands, grasp a weighted paper bag by the handles for two seconds, and then raise it against gravity for two seconds before lowering it back down	Carry shopping bag, carry laundry basket, move item off lap
Stabilize object	Hold a plastic mixing bowl with the affected limb for two seconds. Then, while continuing to stabilize the mixing bowl, simulate stirring using a mixing spoon in the non-affected limb for five seconds.	Cook, meal preparation, filling a container/bag, drying dishes, housekeeping, basic hobbies
Move small object	Pick up a dish towel, rotate the body to reposition the towel to a new location, hold it in the air for two seconds, and then drop it	Simple clean up, laundry, personal care, grooming
Twist open object	Grasp a plastic water bottle with the affected limb for two seconds. Then, while continuing to hold the water bottle, twist off the cap and place it on the table using the non-affected limb	Drinking, feeding, cooking, meal preparation, brushing teeth
Transfer large object	Using both hands, grasp a laundry basket bag by the handles for two seconds, and then raise it against gravity for two seconds before lowering it back down	Laundry, moving boxes, packing suitcase, office work, unloading groceries

2) Patient Reported Outcomes

a) Canadian Occupational Performance Measure (COPM)

The COPM assesses an individual's perceived occupational performance and satisfaction in the areas of self-care, productivity, and leisure. Performance and satisfaction are self-assessed separately on 10-point scales. COPM has been validated in the stroke population [20], and the MDC is 1.7 points for performance and 2.7 points for satisfaction. The COPM has been used previously with myoelectric orthosis users [11], [21]. As is standard clinical practice, the patient worked with a therapist to identify various goals within the domains of self-care, productivity, and leisure. The patient then identified their top five functional goals. The therapist who identified these goals was the same therapist who would later assess these goals, but not the same therapist who performed therapy with the patient around these goals. At follow-up, patients' answers reflected their performance and satisfaction after having used the myoelectric orthosis as an assistive device.

b) Stroke Impact Scale (SIS)

The SIS assesses disability and health-related quality of life after stroke. Performance is self-assessed on a 5-point Likert scale across 8 domains (strength, ADLs, mobility, hand function, communication, emotion, memory/thinking, and participation/role). The SIS has been validated in the stroke population, and the MCID is 9.2, 5.9, 4.5, and 17.8 for the strength, ADLs, mobility, and hand function domains,

respectively [22], [23]. Scores on the SIS have previously been shown to improve with the use of a myoelectric orthosis [23]. At follow-up, patients' answers reflected their quality of life having used the myoelectric orthosis as an assistive device.

3) Motor Control Outcomes

a) Fugl-Meyer Assessment (FMA-UE)

The FMA-UE assesses motor recovery after stroke. Performance is scored on a 3-point Likert scale across 33 items assessing movement coordination and reflex activity, with higher scores indicating less arm impairment. The FMA-UE has been validated in the stroke population, with an MCID of 5.25 points and an MDC of 5.2 for overall upper-limb function. Scores on the FMA-UE have previously been shown to improve with the use of a myoelectric orthosis [17], [21], [24], [25]. The FMA-UE was performed when the patient was not wearing the device.

F. Statistical and Clinical Analysis

All data were screened for normality using the Anderson-Darling test. Separate paired t-tests were performed between the baseline and follow-up scores for each patient-reported outcome and motor recovery outcome. For the functional dexterity outcomes, a one-way ANOVA was performed among the three conditions: 1) baseline without the myoelectric orthosis, 2) follow-up without the myoelectric orthosis, and 3) follow-up with use of the myoelectric orthosis. Post-hoc pairwise multiple comparisons were then performed using a Dunn-Sidak correction for multiple comparisons. Each patient's score and the average score among patients were also compared with the published MCID or MDC (if the MCID was unavailable).

III. RESULTS

A. Improved Performance on Bimanual ADLs (CAHAI-13)

Participants' baseline performance was 13.75 ± 0.25 , indicating severe upper-limb impairment with minimal functional contribution from the paretic arm. When using the myoelectric orthosis, participants' follow-up performance was 29.25 ± 1.03 , indicating consistent supportive use of the paretic arm in bilateral activities (Fig. 2A). Use of the myoelectric orthosis resulted in a 15.5-point increase (112.7%) from baseline, which is statistically significant ($p = 0.0015$) and above the MDC (6.3). Additionally, all four participants individually exceeded MDC.

Participants also demonstrated some functional motor recovery after using the myoelectric orthosis in the clinic and at home for 6 weeks. Follow-up performance without the use of the myoelectric orthosis was 19.25 ± 2.75 , indicating supportive use of the paretic arm in a small subset of bilateral activities. Follow-up scores represent a 5.5-point increase (40%) from baseline, although this was not statistically significant ($p = 0.3951$) and below the MDC (6.3).

B. No Improvement in BBT Scores

Scores range from 0 (unable to pick up or lift a single block) to ~80 (average peak human performance across the lifespan). Participants' baseline performance was 0 ± 0 . When using the myoelectric orthosis, participants' follow-up performance was 1.50 ± 0.87 (Fig. 2B). Use of the myoelectric orthosis resulted in an average increase of 1.50 blocks from baseline, although this was not statistically significant ($p = 0.4520$) and is below the MDC (5.5). Follow-up performance



without the use of the myoelectric orthosis was 0.50 ± 0.29 , an average increase of 0.50 blocks from baseline that is also not statistically significant ($p = 0.4520$) and below the MDC (5.5).

C. Improved Performance and Speed on All Select ADLs

The select ADLs assess bimanual function necessary for a range of ADLs (e.g., stabilizing, transferring, and opening objects). Performance ranges from 0 (unable to complete the first subcomponent of all ADLs) to 25 (able to complete all tasks in full). The tasks are also timed, and the worst possible time is 1125 s (maximum time allowable per subcomponent summed across tasks). Participants' baseline performance was 0 ± 0 and 1125 ± 0 s. Follow-up performance without myoelectric orthosis use was similar: 0.75 ± 0.75 and 1097.50 ± 27.50 s. However, when using the myoelectric orthosis,

participants' follow-up performance was 22.25 ± 1.25 and 355.25 ± 58.08 s, a significant improvement (p 's < 0.005) indicating that all tasks could be completed in full within the time limit (Fig. 2C).

D. Improved Perceived Performance and Satisfaction

For both COPM performance and satisfaction, the worst score is 0, and the best score is 10. At baseline, participants rated their perceived performance at 1.55 ± 0.25 , indicating they prioritized tasks they were unable to do at all. At follow-up, participants rated their perceived performance at 4.80 ± 0.54 (Fig. 3A). That is, use of the myoelectric orthosis resulted in a 3.25-point increase (209.7%), which is statistically significant ($p = 0.0209$) and above the MDC (1.7).

At baseline participants rated their satisfaction for the same 5 self-identified activities at 1.40 ± 0.22 out of 10. At follow-

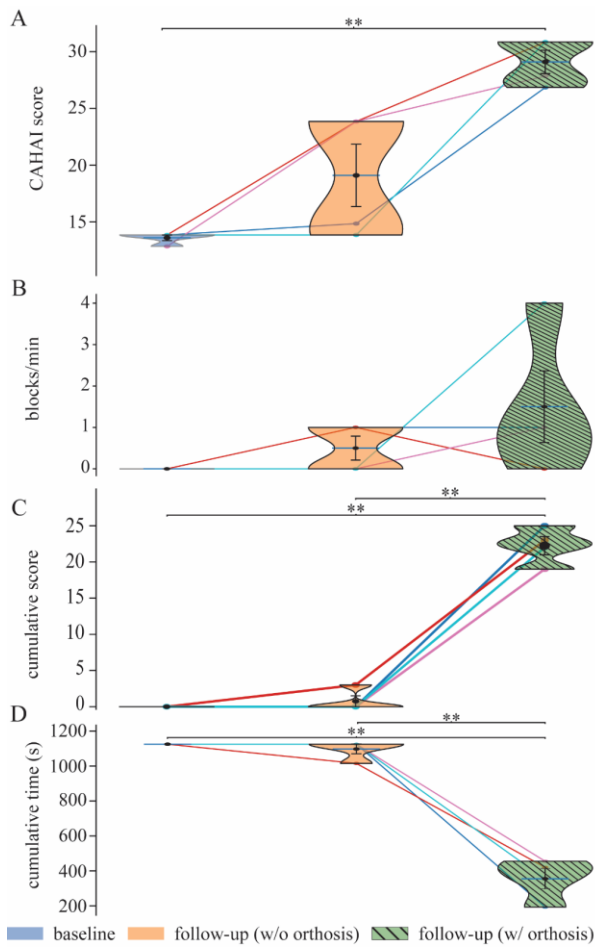


Figure 2: Functional dexterity outcomes at baseline and follow-up (6-weeks). Follow-up scores are shown with the myoelectric orthosis and without. **A)** CAHAI-13 scores with the myoelectric orthosis at follow-up were significantly greater than the baseline and follow-up scores without the device. Follow-up scores with the myoelectric orthosis were also greater than the MDC (6.3). **B)** BBT scores were not significantly different among any of the conditions, and were below the MDC (5.5). **C)** Scores on the select ADLs with the myoelectric orthosis at follow-up were significantly greater than the baseline and follow-up scores without the device. **D)** Similarly, total completion times for the select ADLs with the myoelectric orthosis at follow-up were significantly lower than the baseline and follow-up scores without the device. Data from four stroke survivors ($N = 4$). Colored lines show individual participant trajectories. Violin plots with overlaid mean $\pm$ standard error of the mean summarize the group distribution for each condition. Double asterisks (**) denote statistical significance at the 0.01 alpha level.

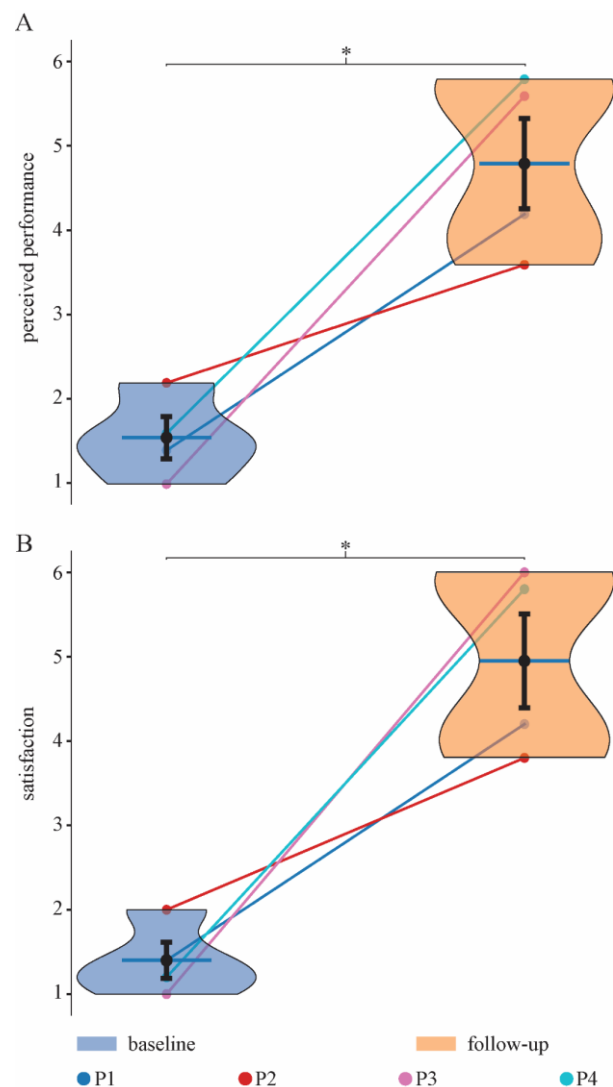


Figure 3: COPM self-reported perceived performance **(A)** and satisfaction **(B)** at baseline and follow-up (6 weeks). Both changes were statistically significant and greater than the MDC (1.7 for performance and 2.7 for satisfaction). Data from four stroke survivors ($N = 4$). Colored lines show individual participant trajectories. Violin plots with overlaid mean $\pm$ standard error of the mean summarize the group distribution for each condition. Asterisks (*) denote statistical significance at the 0.05 alpha level.



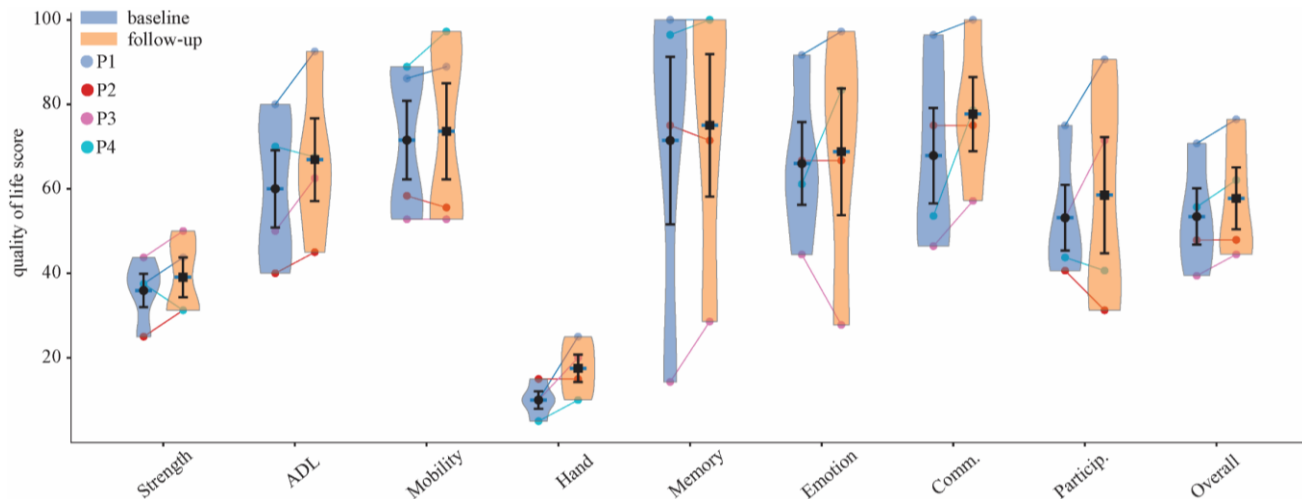


Figure 4: SIS quality of life within eight different domains at baseline and follow-up (6 weeks). No statistically significant differences were observed, but the average improvement in the ADL domain surpassed the MCID (5.9). Individually, P1 and P3 exceed the MCID in the ADL category and P4 exceeded the MCID for mobility (4.5). Data from four stroke survivors (N = 4). Colored lines show individual participant trajectories. Violin plots with overlaid mean $\pm$ standard error of the mean summarize the group distribution for each condition.

up, participants rated their satisfaction at 4.95 ± 0.56 (Fig. 3B). That is, use of a myoelectric orthosis resulted in a 3.55-point increase (253.6%), which is also statistically significant ($p = 0.0182$) and above the MDC (2.7).

E. Improved Quality of Life

The primary metric for quality of life was the SIS assessment, with higher scores representing greater improvement. Across all patients, we found no significant differences for the different domains of the SIS (Fig. 4). However, three participants surpassed the MCID for the ADL category (5.9), and one participant passed the MCID for the Mobility category (4.5).

F. Improved Motor Control (FMA-UE)

Participants' baseline scores were 20.00 ± 10.58 , indicating severe upper-limb impairment. After using the myoelectric orthosis, participants' follow-up performance was 27.00 ± 12.54 . That is, use of the myoelectric orthosis resulted in a 7-point increase (35%) from baseline (Fig. 5), which is statistically significant ($p = 0.0305$) and above the MCID (5.25) and MDC (5.2). This group effect was driven by three of four participants individually exceeding both the MCID and MDC.

IV. DISCUSSION

In this pilot study, we examined whether integrating an assistive myoelectric orthosis into a structured 6-week goal-oriented therapy program could improve motor control, quality of life, and functional dexterity. Consistent with prior work, we show significant improvements in motor control, quality of life, and functional dexterity [3], [9], [12], [17]. Unique to this work, however, we show that these improvements persist even when doing conventional standard-of-care goal-oriented therapy with the assistive myoelectric orthosis. Also novel to this work is the demonstration that significant and clinically meaningful gains can be seen across all domains, even in a small cohort of four individuals and with as little as 6 weeks of therapy (50 minutes, twice a week).

A key motivation for this study was to identify an optimal primary outcome measure for future RCTs. Most commonly used, validated outcome measures were developed prior to

recent advances in technology-assisted rehabilitation and do not adequately capture the functional contributions of myoelectric orthoses. For example, the BBT, in theory, appears to be a logical outcome measure: it is widely used in clinical practice [18], validated in the stroke population [19], assesses gross hand function commonly supported by commercial myoelectric orthoses, and has previously demonstrated responsiveness to myoelectric orthosis use [12]. However, BBT exemplifies the challenges of applying legacy outcome measures to emerging technologies. Specifically, it does not reflect how patients use myoelectric orthoses during real-world activities of daily living (ADLs). In this study, COPM goals consistently prioritized bimanual functional tasks in which the orthosis-assisted hand provided object stabilization through a power grasp while the contralateral hand performed manipulation. To align with contemporary

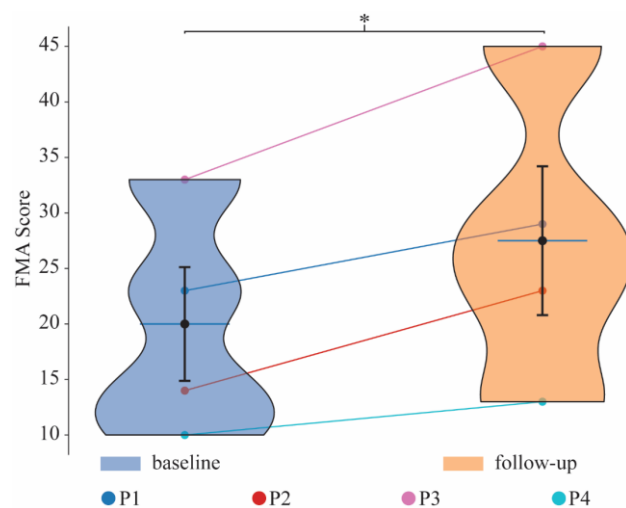


Figure 5: FMA-UE score at baseline and follow-up (6 weeks). Follow-up scores after 6 weeks of using the myoelectric orthosis were significantly greater than baseline and above the MCID (5.25) and MDC (5.2). Data from four stroke survivors (N = 4). Colored lines show individual participant trajectories. Violin plots with overlaid mean $\pm$ standard error of the mean summarize the group distribution for each condition. Asterisks (*) denote statistical significance at the 0.05 alpha level.



standard-of-care therapy, training emphasized these functional goals, and patients likely continued similar use patterns in the home environment. This functional role of the orthosis is distinctly different from the type of unilateral paretic-limb function assessed by the BBT. The BBT emphasizes rapid manipulation of small objects and relies heavily on pinch grip and speed. In contrast, myoelectric-orthosis-assisted tasks often require slow, controlled, and accurate stabilization rather than speed. Although improvements in BBT performance with myoelectric orthoses have been reported, the lack of observed change in this study likely reflects a mismatch between the functional skills practiced with the orthosis and the constructs measured by the BBT, rather than a lack of meaningful functional benefit.

In contrast to the BBT, the CAHAI naturally involves real-world tasks that more closely resemble COPM goals and the function of myoelectric orthoses. Significant and clinically meaningful gains were observed in all participants. The CAHAI is also widely used and well validated in the stroke population, making it the recommended primary outcome for future RCTs with myoelectric orthoses.

Future work should consider validating the select ADLs reported here and in prior works [9], within the stroke population. The select ADLs offer excellent sensitivity to hand and elbow function and the timing data offers an objective quantitative measure of performance that removes interrater variability. Beyond the stroke population, these select ADLs would also likely be particularly sensitive to several other patient populations (e.g., transhumeral amputation, shoulder disarticulation, cervical spinal cord injury, traumatic brain injury, and other neurological injuries).

Within the quality-of-life domain, we saw significant improvements on the COPM for both perceived performance and satisfaction. This improvement is most likely due to the fact that therapy revolved around patient-specific goals, in contrast to prior works that focused on using the myoelectric orthosis on the same select functional tasks across participants [21]. Importantly, we show that significant gains on the COPM can be achieved with as few as four patients undergoing conventional therapy for just 6 weeks.

Although we did not achieve statistical significance on the SIS (likely due to the small sample size), we did see improvements beyond the MCID in the ADL category. This is likely because our goal-based therapy reflected patients' individual ADL priorities. Interestingly, we did not observe improvements in hand or strength; this may be due to the limited sample size, the duration of this study, or the fact that not all questions in this category are relevant to myoelectric orthosis use. For example, a myoelectric orthosis is unlikely to help with tying shoelaces or picking up a dime. Instead, patients showed more improvement in the mobility category, with one patient even exceeding the MCID. We suspect that the myoelectric orthosis provided stabilizing weight and a more natural arm swing, which in turn produced a more typical gait pattern with less compensatory trunk movement. Indeed, patients self-reported improved balance and walking speed throughout the study. Future work may be able to evaluate the effects of myoelectric orthoses on mobility using the Timed Up and Go (TUG) and/or the 10-Meter Walk Test. Finally, within the motor recovery domain, we saw a significant improvement in FMA-UE scores, consistent with prior work

[17]. Three patients also achieved MDC and MCID within 6 weeks.

As a pilot study, the findings are preliminary, and the generalizability of this work is limited by the small sample size. Future work should include a larger sample size and a matched control group. Multiple timepoints should be considered to assess sustained gains relative to the standard of care. Remote monitoring of device usage could also provide an objective measure of adherence to home therapy and sustained integration into daily life. Quantifying variability in adherence could strengthen the interpretation of outcomes across individuals.

Collectively, these results lay the groundwork for future RCTs. Based on the findings herein, we recommend that future RCTs use goal-based therapy in accordance with conventional standard-of-care guidelines (~50 minutes/visit, ~20-24 visits) for both the interventional and control group. Additionally, we recommend the CAHAI as a robust primary outcome measure, and the COPM and FMA-UE as secondary outcomes. Finally, we recommend a primary endpoint at 12+ weeks and a sample size of 20+ for both the myoelectric orthosis and age-matched control cohorts.

V. CONCLUSION

This pilot study provides preliminary evidence that 6 weeks of standard-of-care therapy with a myoelectric orthosis can improve engagement in functional tasks, patient-reported quality of life, and motor control. This work corroborates the growing body of literature showing that myoelectric orthoses are highly effective at improving clinical outcomes for stroke survivors and sets the stage for future randomized controlled clinical trials.

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