Feasibility and efficacy of upper limb robotic rehabilitation in a sub-acute cervical spinal cord injury population

Running title: Upper limb robotic rehabilitation in SCI

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Abstract

Study Design: Multi-centre pilot study.

Objective: To investigate the use of an upper limb robotic rehabilitation device (Armeo®Spring, Hocoma AG, Switzerland) in a sub-acute cervical spinal cord injury (SCI) population.

Setting: Two Canadian inpatient rehabilitation centres.

Methods: Twelve subjects (motor level C4-C6, AIS A-D) completed training, which consisted of 16.1 ± 4.6 sessions over 5.2 ± 1.4 weeks. Two types of outcomes were recorded: (1) feasibility of incorporating the device into an inpatient rehabilitation program (compliance with training schedule, reduction in therapist time required, and subject questionnaires); (2) efficacy of the robotic rehabilitation for improving functional outcomes (Graded and Redefined Assessment of Strength, Sensibility and Prehension (GRASSP), Action Research Arm Test (ARAT), grip dynamometry, and range of motion).

Results: By the end of the training period, the robot-assisted training was shown to require active therapist involvement for 25 ± 11% (mean ± SD) of the total session time. In the group of all subjects, and in a sub-group composed of motor incomplete subjects, no statistically significant differences were found between intervention and control limbs for any of the outcome measures. In a sub-group of subjects with partial hand function at baseline, the GRASSP Sensibility component showed a statistically significant increase (6.0 ± 1.6 (mean ± SEM) point increase between baseline and discharge for the intervention limbs, versus 1.9 ± 0.9 points for the control limbs).

Conclusions: The pilot results suggest that individuals with some preserved hand function after SCI may be better candidates for rehabilitation training using the Armeo®Spring device.

Key words: Upper limb robotic rehabilitation; sub-acute spinal cord injury; Armeo®Spring; feasibility; GRASSP; ARAT.

Introduction

Activity-based rehabilitation is currently one of the principal strategies to promote functional recovery after a neurological injury, such as spinal cord injury (SCI) or stroke. In recent years, robotic devices have been proposed to facilitate or supplement rehabilitation. For the upper limbs, examples include: the MIT-Manus [1,], the MIME [2], the ARM guide [3], the Bi-Manu-Track [4], the GENTLE/s [5], the T-WREX [6, 7], and the ARMin [8].

The main motivation for robotic rehabilitation devices is to assist in the repetitive labour-intensive manual therapy delivered by therapists as they move a patient's limbs during exercises. Without creating additional time demands on therapists, robotic devices could perform the repetitive mechanical aspects of therapy, thereby increasing the amount of therapy for each patient and/or increasing the number of patients undergoing therapy simultaneously [9, 10, 11]. Virtual-reality interfaces may also increase patient engagement. By delivering more rehabilitation and increasing patient motivation, robotic rehabilitation might improve functional outcomes [2, 12, 7, 8], although current evidence from stroke patients suggests that improvements are due to the intensity of the therapy, regardless of delivery by robotic or conventional means [13, 14].

Given the need for novel upper limb therapies after cervical SCI [15], the evaluation of robotic rehabilitation in this population is warranted, but to the best of the authors' knowledge, no studies have examined the use of upper limb rehabilitation robotics in a sub-acute SCI population. We therefore present a multi-centre pilot evaluation of a commercial upper limb rehabilitation device, the Armeo®Spring (Hocoma AG, Switzerland). Our goals were to establish the feasibility of using the Armeo®Spring in an SCI inpatient setting, as well as to gather preliminary data on the device's efficacy. The Armeo®Spring and its academic predecessor the T-WREX have previously been used with stroke

survivors [6, 7] and in a population with multiple sclerosis [16], but its usefulness in patients with cervical SCI is not known. Portions of these results have been presented in conference format [17].

Methods

1. Study Design

Fifteen subjects with sub-acute cervical SCI were recruited from the inpatient populations at two rehabilitation centres. The inclusion criteria were to have sustained a traumatic cervical SCI with a motor level between C4 and C8 (as defined by the International Standards for the Neurological Classification of Spinal Cord Injury (ISNCSCI), and evaluated by the clinical staff). Subjects with a history of neuromuscular disease, severe upper limb spasticity, severe shoulder pain, unable to sit upright for 30 minutes, or unable to understand and follow instructions were excluded. Subject demographics are provided in Table 1.

Figure 1 shows the Armeo®Spring. The user's arm is placed into an exoskeleton that provides adjustable anti-gravity weight support of the arm through a system of springs (no actuators). The orthosis allows movement along five degrees of freedom (DOF): three DOF at the shoulder to allow shoulder flexion-extension, abduction-adduction and internal/external rotation, one DOF at the elbow to allow flexion-extension and one DOF at the radio-ulnar joint to allow pronation-supination of the wrist. The orthosis also includes a hand grip pressure sensor. Exoskeleton movements are relayed to a computer and control a cursor during a number of different virtual reality (VR) tasks.

The range of motion (ROM) needed to control the VR tasks is adjustable. The tasks train different aspects of upper limb function, including reaching movements in various directions, pronation/supination at the radio-ulnar joint, and hand grip strength.

Subjects were scheduled for 3 to 5 one-hour training sessions per week for six weeks. Compliance with the training schedule was one of the outcome measures of the study. Training was unilateral. The choice of which arm to train was made in consultation with each subject, and in accordance with their rehabilitation goals. Both arms continued to receive conventional occupational and physical therapy exercises as per the standard of care in the rehabilitation centres. The arms not receiving robotic rehabilitation served as the control group for the efficacy outcomes (see below). The anti-gravity weight support and the type and difficulty of VR activities were tailored to each subject's capabilities at the initial session, and adjusted throughout the training to ensure that the exercises remained challenging. The adjustments were made by the investigators delivering the training sessions (PT and MAM) and primarily took the form of increasing the level of difficulty of the games, the number of repetitions, and introducing more difficult games into the training program when subjects recovered sufficient function. The study protocol was approved by the research ethics committees at both sites.

2. Feasibility Outcomes

Feasibility outcomes focused on integrating robotic training into the rehabilitation program of SCI inpatients, given that the number of activities that patients can be involved in is limited by scheduling consideration both for the clinical staff and for the subjects themselves.

Compliance: The total number of sessions attended, total length of training (in weeks), and average number of sessions per week were tallied for each subject.

Therapist time: Although each training session was fully supervised, the investigator delivering training recorded the amount of time that was spent actively assisting the subject (i.e., assisting with inserting and removing the arm from the device, inputting commands to the computer and adjusting settings, etc.), as opposed to monitoring the training and guiding the subject's activities verbally. The ratio of active assistance time to the total length of the session was used to measure direct therapist involvement.

Subject questionnaires: At the end of the training period, each subject provided feedback about their experience with the Armeo®Spring in the form of a questionnaire (see Table 3). The questionnaire used a 7-point Likert scale (1: "Disagree strongly", 7: "Agree strongly").

3. Efficacy Outcomes

These outcomes collected data on the efficacy of the Armeo®Spring in improving upper limb function. Assessments were conducted before training (baseline), at the end of the training block (discharge), two weeks after the end of the training (2 week follow up), and six weeks after the end of the training (6 week follow up). Both of the subject's arms were assessed, with the group of limbs receiving conventional rehabilitation, but no robotic rehabilitation, serving as the control for the group of limbs receiving both conventional and robotic rehabilitation (interventional group).

Graded and Redefined Assessment of Strength, Sensibility and Prehension (GRASSP): The GRASSP is a clinical measure of upper limb impairment after tetraplegia [18]. It includes manual muscle testing

(MMT) of 10 upper limb muscles (Strength), sensory testing of the fingertips using monofilaments (Sensibility), ability to form different types of grasps (Qualitative Prehension), and performance on a set of functional tasks (Quantitative Prehension).

Action Research Arm Test (ARAT): The ARAT uses a series of functional tasks to evaluate grasp, grip, and pinch function, as well as gross movement of the upper limb [19].

Dynamometry: The maximal grip strength for each hand was measured using a Baseline® hand dynamometer (Fabrication Enterprises Inc., USA). The average of three trials was used for each assessment.

Three analyses of the outcomes were performed. The first analysis included all subjects (population of intervention arms compared to population of control arms). The second analysis used only the sub-group of limbs with some hand function at baseline, defined as baseline MMT scores of 2 or more in at least one of the 6 hand function muscles assessed in the GRASSP test (extensor digitorum, opponens pollicis, flexor pollicis longus, flexor digitorum profundus at the middle finger, finger abductors at the little finger, and first dorsal interossei). This determination was made separately for the control and intervention limbs (i.e., a given subject can have either, both, or neither limbs included in this analysis, depending on the level of function in each of the two hands). This sub-group was motivated by the fact that subjects with some hand function were able to use the grip module on the Armeo®Spring to access a greater number of training exercises. The third analysis included only subjects with motor incomplete injuries at baseline (ASIA Impairment Scale (AIS) grade C or D).

In addition to standardized assessments, we analyzed the ROM measurements provided by the Armeo®Spring. The device requires users to move through their comfortable ROM at the beginning of each session, and adjusts the VR workspace accordingly. We additionally required that subjects

reach as far as possible in every direction at the beginning of each session, and analyzed this "maximal" ROM information. The components of the recorded ROM are the right-to-left range, the close-to-far range (where close is trying to touch one's abdomen and far is straightening the arm forward), and the top-to-bottom range (where bottom is limited by the subject's knees). The total ROM volume is the product of these three values. The mean of the ROM volumes for the first three sessions was used as the baseline ROM, and the mean of the last three sessions as the discharge ROM.

The efficacy outcomes and subject questionnaires were collected by investigators who were not involved in delivering the rehabilitation sessions (JZ and NK).

Results

Of the 15 subjects recruited, 3 dropped out of the study before completing training. One cited a busy schedule as his reason for dropping out, the second cited a combination of busy schedule and secondary health complications (unrelated to the Armeo® training), while the third subject cited a lack of interest in the Armeo® training.

Ten of the remaining 12 subjects chose to train the arm that was dominant before injury. One subject trained the arm that was non-dominant before injury because it was less affected by the injury. One subject trained the non-dominant arm because of pain when moving the dominant arm.

The distribution between the two centres of the 12 subjects having completed training was 5 at one centre and 7 at the other.

The number of limbs resulting from each of the sub-groups analyzed is shown in Table 2 for each time point.

1. Feasibility Outcomes

Compliance: The average number of training sessions conducted per subject was 16.1 ± 4.6 (mean ± standard deviation, SD), and ranged from 9 to 24. Training duration varied from 2.3 to 7.1 weeks, with a mean of 5.2 ± 1.4. Subject 5 was discharged earlier than expected, and accounts for the minimum in both metrics (9 sessions delivered over 16 days). The average number of sessions per week was 3.2 ± 0.8. The average length of the sessions was 43 ± 10 minutes, and ranged from 20 to 74 minutes.

Therapist Time: The mean ratio of active assistance time to total session length was 0.41 ± 0.27 (mean ± SD), across all sessions for all subjects. Using only the last three training sessions of each subject, the ratio was 0.25 ± 0.11. In contrast, using the first three training sessions, the ratio was 0.61 ± 0.30. These two values were significantly different ($p < 0.01$ using a one-way ANOVA). More therapist effort was needed at the beginning of training, while the subject-specific rehabilitation program was developed.

Subject questionnaires: The results of the discharge questionnaire filled out by the subjects are provided in Table 3.

2. Efficacy Outcomes

GRASSP: For the total subject population group (Figure 2), no significant differences were observed for any of the GRASSP test sub-scores, at any time point (Kruskal-Wallis non-parametric analysis of variance, defining statistical significance as $p \leq 0.05$).

For the sub-group with some hand function (Figure 3), significant differences were found between the intervention and control groups in the GRASSP Sensibility sub-score: at discharge, the intervention limbs improved by 6.0 ± 1.6 points (mean ± standard error of the mean, SEM) and the control limbs by 1.9 ± 0.9 points ($p = 0.04$); at the two-weeks follow-up, the intervention limbs had improved by 10.0 ±2.0 points and the control limbs by 1.5 ± 0.9 points ($p = 0.04$). The Sensibility score comparison at the 6 weeks follow up did not reveal a significant difference between the two groups ($p = 0.12$). None of the other GRASSP sub-scores were statistically significant for between group differences at any time points for this sub-group.

For the motor incomplete sub-group, or AIS-C and AIS-D subjects (Figure 4), no significant differences were found on any sub-score, at any time point.

ARAT: The changes in ARAT scores are shown in Figure 5. No statistically significant group differences were found at any time points, for any stratification.

Grip dynamometry: The changes in dynamometer readings are shown in Figure 6. No statistically significant group differences were found at any time points, for any stratification.

ROM: For each subject, the discharge ROM value was expressed as a percentage of the baseline ROM value. The mean and standard error of the mean of the discharge ROM were 101.9 ± 14.7%,

compared to 100 ± 0% at baseline (n = 12 at both time points), a non-significant difference (p = 0.89 using a one-way ANOVA).

Discussion

Feasibility:

Our results show that incorporating upper limb robotic training into the rehabilitation program of sub-acute SCI inpatients is feasible, and that the device allowed more rehabilitation exercises to be performed with progressively less hands-on involvement by the therapist.

In addition to therapist schedules, it is also important to look at patient schedules: additional training time is limited by other rehabilitation activities, subject fatigue, ongoing medical complications and discharge dates. Our target for frequency of training (3-5 sessions/week) was met with 3.2 ± 0.8 sessions per week, though two of the subjects who dropped out of the study cited scheduling as a factor. The duration of training was slightly lower than desired, primarily due to discharge date constraints. The amount of time that any novel intervention requires for making a measurable impact must be compared to limitations on scheduling the necessary sessions and length-of-stay.

Subjects found the Armeo®Spring easy to use and helpful for tracking their progress, and reported a moderately beneficial impact on their motivation to perform their exercises. Despite these benefits, subjects did not express any preference for using the Armeo®Spring compared to conventional therapy.

Efficacy:

Despite the increased therapy hours, this pilot study demonstrated few functional benefits in the limbs receiving Armeo® training, compared to the limbs not receiving robotic training. Nevertheless, our small sample size prevents us from drawing any definitive conclusions. We observed a statistically significant improvement only in the GRASSP Sensibility scores of subjects with partial hand function at baseline. The control and intervention groups did not have significantly different Sensibility scores at baseline ($p = 0.12$ on a Kruskal-Wallis test), and neither group was subject to ceiling effects for the scale (one subject did reach the maximum Sensibility score of 24 at discharge, but for both limbs). Nonetheless, the Sensibility difference between the two groups was larger at baseline (13.5 ± 2.3 for the intervention group vs. 18.8 ± 1.4 for the control group) than at discharge (19.5 ± 1.5 for the intervention group vs. 20.7 ± 0.8 for the control group). The observed change in Sensibility score should therefore be confirmed in a larger study to ensure that it was not due to differences between our control and intervention limbs. The Armeo®Spring does not directly address tactile sensation, but the training of the subjects with partial hand function generally focused heavily on exercises that include grip function, and this emphasis on the hand might have been reflected in the GRASSP Sensibility score, which is based on testing at the fingers only (no upper arm). These observations suggest that individuals able to incorporate grip exercises in their training may be most likely to benefit from Armeo®Spring training.

Limitations:

The small number of subjects in our pilot study likely resulted in insufficient statistical power to detect changes, and may account for the limited functional improvements observed. Stratifying the population proved beneficial in identifying the effects and possible trends for robotic training of upper limb function, but also reduced the number of subjects in each comparison. Another possible factor is the amount of robotic rehabilitation delivered (dose and duration), which may have been insufficient or too variable between subjects to produce measurable changes.

Our study did not include an independent control group of subjects undergoing no Armeo® training, but an equivalent amount of additional conventional therapy in the intervention arm. This study was a pilot project aiming to establish that this type of therapy can be effectively incorporated into the rehabilitation program of individuals with sub-acute SCI, and to collect preliminary efficacy data that will inform the design of future studies. In this context, the use of the untrained arms as a control group is justified, and ensures that the control limbs were matched to the intervention limbs for the amount of conventional therapy received and demographic considerations. Asymmetries in the amount of recovery between the two limbs of a given subject are expected to average out over the population. Note that differences between control and intervention limbs were also examined on a subject-by-subject basis rather than as a population (results not shown), but no additional trends were identified using this method. An additional consideration is that unilateral training is known to produce a small strength increase in the contralateral homologous muscle ("cross-education" [20]). In the population investigated here, however, any cross-education occurring in the untrained arm as a result of the Armeo® training is likely negligible compared to the combined effects of conventional rehabilitation and spontaneous recovery after SCI [21].

Conclusion

We provided the first report on the use of upper limb robotic rehabilitation in a sub-acute cervical SCI population. The device accomplished its goal of increasing the amount of rehabilitation training while reducing the amount of active therapist time required. This small study did not identify that robotic rehabilitation translated into defined functional benefits, but a larger study is needed before definitive conclusions can be reached. Our results suggest that a more homogeneous subject

population should be focused on, particularly subjects with cervical SCI who are able to perform some minimal hand movements.

Acknowledgments

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Conflicts of Interest

The authors declare no conflicts of interest.

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Table 1: Subject demographics. Subjects denoted with an asterisk dropped out of the study before completing training, and are not included in the analysis. Motor level and AIS grade are as defined by the International Standards for the Neurological Classification of Spinal Cord Injury (ISNCSCI).

Subject number	Age	Gender	Time Since Injury	Arm Trained	Motor Level	AIS Grade
1	21	M	105 days	R	C6	D
2	19	M	173 days	R	C4	A
3	55	M	167 days	R	C5	B
4*	25	M	80 days	R	C5	B
5	55	M	75 days	R	C5	D
6*	25	M	105 days	R	C6	A
7*	53	M	52 days	R	C4	C
8	61	M	86 days	L	C6	C
9	75	F	78 days	R	C5	D
10	56	M	36 days	R	C4	B
11	29	M	72 days	R	C5	A
12	34	M	29 days	L	C5	B
13	46	M	30 days	R	C5	D
14	46	M	21 days	L	C6	D
15	23	M	31 days	R	C6	B

Table 2: Number of limbs in the control and intervention groups, at each time point and for each stratification of the subject population. In the "All subjects" and "Motor incomplete" groups, each subject has one intervention limb and one control limb. In the "Hand function" group, the function in each hand is evaluated separately (e.g., at baseline, 6 of the 12 subjects had some hand function in the intervention limb, whereas 9 of 12 subjects had some hand function in the control limb).

	Baseline	Discharge	+2 weeks	+6 weeks
All subjects				
Intervention	**12**	**12**	**8**	**7**
Control	**12**	**12**	**8**	**7**
Hand function group				
Intervention	**6**	**6**	**2**	**2**
Control	**9**	**9**	**6**	**5**
Motor incomplete group				
Intervention	**6**	**6**	**2**	**1**
Control	**6**	**6**	**2**	**1**

Table 3: Subject discharge questionnaire with mean score (out of 7) and standard deviation for each question. A score of 1 mean "Disagree strongly", a score of 7 means "Agree strongly", whereas a score of 4 is "Neither agree nor disagree".

Question	Mean Score (± SD)
Q1. The ARMEO® was enjoyable to use.	5.2 ± 1.1
Q2. It was easy to understand how to use the ARMEO®.	7 ± 0
Q3. The games increased your motivation to perform your exercises.	5.3 ± 1.8
Q4. You would be comfortable using the ARMEO® with only minimal supervision by a therapist.	6.4 ± 0.9
Q5. You felt that the ARMEO® training was as effective for rehabilitation as your usual rehabilitation sessions with a therapist.	4.7 ± 2.2
Q6. The ARMEO® was helpful for tracking the progress of your rehabilitation.	5.5 ± 1.7
Q7. The length of the sessions was appropriate.	6.3 ± 1.7
Q8. The number of sessions per week was appropriate.	6.1 ± 1.5
Q9. You felt that the ARMEO® exercises were more relevant to activities in your daily life than conventional rehabilitation.	4 ± 2
Q10. You would use the ARMEO® in your free time if it was available to you.	4.7 ± 2.7
Q11. You preferred the ARMEO® training to conventional rehabilitation.	3.6 ± 1.9
Q12. The ARMEO® is appropriate for someone with your level of lesion.	5.8 ± 1.6
Q13. The ARMEO® is appropriate for someone with your type of injury (i.e. AISI A, B, C, or D).	5.8 ± 1.7

Figure Captions

Figure 1: Subject positioned within the Armeo®Spring device and engaged in a VR exercise.

Figure 2: Change in GRASSP sub-scores from baseline for the intervention and control limb groups, using all subjects. Error bars reflect the standard error of the mean.

Figure 3: Change in GRASSP sub-scores from baseline for the intervention and control limb groups, using only limbs with partial hand function at baseline. Error bars reflect the standard error of the mean. Asterisks denote statistically significant differences.

Figure 4: Change in GRASSP sub-scores from baseline for the intervention and control limb groups, using only motor incomplete subjects. Error bars reflect the standard error of the mean.

Figure 5: Change in ARAT score from baseline for the intervention and control limb groups. The top figure shows the data from all subjects, the middle figure shows the data from limbs with partial hand function at baseline, and the bottom figure shows the data from subjects with motor incomplete injuries. Error bars reflect the standard error of the mean.

Figure 6: Change in grip dynamometer readings from baseline for the intervention and control limb groups. The top figure shows the data from all subjects, the middle figure shows the data from arms with partial hand function at baseline, and the bottom figure shows the data from subjects with motor incomplete injuries. Error bars reflect the standard error of the mean.

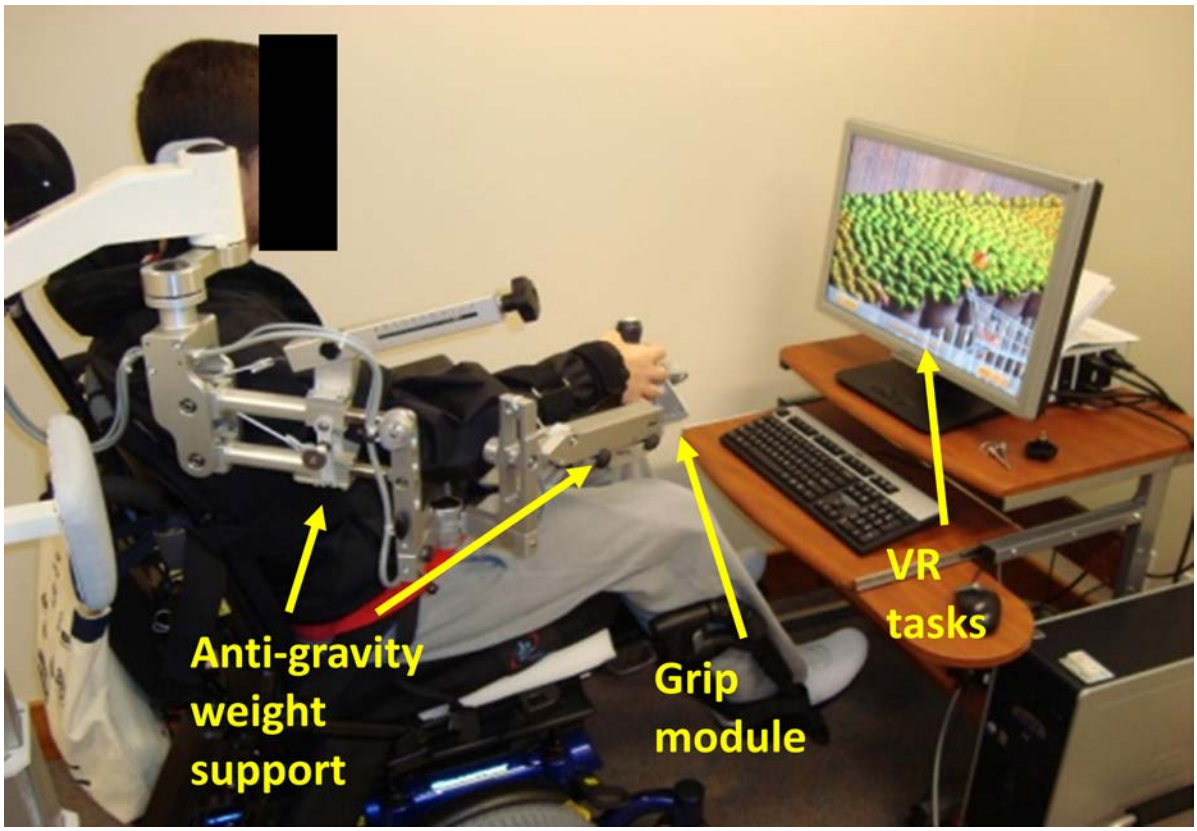
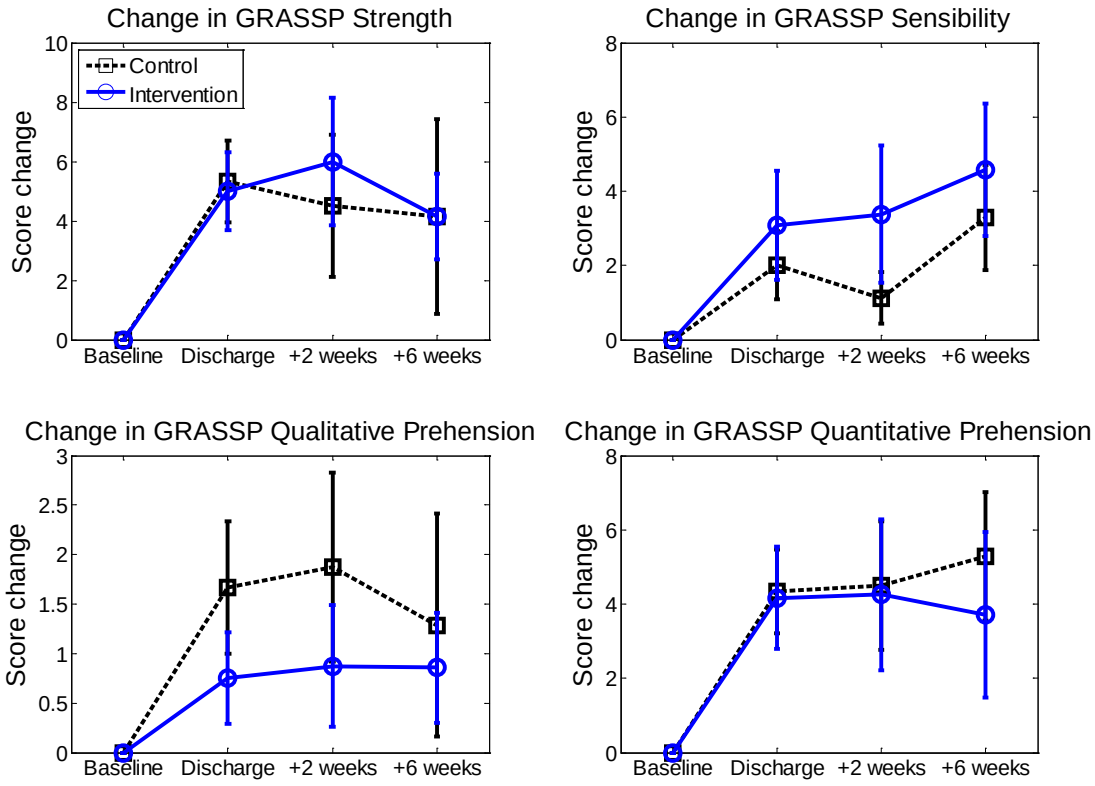


Figure 1


Change in GRASSP Strength
Control
Intervention
Score change
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Change in GRASSP Qualitative Prehension
Change in GRASSP Quantitative Prehension

Figure 2

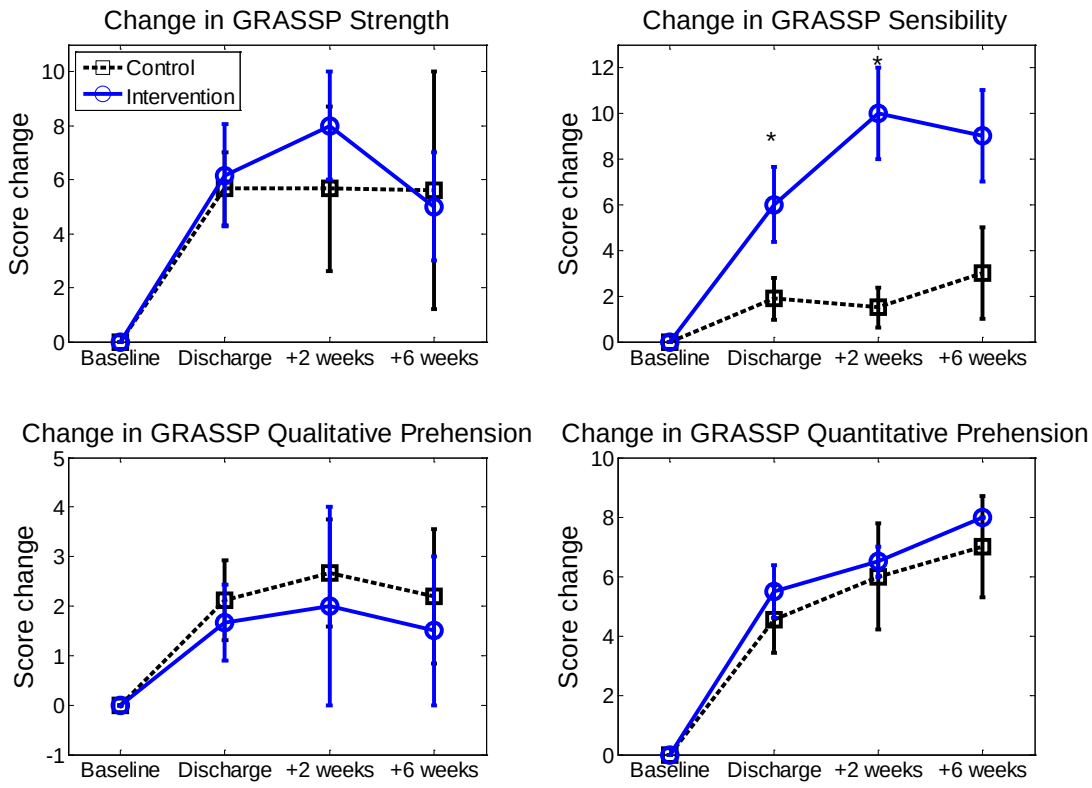
Change in GRASSP Strength
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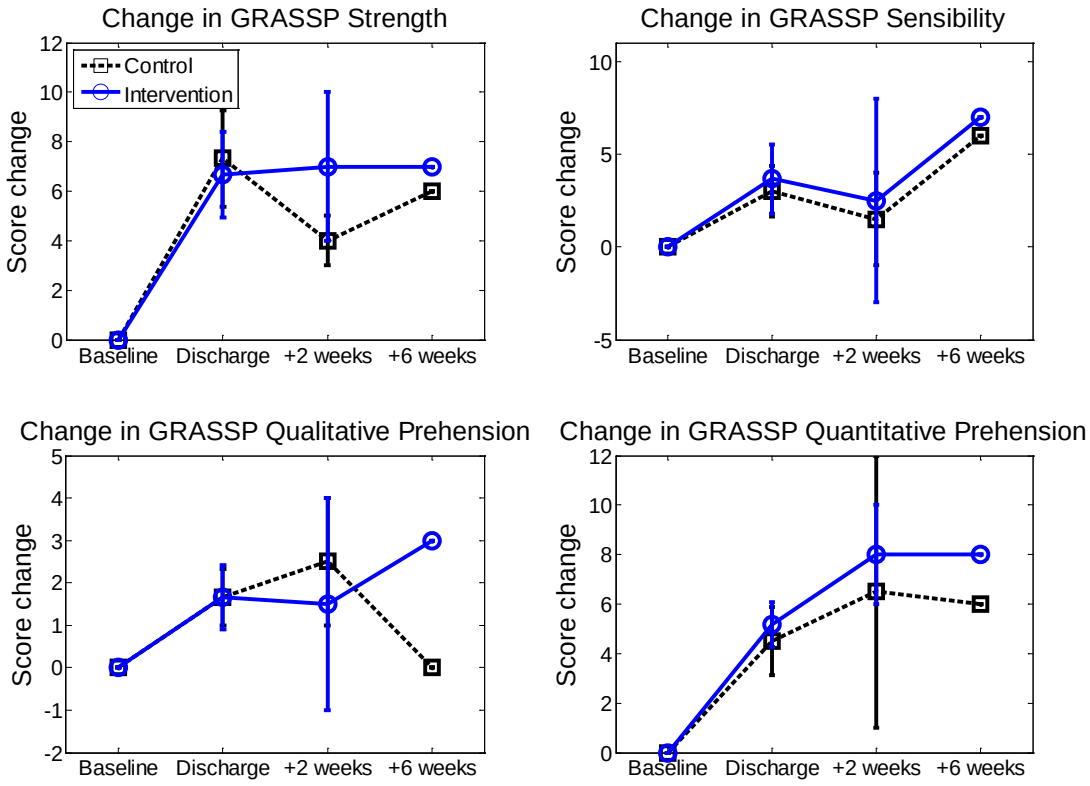
Figure 3


Change in GRASSP Strength
Control
Intervention
Score change
Baseline
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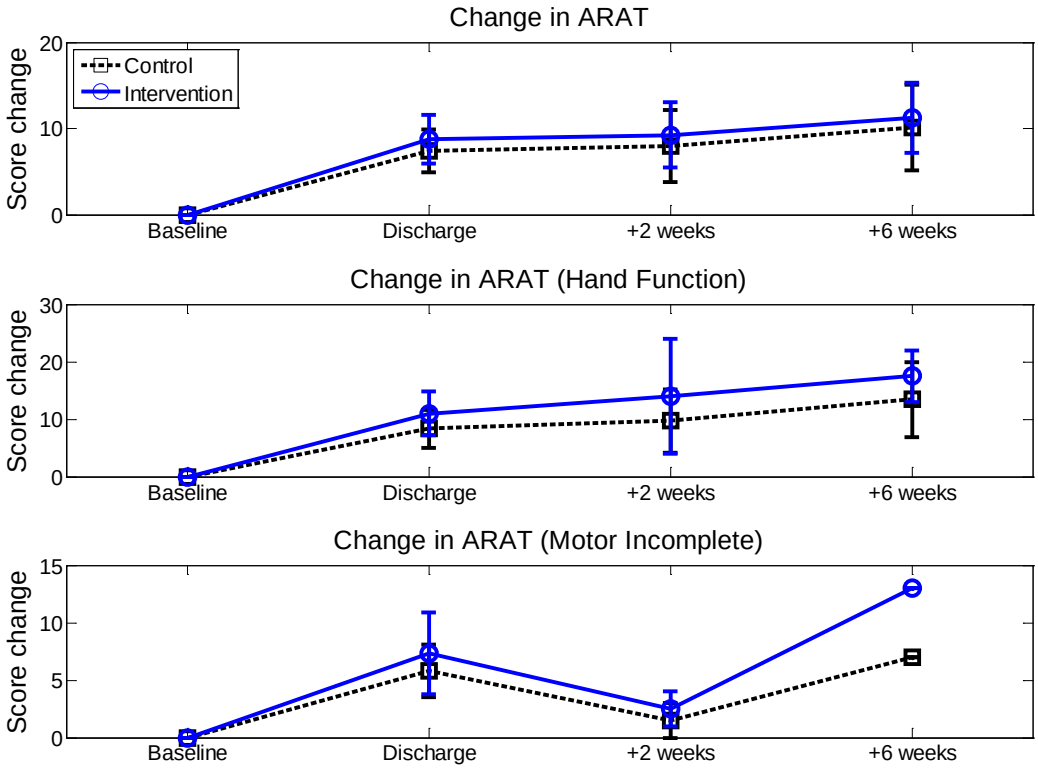
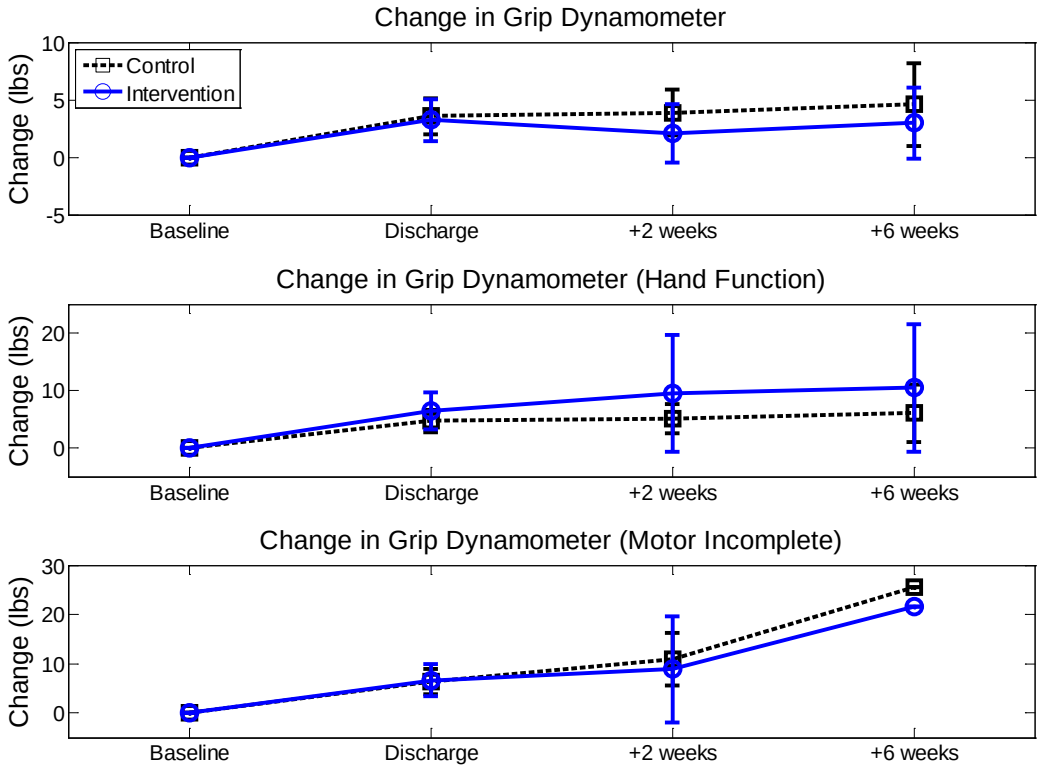
+2 weeks
+6 weeks
Change in GRASSP Sensibility
Change in GRASSP Qualitative Prehension
Change in GRASSP Quantitative Prehension

Figure 4


Change in ARAT
Score change
Control
Intervention
0
10
20
Baseline
Discharge
+2 weeks
+6 weeks
Change in ARAT (Hand Function)
Score change
0
10
20
30
Baseline
Discharge
+2 weeks
+6 weeks
Change in ARAT (Motor Incomplete)
Score change
0
5
10
15
Baseline
Discharge
+2 weeks
+6 weeks

1

2 **Figure 5**


Change in Grip Dynamometer
Control
Intervention
Change (lbs)
10
5
0
-5
Baseline
Discharge
+2 weeks
+6 weeks
Change in Grip Dynamometer (Hand Function)
Change (lbs)
20
10
0
Baseline
Discharge
+2 weeks
+6 weeks
Change in Grip Dynamometer (Motor Incomplete)
Change (lbs)
30
20
10
0
Baseline
Discharge
+2 weeks
+6 weeks

1

2 **Figure 6**