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Effect of Gravity on Robot-Assisted Motor Training After Chronic Stroke: A Randomized Trial

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Abstract

Objectives—To determine the efficacy of 2 distinct 6-week robot-assisted reaching programs compared with an intensive conventional arm exercise program (ICAE) for chronic, stroke-related upper-extremity (UE) impairment. To examine whether the addition of robot-assisted training out of the horizontal plane leads to improved outcomes.

Design—Randomized controlled trial, single-blinded, with 12-week follow-up.

Setting—Research setting in a large medical center.

Participants—Adults (N=62) with chronic, stroke-related arm weakness stratified by impairment severity using baseline UE motor assessments.

Interventions—Sixty minutes, 3 times a week for 6 weeks of robot-assisted planar reaching (gravity compensated), combined planar with vertical robot-assisted reaching, or intensive conventional arm exercise program.

Main Outcome Measure—UE Fugl-Meyer Assessment (FMA) mean change from baseline to final training.

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A commercial party having a direct financial interest in the results of the research supporting this article has conferred or will confer a financial benefit on the author or one or more of the authors. Krebs is a coinventor of the Massachusetts Institute of Technology (MIT) held patent for the robotic device used in this work and holds equity positions in Interactive Motion Technologies Inc, a company that manufactures this type of technology under license to MIT.

Results—All groups showed modest gains in the FMA from baseline to final with no significant between group differences. Most change occurred in the planar robot group (mean change $\pm$ SD, 2.94 ± 0.77 ; 95% confidence interval [CI], 1.40 – 4.47). Participants with greater motor impairment ($n=41$) demonstrated a larger difference in response (mean change $\pm$ SD, 2.29 ± 0.72 ; 95% CI, 0.85–3.72) for planar robot-assisted exercise compared with the intensive conventional arm exercise program (mean change $\pm$ SD, 0.43 ± 0.72 ; 95% CI, –1.00 to 1.86).

Conclusions—Chronic UE deficits because of stroke are responsive to intensive motor task training. However, training outside the horizontal plane in a gravity present environment using a combination of vertical with planar robots was not superior to training with the planar robot alone.

Keywords

Rehabilitation; Robotics; Stroke; Upper extremity

Rehabilitation after a stroke is beneficial, but no specific approach has been shown to be superior.¹ Evidence suggests intensity, repetition, and task-specific practice are key elements supporting motor recovery.^{1–3} Clinical practice has been slow to incorporate these principles, and rehabilitation of the upper extremity (UE) is often incomplete with deficits remaining in 55% to 75% of survivors 6 months after onset.⁴ Therapeutic robots provide a novel rehabilitation approach providing repetitive training in a highly controlled and replicable manner affording careful implementation of neuro-plasticity and motor control learning principles and examination of factors influencing recovery.⁵

Previous studies employing a single type of robot in the chronic phase of recovery found improvements in arm impairment and motor outcomes,^{6,7} but functional ability gains were not robust.^{8,9} A recent study¹⁰ used a combination of planar, vertical (antigravity), wrist, and hand robot training and showed improvements in both arm impairment and functional recovery, but the added value of each robot modality was not addressed.

The purpose of this randomized controlled trial was to investigate the added value of training 2 versus 3 dimensions including antigravity training¹¹ and compare the combination of vertical and planar robot with planar alone. We also compare the effectiveness of these robot-assisted modalities to a positive control group of intensive conventional arm exercise (ICAE). We hypothesized that planar robot training combined with robot-assisted reaching outside the constrained gravity-compensated horizontal plane would be superior to gravity-compensated planar robot therapy alone. It was also hypothesized that a 6-week program of robot-assisted motor training would be more efficacious than intensive conventional arm exercise across impairment, function, and activity measures. A previous uncontrolled study showed greater benefits in severely affected patients^{12,13} that we sought to replicate as others suggest otherwise with larger benefits for less impaired participants.¹⁴

METHODS

This was a prospective, randomized, single-blinded, controlled trial. All participants gave written informed consent prior to enrollment through methods approved by the governing

institutional review boards, and all procedures followed protocol in accordance with the ethical standards of the institutional review boards.

Participants

A total of 147 community-dwelling adults with a diagnosis of chronic stroke were referred by clinicians or advertisements for study criteria screening (table 1). Sixty-two met all criteria and proceeded to randomization (fig 1). This population was 54% men, had a mean age of 57.8 ± 10.7 years, and presented 4.2 ± 5.48 years poststroke. Stroke type was ischemic in 89%, hemorrhagic in 11%, and 3 participants had a history of multiple strokes (table 2). Prior to randomization, participants demonstrated stable motor performance for 3 pretraining Fugl-Meyer Assessment (FMA) (test score differences ≤ 2 points). Between group differences were minimized using a computer randomization scheme stratified by the mean UE FMA baseline score. A score of 25 or below was considered severe impairment.¹⁵ The groups had similar baseline characteristics with a large percentage presenting with severe impairment (see table 2). Five participants withdrew because of medical or personal reasons, allowing for analysis of 57 participants.

Outcome Measures

All evaluations were performed by the same therapist who had established inter- and intrarater reliability on the FMA in a previous study.¹⁰ Clinical and robot outcome testing was performed at baseline, midpoint, final, and at 12-week follow-up. Clinical measures of motor impairment, UE function, and quality of life were completed by a single, experienced evaluator blinded to group assignment. The primary outcome measure was the mean change in the UE portion of the FMA from baseline to final training. The FMA is an impairment level measure specific to patients poststroke. The motor section incorporates stages of recovery and examines arm movement, coordination, and reflexes.¹⁶ Scores are based on a 3-point ordinal scale, ranging from 0 to 66, with higher scores indicating less impairment. It has been shown to be both internally and externally valid.¹⁷ Additional clinical outcome measures were the Wolf Motor Function Test (WMFT) and the Stroke Impact Scale (SIS), version 3.¹⁸ The WMFT¹⁹ is a measure of arm function based on performance time, movement quality, and the ability to move a weight. Fifteen timed performance tests progress from simple to complex, and 2 tests include moving a weight against gravity. It has good interrater reliability and high criterion validity with the UE portion of the FMA when used with patients with chronic deficits.^{19,20} The SIS is a self-report outcome measure assessing stroke recovery within 8 clinically relevant domains contributing to a change in quality of life. It has been shown to be reliable, valid, and sensitive to change.¹⁸ The specific domains of activities of daily living (ADLs), mobility, and hand function were used.

Robot Metrics

Movement kinematics and kinetics were recorded using the robot as a low-friction measurement device. Each participant was asked to make: (1) 80 point-to-point movements similar to the training protocol; (2) 20 circle-drawing movements (untrained movements); and (3) 20 isostatic attempts to flex/extend or abduct/adduct the shoulder against the robot force transducer. Robot derived metrics extracted from the point-to-point movements included: (1) aiming (mean movement direction relative to target); (2) deviation from a

straight line; (3) mean speed; (4) peak speed; (5) smoothness (mean speed divided by peak speed);²¹ and (6) duration. Metrics extracted from the circle drawing kinematics and isostatic shoulder testing included the axes ratio (ratio of the minor and major axes of the ellipse best-fitting the data)²² and peak arm force, respectively. Quantitatively, these metrics assess motor change and recovery by showing whether aiming to a target improved, movement became faster or smoother, control of isolated shoulder and elbow movements improved, and whether shoulder strength improved.^{21,23,24}

Interventions

All interventions were provided by the same therapist for 6 weeks: 1 hour 3 times a week for a total of 18 sessions. Robot therapy included the use of 2 different robots specifically designed for UE neurologic rehabilitation. Robot-assisted planar reaching was performed with a 2 degree of freedom shoulder-elbow robot (InMotion 2.0 Shoulder/Arm Robot).^a The combined robot group (planar with vertical) used the planar shoulder-elbow robot for gravity-compensated horizontal reaching followed by the 1-degree of freedom linear robot (InMotion Linear Robot)^a in its vertical position for reaching against gravity. The robots provided assistance with a performance-based algorithm, adapting forces as needed to challenge or assist movement. This algorithm, introduced in 2002,²⁵ continuously challenges the patient by modifying (1) the time allotted for the patient to make the move and (2) the primary stiffness of the impedance controller that guides the movement. The better the patient performs, the more he or she is challenged to move quicker and receive less guidance. In addition, compliant and back-drivable programming allowed for expression of movement outside a rigid trajectory. The ICAE sessions were time matched with the robotic sessions. Rate of movement repetition was not precisely matched to the robot, but overall intensity was greater than that of a conventional exercise program.²⁶

Robot-Assisted Planar Reaching

Participants performed reaching in the horizontal plane while seated wearing a torso harness to decrease compensatory trunk movement. Reaching focused on the completion of shoulder and elbow movements toward visual targets within this gravity compensated plane. The participant's arm was supported throughout the movement in the robot arm, and straps were used as needed to maintain a cylindrical grasp. As many repetitions as possible were performed with the participant's paretic arm reaching toward 8 targets in a point-to-point circular pattern. If a task could not be completed volitionally, the robot provided assistance in addition to continual visual feedback on target location and arm position. A summary graph of the individual's performance appeared after every 80 movements. A typical session included 64 unassisted and 1280 assist-as-needed point-to-point movements for a total of 1344 movements.

Combined Planar and Vertical Robot-Assisted Reaching

Participants in this group performed 30 minutes of reaching with the planar robot described above, followed by 30 minutes of reaching against gravity with the vertical robot. The

^aInteractive Motion Technologies Inc, 80 Coolidge Hill Rd, Watertown, MA 02472.

involved hand independently grasped the robot handle or was assisted with strapping. Arm positioning included 45° to 65° of shoulder abduction (in the scapular plane) for elevation in a diagonal pattern away from the body to shoulder height, followed by lowering toward the body. This positioning was chosen to promote elbow extension and encourage isolated shoulder movements outside the predominating flexor synergy pattern. Movements were directed toward 3 visually guided targets in a linear pattern. A typical combined robot session consisted of 32 unassisted and 640 assist-as-needed movements with the planar robot and 32 unassisted and 640 assist-as-needed movements with the vertical robot for a total of 1344 movements.

Intensive Conventional Arm Exercise

Participants in this group performed exercises emphasizing active movement of the affected arm while in a seated position. The session included 40 minutes of active repetitive arm motions using an arm ergometer,^b a timed target-specific skate-board activity reaching from a center point outward, and shoulder and elbow range of motion exercises. Task-specific and functional reaching activities for cone reaching and simulated drinking from a cup also focused on active shoulder and elbow movements. Assistance was provided by the subject's less impaired arm or by the therapist as needed. In addition, passive and guided stretching activities were performed for 10 minutes with an additional 10 minutes for repositioning and rest between activities. Approximately 650 total arm motions were completed per session. Of notice, ICAE delivered a 15-times fold increase in intensity compared with usual conventional therapy for chronic patients, which in general includes 45 movements per session.²⁶

Data Analysis

A prestudy sample size calculation predicted a need for 40 subjects per group for an alpha of 5%, power of 95%, with an allowance of 10% attrition for a total of 120 subjects. A midstudy futility analysis showed a need for 99 participants per group to show the benefit of the addition of vertical training over ICAE. Therefore, the study was stopped after 62 subjects had been enrolled.

A baseline measure for each clinical outcome was defined by computing the average of the 3 evaluations prior to training. An analysis of variance of the baseline FMA scores examined group differences at enrollment. Linear mixed models analyzed changes at the posttraining time points jointly, with time, group, and time by group interaction as the fixed effects for each outcome measure. To address correlation among repeated measures, a compound symmetry covariance structure was assumed, which meant all posttraining FMA changes had equal variance and the correlations between any pair of FMA changes were equal. An analysis of all robot interventions compared with intensive conventional arm exercise for FMA total change was also completed using linear mixed models. To test whether there is change in FMA at each posttraining point for each intervention, the average change at each posttraining time point within each group was estimated by the linear combination of the fixed effects in the above linear mixed model. The corresponding SEs were adjusted for the

^bMonarch Rehab Trainer 881E, Monark Exercise Ab, Kroons väg 1780 50 Vansbro, Sweden.

above covariance structure so the hypothesis testing correctly took the repeated measures into consideration. To adjust for 2 treatment comparisons and interim monitoring for the treatment effect, the significance level was set at .025 (2-sided P).¹⁰ We employed a similar approach for WMFT and SIS.

As a secondary analysis, we compared the FMA, WMFT, and SIS changes between groups for participants with baseline FMA ≥ 25 ($n=41$) using the linear mixed model as noted above. All clinical outcome statistical analysis was performed with SAS Software, version 9.1.^c

Robot metric values were compared between groups at baseline using the analysis of variance models. The same approach was employed to compare changes in the robot-based metrics between groups from baseline to each posttraining timepoint. All statistical analysis was performed with Statview, version 5.0^d and MATLAB, software version 2010.^e

RESULTS

Primary Outcome

There were no group differences ($P=.63$) for the baseline FMA scores (fig 2). Analysis of the changes in the FMA outcome scores ($n=57$) showed no significant differences for the FMA between the 3 interventions ($P=.38$ for group main effect) or between robotic training as a whole compared with the intensive conventional arm exercise control ($P=.26$). The planar robot group had a larger change at final and follow-up, but these changes were not statistically significantly different from the changes in the intensive conventional arm exercise group ($P=.12$ and $P=.19$, respectively) (means $\pm$ SEs in table 3). With our current sample size and the observed within group SD (4.0), the power of detecting the observed difference between the planar and intensive conventional arm exercise groups was 41% (type II error probability = .59). An examination of within group changes did show statistical significance for the 2 robotic groups not seen in the intensive conventional arm exercise (see fig 2). A subgroup analysis (table 4) of participants with a baseline FMA of 25 or less demonstrated a larger positive response for the FMA (mean $\pm$ SE, 2.29 ± 0.72 ; 95% confidence interval [CI], 0.85–3.72) for planar robot-assisted exercise compared with ICAE (mean $\pm$ SE, 0.43 ± 0.72 ; 95% CI, -1.00 to 1.86), showing a trend toward significance ($P=.07$) for the planar training over intensive conventional arm exercise at final.

Secondary Outcomes

Analysis of the changes in WMFT scores showed no significant differences ($P=.58$ for the group main effect) between the groups for speed of motor task performance (see table 3). Based on linear mixed models, the planar with vertical group had a larger change with significance in SIS ADLs scores at final (mean $\pm$ SE, 5.95 ± 2.74 ; 95% CI, 0.49–11.40) compared with the intensive conventional arm exercise group (mean $\pm$ SE, -3.19 ± 2.46 ;

^cSAS Inc, 100 SAS Campus Dr, Cary, NC 27513.

^dStatview, SAS Institute Inc, 2 Embarcadero Center, Suite 200, San Francisco, CA 94111-3834.

^eMATLAB, 3 Apple Hill Dr, Natick, MA 01760.

95% CI, - 8.08 to 1.69; difference in mean $\pm$ SE between the 2 groups is 9.14 ± 3.68 ; $P = .02$).

Interestingly, among the more impaired patients, the planar group had a larger WMFT time change (see table 4) at final compared with the intensive conventional arm exercise based on linear mixed models (mean $\pm$ SE in planar, -6.64 ± 2.30 ; mean $\pm$ SE in ICAE, 0.02 ± 2.30 ; difference in mean $\pm$ SE, 6.67 ± 3.23 ; $P = .04$). However, this was not significant based on our cutoff of .025. An analysis of the SIS for this subgroup showed the planar with vertical group had larger change with significance at final for SIS ADLs score compared with the intensive conventional arm exercise group (mean $\pm$ SE in planar with vertical, 7.75 ± 2.96 ; mean $\pm$ SE in ICAE, -2.31 ± 2.60 ; difference in mean $\pm$ SE, -10.06 ± 3.94 , $P = .01$). In addition, the planar group had a large change at final for SIS hand score compared with the intensive conventional arm exercise group (difference in mean $\pm$ SE, -11.54 ± 5.33 , $P = .03$). However, this was not significant based on our cutoff of .025.

Robot Metrics

Robot metrics were examined as they may afford better resolution than the clinical scales.²⁷ The baseline metrics were analyzed and found to be comparable between groups. At final training, the robotic groups improved more and demonstrated a statistically superior performance in aiming over the intensive conventional arm exercise (table 5). There were no significant differences between the 2 robotic groups; however, the planar alone showed a positive trend toward significance for deviation, smoothness, and ellipse ratio. At follow-up, the robot groups maintained the significant advantage in aiming over intensive conventional arm exercise. The changes in performance for the robot metrics were consistent with the clinical scales except for speed, where the intensive conventional arm exercise and planar group had a noticeable trend over the planar with vertical.

DISCUSSION

The efficacy of robotic exercise was compared with a positive control consisting of intensive conventional arm exercise in individuals with long standing impairment after stroke. On the primary outcome, all 3 groups showed modest gains from baseline to final training without significant differences. The 2 robotic groups, however, had significant within-group changes at final and after a retention period not seen in the intensive conventional arm exercise control. The planar robot training showed the greatest differential gains particularly for our participants with severe motor impairment. In addition, the robot-derived performance metrics showed superiority of the 2 robot groups in aiming performance with trends in other metrics favoring the planar robot group, including the untrained circle task. In contrast, when reporting ADLs on the SIS, the planar with vertical group showed greater change compared with the control, which was also seen when the analysis was restricted to those with severe motor impairment. Taken together, our findings disproved our hypothesis that a combination of planar with vertical robot-assisted reaching would lead to superior overall results and established partial support that robot training is superior to a positive control consisting of intensive conventional arm exercise.

Are Robotic Interventions Beneficial for Chronic Moderate to Severe Impairments?

Stroke survivors with moderate to severe impairments are not only more limited in their daily functioning than those with mild impairments, they have also not been targeted for recovery by successful interventions such as constraint induced therapy.²⁸ A consistent finding in our study was the positive change across multiple domains of UE motor control for robot-trained participants with more severe deficits. This is in contrast with other robot studies,^{7,14} but supportive of a previous study where intense short-term planar robot training was beneficial in long standing severe impairment.¹³

Findings examining repetitive training in the acute phase of recovery²⁹ suggest a 6 to 7 point (10%) change on the FMA to be meaningful; however, a 3-point (5%) change may be meaningful for individuals with long standing severe impairment.¹⁰ Clinical examples of function gained from a 3-point incremental FMA change include improving from 11 to 14 for lifting of the arm to wash the axilla, or from 19 to 22 to straighten the arm and place it in a sleeve. The modest changes on the FMA for our participants at final were durable at retention, suggesting continued use of the affected arm for daily activities such as these after training. As seen in a recent study of robot training compared with a positive control intensity-matched conventional training, intensity is key for improving recovery.¹⁰ Like the study by Lo et al,¹⁰ our 2 robotic interventions of similar repetitive intensity did lead to similar improvements in FMA but not so clearly for the secondary outcomes. Indeed our findings for the combined robotic training group suggest that intervention type and practice schedules are important additional considerations to repetitive intensity.^{30,31}

Is a Combination of Gravity Compensated and Noncompensated Robot Training Beneficial?

Independence in everyday activities includes the ability to execute reaching motions at any given moment despite the influences of gravity. Success depends on the accurate assessment of motor demands, retrieval of motor commands, and adaptability based on generalization from past experiences and sensory feedback. Generalization is beneficial when skill transfer occurs but can be detrimental when interference occurs.³² In this investigation, the robot interventions were primarily differentiated by the presentation of 2 different types of reaching (gravity compensated and antigravity) versus reaching in a single (gravity compensated) horizontal plane. It was hypothesized that a combined robotic training program would enhance recovery by increasing task challenge and generalization of reaching in more than 1 context. The successive presentation of arm activities with different environmental and motor demands did not lead to better overall group outcomes. One interpretation of these results is that the motor system uses 2 distinct internal models for whole arm antigravity reaching and gravity compensated planar reaching, and our blocked training in close succession interfered with motor consolidation.^{33,34} This interpretation is supported by a prior robotic study that found 6 weeks of gravity noncompensated vertical reaching promoted recovery in chronic stroke if it followed, rather than abutted, 6 weeks of gravity-compensated planar reaching.³⁵ Whether motor memories become consolidated³⁶ or whether practice sequencing is integral for motor memories³⁷ is a complex question that this study design cannot answer.

However, given the positive findings that the combined group had with reporting ADLs as well as the results of the previous study,³⁵ it seems plausible that further investigation of different sequencing of the 2 robot therapies might be warranted. For example, perhaps combining 2 robotic therapies in alternating days or weeks would provide a more optimal recovery curve across impairment, function, and participation. Perhaps, even, each domain might require a different schedule. Optimizing the sequence and demand of therapy is clearly an important necessary future step in using robotic rehabilitation to optimize stroke recovery.

Study Limitations

Several limitations should be considered when interpreting our data. First, our sample size was small given the modest changes on our outcome measures. For the FMA, we would have needed 99 participants per group to achieve a significance level of 80%, and the WMFT may not have been sensitive to our chronic stroke population because of a floor effect of task difficulty.³⁸ Second, our inclusion criteria allowed for a heterogeneous population and mean data scores may have masked findings. Third, our interventions were time-matched and not intensity-matched, allowing for variability in the actual number of repetitions delivered per participant. Fourth, the small advantage of the planar group in the robot metrics could be explained by the fact that this group had more practice on the tested movements (albeit with robot assistance). However, we did include an evaluation of a task that had not been trained, the circle task, and the same qualitative advantage still held. Furthermore, a previous study³⁹ evaluated repeated testing with the robot and did not see a change across time, suggesting stability of the measurement.

CONCLUSIONS

This investigation extends prior research on robotic therapy in the chronic phase of stroke for individuals with moderate to severe motor impairments by evaluating change over multiple domains as well as uniquely testing planar gravity-compensated training against combined planar with gravity noncompensated vertical training. It adds to the evidence that individuals greater than 6 months poststroke are capable of motor improvements, but it questions the presumed advantage of adding robotic training in a 3-dimensional space to that in 2-dimensional space. At the same time, it expands interest in research on the interplay between stroke recovery, training structure, and motor learning processes such as consolidation and interference.

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List of Abbreviations

ADLs activities of daily living

CI	confidence interval
FMA	Fugl-Meyer Assessment
ICAE	intensive conventional arm exercise
SIS	Stroke Impact Scale
UE	upper extremity
WMFT	Wolf Motor Function Test

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Fig 1.
Enrollment. Abbreviation: F/u, follow-up.

Fig 2.

This figure of FMA change scores shows the sample means and SDs at each baseline evaluation and each posttraining time point by intervention groups. *P* was based on paired *t* tests. Scores at the baseline demonstrate stability and were without significant between group differences. The within group change from baseline to final showed a significant benefit for both robotic groups: planar 2.79 ± 3.82 ($P=.005$) and planar with vertical 1.69 ± 2.19 ($P=.005$). This benefit was also seen from baseline to follow-up: planar 3.27 ± 3.27 ($P=.002$) and planar with vertical 2.51 ± 3.33 ($P=.007$).

Table 1**Inclusion and Exclusion Criteria**

Inclusion Criteria	Exclusion Criteria
Diagnosis of clinically defined, unilateral hemiparetic stroke with radiologic exclusion of other possible diagnoses *	Serious complicating medical illness and/or stroke occurring within the previous 6mo
Onset of stroke >6mo before randomization for ischemic stroke, >12mo for hemorrhagic stroke	Contractures or orthopedic problems limiting the range of joint movement in the potential study arm
Manual muscle testing of grade 3 or lower for at least 1 muscle of the affected arm	Visual loss limiting the ability to see the test patterns on the robot monitor
18y of age	Botox injection to the study arm within 3mo of enrollment or during the study Any change in exercise regimen during the study period (starting or discontinuing)

* More than 1 stroke affecting the same hemisphere was allowed for study enrollment.

Table 2

Characteristics

Characteristic	Planar	Planar With Vertical	ICAE
Participants (withdrawn)	20 (0)	21 (3)	21 (2)
Age (y)	57±12	60±13	56±6.3
Men:women (%)	55:45	56:44	53:47
Years since stroke	3±2	5±8	4±6
Ischemic:hemorrhagic	16:4	16:2	19:0
Multiple stroke	1	0	2
Cortical stroke	0	1	0
Subcortical stroke	6	6	7
Cortical with subcortical	12	7	10
Location (missing/unknown)	2	4	2
% with severe impairment (baseline FMA score < 25)	70	72	74
Baseline outcome scores			
Fugl-Meyer*	20.3±14.7	16.5±10.6	18.2±12.5
Wolf Motor mean time [†]	71.5±40.2	87.1±35.7	82.8±33.3
SIS [‡]			
ADLs	73.2±15.7	70.6±14.4	71.4±14.0
Hand	18.0±28.5	7.9±5.5	15.5±20.9
Mobility	80.5±12.8	81.1±12.3	79.5±18.1

NOTE. Values are mean ± SD or as otherwise indicated.

* Maximum score for UE FMA is 66.

[†] Maximum score for WMFT is 120s with a lower score indicating better function.

[‡] SIS maximum score per domain: ADLs (100), hand (100), mobility (100).

Table 3

Clinical Outcome Scores

Outcome Measure	Baseline to Final			Baseline to Follow-Up		
	Planar (n=20)	Planar With Vertical (n=18)	ICAE (n=19)	Planar (n=20)	Planar With Vertical (n=18)	ICAE (n=19)
All (N=57)						
FMA *	2.94±0.77 (1.40 to 4.47)	1.70±0.80 (0.09 to 3.28)	1.19±0.78 (-0.36 to 2.74)	3.30±0.80 (1.72 to 4.88)	2.61±0.81 (0.99 to 4.23)	1.82±0.78 (0.26 to 3.37)
Mean difference (95% CI)						
<i>P</i>	.0002	.04	.13	.0001	.002	.02
WMFT ^{†‡}	-4.38±2.05 (-8.46 to -0.31)	-2.85±2.13 (-7.10 to 1.37)	-1.71±2.06 (-5.79 to 2.37)	-4.53±2.12 (-8.73 to -0.33)	-3.37±2.16 (-7.66 to 0.92)	-2.77±2.07 (-6.88 to 1.34)
Mean difference (95% CI)						
<i>P</i>	.04	.18	.41	.03	.12	.18
SIS [§] ADLs	1.92±2.74 (-3.54 to 7.37)	5.95±2.74 (0.49 to 11.40)	-3.19±2.46 (-8.08 to 1.69)	3.29±2.80 (-2.28 to 8.86)	-1.35±2.78 (-6.93 to 4.22)	-2.60±2.54 (-7.65 to 2.45)
Mean difference (95% CI)						
<i>P</i>	.49	.03	.20	.24	.63	.31
SIS hand	10.99±3.96 (2.21 to 17.99)	8.96±3.96 (1.08 to 16.85)	-0.28±3.53 (-7.31 to 6.76)	8.11±4.07 (0.01 to 16.21)	5.17±4.07 (-2.93 to 13.26)	4.87±3.68 (-2.45 to 12.20)
Mean difference (95% CI)						
<i>P</i>	.01	.03	.94	.05	.21	.19
SIS mobility	0.71±2.96 (-5.17 to 6.60)	6.47±2.96 (0.59 to 12.36)	1.23±2.63 (-3.00 to 6.47)	1.65±3.04 (-4.41 to 7.71)	-0.67±3.04 (-6.76 to 5.36)	1.30±2.75 (-4.18 to 6.77)
Mean difference (95% CI)						
<i>P</i>	.81	.03	.64	.59	.82	.64

NOTE. The table is a comparison of mean change scores for study baseline to final and study baseline to follow-up. Values are mean ± SE or as otherwise indicated.

*The FMA change scores showed a significant positive change for the planar robot group at final and follow-up. A significant positive change on the FMA was also seen at follow-up for the planar with vertical group.

[†]The WMFT change scores showed a trend for improvement for the planar group at final and follow-up.

[‡]A negative number for the WMFT indicates improvement as a decrease in time to complete the task.

[§]The SIS showed a trend for improvement in the planar robot group at final and follow-up in the physical domain subsection for the hand.

The planar with vertical group showed a trend for improvement in the subsections for ADLs, hand, and mobility at final.

Clinical Outcome Scores for Participants With Severe Impairment Based on Baseline Fugl-Meyer Scores of 25 or Less

Table 4

Outcome Measure	Baseline to Final			Baseline to Follow-Up		
	Planar (n=14)	Planar With Vertical (n=13)	ICAE (n=14)	Planar (n=14)	Planar With Vertical (n=13)	ICAE (n=14)
Severe (n=41)						
FMA *	2.29±0.72	1.15±0.75	0.43±0.72	2.09±0.75	1.38±0.76	0.71±0.72
Mean difference (95% CI)	(0.85 to 3.72)	(-0.33 to 2.64)	(-1.00 to 1.86)	(0.61 to 3.58)	(-0.14 to 2.89)	(-0.72 to 2.15)
P	.002	.13	.55	.01	.07	.32
WMFT ^{†‡}	-6.64±2.30	-0.31±2.37	0.02±2.30	-4.36±2.37	-0.37±2.42	-2.22±2.28
Mean difference (95% CI)	(-11.20 to -2.09)	(-5.04 to 4.42)	(-4.53 to 4.58)	(-9.09 to 0.36)	(-5.19 to 4.44)	(-6.77 to 2.33)
P	.005	.90	.99	.07	.88	.33
SIS [§] ADLs	2.95±2.82	7.75±2.96	-2.31±2.60	3.95±2.93	-2.23±3.22	-2.28±2.77
Mean difference (95% CI)	(-2.70 to 8.61)	(1.81 to 13.69)	(-7.51 to 2.90)	(-1.92 to 9.81)	(-8.69 to 4.23)	(-7.83 to 3.26)
P	.30	.01	.38	.18	.49	.41
SIS hand	10.0±3.92	6.50±4.11	-1.54±3.61	2.36±4.04	3.03±4.41	3.15±3.80
Mean difference (95% CI)	(2.14 to 17.86)	(-1.74 to 14.74)	(-8.77 to 5.69)	(-5.73 to 10.45)	(-5.81 to 11.87)	(-4.49 to 10.76)
P	.01	.12	.67	.56	.49	.41
SIS mobility	-0.51±3.13	8.61±3.28	2.99±2.88	-1.96±3.27	-3.05±3.63	5.01±3.11
Mean difference (95% CI)	(-6.78 to 5.77)	(2.03 to 15.19)	(-2.78 to 8.76)	(-8.51 to 4.59)	(-10.33 to 4.23)	(-1.21 to 11.24)
P	.87	.01	.30	.55	.41	.11

NOTE. The table is a comparison of mean change scores for study baseline to final and study baseline to follow-up. Values are mean ± SE or as otherwise indicated.

*The FMA change scores showed significant positive change for the planar group at final and trend at follow-up.

[†]The WMFT change scores showed significant positive change for the planar group at final and trend with increased variability at follow-up.

[‡]A negative number on the WMFT indicates improvement as a decrease in time to complete the task.

[§]SIS physical domain subsection results showed trends toward improvement immediately after therapy in both robotic treatment groups.

Table 5

Robot Metrics

Robot Metric	Baseline to Final			Baseline to Follow-Up		
	Planar (n=19)	Planar With Vertical (n=18)	ICAE (n=18)	Planar (n=17)	Planar With Vertical (n=16)	ICAE (n=16)
Aim* (rad)	-0.159±0.161 [†]	-0.135±0.133 [†]	-0.005±0.100	-0.150±0.135 [†]	-0.168±0.107 [†]	-0.062±0.119
Deviation* (m)	-0.006±0.009 [‡]	-0.003±0.006	-0.001±0.007	-0.005±0.005	-0.004±0.006	-0.005±0.008
Mean speed (m/s)	0.008±0.036	0.001±0.028	0.013±0.013	0.008±0.033 [?]	-0.004±0.019	0.013±0.014 [§]
Peak speed (m/s)	-0.013±0.077	-0.012±0.075	0.020±0.024	-0.010±0.078	-0.027±0.058	0.013±0.027 [§]
Smoothness (nondimensional)	0.066±0.069 [‡]	0.050±0.045	0.036±0.047	0.061±0.055	0.047±0.041	0.049±0.057
Duration* (s)	-0.834±0.960	-0.377±1.958	-0.646±1.227	-0.690±0.950	-0.344±1.629	-0.761±1.761
Ellipse ratio (nondimensional)	0.138±0.156 [‡]	0.093±0.090	0.069±0.109	0.124±0.148	0.083±0.126	0.141±0.147
Z force (N)	2.844±4.755	3.359±6.174	1.764±6.496	3.466±5.417	4.228±9.372	2.195±5.037

NOTE. Values are mean ± SD.

* A negative value indicates improvement.

[†] Statistical significance for planar and for planar with vertical versus ICAE ($P<.022$).[‡] Statistical trend for planar and planar with vertical group versus ICAE ($P<.10$).[§] Statistical trend for ICAE and planar versus planar with vertical ($P<.10$).