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ORIGINAL RESEARCH

Comparison of Robotics, Functional Electrical Stimulation, and Motor Learning Methods for Treatment of Persistent Upper Extremity Dysfunction After Stroke: A Randomized Controlled Trial

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Abstract

Objective: To compare response to upper-limb treatment using robotics plus motor learning (ML) versus functional electrical stimulation (FES) plus ML versus ML alone, according to a measure of complex functional everyday tasks for chronic, severely impaired stroke survivors.

Design: Single-blind, randomized trial.

Setting: Medical center.

Participants: Enrolled subjects (N = 39) were >1 year postsingle stroke (attrition rate = 10%; 35 completed the study).

Interventions: All groups received treatment 5d/wk for 5h/d (60 sessions), with unique treatment as follows: ML alone (n = 11) (5h/d partial- and whole-task practice of complex functional tasks), robotics plus ML (n = 12) (3.5h/d of ML and 1.5h/d of shoulder/elbow robotics), and FES plus ML (n = 12) (3.5h/d of ML and 1.5h/d of FES wrist/hand coordination training).

Main Outcome Measures: Primary measure: Arm Motor Ability Test (AMAT), with 13 complex functional tasks; secondary measure: upper-limb Fugl-Meyer coordination scale (FM).

Results: There was no significant difference found in treatment response across groups (AMAT: $P \geq .584$; FM coordination: $P \geq .590$). All 3 treatment groups demonstrated clinically and statistically significant improvement in response to treatment (AMAT and FM coordination: $P \leq .009$). A group treatment paradigm of 1:3 (therapist/patient) ratio proved feasible for provision of the intensive treatment. No adverse effects.

Conclusions: Severely impaired stroke survivors with persistent (>1y) upper-extremity dysfunction can make clinically and statistically significant gains in coordination and functional task performance in response to robotics plus ML, FES plus ML, and ML alone in an intensive and long-duration intervention; no group differences were found. Additional studies are warranted to determine the effectiveness of these methods in the clinical setting.
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Treatment methods using motor learning (ML) principles for the treatment of persistent upper-limb dysfunction after stroke have been reported in the literature.[1-11] Some have compared the application of ML principles with neurorehabilitation methods (eg, Bobath concept, neurodevelopmental treatment).[1,2] Still, others have used bilateral upper-extremity exercise[3] or constraint-induced motor therapies for mild/moderate upper-extremity

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dysfunction.[4-11] Most of these studies showed promising results, but stroke survivors did not recover normative function, and gains were statistically significant but small.

In addition to ML-based treatment strategies, technology-based upper-limb therapies (eg, robotics training, functional electrical stimulation [FES]) have also produced some positive results. Treatment with robotics has shown statistically significant gains in measures of impairment for chronic stroke survivors,[12-17] but some reported gains were not considered clinically significant according to an outcome measure of coordination.[18] At the same time, surface FES was reported beneficial with chronic stroke subjects according to measures of impairment.[19,20] Although robotics and FES have each shown promise, there is a paucity of information regarding the comparative benefit. Additionally, there is little evidence of whether or not a treatment paradigm using a combination of ML therapy and technology-based therapy would be superior to ML alone, according to a homogeneous measure of the performance of actual complex functional tasks of everyday life; rather, a number of reported outcome measures contain a mixture of impairment items and functional task items. Finally, many studies have focused on mildly to moderately impaired stroke survivors, with significantly less attention paid to the severely impaired (≤36 points on the upper-limb motor Fugl-Meyer [FM] score[21]). Therefore, in consideration of all these issues together, the purpose of this study was to investigate, for severely impaired, chronic stroke survivors, the comparative response to treatment using shoulder/elbow robotics plus ML versus wrist/hand FES plus ML versus ML alone according to a measure of actual complex functional tasks of everyday life.

Methods

Study design

This was a randomized controlled trial comparing response to treatment across 3 different treatment groups: robotics plus ML, FES plus ML, and ML. Subjects in all 3 groups received treatment for 5h/d for 5d/wk for 12 weeks (60 treatment visits). Measures were acquired at pre- and posttreatment.

Participants

There were 174 phone inquiries regarding the study. Of these, 135 did not meet criteria for an in-person screen (fig 1). Thirty-nine subjects participated in an in-person screen. Study inclusion criteria included persistent (>1y), upper-extremity impairment; at least a trace muscle contraction in the wrist extensors; single unilateral stroke; mobility and function sufficient for independent performance of activities (eg, toileting, eating lunch during the treatment days); stable medical condition; no other prior neurologic condition; and ability to follow 2-step commands. The study was conducted under the oversight of the institutional review board of the medical center. All subjects provided informed consent prior to study participation.

List of abbreviations:

AMAT	**Arm Motor Ability Test**
AMAT-F	**AMAT Function scale**
AMAT S/E	**Arm Motor Ability Test for shoulder/elbow**
AMAT S/E-F	**AMAT S/E Function scale**
AMAT W/H	**Arm Motor Ability Test for wrist/hand**
AMAT W/H-F	**AMAT W/H Function scale**
FES	**functional electrical stimulation**
FM	**Fugl-Meyer**
ML	**motor learning**

Technology

Robotics training was implemented using the InMotion2 Shoulder-Elbow Robot.[a] This robotic device is a 2-degrees-of-freedom system that is back-drivable and impedance-controlled to allow for near-frictionless movement in a horizontal plane. The robot used the QNX real-time operating system,[b] which allowed for high-performance control and integrated graphics. Subjects were seated comfortably in a chair with their hemiplegic forearm and hand supported by a forearm cradle and cone-shaped hand support. Training movements were shoulder/elbow movements of flexion/extension and horizontal shoulder movements from a center target to and from 8 points located on a circle around the center point.

FES was provided with the commercially available EMS+2 stimulator[c] and surface gel electrodes (flexible PALS surface electrodes[d]). The EMS+2 is a portable, battery-operated, 2-channel surface electrical stimulator that delivers a biphasic, symmetrical, rectangular output for each of the 2 available channels. The stimulation parameters were as follows: 300-millisecond pulse width, 40Hz, and amplitude varied according to subject tolerance. The muscles stimulated included wrist and finger flexors/extensors and forearm supinators/pronators.

Interventions

The goal of training was recovery of the movement components composing functional tasks and recovery of performance of the whole complex task. Treatment was based on ML principles including the following: movement practice as close to normative as possible,[22,23] high number of repetitions,[24-27] attention to the motor task,[28] and training specificity.[29] Progression of training was based on the recovery of volitional capability and motor task difficulty, according to the motor task difficulty hierarchy shown in appendix 1. ML exercises were provided for training-isolated joint movement coordination of the scapula, shoulder, elbow, forearm, wrist, fingers, and thumb; task component movements; and whole arm/hand functional training (appendix 2).

Examples of practiced task components are reaching, grasp preparation, and grasp release. To encourage participation, functional tasks that were meaningful to the subject were used. We used a 1:3 group therapy paradigm, whereby 1 therapist treated a group of 3 subjects for 5h/d. There were 3 interventionists; each one was assigned to 1 of the 3 treatment groups. Standardization of treatment was addressed through weekly meetings that included identification of subject impairments and consensus of treatment addressing each given impairment.

Those in the robotics plus ML group used the robot for 1.5h/d. For the remainder of the day they were provided with ML without technologies (3.5h). Similarly, those in the FES plus ML group used FES for 1.5h/d. The ML group was provided with the ML intervention for 5h/d.

Primary outcome measure: Arm Motor Ability Test

All measures were acquired at pre- and posttreatment. There was 1 assessor, who was blinded to the group assignment of the subject. The primary outcome measure was the Arm Motor Ability Test (AMAT), which is a homogenous measure of functional tasks of

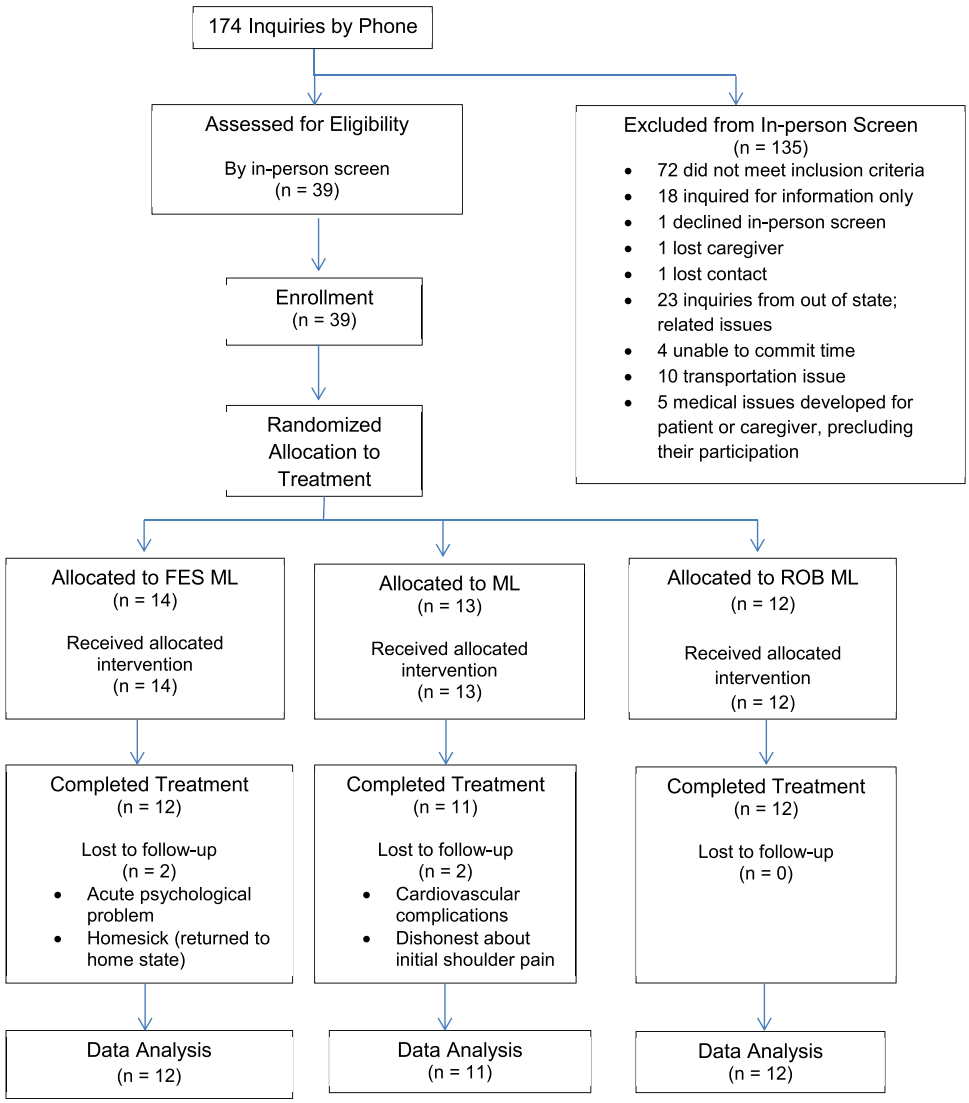

Fig 1 Consolidated Standards of Reporting Trials diagram. Depiction of subject selection, group allocation, attrition and data analysis. Abbreviations: FES ML, FES plus ML group; ML, ML group; ROB ML, robotics plus ML group.

everyday living.[30] The AMAT consists of 13 complex functional tasks, which are videotaped and timed for performance. Examples of the AMAT tasks of everyday living are as follows: pick up and drink from a mug and pick up comb and comb hair.

Secondary measures

Because the robotics and FES technologies were focused on shoulder/elbow or wrist/hand, respectively, we used 2 AMAT subscales: AMAT for shoulder/elbow (AMAT S/E) and AMAT for wrist/hand (AMAT W/H). The AMAT S/E and AMAT W/H subscales were scored by recording the time of the shoulder/elbow movements or the wrist/hand movements, respectively, performed during each AMAT task performance. These subscales have shown good validity and reliability (AMAT S/E intraclass correlation coefficient: .82; AMAT W/H intraclass correlation coefficient: .96).[31]

The FM coordination scale is a measure of limb joint movement coordination,[32] with good validity and intra- and interrater reliability, used in most upper-limb rehabilitation studies of stroke.[33] In addition to using the overall FM upper-limb motor score, we generated values for the shoulder/elbow movement items and wrist/hand items, summing them for each participant into the subscale scores of FM for shoulder/elbow and FM for wrist/hand, respectively.

In addition to the quantitative timed AMAT used for the primary measure, the AMAT can be scored using an ordinal, observational scale (0–5 points; AMAT Function scale [AMAT-F]). To investigate clinical significance within groups, we used the AMAT-F for which others have reported that a gain of .21 points is indicative of clinical significance.[34,35] The AMAT-F has shown correlation with the clinically meaningful FM score.[36]

Statistical analyses

Analyses were completed using the IBM SPSS version 19.0 statistical software package.[e] Baseline measures were compared across the 3 treatment groups for the AMAT and FM coordination scale using the nonparametric Kruskal-Wallis test. For the primary study question of group treatment difference on the AMAT, the Kruskal-Wallis test was used on the improvement scores (pre-post). Additionally, 95% confidence intervals for mean differences for pairwise

Table 1 Subject characteristics

Group	Stroke Type				Years Poststroke		Age Range (y)		Sex		Baseline FM Upper-Limb Score (SD)
	Cortical	Subcortical	Both	Brainstem	1–3	≥4	21–49	50–81	Male	Female	
ML	6	1	2	2	8	3	2	9	6	5	23.58±5.86
FES plus ML	6	3	3	0	10	2	3	9	7	5	22.85±6.92
Robotics plus ML	3	4	4	1	9	3	2	10	10	2	22.62±5.66

NOTE. Values for stroke type, years poststroke, age range, and sex are n.

comparisons were completed. A similar group analysis was conducted on the secondary measure of the FM coordination scale. For the additional secondary within-group analyses, we made pre-/posttreatment comparisons within each group using the Wilcoxon signed-rank test. A 95% Hodges-Lehman confidence interval was included for estimating the median change from pre- to posttreatment. To correct for multiple testing, sets of related hypotheses were grouped together,[37] and then the Holm Bonferroni stepdown correction method was used to determine statistical significance.[38] For the secondary measure, the ordinal AMAT-F measure and the subscales of AMAT S/E Function scale (AMAT S/E-F) and AMAT W/H Function scale (AMAT W/H-F), we calculated the following descriptive statistics: mean AMAT-F score for each individual across the task scores for both pre- and posttreatment, change score, and group means and change score. We inspected each group change score relative to the value of 0.21 point (clinically significant change for the AMAT-F).

Results

A total of 39 subjects enrolled in this study, with all but 1 subject in the severe range of impairment, according to the upper-extremity motor FM score ≤36 points[21] (table 1). The attrition rate was 10% (4/39) (see fig 1). There were 4 subjects who enrolled (2 in the ML alone group, 2 in the FES plus ML group) but did not complete the study. Their characteristics did not alter the relative subject characteristics across groups, and the characteristics are as follows: sex (FES plus ML group: 1 woman and 1 man; ML alone group: 2 men), stroke type (FES plus ML: cortical [n=1] and subcortical [n=1]; ML alone group: cortical [n=2]), years poststroke (FES plus ML group: 1–3y [n=2]; ML alone: 1–3y [n=1] and injury >4y [n=1]), and age (FES plus ML group: 50–81y [n=2]; ML alone group: 50–81y [n=2]). The reasons for their withdrawing from the study were things such as transportation and family issues. A total of 35 subjects completed the study (see fig 1). The analyses subsequently reported were conducted on those who completed the study. No adverse events occurred as a result of participation in the study.

Prior to beginning treatment, there was no statistically significant difference among the 3 treatment groups based on baseline AMAT ($P \geq .866$) or baseline FM score ($P \geq .966$).

AMAT measure

Group comparison

For the primary measure (AMAT), there was no significant difference across groups regarding treatment response ($P \geq .584$). Similarly, for the secondary measures of the AMAT

Table 2 No significant difference between groups for AMAT measure of complex function

AMAT Measure	Comparison Groups	Pretreatment (s)	Posttreatment (s)	Mean Change Score (s)	Mean Difference 95% CI (s)	*P*
AMAT	ML vs FES+ML	ML: 1794±479	ML: 1417±637	377	−124 (−430 to 182)	.584
		FES+ML: 1868±501	FES+ML: 1367±566	501		
	ML vs ROB+ML	ML: 1794±479	ML: 1417±637	377	−28 (−334 to 278)	.972
		ROB+ML: 1868±597	ROB+ML: 1463±573	405		
	ROB+ML vs FES+ML	ROB+ML: 1868±597	ROB+ML: 1463±573	405	−96 (−395 to 206)	.712
		FES+ML: 1868±501	FES+ML: 1367±566	501		
AMAT S/E	ML vs FES+ML	ML: 931±288	ML: 709±316	222	−27 (−194 to 141)	.917
		FES+ML: 956±285	FES+ML: 707±263	249		
	ML vs ROB+ML	ML: 931±288	ML: 709±316	222	−46 (−213 to 122)	.786
		ROB+ML: 979±286	ROB+ML: 711±267	268		
	ROB+ML vs FES+ML	ROB+ML: 979±286	ROB+ML: 711±267	268	18 (−146 to 182)	.960
		FES+ML: 956±285	FES+ML: 707±263	249		
AMAT W/H	ML vs FES+ML	ML: 864±250	ML: 682±326	182	−70 (−257 to 117)	.631
		FES+ML: 912±245	FES+ML: 660±320	252		
	ML vs ROB+ML	ML: 864±250	ML: 682±326	182	43 (−143 to 231)	.831
		ROB+ML: 890±325	ROB+ML: 751±320	139		
	ROB+ML vs FES+ML	ROB+ML: 890±325	ROB+ML: 751±320	139	−113 (−297 to 69)	.288
		FES+ML: 912±245	FES+ML: 660±320	252		

NOTE. Values are mean ± SD or as otherwise indicated.
Abbreviations: CI, confidence interval; FES+ML, FES plus ML group; ML, ML group; ROB+ML, robotics plus ML group.

Table 3 Within-group gains in functional task performance (AMAT) for each of the 3 treatment groups

Treatment Group	Functional Task Measure	Pretreatment (s)	Posttreatment (s)	Median Difference (95% CI) (s)	*P*
ML	AMAT	1794±479	1417±637	−277 (−341 to −217)	.003*
	AMAT S/E	931±288	709±316	−209 (−284 to −155)	.003*
	AMAT W/H	864±250	682±326	−144 (−344 to −51)	.009*
FES plus ML	AMAT	1868±501	1367±566	−415 (−655 to −290)	.002*
	AMAT S/E	956±285	707±263	−206 (−387 to −115)	.002*
	AMAT W/H	912±245	660±320	−232 (−374 to −133)	.003*
Robotics plus ML	AMAT	1868±597	1463±573	−402 (−509 to −298)	.002*
	AMAT S/E	979±286	711±267	−262 (−339 to −208)	.002*
	AMAT W/H	890±325	751±320	−119 (−207 to −72)	.003*

NOTE. Values are mean ± SD or as otherwise indicated.
Abbreviation: CI, confidence interval.
* Adjusted *P* value.

S/E and AMAT W/H subscales, there was no difference across groups in treatment response ($P \geq .786$ and $P \geq .288$, respectively) (table 2).

Within-group improvement

All 3 treatment groups demonstrated a statistically significant improvement according to the AMAT, AMAT S/E, and AMAT W/H, after adjusting for multiple tests ($P \leq .009$) (table 3).

Coordination impairment secondary measures

Group comparison

For the secondary measures of joint coordination (FM scale, FM scale for shoulder/elbow, FM scale for wrist/hand), there was no significant difference across groups regarding treatment response (FM scale: $P \geq .590$; FM scale for shoulder/elbow: $P \geq .979$; FM scale for wrist/hand: $P \geq .340$) (table 4).

Within-group improvement

All 3 treatment groups demonstrated a statistically significant within-group improvement according to the FM scale, FM scale for shoulder/elbow, and FM scale for wrist/hand after adjusting for multiple tests ($P \leq .007$) (table 5).

Descriptive statistics for the AMAT-F scale

Table 6 provides descriptive statistics for the ordinal AMAT-F scale, AMAT S/E−F, and AMAT W/H−F for each of the 3 groups. Pre-/posttreatment change scores for all measures were >.21 point, which is considered the minimum value for clinically important improvement. All scores, except for 2 change

Table 4 No significant difference between groups according to gain in coordination (FM scale)

Functional Task Measure	Groups Compared	Pretreatment (points)	Posttreatment (points)	Mean Change Score for Each Group	Group Mean Difference (95% CI) (points)	*P*
FM scale	ML vs FES+ML	ML: 23.6±5.8	ML: 33.5±8.3	9.9	1.1 (−4.1 to 6.2)	.867
		FES+ML: 23.5±6.5	FES+ML: 32.3±7.9	8.8		
	ML vs ROB+ML	ML: 23.6±5.8	ML: 33.5±8.3	9.9	2.2 (−3.1 to 7.2)	.590
		ROB+ML: 23.6±5.9	ROB+ML: 31.3±6.2	7.7		
	ROB+ML vs FES+ML	ROB+ML: 23.6±5.9	ROB+ML: 31.3±6.2	7.7	1.1 (−4.0 to 6.0)	.877
		FES+ML: 23.5±6.5	FES+ML: 32.3±7.9	8.8		
FM scale for shoulders/elbows	ML vs FES+ML	ML: 12.7±2.9	ML: 16.4±3.9	3.7	0.1 (−2.6 to 2.2)	.979
		FES+ML: 12.7±3.5	FES+ML: 16.5±3.9	3.8		
	ML vs ROB+ML	ML: 12.7±2.9	ML: 16.4±3.9	3.7	0 (−2.5 to 2.4)	.999
		ROB+ML: 12.9±1.9	ROB+ML: 16.6±2.5	3.7		
	ROB+ML vs FES+ML	ROB+ML: 12.9±1.9	ROB+ML: 16.6±2.5	3.7	0.1 (−2.2 to 2.6)	.984
		FES+ML: 12.7±3.5	FES+ML: 16.5±3.9	3.8		
FM scale for wrists/hands	ML vs FES+ML	ML: 9.1±2.6	ML: 14.7±4.7	5.6	1 (−2.3 to 4.5)	.728
		FES+ML: 8.8±3.5	FES+ML: 13.4±4.2	4.6		
	ML vs ROB+ML	ML: 9.1±2.6	ML: 14.7±4.7	5.6	1.9 (−1.4 to 5.4)	.340
		ROB+ML: 8.3±4.3	ROB+ML: 12.0±4.1	3.7		
	ROB+ML vs FES+ML	ROB+ML: 8.3±4.3	ROB+ML: 12.0±4.1	3.7	0.9 (−2.4 to 4.2)	.777
		FES+ML: 8.8±3.5	FES+ML: 13.4±4.2	4.6		

NOTE. Values are mean ± SD or as otherwise indicated.
Abbreviations: CI, confidence interval; FES+ML, FES plus ML group; ML, ML group; ROB+ML, robotics plus ML group.

Table 5 Within-group gains in impaired coordination (FM) for each of the 3 treatment groups

Treatment Group	Coordination Measure	Pretreatment (points)	Posttreatment (points)	Median Gain Score (95% CI) (points)	*P*	Mean Gain Score
ML	FM	23.6±5.8	33.5±8.3	9 (7.5–12.5)	.003*	11
	FM scale for shoulders/elbows	12.7±2.9	16.4±3.9	3.5 (2.5–4.5)	.003*	4
	FM scale for wrists/hands	9.1±2.6	14.7±4.7	5 (4.0–7.5)	.003*	6
FES+ML	FM	23.5±6.5	32.3±7.9	8 (5.5–12)	.002*	10
	FM scale for shoulders/elbows	12.7±3.5	16.5±3.9	4 (2.0–6.0)	.005*	4
	FM scale for wrists/hands	8.8±3.5	13.4±4.2	5 (2.0–7.0)	.003*	5
ROB+ML	FM	23.6±5.9	31.3±6.2	7.8 (4.5–11)	.003*	8
	FM scale for shoulders/elbows	12.9±1.9	16.6±2.5	3.5 (2.5–5.0)	.002*	3
	FM scale for wrists/hands	8.3±4.3	12.0±4.1	4.0 (1.5–5.0)	.007*	4

NOTE. Values are mean ± SD or as otherwise indicated.
Abbreviations: CI, confidence interval; FES+ML, FES plus ML group; ML, ML group; ROB+ML, robotics plus ML group.
* Significant according to adjusted *P* value.

scores, were less than or equal to twice the minimum value for clinically important improvement. The 2 individual participant change scores, which were the smallest, were in the robotics group plus ML group (AMAT-F, .37 point; AMAT W/H–F: .26 point).

Descriptive statistics for the FM coordination scale

Descriptive statistics for the FM coordination measure provide some additional insight into the level of clinically significant change for the subjects in each of the treatment groups. In the robotics plus ML and FES plus ML groups there were 75% and 92% of subjects, respectively, with a clinically significant gain in coordination impairment (≥4.25 points on the FM coordination scale). For the ML alone group, 100% of subjects were equal to or beyond a clinically significant gain. No subjects in the study worsened. Highest FM gain score for a participant in each group was: FES plus ML (25 points); robotics plus ML (15 points); and ML alone (18 points).

Table 6 AMAT-Function ordinal measure descriptive statistics showing clinically significant change scores*

Treatment Group	Pretreatment	Posttreatment	Change Score*
a. AMAT function measure			
ML	1.82±0.48	2.30±0.77	0.48±0.34
FES+ML	1.78±0.53	2.22±0.62	0.44±0.24
ROB+ML	1.75±0.60	2.13±0.56	0.37±0.25
b. AMAT S/E function measure			
ML	2.12±0.53	2.55±0.67	0.43±0.23
FES+ML	2.04±0.52	2.47±0.56	0.42±0.35
ROB+ML	2.00±0.57	2.44±0.42	0.44±0.30
c. AMAT W/H function measure			
ML	1.37±0.57	1.89±0.93	0.53±0.61
FES+ML	1.42±0.67	1.92±0.71	0.50±0.27
ROB+ML	1.35±0.73	1.60±0.82	0.26±0.21

NOTE. Values are mean ± SD.
Abbreviations: FES+ML, FES plus ML group; ML, ML group; ROB+ML, robotics plus ML group.
* Clinically significant improvement is >.21 points.

Discussion

Direct comparison of shoulder/elbow robotics, wrist/hand FES, and ML

To our knowledge, this is the first study of chronic stroke survivors making a comparison of robotics and FES and a direct comparison of either technology with intensive ML. We found no significant difference among the 3 groups in terms of treatment response, according to a measure of 13 complex functional tasks and an impairment measure of joint coordination. This could have been because all 3 groups received treatment that was based on ML principles (eg, as close to normative practice as is possible, focused attention on the task, high number of daily practice repetitions of motor task components, whole-task practice of functionally meaningful tasks, and generalization of movement component practice to >1 type of whole-task practice). In preliminary work, we reported that emphasis of shoulder/elbow robotics treatment resulted in significantly greater gains in AMAT S/E versus treatment with FES emphasis for the wrist/hand. We also found the converse; that is, emphasis of wrist/hand FES treatment resulted in significantly greater gain in AMAT W/H versus treatment with emphasis on shoulder/elbow robotics.[31] However, that sample size was very small (n=6 and n=6, respectively).[31] The current results did not bear out our findings from that preliminary work. Because all 3 groups had the benefit of comprehensive coordination training, any unique advantage of either robotics or FES could have been superseded by the importance of the general framework and principles of treatment. It could be that the hours of ML without the technologies served to consolidate newly learned joint coordination that was gained through the use of either robotics or FES. Alternatively, a larger sample size may show a significant group difference.

Considerations of extent of recovery, level of impairment, and treatment duration/intensity for severely impaired chronic stroke survivors

This study contributes to the literature in the extent of improvement that was shown in the FM joint coordination measure for all 3 groups of more severely involved participants in the chronic phase (>1y after stroke). In our consideration of the literature here, we are focusing on studies of others that enrolled stroke survivors at ≥6 months poststroke because some have reported spontaneous or endogenous recovery up to 3 to 6 months after stroke, which could confound a study of group difference.

Contrasting response to treatment for the less impaired subjects in other studies versus the more impaired subjects in the current work

Our study cohort was in the severely impaired category (baseline upper-limb motor FM score ≤36 points). Even still, compared with the work of others for mild to moderately impaired stroke survivors, the gain scores in our study of the severely impaired were either comparable (robotics plus ML group), higher (ML alone group), or almost twice as high (FES plus ML group) as that reported for the less impaired. For example, for mild to moderately impaired chronic stroke survivors, FM gains were reported in response to treatment as follows. In robotics therapy, gains reported ranged from 3.36 to 9 points.[13,39,40] In FES therapy, a 5-point gain was reported.[41] In ML or exercise, gains of 6 to 8 points were reported.[5,7,10,42,43] In contrast with those studies of lesser impaired individuals, the current study focused on severely impaired stroke survivors and yielded the following results for FM mean gains: the robotics plus ML group yielded 8 points, the FES plus ML group yielded 9 points, and the ML alone group yielded 11 points. In terms of clinically important difference, other studies[18] have suggested that the estimated clinically important difference for the upper-extremity FM coordination scale ranges from 4.25 to 7.25 points in scores. Our results for all 3 groups were beyond those values for the severely impaired. In addition, our gain scores for the AMAT-F scale (see table 6) were more than twice the clinically significant value of .21 point for the ML alone and FES plus ML groups and were greater than clinically significant for the robotics plus ML group.

Potential effect of treatment intensity (number of sessions, hours/session)

Emerging empirical evidence is supporting long-held clinical observation; that is, for recovery of persistent discoordination after stroke, many hours of specifically formulated practice are required.[24,29,44,45] The current study included intensive practice of coordinated tasks (5h/session, 60 sessions); this treatment intensity may help to explain the larger gains reported here in coordination and function for these severely involved stroke survivors. Although Kraft et al[20] studied only 6 subjects in its FES group, they also provided 3 months of treatment, which may explain their high FM mean gain (8 points).

For our other 2 treatment groups (robotics plus ML and ML alone), treatment intensity may also explain gains that were greater for our severely impaired individuals than that reported by other researchers for severely impaired stroke survivors. For example, for severely impaired stroke survivors, others reported FM gains in response to robotics ranging only from 1.2 to 5 points,[15,46-48] and ML alone was reported to have produced only a 4-point FM gain in 46 participants who were more severely impaired.[15] In the current study, more hours of treatment were provided than for these cited studies. Given the results reported here (robotics plus ML group: FM gain of 8; ML alone: FM gain of 11), it is reasonable to consider that greater treatment intensity is needed for the more severely impaired using those 2 types of interventions (ML alone or robotics plus ML groups) to achieve the greater FM score gains.

The current clinical practice milieu prevents the provision of long-duration, high-intensity treatment; therefore, this new information is an important contribution to the literature. One reason for the lack of provision of long-duration interventions in standard clinical care is the out-of-date belief that no more recovery can occur after 3 to 6 months poststroke. In contrast with these inaccurate beliefs, our results are consistent with others who have demonstrated the possibility of motor recovery beyond that time period, through the application of a variety of treatment methods.[3,4,13-17,19,40,43,46-57]

Functional task improvement

Although many research studies report significant gains in impairment, there is less information available regarding the recovery of actual functional tasks in response to experimental interventions, according to a homogenous measure of complex functional task performance (ie, everyday functional tasks). In the current work, the statistically significant improvement within each group for the AMAT (13 complex function tasks) can be explained in a number of ways. First, the high gain in the FM score in all 3 groups may have been sufficiently robust to produce a significant improvement in a measure of 13 actual complex function tasks. Second, the purposeful application of fundamental ML principles could explain both the relatively high gains in coordination (FM score) and AMAT gains. Third, the protocol was specific in practice of joint movement components within the context of actual task practice. (supplemental video S1 shows recovery of coordination and functional capability; available online only at http://www.archives-pmr.org/.)

Patient group delivery of intensive and long-duration intervention

We found that it was feasible to deliver the study protocol using a group treatment method (1:3 ratio of therapist to patients). The relatively high gain in FM scores for all 3 groups could serve as evidence to support the feasibility of the 1:3 therapist to patient ratio. According to the work of others[58,59] and our study therapists' reports, the group treatment paradigm was more reasonably feasible with the use of the robotics or FES technologies because these practice-assist devices could be quickly set up in a manner enabling some independent practice, while the therapist could focus on other participants. This allowed a more calm therapeutic setting and a more satisfying work situation for the therapist.

Cost considerations

We calculated the cost of each of the 3 treatment protocols in this study. The following assumptions were used: therapist cost ($98,000, which is the annual salary for an experienced therapist in Ohio where the study was conducted; source: Department of Veterans Affairs and additional local hospital); shoulder/elbow clinical level robot cost ($89,000) and 5-year robot life; annual robot warranty and maintenance ($8000; source: robot distributing company); and FES cost for a 4-channel table top and 2-channel portable system ($4000), with a 5-year equipment life. We used the facts of our protocol (number of visits; duration of sessions for use of each piece of equipment and ML alone; and a ratio of 1:3, therapist to patient). Our calculations yielded the following costs per patient for the entire treatment protocol: ML alone ($4570), FES plus ML ($4604), and robotics plus

ML ($5686). These costs are in the ballpark in comparison with the calculations of others[15]; however, our treatment was considerably longer, the cost of our robot was significantly less because we used only 1 type of robot, and the robot cost is for a clinical robot. Our ML alone protocol was less expense than the robotics plus ML protocol by $1116 and less than the FES plus ML protocol by $34. Therefore, if a cost differential of approximately $1000 per patient is considered important, then the FES plus ML protocol and/or the ML alone protocol would be preferable.

Study limitations

There were a number of study limitations. First, the sample sizes per group were 11, 12, and 12, respectively. Although there was no significant difference and no indication of a trend in group difference, a larger sample size might have shown group differences. Second, this was a research trial. To determine whether the 1:3 ratio of therapist to patients is practical and beneficial in clinical practice, this treatment paradigm would require testing in a clinical environment. Third, in this study, FES and robotics were differentially targeted to either wrist/hand or shoulder/elbow, respectively; therefore, this study did not make a direct comparison of either robotics versus FES for shoulder/elbow or robotics versus FES for wrist/hand. Rather, this study design was selected and funded based on 2 assumptions. The first assumption was that FES may be preferable for wrist/hand intervention because it can be applied quickly and easily to wrist/hand flexors and extensors, and notably, it provides practice of an actual muscle contraction. In contrast, robotics can encourage and enable less therapeutic passive participation. The second assumption was that robotics may be preferable for shoulder/elbow intervention because it can be quickly and easily set up to support and guide movement of the complex shoulder/elbow movement components composing the reach task. In contrast, FES would have required time-consuming application of multiple electrodes for scapular and limb muscles and control of complex precision timing of multiple muscle activations for the greatest effectiveness.

Fourth, because of limitations in resources, it was not feasible to acquire follow-up data. However, others have documented good maintenance of gains after ML, robotics, and FES. For severely impaired individuals, robotics,[15] ML (intensive therapy[15]), and FES[60] produced gains in response to treatment that were maintained at follow-up. With these reported maintenance gains taken together, along with our high gains after treatment, it is reasonable to consider that gains may have been maintained in the current study. However, further study is required to quantitatively compare follow-up maintenance across groups.

Conclusions

Severely impaired chronic stroke subjects (>1y) with persistent upper-extremity dysfunction can make clinically significant gains in joint movement coordination and functional task performance in response to the 3 tested interventions (ML, combined robotics and ML, combined FES and ML) in an intensive and long-duration intervention. There was no difference in treatment response across the 3 intervention groups according to measures of joint movement coordination or complex functional task performance. It was feasible in the research laboratory to deliver effective group treatment for severely impaired stroke survivors in a 1:3 (therapist/patient) ratio.

Suppliers

a. Interactive Motion Technologies.
b. QNX Software Systems.
c. Staodyn, Inc.
d. Axelgaard Manufacturing Co, Ltd.
e. IBM Corporation.

Keywords

Electric stimulation; FES; Randomized controlled trial, Rehabilitation; Robotics; Stroke; Upper extremity

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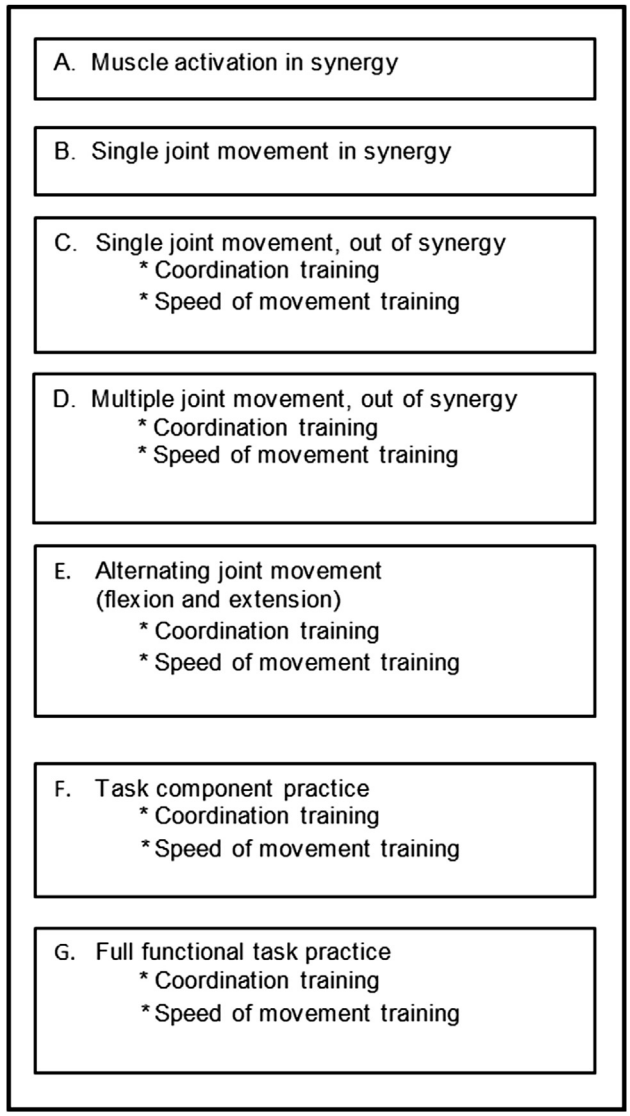
Appendix 1 Upper-Limb Training Protocol: Treatment Progression Hierarchy for Coordinated Movement Practice



Appendix 2 Examples of Functional Tasks Practiced During Training Sessions

- Stir food in a bowl.
- Place objects in kitchen cupboard.
- Carry objects (unilateral and bilateral).
- Write with pen/pencil.
- Type at computer.
- Sweep with broom.
- Throw ball.
- Swing a golf club.
- Sand wood.

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