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Constraint-Induced Therapy Combined with Conventional Neurorehabilitation Techniques in Chronic Stroke Patients with Plegic Hands: A Case Series

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Abstract

Objective—To determine in this pilot study whether the combination of CI therapy and conventional rehabilitation techniques can produce meaningful motor improvement in chronic stroke patients with initially fisted hands. In the past, limited success has been achieved using CI therapy alone for stroke patients with plegic hands.

Design—Case series

Setting—University hospital outpatient laboratory

Participants—Consecutive sample of 6 patients > 1 yr post-stroke with plegic hands

Interventions—Treatment consisted of an initial period of 3 weeks (Phase A) when adaptive equipment in the home, orthotics and splints were employed to improve ability to engage in activities of daily living. This was continued in Phase B, when CI therapy along with selected neurodevelopmental treatment techniques were added.

Main Outcome Measures—Motor Activity Log (MAL), accelerometry, Fugl-Meyer Motor Assessment (F-M)

Results—Patients exhibited a large improvement in spontaneous real-world use of the more-affected arm (mean lower-functioning MAL change = 1.3 ± 0.4 points, $P < 0.001$, $d' = 3.0$), and a similar pattern of increase in an objective measure of real-world more-affected arm movement (mean change in ratio of more- to less-affected arm accelerometer recordings = 0.12 ± 0.1 points, $P = 0.016$, $d' = 1.2$). A large improvement in motor status was also recorded (mean F-M change = 5.3 ± 3.3 points, $P = 0.005$, $d' = 1.6$).

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Conclusions—The findings of this pilot study suggest that stroke patients with plegic hands can benefit from CI therapy combined with some conventional rehabilitation techniques, even long after brain injury. More research is warranted.

Keywords

Stroke; Rehabilitation; CI therapy; Neurodevelopmental treatment; Arm function

Contrary to the prevailing beliefs not so long ago about the ineffectiveness of rehabilitation in chronic stroke, Constraint-Induced Movement therapy (CI therapy)¹ has been shown to produce large improvements in everyday use of the more-affected arm in patients when it is administered >1 year after stroke to patients with mild/moderate to moderately severe motor deficits (Grade 2–4 motor deficit, see Table 1).^{2–4} However, up to 40% of stroke survivors are left with more severe motor impairment of the more-affected arm in the chronic phase,⁵ resulting in substantial reductions in independence and quality of life.⁶ There are currently no proven treatments that improve real-world arm function in chronic stroke patients with plegic hands (Grade 5, see Table 1).

Evidence suggests that CI therapy works in part by lifting a conditioned suppression of movement or learned nonuse of the more-affected arm.^{7, 8} In addition, in correlation with the motor improvement that it produces, CI therapy has been shown to produce increases in grey matter volume in sensorimotor cortex, more anterior motor areas, and hippocampus on both sides of the brain,⁹ as well as other neuroplastic brain changes.^{10–13}

The patients in the first CI therapy study¹ and in the early replications^{3,14–16} had upper extremity motor deficits that could be characterized as mild/moderate (Grade 2 according to the categorization scheme employed here; see Table 1). A subsequent multi-site randomized clinical trial with a positive outcome⁴ employed patients with mild/moderate and moderate motor deficits (Grades 2 and 3). The impression therefore has become general that these are the only patients to whom CI therapy applies.^{17,18,19} However, in the past CI therapy has been employed with success with patients with moderately severe hand motor deficits (i.e., Grade 4 patients) in this laboratory²⁰ and elsewhere.²¹ An attempt was made to treat two patients with initially fistled hands (i.e. Grade 5 patients). No success was achieved with the hand, and there was only modest success at shoulder and elbow, which, in any case, did not transfer to the life situation.²⁰ However, greater success with a subsequent case (Wymore, Morris, & Taub, unpublished data, 2002) led to a more positive outlook and provided the impetus for continuing this line of work. In this study, we tested in preliminary fashion whether patients with functionless hands who are > 1 year post-injury would show improvements in everyday use of their more-affected arm after rehabilitation that combines CI therapy with conventional techniques for regulating tone.

METHODS

Participants

Six community residents with stroke (mean age = 56±11 years, median chronicity = 2.5years, 1 woman) with severe upper-extremity impairment were enrolled in this study. A total of 23 possible candidates were identified who were listed sequentially in our contact database of individuals requesting CI therapy. Six met criteria, consented to participate, and were enrolled in the study. Seventeen did not meet criteria for the following reasons: too high-functioning – 5; receptive or expressive aphasia that would limit ability to be tested with the Grade 4/Grade 5 MAL (see below) – 4; too low-functioning – 3; major health issues – 2; too low cognitively to adequately follow test instructions – 3. All six enrolled patients had undergone conventional rehabilitation therapy in the acute phase. Five had

minimal capacity to extend their wrist with no extension at the fingers; one had minimal capacity to extend at the wrist and one finger. Table 2 presents additional participant characteristics. All subjects met the active range of motion criteria for inclusion in the Grade 5 (severe) category²² (see Table 1). The following main exclusion criteria were used: (1) stroke experienced < 1 year earlier, (2) bilateral or brain stem stroke, (3) balance or ambulation problems (e.g., assistance required for toileting), (4) substantial cognitive deficits (<24 points on the Folstein Mini-Mental State Examination) or aphasia serious enough to prevent valid performance on sample test items during screening, (5) excessive pain, ataxia, or frailty as determined by clinical judgment, and (6) severe end-stage or uncontrolled medical conditions. The study protocol was approved by the institutional review board, and each subject signed an informed consent.

Intervention

CI therapy as applied to patients with deficits that are Grade 2–4 (mild/moderate – moderately severe) in severity consists of three major components: ^{2,8} (a) intensive more-affected arm training on functional tasks for several hours daily for multiple weekdays, (b) a package of behavioral techniques designed to transfer gains from the treatment setting to the real-world (e.g., keeping a daily diary on arm use, daily home practice) and (c) restraint of the less-affected arm to discourage its use.

In this study, the standard CI therapy protocol was modified so that it would be applicable to patients with insufficient initial ability to make movements at the fingers and wrist to permit implementation of the standard CI therapy training procedures employed with higher functioning patients. Consequently, treatment in this study began with an initial period of 3 weeks (Phase A) devoted to use of orthotics/splints and adaptive equipment outside the laboratory. Device selection and instruction for individual subjects was conducted in six 2-hr sessions distributed over this period. The purpose of the orthotics and splints was to maintain the fingers/wrist in better alignment to enhance the use of the arm and hand in activities of daily living (ADL).

Environmental adaptations to facilitate use of the plegic hands included door knob turners, terry cloth bath mitts, adaptive drawer pulls, “pencil pushers” (built-up foam on pencils that were used to push buttons), Dycem wraps around utensils, scoop dishes and adaptive cups. The adaptive equipment and orthotics were updated throughout the entire intervention as needed. (Phase A is described in greater detail in an initial case report.²²)

In Phase B of the intervention, use of the Phase A devices was continued, and in addition CI therapy was administered for 15 consecutive weekdays combined with neurodevelopmental treatment (NDT) techniques for managing tone and facilitating movement (e.g., tapping, weightbearing, placing and holding)²³ as well as use of ice baths and vibration. Treatment was carried out in 3-hour morning and afternoon sessions separated by a 1-hour lunch period. Rest breaks were provided as needed. Weight-bearing and stretching procedures were given for 1 hour at the beginning of each of the 2 daily sessions in order to reduce tone.

CI therapy was carried out in the second and third hours of the morning and afternoon sessions. Brief periods of conventional procedures such as stretching and weightbearing were interpolated in the CI therapy activities to reduce hypertonicity and improve movement as needed. Shaping was used during training. It is a widely used behavioral training technique in which a desired motor or behavioral objective is approached in small steps, by successive approximations.²⁴ Shaping is commonly used in CI therapy²⁵ and clinically it appeared to be particularly important with these patients. The training tasks were carried out in sets of ten 30–45 sec trials; rests were given between trials and there were longer rests between sets of 10 trials to prevent fatigue. Specific qualitative and quantitative feedback,

coaching, modeling and encouragement were used throughout and especially immediately before and after trial performance. The shaping tasks were designed specifically to maximize the subjects' movements in areas that exhibited the most pronounced deficit and that appeared to have the greatest potential for improvement. The goal was to transfer the movement skills or movement components addressed during the NDT sessions to the shaping tasks and ultimately to real world functional activities. Examples of the shaping tasks are: touching chin/mouth, pushing cones, touching shoelaces, peg board, touching wall in standing. ADL practice was also given in the laboratory. It involved repetitive task performance, as does shaping, but systematic feedback was reduced while trial length was increased. The use of both upper extremities was included in selected ADL practice. Some ADL practice focused on training the more-affected arm as a "helper" or gross assist during everyday activities (e.g., use of the more-affected hand to stabilize containers while the less-affected hand opened the lids, opening cabinets using adaptive drawer straps, and holding a checkbook or receipts down while signing). ADL practice also involved training in using the more-affected arm alone in the performance of more easily accomplished tasks, such as flipping a light switch and pushing open a door. Performing functional task practice with both limbs seemed to aid the participant in enabling real world use of the more-affected upper extremity. (With higher functioning participants, bilateral tasks are not carried out and the more-affected arm is trained in independent use, not as a helper.) The use of tone-reducing procedures and providing adequate rest intervals to prevent fatigue from degrading motor performance necessitated increasing treatment duration from the standard 3.5 hours² to 6 hours; however, the amount of time devoted to CI therapy procedures each day remained unchanged from the standard protocol. Treatment was provided by an occupational or physical therapist, each with over 12 years experience, followed by 7 and 4 years of CI therapy research work, respectively. Both had been certified to provide neurodevelopmental therapy (NDT), from which the main conventional neurorehabilitation techniques employed here were derived.

All the behavioral components of the CI therapy transfer package were included in this protocol to maximize participant accountability for compliance with the requirements of treatment and to induce transfer of newly learned skills to the life situation.^{2,8} During the CI therapy/NDT portion of the protocol, the Grade 4/5 Motor Activity Log (Grade 4/5-MAL, see below) was administered daily. A written behavioral contract was drawn up in which the therapist and patient agreed on typical activities during the daily routine outside the laboratory that should be performed with the more-affected arm. Problem-solving was important in determining how barriers to use of the more-affected extremity perceived by a patient could be overcome. A daily home diary detailed attempted use of the more-affected arm that focused on activities agreed upon in the behavioral contract. During treatment and after its completion, patients were assigned home practice that consisted of movement exercises from the NDT portion of the treatment and a variety of ADL activities in addition to the activities included on the Grade 4/5 MAL, each of which they were instructed to try every day if they seemed feasible. The change in the per cent of Grade 4/5 MAL items for which there was a score greater than zero during treatment can be considered an index of adherence with that instruction. For the group, mean MAL daily items receiving a score greater than zero was $73.5 \pm 22\%$. Some of the activities were reported during daily test administration as not being attempted because motor ability was much less than would be required to make task accomplishment possible.

Part of the time patients wore a mitt with a heavily padded undersurface that prevented use of the hand for most purposes. In work with higher functioning participants, the mitt is worn for a target of 90% of waking hours. However, this was not an appropriate goal for these participants since the more-affected hand was so low functioning initially that when the less affected UE was inactivated by the mitt, they would tend to be functionally "shut down".

Thus, the requirement to wear the mitt outside the laboratory was relaxed. Activities involving specific safety risks were identified when the less-affected extremity should be used after doffing the padded mitt (e.g., using a cane during walking, negotiating stairs, driving, handling hot foods or liquids). The target percent of time for wearing the mitt was 50% for each patient. The amount of time patients wore the mitt each day was measured automatically by a sensor inserted in the mitt²⁶ and recorded daily. The mean mitt-wearing time for the group was $44.5 \pm 4.9\%$ of waking hours.

Outcome Measures

Two measures of daily use of the more-affected arm in the life situation were employed. The Grade 4/5 Motor Activity Log (Grade 4/5-MAL) is a scripted, structured interview during which patients were asked to rate how well and how much they used their more-affected arm to complete 30 commonly encountered upper-extremity tasks over a specified period. The Arm Use scale ranges from 0 (no use of the more-affected arm) to 5 (normal use of the more-affected arm), and has 11 points with definitional anchors at 6. The original MAL,¹ designed for patients with mild/moderate and moderate motor deficits, has reliability and validity.^{27–29} The use of the Grade 4/5 MAL here was accompanied by accelerometry, with which it showed a marked correspondence (see Results). Accelerometry is an objective measure of activity used to validate the original MAL.³⁰ Preliminary analyses suggest that the Grade 4/5 MAL has a high test-retest reliability ($r = 0.95$, $n = 10$) and high internal consistency (Chronbach's $\alpha = 0.95$, $n = 30$).³¹ The Grade 4/5-MAL is administered using the same methodology as the original MAL. "Probing" and verifying questions were asked after item answers, procedures designed to promote test reliability.^{27–29} A standardizing videotape illustrating what was meant at each of the five main rating steps above zero for each of eight activities of daily living (ADL) appearing on the test was shown before the first test administration and as many times afterwards as the tester thought appropriate. The videotape was used to promote a uniform, laboratory-standard frame of reference across subjects.^{27–29}

For this study, 10 of the last 20 of the 30 original tasks on the MAL were replaced with tasks that were more suitable for patients with severe impairment, thereby constituting a Grade 4/5 or Lower Functioning Motor Activity Log (Grade 4/5-MAL); see Appendix 1A for a listing of the questions and the items deleted from the original (higher-functioning) MAL, and Appendix 1B for the Arm Use scale. The test was administered to the participants immediately before Phase A of the intervention, at the end of phase A, every day during phase B, immediately after Phase B, by telephone weekly for the first 4 weeks following the end of treatment, and at 6- and 12-month follow-up. The accelerometry ratio was obtained by asking patients to wear accelerometers on each arm for 3 days before and after each phase of the treatment and calculating the ratio of more-affected to less-affected arm recordings for each observation period. This provided an objective measure of the amount of movement patients made outside the laboratory setting during the entire waking-hour period, including when the patients were outside the laboratory in the real world environment.³⁰ The accelerometry ratio has strong evidence of reliability and face validity for measuring real-world upper extremity rehabilitation outcome.^{30–33}

The Fugl-Meyer Motor Assessment (F-M) was also employed. It is a standard in-laboratory test used to assess motor function after stroke.³⁴ Patients are asked to perform different movements to the best of their ability. The upper extremity motor portion of the F-M was administered immediately before and after Phase B. Active range of motion was measured by goniometer immediately before and after each Phase. Single items from a Participant Opinion Survey (POS) that were rated using a 0–7 scale were used to assess satisfaction with arm use before and after Phase B and satisfaction with treatment after Phase B.

Data Analysis

Changes in the outcome measures from before Phase A to after Phase B (i.e., baseline to end-CI therapy) were analyzed using paired *t*-tests, except for change in the single item rating on satisfaction with arm use, which was analyzed using a Wilcoxon signed-rank test. If any of these omnibus tests were significant, changes for Phase A and B were tested separately following Fisher's protected *t*-test method for controlling family-wise Type I error.³⁵ One-tailed tests ($\alpha = .05$) were employed based on data from previous CI therapy studies in chronic stroke. Effect Size for the treatment outcomes was characterized using d' , which is the mean change on an outcome divided by its *SD*. In the meta-analysis literature, d' values $> .57$ are considered large.³⁶ For the accelerometry data, missing values for one patient at baseline and another after Phase A were imputed following the conservative assumption of no change from baseline to end-Phase A.

RESULTS

Figure 1 shows strikingly similar patterns of changes in the real-world outcomes, i.e., the Grade 4/5-MAL and accelerometry ratio. Gains from baseline to end-treatment on the Grade 4/5-MAL were very large (mean = 1.3 ± 0.4 points, $P < 0.001$, $d' = 3.07$), as were increases in the accelerometry ratio (mean = 0.12 ± 0.10 points, $P = 0.016$, $d' = 1.2$). Moreover, significant gains for both the Grade 4/5-MAL and accelerometry ratio were observed in each Phase (A: orthotics and adaptive equipment; B: expanded CI therapy) of the intervention (see Table 3). At 6-month follow-up, Grade 4/5-MAL gains were 85% of those immediately after treatment (mean change from baseline = 1.1 ± 0.6 , $P = 0.009$, $d' = 1.8$). At 1-year, Grade 4/5-MAL gains were 46% of those at post-treatment (mean change from baseline = 0.7 ± 0.6 , $P = 0.046$, $d' = 1.2$). Figure 2 shows that there was a large shift from pre- to post-treatment in the proportion of upper-extremity tasks on the Grade 4/5 MAL scored 0 (no use) or 1 (very poor use) to 2 (poor use) or 3 (half as good as pre-stroke). Before the intervention, patients, on average, scored more-affected arm use as a 0 or 1 for 79% of the items; 21% of items were scored as a 2 or 3. After the intervention, patients, on average, scored more-impaired arm use as 0 or 1 for just 23% of the items; 77% of items were scored as a 2 or 3.

Reduction in motor impairment as measured by the upper-extremity portion of the F-M and increase in active range of motion was substantial. F-M scores rose by 26% from before to after Phase B (mean = 5.3 ± 3.3 points; $P = 0.005$, $d' = 1.6$). Active range of motion as a percent of the normal range for 6 upper-extremity joint movements improved on average by 35% from baseline to after Phase B ($P = 0.001$, $d' = 2.6$). Table 3 lists changes for individual joint motions in degrees; improvements by joint movement in order from largest to smallest were: elbow extension ($d' = 2.0$), forearm pronation ($d' = 2.0$), shoulder flexion ($d' = 1.1$), shoulder abduction ($d' = 0.9$), forearm supination ($d' = 0.8$), and wrist extension ($d' = 0.7$). On the POS, Satisfaction with treatment was rated 6.5 ± 0.5 out of 7, while satisfaction with more-affected arm use rose from 2.3 ± 1.8 before treatment to 4.3 ± 1.8 afterwards (mean change = 2.0 ± 2.3 points, $P < 0.028$, $d' = 0.9$).

Clinical Observations

The frequent repetition of movement during some treatment exercises tended to increase tonus in the more-affected arm; this was counteracted by interpolating periods of stretching, oscillation (i.e., shaking) of the limb, and weight bearing. This regimen was recommended to the participant for continuation after the end of treatment. In the therapist's opinion, treatment resulted in improved posture, decreased synergistic movement patterns, and improved tone in the trunk, though no systematic data were collected in these areas.

DISCUSSION

In this study, a standard CI therapy protocol³⁷ was combined with several procedures employed in NDT and other conventional rehabilitation therapies to produce a substantial treatment effect in chronic post-stroke patients with initially plegic (5 subjects) or nearly plegic (1 subject) hand. The increase in real-world arm use recorded on the Grade 4/5-MAL after treatment was greater than the Minimum Clinically Important Difference (MCID) as defined by either of two criteria: a) 140% greater than one index;^{27,29} and b) 40% greater than another.³⁸ The Effect Size index (d') for real-world improvement was 2.8. As noted, 0.57 is considered large for this index by convention.³⁶ In addition, substantial improvement was observed in motor impairment (F-M $d' = 1.6$, active range of motion $d' = 2.6$). It is of interest that the Grade 4/5 MAL results and the results for accelerometry, an objective measure of amount of extremity movement, shadowed each other closely after both phases of treatment, as indicated in Figure 1.

Successful motor rehabilitation in patients with motor deficits as severe as those in this study has not been reported previously. These results are preliminary. The sample size was small and in this case series there was no control group. However, in view of previous research in which CI therapy was shown not to be due to nonspecific effects in patients with lesser motor deficits than those studied here, the results may be considered suggestive and would appear to warrant further research.

Limitations and Future Research

The testers in this study were not blinded, and the data on reliability of the Grade 4/5 MAL has not been subject to peer review and published. However, the test was administered in the same manner as the original MAL including use of “probing” and verifying questions and repeated screening of a videotape designed to promote reliability and a common frame of reference for rating.^{27–29} The present small-sample case series must be considered preliminary. Testing of the findings from this study in a Phase II randomized controlled trial that corrected these limitations would be an important next step.

In future research it would be of value to determine if the initial 3-week orthotics-splinting and adaptive equipment period could be dispensed with as a separate treatment phase, and instead incorporated into the main Phase B period without loss of treatment effect. It would also be of value to determine optimal time post-stroke onset to efficaciously provide this kind of combined treatment program, the retention of the treatment effect over time, and to have a control group to separate the contribution of the two different treatment approaches. Shaping of hand movement with patients who initially had a fisted hand was predicated on reducing the flexor tone in the fingers. In this study, the necessary relaxation of tone and facilitation of active movement was achieved by techniques employed in NDT and other procedures used in conventional rehabilitation, such as icing (especially) and tapping. However, there are several other procedures that might help just as much or more. These include: transcutaneous electrical stimulation (TENS), functional electrical stimulation (FES), EMG-triggered FES, botulinum toxin injection, robot-assisted movement, and transcutaneous cortical stimulation (TMS). These techniques by themselves have been shown to be effective in the laboratory to varying extents, but by and large none has been shown to reliably produce clinically significant transfer of increased use of a more-affected arm to the real world situation. Combining one or more of these techniques with CI therapy either as a preceding or concurrent procedure might be of therapeutic significance.

Conclusions

This pilot study supports the potential value of combining CI therapy with conventional neurorehabilitation techniques for use with patients with plegic hands by suggesting in preliminary fashion that, contrary to previous thought and practice, such low functioning patients can benefit from this approach even long after their brain injury. Early evidence is presented suggesting that appropriate methods can uncover suppressed motor capacity and stimulate and harness neuroplastic changes to produce therapeutic improvement in severely impaired, chronic stroke patients in what has been thought to be an intractable condition.

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Figure 1.

Effect of CI therapy on real-world arm use in patients with plegic hands. Two measures of daily use of the more-affected arm in the life situation are plotted. The line represents the mean Grade 4/5 Motor Activity Log (Grade 4/5-MAL) Arm Use scale scores; the bars represent the mean ratio of more-affected to less-affected arm accelerometer recordings. * $P < .05$ for both Grade 4/5-MAL scores and accelerometer ratios.

Figure 2.

Number of Grade 4/5-MAL Items with Low (0, 1) and Moderate (2, 3) Arm Use Scores Before and After Treatment.

Note. The total number of items was 30. Scale: 0 = no use, 1 = very poor use, 2 = poor use, 3 = half as good use as pre-stroke, 4 = almost normal use, 5 = normal use.

Table 1
Stratification of Severity of Impairment: Active Range of Motion and Mean MAL Score Criteria

Impairment	Shoulder	Elbow	Wrist	Fingers	Thumb
Grade 2 (MAL < 2.5 for AS & HW scales)	Flexion 45° and abduction 45°	Extension 20° from a 90° flexed starting position	Extension 20° from a fully flexed starting position	Extension of all MCP and IP (either PIP or DIP) joints 10°*	Extension or abduction of thumb 10°
Grade 3 (MAL < 2.5 for AS & HW scales)	Flexion 45° and abduction 45°	Extension 20° from a 90° flexed starting position	Extension 10° from a fully flexed starting position	Extension 10° MCP and IP (either PIP or DIP) joints of at least 2 fingers†	Extension or abduction of thumb 10°
Grade 4 (MAL < 2.5 for AS & HW scales)	Flexion 45° and abduction 45°	Extension 20° from a 90° flexed starting position	Extension 10° from a fully flexed starting position	Extension of at least 2 fingers > 0° and < 10°‡	Extension or abduction of thumb 10°
Grade 5 (LF-MAL < 2.5 for AS & HW scales)	At least one of the following: Flexion 30° abduction 30° scaption 30°	Initiation‡ of both flexion and extension	Must be able to either initiate‡ extension of the wrist or initiate extension of one digit		

MAL indicates Motor Activity Log; AS & HW scales indicate Amount and How Well Scales of the MAL; MCP indicates metacarpophalangeal joints; IP indicates interphalangeal joints; PIP indicates proximal interphalangeal joints; DIP indicates distal interphalangeal joints; LF-MAL indicates Lower Functioning Motor Activity Log.

Each movement must be repeated 3 times in 1 minute. Grade 6 patients would fall below the minimum Grade 5 criteria.

* Informally assessed when picking up and dropping a tennis ball.

† Informally assessed when picking up and dropping a washcloth.

‡ Initiation is defined for the purposes of criteria as minimal movement (i.e., below the level that can be measured reliably by goniometer).

Table 2

Participant Characteristics

	S1	S2	S3	S4	S5	S6	Mean±SD/Number
Age (years)	75	57	45	58	54	52	56.9±9.8
Years since stroke	3	19	3	2	1	2	5.1±6.8
Ethnic group							
European American	Yes	Yes	No	No	Yes	Yes	4
African American	No	No	Yes	Yes	No	No	2
Side of paresis							
(R – right, L – left)	R	L	R	R	R	R	5R/1L
Pre-stroke dominant side (R – right, L – left)	L	R	R	R	R	R	5R/1L
Real-world more-affected arm use – Pre-treatment							
LF-MAL Arm Use scale (0–5 points)	0.5	0.6	0.4	0.4	1.6	0.9	0.7±0.5
Accelerometry ratio	0.35	0.41	0.46	0.47*	0.54	0.53	0.46±0.07
More-affected arm motor capacity – Pre-treatment							
FMA upper-extremity motor score (0–66 points)	29	19	18	23	20	35	24±7
Active range of motion (degrees) – Pre-treatment							
Shoulder flexion	40	30	40	45	55	135	58±39
Shoulder abduction	55	20	60	75	105	135	75±40
Elbow extension	105	0	90	50	90	125	77±45
Forearm pronation	0	40	70	50	50	45	43±23
Forearm supination	0	0	0	5	5	15	4±6
Wrist extension	48	0	55	8	110	115	56±49
Mean (% normal) [‡]	25.8	13.0	40.0	29.0	48.5	64.2	37±18

* Missing datum was replaced with the post-Phase A (i.e., pre-CI-therapy) value following the conservative assumption of no change after Phase A.

[‡] Range of motion values for movements listed above were converted to percent of normal range values; the average of these transformed values was then calculated. Normal range of motion values for these movements were: shoulder flexion (0–180°), elbow extension (150–0°), forearm pronation (0–80°), forearm supination (0–80°) wrist extension (0–70°). Normal ranges are based on Hislop and Montgomery.¹ Active range of motion could not be measured reliably for other upper-extremity joints (e.g., finger joints, wrist flexion) because of problems such as rebound movements after a joint was put in the neutral position and because of periodic problems with spasticity and excess tone at these joints.

LF-MAL indicates Lower Functioning Motor Activity Log. FMA indicates Fugl-Meyer Motor Assessment.

Reference

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¹Hislop H, Montgomery J. *Daniels and Worthingham's Muscle Testing: Techniques of Manual Examination*. Philadelphia: W.B. Saunders; 2002.

Table 3

Change in Outcome Measures for Phase A, Phase B, and Phase A+B

Outcome	S1	S2	S3	S4	S5	S6	Mean $\pm$ SD	t value	P value	Effect Size (d) [*]
<i>Phase A (baseline to pre-CI therapy)</i>										
LF-MAL Arm Use scale (0–5 points)	0.7	0.4	0.8	0.3	0.5	0.4	0.5 $\pm$ 0.2	6.3	0.001 [†]	2.6
Accelerometry ratio	0.00	0.11	0.05	0.00	0.03	0.04	0.04 $\pm$ 0.04	2.3	0.035 [†]	0.9
<i>Active range of motion (degrees)</i>										
Shoulder flexion	15	12	–10	23	5	15	10.0 $\pm$ 11.4	.	.	0.9
Shoulder abduction	–5	50	5	–20	7	0	6.2 $\pm$ 23.5	.	.	0.3
Elbow extension	–20	0	–7	30	35	5	7.2 $\pm$ 21.4	.	.	0.3
Forearm pronation	40	20	0	–20	–5	0	5.8 $\pm$ 21.1	.	.	0.3
Forearm supination	10	0	0	–5	–5	5	0.8 $\pm$ 5.8	.	.	0.1
Wrist extension	–28	5	3	17	15	10	3.7 $\pm$ 16.4	.	.	0.2
Mean (% normal) [‡]	6	11	–1	0	5	4	4.1 $\pm$ 4.1	2.0	0.051	1.0
<i>Phase B (pre- to post-CI therapy)</i>										
LF-MAL Arm Use scale (0–5 points)	1.2	0.2	0.6	1.1	0.6	1.2	0.8 $\pm$ 0.4	5.1	0.002 [†]	2.1
Accelerometry ratio	0.06	0.02	0.03	0.01	0.11	0.26	0.08 $\pm$ 0.10	2.1	0.044 [†]	0.9
FMA upper extremity motor score	2	5	7	4	11	3	5.3 $\pm$ 3.3	4.0	0.005 [†]	1.6
<i>Active range of motion (degrees)[‡]</i>										
Shoulder flexion	–25	40	20	17	25	10	14.5 $\pm$ 21.8	.	.	0.7
Shoulder abduction	15	5	20	22	–6	15	11.8 $\pm$ 10.5	.	.	1.1
Elbow extension	35	15	22	5	–25	10	10.3 $\pm$ 20.2	.	.	0.5
Forearm pronation	–20	0	5	25	22	15	7.8 $\pm$ 16.7	.	.	0.5
Forearm supination	15	5	0	0	60	15	15.8 $\pm$ 22.7	.	.	0.7
Wrist extension	45	–5	5	–5	0	–20	3.3 $\pm$ 22.1	.	.	0.2
Mean (% normal) [‡]	7	6	8	9	16	8	8.9 $\pm$ 3.6	2.4	0.029 [†]	2.5
<i>Phase A+B (baseline to post-CI therapy)</i>										
LF-MAL Arm Use scale (0–5 points)	1.9	0.6	1.4	1.3	1.1	1.7	1.3 $\pm$ 0.4	7.4	0.001 [†]	3.0
Accelerometry ratio	0.06	0.13	0.08	0.01	0.14	0.30	0.12 $\pm$ 0.10	2.9	0.016 [†]	1.2

Outcome	S1	S2	S3	S4	S5	S6	Mean $\pm$ SD	t value	P value	Effect Size (d) [*]
FMA upper extremity motor score	2	5	7	4	11	3	5.3 $\pm$ 3.3	4.0	0.005 [†]	1.6
Active range of motion (degrees)										
Shoulder flexion	-10	52	10	40	30	25	24.5 $\pm$ 22.0	.	.	1.1
Shoulder abduction	10	55	25	2	1	15	18.0 $\pm$ 20.2	.	.	0.9
Elbow extension	15	15	15	35	10	15	17.5 $\pm$ 8.8	.	.	2.0
Forearm pronation	20	20	5	5	17	15	13.7 $\pm$ 7.0	.	.	2.0
Forearm supination	25	5	0	-5	55	20	16.7 $\pm$ 22.1	.	.	0.8
Wrist extension	17	0	8	12	15	-10	7.0 $\pm$ 10.3	.	.	0.7
Mean (% normal) [‡]	13	17	7	9	21	12	13.0 $\pm$ 5.1	6.1	0.001 [†]	2.6

^{*} d is a repeated measures Effect Size index; it is the mean change divided by its standard deviation (SD). In the meta-analysis literature, d values $> .57$ are considered large.¹

[†] $P < .05$

[‡] Range of motion values for movements listed above were converted to percent of normal range values; the average of these transformed values was then calculated. Normal range of motion values for these movements were: shoulder flexion (0–180°), elbow extension (150–0°), forearm pronation (0–80°), forearm supination (0–80°) wrist extension (0–70°). Normal ranges are based on Hislop and Montgomery, 2002². Active Range of Motion could not be measured reliably for other upper-extremity joints (e.g., finger joints, wrist flexion) because of problems such as rebound movements after a joint was put in the neutral position and because of periodic problems with spasticity and excess tone at these joints.

LF-MAL indicates Lower Functioning Motor Activity Log. FMA indicates Fugl-Meyer Motor Assessment.

References

- ¹ Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.
- ² Hislop H, Montgomery J. *Daniels and Worthingham's Muscle Testing: Techniques of Manual Examination*. Philadelphia: W. B. Saunders; 2002.

Appendix 1A

Items on the Grade 4/5 Motor Activity Log (Grade 4/5-MAL) *

-
- 1 Turn on a light with a light switch
 - 2 Open a drawer
 - 3 Remove an item of clothing from a drawer
 - 4 Pick up a phone
 - 5 Wipe off a kitchen counter or other surface
 - 6 Get out of a car (*includes only the movement needed to get the body from sitting to standing outside of the car once the door is open*)
 - 7 Open a refrigerator
 - 8 Open a door by turning a door knob/handle
 - 9 Use a TV remote control
 - 10 Wash your hands (*includes lathering and rinsing hands; does not include turning water on and off with a faucet handle*)
 - 11 Flush the commode
 - 12 Use a towel (*after bathing*)
 - 13 Put on your socks
 - 14 Maintain your balance or provide support while sitting (*arm on table or armrest*)
 - 15 Put on your shoes (*includes tying laces or fastening straps*)
 - 16 Put on your pants or undergarments (*includes starting pants over feet and pulling them up over hips – but not fastening them*)
 - 17 Get up from a chair with armrests
 - 18 Roll over in bed
 - 19 Apply soap to your body while bathing
 - 20 Sit up on the side of the bed (*from lying down*)
 - 21 Brush your teeth (*does not include preparation of toothbrush or brushing dentures unless the dentures are brushed while left in the mouth*)
 - 22 Push off/pull up bed covers
 - 23 Steady yourself while standing
 - 24 Carry an object in your hand (*draping an item over the arm is not acceptable*)
 - 25 Use a fork or spoon for eating (*refers to the action of bringing food to the mouth with a fork or spoon*)
 - 26 Wipe your mouth
 - 27 Pick up a cup by a handle
 - 28 Put on a pullover
 - 29 Eat half a sandwich or finger foods
 - 30 Write on paper (*if dominant arm was most affected*)
- OR
- Hold paper while writing (*if non-dominant arm was most affected*)
-

* 10 items were added to the Grade 4/5-MAL that do not appear on the MAL administered to higher functioning patients to substitute for 10 items that were deleted from the latter test. There were 30 items on each test.

Items added: 11,14,16,18,19,20,22,23,26,28.

Items deleted from the 30-item MAL administered to higher-functioning patients:

Turning water off/on with knob/lever on faucet

Take off your socks

Take off your shoes

Pull chair away from table before sitting down

Pull chair toward table after sitting down

Pick up a glass, bottle, drinking cup, or can (does not need to include drinking)

Put on makeup base, lotion, or shaving cream on face

Use a key to unlock a door

Comb your hair

Button a shirt

Appendix 1B**LF-MAL Arm Use Scale (Ratings may be made in half steps)**

-
0 –	The weaker arm was not used at all for that activity (Never)
1 –	The weaker arm was moved during that activity, but was not helpful (Very Poor)
2 –	The weaker arm was of some use during that activity, but needed help from the stronger arm or moved very slowly or with difficulty (Poor)
3 –	The weaker arm was used for the purpose indicated, but movements were slow or were made with only some effort (Fair)
4 –	The movements made by the weaker arm were almost normal, but were not quite as fast or accurate as normal (Almost Normal)
5 –	The ability to use the weaker arm for that activity was as good as before the stroke (Normal)
-