A Placebo-Controlled Trial of Constraint-Induced Movement Therapy for Upper Extremity After Stroke

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Background and Purpose—Constraint-Induced Movement therapy (CI therapy) is a neurorehabilitation technique developed to improve use of the more affected upper extremity after stroke. A number of studies have reported positive effects for this intervention, but an experiment with a credible placebo control group has not yet been published.

Methods—We conducted a placebo-controlled trial of CI therapy in patients with mild to moderate chronic (mean=4.5 years after stroke) motor deficit after stroke. The CI therapy group received intensive training (shaping) of the more affected upper extremity for 6 hours per day on 10 consecutive weekdays, restraint of the less affected extremity for a target of 90% of waking hours during the 2-week treatment period, and application of a number of other techniques designed to produce transfer to the life situation. The placebo group received a program of physical fitness, cognitive, and relaxation exercises for the same length of time and with the same amount of therapist interaction as the experimental group.

Results—After CI therapy, patients showed large (Wolf Motor Function Test) to very large improvements in the functional use of their more affected arm in their daily lives (Motor Activity Log; $P<0.0001$). The changes persisted over the 2 years tested. Placebo subjects showed no significant changes.

Conclusion—The results support the efficacy of CI therapy for rehabilitating upper extremity motor function in patients with chronic stroke. **(*Stroke*. 2006;37:1045-1049.)**

Key Words: controlled clinical trials ■ rehabilitation ■ stroke ■ treatment outcome

At present, there is little experimental evidence available indicating that physical rehabilitation is effective for patients with chronic stroke; the prevailing view has been that the amount of motor recovery present at 1 year after stroke is the level at which patients will remain.[1] The literature is even equivocal on the value of rehabilitation for subacute patients.[1] However, preliminary studies from this laboratory have provided data that Constraint-Induced Movement (CI) therapy can produce a large improvement in the amount of use of the more-impaired arm in patients with chronic stroke.[2–4] These results have been replicated in studies from other laboratories.[3] This improvement is of interest because it is reported to transfer to the life situation and persist for ≥2 years.

The treatment used here differs from conventional physical rehabilitation in its duration and intensity. It involves training of the more affected extremity by shaping for 6 hours per day over consecutive weeks while constraining use of the less affected extremity for the majority of waking hours during this period to induce increased use of the more affected limb. In addition, several techniques are used to achieve transfer of improved motor function to the life situation. The treatment was derived from research with monkeys[5] and may be considered 1 of a new class of neurorehabilitation techniques founded on basic research in neuroscience and behavioral science that give promise of efficacy.[6]

There are >120 published studies using either the original technique or, in many cases, a variant. The magnitude of the treatment effect has varied, but all studies report a positive outcome. However, a major barrier to the resolution of doubt concerning the technique is the absence of a study with a credible placebo control group. We report such a study here.

Methods

Participants

Individuals with chronic stroke were recruited mainly by advertising in periodicals. Respondents were screened using structured telephone interviews and then structured examinations by a physical therapist and a neurologist or physiatrist. Eligible individuals were assigned to either a CI therapy (n=21) or placebo control group (n=20). The 2 groups were matched on initial motor deficit by assigning participants to each group in blocks on the basis of scores

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on the Wolf Motor Function Test (WMFT; see below) performance time (PT) scores. When a block of subjects was assembled, it was assigned to the group that would result in the smallest between-group difference in initial WMFT scores. The following main exclusion criteria were used: (1) stroke experienced >1 year earlier, bilateral or brain stem stroke; (2) lack of ability to actively extend ≥10° at metacarpophalangeal and interphalangeal joints and 20° at wrist (the focal criterion); (3) balance or ambulation problems (eg, assistance required for toileting); (4) substantial use of the involved upper extremity in the life situation as evidenced by a score >2.5 on the motor activity log (MAL) amount of use scale (see below); (5) major 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; (6) excessive pain, spasticity, ataxia, or frailty as determined by clinical judgment; and (7) severe end-stage or uncontrolled medical conditions. The following were not exclusion criteria: (1) somatosensory deficit, (2) long duration of symptoms, and (3) nature or amount of previous physical therapy. Participant characteristics are summarized in Table 1. The study protocol was approved by the institutional review board, and each subject signed an informed consent.

Interventions

The CI therapy group received both components of a published protocol[2] derived from the work with deafferented monkeys (ie, paretic arm training and contralateral arm restraint).[5] The training was administered intensively for 6 hours per day with an additional hour of interpolated rest on each weekday of the 2-week treatment period. The training consisted primarily of a procedure termed shaping (supplemental Appendix I, available online at http://stroke.ahajournals.org),[7,8] which involved: (1) quantifying and very frequent immediate feedback concerning improvements in the speed and quality of movement (QOM), (2) selecting tasks that were tailored to address the motor deficits of the individual patient, (3) modeling, prompting, and cuing of task performance, and (4) systematically increasing the difficulty level of the task performed in small steps when 5 trials of improved performance occurred. The CI therapy participants also wore a resting hand splint/sling ensemble on their less affected upper extremity that prevented use of that arm for a target of 90% of waking hours for the entire 14-day treatment period. The rationale was to promote use of the more affected arm outside the laboratory when safety permitted. Additional behavioral techniques, such as behavioral contracts and problem solving (supplemental Table I, available online at http://stroke.ahajournals.org) were used to facilitate transfer of treatment gains from the therapeutic to the home setting.

The placebo control group was designed to control for the duration and intensity of patient–therapist interactions and therapeutic activities. These participants received a general fitness program in which they performed strength, balance, and stamina training exercises, played games that provided cognitive challenges, and practiced relaxation exercises for 6 hours per day for 10 consecutive weekdays. Their answers to a laboratory standard questionnaire about their expectations before the intervention (Table 1) suggests that they found the control treatment to be credible.

TABLE 1. Demographic, Stroke-Related, and Expectancy Characteristics of CI Therapy Patients and Placebo Controls

Characteristic	CI Therapy (n=21)	Control (n=20)
Demographic		
Age, y	54.6±12.1	50.7±19.2
Female	10	4
Ethnic group		
European-American	12	19
African American	8	1
Asian	1	0
Stroke-related		
Paresis of right side	11	9
Paresis of dominant side	11	9
Time since stroke, y	3.6±4.5	5.3±3.9
Between 1 and 2 y	14	5
Between 2 and 5 y	4	8
Between 5 to 20 y	3	7
Expectancy (maximum=10)		
Credibility of treatment	7.7±2.3	7.6±2
Treatment outcome expectancy	8.1±1.3	7.9±1.8
Self-efficacy for wearing restraint device	8.1±1.7	n/a
Self-efficacy for training more impaired arm	8.4±1.8	7.7±1.8

Values are mean±SD.

Measures

Treatment outcomes were assessed in the domains of real-world arm use and arm motor ability. The MAL[2] is a structured interview that measures how well (11-point QOM scale) and how much (11-point amount of use [AOU] scale) patients use their more impaired arm in their life situation for accomplishing 14 activities of daily living (supplemental Appendix II, available online at http://stroke.ahajournals.org). Analyses indicate that it is a reliable, stable, and valid measure of real-world arm function.[9–11] The QOM or arm use score is reported because data suggest that the QOM scale is more internally consistent and reliable than the AOU scale and that it captures components of the amount as well as quality of arm use outside the laboratory.[9,10] The upper extremity actual amount of use test (AAUT) is an in-laboratory observational measure of arm function that is thought to index how much patients actually use their more impaired arm in their daily lives.[9] Patients are videotaped without their awareness (but after previous agreement to permit videotaping) while they are guided through a standardized scenario that includes 17 activities that afford an opportunity to use their more impaired arm. Trained masked observers evaluate how much (2-point AOU scale) and how well (5-point QOM scale) patients use their more impaired arm from videotape. Only the QOM or arm use score is reported because scores from the 2 scales were redundant (pretreatment and post-treatment r_{QOM}, AOU >0.9; $P<0.0001$). The test–retest reliability of the AAUT arm use scale ($r=0.76$) and its convergent validity with the MAL ($r>0.45$; $P<0.01$) are adequate.[9] The WMFT is a laboratory test of motor ability that evaluates the speed (PT) and coordination (functional ability [FA] scale) with which patients complete 14 tasks using their more impaired arm. PT is recorded live by the tester; FA is scored from videotape by trained masked observers using a 5-point scale. The WMFT has an established reliability and validity.[12,13] The masked observers who rated the WMFTs and AAUTs from this study exceeded a criterion of 0.9 agreement with a benchmark set of scored videotapes before rating study data. The MAL and WMFT are considered primary measures of CI therapy outcome;[2,9] the AAUT provides an objective, convergent measure of real-world arm use.[9] Expectations of improvement and self-efficacy for following the study procedures were also assessed using a 4-item questionnaire.[9] The schedule of testing is summarized in supplemental Table II, available online at http://stroke.ahajournals.org.

Data Analysis

Data were analyzed using repeated-measures ANOVAs, followed by Tukey tests when appropriate. Testing occasion and treatment condition were represented as within-subjects (time), and between-subjects (group) factors, respectively. The efficacy of CI therapy was assessed by testing their interaction (group×time effect). The retention of treatment gains over long-term follow-up was evaluated using Tukey tests because these data were available only for the CI therapy

group. ANOVAs and χ^2 tests were used to evaluate between-group differences in demographic variables. Two-tailed tests with an α of 0.05 were used. Post hoc ANOVAs and regression analyses, with the Bonferroni correction for multiple tests, were used to examine the relationship of initial participant characteristics to treatment gains. Effect sizes were indexed using Cohen's f (small $f=0.1$, medium $f=0.25$, large $f=0.4$) for between-group comparisons and Cohen's d' (small $d'=0.14$, medium $d'=0.36$, large $d'=0.57$) for within-group comparisons.[14]

Results

Initial Differences Between Groups

There was a trend toward a significantly larger number of women in the CI therapy group than in the control group ($P=0.06$; Table 1). This difference was noteworthy because female CI therapy patients showed larger gains than males on the MAL ($P=0.02$; $f=0.23$): women improved 2.1±0.4 points ($d'=5.3$), whereas men improved 1.5±0.6 points ($d'=2.5$). The CI therapy group was also more racially diverse than the fitness controls ($P=0.02$; Table 1), and there were additional initial differences between the groups on some of the measures (arm strength, mood). However, these differences were unlikely to have influenced the findings regarding efficacy because there were no significant relationships between the initial values of these parameters and treatment gains in the CI therapy group.

Changes from Pretreatment to Post-Treatment

The CI therapy group showed very large improvements in the quality and amount of more impaired arm use outside the laboratory relative to the general fitness control group. On the MAL arm use scale, CI therapy subjects reported a mean increase of 1.8 points, whereas controls reported no change ($P<0.0001$; $f=3.0$; Table 2; Figure). The patients' reports were corroborated by those of their caregivers ($P<0.0001$; $f=0.8$; Table 2). Furthermore, the MAL results were confirmed by the AAUT. CI therapy participants (n=15) showed an 87.5% increase on the AAUT arm use scale; controls (n=17) exhibited a 20% decrease ($P=0.0003$; $f=0.5$; Table 2).

On the WMFT, CI therapy subjects showed moderate improvements in the speed with which they completed tasks in the laboratory with their more impaired arm relative to the controls. The CI therapy group (n=21) exhibited a −2.3±0.7 s decrease in PT, whereas the control group (n=18) displayed a 0.5±3.6 s increase ($P=0.005$; $f=0.23$; Table 2). On the WMFT FA scale, which measures movement quality, CI therapy subjects showed a trend toward a significant improvement relative to controls ($P=0.1$; $f=0.08$; Table 2).

Persistence of Improvements

CI therapy subjects retained the gains made in real-world arm use during treatment over the initial 4-week follow-up period (NS). The improvement in the patient MAL score (n=19) at the 4-week follow-up, relative to pretreatment, remained at 1.8±0.8, and the caregiver MAL score (n=12) remained at 1.6±1.0. Controls displayed no significant changes in their MAL scores at the 4-week follow-up period (n=18) or ≈3 months after treatment (n=16).

TABLE 2. More Impaired Arm Motor Outcomes for CI Therapy Patients and Placebo Controls

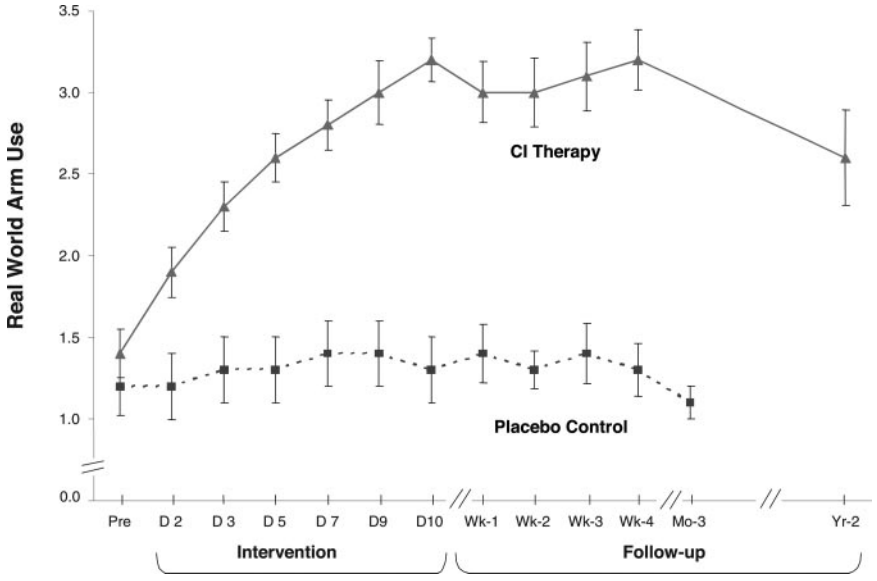
	CI Therapy (n=21)			Placebo Controls (n = 20)			Size (f)* and Significance Level (P) of Between-Group Differences in Change	
Test	Pre	Post	Change	Pre	Post	Change	f*	P
Real-world outcomes								
(MAL; maximum=5)								
Arm use rated by patient†	1.3±0.6	3.1±0.6	1.9±0.6	1±0.5	1.1±0.5	0.1±0.3	3.6	<0.0001
Arm use rated by caregiver	1.1±0.1	2.6±0.7	1.6±0.9	1±0.5	1.2±0.4	0.2±0.5	0.8	<0.0001
AAUT								
Arm use scored by blinded rater† (maximum=4)	0.8±0.4	1.5±0.9	0.7±0.7	1±0.7	0.9±0.6	−0.2±0.5	0.5	0.0003
Laboratory outcomes								
WMFT								
Performance time(s)‡	5.3±3.1	3±1.1	−2.3±2.3	4.1±2.5	4.6±4.4	0.5±3.6	0.2	0.005
Functional ability (maximum=4)	3±0.4	3.2±0.4	0.2±3	2.9±0.4	2.9±0.5	0±0.4	0.1	0.1

Values are mean±SD.

*Cohen's f is a measure of effect size (small $f=0.1$, medium $f=0.25$, large $f=0.4$); it indexes the magnitude of the differences between the 2 groups in preintervention to postintervention change. For each outcome, it is the variance in the relevant outcome measure accounted for by the group (CI therapy, placebo control)×time (preintervention, postintervention) interaction divided by the error variance for this factor.[14]

†AAUT scores were available from 15 CI therapy patients and 17 controls. The AAUT was not conducted with the first 4 participants because development of the test had not yet been completed; pretreatment or post-treatment AAUT data from 5 other subjects were missing because of videotaping errors. Subjects with and without AAUT scores did not have significant differences in arm use on the MAL at pretreatment or in pretreatment to post-treatment change on the MAL.

‡On the WMFT, the improvement in PT ($f=0.23$; 46%) was substantially larger than in FA ($f=0.08$; 6%). The relatively large gains in PT can be explained by the emphasis placed in CI therapy on the rate of performance rather than the quality of movement during training. The parameter shaped during training is typically the No. of repetitions during a fixed interval or the time to perform a fixed No. of repetitions rather than movement pattern.



Mean MAL arm use scores from CI therapy (n=21) and placebo control (n=20) participants. CI therapy subjects showed a very large improvement in arm use outside the laboratory from pretreatment to post-treatment (1.8±0.6; $P<0.0001$; $d'=3.0$), whereas controls showed little change. In follow-up, CI therapy subjects retained all of their immediate treatment gains 4 weeks after therapy and showed only a 23% decrease from post-treatment levels of real-world arm use 2 years afterward.

At 2-year follow-up, the treatment group (n=14) showed a very large improvement on the MAL (1.0±1.1) relative to pretreatment ($P<0.05$; $d'=0.9$). Relative to post-treatment, this represented a 0.7±0.9 (23%) decrease ($P<0.05$; $d'=0.8$). Long-term follow-up was not collected from 33% of the treatment group because these patients were deceased, could not be contacted, or refused to complete testing. Similar gains at post-treatment for participants with and without 2-year follow-up suggested that these missing data did not bias the long-term follow-up results; CI therapy subjects who completed 2-year follow-up reported a 1.7±0.6 gain at post-treatment, whereas subjects who did not reported a 1.9±0.7 gain. However, it was still possible that subjects who completed 2-year follow-up showed smaller decrements in arm use over the follow-up than subjects who did not.

Relation of Treatment Change to Initial Participant Characteristics

There were no significant associations between pretreatment arm motor ability (WMFT) or real-world arm use (MAL) and gains in real-world arm use within the segment of the population with chronic stroke we worked with (ie, patients with mild/moderate motor deficit). Side of paresis, paresis of the prestroke dominant arm, chronicity, age, and race had no effect on treatment outcome.

Discussion

As in previous experiments,[2–4] patients receiving CI therapy showed large to very large increases in spontaneous use of their more impaired arm in the real-world environment, as indexed by the effect size of the change in MAL scores, and moderate improvement in more-impaired arm motor ability, as shown by a laboratory motor performance test (WMFT). In contrast, patients given a credible placebo intervention did not show a significant change in either of these measures.

Van der Lee et al used a form of CI therapy that was modified in important respects (training on a group basis using "housekeeping activities, handicrafts, and games" in a relaxed atmosphere).[15] The treatment effect reported was smaller (but still significant) than in this study, but these results are at variance with those of the other studies[3] that have followed the protocol in our initial publication (one-on-one training, intensive approach, use of specific upper extremity tasks tailored to the motor deficits of individual patients).[2,8]

A finding of interest was that female patients showed larger gains on the MAL than males. A possible explanation is that women may receive more frequent or more powerful reinforcement of more impaired arm use from their social environment than men. Another possibility consistent with recent animal studies is that differences between women and men in gonadal hormone levels might enhance therapy-induced brain plasticity in the women.[16] Any bias introduced by the differences in gender between groups (48% versus 20% female for CI therapy versus control groups, respectively) was not large enough to alter conclusions regarding the efficacy of CI therapy. We estimated that the mean improvement among CI therapy subjects on the MAL arm use scale would be 1.7 if there were the same smaller number of women in the CI therapy group as in the control group rather than the 1.9 that was actually recorded.

CI therapy is thought to achieve its therapeutic effect by 2 linked but independent mechanisms: overcoming learned nonuse and use-dependent neural plasticity.[3] The first mechanism was observed in the primate experiments on which CI therapy is based. When somatic sensation is surgically abolished by dorsal rhizotomy from a single forelimb in monkeys the deafferented extremity is never used. Converging evidence indicated that this nonuse is a learning phenomenon, involving a suppression of movement that develops in the early period after the central nervous system damage. This learned inhibition of movement can be overcome with techniques similar to those used in CI therapy.[5] This research suggests that some part of the substantial deficit in spontaneous use of the more impaired arm often observed in patients with stroke, when accompanied by relatively modest deficits in more impaired arm motor ability, is attributable to learned nonuse. The rapidity with which large improvements

in real-world arm use occurred in this and other studies[2–4] is consistent with the lifting of a learned inhibition of movement, as observed in the course of recovery in deafferented monkeys undergoing CI therapy-like procedures. The smaller improvements in motor ability observed in CI therapy patients, as reflected in scores on the WMFT, would be accomplished on the basis of motor learning, which is typically a slower process. Evidence for this formulation and its mode of operation have been described in detail previously.[2,3,5,6]

With regard to the second mechanism underlying its therapeutic effect, CI therapy has been shown to generate a large use-dependent brain reorganization in which substantial new areas of the brain are recruited into the innervation of movement of the more affected extremity. This is correlative with the large changes in function that CI therapy produces in humans after stroke and monkeys after simulated stroke and deafferentation.[6] The present experiment adds the support of a placebo-controlled trial to the possibility that this activity-dependent brain plasticity can be harnessed through appropriate behavioral or rehabilitation techniques to produce a clinically meaningful therapeutic effect on chronic motor deficits after neurological damage. The traditional view that chronic stroke patients are refractory to treatment needs to be reconsidered.

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References

1. Duncan PW. Synthesis of intervention trials to improve motor recovery following stroke. *Top Stroke Rehabil*. 1997;3:1–20.
2. Taub E, Miller NE, Novack TA, Cook EW III, Fleming WC, Nepomuceno CS, Connell JS, Crago JE. Technique to improve chronic motor deficit after stroke. *Arch Phys Med Rehabil*. 1993;74:347–354.
3. Taub E, Uswatte G, Pidikiti R. Constraint-induced movement therapy: a new family of techniques with broad application to physical rehabilitation–a clinical review. *J Rehabil Res Dev*. 1999;36:237–251.
4. Taub E, Lum PS, Hardin P, Mark V, Uswatte G. AutoCITE: automated delivery of CI therapy with reduced effort by therapists. *Stroke*. 2005;36:1301–1304.
5. Taub E. Somatosensory deafferentation research with monkeys: implications for rehabilitation medicine. In: Ince LP, ed. *Behavioral Psychology in Rehabilitation Medicine: Clinical Applications*. New York, NY: Williams & Wilkins; 1980:371–401.
6. Taub E, Uswatte G, Elbert T. New treatments in neurorehabilitation founded on basic research. *Nat Rev Neurosci*. 2002;3:228–236.
7. Skinner BF. *The Behavior of Organisms*. New York, NY: Appleton-Century-Crofts; 1938.
8. Taub E, Burgio L, Miller NE, Cook EW III, Groomes T, DeLuca S, Crago J. An operant approach to overcoming learned nonuse after CNS damage in monkeys and man: the role of shaping. *J Exp Anal Beh*. 1994;61:281–293.
9. Uswatte G, Taub E. Implications of the learned nonuse formulation for measuring rehabilitation outcomes: lessons from constraint-induced movement therapy. *Rehabil Psychol*. 2005;50:34–42.
10. Uswatte G, Taub E, Morris D,Vignolo M, McCulloch K. Reliability and validity of the upper-extremity Motor Activity Log-14 for measuring real-world arm use. *Stroke*. 2005;36:2493–2496.
11. van der Lee J, Beckerman H, Knol D, de Vet H, Bouter L. Clinimetric properties of the motor activity log for the assessment of arm use in hemiparetic patients. *Stroke*. 2004;35:1–5.
12. Morris D, Uswatte G, Crago J, Cook EW III, Taub E. The reliability of the Wolf Motor function test for assessing upper extremity motor function following stroke. *Arch Phys Med Rehabil*. 2001;82:750–755.
13. Wolf SL, Catlin P, Ellis M, Link Archer A, Morgan B, Piacentino A. Assessing Wolf motor function test as outcome measure for research in patients after stroke. *Stroke*. 2001;32:1635–1639.
14. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Hillsdale, NJ: Lawerence Erlbaum Associates; 1988.
15. Van der Lee J, Wagenaar R, Lankhorst G, Vogelaar T, Devillé W, Bouter LM. Forced use of the upper extremity in chronic stroke patients: results from a single-blind randomized clinical trial. *Stroke*. 1999;30:2369–2375.
16. Kolb B. Overview of cortical plasticity and recovery from brain injury. *Phys Med Rehabil Clin N Am*. 2003;14:S7–S25.

Appendix I

Shaping Guidelines

Shaping is a training method in which a motor or behavioral objective is approached in small steps by successive approximations (ie, a task is gradually made more difficult with respect to a subject's motor capabilities). It may be viewed as a formal elaboration of training techniques commonly used by physical and occupational therapists giving patients task practice. It differs in that it is systematic, proceeding by certain general rules that are specifiable, and it is quantified. It also differs in that patients are given frequent and explicit feedback concerning even small improvements in performance. A battery of ≈120 tasks has been developed by the CI Therapy Research Group. The following principles are for use as guidelines when shaping is used for inducing recovery of motor function.

Shaping tasks should be selected for patients by considering: (1) specific joint movements that exhibit the most pronounced deficits, (2) the joint movements that therapists believe have the greatest potential for improvement, and (3) patient preference among tasks that have similar potential for producing the same improvements.

Each subject's shaping program is individualized consisting of 10 to 15 tasks selected primarily from the basic battery of tasks. However, new tasks can be created for a patient if that would appear to be advantageous for that person's individual motor deficits. Each task is usually performed in a set of 10 30-second trials. At the end of each set of 10 trials, the task is typically changed.

One measure frequently used is the number of task repetitions performed within the 30-second trial period. An alternate measure used less frequently is time required to carry out a set number of task repetitions.

The results are recorded on a data sheet and graphed by hand on a trial-by-trial basis; both types of information are presented to the subject immediately.

The level of difficulty of the shaping task should be slightly beyond what a patient can accomplish easily, thereby encouraging him/her to do a little better than on the previous trial.

Each task has a preliminary shaping plan established in which the parameters along which task difficulty will be made more difficult are specified.

When increasing the level of difficulty of a task the parameter selected for change should relate to the subject's movement problems. For example, if the subject's most significant movement deficits are with thumb and finger dexterity and an object flipping task is used, the difficulty of the task would be increased by making the object progressively smaller if the problem was in flexion/adduction or progressively larger if the problem was in extension/abduction. If there is a significant deficit in elbow extension and a pointing or reaching task is used, the shaping progression might involve placing the target object at increasing distances from the subject.

The shaping task is made progressively more difficult only as the patient improves in performance. The amount of difficulty increase should be such that it is clear that the patient will be able to accomplish the task, although with effort.

One criterion for increasing the level of difficulty might be when the mean of the last 5 trials exceeds the mean of the previous 5 trials, not taking into consideration whether some of the trials are in the previous set, or, alternatively, when 4 of the last 5 trials exceeds the mean of the previous 5. The therapist should keep a hand calculator available for rapid calculation.

Another criterion for moving on to the next higher level of task difficulty might be when the patient has reached a relative plateau in performance scores. For example, when a subject has performed 10 consecutive trials with no clear improvement, the next level of difficulty might be introduced. If subjects are permitted to remain at a given level of mastery for too long, they frequently become "locked in" at that level. Subsequently, improvement becomes more difficult to achieve.

Positive reinforcement or reward should be provided visually (ie, shaping data forms and graphs of performance) and verbally.

An important function of the therapist is to act as a "cheerleader," continuously encouraging subjects on a moment-to-moment basis to keep improving their performance.

Performance regressions are never commented on negatively or punished and are usually ignored.

If a patient is experiencing excessive difficulty with a task, a simpler task involving similar movements can be substituted.

Shaping tasks should be modeled by the therapist for the patient and verbal prompts and suggestions provided liberally.

Rest intervals should be allowed during each shaping session. The rest periods can be the same length as the time required for a set of 10 trials, although longer intervals are sometimes needed to prevent fatigue because patients with neurological damage often find movement effortful. Rest intervals should also be introduced between trials as needed.

In experiments performed by the CI Therapy Research Group, rate of performance is usually kept at 25 trials per hour. Many patients can easily go faster, but to establish a uniform intensity of training, performance is maintained at a rate that all patients can carry out. However, for nonexperimental clinical work, the patient can be allowed to perform at a rate that is comfortable for them.

Therapists can rate the performance of each shaping task trials using the QOM movement scale presented in supplemental Appendix II and provide this information to subjects, unless they frequently contest the therapist's judgment, in which case the rating can be dispensed with.

Encouragement and QOM ratings should be presented to the subjects on ≥50% of the trials; the objective data should be presented after each trial.

Placement of test objects used should be recorded on the shaping data sheet so that the task can be duplicated. Removable markers on the task performance table can also be used for this purpose. Any placement changes when a shaping task is made more difficult should be noted on the data sheet.

Only 1 shaping parameter at a time should be varied. For example, for an elbow extension task, there would be 3 parameters that could be changed: time to carry out a given number of repetitions, number of repetitions performed in a

trial period, and distance. The time and number of repetitions can be held constant and the distance can be slowly increased until the subject can no longer perform a specified number of extensions in a given period of time (eg, 10 extensions in 30 seconds) Alternatively, distance can be held constant (eg, 8 inches) and the subject encouraged to progressively increase the number of repetitions in a set period of time (eg, 30 seconds). If >1 parameter is varied (eg, both distance and number or repetitions) the quantification is less meaningful. If the trainer feels that a subject would benefit from varying a second parameter, that is permissible. However, because the task requirements are now being changed along a new dimension, the data must now be considered separately.

Examples of Shaping Tasks

Ring Toss

Plastic rings and a plastic bar or prong are used for this task. The subject places a plastic ring onto a plastic prong/bar that is either held by the trainer or inserted into a base placed on a table.

Potential Shaping Progressions

The prong/bar can be moved farther away to challenge elbow extension. The prong/bar can be placed higher to challenge shoulder flexion. The prong/bar can be placed more to the more affected side to challenge shoulder horizontal abduction.

Potential Feedback Variables

Potential feedback variables are the number of rings placed on the prong/bar in a given time period or the time required to place a set number of rings on the prong/bar.

Movements Emphasized

Movements emphasized are pincer grasp, wrist extension, elbow extension, and shoulder flexion.

Blocks Onto a Box

Activity Description

A box and several blocks are used for this task. The subject moves small wooden blocks from the table to the top of a box. The placement and height of the box depend on the movements the therapist is attempting to improve. For example, the box can be placed directly in front of the subject to challenge should flexion and elbow extension or placed to the side to challenge shoulder abduction and elbow extension.

Potential Feedback Variables

Potential feedback variables are the number of blocks placed on the box in a given period of time or the time required to place a set number of blocks on the box.

Movements Emphasized

Movements emphasized are pincer grasp, wrist extension, elbow extension, and shoulder flexion.

Pegboard

Activity Description

A pegboard and pegs are used with this task. The subject lifts a wooden peg and places it in a designated hole on the pegboard. The pegboard can be placed flat or more vertically at any angle depending on the movements the therapist wishes to improve. For example, the flat pegboard position challenges elbow extension; the vertical pegboard position challenges elbow extension with shoulder flexion.

Potential Shaping Progression

The pegboard can be placed farther away to challenge elbow extension. The pegboard can also be placed in a more vertical position or raised to challenge shoulder flexion.

Potential Feedback Variables

Potential feedback variables are the number of pegs placed in holes in a given period of time and the time required to fill the pegboard or place a given number of pegs.

Movements Emphasized

Movements emphasized are pincer grasp, wrist extension, elbow extension, and shoulder flexion.

TABLE I. Additional Techniques Used in CI Therapy to Facilitate Transfer of Treatment Gains From the Therapeutic Setting to the Home

Technique	Description
Behavioral contract	At the outset of treatment, the therapist negotiates a contract with the participant and caregiver, if one is available in which they agree that the participant will wear the restraint device whenever it is safe for up to 90% of waking hours and use his or her more impaired arm as much as possible outside the laboratory. Specific activities during which the participant can practice using the more impaired arm are discussed together and written down.
Daily home dairy	During treatment, the participant catalogs how much he or she has worn the restraint device and used the more affected arm for the activities specified in the behavioral contract. The diary is kept for the part of the day spent outside the laboratory and is reviewed each morning with the therapist.
Home practice exercises	During treatment, participants are asked to spend 15 to 30 minutes at home on a daily basis performing specific upper-extremity tasks repetitively with their more affected arm. The tasks typically employ materials that are commonly available (eg, stacking styrofoam cups). Toward the end of treatment, an individualized post-treatment home practice program is drawn up consisting of similar tasks. Participants are encouraged to do these tasks for 30 minutes daily after the 2-week treatment period.
Problem solving	During treatment and 4 weekly phone contacts after treatment, the therapist helps the participant to think through any barriers to using their more impaired arm. For example, if a patient is concerned about spilling liquid from a glass, the therapist may suggest only filling the glass halfway.

Appendix II

Items on the Motor Activity Log-14 (MAL-14)

Items on the MAL-14 are hold book, use towel, pick up glass, brush teeth, shave/apply makeup, open door with key, write/type, steady myself, put arm through clothing, carry object, grasp fork/spoon, comb hair, pick up cup, and button clothes.

MAL Scales (Ratings may be made in half steps)

Quality of movement (QOM) is as follows: (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); and (5) the ability to use the weaker arm for that activity was as good as before the stroke (normal).

Amount of Use (AOU)

AOU is as follows: (0) did not use more-affected arm (not used); (1) occasionally used more affected arm but only very rarely (very rarely); (2) sometimes used more affected arm but did the activity most of the time with stronger arm (rarely); (3) used more affected arm about half as much as before the stroke (half prestroke); (4) used more affected arm almost as much as before the stroke (three fourths prestroke); and (5) used more affected arm as often as before the stroke (same as prestroke).

TABLE II. Schedule of Testing: MAL, AAUT, and WMFT

	MAL			
Occasion	Patient	Caregiver*	AAUT	WMFT
Pretreatment	√	√	√	√
Every other day during treatment†	√			
Post-treatment	√	√	√	√
Weekly follow-up for 1 month‡	√			
3-month follow-up§	√			√
2-year follow-up‡	√			

*If patients lived with a family member or had a regular caregiver, this individual was asked to complete a MAL regarding the patient immediately before and after treatment and a month after treatment. Seventeen patients in each group had caregivers.

†Half the items on the MAL were rated using the arm use scale each day. Scores from the 2 halves were combined every second day to obtain a test score.

‡It was not possible to evaluate long-term retention of gains in motor ability on the WMFT because follow-up data on that test were available for less than half the subjects receiving CI therapy. Long-term follow-up data was available for a larger No. of subjects on the MAL because it was administered over the telephone when participants were not able to return to the laboratory for testing.

§The last follow-up for the placebo controls was obtained 3 months after fitness training; they were given CI therapy at this point for ethical reasons.