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A novel approach to stroke rehabilitation: Robot-aided sensorimotor stimulation

[Articles]

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Outline

Graphics

Abstract^

Objective: In patients with stroke, the authors tested whether additional sensorimotor training of the paralyzed or paretic upper limb delivered by a robotic device enhanced motor outcome.

Methods: Fifty-six patients with stroke and hemiparesis or hemiplegia received standard poststroke multidisciplinary rehabilitation, and were randomly assigned either to receive robotic training (at least 25 hours) or exposure to the robotic device without training. Outcomes were assessed by the same masked raters, before treatment began and at the end of treatment, with the upper extremity component of the Fugl-Meyer Motor Assessment, the Motor Status score, the Motor Power score, and Functional Independence Measurement.

Result: The robot treatment and control group had comparable clinical characteristics, lesion size, and pretreatment impairment scores. By the end of treatment, the robot-trained group demonstrated improvement in motor outcome for the trained shoulder and elbow (Motor Power score, $p < 0.001$; Motor Status score, $p < 0.01$) that did not generalize to untrained wrist and hand. The robot-treated group also demonstrated significantly improved functional outcome (Functional Independence Measurement–Motor, $p < 0.01$).

Conclusion: Robot-delivered quantitative and reproducible sensorimotor training enhanced the motor performance of the exercised shoulder and elbow. The robot-treated group also demonstrated improved functional outcome. When added to standard multidisciplinary rehabilitation, robotics provides novel therapeutic strategies that focus on impairment reduction and improved motor performance.

Modern stroke therapeutics rely on prevention programs, treatment of the acute event, and most recently, renewed efforts to enhance the recovery process. Recent controlled studies have demonstrated enhanced functional outcome when patients participate in multidisciplinary rehabilitation activity. [1,2] The natural course for brain injury after stroke includes some recovery, [3] and for patients with comparable damage the recovery for the upper and lower limbs proceeds over a similar time course. [4-6] Lower extremity impairment yields to more functional improvements and less disability than upper extremity impairment. [7] Several investigators have faced the challenges of upper limb rehabilitation with the use of increased intensity of standard physical therapy treatments, [8-10] device-enhanced treatment, [11-13] neuromuscular stimulation, [14,15] or specially focused sensorimotor activity, called "constraint-induced," for the affected limb. [16,17] The results have been generally encouraging; focused sensorimotor exercise appears to produce better motor outcome. These recent controlled studies promise an objective rationale for the choice among different sensorimotor exercise strategies that may be added to the rehabilitation of the upper limb paralyzed by stroke.

We have approached the argument about optimal choice for the rehabilitation of the upper limb with a novel candidate: a robotic device that interacts with the patient in real-time. This device can manipulate a powerless limb just like any hand-over-hand therapy or measure the speed and direction of a patient-generated movement with imperceptible differences in the patient's sensorimotor experience. [18-20] We reasoned that a device that provided quantifiable and reproducible physical activity along these lines could also be used to train the affected limb in patients with stroke and test whether this additional sensorimotor activity enhanced motor outcome. The interactive robotic device measured a patient's movement and, if necessary, guided the upper limb through a stereotyped pattern. Movement sessions were goal-directed and the device supplied visual, auditory, and tactile feedback concerning the accuracy of the movement. Robot training supplemented the standard poststroke multidisciplinary rehabilitation programs. Past pilot and follow-up studies demonstrated beneficial effects on upper limb motor recovery. [21,22] The current study tested whether additional

sensorimotor exercise delivered by a robotic device improved the motor outcome as measured by decreased impairment specific to the exercised limb, and whether it had an impact on disability.

Subjects and methods.^

Subjects.^

Fifty-six consecutive stroke survivors admitted to an inpatient rehabilitation stroke unit on an average of 2 weeks after their first single stroke were randomized to a robot training or robot exposure experience. The patients were between the ages of 27 and 83 and had hemiparesis or hemiplegia of the upper and lower extremity. Sensory or visual field impairment, aphasia, or cognitive impairment were not exclusion criteria, but the patient needed to be able to follow simple instructions. All robot-trained patients participated in at least 25 sessions that occurred daily for 1 hour, 5 days a week. These temporal constraints were an attempt to reconcile past successful procedure [21] with current health care policies requiring more rapid admission and discharge. The protocol was approved by the institutional review board of the Burke Rehabilitation Hospital and the Committee on the Use of Humans as Experimental Subjects of the Massachusetts Institute of Technology. Written informed consent was obtained from all patients. Patients and the medical and rehabilitation team providing the clinical care were "masked" to the group assignment.

Robotic device: MIT-MANUS.^

To manipulate and measure the movement of a patient's limb, we developed an interactive robot called MIT-MANUS. [18,19] A key feature of this device is the low near isotropic inertia and reduced friction in the arm so that it will "get out of the way." The patient can move the arm easily, and the device permits objective measurement. Likewise, it guides the limb and provides a sensorimotor experience that responds quickly, just like a "hand-over-hand" therapy. The combination of these features is captured in the engineering term "back-driveability," [23] and reflects the essential advance of this design. [18] Common industrial robots and some robotic devices in clinical use lack these unique performance features.

Intervention.^

All patients experienced similar standard physical and occupational poststroke therapy. For 1 hour per day, 5 days a week, patients in the

robot-treated group were required to move the handle at the tip of a robot, which in turn moved a cursor on a screen. [19-22] A trained research assistant provided a standardized set of instructions and was always in attendance. The patient sat with shoulders strapped into a custom foam-lined chair that could be positioned to face a support board on which was drawn a series of round targets (1 cm), over which the robot arm and handle was suspended. The patient ś paralyzed limb was supported at the elbow by a low friction pad that slid along the surface of the support board. No patient could voluntarily grip the handle at the tip of the robot, so the patient ś hand was placed in a custom foam-lined holder that was attached to the handle. The wrist was in a neutral position and the fingers were placed around the handle. The patient faced a video screen that provided visual feedback in the form of targets identical to those drawn on the support board in front of the patient and that tracked the movement of the robot handle. Auditory feedback indicated correct movements. If the patient did not respond, the robot guided the patient ś hand to the target in the same fashion as "hand-over-hand" therapy. [19-21] The exercise protocols focused on shoulder and elbow movement patterns and were organized in three batches, each batch consisting of 20 repetitions. These trials were preceded once by technician-guided exercise for a complete protocol. Over the minimum 25 sessions, robot-trained patients received at least 1500 repetitions of goal-directed movement to a target.

The control group received a similar initial exposure to the robot with the exception that half the trials were performed with the unimpaired upper limb, and when the patient could not perform the task with the affected limb, he or she used the unimpaired limb to complete the task or the technician assisted the movement. The robot never actively moved the limbs of patients in the control group. The control group was exposed to the robot 1 hour per week.

Assessment. ^

The patients were characterized with respect to age, gender, side of stroke, timing of stroke onset to rehabilitation admission and to first evaluation for the trial, and duration of time in the trial and of rehabilitation. We recorded the presence or development of pain in the shoulder, elbow, and hand for movement initiation, midmovement, and the end of movement, as well as the presence and development of shoulder-hand syndrome and medical comorbidity (hypertension, coronary artery disease, diabetes mellitus, infection, and depression).

At the start and at the end of the trial, the same masked therapist, who was not the treating therapist, measured motor impairment with the subsection of the Fugl-Meyer scale for shoulder/elbow and coordination (FM-SEC; 42 out of 66), Fugl-Meyer scale for wrist/hand (FM-WH; 24 out of 66), [24] Motor Power score (MP; maximum score = 20), Motor Status score for shoulder and elbow (MS-SE; maximum score = 40), and Motor Status score for wrist and hand (MS-WH; maximum score = 42). [21,22,25] As described, the MP measured strength in proximal muscles of the arm, specifically grading shoulder flexors and abductors and elbow flexors and extensors on the standard six-point scale in which 0 = no contraction, 1 = trace contraction, 2 = active movement possible with gravity eliminated, 3 = antigravity strength, 4 = reduced function but adequate to overcome some resistance, and 5 = normal strength. [25] A patient ś score comprised the sum of the subscores. The MS scores attempted to quantify discrete movements around joints, and, in addition, to measure functional movement patterns that were comparable to FM measures. The MS-SE and -WH isolated and graded muscle strength in shoulder, elbow/forearm, wrist, and hand movements with the FM three-point scale (0 = cannot perform at all, 1 = performs partly, 2 = performs faultlessly). [20,22,24] Scores represented the sum of subscores. For example, in the FM evaluation for the shoulder/elbow and forearm there was a 30-point scale that recorded flexor, extensor, and mixed synergies. In the MS-SE evaluation for the shoulder/elbow, there was a 40-point scale that recorded discrete shoulder and upper arm movement. For example, in the standard FM 12-point measure of flexor synergy the patient moved the affected arm to the ipsilateral ear, with the forearm supinated. The MS-SE measured the patient ś movement to touch the opposite shoulder and the top of the head. For the final component the patient needed to place and hold the affected limb, [26] so that the total score was 22 points. The remaining extensor and mixed synergy measures in the FM comprised 18 points, and were similar to the MS-SE measures.

At the start and at the end of the trial, therapists and rehabilitation nurses who were unaware of a patient ś group assignment and who were Functional Independence Measure (FIM) –certified rated the total FIM. [27,28] The self care (maximum = 42), mobility (maximum = 21), and locomotion (maximum = 14) subsections were combined to yield a FIM Motor score. The communication (maximum = 14) and social cognition score (maximum = 21) were combined for the FIM Cognition score.

Stroke type (hemorrhagic or nonhemorrhagic) and stroke lesion volumes were estimated by outlining the damaged area on each CT or MR image and multiplying by the slice thickness (obtained on average 4 days after the stroke). Two investigators independently evaluated lesion location information using a standard atlas.

Analysis.^

In past pilot studies impairment measured by the FM score was insensitive to motor changes that occurred from the 2 to 3 weeks after the acute stroke to 6 to 10 weeks later. 21 Because these motor changes were visible, the MS-SE, MS-WH, and MP scales were developed. 21,22,25 Using the demonstrated changes in these scales, a power analysis suggested that 25 patients would be sufficient for anticipated changes in both the MS-SE and MP. In the current study these scales demonstrated a significant correlation with each other and with the FM-SEC and FM-WH ($p < 0.001$).

We performed a Kruskal-Wallis analysis and, when indicated, Mann-Whitney *U* tests on the pre- and post-treatment motor impairment scores of the FM-SEC, FM-WH, MS-SE, MS-WH, and MP for the shoulder/elbow. A Mann-Whitney *U* test was also performed on the median change over the interval from pre- to post-treatment. The same analysis strategy was used for the disability measures. Because there are no reliable and valid measures for bimanual tasks, the FIM Motor subsections, which include self-care, mobility, and locomotion, comprised an estimate of motor disability. The FIM Cognition subscore was also used. Student s *t*-tests were used to examine differences in lesion size and the various temporal measures.

Results.^

The robot-trained and control groups were comparable with respect to age, gender, side of stroke, stroke onset to rehabilitation admission, initial pre- and final post-treatment evaluation, and total days in rehabilitation (see table 1; Student s *t*-test or $[chi]^2$, NS). Further, the number of patients in each group with hypertension, coronary artery disease, diabetes mellitus, infection, or depression was comparable ($[chi]^2$ values ranged from 0.44 to 2.29, NS). The groups had similar incidence and development of pain in the affected limb, whether on movement initiation, midmovement, or end movement ($[chi]^2$ values ranged from 0.2 to 2.3, NS). The results for the development of shoulder/hand syndrome favored the controls, but was not significant (robot trained = 2, control = 6, $[chi]^2 = 3.06$, NS). Before the

treatment, there was no difference in the number of patients with shoulder/hand syndrome (robot trained = 0, control = 1).

Table 1. Subject characteristics

A Kruskal-Wallis analysis of the FM-SEC, MP, MS-SE, FM-WH, and MS-WH before and after treatment revealed significant differences (p s ranged from < 0.001 to $= 0.03$) for all the impairment measures except FM-WH. Subsequent Mann-Whitney U tests demonstrated differences confined to the MP ($p < 0.005$) and the MS-SE ($p < 0.05$) measures after treatment (table 2) and on the interval changes from pre-to post-treatment (see table 2;$p < 0.001$ and $p < 0.01$). There were no significant differences between the groups before treatment (see table 2; pretreatment). The box plots in figure 1A and 1B show the distribution of 50% of the scores around the median; extension bars include 90% of the measures. There was an equal number of outliers across groups. At pretreatment the groups were comparable on the motor impairment measure of the shoulder/elbow (MP and MS-SE scores). However, the robot-trained group experienced significantly decreased motor impairment in the muscle groups specifically exercised by the robotic device after treatment. The significantly improved function of shoulder and elbow movement for the robot-trained group did not generalize to the wrist and hand.

Table 2. Median motor impairment scores for robot-trained and control subjectsValues are mean ± SD.

Figure 1. (A) Median Motor Power (MP) measure for the shoulder and

elbow in robot-trained (gray bars; n = 30) and control (white bars; n = 26) subjects at the beginning and end of the study, and the interval change. Full description of the data shows median, quartiles, and outliers. There are few outliers and the number is comparable across groups. *p < 0.005; #p < 0.001. (B) Median Motor Status score for shoulder and elbow (MS-SE) in robot-trained (gray bars; n = 30) and control (white bars; n = 26) patients at the beginning and end of the study, and the interval change. *p < 0.05; #p < 0.01. (C) Median Functional Independence Measure (FIM) motor score in robot-trained (gray bars; n = 30) and control (white bars; n = 26) subjects at the beginning and end of the study, and the interval change. *p < 0.05; #p < 0.01.

Analysis of the brain injury information demonstrated comparable numbers of patients in each group with hemorrhagic or nonhemorrhagic stroke (see table 1; $[chi]^2$ = 0.69, NS) and with damage confined to the subcortical region or the cortex or subcortical and cortical regions ($[chi]^2$ = 0.60, NS). Twelve robot-trained and 13 control patients sustained a middle cerebral artery stroke that damaged the cortex and white matter of the lateral and inferior frontal lobe (Brodmann ś areas 4 and 6), the superior and anterior parietal lobe, and the superior temporal lobe and insula. One patient in each group had an anterior cerebral artery stroke that nevertheless paralyzed the arm and hand. Five patients in each group had their stroke confined to the capsular white matter; the remaining patients in each group had stroke confined to the subcortical regions (7 controls and 12 robot trained) and damage to the caudate, putamen and globus pallidum, or lateral posterior thalamus. There were no differences between these categories ($[chi]^2$ = 0.46, NS). Finally the estimate of lesion volume was comparable between groups (see table 1, t = 1.2, NS).

Although there were no significant differences in the location or volume of the lesions between the groups, there was a trend for the controls to sustain strokes of larger volume on average than the robot-trained patients. An additional analysis displays the number of patients with lesion volumes in bins of 25 cm^3. The histogram (figure 2A) depicts the distribution for all patients (<100 cm^3, n = 42; >100 cm^3, n = 14). A Mann-Whitney test of whether differences in impairment outcome might result from lesion volume alone revealed no significant differences on any measure of impairment as a function

of the volume of the lesion (*p* s ranged from 0.14 to 0.51). The distribution of the lesion volumes for robot-trained and control patients was comparable (see figure 2, B and C). When all patients with lesion volumes <100 cm^3 were analyzed, the robot-trained group had higher median MP and MS-SE scores than the controls on post-treatment and on the interval measure from pre- to post-treatment (*p* s ranged from 0.004 to 0.02). The groups were comparable on pretreatment MP and MS-SE measures (*p* s ranged from 0.46 to 0.65). There were no other significant effects on other impairment measures. Because the robot-trained and control group with lesion volumes <100 cm^3 had comparable regional damage (see above), and differed only in the robot training experience, it is possible that the superior motor outcome in the shoulder and elbow resulted from that training. When the patients with lesion volumes >100 cm^3 were analyzed alone, there were no differences in any of the impairment measures between the controls and robot-trained patients (*p* s ranged from 0.89 to 0.94).

Figure 2. Distribution of the lesion size (in cm^3) in (A) all patients, (B) robot-trained patients, and (C) controls.

A similar analysis of the FIM motor scores revealed that the robot-trained group performed better than the controls on pre- and post-treatment and on the interval between pre- and post-treatment (see table 3 and figure 1C). The robot-trained group was also better on the FIM cognition scores, except that both groups improved comparably from pre- to post-treatment. Because the scores were not assessed with the restriction of using only the affected or the unaffected upper limb, a definitive conclusion about the link among decreased upper limb motor impairment, increased motor function, and decreased disability is not possible.

Table 3. Median disability scores for robot-trained and control

subjectsValues are mean ± SD.

Discussion.^

These data demonstrate that a specific sensorimotor intervention enhanced motor recovery after stroke. Based on the similarity of overall rehabilitation experience and the comparability of the groups with respect to clinical and neurologic variables and initial degree of impairment, the results suggest that this novel use of robotics positively affected motor outcome. The results are consistent with our past pilot and follow-up studies of improved motor outcome in the exercised limb in groups of patients with stroke and upper limb paresis who experienced robotic training. [21,22] The relationship of improved motor function in the upper limb and the overall change in disability is less clear. Currently, a reliable and valid disability estimate for bimanual tasks has not been standardized. Although the robot-trained group demonstrated significantly greater improvement over the treatment period on functional motor scales, by chance, the robot-trained group had less motor and cognitive disability at the start. In view of the comparability both of the location and volume of the lesions and the initial impairment measures, it is unlikely that the positive effect of robotic training depended solely on these disability factors.

The rules that govern the relationship between impairment and disability are not always apparent. Clearly, whether decreasing impairment has an impact on disability has become the defining litmus for the success of a patient ś rehabilitation experience. Therapeutic maneuvers in rehabilitation initially focus on impairment but give way to broader education that directly attempts to alter disability. We have taken the approach that there is insufficient information about the limits of change for certain motor impairments. Further, we argue that a test of the hypothesis that motor recovery depends on motor learning might increase understanding of those limits, and, in part, the relationship between impairment and disability. We are currently manipulating the functional movements of stroke patients and testing them for motor learning capacities that have been observed in unimpaired individuals, e.g., limited generalization, order effects, interference, and blending of apparent movement segments or submovements. [19] If motor recovery depends on motor learning we will be able, at least, to tailor the optimal

therapy to the particular patient, and in certain circumstances, increase the recovery. Alternatively, there may be other models for motor recovery.

Our results are consistent with the positive effect that other investigators have demonstrated, using a variety of techniques, in which focused additional therapy produces impairment reduction. [10] Whereas a major question for the health care industry is whether impairment reduction is more effective or efficient than disability reduction or functional improvement by standard multifactorial approaches, impairment reduction provokes the biologic question of whether the damaged adult CNS can reorganize. For example, consistent with our finding, investigators have demonstrated that the addition of 30 minutes of a pushing exercise of the paretic upper limb over 30 sessions to a program of poststroke rehabilitation facilitated motor recovery of that paretic limb. [13] Greater intensity (not defined specifically) of training both upper and lower limb in another study was not effective for upper limb recovery, but was effective for lower limb recovery. [9] A general attempt to enhance rehabilitation with an "eclectic . . . selection of treatment techniques" led to improved motor outcome at 6 months poststroke, but the control group had caught up with the treatment group by 1 year. [11,12] Other approaches to the same subject need mention; despite the small numbers of patients in the controlled trials (less than 15), these methods have demonstrated positive effects on motor outcome. For example, the technique of constraining the unaffected limb so that the patient is forced to use the paralyzed limb has demonstrated positive effects on motor outcome for 6 months to 2 years. [16,17] Neuromuscular stimulation of the paralyzed limb demonstrates benefits in motor outcome weeks to months after the stroke. [14] Robotic strategies may provide some advantages to these techniques; whether one strategy is better than another is an empirical issue. The use of robotics will permit the quantification of the sensorimotor input and of the motor outcome. The reproducible delivery of practice trials and dose of therapy can be controlled. The interactive nature of the robot allows treatment of all degrees of paralysis including complete flaccid paralysis.

In the rehabilitation of patients with stroke, controlled trials reflecting a number of different approaches are continuing to uncover the details of motor recovery. The challenge that used to proclaim that there was no evidence to support poststroke rehabilitation needs to be modified to call for studies that define the best treatments for patients after stroke.

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