A comparison of functional and impairment-based robotic training in severe to moderate chronic stroke: A pilot study

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A Comparison of Functional and Impairment-Based Robotic Training in Severe to Moderate Chronic Stroke: A Pilot Study

Hermano Igo Krebs¹,²,³, Stephen Mernoff⁴,⁵, Susan E. Fasoli⁶,⁷,
Richard Hughes⁶, Joel Stein⁶,⁷, Neville Hogan⁸

¹Department of Mechanical Engineering, Massachusetts Institute of Technology; ²Department of Neuroscience, The Burke Medical Research Institute, Weill Medical College of Cornell University; ³Department of Neurology, University of Maryland School of Medicine; ⁴Rehabilitation Hospital of Rhode Island; ⁵Department of Clinical Neurosciences, Brown Medical School; ⁶Spaulding Rehabilitation Hospital; ⁷Department of Physical Medicine and Rehabilitation, Harvard Medical School; and ⁸Department of Brain and Cognitive Science, Massachusetts Institute of Technology.

Please address all correspondence to:
Hermano Igo Krebs
Massachusetts Institute of Technology, Room 3-137
77 Massachusetts Avenue
Cambridge, MA 02139
Phone: 617-253-8112Fax: 617-258-7018
Email: hikrebs@mit.edu

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Abstract

Objective: To compare the outcome of training the functional movement of transport of the arm and grasping an object with the alternative of training the transport of the arm in isolation.

Design: Pretest-posttest comparison.

Setting: Rehabilitation hospitals, outpatient care.

Participants: Volunteer sample of forty-seven persons with persistent hemiparesis from a single, unilateral stroke within the past one to five years.

Intervention: Robotic therapy 3x/week for 6 weeks for the paretic upper limb consisted of either a) sensorimotor, active-assistive impairment-based exercise during repetitive planar reaching tasks, or b) a “free-hand” approach, in which the robot assisted subjects employing the sensorimotor active-assistive exercise to transport the hand to a series of targets, where it stopped to allow the person to interact with actual objects (functional approach 1), or c) transport and manipulation, in which the robot assisted subjects employing active-assistive exercise during repetitive planar reaching tasks while grasping a simulated object and releasing it at the target or followed by grasp and release of a simulated object (functional approach 2).

Primary Outcome Measure: Fugl-Meyer Assessment

Results: All three groups improved from pre- to post-treatment with the sensorimotor impairment based approach demonstrating the best outcome of the three approaches.

Conclusions: Short-term, goal-directed robotic therapy can significantly improve motor abilities of the exercised limb segments in persons with chronic stroke, but contrary to expectation, training both the transport of the arm and manipulation of an object (functionally-based
approaches) did not confer any advantage over training solely transport of the arm (impairment-based approach).

**Key Words:** stroke, rehabilitation, robotics, task specific training.

**Introduction**

Our previous studies have demonstrated the benefits of upper limb robot-assisted therapy for persons in the sub-acute phase of stroke recovery. These studies revealed that persons who received robotic therapy had significant gains in motor coordination and muscle strength of the exercised shoulder and elbow that were not observed in the control group [1, 18-19]. More recently, we extended this research to persons with persistent motor impairments more than six-months post stroke. Our findings with this population showed that repetitive, goal-directed robotic therapy led to statistically significant improvements on the upper limb subtest of the Fugl-Meyer Assessment and Motor Power assessment [3, 5, 17]. Similar results are being observed by other groups working with different robotic devices and protocols (for meta-analyses see [11, 14]).

A potential approach to increase the effectiveness beyond past studies is to develop new whole-arm functionally-based therapy approaches that better integrate robotic therapy with clinical practice to enhance the carry-over of robot trained movements into functional tasks. Two potential approaches to deliver such a functional training are 1) to train functional tasks with the robot or alternatively, 2) to train by aiming at impairment reduction at the capacity level with different robotic modules breaking these functional tasks into components and leave to the therapist to facilitate the carry-over of the observed impairment gains from robotic training into functional activities.
Here we explore the first of these two approaches. We expect that a robotic treatment protocol, properly targeted to emphasize a sequence and timing of sensory and motor stimuli similar to those naturally occurring in daily life tasks, could facilitate carry-over of the observed gains in motor abilities, thereby conferring greater improvements in functional recovery (1st approach listed above). This approach is a departure from our previous robotic rehabilitation research. Our prior research was based on a “bottom-up” approach (2nd approach listed above), which assumed that improvements in underlying capacities would enhance motor function during activities and tasks, leaving it to the therapist to concatenate the different impairment gains into a coherent set of functional gains. We envision that functional rehabilitation robotics will be guided by a “top-down” rehabilitation approach, in which a person’s identified goals for task performance are used in conjunction with our evaluation data to establish a treatment plan. Robotic technology will not only provide remediation for impairments at the capacity or body function levels (e.g. strength, isolated movement), but will also provide task specific, intensive therapy for impaired body functions (e.g. speed or coordination of limb movement) that underlie task performance or activities. While this top-down rationale is very appealing and in line with current therapy views, there are some recent results that question this view and raise the possibility that the opposite might be correct at least for severe to moderate stroke patients, which is the population that we have been focusing on. For example, Platz has shown that therapy aiming at impairment reduction seems to lead to better outcomes than functional/Bobath training for inpatients with severe impairment [13].

As a first step toward applying this “top down” approach to rehabilitation robotics, we wanted to investigate the effects of different robotic therapy approaches on subjects’ ability to reach, grasp, and release with the paretic arm and hand. We compared the effects of repetitive upper limb
reaching training to a protocol in which integrated reach, grasp, and release training was
implemented. We hypothesized that training the shoulder-elbow and hand together (transport of
the arm to the target and grasping/releasing an actual or a virtual object) leads to better outcomes
than simple training for one of the components of this functional task, namely transport of the
arm (reaching to the target).

Methods

Subjects

Forty-seven (47) community-dwelling persons with chronic stroke met inclusion criteria and
volunteered to participate in three sequential studies at Spaulding Rehabilitation Hospital,
Boston, MA and Rehabilitation Hospital of Rhode Island, North Smithfield, RI (see Table 1).
Inclusion criteria were: 1) diagnosis of a single, unilateral stroke within the past one to five years
verified by brain imaging; 2) sufficient cognitive and language abilities to understand and follow
instructions; and 3) stroke-related impairments in muscle strength of the affected shoulder and
elbow larger than 1 and smaller than 4 on the MRC motor power scale. None of the subjects
were engaged in conventional occupational or physical therapy programs during the
experimental trial, and none had received robotic therapy prior to this research. Patients were
enrolled in three sequential groups either at Spaulding Rehabilitation Hospital (Groups A and B)
or Rehabilitation Hospital of Rhode Island (Group C). Group A practiced reaching movements of
the arm between targets shown on a computer screen during robotic therapy at Spaulding
Rehabilitation Hospital. Clinicians classified this task of transporting the arm between bulls-eye
type targets as aiming at impairment reduction. Patients enrolled in Group B employed an “ad-hoc” attempt to test functional robot therapy at Spaulding Rehabilitation Hospital. We implemented a “free-hand” protocol in which the patient interface was comprised of a forearm and wrist support fashioned of sections of PVC pipe which left the paretic hand free for distal tasks. The robot assisted subjects, as needed, to transport the hand to a series of targets, where it stopped to allow the person to interact with actual objects (see Fig. 1). Task difficulty was graded to allow the person to complete the distal tasks without therapist assistance. After completion of each grasp/release or manipulation phase, the robot assisted with transporting the limb toward the next target, as needed. The control algorithm for the transport phase was the same as Group A [7]. Finally, Group C practiced the same transport reaching movement of the arm to the target and grasping of a virtual object (versus an actual object in Group B) at Rhode Island Rehabilitation Hospital. The control algorithm for this group’s transport phase was described elsewhere [10]. Some of the data on subjects engaged in Groups A and B was already included in past publications [4].

<table>
<thead>
<tr>
<th>SUBJECTS</th>
<th>N = 47</th>
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<tbody>
<tr>
<td>Age (y.o. ± sem)</td>
<td>57.5 ± 0.7 (range 27 to 79)</td>
</tr>
<tr>
<td>Lesion Side (Right/Left)</td>
<td>27 R / 20 L</td>
</tr>
</tbody>
</table>

Table 1. Demographics of persons enrolled into the study

--- include Figure 1 here -------

All subjects gave their informed consent to take part in these studies. The experimental protocols were approved by the Human Studies Committee at Spaulding Rehabilitation Hospital and by the
Committee on the Use of Human Experimental Subjects of the Massachusetts Institute of Technology.

**Measures**

After subjects provided informed consent, baseline clinical evaluations to establish motor stability of the involved upper limb were administered at least twice during a one-month observation period prior to robotic therapy. The same evaluation tools were used to assess the effects of robotic therapy after six weeks of intervention.

All groups were evaluated with the Fugl-Meyer Assessment (FMA) for the upper-extremity to examine the presence of synergistic and isolated movement patterns and grasp [6]. The evaluation therapist at Rehabilitation Hospital of Rhode Island was trained by the counterpart at Spaulding Rehabilitation Hospital and tested to ensure the consistency of testing procedures. Therapists were “blinded” to the assigned robot protocol to reduce potential for bias.

In addition to the FMA, robotic evaluations were administered before treatment, after three and six weeks of intervention. These robotic evaluations consisted of planar reaching tasks, circle drawings, and isometric holding tests [2, 7-9, 15-16]. Results on these scales will be reported elsewhere.
Intervention

Robotic therapy was delivered for all groups during an hour long therapy session by the commercial version of the MIT-MANUS robot (InMotion2 from Interactive Motion Technologies, Cambridge, MA). During therapy, subjects were seated comfortably at a table and their paretic arm was placed in a customized arm support attached to the robot end-effector (i.e. the forearm and wrist support (Group B) or a handle with (Group C) or without (Group A) a grasp sensor). Subjects’ trunk movement was restrained by a 5-point seatbelt. All subjects were asked to perform goal-directed, planar reaching tasks that emphasized shoulder and elbow movements. As subjects attempted to move the robot’s handle toward designated targets the computer screen in front of them provided visual feedback of the target location and movement of the robot handle (Fig. 1). Group B training included attempts to grasp and release an actual object. The robot assisted in the transport of the arm to the target location where it stopped to allow the patient to attempt manipulation of an actual object. Because time was allocated after the completion of the transport phase for grasp or manipulation, the total number of point-to-point reaching movements was approximately half that of Group A (although the aggregated number of reaching plus grasping movements was the same as group A). Group C training included attempts to grasp and release a virtual object (by squeezing and releasing the grasp sensor in the handle) and carry it during reaching or to grasp and release the virtual object at the completion of each reaching movement (corresponding to a functional task of reaching and grasping a cup or to the task of carrying this cup towards or away from the person and releasing it). The total number of point-to-point reaching movements in this case was 2/3 that of Group A. A physical or occupational therapist administered each robotic therapy session, ensured proper positioning, and provided verbal instructions and cues, as needed, to orient subjects to the
training tasks. Subjects received one hour of robotic therapy three times per week for six weeks, performing repetitive reaching movements over the course of therapy (respectively 18,000 reaching movements for Group A, 9,000 for Group B, and 12,000 for Group C), with corresponding attempts to grasp and release at the end or during the point-to-point movement (Group B and C).

During sensorimotor robotic therapy, the robot offered as-needed assistance when the person was unable to reach targets independently, much like a therapist provides hand-over-hand assistance during conventional therapy [7]. If subjects were unable to move their arm toward a given target, the robot would assist the person in the attempt to move much like providing passive range of motion. If the individual could initiate but not complete a reach, the robot was compliant to the person’s movement attempts, and gave active assist as needed. The intent of the present pilot study was to examine whether “functional” training (Group B or C) led to better outcomes when compared to impairment based training (Group A) in persons with stable, chronic upper limb paresis after stroke.

**Data Analyses**

Both parametric and nonparametric analyses were performed, and each yielded similar results. For conciseness, we have chosen to report our parametric analyses of the evaluation change scores here. Analyses of variance were used to compare both groups at pre-treatment. Two-tailed Student’s t-tests assessed whether the change scores from pre- to post-treatment were statistically significant for the composite of all patients. Analysis of variance was also used to compare groups’ change scores from pre- to post-treatment. The last pre-treatment evaluation score was
used as the pre-treatment scores for these tests. The strength, or magnitude, of our findings was
determined by calculating the effect size $r$. According to Cohen, $r = .10$ is a small treatment
effect, $r = .30$ or greater represents a moderate effect, and $r = .50$ or greater is a large effect.

Results

As in our previous studies, the composite of all groups receiving robotic therapy demonstrated
significant reductions in motor impairment of the paretic limb from pre- to post-treatment.
Statistically significant gains with moderate effect sizes were found (see Table 2). A comparison
between the approaches showed no advantage to the functionally-based approaches that included
both the transport of the hand and grasp/release (Group B and C) over the impairment based
protocol (Group A). For details see Table 3 for a comparison of Group A versus the composite of
groups B and C and Table 4 for a comparison of group A, B, and C.

A breakdown of the upper extremity Fugl-Meyer Assessment into its shoulder-and-elbow and
wrist-and-hand subcomponents showed that subjects in Group A (impairment) improved
primarily on the shoulder-and-elbow sub-component of the Fugl-Meyer, which was the focus of
training in this group. Subjects were better able to reach toward visual targets during robotic
therapy (as compared to Group B and C). Subjects in Group B and C (functional training
including transport of the arm and grasping/releasing an actual or virtual object) improved
primarily on the wrist-and-hand sub-component of Fugl-Meyer. In fact, patients receiving
impairment-based training (Group A) improved significantly more than those receiving the
functionally-based approach on the shoulder-and-elbow subcomponent (p=0.03 with a large
effect size r=0.79).

<table>
<thead>
<tr>
<th>(MEAN ± STD)</th>
<th>FMA PRE-TREATMENT (/66)</th>
<th>FMA POST-TREATMENT (/66)</th>
<th>PAIRED COMPARISON P-VALUE</th>
<th>COHEN’S EFFECT SIZE</th>
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<tr>
<td>Group A &amp; B &amp; C</td>
<td>25.8 ± 9.9</td>
<td>28.6 ± 10.0</td>
<td>p&lt; 0.0001</td>
<td>r = 0.30</td>
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Table 2. Pre- and Post-Treatment comparison of the composite of all patients.

<table>
<thead>
<tr>
<th>(MEAN ± STD)</th>
<th>FMA PRE-TREATMENT (/66)</th>
<th>CHANGE FMA (/66)</th>
<th>CHANGE FMA S/E (/42)</th>
<th>CHANGE FMA W/H (/24)</th>
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<tr>
<td>Impairment (Group A, N=32)</td>
<td>25.0 ± 9.6</td>
<td>3.0 ± 3.4</td>
<td>2.3 ± 2.5</td>
<td>0.7 ± 1.7</td>
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<tr>
<td>Functionally-Based (Group B &amp; C, N=15)</td>
<td>27.6 ± 13.9</td>
<td>2.1 ± 3.6</td>
<td>0.7 ± 1.4</td>
<td>1.3 ± 1.9</td>
</tr>
<tr>
<td>ANOVA p-value Between Groups</td>
<td>NS</td>
<td>NS</td>
<td>p=0.03</td>
<td>NS</td>
</tr>
<tr>
<td>Cohen’s Effect Size Between Groups</td>
<td>N/A</td>
<td>N/A</td>
<td>r = 0.79 large</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Table 3. Comparison of Changes Pre and Post-Treatment. Here we are comparing the impairment based-approach (group A) with the composite of the functionally-based approaches (group B and C). NS: non-significant (p>0.05); N/A: non-applicable

<table>
<thead>
<tr>
<th>(MEAN ± STD)</th>
<th>FMA PRE-TREATMENT (/66)</th>
<th>CHANGE FMA (/66)</th>
<th>CHANGE FMA S/E (/42)</th>
<th>CHANGE FMA W/H (/24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A Transport of Arm (N=32)</td>
<td>25.0 ± 9.6</td>
<td>3.0 ± 3.5</td>
<td>2.3 ± 2.5</td>
<td>0.7 ± 1.7</td>
</tr>
<tr>
<td>Group B Transport of Arm and Actual Grasp (N=10)</td>
<td>30.7 ± 16.3</td>
<td>2.7 ± 2.1</td>
<td>1.2 ± 1.1</td>
<td>1.5 ± 2.2</td>
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<tr>
<td>Group C Transport of Arm and Virtual Grasp (N=5)</td>
<td>21.4 ± 4.9</td>
<td>0.8 ± 2.5</td>
<td>-0.2 ± 1.6</td>
<td>1.0 ± 1.2</td>
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<tr>
<td>ANOVA p-value</td>
<td>NS</td>
<td>NS</td>
<td>A vs B: p=0.20</td>
<td>NS</td>
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</table>
Table 4. Comparison of Changes Pre and Post-Treatment. Here we are comparing the three groups independently: group A impairment based-approach, group B transport and actual grasp, and group C transport and simulated grasp. NS: non-significant (p>0.05); N/A: non-applicable.

Discussion

These pilot results extend prior research on robotic therapy for persons in the chronic phase of stroke with persistent motor impairments, and add further evidence that continued improvements in motor abilities are possible in persons more than one year post stroke. As in our prior studies the composite of all patients demonstrated significant improvement. Although the gains in clinical scores were modest, the treatment effect sizes indicated by Cohen’s $r$ were moderate and consistent with our previous findings. This result reinforces the efficacy of our robotic therapy methods for persons with chronic motor impairments. These findings indicate that intensive robotic therapy may complement other approaches; it can significantly decrease chronic motor impairments in persons with moderate to severe upper limb dysfunction, with whom techniques such as constraint-induced therapy could not be used.

Of interest here is the comparison between robotic training approaches focused on impairment and functionally-based approaches. Remarkably, neither of the functionally-based approaches which integrated training of limb transport with grasp/release (Group B and C) outperformed the impairment-based approach training of limb transport in isolation (group A). Furthermore while group A improved primarily in the shoulder-and-elbow limb segment, the improvement was larger in the wrist-and-hand component of the Fugl-Meyer Assessment for persons enrolled in
groups B and C. We speculate that persons in the latter groups focused their attention on attempting to grasp and release the object rather than on the transport of the arm, relying on the robot to move them to the target. Grasping and releasing the object may have been perceived by these subjects as the hardest component of this functional task, consuming their available attentional resources.

The importance of attention and subject participation is confirmed by the previous finding by Lynch and colleagues at the Burke Medical Research Institute who demonstrated that patients exercising on a continuous passive motion machine while watching TV did not improve in their ability to voluntarily move their arm [12]. That protocol attempted to replicate the intensity and number of movements of our robotic protocol, but omitted the visually-guided, attention-demanding interactive characteristic of our inpatient sensorimotor training [1, 18-19]. Our result here reinforces the need for active participation and engagement of the patient in all phases of therapy.

The results of these pilot studies also question the 1st concept of delivering functionally-based therapy via training whole-arm movement with the robot. It suggests that maybe the 2nd concept in which the robotic therapy aims at impairment reduction and the therapist works with the patient to integrate these impairment gains into functional tasks might be the best way to take full advantage of the robotic tool. Persons with severe to moderate impairment due to stroke might not be able to cope simultaneously with all of the different components of the task and may be forced to focus on only one of them. If that is the case, the “bottom-up” approach described in the introduction as an alternative might be more beneficial. Until patients have developed the whole repertoire of movements required to complete the task, they might not fully benefit from functionally-based robotic rehabilitation approaches. Platz came to a similar conclusion for
inpatients [13] suggesting that this factor may be related to severity of impairment rather than phase of recovery after stroke. For persons with moderate to severe upper limb dysfunction intensive robotic therapy might serve the patient better if focused on impairment, leaving the functional integration of those gains for a later phase. This would complement (rather than contradict) techniques such as constraint-induced therapy that focus on persons with mild impairment.

Several potential limitations of the present study deserve mention. First the number of subjects enrolled in groups B and C are small. Second, the number of reaching movements was smaller for groups B and C and that might explain the smaller improvement on the shoulder-and-elbow assessment. Third, while subjects were trained using the same class of robots, they trained in different Hospitals. While the robot delivered protocol tends to minimize the influence of personnel, the verbal feedback and cueing can not be fully controlled even though we attempted to minimize this variability by training personnel at Rehabilitation Hospital of Rhode Island with the clinical team at Spaulding Rehabilitation Hospital. Also, this was an open-label study, but we speculate that if bias was at play here the evaluating therapists would bias the results in favor of the functionally-based approaches. Therefore, while assessor bias cannot be ruled out as a potential influence on our clinical data, we doubt its importance. Finally, we did not administer functional measures of motor performance (e.g., the Wolf Motor Function Test) and hence cannot compare outcomes on a functional level for all groups.

Conclusion
The results reported here reinforce our earlier findings that short-term, goal-directed robotic therapy can significantly improve motor abilities of the upper extremity in persons with chronic stroke. We hypothesized that training the shoulder-elbow and hand together (transport of the arm to the target and grasping/releasing an actual or a virtual object) leads to better outcomes than training focused on components of this functional task, namely transport of the arm (reaching to the target). Our results did not support this hypothesis. We speculate that until a minimum set of body functions are present, robotic training might serve a patient best if it focuses on impairment reduction, leaving it to integrate motor gains into function during a later phase of treatment.
Acknowledgments and Disclosures

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References


Figure 1. Impairment and Functional Based Approaches for Robotic Therapy. Top left photo shows a patient receiving impairment training that consisted of a series of reaching movements to targets shown on a computer screen (Group A). Top right photo shows one of us (Dr. Fasoli) demonstrating the “free-hand” approach in which the robot assisted during reaching movements to actual targets and the patient manipulated actual objects (Group B). Bottom left photo shows a patient exercising reaching while grasping a virtual token to a target and then releasing the token. Bottom right plot shows an example of the grasp force during this reaching movement.