

Development of robots for rehabilitation therapy: The Palo Alto VA/Stanford experience

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Abstract—For over 25 years, personal assistant robots for severely disabled individuals have been in development. More recently, using robots to deliver rehabilitation therapy has been proposed. This paper summarizes the development and clinical testing of three mechatronic systems for post-stroke therapy conducted at the VA Palo Alto in collaboration with Stanford University. We describe the philosophy and experiences that guided their evolution. Unique to the Palo Alto approach is provision for bimanual, mirror-image, patient-controlled therapeutic exercise. Proof-of-concept was established with a 2-degree-of-freedom (DOF) elbow/forearm manipulator. Tests of a second-generation therapy robot producing planar forearm movements in 19 hemiplegic and control subjects confirmed the validity and reliability of interaction forces during mechanically assisted upper-limb movements. Clinical trials comparing 3-D robot-assisted therapy to traditional therapy in 21 chronic stroke subjects showed significant improvement in the Fugl-Meyer (FM) measure of motor recovery in the robot group, which exceeded improvements in the control group.

Key words: *cerebrovascular accident, hemiplegia, mechatronics, neurorehabilitation, occupational therapy, physical therapy, rehabilitation, robotics, stroke, therapeutic exercise, upper limb.*

BACKGROUND

Collaborative research and development efforts in the area of rehabilitation robotics were initiated in 1978 between the Department of Veterans Affairs (VA) Palo Alto Health Care System and the School of Engineering at Stanford University. In that era, the dominant philosophy was to attempt to replace lost or impaired anatomy. This approach required trade-offs among size, weight, power, and complexity of robotic manipulators, thus limiting their functional performance (1). During the period of leadership under Professor Larry Leifer, the philosophy at the Palo Alto Rehabilitation Engineering Research and Development Center (now the Rehabilitation Research and Development Center of Excellence on Mobility [RRDC]), was to replace functional abilities lost as a result of injury or disease, not to replace the impaired or missing anatomy. Over time, the scope of robotic research at the RRDC expanded to include vocational, educational, and therapeutic applications.

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In the early 1980s, the Stanford Robotic Aid Project was initiated with funding from the VA and technical assistance from Unimation's Advanced Development Laboratory. Professors Bernard Roth at Stanford and Inder Perakash, VA Spinal Cord Injury Service Chief, were co-investigators with Professor Leifer. Dr. Vernon Nickle, an early proponent of rehabilitation engineering, provided the support needed to launch a project of this magnitude and complexity. Instead of a collection of special-purpose devices, the goal was development of a single general-purpose system that could assist a disabled individual to achieve independence in activities of daily living (ADLs). An important driving force behind the evolution of design goals came from the patients at the nearby VA Spinal Cord Injury Service who were involved very early in the development process. Extended field trials with single users and multi-site clinical trials were eventually carried out. As five generations of robotic systems were developed and tested, the focus evolved following the expressed needs of the users. The robots became interactive and acquired capabilities that extended well beyond ADL assistance. A comprehensive review of the RRDC experience in *assistive robotics* has been published by Van der Loos (2). Building on this pioneering work by Leifer, Van der Loos, and colleagues, the scope of robotics research at the RRDC grew during the 1990s to include a new area of interest, *therapeutic robotics*, with applications in stroke rehabilitation (3). Other laboratories were exploring similar applications during this time (4–11) but even now, surprisingly few clinical outcomes have been reported (12–17).

We were motivated to apply mechatronic technology to upper limb rehabilitation therapy for several reasons, including the impact of stroke on veterans, their families, and the VA Health Care Administration; the lack of objective metrics or an established scientific framework for existing treatments; and the association of local collaborators with expertise in robotics, motor control, biomechanics, kinesiology, and medical rehabilitation. Stroke is a common cause of significant residual physical, cognitive, and psychological impairment (18). As the geriatric population increases and more effective therapies for acute stroke management emerge, there will be more survivors living with disabilities. There has also been a trend toward more moderately affected survivors (19), which has increased the demand for stroke rehabilitation in an era of health care cost containment. Efforts to prevent stroke must, therefore, be balanced with pragmatic efforts to prevent disability and maximize quality of life for stroke survivors. Current consensus regarding rehabilitation of

patients with some voluntary control over movements of the involved arm is that they be encouraged to use the limb in functional tasks and receive functional training directed toward improving strength and motor control, relearning sensorimotor relationships, and improving functional performance (20).

Several studies have failed to establish a clear benefit of any one type of stroke therapy over others (21–24). There is some evidence that improved recovery can result from more therapy (25), earlier therapy (26–29), and therapies that incorporate highly repetitive movement training (30). There is also the potential that bilateral exercise as a training paradigm, particularly when the central nervous system (CNS) is undergoing plastic changes early after stroke, may be advantageous. This hypothesis is based on evidence that recovery from hemiplegia is mediated by corticospinal ipsilateral pathways (31,32) and that these same pathways appear to be active in bilateral movements. When normal subjects attempt to perform different movements with the upper limbs simultaneously, the kinematic patterns of one side appear in the movement of the other side (33,34), suggesting that activity in ipsilateral corticospinal pathways is responsible for these bilateral interactions. Thus, a reasonable hypothesis is that bilateral symmetrical exercise early after the stroke will stimulate ipsilateral corticospinal pathways and enhance recovery. Along these same lines, Wolf et al. postulated that bilateral therapies have the potential to target the ventromedial brain stem pathways that terminate bilaterally in the spinal cord (24). They showed that a motor copy training technique using bilateral matching of the integrated electromyography (EMG) from homologous muscles improved upper limb function. In addition, Rathkolb et al. demonstrated improved paretic upper limb movements when preconditioned with mirror-image bilateral movements and EMG feedback (35).

Finally, the mechanisms responsible for the post-stroke loss and recovery of strength, motor control, and normal tone are not fully understood. A major difficulty in identification of these mechanisms and assessment of treatment strategies is the lack of sensitive techniques to quantify impairments and the effects of therapy. The need for more sensitive, objective measures has long been recognized (36). Convinced that, in addition to quantifying motor impairment, unique unilateral and bimanual methodologies for rehabilitation of neurologic impairments would be possible using mechatronics, we began work on an upper limb rehabilitation robot in 1993. This paper presents the development of, and our clinical experiences with, three generations of therapy robots.

UPPER LIMB PATIENT-CONTROLLED MANIPULATION ORTHOSIS

Introduction

A therapist applies two commonly used rehabilitation techniques, passive and active-assisted movements. The therapist moves the paretic limb as the patient either remains passive, or actively attempts to contribute to the movement. Efforts to study and optimize assisted movement therapy have been hindered, in part, by difficulty in establishing which movements are actually intended. To address this issue, we proposed an investigational treatment paradigm for hemiplegic subjects in which both upper limbs are moved in either reciprocal or mirror-image patterns, with assisted movement of the paretic limb under control of the contralateral limb. A preliminary feasibility study was conducted in 1993–1994 with the assistance of Stanford undergraduate and graduate mechanical engineering students.

Method

Two forearm-elbow-arm exoskeletal orthoses were fabricated and linked to produce elbow flexion/extension and forearm pronation/supination in a 2-degree-of-freedom (DOF) master/slave configuration. Movement of the master orthosis elbow joint and forearm rotation were reproduced on the slaved side by either body-powered or servomotor positioning. Optical encoders measured the joint positions. Volitional movement of one arm produced passive or active-assisted, mirror-image motion of the contralateral arm, depending on its muscle force contributions. Six neurologically normal subjects, ages 21–48 years, subjectively tested the performance and comfort of the prototype. These subjects included physical and occupational therapists, engineers, and a physician. Each subject was asked to simulate the motor-control deficits present in flaccid and spastic hemiparesis. Control system stability and response times were evaluated in the servomotor mode.

Results

While simulating flaccid hemiplegia, subjects were able to guide the movement of the “paretic” limb by moving the opposite limb. When the effects of hypertonia were simulated, clinicians on the project felt that the level of effort and the sensory feedback in the body-powered mode were inappropriate. Control system stability and response times were evaluated in the servomotor mode. Clinically acceptable performance was not achieved

using available components. However, in a “brainstorming” session with stroke patients and therapists, the concept of self-controlled therapy was endorsed. These results, along with those from other groups investigating mechatronic systems for arm therapy (7,8,37), provided support for development of a therapy robot having enhanced capabilities. To accommodate multi-joint (shoulder and elbow) functional movements without the need to develop new control systems, we took advantage of in-house expertise and available hardware to rapidly design and develop a clinically acceptable robot-assisted limb manipulation prototype.

MIRROR-IMAGE MOTION ENABLER (MIME): DEVELOPMENT AND VALIDATION OF A PROTOTYPE CLINICAL THERAPY ROBOT

Introduction

Treatment efficacy is usually determined by subjective scales of motor function that reflect the patient's ability to accomplish movements or tasks that are essential components of ADLs. While attainment of maximal function is the ultimate goal of rehabilitation, the theories and methods employed to effect clinical improvements have not been evaluated with sensitive, objective measures of motor performance during functional tasks throughout the recovery process. Quantification of motor performance with continuous variables can potentially detect smaller differences in ability than motor function scales. Abnormal motor performance can be determined by comparison with the performance of neurologically non-impaired individuals or, in the case of hemiparesis, performance of the opposite limb (although we recognize that motor control in the “normal” limb may be affected to some degree; 38,39). In this project, we correlated the interaction force/torque measurements during passive and active-assisted arm movements with a clinical scale of functional recovery of the paretic limb in post-stroke hemiparetic subjects. A detailed description is in the article by Lum and colleagues (3).

Method

In order to produce repeatable movement patterns in the paretic limb, we developed a robot-assisted device capable of moving an upper limb in simple predetermined trajectories by directly controlling the position and orientation of the forearm. This servomechanism used a novel approach to provide adaptive, assistive therapy for a

paretic limb. This initial version of MIME incorporated two commercial mobile arm supports modified to limit arm movement to the horizontal plane, and a 6-DOF robot arm (Stäubli PUMA-260) that applied forces and torques to the paretic forearm through one of the arm supports (**Figure 1**). We elected to use the mobile arm supports so that the weight of the subject's arms would not be borne by the robot, which, for safety reasons, had limited force production capacity. The restriction of the mid-forearm to planar motion still permitted coordinated shoulder and elbow tasks. Optical encoders on the joints of the mobile arm supports measured the position and orientation of the forearms. A 6-axis transducer (Assurance Technology, FF349.1) measured the force/torque interaction between the robot and the paretic limb. System components are shown in **Figure 2**. Movements were produced in preprogrammed forearm position and orientation trajectories or by a position feedback control system that slaved the robot to the movements of the contralateral (normal) limb. In this master/slave mode, the robot continuously moved the paretic limb to the mirror-image position of the opposite limb. Even subjects with flaccid hemiplegia could, therefore, cause movement of their paretic limb by simply moving the normal limb. The master/slave controller ensured that the paretic limb moved with the kinematics the subject intended, at least to the degree the subject was able to produce the desired movements with the control limb. Redundant hardware and software features assured subject safety while exercising in the MIME.

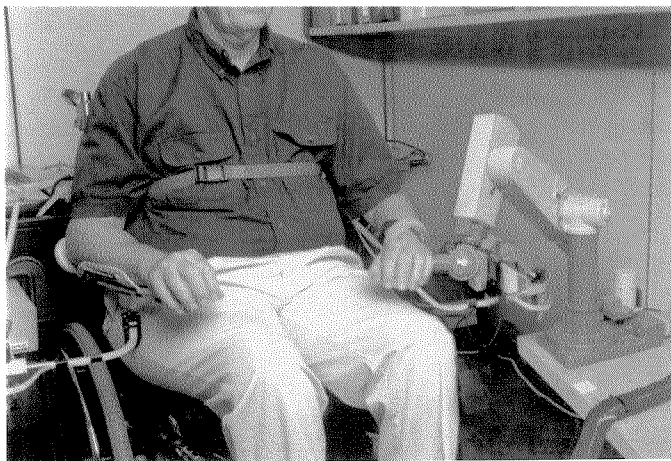


Figure 1.

Robot-assisted arm therapy prototype. Each forearm rests in a splint attached to bilateral mobile arm supports that bear the weight of the limbs. Angle encoders at each joint measure forearm position and orientation.

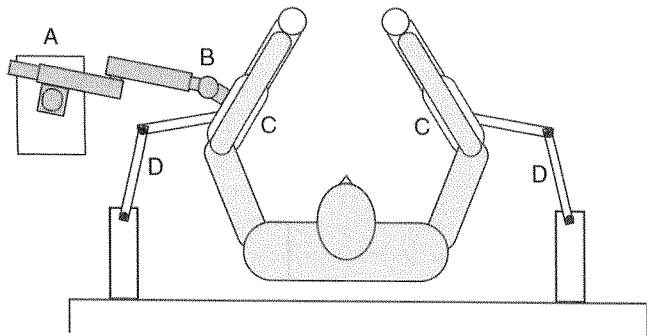


Figure 2.

Overhead view of robot-assisted therapy workstation configured for a subject with left hemiparesis. Subjects with right hemiparesis sit facing the opposite direction. The initial MIME prototype used a Puma-260 robot (A) coupled through a force and torque transducer (B) to one of the forearm splints (C). The splints, which were free to rotate and tilt at the end of modified mobile arm supports (D), supported the weight of the forearms. In the current MIME workstation, the robot is a Puma-560, the paretic limb mobile arm support is eliminated, and a 6-DOF-position digitizer replaces the contralateral support.

Thirteen hemiplegic male subjects, ages 47 to 71 years, 1 to 45 months post-stroke, gave informed consent and were each tested twice within the same week. In addition, six age-matched able-bodied male subjects provided normal control data. Scores for the upper limb component of the Fugl-Meyer (FM) test ranged from 14 to 65 (33.7 ± 22.1 , mean \pm SD). Generally, FM scores <20 indicate severe impairment and scores approaching 60 indicate mild impairment (maximum score = 66, indicating no impairment). The validity and reliability of the FM have been established (40–44).

Subjects were seated with their forearms in the supports. For each of six movement trajectories, they were instructed to remain passive as the robot moved the limb, until data for five passive trials had been collected. The data included the position and orientation of the forearm, and the external forces and torques applied to the arm. Next, the subjects were instructed to contribute voluntarily to movement by pushing or pulling “with approximately one pound of force.” After each trial, subjects were given performance feedback and encouraged to achieve force profiles within 20 percent of the target value. Data from 10 active trials were collected before moving on to the next movement direction. Subjects first performed the sequence with their normal limb, then repeated the sequence using their paretic limb.

Results

For 12 of 13 subjects, MIME successfully assisted the paretic arm movements. The remaining subject, who

had a very high degree of spasticity and flexor tone, applied forces to the robot that overpowered the wrist joint motors, even during passive movements. Completion of the protocol required stabilization of the robot wrist joint. The kinematics showed only minor differences across the other 12 subjects in 95 percent of trials. In the subject with the highest flexor tone, individual trials occasionally showed large deviations from the programmed trajectory.

Performance of stroke subjects reflected their recovery level. Interaction forces during active-assisted movements were highest in the more impaired subjects. However, these forces were often misdirected relative to the desired direction of movement. In the passive trials, no significant relationship was found between the *magnitude* of force and the FM score. The test-retest repeatability of this particular measure was poor; however, the directional errors significantly decreased with increasing motor recovery, as did the negative work. In the active trials, directional errors again decreased with increasing motor recovery, and the work efficiency (the work done divided by the potential work, had the total force been oriented toward the target at all points along the path) of the paretic limb was directly related to the FM score. Test-retest repeatability of directional error and work efficiency was excellent.

Neurologically normal control subjects typically generated force only in the desired direction, with little or no force in other directions. Subjects with high FM scores generated force profiles similar to that of the control subjects. Moderately impaired subjects had difficulty maintaining a constant force throughout the movement, generated large lateral forces, but did not resist passive movement. Severely impaired subjects with low FM scores resisted movement, generating force components in the direction opposite movement. Lateral force components often exceeded the force directed at the target; however, the robot prevented movements off trajectory.

These preliminary results demonstrated the feasibility of quantifying interaction forces during mechanically assisted upper-limb movements. Several performance metrics derived from the interaction forces during passive and active-assisted movements were found to correlate with FM scores. The most descriptive measure of volitional movement was the inability to generate a consistent force in the direction of movement, while eliminating forces in other directions. The observed spread in force directional error and work efficiency across several subjects with similar impairments and FM scores, coupled

with the significant test-retest repeatability, indicates that these measures can provide added insight into the motor status of subjects relative to currently used clinical evaluations. We were encouraged to address the mechanical limitations of MIME and proceed to clinical trials.

MIME: CLINICAL TRIALS WITH A THIRD-GENERATION ROBOTIC THERAPY ASSISTANT

Introduction

A study to compare the clinical effectiveness of robot-assisted upper-limb therapy against conventional therapy began in 1997 at the RRDC. By that time, improved upper-limb motor function had been reported in a test group of acute stroke subjects who received robot-assisted practice of 2-D planar arm movements in addition to their regular therapy (13). It remained to be demonstrated whether robot-assisted therapy differs in efficacy from hands-on treatment. We hypothesized that greater improvements might result from practice with a system that is flexible enough to handle multiple functional movement patterns, that is capable of fully supporting the limb during 3-D movements, and that incorporates passive, active-assisted, resistive, and self-guided modes of therapy. To this end, MIME was redesigned with a larger, stronger robot (PUMA-560). Clinical trials using this third-generation system were initiated to evaluate the therapeutic potential of the methodology. Preliminary reports of the methods and clinical results, presented during 1999 at the 6th International Conference on Rehabilitation Robotics (ICORR '99), Stanford, CA (45) and at the American Academy of Physical Medicine and Rehabilitation Annual Meeting in Washington, DC (16) are summarized here.

Method

The MIME therapy workstation was modified to provide a 3-D workspace and accommodate a larger robot. Subjects are seated in a wheelchair modified to improve seating support and reduce movements of the upper body. They can sit close to either the front or rear of an adjustable height table that has a surface that can be tilted. A PUMA-560 robot is mounted beside the table. It is attached to a wrist-forearm orthosis (splint) via a 6-axis force transducer (ATI, Garner, NC), a pneumatic break-away overload sensor set to 20 Nm torque, and a quick-release coupling mechanism. The subject's arm is strapped into the splint with the wrist in neutral position.

Robot/forearm interaction force and torque measurements from the transducer are recorded and archived by a personal computer. The control program monitors these data and the motion of the robot in order to prevent potentially hazardous situations from occurring. Switches and mechanical stops are strategically placed to permit rapid de-activation of the robot, if necessary.

A 6-axis position digitizer (MicroScribe, Immersion Corp., San Jose, CA) is mounted on the other side of the table. This device is attached to a splint on the other forearm. When the position digitizer is attached to the paretic limb, it can be used to quantify voluntary movement kinematics. When attached to the stronger limb, it provides positional control for the paretic side to follow, thereby implementing the mirror-image, master/slave mode involving both limbs. The system layout remained similar to that of the initial prototype, as shown in **Figure 2**. The unilateral and bimanual capabilities are illustrated in **Figures 3** and **4**. The side of hemiparesis and experimental protocol determines the seating position of the subject. Motion of either limb can be assessed by the digitizer or manipulated by the robot.

The MIME currently operates in three unilateral modes and one bimanual mode. In unilateral operation, any of 12 personalized, preprogrammed trajectories can be selected. The subject's forearm movements can be passive (subject remains passive, robot provides all necessary forces and guidance) or active-assisted (subject initiates movement, the robot provides guidance and any necessary assistance to the paretic arm so that it completes the motion along the path). In order to move the arm toward a target in the active-constrained mode, the subject must produce a force in the direction of movement, against the robot's velocity-sensitive resistance, while experiencing spring-like restoring loads in all other directions. A programmed viscous behavior of 0.25 N per mm/sec (a 10-N force moves the robot at 4 cm/sec) is created by controlling the robot velocity in response to the force level. The stiffness is less than 5 N/mm and 5 Nm/degree, due to the characteristics of the servomechanism. In the bilateral mode, motion of the forearm that is attached to the digitizer commands mirror-image movements by the robot and enables the subject to practice bimanual, coordinated movements with rate and range under his or her control. Maximum interaction force limits are set in the controller software so that excessive muscle tone leading to high resistance causes all movement of the robot to cease.

In an ongoing series of clinical trials, the therapeutic efficacy of MIME is being evaluated in chronic stroke

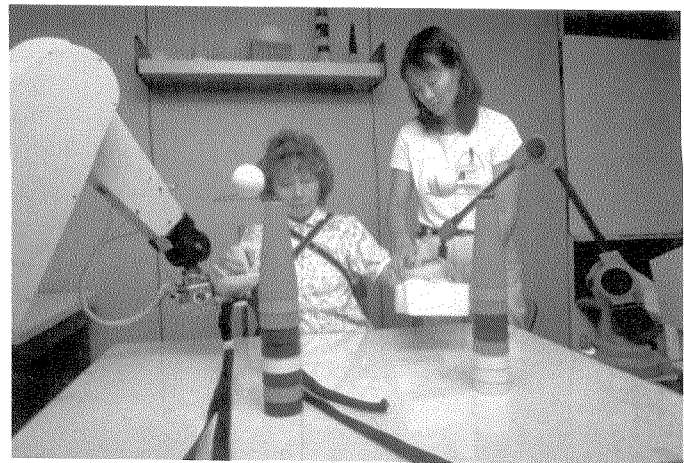


Figure 3.

An occupational therapist oversees bimanual, mirror-image therapeutic exercise performed by a subject with right hemiparesis. The PUMA-560 robot is attached to the right forearm splint. A position digitizer is attached to the left splint. The subject's stronger arm controls the movement of the robot.



Figure 4.

The PUMA-560 robot facilitates unilateral therapeutic exercises in 3 modes and 12 trajectories. A computer controls movement of the robot, with specific preprogrammed tasks tailored to the subject's level of recovery and therapeutic goals.

subjects by comparing functional and motor-control improvements in subjects receiving robot-aided exercise or conventional treatment based on NeuroDevelopmental Therapy (NDT). This report covers the first 23 hemiparetic subjects enrolled. Each was at least 6 months post first stroke. Assignment to the robot or control group was done using a table of random numbers. Outcome data are available for 21 subjects; two robot group subjects were dropped before completing the study. One experienced a

second stroke and the other a fractured hip from a fall at home. Informed consent was obtained in compliance with VA and Stanford University human subject protection policies. Subject demographics are shown in **Table 1**. Subjects continued their usual medical treatments and home exercise regimens. Both groups attended 24 sessions, each 60 minutes in duration, over a 2-month period. A typical session for the robot group began with 5 minutes of stretching. This was followed by tabletop tracing of circles and polygons, then a series of 3-D targeted reaching movements, all assisted by the robot. Each movement progressed from the easiest exercise modes to the most challenging (active-constrained). During active-constrained movements, feedback of the fraction of the movement completed or the time needed to complete three repetitions was used to track and motivate performance. A typical session for the control group included stretching, weight bearing, facilitation (cutaneous and proprioceptive stimulation), games and activities (cone stacking, ball tossing, etc.), and 5 minutes of tracking tasks with the target positioned by the robot. Subjects were informed that the purpose of the study is to evaluate assisted movement of the upper limb as a therapeutic technique following stroke. They were told that either a therapist or a mechanical device would help them move their arm, and that either a robot or a therapist would give them a target to track. By conducting the control group therapy in the same location and providing non-contact exposure to the robot, we sought to minimize nonspecific treatment effects and maintain subject naïveté. A single occupational therapist supervised all sessions. Another therapist, blinded to group assignment, performed subjective outcome assessments.

All subjects were evaluated pre- and posttreatment with clinical and biomechanical measures. An occupational therapist blinded to group assignment evaluated the level of motor function in the paretic limb with the FM exam, the disability level of the subjects with the Barthel ADL scale, and the functional level with the Functional Independence Measure (FIM). The biomechanical evaluations included measures of isometric strength and free-reach kinematics. Electromyographic signals were recorded from shoulder and elbow muscle groups during these evaluations.

Results

Data from the 11 robot group subjects and 10 control subjects who have completed the study indicate that robot-assisted therapy may have advantages over conventional NDT-based therapy techniques. While there have been no significant changes in the Barthel ADL scale or the FIM, most subjects tested to date have exhibited some improvements in the FM assessment of motor function (**Figure 5**). In terms of the overall upper-limb portion of the FM, there is a trend toward greater improvements in the robot group compared to controls, but this trend is not yet significant. However, when considering only the shoulder and elbow portions of the FM, robot group improvements are significantly greater than control group improvements ($p < 0.05$). Improvements in hand and wrist function are no different between groups, an expected outcome because the therapy is targeted toward the elbow and shoulder.

Improvements in strength may be one of the contributing factors underlying this improved shoulder and elbow function. In **Figure 6**, average robot and control

Table 1.
Subject demographics.

	Robot Group	Control Group	
N	11	10	
Age	64.6±12.8	63.3±9.0	Yrs. (Means±SD)
Gender	9M:2F	5M:5F	
Time Since Stroke	26.5±16.1	26.4±20.9	Mos. (Means±SD)
Side of Paresis	7L:4R	7L:3R	
Dominant Side Weak	6	5	Subjects
Initial F-M (U-L)	24.8±16.5	21.8±17.9	
Initial Barthel	89.5±11.1	89.0±6.6	
Initial FIM	112.3±6.3	110.9±9.8	

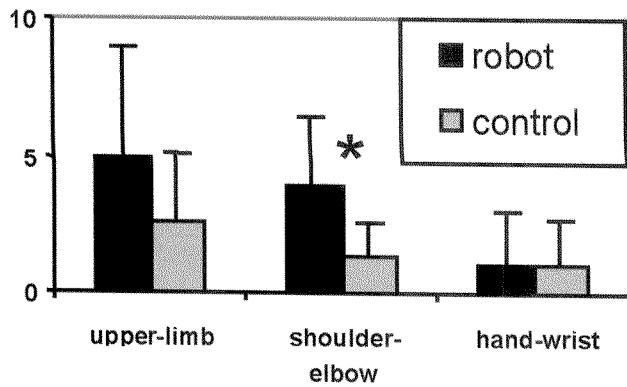


Figure 5. Changes between initial FM assessment of motor function and that observed after completion of the intervention.

group strength changes for eight shoulder- and elbow-resisted movements are compared. All of the strength improvements in the robot group are statistically significant ($p < 0.05$). When compared to the control group, the robot group shows statistically greater improvements in adduction and shoulder flexion strength ($p < 0.05$), with a trend toward greater strength improvements in elbow extension, internal/external rotation, and abduction.

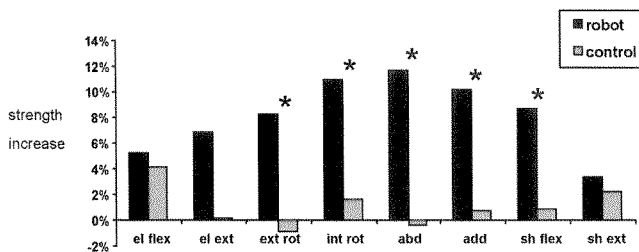


Figure 6. Average robot and control group strength changes for eight shoulder- and elbow-resisted movements. Maximum voluntary isometric contractions were performed with the shoulder abducted 30 degrees in neutral flexion and rotation. The elbow was flexed 90 degrees and the forearm was positioned in neutral pronation/supination.

Robot group subjects often exhibited performance improvements in the training movements over the course of the 2-month treatment period. Decreased resistance to passive movement was common; increased resistance was never observed. None of the experimental subjects exhibited clonus in response to the forces applied by, or to, the robot. The safety features limiting interaction forces between the robot and subjects were never activated during treatment sessions. This is most likely due to

the use of low-velocity movements. Increased work, work efficiency, and decreased force directional errors during active-constrained movements were common.

Figure 7 illustrates an example of improved performance of active-constrained movements clearly due to improved muscle activation patterns. Pre- and posttreatment data are displayed for a robot subject during an active-constrained forward-lateral-up (shoulder-level) reach. Pretreatment, no movement was possible; posttreatment, half the movement could be completed. Pretreatment, only biceps (antagonists) were strongly activated; posttreatment, triceps (agonists) were activated while activation of biceps was suppressed. In addition, several shoulder agonists that were silent pretreatment were activated posttreatment.

The ability to voluntarily reach toward targets increased posttreatment in both robot-assisted and control subjects. There appears to be a trend toward greater

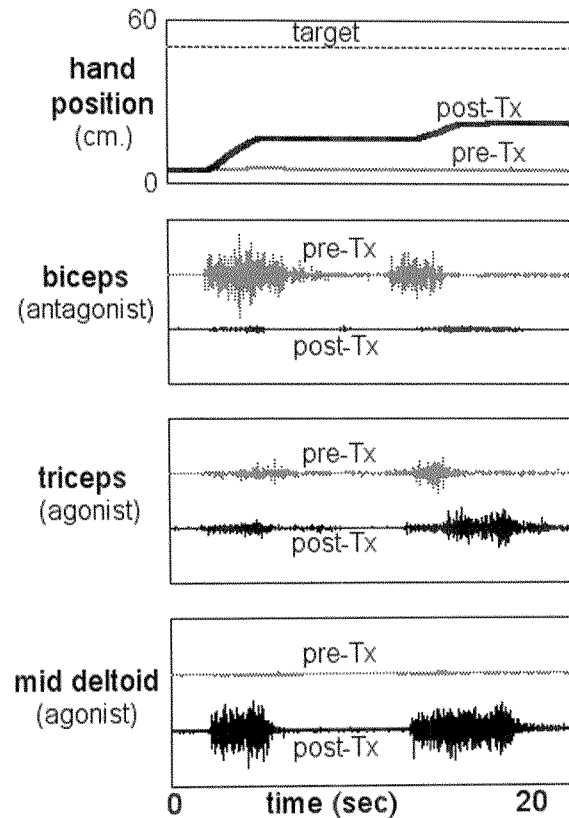


Figure 7. Pre- and posttreatment kinematics and EMG for an active-constrained forward-lateral-up (shoulder-level) reach in one robot group subject. The hand position plot is generated by first calculating the hand movement vector and then the component of this vector along the direction of the desired movement toward the target.

improvements in robot-assisted subjects. Robot-assisted training of reaching movements appears to have had positive carry-over effects to unassisted free-reaching movements, because free reaching was never practiced in the robot group. Confirmation of these observations and identification of the changes responsible for them will require further analysis of the data after completion of the study. Maintenance of improvements will be assessed after all subjects have completed follow-up evaluations.

DISCUSSION

The philosophy behind our approach toward therapeutic applications of robotics has changed from that during the previous work at the RRDC on assistive robotics. The MIME has been designed to produce some of the functions of a therapist; however, helping restore the use of impaired anatomy, i.e., the upper limb, is now the goal. By involving patients and clinicians from the beginning of this effort, we have identified and overcome the limitations of our early prototypes. Subject safety has been successfully addressed. This is an especially important issue because any mechanical device capable of therapeutic stretching of hypertonic muscles also has the potential for injury. Acceptance by subjects and clinicians has been enthusiastic, with no adverse reactions or incidents. The first prototype revealed the advantages of servomotor-powered assisted movement over body power. It was difficult to identify functional tasks that could be performed using only elbow flexion/extension and forearm pronation/supination. Thus, the second-generation prototype incorporated a versatile robotic manipulator that facilitated elbow and shoulder movements. This prototype also provided continuous measures of forearm kinematics. A potential application of kinematic analysis during arm motion has recently been described (46). Such continuous, objective information may contribute to the understanding of normal and hemiparetic motor behavior. The MIME prototype also allowed us to validate the objective interaction force and torque measurements against accepted, subjective clinical scales. The failure of the PUMA-260 to overcome muscle hypertonia, and the desire to create functional tracking tasks without keeping the forearm restricted to planar movements, led to development of the third-generation robotic therapy assistant.

In our clinical efficacy trial, we compared outcomes from robot-assisted therapy directly to those from a conventional therapy program for stroke survivors in the chronic phase of recovery. The treatment intensity and duration

was equivalent for both groups. Robot and control groups received therapy in the Robotics Laboratory at the RRDC and non-contact exposure to the robot was provided to the control subjects. Since the average time post-ictus was over 2 years, it is unlikely that improvements attained by our subjects were due to spontaneous neurological recovery. Failure to demonstrate significant FIM or Barthel ratings is not surprising, as all subjects were well past the time when rapid recovery of mobility, communications, continence, and ADLs is generally expected. The relatively high FIM and Barthel scores in the presence of moderately severe upper limb impairment suggests that these subjects had learned compensatory techniques for performing ADLs.

The improved performance of the robot over conventional therapy was unanticipated. It is particularly encouraging that the greatest improvements occurred in the shoulder and elbow measures, as these are the joints the robot therapy targeted. These results provide support for future studies of robot-assisted therapy in order to optimize functional interventions. They also demonstrate the potential for additional therapy to increase motor control in the "post-recovery" phase. Unanswered questions include the importance of the bimanual and 3-D components of exercise, which are unique to MIME and have not yet been implemented in other clinical trials. The relative contributions of the three unilateral training modes are likewise unknown.

Future studies comparing various robot training protocols will be necessary to answer these questions and guide development of clinically and commercially viable robotic therapy assistants. We have initiated studies to identify the relative contributions of the various components of MIME. Our vision for the future is to answer the above questions and reduce the complexity of MIME to that required for acceptable cost-benefit ratio. A new study during the subacute phase of recovery is comparing outcomes among groups receiving unilateral, bilateral, combined, or a control therapy. Because the master/slave mode of exercise adds significant additional cost and complexity to any potential commercial device, it is important to establish that this mode is absolutely necessary for the effectiveness of the MIME therapy.

CONCLUSIONS

Preliminary data from this ongoing clinical efficacy trial suggest that robot-aided therapy has therapeutic benefits. Improvements have been demonstrated in strength

and in the FM assessment of motor function. Trends in the data suggest that the underlying mechanisms for these results may be increased strength, as well as more appropriate activation and inhibition of muscle groups.

This study supports the conclusions of Hogan, Aisen, Krebs, et al. that robotic manipulation of an impaired limb may favorably effect recovery following a stroke. An important additional finding is that improvements in motor control are possible beyond 6 months following a stroke. The value of the bimanual training that is possible with MIME remains to be conclusively established, as does the added value that this approach may provide very early after stroke. Finally, we do not view robots as replacements for therapists, but believe they have the potential to improve motor performance by providing interactive, intensive training tasks.

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