

A Randomized Controlled Trial of Gravity-Supported, Computer-Enhanced Arm Exercise for Individuals With Severe Hemiparesis

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Background/Objective. The authors previously developed a passive instrumented arm orthosis (Therapy Wilmington Robotic Exoskeleton [T-WREX]) that enables individuals with hemiparesis to exercise the arm by playing computer games in a gravity-supported environment. The purpose of this study was to compare semiautonomous training with T-WREX and conventional semiautonomous exercises that used a tabletop for gravity support. **Methods.** Twenty-eight chronic stroke survivors with moderate/severe hemiparesis were randomly assigned to experimental (T-WREX) or control (tabletop exercise) treatment. A blinded rater assessed arm movement before and after twenty-four 1-hour treatment sessions and at 6-month follow-up. Subjects also rated subjective treatment preferences after a single-session crossover treatment. **Results.** All subjects significantly improved ($P \leq .05$) upper extremity motor control (Fugl-Meyer), active reaching range of motion (ROM), and self-reported quality and amount of arm use (Motor Activity Log). Improvements were sustained at 6 months. The T-WREX group maintained gains on the Fugl-Meyer significantly better than controls at 6 months (improvement of 3.6 ± 3.9 vs 1.5 ± 2.7 points, mean \pm SD; $P = .04$). Subjects also reported a preference for T-WREX training. **Conclusion.** Gravity-supported arm exercise, using the T-WREX or tabletop support, can improve arm movement ability after chronic severe hemiparesis with brief one-on-one assistance from a therapist (approximately 4 minutes per session). The 3-dimensional weight support, instant visual movement feedback, and simple virtual reality software provided by T-WREX were associated with modest sustained gains at 6-month follow-up when compared with the conventional approach.

Keywords: Stroke rehabilitation; Hemiparesis; Arm; Motor control; Robotic upper extremity device; Telerehabilitation

Upper extremity impairment is a common finding after stroke, and more than 80% of individuals who demonstrate severe weakness 6 weeks after stroke develop chronic impairments in arm or hand movement.¹ An intensity–effect relationship exists between the amount of therapy individuals receive and movement gains achieved.^{2–5} However, the amount of therapy a patient receives involving direct contact with rehabilitation therapists is often limited by cost considerations.^{6,7} Patients may exercise without help from a therapist; however, independent movement practice is particularly difficult for individuals who are unable to lift the arm against gravity or have minimal hand movement ability, which may contribute to the reported poor compliance with home exercise programs.^{8–13}

Many researchers have proposed that robotic upper extremity rehabilitation devices might allow patients to receive movement training without the continuous presence of a rehabilitation therapist.^{14–18} Systematic reviews of robotic

therapy suggest that such devices are particularly well suited for improving proximal upper extremity strength and might promote motor recovery to a greater extent than traditional therapy.^{19,20} Nonetheless, robotic devices can be costly, and safety considerations may limit the ability to leave a patient unattended. Furthermore, it has not yet been demonstrated that the robotic properties of these devices—that is, the actuators that account for much of their cost and safety concerns—are indeed necessary to cause the therapeutic effects associated with robotic therapy.^{21–23} Indeed, helping a patient to move with robotic actuators may actually decrease the effort and attention of the patient, especially if the robot can perform the desired movement without contribution by the patient, which in turn may have a negative effect on motor plasticity.^{24,25}

In contrast to actuated upper extremity robots, passive (ie, nonrobotic) arm orthoses are potentially less costly, safer, and are appropriate for semiautonomous training. Devices such as

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the mobile arm support and balanced forearm orthosis²⁶⁻²⁸ have been used in rehabilitation for many years. However, such devices can be difficult to adjust to provide different levels of support or various levels of challenge, and they provide little feedback regarding movement recovery. In addition, it is unclear to what extent movement practice with the arm supported by such a device transfers to improvements in unsupported arm movement ability.

In an effort to address the limitations of these 3 existing approaches (conventional exercise programs, actuated robotics, and passive orthoses) for providing semiautonomous upper extremity therapy, we developed a novel training system called the Therapy Wilmington Robotic Exoskeleton (T-WREX).²⁹ T-WREX is a passive (ie, nonrobotic) arm orthosis that provides support for the arm against gravity and measures arm movement and trace hand grasp as users interact with computer games. It allows users with a moderate to severe impairment to achieve a larger active range of motion (ROM) of arm movement than is possible without the arm support.²⁹ It also enables individuals to begin to use their hand in meaningful ways, even if they retain only trace movement ability. Because it is a passive device, it is also inherently safer than robotic devices. Furthermore, because it is passive, it requires that the user always initiate movement, eliminating the possibility that the user himself or herself could become passive during training. Finally, in contrast to traditional arm supports, it offers easily variable levels of gravity support, is quickly adjustable for different limb sizes, provides a larger 3-dimensional (3D) workspace, and incorporates electronic sensors of arm movement and hand grip force, which allow patients to interact with therapeutic computer games and receive quantitative feedback. A modified version of T-WREX is currently being commercialized by Hocoma A.G. as the Armeo device.

Pilot testing of the T-WREX conducted at the University of California at Irvine indicated that 8 weeks of training can significantly improve arm movement ability for individuals with moderate to severe hemiparesis.²⁹ The pilot study, however, did not answer the question of whether training with T-WREX is more effective than other therapy types. The aim of this present study was to compare motor training with T-WREX with one of the training techniques it was designed to improve: conventional exercises that provide support for the hemiparetic arm on a tabletop surface. This is an exercise technique commonly prescribed in home exercise programs and group therapy sessions at the Rehabilitation Institute of Chicago (RIC). Our primary hypothesis was that training with T-WREX would improve arm movement ability to a greater extent than a matched duration of conventional exercise, because T-WREX allows patients to practice movements within a larger workspace and directs and motivates exercise with computer games. A secondary hypothesis was that exercise with T-WREX would require the same amount of direct therapist supervision as conventional exercises, an important criterion to test to determine whether T-WREX met its design goal of improving on existing methods for *semiautonomous* exercise. We tested

Table 1
Subject Demographics by Group

	Control Group (n = 14)	T-WREX Group (n = 14)	P Values ^a
Gender	7 males, 7 females	11 males, 3 females	.24
Age	56.4 (±12.8)	54.2 (±11.9)	.64
Months poststroke	112.4 (±128.5)	84.5 (±96.3)	.54
Side of hemiparesis	10 left, 4 right	10 left, 4 right	1.0
Type of stroke	8 ischemic, 5 hemorrhagic, 1 unknown	9 ischemic (1 with hemorrhagic conversion), 4 hemorrhagic, 1 unknown	.92

Abbreviation: T-WREX, Therapy Wilmington Robotic Exoskeleton.

^aP values reflect control and T-WREX group comparisons via Student's *t* test or Fisher's exact test.

this hypothesis by measuring the amount of time a supervising therapist spent with each exercise group as they trained in the clinic. Another secondary hypothesis was that stroke survivors would perceive training with T-WREX as more motivating and enjoyable than conventional exercises due to greater range and variety of movements possible with the device, as well as the incorporation of motivating computer games and quantitative feedback. Preliminary results have been reported previously in abstract format.^{30,31}

Methods

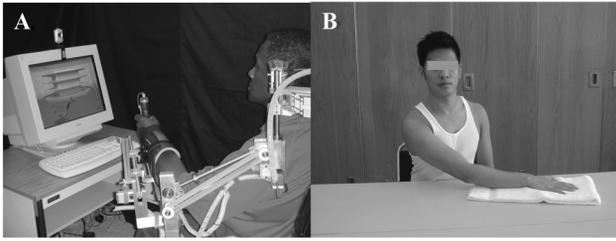
Subjects

Thirty-four adult stroke survivors were enrolled in this project through the RIC Sensory Motor Performance Program, Chicago, Illinois. All subjects experienced a single ischemic or hemorrhagic stroke at least 6 months prior to participation in the study and demonstrated moderate to severe upper extremity hemiparesis (characterized by arm motor Fugl-Meyer scores ≥ 10 and ≤ 30). Exclusion criteria included significant pain or instability of the affected shoulder, current enrollment in ongoing upper extremity therapy, and severe cognitive dysfunction, aphasia, hemispatial neglect, or apraxia sufficient to limit comprehension or completion of experimental tasks. Written informed consent was obtained from all patients, and the institutional review board of Northwestern University approved all procedures. Table 1 shows demographic information for participants.

Device: T-WREX

The T-WREX is a 5 degree-of-freedom arm orthosis that contains no robotic actuators (Figure 1A; see Sanchez et al³³ for a detailed engineering description). The design of the arm support component of T-WREX is based on WREX, a wheelchair-mounted arm support developed as an assistive device for children with neuromuscular disorders.³² T-WREX provides weight support for the arm across a large 3D workspace,

Figure 1
The Therapy Wilmington Robotic Exoskeleton (T-WREX) Arm Orthosis and Control Therapy



Note: A, Subject playing “Grocery Shopping” game with T-WREX. The orthosis provides arm support in 3 dimensions using elastic bands. Sensors measure arm movement and hand grip, allowing the subject to manipulate virtual objects on the computer screen by squeezing, moving, and releasing. B, Subject completing shoulder strengthening exercise with conventional tabletop, semiautonomous therapy.

enabling naturalistic movement across approximately 66% of the normal workspace in the vertical plane and 72% in the horizontal plane.³³ The main structure consists of an arm exoskeleton with elastic bands that relieve the weight of the limb and provide a sense of arm flotation at all positions in the available workspace. Therapists can adjust the number of bands to provide variable levels of arm support. A custom grip sensor consisting of a water-filled cylindrical bladder detects finger movement and allows incorporation of grasp and release practice into arm training.

Instrumentation of the T-WREX with position sensors at each joint enables it to be used as a 3D input device for computer game play with the hemiparetic arm. A custom software package named Vu Therapy was designed at the University of California at Irvine. Games were designed to be intuitive for patients with minor cognitive or perceptual deficits to understand, and mimic functional arm movements to provide training in a simple virtual reality environment. Therapists play an integral role in the initial customization of the software for each patient to optimize the therapeutic benefit. After therapists calibrate the software, reaching targets of each game are automatically adjusted to each patient so that individuals with very little strength can experience success with each task.

Vu Therapy games were developed with the goal of enabling repetitive task-specific practice. Tasks such as grocery shopping, cleaning a stovetop, and playing basketball were created due to their functional relevance and inherent motivation. In this way, stroke survivors who are otherwise unable to use their severely weakened arms in a functional manner are able to practice task-specific movements in a simulated, gravity-reduced environment. Novel auditory and visual feedback is provided throughout game play to maintain the patient’s attention. In addition, users are provided objective feedback of task performance at the end of each game to enhance motivation and awareness of progress.

Assignment and Intervention

This study compared the arm movement of subjects who participated in T-WREX training with control subjects who exercised for the same duration without the device and received approximately the same amount of supervision from a therapist. All subjects participated in twenty-four 1-hour treatment sessions, approximately 3 times per week for 8 to 9 weeks. All treatment sessions were performed in a research laboratory at the RIC. All subjects received 60 minutes of direct training with an occupational therapist, the first 3 sessions to ensure competence with T-WREX and control protocols. After the third treatment, subjects exercised with intermittent supervision from the therapist. The amount of direct therapist intervention or cueing was recorded via stopwatch, over and beyond the time spent performing passive ROM (5 minutes) and obtaining blood pressure and pain ratings (3 minutes) each session. Blood pressure and pain ratings were obtained on all subjects directly before and after treatment each session.

Subjects were randomly assigned to T-WREX or control group by the supervising therapist. To achieve approximately equal numbers for each group, 4 subjects at a time were randomly assigned by lottery. The treating therapist and subjects were blinded to assignment until each subject was consented and enrolled in the project. In the initial stages of recruitment, only a “left-handed” version of T-WREX was available; therefore, only subjects with left hemiparesis were initially recruited. By mid-way through the study a “right-handed” version had been built, and individuals with right hemiparesis were included.

Subjects assigned to the control group participated in conventional exercises, which are the standard of care for therapy groups and home exercise programs at the RIC for individuals with moderate to severe upper limb hemiparesis. Such exercises have been prescribed by therapists in the United States for years,³⁴⁻³⁸ and per the authors’ clinical experience, these exercises continue to be widely accepted and used. Control activities consisted of self-range of motion (SRM) stretches and active range of motion (AROM) strengthening exercises throughout the hemiparetic upper extremity.^{35,36,38} During SRM stretches, participants clasped the hands or arms together and used the strength of the less-affected arm to move the affected arm through the available ROM at each joint. During AROM exercises, the hemiparetic arm was supported against gravity by a tabletop, and a towel was placed under the arm to decrease friction as subjects completed specified movements unilaterally. Additional activities consisted of using the affected arm as a functional assist during a prescribed list of activities of daily living (ADL) tasks (such as wiping a table or holding a container while the less-affected hand opened the lid) as well as hemiparetic upper extremity weight bearing on an open hand with the affected arm extended at the side of the body.^{34,35,37} After 3 sessions of direct training with a therapist, subjects completed the control exercises semiautonomously (in the research clinic, with intermittent therapist supervision) by progressing through a handout containing written descriptions and photographs of each activity (Figure 1B).

Individuals in the experimental group participated in training with T-WREX as described above. After 3 sessions of direct training with a therapist, subjects completed approximately 3 repetitions of 10 therapy games semiautonomously each session (in the research clinic, with intermittent therapist supervision). The initial amount of gravity support provided by T-WREX supported the subject's arm in a neutral, "weightless" position of approximately 45° shoulder flexion and 80° of elbow flexion. After the first 3 days of training, gravity-balance compensation was gradually decreased as deemed appropriate by the supervising therapist (ie, 1 rubber band was removed every third treatment session if the subject demonstrated the ability to complete the games successfully without increased compensatory movements). If compensatory movements were noted with rubber band removal, the band was replaced, and the process was repeated in 3 treatment sessions.

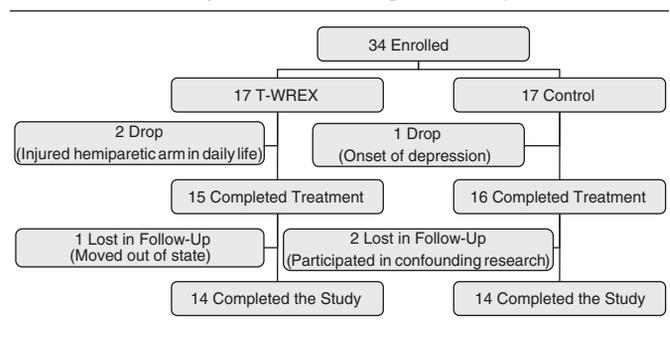
All subjects concluded treatment after 24 training sessions. A home exercise program was not provided to either group for continued training during the 6-month follow-up period, nor was the amount of use of the affected arm monitored.

Assessment Procedures

Subjects were tested before and after 24 treatment sessions and 6 months after treatment completion. A single blinded rater performed the following clinical assessments. The primary outcome measure was the arm motor section of the Fugl-Meyer (AMFM),^{39,40} which assessed arm movement ability outside of synergy patterns. The AMFM score is generated by asking subjects to perform 33 test movements, grading their performance 0, 1, or 2 on each test movement and summing scores.⁴⁰ Secondary outcome measures included functional and quantitative tests of arm movement ability. Functional use of the arm during ADL was evaluated with the Rancho Functional Test for the Hemiplegic/Paretic Upper Extremity.^{41,42} The Quality of Movement (QOM) and Amount of Use (AOU) subscales of the Motor Activity Log (MAL)⁴³ were self-report measures used to determine quality and amount of affected arm use for ADL in the home. A characterization of free reaching was assessed using the Flock of Birds 3D electromagnetic motion capture system, with subjects reaching at shoulder and elbow heights to 5 targets. Reaching ROM deficit was calculated as the mean distance between a marker placed on the subject's wrist and 5 targets, following 5 reach attempts to each target. Grip strength was tested using a Jamar dynamometer.⁴⁴

To provide a subjective comparison of participant preference for the 2 interventions, subjects crossed over to the alternate treatment group for 1 session. After participating in both training methods, subjects completed a brief survey comparing the original and crossover treatments. Questions comparing the T-WREX and tabletop control exercises consisted of a 2-category nominal scale. Subjects were required to choose either "T-WREX" or "Tabletop" treatment on questions such as "Which type of exercise do you prefer" and "Which type exercise makes it easier to track your progress?"

Figure 2
Subject Flow During the Study



Note: T-WREX indicates Therapy Wilmington Robotic Exoskeleton.

Statistical Analysis

A power analysis was conducted before the study began to determine target sample size. Results from previous robotic and unassisted therapeutic studies of the arm suggest that the magnitude of the treatment effect, when compared with a reduced-intensity group, might be expected to at least equal the standard deviation of the treatment effect across the test group.^{19,20} With this effect size, 14 subjects were needed in each group to have an 80% chance of detecting this difference at the .05 confidence level (1-tailed *t* test). To achieve 14 subjects in each group, we enrolled 34 subjects (see Figure 2).

The outcome measures did not deviate significantly from normality (Kolmogorov–Smirnov test, $P > .05$) nor show significant heterogeneity of variance (Levine's test, $P > .05$). The outcome measures were thus analyzed using individual mixed-model analysis of variance (ANOVA) in SPSS, with evaluation (baseline, posttherapy, and 6-month follow-up) as the repeated factor and group (control vs T-WREX), side of hemiparesis, and type of stroke (ischemic vs hemorrhagic) as between-subjects measures. The Greenhouse–Geisser adjustment was used when sphericity was violated ($P < .05$). Planned comparisons were used to evaluate change in assessment measures from pretreatment to posttreatment and pretreatment to 6-month follow-up. The subjective preference for either T-WREX or control therapy was analyzed using Pearson's χ^2 test.

Results

We compared training with T-WREX over 24 sessions to a matched duration of exercises performed at tabletop without a device. At baseline, no significant differences were found between groups in age, sex, months poststroke, side of lesion, or type of lesion (Table 1). There were also no significant differences at baseline between groups for any of the outcome measures, except grip strength (Table 2).

Three subjects dropped out of the study for personal reasons unrelated to the project. Follow-up data were not available for 3 more subjects because 1 individual moved and 2 subjects participated in confounding upper extremity research

Table 2
Baseline Measures

	Group	Baseline ^a	<i>P</i> Between
			Groups at Baseline
Arm Motor	Control	18.1 ± 5.0	.15
Fugl-Meyer (out of 66)	T-WREX	21.7 ± 5.9	
Rancho level (out of 7)	Control	2.9 ± 1.0	.13
	T-WREX	3.4 ± 0.6	
Rancho speed (seconds)	Control	15.9 ± 6.3	.06
	T-WREX	23.4 ± 9.9	
MAL Amount of Use (out of 5)	Control	0.3 ± 0.3	.07
	T-WREX	0.6 ± 0.4	
MAL Quality of Movement (out of 5)	Control	0.3 ± 0.3	.08
	T-WREX	0.6 ± 0.4	
Grip strength (kg force)	Control	4.2 ± 3.0	.01 ^b
	T-WREX	8.2 ± 4.1	
ROM deficit (cm)	Control	12.3 ± 3.1	.51
	T-WREX	15.1 ± 3.3	

Abbreviations: T-WREX, Therapy Wilmington Robotic Exoskeleton; MAL, Motor Activity Log; ROM, range of motion.

^aValues are given as means ± standard deviations.

^b*P* < .05.

projects during the interim period. Data for these subjects were included in the analysis of short-term outcomes and subjective preference.

Data for reaching ROM deficit were available for only 8 subjects in the T-WREX group and 10 subjects in the control group for pre-post evaluations due to a malfunction with the Flock of Birds motion tracking system. Reaching ROM data were not collected at 6 months due to continued system malfunction.

The Rancho Functional Test for the Hemiplegic/Paretic Upper Extremity measures the speed at which subjects

complete a series of functional tasks. When prespeed to post-speed was analyzed, Task 1 (“Hand to Lap”) was excluded because all subjects completed the movement within 2 seconds, and a floor effect existed. Seven subjects (2 T-WREX, 5 control) were excluded from the Rancho speed analysis because Task 1 was the only activity they were able to complete within the Rancho assessment due to the severity of their hemiparesis.

Clinical Outcomes Measures

Subjects in both groups required an average of 3.6 minutes of assistance (±1.9 SD for T-WREX and ±2.8 SD for control exercises) from the occupational therapist for setup or completion of the 60-minute protocol, following the initial 3 sessions of training. No significant changes were noted in blood pressure readings or subjective pain ratings during treatment for either T-WREX or control groups, and there were no adverse events.

Table 3 and Figure 3 show the score changes for the primary outcome measures and compare the relative effectiveness of the 2 therapies using a confidence interval approach. Planned contrasts showed significant or near significant improvements in AMFM, MAL QOM and AOU, and free-reaching ROM deficit after 24 therapy sessions and at 6-month follow-up for both groups (Table 3). The only significant difference between groups was for the AMFM score at the 6-month follow-up (*P* = .04; Table 3 and Figure 3), favoring the T-WREX group. There was no significant effect of side of paresis or type of stroke on any outcome measure.

As stated above, individuals randomly assigned to the T-WREX intervention demonstrated significantly higher baseline scores on grip force, and there was a trend for higher scores on the AMFM

Table 3
Change in Outcome Measures With Training^a

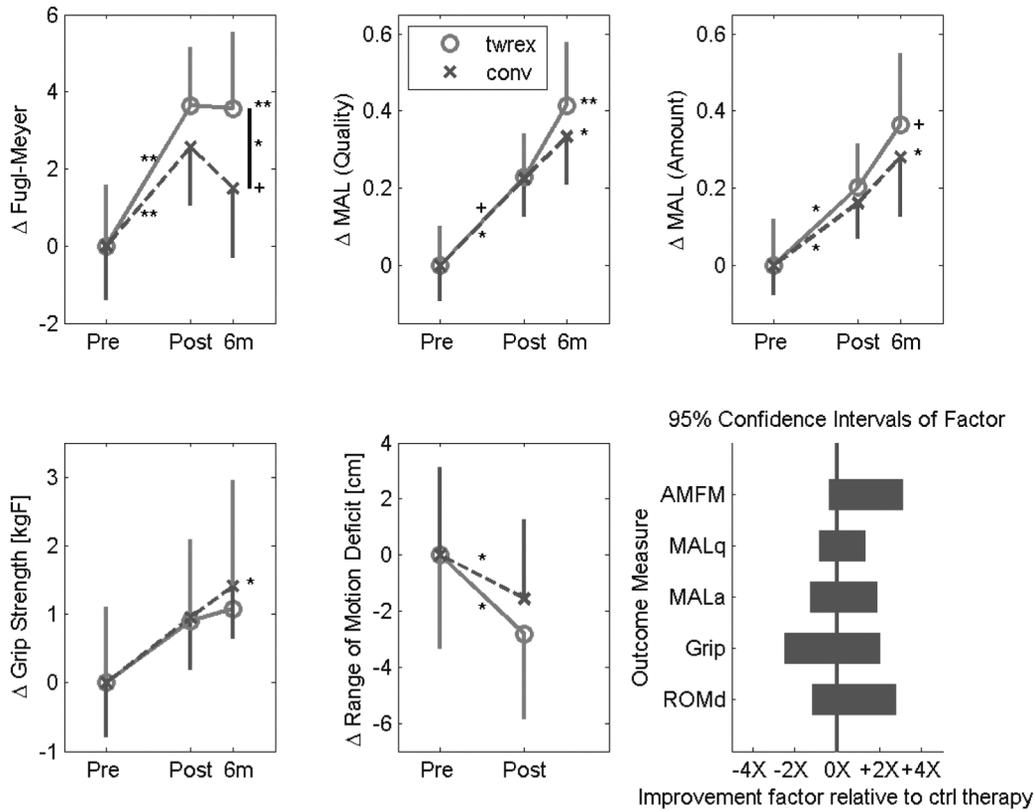
	Group	Change After 24 Sessions (n = 31)	Change After 6 Months, Relative to Baseline (n = 28)	<i>P</i> of Change After 24 Sessions (n = 31)	<i>P</i> of Change After 6 Months (n = 28)	<i>P</i> Between Groups After 24 Sessions (n = 31)	<i>P</i> Between Groups at 6 Months (n = 28)
Arm Motor	Control	2.2 ± 2.6	1.5 ± 2.7	.004 ^b	.06		
Fugl-Meyer (out of 66)	T-WREX	3.3 ± 2.4	3.6 ± 3.9	.001 ^b	.005 ^b	.20	.045 ^b
Rancho level (out of 7)	Control	0.1 ± 0.7	0.1 ± 0.5	.49	.58		
	T-WREX	0.1 ± 0.4	0.0 ± 0.8	.16	.58	.97	.47
Rancho speed (s; n = 21)	Control	1.0 ± 7.3	-2.9 ± 8.7	.68	.30		
	T-WREX	-1.8 ± 8.4	-5.6 ± 7.1	.49	.03 ^b	.36	.17
MAL Amount of Use (out of 5)	Control	0.1 ± 0.3	0.3 ± 0.4	.08	.04 ^b		
	T-WREX	0.2 ± 0.4	0.4 ± 0.7	.08	.06	.59	.75
MAL Quality of Movement (out of 5)	Control	0.2 ± 0.3	0.3 ± 0.4	.04 ^b	.01 ^b		
	T-WREX	0.2 ± 0.4	0.4 ± 0.5	.06	.01 ^b	.77	.55
Grip strength (kg force)	Control	0.8 ± 2.3	1.4 ± 2.2	.16	.03 ^b		
	T-WREX	0.8 ± 3.0	1.8 ± 4.8	.32	.20	.97	.28
ROM deficit (cm; n = 18)	Control	-1.6 ± 2.8	NA	.053	NA		
	T-WREX	-2.8 ± 3.4	NA	.025 ^b	NA	.4	NA

Abbreviations: T-WREX, Therapy Wilmington Robotic Exoskeleton; MAL, Motor Activity Log; ROM, range of motion; NA, not applicable.

^aValues are given as means ± standard deviations. Note that for change in ROM deficit, a larger negative number indicates greater improvement. Data for 3 subjects were not included in 6-month calculations, as these subjects were lost during follow-up.

^b*P* < .05.

Figure 3
Change in Outcome Measures Due to T-WREX and Conventional Therapy



Note: Change in outcome measures were measured after 2 months of therapy (post) and at the 6-month follow-up evaluation (6m); * $P < .05$, ** $P < .01$, + $P < .06$. Vertical bars show 1 standard error. Note that for ROM deficit, a larger negative change indicates greater improvement. The bottom right plot shows a confidence interval analysis comparing benefit of T-WREX therapy to control therapy. These bars show the range in which the mean of each respective outcome measure lies with 95% probability (ie, the confidence interval). This range is expressed as a “factor of improvement,” defined as the improvement in the selected score for T-WREX therapy divided by the improvement in the score for the control therapy. Bars aligned toward the right of the 0X vertical line indicate greater improvement in the T-WREX group, whereas bars aligned to the left indicate greater improvement in the control group. T-WREX indicates Therapy Wilmington Robotic Exoskeleton; AMFM, Arm Motor Fugl-Meyer; MALq, Motor Activity Log Quality of Movement score; MALa, MAL Amount of Use score; ROMd, reaching ROM deficit. Data for confidence intervals were taken from 6-month follow-up relative to baseline evaluation.

and MAL scores (Table 2). We therefore performed a regression analysis to determine whether baseline impairment level predicted treatment outcome. There was a significant but weak correlation between pretreatment MAL AOU ($P = .02$; $r^2 = .17$) and QOM ($P = .03$; $r^2 = .18$) scores with the change in these scores after 24 therapy sessions. However, this correlation revealed that more severely impaired subjects improved to a greater extent on these measures, an effect that would have favored the control group because subjects in that group began at a slightly lower level of ability. Regression analysis revealed no significant relationship between initial AMFM score and change in AMFM ($P = .7$) or between initial impairment level and amount of improvement on any other measure.

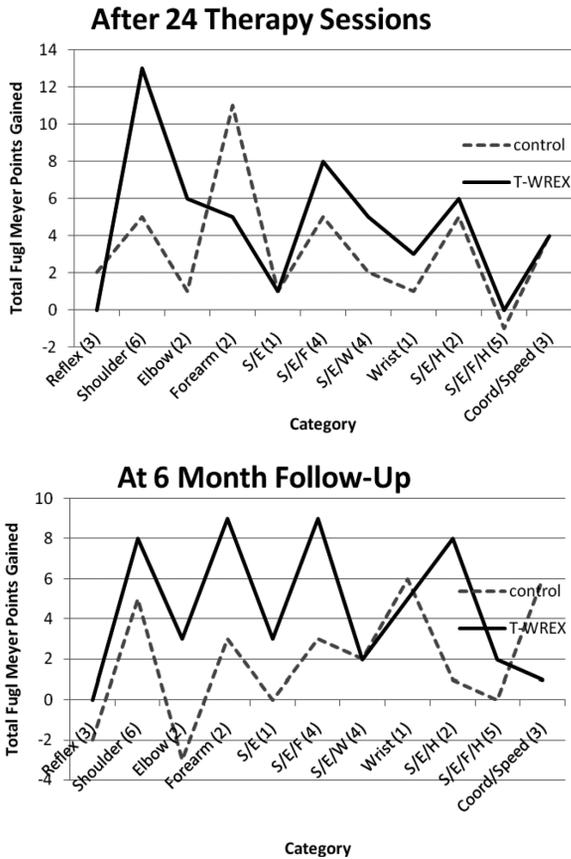
To gain insight into whether subjects demonstrated trends toward proximal or distal upper extremity improvement, as reported in previous studies,^{19,20} we divided the AMFM into categories. Each AMFM task was categorized according to the joint(s) involved in the movement, and total point gains per category were plotted for both treatment groups as a whole (Figure 4). After 24 therapy sessions, the T-WREX group

demonstrated a trend toward larger improvements at the shoulder and elbow compared with forearm and wrist, whereas the control group demonstrated the greatest gains at the forearm. Neither of these trends was resilient at the 6-month follow-up. Overall, individuals in the T-WREX group demonstrated higher point gains in all movement categories with the exception of forearm supination/pronation. Control exercises featured supination and pronation, whereas T-WREX exercises did not incorporate the forearm, and the control group had larger, but nonsignificant improvements in this category (t test, $P = .24$).

User Satisfaction Survey Results

Results from the satisfaction survey issued to participants after 24 sessions of T-WREX or control treatment and 1 cross-over session revealed significant differences in the type of training subjects preferred (see Figure 5). Ninety percent of subjects assigned to T-WREX treatment reported a preference for this type of therapy and would recommend T-WREX over conventional training. In addition, 90% of these subjects found

Figure 4
Total Arm Motor Fugl-Meyer (AMFM) Points Gained for All Subjects in Therapy Wilmington Robotic Exoskeleton (T-WREX) and Control Groups, Analyzed per Joint



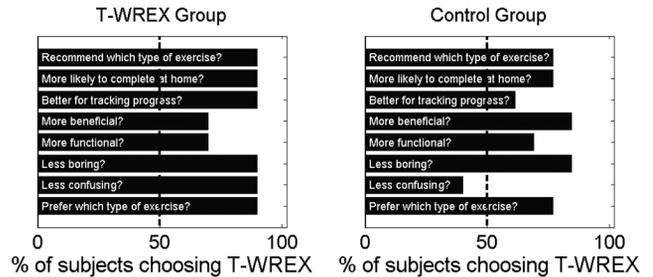
Note: AMFM tasks are categorized according to the joint(s) involved in each test movement. Tasks involving more than 1 joint are categorized as a whole (ie, tasks requiring a combination of shoulder, elbow, forearm, and hand skills are represented as S, E, F, and H, respectively). After 24 therapy sessions, the T-WREX group as a whole demonstrated the same or greater point gains in all categories than the control group with the exception of Forearm (ie, supination/pronation). The larger gain for the control group in the Forearm category was not statistically significant compared with the T-WREX group (2-sided *t* test, *P* = .24). The number in parentheses represents the number of AMFM tasks included per category, out of a total of 33.

the therapy less boring, less confusing, and easier to track their progress than conventional tabletop exercises. Control group participants demonstrated strong preferences for T-WREX therapy, with 85% of controls finding the 1-session sample of T-WREX exercises that they experienced less boring and more beneficial. An average of 70% of subjects from both groups also considered T-WREX more functional, and 83% reported an increased likelihood to complete this therapy in the home over conventional tabletop exercises (Figure 5).

Discussion

This study examined the effectiveness of 2 forms of semi-autonomous arm exercises for individuals who sustained a

Figure 5
Responses From Subjects Enrolled in Therapy Wilmington Robotic Exoskeleton (T-WREX) or Tabletop (Control) Therapy



Note: Subjects were asked to choose “T-WREX” or “Tabletop” (control) therapy in several categories following 1 crossover training session. Left: responses from subjects enrolled in the T-WREX group. Right: responses from subjects enrolled in the control group. Taking the average across groups, the preference for T-WREX was significant in all categories (χ^2 , *P* < .05), except for “More functional?” (*P* = .06) and “Less confusing?” (*P* = .53).

stroke. Both interventions incorporated support for the weakened arm against gravity. Exercise with T-WREX integrated technological enhancements, including 3D weight support across a wide ROM, sensors for arm and hand movement that controlled computer simulations of functional activities, and quantitative feedback. Both forms of exercise produced significant benefits that were sustained for 6 months, and the T-WREX group demonstrated significant but modest improvements over the control group in the AMFM assessment at 6 months. Perhaps as important, subjects could perform the exercises with only brief direct supervision from a therapist (4 minutes for each hour of therapy), and subjects reported a significant preference for treatment with the T-WREX.

Validation of Conventional and Weight-Supported Arm Therapies

This study used a control protocol that is the current standard of care for semiautonomous group or home therapy in many clinics across the United States.³⁵ These semisupervised control exercises were found to have significant benefits on arm movement and function, consistent with another published research study that examined the benefits of a written and illustrated home exercise program after stroke.¹³

The study also provides evidence that supports weight-supported arm therapy as a therapeutic modality. Subjects in the conventional group trained throughout most of the session with the weight of the arm supported by a table, and those in the experimental group received support from elastic bands on the T-WREX orthosis. The supervising therapist periodically decreased the amount of weight support for the T-WREX group; however, the support was rarely decreased to less than 50% of the weight of the arm. We note that the use of weight support for the patient population studied here was almost inevitable, as participants demonstrated significant difficulty lifting the affected arm against gravity, and the types and

amount of exercise these individuals could perform without weight support was very limited.

This study reveals that training with weight support can generalize to movement ability in non-weight-supported conditions, demonstrated here by significant changes in AMFM and MAL scores as well as free reaching ROM to 5 targets. Thus, the human motor system appears to be organized in such a way that training in an environment that requires substantially different forces than the “target environment” may benefit performance in the target environment.

Comparing Outcomes of T-WREX Therapy With Conventional Therapy

We found a statistically significant difference in impairment reduction as measured by the Fugl-Meyer assessment between the T-WREX and conventional therapy groups at the 6-month follow-up, and a similar trend at posttreatment testing, confirming our primary hypothesis. The size of the improved benefit with T-WREX was small (approximately 2 additional AMFM points), and self-report of improved functional use of the upper extremity (with the MAL) was not different between groups. Thus, the observed differential benefit in motor outcome due to T-WREX is best characterized as modest and functionally insignificant. However, we note that even a small benefit provides something to build on in future work if its basis can be understood and optimized.

An outcome that differed between the 2 therapies was patient satisfaction, as patients reported significant preference for T-WREX on a posttreatment survey, which supported 1 of our secondary hypotheses. Although this suggests that subjects may be more likely to complete T-WREX therapy in the clinic or at home, further research in which subjects are given an option of how much training to undergo is necessary to confirm this hypothesis. In addition, the survey tool we employed has not been independently tested for reliability, and any interpretation may be limited by the fact that it was completed after only a single crossover treatment session.

The results lead us to propose, however, that patients will prefer therapeutic modalities that incorporate functional causality,³⁰ quantitative feedback, and entertaining aspects into their design. We argue that rehabilitation technology and programs that incorporate these aspects may prove to be more effective in motivating patients to exercise. Furthermore, although current technologies and exercise programs incorporate some of these aspects, improvements could easily be made by drawing from the rich library of information, actuation, and movement detection technologies now available.

Comparison of T-WREX Training With Robotic Movement Training

The improvements achieved following therapy with the passive T-WREX device are consistent with various research studies previously published on actuated robotic upper extremity devices, which included a chronic stroke population with similar impairment levels ($AMFM \leq 40$) and comparable

duration of treatment.^{45,46} For example, an average gain of 3.7 Fugl-Meyer points was noted with MIT-MANUS training,⁴⁵ and 3.3 points with MIME training after 6 to 8 weeks of 1-hour training 3 times per week,⁴⁶ compared with the 3.3-point gain observed here with T-WREX training. Volpe et al⁴⁷ found similar improvements in upper extremity motor control using intensive robotic training (3.0-point AMFM gain) or a matched amount of therapist-mediated treatment (3.4-point AMFM gain). These findings are consistent with the concept that repetitive effort by the patient is a key stimulus to motor plasticity.^{48,49}

Future Technological Improvements

The present study revealed several possible ways to improve both therapeutic modalities studied here. Similar to other research,^{2,20} our subjects demonstrated difficulty translating increased motor skills to functional ADL. Resilient hand impairments appeared to be a main limiting factor, as hand movement is a critical precursor for functional arm use. The incorporation of more advanced hand, wrist, and forearm training may improve distal recovery and functional carryover, especially for individuals with moderate to severe hemiparesis who traditionally demonstrate smaller gains in function than those with more advanced movement skills.⁵⁰ Conventional therapy may further be improved by enhancing the functional causality, incorporating objective feedback, and improving its entertainment value to increase patient interest and the intensity of volitional movement practice. In addition, T-WREX efficacy may be improved by the addition of computer games that target a greater variety of movements, as well as a mechanism that limits the use of compensatory movement strategies.

Conclusion

The results of this study show that both conventional and T-WREX treatment can lead to modest gains in patients with moderate to severe weakness with less than 4 minutes of direct therapist contact per hour of therapy (following an initial training stage). Future research should examine what components and alterations of the T-WREX and conventional therapy may further enhance upper extremity movement and function.

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