Arm-Training with T-WREX After Chronic Stroke: Preliminary Results of a Randomized Controlled Trial

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Abstract— **This study presents preliminary results of a randomized controlled trial comparing a novel passive arm orthosis training system, the Therapy Wilmington Robotic Exoskeleton (T-WREX), with conventional self-directed upper extremity exercises. Chronic stroke survivors (n = 23) with moderate to severe upper limb hemiparesis trained three times per week for eight weeks with minimal supervision from an occupational therapist. Both groups demonstrated significant improvements in arm movement ability according to the Fugl-Meyer (3.7 point mean improvement in T-WREX group, p = 0.001, and 2.7 point improvement in control group, p = 0.003). Individuals who completed T-WREX training also demonstrated significant gains in self-rated quality of arm movement on the Motor Activity Log (p=0.05), and showed a trend towards greater gains on all clinical measures, although this trend was not significant at the current study size. Post-treatment surveys revealed a subjective preference for T-WREX training over conventional gravity-supported exercises. These preliminary results suggest that the T-WREX is a safe device feasible for clinical use, and effective in enhancing upper extremity motor recovery and patient motivation. Next steps are discussed.**

I. Introduction

RECOVERY of arm function after stroke is an important goal for stroke survivors and rehabilitation professionals. Over 80% of individuals who experience severe hemiparesis after stroke continue to have impaired arm or hand movement skills chronically [1]. Upper extremity hemiparesis inhibits successful completion of basic tasks and limits independence with self-care. In fact, more than one-quarter of individuals with stroke become dependent in activities of daily living (ADL) [2]. Daily activities involving bilateral arm or hand use, such as fastening buttons, zipping pants and opening containers are especially difficult for individuals with hemiparesis to complete. Patients with severe weakness experience difficulty raising the affected arm against gravity, and are challenged with basic activities such as feeding or grooming.

Stroke survivors typically receive intensive hands-on therapy for several weeks after stroke to treat hemiparesis and improve independence. Studies of repetitive task-specific training and constraint-induced movement therapy (CIMT) demonstrate positive effects of intense, therapist-guided rehabilitation [4], [5]. Unfortunately, such interventions are not applicable to all patients. Many therapeutic techniques such as CIMT exclude individuals with severe hemiparesis. These interventions require a baseline level of active wrist movement, and patients with severe movement impairments often do not meet the minimal motor criteria needed to participate [6].

In addition, the expense of therapy limits the application of direct, high-intensity, therapist-mediated rehabilitation. Direct training from an occupational or physical therapist is costly and third party payers have stringent guidelines determining the length of rehabilitation. Institution of the prospective payment system in the U.S. dramatically changed inpatient hospital lengths of stay (LOS) for acute rehabilitation after stroke. On average, the LOS for stroke survivors in physical medicine and rehabilitation units decreased approximately 54% (31.3 days to 14.5 days) after PPS reimbursement was instituted [7].

Research supports the continuation of intense therapy beyond inpatient rehabilitation [8], however, obtaining high-

Figure 1: T-WREX. The orthosis provides gradable support for the arm against gravity using elastic bands, and measures arm movement and hand grasp as the user interacts with computer simulations of functional activities.

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quality therapy after hospital discharge is a challenge for many patients. Many health care settings provide group therapy instead of individualized treatment, potentially resulting in less customized, less intense training. Some outpatients are discharged quickly due to reimbursement limitations, and receive only a written home exercise program to continue. This is intended to be self-directed, and provides little professional or quantitative feedback. Other patients, especially those in rural communities, have poor access to services and receive very little therapy follow-up after hospital discharge.

Some researchers propose the use of robotic devices in upper extremity rehabilitation to circumvent these challenges [10-14]. Potential benefits of robotics include: enabling intense and repetitive practice, providing quantitative feedback, and obtaining real-time data collection and analysis. In addition, many robots are capable of providing assistance and/or resistance similar to a hands-on techniques used by therapists. This may allow patients to practice movement training without a therapist continuously present. Robotic devices can also support the hands-on work of therapists. These devices are able to create unique and engaging environments which enhance patient motivation, as well as generate novel perturbations or manipulations which therapists might otherwise be unable to create [9].

Numerous robotic devices for hemiparetic upper extremity training have been developed, including the Massachusetts Institute of Technology (MIT)-MANUS [10], Mirror Image Motion Enabler (MIME) [11], Assisted Rehabilitation and Measurement (ARM) Guide [12], Bi-Manu-Track [13], GENTLE/S [14], and others. A systematic review of rehabilitation robotics suggests 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 [15]. Nonetheless, the economic benefit of robotics in rehabilitation requires further investigation, as the cost to benefit ratio of rehabilitation robotics has not been clearly defined.

In contrast to the actuated upper extremity robots described above, passive arm orthoses are less costly, enhance safety, and may be appropriate for home use. Passive devices have been used in rehabilitation for many years to assist with movement training and functional ADL. Those used most frequently include the mobile arm support, balanced forearm orthosis (BFO) and Rancho-JAECO multilink arm support [16]-[18]. Although passive orthoses offer significant benefits, there are disadvantages as well. Most have few degrees of freedom and restrict the patient's available workspace. Some devices are difficult to adjust and provide little ability to modify the amount of support for various levels of challenge. In addition, they provide little feedback regarding movement recovery.

To address these issues, we are developing a novel passive arm orthosis training system called the Therapy Wilmington Robotic Exoskeleton (T-WREX) [19](Figure 1). The T-WREX is designed to be a low-cost, passive training device that is easily adjustable, provides variable levels of support in a large 3D workspace, offers quantitative feedback, and enables semi-autonomous arm training. We previously described the initial design and pilot testing of the device with five chronic stroke patients [19]. This paper will provide an update on the device design, and describe preliminary results of an ongoing randomized controlled trial that is comparing motor training with T-WREX to conventional, self-directed motor training.

II. Methodology

A. T-WREX Hardware

The Therapy Wilmington Robotic Exoskeleton (T-WREX) is an antigravity arm orthosis designed to enable individuals with significant arm weakness to achieve intense movement training without the expense of a supervising therapist. It is a passive, five degrees-of-freedom, body-powered device that contains no robotic actuators. It provides a large 3D workspace, enabling naturalistic movement across approximately 66% of the normal workspace of the arm in the vertical plane and 72% in the horizontal plane [19]. It provides a sense of arm flotation in space by balancing the weight of the entire limb. The main structure consists of an arm exoskeleton comprised of two-links; a single link at the forearm and parallelogram-shaped link at the upper arm. Elastic bands are placed on the exoskeleton to achieve gravity-balance of the upper and lower arm at all positions in 3D space. Therapists can adjust the number of rubber bands to provide variable levels of arm support. The patient's arm is attached to the exoskeleton with a padded forearm trough. Once the arm is placed in the T-WREX, weak individuals can move their affected arm more easily due to the support provided against gravity.

The structural design of T-WREX is based on the Wilmington Robotic Exoskeleton (WREX) designed by Dr. Tariq Rahman. The WREX was created as an assistive device for children with neuromuscular weakness such as muscular dystrophy or arthrogryposis [20]. It is a functional gravity-balanced upper limb orthosis that assists children with tasks such as eating and writing. The WREX is currently produced and marketed through JAECO Orthopedic (Hot Springs, Arkansas).

The original WREX was modified at the University of California Irvine Biomechatronics Laboratory to create an adult-sized training device for stroke survivors, called the Therapy WREX (T-WREX). In addition to making the device larger, engineers made T-WREX more durable to resist the uncoordinated forces sometimes generated by adults with stroke. Instrumentation of the device was another important goal. Position sensors were added at each joint, and a custom grip sensor was designed for the hand. Compact rotary potentiometers (Midori America, CP-

2FB(b)) were chosen and are placed in protective aluminum housings at the shoulder, elbow, and forearm [21]. Using the forward kinematic transformation for the device [21], these sensors provide resolution of position measurement of the endpoint of the orthosis within ±0.38 cm. The custom grip sensor allows hand grasp and release activities to be incorporated into arm training. The handgrip contains a hydraulic bladder which detects pressures up to approximately 345 kN/m², with a resolution of about 2.0 kN/m², which is small enough to detect very weak grasp

B. T-WREX Software

Instrumentation of the T-WREX enables it to be used as an input device for computer game play with the hemiparetic arm. Games designed to mimic functional arm movements provide training in a simple virtual reality environment. Earlier versions of T-WREX utilized the web-based system "Java Therapy" 1.0 and 2.0 [22] for game play, however the software was updated as the study progressed. Java Therapy 1.0 required an active internet connection. This presented a problem for providing in-home therapy to patients without high bandwidth internet access or multiple phone lines. Versions 1.0 and 2.0 also lacked a high quality graphic interface. Therefore, a custom, upgraded software package named Vu Therapy was designed at the University of California Irvine. Vu Therapy can be uploaded and used on any computer with or without an active internet connection and contains upgraded graphics capabilities. The games are quantifiable with the T-WREX and were designed to be intuitive for patients with minimal cognitive or perceptual deficits to understand.

Patients can access the games easily through a desktop icon and log-in with a personal username and password. Once a user enters the game-play screen, he or she is prompted to play a pre-selected list of games chosen by the therapist. Therapists play an integral role in customizing the software to optimize the therapeutic benefit for each patient. During initial game setup, the therapist completes a process of software calibration to quantify the patient's current range of motion and active reaching abilities. After calibration is complete, the reaching targets of each game are automatically adjusted to the calibration parameters. Since the game targets correspond with patients' movement abilities, even individuals with very little strength can experience success with each task.

The therapist can also adjust the grip-strength threshold required for success in grasp and releasing tasks. Tasks can be modified to include grasp only, release only, or grasp and release. Clinicians can also choose the number of repetitions the patient must play each game, depending on the amount specific task practice recommended.

Vu Therapy games were developed with the goal of enabling repetitive task-specific practice. Tasks such as self-feeding, grocery shopping, cleaning a stovetop, driving, 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 functionally are able to practice meaningful arm movements in a simulated, gravity-reduced environment. Novel auditory and visual feedback is provided throughout game play to maintain the patient's attention. Users are also provided objective feedback of task performance at the end of each game to enhance motivation and awareness of progress. In addition, the patient and therapist can track progress over time with simple line-graph representations of average performance per day for each activity.

C. Brief Review of Previous Pilot Study

1) Subjects and Methods

A pilot study to test the feasibility of using the T-WREX as a training tool for individuals with chronic stroke was conducted at the University of California at Irvine [19]. Five chronic stroke survivors, average age of 60.2 years and 6.6 years post-stroke were enrolled. All subjects had moderate to severe arm and hand impairment, demonstrating a mean arm motor Fugl-Meyer score of 21.8 (± 8.0 SD). Participants trained with the T-WREX for 45 minutes, 3 times per week for 8 weeks. Subjects used Java Therapy 2.0 to complete approximately three repetitions of 7 different therapy games per session. The degree of gravity-balance compensation was systematically decreased through the two month therapy duration so the subjects were gradually training with greater effects of gravity acting on the arm.

2) Results

All five subjects demonstrated significant improvements in arm movement ability as measured by the Fugl-Meyer [23] score (one sided *t*-test, $p = 0.002$), with a mean improvement of 5 points (±1.87 SD). Subjects demonstrated the most significant improvements in shoulder movement as compared to elbow and hand Fugl-Meyer subscores. 61% of the Fugl-Meyer score improvements were noted in the shoulder and 38% at the elbow. No significant improvements were noted on the Rancho Functional Test [24], or Box and Blocks [25]. Grip strength significantly increased over the 24 treatment sessions for two of the five subjects (linear regression, $p < 0.05$). Three subjects demonstrated significant improvements in free-reaching away from the body with and without support, with a mean improvement of 9% (linear regression, $p < 0.05$). Subjects' blood pressure, heart rate and subjective report of pain were obtained pre and post training on each day of treatment without significant changes in any measure.

D. Ongoing Randomized Controlled Trial

Results of the pilot test indicated that an eight week protocol of T-WREX training can significantly improve arm movement for individuals with moderate to severe hemiparesis, but did not compare training with T-WREX to other therapy types. We therefore began a randomized controlled trial at the Rehabilitation Institute of Chicago Sensory Motor Performance Program with the goal of comparing training with T-WREX with a conventional, self-directed training program.

1) Subjects

To date, 29 subjects have been enrolled. Three subjects dropped out of the study for personal reasons; their data are not included. Inclusion criteria for this phase of the study consist of an incidence of stroke at least 6 months previously, the presence of moderate to severe hemiparesis defined by an Fugl-Meyer score of ≥ 10 and ≤ 30 on the 66 point arm motor section of the Fugl-Meyer assessment, and the ability to comply with the upper extremity training program. The mean time past stroke for the enrolled subjects is 8.8 years, ±9.2 SD. 73.1% of subjects have left hemiparesis, and 38.5% experience dominant UE hemiparesis. Average subject age is 56.9 years (±11.1 SD).

2) Methods

In this randomized controlled trial, the arm movement of subjects who participate in T-WREX training is compared with control subjects who exercise for the same duration and receive approximately the same amount of supervision from a therapist. All subjects participate in training three times per week for eight to nine weeks, for a total of 24 treatment sessions. Each training session lasts 1 hour and patients receive intermittent supervision from an occupational therapist. Within each session, the occupational therapist completes five minutes of passive range of motion stretches with the hemiparetic upper extremity and assists the subjects as needed with activity setup. Blood pressure readings and subjective pain ratings are also obtained by the therapist at the beginning and end of each session.

Subjects randomly assigned to the control group participate in conventional exercises that are commonly prescribed for individuals with moderate to severe upper limb hemiparesis. These exercises are the standard of care for home exercise programs and upper extremity therapy groups. Control participants are provided a handout containing written descriptions and photographs of each exercise or activity to be completed. Control exercises include self range of motion stretches as well as active strengthening exercises for the hemiparetic arm. During these activities, the hemiparetic upper extremity is supported against gravity by a tabletop, and a towel is placed under the arm to decrease friction during movement. Additional training activities consist of hemiparetic upper extremity weight bearing and incorporation of the affected arm as a functional assist during a prescribed list of basic ADL tasks.

Subjects in the experimental group participate in training with T-WREX as described above. Individuals complete approximately three repetitions of 10 therapy games available. Gravity-balance compensation is gradually decreased at set intervals over the 24 treatment sessions, however specific protocols for rubber band removal are based on patient abilities and therapist discretion.

3) Assessment Procedures

All subjects are tested before and after 24 treatment sessions and at a six month follow-up evaluation. A blind rater performs the following clinical assessments during all testing sessions: The arm motor section of the Fugl-Meyer [23] is administered to assess functional arm movement outside of synergy patterns. Speed and functional use of the arm during ADL is evaluated with the Rancho Functional Test for the Hemiplegic Upper Extremity [24]. The Motor Activity Log (MAL) [27] is a self-report measure used to determine quality and amount of affected arm use for ADL in the home. A characterization of free reaching is assessed using the Flock of Birds 3D electromagnetic motion capture system. Grip strength is tested using a Jamar dynamometer [26]. The duration of therapist time spent directly with subjects is recorded via stopwatch each training session.

To assess patient satisfaction with the arm training programs, subjects in the T-WREX and control groups complete a brief survey rating their impression of the therapy after the eight week training protocol and post-testing. In order to provide a subjective comparison between interventions, subjects cross-over to the alternate treatment group for one session and complete a survey comparing the original and cross-over treatment. Questions comparing the T-WREX and "tabletop" control exercises consist of a two category nominal scale. Subjects are 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?"

For brevity, we report here only the ongoing results for the Fugl-Meyer Score, Motor Activity Log, and satisfaction survey outcomes. Paired and non-paired t-tests are used to compare outcome measures with a significance level of 0.05.

III. RESULTS

The ongoing study we report on here is comparing two types of self-directed training for stroke survivors with moderate to severe upper extremity hemiparesis. Specifically, using quantitative measures and standardized clinical assessments of motor function, an eight week period of training with T-WREX is compared to a matched duration of exercises performed at tabletop without the device. 23 subjects have completed treatment and post-treatment evaluations to date. At baseline, no significant differences were found between groups in age, sex, months post-stroke or side of lesion. Only the Fugl-Meyer clinical assessment demonstrated significant differences between groups at baseline. Compared with the control group (n=12), subjects in the experimental group (n=11) had significantly higher scores on the arm motor section of the Fugl Meyer ($p=0.02$) (Fig. 2).

The duration of therapist time spent directly with subjects was recorded via stopwatch each training session. Subjects in the control group required an average 4.1 minutes of assistance (± 3.0 SD) from the occupational therapist to complete the 60 minute protocol. The greatest amount of assistance was generally required for setup and completion of the conventional weight-bearing activities. Subjects in the experimental group required an average of 4.1 minutes assistance (± 2.0 SD) for setup in the T-WREX. These numbers indicate direct supervision or assistance provided during training and do not account for therapist time spent

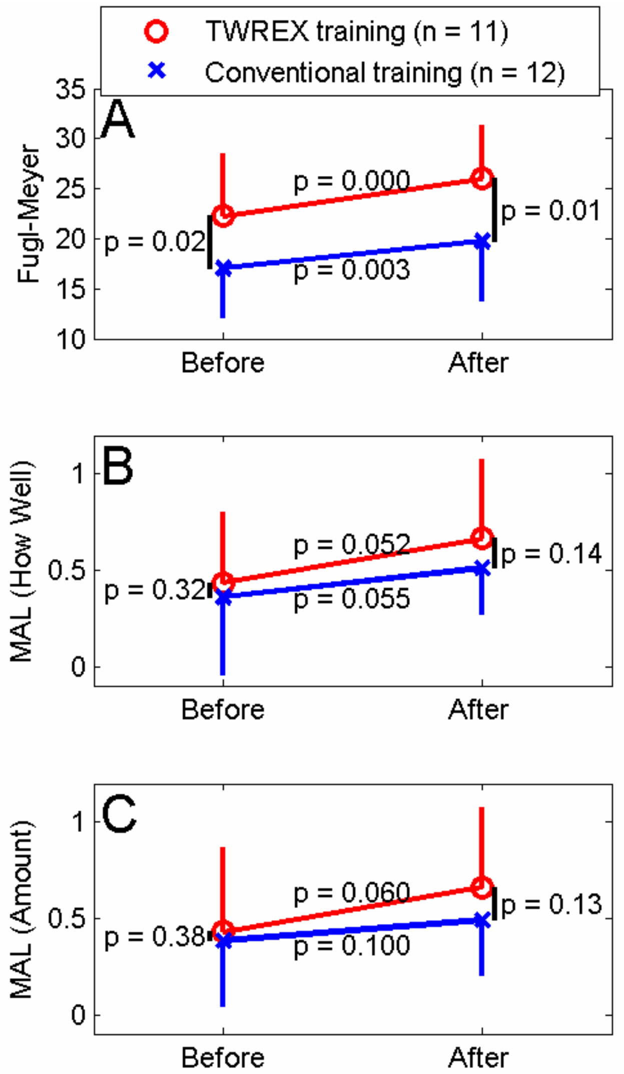

Figure 2: (A) Motor impairment (Fugl-Meyer) score, (B) Self-rated arm function score (Motor Activity Log, How Well Subscale), and (C) Self-rated frequency of arm use (MAL, Amount of Use Subscale) before and after training. The p values are for paired or non-paired t-tests as appropriate.

performing passive range of motion and obtaining blood pressure readings.

After two months of training with comparable levels of therapist supervision, both groups demonstrated significant improvements in Fugl-Meyer scores. Subjects who received T-WREX therapy increased an average of 3.7 points (±2.3 SD, p=0.001), while subjects in the control group exhibited an average gain of 2.7 points (±2.7 SD, p=0.003) [Fig. 2(a)]. Fig. 2(a) depicts a significant difference between groups at the conclusion of treatment (p=0.01). However, when differences in baseline scores are considered, the Fugl-Meyer change from pre to post-treatment is not significantly different between groups (p=0.18), even though subjects in the experimental group trended towards greater gains.

Subjects in the T-WREX group reported significant improvements (p=0.05) in the quality and/or skill of affected arm movement on the Motor Activity Log "How Well" subscale, with an mean improvement of 0.23 points (±0.4 SD) [Fig. 2(b)]. Control subjects reported an average gain of 0.15 points (±0.3 SD), which neared significance [p=0.06, Fig. 2(b)].

Subjects in both groups also reported increased use of the hemiparetic upper extremity on the Motor Activity Log "Amount of Use" subscale. Ratings for amount of arm use in the home are shown in Figure 2(c). The results neared significance (p=0.06) for those who received T-WREX training, with an average increase of .23 points (±0.4 SD). The control group demonstrated smaller gains of 1.1 points (±0.3 SD) that were not significant (p=0.1).

Results from the satisfaction survey issued to participants after eight weeks of T-WREX or control treatment and one cross-over training session revealed significant differences in the type of training subjects' preferred [Fig. 3]. 100% of subjects assigned to T-WREX treatment reported a preference for this type of training and would recommend T-WREX over conventional training. In addition, 100% of these subjects found the therapy less boring and easier to track their progress than conventional tabletop exercises. Control group participants also demonstrated strong preferences for T-WREX therapy, with 89% of controls finding the one-session sample of T-WREX exercises that they experienced less boring and more beneficial. An average of 73% of subjects from both groups also considered T-WREX more functional, and 80% reported an increased likelihood to complete this therapy in the home over conventional tabletop exercises.

No significant changes were noted in blood pressure readings or subjective pain ratings during treatment for either T-WREX or control groups.

IV. Discussion and Conclusion

These preliminary results from an ongoing study indicate that repetitive motor training with T-WREX can reduce motor impairment for chronic stroke survivors with moderate to severe upper extremity hemiparesis. Individuals in the T-WREX and control groups demonstrated significant improvements in arm movement ability according to the Fugl-Meyer scale. Subjects in both groups reported nearly significant gains on the Motor Activity Log in quality and amount of affected arm use in the home setting. Although statistical significance was not achieved with the current sample size, individuals participating in T-WREX training trended towards higher scores on all clinical measures when compared to the control group.

These improvements are noteworthy considering that individuals with severe upper limb hemiparesis often have poorer outcomes following rehabilitation compared to those with greater movement ability [28]. Patients with severe motor impairment are often more challenging for clinicians to engage in preferred training methods due to their lack of active movement. T-WREX enables individuals with severe movement impairments to practice intense, repetitive, simulated task practice. Such practice reduces motor impairment and improves motor function.

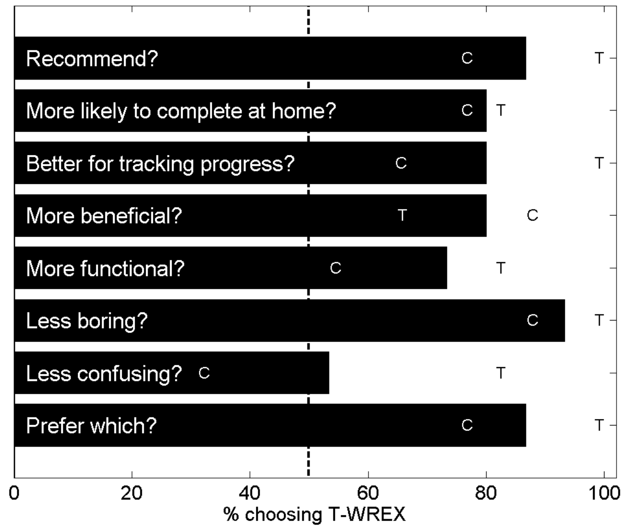

Figure 3: Percentage of subjects reporting subjective preference for T-WREX over tabletop training on a post-treatment survey. Subjects in T-WREX and control groups experienced one cross-over training session with the other protocol, then rated treatment preferences in several categories. The bars show the mean across all subjects, while the "T" and "C" letters show the responses from subjects who experienced T-WREX and conventional (i.e. tabletop) training as their primary therapy protocol broken out as individual groups.

This study also suggests that use of the T-WREX to retrain arm movement is safe and appropriate for use in a clinic setting with minimal therapist supervision. Stroke survivors were able to don and doff the T-WREX orthosis with minimal assistance and/or cueing. After three days of initial training from an occupational therapist, subjects required an average of only 4.1 minutes supervision or assistance to complete the therapy setup. Subjects also responded well to the auditory and visual feedback provided to maintain motivation and awareness of progress.

Limitations of this study include a small sample size, as only 23 subjects have completed pre and post-testing to date. We continue to actively enroll subjects in order to improve the study power. In addition, T-WREX therapy was only compared to one specific type of control therapy. The control exercises represent the standard of care for home exercise programs and group therapy sessions, however the protocol cannot account for all possible varieties of conventional exercises prescribed for individuals with severe upper extremity hemiparesis. In other words, there may be other self-directed, conventional therapy programs that could be more effective than the one studied here.

Improvements in upper extremity motor control noted in the current study, as gauged by the Fugl Meyer score, are similar to those demonstrated with other devices such as the MIT-MANUS and MIME [10, 12], which contain robotic actuators. This suggests that intense patient effort as opposed to robotic forces acting on the arm can induce similar motor recovery. The gains demonstrated by control subjects in this project and a separate study [30] who practiced repeated arm movements without robotic assistance support this hypothesis. If passive methods offer comparable results to sophisticated robotic designs, passive interventions may be preferred due to increased safety, affordability, and potential for home use.

Patient compliance with treatment is an important factor which may have considerable impact on functional outcomes. The specific control protocol in this study was chosen because it represented in our opinion the best standard of care in upper extremity exercises that did not require technology or continuous therapist presence. Both the T-WREX and control training techniques offered passive gravity support (i.e. the tabletop for the control group). However, the control exercises used here lack objective feedback and provide little motivation to continue attending to the treatment. The intermittent supervision provided to subjects in this study may have encouraged proper completion of treatment tasks. However, patients predicted a decreased likelihood to complete control exercises in the home compared to exercises with T-WREX. If patients found the control exercises boring and lacking motivation, there is a high likelihood that they would not practice them in an unsupervised setting. All subjects significantly preferred training with T-WREX, in large part because of the interactive nature of the therapy games. We conclude, therefore, that even if the therapeutic benefits of the device are not substantially greater than conventional self-directed training, the device has potential to improve patient motivation and compliance with treatment for a longer duration than control exercises. An interesting question is whether conventional table-top exercises could be connected to motivating software, thereby also improving patient motivation without the need for an orthosis.

Future research and development directions are as follows. In order to further improve patient attention to T-WREX training, additional Vu Therapy games will be developed that provide greater variety and novelty of game selection. Games will be designed to promote normalized movement patterns and target specific areas of upper extremity weakness, especially those that are difficult for patients to achieve without external support. Improved software calibration that relates the patient's active range of motion in T-WREX to the cursor movement required for the games is another important next step that will further improve the interface between movement attempts and successful game completion. 33% of subjects who completed control exercises reported the tabletop exercises as "less confusing" on the post-treatment survey [Fig. 3]. Although this is likely due to the limited time spent orienting these subjects to the T-WREX games, as controls received only one T-WREX training session, the response may be attributed in part to imperfect software calibration. We will improve calibration so the games become even more intuitive and correspond directly with patients' intended arm movement.

Potential improvements for the T-WREX hardware design include assisting finger flexion and extension, enabling forearm supination and pronation, and allowing greater range of motion in shoulder external rotation. We also intend to design a docking station that allows patients to independently don and doff the T-WREX orthosis in order to make T-WREX usable for telerehabilitation in patients' homes.

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