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Scientific/Clinical Article

## Chronic stroke survivors achieve comparable outcomes following virtual task specific repetitive training guided by a wearable robotic orthosis (UL-EX07) and actual task specific repetitive training guided by a physical therapist

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### ABSTRACT

Survivors post stroke commonly have upper limb impairments. Patients can drive neural reorganization, brain recovery and return of function with task specific repetitive training (TSRT). Fifteen community independent stroke survivors (25–75 years, >6 months post stroke, Upper Limb Fugl Meyer [ULFM] scores 16–39) participated in this randomized feasibility study to compare outcomes of upper limb TSRT guided by a *robotic orthosis (bilateral or unilateral)* or a *physical therapist*. After 6 weeks of training (18 h), across all subjects, there were significant improvements in depression, flexibility, strength, tone, pain and voluntary movement (ULFM) ( $p < 0.05$ ; effect sizes 0.49–3.53). Each training group significantly improved ULFM scores and range of motion without significant group differences. Virtual or actual TSRT performed with a *robotic orthosis* or a *physical therapist* significantly reduced arm impairments around the shoulder and elbow without significant gains in fine motor hand control, activities of daily living or independence.

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### Introduction

There are approximately 795,000 new stroke survivors each year.<sup>1,2</sup> While major advances have been made in early intervention for the treatment of patients post cerebrovascular accident (CVA), the majority of survivors have residual impairments, mobility and disability challenges.<sup>2,3</sup> In the United States, the total cost of medical therapy and lost productivity for patients post stroke is estimated at \$38.6 billion per year.<sup>1</sup>

Early recovery post stroke is based on timely and effective medical management along with spontaneous healing/repair.<sup>4</sup> Recovery in the chronic phase post stroke is based on neural adaptation, emphasizing forced use and progressive task specific repetitive training (TSRT) based on the principles of neuroplasticity.<sup>4–17</sup> Given the expense associated with “one-on-one” training with

a professional therapist and the time required for intense repetitive practice, integrating technology and rehabilitative robotics may conserve manpower, maximize progressive repetitions improve outcome measurements and potentially reduce costs.<sup>18–27</sup> One question is whether stroke survivors can tolerate intense training with a wearable upper limb robotic orthosis (splint). Another question is whether outcomes are comparable when practice occurs in a virtual task practice situation with the assistance of a robotic orthosis,<sup>28–31</sup> compared to actual task practice with a physical therapist. A third question is whether the gains are similar when virtual task specific robotic training involves unilateral versus bilateral training.

The primary aim of this randomized feasibility trial was to determine if survivors more than 6 months post stroke could safely engage in intense virtual TSRT with the UL-EX07 robotic orthosis (90 min sessions, twice a week for 6 weeks). The second aim was to determine if actual TSRT guided by a therapist or virtual TSRT guided by the UL-EX07 robotic orthosis would significantly reduce impairments and enhance function of chronic stroke survivors. The third aim was to determine if post–pre test gains would be similar

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when actual task specific practice was guided by a physical therapist (PT) compared to virtual task specific practice guided by a robotic orthosis (RO). Fourth, the aim was to evaluate if gains were similar when virtual task specific practice was guided by unilateral versus bilateral robotic training with the UL-EX07.

We expected stroke survivors to safely train for 18 h over 6 weeks with the UL-EX07. For community independent survivors, chronic post stroke, we expected 6 weeks (2×/week) of actual or virtual TSRT guided by either a therapist or the UL-EX07 robotic orthosis to increase voluntary movements and reduce impairments, but not necessarily improve fine motor hand control, activities of daily living nor independence. We expected similar post–pre test gains for the stroke survivors training on actual TSRT with a physical therapist or virtual TSRT with the UL-EX07 robotic orthosis. Finally we expected the post–pre test gains to be similar when virtual TSRT involved unilateral or bilateral training with the UL-EX07 robotic orthosis. This study is unique because it is the first controlled clinical trial using a dynamic, wearable UL-EX07 orthosis. With 7 degrees of freedom, the UL-EX07 matches the DOF of a healthy subject and provides access to 95% of normal movement of the human arm. In addition, the UL-EX07 orthosis is easily adjusted to individuals of different weight and height, programmable for unilateral or bilateral training (right of left) and has the potential to be integrated with virtual TSRT or actual TSRT.

## Methods

### Subjects

Male and female individuals between 25 and 75 years of age, greater than 6 months post right or left hemispheric stroke (ischemic or hemorrhagic) were eligible to participate in the study. Subjects had to independent in self care (Stroke Impact Scale scored >50%),<sup>32,33</sup> independent in the community (California Functional Independence Scale [CAFE 40>60%]),<sup>34</sup> with minimal to moderate voluntary function in the affected upper limb (Upper Limb Fugl Meyer [ULFM] score 16–39).<sup>35,36</sup> Subjects needed to be able to communicate in English or come with an interpreter and be able to participate in training sessions at the University of California, San Francisco twice a week for 6 weeks. A subject was excluded if he/she suffered from a neurological disease other than a stroke, had a physically disabling condition related to systemic disease, organ or joint replacement, was severely depressed (Beck Depression Inventory >14),<sup>37</sup> had severe pain (>8 on a scale of 0–10), was not mentally alert (<18 on the VA Mental Status Exam [SLUMS]),<sup>38</sup> or had a skin condition on the hemi-paretic limb which might interfere with wearing the UL-EX07 robotic orthosis during training. All subjects provided signed consent prior to participating in the baseline clinical evaluation. This study was approved by the Committee on Human Research University of California, San Francisco.

Subjects were stratified by severity of impairment based on the ULFM score (low 16–19, moderate 20–29, and high 30–39) and then randomly assigned to one of three intervention groups: actual TSRT working with a physical therapist (PT), virtual TSRT guided by the UL-EX07 used bilaterally (BRO) or virtual TSRT guided by the UL-EX07 used unilaterally (URO) (see Fig. 1). At home, all subjects were encouraged to use the hemi-paretic arm as much as possible in functional tasks and to continue exercises and community activities as previously instructed.

### Training

**Equipment: UL-EX07 robotic orthosis.** The UL-EX07 rehabilitation training system is a novel rehabilitation robotic orthosis composed of three major subsystems: the exoskeleton robot, control

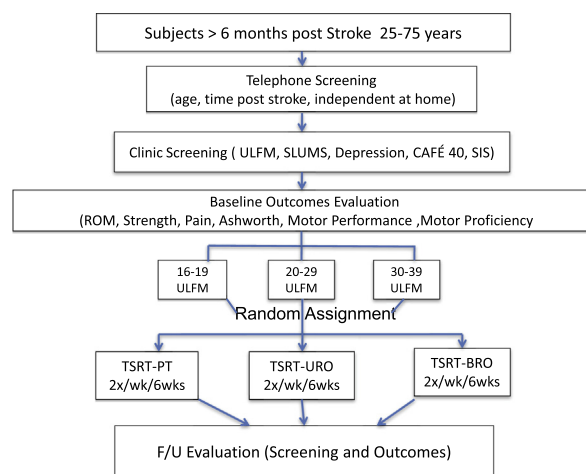


Fig. 1. Flow chart for study.

algorithms and virtual reality video games that interact with UL-EX07.<sup>39–41</sup> The UL-EX07 has 7° of freedom (DOF) that correspond to the DOF of the human arm. It has seven single-axis revolute joints to provide a workspace that overlaps 95% of a healthy human arm workspace and accommodates the range of motion for the flexibility needed to perform daily self care activities (see Fig. 2). Three joints are responsible for shoulder abduction–adduction, flexion–extension and internal–external rotation. A single rotational joint at the elbow allows for elbow flexion–extension. Finally, the lower arm is connected by a three-axis joint resulting in wrist pronation–supination, flexion–extension, and radial–ulnar deviation. There is no hand component. The human–machine interface (HMI) is integrated with four separate, six-axis force/torque sensors attached to the upper arm, the lower arm, the hand grip and at the tip of the exoskeleton, measurements of the interaction forces and torques between the operator and the robotic system to facilitate the admittance control algorithm. The gravity compensation algorithm was used in all the modes of operation rendering the system as weightless from the operator perspective.<sup>40–41</sup>

This robotic orthosis also has low-friction joints to enable smooth movements and it un-weights the arm with gravity compensation.<sup>39,42</sup> During unilateral training, the subject is forced to use voluntary movements when interacting with the virtual task specific training. In unilateral training, the UL-EX07 orthosis provides partial reaching assistance for the subject during one of the 8 training games, Flower (Table 1). Two types of force fields



Fig. 2. Robotic orthosis: UL-EX07 exoskeleton (robotic orthosis).

**Table 1**

Virtual task-oriented repetitive game training wearing the UL-EX07 robotic orthotic

Game	Space dimension (2D or 3D)	Static dynamics	Diagnostic (D) or training (T)	Description of task	Goal of game	Un-weighting (U) and assistance (A)
Flower <sup>a</sup>	3D	S	D	Voluntary reaching to targets distributed in a 3D space starting for a reference position while moving along a straight line including intermediate targets along the way. The goal is to reach all of the intermediate and final targets.	Voluntary abduction, external rotation	U and A
Joints <sup>b</sup>	1D	S	D	Measure the range of motion of each individual joint (shoulder, elbow, wrist) including rotation, fixation/extension, abduction/adduction, pronation/supination (shoulder, elbow, wrist).	Measurement only	U
Paint <sup>c</sup>	3D	S	D	Voluntary reach and explore a 3D curved surface. Reaching locations on the surface are traced by changing their color. The goals are to virtually paint the entire surface.	Voluntary abduction, external rotation	U
Reach	3D	S	D	Voluntary reach exploring a 2D surface. The goal is similar to the paint game in a 2D space.	Reaching out in front, shoulder flexion	U
Pong <sup>d</sup>	1D	S	T	Voluntary motion of the end effector left/right along a straight line while moving a paddle with the goal of engaging a ball moving in a 2D place.	Shoulder external rotation	U
Pinball <sup>e</sup>	1D	D	T	Voluntary wrist flexion/extension with the goal of controlling flippers of a pinball game while hitting a ball up along an inclined surface.	Wrist extension and flexion	U
Circle <sup>f</sup>	2D	D	T	Voluntary motion of the end effector in a circular motion with a similar goal of the Pong game. Hand rotation (like stirring paint). It maps wrist circumduction to a paddle constrained to the edge of a cylinder.	Wrist circumduction	U
Hand Ball		D	T	Voluntary reach motion in a 3D space aiming to hit a virtual ball that is bounced from five surfaces (enclosed room)	Elbow flexion and extension	U

<sup>a</sup> The Flower game provided partial assistance if needed.<sup>b</sup> Subjects played the “joint” game. However, the joint game was really a diagnostic measurement for range of motion so it is not described in detail.<sup>c</sup> For each set, touch center ball with the ball fixed at finger tips. Next touch the furthest balls, and then return to the center ball. There are 11 different ball orientation sets. Touch as many balls as possible along a semi-spherical set of balls. Balls change from green to red when touched. Touch as many balls as possible. Balls fall to the floor when touched.<sup>d</sup> A paddle moves left and right to deflect a moving ball against a computer opponent.<sup>e</sup> Actuate a left and right paddle in a conventional game of pinball. Similar to pong except the ball is constrained to the surface of a cylinder. Subjects bounce the ball off of the distal wall.<sup>f</sup> Subjects bounce a ball off of a distal wall in a 3D environment.

were introduced as an assistive mode: (a) attracting force fields pulling the handle towards the target location and; (b) trajectory shaping force fields pushing the hand toward a straight line trajectory if the subject deviated from it or if the subject moved the arm in a direction inconsistent with the directional movement programmed into the Flower game.

For bilateral movement training, the intact limb assists the paretic limb. To support this mechanism, the desired joint angles are transmitted from the intact limb (Master) to the paretic limb (Slave) utilizing a tele-operation control scheme. The difference in joint angles between the master and slave is fed into the controller to create the joint torque on the slave side. The joint torque on the slave side is controlled and limited to prevent excessive, forced master-initiated movements.

The exoskeleton of the robotic orthosis is mounted on an external frame which is adjusted to fit subjects of various heights and weights.<sup>39,40,42</sup> The orthosis is moved up or down to align the orthotic shoulder joint and left or right to adjust for various distances between the shoulder joint and the orthosis. The remaining joints are adjusted for each subject at the elbow and wrist.

**Virtual TSRT sessions.** Each virtual TSRT training session included a motor control evaluation task where kinematic data were gathered from the embedded sensors within the robotic orthosis and an exercise/treatment component where subjects performed repetitive movements while playing virtual task specific games. The consistency of the kinematic measurements along with the correlation of kinematic measurements with some selected clinical measurements have been reported by Kim et al.<sup>40</sup>

The research assistant stabilized the subject in a standard chair with elastic trunk supports and ranged the arm with slow, gentle pain free movement prior to donning the robotic orthosis. The subject placed the hemi-paretic arm into the exoskeleton with the hand positioned on a handle. If the subject could not grip the fingers around the handle, the hand was stabilized with an elastic wrap. For bilateral training, the less affected limb was placed into the exoskeleton following the same procedures as the hemi-paretic limb. The research assistant recorded the subject's activities during training. All participants interacted with the robotic orthosis for approximately 90 min per session (12 sessions; 18 h) with @ 5 min devoted to subject set up.

A total of eight virtual task specific games (Table 1) were used for repetitive training with the robotic orthosis.<sup>41</sup> In some virtual tasks, the object is static requiring the subject to reach for fixed targets positioned at various heights and widths. In other virtual tasks, the target is dynamic (moving) and the subject tries to interact with target or follow the target. The virtual tasks require multi joint, mid range motions at the shoulder, elbow and wrist but not the hand. The game tasks vary in terms of difficulty and can be adjusted to match subject ability but, the tasks do not increase in difficulty. The screen displays successful performance or the engineer verbally informs subjects about previous performance levels.

**Actual task specific training supervised by the physical therapist.** Subjects training with a licensed physical therapist (PT group) were scheduled for a 90 min appointment. Training was based on the principles of neuroplasticity, using learning-based, task-oriented, repetitive training to drive improved function.<sup>7,10,11</sup> The

intervention was adapted to subject ability, focusing on the hemiparetic upper limb while facilitating trunk balance and postural alignment during functional arm movements. Tasks were primarily unilateral except when the less affected hand was needed to stabilize an object while the hemi-paretic limb performed the task. The therapist encouraged each subject to work in a variety of positions (supine, sitting and standing) to practice voluntary movements without increasing tone. Task practice involved reaching, grasping, object manipulation and self care activities. Dynamic orthoses were not included in training. Of the 90 min, with @ 5 min needed to handle the objects and preparation for task training.

**Baseline and follow up clinical measurements.** The ULFM, Beck Depression Inventory, VA Mental Status Examination (SLUMS), Stroke Impact Scale and Functional Independence (CAFÉ 40) were administered to determine subject eligibility for the study. These screening variables were remeasured after training. The remaining dependent variables were measured immediately before and after training. Active range of motion (ROM) was recorded in degrees following standard range of motion measurements using a plastic goniometer.<sup>43</sup> Measurements were taken for shoulder flexion, abduction, internal rotation and external rotation, elbow flexion and extension and wrist extension and flexion. All range measurements ( $n = 8$ ) were summed to create a total ROM Score for each upper limb. Strength was measured in pounds of force following standard procedures for manual muscle testing<sup>44</sup> and handheld dynamometers (Microfet<sup>45</sup> and Jamar<sup>46</sup>). Shoulder flexion, abduction, external rotation and internal rotation, elbow flexion and extension, wrist flexion and extension and grip strength were measured (pounds). The strength measurements for all the muscle groups ( $n = 9$ ) were summed to create a Total Strength Score for each upper limb.

Each subject self-rated pain in the hemi-paretic limb using an ordinal scale (0–10) as an item on the CAFÉ 40 Functional Independence Test.<sup>34</sup> Fine motor control was measured in terms of skill and speed. Motor skill was based on the results of the Box and Block Test<sup>47</sup> and the Tapper Test.<sup>48</sup> The two scores were added to create a Motor Skill Performance Score. To estimate motor speed, each subject completed the short form of the Wolf Motor Function Test<sup>49</sup> (with the time averaged across tasks and reported in seconds) and the Digital Reaction Time Test (with performance time averaged

across each digit and reported in seconds [milliseconds  $\times$  100]).<sup>50</sup> The two scores were added to create the Motor Proficiency Speed Score. The Modified Ashworth Test<sup>51</sup> was administered to evaluate tone.

#### Research design and data analysis

This was a small, single, blind, randomized clinical feasibility study with 3 treatment groups (See Fig. 1). The evaluator was blinded to group assignment. Tests were scored, coded, entered into data files and checked for accuracy by a second research assistant. The dependent variables were considered independent families. The primary outcomes variables included the post–pre test gain scores for the hemi-paretic limb. To control for the Hawthorne effect, post–pre test measurements were taken on the less affected side.

Across all subjects and by group, the dependent variables were described by mean, standard deviation, post–pre test change (%) scores and effect size. Correlations between the baseline ULFM score and change scores for all the dependent variables were determined using the Pearson Correlation Coefficient. Spider graphs were used to visualize similarities and differences of change scores between the groups.

Across all subjects ( $N = 15$ ), the Student  $t$  test was applied to each dependent variable to determine the significance of the pre–post test change scores ( $p < 0.05$ ). Following the omnibus test, five post hoc contrasts were planned. Based on the small number of subjects in each group, nonparametric tests were applied to analyze statistical significance by group (Paired Wilcoxon;  $p < 0.01$ ) and between groups (Mann Whitney  $U$ ;  $p < 0.01$ ).<sup>52,53</sup> The formula for Cohen's  $d$  was used to calculate the effect size.<sup>54</sup>

## Results

### Subjects

Eighteen eligible subjects initially consented to participate in this study. Three subjects did not participate. Fifteen subjects safely completed the study without adverse events. Thirteen completed all 12 training sessions and two subjects missed 1–3 sessions. All of the subjects in the TSRT–PT group came to all 12 training sessions.

**Table 2**  
Description of subjects

	Gender	Age	Onset of CVA (years post stroke)	Side of hemiplegia	Medications	Fugl Meyer score (baseline)	Degree of CVA
Group 1 (physical therapy)							
Subject 4	2	62	2002 (10)	Left	2	19	Severe
Subject 7	1	68	2000 (12)	Right	2	33	Mild
Subject 9	1	71	2008 (4)	Left	2	31	Mild
Subject 12	1	34	2008 (4)	Right	0	20	Moderate
Subject 14	1	62	2010 (2)	Right	2	20	Moderate
Mean (SD)		59.3 (6.8)	6.4 (4.4)			24.6 (6.8)	
Group 2 (unilateral)							
Subject 1	1	76	1999 (13)	Right	9	36	Mild
Subject 2	2	61	1996 (16)	Right	1	19	Severe
Subject 3	1	44	2008 (4)	Right	4	18	Severe
Subject 8	1	24	2006 (8)	Left	1	19	Severe
Subject 13	1	66	2000 (12)	Left	2	27	Moderate
Mean (SF)		54.2 (20.5)	10.2 (5.0)			23.8 (7.7)	
Group 3 (bilateral)							
Subject 5	1	66	2003 (9)	Right	3	16	Severe
Subject 6	1	58	2001 (11)	Right	1	29	Mild
Subject 10	1	72	1999 (13)	Right	9	28	Mild
Subject 11	1	62	2005 (7)	Left	1	23	Moderate
Subject 15	1	68	2010 (2)	Right	2	26	Moderate
Mean (SD)		65.2 (5.4)	8.4 (4.2)			24.4 (5.2)	



**Table 3**Summary of pre post outcome score across the affected side across all subjects ( $N = 15$ )

Dependent variables	Pre mean (SD)	Post mean (SD)	Mean difference (SD)	% Difference score	$n$ trials	Effect size	Critical $t$ value	Significance
Function/impairments								
Range of motion (degrees) +	663.0 (88.98)	729.0 (92.83)	65.9 (53.93)	+9.9	120	+2.46	13.4	<0.001
Strength (lbs) +	112.5 (44.21)	131.8 (49.02)	19.3 (64.36)	+20.5	105	+0.61	3.12	<0.001
Pain (score) –	3.4 (2.46)	2.3 (1.71)	1.2 (2.15)	–34.1	15	–0.49	2.13	<0.05
Ashworth (score) –	9.5 (3.02)	6.1 (2.34)	3.5 (3.52)	–36.4	40	–0.78	7.71	<0.001
Depression: Beck Scale –	8.9 (7.19)	7.7 (8.50)	–1.2 (6.85)	–13.5	15	–1.73	–3.24	<0.05
Motor performance								
Motor skill +								
Box and block	6.3 (7.92)	8.2 (8.64)	1.9 (0.71)	+30.2	15			
Finger tapper	5.9 (5.59)	5.6 (7.68)	0.3 (2.08)	–5.1	15			
Box and block + tapper	10.65 (6.76)	13.84 (8.26)	3.19 (12.01)	+29.9	30	+0.54	+1.46	NS
Motor speed –								
Wolf motor function	69.4 (42.85)	73.7 (44.76)	4.1 (1.91)	+5.9	15			
Digital reaction time	119.1 (62.50)	115.4 (65.79)	–3.7 (3.28)	–2.9	15			
Wolf motor + digital reaction	191.1 (94.7)	182.6 (95.69)	–9.5 (71.25)	–4.8	30	–0.03	–0.07	NS
Voluntary motor control – FM	24.3 (6.18)	28.9 (7.73)	+4.6 (2.72)	+18.9	15	+3.53	+6.6	<0.001
Mental status: SLUMS +	24.1 (4.16)	23.6 (5.57)	–0.5 (3.94)	–2.20	15	–0.28	–0.52	NS
Independence and self care+								
CAFÉ 40	72.2 (16.59)	74.1 (16.93)	+1.9 (0.33)	+2.60	15			
Self care: SIS	57.4 (14.49)	58.2 (15.39)	+0.9 (0.91)	+1.50	15			
CAFÉ 40 and SIS	129.4 (28.57)	132.3 (30.11)	+2.8 (9.82)	+2.16	30	+0.41	1.10	NS

+Increasing score positive gains. –Decreasing score positive gains. Cohen's  $d$  computer calculator for effect size. Rosenthal  $R$  Meta analysis Procedures for Social Research 1991, Sage Publishing, Newburg, Park, CA.

There were twelve male and three female subjects, between 25 and 75 years of age, 2–16 years post stroke (see Table 2). By group, there were baseline variations by age and time post stroke, but the differences were not statistically significant. Ten subjects had a right hemi-paresis.

#### Change in impairments and function: across subjects

Table 3 summarizes the post–pre test gain scores on the dependent variables for the hemi-paretic side for all subjects. The subjects made significant gains ( $p < 0.05$ ) in voluntary movement and reduction of impairments. The ULFM score increased an average of 4.5 points (18.9%; 3.53 effect size), Range of Motion (9.9%; 2.46 effect size), Strength (20.5%; 0.61 effect size), Pain (–34.1%; –0.49 effect size), Ashworth Score (tone) (–36.4%; –0.78 effect size) and Beck Depression Inventory (–13.5%; –3.24 effect size). Motor Performance Skill, Motor Proficiency Speed, Self Care-Independence were maintained at baseline levels.

Table 4 summarizes the correlation between the baseline ULFM scores and gains on the other dependent variables. There was a significant correlation ( $p < 0.01$ ) between the baseline ULFM score and gains in ROM ( $r = 0.554$ ) and Motor Performance Skill ( $r = 0.651$ ). The initial score on the ULFM explained 30.7% of the gains in ROM and 42.4% of the gains in Motor Performance Skill.

**Table 4**

Summary of the correlation coefficients of baseline Upper Limb Fugl Meyer score and change in the outcomes variables

Outcome variables	$R$
Range of motion	0.554 <sup>a</sup>
Strength	0.023
Pain	–0.117
Ashworth	–0.266
CAFÉ 40 + SIS	0.142
Beck Depression	0.066
SLUMS	–0.011
Motor efficiency – speed	–0.277
Motor performance – skill	0.651 <sup>b</sup>

<sup>a</sup> Fugl Meyer explains 30% of the variance in the change in range of motion.

<sup>b</sup> Fugl Meyer explains 69.4% of the variance in the change in motor performance.

#### Change in dependent variables by and between groups

Table 5 summarizes the change in the post–pre test measurements of the dependent variables by group. Each group made significant gains ( $T = 15$ ;  $p < 0.01$ ) with moderate effect sizes on the ULFM (0.51–0.93) and Total ROM (0.66–0.78). There were no other significant gains by individual group. There was a large effect size for strength for the TSRT–BRO group (1.29) but the variation was large and the difference was not statistically significant. There were no statistically significant pair-wise differences between the groups (Table 6).

Figs. 3–5 illustrate the mean change scores for all of the dependent variables by group. There were several interesting trends. Compared to the robotic groups, the TSRT–PT group made slightly greater gains on the ULFM (0.93 effect size), Motor Performance Skill (0.25 effect size), and Self Care-Independence (0.22 effect size). The TSRT–URO group and the TSRT–PT group had the greatest reduction on the Ashworth Test (tone) (–0.22 and –0.24) and the TSRT–URO group had the greatest gains in Motor Proficiency Speed (–0.10). The TSRT–BRO group had the greatest reduction on the Beck Depression Inventory (–0.26 effect size) and the greatest gains in Strength (1.29 effect size). None of these trends were statistically significant. By joint, all three groups made the greatest gains in ROM and Strength at the shoulder.

#### Descriptive analysis of outcomes on the less affected side

Bilateral measurements were taken for ROM, Strength and Motor Proficiency Speed. At baseline, the subjects had greater flexibility, muscle strength and speed of movement on the less affected side compared to the hemi-paretic side. After training there were minimal, non-significant gains in performance on the less affected side (Table 6).

#### Discussion

This feasibility study confirmed our expectations. Mentally alert, community independent stroke survivors with minimum to moderate arm function, up to 16 years post stroke, safely completed 6 weeks of intense virtual task specific practice guided by a robotic

**Table 5**

Summary of pre and post outcome scores, change scores and effect sizes by training group

Dependent variables outcomes/impairments	Pre (SD)	Post (SD)	Mean difference (SD)	Effect size	Significance ( $T \geq 15$ ) <sup>a</sup>
Range of motion (degrees)					
Physical therapy	666.0 (126.86)	750.8 (129.37)	89.8 (70.77)	+0.67	$T \geq 15$
Unilateral	686.0 (76.76)	733.0 (65.54)	47.0 (42.66)	+0.66	$T \geq 15$
Bilateral	642.2 (67.24)	703.2 (87.66)	61.0 (46.51)	+0.78	$T \geq 15$
Strength (pounds)					
Physical therapy	87.8 (47.58)	104.3 (47.06)	17.5 (14.84)	+0.35	NS
Unilateral	148.5 (43.75)	148.1 (53.32)	-0.4 (14.84)	-0.008	NS
Bilateral	102.1 (8.91)	143.0 (43.80)	40.9 (43.45)	+1.29	NS
Pain (score)					
Physical therapy	3.9 (2.97)	2.6 (1.82)	-1.3 (1.90)	-0.53	NS
Unilateral	3.2 (2.28)	2.8 (2.00)	-0.4 (1.55)	-0.19	NS
Bilateral	3.2 (2.59)	1.4 (1.14)	-1.8 (3.0)	-0.90	NS
Ashworth (score)					
Physical therapy	9.2 (3.10)	6.2 (17.50)	-3.0 (3.20)	-0.24	NS
Unilateral	9.8 (27.70)	5.0 (14.10)	-4.8 (4.80)	-0.22	NS
Bilateral	9.6 (27.20)	7.0 (19.80)	-2.6 (2.60)	-0.11	NS
Motor efficiency speed (s)					
Physical therapy	238.3 (108.25)	241.1 (111.38)	2.8 (37.73)	+0.03	NS
Unilateral	178.7 (79.03)	169.8 (95.31)	-8.9 (108.02)	-0.10	NS
Bilateral	159.5 (95.98)	156.3 (83.55)	-3.2 (25.58)	-0.04	NS
Motor performance skill					
Physical therapy	6.5 (7.30)	9.1 (12.69)	2.6 (5.92)	+0.25	NS
Unilateral	11.8 (11.55)	13.4 (16.82)	1.6 (8.97)	+0.11	NS
Bilateral	18.2 (12.52)	18.9 (18.12)	0.8 (9.97)	+0.05	NS
<b>Dependent variables applied to screening for study eligibility<sup>b</sup></b>					
Upper Limb Fugl Meyer (score)					
Physical therapy	24.6 (6.8)	30.6 (6.92)	6.0 (4.12)	+0.93	$T \geq 15$
Unilateral	23.8 (7.73)	27.8 (7.92)	4.0 (0.19)	+0.51	$T \geq 15$
Bilateral	24.4 (5.22)	28.2 (4.6)	3.8 (0.62)	+0.81	$T \geq 15$
Beck Depression (score)					
Physical therapy	9.8 (27.72)	10.0 (28.28)	0.2 (1.79)	+0.03	NS
Unilateral	7.6 (21.50)	9.2 (26.02)	1.6 (7.50)	+0.07	NS
Bilateral	9.4 (26.59)	4.0 (11.31)	-5.4 (8.38)	-0.26	NS
SLUMS mental ability (score)					
Physical Therapy	23.8 (5.63)	23.4 (7.37)	-0.4 (2.19)	-0.06	NS
Unilateral	24.6 (2.61)	25.2 (3.90)	0.6 (5.27)	+0.18	NS
Bilateral	24.0 (4.64)	22.2 (5.76)	-1.8 (4.27)	-0.35	NS
Self care-independence (SIS and CAFÉ 40) (score)					
Physical therapy	116.3 (30.53)	122.8 (26.69)	+6.5 (10.3)	+0.22	NS
Unilateral	132.4 (35.87)	132.2 (45.08)	-0.2 (11.25)	-0.001	NS
Bilateral	139.7 (16.68)	141.7 (14.42)	+1.8 (8.32)	+0.13	NS

<sup>a</sup> By group the differences were significant for ULFM and ROM, however there were no significant pair-wise differences between the groups.<sup>b</sup> These dependent variables were used to screen patients for eligibility and were monitored for change with training in addition to the other dependent variables after training.

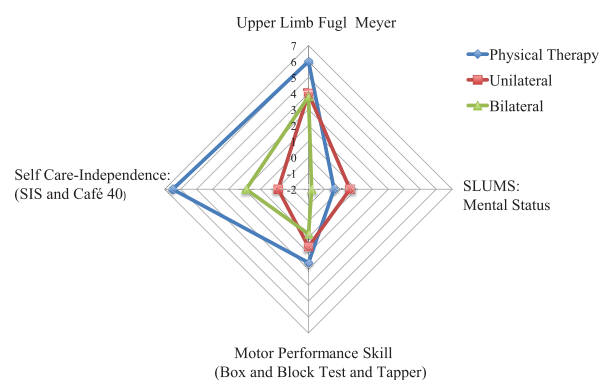
orthosis without adverse events. Survivors post stroke achieved significant improvements in voluntary movement (ULFM), Range of Motion and Strength in addition to significant reductions in pain and tone (Ashworth Scale) on the hemi-paretic upper limb. Motor Proficiency Speed, Motor Performance Skill and Self Care-Independence were maintained but not improved. The subjects completing virtual task specific training with a robotic orthosis and those performing actual task specific practice activities supervised by a physical therapist achieved similar gains on the hemi-paretic side. There were no significant differences between the unilateral and bilateral robotic training groups. No significant gains were measured on the non hemi-paretic limb. Thus, the findings from this feasibility study suggest when intense levels of task specific repetitions are needed, rehabilitation technology such as the UL-EX07 robotic orthosis could be used to free up “one-on-one” time

with a therapist without compromising patient outcomes. Consequently, therapists will need to keep abreast of commercially available assistive rehabilitation robotic technology for the upper limb. Furthermore, collaborative efforts between therapists and engineers should help to make rehabilitative robotic orthoses maximally effective, adaptable to the targeted limb, adjustable for

**Table 6**

Description of mean change scores for the hemi-paretic and less affected side

Side of body	Range of motion (degrees)	Strength (pounds)	Motor proficiency – speed (s)	Motor performance – skill (score)
Hemi-paretic side	+65.9	+40.9	-18.8	+1.6
Least affected side	+2.1	+5.6	+0.2	-0.5

**Fig. 3.** Group trends for change in dependent variables: increased scores represent positive change.

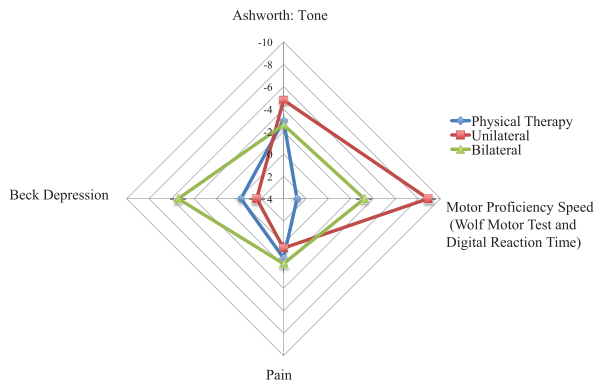


Fig. 4. Group trends for change in dependent variables: decreased scores represent positive change.

a variety of patients, easy to program, comfortable to use, portable and efficient to put on and off.<sup>18</sup>

Retraining patients, chronic post stroke, should exploit the adaptation of the nervous system.<sup>11</sup> Exercise training should involve multiple sensory modalities, promote active subject participation, be tailored to accommodate different degrees of impairment and adapt to changing performance competencies (e.g. variable assistance). In the current study, both the virtual task specific repetitive training guided by the UL-EX07 robotic orthosis and the actual task specific repetitive practice guided by a physical therapist both followed these principles. However, neither training group achieved measurable improvement in fine motor hand control. In the case of the UL-EX07, the upper limb orthosis did not include a hand component and in the virtual task specific training program there were no hand tasks for object manipulation. In PT supervised training, task specific practice included retraining the whole upper limb. With the limited hand function in the subjects, it was difficult to create small increments of change in object manipulation to enable successful, repetitive, coordinated hand and digital movements. The evidence from this feasibility study suggests improving fine motor hand skills may be critical to improving the efficiency and effectiveness of performing activities of daily living and independence.

Our findings were consistent with a number of other rehabilitation robotic studies for patients post stroke.<sup>55–63</sup> One meta-analysis and several randomized clinical trials supported the benefits of shoulder–elbow robotic orthosis training to recover strength, flexibility and voluntary motor movements, but the gains were not translated to improvement in activities of daily living. In some studies, specific hand skills were not measured. In one long

term follow up study by Lo et al.,<sup>61,62</sup> patients participating in assistive robotic training not only made significant improvement in activities of daily living as measured by the Stroke Impact Scale (improved >7.64) but the gains exceeded those measured in subjects training under usual care. On the other hand, Volpe et al.<sup>58</sup> reported patients training with a physical therapist performing guided sensorimotor reach training made significant improvements in function, while those training with a robotic orthosis did not improve their function. Thus, at this time, the evidence supports the benefits of task specific training with a robotic orthosis or with a physical therapist.

Participants admitted to our feasibility study had low to moderate ULFM scores with very low scores on the hand items. With TSRT training, only 4 of 15 subjects improved 1–3 points on these hand items. Hand dexterity skills as measured by the Box and Block Test, Tapper Test, Wolf Motor Function Test and Digital Reaction Time Test were also poor at baseline and follow up. Yet, despite the lack of hand skills, the participants in this study had achieved the ability to be independent at home and in the community. The self-rated items on the Stroke Impact Scale<sup>33</sup> averaged 3 of 5 (somewhat difficult to perform the task or had to use the least affected limb some of the time). The self-rated scores on the items on the CAFÉ 40<sup>34</sup> averaged 5 of 7 (minimal difficulty performing the task, such as more time to perform the task). After many years post stroke, 6 weeks of task specific training (2×/week) assisted by a robotic orthosis or a physical therapist may not provide sufficient intensity of practice to improve the quality, efficiency or effectiveness of performing activities of daily living. Or perhaps “minimal difficulty” is a reasonable performance expectation when hand skills are significantly compromised post stroke.

Our study reported minimal differences in outcomes between the unilateral and bilateral robotic training groups. The aim of stroke rehabilitation is to drive neurogenesis and angiogenesis around the ischemic or hemorrhagic lesion through forced use and repetitive task practice with the hemi-paretic limb.<sup>15–17</sup> Early animal studies confirmed neurogenesis around the area of the stroke induced lesion following constraint induced therapy.<sup>13</sup> However, in spontaneous recovery and usual rehabilitation, a recent brain imaging study of patients acute post stroke reported early activation of the cerebellum and increased connectivity in the ipsilateral pathways<sup>64,65</sup> rather than the preferred increase in connectivity around the area of the lesion. The findings were interpreted as compensatory rather than recovery. Our feasibility study did not measure neurophysiological connectivity, however all three intervention groups emphasized task specific training with the affected limb alone (unilateral robotic group), the affected and less affected limbs moving simultaneously with mirror movements (bilateral robotic group) or with a combination of single handed tasks with the affected limb as well as both limbs working together on two handed tasks (physical therapy group). Further studies are needed to highlight the differences in functional outcomes and specific neurophysiological changes following task specific training of the affected limb with unilateral robotic training, simultaneous bilateral robotic training or functional task practice integrating the affected limb into single and joint limb tasks.<sup>28–31,66</sup>

#### Study limitations

This feasibility study had several limitations. The major limitation was the small number of subjects, limiting the power to find significant differences. The subjects were heterogeneous relative to time post stroke (e.g. 1–16 years) creating large variation in scores on the dependent variables. Another limitation was the lack of a retraining group that included both actual TSRT supervised by a PT supplemented with virtual TSRT guided by a robotic orthosis.

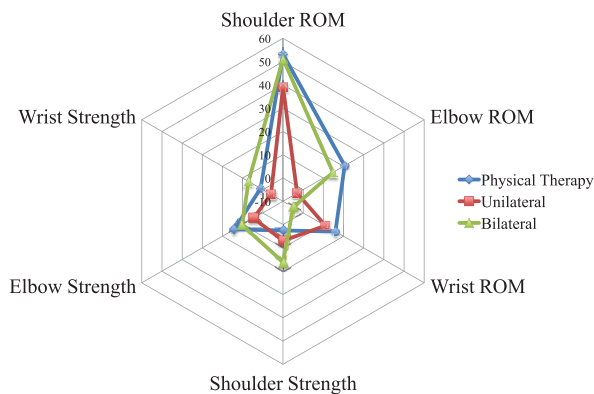


Fig. 5. Group trends of change in range of motion and strength by joint: increased score represents positive change.

In addition, the study did not include neuroimaging to correlate clinical gains with changes in neural connectivity. Further, the study stratified participants by severity of ULFM but not gender and nor time post stroke. In addition, retraining was relatively short with minimal intensity (e.g. 2×/week for 6 weeks).

The UL-EX07 robotic exoskeleton had precise joint biomechanics, simulated normal degrees of freedom, had smooth frictionless movements and was able to un-weight the arm, however, it only provided partial assistance for one virtual game. In addition, the UL-EX07 did not include a hand component. The virtual task specific games included reaching or hitting targets rather than object manipulation tasks. With the exception of the Paint Game, the subjects trained on the tasks in the mid range of motion, limiting the opportunity to challenge end range motions. The virtual games did not progress in difficulty nor incorporate error or reward feedback. Also, during heavy use, the robotic orthosis required frequent maintenance. Although the mechanical failures were not associated with adverse patient effects, it did cause inconvenience when training sessions had to be delayed until repairs could be made.

#### *Clinical implications and future research*

In this era of health care reform, the challenge is to improve patient health and increase access to quality health care services at reduced costs. The results of our feasibility study suggest rehabilitation robotics can be safely integrated into task specific training to reduce expensive “one-on-one” training with a health care professional. On the other hand, training with rehabilitative orthoses requires engineers to develop, service, repair and modify the robotic device and programmers to develop and modify the software programs. Clinical assistants are needed to help subjects decrease stiffness and improve flexibility prior to training. In addition, there are unique costs and challenges to developing rehabilitation robotic orthoses and bringing them to the commercial market.<sup>67</sup> Thus training with rehabilitation technology may assure more intensive repetitions, but it may not be less expensive than “one-on-one” personalized care. Large, multi site longitudinal cost effectiveness and cost benefit studies<sup>67</sup> must be carried out to differentiate the benefits and the costs associated with task specific training with a robotic orthosis compared to a therapist.

A review of the literature and the findings from this feasibility study contribute to a foundation of information that can be used to design future studies to compare the outcomes post stroke following task specific training with a rehabilitation robotic orthosis compared to “one-on-one” retraining with a therapist. Based on the information from this feasibility study, it may be necessary to integrate a hand component into upper limb robotic orthoses if improving hand function is a desired output. The materials and components of the orthosis must be durable to guarantee reliability when heavily used. Virtual task specific training programs need to include specific, hand tasks that simulate functional use. With the gains ranging from moderate to high (e.g. 0.40 to >1.0), at least 40–50 subjects would be needed to have the power of finding differences.<sup>52</sup> To increase the likelihood of finding statistically significant differences, the subjects may need to be more homogeneous in the period of recovery time post stroke (e.g. < 2 years post stroke). Further, to achieve new recovery in patients in the chronic phase post stroke, the intensity of training may need to be more frequent (e.g. 3–5×/week instead of 2×/week)<sup>68</sup> and of longer duration (e.g. 12 weeks instead of 6 weeks). Adding neuroimaging as an outcome variable could help correlate neurophysiological adaptation with changes in impairments and function relative to type of training (e.g., virtual task specific training versus actual task specific training, robotic guided therapy versus PT

supervised therapy, unilateral versus bilateral robotic training).<sup>64,65</sup> Further, when studying the effects of rehabilitation for survivors post stroke, the research design needs to be longitudinal rather than cross sectional.

#### **Summary**

Survivors post stroke are commonly faced with significant impairments of the upper limbs. In this feasibility study, independent survivors, up to 16 years post stroke, significantly reduced impairments following virtual task specific repetitive practice using a robotic orthosis (unilateral or bilateral) or actual task specific practice supervised by a physical therapist, with no significant differences in gains between training groups. However, improving comfort (e.g. reducing tone and pain) and increasing voluntary control of movement, flexibility and strength at the shoulder and elbow did not translate to measurable gains in fine motor hand control, activities of daily living or independence. The findings from this small clinical feasibility study with patients chronic post stroke have identified important parameters about task specific training of the upper limb/that can be integrated to assist clinicians and researchers to develop randomized, longitudinal clinical trials to continue to clarify which variations in task specific repetitive training with and without robotic technology are critical to maximizing recovery, chronic post stroke.

#### **Acknowledgments**

Dr. Byl recruited subjects, trained the clinical research assistants, served as the evaluator for the subjects, and was the site coordinator for the clinical training. Dr. Rosen was the Principal Investigator for the study. He designed the robotic device and trained the engineers responsible for overseeing the robotic training and maintaining the robotic device. Dr. Pitsch served as the primary physical therapist providing usual physical therapy for patients in the PT group. Ms. Fedulow was the research assistant for the study. She randomly assigned patients and supervised the clinical robotic training. Dr. Hyunchul was a doctoral student in computer engineering responsible for maintaining the robotic device. He set up and administered the robotic clinical training. Matt Simpkins was a doctoral student in computer engineering. He maintained the robotic device and helped set up and administer the robotic clinical training. Dr. Nagarajan provided the laboratory used for the robotic training. He supervised the doctoral students on site at UCSF and coordinated a supplemental study on functional magnetic imaging before and after training. Dr. Abrams assisted with the recruitment of subjects. He contributed to the design of the study and the basic clinical evaluation procedures. All of the authors contributed to interpreting the data and the preparation of the manuscript. Graduate students in the Department of Physical Therapy and Rehabilitation Science entered the data and carried out a blinded analysis of the data.

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## Quiz: #283

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- #1. The following is not a major limitation of wearable rehabilitative orthoses?
- a. maintenance and repair
  - b. availability and costs
  - c. lack of a “hand”
  - d. can be integrated with virtual gaming
  - e. comfort and ease of use
- #2. The following is not a critical component of neural recovery of upper limb function in the chronic phase of recovery post stroke
- a. force patients to use affected limb
  - b. progressive, attended, engaging repetitions
  - c. immobilize upper limb for protection
  - d. strengthen the limb with task practice
- #3. The following is not an advantage of a dynamic orthosis over one- on- one care
- a. easy to don/remove
  - b. can provide more repetitions

- c. can control multiple joints and degrees of freedom
  - d. may increase productivity of therapist
- #4. The following is a limitation of this study
- a. patients were chronic post stroke
  - b. small number of subjects
  - c. random assignment
  - d. patient drop outs
  - e. use of nonparametric statistics
- #5. In this study, the outcomes of learning based training using virtual task specific practice with a dynamic orthosis were significantly better than actual task practice supervised by a therapist
- a. true
  - b. false

When submitting to the HTCC for re-certification, please batch your JHT RFC certificates in groups of 3 or more to get full credit.