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Expanding Tele-rehabilitation of Stroke Through In-home Robot-assisted Therapy

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Abstract

Objective: The purpose of this case series was to examine the feasibility of using an in-home robotic therapy telerehabilitation device to produce quality outcomes in functional ability and mood, while satisfying patient need for access to post-stroke rehabilitation at low cost to the client.

Methods: Thirteen chronic stroke survivors with motor impairments of at least one upper or lower extremity were instructed in a home rehabilitation regimen using a robotic device designed for either the hand or the foot. Assessments of function and depression were made prior to initiation and at the end of 3 months of in-home use to determine any change in outcomes. Satisfaction with the device and access to therapy were determined using written and verbal surveys. Cost analysis was performed to compare the economics of the in-home delivery method to the cost of clinic-based physical or occupational therapy. A licensed physical therapist remotely monitored participant progress throughout the treatment period via weekly telephone calls and a secure database.

Results: Compared to baseline, participants showed improvements in depressive symptoms, functional independence, use of the upper extremity in functional tasks, distance walked, and gait speed at final assessment. Participants indicated satisfaction with the device and with their outcomes at the end of the 3 month treatment period. Using the device in the home expanded access to post-stroke rehabilitation for all participants with a reduced cost compared to clinic-based therapy.

Conclusion: Individuals were able to make functional improvements in the use of their impaired extremities post-stroke using a robotic telerehabilitation device in the home. The in-home service delivery regimen reduced the cost of therapy while expanding access to a rehabilitation modality for individuals who would not otherwise have received services. A small sample of mostly males and no comparison group limits the statistical analysis and generalizability of results.

Keywords: Learning; Robotics; Brain, Plasticity; Physical therapy; Occupational therapy; Cerebrovascular accident

Introduction

Stroke is the leading cause of adult disability in the United States, and half of stroke survivors are left with some degree of hemiparesis 6 months after the incident [1]. With almost 6 million existing survivors and 780,000 new survivors each year, stroke costs the U.S. healthcare system more than \$68.9 billion annually [2]. With rising medical costs, the projected yearly cost of care for stroke patients by the year 2025 will be \$108 billion [1]. Compounding this trend, insurance companies have been reducing coverage and increasing copayments/coinsurance rates for members, and reducing reimbursement to healthcare providers [3]. These statistics highlight the urgent need to develop cost-effective treatments for stroke survivors. In the U.S., current and former military service members are able to receive medical care at large regional Veterans Affairs Medical Centers (VAMC) and smaller

community-based outpatient clinics. At some VAMC facilities hundreds of veterans are waiting for rehabilitation, and there can be a delay of months between the time of referral to rehabilitation and the beginning of therapy (AB personal communication). Many veterans have limited access to VA rehabilitation facilities because of where they live. A report by the Centers for Disease Control and Prevention (CDC) shows a national trend of increasing delays in the receipt of needed medical care [3]. Promoting access to appropriate rehabilitation services creates a means of achieving recovery goals and reducing the long-term cost of care for stroke survivors.

Third party payers are relying heavily on outcome measures to determine quality of care and reimbursement rates for services. New models of care delivery that complement the move away from fee-for-service models are underway across the United States. The "pay-for-performance" system will require healthcare providers to regularly report on functional outcome measures for all patients, and to immediately adjust care delivery methods to maximize quality. Recent

guidelines have been published for outcomes reporting for physical therapy services across all patient populations, including those post-stroke [4]. The substantial reliance on functional outcome measures is intended to determine the effectiveness and quality of rehabilitation services.

Much of stroke rehabilitation is focused on one-on-one training with a physical or occupational therapist. Recent studies have shown that components of effective stroke therapy include active, repetitive participation of the patient and repetitive task training [5,6]. Recent neuroscience research results continue to be translated into neurorehabilitative advances that are leading to improvements in therapy, e.g., Constraint Induced Movement Therapy (CIMT) [7] and Accelerated Skill Acquisition Program (ASAP) [8]. The long-range view, based on studies supported by the Agency for Healthcare Research and Quality (AHRQ), is that interventions with relatively modest impact on reducing disability subsequent to stroke are likely to be cost-effective [9]. To develop a more coordinated and consistent approach to stroke care, the American Stroke Association developed the stroke systems of care model (SSCM). One of the recommendations of the SSCM was the implementation of telemedicine (the use of telecommunications technologies to provide medical information and services) to increase access to stroke care, especially in remote areas [10,11]. A recent consensus report on translating stroke research to clinical application acknowledged the potential of robotic-assisted therapy because of its ability to standardize and quantify therapy [12].

Deficits in hand and foot function are the two most disabling impairments experienced by stroke survivors. Nearly 80% of stroke survivors experience upper extremity hemiparesis [2]. Hand grasp and release capability is crucial for many activities of daily living (ADLs) and is one of the most disabling and difficult functions to improve [13,14]. When the lower extremity is involved, foot/ankle strength and mobility impact walking function, which is impaired in two-thirds of acute stroke patients [15]. Since the ability to walk efficiently is important for general health and for health related quality of life, restoration of gait has been considered one of the primary goals of stroke rehabilitation [16]. Improving foot strength and mobility is an important component of successful gait rehabilitation.

In many robotic stroke therapy studies, equivalent outcomes have been shown with either robotic therapy or one-on-one therapeutic delivery [17-24]. The results of these studies indicate that robot-assisted therapy provides consistent, reproducible treatment and measurement of patient performance while providing equivalent outcomes without the need for real-time human oversight [25]. Robot-assisted therapy is a promising option for stroke patients that do not have access to conventional therapy.

Combining telemedicine with in-home robot-assisted therapy for people with residual impairment following stroke has the potential to provide cost-effective, consistently high-quality treatment to patients with limited access to rehabilitation clinics because of location or availability of treatment. Although the components of robotic home delivery of stroke therapy by web-based telemedicine are in place and have been tested, they are underutilized [26]. The purpose of this case series was to demonstrate the ability of an in-home robotic therapy device to: (1) improve quality of care, (2) increase access to rehabilitation, and (3) generate patient satisfaction. At the end of the study we performed a cost analysis to compare the economics of the in-home delivery method to the cost of clinic-based therapy.

Methods

Subjects and study overview

Volunteers between the ages of 18 and 90 with a unilateral ischemic or hemorrhagic stroke within the prior 24 months were recruited for hand or foot in-home robotic rehabilitation. The affected hand or foot must have limited activities of daily living consistent with a score of 1-3 on the motor arm or leg item of the National Institutes of Health Stroke Scale (NIHSS) and a Functional Independence Measure (FIM) score of 17-88 [27]. Due to the physical nature of the robotic rehabilitation therapy, volunteers must have presented with no conditions or injuries limiting the use of the more affected side pre-stroke, and have the ability to demonstrate the presence of some upper or lower extremity voluntary activity, as indicated by the ability to move proximal and/or distal joints against gravity. Those with hemispatial neglect, sensory loss, or receptive aphasia were excluded, as indicated by a score of 2 on item #11 Extinction and Inattention, a score of 2 on item #8 Sensory, or a score of ≥ 1 on item #9 Best Language of the NIHSS, respectively. Finally, participants must have been independent before their stroke, be able to follow simple instructions to operate the robotic user interface, and have had no prior Botox injections within six months of enrollment.

Recruitment was centered on the Atlanta Veterans Affairs Medical Center (VAMC). A total of 40 people in the chronic phase of recovery following stroke were assessed for eligibility and 13 participants were enrolled: 12 male, 1 female; 4 subjects with lower extremity involvement, 9 subjects with upper extremity involvement; a mean of 59.70 (9.40) years of age; and a median of 81 (230.81) days post stroke.

Intervention

Following eligibility approval, users were granted use of the in-home robotic rehabilitation device for a maximum of three months or until alternate access to a clinic based therapy program was established. Two hours of daily Robotic Assisted Therapy (RAT) was prescribed for the duration of the three months. Participants were instructed to start at lower activity levels performed for one hour daily and to increase the standard therapy dosage within the first week. Due to the flexibility of RAT, volunteers were given the option to complete a daily two-hour prescription in multiple sessions if their schedules would otherwise prohibit the full dosage of therapy in a single session. A full description of the robotic intervention, rationale for training principles and exercise dosage prescription are described elsewhere [28].

Robot Assisted Therapy was delivered in the home using either the Hand or Foot Mentor™ devices (Kinetic Muscles, Inc. Tempe, AZ 85282). The Hand Mentor™ device was designed for use by individuals with residual upper limb impairments (Figure 1); and the Foot Mentor™ was designed to be used by those with residual lower limb impairments after stroke. The goal of using the device is to improve active range of motion (AROM) and strength in the distal musculature of the paretic limb of patients with hemiparesis and weakness secondary to stroke.

The Food and Drug Administration (FDA) has classified Hand Mentor™ and Foot Mentor™ devices as a Class I device presenting non-significant risk (NSR). The device itself is comprised of a hand or foot peripheral component wired into a processing unit containing the pneumatic pump and an easy to operate touchscreen interface. An optional cellular modem was attached to allow daily participant

progress to be monitored by an off-site therapist. Only requiring a wall outlet, the robotic device was extremely portable and ideal for home deployment.

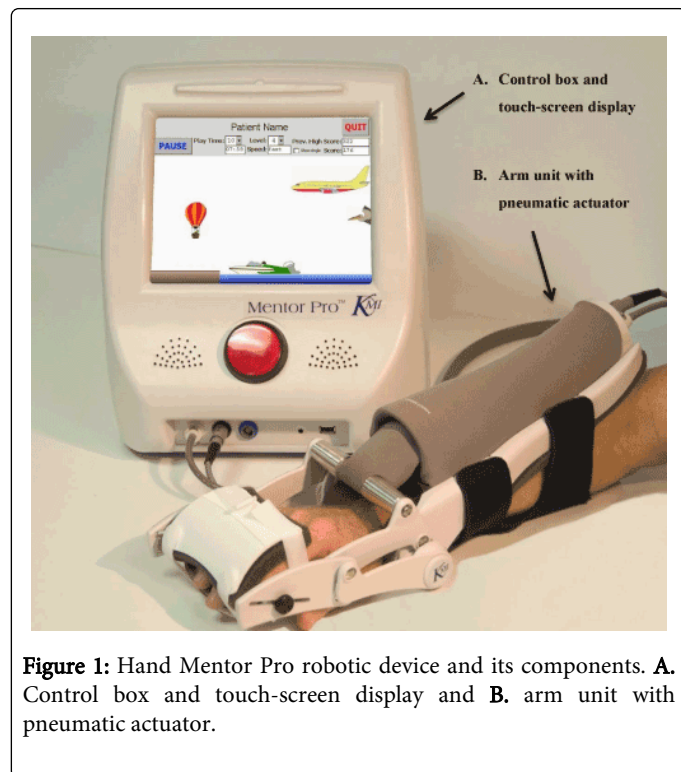


Figure 1: Hand Mentor Pro robotic device and its components. **A.** Control box and touch-screen display and **B.** arm unit with pneumatic actuator.

The robotic device uses computer-game-like training programs for motor control plus one spasticity reduction program [28]. The aim of the training programs is to increase active range of motion (AROM) of wrist and finger flexion and extension and improve the accuracy of these actions. The two main training programs used were balloon and thera-pong. The object of the balloon game is to fly a balloon across the ocean while avoiding obstacles. The aim of the thera-pong game is to defeat the opponent in a simulated table tennis game by earning a higher score. The volunteer uses the affected wrist or ankle to control an in-game paddle (or balloon) by moving it vertically across the left side of the screen, and competes against a computer-controlled opponent.

Participants begin robotic therapy at an easy level, requiring only a small degree of wrist or ankle motion to achieve maximum or minimum height in the balloon or other corresponding games. However, if users consistently demonstrate success at a particular difficulty level (eight successes in ten attempts), the robotic device progresses the user difficulty level, thus requiring greater flexion or extension range of motion to achieve the goal. Conversely, if the user is experiencing difficulty (less than eight successful attempts out of ten), the device will decrease the difficulty level.

A clinical dashboard was utilized to monitor participant performance indicators, including daily time of usage and number of daily cycles (total and for each individual program), resistance to passive movement, passive range of motion angles, and active range of motion angles achieved on the basic and advanced motor control programs. The study therapist remotely monitored daily metrics by logging into a secure server. The therapist dashboard was customized for the target population taking into account data sources and the

goals of the project. Weekly telephone calls were made to participants by a licensed staff physical therapist to discuss rehabilitation progress.

Measures

Quality

Both prior to receiving the robotic rehabilitation device and following completion of therapy, the Functional Independence Measure (FIM[®]) instrument was used to assess physical and cognitive disability in terms of burden of care. The 18 FIM items are divided into two statistically and clinically separate indicators, of which 13 assess disability in motor functions and 5 in cognitive functions.

Depressive symptoms were measured both pre- and post-intervention due to the possible impact on the quality of life of stroke survivors [29,30]. The Center for Epidemiologic Studies Depression (CES-D) scale [31] was chosen for its ability to discriminate between depressed and non-depressed patients in a variety of populations, including stroke patients [32]. Each of the 20 measurement items is rated between 0 and 3, creating a scale range of 0-60 with 16 or above indicating possible depression.

Upper extremity functional limitations were evaluated using the Action Research Arm Test (ARAT) [33]. With a maximum score of 57 indicating normal performance, the test is comprised of 19 items divided into 4 ordinal subscales: grasp, grip, pinch, and gross movement. Time to complete each task is used to determine score.

Lower extremity functional status was assessed using the 10-meter walk test (10MWT) to measure gait speed [34] and the 6-minute walk test (6MWT) to measure gait performance over short distances [35]. In conjunction with other measures, the functional outcome measures were recorded both pre- and post-intervention.

The robotic controller device is programmed to record a variety of data. Daily usage and functional performance data were collected, including maximum angle achieved, usage time, and difficulty level across exercises. All device data were accessible remotely via secure server, and adherence to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rules was strictly maintained.

Satisfaction

A questionnaire was distributed to participants following completion of therapy to assess satisfaction and to provide greater insight into any unanticipated challenges of an in-home robotic rehabilitation intervention. A similar questionnaire was distributed to the investigators/clinicians at the end of the study to determine beliefs about how effective the robotic therapy was for patients, including ease of use and appropriateness of the therapy. Investigators and participants were also asked to state what they would change about the device. Both questionnaires included positive and negative statements about the device and required respondents to select one of four choices: 1 = strongly disagree, 2 = slightly disagree, 3 = slightly agree, and 4 = strongly agree. Satisfaction questionnaires were evaluated based on how strongly patients and investigators agreed or disagreed with positive and negative statements.

Cost

Device and deployment costs were calculated, including the cost of home delivery, support, monitoring and connection, and pickup. Monthly maintenance and server connection costs were added to the device costs and were amortized to zero over the course of an expected usable lifetime of five years. Costs of in-home delivery were totaled across the 90-day treatment period and compared against usual and customary rehabilitation treatment.

Access

Information regarding participant access to occupational or physical therapy was collected during initial assessment or after the subject had completed use of the HM/FM. Investigators asked participants either in person or via telephone whether or not they were participating in therapy during the time period they were using the device to determine the effect of the robotic therapy on veteran access to treatment.

Statistical Analysis

Data were entered into a customized Microsoft Access database, checked for accuracy against data entry forms, and then imported into SPSS, version 21 (IBM, Armonk, NY). Post-treatment measurements were compared to baseline measurements using Wilcoxon signed rank tests (two-tailed) because of the matched-pair design and small sample size. Mean percent change scores from baseline were also calculated for each measure, along with 95% confidence intervals. Partial correlations (partialling baseline score) were calculated to determine if time spent using the robotic devices predicted change from baseline. Finally, mean scores were calculated for participant and therapist responses to surveys measuring satisfaction with use of the robotic devices. Summary data are presented as mean \pm standard deviation, unless otherwise noted.

Results

Quality

The FIM was used to determine level of independence in ADLs both at baseline and end of intervention. The FIM total score (n=12) increased 3.1% from baseline (mean \pm SD = 118 \pm 6.7) to post-intervention (121.3 \pm 3.6, p=0.06) (Figure 2), indicating increased levels of independence in daily activities (required less assistance from either a person or device to accomplish daily tasks) by the end of therapy. Complete independence would be indicated by a score of 126 (18 items; 7 is the highest possible score for each item). Improvement in the physical component from baseline (84.6 \pm 5.7) to post-intervention (87.7 \pm 2.6) was statistically significant (4.0%, p=0.04); however the cognitive component did not change from baseline (33.4 \pm 2.0) to post-intervention (33.7 \pm 2.0, p=0.80).

The CES-D is a brief self-report measure that assesses depressive symptoms over the past week. The mean CES-D score decreased 27.6% from baseline (15.9 \pm 8.9) to post-intervention (10.4 \pm 7.7, p=0.02) (Figure 2), indicating a lower prevalence of depressive symptoms at the final assessment.

The ARAT evaluates upper limb function using timed tasks such as reaching to and gripping various objects. A decrease in time to complete each task corresponds to higher scores (out of a possible 57 points). Subjects using the HM made statistically and clinically

significantly improvements in their ARAT scores from baseline (44.3 \pm 6.9) to post-intervention (52.0 \pm 5.1, p=0.01). These scores reflect a meaningful improvement in functional task performance of 18.7% from baseline (Figure 2). The normative score for patients assessed with the ARAT 6 months post-stroke has been found to be 41.3(20.8)/57 [36]. In patients with chronic stroke, initial assessment on the ARAT has been reported as 29.2(12.5), and the minimum clinically important difference (MCID), or the minimum change in score that reflects meaningful change in function, is considered to be 10% of the measure's total range (i.e. 5.7 points) [37,38].

The 6MWT assesses endurance by measuring distance walked during a 6-minute time period. Subjects who used the FM showed a substantial, though not statistically significant, increase in distance walked from baseline (229.0 \pm 153.9ft.) to post-intervention (402.1 \pm 290.0ft., p=0.07). This reflects a 70.6% increase in mean distance walked (173.1 ft.) (Figure 2). The MCID in chronic stroke survivors has been reported as 50 m (164.04 ft.) [39]. Therefore, participants made meaningful improvement in walking distance by the end of the intervention, although they did not improve to normative levels. Normal walking distance for healthy men between 60-79 years old has been reported as 1729-1876ft [40].

The 10MWT measures gait speed averaged over three timed trials of walking a distance of 10 m. Subjects who used the FM showed a substantial increase in their average gait speed over 10 m from baseline (0.55 \pm 0.41 m/s) to post-intervention (0.92 \pm 0.81m/s, p=0.068), with an overall improvement of 0.37 m/s, or 56.5% (Figure 2). MCID has been reported as small meaningful change = 0.06 m/s, and substantial meaningful change = 0.14 m/s [39] and 0.16 m/s [41]. Normal self-selected gait speed is 1.36 m/s for 60-69 year old men, and 1.33 m/s for 70-79 year old men [42]. Community ambulation requires a gait speed above 0.8 m/s in order to safely cross the street and negotiate obstacles outside the home [43].

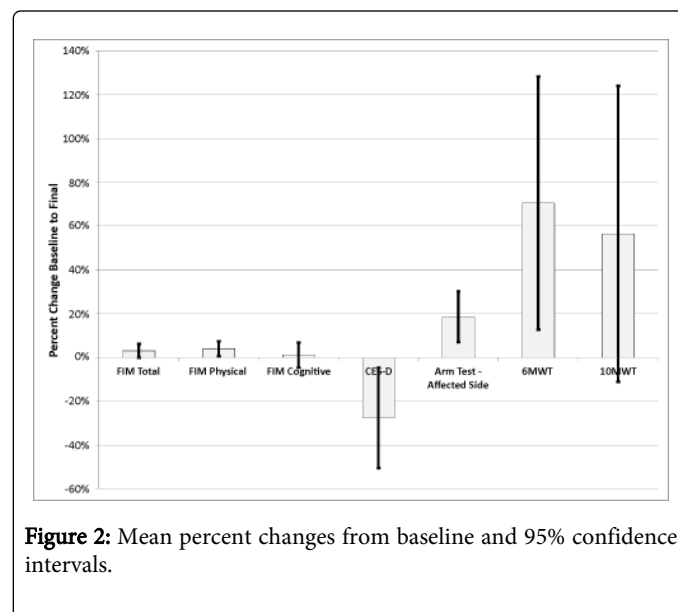


Figure 2: Mean percent changes from baseline and 95% confidence intervals.

Table 1 shows percent change from baseline to post-intervention for each participant, as well as the mean percent change for each measure. Percent changes in CES-D scores ranged from 0.0% (participants A-10, A-02, A-03) to 100.0% (participant A-12), creating the large confidence interval seen in Figure 2. Likewise, the large change seen in mean gait speed on the 10MWT can be attributed to

one individual, who increased gait speed by 148.1%, as compared to much smaller percent changes seen in the other three individuals who used the FM. Similar variability is seen on the 6MWT, for which one participant made negligible improvements in walking distance (10.7%) compared to two individuals who increased their distance by over 100%.

ID	A-04	A-06	A-08	A-10	A-01	A-02	A-03	A-05	A-07	A-09	A-11	A-12	Mean Change (%)
Peripheral	Foot	Foot	Foot	Foot	Hand	Hand	Hand	Hand	Hand	Hand	Hand	Hand	
CESD_1	17	12	15	4	13	25	3	22	32	22	6	20	27.6%
CESD_2	14	14	13	4	12	25	3	15	19	3	3	0	
% Δ CESD	-17.6%	16.6%	-13.3%	0.0%	-8.0%	0.0%	0.0%	-31.8%	-40.6%	-86.4%	-50.0%	-100.0%	
FIM_Total_1	118	110	126	127	112	116	117	123	122	124	166	105	3.1%
FIM_Total_2	116	116	121	124	123	122	120	126	125	126	118	119	
% Δ FIM	-1.7%	5.5%	-4.0%	-2.4%	9.8%	5.2%	2.6%	2.4%	1.6 %	1.7%	1.7%	13.3%	
FIM_Physical_1	87	75	91	92	82	83	82	88	88	90	82	75	4.0%
FIM_Physical_2	86	86	89	89	88	88	87	91	90	91	83	84	
% Δ Physical	-1.1%	14.7%	-2.2%	-3.2%	7.3%	6.0%	6.1%	3.4%	3.3%	1.1%	1.2%	12.0%	
FIM_Cognitive_1	31	35	35	35	30	33	35	35	34	34	34	30	1.1%
FIM_Cognitive_2	30	30	32	35	35	34	3	35	35	35	35	35	
% Δ Cognitive	-3.2%	-14.2%	-8.6%	0.0%	16.7%	3.0%	-5.7%	0.0%	2.9%	2.9%	2.9%	16.7%	
ARAT_1	-	-	-	-	53	50	37	42	40	52	35	45	18.7%
ARAT_2	-	-	-	-	55	57	44	56	51	57	46	50	
% Δ ARAT	-	-	-	-	3.8%	14.0%	18.9%	33.3%	27.5%	9.6%	31.4%	11.1%	
6 MWT_1	75	118.2	360.2	362	-	-	-	-	-	-	-	-	70.6%
6 MWT_2	83	262.42	745	518	-	-	-	-	-	-	-	-	
% Δ 6MWT	10.7%	122.0%	106.4%	43.1%	-	-	-	-	-	-	-	-	
10 MWT_1	0.06	0.38	0.77	0.98	-	-	-	-	-	-	-	-	56.5%
10 MWT_2	0.08	0.47	1.91	1.21	-	-	-	-	-	-	-	-	
% Δ 10MWT	33.3%	23.7%	148.1%	23.5%	-	-	-	-	-	-	-	-	
Days of Access	79	102	40	74	67	88	78	33	89	74	74	27	
Total Time Used (min)	207	3665.3	384	4124	360.5	2165.9	3913.9	1521.8	125	229	1252	306	
Total Cycles	280	6118	949	7762	458	3319	5737	2292	277	456	2541	691	
Mean Used/Day Owned (m:s)	02:37	35:56	09:36	54:43	05:22	24:36	50:10	46:06	01:25	03:05	16:55	11:20	

Mean Cycles/Day Owned	3.54	59.98	23.73	104.89	6.84	37.72	73.55	59.45	3.15	60.16	34.34	25.29
Age	67y	74 y	48 y	46 y	58 y	67 y	59 y	59 y	47 y	41 y	68 y	70 y
Time Since Stroke	29m 9d	15m 5d	1m 28d	4m 5d	2m 21d	2m 1d	6m 10d	28d	3m 11d	2m 10d	1m 27d	2m 18d
Gender	M	M	M	M	M	M	M	M	M	M	M	M
Ethnicity	Af.Am.	Af.Am.	As.	Af.Am.	Af.Am.	Af.Am.	Af.Am.	Cauc.	Af.Am.	Af.Am.	Cauc.	Af.Am.
Age	67y	74 y	48 y	46 y	58 y	67 y	59 y	59 y	47 y	41 y	68 y	70 y

Table 1: Raw Scores for each person at Time 1 (Baseline) and Time 2 (End of Therapy), and Percent Change in Score. Dashes indicate the participant did not perform the test. M: Male; F: Female; y: years; m: months; d: days; Af.Am: African-American; As: Asian; Cauc: Caucasian; % Δ: Percent Change

Table 1 shows raw Scores for each person at Time 1 (Baseline) and Time 2 (End of Therapy), and Percent Change in Score. Dashes indicate the participant did not perform the test. Abbreviations: M, Male; F, Female; y, years; m, months; d, days; Af.Am., African-American; As, Asian; Cauc, Caucasian.

Partial correlation analysis did not show a significant relationship between amount of time spent using the device and any of the outcome measure scores at Time 2 after controlling for Time 1 measurements (CES-D p=0.24; ARAT p=0.69; FIM Total p=0.55; FIM Physical p=0.86; FIM Cognitive p=0.62; 6MWT p=0.74; 10MWT p=0.35).

Satisfaction

Following completion of the intervention, 12 participants responded to 14 statements to measure satisfaction with the HM or FM device (Table 2). Responses were a selection of one of four choices: 1=Strongly Disagree, 2=Slightly Disagree, 3=Slightly Agree, 4=Strongly Agree. For most of the statements, a response of “4” is the most positive response, however for four of the statements a response of “1” is the most positive (strongly disagreeing with the statement). Subjects’ responses on these four questions indicated that they either slightly or strongly disagreed with negative statements about the device. For the positive statements, participants indicated that they either slightly or strongly agreed (mean ≥ 3.0). Participants generally disagreed with the negative statements (mean ≤ 2.0), however the mean response to the statement concerning donning and doffing the peripheral hand or foot piece was slightly above 2.0, indicating that participants had some difficulty with this aspect of using the HM or FM.

Statement	Mean (SD)
1. The instructions for using The Hand or Foot Mentor were clear and easy to understand	3.8 (0.45)
2. This therapy was relevant to my rehabilitation	3.5 (0.67)
3. My function was improved	3.6 (0.70)
4. The games were appropriate	3.7 (0.65)
5. The games were hard to see	1.3 (0.65)
6. This therapy challenged me	3.3 (0.87)

7. I got bored with the games	2.0 (1.18)
8. I enjoyed playing the games	3.6 (0.67)
9. This therapy was too difficult	1.7 (0.99)
10. The pace was just right	3.1 (1.24)
11. I had trouble donning and doffing	2.2 (1.27)
12. The games were easy to play	3.3 (1.07)
13. Overall, I am satisfied with the progress I made using the Hand/Foot Mentor	3.4 (1.08)
14. Therapy with the Hand/Foot Mentor met my expectations	3.2 (1.19)

Table 2: Means (SD) for participant responses to satisfaction survey (n=12) 1= Strongly Disagree, 4 = Strongly Agree.

Based on participant responses to survey questions, overall satisfaction with the devices was high. Figure 3 separates volunteers and their responses into two groups based on whether they used the HM or the FM.

Participants were also asked what they would change about the device, and most responses involved adding more games with greater levels of difficulty, refining the system for sending data to the secure server after use, and making the computer component of the controller device smaller and easier to handle.

Three investigators completed a 16-item survey at the completion of the intervention. They were asked questions regarding their satisfaction with using the robotic in-home protocol to deliver care to stroke survivors (Table 3). Survey responses were structured in the same manner as the Patient Questionnaire (1=Strongly Disagree, 2=Slightly Disagree, 3=Slightly Agree, 4=Strongly Agree). Only one negative statement was included on this survey, requiring a response of disagreement as a positive response. Therapists generally responded positively to using the HM and FM devices with participants. In particular, all three therapists strongly agreed to the statement, “This therapy was relevant to stroke rehabilitation” (mean of 4.0). Responses were positive (> 3.0) on most statements, although investigators disagreed slightly with statements regarding the ease of donning/doffing and reliability of the device. Suggestions for improvement

included: creating games more relevant to motor learning; developing a mechanism in the device to measure and track motor learning; making instructions and device adjustments simpler with an option to omit adjustment screens for participants who have more confusion or difficulty with the electronic component of the device; refining the electronics to reduce problems with logging in, screen freezing and data transmission; adding greater difficulty levels for patients who begin treatment at a higher functional level.

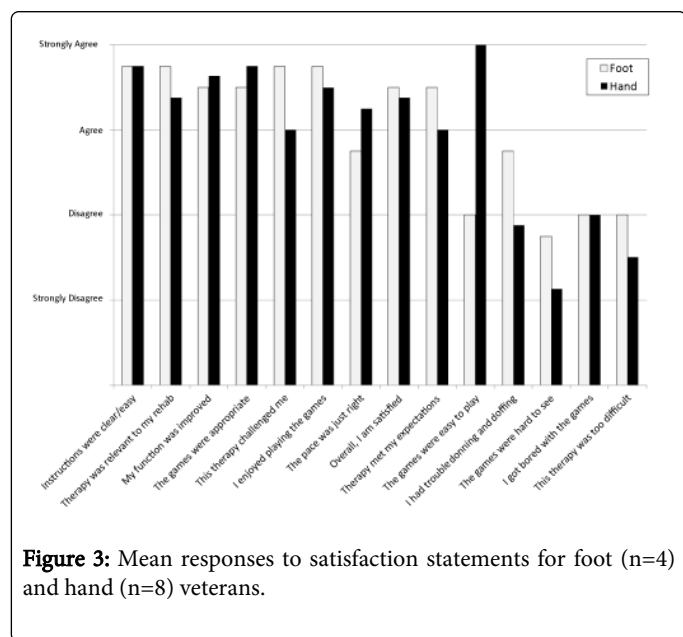


Figure 3: Mean responses to satisfaction statements for foot (n=4) and hand (n=8) veterans.

Access

Investigators surveyed the participants to determine if they were receiving physical or occupational therapy during the time they were using the HM or FM in the home. Only one participant was attending outpatient rehabilitation during the period of the robotic in-home intervention. However, this participant was able to use the robotic device in the home as an adjunct to formal therapy, increasing rehabilitative activity time. All other participants reported either they had not received therapy since being discharged from inpatient rehabilitation, or they had received outpatient home-based therapy for a short time after hospital discharge, but these services had ended. Therefore, the in-home robotic therapy intervention increased or extended access for all participants.

Cost

While cost data were collected, this case series was not designed to be a clinical investigation of the costs of RAT, and no control group was used as comparison. Total RAT costs were calculated based on the cost of equipment; device maintenance and data connection; home delivery, support, and pickup; and weekly clinician follow-up and monitoring. These costs were compared against usual and customary outpatient therapy at the VAMC defined as three one-hour sessions per week for 90 days.

Statement	Mean (SD)
1. The instructions for using The Hand or Foot Mentor were clear and easy to understand	3.3 (0.58)

2. This therapy was relevant to stroke patient rehabilitation	4.0 (0.00)
3. In general, the Mentor helped to improve subjects' function	3.7 (0.58)
4. The games were appropriate	3.7 (0.58)
5. This therapy can help to reduce backlogs	3.7 (0.58)
6. This therapy can deliver benefits sooner to veterans	3.7 (0.58)
7. The Mentor system was reliable	2.7 (0.58)
8. The Mentor system is suitable for integration with VA processes	3.3 (1.15)
9. This therapy was too difficult	1.3 (0.58)
10. The pace was just right	3.0 (0.00)
11. Subjects had trouble donning and doffing	2.0 (1.00)
12. The games were easy to play	2.7 (0.58)
13. Training on the use of the device was adequate	3.7 (0.58)
14. Therapy with the Hand/Foot Mentor met my expectations	3.3 (0.58)
15. Mentor Reports were easy to understand	2.7 (0.58)
16. Feedback to subjects was useful	3.3 (0.58)

Table 3: Means (SD) for therapist responses to satisfaction survey (n=3) 1= Strongly Disagree, 4 = Strongly Agree.

The estimated monthly equipment cost of \$82.14 and \$54.76 for the foot and hand robotic devices, respectively, was amortized over an expected five-year lifetime. This was combined with the cost of an annual maintenance and hosting contract of \$1,199 per device to cover device repairs and the data connection and online portal for therapist monitoring of progress. Corresponding transit costs were calculated based on a study average round-trip distance of 42.78 (19.95) miles using the standard VA mileage reimbursement rate of \$0.415 per mile [44] and 60.5 (22.6) minutes. RAT therapist costs at \$65.23 an hour consisted of the cost of time to deploy a two-person team to participant homes for device installation and orientation, repairs or device reorientation due to user error (eight repair trips across twelve subjects), device pickup, and weekly therapist monitoring and telephone based follow-up calls. Projected outpatient therapy transit and therapist costs for three one-hour sessions held weekly at the Atlanta VAMC were based on patient mileage reimbursements and the projected cost of a physical therapist at \$38.56 taken from the State of Georgia Bureau of Labor Statistics [45].

Discussion

The purpose of this case series was to demonstrate the utility of using telerehabilitation through in-home robot-assisted therapy for stroke survivors. Patients in the chronic phase of stroke recovery can progress quickly after participating in an in-home intervention that focuses on improving upper and lower extremity AROM. Results of our study indicated meaningful improvements in measures of quality of care, access to therapy, patient satisfaction, and cost of therapy following stroke.

Quality

Our study demonstrated that individuals with chronic stroke using in-home robot-assisted therapy made meaningful improvements in their ability to perform functional tasks, such as walking, reaching, and grasping. Prior research using robot-assisted therapy following stroke found similar improvements. In a study by Lo et al. comparing post-stroke rehabilitation interventions, subjects participated in 36 sessions of therapy over 12 weeks, randomized to robot-assisted therapy, intensive therapy to match movements and tasks performed with the robot-assisted rehabilitation protocol, or usual and customary care (UCC). The group performing robot-assisted therapy reported better outcomes on the motor function and social participation components of the Stroke Impact Scale (SIS) at 12 weeks compared to UCC. There was no difference on SIS scores between the robot-assisted and intensive therapy groups. Additionally, no differences existed between groups on speed of motor-task performance measured by the Wolf Motor Function Task (WMFT). Non-significant differences in Fugl-Meyer Assessment (FMA) scores at 12 weeks suggested greater improvement in motor task performance for robot-assisted therapy versus UCC. No differences were found on WMFT, FMA, and SIS scores between robot-assisted and intensive therapies, however both groups demonstrated better outcomes than UCC at all intervals (4, 6, 12, 36 weeks) [24].

Kutner et al. studied the use of the HM as part of a comprehensive rehabilitation paradigm following stroke. In their randomized controlled trial, 60 hours of repetitive functional task practice (RTP) was compared to 30 hours of RTP combined with 30 hours of HM use over a course of 3 weeks. Both groups showed statistically significant improvements in ratings of health-related quality-of-life and ability to perform ADLs/IADLs on the Stroke Impact Scale, with no differences between groups. These improvements were maintained at a 2-month follow-up [23]. Participants in our case series showed a reduction in depressive symptoms, increased self-reported independence in ADLs, and improvements in their ability to perform functional tasks. Frequency of negative feelings and level of difficulty with daily tasks have been shown to be significant predictors in self-reported ratings of health-related quality-of-life in stroke survivors [46], supporting the importance of the outcomes of our study.

In a case study by Linder et al. (2013), the HM was used as part of a comprehensive home exercise program (HEP) for the UE of a patient 5.5 months after stroke. Their case study included specific progressive range of motion, strengthening, and functional exercises that were performed in addition to the HM protocol. Daily use of the affected UE was monitored via therapist telephone calls and an activities log. The patient in their case study demonstrated improved ARAT scores for the affected UE by 16 points following 8 weeks of robot-assisted therapy and an HEP [28]. Their results support our findings following a 3-month period using the same in-home robotic therapy device. However, although our participants were instructed to utilize the affected UE as much as possible within the limits of safety for daily activities, use of the UE was not monitored. Additionally, our participants were not instructed in a supplemental home exercise program for the proximal UE. The patient in the case study by Linder et al. scored 21/57 on ARAT initial assessment. Typical ARAT score at initial testing has been reported as 29.2(12.5)/57 in patients who were on average 3.6 years post date-of-incident [37], and the normative score for patients assessed with the ARAT 6 months post-stroke has been found to be 41.3(20.8)/57 [36]. Our participants' mean score at initial assessment was 44.3/57, with a mean of 182 days (6.07 months)

after stroke, indicating that our participants began their trial of robot-assisted rehabilitation with a greater than average ability to use the affected UE for functional tasks post-stroke. Despite differences in functional ability using the affected UE at initial assessment, our outcomes are consistent with meaningful improvements in UE function following a trial of robot-assisted therapy demonstrated in the literature.

In a population of community-dwelling, non-smoking males, age 60-79, with independent function and no history of dizziness, a walking distance of 527-572m (1729-1876 ft.) on the 6MWT is considered normal [40]. Participants in our cohort did not demonstrate large enough improvements on the 6MWT to reach the distances demonstrated by independent community-dwellers. However, they achieved meaningful improvements in walking distance, exceeding the MCID (164.04 ft.) for the 6MWT [39].

Comfortable gait speed in meters per second for able-bodied men in their 6th and 7th decade has been reported as 1.36 – 1.33 m/s [42]. MCID has been reported as small meaningful change = 0.06 m/s and substantial meaningful change = 0.14 m/s [39] and 0.16 m/s [41]. Although our participants did not reach normal gait speeds, they made meaningful improvements, increasing their speed on the 10MWT by a mean of 0.37 m/s after use of the FM over a 3-month period. Gait speed can also be used to assess the ability of individuals to ambulate in the home and in the community post-stroke. Bowden et al. identified cut-off speeds for household ambulators (<0.4 m/s), limited community ambulators (0.4-0.8 m/s), and community ambulators (>0.8 m/s) [43]. Of 4 participants using the FM in this study, one improved from a household ambulator to a limited community ambulator, one improved from a limited community ambulator to a community ambulator, and one increased his gait speed to above average as a community ambulator.

Due to our small sample size, we were not able to perform statistical analysis to explore which factors, if any, were predictive of successful outcome. We did not find a correlation between amount of time spent using the HM/FM and degree of improvement from beginning to end of treatment. It cannot be ascertained whether this finding was a result of our small sample size or because a relationship between these variables truly does not exist.

Patient satisfaction

Participants in this project generally expressed satisfaction with the Hand/Foot Mentor devices, regardless of frequency or duration of use. Participants articulated positive comments, such as, "I can really feel the difference in my hand," "The games were fun to play," "I can grab things better with my hand," "I can take walks after dinner and meet with neighbors," and "I liked challenging myself with the games."

Comments of dissatisfaction generally focused on technical aspects of the device, such as recurrent freezing of the computer games and taking too long/failure of the device to send data to the secure server. Two participants with larger-sized hands noted occasional difficulty donning the Hand Mentor device, and they experienced swelling in their hands after use. This did not prevent them from continuing to use the device on subsequent days.

Frequency and duration of use varied between participants and seemed related to external factors such as return to work activity, illness, travel, and family obligations (death in family, holidays). Internal motivation also played a role in the frequency and duration of use, the discussion of which is beyond the scope of the current project

and would be purely speculative. Future investigations should utilize structured interviews to explore motivating factors related to use of the device.

Accessibility

Many factors determine access to rehabilitation following a stroke. Distance to a clinic is an important factor for many patients, often determining how long and how often they are able to participate in therapy. The improvements in function using robot-assisted therapy found by Lo et al. in 2010 were the result of therapy administered in a clinical setting under the direct supervision of a therapist. In contrast, participants in our study were able to realize functional gains while performing therapy in their own homes with minimal therapist supervision. Ease of access to the robotic device (in the home vs. in the clinic) affords patients the opportunity to perform rehabilitation exercises daily without having to spend time or money on travel. The in-home model also appeared to decrease the travel burden on caregivers; however there were additional responsibilities for the caregivers associated with the in-home delivery. The question of alteration in caregiver burden with in-home robotic telerehabilitation is important to explore further.

Availability of rehabilitation services can be limited by the amount of therapy resources in an area or by third-party payer restrictions. Our cohort of stroke survivors was part of the VA healthcare system, in which regional clinics with therapy services are limited, and patients may experience backlogs in scheduling appointments. Additionally, once outpatient rehabilitation benefits are exhausted, any additional treatment would have to be paid for via supplemental or out-of-pocket resources. The Hand and Foot Mentor devices allowed patients to perform rehabilitation activities as part of a home exercise program, bypassing scheduling and outpatient benefits restrictions.

Many of the volunteers in our study stated that they had received therapy prior to participating in this project; however their therapy had been exhausted or discontinued. Only one of the 13 participants in this project was receiving Physical or Occupational Therapy while using the Hand or Foot Mentor. Therefore, had they not participated in our study, these patients would not have received any type of rehabilitation during this time period. The Hand/Foot Mentor device was able to extend therapy services to these individuals, thereby improving accessibility to rehabilitation following stroke.

Cost

The monthly cost of deploying a hand or foot device at \$315.80 and \$343.18, respectively, are considerably lower than the projected cost of comparable outpatient therapy at \$734.61, representing an average cost savings of 55.15%. The largest savings were in the elimination of repeated in-person therapist costs at \$503.00 per month versus a one-time installation, pickup and weekly monitoring cost at \$86.88 per month, a reduction of 82.73%. Because patients were no longer required to drive an average of 558.09 miles (representing \$231.61 per month in mileage reimbursements), transit costs dropped to \$74.25 per month, or a savings of 67.94% (Table 4).

When compared against other forms of RAT studied by Lo et al., the MentorPro system does not require a therapist to be present, which was reported to cost \$120 per session [47]. The system also has a lower cost of equipment at \$2.25 per daily session on average across the hand and foot devices. This is compared to \$20 per session, as reported by Lo et al. The mobility and portability of the system also

allow for home deployment scenarios. In-home use requires a one-time deployment and pickup, each costing \$74.25. This replaces an average transportation cost of \$17.10 per session across an average of 32.8 sessions, each with a cost of \$561.

Approximately 15,000 veterans are hospitalized annually for stroke-related diagnosis, with 5,920 new veteran stroke survivors in 2007 [48]. While the results potentially represent a 55.15% reduction of outpatient therapy costs across both arm and foot devices for stroke survivors, these are estimated costs. This study was not designed to directly compare costs and had no control group.

Limitations and future directions

There are several limitations to our study. We recruited a small sample from the veteran population in the metropolitan Atlanta area. Because of our sample population, our participants consisted of a much greater number of men than women. Therefore, the generalizability of our results is limited. Additionally, our study did not utilize a control or comparison group to identify if improvements were due to the in-home robot-assisted therapy or natural recovery patterns. However, the combination of time since stroke, large change scores, and lack of formal rehabilitation makes a persuasive argument for benefits being due to the intervention. Statistical analysis was limited by sample size, and we were not able to identify variables predictive of successful outcomes.

Patient characteristics (age, sex, pre-stroke disability), together with stroke severity measurements can be used to predict measures of disability at any time up to one year after stroke [49]. Initial severity of paresis remains the best predictor of recovery of arm function [14,50,51]. One study showed that the Fugl-Meyer Assessment (FMA) [52] score at 30 days predicted 86% of the variance in recovery of motor function at 6 months [50]. It could be argued that the observed responsiveness to the in-home robot-assisted therapy seen in this study is the result of a cohort of patients with relatively mild-to-moderate impairment. Further investigation with more severely impaired populations of stroke survivors may help elucidate our initial observations.

Future studies with the HM and FM should utilize larger sample sizes, and involve non-veteran participants with heterogeneous levels of impairment. Additionally, structured interviews with subjects would greatly enhance our understanding of patient satisfaction with the device, usage barriers and motivating factors.

	RAT (Foot)	RAT (Hand)	Outpatient Therapy (Projected)	Average Savings of RAT
Cost of Robotic Device	\$ 82.14	\$ 543.76	-	
Device Maintenance and Hosting	\$ 99.92	\$ 99.92	-	
Therapist Costs	\$ 86.88	\$ 86.88	\$ 503.00	82.73%
Transit Costs	\$74.25	\$ 74.25	\$ 231.61	67.94%

Total Cost	Monthly	\$ 343.18	\$ 315.80	\$ 734.61	55.15%
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Table 4: Analysis of monthly costs of Hand or Foot RAT and Comparable Projected Outpatient Therapy (three one-hour weekly physical therapy sessions). Dashes represent a value of zero.

Summary

As the number of stroke survivors in the U.S. rises, it becomes increasingly important to deliver early and effective rehabilitation services for individuals with residual limb impairments while minimizing costs. Telerehabilitation and robot-assisted therapies have the potential to achieve ease of access while providing a satisfying rehabilitation experience for patients. The results of our case series support previous work indicating the feasibility of incorporating robotic telerehabilitation into the continuum of care for patients post-stroke. Our study adds to the research by demonstrating that use of robot-assisted therapy in the home can lead to meaningful improvement in functional outcomes, increase access to care, and generate patient satisfaction in a cost-effective manner.

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