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Home-based Therapy after Stroke Using the Hand Spring 2017.2695379. **Operated Movement Enhancer (HandSOME)**

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Abstract

In previous work, we developed a lightweight wearable hand exoskeleton (HandSOME) that improves range of motion and function in laboratory testing. In this pilot study, we added the ability to log movement data for extended periods and recruited 10 chronic stroke subjects to use the device during reach and grasp task practice at home for 1.5 hours/day, 5 days per week, for 4 weeks. Seven subjects completed the study, performing 448 ± 651 hand movements per training day. After training, impairment was reduced (Fugl-Meyer Test; gain= 4.9 ± 4.1 ; p=.039) and function was improved (Action Research Arm Test; gain= 3.3 ± 2.6 ; p=.032). There was a significant correlation between gains in the Action Research Arm Test and the number of movements during training $(r=0.90; p=.005)$. Proximal arm control also improved, as evidenced by a significant reduction in the reach path ratio ($p=0.038$). Five subjects responded well to the treatment, having gains of 6 points or more on the Fugl-Meyer or Action Research Arm Test, and achieving significant gains in digit extension (gain=19.8 \pm 10.2 degrees; p=0.024). However, all of the gains that were significant immediately after training were no longer significant at the 3 month follow-up. This treatment approach appears promising, but longer periods of home training may be needed to achieve sustainable gains.

Keywords

Exoskeleton; Hand; Neurorehabilitation; Stroke; Therapy

I. Introduction

There are 800,000 new strokes in the United States each year [1]. Movement deficits associated with stroke include a reduced range of motion (ROM) of the affected upper extremity and abnormal interjoint coordination. Individuals with stroke thus tend to have long lasting difficulty in performing activities of daily living (ADL) such as reaching, grasping and lifting objects. Rehabilitation technologies have the potential to promote motor recovery after stroke. Robotic therapies provide precise and repetitive movement training, and require less supervision from therapists [2]. A recent meta-analysis of 34 clinical trials found upper extremity robotic therapy improved ADL ability, function and strength when compared to other interventions, but the advantages of robotic therapy may not be large enough to be clinically relevant [3]. Robotic technologies that have been tested in clinical trials are mainly focused on recovery of the shoulder and elbow, and often involve practicing components of ADL without the ability to manipulate real objects [4]. However, the notion of task specificity demands that all limb segments involved in a task must be rehabilitated in a coordinated fashion [5]. While recent studies have challenged the importance of task specificity [6], [7], other studies have found that motor learning relies on sensory and biomechanical feedback loops during multi-joint movement [8]. To enable task specific training, devices are needed that allow practice of complex multi-DOF tasks involving use of the hand to grasp and manipulate objects, since hand function is crucial to a functional limb [9].

Several robots have been developed that assist movements of the hand isolated from the rest of the limb [10], [11], [12], [13], [14], [15], [16], [17], [18]. These devices require sitting in the clinic with the arm supported in a pre-defined posture and/or don't allow interacting with objects. The potential to transfer gains to real life situations could be limited, given growing evidence of abnormal coupling of proximal and distal control in stroke patients, such that arm posture [19], activation level of proximal muscles [20], and level of arm support [21] can affect control of hand muscles. Examples of hand robots that can be used during ADL practice include the Hand-of-Hope, which is powered by five linear actuators and offers individual control of each digit [22]. The PneuGlove [23] is a pneumatically powered glove that contains air bladders that extend the fingers when inflated. Cybergrasp (Immersion Inc, San Jose, CA) uses cables routed through a linkage mounted to the back of the hand [24]. Extension force in each cable is controlled with five motors located remotely. The X-Glove is a portable device with 5 linear actuators that independently extend the digits [25]. These approaches are promising, with the ability to finely control assistance levels to each digit during task practice. However, these robots are complex, tethered and costly, which may limit integration with daily activities and transition to home-based therapy interventions.

In this study we performed a feasibility study on home use of Hand Spring Operated Movement Enhancer (HandSOME), which utilizes springs for finger extension assistance allowing for lightweight, inexpensive, and portable actuation that enables integration of the impaired hand into ADL practice. While some commercially available portable passive devices exist, including the SaeboFlex [26] and SaeboGlove (Saebo Inc., Charlotte NC), the spring assistance from these devices allows for limited finger ROM. In the case of the SaeboFlex, only large objects can be grasped because the applied torque increases rapidly as

the fingers close, requiring high flexor forces when grasping small objects. Previously, we showed that HandSOME could improve ROM and functional grasp when worn by individuals with stroke [27]. While most stroke patients regain the ability to flex their fingers voluntarily, they have limited recovery of volitional extension. This pattern of recovery is due to involuntary activation of flexors, inability to activate the extensors and flexor hypertonia (increased resistance to passive extension) [28][29]. The path of the springs on HandSOME provide an extension torque that approximately matches the torque required to open the fingers passively, thereby compensating for flexor hypertonia and maximizing ROM [27]. HandSOME also couples thumb and finger movement through a linkage to ensure coordinated grasp and functional use of the hand.

The goal of this feasibility study was to determine the degree that subjects would comply with this home-based intervention, as measured by the number of movement repetitions performed. We identified the dropout rate and assessed the main challenges to compliance. Finally, we measured the magnitude of gains in function and ROM after home training with HandSOME, to determine if a larger scale controlled study was justified.

II. Methods

Ten subjects were enrolled into the study (Table 1). All subjects had a diagnosis of stroke more than six months prior to entry into the study, impaired ability to open the affected hand and difficulty performing reach and grasp tasks. Subjects were required to have trace ability to extend the wrist and fingers and full passive wrist ROM. All participants provided informed consent. The study protocol was approved by the Institutional Review Board of MedStar Health Research Institute.

A. HandSOME intervention

HandSOME (Fig.1) uses a four bar linkage to coordinate the movement of the finger metacarpophalangeal (MCP) joints and the thumb carpometacarpal (CMC) joint, ensuring normal kinematics during pinch-pad grasp. As the digits close, the spring assistance decreases, enabling a large ROM without fatiguing the subject when grasping objects. The magnitude of the torque assistance is adjustable by changing the number of elastic cords. We used two types of elastic cords: a thick polypropylene covered elastic cord (stiffness $k = 297$) N/m) and a thin elastic cord (k = 89 N/m). Both cord types were 5cm long at rest length and the therapist could customize the number and type of cords for each subject. Fig. 2 shows typical assistance profiles from the three most common spring configurations. Friction was less than 0.038 Nm [27].

During the first visit to the clinic, the therapist fitted HandSOME to the subject's hand and provided training on how to don the device independently. The subjects were asked to perform 90 minute therapy sessions at home, at least five times a week for four weeks. Each training session began with donning the HandSOME and focused on the object manipulation tasks prescribed by the physical therapist. The movement of the affected hand was measured by an encoder (E4 optical rotary encoder, US Digital, Vancouver, WA) at the center of the MCP joints and Arduino-based logging electronics that were integrated into HandSOME. Once a week, the subject returned to the clinic to download stored data and replace the

battery integrated into the logging electronics. During this visit, the therapist would troubleshoot any problems the subject was having, adjust the tasks to be performed during the week and adjust the HandSOME spring configuration if needed. During all clinic visits, the number of practice repetitions was kept to a minimum so that any gains could be attributed to the home practice.

The therapist developed a list of tasks to perform during the home training based on subject ability and preferences. Subjects used objects at their home similar to the following: water bottle, pill bottle, pen, large object (3–4″ width), small object (1/2–3/4″ width), jar with lid. The bimanual tasks were to remove and then replace the pill bottle cap and jar lid. The other tasks were to pick up the object and place at another location. Tasks were graded in several ways based on therapist judgement. Targets started on the tabletop and progressed by moving further away from the body and more laterally. Once this was achieved, targets were progressed to different heights. If the subject had mastered all of these levels, objects were made heavier. Additionally, the therapist could ask the subject to perform the tasks standing (easier) or sitting (harder), or with a pronated (easier) or neutral forearm posture (harder).

B. Clinical outcome measures

All assessments were performed before and after the 4-week training intervention and again 3 months after the end of training. The Fugl-Meyer assessment of the upper extremity (FM) was used to assess motor impairments at the shoulder, elbow, wrist and fingers [30]. The FM evaluates reflexes, coordination patterns and the ability to perform several simple movements. The Action Research Arm Test (ARAT) was used to assess functional use of the upper extremities [31]. It is based on performance of 19 items that are divided into four subscales: Grasp, Grip, Pinch, and Gross movement. The Motor Activity Log (MAL) assessed use of the limb at home [32]. It is a structured interview during which respondents are asked to rate how they use their more-impaired arm for 28 ADL in the home. Activities include brushing teeth, buttoning a shirt or blouse, and eating with a fork or spoon. The Modified Ashworth Scale (MAS) was used to assess hypertonia at the fingers, wrist and elbow [33].

C. Biomechanical outcome measures

Subjects were seated in front of a table and performed 2 repetitions of 5 tasks. The tasks were: 1) full digit flexion/extension: straightening the fingers as much as possible from a closed fist position; 2) thumb opposition: touching the thumb to the tip of the 5th digit; 3) grasp a water bottle and bring to mouth to drink; 4) pick up a small nut and put it on the top of a shelf; 5) grip strength was quantified with a dynamometer (JAMAR 5030J1 Hand Dynamometer). Tasks 1 and 2 were used to measure the ROM in the thumb and fingers. Tasks 3 and 4 measured how well the arm and hand were coordinated during reach and grasp. Motion capture was performed with an electromagnetic motion capture system, the MiniBirds® (Ascension Technologies) controlled by the Motion Monitor® Software (Innovative Sports Technology). Electromagnetic markers were taped to the nail of the thumb, index, middle and ring fingers. Additional markers were placed on the back of the hand and at the wrist. The position and orientation of each marker were sampled at 120 Hz.

The thumb abduction angle and total extension angle of each digit, defined as the sum of the three extension joint angles within that digit, were calculated based on the Euler sequences recommended by the International Society of Biomechanics [34]. For Tasks 1 and 2, extension ROM of all 4 digits were averaged to provide a general measure of the ability to open the hand.

For the reach and grasp tasks (Tasks 3 and 4), the hand path ratio was calculated based on the wrist marker data. Hand path ratio is the length of the path of the wrist marker normalized to the length of the straight line that connects the start and stop points of the movement [35]. Smaller hand path ratios indicate more direct movements and less reliance on proximal compensation. For each trial, visual inspection was used to mark 3 time points: the start of movement, the time when the object was grasped and the time when the object was at its final location. The straight line path and actual path length taken between these 3 locations was calculated and used to form the hand path ratio.

D. Training Intensity

The total number of movements each subject performed during the training sessions was calculated from the HandSOME encoder data, which measured MCP flexion/extension. Velocity peaks greater than 5 deg/sec in amplitude and separated by more than 120ms were identified. A movement was defined by the time points before and after the peak where velocity dropped to below 10% of the peak velocity. The peak was ignored if velocity did not drop below 10% of peak velocity before the next peak. Movement amplitudes were calculated from these start and stop time points. Movements less than 4 degrees were not included.

E. Data analysis

The Shapiro Wilk test was performed on all data to test normality assumptions for statistical analysis. Paired t-tests were used to determine significant differences between the posttraining and baseline time points, and between the follow-up and baseline time points. A Bonferroni correction was applied to account for multiple comparisons; all p values were multiplied by a factor of 2. The effect of training intensity on functional improvement was determined by calculating the correlation between ARAT score gains and number of movements performed during training.

III. Results

Seven subjects completed the protocol. Six of these subjects donned the device independently and one required help from a caregiver. Three subjects dropped out due to difficulty donning and doffing the device and lack of caregivers at home to assist. The 7 subjects who completed the study were generally positive about the treatment and several commented that they were trying to use their hand more after the 4 week training period. The number of movements (including both flexion and extension) varied considerably across the 7 subjects from a low of 43 per day to a high of 1873 per day (mean of 448 ± 651 movements per day). One subject performed a total of 37460 movements, while the rest of the subjects performed less than 9300 movements. The total movement number distribution

was normalized with a log transformation before statistical analysis (Shapiro-Wilk, p=0.55). The number of hours the device was used varied widely from 3 to 33 hours. There was a significant correlation between hours of training and movements performed $(r=0.82,$ p=0.026), which supports the notion that subjects who performed a low number of movements did not comply with the 1.5 hours per day guideline. There was no evidence that compliance was affected by impairment level. The correlation between number of movements and impairment level (baseline FM) was not significant ($r=0.52$, $p=0.23$). Additionally, two of the dropouts had baseline FM scores below the mean, while the third had a baseline FM above the mean.

The training did not increase hypertonia in the fingers, wrist or elbow (Table 2). Average MAS scores were not increased at the post training or follow-up time points relative to baseline (p>0.6). There was a significant decrease in impairment at the post time point; FM scores increased by 4.9 ± 4.1 points (p=0.039). There were also significant gains in function at the post time point; ARAT scores increased by 3.3 ± 2.6 (p=0.032). There was a strong and significant correlation between the number of movements performed and gains in function, as measured by the ARAT ($r=0.90$, $p=.005$) (Fig. 3). Five subjects (#3, #4, #7, #8, #10) responded well to the intervention and had gains of 6 points or more on either the ARAT or the FM at the post time point, which meets or exceeds the Minimum Clinically Important Difference (MCID) for these clinical tests [36], [37]. However, gains in the FM and ARAT were no longer significant at the 3 month follow-up (Table 2). Gains in amount of functional limb use at home (MAL) were not significant at the post time point, but gains approached significance at the 3 month follow-up; MAL scores increased by 0.33 ± 0.32 (p=0.07) at follow-up.

Biomechanical data were generally consistent with clinical outcomes. As a group, there were no significant changes in digit extension or thumb abduction throughout the study (Table 2). However, there was a large variance across subjects, and the 5 subjects who responded well to the treatment, as determined by clinical score gains greater than MCID, all had improved finger extension and thumb abduction (example data are shown in Figs. 4&5). This subgroup of 5 subjects achieved significant gains at the post-training time point in digit extension (mean gain=19.8 \pm 10.2 degrees, p=0.024). However, at the 3-month follow-up, gains were no longer significant in digit extension (mean gain= 1.4 ± 29.3 degrees, p=1.0).

Improvements in proximal arm control were evidenced by changes in the reach path ratio (Table 2). The ratio decreased significantly at the post-training time point $(p=0.038)$, but changes were no longer significant at the 3-month follow up (p=0.340). Grip strength did not change significantly across the 3 time points.

IV. Discussion

In this convenience sample of 10 chronic stroke subjects, three individuals withdrew from the study due to difficulty donning the device. Of the remaining 7 individuals, 5 achieved clinically significant improvements in impairment (FM) and/or functional (ARAT) use of their affected limb. This result is promising considering that the training was done at home

with inexpensive technology and without therapist supervision. The only treatment-related burden on the clinical staff was a weekly visit with the therapist to troubleshoot any problems and adjust the treatment regimen. This protocol could be easily integrated with the outpatient phase of usual care and could potentially improve the rate and level of recovery of individuals after stroke.

The ability to independently and easily don the device was critical for compliance. Three subjects dropped out predominantly due to difficulty donning the device and all subjects preferred trying to don the device themselves, despite having caregivers who could assist. Future work is needed to improve independent use for this population. Additionally, two individuals completed the study but did not have clinically significant gains after the intervention. At baseline these individuals were not substantially more impaired than other study subjects (Table 1). However, these individuals performed 2312 and 867 total movements during the intervention, which was well below the group mean of 8957 movements. Reduced compliance and engagement with the home-based intervention could have been a factor for these individuals. Additionally, the potential for gains may have already been exhausted in these 2 subjects; they were the only subjects in the group who participated in a prior treatment study that involved 24 hours of upper extremity therapy, 12 of which involved using the HandSOME in conjunction with an arm robot [38]. A larger sample size could provide additional information about the characteristics of the individuals most likely to benefit from the treatment.

Across all subjects, the average number of movements completed per day was 448, which is much higher than the number of movements performed during a conventional therapy session (32 functional and 54 ROM movements) [39]. However there was large variation across subjects in total movements performed, and a strong correlation was observed between ARAT score gains and the number of movements practiced. We chose to perform correlations with the ARAT because it tests functional reach and grasp tasks, which were the focus of the home training. However, this dose effect has not been consistently observed in studies of individuals with partial ability to open the hand (as were used in our study). A recent study carefully controlled the number of repetitions during massed practice therapy, and found no dosage effect in chronic stroke subjects who received 3200, 6400, 9600 or 10,808 repetitions of upper extremity tasks [40]. Additionally, a recent multisite study of 361 subacute stroke patients found no differences between groups who received 28.3 hours of intensive task oriented training, 26.7 hours of occupational therapy and a usual and customary care group that received 11.2 hours of occupational therapy [41]. While the number of movement repetitions were not reported in this study, it is likely the groups who received more time in therapy received much higher numbers of task repetitions. These studies support the notion that the effects of task specific training may plateau at a certain number of repetitions. While our small pilot study is not directly comparable to these larger controlled studies, the presence of subjects in our study who performed a very low number of movements may have contributed to the significant dosage effect we observed in our data.

Our study also showed the importance of the inclusion of long term follow-up assessments when examining clinical interventions. There was a striking decline in nearly all clinical and biomechanical measures between the post and follow-up time points. All of the significantly

improved outcomes at the post time point were no longer significant at the follow-up time point (FM, ARAT, reach path ratio). The 5 subjects who responded well to the treatment and

had significant gains in extension ROM immediately after treatment, returned to baseline levels 3 months later. The "threshold" hypothesis put forward by Schweighofer could explain this result [42]. They used a sophisticated computational model to predict that if motor training brings performance above a certain threshold, spontaneous arm use will be sufficient to drive further gains in performance and spontaneous use. However, performance gains that don't reach the threshold for promoting spontaneous arm use will be in vain and any gains immediately after training will be lost at followup. One subject did perform a very large number of repetitions during training (1873 movements per training day). However, this subject also did not cross the threshold, as his clinical scores did not improve further at the 3-month followup. To promote spontaneous use of the affected limb, in future studies, subjects will be asked to wear the device as an orthosis to assist during real ADL in addition to the regimen prescribed by the therapist. We will also fabricate customized plastic versions of the HandSOME that will be given to subjects to use during the follow-up period, in the hopes that highly motivated subjects will continue using the device without any direct contact with therapists.

The learned nonuse hypothesis states that stroke patients do not spontaneously use the affected limb despite having adequate motor capacity because of a conditioned behavior to compensate with the other limb [43]. CI therapy has been designed to reverse learned nonuse and has been shown to improve both motor capacity and spontaneous arm use [44]. The learned nonuse phenomenon could explain the gains we observed immediately after treatment that were lost at followup, presumably because the subjects returned to their baseline levels of limb use during the followup period. The addition of the "transfer package", used in CI therapy to promote spontaneous limb use, may have prevented the losses at followup. The role of learned nonuse could be tested by using subacute patients, who would be less affected by learned nonuse, or assessing the degree of nonuse in chronic subjects by comparing baseline clinical scores with those at hospital discharge.

HandSOME is similar conceptually to the Script Passive Orthosis (SPO), which provides individualized spring extension assistance at the wrist and each digit [45]. A home-training study with SPO reported gains in the FM similar in magnitude to what we observed [46], however a second controlled study found no differences between this experimental home treatment and a control group that received a standard home exercise regime [47]. Similar to our results, these 2 studies with SPO also observed a large variance across subjects in the amount of therapy performed and significant dosage effects. However, there are many differences between the SPO intervention and ours. The SPO intervention focused on joint ROM exercises, with the arm supported against gravity (SaeboMAS), and prompted by video games. Our intervention involved functional unimanual and bimanual tasks, such as reaching, grasping and manipulating real objects at the patient's home, and allowed movement practice anywhere in the home, including while standing. This focus on functional tasks may explain the gains we observed in the ARAT. However, this required adequate proximal arm and grip strength to allow completion of tasks. These 2 protocols could be combined for maximum effect, with subjects initially performing ROM exercises

with gravity support, and as strength improved, this could be followed by practice of functional tasks throughout the home.

There are also technical differences between the SPO and HandSOME. SPO allows individual control of the 5 digits, while HandSOME uses a 4-bar linkage to couple the digits together as one-DOF. This guarantees that objects can be grasped with a simple grasping pattern, even of coordination between joints is poor. At the wrist, HandSOME uses a standard soft wrist splint if needed, while the SPO provides spring assistance to wrist flexion/extension movement. SPO uses a leaf spring combined with an elastic cord to provide a fairly constant torque offset to the digits. In contrast, HandSOME provides a torque profile that decreases as the fingers flex, so that excessive grasp force is not needed to overcome the springs when grasping small objects. Further study is needed to determine if any of these differences are clinically relevant.

Although in many cases the alternative to independent home therapy is no therapy at all, the lack of a control group is a limitation of this study. It is not possible to determine if similar or even better results could have been achieved with a different home therapy program that did not include HandSOME. However, few functional tasks would have been possible without the use of HandSOME since subjects were selected who had major difficulty performing grasp and release tasks unassisted and use of the device greatly expanded the range of tasks that could be practiced at home.

Future work will focus on improving the usability of the device to increase compliance. We plan to use a single strap for all 4 fingers if subjects have difficulty using the multiple strap method. We also plan to reduce the overall bulkiness of the structure which may limit using the device as part of real ADL performance. Additionally, current work involves a more complicated high-DOF version of the HandSOME that allows for a larger range of movement patterns, including pointing, typing, key grip, power grasp and fine pinch [48]. We also observed that hand opening ability decreased when the arm was lifted against gravity, even when wearing HandSOME. We are developing a wearable passively powered exoskeleton to be used in conjunction with HandSOME that provides variable levels of gravity compensation for the shoulder [49]. This would reduce the effort required to complete tasks for subjects with proximal weakness, potentially improving compliance.

Overall the results from this study showed that individuals with stroke can achieve significant improvements after 4-weeks of independent home intervention with the HandSOME device. While these results are preliminary, and retention of gains remains to be demonstrated, these findings are promising due to the low cost of the intervention and the potentially straightforward integration of this intervention into outpatient therapy. Additional examination of the use of HandSOME for independent home therapy is recommended.

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Biographies

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Fig. 1.

Hand Spring Operated Movement Enhancer (HandSOME). The encoder measures movement and a battery powered datalogger saves position data of the hand. The four bar linkage couples movement of the thumb and fingers. Elastic cords provide assistance torque to counter balance flexor hypertonia and assist weak extensor muscles. The assistance level can be changed by adjusting the number of cords. A fitting pad customizes the location of Velcro loops that hold the fingers in place.

Typical assistance torque profiles used during training. Full flexion is 90 degrees and full extension is 180 degrees.

Correlation between log of number of movements and gains in the ARAT immediately after training (r=0.90, p=.005).

Fig. 4.

Data from subject 3 during Task 1 (range of motion test), showing gains in index finger extension post training. Gains were mostly retained at the followup time point. The ideal curve would peak at 180 degrees, full extension.

Fig. 5.

Data from subject 7 during Task 2 (thumb opposition task). Gains in thumb range of motion were apparent post training, but performance had returned to baseline levels by the followup time point. The ideal curve would range from 0 to 90 degrees of abduction.

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Table 1

Patients that withdrew from the study prior to completion. 5 ₹, Ĕ

Mean (SD) Changes in Outcomes Measures Mean (SD) Changes in Outcomes Measures

full extension is 180 degrees on de Brees $\#$ decreases indicate improvement decreases indicate improvement

FM= Fugl-Meyer, ARAT= Action Research Arm Test, MAL=Motor Activity Log, MAS= Modified Ashworth Scale FM= Fugl-Meyer, ARAT= Action Research Arm Test, MAL=Motor Activity Log, MAS= Modified Ashworth Scale