NeuroRehabilitation 22 (2007) 1–5
IOS Press

Orthotic aided training of the paretic upper limb in chronic stroke: Results of a phase 1 trial

John F. Farrell[a], Henry B. Hoffman[a], Janet L. Snyder[a], Carol A. Giuliani[b] and Richard W. Bohannon[c,*]
[a]*Saebo, Inc., Charlotte, NC, USA*
[b]*University of North Carolina, Chapel Hill, NC, USA*
[c]*Physical Therapy Consultants, West Hartford, CT, USA*

Abstract. This was a phase 1 investigation of an upper limb training program using the SaeboFlex dynamic orthosis to improve upper limb motor status. Thirteen individuals with chronic hemiparesis from stroke (age 26–71 years) participated. After being fitted with a SaeboFlex orthosis, each participant was engaged in 5 days of training (6 hours per day) that consisted of repetitive, task oriented activities with the SaeboFlex, exercises, and functional electrical stimulation. Individuals demonstrated improvements in movement at the shoulder and elbow. Wrist extension also improved, but wrist flexion and finger movement did not. Two more global measures of upper limb status improved. Muscle tone decreased. All participants remained pain free. This investigation demonstrates that a program using the orthosis was accompanied by many desirable changes and no untoward consequences.

Keywords: Stroke, arm, hand, recovery, rehabilitation

1. Introduction

Stroke is the most prevalent disabling neurologic disease in the industrialized world. One of the most common consequences of stroke is a loss of motor capacity contralateral to the vascular lesion. This loss can be particularly problematic in the upper limb, as it is severely paretic in over 50 percent of the patients discharged from the hospital after stroke [11]. Although some motor recovery usually occurs, most individuals whose initial weakness is severe do not regain functional use of the upper limb [16,18]. This failure to regain upper limb function is primarily the result of agonist muscle weakness [4], but factors such as impaired motor control [8] and spasticity [5] can also contribute.

Recently, some success has been realized in treating individuals with stroke who have residual limitations in upper limb function. One treatment of particular note is constraint induced therapy, which involves many hours of practice with the affected hand while the unaffected limb is constrained by a sling or other means. Several randomized-controlled trials have shown such therapy to improve both self-reported and observed use of the paretic upper limb of patients with stroke [12,14,17]. Another promising treatment is robotics. Robotics involves interactive, machine-assisted/resisted movement of the paretic upper limb and provision of computer-generated feedback. Randomized controlled trials provide evidence for the effectiveness of robotic based treatments [2,9]. The success of these 2 interventions notwithstanding, they are not practicable for most patients and do not address the difficulty that many have in opening their hands following a stroke. To help ameliorate this problem, 2 of the authors developed an upper limb training program using a dynamic orthosis (SaeboFlex) for the hand.

*Address for correspondence: Dr. Richard W. Bohannon, PT, NCS, FAHA, Physical therapy Consultants, 130 Middlebrook Road, West Hartford, CT 06119, USA. Tel.: +1 860 233 1033; Fax: +1 860 233 0609; E-mail: ptconsultant@comcast.net.

ISSN 1053-8135/07/$17.00

The purpose of this phase 1 study of individuals with chronic hemiparesis after stroke was to describe their response to a motor retraining program incorporating the SaeboFlex. We hypothesized that a program involving repetitive practice of grasp and release activities with the aid of the SaeboFlex would result in improved motor function.

2. Method

2.1. Patients

Individuals were recruited to participate in the trial via a web site and advertisements in stroke magazines. To be eligible for inclusion, individuals were required to: 1) have a time since onset of stroke of at least 6 months, 2) be at least 18 years of age, 3) be able to follow multipart verbal instructions, 4) have a threshold of active motion in the upper limb (i.e., 10° of shoulder flexion/abduction, 10° of elbow flexion/extension, and one-quarter range of volitional finger flexion when the hand was positioned in wrist and finger extension), 5) be capable of egressing from a chair and standing for 2 minutes without an assistive device, and 6) be either independent in self-care or have a caretaker to provide assistance. Individuals were excluded if their affected upper limb was flaccid, if their affected hand or wrist had joint deformities or contractures, or if they were able to voluntarily extend their wrist and fingers through the full range. A convenience sample of 13 individuals meeting the aforementioned criteria participated. Each provided written informed consent. There were 6 women and 7 men in the sample. Nine were paretic on the left and four were paretic on the right. The mean (standard deviation) of their age was 54.1 (13.8) years. The mean (standard deviation) of their time since onset was 4.1 (3.9) years.

2.2. Measures

Pre-intervention measures of the paretic upper limb were obtained by a clinician with over 5 years of experience using standard procedures. The same clinician, without reference to pre-intervention measures, repeated the measures post-intervention. Active range of motion of the shoulder, elbow, and wrist was measured goniometrically. Specifically documented were active excursion of shoulder flexion/abduction, elbow flexion/extension, and wrist flexion/extension. Finger flexion and extension movements were described on the basis of observation. Flexion was dichotomized as full or partial. Extension was dichotomized as absent or partial. Overall status of the paretic limb was characterized using the Fugl-Meyer Upper Extremity Assessment [6] and the Motor Status Score [1]. The Modified Ashworth Scale was used to measure the tone of nine muscle groups [3]. Lower scores indicate less muscle tone. To facilitate the calculation of a sum Modified Ashworth Score (maximum possible = 45) individual scores were first converted to values of 0 to 5. Pain ratings, using a standard 0 to 10 scale [10], were documented “at rest” and “with activity”.

2.3. Intervention

The 5 day per week, 6 hour per day intervention included 3 components but focused on practicing tasks while wearing the SaeboFlex orthosis (Fig. 1). The SaeboFlex orthosis, which was designed to allow rapid training of grasping and releasing with the affected hand, consists of a wrap around forearm support attached to a dorsal hand platform that anchors two spring attachments. Individual finger sleeves are attached to the springs by high tensile polymer line to provide assistance with finger extension. Spring tensile strength can be adjusted for the appropriate amount of finger extension assistance needed.

Once fitted and educated in the basics mechanics of using the SaeboFlex orthosis, patients began a multi-tiered activity protocol based on systems theory and motor control principles [15]. Three considerations were foundational to the activities: 1) practice is an important factor in motor learning, 2) active problem solving is vital for motor learning and retention to occur, and 3) hand use is a driving factor for recovery of arm function. Intervention tasks included picking up lightweight objects such as a 7.6 cm diameter sponge ball (weighing < 60 g) and placing it on or in various targets (e.g., 28 cm $\times$ 32 cm $\times$ 40 cm plastic storage crate). The elevation and placement of the target container were modified to elicit increased movement at certain joints based on the rehabilitation needs of the individual participant. Additionally, targets were selected or modified to require increasingly precise placement of the ball. Participants were continually challenged with a multitude of creative and stimulating tasks, such as tic- tac- toe, as their abilities increased. Altering the environment and tasks forced participants to engage in active problem solving. Movement accuracy was emphasized but no limitations were placed on the quality of movement or strategies employed by the

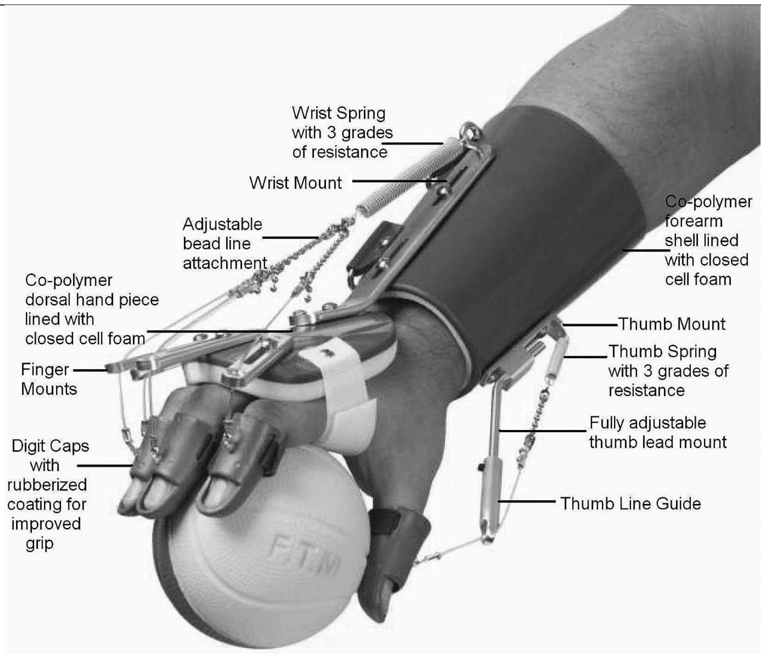

Fig. 1. SaeboFlex orthosis applied to the upper limb.

participant. Assistance included stabilizing objects to be grasped, (e.g. transferring a ball from one target to another might require placing the ball in the palm of the hand until independent grasp could be accomplished) and verbal instruction to help facilitate grasp and release. Assistance was decreased as the participant became more independent in the tasks.

The other, more minor components of the intervention, were exercise and neuromuscular electrical stimulation [13]. Exercise focused on strengthening, motor control and range of motion. It was conducted during 2 or 3, 30-minute daily sessions. Strengthening exercises were targeted primarily at proximal muscle groups and were customized to the individual. The isolated exercise movements were then integrated into the functional task as quickly as possible. Neuromuscular electrical stimulation targeted weak wrist and finger extensors. Twenty minutes of the stimulation was provided in combination with volitional muscle activation. Current was delivered at an intensity level sufficient to produce muscle tetany. The cycle was set at 8 seconds on/16 seconds off.

2.4. Analysis

Data were summarized descriptively. Where warranted, Wilcoxon Matched Pairs Signed Rank Tests were used to compare pre- and post intervention measures. The critical probability level was $p < 0.05$.

3. Results

Most of the measures used in this study improved over the course of the 5 day intervention. Active excursion increased significantly for all shoulder and elbow movements (Table 1). At the wrist, extension increased significantly but flexion did not. Finger flexion did not change as all 12 individuals who had full range on the first day also had full range on the final day and as the 1 individual who had partial range on the first day also had partial range on the last day. Finger extension, which was absent in all but 1 individual on the first day, improved to partial range in only one patient. The 1 individual who had partial range of finger extension on the first day did not change. Both measures used to characterize upper limb status (Fugl-Meyer and Motor Status Assessment) improved significantly over the course of the intervention (Table 1). Muscle tone decreased over the course of the intervention (Table 1). No patient reported any pain in the upper limb, either before or after the intervention.

4. Discussion

We hypothesized that by assisted hand opening the SaeboFlex orthosis would provide participants with enhanced opportunities for goal directed upper-limb tasks

Table 1
Comparison of Pre- and Post- Intervention Measures of Upper Limb Status

Measure (units)	Pre-Intervention	Post-Intervention	Wilcoxon Results	
	Median/Mean ± SD	Median/Mean ± SD	Z	p
Shoulder flexion (degrees)	50.0/46.6 ± 43.0	60.0/62.0 ± 38.0	−3.182	0.001
Shoulder abduction (degrees)	60.0/60.2 ± 22.6	64.0/76.5 ± 27.9	−3.064	0.002
Elbow flexion (degrees)	116.0/109.6 ± 23.4	124.0/117.5 ± 18.4	−2.536	0.011
Elbow extension (degrees)	50.0/67.3 ± 53.0	88.0/93.8 ± 37.7	−2.666	0.008
Wrist flexion (degrees)	20.0/21.2 ± 20.6	30.0/25.8 ± 19.9	−1.604	0.109
Wrist extension (degrees)	0.0/10.0 ± 16.3	5.0/16.2 ± 20.0	−2.207	0.027
Fugel-Meyer-Upper Limb	26.0/25.7 ± 5.7	30.0/31.0 ± 8.2	−3.187	0.001
Motor Status Assessment	23.8/25.7 ± 9.6	27.8/29.7 ± 6.0	−3.186	0.001
Summed Ashworth	10.0/10.5 ± 4.3	7.0/6.9 ± 2.7	−3.071	0.002

and thus improve limb movement and function. Like constraint induced therapy [12,14,17] and robotics [2, 9], the SaeboFlex orthosis involved repetitive practice. Although the intervention included other components, we believe that the major component of the intervention (repetitive practice with the SaeboFlex orthosis) may have resulted in the hand becoming redefined in the participant's schema as a functional unit. Gordon [7] stated "it is the hand that guides the arm rather than the other way around." According to motor learning theories, motor programs are not simple stimulus-response patterns but are dependent on sensory and biomechanical feedback loops for appropriate modification [7]. If this is true, then the proprioceptive feedback received from the paretic hand and fingers when positioned by the SaeboFlex in a functional grasp position might contribute to improved proximal motor control.

It is proper at this point to acknowledge the several weaknesses in our research design. The first has already been alluded to; that is, as the intervention was multifaceted, improvements cannot be attributed with assurance to the repetitive training with the SaeboFlex. This is particularly true as there was no control group. Second, the 2 investigators who served as the clinical therapists for all treatment sessions were involved in the design and marketing of the SaeboFlex program. The potential of bias, therefore, is present. Third, although research has supported the metric properties of the measures used, they were all obtained by a single therapist whose ability to obtain reliable measurements has not been confirmed. Fourth, no follow-up was conducted. Such was not possible as participants lived in various cites/states and were unavailable.

While the aforementioned weaknesses limit the strength of the evidence, this is an initial study exploring the efficacy of the SaeboFlex protocol. Given the increased upper limb mobility and enhanced grasp capabilities demonstrated by participants using the SaeboFlex, further investigation is certainly warranted.

References

[1] M. Aisen, J. England, S. Fasoli, H.I. Krebs, N. Hogan and B.T. Volpe, Assessing the Motor Status Score: a scale for the evaluation of upper limb motor outcomes in patients after stroke, *Neurorehab Neural Repair* **16** (2002), 283–289.

[2] M. Aisen, H.I. Krebs, N. Hogan, F. McDowell and B.T. Volpe, The effect of robot-assisted therapy and rehabilitative training on motor recovery following stroke, *Arch Neurol* **54** (1997), 443–446.

[3] R.W. Bohannon and M. Smith, Interrater reliability of a Modified Ashworth Scale of muscle spasticity, *Phys Ther* **67** (1987), 206–207.

[4] C.G. Canning, L. Ada, R. Adams and N.J. O'Dweyer, Loss of strength contributes more to physical disability after stroke than loss of dexterity, *Clin Rehabil* **18** (2004), 300–308.

[5] H.P. Francis, D.T. Wade, L. Turner-Stokes, R.S. Kingswell, C.S. Dott and E.A. Coxon, Does reducing spasticity translate into functional benefit? An exploratory meta-analysis, *J Neurol Neurosurg Psychiatry* **75** (2004), 1547–1551.

[6] A.R. Fugl-Meyer, L. Jaasko, I. Leyman, S. Olsson, and S. Steglind, The post-stroke hemiplegic patient: A method for evaluation of physical performance, *Scand J Rehabil Med* **7** (1975), 13–31.

[7] J. Gordon, Assumptions underlying physical therapy intervention: theoretical and historical perspectives, *Movement Science: Foundations for Physical Therapy in Rehabilitation*, Rockville, MD: Aspen Press, 1987, 1–30.

[8] M. Levin, Interjoint coordination during pointing movements is disrupted in spastic hemiparesis, *Brain* **119** (1996), 281–293.

[9] P.S. Lum, C.G. Burgar, P.C. Shor, M. Majmundar and M. Van der Loos, Robot-assisted movement training compared with conventional therapy techniques for the rehabilitation of upper-limb motor function after stroke, *Arch Phys Med Rehabil* **83** (2002), 952–959.

[10] T. Lundeberg, I. Lund, L. Dahlin, E. Borg, C. Gustafsson, L. Sandin, A. Rosen, J. Kowalski and S. Eriksson, Reliability and responsiveness of three different pain assessments, *J Rehabil Med* **33** (2001), 279–283.

[11] H. Nakayama, H.S. Jørgensen, H.O. Raaschou and T.S. Olsen, Compensation in recovery of upper extremity function after stroke: The Copenhagen Stroke Study, *Arch Phys Med Rehabil* **75** (1994), 852–857.

[12] S.J. Page, S. Sisto, P. Levine and R.E. McGrath, Efficacy of modified constraint-induced movement therapy in chronic stroke: A single-blinded randomized controlled trial, *Arch Phys Med Rehabil* **85** (2004), 14–18.

[13] M.B. Popovic, D.B. Popovic, T. Sinkjaer, A. Stefanovic and L. Schwirtlich, Restitution of reaching and grasping promoted by functional electric therapy, *Artificial Organs* **26** (2002), 271–275.
[14] A. Sterr, T. Elbert, I. Berthold, S. Kölbel, B. Rockstroh and E. Taub, Longer versus shorter daily constraint-induced movement therapy of chronic hemiparesis: an exploratory study, *Arch Phys Med Rehabil* **83** (2002), 1374–1377.
[15] A. Shumway-Cook and M.H. Woolacott, *Theories of Motor Control*, Motor Control Theory and Practical Applications. Baltimore, MD: Williams and Wilkins, 1995, 3–21.
[16] A. Sunderland, D. Tinson, L. Bradley and R. Langton Hewer, Arm function after stroke. An evaluation of grip strength as a measure of recovery and a prognostic indicator, *J Neurol Neurosurg Psychiatry* **52** (1989), 1267–1272.
[17] J.H. Van der Lee, R.C. Wagenaar, G.J. Lankhorst, T.W. Volgelaar, W.L. Devillé and L.X. Bouter, Forced use of the upper extremity in chronic stroke patients. Results from a single-blind randomized clinical trial, *Stroke* **30** (1999), 2369–2375.
[18] D.T. Wade, R. Langton-Hewer, V.A. Wood, C.E. Skilbeck and H.M. Ismail, The hemiplegic arm after stroke: measurement and recovery, *J Neurol Neurosurg Psychiat* **46** (1983), 521–524.