



EFFICACY OF MYOELECTRIC BRACING IN MODERATELY IMPAIRED STROKE SURVIVORS: A RANDOMIZED, CONTROLLED TRIAL

Stephen J. PAGE, PhD, MS, OTR/L, FAHA, FACRM, FAOTA^{1,3}, Christine GRIFFIN, OTR/L, MS, BCPR¹ and Susan E. WHITE, PhD, RHIA, CHDA²

From the ¹Occupational Therapy Division, School of Health and Rehabilitation Sciences, The Ohio State University, ²The James Cancer Hospital and Solove Research Institute, The Ohio State University and ³Neurorecovery Unlimited, LLC, Columbus, OH, USA

Background: Repetitive, task-specific practice increases functioning of the paretic upper extremity and decreases upper extremity motor impairment. One method to increase participation in repetitive, task-specific practice is an upper extremity myoelectric device, called the “Myomo”, which uses surface electromyography signals to assist with active movement of the moderately impaired hemiplegic upper extremity.

Objective: To determine the efficacy of regimens comprised of: (i) Myomo + repetitive, task-specific practice; (ii) repetitive, task-specific practice only; and (iii) Myomo only on outcomes for hemiplegic arm.

Methods: Using a randomized, controlled, single-blinded design, 34 subjects (20 males; mean age 55.8 years), exhibiting chronic, moderate, stable, post-stroke, upper extremity hemiparesis, were included. Participants were randomized to one of the above conditions, and administered treatment for 1 h/day on 3 days/week over an 8-week period. The primary outcome measure was the upper extremity section of the Fugl-Meyer Impairment Scale (FM); the secondary measurement was the Arm Motor Activity Test (AMAT).

Results: The groups exhibited similar score increases of approximately +2 points, resulting in no differences in the amount of change on the FM ($H = 0.376$, $p = 0.83$) and AMAT ($H = 0.978$, $p = 0.61$).

Conclusion: The results suggest that a therapeutic approach integrating myoelectric bracing yields highly comparable outcomes to those derived from repetitive, task-specific practice-only. Myoelectric bracing could be used as alternative for labour-intensive upper extremity training due to its equivalent efficacy to hands-on manual therapy with moderately impaired stroke survivors.

Key words: stroke; occupational therapy; upper extremity; rehabilitation; hemiplegia.

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Correspondence address: Stephen Page, Occupational Therapy Division, School of Health and Rehabilitation Sciences, The Ohio State University, Columbus, OH, USA. E-mail: SPPageNeuro@gmail.com

Approximately 6.6 million Americans have experienced a stroke (1), making it a leading cause of serious, long-term disability (2). Most survivors exhibit

LAY ABSTRACT

After stroke, people often have difficulty moving one arm. This randomized controlled study examined a device that amplifies and helps muscle activity. Specifically, the study examined the effect of this device when it is provided as a component of conventional arm therapy, vs when it is provided by itself, or when conventional arm therapy is provided by itself. The study found that all 3 conditions render comparable benefits in terms of being able to move the arm again, and in terms of being able to use the arm for functional, valued, everyday tasks. This is an important finding; incorporation of the device alleviates some of the effort expended by the treating therapist and allows the patient to participate more actively in the therapy regimen. Therefore, this regimen could be used instead of a conventional regimen that relies solely on the therapist treating the client in a one-on-one fashion.

moderate impairment of the upper extremity (UE) (3–5), which is typified by limited active movement in their paretic shoulders, elbows, wrists and fingers. Efficacious UE regimens that facilitate neuroplasticity and UE recovery (6–8) emphasize integrating the paretic UE in repetitive, task-specific practice (RTP) attempts (9). However, the dense level of UE deficit exhibited by people with moderate-to-severe impairment undermines participation in RTP and, ultimately, UE recovery (10).

Myoelectrically-controlled devices have been integrated into prosthetic limb designs for decades (11), and, more recently, have been integrated with RTP in moderately impaired stroke survivors (8, 12). During RTP sessions, patients’ electromyography (EMG) activity in the affected biceps and triceps is transmitted to a powered orthosis. Based on the amount of real-time EMG activity displayed on an “app”, the clinician can regulate the physical assistance provided by the device to facilitate paretic elbow flexion and/or extension and, ultimately, task completion. In preliminary studies, integration of a myoelectric device (called the “Myomo”) into RTP was as efficacious as manual practice in reducing paretic UE impairment and increasing function in moderately-impaired stroke survivors (8, 12). This is a potentially significant finding, given that therapist-guided practice with moderately-impaired stroke survivors can be time-consuming and taxing for both the clinician and the patient.

Table I. Contact time features of each intervention group

Group	Amount of Myomo therapy	Amount of RTP	Total intended contact time
Myomo + RTP	½ h/day, 3 days/week for 8 weeks = 12 contact hours	½ h/day, 3 days/week for 8 weeks = 12 contact hours	24 contact hours
RTP	0 contact hours	1 h/day, 3 days/week for 8 weeks = 24 contact hours	24 contact hours
Myomo	1 h/day, 3 days/week for 8 weeks = 24 contact hours	0 contact hours	24 contact hours

Myomo: upper extremity myoelectric robotic device; RTP: repetitive task practice.

As a next step, the primary aim of this study was to compare the efficacy of a RTP regimen comprising Myomo use only (Myomo) with the efficacy of time-matched regimens in which subjects participated in Myomo-based practice and RTP in equal amounts, or in RTP only. Despite the fact that myoelectric devices have been applied to a variety of clinical populations, this was the first randomized controlled study comparing their efficacy with the current gold standard of rehabilitative care (i.e. RTP). It was hypothesized that Myomo therapy with RTP would result in significantly greater reductions in UE impairment and activity limitation than the other 2 conditions.

METHODS

Participants

Study subjects were recruited using approved advertisements distributed to local stroke support groups and outpatient rehabilitation clinics. The inclusion criteria were: (i) UE Fugl Meyer score $\geq 10 \leq 25$; (ii) presence of volitionally activated EMG signal from the paretic biceps brachii of at least 5 μ V amplitude; (iii) stroke experienced >12 months prior to study enrollment; (iv) a score ≥ 24 on the Folstein Mini Mental Status Examination (MMSE); (v) age ≥ 35 and <85 years; (vi) experienced one stroke; (vii) discharged from all forms of physical rehabilitation; (viii) Myomo brace fits properly on affected arm without discomfort (i.e. no red marks or discomfort observed in 10 min of use during fitting). Exclusion criteria were: (i) excessive pain in the affected hand, arm or shoulder, as measured by a score ≥ 5 on a 10-point visual analogue scale; (ii) excessive spasticity at the affected elbow, defined as a score of ≥ 2 on the Modified Ashworth Spasticity Scale; (iii) currently participating in any experimental rehabilitation or drug studies; (iv) apraxia (<2.5 on the Alexander scale); (v) severe sensory loss in the affected hand (Nottingham Sensory Assessment scale at least 75% of normal); (vi) severe language deficits (score <2 on National Institutes of Health Stroke Scale (NIHSS) question 9); (vii) uncontrolled cardiovascular, or pulmonary disease, or other disease that would preclude involvement in a therapeutic treatment; (viii) history of neurological disorder other than stroke; (ix) other significant pain or skin irritation in the UE that would be exacerbated with the use of the brace; (x) substantial contracture of the elbow, defined as $>20^\circ$ of elbow flexion, as measured at the baseline evaluation; (xi) mood disorder, assessed with a Geriatric Depression Scale ≥ 18 ("possible major depression").

Sample size justification

From preliminary data obtained using the Myomo, an increase of 3.5 on the FM scale was estimated for the Myomo + RTP treatment. Conservatively, it was computed that over 80% power would be available to detect the difference if the Myomo (or

RTP) group had an increase of 1.25 with a standard deviation (SD) of 1.5 or an increase of 0.5 with a SD of 2.

Study design and randomization

This was a randomized, controlled, single-blinded study in which subjects were randomized by the research coordinator using a computer-generated randomization number table to receive: (i) Myomo combined with RTP (Myomo + RTP); (ii) RTP only (RTP), which constitutes the most frequently used regimen in clinical environments; (13, 14); or (iii) Myomo therapy only (Myomo). The coordinator also matched groups for age and FM score, which was the primary outcome variable. As shown in Table I, contact time (i.e. frequency, duration) was kept consistent among all 3 groups, with only the content of the interventions varied by treatment group. ClinicalTrials.gov: NCT01654315.

Apparatus

The Myomo (Fig. 1) is US Food and Drug Administration (FDA)-approved, non-invasive, lightweight, wearable system that uses surface EMG signals from the user's affected elbow flexor and extensor muscles to control a powered orthosis that assists with movement of the paretic UE. The device continuously monitors the surface EMG signals, and these signals are filtered and processed to infer a desired joint torque. Signal processing of the EMG is accomplished through a system comprised of off-the-shelf EMG sensors, analogue signal-processing components, and digital signal-processing components. The signal-processing algorithm enables bidirectional control, from a single degree of input, through the use of a unilateral active assist, combined with a competing passive force. The parameter of system gain (amount of assistance in the active assist direction) generally varied during the course of a session as the subject fatigued. The base unit for software gain corresponded



Fig. 1. Myomo device.

to 12 V of motor voltage per volt of surface EMG voltage. The parameter for the passive opposing force was generally constant throughout a therapy session, and usually changed slightly from session to session to account for changes in muscle tone. The treating therapist could adjust the system parameters to alter the amount of assistance that the device provided.

Interventions

RTP (either with or without the Myomo) was used as the basis for intervention, regardless of the group to which a subject was assigned, to encourage functional use of the affected UE. Tasks were selected by the patient, in collaboration with his/her treating therapist, and on the basis of each subject’s preferences. The tasks were selected so the patient was challenged, as this appears to be a major factor in facilitating cortical plasticity (15), and since support for the use of RTP as a fundamental basis for retraining UE function is well-established (16, 17). Upon selecting tasks, they were practiced during therapy sessions and under the supervision of a study team member in smaller components that required successful completion before the entire task was completed in its entirety. Subjects completed activities in standing, seated, supine, and side-lying positions, thus imposing postural control and weight-shifting demands, while temporal domain elements were engaged by requiring the patient to repeat the task components or total task activity as frequently as possible during a defined time interval. “RTP” consisted of the above approach, practiced without the device on. Myomo intervention involved the subject wearing the device either during all (Myomo only) or half (Myomo + RTP) of the session. The latter was chosen as a study condition, since it is often the case that therapists will intersperse device-oriented approaches with movement attempts that do not use the device to encourage learning and control that is generalizable. When performing each movement, the lowest amount of assistance by the device to complete the task was used.

Outcome measures

A rater who was blinded to intervention administered outcome measures twice before intervention, and one week post-intervention (POST). (i) The primary outcome for this study was the UE section of the FM (18), which assessed UE impairment. The measure takes into account evolving synergy patterns as well as isolated strength, coordination, and hypertonia. Data are based on a 3-point ordinal scale (0= cannot perform; 2= can perform fully) for a total score of 66. The FM has been shown to have strong test-retest reliability (total=0.98–0.99; subtests=0.87–1.00), inter-rater reliability, and construct validity (19, 20). (ii) The Arm Motor Activity Test (AMAT) (21) was the secondary outcome for this study and was used to determine whether changes occur in activity limitation. The AMAT is a 13-item test in which ADLs are rated according to a functional

Table II. Characteristics of participants

Characteristics	Myomo only (n = 14)	Myomo + RTP (n = 8)	RTP only (n = 9)
Age, years, mean (SD)	55.79 (9.25)	52.89 (11.38)	57.22 (7.68)
Men, n (%)	9 (60)	4 (40)	5 (55)
Hemiparesis affecting right UE, n (%)	5 (33)	3 (30)	2 (22)
Affected same side as dominant, n (%)	5 (33)	2 (20)	2 (22)

UE: upper extremity; Myomo: UE myoelectric robotic device; RTP: repetitive task practice.

ability scale that examines affected limb use (0= does not perform with affected arm; 5= does use arm at a level comparable to unaffected side) and a Quality of Movement Scale (0= no movement initiated; 5= normal movement).

Statistical analyses

Because the groups were independent of one another, the sample was relatively small, and the stroke population can be heterogeneous even with strict study criteria, we applied a Kruskal–Wallis test to examine differences between magnitude of change between groups ($\alpha=0.05$). All analyses were carried out using JMP Pro 12 (statistical discovery from SAS, Cary, NC, USA)

RESULTS

Applying the above study criteria, 34 stroke survivors were enrolled after signing consent forms approved by the ethics board. Of these individuals, 31 completed the protocol and were analysed (18 males, mean age 55.38±9.35 years; 10 hemiparesis affecting the right UE; 9 hemiparesis affecting same side as dominant). Fig. 2 depicts the flow of subjects through the study. Each group was similar in initial characteristics, as shown in Table I.

On the primary outcome measure, all 3 groups exhibited near-identical score increases of approximately +2 points, resulting in no differences in the amount of change (Table III). On the secondary measure, both groups incorporating the Myomo exhibited nearly-identical score increases of approximately +1 point, while the RTP group exhibited a score increase of +2.6 points. The between-group comparison for FM and AMAT showed there were no significant differences between groups on all measures (FM: $H=0.376, p=0.83$; AMAT: $H=0.978, p=0.61$). The most commonly-practiced tasks were using the UEs

Table III. Behavioural outcomes

Group	Average Pre FM Mean (SD)	Post FM Mean (SD)	Score change	Between-group p-value	Average Pre AMAT Mean (SD)	Average Post AMAT Mean (SD)	Score change	Between-group p-value
Myomo only (n = 14)	19.64 (3.81)	22.42 (4.44)	+2.78	0.83	28.35 (7.33)	29.21 (8.67)	+0.86	0.61
Myomo + RTP (n = 8)	18 (5.90)	20.87 (6.40)	+2.37		26.87 (6.53)	28.62 (8.38)	+1.75	
RTP only (n = 9)	17.61 (4.43)	20.44 (5.59)	+2.84		22.77 (6.55)	25.33 (5.24)	+2.56	

“Average Pre” denotes scores obtained at Pre-1 and Pre-2, which were averaged to create a single mean score. “Post” denotes mean of individual scores obtained after intervention.

Myomo: UE myoelectric robotic device; RTP: repetitive task practice; FM: Fugl-Meyer; AMAT: Arm Motor Activity Test; SD: standard deviation.

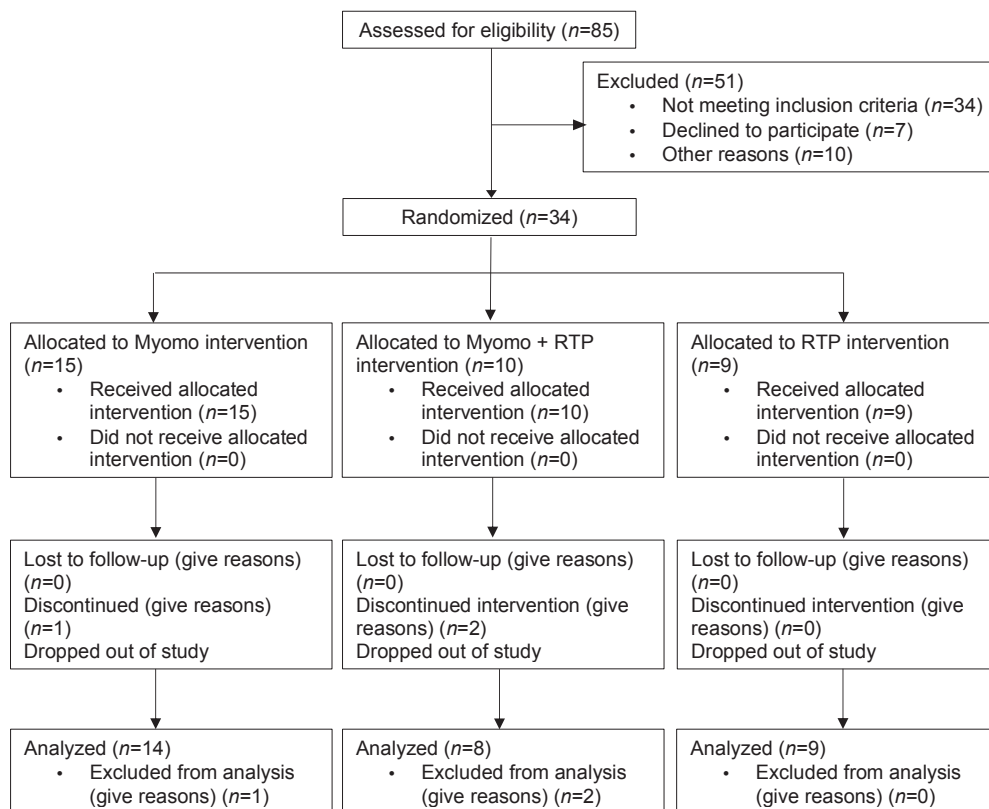


Fig. 2. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

to sit to stand from a flat surface, turning on a wall-mounted light switch, moving a cup or food item to/from the mouth, bringing a comb/brush to the head, and, from a seated position, placing items onto a table.

DISCUSSION

There are few treatment options available for the burgeoning population of stroke survivors with moderate impairment of the UE. In this single-centre, randomized controlled trial, the primary aim was to compare efficacy of Myomo + RTP with RTP only and Myomo use only on paretic UE impairment. It was hypothesized that Myomo therapy with RTP would result in significantly greater reductions in UE impairment and activity limitation than the other 2 conditions. All treatments were matched for session duration, frequency, and their timing, relative to pre- and post-testing (Table I) and subjects were matched in key demographic characteristics across treatment groups (Table II). Nonetheless, after intervention, score changes were comparable across groups, leading us to reject the primary study hypothesis. Consistent with preliminary work (8) these findings confirm that approaches integrating myoelectric brace use yield comparable functional effects to those derived from RTP-only in the increasing

population of stroke survivors with moderate UE impairment. This is a notable finding, given that manual treatment approaches guided by a therapist (i.e. RTP only) can be time and labour-intensive and taxing for both the therapist and the client. This is especially true in the moderately-impaired population, which tends to exhibit a variety of motor impairments (e.g. synergistic UE movements; limited active UE movement), which can undermine active RTP participation, and make treatment time- and labour-intensive. Myoelectrics may, thus, provide a straightforward approach that aids subjects in movement attempts with comparable efficacy to manually based approaches, and with the added benefit of providing real-time information to the patient and therapist, using the “app” described above. Given that all participants were in the chronic stage of recovery, and that changes were exhibited during a time when no other rehabilitative or physical exercise approaches were provided, the changes were probably attributable to the intervention rather than to chance.

It is worth noting that the amount of reduction in UE impairment and activity limitation exhibited by subjects in this study were consistent with previous Myomo studies, and with our conservative power estimate. For instance, Page et al. (8, 22) reported that use of the Myomo with RTP elicited reduced paretic UE impairment (+2

points on the FM), and increased ability to perform valued activities, while Stein and colleagues (12) reported larger treatment effects with a Myomo-based approach. The results of this study corroborate those of previous work. This level of consistency provides strong support for the precept that treatments incorporating portable myoelectrics are as efficacious as RTP, and constitute a viable option for stroke intervention.

While the study design exerted high internal control, and subject demographics were well matched among the 3 groups, several limitations should be noted associated with the study. First, the device tested in this trial did not always work as expected. For example, occasional sessions were interrupted by having to adjust EMG sensor pads, poor Bluetooth communication between the device and tablet-based application that enables control of the device, and/or to affix a new device to a particular subject's UE. While sessions were continued for the appropriate duration, this was, nonetheless, an interruption that could have diminished continuity of practice, and occurred on a total of 6 occasions. Secondly, although lightweight, the device was somewhat cumbersome on the paretic UE, and made some functional task performance awkward, such as reaching to the mouth during simulated self-feeding tasks. Thirdly, to exert appropriate control across subjects, the tasks in which subjects could engage during RTP was limited to specific bilateral UE activities (e.g. lifting a laundry basket) and unilateral tasks (e.g. drinking from an adapted cup using the paretic UE). This restriction was a study strength in terms of maintaining a consistent treatment regimen across subjects; yet, in the clinic, subjects will often be permitted to choose the functional activities in which they engage. Future studies may wish to allow subjects to select activities in order to increase relevance generalizability, and, possibly, outcomes associated with RTP participation. Future studies would also be strengthened by larger sample sizes.

Conclusion

Participation in RTP incorporating a myoelectric device was associated with comparable motor changes to manually-based therapies in which the subject practiced with the guidance and hand-over-hand assistance of a licensed therapist. These changes occurred with therapist contact time kept equal between groups. Further studies will be needed to show whether myoelectric bracing could be viably used as alternative for labour-intensive UE training, and/or used as an augmentative strategy that would have equivalent efficacy to hands-on, manual therapy with moderately impaired stroke survivors.

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REFERENCES

1. Mozaffarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, Cushman M, et al. Heart disease and stroke statistics--2015 update: a report from the American Heart Association. *Circulation* 2015; 131: e29–e322.
2. Prevalence and most common causes of disability among adults – United States, 2005. *MMWR Morb Mortal Wkly Rep* 2009; 58: 421–426.
3. Broeks J, Lankhorst G, Rumping K, Prevo A. The long-term outcome of arm function after stroke: results of a follow-up study. *Disabil Rehabil* 1999; 21: 357–364.
4. Mayo NE, Wood-Dauphinee S, Côté R, Durcan L, Carlton J. Activity, participation, and quality of life 6 months poststroke. *Arch Phys Med Rehabil* 2002; 83: 1035–1042.
5. Heller A, Wade DT, Wood VA, Sunderland A, Hower RL, Ward E. Arm function after stroke: measurement and recovery over the first three months. *J Neurol Neurosurg Psychiatry* 1987; 50: 714–719.
6. Wolf SL, Winstein CJ, Miller JP, et al. Effect of constraint-induced movement therapy on upper extremity function 3 to 9 months after stroke: the EXCITE randomized clinical trial. *JAMA* 2006; 296: 2095–2104.
7. Page SJ, Levine P, Leonard A, Page SJ, Levine P, Leonard A. Mental practice in chronic stroke: results of a randomized, placebo-controlled trial. *Stroke* 2007; 38: 1293–1297.
8. Page SJ, Hill V, White S. Portable upper extremity robotics is as efficacious as upper extremity rehabilitative therapy: a randomized controlled pilot trial. *Clin Rehabil* 2013; 2: 494–503.
9. Winstein CJ, Wolf SL, Dromerick AW, et al. Effect of a task-oriented rehabilitation program on upper extremity recovery following motor stroke: the ICARE randomized clinical trial. *JAMA* 2016; 315: 571–581.
10. Hendricks HT, van Limbeek J, Geurts AC, Zwartz MJ. Motor recovery after stroke: a systematic review of the literature. *Arch Phys Med Rehabil* 2002; 83: 1629–1637.
11. McLean L Scott RN. The early history of myoelectric control of prosthetic limbs (1945–1970). In: A. Muzumdar, editor. *Powered upper limb prostheses*. Berlin: Springer-Verlag; 2004: p. 1–2.
12. Stein J, Narendran K, McBean J, Krebs K, Hughes R. Electromyography-controlled exoskeletal upper-limb-powered orthosis for exercise training after stroke. *Am J Phys Med Rehabil* 2007; 86: 255–261.
13. Jette DU, Latham NK, Smout RJ, Gassaway J, Slavin MD, Horn SD. Physical therapy interventions for patients with stroke in inpatient rehabilitation facilities. *Phys Ther* 2005; 85: 238–248.
14. Latham NK, Jette DU, Coster W, et al. Occupational therapy activities and intervention techniques for clients with stroke in six rehabilitation hospitals. *Am J Occup Ther* 2006; 60: 369–378.
15. Kleim JA, Barbay S, Cooper NR, et al. Motor learning-dependent synaptogenesis is localized to functionally reorganized motor cortex. *Neurobiol Learn Mem* 2002; 77: 63–77.
16. Mulder T, Zijlstra W, Geurts A. Assessment of motor recovery and decline. *Gait Posture* 2002; 16: 198–210.
17. Woldag H, Hummelsheim H. Evidence-based physiothera-

peutic concepts for improving arm and hand function in stroke patients. *J Neurol* 2002; 249: 518–528.

18. Fugl-Meyer AR., Jaasko L, Leyman I, Olsson S, Steglind, S. The post-stroke hemiplegic patient. I. A method for evaluation of physical performance. *Scand J Rehabil Med* 1975; 7: 13–31.
19. Duncan PW, Propst M, Nelson SG. Reliability of the Fugl-Meyer Assessment of sensorimotor recovery following cerebrovascular accident. *Phys Ther* 1983; 6: 1606–1610.
20. Di Fabio RP, Badke MB. Relationship of sensory organization to balance function in patients with hemiplegia. *Phys Ther* 1990; 70: 542–548.
21. Kopp B, Kunkel A, Flor H, et al. The arm motor ability test: reliability, validity, and sensitivity to change of an instrument for assessing disabilities in activities of daily living. *Arch Phys Med Rehabil* 1997; 78: 615–620.
22. Page SJ, Hermann VH, Levine PG, Lewis E, Stein J, DePeel J. Portable neurorobotics for the severely affected arm in chronic stroke: a case study. *J Neurol Phys Ther* 2011; 35: 41–46.