Task-Specific, Patient-Driven Neuroprosthesis Training in Chronic Stroke: Results of a 3-Week Clinical Study

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OBJECTIVE. We examined the efficacy of a clinically based regimen in which a woman 16 months’ post-stroke participated in daily practice sessions of valued activities of daily living (ADLs). A unique aspect of this intervention was that it was largely patient driven, with the patient practicing ADLs while wearing an electrical stimulation neuroprosthesis.

METHOD. The Fugl-Meyer Assessment (FM), Action Research Arm Test (ARA), Arm Motor Activity Test (AMAT), and Canadian Occupational Performance Measure (COPM) were administered before intervention. Therapy consisted of 3-hr ADL training sessions every weekday during a 3-week period using a neuroprosthesis featuring functional electrical stimulation during treatment sessions. One week after the end of the treatment phase, the FM, ARA, AMAT, and COPM were again administered.

RESULTS. The patient exhibited reduced impairment (FM score change from 31 to 35), decreased time needed to complete AMAT tasks (from 998 s to 558 s), and increased ARA score (from 27 to 31).

CONCLUSIONS. Clinically meaningful changes were realized with distant or minimal therapist supervision, making this regimen a practical and efficacious alternative.


Stoke is the leading cause of serious, long-term disability among adults in the United States (American Heart Association, 2006). Of all stroke-induced impairments, arm hemiparesis may be the most disabling, given its impact on ability to perform activities of daily living (ADLs). Yet, despite the growing need for effective rehabilitation strategies, motor rehabilitation for the affected arm has a negligible functional impact (Duncan, 1997).

Several authors have reported reduced spasticity in the affected arm and increased active range of motion following the use of surface neuromuscular electrical stimulation (NMES; Chae et al., 1998; Powell, Pandyan, Granat, Cameron, & Stott, 1999; Sonde, Gip, Fernaeus, Nilsson, & Viitanen, 1998). Conventional NMES typically uses surface electrodes placed proximally and distally on the extensor carpi radialis longus, extensor carpi radialis brevis, extensor carpi ulnaris, extensor digitorum, and adductor pollicis. A cyclic stimulation pattern is then sent through surface electrodes. Whereas protocols encouraging task-specific, affected-limb use convey motor learning via cortical reorganization in stroke (Szafarski, Page, Kissela, Levine, & Lee, 2006), conventional surface NMES may be suboptimal because patients are not responsible for volitionally activating their muscles (i.e., their participation is passive), and little motor relearning occurs. Given that repeated, task-specific, affected-arm use increases function, an electrical stimulation device that encourages ADL-specific training would overcome conventional NMES limitations.
In this study, we examined the response of a chronic stroke patient to high-dosage, one-on-one therapy sessions over a 20-day period. The therapy sessions included use of an electrical stimulation neuroprosthesis that enabled practice of functional, task-specific activities. The daily session duration was 3 hr, which was consistent with high-duration, task-specific training protocols that have shown efficacy in stroke (Sterr et al., 2002). Recent researchers have used costly automated approaches (e.g., Whitall, McCombe Waller, Silver, & Macko, 2000) or therapy regimens requiring considerable amounts of daily practice (Taub et al., 2006). An advantage of this protocol was its use of task-specific training using a commercially available, clinical neuroprosthesis that could be donned and doffed by the patient and used at home. We hypothesized that the ADL-specific therapy intervention would decrease arm impairment and increase enhance motor function and ADL performance.

Method

Participant

Advertisements were placed in outpatient therapy clinics in the midwestern United States. A research team member screened volunteers using the following inclusion criteria: (1) 10° of active extension in the affected wrist and two additional digits of the affected hand; (2) stroke experienced more than 3 months before study enrollment; (3) a score of 70 or more on the modified Mini-Mental State Examination (MMSE; Teng & Chui, 1987); (4) age between 35 and 85 years; (5) no excessive spasticity in the more-affected upper limb, defined as a score of ≤3 on the Modified Ashworth Spasticity Scale; (6) no excessive pain in the more-affected upper limb, as measured by a score of ≤4 on a 10-point visual analog scale; (7) having experienced only one stroke; (8) discharged from all forms of physical rehabilitation; and (9) a detectable surface electromyograph signal of ≥5 μV or more from the extensor carpi radialis of the affected limb. Exclusion criteria were (1) participating in any experimental rehabilitation or drug studies; (2) being pregnant; and (3) having an uncontrolled seizure disorder.

Using these criteria, a volunteer was identified via an advertisement in a local therapy clinic. She reviewed and signed an approved consent form. The participant was a 61-year-old African American woman with a past medical history significant for diabetes mellitus and high blood pressure. She had experienced a right hemorrhagic stroke 16 months before study entry, as evidenced by a computed tomography scan and magnetic resonance imaging. On hospital discharge, she was admitted to a skilled-nursing facility and then to outpatient therapy at a local hospital. The stroke resulted in dense left hemiplegia; however, the participant gained improvements in use of the affected arm and leg. She continually complained of left-foot numbness and difficulty gripping with left hand. After her stroke, the participant returned to living with her daughter. At 4 months’ poststroke, the participant exhibited 3+/5 strength for wrist flexion, extension, grip, and digit extension. She had 4+/5 strength in her shoulder flexors and biceps. At 10 months poststroke, the participant was living in a two-story home with 15 stairs to the entrance. She required assistance to descend the stairs but was able to ascend stairs independently. The participant began attending outpatient physical therapy to address walking and stairs at this time, and at the initial evaluation for this regimen, the participant exhibited lower-extremity spasticity and flexor synergy interfering with ambulation, and she used a cane for walking. She had deficits with balance, gait, and motor function. Her goals included joint protection and ADL compensatory strategies, home exercise program, ascending and descending stairs safely, and ambulating more than 10 ft. The outpatient therapy that she had received 10 months’ poststroke included instruction in joint protection and ADL compensatory strategies, instruction in a home exercise program, gait training, balance training, and strengthening for left hip and ankle, as provided by a physical therapist.

When the participant entered the study, she was able to walk independently. Her Modified Ashworth Scale scores were 0 in the biceps, triceps, wrist, and fingers. The participant was right-hand dominant, and her left arm was affected by the stroke. Her motor scores before and after intervention are described later in this article. She was motivated and met study inclusion criteria and thus was chosen to participate in this case study.

Apparatus

The Bioness H–200 system (Bioness Incorporated, Valencia, CA) is a microprocessor-based, U.S. Food and Drug Administration–approved, neuromuscular NMES device that was administered as part of the structured exercise program described here. It consists of a forearm–hand molded prosthesis that contains an array of five surface electrodes ranging in size from 2 cm × 2 cm to 6 cm × 4 cm. The electrodes are positioned over the extensor digitorum, extensor pollicis brevis, flexor digitorum superficialis, flexor pollicis longus, and adductor pollicis muscles. Electrode position within the prosthesis is custom fitted for each patient to optimize the contraction of the digit flexors and extendors. Once the optimal position is determined, the five electrodes are secured within the prosthesis. This individualized electrode position enhances the consistency of stimulation with each use. The electrodes are connected to a stimulator that
delivers alternating current at a carrier using a sinusoidal, balanced waveform with a frequency of 11 KHz and pulse bursts at 36 Hz ranging from 0.01 to 0.5 mS.

For this study, the stimulator was set in an interrupted pulses mode with the contraction and relaxation intervals set at 6 s on, 6 s off. Two seconds ramp up and ramp down was included in the 6 s, resulting in 3 s of sustained tetanic contraction that either flexed or extended the digits.

Outcome Measures

We used the upper-extremity scale of the Fugl-Meyer Scale (FM; Fugl-Meyer, Jaasko, Leyman, Olsson, & Steglin, 1975) to determine whether affected-arm impairment changes occurred after participation in the intervention. The FM assesses several dimensions of impairment, including range of motion, pain, sensation, and movement. Data arise from a 3-point ordinal scale (ranging from 0 = cannot perform to 2 = can perform fully), and items are summed to provide a maximum score of 66. The FM offers impressive test–retest reliability (total = 0.98–0.99; subtests = 0.87–1.00) and construct validity (DiFabio & Badke, 1990).

The Action Research Arm Test (ARA; Lyle, 1981) was used to determine whether fine motor skill changes occurred in the affected hand and fingers as a result of participation. The ARA is a 19-item test divided into four categories (grasp, grip, pinch, and gross movement), with each item graded on a 4-point ordinal scale (0 = cannot perform no part of the test; 1 = performs test partially; 2 = complete test but takes abnormally long time or has great difficulty; 3 = performs test normally) for a total possible score of 57. The test is hierarchical in that if the patient is able to perform the most difficult skill in each category, he or she will be able to perform the other items within the category, and thus they need not be tested. The ARA has high intrarater (r = .99) and retest (r = .98) reliability and validity (Lyle, 1981; van der Lee et al., 2001).

We used the Arm Motor Activity Test (AMAT; Kopp et al., 1997) to determine whether changes occurred in ability to perform valued ADLs with the affected arm. The AMAT is a 13-item test in which ADLs are rated according to a functional ability scale that examines affected-limb use (ranging from 0 = does not perform with affected arm to 5 = does use arm at a level comparable to unaffected side) and a Quality of Movement Scale (ranging from 0 = no movement initiated to 5 = normal movement). The ADLs, which are further subdivided into subactivities to be rated, include use of a knife and fork, eating with a spoon, combing hair, and tying shoelaces. The AMAT is a valid, stable, and reliable scale and correlates positively with other stroke-specific functional scales (Kopp et al., 1997).

The Canadian Occupational Performance Measure (COPM; Law et al., 1998) is an interview used to identify occupational performance problems and to measure satisfaction and importance of tasks according to the patient. After questions are asked, clients identify on a scale ranging from 0 to 10 the importance of the task to them, their perception of their performance with skills, and their satisfaction with their performance. Once the top five activities are determined, these tasks are used to guide the treatment. The test is usually administered at baseline and discharge to determine change in performance and satisfaction. If the number is positive, there was change for the better. If the number is negative, then the person’s perception of his or her skills has lessened. In 2004, the COPM was reported to be a valid, reliable, clinically useful, and responsive outcome measure for occupational therapist practitioners and researchers (Carswell et al., 2004).

Testing and Intervention

We used a pretest–posttest case study design. Specifically, after screening and completing an approved consent form, all of the outcome measures were administered in our laboratory by a team member who was unaware of the intervention to be administered. It took approximately 1.5 hr to administer all measures to the participant, excluding the initial evaluation and COPM. Five days after pretesting, the participant returned to the laboratory and met with the treating therapist. The additional evaluations were administered at the following appointment, the H-200 was fitted to the patient, and she was shown how to use the device during an education session lasting 1 hr.

Over the next 5 weekdays, the participant engaged in a home-based, “ramping-up” phase. The purpose of this phase was to acclimatize her to the electrical stimulation sensation and the device and to build up muscle endurance for the “high-duration” phase that was to come. During the ramping-up phase, the participant gradually increased by 5 min per day the duration of stimulation while at home. On the first day, she stimulated for 10 min and increased duration by 5 min each day until she had stimulated for 30 min on Day 5.

During the weekdays of the next 3 weeks, the participant was engaged in 3-hr-long therapy sessions in our research laboratory. The first 30 min of each session consisted of stretching the affected arm and shoulder and working on range of motion. Stretching and exercises during this period included the following: upper trapezius, scalenes, and middle trapezius stretching; shoulder flexion while standing; shoulder flexion with elbow supported; shoulder extension; elbow flexion and extension with shoulder and elbow support with forearm in supination; elbow flexion and extension with arm at neutral without support; wrist extension via weight bearing while standing at table; wall push-ups; and self range of motion of wrist extension. As the participant
progressed through treatment, different exercises were incorporated, including holding the hand behind the head and moving the shoulder from flexion to abduction while the shoulder was in 90° flexed position and holding arm in sagittal plane with 90° shoulder flexion. The goal was for the participant to complete these exercises independently, which she did after a few sessions.

During the subsequent 2.5 hr of each session, the patient used the H-200 for ADLs. Following stroke, some patients lose independent control over select muscle groups, resulting in coupled joint movements that are often inappropriate for the desired task. These coupled movements are known as synergies (Brunnstrom, 1970). ADLs performed using the H-200 were purposefully attempted out of synergy whenever possible to abolish these suboptimal movement patterns. The H200 program ran for 30-min increments with the following personal program every time (Table 1).

The electrical stimulation was administered in a cyclic stimulation pattern for 6 s of stimulation, then 6 s of rest, for the entire duration of the stimulation session. During the stimulation program, the participant engaged in activities correlating to the stimulation sequence. For example, she grasped a fork when the stimulation was extending her digits and then brought it to her mouth during the digit flexion phase. Performance of all activities was planned as described earlier, so that performance of ADLs coincided with provision of stimulation. The first two sessions focused on sensory awareness with stimulation for the participant to use the prosthesis for ADLs; however, the remainder of the sessions focused on using the neuroprosthesis to complete functional activities that were determined by the COPM. Exercises were executed with and without stimulation and are listed in Table 2.

The participant used ring splints intermittently to assist with static stretching and correct joint positioning during functional movements. The participant also completed self range of motion of digits during the “quick” phases of the program to stretch the digit muscles, assisting with elongation of the muscles that exhibited increased tone because of spasticity. She often exhibited mirror movements in which she tried to move her affected hand by simulating with the unaffected hand. To inhibit this response, the participant was told to hold onto objects or to put her hand flat on the table or in her pocket.

The participant returned to the research laboratory 5 days after the intervention period was complete, and the outcome measures were administered in the same order as pretesting. The posttesting was administered by the same team member who had previously administered the measures. He was unaware that the participant had participated in any intervention.

Results

During the course of the intervention, the participant complained of minor fatigue 3 times and shoulder pain twice because of exercises yet provided no persistent complaints or limitations. Device compliance at home was 100%, as measured by a monitor in the device, and the participant attended all clinical sessions.

Before the intervention, the participant was unable to use her right arm for most ADLs and was able to actively extend the affected wrist only 10° and two digits minimally, which was required for study inclusion. Scores obtained before intervention on the FM, AMAT, and ARA reflected this level of movement and are shown in Table 3.

After intervention, the participant’s scores changed as follows:

- FM score increased from 31 before intervention to 35 after intervention, indicating diminished impairment in the affected arm.
- AMAT score only decreased from 99 to 98; however, the time needed to complete AMAT tasks decreased from 998 s to 558 s, reflecting the markedly improved proficiency with which she completed the AMAT ADLs.
- ARA score increased from 27 to 31, indicating increased fine motor skill in the affected hand, and specific score increases were noted on the grip and pinch scales.
- Posttreatment scores on the COPM at baseline included a performance score that increased from 1.2 to 7 posttreatment (a change of 5.8), and a satisfaction score that increased from 3.2 to 7.5 posttreatment (a change of 4.3), indicating that she felt as though she was performing tasks better and that she was more satisfied with how she performed specific tasks.

### Discussion

Research has suggested that participation in task-specific, repetitive training regimens increases affected arm use and function. Yet, because of diminishing lengths of stay, occupational therapists are often limited in their ability to provide such interventions to their patients. The current study examined outcomes associated with participation in a 3-week, task-specific training regimen, in which a patient with chronic stroke used a commercially available neuroprosthesis on her affected arm. The therapy sessions were patient driven and allowed opportunity for motor relearning and for the patient to complete some aspects of treatment independently. Whereas therapists often physically assist patients with tasks, an advantage of the approach described here was that the neuroprosthesis provided support and facilitation to the patient’s affected arm, usually without physical intervention by the therapist. This facet may provide therapists with the opportunity to supervise multiple patients at one time, as needed. Future work by our group will examine this possibility.

After intervention, the participant exhibited decreased impairment in the affected arm, increased fine motor skill, and more rapid ability to perform valued ADLs. More important, these changes were comparable to those reported with use of higher duration regimens, such as constraint-induced movement therapy (Taub et al., 2006), making this protocol a viable, practical alternative to such high-duration regimens. Functionally, the participant reported that she was using the affected arm for ADLs such as grooming, picking up grandchildren, zipping clothing, and applying deodorant. She was also better able to hold and let go of objects (e.g., a favorite coffee cup, her hairbrush) and reported using the arm more for ADLs. However, we did not measure affected arm use, which constitutes a study limitation.

Although largely patient driven, the participant most enjoyed the clinical treatment sessions, and her biggest challenge was arranging transportation to the rehabilitation facility. Although the ability to attend sessions may constitute a challenge for some patients and is a study limitation, an alternative is performing the sessions over the Internet. Recent groups have reported success with this approach, using free network meeting software to administer modified constraint-induced therapy over the Internet (Page & Levine, 2006). Our team is currently examining this possibility, again using the neuroprosthesis described in this article and free network meeting software and digital cameras mounted on computers.

Taken together, these findings add to a growing body of literature suggesting that task-specific repetitive training increases function, even months and years poststroke. A larger trial using the device tested here is now under way to examine this intervention’s impact with a larger and more diverse group of participants and to examine the long-term impact of neuroprosthesis training and will overcome limitations of the current study. Several potential participants were also excluded from this trial because of excessive spasticity or inadequate active movement in the proximal portions of their arms. Indeed, recent data suggest that other therapies can be effectively combined with botulinum toxin A administration to address the former issue (Page, Elovic, Levine, & Sisto, 2003), whereas electrical stimulation could perhaps address the latter concern. Future studies will further examine these treatments as possible gateways to neuroprosthesis use, as described in this study. Many researchers (e.g., Morris & Taub, 2001) have also suggested that a behavioral contract should be administered as part of task-specific protocols like this, both so that participants fully understand therapy requirements and to better ensure therapy compliance. Although not used in the current study, newer protocols by our group are using such contracts during the consent process.

It is commonly believed that spontaneous motor recovery is limited to the first 3 to 6 months following stroke (e.g., Jorgenson et al., 1995). The participant in this study was reported to have plateaued, resulting in her being discharged from her outpatient therapy regimen. However, given the short amount of time in which the patient exhibited changes
and the fact that she was not participating in any other intervention at the time that she exhibited these changes, it is likely that her motor improvements were a result of participation in this intervention. Current efforts are examining the efficacy of the approach described in this article in a randomized controlled manner.

Although electrical stimulation and ADL training are each reimbursed using existing current procedural terminology codes, the described protocol duration may be suboptimal for some patients. At the same time, it is plausible that therapy sessions of even less duration could produce motor changes. Indeed, some evidence (e.g., Classen, Liepert, Wise, Hallert, & Cohen, 1998) has suggested that as little as 15 min of task-specific training is sufficient for cortical reorganization and motor learning to occur. The occupational therapy profession should thus proceed with dose-response work to confirm if there is an optimal duration at which this therapy is maximally efficacious.

As noted by Sterr et al. (2002), “The demanding nature of behavioral intervention techniques can be a major concern in stroke patients; it may also act against the therapy’s effectiveness, when a patient is pushed beyond his/her endurance limits and becomes fatigued” (p. 1374). As stated earlier, the length of individual sessions, and the endurance required to participate in them, has been noted as a critical limitation of newer training approaches such as constraint-induced therapy, which requires participation in 6-hr-per-day ADL training sessions (e.g., Page, Levine, Sisto, Bond, & Johnston, 2002). Results of this study suggest that one way to facilitate patient-driven, task-specific practice that does not fatigue patients is through functional electrical stimulation. The device used in this study supports the wrist in a functional position, provides consistent electrode placement and stimulation parameters, and was easy to use. Moreover, the device allowed the patient to use electrical stimulation while allowing the patient to engage in occupation. We hypothesize that this combination may optimize the brain’s ability to reorganize in a manner most functional to the patient, given that previous studies have shown use-dependent cortical reorganizations following outpatient ADL training (e.g., Szaflarski et al., 2006). Current research is examining this hypothesis using functional magnetic resonance imaging. ▲

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