Training of Reaching in Stroke Survivors With Severe and Chronic Upper Limb Paresis Using a Novel Nonrobotic Device

A Randomized Clinical Trial

Ruth N. Barker, PhD; Sandra G. Brauer, PhD; Richard G. Carson, PhD

Background and Purpose—Severe upper limb paresis is a major contributor to disability after stroke. This study investigated the efficacy of a new nonrobotic training device, the Sensorimotor Active Rehabilitation Training (SMART) Arm, that was used with or without electromyography-triggered electrical stimulation of triceps brachii to augment elbow extension, permitting stroke survivors with severe paresis to practice a constrained reaching task.

Methods—A single-blind, randomized clinical trial was conducted with 42 stroke survivors with severe and chronic paresis. Thirty-three participants completed the study, of whom 10 received training using the SMART Arm with electromyography-triggered electrical stimulation, 13 received training using the SMART Arm alone, and 10 received no intervention (control). Training consisted of 12 1-hour sessions over 4 weeks. The primary outcome measure was “upper arm function,” item 6 of the Motor Assessment Scale. Secondary outcome measures included impairment measures; triceps muscle strength, reaching force, modified Ashworth scale; and activity measures: reaching distance and Motor Assessment Scale. Assessments were administered before (0 weeks) and after training (4 weeks) and at 2 months follow-up (12 weeks).

Results—Both SMART Arm groups demonstrated significant improvements in all impairment and activity measures after training and at follow-up. There was no significant difference between these 2 groups. There was no change in the control group.

Conclusions—Our findings indicate that training of reaching using the SMART Arm can reduce impairment and improve activity in stroke survivors with severe and chronic upper limb paresis, highlighting the benefits of intensive task-oriented practice, even in the context of severe paresis. (Stroke. 2008;39:1800-1807.)

Key Words: electrical stimulation ■ severe paresis ■ stroke ■ training ■ upper extremity

A growing body of evidence indicates that intensive and repetitive task-oriented practice promotes upper limb recovery.1 Typically, however, stroke survivors with severe upper limb paresis are unable to participate in task-oriented training because they have insufficient underlying movement.2 Correspondingly, our investigations have demonstrated that, from the stroke survivors’ perspective, “not enough movement to work with” is the greatest barrier to recovery.3 This may explain why those with severe paresis show little improvement and hence are increasingly excluded from active rehabilitation.4

More recently novel interventions such as automated arm movement training5 and robot-assisted therapy6,7 have been found to reduce arm impairment in stroke survivors with severe paresis. Although promising, these interventions are not accessible to the majority of stroke survivors due to cost. Clearly, there is a pressing need to develop economical nonrobotic devices to aid the stroke survivor with severe paresis. With a view to achieving this objective, a low-cost, nonrobotic training device, the Sensorimotor Active Rehabilitation Training (SMART) Arm, was developed to train reaching (see Figure 1). The device was designed to reduce task difficulty by decreasing the degrees of freedom to be controlled and by minimizing resistance to the movement. Provision was made for increments in load to promote increases in muscle strength, and continuous computer-augmented visual feedback of the position of the limb was provided to enhance motor learning.8 The primary aim of this device was to enable the stroke survivor with severe paresis to actively participate in intensive and repetitive task-oriented practice, where previously this had not been possible.
On the basis of previous studies, we hypothesized that additional benefits could be accrued if the SMART Arm was used with electromyography-triggered electric stimulation (EMG-stim). In the present study, we used stimulation of triceps brachii to assist with execution of the reaching movement through full range elbow extension. Beyond the training session, benefits that were expected included an increase in strength of triceps and an increase in the range of elbow extension. Most importantly, however, it was anticipated that use of EMG-stim would promote motor learning. The rationale was that stroke survivors with severe paresis would lack appropriate proprioceptive feedback due to a lesion involving sensory pathways or secondary to immobility or use of maladaptive movement patterns. Use of EMG-stim during training of normal movement patterns would reinstate appropriate proprioceptive feedback. Because the stroke survivor voluntarily initiated the movement, the neural activity associated with the specification of the goal and outcome of movement would converge temporally as well as spatially in key brain centers. In this regard, it has been posited that neural circuits in the limbic cortex assume a specific role in integrating peripheral afferent-derived feedback of performance with the output of the voluntary motor systems. This sensorimotor integration is assumed to provide a basis on which motor learning can proceed. Because the level of activity necessary to trigger the electric stimulation increased progressively during the course of practice, the progressive, incremental utilization of neural resources could further enhance motor learning.

Thus, the purpose of this study was to determine if practice of reaching using the SMART Arm could improve arm function in stroke survivors with severe paresis. We hypothesized that practice of reaching using the SMART Arm would improve arm function and in addition, that further benefits would be accrued when training was performed in conjunction with EMG-stim.

Methods

Participants
Stroke survivors who volunteered to participate in the study were people drawn from Brisbane, Australia, who responded to media releases and who met the following inclusion criteria: diagnosed with a first-time stroke, stroke interval before study onset at least 6 months, aged between 18 and 80 years, severe upper limb paresis as indicated by a Medical Research Council grade 1 to 3 for triceps brachii, an inability to complete a standardized supported reaching task (push a target [25-g sandbag] off the edge of a table from a position of 90° to 180° elbow extension), a detectable electromyographic signal from the surface of the paretic triceps, no arm rehabilitation services for at least 1 month before the first test date, resident within a 90-minute drive of the university and able to travel to the university for testing, able to understand the study purpose and procedure, and provide informed consent. The exclusion criteria were: upper limb comorbidities that could limit functional improvement (eg, arthritis, pain, other neurological disorders), unable to tolerate cutaneous electric stimulation, and elbow contracture of greater than 15°.

Protocol
A single-blind randomized clinical trial was conducted over a 12-month period. Stroke survivors who satisfied the inclusion criteria were randomly allocated to one of 3 groups: training of reaching using the SMART Arm with EMG-stim (SMART Arm/H11001 stim), training of reaching using the SMART Arm alone (SMART Arm), and control (no intervention). The randomization sequence, drawn up by a computerized number generator, and the group allocation were concealed from all study personnel except trainers throughout the entire study. Trainers and participants were informed of group allocation by telephone or e-mail after baseline testing. All testing and analysis was performed by individuals blinded to group allocation. Participants were instructed to continue existing home programs but to abstain from new rehabilitation during the study period.

Intervention
The control group received no intervention. Both intervention groups received 12 training sessions of 60 minutes’ duration, 3 sessions a week with at least 1 day between sessions over a 4-week period within each participant’s residence. Two physiotherapists, trained in delivery of the intervention, supervised all training according to a standardized set of instructions. All sessions began with a 5-minute warmup period designed to increase arm flexibility. Participants
were then seated on a chair beside the SMART Arm. They were restrained by a seatbelt to restrict compensatory trunk movements and encourage recovery of premorbid movement patterns, which has been shown to lead to better functional outcomes. The affected arm was positioned in pronation and wrist extension (0° to 45°) in a customized thermoplastic splint that prevented active movement. The splint had an aluminum frame that was fixed to a manipulandum. This was mounted on a linear slide to which a potentiometer was attached to transduce displacement, which was provided continuously to the participant in real-time as a bar displayed on a computer monitor. The height of the bar varied in accordance with the displacement of the arm, i.e., extent of reach. At the start of each training session, a horizontal target line was superimposed on the display at a position that corresponded with the participant’s maximum passive reaching distance as established at the beginning of each individual session. The system was programmed such that changes in the color of the real-time bar occurred when 50%, 75%, 90%, and 100% of the individual’s maximum passive reaching distance (i.e., the target line) were achieved. Loads opposing extension of the elbow were applied through a fine high tensile wire connected to the base of the manipulandum and suspended over a pulley at the rear of the table.

Starting from a standardized position, the participant was required to push along the linear slide to reach the target. Participants received continuous visual feedback of reach extent and verbal encouragement from the trainer. After each voluntary attempt that fell short of the target, the trainer manually assisted the participant to reach the target. This was done to ensure that the range of movement through which training occurred was consistent across participants. Based on a training dose established during pilot testing, 60 repetitions per session (6 sets of 10) were undertaken in each of the first 3 sessions and 80 repetitions (8 sets of 10) in each of the remaining 9 sessions. Load was introduced or increased once the target was reached without assistance from the trainer for all 10 repetitions in a set. For each session, number of repetitions, mean reaching distance (\(\text{mm}\)), and load (ounces) were recorded.

The EMG-stim group received electrical stimulation of the lateral head of triceps brachii through an Automove 800 (AM 800) facilitation stimulation microprocessor. Three surface electrodes (diameter 50 mm) were applied, one above the area of the triceps brachii motor point (lateral head), one at the muscle insertion, and a ground electrode on the forearm. The same electrodes were used to monitor electromyographic activity level and to deliver electric stimulation. When prompted by a tone, the participants were required to initiate the reaching task. When the level of activation of triceps brachii reached an initial target threshold of 50 μV electromyographic activity, electric stimulation to triceps brachii was automatically triggered. The threshold level was reached on a given trial, the unit was programmed to automatically move the target level
higher for the next trial. If the threshold level was not achieved, the machine was programmed to automatically adjust the threshold down to the average of the electromyography generated on the preceding 3 attempts. Stimulus parameters consisted of a 1-second ascending ramp, 5 to 10 seconds of 200-μsec pulse width biphasic stimulation at 50 Hz, and a 1-second descending ramp with a 10- to 20-second rest period between trials as appropriate for the individual participant. Duration of the stimulation was set manually to match the time required by the individual participant to achieve the reaching task. The stimulus intensity was set to the maximum that could be tolerated by that participant.

Outcome Measures
Assessment took place during the 3 days before the start of training, within 3 days after training had stopped (4-week end point), and at 2 months follow-up (12-week end point). Assessment of the control participants occurred within the same timeframe. The order of measurements was the same for all participants. The primary outcome measure was the upper arm function (item 6) of the Motor Assessment Scale (MAS). Secondary outcome measures included triceps muscle strength, resistance to passive elbow movement, and peak isometric force as measures of impairment, and distance reached as the secondary measure of arm activity.

Clinical Measures
The MAS is designed to measure recovery of the affected limb over 3 task-oriented subscales, each scored from 0 to 6. “Upper arm function” (item 6) was used for analysis, whereas “hand movements” (item 7) and “advanced hand activities” (item 8) were used to confirm severity at baseline and to monitor carryover into improvement of hand activities. The reliability and validity of this measure with the stroke population has been documented previously.14 Manual muscle testing was used to assess triceps brachii “power” on a scale from 0 (no activity) to 5 (normal power) with the addition of plus and minus scores to denote the percentage of the range through which movement could be performed.15 Good intra- and interrater reliability has been demonstrated for this scale.16 Resistance to passive elbow extension was measured using the modified Ashworth scale, reported as a reliable and valid measure after stroke.17 Participants assumed a supine position with the arm supported in the vertical position for assessment of the modified Ashworth scale and triceps manual muscle testing.

Laboratory Measures
Two reaching tasks were assessed, a dynamic reaching task designed to measure maximum distance reached and an isometric reaching task designed to measure the maximum isometric force that could be generated in a multijoint condition. For each task, participants were seated at a custom-built apparatus with the upper arm in a pendant position, the elbow flexed, and the forearm and hand restrained in pronation through a custom-built brace. Trunk movement was restricted by a harness. A computer monitor in front of the participant provided visual feedback on a vertical bar scale. Time series data were collected and stored using Labview software (National Instruments) and processed using custom computer routines. Setup dimensions were identical for the 3 testing sessions.

For the dynamic reaching task, the testing apparatus was configured similarly to the SMART Arm training device. In 3 separate trials, after a tone, participants were asked to “reach as far as you can.” Continuous visual feedback on linear displacement was provided, and verbal encouragement was given. For each trial, linear displacement over a 5-second period and peak displacement were recorded. Mean peak displacement across the 3 trials was calculated. For the isometric reaching task, the elbow was flexed at 150° and supported in a padded cradle with the hand restrained in pronation by the brace. The participant was required to push against a manipulandum that was instrumented to measure force. In 3 separate trials, after a tone, participants were asked to “push as hard and as fast as possible” and to “keep pushing until I say stop.” Continuous visual feedback on force applied was provided, and verbal encouragement was provided, and verbal encouragement was given.

Table 1. Participant Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>SMART Arm+Stim (n=10)</th>
<th>SMART Arm (n=13)</th>
<th>Control (n=10)</th>
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</thead>
<tbody>
<tr>
<td>Age, years*</td>
<td>61 (16)</td>
<td>67 (8)</td>
<td>69 (11)</td>
</tr>
<tr>
<td>Time since stroke, years*</td>
<td>5 (4.9)</td>
<td>3.4 (2.6)</td>
<td>3 (2.5)</td>
</tr>
<tr>
<td>Arm affected, left/right</td>
<td>6/4</td>
<td>11/2</td>
<td>5/5</td>
</tr>
<tr>
<td>MAS 6, upper arm function, 0–6†</td>
<td>0 (0)</td>
<td>1 (0–3)</td>
<td>1 (0–2)</td>
</tr>
<tr>
<td>MAS 7, hand movements, 0–6†</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>MAS 8, advanced hand activities, 0–6†</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Modified Ashworth scale, 0–4†</td>
<td>2 (1–3)</td>
<td>1 (1–2)</td>
<td>1 (0–2)</td>
</tr>
<tr>
<td>Triceps muscle grade, 0–5†</td>
<td>3 (3–3)</td>
<td>3 (3–3)</td>
<td>3 (3–3)</td>
</tr>
<tr>
<td>Distance reached, mm*</td>
<td>252 (72)</td>
<td>302 (148)</td>
<td>224 (122)</td>
</tr>
<tr>
<td>Peak force, N*</td>
<td>81 (34)</td>
<td>104 (48)</td>
<td>102 (59)</td>
</tr>
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*Mean (SD). †Median (interquartile range).

was given. During each contraction, force was obtained over a 5-second period. Mean peak force across the 3 trials was calculated.

Analysis
Statistical analysis was performed using SPSS (version 11). The primary analysis was intention to treat. Those who completed the study were compared with those who did not using Kruskal-Wallis for nonparametric data and one-way analysis of variance for continuous data. The effects of time were determined using repeated-measures analysis of variance and the effect of group using repeated-measures analysis of covariance with baseline as the covariate. The primary end points for the trial were 4 weeks (posttraining) and 12 weeks (follow-up). Pairwise comparisons were used to determine the differences between time points and between groups. Effect sizes were calculated using partial eta squared ($\eta^2$). The mean difference (95% CIs) between each training group and the control group were calculated based on pooled scores (posttraining and follow-up). Results were accepted as statistically significant at $P<0.05$. Sample size was determined on the basis of ability to detect a clinically significant improvement in the primary outcome measure, the MAS upper arm function. A change in score of one (SD 0.5) represents an incremental increase in requirements for control over greater numbers of degrees of freedom and was therefore considered to be a clinically significant improvement. To achieve 80% power and a significance of 0.05, 12 subjects were required per group, for a total of 36 subjects. To allow a 10% dropout rate, 42 participants were recruited.

Results
Forty-two subjects were recruited to the randomized clinical trial and 33 were included in the analysis (see Figure 2). There were no significant differences at baseline between those who completed the study and those lost to follow-up. Of the participants who were included in the final analysis, 10 received training using the SMART Arm with EMG-stim, 13 received training using the SMART Arm without EMG-stim, and 10 received no training. Characteristics of participants included in the final analysis are outlined in Tables 1 and 2. All participants had an initial score of 3 or less on MAS upper arm function (unable to hold the arm when placed in...
At baseline, the group allocated to SMART Arm alone had a higher level of function and a greater proportion of males (11 of 13) than the other 2 groups. Participants allocated to SMART Arm+stim were, on average, more impaired than participants in the other 2 groups.

All participants allocated to both SMART Arm groups completed 12 hours of training. Pain was reported infrequently and on no occasion prevented training. There were no adverse effects reported. Average training dose was comparable for the 2 training groups in terms of repetitions and load but did not reach the distance of reaching distance of 10). Figures 3 and 4. A group×time interaction was demonstrated for activity measures—upper arm function (F16,60=7.47, P<0.01, ηp2=0.33), peak distance (F4,60=3.11, P<0.05, ηp2=0.17)—and for impairment measures—triceps strength (F4,60=3.84, P<0.01, ηp2=0.20), peak force (F4,60=4.0, P<0.01, ηp2=0.21), and modified Ashworth Scale (F4,60=5.521, P<0.01, ηp2=0.27). Improvements in hand movements occurred for 6 participants (SMART Arm+stim, n=1; SMART Arm [ie, no EMG-stim], n=5) with an increase in scores between 1 and 5 units with an average improvement of 2 units. Improvement in advanced hand activities occurred for 2 participants (SMART Arm, n=2) by a score of 1 unit.

The difference in the degree of improvement exhibited by the 2 SMART Arm training groups was not statistically reliable. However, both groups improved to a greater degree than the control group. A main effect of group was demonstrated for all measures—upper arm function (F2,29=7.08, P<0.01, ηp2=0.33), peak distance (F2,29=4.73, P<0.05, ηp2=0.25), triceps strength (F2,29=7.03, P<0.01, ηp2=0.33), peak force (F2,29=10.062, P<0.001, ηp2=0.41), and modified Ashworth scale (F2,29=4.25, P<0.01, ηp2=0.28). Mean differences in change scores (95% CIs) demonstrated that those who trained with EMG-stim improved more than the control group for all measures—upper arm function (2.1 [1.0 to 3.1]), peak distance (74 mm [22 to 127]), triceps strength (1.5 [0.73 to 2.3]), peak force (41 N [14 to 68 N]), and modified Ashworth scale (−1.5 [−2.3 to −0.7]). Those who received

<table>
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<th>Table 2. Comparison of Outcomes for the 3 Groups</th>
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<tr>
<td>Arm Activity</td>
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<tr>
<td>Upper arm function*</td>
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<tr>
<td>Week 0 (baseline)</td>
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<td>Week 4 (posttraining)</td>
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<tr>
<td>Week 12 (follow-up)</td>
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<tr>
<td>Distance reached, mm†</td>
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<tr>
<td>Week 0 (baseline)</td>
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<tr>
<td>Week 4 (posttraining)</td>
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<tr>
<td>Week 12 (follow-up)</td>
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<td>Triceps strength (grade)*</td>
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<td>Week 0 (baseline)</td>
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<td>Week 4 (posttraining)</td>
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<td>Peak force, N†</td>
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<tr>
<td>Week 12 (follow-up)</td>
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</tbody>
</table>

*Median (interquartile range); †Mean (SD).
‡P<0.05; §P<0.01; †P<0.001 within group differences over time.
SMART Arm training alone improved more than the control group for upper arm function (1 [0.1 to 1.8]), triceps strength (0.8 [0.1 to 1.6]), peak force (64 N [31 to 97 N]), and modified Ashworth scale (−0.7 [−1.5 to −0.1]), but not for peak distance (39 mm [−10 to 88]).

**Discussion**

The findings of this study demonstrated that practice of reaching using the SMART Arm, with or without EMG-stim, significantly increased function (at the impairment and activity level) in stroke survivors with severe and chronic paresis. These changes were maintained for at least 2 months after training had stopped. Changes were not detected for participants in the control group. The degree of improvement exhibited by those who trained with EMG-stim compared with those who trained without EMG-stim did not differ reliably.

This study demonstrated that when task-oriented training was made physically possible for stroke survivors with severe upper limb paresis, clinically significant improvements were made. After 12 hours of practice, upper arm function improved by a score of 2 out of 6, indicating improvement in performance from a single joint action to a multijoint action. The distance that could be reached improved by 33% (92 mm) and the peak force that could be generated increased by 49% (46 N). This suggests that stroke survivors with severe paresis do have potential for recovery and therefore must be considered for active rehabilitation.

It cannot be inferred directly that the changes that were observed resulted in an improved ability to perform daily functional tasks. As participants were characterized initially by a severe level of paresis and the training dose was relatively small, this was not an expected outcome. By the end of the intervention, however, most of the participants were able to use the device to perform repetitive task-oriented reaching practice, thus enabling them to exhibit a level of upper limb function whereby they could reasonably be expected to begin more independent rehabilitation tasks.

The potency of the current intervention may be attributed to the fact that training targeted not only muscle weakness, which was the key manifestation of the underlying impairment, but also the reacquisition of the multijoint reaching movement, the loss of which is a key cause of upper limb disability. Training of reaching resulted in positive transfer to other arm activities as reflected by MAS measures of “upper arm function” and, in some individual cases, measures of “hand movements” and “advanced hand activities.” It is likely that the degree of weakness in many muscles involved in reaching was so great that even small improvements in muscle strength engendered by the training led to marked improvements in their capacity to undertake other upper limb activities. In addition, an increase in joint flexibility and extensibility may have occurred throughout the shoulder, arm, and hand, thereby alleviating an additional source of resistance to the execution of many upper limb movements. Most importantly, however, is that stroke survivors were
provided with the opportunity to practice reaching such that the working point (or end effector), in this case the hand, moved along a straight-line path. It is well established that in point-to-point reaching, between one spatial location and another, the human motor system prefers to have the working point move in a straight line with a smooth, asymmetrically bell-shaped tangential speed profile. In normal conditions, the rest of the effector system will be used in whatever way is necessary to achieve the preferred motion of the working point. Hence, the reaching task will have provided a natural context for training with potential transfer to everyday upper limb tasks, consistent with the goals of a task-oriented approach to stroke rehabilitation.

Contrary to our hypothesis, those who trained with EMG-stim did not demonstrate benefits as a result of training that were reliably greater than those exhibited by the group who received SMART Arm training alone. It is possible therefore that it was repetitive nature of the training, common to both interventions, that was principally responsible for the observed changes in arm function. The absence of a clear advantage for those participants who trained with EMG-stim may be due also to the fact that they were principally trained to increase the degree of muscle activation required to initiate reaching. In contrast, those who did not receive EMG-stim were trained to reach the target not only by actively initiating the movement, but also by virtue of the fact that there was no impulse generated by prior stimulation by voluntarily recruiting the actuating muscles throughout the full range of movement. Ironically, it is the absence of a pronounced benefit for the group that received EMG-stim that highlights one of its major limitations that must be considered further.

It is also possible that the benefits of EMG-stim were obscured by participants who developed maladaptive methods for triggering the delivery of electrical stimulation. In these “trick” methods, electrical stimulation could be delivered when patterns of muscle activity not generative of the
desired movement outcome were produced as long as the triceps brachii muscle was engaged to the required degree. These observations suggest that the electromyographic activity of a single muscle may not be the optimal basis on which to trigger electric stimulation in the context of a multijoint reaching task.

It is important to consider methodological limitations in this study. The number of participants recruited to 2 groups (n=10) did not reach that estimated in power calculations (n=12); however, statistically significant and clinically meaningful change scores were evident between groups. Similarly, differences remained despite intrinsic variation between participants (eg, age, time since stroke, impairment) and uneven group numbers that could have limited the capacity to detect differences between the groups. In addition, although adjustment was made for differences that existed at baseline, the group who received training without EMG-stim contained more males than the other 2 groups, perhaps providing greater scope for change. It is also likely that those who trained with EMG-stim, who were the most impaired before training, experienced greater barriers to skill acquisition than those who trained without EMG-stim. Notwithstanding these considerations, however, the results of the present study provide clear evidence that practice of reaching using the SMART Arm with or without EMG-stim for 12 hours over a 4-week period reduced arm impairment and improved activity in stroke survivors with severe paresis. Because the capacity to undertake task-oriented practice was achieved, the next step will be to explore whether further independent practice that would be considered of sufficient intensity to promote skill acquisition would lead to improvement across all levels of arm function (impairment, activity, and participation).

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Disclosures
None.

References
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