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ORIGINAL ARTICLE

Assisted Movement With Proprioceptive Stimulation Reduces Impairment and Restores Function in Incomplete Spinal Cord Injury

Deborah Backus, PT, PhD,[a] Paul Cordo, PhD,[b,c] Amanda Gillott, OT,[d] Casey Kandilakis, PT, DPT,[a] Motomi Mori, PhD,[e] Ahmed M. Raslan, MD[f]

From the [a]Crawford Research Institute, Shepherd Center, Atlanta, GA; [b]Department of Biomedical Engineering, Oregon Health & Science University, Portland, OR; [c]AMES Technology Inc, Portland, OR; [d]Post-Acute SCI Rehabilitation, Shepherd Center, Atlanta, GA; [e]Division of Biostatistics, Department of Public Health and Preventive Medicine, Oregon Health & Science University, Portland, OR; and [f]Department of Neurological Surgery, Oregon Health & Science University, Portland, OR.

Abstract

Objective: To test whether treatment with assisted movement with enhanced sensation (AMES) using vibration to the antagonist muscle would reduce impairments and restore upper limb function in people with incomplete tetraplegia.

Design: Prospective, pre-post study.

Setting: Laboratory and rehabilitation hospital.

Participants: We recruited 15 arms from 10 individuals (8 men; mean age, 40.5y; mean years postspinal cord injury [SCI], 3) with chronic, incomplete tetraplegia.

Intervention: Two or three 20-minute sessions per week over 9 to 13 weeks (25 sessions total) on the AMES device, which combines repeated movement with targeted vibration to the antagonist muscle.

Main Outcome Measures: Strength and active motion tests on the AMES device; International Standards for the Neurological Classification of SCI (ISNCSCI) motor and sensory examinations; Modified Ashworth Scale (MAS); grasp and release test (GRT); Van Lieshout Test (VLT); and Capabilities of Upper Extremity questionnaire (CUE).

Results: The AMES strength test scores improved significantly in metacarpophalangeal flexion ($P=.024$) and extension ($P=.007$) and wrist flexion ($P=.001$) and extension ($P<.000$). The AMES active motion scores improved in the hand ($P=.001$) and wrist ($P=.001$). The MAS and ISNCSCI scores remained unchanged, whereas the GRT scores increased ($P=.025$). Post hoc analysis showed a trend from pre- to posttreatment ($P=.068$) and a significant change from pretreatment to 3-month follow-up ($P=.046$). There was no significant change in the VLT ($P=.951$) or the CUE ($P=.164$). Five of the 10 participants reported a return of sensation to the digits after the first, second, or third treatment session.

Conclusions: People with chronic, incomplete tetraplegia may experience improvements in impairments and function after treatment on a device combining assisted movement and proprioceptive stimulation. Further investigation is warranted.

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People with tetraplegia desire greater arm and hand function to improve their participation and quality of life.[1,2] Those with complete tetraplegia have options for improving upper limb (UL) function (ie, tendon transfers,[3] neuroprosthetics[4,5] bracing[6]). However, for the approximately 40% of people with tetraplegia who have motor incomplete injuries,[7] there has been little progress in our understanding of how to manage the resulting UL impairments, which further limit the ability to facilitate functional gains. There is little guidance for occupational and physical therapists regarding how to distinguish and treat spasticity,

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dyssynergia, weakness, and diminished somatosensation, impairments that limit UL function in people with tetraplegia.

Recent evidence in people with cerebrovascular accident (CVA) demonstrates that impairment-oriented treatment can lead to improvements in UL strength and coordination and function.[8-10] In an earlier study,[8,9] we demonstrated that assisted movement with enhanced sensation (AMES) using muscle vibration and torque biofeedback resulted in significant increases in strength and joint position control and functional improvements in the UL of people with chronic hemiplegia as a result of CVA.

Although the location of neural damage may differ, the sensorimotor impairments in those with incomplete spinal cord injury (SCI) are similar to those with CVAs. Therefore, the possibility exists that impairment-oriented treatment may be effective in people with incomplete tetraplegia as well. We assessed UL impairment and function in participants with chronic (>1y) incomplete tetraplegia as a result of traumatic SCI after 25 sessions of AMES treatment and again 3 months after treatment ended to test the hypothesis that AMES treatment would reduce impairment and restore UL function in these people.

Methods

Participants

Prospective participants were identified from a database of people who indicated interest in research opportunities or who contacted an investigator in response to an advertisement. Candidates were screened to determine general eligibility. Medical approval for participation was required prior to initiating study procedures.

Criteria for participation in the study included the following: traumatic cervical, motor incomplete SCI (C2-7); age between 18 and 65 years; at least 1 year post-SCI; able to tolerate sitting upright for at least 1 hour; able to identify >70% of the time the correct direction of the passive finger/wrist motion in the UL being treated; motor grade >1 in the wrist extensors, finger flexors, and finger abductors of the UL being treated; and cognitively and behaviorally capable of complying with study procedures.

Exclusion criteria included the following: >50% loss of range of motion as a result of fracture, osteoarthritis or rheumatoid arthritis, or contractures; concomitant traumatic brain injury or CVA (participants who sustained mild traumatic brain injury with no evidence of structural abnormalities as obtained from medical record, physician clearance letter, or participant/caregiver report qualified for the study); chronic intrathecal baclofen therapy; uncontrolled seizure disorder; uncontrolled high blood pressure/angina; participation in an activity-based or other therapy program; progressive neurodegenerative disorder; or any of the following conditions in the treated UL: pain or exercise intolerance, deep vein thrombosis, peripheral nerve injury, skin condition leading to nontolerance of the device, or botulinum toxin treatment in the previous 5 months. Whether the candidate met the criteria was determined via responses on a participant questionnaire, their medical record, when available, or through the medical release form signed by the candidate's physician. Eighteen candidates were screened for inclusion of either of their ULs. If both ULs met the inclusion criteria, then both were enrolled in the study. There were 5 people who failed the screening for participation. Three candidates were excluded because they were too strong, 1 because of chronic degeneration of the spine, and 1 for no active abduction in the little finger. Five participants were enrolled for both ULs. In total, 18 ULs from 13 participants with traumatic SCI were enrolled in the study. Three enrolled participants withdrew from the study before completing all treatments and the posttreatment evaluation, leaving for analysis a total of 15 limbs in 10 people, all of which received both pre- and posttreatment evaluations. One dropout stopped attending sessions and could not be reached; 1 became ill, requiring hospitalization; and a third injured his hand and was unable to continue the study. These latter 2 adverse events were reported to the institutional review board (IRB). Informed consent was obtained from all participants using a form approved by the IRB.

When both ULs qualified for the study, treatment of both limbs was done consecutively, with the dominant UL being treated first and the nondominant being treated after the dominant UL had completed all treatment sessions and performed the follow-up evaluation.

List of abbreviations:

AMES	**assisted movement with enhanced sensation**
CUE	**Capabilities of Upper Extremity**
CVA	**cerebrovascular accident**
GRT	**grasp and release test**
IRB	**institutional review board**
ISNCSCI	**International Standards for Neurological Classification of Spinal Cord Injury**
MAS	**Modified Ashworth Scale**
MCP	**metacarpophalangeal**
SCI	**spinal cord injury**
UL	**upper limb**
VLT	**Van Lieshout Test**

Therapy device and procedure

Identical study activities were carried out at 2 sites (sites 1 and 2), with site 1 serving as the coordinating center. At each site, a physical or occupational therapist performed the outcome measures, and a trained treatment specialist performed the treatment with the AMES device[a] (fig 1) in a therapy gym.

At the beginning of each treatment session, 2 tests were performed using the AMES device. In the strength test, performed first for the metacarpophalangeal (MCP) joints (all 4 combined) and then for the wrist, the participant made 6 maximal-effort contractions (3 in extension, 3 in flexion) while the AMES device held the hand static. The peak volitional torque produced during each of the 3 maximal efforts by the MCP joints and the wrist in each direction was averaged to provide an estimate of strength for that joint in that direction for that day. The treatment specialist also used the strength test results to adjust the participant's target levels of assistance for the treatment session.

In the active motion test, which measured joint coordination and active range of motion, the participant was instructed to follow a graphically presented target on the video screen by rotating the MCP joints or wrist in the AMES device through a 30° arc. The target moved at 2° through the equivalent of ±15° extension and then ±15° flexion of all MCP finger joints or wrist, with intermittent 2- to 3-second pauses at 6 stop points. For this test, the AMES device was set for minimal resistance to the applied movement. Scoring was based on the total time spent with the cursor in line with the target.

After the completion of testing in each session, the participant received treatment on the AMES device. During the AMES treatment of the MCP joints (20min), the AMES device flexed and

Fig 1 AMES treatment device.

extended all of the MCPs of the thumb and fingers simultaneously and cyclically, with the participant assisting this motion. Each complete cycle of movement included 30° MCP extension (hand opening) and 30° MCP flexion (hand closing). Vibration (60 pulses/s, 2-mm displacement) was applied to the MCP flexor tendons during hand opening and to the extensor tendons during hand closing to exaggerate the proprioceptive input that would naturally occur during the movement. Treatment of the wrist was carried out similarly (10min), with cyclical wrist extension and flexion movements (30° at 5°/s) and vibration applied to the wrist flexors and extensors, respectively. In all cases, the effort during movement was shown as visual biofeedback on the computer screen in front of the participant.

Each participant trained 2 or 3 times a week for a total of 25 therapy sessions over a period of 9 to 13 weeks. The AMES device logged the duration of each treatment session and the results of the strength and active motion tests. The AMES strength and active motion tests were not performed at the 3-month follow-up evaluation.

Outcome measures

Evaluation of impairment and function

In addition to the AMES strength and active motion tests during each treatment session, a qualified physical therapist or occupational therapist evaluated each participant before the study, after the last treatment, and 3 months after treatment ended. The clinician first determined the participant's motor and sensory scores of the treated UL according to the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI).[11] The Modified Ashworth Scale (MAS)[12] was used to evaluate spasticity in the wrist and finger flexors and extensors and in the elbow flexors and extensors; the 4 scores were summed for analysis. Function was evaluated with the grasp and release test (GRT)[13] and Van Lieshout Test-short version (VLT).[14] The participant's perception of function was assessed using the self-evaluation Capabilities of Upper Extremity (CUE) instrument questionnaire.[15]

Data acquisition and analysis

On enrollment, each participant was assigned a numerical code that was used to identify data collected in the course of the study. All data were stored either on a computer using the participant code as an identifier or in a locked file cabinet in the study coordinator's office. The data were accessible to the principal investigator, coinvestigators, and study coordinator.

The unit of analysis was 1 UL, and each UL is considered independent, even when both ULs from the same participant were treated. The analysis set of this single-arm, proof-of-concept study included 15 ULs from 10 participants, all of whom minimally completed both pre- and posttreatment evaluations. Two ULs from 1 participant, who fell outside the allowable age range (71.5y), are included in the analysis set. This protocol deviation was reported to the IRB. Prior to enrolling the first participant, the GRT was designated as the primary outcome variable. Because the AMES strength and active motion tests were performed 25 times, the average scores for sessions 1 through 3 were designated as the pretreatment score, and average scores for sessions 23 through 25 were designated as the post-treatment score. Averages were used for these initial and final test scores to minimize the effects of day-to-day variability and motor learning.

The Shapiro-Wilk test was used to assess the normality of the distribution for each outcome variable. Because there was no strong indication of nonnormality, the mixed-effects model (with a random subject effect) was used to analyze the MAS, ISNCSCI (motor: C5-T1; sensory: C2-T2), GRT, VLT, and CUE outcome variables. Specifically, we evaluated whether there was a significant change over time in these scores (pre, post, follow-up).

Table 1 Participant demographics

Variable	Level	Participant	UL
Sex	Female	2 (20)	
	Male	8 (80)	
Enrollment per site	Site 1	7 (70)	12 (80)
	Site 2	3 (30)	3 (20)
Level of injury	C2-3	3 (30)	
	C4-7	7 (70)	
No. of sessions	24		1 (7)
	25		13 (87)
	26		1 (7)
Age at SCI (y)		40.5±13.0 (24.3–71.5)	
ASIA motor score		15.8±3.9 (9.0–21.0)	
Time since injury (y)		3.0±1.1 (1.0–4.9)	

NOTE. Values are n (%) or mean ± SD (range).
Abbreviation: ASIA, American Spinal Injury Association.

Bonferroni multiple comparison was used for pairwise time comparisons (pre vs post, pre vs follow-up, post vs follow-up). Because the data from the AMES strength and active motion tests were not normally distributed, the Wilcoxon signed-rank test was used to evaluate pre- versus postchanges. No multiple comparison procedure was performed to control the overall type I error of multiple outcome variables because this was a small proof-of-concept study to investigate safety and provide preliminary evidence of clinical efficacy. All statistical analyses were performed using SAS version 9.3.[b]

Results

Participant demographics are presented in table 1.

Treatment effect on impairment level

Table 2 provides the means and SDs of clinical impairment assessments. There was no change in the MAS or ISNCSCI scores. In contrast, figure 2 presents significant improvements in the MCP joints and wrist strength and joint control as measured by the AMES strength and active motion tests, respectively.

Treatment effect on function

Table 2 presents the scores for the GRT, VLT, and CUE. Only the GRT scores were significantly improved after training. The GRT scores also increased slightly between posttreatment and 3 months after the treatment ceased.

Changes in somatosensation

Although we did not systematically test for changes in somatosensation, 5 of the 10 participants spontaneously reported a return of sensation to the digits after the first, second, or third treatment session. Their comments, which were transcribed by the treatment specialist, included "I can feel my fingers for the first time since my injury"; "I can feel the bed sheets now"; and "I could feel enough to unlock the brake on my walker."

Discussion

Overall, treatment with a device that combines repeated movements with targeted vibration to the antagonist muscle led to some improvements in impairments and UL function in this population of people with chronic, incomplete tetraplegia as a result of traumatic SCI.

The AMES strength and active motion test scores improved in both the MCP joints and wrist flexion and extension. Interestingly, we did not find significant changes in either the ISNCSCI or MAS outcome measures. The American Spinal Injury Association developed the ISNCSCI as the recommended practice guideline for evaluating and classifying the neurologic impairment of SCIs.[13] The ISNCSCI only assesses 5 muscles of the UL (and 5 in the lower limb). Changes observed in UL function may be caused by changes in muscles not tested with the ISNCSCI. The MAS has been criticized as not being sensitive to the alterations in muscle tone and spasticity seen in SCI[16-18] and may not have been useful in determining changes in tone and spasticity in this study. The potential also exists that changes in tone and spasticity were not necessary for the changes observed in the AMES strength and motion test scores and function.

There was a 23% increase in GRT scores between pre- and posttreatment. Further, we recorded an additional 7.6% increase in scores between posttreatment and follow-up. Although not significant, this increase nominally demonstrates that UL function restored during the course of treatment was retained, at least for the first 3 months posttreatment.

Table 2 Descriptive statistics

Outcome (range of scores)	No. of Limbs (pre-tx, post-tx, follow-up)	Pre-tx, Mean ± SD	Post-tx, Mean ± SD	3mo Follow-Up, Mean ± SD	*P* (pre-tx to follow-up)
Clinical assessment of impairment					
MAS (0–20)	15, 14, 13	5.3±3.4	4.4±3.2	4.2±3.3	.371
ISNCSCI motor (0–25)	15, 13, 11	15.3±3.9	14.6±4.4	16.1±4.7	.299
ISNCSCI sensory-light touch (0–18)	15, 14, 12	14.1±3.3	13.8±3.3	14.5±3.1	.459
ISNCSCI sensory-pin prick (0–18)	15, 14, 12	10.5±5.4	11.3±5.3	11.1±4.6	.343
Assessment of function					
GRT (no maximum)	15, 15, 13	58.5±37.9	72.0±40.0	77.5±44.9	.025
VLT (0–50)	15, 15, 13	27.2±11.8	27.3±11.1	27.4±12.6	.951
CUE (32–224)	12, 14, 13	58.2±23.0	64.1±24.6	63.8±25.8	.164

Abbreviation: tx, treatment.

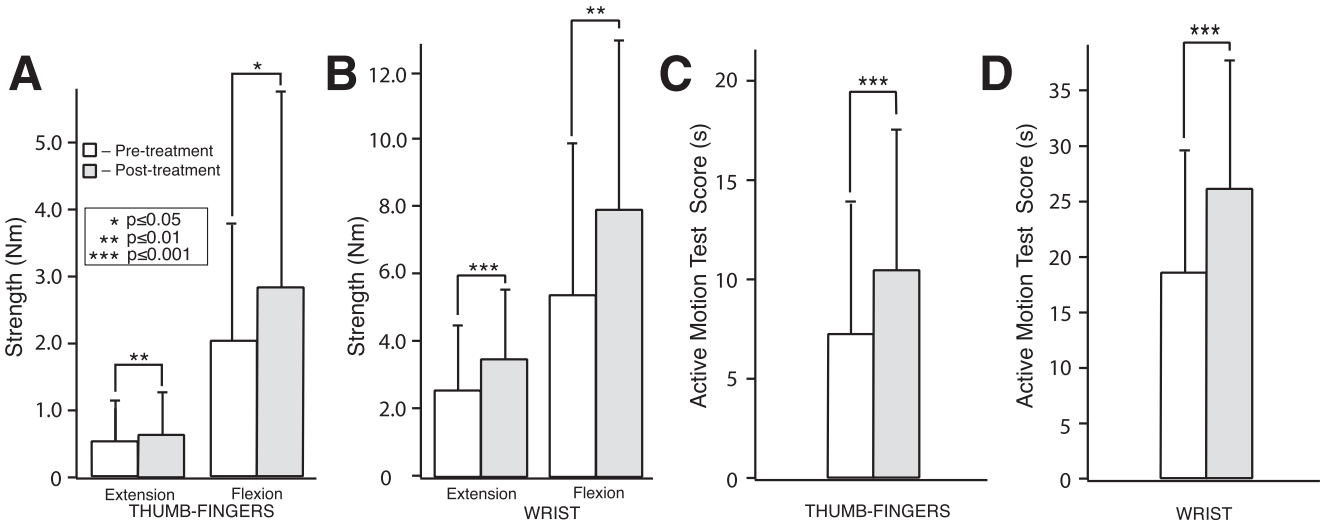

Fig 2 Reduction of UL impairment. Each bar graph includes test scores obtained before receiving treatment (open bars) and after completing all treatments (filled bars). Strength test scores increased significantly for MCP extension and flexion (A) and for wrist extension and flexion (B). Active motion test scores also increased significantly for the MCP joints (C) and the wrist (D). Strength units are in newton meters, and active motion units are 0.1 seconds. *$P \leq .05$; **$P \leq .01$; ***$P \leq .001$.

However, there was no change on the VLT. There were 2 patterns of scores observed. In some cases, the participants were too strong for the VLT, such that if they were able to do the VLT tasks before, they could also do them after. In other cases, if the participant had a low score at baseline, he or she also had a low score after completing 25 treatments. Change was difficult to see, suggesting that for this population of participants with incomplete tetraplegia, the VLT may not be an appropriate measure. That there was a change in the GRT scores, but not in the VLT, may be caused by the complexity of the tasks in the VLT. Specifically, the VLT tasks often require transport of the UL, not just function of the distal UL, whereas the tasks for the GRT are performed in a much smaller space, requiring less transport of the entire UL. The CUE also consists of complex tasks, which may also explain the lack of significant improvement in those scores as well. Participants may have improved in distal function and not proximal function; therefore, there would be a discrepancy in these scores. This requires further investigation.

The data from this study suggest that people with incomplete tetraplegia, even several years post-SCI, can achieve improvements in impairments and function with repetitive, impairment-oriented therapy that combines assisted movement with muscle vibration. By reducing the extent of impairment in people with dysfunctional ULs, latent capacity for both sensory and motor function can emerge, even in the severely impaired. This is an important area requiring further study. Unfortunately, people with incomplete tetraplegia often have difficulty obtaining treatment to address their unique sensorimotor impairments. They are often treated in a similar fashion to those with complete tetraplegia, using bracing and substitution for their dysfunction, when in fact they have the potential for greater independent function if given the opportunity, such as with impairment-oriented interventions (eg, AMES).

The mechanisms underlying the changes observed in this study remain to be elucidated. The goal of this pilot study was to first explore the potential for people with chronic incomplete tetraplegia to demonstrate changes in impairments and function after treatment with repeated movement and enhanced sensation. Therefore, a comparison has not yet been made between the outcomes after repeated treatment alone, vibration alone, and a combination of the 2 treatments, as used in this study.

Insights into potential mechanisms can be gained, however, from other studies in people with incomplete tetraplegia. Our findings are in line with previous studies, which showed that repetitive physical training with submotor threshold electrical stimulation to the median nerve improved somatosensation and strength in people with chronic tetraplegia >1 year post-SCI.[19-21] Given that the median nerve supplies the skin and other tissues of the thumb, index, and middle fingers, electrical stimulation provided in this fashion likely activated somatosensory input from a wide variety of mechanoreceptors throughout the nerve's sensory field(s). Muscle vibration as applied in our study provided a different type of stimulation. Vibration via ≥1 tendon activates principally muscle spindle Ia afferents; although, a small number of cutaneous afferents located directly under the probe will also be activated. Furthermore, the AMES vibrators can specifically alternate the activation of muscle spindles from one side of the joint to the other during treatment, as occurs during natural movement. Therefore, the AMES approach to augmenting proprioceptive input may be perceived by the central nervous system as more natural than electrical nerve stimulation, which could then produce a more pragmatic form of central nervous system plasticity and lead to greater functional improvements. Further study is warranted to test this hypothesis.

Study limitations

This was a single-arm trial without a placebo group; therefore, we did not control for expectancy effect or natural recovery processes. Furthermore, the SCI was not fully characterized in the participants of this study. Specifically, the zone of partial preservation and extent of the remaining function were not defined. If a participant had a motor examination within a year, another one was not performed, except for the 5 key muscles of

the ISNCSCI[13] at the time of pre- and postassessments. The inclusion criteria were chosen, however, to allow more homogeneity in the sample, by having all participants have similar functional abilities. Future studies should use methods to characterize the SCI more clearly to allow better interpretation of the findings.

Another limitation is that changes in somatosensation described verbally by the participants were not quantified. Given the role somatosensation may play in the normative control of UL movement[22-27] and the aforementioned anecdotal evidence for changes in somatosensory perception, further research is warranted in which somatosensation is accurately and comprehensively tracked throughout the study.

Finally, in this study, 5 participants trained on the AMES device with both qualified ULs, one after the other. Treating the first UL could have affected subsequent outcomes in the second UL as a result of bilateral effects. This requires further investigation.

Conclusions

Some people with chronic incomplete tetraplegia may experience improvements in impairments and function after impairment-oriented treatment on a novel device combining repeated movements with targeted vibration. These findings suggest that further investigation is warranted.

Suppliers

a. AMES Technology Inc, 657 SW Regency Pl, Portland, OR.
b. SAS Inc, 100 SAS Campus Dr, Cary, NC 27513-2414.

Keywords

Feedback, sensory; Proprioceptive feedback; Rehabilitation; Spinal cord injuries; Upper extremity

Corresponding author

Deborah Backus, PT, PhD, Shepherd Center, 2020 Peachtree Rd NW, Atlanta, GA 30309. *E-mail address:* Deborah_backus@shepherd.org.

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