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Combining Spinal Cord Transcutaneous Stimulation with Activity-based Training to Improve Upper Extremity Function Following Cervical Spinal Cord Injury*

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***Abstract*— Recovery of upper extremity (UE) function is the top priority following cervical spinal cord injury (SCI); even partial function restoration would greatly improve the quality of their life and thus remains an important goal in SCI rehabilitation. Current clinical therapies focus on promoting neuroplasticity by performing task-specific activities with high intensity and high repetition. Repetitive training, paired with functional electrical, somatosensory, or transcranial magnetic stimulation, has been evaluated to augment functional recovery in chronic SCI, but improvements were modest. Evidence has demonstrated that the non-invasive spinal cord transcutaneous stimulation (scTS) can increase the excitability of spinal circuits and facilitate the weak or silent descending drive for restoration of sensorimotor function. Currently, we are conducting a multicenter randomized clinical trial to investigate the efficacy and potential mechanisms of scTS combined with activity-based training (ABT) to facilitate UE function recovery in individuals with tetraplegia. The preliminary outcomes from our four individuals with complete and incomplete injury demonstrated that the combination of scTS and ABT led to immediate and sustained (for up to 1-month follow-up) UE function recovery. Notably, one individual with motor complete injury showed a 5-fold improvement in UE function quantified by the Graded Redefined Assessment of Strength, Sensibility, and Prehension following scTS+ABT, as compared to receiving ABT alone. These functional gains were also reflected in the increased spinal excitability by measuring the scTS-evoked muscle response of UE motor pools, suggesting physiological evidence of reorganization of the non-functional, but surviving spinal networks after spinal transcutaneous stimulation.**

***Clinical Relevance*—This study offered the preliminary efficacy of combining scTS and ABT to facilitate UE function recovery following cervical SCI.**

I. Introduction

Approximately 60% of individuals following spinal cord injury (SCI) [1], an annual incidence of 54 cases per one million people in the United States, suffer from tetraplegia resulting in severe impairments of motor, sensory, and autonomic function at and below the level of the injury. Surveys [1], [2] of individuals with tetraplegia have revealed that recovery of upper extremity (UE) function is ranked as the top priority. Even partial restoration of UE volitional function would greatly improve the quality of life [1] and thus remains a compelling rehabilitation goal.

Function recovery after SCI largely depends on the preservation of anatomical descending and ascending pathways, and likely on the physiologic reorganization of the brain and spinal cord [3], [4]. Current SCI rehabilitation therapies focus on promoting activity-dependent neuroplasticity to enhance sensorimotor recovery by involving repetitive use of the affected muscle groups through exercise with some voluntary control. Repetitive task-specific training (massed practice), combined with functional electrical stimulation [5], [6], somatosensory stimulation [3], [7], or transcranial magnetic stimulation [8], have been evaluated for augmentative effects on function recovery after SCI, but improvements were modest.

Growing evidence has demonstrated that spinal cord transcutaneous stimulation (scTS) can increase the excitability of spinal circuits and facilitate the weak or silent descending drive for restoration of motor and sensor function after SCI [9]–[16]. Neurophysiological testing [17]–[19] suggested that scTS may predominantly recruit large-to-medium diameter proprioceptive and cutaneous afferents within posterior rootlets/roots. Lumbosacral scTS applied in chronic SCI has shown capability in generating rhythmic activity during robotic-driven treadmill stepping in complete SCI [20], facilitating residual stepping capability in incomplete SCI [9], [10], [18], and enabling voluntary control of movement in motor complete SCI [11], [12]. So far, only a few studies have reported the effects of combining scTS with physical training on UE function recovery in a small number of individuals with tetraplegia. Gad *et al*. [15] reported that maximum voluntary hand grip forces increased by ~325% (scTS on) and ~225% (scTS off) in 6 chronic SCI following 8 sessions of scTS combined with training. *Inanici* et al. [13], [16] demonstrated that scTS combined with intensive training improved UE motor score, pinch strength, sensation on trunk dermatomes, and overall neurologic level of injury in people with chronic, complete and incomplete cervical SCI. Our previous case study [14] on one individual with chronic, complete tetraplegia showed that the maximum voluntary handgrip force improved by 283.4% (left) and 30.7% (right) after only 18 hours of scTS combined with activity-based training (ABT). Moreover, these gains persisted at 233.5% (left) and 11.5% (right) for over 3

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months without further treatment. To fill the research gap, we are currently conducting a multicenter randomized clinical trial to investigate the efficacy and potential mechanisms of scTS combined with ABT on UE function recovery in individuals with tetraplegia. In this study, we present some preliminary functional outcomes collected from four participants in our ongoing clinical trial.

II. Methods

A. Participants

Four individuals with chronic cervical SCI participated in this study (as shown in Table I). The inclusion criteria included: 1) history of a traumatic cervical SCI, 2) levels of C1- C8; 3) ages of 18-75 years; 4) American Spinal Injury Association Impairment Scale (AIS) A-D; and 5) at least 12 months since the onset of SCI. This study was conducted with the approval of the Institutional Review Board (IRB) at Kessler Foundation, and informed consent was obtained from all participants.

TABLE I. Participant Demographic Information

Subject ID	Gender	Age	AIS	NLI	Years Post-Injury
S01	Male	25	A	C4	4
S02	Male	62	D	C3	9
S03	Male	41	B	C4	7
S04	Male	78	D	C1	6

B. Study Design

This study was conducted as a part of our ongoing three-arm, multicenter, open-label randomized controlled trial. The protocol consisted of an assessment of outcome measures at baseline, 60 sessions of intervention, re-assessment at post-intervention, and a one-month follow-up visit. Subject S01 and S04 were randomly assigned to Arm 1, in which they received 60 sessions of scTS+ABT intervention; subject S02 was randomized to Arm 2 (40 sessions of scTS+ABT and then 20 sessions of ABT only); while S03 was assigned to Arm 3 (20 sessions of ABT first and then 40 sessions of scTS+ABT). During the intervention, each participant received UE ABT supervised by physical therapists, with or without the constant scTS applied depending on their treatment arm assignment. The intervention was 60 minutes/session and 2~3 sessions/week. During the follow-up, the participant did not receive further treatment. For safety, blood pressure and heart rate were closely monitored throughout all sessions.

C. Spinal Cord Transcutaneous Stimulation (scTS)

Sub-threshold scTS were delivered at the cervical and thoracic spinal segments over the dorsal skin by using a five-channel constant current stimulator (BioStim-5, Cosyma). Round (Ø 2.5 cm) self-adhesive stimulating electrodes (STIMEX, Schwa-medico GmbH, Germany) were placed at the midline of spinous processes as cathodes and a pair of rectangular anodes electrodes (8 x 13cm) were placed over the anterior iliac crests of the pelvis as anodes. The stimulation waveform was biphasic, rectangular pulses with 1ms duration [13]–[16], filled with a carrier frequency of 5kHz. Mapping sessions were conducted to determine the target stimulation sites, intensity, and burst frequency, for each participant. The stimulation intensity was gradually increased from 0mA to 120mA (if tolerable by the subjects) in 5mA increments to obtain the recruitment curve of responses from UE muscles at each stimulation site. The resulting response profiles later guided the voluntary mapping, in which varying combinations of parameters were tested to enable greater strength, a larger range of joint motion, and better UE motor function performance. Target parameters were sub-threshold for UE muscle activation and verified by the absence of visible muscle contraction. The stimulation parameters were re-adjusted as needed throughout the intervention based on the participant's performance and comfort level.

D. Activity-based Training (ABT)

UE training included grasping, pinching, and other gross and fine motor skill. The hand grasp task focused on grasping objects with different shapes and weights (i.e. weighted container and tennis ball) and placing/removing them from small storage containers; the pinch task involved picking up, translating, and releasing small objects with varied sizes (i.e. blocks, dices, marble balls, nuts, etc.). The dosage was 60 minutes/session, with approximately 15 minutes allocated on each UE side and task. The task difficulty level would be increased if the participant was able to achieve more than 100 repetitions in three consecutive sessions. This progressive strategy ensures that the appropriate amount of repetitions and level of difficulty were maintained throughout the intervention. 1-minute rest periods were provided between activities to avoid fatigue.

E. Outcome Measures

1) The Graded Redefined Assessment of Strength, Sensibility, and Prehension (GRASSP)

GRASSP version 1.0 [21] (Neural Outcomes Consulting Inc. Toronto, ON, Canada) was used as the primary outcome measure in this study. It evaluates UE strength, sensation, the ability to complete different grasp patterns, and the ability to utilize those grasp patterns to complete functional activities [21]. GRASSP has excellent test–retest reliability and adequate-to-excellent concurrent validity.

2) Lateral Key Pinch Force

Lateral pinch force was measured from both hands by using a hand-held dynamometer (Echo, JTECH Medical, Midvale, Utah) with scTS disabled. To avoid compensation movement, testing was performed with participants seated upright, shoulder adducted and neutrally rotated, elbow flexed 90 degrees, and forearm in the neutral position. A total of three trials were assessed on each side, with a rest break between trials. The average of three maximal force measurements per trial was calculated.

3) Neuromuscular Recovery Scale (NRS)

The NRS was measured to evaluate the functional capabilities of individuals with SCI relative to normative performance. Seven sub-items were tested focusing on upper extremity and trunk function, including forward reach and grasp, door pull and open, overhead press, sit up, sit, reverse sit up, and trunk extension in sitting. The rating scale represents a hierarchy of performance from the lowest level (scored phase 1A) to a high level of capacity (scored phase 4).

4) Spinal Excitability

Neurophysiological tests were performed to assess the spinal excitability via the recruitment curve of UE muscles response with increasing stimulation intensity. Monophasic scTS with 1-ms pulse width and an inter-stimuli interval of 5s

was applied to elicit evoked potentials by using a constant current electrical stimulator (DS7A, Digitimer, Welwyn Garden City, UK). The stimulation intensity was gradually increased from 5mA to 100mA (if tolerable by the subjects) in 5mA increments to obtain the recruitment curve of responses simultaneously. Stimulation was delivered at spinal segments above and below the lesion when participants remained in the supine position with both arms resting along the body. EMG signals were collected from 8 muscles on each arm and hand via a 16-channel EMG data collection system (MA-400, Motion Lab Systems, Inc., Baton Rouge, LA) and sampled at a rate of 10 kHz. The data were filtered using a 60-Hz notch filter and a Butterworth band-pass filter of 10-1000 Hz to remove power supply interference, motion artifacts, and other environmental noises. A peak-to-peak analysis was performed in MATLAB (MathWorks Inc., Natick, MA, USA) software to evaluate the motor response.

III. Results and Discussion

All four participants demonstrated a higher total score of GRASSP after receiving the intervention of scTS+ABT, indicating that the combined intervention successfully led to UE function recovery in each individual. People with complete tetraplegia typically do not show significant function recovery beyond the first year after injury. Our first participant (S01, C4 AIS A) with such complete injury dramatically improved his GRASSP score from 24/232 to 57/232 following only 60 sessions of scTS+ABT intervention, as shown in Fig. 1A. His strength in both hands and arms was progressively increased almost 3-fold (from 12/100 to 35/100) at the end of the intervention (Fig. 1B). He was unable to perform any hand task evaluated in GRASSP Prehension Ability testing when he joined this study. It was only possible after 60 sessions of scTS+ABT that he regained the capability to perform cylindrical grasping and tip-to-tip pinching tasks for the first time since his injury, as demonstrated in Fig. 1C. Similar progression of UE functional recovery was observed in our third participant (S03, C4 AIS B) with motor complete tetraplegia. His intervention started with 20 sessions of ABT only and the total score of GRASSP improved by only 3 points during the phase of receiving training only. It was only during subsequent 40 sessions of ABT combined with scTS that he began to demonstrate significant UE function recovery (from 54/232 to 69/232 measured in GRASSP), with 5-fold

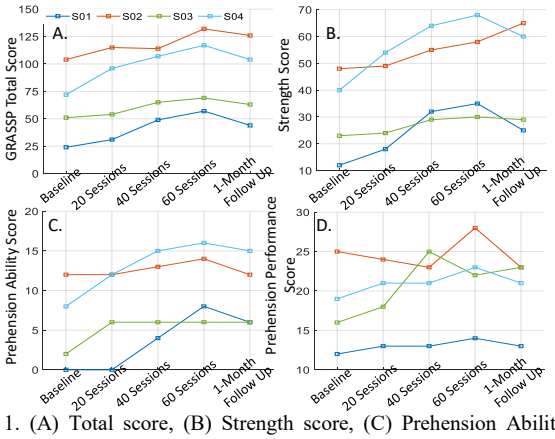

Fig. 1. (A) Total score, (B) Strength score, (C) Prehension Ability, (D) Prehension Performance of GRASSP evaluated at the baseline, 20-, 40-, 60-session post, and 1-month follow-up for subject S01-04.

improvement as compared to ABT alone (Fig. 1A). UE functional gains in GRASSP strength and prehension score during the course of scTS+ABT improved 6-fold (Fig. 1B) and 3.5-fold (Fig. 1D), as compared to 1 point (strength) and 2 points (prehension) observed after ABT only. The remaining two participants (S02, C3 AIS D; S04, C1 AIS D) with incomplete injury and central cord syndrome improved their GRASSP total score by 10/232 and 35/232 after the initial 40 sessions of scTS+ABT. S02 further improved his score by 18/232 after receiving additional 20 sessions of ABT only; while S04's score increased by 10/232 with additional 20 sessions of scTS+ABT intervention. Most notably, for all four participants, the UE function gains were maintained at a similar level during 1-month follow-up without receiving any further intervention. These results indicated that scTS combined with ABT may modulate the neuroplasticity of spinal network for long-term functional recovery.

Three participants (S01, S03, and S04) showed enhanced lateral pinch force in both hands during the course of scTS+ABT intervention (as shown in Fig. 2). After 60 sessions of the combined intervention, the pinch force improved by 12.1% (left) and 11.7% (right) in S01; 8% (left) and 14.9% (right) in S04. During 1 month of follow-up, S04's lateral pinch force was further improved by 9.3% (left) and 4.5% (right), as compared to those at post-intervention. S03 improved his pinch force by 27.6% (left) and 29.7% (right) after the initial 20 sessions of ABT alone. Additional 40 sessions of scTS+ABT further enhanced his pinch force by 42.2% (left) and 43.2% (right), with more than 1.5-fold strength gains compared to ABT alone. The pinch force gains at the 1-month follow-up were sustained at 120% (left) and 65% (right) as compared to baseline values.

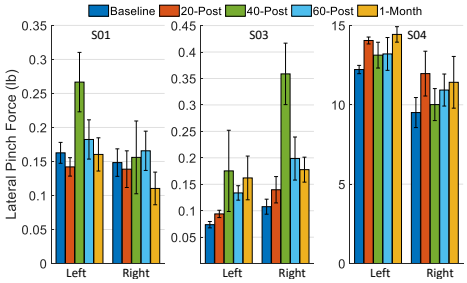

Fig. 2. Bilateral lateral pinch force measured at the baseline, 20-, 40-, 60-session post, and 1-month follow-up for S01 (A), S03 (B), and S04 (C).

Table II summarized NRS sub-test scores for each participant at baseline, post-intervention, and 1-month follow-up. All participants demonstrated improved trunk control at post-intervention, as compared to baseline. For example, S01 was unable to maintain proper trunk posture during sitting (Sit score: 1A) when he joined the study. At the end of the intervention, he was able to both attain sitting with an

TABLE II. Neuromuscular Recovery Scale Evaluated at the Baseline, Post- intervention, and 1-month Follow-up.

Task	S01			S02			S03			S04		
	Baseline	Post	1-Mo	Baseline	Post	1-Mo	Baseline	Post	1-Mo	Baseline	Post	1-Mo
Sit	1A	2A	1B	1C	3B	3B	1B	2C	2B	1C	3A	3A
Sit Up	1C	1B	2A	3A	4A	4A	1C	2B	2B	3B	3C	3C
Reverse Sit Up	1C	1C	2A	2A	2C	2C	1C	2A	2A	2C	4A	3B
Trunk Extension	1B	2A	1B	1C	3B	3B	1C	1C	1C	2C	3B	2C
Overhead Press (L)	2A	2A	2A	1C	3A	3A	2A	3A	3A	1C	3A	3C
Overhead Press (R)	1C	2A	1C	1C	1C	2A	2A	3A	3A	1C	2B	2A
FWD Reach & Grasp (L)	1C	2C	1C	2A	3A	3A	2B	2C	2C	1C	2C	2C
FWD Reach & Grasp (R)	1A	2A	1C	1C	2B	2B	2B	2C	2C	1C	2C	1C
Door Pull & Open (L)	2A	2A	1C	1C	3B	3B	2C	2C	2C	1B	4A	3B
Door Pull & Open (R)	1C	1C	1B	1C	3A	2C	2C	2C	2C	1B	3B	3A
Can Manipulation	1C	2A	1C	1C	2B	2C	2A	2C	2C	1C	2C	2C

Unable to Perform 1A 1B 1C 2A 2B 2C 3A 3B 3C 4A 4B 4C Full Recovery

appropriate posture of the trunk and position of pelvis for approximately one minute (Sit score: 2A). S02 and S04 demonstrated dramatic improvements in trunk extension sitting that they were able to return to sitting while maintaining lumbar and thoracic spine extension without significant effort (score: 3B). It is noteworthy that no trunk or trunk-arm combined training task was provided during the intervention.

Increased level of spinal excitability was observed in all four participants after receiving the combined intervention of scTS and ABT. As an example, Fig. 3 demonstrates scTS-induced evoked potentials measured from proximal to distal UE muscles in S02 when the stimulation pulses were applied at C3-4 with intensities ranging from 5mA to 55mA at baseline, 40 sessions (scTS+ABT) post, and 60 sessions (ABT only) post. Following 40 sessions of scTS+ABT, S02 exhibited 1) higher amplitudes of evoked potentials measured from UE motor pools (Fig. 3A), and 2) lower excitation threshold (Fig. 3B), as compared to baseline. However, the subsequent 20 sessions of ABT only, did not further increase the evoked potential amplitude and lower the excitation threshold (shown as the blue curves in Fig. 3B). This finding may suggest that an increased level of spinal network excitability may be primarily modulated by scTS. One potential mechanism is that sub-threshold scTS increased the excitability of spinal networks, and in turn brought interneurons and motor neurons closer to the motor threshold to facilitate the impaired post-injury descending drive [11], [13]. The combination of scTS and ABT led to sustained changes in neural networks and long-term UE functional recovery following SCI [13].

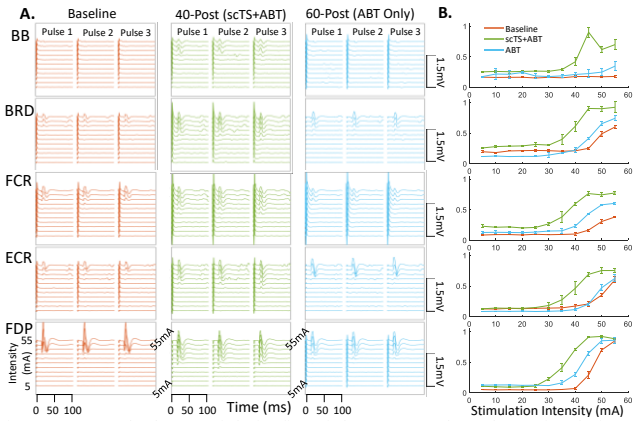

Fig. 3. (A) Evoked potentials in five right UE muscles when stimulating at C3-4 with three pulses (5s inter-stimuli interval, 5-55mA, increment of 5mA). (B) Recruitment curve of the peak-to-peak amplitude of the averaged responses (n=3). BB, biceps brachii; BRD, brachioradialis; FCR, flexor carpi radialis; ECR, extensor carpi radialis; FDP, flexor digitorum profundus.

It is noteworthy that scTS was well tolerated by all four participants. No significant adverse events related to spinal stimulation (pain/discomfort and skin integrity) or ABT (musculoskeletal injuries, heart rate, and oxygen saturation levels) were observed. The functional and neurological outcomes presented in this study provided preliminary evidence that the non-functional, but surviving spinal networks can be neuro-modulated by the combination of scTS and ABT for immediate and long-term function recovery after SCI. More detailed research findings with a larger sample size and statistical analysis are expected at the completion of our ongoing multicenter, randomized clinical trial.

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