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Effects of Hybrid-Functional Electrical Stimulation (FES) Rowing Whole-Body Exercise on Neurologic Improvement in Subacute Spinal Cord Injury: Secondary Outcomes Analysis of a Randomized Controlled Trial

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Abstract

Study Design—Secondary outcome measures analysis of a randomized, controlled study.

Objective—To assess the effects of hybrid-functional electrical stimulation (FES) rowing on motor and sensory recovery in individuals with spinal cord injury (SCI) 6–18 months post-injury.

Setting—Outpatient rehabilitation network.

Methods—25 participants 6–12 months after SCI were randomly assigned to hybrid-FES rowing (n=10) or standard of care (n=15) groups. The hybrid-FES rowing group completed 6 months of rowing scheduled 3 times per week for 26 weeks at an exercise intensity of 70–85% of maximal heart rate. The standard of care group either participated in an arm ergometer exercise program (n=6) or a waitlist without an explicit exercise program (n=9). Changes in motor score and combined sensory score of the International Standards for Neurological Classification of SCI (ISNCSCI) were analyzed.

Results—Both groups demonstrated increases in motor and combined sensory scores, but no significant differences were noted between intervention groups (motor difference mean \uparrow 1.3 (95% CI, -1.9 to 4.4), combined sensory difference mean \downarrow 10 (-30 to 18)). There was an average of 63% adherence to the hybrid-FES rowing protocol, with no significant correlation in changes in motor or combined sensory score in the hybrid-FES rowing group with total distance or time rowed.

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Authors' Contributions

RCC was responsible for extracting and analyzing data, interpreting results, and writing the report.

JAT was responsible for designing the study protocol, overseeing data collection, and providing feedback on the report.

RS was responsible for designing the study protocol, analyzing data, interpreting results, and writing the report.

Statement of Ethics

The present study was approved by the Institutional Review Board at Spaulding Rehabilitation Hospital. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

Data Archiving

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest

The authors have no competing financial interests in relation to the work described.

Conclusions—No significant effects to neurologic improvement were found with hybrid-FES rowing when compared with standard of care interventions in individuals with SCI 6–18 months post-injury.

Introduction

Neurologic improvement after spinal cord injury (SCI) can have significant impact on the individuals' functional status and independence. Functional electrical stimulation (FES) for exercise training is a rehabilitation intervention that allows for assisted exercise of weakened or paralyzed muscles. Hybrid-FES, a variant of FES that allows for whole-body exercise, may have substantial effects on cardiovascular health [1,2], but there has been limited research to determine if this intervention augments the normal neurologic changes that occur after SCI. The potential for natural neurologic improvement is greatest during the first six months after injury, with incremental documented continued improvement out to 12–18 months post-injury [3]. It is possible that FES-assisted exercise over these time periods may affect this recovery process.

In patients with chronic SCI (mean 96 months post-injury; range 18–519), FES cycling has been shown to improve motor scores without increasing spasticity [4]. However, these improvements may reflect a reversal of the effects of detraining rather than neurologic recovery, since these individuals were beyond the window of greatest natural neurologic improvement. Smaller randomized clinical trials have shown benefit in hand grasp function with FES in patients with incomplete tetraplegia at two months post-injury when compared with conventional hand therapy [5,6], and in a rat model, FES improved locomotion recovery at one week post-injury [7]. These early studies may suggest that afferent neuronal drive may play a role in neurorecovery when FES is utilized earlier post-injury [7].

An alternate form of FES-assisted exercise is hybrid-FES rowing, which uses a modified rowing ergometer with FES of the weakened or paralyzed lower extremities muscles to allow for whole-body exercise using both upper and lower extremities. Hybrid-FES rowing can produce 30% greater aerobic demand than standard arm ergometer exercises in individuals with SCI [8]. Exercise at higher aerobic demand will result in greater physical activity, which is associated with improvement in cardiovascular risk factors, including lesser abdominal fat and lower fasting glucose [9]. However, it is not known whether this increased aerobic demand through engagement in whole-body exercise has direct effects on neurologic recovery. A recent literature review suggests that increased aerobic demand can increase brain derived neurotrophic factor (BDNF) concentration, which may affect neuronal plasticity [10]. Given this gap in knowledge, we assessed the effects of hybrid-FES rowing on motor and sensory recovery in individuals within 18 months of SCI.

Methods

Trial design

This study is an analysis of secondary outcome measures collected for clinical trial (NCT02139436, primary outcomes are in analysis at time of print). The trial is a crossover group, superiority trial, with an experimental arm, a wait-list time control arm, and an active

comparator control arm. The allocation ratio between the experimental arm and the two control arms was 1:1. Participants in the control arms were allowed to cross over to the experimental arm after 6 months in their initial allocation.

Participants

Individuals aged 20–40 years with SCI classified as American Spinal Injury Association Impairment Scale (AIS) A-C [11] and neurological level of injury C5-T12, 3 months post-injury were recruited for the study. For the present study's secondary analysis, participants were restricted to those who started the study no earlier than 6 months post-injury and completed the study within a month of 18 months post-injury. Additional inclusion criteria included 1) discharged to the community from inpatient rehabilitation prior to enrollment, 2) medically stable (no treatment for deep vein thrombosis, no orthostasis, no spinal precautions or weight-bearing precautions associated with a healing long-bone fracture), 3) body mass index 18.5–30 kg/m², and 4) able to tolerate the FES without sustained autonomic dysreflexia. All individuals were able to follow directions and had full dynamic knee flexion/extension when their leg muscles (rectus femoris, vastus medialis, vastus lateralis, biceps femoris, and semitendinosus) received FES, up to maximal intensity of the device (approximately 110 mA). Exclusion criteria included 1) blood pressure >140/90 mmHg and 2) significant arrhythmias, coronary disease, diabetes, renal disease, cancer, epilepsy, current use of cardioactive medications, current grade 2 or greater pressure injuries at relevant contact sites, other neurological disease, peripheral nerve compressions or rotator cuff tears that limit the ability to row, or history of a bleeding disorder. All individuals were recruited from a single rehabilitation network (Spaulding Rehabilitation Network, Boston, MA) and provided written informed consent prior to enrollment in this IRB-approved study.

Interventions

The experimental arm received hybrid-FES rowing and the two control arms received standard of care. The hybrid-FES rowing group completed 6 months of hybrid-FES rowing scheduled 3 times per week for 26 weeks. This group required a strength training protocol using FES to achieve full knee flexion-extension for 30 minutes without rest prior to beginning FES-assisted rowing. These sessions were performed 3–5 times per week for 2 to 12 weeks. Participants then underwent graded exercise testing using hybrid-FES rowing with an initial workload of 10 watts for 2 minutes with increasing workload by 10 watts every 2 minutes to peak exercise capacity determined by computer-assisted open circuit spirometry (ParvoMedics, Sandy, UT). Maximum heart rate was recorded as maximum reached during this pre-intervention graded exercise testing. Row training sessions were composed of 6 sets for 5 minutes at 60% maximal heart rate with a work-to-rest ratio of 2:1, progressed to exercise intensity of 70–85% maximal heart rate for 30–40 minutes, which was previously shown to increase aerobic capacity [8]. Full details of this strength training, graded exercise testing, and hybrid-FES rowing protocol have been described previously [8]. The standard of care group included participants who were either in an arms-only exercise program using an upper body ergometer (Concept2, Morrisville, VT) as an active comparator or a waitlist without an explicit exercise program. Graded exercise testing for the arms-only exercise group was performed similarly to the hybrid-FES rowing group except using an arms-only rowing test. The standard of care group did not have requirements or restrictions in exercise

frequency or intensity, and the hybrid-FES rowing group was not restricted from performing exercise outside of the intervention.

Outcomes

Clinical testing with the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) exam [11] and the modified Ashworth scale (MAS) [12] was completed by a trained SCI medicine physician at baseline and 6-month follow-up. Total amount of exercise completed was quantified by distance rowed, average percentage of maximum heart rate achieved per rowing session, average wattage output per session, and total time logged on the rowing machine throughout the study period.

Sample size

Sample size for the present secondary analysis were based on mean motor score changes in Sadowsky's study on FES cycling [4]. Twenty-four participants were required to show an expected effect size of 7.5, with a population standard deviation of 6.5, in motor score with a power of 0.80 and alpha of 0.05.

Randomization

An allocation sequence was determined prior to enrollment by the principal investigator of 1) hybrid-FES rowing, 2) arm ergometer, 3) hybrid-FES rowing, 4) waitlist. Participants were pseudorandomized to the three study arms prior to obtaining baseline measurements based on this allocation sequence and order of enrollment. Participants were not informed of their allocation until after enrollment.

Statistical Analysis

Statistical analysis was performed using SPSS software (IBM, Version 24.0, Armonk, NY). Based on previous literature [4], baseline characteristics and between-group analysis of changes in motor score, sensory score, and MAS were completed using unpaired t-tests for continuous variables and chi-squared test for categorical variables, with a p-value < 0.05 treated as statistical significance. Additionally, a one-way between-group ANCOVA was completed for changes in motor score and sensory score to control for time since injury. To determine if exercise dosage had an effect on neurologic changes, parameters for total amount of exercise for the hybrid-FES rowing group were compared with changes in motor score, sensory score, and lower extremity MAS using Pearson correlation. For subgroup analyses, participants were divided based on level of injury (tetraplegia vs. paraplegia) given the potential difference in upper extremity neurologic change, as well based on AIS classification. Participants with baseline AIS A were considered clinically complete injuries, and participants with baseline AIS B or C were considered clinically incomplete injuries. As per convention [13], changes in the motor and combined sensory scores were quantified using an annualized rate of recovery by dividing the amount of recovery between two successive exams by the number of days between examinations and multiplying by 365. Participants that crossed over from the standard of care group to the hybrid-FES rowing group after 6 months were treated as independent participants, with the standard of care 6-month follow-up scores treated as the baseline scores of hybrid-FES rowing.

Results

68 participants with subacute SCI were assessed for eligibility for the study, with 54 completing at least baseline ISNCSCI measure. Of these 54 participants, 23 had follow-up ISNCSCI data within 18 months post-injury. There were 10 participants in the hybrid-FES rowing group and 15 in the standard of care group (6 on the waitlist without structured exercise program and 9 completing arm ergometer exercise), with 2 participants who completed 6 months of arm ergometer exercise crossing over from the standard of care group to the hybrid-FES rowing group (Figure 1). There were no significant baseline differences between groups (Table 1).

From baseline to 6-month follow-up, both groups demonstrated increases in motor and combined sensory scores in the complete and incomplete tetraplegia groups without any significant differences between groups (Table 2 and Table 3, see Supplemental Figure for participant-level data). The complete and incomplete paraplegia groups demonstrated no significant recovery of lower extremity motor function or combined sensory scores. One-way ANCOVA controlling for the effects of time since injury did not show statistically significant change between hybrid-FES rowing and standard of care groups (motor: $F=1.2$, $p=0.28$; sensory: $F=1.8$, $p=0.20$). Only one participant, with C7 AIS C SCI in the standard of care arm ergometer exercise group, had a lower extremity motor score change from 0 to 1 in a single myotome (left L5). Otherwise, no lower extremity myotomes tested, including those that received FES, had any increase in lower extremity motor score. The change in lower extremity spasticity between groups did not reach statistical significance, with a MAS increase of 3.5 (11) in the standard of care group and decrease of 2.9 (12) in the hybrid-FES rowing group, with a mean difference of 6.4 (95% CI, -4.2 to 17).

The 10 participants that underwent hybrid-FES rowing completed an average of 1.9 (0.6) whole-body exercise sessions per week over the 6-month period. The average total distance rowed was 153 (106) kilometers, at an average power of 29 (16) watts and average percent maximum heart rate of 79% (6.5) per session. There was no significant correlation between these metrics quantifying amount/quality of work and changes in motor score ($p=0.07-0.44$), sensory score ($p=0.13-0.98$), or MAS ($p=0.09-0.75$). There were no reported adverse events of autonomic dysreflexia or cardiac arrhythmia during exercise training sessions with this intervention.

Discussion

This study is the first to assess the effects of hybrid-FES rowing exercise training on neurologic change in individuals with SCI up to 18 months post-injury. No significant increases in motor or sensory score were found when compared to standard of care. Additionally, no significant changes were found in sub-group analyses based on initial neurological level of injury or AIS classification, and there was no significant correlation with the amount of exercise training and corresponding neurologic changes.

Our motor score change data is consistent with the previously published literature. Waters [13] showed that at 6–12 months and 12–24 months post-injury, the average motor score

change was 1.7 (1.9) for both time periods in individuals with complete tetraplegia. Our data showed mean motor score changes of 2.5 (3.8) in the hybrid-FES rowing group and 1.0 (3.7) in the standard of care group, suggesting that hybrid-FES rowing exercise has no negative impact on the natural course of neurologic change after SCI and could potentially be beneficial. Similar to data from the SCI Model Systems, Sygen, and European Multicenter Study about Spinal Cord Injury (EMSCI) databases that showed variable light touch and pinprick score changes [3], our sensory score data had wide variability. This may also be due to lower inter-rater reliability of sensory testing, especially for incomplete injuries (for incomplete vs. complete injuries: 0.86 vs. 0.99 in light touch, 0.69 vs. 0.99 in pin prick, and 0.95 vs. 1.0 in motor score) [14]. With four different SCI physicians completing ISNCSCI exams for this study, this may have contributed to variability.

Interestingly, the motor and sensory score changes in the hybrid-FES rowing intervention group appear to be smaller than those found in Sadowsky's study [4] on FES cycling in chronic SCI patients. In that chronically injured population, the intervention demonstrated an average motor score increase of 8 (10), an average pinprick score increase of 6 (15), and an average light touch score increase of 6 (11). This may be due to differences in the FES intervention or duration of exercise training (average 30 months in chronic injury study versus 6 months in the present subacute study). There may also be an effect of detraining that occurs after 2 years post-injury, with subsequent reversal of detraining with FES. In the present study, no lower extremity motor scores increased after FES training, suggesting that the changes in the previous chronic SCI study are less likely to be facilitated neurologic recovery.

While no significant changes to neurologic improvement with hybrid-FES rowing were noted in the present study during this time window, patients with SCI may still benefit from hybrid-FES rowing as an early rehabilitation intervention. It is possible, as with previous studies, that FES may benefit only a subset of the population with incomplete injuries [5,6] or at an earlier time post-injury [5,6,7]. Additionally, individuals with SCI have a high risk of developing cardiometabolic disease, and it has been shown that this risk increases early after injury [15]. With cardiovascular health benefits such as increased aerobic capacity [8], hybrid-FES rowing can be considered in individuals with SCI earlier in their rehabilitation process to possibly help mitigate these effects.

Limitations

One of the main limitations was that this was an analysis of secondary outcome measures. Though a minimum required sample size was reached, using a subset of participants of the larger trial affected the allocation ratio and randomization. Baseline characteristics, however, were not significantly different between groups in this secondary analysis. Additionally, compared to the effects of FES cycling on chronic patients with SCI [4], it is possible that the effects of whole-body exercise on neurologic recovery may be too small to ascertain from the variability in neurologic improvement during the first 18 months after injury. Based on the longitudinal data from SCI Model Systems, Sygen, and EMSCI databases, motor change can increase an average of 10–14 points in individuals with complete tetraplegia and 30–50 points in individuals with incomplete tetraplegia in the first year after injury [3].

However, based on the Sygen data, 78–93% of this change occurred in the first 6 months after injury [3], which was a timeframe excluded from the present study.

Another limitation is inter-rater reliability. While inter-rater reliability for the ISNCSCI is relatively high, especially for motor score [14], we did not specifically test for this in the present study. Additionally, the modified Ashworth scale has a low inter-rater reliability of 0.53–0.77 in lower extremity muscles in patients with SCI [12]. Thus, having multiple raters may have prevented noting statistically or clinically significant change. Future research studies may benefit from using a single rater to reduce this variability.

Conclusions

Hybrid-FES rowing does not improve natural neurologic recovery or spasticity during 6 to 18 months after SCI, regardless of level of injury, AIS classification, or total amount of hybrid-FES rowing completed, when compared to the current standard of care. Given the breadth of level of injury and AIS classifications studied, these findings are likely generalizable to the SCI population. It may be considered early in rehabilitation to counteract the effects of detraining that occur after SCI and provide increased aerobic demand to help mitigate cardiovascular risk.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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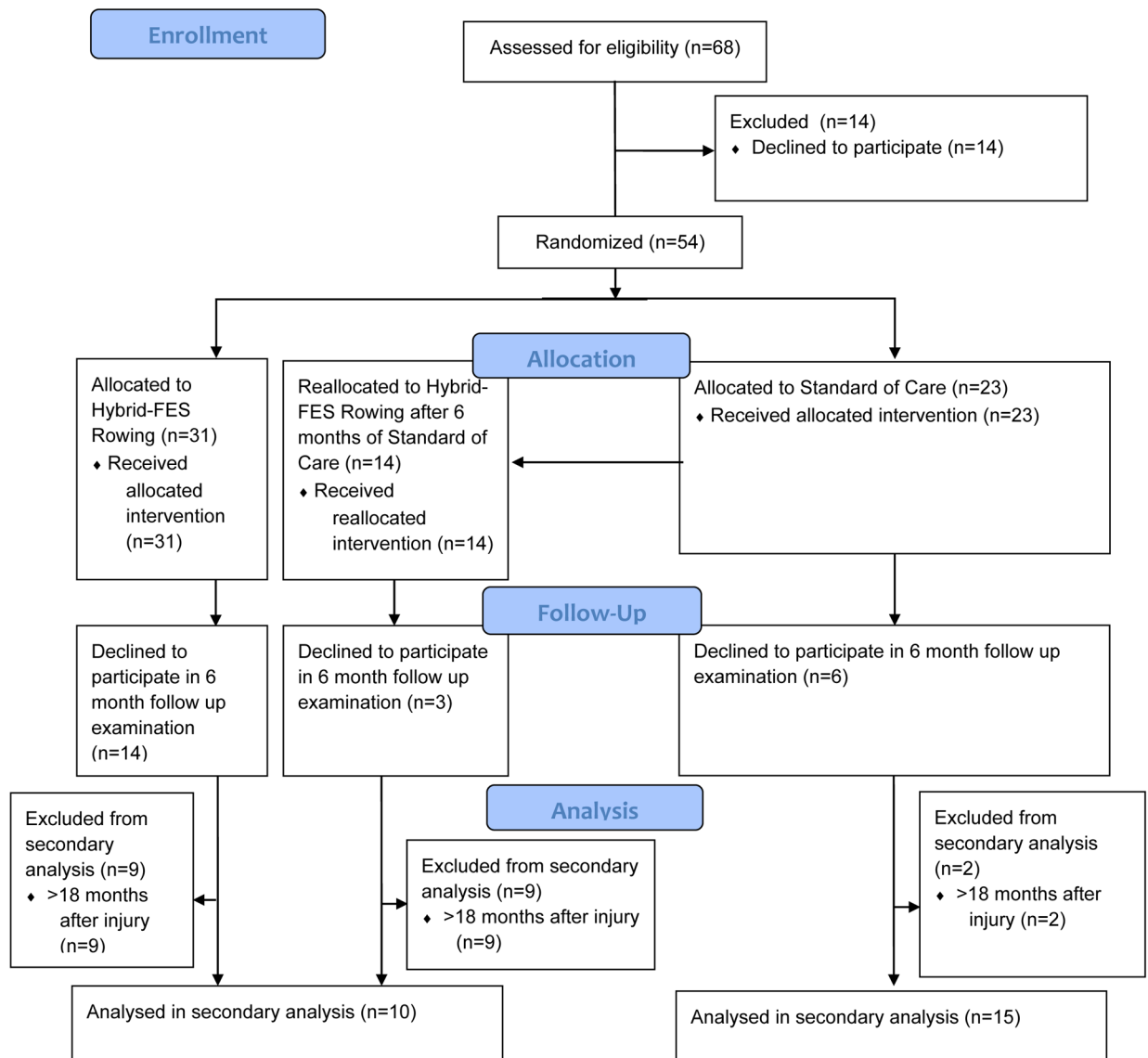


Figure 1.
CONSORT flow diagram.

Table 1.

Baseline characteristics of study participants. AIS = American Spinal Injury Association Impairment Scale.

	Hybrid-FES Rowing (n=10)	Standard of Care (n=15)	p-value (2-tailed)
Age, years, mean (SD)	30 (6.3)	28 (6.2)	0.51
Gender			0.77
<i>Male, n</i>	9	14	
<i>Female, n</i>	1	1	
Time since injury, months, mean (SD)	16 (2.3)	14 (3.0)	0.08
Level of Injury			0.14
<i>Tetraplegia, n</i>	7	6	
<i>Paraplegia, n</i>	3	9	
AIS at baseline, tetraplegia			0.39
<i>Complete tetraplegia (AIS A), n</i>	4	2	
<i>Incomplete tetraplegia (AIS B, C), n</i>	3	4	
AIS at baseline, paraplegia			0.37
<i>Complete paraplegia (AIS A), n</i>	2	8	
<i>Incomplete paraplegia (AIS B, C), n</i>	1	1	

Table 2.

Change in motor score. Total maximal motor score is 100 points. AIS = American Spinal Injury Association Impairment Scale. FES = Functional Electrical Stimulation. SD = Standard Deviation.

	Hybrid-FES Rowing			Standard of Care			Mean between group difference (95% CI) in motor score change	p-value (2-tailed)
	Baseline	6 Month	Mean Change	Baseline	6 Month	Mean Change		
Motor score, overall, mean (SD)	39 (15)	40 (14)	↑ 2.3 (3.8)	43 (11)	44 (10)	↑ 1.0 (3.7)	1.3 (-1.9 to 4.4)	0.53
Motor score, all tetraplegia, mean (SD)	32 (16)	34 (15)	↑ 3.8 (4.3)	33 (12)	35 (11)	↑ 2.9 (5.6)	2.9 (-5.5 to 7.4)	0.76
<i>Motor score, complete tetraplegia (AIS A), mean (SD)</i>	39 (10)	41 (8.5)	↑ 4.4 (5.0)	30 (2.8)	32 (2.1)	↑ 2.0 (0.4)	2.4 (-9.6 to 14)	0.56
<i>Motor score, incomplete tetraplegia (AIS B,C), mean (SD)</i>	25 (20)	26 (19)	↑ 3.2 (4.5)	35 (15)	36 (13)	↑ 3.4 (7.2)	-0.12 (-12 to 12)	0.98
Motor score, all paraplegia, mean (SD)	50 (0)	50 (0)	0 (0)	50 (0)	50 (0.33)	↓ 0.2 (0.7)	0.22 (-0.53 to 0.98)	0.53
<i>Motor score, complete paraplegia (AIS A), mean (SD)</i>	50 (0)	50 (0)	0 (0)	50 (0)	50 (0.35)	↓ 0.3 (0.7)	-0.25 (-1.2 to 0.71)	0.57
<i>Motor score, incomplete paraplegia (AIS B,C), mean (SD)</i>	50	50	0	50	50	0	0	0

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Table 3.

Change in combined sensory score. Total maximal combined sensory score is 224 points. AIS = American Spinal Injury Association Impairment Scale. FES = Functional Electrical Stimulation. SD = Standard Deviation.

	Hybrid-FES Rowing			Standard of Care			Mean between group difference (95% CI) in combined sensory score change	p-value (2-tailed)
	Baseline	6 Month	Mean Change	Baseline	6 Month	Mean Change		
Combined sensory score, overall, mean (SD)	91 (41)	94 (35)	↑ 3.6 (21)	101 (22)	102 (33)	↑ 14 (40)	-10 (-30 to 18)	0.46
Combined sensory score, all tetraplegia, mean (SD)	68 (37)	73 (27)	↑ 6.8 (25)	96 (32)	95 (47)	↑ 24 (61)	-17 (-81 to 47)	0.53
<i>Combined sensory score, complete tetraplegia (AIS A), mean (SD)</i>	61 (11)	72 (19)	↑ 12 (28)	63 (6.4)	72 (11)	↑ 16 (27)	-4 (-84 to 76)	0.88
<i>Combined sensory score, incomplete tetraplegia (AIS B,C), mean (SD)</i>	75 (56)	74 (38)	↑ 1.7 (28)	118 (14)	107 (56)	↑ 28 (76)	-27 (-147 to 94)	0.6
Combined sensory score, all paraplegia, mean (SD)	125 (10)	125 (17)	↓ 1.0 (16)	104 (16)	105 (23)	↑ 7.5 (20)	-8.5 (-34 to 17)	0.48
<i>Combined sensory score, complete paraplegia (AIS A), mean (SD)</i>	122 (9.8)	118 (12)	↓ 6.8 (9.6)	103 (17)	105 (24)	↑ 8.4 (22)	-17 (-47 to 13)	0.23
<i>Combined sensory score, incomplete paraplegia (AIS B,C), mean (SD)</i>	134	144	↑ 21	112	112	0	-21	