Combined Use of Body Weight Support, Functional Electric Stimulation, and Treadmill Training to Improve Walking Ability in Individuals With Chronic Incomplete Spinal Cord Injury

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Objective: To assess the effect of an intervention combining body weight support (BWS), functional electric stimulation (FES), and treadmill training on overground walking speed (OGWS), treadmill walking speed, speed and distance, and lower extremity motor scores (LEMS).

Design: Before and after comparison.

Setting: Miami Project to Cure Paralysis.

Participants: Nineteen subjects with American Spinal Injury Association class C injury who were at least 1 year postinjury and had asymmetrical lower extremity function.

Intervention: Subjects trained 1.5 hours per day, 3 days per week, for 3 months. The training consisted of body weight–supported treadmill walking assisted by electric stimulation. Stimulation was applied to common peroneal nerve of the weaker lower extremity (LE) and timed to assist with the swing phase of the step cycle.

Main Outcome Measures: OGWS in the absence of both BWS and FES; LEMS, and treadmill training parameters of speed and distance.

Results: Over the course of training, there was a significant increase in OGWS (from .12 $\pm$ 0.8m/s to .21 $\pm$ .15m/s, $p =$ .0008), treadmill walking speed (from .23 $\pm$ .12m/s to .49 $\pm$ .20m/s, $p = .00003$), and treadmill walking distance (from 93 $\pm$ 84m to 243 $\pm$ 139m, $p = .000001$). The median LEMS increased significantly for both the stimulated and nonstimulated leg (from 8 to 11 in the FES-assisted leg, from 15 to 18 in the nonassisted leg, $p < .005$ for each).

Conclusions: All subjects showed improvement in OGWS and overall LE strength. Further research is required to delineate the essential elements of these particular training strategies.

Key Words: Electric stimulation; Exercise test; Gait; Rehabilitation; Spinal cord injuries; Walking.

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MANY INDIVIDUALS with incomplete spinal cord injury (SCI) have the potential to walk.[1-6] In recent years, numerous studies have investigated the effect of gait training in individuals with incomplete SCI to improve walking function. The experimental interventions have mainly been of 2 types: functional electric stimulation (FES)[7-13] or body weight support (BWS),[14-20] the latter at times in conjunction with pharmacologic agents.[21-23] Results of these studies, with regard to improvement in walking ability, have been promising.

BWS assists the stance cycle of gait, allowing lower extremity (LE) loading to vary according to the capabilities of the participant and providing assistance to balance by stabilization of the trunk. Previous investigations have assessed the effects of different levels of BWS on various treadmill gait parameters including hip and knee angle displacements, mean muscle burst amplitude, and temporal gait measures. Of the BWS conditions studied, the 30% BWS condition produced the gait parameters most closely resembling those measured at 0% (full weight bearing).[24] In addition, during overground walking with levels of BWS greater than 30%, subjects are unable to generate the ground reaction forces necessary to propel themselves forward (personal unpublished observation). The motorized treadmill provides rhythmic timing cues and assists with retropulsion of the stance limb, which promotes hip extension. This hip extension may be critical to the initiation of the swing phase.[25,26] The swing phase of gait can be assisted with FES by using the flexion withdrawal response evoked with electric stimulation to the common peroneal nerve. This use of FES eliminates the need for manual assistance, the provision of which may impose strenuous physical demands on the therapist or trainer.

Although there have been no reports of prior investigations of the combined use of these interventions in individuals with incomplete SCI, this combined approach has considerable theoretical support,[27] and as been used successfully in individuals with hemiplegia. Hesse et al[28] investigated the use of multichannel electric stimulation in combination with treadmill training and BWS in 11 nonambulatory individuals with hemiparesis (9 due to cerebrovascular accident [CVA:5 hemorrhagic, 4 ischemic], 1 each to trauma and tumor). After the program, improvements were seen across all subjects in gait parameters such as velocity, stride length, and cadence. Although this study has interesting implications for walking in individuals with chronic incomplete SCI, there are limitations that prevent the findings from being fully applicable to that population. In addition to difference in neurologic etiology, 5 of the subjects with CVA were within 5 months postinsult, a time during which spontaneous recovery of function is to be expected.[29]

This investigation sought to assess changes in walking function and voluntary limb control, as well as the relationships among these variables, in individuals with chronic (defined as at least 1 year postinjury[16]) incomplete SCI who are classified as American Spinal Injury Association (ASIA) class C.[30] My

Table 1: Walking Mobility Criteria for Levels of Ambulation

Criterion	Description
1. Physiologic ambulator	Endurance, strength, or level of assistance required make the ambulation not functional. May require assistance to stand. (Walks for exercise only.)
2. Limited household ambulator	Walks in the home but limited by endurance, strength, or safety. (Walks rarely in the home/never in community.)
3. Independent household ambulator	Walks continuously for distances that are considered reasonable for inside the home. May require assistance with stairs inside and curbs, ramps outside the home. A wheelchair may be used outdoors. (Walks occasionally in home/rarely in community.)
4. Limited community ambulator	Walks outside the home and can manage, doors, low curbs, and ramps. A wheelchair may be used for long distances. (Walks regularly in the home/occasionally in community.)
5. Independent community ambulator	Walks for distances of approximately 400 meters (¼ mile) at a speed at least 50% of normal. Can manage all aspects of walking safely, including curbs, stairs, and doors. (Walks regularly in the community [rarely/never uses wheelchair].)

NOTE. Data from Perry et al.[32]

selection of individuals who were at least 1 year postinjury was based on literature indicating that gains in walking ability plateau by the first postinjury year.[6,31] I hypothesized that with training, subjects would show an improvement in walking speed, both on the treadmill and overground, an increase in treadmill walking endurance, and an increase in LE strength.

METHODS

Subjects

Nineteen individuals (13 men, 6 women; mean age, 31.7 ± 9.4yr) participated in this study. Thirteen subjects presented with tetraplegia, 6 with paraplegia. All subjects had ASIA class C injuries (sensory and motor function are preserved below the level of the lesion, but at least half of the muscles below the level of the lesion have a grade < 3). Median time postinjury was 56 months (range, 12–171mo). All subjects signed an informed consent consistent with University of Miami regulations for protection of human subjects.

Inclusion criteria included asymmetric LE strength with the ability: (1) to rise from sit to stand, using upper extremity assistance, and no more than moderate assistance from another person; (2) to stand upright on both legs with no more than 30% BWS; (3) with 30% BWS, to advance the stronger leg independently with the treadmill speed at 0.1 miles per hour; and (4) in the weaker leg, to display a robust flexion withdrawal reflex at tolerable levels of electric stimulation. One subject (S9) was unable to complete the final 2 weeks of the training program owing to a family emergency that arose in the 10th week of training.

Testing

Subjects were tested prior to and following participation in the training program. The primary measure of interest was overground walking speed (OGWS) in the absence of BWS and FES, which was assessed based on distance traversed in a 2-minute timed walk along an 80-foot oblong track. Subjects were allowed to use their preferred assistive device and any necessary orthotic devices, and walked at their fastest comfortable walking speed (instructed as "you will be walking for 2 minutes, walk at a quick pace, but not so fast that you will be exhausted at the end"). Subjects were also tested while walking at their fastest comfortable walking speed on a motorized treadmill during which time they were videotaped from the sagittal view (on the side of the weaker limb) for later kinematic analysis. The level of BWS and the timing of FES during the initial and final treadmill testing were adjusted to allow the subject to walking with optimal gait quality. Voluntary motor control in the LEs was assessed according to ASIA standards,[30] with the combined score of the hip flexor, knee extensor, ankle plantarflexor, ankle dorsiflexor, and great toe extensor comprising the lower extremity motor score (LEMS).[6,31] A pretraining walking mobility score was established for each subject by asking subjects to rate their typical walking practice based on a modified version of the scale developed by Perry et al[32] (table 1).

For the overground walking tests, subjects were strapped into a safety harness[a] that was suspended from a ceiling-mounted track-and-trolley assembly. This was only for safety and no weight support was provided during the overground testing. If the subject required manual assistance to advance the weaker leg during overground walking, this assistance was provided and noted. Subjects were allowed 3 sessions to become accustomed to walking on the treadmill with the BWS and FES prior to the onset of the initial testing session.

Training

Subjects participated in a 36-session (3d/wk for 12wk) training program of BWS and FES-assisted treadmill walking. Subjects were allotted a 1.5-hour block of time during which they were permitted to determine their own walk/rest bouts. BWS was provided by a harness suspended from an overhead support. The level of BWS provided to each subject could be increased or decreased via a motorized winch and could be monitored via an light-emitting diode display. Electric stimulation (Grass S88 stimulator coupled to an SIU5 stimulus isolation unit[b]) to the common peroneal nerve was triggered at time of terminal stance to elicit a flexion withdrawal response to assist with stepping in the weaker limb. Stimulation parameters were: 500ms train, 50 pulses/s, 1ms pulse duration, and between 60 to 100 volts depending on subject tolerance and the level of stimulation necessary to elicit a robust flexion withdrawal reflex. Within each training session, the treadmill speed and amount of support (up to 30% BWS) provided was adjusted to allow the subject to walk optimally on the treadmill. Subjects were encouraged to walk as fast as they could while preserving good gait kinematics and were told that walking distance (time) was not important. For each walking bout, the time and distance of the walk were recorded. No attempts were made to wean the subject from use of BWS or FES over the course of training.

Data Analysis

Data were analyzed using Microsoft Excel 97 SR-2 Statistical Tool Pac[c] and customized programs. The required level of significance for all tests was p equal to .01. Both parametric and nonparametric statistical methods were used to compare changes in walking parameters and LEMS pre- and posttraining. One-tailed, paired t tests were used to test the hypothesis that OGWS, treadmill walking speed (TWS), and treadmill walking distance increased with training. Effect size and power calculations for changes in OGWS were calculated and adjusted for repeated measures according to the technique recommended by Portney and Watkins.[33] Wilcoxon's test, a matched-pairs, signed-rank test for ordinal data,[34] was used to compare LEMS within and between legs pre- and posttraining. Pearson's product-moment correlation (r) was used to test the relationships among OGWS and TWS. Spearman's rank correlation coefficient (r_s), a nonparametric equivalent to the Pearson r, for correlations among ordinal data,[33] was used to assess the relationship between LEMS and the subject's initial walking mobility scores as well as to test the relationship between these 2 variables and OGWS.

RESULTS

Walking Parameters

Individual subject data for OGWS (tested pre-, posttraining) and TWS and treadmill distance per session are given in figure 1. The OGWS reflects the speed the subjects were able to walk independently (no BWS, no stimulation) using whatever assistive device they typically used. At the time of the initial test, 6 subjects (S1, S2, S6, S10, S12, S18) required manual assistance to advance their weaker leg; by the final test only 2 subjects continued to require this assistance (S6, S12). Treadmill speed and distance reflect subject performance under the training condition (assisted by both BWS and stimulation).

Mean OGWS (m/s) improved over the course of training (initial = .12 ± 0.8m/s; final = .21 ± .15m/s; fig 1A), as did mean TWS (initial = .23 ± .12m/s; final = .49 ± .20m/s; fig 1B). The OGWS and TWS increases were seen in all subjects (median change, 77% and 106%, respectively; fig 2), these changes were statistically significant (OGWS: p = .0008; TWS: p = .00003) and the effect size for OGWS was large (r = .77), yielding a statistical power of 65%. There was a good correlation between OGWS and TWS, at both the beginning (r = .71) and end (r = .82) of training, but there was no relationship between pre-post change in walking speed overground versus that on the treadmill ($r = -.07$).

Mean treadmill distance/session (initial = 93 ± 84m; final = 243 ± 139m; fig 1C) increased significantly (p = .000001). Most subjects experienced an increase in treadmill walking distance (median change, 253%); however, there were 2 subjects (S6, S14), who walked a shorter distance as the treadmill speed increased (−17% and −63%, respectively). In these subjects, walking distance was sacrificed to attain faster speeds.

Prior to the onset of training, a walking mobility score was established for each subject based on his/her typical walking practice. There was a good correlation (r_s = .74) between initial OGWS and mobility scores.

Lower Extremity Motor Scores

LE strength, as indicated by LEMS, increased over the course of training (fig 3). There was a median increase of 3 points in each leg (from score of 8 to score of 11 in the FES-assisted leg, from 15 to 18 in the nonassisted leg); this increase was statistically significant in each case ($p < .005$ for each). The difference between the FES-assisted and nonassisted leg was statistically significant ($p < .005$) both pre- and posttraining; this was expected given the inclusion criteria of marked asymmetry in leg strength. In 4 individuals, LEMS for 1 leg were lower after than before training, and in 3 individuals 1 leg showed no change.

A relationship was found between walking speed and strength as indicated by a moderate correlation (r_s = .64) between pretraining OGWS and LEMS; posttraining OGWS and LEMS showed a fair correlation (r_s = .39). There was little or no correlation between the change in OGWS and the change in LEMS ($r_s = -.16$). There was a moderate correlation (r_s = .60) between pretraining LEMS and mobility scores (as established prior to training).

Follow-Up

Because most subjects did not live locally, we were able to do only limited follow-up after posttraining assessment. Four study participants (S1, S2, S5, S11) were available for reevaluation at posttraining time intervals of 2 months to 1 year. Three of these individuals (S1, S2, S5) demonstrated OGWSs that were as good or better than that of their final evaluation. One subject (S11) did not retain the gains made during participation in the training program. However, this individual had undergone surgery (revision of cervical decompression and fusion, unrelated to participation in the study) during the poststudy year and had subsequently had a prolonged period during which she was unable to ambulate. This may account for the loss of the gains made during the training program. These findings agree with those of Wernig et al[35] who evaluated subjects between 6 months and 6.5 years after participation in a training program of BWS and treadmill training, and found that the vast majority maintained the gains achieved with training.

DISCUSSION

All of the subjects who participated in this study demonstrated an improvement in OGWS. All subjects had SCI of at least 1 year's duration, and therefore I attribute the increase in walking speed to participation in the study. Walking speed has been suggested to be the criterion standard of walking ability in neurologically compromised individuals.[36-38] The finding of statistical significance, together with the effect size, suggests that these are meaningful changes in OGWS. The good correlation between OGWS and TWS supports the notion that those who are able to walk fastest on the treadmill are also able to walk fastest overground. However, the lack of correlation between change in OGWS and change in TWS suggests that there is little relationship between the amount of improvement in OGWS and improvement in treadmill training speed.

The finding that LEMS correlated with walking speed agrees with prior studies by Waters et al.[6,31,39] The change in LEMS was statistically significant, but whether this change (a median of 3 points) is functionally significant is debatable. The finding that there is a moderate correlation between OGWS and mobility score and between LEMS and mobility score demonstrates that, in addition to individuals with stroke,[32] mobility scores may be applicable to ambulatory individuals with SCI. No relationship, however, was found between the change in LEMS and the change in OGWS.

The use of time-delimited walk tests is increasingly common in the rehabilitation literature[40-45] because they inherently include a reproducible measure of exercise tolerance as well as speed. The decision to use the 2-minute walk test (rather than tests of other time durations) is based on evidence that this is

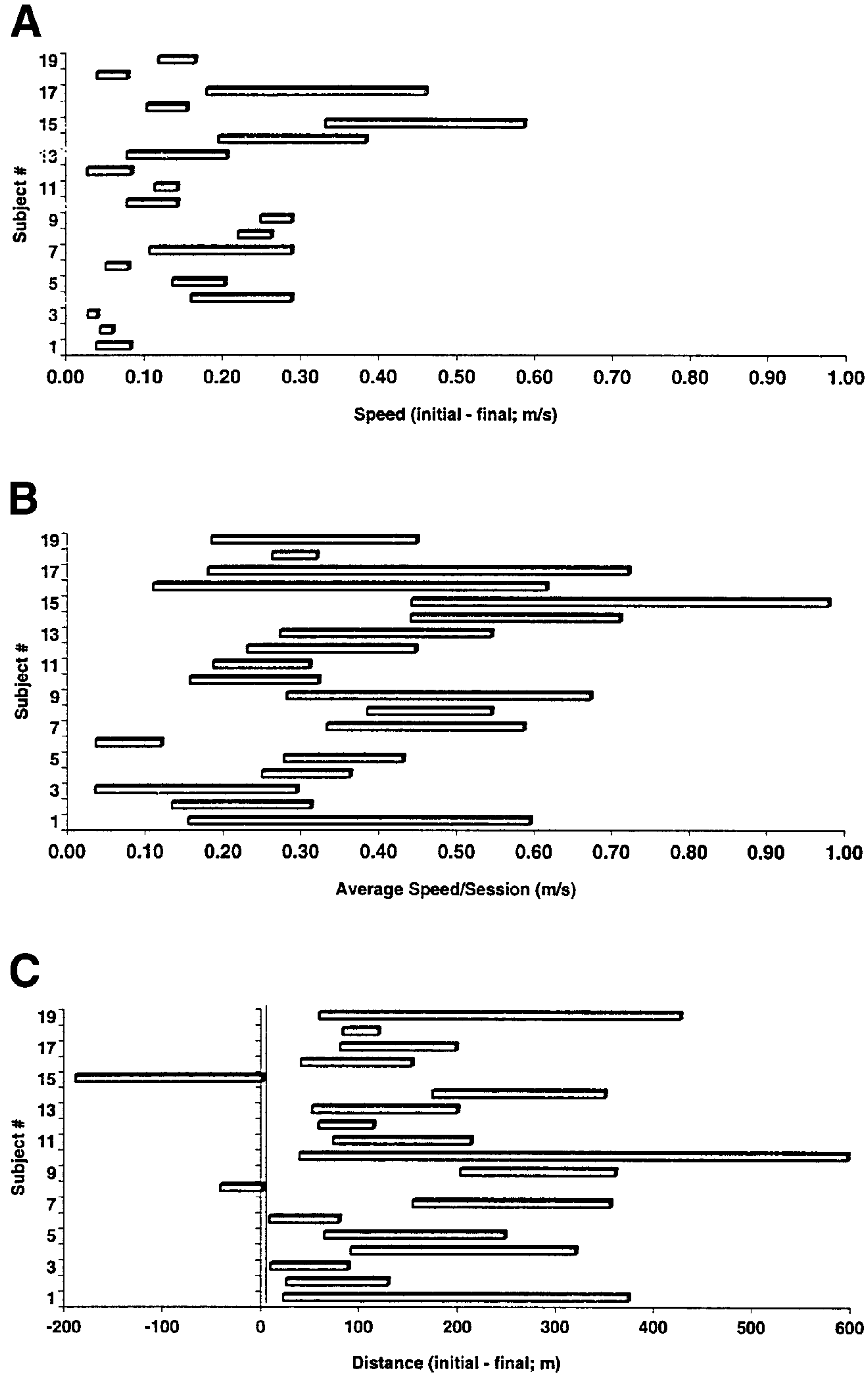

Fig 1. Initial and final values for (A) OGWS (independent: no BWS, no stimulation); (B) TWS (assisted by BWS and stimulation); and (C) TWS (assisted by BWS and stimulation). Changes in speed were in the positive direction, 2 subjects (S8, S15) had lower treadmill walking distances in the final test compared with initial values (see text).

a reliable test that compares favorably with time-delimited tests of longer durations.[46] Also, in addition to providing a functional time period over which to calculate walking speed, preliminary work suggests that 2 minutes is the minimum time required for an individual with SCI to reach a metabolic steady-state during ambulation (Patrick L. Jacobs, PhD, exercise physiologist, written communication, Sept 1999).

Recent evidence[40,47] suggests that, to maximize locomotor performance in individuals with central nervous system pathology, subjects must train at a pace that approximates normal walking speeds. None of the subjects approached normal OGWSs in their independent walking by the end of the study, but 7 of the 19 subjects (37%) effectively doubled their OGWS. Cerny et al[48] suggest that individuals with SCI who

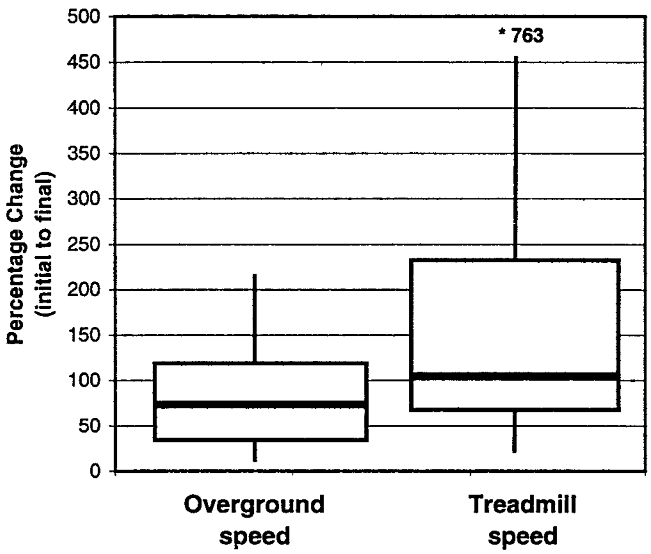

Fig 2. Median (thick bar), lower quartile (lower border of box), upper quartile (upper border of box), and range (vertical bar) for changes in over-ground and treadmill walking speeds. One outlier for treadmill speed is noted by (*) and the value is given.

walk at speeds of less than 0.9m/s (54m/min or 2.0 miles/hr) are unlikely to use walking as their primary mode of locomotion. However, this conclusion was based on a study of 10 individuals with paraplegia, all of whom required bilateral knee-ankle-foot orthoses (KAFOs), and only 2 of whom used walking as their primary means of locomotion. In the present study, the 2 individuals (S9, S14) who walked as their primary means of locomotion did not use orthoses (although this might have been recommended to them), had a LEMS of 31 and 28, respectively, and had 1 leg that was appreciably stronger. Part of this difference may be because the swing-through gait used with bilateral KAFOs in individuals with low-level spinal injury is faster than that which may be accomplished with a reciprocal gait pattern in an individual with incomplete injuries at higher spinal levels. I think that, despite the fact that subjects in this study may not have become community ambulators by the end of the training period, the improvements in walking function obtained as a result of training will have positive benefits in many other aspects of their daily lives.

I was especially interested in individuals with asymmetric lower extremity involvement, because these individuals would most closely resemble the subjects with hemiplegia studied previously. Although significant changes in walking speed and lower extremity strength were found, as was seen in individuals with hemiplegia, these outcome measures were more variable in our sample of individuals with incomplete SCI than they were in the prior sample of individuals with hemiplegia.[28] This study included only subjects who had ASIA class C injuries; this category is broadest of all the ASIA categories. From a maximum possible score of 50 (5 muscle groups in each leg with a maximum possible score of 5 for each group), this category includes individuals whose LEMS range from a low of 1 to a high of 32. It is suggested that this variability in the incomplete SCI subject population likely accounts for a great degree of the variability in outcomes.

In addition to the differences in subject population, a minimalist approach was taken to the amount of assistance provided. Instead of a multichannel stimulation protocol, a simplified approach was employed using only a single channel of stimulation to evoke a flexion reflex to assist with the swing phase of gait. Use of a spinal reflex to facilitate stepping has clear advantages over either multichannel stimulation or manual assistance. In addition to providing direct motor excitation to the ankle dorsiflexors, such stimulation has reduced antagonist (extensor) muscle spasticity[49] (defined as a velocity-dependent increase in resistance to passive stretch)[50] and modulated spinal reflex activity in a way that may be functionally beneficial.[51] Although it is well recognized that sensory input is important for the modulation of the output of the locomotor generator,[26] evidence also suggests that sensory input may facilitate locomotor recovery following a spinal lesion.[52]

Locomotor function is affected by an individual's muscular strength, cardiovascular endurance, and the ability of the nervous system to recruit effectively and efficiently the appropriate motoneurons. Evidence suggests that the human spinal cord contains circuitry that is capable of producing locomotor-like output.[14,19,53-55] The present intervention takes advantage of spinal circuitry to assist with production of stepping (through the use of the flexion withdrawal reflex) and uses the concepts of task-oriented training. This study indicates that such a training regimen can affect important functional measures such as OGWS and LE strength in individuals with chronic SCI.

Limitations

Subjects who participated in this study demonstrated asymmetrical LE function with severe strength deficits in at least 1 leg; because of this, these results may not be generalizable to all subjects with chronic incomplete SCI. In addition, no comparison group was used, therefore, it is possible that similar results may be obtained with only 1 form of intervention (BWS or FES) or with more conventional types of training.

Further Development

A number of subjects reported that, in addition to improvements in OGWS and LE strength, they had experienced other benefits to the training. The most commonly cited secondary benefits were improved ability to perform transfers and stair-climbing tasks, and improved standing balance. Two subjects also reported improved bowel and bladder function. Future studies should attempt to assess these functions in a standardized way before and after the subjects' participation in the study. No adverse effects were reported.

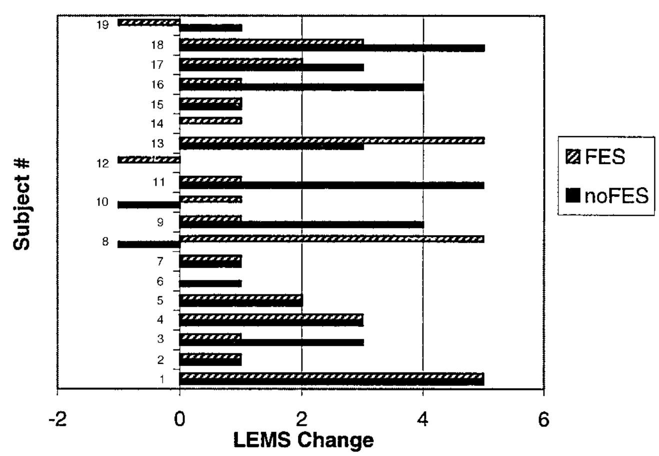

Fig 3. Change in LEMS over the course of training. Stippled and solid bars indicate scores for the FES and no-FES leg, respectively. Absent bar indicates no change in score.

CONCLUSIONS

Subjects with incomplete SCI, who retain some capacity for ambulation, would likely benefit from a walking program that combines BWS, FES, and treadmill training. Although the amount of improvement in walking speed (as measured by increased OGWS) varies with individual participant characteristics, this training clearly has positive effects on function. Use of FES for assistance with limb advancement offers advantages over other forms of assistance. This training regimen employs the principles of task-oriented training and uses the purported locomotor-generating circuitry of the spinal cord.

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Suppliers

a. Maine AntiGravity Systems, 299 Presumpscot St, Portland, ME 04103.
b. Astro-Med Inc, Astro-Med Industrial Park, 600 E Greenwich Ave, West Warwick, RI 02893.
c. Microsoft Corp, One Microsoft Way, Redmond, WA 98052.