

Influence of a Locomotor Training Approach on Walking Speed and Distance in People With Chronic Spinal Cord Injury: A Randomized Clinical Trial

Edelle C. Field-Fote, Kathryn E. Roach

Background. Impaired walking limits function after spinal cord injury (SCI), but training-related improvements are possible even in people with chronic motor incomplete SCI.

Objective. The objective of this study was to compare changes in walking speed and distance associated with 4 locomotor training approaches.

Design. This study was a single-blind, randomized clinical trial.

Setting. This study was conducted in a rehabilitation research laboratory.

Participants. Participants were people with minimal walking function due to chronic SCI.

Intervention. Participants ($n=74$) trained 5 days per week for 12 weeks with the following approaches: treadmill-based training with manual assistance (TM), treadmill-based training with stimulation (TS), overground training with stimulation (OG), and treadmill-based training with robotic assistance (LR).

Measurements. Overground walking speed and distance were the primary outcome measures.

Results. In participants who completed the training ($n=64$), there were overall effects for speed (effect size index $[d]=0.33$) and distance ($d=0.35$). For speed, there were no significant between-group differences; however, distance gains were greatest with OG. Effect sizes for speed and distance were largest with OG ($d=0.43$ and $d=0.40$, respectively). Effect sizes for speed were the same for TM and TS ($d=0.28$); there was no effect for LR. The effect size for distance was greater with TS ($d=0.16$) than with TM or LR, for which there was no effect. Ten participants who improved with training were retested at least 6 months after training; walking speed at this time was slower than that at the conclusion of training but remained faster than before training.

Limitations. It is unknown whether the training dosage and the emphasis on training speed were optimal. Robotic training that requires active participation would likely yield different results.

Conclusions. In people with chronic motor incomplete SCI, walking speed improved with both overground training and treadmill-based training; however, walking distance improved to a greater extent with overground training.

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It has been estimated that 12,000 people in the United States sustain spinal cord injury (SCI) each year.¹ The loss of motor function associated with SCI often produces severe limitations on mobility and self-care. However, because of advances in the medical management of acute SCI, more people now retain or recover some motor function.² Preserved motor function improves the possibility that these people may be able to walk at least short distances. The ability to stand and walk through a narrow entryway or to negotiate confined spaces inaccessible to a wheelchair provides opportunities to participate in activities that might otherwise be inaccessible.

The early 1990s ushered in a time of great interest in treadmill-based locomotor training for people with SCI. In a study with a small sample of participants, Barbeau and Blunt³ described treadmill-based locomotor training with a harness-lift system to provide partial body-weight support (BWS). The approach was hailed as one of the first models of rehabilitation to be grounded in a scientific basis, as earlier work had demonstrated that, with BWS, animals with complete spinal cord transection could step on a treadmill. In animals with complete spinal cord transection, movement of the limbs below the level of transection is observed only in response to afferent input. For example, when afferent input is supplied by a moving treadmill, the spinal central pattern-generating circuitry is activated and evokes innate rhythmic behaviors, such as stepping (for a review, see Bouyer⁴). The moving surface of the treadmill supplies biomechanical assistance for the stance phase of stepping and neural assistance for initiation of the swing phase. During the stance phase, the treadmill belt assists with moving the limb into extension and promotes hip extension during terminal stance. During terminal stance,

excitation of stretch receptors in the hip flexor muscles interacts with the spinal central pattern-generating circuitry, promoting termination of the stance phase and initiation of the swing phase.⁵ On the basis of this evidence, it may seem logical to suppose that treadmill-based locomotor training offers advantages over overground locomotor training for people with SCI.

During treadmill-based locomotor training, stepping can be assisted in various ways, such as the manual assistance of a trainer, the mechanical assistance of a robotic gait orthosis, or electrical stimulation. Each approach has particular advantages. A trainer providing manual assistance can encourage the individual to voluntarily generate the portions of the cycle that he or she is able to control but can assist with portions over which the individual has less control. This approach likely balances voluntary effort and external assistance consistent with the “assist-as-needed” concept, which is thought to promote motor learning.^{6,7} Although robotic assistance may be configured to provide assistance as needed, it also can be used to provide maximal assistance to produce kinematically appropriate limb movement. In this mode, the device provides passive mechanical guidance, thereby eliciting precise gait-specific proprioceptive input—information that is thought to facilitate motor learning by contributing to the development of an accurate internal representation for the movement experience.⁸ Finally, electrical stimulation can be used to produce a flexion withdrawal response for stepping. It has been suggested that this approach targets the spinal circuitry,⁹ as the flexor reflex afferents are believed to be part of the pattern-generating circuitry underlying locomotor output.^{10–13}

Thus far, there is no consensus about the best approach for locomotor train-

ing after SCI. A systematic review concluded that there is insufficient evidence from randomized clinical trials to conclude that any approach improves walking function more than another approach.¹⁴ In the largest randomized trial of locomotor training in people with SCI, treadmill-based locomotor training with manual assistance and BWS was compared with conventional overground locomotor training in participants with acute SCI. The investigators concluded that there was little difference in outcomes related to walking speed and distance between treadmill-based training and overground training for people with acute SCI.¹⁵ Although no differences between treadmill-based training and overground training were observed in people with acute SCI, it could be argued that training in the overground environment provides an experience that most closely resembles the functional task of walking. Overground locomotor training allows people to learn how to generate and control the forces necessary to initiate stepping, to move their bodies overground, and to practice and improve performance.

The objective of this study was to determine whether there are differences in walking speed and distance outcomes associated with 4 locomotor training approaches in people with chronic SCI. Earlier studies of locomotor training in people with SCI were restricted to comparisons of 2 groups; therefore, differences in study inclusion criteria, training duration, and training dosage limited the ability to make meaningful comparisons of approaches. All 4 approaches that we compared incorporated BWS but differed in the type of assistance provided for stepping (ie, manual, electrical stimulation, or mechanical) and the environment in which training was performed (ie, treadmill or overground). The approaches were intended to emphasize

particular aspects of the various mechanisms that contribute to locomotion.

On the basis of our earlier study,⁹ we hypothesized that a treadmill-based training approach that incorporated electrical stimulation to evoke a flexion withdrawal reflex would be associated with the greatest improvements in both walking speed and walking distance. This hypothesis was based on our supposition that a combination of the flexion withdrawal response (thought to be involved with the spinal locomotor pattern-generating circuitry)^{10–13} and the moving treadmill would provide optimal drive to the spinal locomotor centers, resulting in superior gains. Preliminary results from an interim data analysis have been published elsewhere.¹⁶

Method

Design Overview

This study was a single-blind, randomized clinical trial.

Setting and Participants

The study took place at The Miami Project to Cure Paralysis, Miller School of Medicine, University of Miami. Participant enrollment commenced May 2002, and the final participant completed training in December 2008. People with chronic (≥ 1 year) SCI were recruited. Eligibility criteria for the study included American Spinal Injury Association Impairment Scale classification C or D,¹⁷ injury at or above T10, ability to take at least 1 step with 1 leg, and ability to rise to a standing position with, at most, moderate assistance (50% effort) from 1 other person. Exclusion criteria were current orthopedic problems, history of cardiac condition, or radiographic evidence of hip pathology that could be aggravated by training. All participants gave written and verbal informed consent according to the protocol of a study approved by the Human Studies Research Office, Miller School of Medicine, University of Miami.

The research volunteer registry at The Miami Project to Cure Paralysis was the primary means of recruitment. Of the 3,396 entries available at the start of the study, 802 (23.6%) were identified as possibly being suitable for inclusion on the basis of queries about injury level, American Spinal Injury Association Impairment Scale classification, and assistive devices used for walking. A total of 133 registrants who were contacted expressed interest in being screened. Twenty-two people who sent video recordings and 33 people who were screened on-site did not meet the inclusion criteria. Seventy-eight people provided consent to participate; 4 were excluded for various reasons before randomization. Ten people did not complete the training and were lost to follow-up. The breakdown by group is shown in the CONSORT (Consolidated Standards of Reporting Trials) diagram (Fig. 1).

Randomization and Interventions

Participants were stratified into 1 of 4 strata on the basis of pretraining Lower Extremity Motor Scores (LEMS)¹⁷: stratum 1=LEMS of 1 to 10, stratum 2=LEMS of 11 to 21, stratum 3=LEMS of 22 to 32, and stratum 4=LEMS of 32 to 40. Stratified randomization was used to assign participants to 1 of 4 BWS training groups: (1) treadmill-based training with manual assistance (TM), (2) treadmill-based training with stimulation (Digitimer DS7AH*) (TS), (3) overground training with stimulation (WalkAide stimulator[†]) (OG), or (4) treadmill-based training with robotic assistance (Lokomat robotic gait orthosis[‡]) (LR). Participants trained 5 days per week for 12 weeks (target=60 sessions). The mean number of training sessions

completed was 49 (SD=7, range=27–58).

For all training approaches, BWS was provided by a harness and overhead lift. Our goal was to impose the maximum lower-extremity weight-bearing load during walking. Excessive knee flexion during the stance phase (ie, $> \sim 40^\circ$) or toe dragging during the swing phase indicated that BWS was insufficient and cued the trainers to increase BWS. Except for the first week of training, BWS was maintained at or below 30%. This level of support has been shown to be associated with gait kinematics resembling those of unsupported walking.¹⁸ Higher levels of support in the overground condition are associated with participants having difficulty with forward progression.⁹

The form of assistance provided for stepping was specific to each training approach. For the TM approach, unilateral or bilateral manual assistance for stepping was provided in accordance with published guidelines.¹⁹ Participants were encouraged to step voluntarily to the extent possible. For the TS approach, bilateral stimulation to the common peroneal nerves was used to elicit a flexor reflex response. Stimulation was manually triggered to coincide with the onset of stepping. The intensity was adjusted to elicit a robust response, and pulse parameters were adjusted during the training session to manage habituation. For the OG approach, portable electrical stimulators were secured to the upper calf in an electrode position identical to that used in the TS approach. To the extent possible, stimulus pulse parameters were similar for the TS and OG approaches. However, the intensity supplied by the portable device used in the OG approach was adjusted to produce ankle dorsiflexion during the swing phase. For the LR approach, participants were secured to the robotic gait orthosis

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[†] Hanger Orthopedic Group Inc, Two Bethesda Metro Center, Suite 1200, Bethesda, MD 20814.

[‡] Hocoma AG, Industriestrasse 4, Zurich, Switzerland.

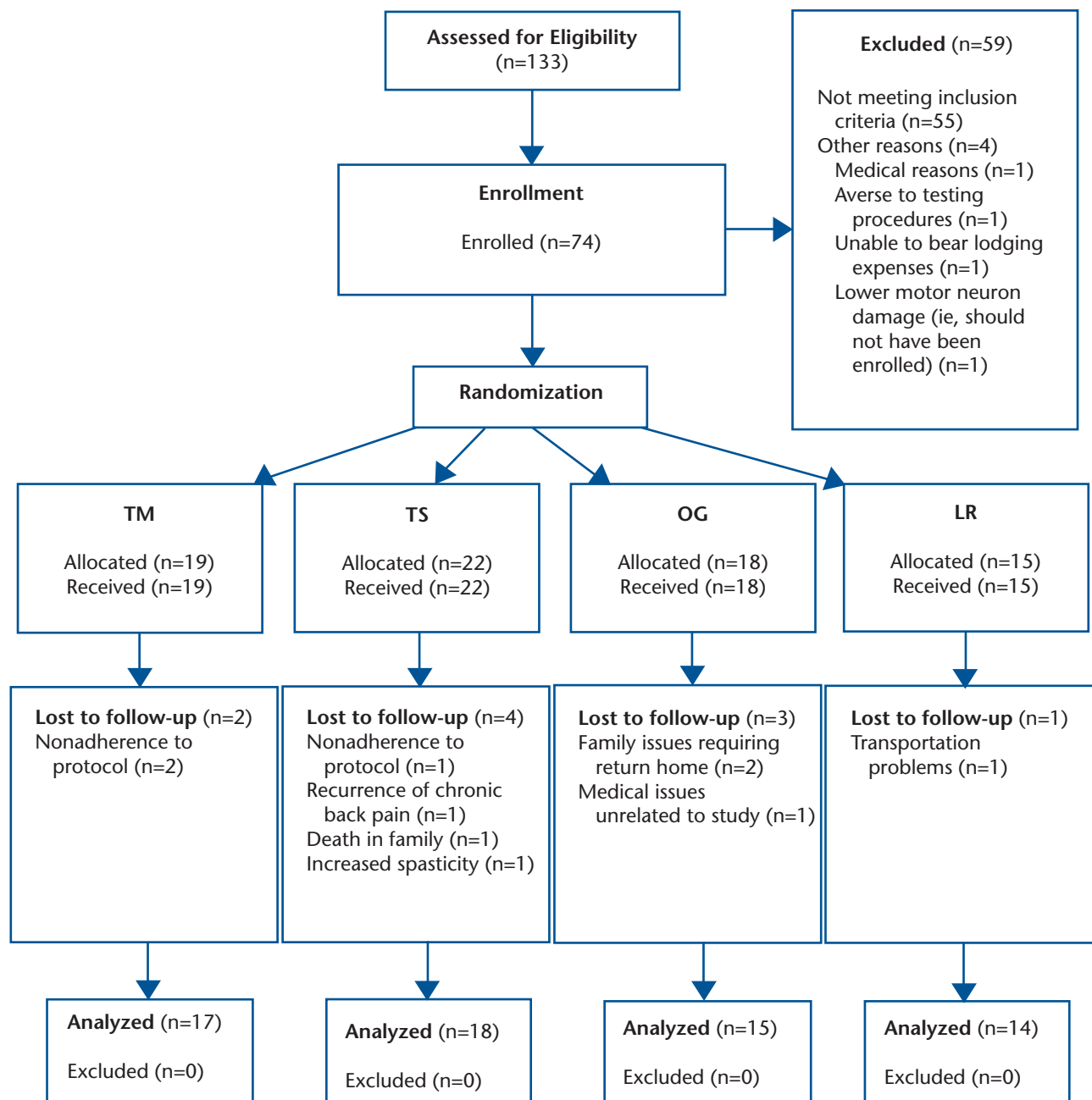


Figure 1.

Flow of participants through the locomotor training study. LR=treadmill-based training with robotic assistance, OG=overground training with electrical stimulation, TM=treadmill-based training with manual assistance, TS=treadmill-based training with electrical stimulation.

according to manufacturer instructions. The device was used to impose a kinematically consistent gait pattern; guidance forces were set at 100% to provide maximal assistance throughout the step cycle. Although participants were encouraged to “walk with the robot,” no attempt was made to monitor the forces of the interaction between the participant and the device.

Participants in all groups were encouraged to walk as fast as possible without regard for the duration of their walking bouts and were allowed to rest as needed. Participants were asked to rate their level of perceived exertion on a 15-point Borg scale (6 [rest]–20 [exhaustion]) after each walking bout and were encouraged to aim for an exertion level of at least 13 (moderate). For participants in the treadmill-based training groups, the treadmill speed was increased at the start of each session to the level at which stepping quality began to degrade and then was reduced to the level at which stepping quality was acceptable. Speed was increased periodically during the sessions to determine whether the participants could tolerate a faster speed. Participants in the OG group were encouraged to walk as fast as possible around a 24.4-m (80-ft) track over which a mobile, motorized BWS lift was suspended.

Participants were allowed to use handrails and assistive devices for balance as needed. Participants in the treadmill-based training groups were encouraged to swing their arms and were discouraged from bearing weight through the upper extremities. However, they were allowed to use handrails for balance.²⁰ Participants in the OG group were allowed to use their preferred upper-extremity assistive devices. No attempt was made to advance participants to less supportive assistive

devices. Participants who wore lower-extremity orthotic devices performed the initial training sessions without the devices, and the investigator (E.C.F.F.) made a clinical judgment regarding the safety of allowing the participants to continue training without the orthotic devices. If participants were unable to maintain a safe position of the lower-extremity joints (eg, exhibiting excessive supination or inadequate dorsiflexion), the orthotic devices were used during training in addition to the form of assistance used for the assigned training approach. Additional details regarding the training protocol are available in a preliminary report.¹⁶

Outcome Measures and Follow-up

Primary outcome measures. Overground walking ability was evaluated over a short distance (10 m) to assess walking speed and over a longer distance to assess functional walking capacity (distance traversed in 2 minutes). Walking tests were performed before and after training, without BWS or assistance for stepping. Participants used the assistive or orthotic devices (or both) with which they were most comfortable. For both the test of speed and the test of distance, participants were given the instruction to “walk at your fastest comfortable speed.” The tests were scheduled on different days to minimize the effects of fatigue.

Short-distance overground walking speed was calculated from the average walking speed in 5 trials, captured as the participant walked over a 10-m path, the central 6 m of which was a calibrated motion capture area (Vicon Peak 8-camera 3-dimensional system[§]); complete methods related to kinematic data capture are described

elsewhere.²¹ Participants were allowed to rest as needed between trials. Functional walking capacity was assessed with a 2-minute walk test. The distance traversed was determined from a video record obtained as participants walked around a 24.4-m (80-ft) oblong track with demarcations indicating 1.5-m (5-ft) increments. The people who captured and analyzed the kinematic and video data used to calculate walking speed and distance were unaware of training group assignments.

Secondary outcome measure. Lower-extremity motor scores¹⁷ were used as a measure of the strength (force-generating capacity) of the right and left lower extremities.

Follow-up. When we initiated the clinical trial, we had no plans for follow-up testing. Once the trial was under way, we recognized the value of examining whether training effects were retained after the completion of the study. Therefore, we performed follow-up testing for a convenience sample of 10 participants who were classified as showing improvement at the conclusion of training (ie, walking speed increased by at least 0.05 m/s; see “Data Analysis” section) and who were able to return for testing at least 6 months later.

Data Analysis

Sample size calculations were based on the assumption of a large effect size for an analysis of variance (ANOVA) comparing pretest-posttest intervention changes in walking speed for the 4 training groups. On the basis of this assumption, a sample size of 16 participants per group was required to achieve a power of 0.8. All data were managed with Microsoft Excel^{||} and analyzed with

[§] Peak Performance Technologies Inc, 7388 S Revere Pkwy, Suite 603, Englewood, CO 80112.

^{||} Microsoft Corp, One Microsoft Way, Redmond, WA 98052-6399.

SAS version 9.1.3.[#] The demographic and clinical characteristics of participants lost to follow-up were compared with those of participants completing the study by use of Student *t*-test and chi-square statistics. The baseline characteristics of the participants assigned to the 4 intervention groups were compared by use of ANOVA and chi-square analysis. The pretest-posttest intervention changes for the 4 intervention groups were compared by use of a repeated-measures ANOVA to examine both the time \times group interaction and the time effect. When the time \times group interaction was significant, pair-wise contrast analysis was used. When the time effect was significant, paired *t* tests were used to examine pretest-posttest intervention changes by group. The effect size index (*d*) was calculated for speed, distance, and LEMS for each intervention group by dividing the mean change score for each group by the standard deviation of the baseline score for that group.

The proportion of participants in each training group whose change in 10-m walking speed was 0.05 m/s or greater was determined. This degree of change in speed was considered the minimally important difference (MID) on the basis of earlier studies of community-dwelling people with SCI²² and older people who were healthy.²³ The MID for walking distance was calculated to be 4 m on the basis of a test-retest reliability value of .97²⁴ and a baseline standard deviation of 23.9 (for participants in the present study) for the 2-minute walk test distance. Participants were classified as showing improvement in either walking speed or walking distance if they met or exceeded the respective MID values.

For the purposes of data analysis, participants were categorized as “more impaired” or “less impaired” on the basis of LEMS; if the LEMS were greater than 15 for at least 1 leg and greater than or equal to 10 for the other leg, then the participant was categorized as less impaired. All other participants were categorized as more impaired. This categorization was based on earlier findings from our laboratory¹⁶ and others indicating that there is a strong relationship between LEMS and walking ability.^{25–27} Previous literature also indicated that people with at least 1 strong leg have the potential to achieve functional walking.²⁷ Chi-square analysis was used to compare the proportions of participants in the intervention groups who showed improvements, by LEMS impairment group.

We used a repeated-measures ANOVA followed by paired *t* tests to examine the retention of improvement in a convenience sample of 10 participants who were classified as showing improvement in walking speed at the conclusion of training and who were available for follow-up testing at least 6 months later. A correlation coefficient was calculated to examine the relationship between the time since the conclusion of training and the retention of improvement.

Role of the Funding Source.

Funding support for this study was provided by National Institutes of Health grant R01HD41487 (to Dr Field-Fote) and The Miami Project to Cure Paralysis.

Results

Sixty-four of the 74 participants who were randomly assigned to training groups completed the study (86% completion rate). Therefore, because data following training were not available for all of the participants, analysis was performed on protocol rather than intention to

treat. The age, height, weight, and LEMS of the 10 participants who did not complete training or follow-up testing were similar to those of the participants who completed the study. However, the 10 participants who did not complete the study walked more slowly (0.06 versus 0.18 m/s; $P < .0001$) and walked shorter distances (5.16 versus 21.0 m; $P < .0001$) before training than did the participants who completed the study. There were no significant differences among the 4 training groups in demographic characteristics, baseline LEMS, 10-m walking speed, or 2-minute walk test distance (Tab. 1).

Overall, there was a significant time effect of training on walking speed ($P < .0001$) (Tab. 2). The improvement in walking speed was statistically significant for the OG, TS, and TM groups but not for the LR group. The effect size was moderate ($d = 0.43$) for the OG group and small for both the TS group and the TM group ($d = 0.28$). Although the groups had different pretest-posttest intervention changes in walking speed, the time \times group interaction approached but did not reach statistical significance ($P = .0930$).

Overall, there also was a time effect of training on walking distance ($P < .0001$) (Tab. 2). The increase in walking distance was statistically significant for the OG and TS groups but not for the TM and LR groups. The effect size was moderate for the OG group ($d = 0.40$) and small for the TS group ($d = 0.16$). The time \times group interaction was statistically significant ($P = .0004$), and *post hoc* testing indicated that the increase in the OG group was significantly greater than that in any treadmill-based training group ($P \leq .01$) (Tab. 2).

The LEMS of participants in all 4 training groups increased by 8% to 13% after the intervention. There

[#] SAS Institute Inc, 100 SAS Campus Dr, Cary, NC 27513-2414.

Table 1.
Baseline Equivalence of Groupwise Demographic Characteristics^a

Characteristic	\bar{X} (SD) for Participants in Training Group:				P
	TM (n=17)	TS (n=18)	OG (n=15)	LR (n=14)	
Age, y	39.3 (14.6)	38.5 (12.7)	42.2 (15.7)	45 (8.0)	.52 ^b
Height, m	1.8 (0.1)	1.8 (0.1)	1.7 (0.1)	1.8 (0.1)	.29 ^b
Weight, kg	80.1 (13.9)	78.6 (14.9)	86.1 (21.0)	82.0 (15.9)	.61 ^b
Sex (% men)	82.3	77.8	73.3	85.7	.85 ^c
Race (% of participants)					.96 ^c
White or non-Hispanic	58.8	44.4	40.0	42.9	
Hispanic	29.4	38.9	40.0	35.7	
African American	11.8	16.7	20.0	21.4	
LEMS, left leg	12.9 (5.3)	14.3 (5.8)	12.2 (6.4)	12.7 (6.9)	.76 ^b
LEMS, right leg	13.6 (6.4)	14.3 (5.6)	14.0 (6.0)	12.9 (6.4)	.92 ^b
Short-distance overground walking speed, m/s	0.17 (0.14)	0.18 (0.18)	0.19 (0.20)	0.17 (0.10)	.98 ^b
Distance walked in 2 min, m	22.1 (21.4)	20.6 (23.1)	24.0 (35.3)	16.8 (11.3)	.87 ^b

^a TM=treadmill-based training with manual assistance, TS=treadmill-based training with electrical stimulation, OG=overground training with electrical stimulation, LR=treadmill-based training with robotic assistance, LEMS=Lower Extremity Motor Score.

^b As determined with analysis of variance.

^c As determined with chi-square analysis.

were no significant between-groups differences in changes in LEMS for the right leg ($P=.9630$) or the left leg ($P=.7818$) (Tab. 2). Generally, compared with participants who were more impaired, a larger proportion of participants who were less impaired met or exceeded the MID for both walking speed ($P<.0001$) (Fig. 2) and walking distance ($P=.0611$) (Fig. 3). Among participants who were less impaired, a larger proportion of participants in the OG group than in the treadmill-based training groups met or exceeded the MID for both walking speed and walking distance (Figs. 2 and 3). However, among participants who were more impaired, the TS group had the largest proportion of participants who met or exceeded the MID for speed, whereas the OG group had the largest proportion of participants who met or exceeded the MID for distance.

Ten participants whose improvement in 10-m walking speed met or exceeded the MID of 0.05 m/s dur-

ing the intervention phase of the study were available for follow-up testing to assess the retention of training effects. These participants were tested an average of 20.3 months (SD=14.3 months) after the completion of training. Four of these participants had received the OG intervention, and 2 participants had received each of the other 3 interventions. The participants improved an average of 0.15 m/s (SD=0.09 m/s) by the conclusion of training. The participants declined an average of 0.06 m/s (SD=0.07 m/s) between the conclusion of training and follow-up testing. However, at follow-up, these participants were an average of 0.08 m/s (SD=0.07 m/s) faster than they had been before training (Fig. 4). There was no correlation between the time since the conclusion of training and the decline in walking speed ($r=-.21$, $P=.55$).

Discussion

We had hypothesized that of the 4 training approaches, the TS ap-

proach would best activate the spinal locomotor circuitry and, therefore, would result in the greatest improvements in walking function. Our hypothesis was not supported. The OG approach was associated with significantly greater improvements in walking distance, and the effect size was greater for both speed and distance in the OG group than in any of the treadmill-based training groups. Furthermore, although the TS group had the largest proportion of participants who were more impaired and who met or exceeded the MID for walking speed, the OG group had the largest proportion of participants who were less impaired and who met or exceeded the MID for walking speed. In addition, the OG group had the largest proportion of participants who met the MID for walking distance among both participants who were less impaired and participants who were more impaired.

In both people with SCI and people with stroke, there is a strong rela-

Table 2.
Pretest-Posttest Intervention Change by Training Group^a

Characteristic	\bar{X} (SD) for Participants in Training Group:												p^b
	TM (n=17)			TS (n=18)			OG (n=15)			LR (n=14)			
	Pretest	Posttest	Diff	Pretest	Posttest	Diff	Pretest	Posttest	Diff	Pretest	Posttest	Diff	
Short-distance overground speed (m/s)	0.17 (0.14)	0.22 (0.17)	0.04 (0.07) ES=0.28	0.18 (0.18)	0.23 (0.18)	0.05 (0.09) ES=0.28	0.19 (0.21)	0.28 (0.28)	0.09 (0.11) ES=0.43	0.17 (0.10)	0.18 (0.10)	0.01 (0.05) ES=0.10	Time: $P< .0001$ Time \times group: $P= .0930$
Distance walked, m	22.1 (21.4)	23.0 (21.1)	0.8 (7.7) ES=0.04	20.6 (23.1)	24.4 (24.3)	3.8 (6.3) ES=0.16	24.0 (35.3)	38.3 (46.1)	14.2 (15.2) ES=0.40	16.8 (11.3)	17.9 (11.9)	1.2 (5.1) ES=0.11	Time: $P< .0001$ Time \times group: $P= .0004$
LEMS, left leg	12.9 (5.3)	14.6 (5.7)	1.7 (1.8) ES=0.32	14.3 (5.8)	15.5 (6.2)	1.5 (2.7) ES=0.25	12.2 (6.4)	13.3 (7.3)	1.1 (1.5) ES=0.17	12.7 (6.9)	13.9 (6.5)	1.2 (3.2) ES=0.17	Time: $P< .0001$ Time \times group: $P= .8718$
LEMS, right leg	13.6 (6.4)	15.2 (6.3)	1.5 (2.1) ES=0.23	14.3 (5.6)	15.8 (4.7)	1.6 (2.0) ES=0.28	14.0 (6.0)	15.7 (6.9)	1.7 (2.3) ES=0.28	12.9 (6.4)	14.1 (6.6)	1.3 (1.5) ES=0.20	Time: $P< .0001$ Time \times group: $P= .9630$

^aTM=treadmill-based training with manual assistance, TS=treadmill-based training with electrical stimulation, OG=overground training with electrical stimulation, LR=treadmill-based training with robotic assistance, Diff=mean difference between pretest and posttest scores, LEMS=Lower Extremity Motor Score, ES=effect size (mean change score/standard deviation of pretest). Bolded Diff values are statistically different from 0.

^bAs determined with repeated-measures analysis of variance.

tionship between walking distance and walking speed.^{27,28} However, it could be argued that the ability to enter a confined space such as a toilet stall or to maneuver around a kitchen while preparing a meal is likely to be limited more by the distance that an individual can walk than by walking speed. Given that the OG approach ordinarily is the least equipment- and personnel-intensive training option, it is clinically relevant that this approach was superior to the treadmill-based approaches in many ways.

We speculate that the reason why the OG approach was associated with greater improvements than the treadmill-based approaches may have been the requirements for walking after SCI. In the intact vertebrate nervous system, the spinal locomotor pattern generators are activated by the supraspinal centers (for a review, see Grillner et al²⁹). Step initiation also is a function of the supraspinal centers.³⁰ Damage to the spinal pathways means that the supraspinal centers have limited access to the spinal locomotor circuitry that contributes to proficient walking; it also indicates impaired conduction of signals related to descending drive for step initiation. Although treadmill walking takes advantage of the moving support surface to facilitate walking through afferent activation of the spinal locomotor centers³¹ (in effect substituting for the loss of supraspinal input), overground walking is distinguished by its greater demand for voluntary effort for step initiation and forward progression. Consequently, rather than focusing on “re-training the injured spinal cord”³² to improve overground walking function, it may be more valuable for people with SCI to focus on learning to execute the repetitive sequences of step initiation during overground walking and thereby to maximize

supraspinal drive to the spinal locomotor circuitry.

The idea that people with SCI have impaired mechanisms of gait initiation is supported by earlier studies showing that even people with SCI who have good walking function (eg, able to take at least 10 steps with no assistance or assistive device) require significantly more time to initiate a voluntary step after an auditory cue than do people without a disability.³³ In a recently published case series, a crossover design was used to compare outcomes associated with a skilled overground walking program and a treadmill-based locomotor training program.³⁴ Although both types of training were effective at improving walking function, skilled overground walking was associated with greater gains in most of the outcome measures, including walking speed, walking endurance, balance confidence, and stair climbing.³⁴ The overground walking program included elements that required continuous, active engagement for volitional movement, such as stepping over obstacles and walking up ramps. These findings lend support to the concept that voluntary effort and maximizing descending drive may be key considerations for locomotor training in people with SCI.

The findings related to improvements in lower-extremity strength across all groups and the lack of between-group differences in strength are noteworthy. These results are consistent with our previously reported findings, namely, that measures of gait quality (step length, cadence, and symmetry) improved to similar degrees in all groups, with no between-group differences.²¹ Although lower-extremity strength is correlated with walking speed in people with SCI^{16,25-27} and gait quality presumably influences walking function, strength and gait quality do not account for the larger improvements in walking function

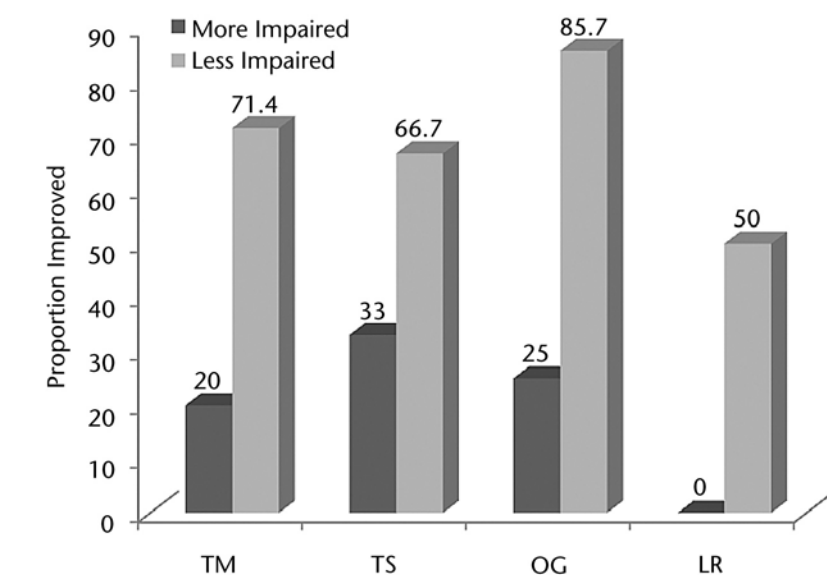


Figure 2.

Proportions of “less impaired” and “more impaired” participants in each training group who achieved a minimally important difference in walking speed. Dark gray bars represent participants classified as more strength impaired. Light gray bars represent participants classified as less strength impaired. Values represent the proportion of participants in a category whose walking speed had improved by at least 0.05 m/s after training. LR=treadmill-based training with robotic assistance, OG=overground training with electrical stimulation, TM=treadmill-based training with manual assistance, TS=treadmill-based training with electrical stimulation.

achieved by participants in the OG group. Alternatively, it is possible that LEMS used as measures of muscle strength are not sufficiently sensitive to detect training-related changes in muscle force-generating capacity that may contribute to improvements in walking function.

We found that, on average, participants who returned for follow-up testing still walked faster than they had before training but that their walking speed at follow-up had declined relative to their walking speed at the conclusion of training. There was no apparent relationship between time since training and decline in speed, suggesting that retention in participants tested 6 months after training was similar to that in participants tested 2.5 years after training. The sample of participants ($n=10$) who were able to return for follow-up retention testing was too small to allow an analysis of between-groups

differences in retention. However, although the sample was small relative to the full study cohort, the mean time since training was more than 1.5 years, making this the largest data set for long-term retention of overground walking outcomes in participants with chronic SCI. Hicks et al³⁵ assessed retention for up to 8 months in a sample of 13 participants who had chronic SCI and who had been trained for 12 to 15 months (144 sessions). However, because 11 of the participants in that study were unable to stand or walk at the start of training, overground walking outcomes were measured only with a categorical scale based on what assistive devices the participants required and whether they were able to walk fewer or more than 5 steps, and walking speed was assessed only on the treadmill with BWS. Additional research is needed to identify factors predicting the retention of improvements after interventions.

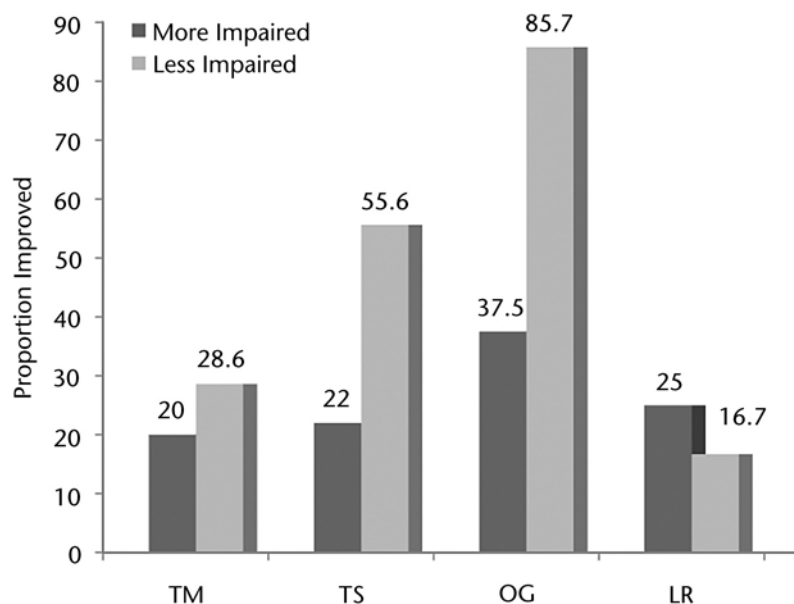


Figure 3.

Proportions of less impaired and more impaired participants in each training group achieving a minimally important difference in walking distance. Dark gray bars represent participants classified as more strength impaired. Light gray bars represent participants classified as less strength impaired. Values represent the proportion of participants in a category whose walking distance on the 2-minute walk test had improved by at least 4 m after training. LR=treadmill-based training with robotic assistance, OG=overground training with electrical stimulation, TM=treadmill-based training with manual assistance, TS=treadmill-based training with electrical stimulation.

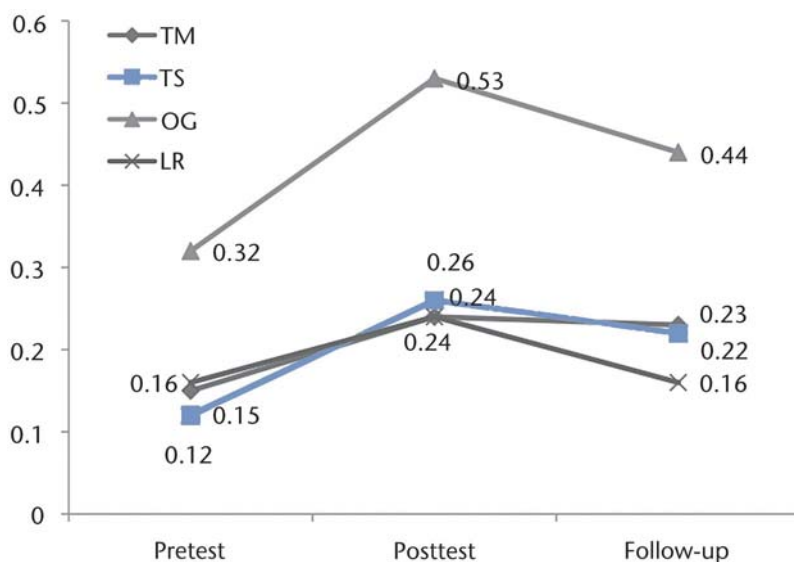


Figure 4.

Changes in walking speed overall and by training group. Data were obtained before training, at the conclusion of training, and at follow-up (retention) from 10 participants who had improved by the conclusion of training, overall and by training group. All 10 participants returned for follow-up retention testing at least 6 months (mean=20.3 months, SD=14.3 months) after completing training. LR=treadmill-based training with robotic assistance, OG=overground training with electrical stimulation, TM=treadmill-based training with manual assistance, TS=treadmill-based training with electrical stimulation.

Restoration of Walking Ability Follows the Same Principles as Other Forms of Motor Learning

Our findings indicated that the attributes of overground training were superior to those of the other 3 approaches for promoting functional walking capacity. The fundamental principles of motor learning include intensive, repetitive training, task specificity, and the opportunity to solve problems.³⁶⁻³⁸ Our results indicated that the experiences necessary to improve walking function follow principles known to be true for learning other motor behaviors. Activity-dependent plasticity requires repetition and intensive practice.³⁶ In people with subacute stroke, a comparison of overground training and treadmill-based training revealed that although walking speed improved to the same extent in both groups, there was a greater improvement in walking distance in the treadmill-based training group.³⁹ The authors attributed these findings to the larger amount of practice obtained by the treadmill-based training group in the 30-minute training sessions.³⁹ In the present study, although all 4 training approaches challenged the participants in terms of both intensity and amount of training, people who trained with the treadmill-based approaches walked at significantly faster training speeds¹⁶ and thus were likely to have taken more steps per session and to have more practice. Therefore, in the present study, it is likely that factors other than the amount of practice contributed to the greater improvements observed with the OG approach. Perhaps the elements that contribute to an optimal training regimen for people with hemiplegia caused by stroke are different from those for people with tetraplegia or paraplegia caused by SCI.

Although the kinematics and temporal aspects of walking on a treadmill are very similar to those of over-

ground walking, from the perspective of task specificity there are clear differences between these 2 walking environments in terms of joint moments at the ankle, hip, and knee and differences in joint power at the knee and hip.⁴⁰ Learning to generate and control these forces while walking on a treadmill may not transfer completely to the motor output that is necessary for overground walking. Lee and Hidler⁴⁰ speculated that these differences may result in the development of motor strategies for treadmill walking that are different from those for overground walking. A study done to directly assess the extent of transfer of training from a split-belt treadmill to overground walking revealed only partial transfer of the pattern learned on the treadmill.⁴¹ It seems reasonable to conclude that the overground locomotor training task or environment best allows an individual to learn to generate and control the forces necessary to initiate stepping, to move the body overground, and to practice and improve performance. Along these lines, it could be argued that the participants trained with the OG approach had the advantage of training that closely mimicked the manner in which they were tested. However, given that the goal of locomotor training is to improve functional walking capacity in the real-world environment, overground walking speed and distance are the most salient outcome measures. Although it is likely that the results of the present study would have been different if treadmill walking speed and distance had been the outcomes of interest, the relevance of such measures to real-world function is questionable.

The motor learning needed for improved walking function appears to require more than simple repetition³⁴ and benefits from the opportunity to make and correct errors.⁴² In the present study, the overground

training environment likely provided greater variety in the walking task than did the more predictable treadmill training environment (especially with regard to the fixed, 100% assistance parameters that we used in the LR approach). Participants in the OG group needed to lift and advance their assistive devices and negotiate 4 curves on the 22.4-m track above which the BWS system was suspended. There is evidence from training studies of people with SCI⁴³ and stroke,⁴⁴ as well as from animal models,⁷ that variability is important for locomotor learning. Furthermore, there is evidence that after central nervous system injury, training in skilled behaviors such as walking or climbing in challenging environments (ie, ropes, rods, ladders, obstacles) is associated with changes in corticomotor neural structure, whereas no plastic effects are associated with treadmill training.⁴⁵ We propose that, for walking function, the task specificity of training and the opportunity to solve the biomechanical and kinetic problems experienced in the overground condition were important factors contributing to the results associated with overground locomotor training.

Limitations

The present study had several limitations. First, we do not know whether the training dosage was optimal for improving walking speed and distance. The number of training sessions, the duration of each training session, and the training frequency were meant to represent a training dosage that would be challenging but tolerable for the target study population. This training dosage was based on clinical judgment in the absence of experimental evidence related to the optimal training dosage. Second, we focused on walking speed during training rather than on other aspects of walking, such as asking participants to focus on producing optimal kinematics. Although

training at faster speeds has been shown to be associated with greater increases in walking function in people with stroke,⁴⁶ training speed does not appear to be an important determinant of locomotor outcomes in people with SCI.¹⁶ Third, all but a few of the participants in the present study used a wheelchair as their primary means of mobility and therefore did not ambulate in the community. For this reason, the amount of change that is qualified as meaningful change in this group may be smaller than that necessary for meaningful change in people who use walking as their primary means of mobility. Fourth, the training parameters used in the robotic gait orthosis approach were configured to impose a kinematically appropriate gait pattern, and stepping proceeded regardless of whether participants contributed effort. Therefore, different results may be obtained if the training parameters require participants to actively generate stepping to assist the robotic device. A final limitation was that only a small proportion of participants were able to return for assessment of the retention of training effects. Unfortunately, because many participants resided outside the local area, traveling was financially burdensome. This limitation resulted in an incomplete assessment of the influence of the training approach on retention.

Conclusions

People with chronic motor incomplete SCI have the potential to increase their overground walking speed and walking distance in a specified time (ie, functional walking capacity). Overground locomotor training resulted in greater improvements in functional walking capacity than did treadmill-based training. Several characteristics of overground locomotor training likely contributed to the greater gains observed with this approach. These include greater specificity of training for the

real-world task of walking, increased voluntary effort for step initiation and forward progression, and more opportunities for learning how to generate and control the forces required for walking overground. We suggest that in people with SCI and minimal walking ability, walking distance is arguably a better indicator of walking function than is walking speed. Further work is needed to determine the optimal training dosage.

Both authors provided concept/idea/research design and writing. Dr Roach provided data analysis. Dr Field-Fote provided project management, fund procurement, participants, and facilities/equipment. The authors acknowledge the contributions of the staff of the Neuromotor Rehabilitation Research Laboratory at The Miami Project to Cure Paralysis, especially Saumitra Sinha Ray, Kathleen Manella, Stephen Lindley, Rebecca Avshalom, and Lea Lenahan.

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Invited Commentary

D. Michele Basso

Recovery of function after spinal cord injury (SCI) depends on a complex interaction between severity of injury and the type and intensity of training. The paradigm shift toward activity-dependent neurorehabilitation makes it important to identify the critical training features that promote locomotor recovery. Field-Fote and Roach¹ completed an ambitious randomized clinical trial to determine which of 4 types of activity-

based training for locomotion produced important gains in gait speed and distance after chronic incomplete SCI. The 4 paradigms all provided body-weight support, which is well-justified, given evidence from experimental and human SCI studies that some unweighting optimizes muscle activation and stepping kinematics.²⁻⁵ The 4 training groups were: treadmill training with manual assistance (TM), treadmill training

with stimulation of flexor reflex afferents (TS), robotic treadmill training (LR), and overground walking with stimulation and an assistive device (OG).

The scientific rationale for each of the paradigms appears to depend on using manual assistance, electrical stimulation, or robotics to drive motor learning and, ultimately, to improve overground locomotion. Effective motor

learning depends on multiple factors such as trial and error during practice, specificity of training, intensity and scheduling of practice, and type of practice environment.⁶ These important motor learning parameters varied widely across groups. For instance, 3 groups trained in a novel environment (ie, on the treadmill), and 1 group participated in task-specific training (ie, overground locomotion). In addition, 2 groups (TM, OG) experienced variable practice with trial and error from step-to-step, whereas 2 groups had little trial and error (TS) or no trial and error (LR). Given that the OG group completed task-specific training with some variable practice, it would be reasonable to expect them to perform better on tests of overground locomotion. Indeed, Field-Fote and Roach showed significant gains in walking distance for the OG group. As a test of motor learning in chronic incomplete SCI, the current study provides strong evidence that task-specific training with trial and error during practice promotes greater locomotor endurance. On average, people walked 15 m farther after 30 to about 50 sessions of OG training. Although this distance seems relatively small, it is the equivalent of half a basketball court or crossing a 4-lane road. Such gains would easily support greater in-home ambulation, as suggested by Field-Fote and Roach.

Gait speed is perhaps the most widely used measure of recovery in clinical trials for SCI and has been identified as preferable to measures of endurance such as the Six-Minute Walk Test.⁷⁻⁹ The results for gait speed in the study by Field-Fote and Roach were not as clear-cut as those for endurance. Using a robust statistical design, the main finding was that all groups had significant improvement in gait speed over time (main effect of time), but that no single group outperformed another, as indicated by the nonsignificant in-

teraction. In a strict statistical approach, application of *post hoc* analyses are deemed unnecessary when an interaction is nonsignificant. A similar statistical result occurred in a preliminary analysis of 27 individuals reported in 2005.¹⁰ Thus, the addition of considerably more participants to the trial ($n=37$) did not help to consolidate variability in gait speed and clarify the effect of activity-based training on short-distance locomotion.

A major barrier to clinical trials in SCI is the large variability in rate and extent of recovery. This variability provides a moving target by which to gauge the efficacy of any pharmaceutical or rehabilitative intervention. The current study by Field-Fote and Roach appears to be the largest randomized clinical trial for chronic SCI, and yet the outcome suggests that, at least for gait speed, the trial was too small. This means that future clinical trials must take great care to control the high variability and yet remain clinically relevant. What might account for high variability within an SCI-focused clinical trial? Two typical factors, severity of SCI (based on strength scores) and spontaneous or natural recovery, were well-controlled across all groups in the current trial. A third factor, level of SCI, likely affects overground speed. People with tetraplegia might have less trunk control or poor hand control, which would interfere with their use of assistive devices. Future trials may need to balance enrollment of participants with paraplegia and tetraplegia across groups.

Great care also must be used when collecting 10-m walk data to avoid introducing unnecessary variability. Typically, gait speed is calculated over the central 10-m portion of a 15-m walk. By eliminating the first and last few meters when deriving speed, referred to as a "flying start," acceleration and deceleration effects

on gait speed are prevented. Use of a flying start and collection over a full 10-m distance will be necessary to reduce volatility of gait speed values. Lastly, data from the current trial suggest that measures of locomotor endurance and short-distance speed may reflect different rather than redundant components of locomotor recovery in people with chronic SCI. Future trials should venture to include both measures in order to fully capture motor recovery after SCI.

Field-Fote and Roach should be commended for moving beyond statistical findings and providing results in a clinically meaningful manner. The effect size indicates the improvement in speed or distance relative to the variability of the group before training (standard deviation). The highest effect size for gait speed and distance occurred in the OG group (0.43 and 0.40, respectively) and were designated as moderate effects. Furthermore, minimally important difference (MID) was used to stratify responders from nonresponders. The MID represents the criterion value that scores must surpass in order to be outside the measurement error of the test. For gait speed and distance, the MID was surprisingly low at 0.05 m/s and 4 m for people with incomplete SCI, respectively. Thus, responders were those individuals who walked at least 4 m farther than before training or attained speeds 0.05 m/s faster.

To make MID more clinically relevant, it is important to anchor it to functional improvements. Recent evidence from the European Multi-center Study About SCI established minimum gait speeds associated with various levels of functional ambulation for people with a full range of SCI (ASIA impairment scale A-D) up to 1 year after injury.¹¹ It appears to be the first validation of gait speeds for functional ambulation in people with SCI. The minimum

speed ($\bar{X} \pm SD$) for supervised in-home walking was 0.09 ± 0.01 m/s, almost 2 times higher than the MID. For unassisted in-home ambulation, gait speed was 0.15 ± 0.08 m/s, which is 3 times higher than the MID. Community ambulation with an assistive device was associated with a minimum speed of 0.44 ± 0.14 m/s, nearly 9 times higher than the MID. These speeds are quite similar to threshold values established for household and community ambulators after stroke.¹² Thus, using MID to estimate functional gains in walking must be considered with caution in people with chronic SCI, as the threshold appears to be below clinically meaningful levels.

The current study provides clear evidence that task-specific training is critical to induce recovery of locomotion at chronic time points after incomplete SCI. Further study is needed to determine whether a combination of treadmill-assisted training and translational training in the over-ground environment will produce equal or greater benefits as those reported for speed and endurance. Fu-

ture studies in SCI will require randomization according to level and severity of SCI, careful selection and delivery of outcome measures, consideration of clinical relevance, and an experimental design that balances motor learning factors.

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Author Response

Edelle C. Field-Fote, Kathryn E. Roach

We thank Basso for her thoughtful commentary¹ on our article.² Her perspective is particularly valuable, given her experience with studies of spinal cord injury in both humans and in animal models. As Basso notes, identifying the critical training features that best promote locomotor recovery is essential for optimal outcomes. We are pleased that the commentary focuses on what we feel is the primary message of our study: task-specific training that capitalizes on the principles of motor

learning appears to be beneficial for improving walking function in individuals with spinal cord injury, even many years after injury. Studies of neuroplasticity in animal models have demonstrated that simply repeating a movement is not sufficient for motor learning.³ As we note in our article, allowing variability in the task being practiced provides opportunities to make and correct movement errors. The opportunity to correct errors seems to be associated with greater improvements in con-

trol of movement, not only as related to improving gait⁴ but also as related to other motor behaviors such as reaching to a target⁵ (for a review, see Bastian⁶).

In our study, although the over-ground training group arguably may have experienced the greatest amount of opportunity for error correction, there may be other training features that contributed to the larger effect size for both walking speed and walking distance in this

group. The overground training group walked with electrical stimulation to assist dorsiflexion. This form of stimulation that has been shown to be associated with improved reciprocal inhibition,⁷ improved phase-dependent reflex modulation during gait,⁸ improved active dorsiflexion (even in the absence of stimulation),⁹ and greater cortical drive to the dorsiflexor muscles.¹⁰ Furthermore, the group assigned to receive treadmill-based training with electrical stimulation experienced the second largest effect size for walking distance and had the largest proportion of “more-impaired” participants who met or exceeded the minimally important difference for walking speed. Given that electrical signals are the language of the nervous system, the influence of the electrical stimulation for promoting adaptive neuroplasticity deserves consideration (see Field-Fote¹¹ for a review).

The commentary makes some excellent points regarding areas of importance for future study, as well as limitations of the current study. The great range in clinical presentation among individuals with spinal cord injury makes large numbers of participants necessary if investigators are to draw definitive conclusions. Although we made the attempt to control for the influence of spontaneous recovery and severity of injury, we did not control for the influence of level of injury. As Basso points out, in individuals who require the use of assistive devices, deficits in upper-extremity function and trunk control might be expected to influence walking capacity. For this reason, the approach that is best for individuals with tetraplegia may be different than the approach that is most beneficial for those with paraplegia.

Basso also notes a technical limitation in our study that warrants men-

tion. Our approach to assessment of walking speed was slightly different from what is typical. The 10-Meter Walk Test is a standardized clinical measure of walking speed, wherein the individual walks over a 15-m walkway and the central 10 m is timed using a stopwatch. We used a modified approach due to technical considerations. We calculated walking speed based on data from 3-dimensional motion capture in a calibrated space. Camera limitations prevented us from capturing the full 10 m of the walkway; therefore, we opted for the accuracy of the 3-dimensional motion capture system in a 6-m distance versus using a stopwatch over the 10-m distance.

We agree with Basso that the minimally important difference for walking speed required for community ambulation is likely to be considerably higher than that observed in our participants, and it is true that walking speed is the most widely used measure of recovery of locomotor function. The fact that our sample size was insufficient to detect significant between-group differences in speed may suggest that if the goal is to improve walking speed, then any of the training approaches are appropriate. However, as we note in the article, it may be time to reconsider the focus on speed, as walking distance may be a more salient measure. In individuals with stroke, for example, the 6-minute walk distance has been shown to be the best predictor of community ambulation among numerous outcome measures, including walking speed.¹² For individuals who use a wheelchair as the primary means of mobility, it matters little if they can speedily make it from point A to point B if their goal was to make it to point C and they lack the endurance to make it that far.

Although most of the participants in our study were unlikely to be com-

munity ambulators, the degree of improvement we observed in walking distance *is* likely to make a difference in their ability to walk in the home and to walk for limited distances in other environments. Indeed, many participants reported anecdotally that, following participation in the study, they were able to perform activities from which they had previously been restricted. Often these accomplishments reflect simple pleasures that so many of us take for granted, such as walking a daughter down the aisle at her wedding, walking out to retrieve mail from the mailbox on a sunny day, or getting out of the wheelchair to walk to a “regular” chair near the window to dine with friends at a restaurant when previously they had had to sit near the entryway because the wheelchair could not pass between tables. For individuals who have great limitations of motor function, even small improvements can make a meaningful difference in their level of activity, quality of life, and ability to participate in society.

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