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The Evolution of Walking-Related Outcomes Over the First 12 Weeks of Rehabilitation for Incomplete Traumatic Spinal Cord Injury: The Multicenter Randomized Spinal Cord Injury Locomotor Trial

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Abstract

Background—The Spinal Cord Injury Locomotor Trial (SCILT) compared 12 weeks of step training with body weight support on a treadmill (BWSTT) that included overground practice to a defined but more conventional overground mobility intervention (CONT) in patients with incomplete traumatic SCI within 8 weeks of onset. No previous studies have reported walking-related outcomes during rehabilitation.

Methods—This single-blinded, randomized trial entered 107 American Spinal Injury Association (ASIA) C and D patients and 38 ASIA B patients with lesions between C5 and L3 who were unable to walk on admission for rehabilitation. The Functional Independence Measure (FIM-L) for walking, 15-m walking speed, and lower extremity motor score (LEMS) were collected every 2 weeks.

Results—No significant differences were found at entry and during the treatment phase (12-week mean FIM-L = 5, velocity = 0.8 m/s, LEMS = 35, distance walked in 6 min = 250 m). Combining the 2 arms, a FIM-L 4 was achieved in < 10% of ASIA B patients, 92% of ASIA C patients, and all of ASIA D patients. Walking speed of 0.6 m/s correlated with a LEMS near 40 or higher.

Conclusions—Few ASIA B and most ASIA C and D patients achieved functional walking ability by the end of 12 weeks of BWSTT and CONT, consistent with the primary outcome data at 6 months. Walking-related measures assessed at 2-week intervals reveal that time after SCI is an important variable for entering patients into a trial with mobility outcomes. By about 6 weeks after entry, most patients who will recover have improved their FIM-L to >3 and are improving in walking speed. Future trials may reduce the number needed to treat by entering patients with FIM-L < 4 at > 8 weeks after onset if still graded ASIA B and at > 12 weeks if still ASIA C.

Keywords

Spinal cord injury; Rehabilitation; Walking outcomes; Treadmill training; Locomotion

For patients who suffer a traumatic spinal cord injury (SCI), the most visible disability is the inability to walk at all or at least with a reciprocal gait at velocities that permit community ambulation.¹ The Spinal Cord Injury Locomotor Trial (SCILT) was developed from studies in animal models of recovery of hindlimb stepping after complete low thoracic SCI that employed a moving treadmill belt and limb loading.^{2,3} These findings led to studies of locomotor training on a treadmill with partial weight support as needed by patients with complete and incomplete SCI, along with physical and cognitive cues to try to improve kinematic, spatiotemporal, and kinetic features of stepping.^{4,5} The experimental technique has been called body weight–supported treadmill training (BWSTT).

Prior clinical studies had not compared equal amounts of BWSTT to another form of mobility training to test for efficacy. Research studies used historical controls or an A–B design with unmasked outcome measurements, but they did provide insight into the best strategies to employ for BWSTT.^{6–11} The SCILT was a parallel group, multicenter, randomized clinical trial (MRCT) with a blinded assessor that compared 2 interventions for walking—BWSTT and overground training versus a similar intensity of a defined control (CONT) program of standing and overground mobility training in patients admitted for rehabilitation within 8 weeks of an incomplete traumatic SCI.¹² The primary hypotheses were: 1) Patients graded as American Spinal Injury Association (ASIA) B (motor complete, sensation present below the lesion) and C (some but not useful motor function) in the BWSTT group will recover supervised or independent walking for 150 feet (Functional Independence Measure–Locomotor score, FIM-L = 5) significantly more often compared to those in the CONT group at 6 months after SCI, and 2) ASIA D (useful motor function present) patients assigned to BWSTT will walk overground significantly faster than the CONT group.

The primary outcomes at 6 months after entry have been reported.¹³ In brief, no significant differences were found at entry between the 2 treatment groups or at 6 months for the FIM-L, walking speed, and distance walked in 6 minutes in those who became able to ambulate. In the upper motor neuron (UMN) patients, 35% of ASIA B, 92% of ASIA C, and all ASIA D patients walked independently (FIM-L = 6). Velocities for UMN ASIA C and D patients were not significantly different for BWSTT (1.1 ± 0.6 m/s, $n = 30$) and CONT (1.1 ± 0.7 m/s, $n = 25$) groups. These patients walked, on average, with the need for 1 ankle brace. The mean velocities of these groups would make community ambulation feasible.^{14,15}

This report compares outcomes for BWSTT and CONT at the end of training, which was a planned secondary analysis. These analyses, however, emphasize the evolution of changes in walking speed, FIM-L, lower extremity motor score (LEMS), walking distance, and ASIA grade over the period of training, which corresponds to a typical period of inpatient and outpatient rehabilitation. Only a few prospective reports are available about the likelihood for recovery of walking in the first months after traumatic SCI.^{16–19} No prospective studies prior to the start of the SCILT had reported the recovery of the ability to walk by functional measures such as walking speed, endurance, and the FIM-L during initial inpatient and outpatient rehabilitation for traumatic SCI. These outcome measures pose a higher threshold for gains that are of value to patients than the outcome measures usually employed by acute SCI trials, in which the change in ASIA grade and motor strength tends to be used. By examining these SCILT data at biweekly intervals, future investigators may better ascertain the most reliable time after SCI to initiate a trial that reduces the number-needed-to-treat when the aim is to increase the percentage of patients who can walk with a reciprocal gait without physical assistance at functional walking speeds and distances.

METHODS

Study Design

Patients entered into SCILT had an incomplete SCI that was graded ASIA B, C, or D with a lesion below C-4 on at least one side to as low as L-3 on admission for rehabilitation. The FIM-L score had to be < 4. (FIM-L scale: 1 = dependent, total physical assistance; 2 = maximum assistance, 1 helper to walk 50 feet and patient assists <50%; 3 = moderate assistance, one helper to walk 50 feet and patient assists 50%–75%; 4 = minimal assistance, one helper to walk at least 50 feet and patient assists >75%; 5 = supervision, no contact by helper to walk at least 50 feet; 6 = independent with equipment to walk at least 150 feet in a reasonable time; 7 = independent to walk >150 feet without assistive devices in a reasonable time.) In fact, nearly all patients at the time of randomization were graded FIM-L = 1 to 2. Walking speed for a 15.2 m timed walk and walking distance were too poor to record at entry in any of the patients.¹³ Patients received an average of 45 1-hour mobility therapy sessions (BWSTT or CONT) over 12 weeks as inpatients and outpatients, in addition to routine physical, occupational, and nursing therapies. The level of intensity of mobility training was likely greater than a patient might receive in the community who could not walk at all and was graded ASIA B, because these patients were required to practice standing in the CONT group and stepping therapies in the BWSTT group despite having no motor control for the legs. The intensity of treatment for ASIA C and D patients was not greater by any reported standard than what patients who were making progress in stepping may have received. The MRCT controlled the intensity of patient contact and treatment to enable an unbiased comparison of the 2 strategies of physical therapy.

Recruitment

The MRCT recruited potential patients by screening all admissions (1434 patients) to 6 rehabilitation centers from June 2000 to January 2003.¹² Patients with a cervical to T-10/T-11 lesion were designated as the UMN group. Patients with T-11 to L-3 lesions were designated as the lower motor neuron (LMN) group if they had no UMN neurological signs.

At a mean of 4.5 weeks after onset of SCI, 111 UMN and 35 LMN patients were randomized. The majority of excluded patients had a complete SCI, onset beyond 8 weeks prior to admission for rehabilitation, or FIM-L > 3. Eight UMN patients (BWSTT n = 6, CONT n = 2) and 5 LMN patients (BWSTT n = 4, CONT n = 1) dropped out prior to completing 6 weeks of intervention, mostly within the first week. They were not included in this report. Patients were assigned to their treatment groups using a random, permuted block design with the factors UMN - LMN and ASIA B - C - D across all clinical unit sites, and generated by the independent UCLA Statistical Coordinating Unit. Institutional review board approval was obtained from each site. Written informed consent was obtained from each patient prior to inclusion.

Outcome Measures

The main outcome measures in the SCILT were the FIM-L and the overground walking speed for patients who regained the ability to perform this task. Walking speed was calculated for the faster of two 50-foot (15.2-meter) walks in patients who were able to walk that distance with moderate or less assistance. Patients were asked to walk as fast as safely possible. Walking speed, FIM-L, LEMS (range 0 to 50; maximum of 5 for each of 5 key muscles of each leg, using the British Medical Council scale), and ASIA grade were obtained at entry and every 2 weeks when feasible for 12 weeks by trained blinded assessors at each site. Walking distance in 6 minutes in patients who could walk with moderate or less assistance was obtained at entry and at 12 weeks. These measures were also repeated at 6 and 12 months after entry. In addition, an ASIA grade was obtained from records obtained during the acute hospitalization within approximately 96 hours after SCI for a comparison of initial severity to severity at the time of entry into SCILT.

Statistical Analysis

A 4-way design was employed with 3 stratification factors (UMN, LMN, clinical unit site), 1 treatment factor, a repeated measure time factor (onset of SCI to randomization), and the primary endpoint (FIM-L or walking speed) for ASIA B, C, and D entries. The analyses were conducted on those patients who had performance data, such as walking speed, available. The 2 interventions were assessed at 12 weeks using a standard ANOVA multiple classification analysis with the standard and permutable *F* test. The 12-week analyses also replicated a primary outcomes data analysis using a robust regression approach with a 2-way design. Where the distributions were bi-modal, a logistic regression analysis was performed using the standard asymptotic (Wald) or quasi-exact method. To assess for a relationship between walking speed and the LEMS, a scatter plot of the data at 12 weeks was carried out. A piecewise linear regression analysis of the walking speed and the LEMS score bivariate data was performed and the best fit determined for the strength needed to achieve a minimally functional walking speed.

RESULTS

BWSTT Versus CONT at End of Treatment

For the 12-week analyses, we present the data for the same groups as reported for the 6-month efficacy analyses, that is, patients with UMN and LMN lesions, initial FIM < 4, and

outcome data available at 3 months.¹³ These results did not differ from the intention-to-treat analyses. Using a mixed model that incorporated the measurement points performed at 2-week intervals during the period of training, no differences were found at these intervals or at the end of training (3 months) between patients who received BWSTT versus CONT for FIM-L ($P = .10$). No differences were found for walking speed ($P = .86$) and LEMS ($P = .68$). Only 12-week outcomes were obtained for distance walked in 6 minutes; no difference between treatment arms was found ($P = .41$). A difference was found for each measure ($P = .01$ to $P = .001$) in favor of better outcomes for patients entered sooner (<4 weeks) after SCI than later (>4 weeks).

Changes Related to Walking Over Time of Treatment

Comparisons of the assessments at 6 and 12 weeks are shown in Table 1 for patients graded ASIA B at entry. At the end of treatment, no one had achieved a physically unassisted gait, although some had improved to ASIA C. Figure 1 shows the trends in changes for the patients in these tables at 2-week intervals from entry to 12 weeks for the FIM-L (1a), walking speed for the few who were able to walk 15 m (1b), and the LEMS (1c). Locomotor assessments at 6 and 12 weeks after entry are shown in Table 2 for the ASIA C and D patients. At entry, these patients had a mean LEMS of 20 for BWSTT and 18 for CONT, FIM-L = 1.0 for both, and no measurable walking speed or distance. Gains over the course of training became apparent by 6 weeks after entry (Figure 2). The FIM-L reached a mean of 3 to 4 by this time (Figure 2a), and the rise in the slope of the walking speed increased (Figure 2b), meaning that patients had improved to needing only moderate to minimal assistance to perform the 15-m walk. Gains for all measures were remarkable by 12 weeks, with the median patient attaining supervised or independent walking with an assistive device. Walking speed for the 15.2-m walk correlated with the FIM-L ($r = .80$, $P < .001$), walking distance in 6 min ($r = .92$, $P < .001$), and somewhat less with the LEMS ($r = .64$, $P < .001$), which was similar to the results reported at 6 and 12 months.

Relationship Between More Functional Walking Speed and LEMS

Figure 3 shows the relationship of the LEMS to the walking speed for UMN patients with cervical lesions ($N = 75$ for combined BWSTT and CONT) who had measurable velocities. From this 3-month data, we looked for a predictor of faster and perhaps more functional walking speeds based on the lower extremity strength. The regression curve (model) was represented by a spline at LEMS = 40 or by a quadratic in the LEMS. The $\text{Speed}_3 = \beta_0 + \beta_1 * \text{LEMS} + \beta_2 * (\text{LEMS} - 40) = 0.132 + 0.015 * \text{LEMS} + 0.067 * (\text{LEMS} - 40)$. The spline, essentially 2 straight lines, provided an improved fit compared to a sinusoidal curve, with the slope before LEMS of 40 equal to 0.015 and the slope after LEMS of 40 to be 0.082.

Changes Over the Course of the MRCT

Tables 3 (ASIA B patients) and 4 (ASIA C, D patients) summarize the mean scores and quartiles of all SCILT patients for the FIM-L and walking speed for each arm of the trial at the end of treatment, then at 6 and 12 months after entry. The ASIA B patients in both arms generally required maximum to moderate assistance to walk by the FIM-L criteria at each assessment; about 20% improved over time to achieve walking speeds that exceeded 0.3

m/s. The walking speed for the lowest quartile in each arm of the MRCT for the ASIA C and D patients (Table 4) doubled from 0.4 to 0.8 m/s between 3 and 12 months. Continuation of the mean gains made during rehabilitation for ASIA C and D patients in each arm continued out to 6 months, with lesser gains out to 12 months for the CONT than the BWSTT group. The BWSTT arm, however, started from a somewhat lower mean speed at 6 months and 5 CONT patients had no 12-month data, so the changes from 6 to 12 months may represent a relative plateau effect, as most patients had already achieved functional walking speeds. Walking speed at 12 weeks correlated highly with the velocity at 6 months ($r = .91$).¹³

Change in ASIA Scores From Onset of SCI

The early course of patients who were graded ASIA A and B at onset of SCI, prior to admission for rehabilitation and randomization into SCILT, was evaluated because changes in ASIA scores may be of interest in future trials of biologic interventions for neural repair.^{20,21} An examination performed at approximately 96 hours after onset of SCI was available for all but 6 entries. The reliability of this examination bears some uncertainty, because grading was not performed by a SCILT-trained investigator. Table 5 shows that 15 patients were graded ASIA A at onset, of which 11 improved to ASIA B and 4 to ASIA C by the time of entry into SCILT. Of these B patients who completed the trial, all but 1 remained ASIA B at 12 weeks after entry. The changes in acutely graded ASIA B patients are shown in the middle column. Of the 56 patients graded ASIA B at onset who later were entered into SCILT, 32 were still ASIA B at the time of entry and 24 had improved to ASIA C or D. After 4 weeks of rehabilitation, 20/32 were still graded ASIA B and 35 of the original 56 had converted to C and D, with one dropout. At 12 weeks, 11 remained ASIA B and 42 had converted to C or D with 3 dropouts. In comparison, of the 43 patients who were graded ASIA B at entry into SCILT (some were ASIA A or B at onset of SCI), 36 completed the trial; 18 remained ASIA B, 15 improved to C, and 3 to D. Thus, about 50% of the ASIA B patients improved their grade from entry (a mean of 4.5 weeks after SCI) to 12 weeks later, whereas 45 of 56 (80%, not accounting for a few dropouts) who were ASIA B at the onset of their SCI improved one or more ASIA grades by the end of the intervention. In addition, of the 56 ASIA B patients at the time of onset of SCI, 21 with a UMN lesion and 6 with an LMN lesion had a FIM-L ≥ 4 at the end of treatment. Their mean walking speed was 0.74m/s ($SD, 0.57$) and 0.62m/s ($SD, 0.35$), respectively. Thus, only 50% developed functional walking skills, whereas 80% had improved their ASIA grade. Also, only 1 of the 29 patients with a FIM-L < 4 had a recordable walking speed (0.05 m/s) at 12 weeks after entry into the trial.

DISCUSSION

The finding of no difference in functional walking outcomes for BWSTT and CONT at 12 weeks was in parallel to the results of the primary analysis of the MRCT at 6 and 12 months.¹³ The SCILT provides previously unavailable data about the recovery of functional walking over the time of rehabilitation for incomplete traumatic SCI. These analyses suggest that the time after injury is an important variable for planning clinical trials to lessen walking disability. In this secondary analysis for outcomes by the end of a 12-week intervention, the MRCT revealed equal levels of functional independence for walking,

walking speed, walking distance, and lower extremity strength for ASIA B, C, and D patients in each arm of the trial. These gains over 12 weeks were remarkable. The median ASIA C patient walked independently for at least 150 feet (FIM-L 6 or 7) at 0.78 m/s, and covered 212 m within a 6-min walk. The walking speed used by patients for the 15-m walk was only about 10% higher than during the 6-minute walk for each quartile. ASIA B patients, especially those with a UMN lesion, usually remained unable to walk. The finding that patients who started their rehabilitation sooner (<4 weeks after onset) had better outcomes, which was noted in the primary outcome analysis as well, does not imply that an earlier start of rehabilitation for walking led to better outcomes. More likely, entry within 4 weeks allowed some patients to start at a lower level of function than they would have been had they entered SCILT at 4 to 8 weeks after onset of SCI.

Other studies found that from 75% to 85% of patients who were graded ASIA A within a few days of SCI remained ASIA A 1 year later.^{17,22} Most of those who did improve, as in SCILT, only reached the grade of ASIA B (Table 5). If incomplete and graded ASIA B within 72 hours after onset, however, only about 20% of patients in prior studies remained ASIA B a year after SCI. About one half of the SCILT patients who were graded ASIA B at entry (mean of 4.5 weeks after onset) reached a higher grade (15 ASIA C and 3 ASIA D) at 12 weeks, but none achieved a functional walking speed and distance by 12 weeks. Prior studies reported that about 75% of patients graded ASIA C within the first few days after SCI improved to ASIA D or better by 1 year.¹⁷ Approximately 68% (52/76) of ASIA C patients at the time of entry into SCILT improved to ASIA D by 12 weeks later. Thus, an improvement by at least one grade arises often in ASIA B and C patients who still have this grade within 4 to 8 weeks of SCI. The change in ASIA grade, however, seems an insensitive measure to use to power acute incomplete SCI trials, at least for walking interventions.

Early gains in motor control, represented by improving strength, are consistent with restitution and greater substitution by spared spinal pathways and central reorganization driven by practice in both arms of the SCILT.^{23,24} The ability of the ASIA C and D CONT group to practice stepping as strength and balance improved probably lessened the likelihood that BWSTT would serve as a sharp enough contrast to CONT in terms of intensity of weight bearing and training. Greater motor control for walking in terms of walking speed (approaching and exceeding 0.6 m/s for limited community ambulation) and strength was found as the LEMS approached and exceeded 40 of a possible 50 points (Figure 3). Prior studies had shown that the higher the LEMS, the more likely a patient was to recover the ability to walk without physical assistance. A LEMS at 1 month >20 was associated with an independent reciprocal gait by 6 months after incomplete cervical tetraplegia.^{25,26} The mean LEMS of the ASIA C and D SCILT patients was approximately 20 at an average of 4 weeks after onset (Figure 2). Changes in the motor score do not of course have equivalent meaning across patients. For example, a 10-point gain in the lower extremities may not lead to useful motor function for walking if the changes increase from 0 or 1 to only 2 or 3 in 6 muscle groups of the legs. In the Sygen Study of patients with acute complete and incomplete traumatic SCI,²⁷ gradual improvement in motor scores for the upper and lower extremities ended between weeks 8 and 26 after SCI. The amount of gain was greater in less severe injuries. In SCILT patients, the LEMS doubled, on average,

between entry and 12 weeks. As the LEMS increased from 20 toward 40 and especially over 40, functional walking speeds improved significantly (Figure 3).

The gains across quartiles and time in UMN and LMN ASIA C patients, and the lack of clinically important gains for walking in ASIA B patients (Tables 3 and 4), offer insights into future studies of adjunct interventions for recent SCI. ASIA D patients can be expected to achieve highly functional gains with rehabilitation that provides mobility interventions. ASIA C patients are especially likely to achieve walking speeds that permit community ambulation if they reach a FIM-L score ≥ 3 by approximately 6 weeks (Table 2 and Figure 2) after starting their rehabilitation (8–14 weeks after onset of SCI). The rather high likelihood of functional gains by then suggests no need for augmentation of locomotor training for most patients graded ASIA C and D. On the other hand, patients who are still graded ASIA B with a UMN lesion by about 8 weeks after SCI are unlikely to achieve functional walking, compared to those who were graded ASIA B at onset of the incomplete SCI. A panel of the International Campaign for Cures of spinal cord injury Paralysis (http://www.icord.org/ICCP/ICCP_SCI_Guidelines1.doc) recently estimated that only 65 patients in each arm of an RCT would be needed to power a trial for a 10-point gain ($\beta = 0.05$) on the ASIA motor score by 1 year for patients with a cervical lesion who were graded ASIA B at 8 weeks after onset.²⁸ For ASIA A patients in the same time frame, only 19 patients were estimated to be necessary to power a trial to test the efficacy of a biological intervention. Most of the motor gains would be within 2 root levels of the lesion, so very few of these patients, as suggested by SCILT, would recover a reciprocal gait with less than maximal assistance. The motor score, however, would be a better outcome target than a change in ASIA grade if recovery of walking were not the primary outcome. Based on the SCILT and limited walking outcomes data from the Sygen trial, a general estimate of the number needed to treat to achieve a FIM-L > 3 by 6 months using the ASIA scores is as follows. If ASIA A at 72 hours after onset, no more than 10% will walk, and if still ASIA A by 4 weeks, less than a few percent may recover walking. If ASIA B at 72 hours, from 15% to 40% may walk, but by 8 weeks after onset, perhaps 10% may recover. To get 30% more patients walking with less than considerable physical help with the power set at 0.8, a trial would need approximately 12 to 18 patients graded ASIA A and 23 to 34 graded ASIA B in each arm at 72 hours and about a third fewer at 8 weeks after SCI to determine whether an experimental intervention, such as a biological therapy for neural repair, could be revealed to have efficacy.

Thus, future RCTs for walking outcomes can test experimental approaches^{20,29–31} without the confounder of progressive gains in motor control that would require a high number of entries, if the trials enter ASIA A patients beyond 3 to 4 weeks and ASIA B patients beyond 8 weeks after onset of SCI. The SCILT suggests that few of these patients recover functionally useful walking beyond this time frame, at least without adjuncts that go beyond the design of SCILT. For ASIA C patients, walking ability increased over time in most cases. Future trials may want to use adjuncts for the relatively few patients who still require considerable physical assistance (FIM-L < 3) by approximately 20 weeks after onset, given that we entered patients up to 8 weeks postonset and trained them for another 12 weeks.

CONCLUSIONS

The SCILT MRCT found no differences in walking outcomes after 12 weeks of the assigned therapy, as well as at the planned 6- and 12-month primary outcomes. Independence in walking based on the FIM-L and walking speed was consistently similar at 2-week intervals and improved roughly in parallel to increases in lower extremity strength (LEMS). For patients referred to inpatient rehabilitation who are still graded ASIA B at 4 to 8 weeks after injury, gains in the ability to walk are modest, and few achieve functional ambulation. Functional ambulation for those graded ASIA C and D, however, is often achieved by 12 weeks of rehabilitation but is less likely to be reached by only 6 weeks of therapy. Patients who are graded ASIA C and D on admission for rehabilitation are likely to recover the ability to walk at the leisurely velocities used by healthy individuals for the distances needed for community activities by 6 months.

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APPENDIX THE SCILT GROUP

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Figure 1.

Changes in the (A) Functional Independence Measure–Locomotor (FIM-L) score, (B) walking speed, and (C) lower extremity motor score (LEMS) measured biweekly over 12 weeks of either body weight–supported treadmill training or the control mobility training for ASIA B patients. The number of patients is found in Table 1. Poor outcomes were found for both treatment groups in the trial. The vertical bars represent the standard error. TX = treatment group; BWSTT = body weight–supported treadmill training.

Figure 2.

Changes in the (A) Functional Independence Measure–Locomotor (FIM-L) score, (B) walking speed, and (C) lower extremity motor score (LEMS) measured biweekly over 12 weeks of either body weight–supported treadmill training or the control mobility training for American Spinal Injury Association (ASIA) C and D patients. The number of patients is found in Table 2. The vertical bars represent the standard error. TX = treatment group; BWSTT = body weight–supported treadmill training.

Figure 3.

Piecewise regression analysis of walking speed in relation to the lower extremity motor score (LEMS) at the end of training reveals that a slow but functional walking speed of 0.60 m/s tended to be reached as the LEMS approached 40 and then increased to more functional velocities as the LEMS exceeded 40.

Table 1

Table 1A. Functional Independence Measure–Locomotor Score (range, 1–7) at 6 and 12 Weeks After Entry as ASIA B

Time	Group	Number	Mean	Median	SD	Lower Quartile	Upper Quartile
6 wks	BWSTT	14	1.07	1.0	0.27	1.0	1.0
	CONT	17	1.06	1.0	0.24	1.0	1.0
12 wks	BWSTT	13	1.31	1.0	1.11	1.0	1.0
	CONT	16	1.94	1.0	1.73	1.0	2.5

Table 1B. Walking Velocity (m/s) at 6 and 12 Weeks After Entry as ASIA B

Time	Group	Number	Mean	Median	SD	Lower Quartile	Upper Quartile
6 wks	BWSTT	1	0.11	0.11	—	0.11	0.11
	CONT	2	0.16	0.16	0.08	0.10	0.23
12 wks	BWSTT	1	0.41	0.41	—	0.41	0.41
	CONT	4	0.27	0.30	0.13	0.18	0.36

Table 1C. Lower Extremity Motor Score (range, 0–50) at 6 and 12 Weeks After Entry as ASIA B

Time	Group	Number	Mean	Median	SD	Lower Quartile	Upper Quartile
6 wks	BWSTT	14	4.1	2.0	5.5	0.0	7.0
	CONT	16	4.6	2.0	6.5	0.0	6.0
12 wks	BWSTT	13	6.1	2.0	8.6	0.0	7.0
	CONT	16	7.3	2.0	10.3	0.0	11.5

Table 1D. Walking Distance (m) 12 Weeks After Entry as ASIA B

Time	Group	Number	Mean	Median	SD	Lower Quartile	Upper Quartile
12 wks	BWSTT	9	10.7	0.0	32.0	0.0	10.0
	CONT	12	16.4	0.0	36.3	0.0	15.5

ASIA = American Spinal Injury Association; BWSTT = body weight–supported treadmill training; CONT = control.

Table 2

Table 2A. Functional Independence Measure-Locomotor Score (range, 1–7) at 6 and 12 Weeks After Entry as ASIA C or D

Time	Group	Number	Mean	Median	SD	Lower Quartile	Upper Quartile
6 wks	BWSTT	39	3.0	3.0	2.1	1.0	5.0
	CONT	39	3.9	4.0	2.1	2.0	6.0
12 wks	BWSTT	43	4.7	5.0	2.1	4.0	6.0
	CONT	40	5.5	6.0	1.4	5.0	6.0

Table 2B. Walking Velocity (m/s) at 6 and 12 Weeks After Entry as ASIA C or D

Time	Group	Number	Mean	Median	SD	Lower Quartile	Upper Quartile
6 wks	BWSTT	21	0.69	0.64	0.40	0.38	0.95
	CONT	29	0.51	0.35	0.42	0.21	0.76
12 wks	BWSTT	34	0.85	0.78	0.55	0.40	1.27
	CONT	37	0.84	0.90	0.54	0.39	1.17

Table 2C. Lower Extremity Motor Score (range, 0–50) at 6 and 12 Weeks After Entry as ASIA C or D

Time	Group	Number	Mean	Median	SD	Lower Quartile	Upper Quartile
6 wks	BWSTT	40	29.1	33.0	14.2	17.0	40.5
	CONT	39	29.5	30.0	11.5	21.0	37.0
12 wks	BWSTT	43	34.7	39.0	13.3	27.0	46.0
	CONT	40	35.7	36.5	11.3	26.5	44.5

Table 2D. Walking Distance (m) at 12 Weeks After Entry as ASIA C or D

Time	Group	Number	Mean	Median	SD	Lower Quartile	Upper Quartile
12 wks	BWSTT	34	247.7	212.3	187.6	68.6	381.0
	CONT	36	251.3	238.8	203.7	80.8	363.9

ASIA = American Spinal Injury Association; BWSTT = body weight-supported treadmill training; CONT = control.

Table 3

Comparison in ASIA B Patients of Means for FIM-L and Walking Speed at End of Treatment (3 m) and at Follow-up at 6 and 12 Months After Entry

Group	Variable	Time (mo)	Number Patients	Mean	Std Error	Lower Quartile	Median	Upper Quartile
CONT	Speed m/s	3	4	0.27	0.06	0.18	0.30	0.36
		6	7	0.24	0.09	0.09	0.15	0.39
		12	3	0.72	0.08	0.56	0.76	0.85
FIM-L (1-7)		3	16	1.9	0.4	1.0	1.0	2.5
		6	16	2.5	0.5	1.0	1.0	4.0
		12	14	2.1	0.6	1.0	1.0	4.0
BWSTT	Speed	3	1	0.41	—	0.41	0.41	0.41
		6	3	0.22	0.07	0.09	0.23	0.33
		12	4	0.25	0.08	0.14	0.25	0.35
FIM-L		3	13	1.3	0.3	1.0	1.0	1.0
		6	11	2	0.6	1.0	1.0	2.0
		12	11	2.7	0.7	1.0	1.0	6.0

ASIA = American Spinal Injury Association; FIM-L = Functional Independence Measure-Locomotor; CONT = control; BWSTT = body weight-supported treadmill training.

Comparison in ASIA C and D Patients of Means for FIM-L and Walking Speed (m/s) at End of Treatment (3 m) and at Follow-up at 6 and 12 Months After Entry

Table 4

Group	Variable	Time (mo)	Number	Mean	Std Error	Lower Quartile	Median	Upper Quartile
CONT	Speed	3	37	0.84	0.09	0.39	0.90	1.17
		6	33	1.09	0.10	0.66	1.02	1.39
		12	28	1.09	0.10	0.74	1.02	1.39
	FIM-L	3	40	5.5	0.23	5.0	6.0	6.0
		6	37	5.6	0.27	6.0	6.0	6.0
		12	31	5.6	0.32	6.0	6.0	6.0
BW/STT	Speed	3	34	0.85	0.09	0.40	0.78	1.27
		6	36	0.98	0.10	0.47	1.02	1.45
		12	36	1.21	0.11	0.80	1.17	1.69
	FIM-L	3	43	4.7	0.3	4.0	5.0	6.0
		6	40	5.3	0.3	5.0	6.0	6.5
		12	40	5.8	0.3	6.0	6.0	7

Table 5

Conversions in ASIA Grade From Onset of SCI to Randomization Into SCILT, Then During Participation

By 3 Days After Onset of SCI	ASIA A N = 15			ASIA B N = 56			ASIA C N = 52	
Grade (A-D)	B	C	D	B	C	D	C	D
At entry into SCILT	11	4	-	32	21	3	49	3
4 weeks after entry	9	-	-	20	11	-		
	↓ 2d			↓	↓ 1d	↓		
8 weeks	8	-	-	13	4	1		
	↓ 1d			↓	↓ 2d	↓		
12 weeks	7	-	1	11	1	1	17	29
	↓			↓			↓ 3d	
6 months	7	-	-	11	-	-		

ASIA = American Spinal Cord Injury impairment; SCI = spinal cord injury; SCILT = Spinal Cord Injury Locomotor Trial; d = dropout.