Robotic-Assisted, Body-Weight–Supported Treadmill Training in Individuals Following Motor Incomplete Spinal Cord Injury

Background and Purpose. Performance of therapist-assisted, body-weight–supported treadmill training (BWSTT) to enhance walking ability of people with neurological injury is an area of intense research. Its application in the clinical setting, however, is limited by the personnel and labor requirements placed on physical therapists. Recent development of motorized ("robotic") rehabilitative devices that provide assistance during stepping may improve delivery of BWSTT. **Case Description.** This case report describes the use of a robotic device to enhance motor recovery and ambulation in 3 people following motor incomplete spinal cord injury. **Interventions.** Changes in motor impairment, functional limitations, and locomotor disability were monitored weekly during robotic-assisted BWSTT and following transition to therapist-assisted BWSTT with the assistance of one therapist. **Outcomes.** Following this training, 2 patients recovered independent over-ground walking and another improved his gait speed and endurance. **Discussion.** The use of robotic devices may assist physical therapists by providing task-specific practice of stepping in people following neurological injury. [Hornby TG, Zemon DH, Campbell D. Robotic-assisted, body-weight–supported treadmill training in individuals following motor incomplete spinal cord injury. *Phys Ther.* 2005;85:52–66.]

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Statistics indicate that a large proportion of people with spinal cord injury (SCI) who sustain motor incomplete lesions can regain some recovery of over-ground ambulation.[1–3] Although improvements in motor function can be substantial during rehabilitation, decreased walking speed[4] and impaired lower-extremity coordination and postural stability limit the capacity for functional, community ambulation.[5,6] Over the past 2 decades, the use of body-weight–supported treadmill training (BWSTT) to enhance motor function and ambulation in individuals with SCI, stroke, or other neurological injuries has received considerable attention.[7,8] Body-weight–supported treadmill training involves practice of stepping on a motorized treadmill while unloading a percentage of a person's body weight using a counterweight-harness system. Manual assistance is provided as necessary to promote upright posture and lower-extremity trajectories associated with normal human gait.[9] Practice of "kinematically" correct stepping is thought to enhance the afferent feedback associated with normal locomotion and, therefore, maximize plasticity within spinal and supraspinal neural circuits.[10–12]

Use of robotic locomotor training devices in the rehabilitation setting could potentially augment recovery of ambulation in people following neurological injury by increasing the total duration of training and reducing the labor-intensive assistance provided by physical therapists.

In clinical studies involving individuals with gait dysfunction following damage to the central nervous system, BWSTT has been shown to provide greater improvements in locomotor ability, motor function, and balance than conventional rehabilitation techniques.[13,14] Despite these potential benefits, its practice in the clinical setting is limited due to the labor-intensive requirements of providing such therapy. Specifically, up to 3 trained individuals may be required to provide manual assistance of upright stepping patterns in people with substantial gait impairments.[9] Furthermore, in people with extensive weakness or involuntary motor behaviors, pro-

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Figure 1.
The driven gait orthosis (DGO) (Lokomat) used during robotic-assisted treadmill training. Image used with permission from Hocoma AG Inc, Zurich, Switzerland.

Table 1.
American Spinal Injury Association (ASIA) Impairment Classification Scale[a]

A=Complete	No motor or sensory function is preserved in the sacral segments S4–S5
B=Incomplete	Sensory but no motor function is preserved below the neurological level and includes the sacral segments S4–S5
C=Incomplete	Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3
D=Incomplete	Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade of 3 or more
E=Normal	Motor and sensory function are normal

[a] Reprinted with permission of the American Spinal Injury Association from: *International Standards for Neurological Classification of Spinal Cord Injury*. Rev ed. Chicago, Ill: American Spinal Injury Association; 2002.

viding consistent, appropriate manual assistance may be difficult because of the physically demanding nature of the task.

To improve delivery of BWSTT, the Lokomat* (Fig. 1), a locomotor training device, was developed recently.[15,16] This driven (motorized) gait orthosis (DGO) is a computer-controlled, exoskeletal device that is secured to a person's legs while he or she is supported over a motorized treadmill† using a counterweight unloading system similar to therapist-assisted BWSTT. In place of physical therapists, the motorized exoskeleton generates passively guided, symmetrical lower-extremity trajectories that are consistent with a normal physiological gait pattern. These movements are thought to provide some of the critical sensory cues necessary for maintaining and enhancing locomotor ability.[9]

Use of robotic locomotor training devices in the rehabilitation setting could potentially augment recovery of ambulation in people following neurological injury by increasing the total duration of training and reducing the labor-intensive assistance provided by physical therapists. Although passive guidance during practice of a voluntary motor task has been shown to be less effective in enhancing motor learning than unrestricted practice,[17,18] the use of passive guidance could be beneficial early during motor skill acquisition.[19] An optimal locomotor rehabilitation strategy might theoretically allow practice of kinematically correct gait patterns using robotic-assisted BWSTT when the need for assistance is extensive and allow the patient to transition to therapist-assisted stepping practice when voluntary motor control has improved. The purpose of this case report is to describe the use of the DGO in the clinical setting and the transition to therapist-assisted BWSTT in an attempt to augment voluntary recovery of motor function and ambulation following motor incomplete SCI.

Case Descriptions

Patients

Three patients (2 male, 1 female) with SCI who were receiving treatment at the Rehabilitation Institute of Chicago were consecutively enrolled to participate in locomotor training sessions. Patients were selected because of their previous history of traumatic or non-traumatic, nonprogressive SCI, with an American Spinal Injury Association (ASIA) Impairment Scale classification of C or D,[20] which indicates motor incomplete lesions, and neurological level of T10 or higher (Tab. 1). These initial guidelines were established to monitor improvements in motor impairments and functional improvements during locomotor training; people with motor complete SCI were excluded. The patients selected were medically stable and without a history of concurrent severe medical illness, including unhealed decubiti, cardiorespiratory disease that limited exercise performance, orthostatic hypotension (blood pressure decrease greater than 20 mm Hg [systolic] or greater than 10 mm Hg [diastolic]), or history of traumatic brain injury. All patients had range of motion in bilateral hip, knee, and ankle joints that was adequate for normal gait, and they were within the size restrictions necessary to walk with the assistance of the Lokomat (ie, greater trochanter to lateral epicondyle >35 cm or <47 cm; pelvis width <50 cm, thigh circumference measured 14 cm above the knee axis <57 cm, and body weight <150 kg). Written and verbal consent were obtained from each patient.

* Hocoma AG, Florastrasse 47, 8008 Zurich, Switzerland.
† Woodway GmbH, Steinackerstrasse 20, D79576 Weil am Rhein, Germany.

The 3 patients described in this case report were chosen because of their history of motor incomplete SCI of varying duration since the initial injury and their varying degrees of motor and ambulatory capacity. A description of each patient follows, including the initial ASIA assessment between 72 hours and 1 week after the injury, which has been shown to provide an initial prognosis of recovery of ambulatory function.[21]

Patient 1 history. Patient 1 was a 13-year-old girl with a motor incomplete C6 lesion from trauma 6 weeks previously. Her initial ASIA classification, performed during the first week following her injury, was ASIA B, indicating a sensory incomplete, motor complete injury. At the seventh day after the injury, the patient reported intact light-touch sensation, although she could not distinguish sharp from dull sensation. Lower-extremity motor recovery was first evident 5 weeks following the initial injury (patient was therefore classified as having motor incomplete SCI), but the patient could not tolerate upright standing for more than 10 minutes until the sixth week postinjury, when training was initiated. Her impairment classification immediately before training was ASIA C. Patient 1 was prescribed 15 mg of oral baclofen, which was terminated following 2 weeks of locomotor training due to increased patient report of drowsiness and fatigue. The patient was subsequently prescribed 4 mg of tizanidine per day following 4 weeks of training. This dosage was maintained throughout the remainder of the locomotor sessions. Following 20 weeks of BWSTT (60 sessions), the patient was classified as ASIA D.

Patient 2 history. Patient 2 was a 40-year-old man with a T2 lesion and an initial ASIA B classification (pinprick sensation absent in the first 3 to 7 days after injury) secondary to a spinal vascular accident 5 weeks before training. His ASIA classification at the beginning of training was ASIA C. Voluntary lower-extremity movements were present 3 weeks following injury, and the patient began training at 5 weeks after the injury (ASIA C). Patient 2 was prescribed 30 mg of baclofen per day, and medications were unchanged throughout training. His impairment classification was ASIA D following all formal locomotor training that lasted 16 weeks (48 sessions).

Patient 3 history. Patient 3 was a 43-year-old man with a C6 injury and an ASIA C classification following a traumatic accident 18 months before our intervention. His initial classification during the first week after injury also was ASIA C. He was not prescribed antispasticity medications throughout treadmill training. Following BWSTT, patient 3 remained at the ASIA C classification. During the sixth through ninth weeks of locomotor training, BWSTT was performed intermittently because of an illness unrelated to the patient's initial neurological diagnosis. The patient was referred back to his primary rehabilitation physician, and he was allowed to continue locomotor training. The total duration of training was 16 weeks (39 sessions).

Examination

Examination of impairments, functional limitations, and locomotor disability was performed weekly using standardized tests and measures described below. All tests and measures were performed by a physical therapist (TGH, DHZ) or a physical therapist assistant (DC), and the results, when possible, were confirmed by another therapist.

Lower-Extremity Motor Scores. To assess the ability of patients with SCI to move their lower-extremity joints through their available range of motion and resist manual perturbations, manual muscle testing was performed using the ASIA motor assessment guidelines.[20] Specific muscle groups tested correspond roughly with segmental innervation levels L2–S1 and included hip flexors, knee extensors, ankle dorsiflexors, great toe extensors, and ankle plantar flexors, with ordinal scores (0–5) assigned as established by the ASIA Impairment Scale. The total scores from all lower-extremity muscles tested bilaterally were summed to provide the Lower-Extremity Motor Score (LEMS). Despite the high correlation of ASIA motor scores with conventional manual muscle testing in all major muscle groups of the lower extremity,[22] Noreau and Vachon[23] reported decreased sensitivity of manual muscle testing in people with SCI at grades greater than 3 and Jonsson et al[24] found inconsistent interrater reliability of motor scores generated during ASIA assessment (Kappa statistics=.48–.89 for LEMS). The LEMS, however, has been shown to predict gait speed and oxygen consumption during ambulation in people following SCI.[25] When possible, weekly LEMS measurements were confirmed with another therapist, although intertester reliability was not specifically measured.

Locomotor disability. The patients' scores on the Functional Independence Measure (FIM)[26] locomotor subscale and the Walking Index for Spinal Cord Injury II (WISCI II)[27] were used to measure locomotor ability. For the FIM locomotor subscale score, the primary mode of locomotion in the community (walking/wheelchair) was determined for each patient at the beginning and end of training by assigning an ordinal rating (1–7) to the amount of physical assistance or use of assistive devices or braces required. We also recorded the FIM locomotor subscale score for over-ground ambulation weekly, regardless of the primary mode of locomotion used. This measure provided an estimate of improvement in over-ground ambulation. Interrater reliability of FIM mobility subscale scores for walking/wheelchair use has been estimated to be fair to poor (Spearman coefficient=.60, Kappa statistic=.40) in a diverse population of patients with SCI.[28]

The WISCI II[27] measurement scale was used to more precisely examine the use of assistive devices, lower-extremity bracing, and physical assistance during over-ground walking. The WISCI II assigns ordinal scores for locomotor performance, with a score of 0 indicating that a person is unable to ambulate with assistance and a score of 20 indicating that the person can ambulate at least 10 m without assistive devices, bracing, or physical assistance. Interrater agreement was 100% for the original WISCI scale.[29] Small alterations in the revised version (WISCI II) likely do not change the psychometric properties of the tool.[27] An exception to the standard administration of the scale was made, however, by allowing people to use a wheeled walker during testing.

Gait speed and endurance. Over-ground gait speed was examined using the 10-Meter Walk Test, which has been used previously with people with various neurological injuries,[30] including those with spinal cord lesions.[31] Individuals using an assistive device during initial examination of the 10-m walk were examined with a similar device during subsequent testing. Patients were asked to ambulate at their "normal, comfortable" speed. To calculate gait speed, time was recorded during the middle 6 m of the 10-Meter Walk Test to allow for effects of acceleration and deceleration.[32] Single measurements were taken to minimize the effects of fatigue. Researchers in studies of gait speed over short distances in people with and without neurological impairments, using Pearson correlation coefficients (r), have estimated good interrater reliability (r=.99) and test-retest reliability (r=.89–.90).[30,33] The reliability of data obtained with the 10-Meter Walk Test in a large sample of patients with SCI has not been estimated.

In individuals with neurological injury, the 10-Meter Walk Test can overestimate gait speed over longer distances because of impaired aerobic capacity.[34] The 6-Minute Walk Test, a measure commonly used with people with various cardiopulmonary disorders,[35] was therefore used to estimate walking endurance. This test measures the distance ambulated during 6 minutes with interrater reliability estimated to be high (intraclass correlation coefficient [ICC]=.95) in community-dwelling elderly people.[36] As with the 10-Meter Walk Test, patients were tested weekly with the assistive device used during initial testing. There are no reports of reliability of data obtained with the 6-Minute Walk Test in people with SCI. To minimize fatigue, only single measurements were taken each week.

Timed "Up & Go" Test. To examine performance during a multitask behavior, we used the Timed "Up & Go" (TUG) Test,[37] which measures the time to rise from a standard height chair, ambulate 3 m, and return to the chair without physical assistance. Assistive devices and braces were used as necessary, although no assistance was provided during the task. If physical assistance was required, the results of the test were excluded. The TUG has been used as a clinical tool to detect fall risk in elderly people,[36] with inconsistent test-retest reliability (ICC=.50–.92) reported among community-dwelling elderly people,[36–38] but reliability within individuals with SCI has not been estimated.

Postural stability. The ability to maintain postural stability in standing or sitting during a reaching task without upper-extremity support was examined using the Functional Reach Test[39] and modified sitting Functional Reach Test.[40] For the assessment of horizontal reach in sitting and standing, patients were asked to reach forward as far as possible with one arm extended while standing or sitting independently. Maximum distance was measured (in inches) with a ruler. For 3 trials, the highest reaching distance was recorded. Distances greater than 10 in (25.4 cm) has indicated a minimal risk for falling[41] and, therefore, were recorded as ">10 in." Reliability of data obtained with the standing Functional Reach Test has been estimated in elderly people (interrater ICC=.98, test-retest ICC=.92)[38] but not in people with motor incomplete SCI. A previous report indicated good test-retest reliability (ICC=.85–.94) using the modified sitting Functional Reach Test in people with SCI[40] in which they used a backboard for support. As with the standing Functional Reach Test, we did not provide physical support.

The clinical examinations described were performed each week either before locomotor training or on a separate day. The sequence was consistent during all testing sessions across all patients in the following order: LEMS, sitting reach, standing reach, TUG, 10-Meter Walk Test, and, 6-Minute Walk Test. The FIM locomotor subscale scores and WISCI II scores were determined during the 10-Meter Walk Test and 6-Minute Walk Test.

Interventions

In addition to concurrent physical therapy and occupational therapy sessions, all patients attended scheduled locomotor training sessions, consisting of either robotic- or therapist-assisted BWSTT. The details of, and the rationale for, each training paradigm are provided.

Robotic-assisted BWSTT. The design and control of the DGO used to provide robotic-assisted BWSTT has been reported previously.[15] Body-weight support was provided using a harness-counterweight system over a motorized treadmill. The exoskeletal orthosis was secured to patients at the trunk, pelvis, and both lower extremities using adjustable cuffs with Velcro‡ straps, with hip and knee joints aligned to those of the DGO. The DGO was attached to the treadmill/support frame with a 4-bar linkage and a spring-loaded counterweight system, which provided vertical support and unweighting of the exoskeletal device (ie, the weight of the DGO did not contribute to the loading experienced by the patients during robotic-assisted BWSTT). Actuators at hip and knee joints on both legs, programmed by 2 personal computers and a current controller, powered the DGO to generate a physiological gait pattern timed to the speed of the treadmill belt. Elastic straps were fitted around the patient's footwear over the heads of the metatarsals and secured to a rigid extension of the exoskeleton to ensure toe clearance during swing phase. In conjunction with body-weight support, the DGO provided trajectory-controlled, guided assistance of the hip and knee joints in the sagittal plane during both stance and swing phases of gait, with nonactuated ankle support (Fig. 1).

Robotic-assisted BWSTT was scheduled 3 times per week around existing inpatient and outpatient therapy sessions. Speed of training was set between 2.0 and 2.5 kmph (1.2–1.6 mph) as determined by patient tolerance and comfort. The total distance walked per session was determined by patient tolerance and was limited to a maximum of 1,000 m. The amount of body-weight support provided was minimized to allow maximum lower-extremity loading without evidence of excessive knee flexion during stance or toe drag during swing. Patients were instructed to voluntarily generate lower-extremity movements that were consistent with the assisted stepping pattern. An approximation of the forces generated by the person within the DGO was detected by load sensors within the joint motors aligned at the hip and knee and were displayed graphically on a computer monitor. Estimates of sagittal-plane forces generated by the patients during robotic-assisted BWSTT were provided to the physical therapists. Specific feedback provided to the patients included verbal encouragement and a full-length mirror placed in front of the patient during treadmill training. The total time allotted for BWSTT sessions was 1 hour, including setup time and a rest period as needed.

Therapist-assisted BWSTT. Three limitations of the DGO necessitated a transition from robotic- to therapist-assisted BWSTT during the course of rehabilitation. First, current models of robotic locomotor devices used in clinical populations, including the Lokomat, are passive in nature, with a predetermined trajectory that does not alter limb kinematics according to the forces generated by the user. Despite similarities in lower-extremity electromyographic patterns during robotic-assisted BWSTT,[16] passive guidance during voluntary performance of motor tasks may hamper motor learning[17] and neural plasticity.[18]

Second, robotic-assisted training was limited by the speed at which the orthosis could provide a comfortable gait pattern. The maximum speed attained was 2.5 kmph (1.6 mph), which is at the lower limit of speeds recommended during BWSTT.[9,42] Previous randomized controlled trials on the effects of treadmill speed during BWSTT in people with stroke have noted greater improvements in over-ground gait speed in groups that trained at the highest treadmill speed.[43,44]

Finally, physical attachment of the DGO to patients during training is necessary to ensure normal lower-extremity trajectories, but this may impede performance by generating afferent inputs not typically associated with ambulation. In particular, elastic straps attached to cuffs surrounding the metatarsal heads are necessary to help with toe clearance during swing, but they may delay or decrease appropriate flexor muscle activity during swing phase initiation. In experimental feline studies, tactile plantar surface stimulation[45] and ankle extensor force generation[46] have been shown to be important afferent inputs that can augment and prolong extensor muscle activity during the stance phase of locomotion. Despite appropriate body-weight unloading before swing initiation, continuous plantar pressure and passive plantar-flexor loading provided by the elastic restraints may delay the transition to swing phase.[47,48] These inputs are considered critical to generating normal locomotor activity during therapist-assisted BWSTT.[9]

The transition from robotic- to therapist-assisted BWSTT was, therefore, performed to encourage voluntary stepping patterns, enhance treadmill speed, and minimize conflicting sensory input in order to enhance locomotor performance. This transition was attempted when patients were able to generate normal stepping kinematics and upright posture with assistance provided by only one physical therapist, similar to the personnel requirements of robotic-assisted BWSTT. Body-weight support was provided using the same counterweight-harness system and guidelines for unloading that were used during robotic training. Manual assistance was provided at the lower extremities as necessary, with adjustable straps attached from the harness at the level of the pelvis to the side rails to assist with balance. Patients were encouraged to generate reciprocal arm swing during treadmill stepping, but were allowed to hold onto side rails as necessary to maintain postural control (for alternative methods of training, please see Behrman and Harkema[9] and Visintin and Barbeau[49]). If the physical therapists noted

‡ Velcro USA Inc, 406 Brown Ave, Manchester, NH 03103.

increased reliance on the upper extremities to maintain upright posture, the amount of body-weight support was increased and the patients were encouraged to reduce upper-extremity weight bearing.

The ability to perform therapist-assisted BWSTT was assessed when patients had recovered over-ground ambulatory function with minimal physical assistance and assistive devices and braces as required (FIM locomotor subscale scores for ambulation ≥4). Weekly evaluations of therapist-assisted BWSTT were performed to determine whether the patients with SCI could ambulate at a minimum treadmill speed of 2.0 kmph for 1,000 m with assistance from only one physical therapist. If patients could not sustain upright posture or normal kinematics, robotic-assisted training was performed for the remainder of the session. Following successful transition to therapist-assisted BWSTT, treadmill speed was increased up to 5.0 kmph (3.1 mph) as tolerated, with rest periods allowed as necessary. The total training distance per session was limited to 1,000 m during a 1-hour session.

Therapist-assisted BWSTT was terminated when the subject's functional recovery had reached a plateau for at least 4 weeks. This plateau was defined as a lack of increase in their FIM locomotor scores, WISCI II scores, and a less than 10% increase in gait speed or distance during the 10-Meter Walk Test and 6-Minute Walk Test.

Patient 1 training. Patient 1 received locomotor training 3 times per week for 20 weeks (60 sessions), using the DGO for the initial 8 weeks. The amount of body-weight support during initial locomotor training using robotic assistance was 75% of her body weight. The speed of locomotor training was set at 2.0 kmph for the duration of robotic-assisted training.

Attempts to transition the patient from robotic- to therapist-assisted training began following 7 weeks of training, but the transition was accomplished after week 8 (24 sessions). Body-weight support was reduced to 43% at this time, with assistance required only on the right leg during the swing phase of gait. Therapist-assisted BWSTT continued for 12 additional weeks, with treadmill speed increased up to 4.0 kmph as tolerated. The amount of body-weight support was adjusted as tolerated, with minimum unloading at 15%. Within each 1-hour session, the total duration of walking training varied between 21 and 30 minutes.

Treadmill training was terminated at the end of 20 weeks because of a plateau of walking distance (141–146 m [470–485 ft]) performed during the 6-Minute Walk Test during the final 4 weeks of training. During the final 2 weeks of training, she required therapist assistance to execute stepping only at treadmill speeds greater than 3.5 kmph.

Patient 1 received 3 to 5 hours of physical therapy and occupational therapy per day during the first 12 weeks of locomotor training; at week 12, the patient was discharged from inpatient rehabilitation and therapy was reduced to 6 sessions per week. Interventions consisted of transfer training, performance of activities of daily living, active and passive range of motion exercises for the upper and lower extremities, postural stability training, and, when appropriate (approximately week 6 posttraining), gait and stair training. Following recovery of over-ground ambulation with assistance from a physical therapist, approximately 45 minutes of gait and stair training were performed during each physical therapy session.

Patient 2 training. Patient 2 received BWSTT 3 times a week for 16 weeks (48 sessions), using the DGO for the initial 9 weeks (27 sessions). The amount of body-weight support provided during the first session was 59%, and locomotor treadmill speed started at 2.0 kmph but increased to 2.5 kmph, as tolerated. Attempts to transition the patient to therapist-assisted training occurred following week 6 of training, and the attempts were successful after 9 weeks, when body-weight support was 29%. Training continued with therapist assistance provided on the left leg during both stance and swing phases as needed. Treadmill speed was altered between 2.5 and 5.0 kmph as tolerated, and body-weight support ranged from 0% to 29%. Treadmill training was terminated at the 16th week because total distance ambulated during the 6-Minute Walk Test performed over the final four weeks varied only slightly from 188 to 190 m (625–632 ft). Therapist assistance was not required during the last 3 weeks of treadmill training at speeds less than 3.0 kmph.

Patient 2 received daily physical therapy and occupational therapy for 3 to 5 hours per day during the first 4 weeks of locomotor training during his inpatient rehabilitation. Following discharge, outpatient physical therapy continued at 3 sessions per week throughout the remainder of the training sessions. Occupational therapy was discontinued at 2 weeks following discharge from inpatient rehabilitation. Physical therapy provided during the locomotor training consisted primarily of practice of activities of daily living, passive range of motion exercises, balance training, and gait and stair training. Following week 5 posttraining, the majority of physical therapy interventions focused on gait retraining interventions.

Patient 3 training. Patient 3 performed locomotor training 1 to 3 times a week for 16 weeks (39 total sessions).

Table 2.
Changes in Standardized Measurements and Amount of Body-Weight Support Throughout Locomotor Training[a]

	Patient 1			Patient 2			Patient 3		
	Initial	**Transition**	**Final**	**Initial**	**Transition**	**Final**	**Initial**	**Transition**	**Final**
ASIA classification	C	C	D	C	D	D	C	C	C
Body-weight support (%)	75	43	15	59	29	0	46	12	12
LEMS (0–50)	6	43	48	19	46	50	31	30	31
FIM locomotor subscale score (1–7)	0	4	6	0	5	6	5[b]	6	6
WISCI II score (0–20)	0	8	16	0	13	13	13	13	13
Gait speed (m/s)		0.29	0.55		0.36	0.58	0.11	0.14	0.21
Gait endurance (ft)		243	480		460	632	100	179	204
Timed "UP & Go" Test(s)					30.6	18.5			
Functional Reach Test: sitting (in)		>10	>10		>10	>10	>10	>10	>10
Functional Reach Test: standing (in)		4	7		6	>10	10	7	6

[a] The degree of motor impairment, functional limitations, and locomotor disability are reported at the initial examination session, at the transition from robotic-assisted training to therapist-assisted training, and following all formal locomotor training sessions. The minimum amount of body-weight support required to perform body-weight–supported treadmill training using either robotic or therapist assistance also is recorded. Locomotor subscale scores for ambulation are used in this report to assess over-ground walking ability specific to the training paradigm used here. ASIA=American Spinal Injury Association, LEMS=Lower-Extremity Motor Score, FIM=Functional Independence Measure, WISCI II=Walking Index for Spinal Cord Injury II.
[b] Denotes the household exception for ambulation, in which the patient was unable to ambulate 150 ft, but could ambulate 50 ft without physical assistance.[25]

Treadmill speed during robotic-assisted BWSTT varied between 2.0 and 2.5 kmph. The initial amount of body-weight support was 46% and was reduced throughout training. Attempts to transition the patient to therapist-assisted BWSTT occurred following the fourth week and were successful during the seventh week of training (20 sessions). Following the successful transition, body-weight support was between 12% and 37% during therapist-assisted training, with assistance provided on the left leg throughout therapist-assisted BWSTT. Treadmill speed varied from 2.0 to 4.5 kmph during therapist-assisted training. Minimum unloading during the final week of treadmill training remained at 12%.

Because the patient was ill during the weeks 4 through 7 of training, robotic- and therapist-assisted BWSTT continued despite an early plateau and decline in over-ground walking performance. Treadmill training continued beyond this initial plateau period until walking distance did not increase substantially during the weeks 12 through 16 of locomotor training (range of walking distance during the 6-Minute Walk Test=57–61 m [189–204 ft]).

Throughout the duration of locomotor training, patient 3 received 3 sessions of both physical therapy and occupational therapy per week. Physical therapy sessions focused primarily on gait training, lower-extremity strengthening exercises, and postural stability in standing and walking, including stair training. Occupational therapy sessions focused primarily on bilateral manual dexterity and coordination exercises.

Outcomes

Changes in motor impairment, functional limitations, and locomotor disability were assessed weekly using standardized measures. Table 2 outlines the changes in these measures before training, following the transition to therapist-assisted BWSTT, and the final outcomes. Figure 2 illustrates the weekly changes in LEMS and distance ambulated during the 6-Minute Walk Test for each patient and notes the time period of initial and final attempts to make the transition from robotic-assisted BWSTT to therapist-assisted BWSTT.

Patient 1

Lower-Extremity Motor Scores. Patient 1 had an initial LEMS of 6/50, which improved to 43/50 following 8 weeks of training and the transition to therapist-assisted BWSTT (Fig. 2A). The patient's LEMS was lower on the right lower extremity compared with the left lower extremity (19/25 versus 24/25). Her final LEMS was 48/50. The change in LEMS over the first 12 weeks of training is shown in Fig. 2A.

Locomotor disability. Patient 1 was unable to ambulate prior to training, and the primary method of locomotion was with a manual wheelchair. Following 8 weeks of training, she was able to ambulate over ground; however, she required minimal assistance from one physical therapist (FIM locomotor subscale score for ambulation=4) and used a walker, but no lower-extremity bracing (WISCI II score=8). Her final FIM score was 6 (modified independence) and WISCI II score was 16, indicating

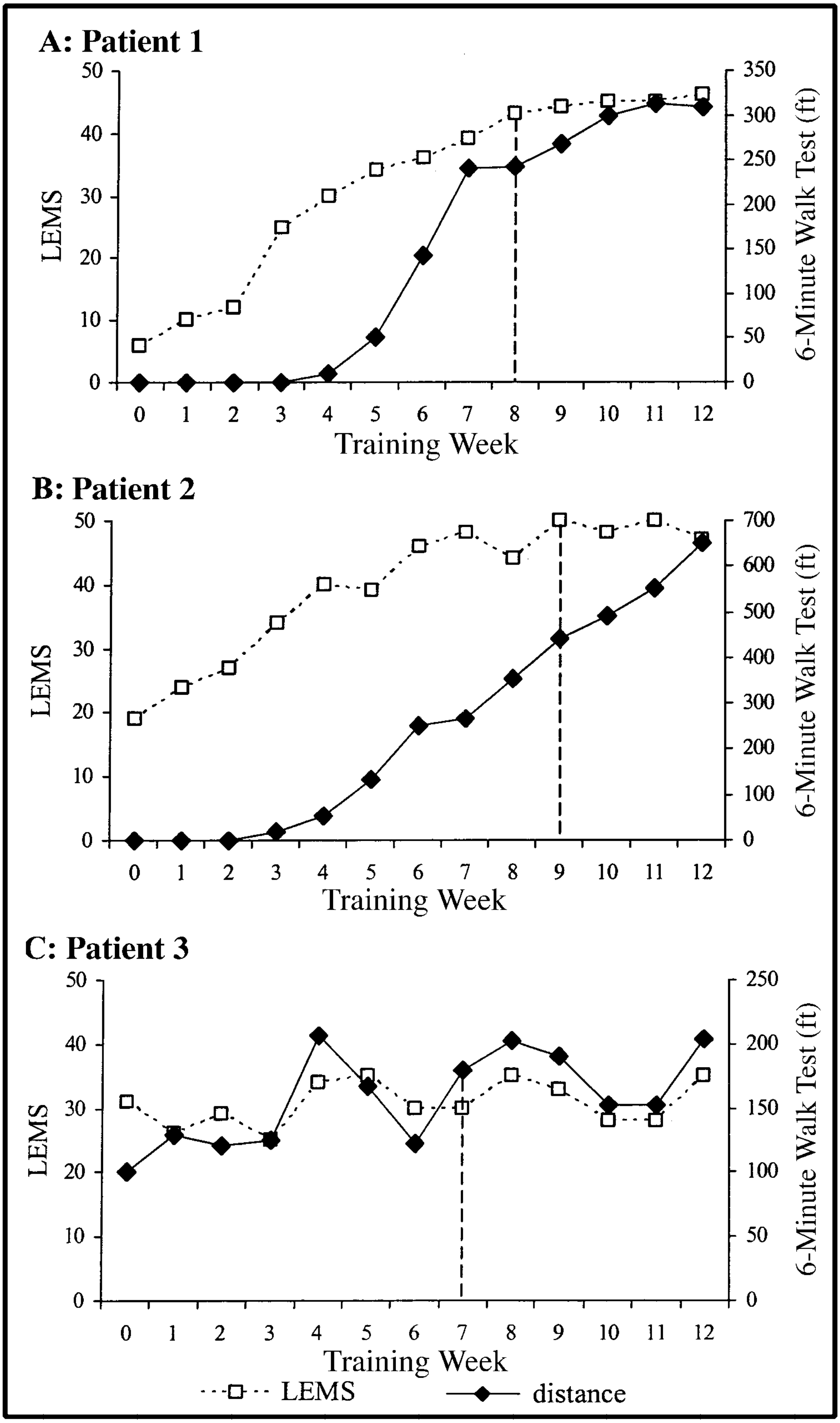

Figure 2.
Changes in Lower-Extremity Motor Scores (LEMS) and 6-Minute Walk Test measurements throughout 12 weeks of treadmill training. Weekly assessment of LEMS (□) and distance ambulated during the 6-Minute Walk Test (◆) are shown. Dashed lines indicate the week of successful transition to therapist-assisted body-weight–supported treadmill training (BWSTT).

use of 2 crutches and no braces, with ambulation as the primary mode of locomotion in the community.

Gait speed and endurance. Improvements in walking speed and distance were observed in patient 1 following initial attempts at over-ground ambulation at week 4 (Fig. 2A). Her gait speed was 0.29 m/s during the 10-Meter Walk Test at week 8, and total distance ambulated during the 6-Minute Walk Test was 73 m (243 ft). From weeks 16 to 20, the patient's performance during the 6-Minute Walk Test varied from 138 to 146 m (460–485 ft), without consistent increases in distance ambulated. Therapist-assisted BWSTT was terminated at the end of week 20. Following all robotic- and therapist-assisted locomotor training, the patient's final gait speed was 0.55 m/s and distance ambulated during the 6-Minute Walk Test was 144 m (480 ft).

Timed "Up & Go" Test. Patient 1 was unable to perform a sit-to-stand transfer without physical assistance throughout the training period. Assistance from sitting to standing was provided by a family member for performance of community ambulation.

Postural stability. Patient 1 could not sit independently for the first 4 weeks of training, and she could not stand independently for the first 7 weeks of training. Following her transition to therapist-assisted training, her sitting forward-reach distance was more than 25 cm (10 in) and standing reach was 10 cm (4 in). Her final scores for reaching tests were more than 25 cm (10 in) in sitting and 18 cm (7 in) in standing.

Patient 2

Lower-Extremity Motor Scores. The LEMS for patient 2 was 19/50 upon initial examination (10/25 for the right extremity), with increases over the next 7 weeks (Fig. 2B). At week 6 of training, his LEMS had improved to 46/50, with lower scores present only on the left lower extremity (21/25). Upon transition to therapist-assisted BWSTT and following completion of all locomotor training, his total LEMS was 50/50.

Locomotor disability. Patient 2 was unable to ambulate until the third week of training, and a manual wheelchair was his primary mode of locomotion. His FIM locomotor subscale score for over-ground ambulation was 4 when therapist-assisted BWSTT was attempted (week 7) and 5 when the transition from the DGO was successful (week 9), with assistance on his left lower extremity as necessary. His WISCI II score was 13 following discontinuation of the use of the DGO, indicating the use of a walker and no braces. The final FIM locomotor subscale score was 6, with over-ground ambulation as his primary method of locomotion, and his WISCI II score remained at 13.

Gait speed and endurance. Patient 2 was able to walk over ground by week 3 of training. His gait speed was 0.26 m/s during initial attempts at therapist-assisted training and 0.36 m/s at week 9 following transition from the DGO. During the 6-Minute Walk Test, the total distance ambulated was 138 m (460 ft) at the transition to therapist-assisted BWSTT. Both gait speed and endurance increased through the 12 weeks of locomotor training, following which only small changes were observed. The patient ambulated 195 m (650 ft) in 6 minutes at the end of 12 weeks of combined robotic- and therapist-assisted BWSTT, and subsequently varied between 186 and 192 m (620–639 ft) over the last 4 weeks. Final gait speed was 0.58 m/s, and distance ambulated during 6 minutes was 190 m (632 ft).

Timed "Up & Go" Test. Subject 2 was unable to perform the TUG at initial examination, but he performed the task without physical assistance in 30.6 seconds at the transition to therapist-assisted BWSTT. Time to perform the TUG during the final examination was 18.5 seconds.

Postural stability. Patient 2 could not sit or stand independently without upper-extremity support or physical assistance at initial examination, but he was able to reach more than 25 cm (10 in) in sitting and 15 cm (6 in) during standing after the transition to therapist-assisted BWSTT. His final sitting and standing Functional Reach Tests were both more than 25 cm (10 in). Despite recommendations from the primary physical therapist to utilize a wheelchair for community locomotion for safety, the patient continued to ambulate as her primary mode of locomotion at all times.

Patient 3

Lower-Extremity Motor Scores. The LEMS for patient 3 was 31/50 upon initial examination, with decreased motor scores evident on his left lower extremity (11/25) and some variability in LEMS throughout the training period. At week 7 of training when the patient transitioned to therapist-assisted BWSTT, his LEMS had decreased slightly to 30/50 (10/25 on left leg). The weekly LEMS measurements were variable, and his final LEMS was 31/50, with similar motor scores at all muscle groups tested.

Locomotor disability. Patient 3 was ambulatory before locomotor training, although his primary mode of community locomotion was a manual wheelchair with maximal assistance (FIM score=2). During ambulation, he required a walker without physical assistance or braces (WISCI II score=13), but he could not walk a minimum of 50 m (~150 ft). His FIM locomotor subscale score for over-ground ambulation, therefore, was rated as 5, using the household ambulation exception for the FIM locomotor scale. His FIM locomotor subscale score for over-ground ambulation increased to 6 following initial attempts to perform therapist-assisted training, although he continued to use his wheelchair as the primary mode of locomotion. His FIM locomotor subscale score, therefore, remained at 2. His WISCI II score of 13 did not change throughout training.

Gait speed and endurance. Initial gait speed for patient 3 was 0.11 m/s during the 10-Meter Walk Test, and distance ambulated in 6 minutes was 30 m (100 ft). Small improvements in gait speed and endurance were observed, with fluctuations throughout the duration of training. Attempts to transition to therapist-assisted training occurred when the patient could ambulate 61 m (206 ft) during the 6-Minute Walk Test at week 4 (Fig. 2C), although successful discontinuation of the DGO occurred at week 7, when gait speed and endurance were measured at 0.14 m/s and 54 m (179 ft) for the 10-Meter Walk Test and 6-Minute Walk Test, respectively. During the final 4 weeks of therapist-assisted BWSTT, gait speed and distance remained relatively unchanged: the final gait speed was 0.21 m/s, and distance ambulated in 6 minutes was 61 m (204 ft).

Timed "Up & Go" Test. Patient 3 was unable to perform a sit-to-stand transfer without physical assistance throughout the training period.

Postural stability. Patient 3 could reach more than 25 cm (10 in) in both sitting and standing with supervision at the initial examination. Sitting functional reach remained more than 25 cm (10 in) through out training, although standing functional reach decreased to 18 cm (7 in) and 15 cm (6 in) at the transition and final measurements, respectively.

Discussion

In this case report, we have described the use of a locomotor training device on 3 people with impaired motor function and ambulatory capacity following a motor incomplete SCI. Use of the DGO allowed the patients to practice stepping with only one therapist required to initiate and monitor training. When possible, locomotor training was performed without the robotic device, and patients continued to perform BWSTT with the assistance of only one therapist as needed to approximate normal stepping kinematics. Following both robotic- and therapist-assisted BWSTT, all 3 patients demonstrated improvements in their independent over-ground ambulation, as revealed by increases in gait speed and endurance between initial and final examinations, with variable effects between patients. Improvements in motor impairments, postural stability, FIM locomotor subscale scores for ambulation, and WISCI II scores were evident in the first 2 patients. In the third patient, substantial fluctuations in the weekly performance of motor and functional tests, including a reduction in the standing reach distance, limit our ability to state definitively whether the patient demonstrated substantial functional improvements following combined robotic- and therapist-assisted BWSTT.

The lack of controlled conditions prohibits identification of a causal relationship between the observed changes and robotic- or therapist-assisted locomotor training. All patients, for example, were participating in physical therapy and occupational therapy throughout the duration of BWSTT. In the first 2 patients, administration of antispasticity medications may have also contributed to changes in motor and ambulatory capacity. Spontaneous neurological recovery also was most likely a critical factor responsible for the observed improvement in motor ability. People with motor incomplete SCI improve voluntary motor function rapidly during the first 2 months following initial injury, the rate of which declines considerably after 3 to 6 months[50,51] and is thought to be complete by 2 years following injury.[21,52] Spontaneous recovery likely contributed to the motor recovery in the first 2 patients, when initiation of BWSTT occurred during the first 2 months following SCI. In contrast, at 18 months after injury, the effects of spontaneous recovery on the improvements in the third patient were likely minimal.

Other factors that may contribute to motor and functional recovery following injury include the age of the person following initial injury,[1,3,53] the level of injury,[2] and the initial motor score or degree of sensory sparing.[3,53,54] For example, although 75% of people with an SCI initially classified as ASIA C recover functional ambulation, people less than 50 years of age with motor incomplete tetraplegia assessed at ASIA C within the first 72 hours after the injury are more likely to recover ambulation than those older than 50 years of age.[1,3] Prediction of mobility following motor incomplete paraplegia is more difficult,[55] however, with recovery of community ambulation possibly dependent on the extent of lower-extremity motor return in the first month after injury.[49] Motor recovery may have been enhanced in patient 1 because of her relatively young age, although no specific information has been detailed in the literature regarding differences in patients less than 50 years of age.

For individuals without voluntary motor function below the lesion level, the degree of sensory sparing early following injury has been shown to be an important predictor of walking recovery.[2,51,54] In general, 50% of people with an SCI classified as ASIA B within the first week after an injury can recover some form of overground ambulation within the first year.[51] More precisely, individuals with partial preservation of pinprick sensation in the most caudal levels demonstrate recovery of walking ability to a similar extent as those with an initial motor incomplete injury.[2] In contrast, the recovery of ambulation in people with partial preservation of light touch sensation immediately following injury is approximately 10% to 33%.[2,54]

The initial degree of motor and sensory sparing following injury also may have contributed to motor recovery, with patients 1 and 2 regaining voluntary lower-extremity motor control at 3 weeks or later following the initial injury. As indicated by their degree of sensation tested in the first weeks, both patients had partial preservation of dorsal column, but not spinothalamic, tract function, and, therefore, had relatively similar prognoses for recovery of ambulation. The delay in initial return of motor function in the first patient may have contributed to her decreased motor and functional recovery compared with the second patient, although data describing the relationship of delay of motor return more than 1 week following injury to the eventual motor and functional recovery are not available.

In the third patient, initial voluntary motor control occurred in the first week after the injury, and, therefore, prognosis of recovery of community ambulation was substantially greater when compared with patients 1 and 2. However, final motor and functional abilities of the third patient following all locomotor training were less than those of the other 2 patients. The primary difference between the motor recovery demonstrated in patient 3 and the other patients appears to be the timing of locomotor training following injury. The patient did not perform BWSTT early following injury, although he did perform ambulatory tasks with conventional rehabilitation interventions. Unfortunately, no data currently are available that describe the effects of delayed locomotor training in humans after SCI, although research has shown some evidence of an optimal time frame in rodents with SCI.[56] These data in humans are necessary to optimize interventions for maximization of motor recovery following SCI.

Despite a potential role of spontaneous recovery to the functional improvements observed in at least 2 of the patients, previous studies of people with gait dysfunction have illustrated the potential benefits of therapist-assisted BWSTT.[7–9] In addition, preliminary results of the effects of robotic-assisted BWSTT (8 weeks, 3–5 sessions per week, 45 minutes per session) in 20 individuals with chronic SCI (>2 years duration) have demonstrated approximately 50% improvements in gait speed and endurance in those patients who were ambulatory prior to entry into the study (n=16).[57] It is likely that robotic- and therapist-assisted BWSTT contributed to improvements in motor function observed in this report, although the extent of the effect of each training regimen is unclear. Determination of whether robotic-assisted training is equivalent to therapist-assisted BWSTT will be elucidated in future work.

Although the improvements in motor function following therapist-assisted treadmill training are significant,[7–9] its practice in the clinical setting is limited by the labor-intensive nature of the task. This limitation has prompted development of robotic devices to assist in the rehabilitation of ambulation in patients with neurological injury.[15,16,58,59] Indeed, many rehabilitation techniques are mechanical in nature and amenable to automation. Considering the importance of the amount of practice in the acquisition and retention of acquired motor behaviors,[19] the development of rehabilitation devices that provide prolonged repetition of various motor skills should enhance task-specific motor learning. Recent reports on individuals with upper-extremity hemiparesis following stroke indicated that robotic-assisted reaching therapy improved upper-extremity motor function to a greater extent as compared to therapy without robotic assistance when allotted similar duration of practice.[60] In a separate study,[61] similar improvements in upper-extremity function in groups receiving robotic-assisted therapy and manual interventions provided by a therapist were observed when the amount of practice (ie, number of repetitions of a reaching task) was standardized. These interventions indicate that robotic-assisted practice of reaching is at least equivalent to therapist-assisted training.

Similar to devices used for the upper extremities, development of robotic locomotor devices may enhance the quality and duration of stepping practice. As with therapist-assisted BWSTT, robotic-assisted training provided some of the critical sensory inputs that are thought to optimize locomotor relearning following neurological injury, including: providing maximum weight bearing as tolerated, facilitating upright posture, and ensuring intralimb and interlimb kinematics associated with normal walking.[9] Therapist-assisted BWSTT, which provides these important sensory cues, could have been provided to patients early during locomotor training only following recruitment and training of additional therapists. Despite potential drawbacks of the DGO, robotic-assisted locomotor training provided this afferent input for an extended duration without the assistance of additional therapists.

With future studies determining the effectiveness of rehabilitative robotic devices and their eventual cost containment with increasing competition, it is likely that these instruments will become commonplace in the rehabilitation setting. The challenge for therapists managing people with neurological injuries will be to decide which patients are appropriate for automated interventions, the intensity and duration of interventions, and when the robotic device is no longer necessary. Following neurological injury, practice of various movements using robotic assistance may be helpful in getting the movement close to the "normal" or expected kinematic pattern necessary to perform a task. Once a patient can voluntarily generate motor behaviors approximating the desired movement, the use of physical guidance may no longer be effective.[19] Establishing criteria for terminating use of automated assistive devices that provide strict physical guidance will enhance delivery of appropriate therapeutic interventions to maximize function following injury.

In the case of BWSTT, criteria to transition patients from therapist-assisted BWSTT to over-ground ambulation have been established previously, specifically when a patient can approximate normal gait kinematics on the treadmill with less than 20% unloading.[9] In the patients described in our case report, our initial guidelines to allow patients to practice stepping behaviors in a less restrictive training paradigm (ie, therapist-assisted training) were established when FIM locomotor subscale scores for ambulation were greater than or equal to 4, indicating that the patient provided more than 75% of the effort required to ambulate at least 50 m (150 ft), or, using the "household exception" for the FIM, no assistance was needed, but the patient could ambulate a minimum of 17 m (50 ft).[25] In practice, the patients described here were able to perform therapist-assisted BWSTT when their gait speed and endurance were sufficient to enable them to ambulate approximately 50 m with minimal or no assistance. Specifically, the patients were able to ambulate at least 60 m during the 6-Minute Walk Test at least once in 3 weeks prior to successful transition to therapist-assisted training (Fig. 2).

Other factors, such as the amount of body-weight support provided during training or improvements in LEMS and postural stability, may have contributed to the ability to terminate robotic-assisted treadmill training, but individually may be inappropriate as criteria for transitioning to therapist-assisted BWSTT. For example, although the DGO may assist in both the swing and stance phases of gait, the amount of body-weight support can be regulated independently from the robotic device. With LEMS and postural stability, people with SCI require substantial voluntary trunk and lower-extremity control to perform over-ground ambulation. These clinical measures do not specifically measure walking behavior, and may be limited in their ability to predict walking performance with therapist-assistance.

Other clinical assessments, such as the TUG and WISCI II, measure some aspect of walking ability, but were also insufficient to determine ability to transition patients to therapist-assisted BWSTT. Use of the TUG, for example, was possible in only one patient who did not require assistance to perform a sit-to-stand transfer, although all patients could walk once they were standing. The ability to recover sufficient muscle power and postural control to rise from a sitting position to a standing position is clinically important, but was not indicative of the capacity to initiate therapist-assisted training.

For the WISCI II, values were consistent in all patients during the transition to therapist-assisted BWSTT, with patients requiring only a walker with no braces with (WISCI II=8) or without (WISCI II=13) physical assistance to ambulate 10 m at the transition to therapist-assisted training. However, a measure of physical assistance is provided by the FIM subscale score, and the WISCI II does not measure ambulation over a longer duration. The WISCI II, therefore, may be limited in its ability to predict successful transition to therapist-assisted BWSTT.

Considering the task requirements of sustaining locomotor activity during 30-minute training sessions, gait speed and gait endurance, in particular, may be more appropriate indicators of the ability of patients to transition to therapist-assisted training with one therapist. All patients described in our case report were able to successfully make this transition when they were able to ambulate more than 50 m over a 6-minute period, with or without minimal physical assistance. Although the requirements for people with SCI to perform therapist-assisted BWSTT for a minimum of 1,000 m at 2.0 kmph are admittedly arbitrary, these parameters were established as the minimum distance and speed of training that could be provided during a 1-hour session of BWSTT. Unfortunately, there are no universally accepted criteria for the duration and intensity of therapist-assisted BWSTT necessary to elicit improvements in locomotor behaviors in people with neurological injury, although attempts to standardize training have been promulgated recently.[41] With improvements in rehabilitation devices, future studies will be needed to establish specific guidelines for appropriate locomotor training parameters for people using robotic- and therapist-assisted treadmill training as well as for over-ground ambulation training.[9,41]

In summary, this case report delineates the progression of locomotor recovery in 3 people with motor incomplete SCI, in which all patients improved their walking ability to a variable extent during the course of robotic-and therapist-assisted BWSTT in addition to conventional rehabilitation. Experimental trials are necessary to evaluate the safety and effectiveness of such devices with an appropriate patient population. Pending the results of these future studies, rehabilitation therapists must be equipped with various decision-making algorithms for implementation of these devices to maximize neurological recovery following injury.

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