Exoskeletal-Assisted Walking for Persons with Motor-Complete Paraplegia

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ABSTRACT

Persons with motor-complete spinal cord injury (SCI) suffer permanent paralysis and loss of mobility. This immobilization limits their ability to access the world as they knew it. Exoskeletal technology has been used in the US and Europe by persons with SCI to perform upright activities of daily living. A single-group, pre/post intervention pilot study was performed to determine the number of sessions and level of assistance needed to execute standing, walking, and stair climbing skills in a powered exoskeleton (ReWalk™). Seven persons with motor-complete paraplegia were studied over an average of 45±20 sessions. Sessions consisted of 1 to 2 hours of standing and overground ambulation for 3 sessions per week. All 7 participants learned to perform sit-to-stand, stand-to-sit, and to walk 50 to 166 m in 6 minutes with none (n=4) to varying levels (n=3) of assistance. Four of 7 participants learned to ascend and descend ≥5 stairs with assistance, and these 4 also achieved some outdoor-specific walking skills. No relationship with achievement of exoskeletal-assisted mobility skills was found with duration or level of SCI; however, the participant with the highest cord lesion (thoracic level 1) did require the most assistance. These preliminary results suggest that exoskeletal-assisted walking and other mobility skills can be performed independently by persons with motor-complete SCI. Future advances in exoskeletal technology and ongoing training may improve overall mobility and independence in the home, work, military, and/or community environments.

1.0 INTRODUCTION

There are approximately 42,000 veterans who have a spinal cord injury (SCI) and are eligible for medical care in the United States Department of Veterans Affairs (DVA). Medical care for veterans with a spinal cord injury or disorder is the largest single network of care in the US with 24 regional VA SCI Services located at VA Medical Centers throughout the USA. As of 2009, it was estimated that each year, after stabilization at a trauma center, about 450 newly injured veterans and active duty service men and women receive rehabilitation in the VA SCI network of care [1].

SCI results in various degrees of neurological deficit and is commonly classified by vertebral level and the degree of completeness of the injury using the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) [2]. Individuals with traumatic, motor-complete SCI abruptly lose the ability to stand and walk, usually spending the rest of their lives dependent on a wheelchair for mobility. The resultant loss of the ability to stand and walk not only adversely alters their mobility, making them dependent on the accessibility of buildings and communities for admittance, but also has the potential to decrease their professional opportunities, social integration, and their health and well-being. The extreme inactivity imposed from paralysis leaves these individuals at risk for many secondary medical conditions, such as adverse body composition alterations [3-5], increased risk for insulin resistance, diabetes and cardiovascular disease [6-11], and difficulty with bowel evacuation [12-14].

Attempts to restore walking abilities by either mechanical devices or intensive locomotor training have been tested. Mechanical devices such as reciprocating gait orthoses (RGOs) or advance reciprocating gait orthoses (ARGOs) have been shown to permit standing and walking in persons with paraplegia. These mechanical devices have had limited success for regular use mostly due to difficulty in acquiring the necessary skill and strength to use them and the high energy costs associated with ambulation [15-17]. Therapy for neurological recovery of walking in persons with incomplete SCI has included overground gait training [18] and locomotor training with the use of body weight supported treadmill training by either a robotic training system (Lokomat) [19, 20] or manual placement of the feet during the treadmill walking [21]. Significant improvement in balance and ambulation has been reported in persons with incomplete SCI after intensive, activity-based therapeutic locomotor training in all modes studied [22, 23]. Significant gains in lower extremity motor scores have also been reported after intensive locomotor training [24]. One limitation of activity-based therapeutic locomotor training programs is the inability to receive or to continue this therapy at home. A viable technology that can be used at home to continue or maintain gains from a hospital-based program does not yet exist, but is obviously needed.

Robotic-assisted powered exoskeletons are a relatively new technology that has been demonstrated in initial studies to be safe and effective for standing and walking in persons with motor-complete paraplegia [25-27]. Zeilig and colleagues studied 6 participants with chronic, motor-complete paraplegia who completed 7 to 24 training sessions. The 6 participants demonstrated an ability to walk 18 to 72 meters in the exoskeletal suit during a six-minute walk test. The investigators reported no falls and that the device was well-tolerated without excessive skin pressure, pain, or cardiovascular or musculoskeletal problems [26]. Esquenazi et al., reported on the distances and velocities of 12 patients with motor-complete paraplegia who were trained to use a powered exoskeleton (ReWalk™). This group concluded that while there was a high degree of variability in performance, most patients were able to walk with skill levels needed for limited community ambulation. Both studies concluded that the ReWalk had significant potential to safely facilitate over ground walking in persons with paraplegia.

Exoskeletons offer the possibility to adapt the paralyzed person to the existing environment, rather than adapt the environment to the wheelchair. Powered exoskeletons may permit the individual with paralysis to perform functional/vocational standing, walking and stair climbing tasks. Restoration of these abilities has the possibility to assist those with SCI to be able to return to alternative military employment or transition to civilian life. Walking on a regular basis may also improve health and well-being. The primary purpose of this study was to identify specific exoskeletal-assisted mobility skills for standing, walking and stair climbing, and to evaluate the number of training sessions and to determine the level of assist needed to achieve these tasks. The secondary goals were to begin to identify additional key indoor and outdoor mobility skills needed for successful home/community use.

2.0 METHODS

Research design and outcomes studied

A single group, pre/post intervention pilot study was performed to determine the number of sessions and level of assistance needed to perform standing, walking, and stair climbing skills in the exoskeleton (ReWalk™).

Participant selection

A convenience sample of interested and eligible participants was enrolled in the study. Persons between 18 and 65 years of age with motor-complete paraplegia from thoracic vertebral level 1 to 12 (T1 to T12) with greater than 6 months elapsed since their SCI, who were between 160 and 190 cm in height, weighed <100 kg, and had the ability to provide their own consent, were included. Potential participants were excluded if they had any of the following: diagnosis of another neurological injury or disease other than SCI, had a lower extremity fracture in the past 2 years, a knee (femoral neck or proximal tibia) bone mineral density (BMD) <0.70 gm/cm^2, a hip T-score <-3.0, severe spasms defined as an Ashworth score of 4.0, flexion contractures limited to 35º at the hip and 20º at the knee, diagnosis of severe lower extremity heterotopic ossification limiting range of motion in the hip or knee joints, atherosclerosis, congestive heart failure, history of myocardial infarction, hypertension (systolic >140 and diastolic >90 mmHg blood pressure), trunk or lower extremity pressure ulcer, pregnant or lactating females, and/or had a severe concurrent medical disease, illness, systemic or peripheral infection, psychopathology, or other condition that the study physician, in his or her clinical judgement, considered to be exclusionary to safely participate. Of the 12 potential participants screened, 5 were excluded: 2 for low BMD, 1 for a medical condition and 2 were not able to participate due to their work schedules. This left 7 persons with motor-complete paraplegia who were eligible and participated in the exoskeletal-assisted walking study. The study was approved by the Institution Review Board at the James J. Peters VA Medical Center, Bronx, NY. Informed consent was obtained from all 12 persons screened after several meetings describing the risks and commitments to the study, allowing time for the participants to think about their decision and ask questions. The operation of the exoskeletal device was explained in detail and videos of a sample ReWalker were shown to each participant prior to the first session. This study was registered at ClinicalTrials.gov, Identifier: NCT01454570.

Exoskeletal device description, participant fittings and device settings

The exoskeleton device was developed to permit a person with paraplegia, who does not have volitional movement of their lower extremities to be able to fully weight bear while standing, to ambulate over ground and to ascend and descend stairs. The system, described from the ground up, includes footplates, bilateral robotic exoskeletons on each thigh and lower leg, hinged knee joints, a pelvic band, strapping mechanisms for the legs, hips and trunk, a tilt sensor located on the left pelvic band that measures trunk forward tilt angle, a backpack which stores the batteries and the computer-based control system, and a remote-control wristband for mode selection. The remote control contains separate selections for standing, walking, sitting, and stair up and down modes. The device requires the use of lofstrand forearm crutches to maintain balance for standing and ambulation.

The upper and lower leg lengths and the hip width were measured in each participant for proper device fitting. Alignment of the exoskeleton's knee and hip joints with the participant's knee and hip joints and proper pelvic band fit were critical for an appropriate fitting to ensure success with use. Once the participant was properly fitted, the device was placed on a chair without armrests to which the participant transferred. The foot plate was placed in the shoe under the insole and then participant's feet were placed in their shoes. The Velcro straps were connected snugly around the chest, abdomen, upper thigh, lower thigh, and calf. A diagram and detailed description of the ReWalk exoskeleton may be found in a report by Esquenazi and colleagues [25]. Once the device was donned, while still seated, the participant places the crutches behind the hips and the "stand" signal was selected from the remote control. During the subsequent 5-second period, the participant used crutches to lean forward in the chair. Three beeps then indicated that the device was standing. Because the user has moved their body weight over their feet, the device stands the participant up with limited effort. As the unit approached its final standing state, the participant continued to lean forward while simultaneously bringing both crutches to the front to a standing balanced position.

During the first session, participants were instructed to maintain their standing balance with both crutches and then to perform weight shift exercises, followed by maintaining their balance with just one crutch. The participant was then instructed to return to a seated position by selecting the "sit" mode on the remote control and having the participant place their crutches behind them, alongside the sides of the chair. The exoskeleton then beeps 3times to signal that it will lower the person slowly back to the seated position. Once the skills of sit-to-stand, standing balance and stand-to-sit tasks were accomplished, the participant was given instructions for stepping and walking. A predetermined tilt angle setting of approximately 6º was used for the first step and subsequent walking. The participant was instructed to weight shift on to the left foot and to lean slightly forward to allow the right foot to be unweighted. The trainer had selected the "walk" mode from the remote control and the participant had a 2-second window to perform the weight shift on to left foot and lean forward for the step initiation. Once the right leg had finished the swing phase, the participant stepped forward and lateral onto the right leg while adjusting the position of the crutches forward in preparation for the next step. This action caused the left leg to be unweighted and allowed it to swing through the step cycle. The participant continued this series of weight shifts and leaning to maintain a continuous walking pattern. Participants were able to halt their stepping/walking by not leaning forward into the 6º of flexion. This preventative action caused the device to stop walking (arrest walking) and trigger the device to go to "stand" mode once a 2 second window had passed. Participants were also able to arrest their walking by planting their swing foot on the ground, which then triggered the device to go back into "stand" mode. Participants were able to slow down their side-to-side shifting motion, which then served to slow down the walking velocity.

Verbal cues for timing of weight shifts, forward flexion at the hip and body position were provided to the participants by the trainers. Body weight support and/or off loading was provided fully by the exoskeletal-device. The level of trainer assistance was quantified by the following four categories of trainer-assisted efforts: 1) maximal assistance (max assist) - the trainer had both hands on the pelvic band of the device and provided significant and frequent weight shift and balance support to the participant during the majority of the mobility activity; 2) moderate assist (mod assist) - the trainer had both hands on the pelvic band or other part of the device and provided occasional weight shift and/or balance support to the participant during the mobility activity; 3) minimal assist (min assist) - the trainer had one hand on the device and provided infrequent balance support; and 4) close contact guard/no assist (CCG/no assist) - the trainer did not have either hand on the device, but was near enough to step in with assistance, if necessary. Heart rate and blood pressure were measured before, during and after each session was completed before the participant returned to a seated position. The participants were asked to provide their overall rating of perceived exertion (RPE) for the entire session using the Borg Scale.

Velocity and speed settings

The ReWalk exoskeleton maximum achievable speed setting was identified as the fastest step time (600 ms) and 0 delay between steps. It was the maximum speed that the unit moved per step (step time per stride, which was 2 x step time + delay time between steps and expressed in ms/stride or ms/step). The maximum speed setting of the ReWalk exoskeleton had no bearing on limb length or the participant who was in it. The ReWalk exoskeleton velocity was the distance walked/time (m/s), which specifically factors in leg length. ReWalk exoskeleton velocity was determined by the speed setting (step time and delay between steps), and stride length (hip flexion, hip extension, and lower extremity length) and as such was individualized for each participant.

Exoskeleton-assisted mobility skills

There were three mobility components for training the participants to use the exoskeleton: standing, walking and stair climbing. The primary standing skills consisted of sit-to-stand, stand-to-sit, double and single arm crutch standing balance, weight shifts, and standing pivot turns. The secondary standing skills included self-activation of the remote-control wristband and retrieving an item from above the head. The primary walking skills included: walking 10 meters and walking pivot turns in both directions. The secondary walking skills included arresting gait on command, maneuvring to a wall rest, walking on carpet, navigating a push button electric door, navigating an elevator, and navigating a revolving door. Additional secondary walking skills for walking outdoors included walking on concrete, uneven ground surfaces, up and down a slight slope, and up and down a curb. Additionally, a set of $\geq$5 steps were used to train and determine ascent and descent of stair skills.

The number of training sessions to achieve the primary standing and walking skills were recorded for each participant and reported in training session blocks (1-2, 3-5, 6-10, 11-15, 16-25, 26-40, and >40). Most training sessions focused on learning the walking skills. Two routinely used walk tests were performed at least on a weekly basis: 10-meter walk test for time (i.e., the time in seconds that it takes to walk 10 meters with a 2 meter lead-in) and a 6-minute walk test for distance (i.e., the number of meters travelled in 6 minutes). A stop watch and wheeled distance meter were used to measure time and distance in both walk tests. The two walking tests were performed in a hospital hallway on a linoleum floor, free of obstacles. Additional skills for indoor standing and walking were taught when possible, and included navigating an automatic push button door, a revolving door and an elevator. Ascending and descending stairs were offered to participants who had achieved 100±20 m in a 6-minute walk test with CCG/no assist and were willing to substitute stair ascent and descent practice for the walking session.

Statistical Analyses

Results are reported individually by participant and as a mean±SD. The number of sessions to achieve exoskeletal-assisted mobility skills were recorded and reported in the blocked sessions, as described above. Two separate linear regression models were used to determine the relationship between best distance or velocity walked and duration and level of injury.

3.0 RESULTS

All 7 participants in the exoskeletal-assisted walking program had motor-complete paraplegia (T1 to T11); 6 were males and 1 was female, with a mean age of 42±12 years. The participants were chronically spinal cord injured from 1.5 to 14 years post SCI at the start of the exoskeletal-assisted walking program. The individual demographic characteristics of the study group are provided (Table 1).

The study group participated in 3 sessions per week of 1 to 2 hours per session for an average of 45±20 sessions, range of 15 to 70 sessions. Generally, during the early sessions (5 to 10), the participants were able to walk for about 30 minutes, but as tolerance, skill and efficiency progressed, the participants were able to perform 1.5 to 2.0 hours per session of actual walking time, thus performing exoskeletal-assisted walking of 4 to 6 hours per week. Participants 2 and 6 were prematurely withdrawn at session 25 and 15, respectively, due to a work-related transfer out-of-state and an unexpected school schedule change.

The number of sessions to achieve the exoskeletal-assisted mobility skills and the trainer level of assist for each participant is provided (Table 2). All 7 participants were able to perform the standing skills of sit-to-stand, one and two-arm crutch balance for 1 minute and stand-to-sit by the first or second sessions (Table 2). Of note, by the second session, 5 of 7 participants were able to perform the standing skills with only close contact guard or minimal assistance, while 2 participants required moderate assistance to perform these skills (Table 2). Dependent upon standing skill level, on the first through third sessions, participants were able to perform weight shifting from foot-to-foot in preparation for walking. All 7 participants were able to walk 10 meters with minimal to maximal assistance by 3 to 5 sessions. Walking with close contact guard or no assistance was achieved in 4 of 7 participants (1 participant walked with no assistance on the third session, 1 participant by 5 to 10 sessions and 2 participants by 10 to 15 sessions). Participants 1, 3, 4, and 5 were able to progress to the secondary walking skills and stair skills by 15 to 25 sessions (Table 2).

The average heart rate responses for the first 30 sessions were measured during each component of the training sessions (Figure 1). During the 6-minWT, participants demonstrated the greatest average heart rates. There was a large amount of variability in all conditions except for that of seated pre walking (Figure 1). The immediate post walking average heart rate, blood pressure and RPE responses across the training sessions are reported for the study group as the averages for session blocks (Table 3). During the first few training sessions, the participants reported a relatively high average RPE of 15±2 units. The RPE decreased over the course of the training sessions to 10±3 units by sessions 26 to 40 (Table 3). This decrease in perceived exertion occurred simultaneously with increased walking distance and duration of the session length, indicating an improved level of efficiency while walking in the device.

There was variability among the participants for skill level of walking velocity, time and distance. The average maximum velocity setting for the 7 patients was 0.508±0.161 m/s (0.389 to 0.814). The best achieved 10-meter walk times and 6-minute walk distances are reported for each participant (Table 4). Participants 3, 4, and 5 achieved the fastest 10-m walk times and walked the greatest distance in 6 minutes (Table 4). The participant with the highest lesion (T1) was the most challenged for performing the walk tests. Linear regression analysis of the group as a whole showed that maximum walking velocity was not related to duration or level of injury (Figure 2).

Skill levels for the secondary standing and walking tasks, as well as the level of independence to perform them are provided (Table 5). All 7 participants were able to transfer into and out of the device and manage the chest, thigh and calf straps independently. Six of 7 participants needed assistance to put their feet into the shoes. Five participants were able to use the remote-control wristband independently. Four participants were able to retrieve an object from a shelf above their head while standing in the device. Five participants were able to perform the secondary indoor walking skills of arresting the walking gait on command, manoeuvring to a wall to rest and navigating a push button door independently and 2 participants performed these skills with assistance. Four participants were able to walk outdoors. The outdoor walking skills and level of independence are reported (Table 5).

There were no study related serious adverse events. In over 500 hours of exoskeletal-assisted walking there were no falls, edema, joint swelling, dysreflexia, or accidental bowel or bladder releases. During the early sessions, 3 participants developed mild skin abrasions after walking. These mild abrasions were resolved with equipment adjustment and additional padding and none resulted in the prevention of participation in training sessions. After increased walking time of up to 2 hours per session, 2 participants developed moderate skin abrasions that were subsequently resolved with equipment adjustment and padding. These moderate abrasions required allowing the skin to heal over about a week prior to re-starting the training sessions. The skin abrasions completely resolved in all cases.

4.0 CONCLUSIONS

Individuals with motor-complete paraplegia demonstrated proficient indoor walking and some outdoor walking skills with the use of the ReWalk exoskeleton. The indoor standing and walking skills were performed safely with no falls, reproducing the findings of two other groups [25, 26]. In addition to demonstrating achievement of walking ability, this study showed that persons with motor-complete paraplegia could perform other indoor skills such as reaching for an item in a cabinet above the head, navigating an automatic door and an elevator, and walking on carpet. Additional support for community-based use of this device was demonstrated in some of the participants who were able to perform outdoor mobility skills such as walking on concrete, uneven ground surfaces, slight slopes, and up or down a curb. To our knowledge, this is the first report of persons with motor-complete paraplegia performing community-based skills in an exoskeleton and warrants support for studies examining the challenges and feasibility of community re-integration.

Indoor- and outdoor-specific exoskeletal mobility was shown to be velocity-dependent. Persons with SCI used a ReWalk to achieve walking distances and velocities needed to ambulate in limited community ambulation settings such as has been identified for the stroke population [28, 29]. van Hedel and colleagues demonstrated that persons recovering from incomplete SCI (AIS C and D) who could walk (with aid) at a minimum velocity of 0.44±0.14 m/s or better were able to walk outdoors [30]. Their work is consistent with our findings in 3 of 7 participants who walked at velocities between 0.42 to 0.50 m/s and were also able to walk outdoors. Ambulation skills, such as walking on uneven terrain, managing a curb or stairs, and walking on an uncrowded side walk, were achieved by 3 of the ReWalkers. Bowden and colleagues demonstrated that the velocity at which gait-impaired persons were able to ambulate had a direct correlation to the environments in which they walking on a daily basis [29].

Using the ReWalk, each participant was challenged to perform characteristic tasks of the environment such as walking through a revolving door or getting to an elevator before the doors closed. The ability to perform these tasks often corresponded to successful achievement of specific walking velocities. Further definition of minimal walking velocities is needed accomplish these additional daily living tasks in a more precise manner for training. This study served as a learning process for the investigators as well as the participants; as such, in retrospect most skills could have been introduced sooner in the training process. Participants were able to perform these tasks in the institutional setting; however, further testing in home, community, or work settings is needed to more precisely evaluate the effect of environmental nuances not replicated in hospital-based simulation.

During various activities, such as ambulation with functional neuromuscular stimulation, graded arm exercise testing, functional electrical stimulated rowing, and wheelchair ergometry, RPE in those with SCI has been demonstrated to correlate with heart rate and oxygen consumption [31-34]. An encouraging finding in our study was that with training the participants were able to tolerate longer sessions and walk greater distances during each session with lower reported RPEs. This finding strongly indicates that a higher level of efficiency was being achieved for the exoskeletal-assisted walking with increased skill in using the device. Unlike other walking devices, such as those classified as unpowered gait orthoses, walking in the ReWalk was well-tolerated for several hours per day.

Functioning in one's surroundings requires practical tolerance of the assistive device, as well as mobility and skill. Participants were progressively challenged to improve their walking velocity; as velocity improved there was a corresponding attainment of upright movement-related skills for other activities of daily living. The findings in these 7 participants with motor-complete paraplegia are strongly supportive for the comfortable use of an exoskeletal-assisted walking device to provide standing, walking and stair climbing mobility skills that are well below the fatigue threshold for use in their home, work and community surroundings. Integration of an exoskeleton for use outside of the institutional setting necessitates the ability to perform environment-specific functional tasks; tasks that would be an extension of the skills attained in the hospital setting.

Figures

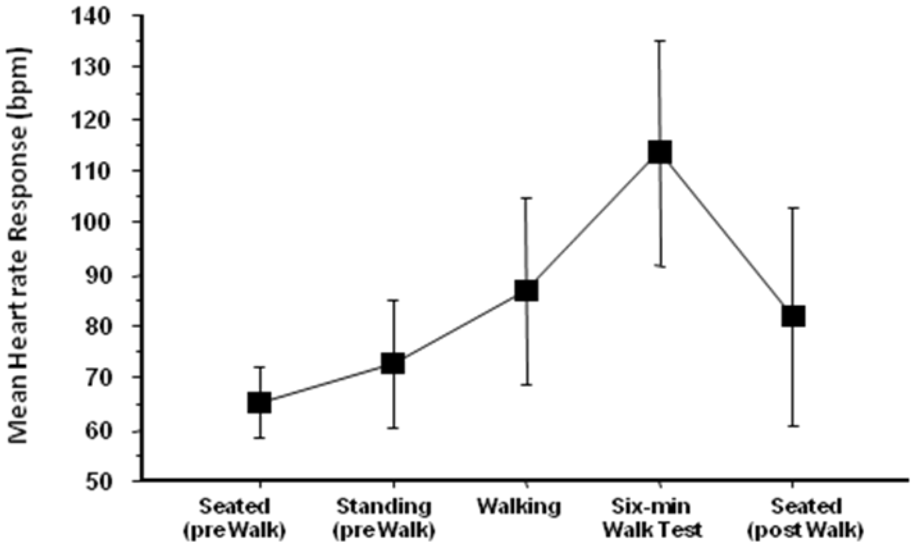

Figure 1: Mean Heart Rate Responses during the Exoskeletal Training Sessions

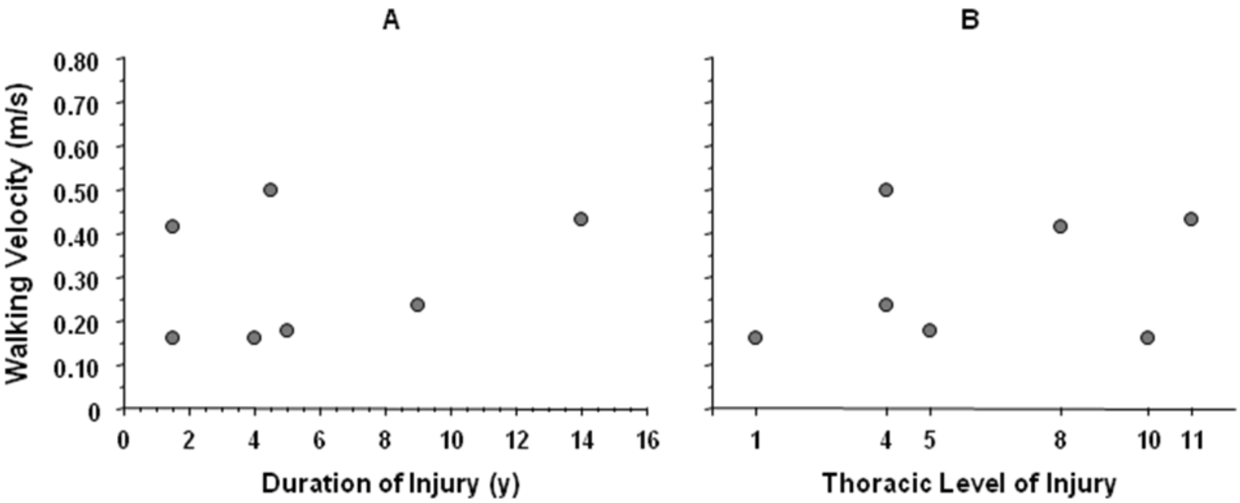

Figure 2: Best Walking Velocity for the 10-meter Walk Test by Duration of Injury (A) and Level of Lesion (B)

Tables

Table 1: Demographic Characteristics of the Study Group

SID#	Age (y)	DOI (y)	Ht (cm)	Wt (kg)	Gender	LOI	AIS	Ethnicity
1	34	9.0	173	66.7	Male	T4	B	Caucasian
2	48	4.0	168	68.0	Male	T10	A	Caucasian
3	44	4.5	183	77.1	Male	T4	A	Asian/Pacific Islander
4	58	1.5	160	64.4	Female	T8	A	Caucasian
5	61	14.0	175	72.6	Male	T11	A	Caucasian
6	24	5.0	185	74.8	Male	T5	A	Caucasian
7	40	1.5	183	88.5	Male	T1	B	Caucasian
Mean	44	5.6	175	73.2				
SD	12	4.1	8	7.5				

SID#=study identification number; y=years; DOI=duration of injury; cm=centimeters; kg=kilograms; T=thoracic; c=cervical; LOI=level of injury; AIS=American Spinal Cord Injury Impairment Scale, where A=complete motor and complete sensory denervation and B=complete motor, but incomplete sensory denervation below the level of lesion; Ethnicity=Caucasian is not of Hispanic origin.

Table 2: Number of Sessions and Level of Assist by Exoskeleton-assisted Mobility Skill and Total Number of Sessions Completed by the Participants

SID#	Standing Skills		Walking Skills		Stair Skills		Total No. of Sessions
	Sessions	Level of Assist	Sessions	Level of Assist	Sessions	Level of Assist	
1	1 to 2	Mod assist	5 to 10*	Mod assist	15 to 25	Mod assist	70 (20*)
2	1 to 2	CCG/NA	10 to 15	CCG/NA	-	-	25
3	1	Min assist	5 to 10	CCG/NA	15 to 25	Mod assist	64
4	1	Min assist	<5	CCG/NA	15 to 25	Mod assist	43
5	1	Min assist	10 to 15	CCG/NA	15 to 25	Mod assist	49
6	1 to 2	Min assist	10 to 15	Min assist	-	-	15
7	1 to 2	Mod assist	10 to 15	Mod assist	-	-	48
						mean±SD	45±20

SID#=study identification number. Mod assist=moderate assistance, trainer has both hands on at all times and assists with balance but not weight bearing; CCG/NA=close contact guard/no assistance, trainer is not touching participant but is there to lend a hand if needed; and Min Assist=minimal assistance, trainer has one hand on for balance. *Represent the number of sessions after start up and staff learning curve for the first participant to complete the skills. Standing skills: sit-to-stand, stand-to-sit, double and single arm crutch standing balance, weight shifts, and standing pivot turns; Walking skills: walk 10 meters and pivot turns in both directions. Stair skills: ascend and descend 5 steps. A dash represents that the participant did not perform these skills.

Table 3: Immediate post Walking Average Heart Rate, Blood Pressure and Rating of Perceived Exertion across the Sessions

Sessions	**HR** (bpm)	**SBP** (mmHg)	**DBP** (mmHg)	**RPE**
1 to 5	89±17	136±16	70±6	15±2
6 to 10	98±19	124±22	68±10	14±2
11 to 15	90±17	132±14	72±10	13±3
16 to 25	89±18	128±16	70±10	11±3
26 to 40	87±18	126±20	68±8	10±3
> 40	106±25	124±18	70±10	8±1

HR=heart rate, bpm=beats per minute, SBP=systolic blood pressure, mmHg=millimeter of mercury, DBP=diastolic blood pressure, RPE=rating of perceived exertion using the Borg scale. Scale range is 6 (no exertion) to 20 (maximal exertion).

Table 4: Best Achieved 10-Meter and 6-Minute Walk Tests

SID#	**10 meter Walk Time**		**6-min Walk Distance**	
	Seconds	**m/s**	**Meters**	**m/s**
1	39	0.256	90.2	0.251
2	62	0.161	50.5	0.140
3	20	0.500	166.0	0.461
4	24	0.417	139.0	0.386
5	23	0.435	137.4	0.382
6	56	0.179	60.2	0.167
7	61	0.164	50.8	0.141
Mean	41	0.302	99.1	0.275
SD	19	0.145	48.0	0.133

SID#=study identification number; m/s = meters per second; Note: the 4 fastest participants (#'s 1, 3, 4, & 5) were also able to walk outside.

Table 5: Number of Participants who Achieved Skills for Additional Tasks

	Performs Task		Unable to Perform Task	Not Tested*
	No Assistance	With Assistance		
Donning/doffing Device				
transfer in	7			
transfer out	7			
manages chest straps	7			
manages thigh straps	7			
manages calf straps	7			
feet in/out of shoes	1	6		
Secondary Indoor Standing Skills				
self-activate the remote watch	5		2	
retrieve item from above head	4	1		2
Secondary Indoor Walking Skills				
arrest gait on command	5	2		
maneuver to a wall rest	4	3		
walk on carpet	2	2	2	1
navigate a push button door	5	2		
navigate an elevator	4			3
navigate a revolving door	3			4
Outdoor Walking Skills				
walk on concrete	3	1	1	2
walk on uneven ground surface	3	1	2	1
walk up or down a slight slope	2	2	2	1
walk up or down a curb		3	2	2

*Reasons for "Not Tested" included early study withdrawal in 2 participants and location and distance from the laboratory to perform the task.

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