Time and Effort Required by Persons with Spinal Cord Injury to Learn to Use a Powered Exoskeleton for Assisted Walking

Allan J. Kozlowski, PhD,¹ Thomas N. Bryce, MD,¹ and Marcel P. Dijkers, PhD¹

¹Department of Rehabilitation Medicine, Icahn School of Medicine at Mount Sinai, New York New York

Background: Powered exoskeletons have been demonstrated as being safe for persons with spinal cord injury (SCI), but little is known about how users learn to manage these devices. **Objective:** To quantify the time and effort required by persons with SCI to learn to use an exoskeleton for assisted walking. **Methods:** A convenience sample was enrolled to learn to use the first-generation Ekso powered exoskeleton to walk. Participants were given up to 24 weekly sessions of instruction. Data were collected on assistance level, walking distance and speed, heart rate, perceived exertion, and adverse events. Time and effort was quantified by the number of sessions required for participants to stand up, walk for 30 minutes, and sit down, initially with minimal and subsequently with contact guard assistance. **Results:** Of 22 enrolled participants, 9 screen-failed, and 7 had complete data. All of these 7 were men; 2 had tetraplegia and 5 had motor-complete injuries. Of these, 5 participants could stand, walk, and sit with contact guard or close supervision assistance, and 2 required minimal to moderate assistance. Walk times ranged from 28 to 94 minutes with average speeds ranging from 0.11 to 0.21 m/s. For all participants, heart rate changes and reported perceived exertion were consistent with light to moderate exercise. **Conclusion:** This study provides preliminary evidence that persons with neurological weakness due to SCI can learn to walk with little or no assistance and light to somewhat hard perceived exertion using a powered exoskeleton. Persons with different severities of injury, including those with motor complete C7 tetraplegia and motor incomplete C4 tetraplegia, may be able to learn to use this device. **Key words:** adverse events, ambulation, assistive technology, exercise, exoskeleton, spinal cord injury, walking

Of the estimated 250,000 persons in the United States living with a spinal cord injury (SCI),¹ most have permanent impairments that make walking, with or without traditional assistive devices, difficult, if not impossible.² The options for persons with SCI who do not have the requisite strength in the muscles supporting the hip and knee to allow overground walking include knee-ankle-foot orthoses (KAFOs), isocentric reciprocating gait orthoses, and other similar devices, typically used in combination with forearm crutches. However, users of such devices face high energy demands³⁻⁵ and significant stresses to upper extremity musculoskeletal structures.⁶ Consequently, most abandon the use or at least the frequent use of such orthoses soon after learning to master them,⁷⁻¹¹ and they continue to use wheelchairs as their primary means of mobility.

Although some persons with SCI use manual wheelchairs for exercise, sports, and competition, most wheelchair use leads to a sedentary lifestyle, as simply pushing the wheels while performing daily routines may not result in adequate exercise. These individuals are at risk for secondary problems, including pressure ulcers,¹² obesity,^{13,14} diabetes mellitus,¹⁵ osteoporosis,¹⁶ and other chronic health conditions that increase the risk of mortality.^{17,18}

Body weight-supported treadmill training (BWSTT), introduced about 20 years ago, provides stationary “walking” opportunities to persons with SCI using robot-assisted (eg, Lokomat)¹⁹ or clinician-assisted stepping,²⁰ and it may reduce secondary complications.^{21,22} BWSTT has been associated with decreased spasticity²³⁻²⁶ and spasticity medication use,²⁷ decreased pain intensity²³ and pain medication

Corresponding author: Allan J. Kozlowski, PhD, BSc (PT), Department of Rehabilitation Medicine, Icahn School of Medicine at Mount Sinai, 1 Gustave L. Levy Place, Box 1240, New York, NY 10029; phone: 212-824-8378; fax: 212-348-5901; e-mail: allan.kozlowski@mssm.edu

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use,²⁷ cardiovascular changes including reduced blood pressure (BP) variability in sitting and standing,^{28,29} reduced resting heart rate (HR),³⁰ improved blood lipid profile,³¹ and improved glucose regulation.³² Muscle cross-sectional area and mass of the leg muscles increase,^{31,33-35} and perceived quality of life (QOL),²⁵ overall psychological well-being,³⁶ life satisfaction,^{34,36} and satisfaction with physical function^{34,36} also appear to improve with BWSTT. BWSTT provides exercise, but because walkers are suspended over the treadmill, they do not gain mobility, unless the walking results in neuroplasticity and other changes that improve the capacity for overground walking, with or without orthoses and/or crutches.³⁷

Powered exoskeleton technology to assist overground walking may offer a mobility alternative to wheelchair use.³⁸⁻⁴¹ As the effects of BWSTT and walking with lower extremity orthoses may be similar,⁴² exoskeleton-assisted walking might also mitigate the previously described secondary consequences of SCI through an exercise effect.

Early reports have described the safety and tolerance of exoskeleton-assisted walking,^{43,44} outlined protocols for training,^{45,46} and examined body composition changes⁴⁷ and ground force reactions⁴⁸ for persons with paraplegia using powered exoskeletons. The purpose of this study is to describe the time and effort required by a small sample of persons with paraplegia and tetraplegia to learn to use a powered exoskeleton. Our objectives were to determine, for those who could learn to use the device, the time taken to achieve walking with 2 levels of assistance (effort) and to identify benefits reported by users beyond the ability to walk.

Methods

We used a longitudinal cohort design with a convenience sample. The study was approved by our institutional review board, and all subjects gave signed informed consent.

The first-generation Ekso (Ekso Bionics, Richmond, CA) is a wearable robot that consists of an exoskeleton framework for the lower limbs with (1) electric motors to power movement for the hip and knee joints, (2) passive spring-loaded ankle joints, (3) foot plates on which the user stands, and

(4) a backpack that houses a computer, battery supply, and wired controller (**Figure 1**). The rigid backpack, in addition to carrying the computer and batteries, is an integral structural component of the exoskeleton and provides support from the posterior pelvis to the upper back. The exoskeleton attaches to the user's body with straps over the dorsum of the foot, anterior shin and thigh, abdomen, and anterior shoulders. The limb and pelvic segments are adjustable to the user's leg and thigh length, and the segment across the pelvis is adjustable for hip width and hip abduction angle.

The instruction protocol established by the manufacturer has users starting to stand and walk with help of a front-wheeled walker and with the exoskeleton attached to a ceiling rail tether. Although the device provides all the power required to stand up, sit down, and walk, the instructor (a physical therapist [PT]) initially provides assistance to maintain the user's center of mass over the base of support to prevent falling. At first, steps are initiated one at a time by the instructor as the user is guided to a position of stance on one foot. The onboard computer coordinates the knee and hip movement needed, given the user's physical size characteristics, to achieve the desired step. As the user learns to weight-shift to a stance position, the exoskeleton can be set to automatically trigger steps when the user hits preset targets for forward and lateral weight shifts onto the stance leg. Users also progress from standing up, walking, and sitting down with a front-wheeled walker to using Lofstrand crutches. Over time, instructors reduce the level of assistance they provide and increase the duration of walking during a session.

We established our inclusion and exclusion criteria for this study (**Table 1**) based on the manufacturer's recommendations, which include general limits for height and weight, limb segment length, segment discrepancies, and hip width. Additional exclusion criteria included medical instability and risk of bone fracture as determined by the physician screener, an inability to tolerate standing, and insufficient joint and muscle function to permit exoskeleton-assisted walking. We recruited participants through e-mails sent to a distribution list, posters, and physician referral. Those interested in the study were provided with the general screening criteria and asked to screen

Figure 1. Ekso powered exoskeleton.

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • Lower extremity weakness/paralysis due to spinal cord injury, Guillain-Barré syndrome, multiple sclerosis, or generalized weakness caused by other conditions^a • Height between 5 ft, 2 in. and 6 ft, 2 in. (1.6 m to 1.9 m)^b • Weigh 220 lbs (100 kg) or less • Hip width in the standing position 16.5 in. (42 cm) or less • Upper leg length discrepancy ≤ 5 in. (1.3 cm) or lower leg discrepancy ≤ 7.5 in. (1.9 cm) • Independent with static sitting balance and level transfers from wheelchair to bed • Sufficient functional upper extremity strength to manage a front rolling walker or crutches • Currently involved in a standing program or passed a 30-minute standing frame trial prior to evaluation. • Modified Ashworth score of 2 or less in both lower extremities • Able to safely follow directions 	<ul style="list-style-type: none"> • Weightbearing restrictions • Spinal instability (or spinal orthotics unless cleared by a physician) • Unresolved deep vein thrombosis • Significant osteoporosis that prevents safe standing or may increase the risk of fracture caused by standing or walking • Uncontrolled autonomic dysreflexia • Skin integrity issues on surfaces that would contact the device or on buttocks • Limited range of motion, as follows: <ul style="list-style-type: none"> ◦ <u>Hip</u>: less than 5° degrees of extension or less than 110° of flexion ◦ <u>Knee</u>: less than full extension or less than 110° of flexion ◦ <u>Ankle</u>: less than 0° of dorsiflexion or less than 25° plantarflexion ◦ <u>Shoulder</u>: less than 50° of shoulder extension • Pregnancy • Colostomy • Any other medical or other issue that might prevent safe standing or walking

^aPersons who are functional walkers over short distances MAY be appropriate candidates.

^bAlthough height is used as a "screener," leg segment measurements actually determine candidate suitability. The Ekso can accommodate persons with thigh lengths between 51 and 61 cm and leg lengths between 48 and 64 cm.

themselves in or out. Those who screened in and provided signed informed consent underwent a medical review by a physiatrist who specializes in SCI rehabilitation. Candidates who passed the medical review were evaluated by a PT for fit and suitability for walking based on limb segment and pelvic measurements and assessments of joint range of motion, spasticity, and standing tolerance. Candidates who passed the PT examination were set up in the exoskeleton for a standing and walking trial, and those who succeeded in the trial were scheduled for instruction sessions. We report participant characteristics for age at enrollment, neurological level of injury (NLI), American Spinal Injury Association Impairment Scale (AIS) category for completeness of injury, time since SCI, height, weight, and body mass index (BMI).

Participants were provided up to 24 sessions of instruction that were scheduled once or twice weekly. Each session was up to 2 hours in length and included transferring into the device arranged on an office chair; donning, standing, walking, sitting, doffing; and transferring out of the exoskeleton. As participants progressed to require less assistance and tolerate longer walk times, they were also challenged with more advanced tasks, such as walking on carpet and rough concrete surfaces; going up and down ramps

(up to 8% grade); opening doors; pushing button to summon, entering, and exiting elevators; and standing at a counter and retrieving an item from a high cupboard.

We defined time and effort as the number of sessions required to use the exoskeleton to stand up, walk for at least 30 minutes, and sit down with little or no assistance. We measured standing/sitting and walking by the level of assistance reported by the PT using a rating scale adapted from the FIM (**Table 2**). This adapted scale has not been validated. Our primary outcome was the number of sessions needed to achieve a rating of “minimal assistance” and the number of sessions required until the rating became “contact guard only” for standing/sitting and for walking.

Secondary outcomes include measures of walking tolerance and physical exertion. We report walking tolerance as the participant’s achievements (walk time [time spent taking steps], up time [time spent standing and taking steps], number of steps, and approximate distance walked) during his/her longest walk and for the 2-minute walk test (distance walked). Walk time, up time, and number of steps are recorded by the exoskeleton’s computer. We report heart HR, BP, and ratings of perceived exertion (RPE) on the 6- to 20-point Borg scale^{49,50} as indicators of physical exertion. HR and BP were

Table 2. FIM rating scale and the adapted rating scale for exoskeleton-assisted walking

Score	FIM descriptor	Exoskeleton assistance scale descriptor
No assistance required		
7	Complete independence	Complete independence (no supervision needed)
6	Modified independence (patient requires use of a device, but no physical assistance)	Close supervision (helper is nearby but does not need to touch the person or the exoskeleton)
Assistance required (modified dependence)		
5	Supervision or setup	Contact guard (user provides 100% of effort; helper maintains touch or near-touch contact, but provides no assistance)
4	Minimal contact assistance (patient can perform 75% or more of task)	Minimal assistance (user provides 75% or more of effort required to perform task, but less than 100%)
3	Moderate assistance (patient can perform 50% to 74% of task)	Moderate assistance (user provides 50%-74% of effort required to perform task)
Assistance required (complete dependence)		
2	Maximal assistance (patient can perform 25% to 49% of task)	Maximal assistance (user provides 25%-50% of effort required to perform task)
1	Total assistance (patient can perform less than 25% of the task or requires more than one person to assist)	Total assistance (user provides less than 25% of effort required to perform task)

measured in sitting pre-session, immediately upon sitting down post-session, and in standing at mid-session, whereas RPE was measured in standing at all 3 points. We estimated metabolic equivalent of task units (METs) using a prediction equation based on the ratio of exercise HR to resting HR, using the mid- and pre-session HRs, respectively.⁵¹ It should be noted that the estimates for the participants with tetraplegia may not be valid, as the prediction equation was developed for persons with paraplegia.⁵¹ We also report the lowest level of assistance required for donning and doffing in any session and the acquisition of advanced skills such as walking on carpets and ramps. We monitored participants for any adverse events and documented other benefits reported anecdotally by participants at any time during the study. Adverse events of special interest included falls as well as abrasions or pressure sores resulting from the device.

For the cohort, we assessed time and effort with survival analysis that models the time elapsed for one or more events to occur. For time, we used the number of sessions users needed to learn to use the exoskeleton for the events of effort (initially with minimal assistance and subsequently with contact guard assistance) for standing/sitting and for walking, respectively. We also report median number of sessions needed to reach both levels of assistance, with the 95% confidence intervals (95% CIs), and provide appropriate descriptive statistics for secondary outcomes.

Results

Of the 22 participants enrolled (all males), 9 screen-failed (1 for a medical condition, 1 for limb length discrepancy, and 7 for insufficient joint range of motion), and 6 had incomplete data on the primary outcome (4 participated only in one training session, and 2 completed training before the final data collection protocol was set). The 7 participants with sufficient data ranged in age from 21 to 49 years, height from 1.75 to 1.89 m, weight from 64 to 89 kg, BMI from 20.1 to 27.2, and time since injury from 0.4 to 7.4 years (**Table 3**). Two participants had tetraplegia and 5 paraplegia; 5 had motor-complete injuries (AIS A or B). Two participants completed fewer than 20 sessions because of excessive missed sessions, which were claimed to be due to transportation issues. Participants completed all sessions without any of the screened for or other adverse events, although some had post-session blanchable erythema of the skin at the thigh and/or shank strap locations that resolved quickly. One participant presented with mild pedal edema bilaterally before a session, likely resulting from a reported change in medication, that did not worsen with walking.

Six participants managed to walk with minimal assistance in a median (95% CI) of 8 (5.4-10.6) sessions, and 5 of them achieved contact guard or close supervision assistance in a median of 15 (7.8-22.2) sessions (**Figure 2A** and **Table 4**). Likewise, 6 participants managed to stand/sit with

Table 3. Participants' injury and other characteristics

Subject ID	Age class, years	NLI	AIS	TSI	Height (m)	Weight (kg)	BMI
5	16-30	T8	A	<1	1.75	73	23.6
12	16-30	C8	B	<1	1.88	82	23.1
13	31-45	C4	C	6-10	1.78	64	20.1
14	46-60	L1	C	<1	1.78	82	25.8
15	16-30	T9	A	<1	1.83	82	24.4
19	31-45	T9	A	1-5	1.89	89	25.1
24	46-60	T10	C	<1	1.80	89	27.2
Median	36	T9	B	0.5	1.78	82	24.4

Note: AIS = American Spinal Injury Association Impairment Scale; BMI = body mass index; NLI = neurological level of injury; TSI = time since injury (year category).

Figure 2. (A) Survival curves for number of sessions required for 2 levels of assistance with walking and (B) standing and sitting.

Table 4. Participants' best achievements

Subject ID	Session ^a	Longest walk				2-minute walk		Least assistance needed	
		Walk time, min	Up time, min	Distance, m	Steps, n	Distance, m	Speed, m/s	Stand/sit	Walk
5	20/24	94	107	670	2,616	17.9	0.15	CG	CG
12	19/24	62	80	427	1,601	24.9	0.21	CS	CS
13 ^b	10/20	28	68	110	561	13.8	0.11	Mod	Min
14	17/17	49	62	366	1,761	22.0	0.18	CS	Min
15	18/20	39	57	183	904	16.3	0.14	CG	CG
19	7/8	52	69	274	1,040	16.2	0.13	Min	Min
24	21/21	71	87	667	2,190	17.1	0.14	CS	CS

Note: CS = close supervision; GC = contact guard; Max = maximal; Min = minimal; Mod = moderate.

^aSession number for longest walk/total sessions provided.

^bThis participant's best effort was performed with a front-wheeled walker. The best effort with crutches was walk time 28 minutes, up time 58 minutes, steps taken 359, 2-minute walk distance 11.3 m, and walk speed 0.9 m/s with minimal assistance.

minimal assistance in 8 (5.4-10.6) sessions, and 5 of these were able to stand/sit with contact guard assistance or less in 18 (8.3-27.7) sessions (**Figure 2B** and **Table 4**). Their longest walks ranged from 561 to 2,616 steps and were performed in 28 to 94 minutes of walk time and 57 to 107 minutes of up time (**Table 4**). Their longest 2-minute walk test distances ranged from 13.8 to 24.9 m with average speeds of 0.11 to 0.21 m/s (**Table 4**). Five participants walked on carpet and 5 walked up and down ramps with grades of 5% to 8%, all with minimal to moderate assistance; 3 were able to position themselves at a counter and independently retrieve an item from a high cupboard, and 1 was able to independently open doors (inward and outward). All participants could push the button to summon the elevator, but they usually required the doors to be held for them to enter and exit, largely because at the training site any of 4 elevator cars could arrive and the doors remained open for 15 seconds only.

All participants demonstrated HR changes and reported RPEs consistent with light to moderate exercise (**Table 5**). At pre- and at mid-session, median HR measurements ranged from 75 to 104 and 72 to 132, respectively, and median RPEs ranged from 6 to 13 and 8 to 15, respectively. The pre- to mid-session HR ratios represented estimated METs ranging from 1.0 to 3.9. Participants also demonstrated BP changes indicative of light to moderate intensity exercise (increased systolic pressures mid-session with relatively stable

diastolic pressures), although measurements pre-, mid-, and post-session were highly variable.

Donning the exoskeleton took users 5 to 10 minutes and doffing took less than 5 minutes, excluding transfer times from the wheelchair to the office chair or vice versa. Only 1 participant with C4 tetraplegia was not independent in transfers to and from the exoskeleton. Three participants with paraplegia demonstrated the ability to self-don and -doff, and 2 required assistance (1 with foot and shank straps and 1 with the lumbar support). Participants with tetraplegia required assistance with positioning their feet and legs and applying all of the straps.

Participants reported some secondary benefits to exoskeleton-assisted walking: 2 noted more regular bowel movements that were easier to manage after walking sessions, 2 reported improved sitting balance and posture, 3 claimed sleeping better after walking sessions, and 1 reported reductions in pain and spasticity with reduced need for medications. All expressed a desire to continue routine walking in an exoskeleton.

Discussion

Our study quantified the time and effort required by 7 persons with motor complete and incomplete paraplegia, motor complete C8 tetraplegia, and motor incomplete C4 tetraplegia to learn to use a powered exoskeleton. All but 1 participant with

Table 5. Indicators of exertion

Subject ID	No. of sessions received	Heart rate			Borg RPE			METs ^a Median (minimum -maximum)
		Median (minimum - maximum)			Median (minimum - maximum)			
		Pre-session	Mid-session	Post-session	Pre-session	Mid-session	Post-session	
5	24	75.5 (58-106)	106 (74-130)	88 (89-98)	6 (6-8)	8 (6-10)	10.5 (8-15)	2.6 (1.7-3.7)
12	24	76 (56-105)	94 (67-105)	78 (53-103)	6 (6-13)	9 (6-13)	9 (6-12)	2.1 (1.2-3.9)
13	20	76.5 (68-115)	117.5 (83-134)	93 (72-112)	13 (11-20)	15.5 (12-20)	18.5 (14-20)	2.8 (1.0-3.5)
14	17	77(52-98)	72 (57-106)	79 (55-98)	9 (6-11)	10 (6-12)	11 (6-12)	1.6 (1.1-2.0)
15	20	71 (60-96)	104 (71-136)	89 (65-122)	7 (7-9)	9 (7-11)	9 (7-12)	2.8 (1.5-3.6)
19	8	77.5 (55-89)	100.5 (62-104)	88 (64-97)	6 (6-8)	7.5 (6-10)	7.5 (7-11)	2.2 (1.8-3.4)
24	21	104 (86-114)	132 (60-154)	108 (94-135)	7 (6-10)	9 (7-14)	10 (9-17)	2.1 (0.6-3.2)

Note: HR = heart rate; METs = metabolic equivalent of task units, predicted as 2.49 (Mid-HR/Pre-HR) - 0.99⁵¹; RPE = rating of perceived exertion.

^aMET values are predicted from an equation based on sample of persons with paraplegia⁵¹ and may not be valid for persons with tetraplegia or high paraplegia.

the highest NLI could stand, walk, and sit with no more than minimal assistance, and half did so by session 8. The activity was reported as enjoyable, seemed to provide mild-to-moderate intensity exercise, and did not require undue exertion or result in adverse events. This small cohort study provides insights from which we can speculate about future research and the roles that powered exoskeletons could play in community life and rehabilitation for persons with SCI.

Although the sample was too small to support strong conclusions, time since injury and age may be more important factors in learning to use an exoskeleton than NLI (at least up to C8 or C7) or completeness of injury. The fastest learners were younger and more recently injured than the slowest ones. The participant with C4 AIS B tetraplegia was one of the fastest to learn and most skilled at using the exoskeleton, walking with crutches and minimal assistance in session 4 and contact guard assistance in session 10; whereas the participant with L1 AIS C paraplegia did so in sessions 9 and 10, respectively. However, these and other characteristics, including the skill and confidence of the PT instructors, are likely factors that interact in complex ways to influence users' ability to learn and consequently the number of sessions they require to achieve independence.

With respect to level of assistance needed, our findings are comparable to those of a study using a different brand of device in which over half the participants attained close supervision in 5 to 15 sessions, although they walked at speeds of 0.16 to 0.50 m/s in a 10-meter walk test.⁴⁶ Participants' longest walk times and distances in a study using the same device ranged, respectively, from 28 to 60 minutes and 107 to 523 m with a walker or crutches, but these were achieved in 6 sessions.⁴⁴ Most of those participants with paraplegia learning to use the Ekso exoskeleton required moderate assistance to don and doff and improved by 1 level of assistance over 6 sessions.⁴⁴ In contrast, persons with paraplegia learning to use a different device (ReWalk) were independent with fastening the leg, thigh, and torso straps but not their shoes,⁴⁶ presumably due to the configuration of the in-shoe footplate. Measurements of HR and RPE for users of the other device were also consistent with light to moderate exercise, although RPE decreased with

longer duration walks for those who performed more than 40 sessions.⁴⁶ Also comparable were the anecdotal reports of improvements in pain,⁴⁵ spasticity,^{44,45} bowel function,⁴⁵ and bladder function.⁴⁵ These improvements and changes to other secondary conditions will require systematic evaluation.

A recent software upgrade to the exoskeleton we used in this study allows adjustment of the contribution of the motors bilaterally or unilaterally, which may provide a means to grade the exercise intensity for persons with some lower extremity large muscle function (eg, those with AIS C injuries), allowing them to work at higher target heart rates than is possible with the previous full-assist mode or perhaps even through pushing a wheelchair. It needs to be explored whether variable-assist exoskeleton walking differs in intensity from BWSTT.

The currently available exoskeletons have some limitations in clinical practice and personal use. The first-generation Ekso was marketed specifically for use in rehabilitation treatment and research. It is not approved for home use, nor was it designed for independent, unsupervised use. The design of and manufacturer's conditions for use of other exoskeletons may, however, permit more independent walking in the community. In 2014, the US Food and Drug Administration (FDA) approved marketing of the ReWalk Personal System for persons with SCIs from T7 to L5 when accompanied by a specially trained caregiver.⁵² For persons with SCIs from T4 to T6, the use of the ReWalk remains limited to rehabilitation institutions. Regardless of availability for home or institutional use, purchase cost of either device remains a barrier to access.

Studies have demonstrated the time and effort required for routine walking with the ReWalk^{43,45,46} and safety of Ekso for persons with paraplegia.⁴⁴ We have extended this evidence to include the time and effort required by selected persons with tetraplegia to learn to use the Ekso. The next wave of studies should focus on the body structures, body functions, and activities that can be expected to change in periods of up to a few months of regular exoskeleton use, such as neuropathic and musculoskeletal pain, spasticity, bowel function, sitting balance and posture, and mood and

depression. Longer timeframes may be required to evaluate changes to cardiovascular regulation, bone health, and restrictions of participation such as employment.

Exoskeletons can serve several functions for persons with SCI: (a) mobility alternative to a wheelchair; (b) exercise modality to promote physical, mental, and social wellness; (c) gait training modality used in inpatient or outpatient rehabilitation; (d) facilitating environment for plasticity in which neurologic repair can take place; or (e) some combination thereof. Research is needed to examine the ability of individuals to safely and effectively use specific exoskeleton brands and models in institutional, home, and community environments as these devices become available for these applications.

Limitations

Recruitment and retention of participants are very difficult for studies with intensive interventions, and it is extremely expensive to conduct these studies because of the treatment staffing needs. Therefore, although statistically larger studies are preferable, in practice, we need to learn what we can from intensive studies of a relatively small number of participants. Descriptive results for a small convenience sample in a preliminary study may not generalize to the population of persons with SCI; we lack power to statistically identify the personal and injury characteristics associated with the ability to learn to walk using the exoskeleton. We enrolled no female participants and did not provide training beyond 24 sessions. Measurement properties of our clinician-rated scale for level of assistance have not been examined.

Conclusion

Our early findings indicate that a wide range of persons with SCI, including those with tetraplegia (motor complete C7 and motor incomplete C4), can learn to use the Ekso, although some users may continue to require minimal or even moderate assistance beyond 24 instruction sessions, regardless of injury level or completeness. Trials with large, diverse participant samples are needed to determine who can use these devices

with confidence and the role of the devices in household and community mobility and as a way to provide exercise. Larger studies are also needed to examine the potential of exoskeleton walking to facilitate neuronal plasticity and recovery following SCI.

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Device status: This article describes the use of the Ekso Generation 1 powered exoskeleton device by persons with spinal cord injury. At the time of data collection, the Ekso Generation 1 was registered as a Class 1 device (Exerciser, Powered) with the US Food and Drug Administration (FDA), Registration Number (3009495988). The Ekso Generation 1 powered exoskeleton has been marketed by Ekso Bionics for use in clinical rehabilitation by persons with spinal cord injury or other similar neurological weakness, under the supervisor of a physical therapist trained and certified by Ekso Bionics. Ekso Bionics has since provided notice of intent to submit a 510(k) submission to the FDA seeking reclassification of the Ekso as a Class 2 device (Powered Exoskeleton).

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