Assessment of In-Hospital Walking Velocity and Level of Assistance in a Powered Exoskeleton in Persons with Spinal Cord Injury

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Background: Individuals with spinal cord injury (SCI) often use a wheelchair for mobility due to paralysis. Powered exoskeletal-assisted walking (EAW) provides a modality for walking overground with crutches. Little is known about the EAW velocities and level of assistance (LOA) needed for these devices. **Objective:** The primary aim was to evaluate EAW velocity, number of sessions, and LOA and the relationships among them. The secondary aims were to report on safety and the qualitative analysis of gait and posture during EAW in a hospital setting. **Methods:** Twelve individuals with SCI ≥1.5 years who were wheelchair users participated. They wore a powered exoskeleton (ReWalk; ReWalk Robotics, Inc., Marlborough, MA) with Lofstrand crutches to complete 10-meter (10MWT) and 6-minute (6MWT) walk tests. LOA was defined as modified independence (MI), supervision (S), minimal assistance (Min), and moderate assistance (Mod). Best effort EAW velocity, LOA, and observational gait analysis were recorded. **Results:** Seven of 12 participants ambulated ≥0.40 m/s. Five participants walked with MI, 3 with S, 3 with Min, and 1 with Mod. Significant inverse relationships were noted between LOA and EAW velocity for both 6MWT (Z value = 2.63, Rho = 0.79, P = .0086) and 10MWT (Z value = 2.62, Rho = 0.79, P = .0088). There were 13 episodes of mild skin abrasions. MI and S groups ambulated with 2-point alternating crutch pattern, whereas the Min and Mod groups favored 3-point crutch gait. **Conclusion:** Seven of 12 individuals studied were able to ambulate at EAW velocities ≥0.40 m/s, which is a velocity that may be conducive to outdoor activity-related community ambulation. The ReWalk is a safe device for in-hospital ambulation. **Key words:** *community ambulation, gait analysis, gait velocity, level of assistance, paralysis, powered exoskeleton, ReWalk, spinal cord injury*

Wearable robotic devices to enable persons with paralysis to ambulate overground have been explored for persons with spinal cord injury (SCI) for over 40 years.[1] Limited success was achieved due to restrictions in material, design, and battery life. Modern day exoskeletons permit persons with SCI to walk overground using crutches. For these devices to become applicable in a paralyzed person's daily life, they need to allow the user to move safely at speeds conducive to performing various activities. In persons with incomplete SCI, a walking velocity of 0.40 m/s is considered to be the threshold that separates limited community ambulators from wheelchair community users.[2]

Although the efficacy of exoskeletal-assisted walking (EAW) in mitigating the secondary medical consequences of SCI is uncertain, persons with nonambulatory, chronic SCI have known risks for osteoporosis,[3-5] obesity,[6-9] coronary heart disease,[10-12] diabetes,[13,14] and impairments in bowel function.[15,16] In addition, they have significant loss in quality of life due to issues with employment, marriage, and community integration.[17] Rehabilitative interventions such as partial body weight–supported treadmill walking studies have shown improvements in self-reported wellness, as well as cardiovascular and metabolic benefits.[18-20] However, these improvements are transient and revert to previous levels after training has been discontinued. Consistent EAW in

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Top Spinal Cord Inj Rehabil 2015;21(2):100–109

www.thomasland.com

doi: 10.1310/sci2102-100

a home or community setting could provide such long-term benefits to persons with SCI.

Little is known about the EAW velocities and the level of assistance (LOA) needed for these devices. Our primary aim was to evaluate EAW velocity, number of sessions, and LOA and the relationships among them. The secondary aims were to report on safety and the qualitative analysis of gait and posture during powered EAW in a controlled, hospital setting.

Methods

Setting

Data were collected at Veterans Affairs Rehabilitation Research & Development National Center of Excellence for the Medical Consequences of Spinal Cord Injury, James J. Peters VA Medical Center, Bronx, New York.

Selection

Adults between 18 and 65 years old with chronic (>6 months) motor complete and incomplete paraplegia due to traumatic or nontraumatic SCI at low cervical level and below were eligible for the study. All participants were prescreened for eligibility (**Table 1**) and provided signed informed consent. Consented participants were screened for bone mineral density (BMD) using dual-energy x-ray absorptiometry (DXA) and fracture history. A custom measurement of the distal femur and proximal tibia was obtained according to the procedures described by Shields.[21] A review of the participants' medical records and a physical examination by the study physician were performed. The International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) were used to measure neurological injury level, and the injury was classified according

Table 1. Inclusion and exclusion criteria

Inclusion criteria

1. Do you have paraplegia ?
2. Is your SCI greater than 6 months ?
3. Are you between the ages of 18 to 65 years ?
4. Is your height between 160 and 190 cm ?
5. Do you weigh less than 100 kg ?
6. Are you legally able to sign for your own consent ?

Exclusion criteria

1. Diagnosis of neurological injury other than SCI including:
    a. Multiple sclerosis,
    b. Stroke,
    c. Cerebral palsy,
    d. Amyotrophic lateral sclerosis,
    e. Traumatic brain injury,
    f. Spina bifida,
    g. Parkinson's disease, or
    h. Other neurological condition that the study physician considers in his/her clinical judgment to be exclusionary;
2. Severe concurrent medical disease, illness, or condition;
3. Recent lower extremity fracture within the past 2 years;
4. DXA results indicating a t-score below -3.0 at the lumbar spine and bilateral proximal femurs;
5. Knee BMD <0.70 g/cm^2;
6. Systemic or peripheral infection;
7. Atherosclerosis, congestive heart failure, or history of myocardial infarction;
8. Trunk and/or lower extremity pressure ulcers;
9. Other illness that the study physician considers in his/her clinical judgment to be exclusionary;
10. Severe spasticity (defined by an Ashworth score of >4.0 or clinical impression of the study physician or physical therapist);
11. Significant contractures defined as flexion contracture limited to 35° at the hip and 20° at the knee; or
12. Diagnosis of heterotropic ossification of the lower extremities.

Note: BMD = bone mineral density; DXA = dual-energy x-ray absorptiometry; SCI = spinal cord injury.

to the American Spinal Injury Association Impairment Scale (AIS). The institutional review board of James J. Peters VA Medical Center reviewed and approved all aspects of this study.

Powered exoskeletal device

Participants wore a powered exoskeleton (ReWalk; ReWalk Robotics, Inc., Marlborough, MA) with Lofstrand crutches to walk overground as previously described by Fineberg et al.[22] ReWalk has US Food and Drug Administration (FDA) indication for a class 2 device. The FDA indication consists of institutional use for persons with T4-L5 and personal use for persons with paraplegia at T7-L5. The user must be accompanied by a trained companion. Personal athletic shoes were worn with the exoskeleton (Aetrex Worldwide, Inc., Teaneck, NJ). The crutches were used by participants to guide transfers and help them maintain balance while standing and during ambulation. Stepping is accomplished by activating a command on the remote controller worn by the participant on the wrist followed by his or her forward and lateral lean. When initiating a step, a tilt sensor on the pelvic band of the device detects the user's trunk movement according to the setting predetermined by the trainer. The right leg always takes the first step. Subsequent steps are triggered by each additional forward and lateral shift onto the contralateral leg. The onboard control unit can be connected to a computer, which allows the trainer to adjust the hip and knee flexion angles and shifting parameters. Shifting parameters include tilt angle, delay between steps, and step time. Tilt angle determines the degree of trunk leaning to initiate a step. Delay between steps is the time allotted for the user to weight-shift to achieve the desired trunk tilt angle before the device times out. The shorter the step time, the faster the swing phase. The step length increases with increasing hip flexion angle and is related to leg length. Therefore, the walking speed is largely determined by a combination of the hip flexion, step time, and the individual's ability to weight-shift, activating the tilt sensor consistently without delay between steps or stopping. Fully charged batteries allow 4 hours of continuous walking. Potential risks with walking in device are falls, skin abrasions, dizziness, light-headedness, and neck and shoulder pain.

Powered EAW training and safety

Initial training sessions were staffed with 2 trainers and lasted up to an hour. One trainer acted as a spotter while the other provided explanation and feedback. As the skill and endurance of the participant improved, only one trainer was required for spotting the participant. Session time was progressed from 1 to 2 hours, as tolerated. The trainers took precautions to ensure proper device fitting and applied padding to avoid potential skin abrasions near bony prominences and points of contact with the device. During the early stages of training, systolic and diastolic blood pressure (SBP, DBP) were monitored before the session began while the participant was seated, during standing, and during EAW to detect sudden decreases indicating orthostatic intolerance (fall in SBP >20 mm Hg or DBP >10 mm Hg) or increases indicating a hypertensive response to the activity (SBP >180 mm Hg; DBP >100 mm Hg). Heart rate (HR) was monitored during seated resting, standing, and EAW. Seventy percent of maximum predicted HR values (220 - age) was used as an upper limit for EAW session discontinuation. Once the participant's endurance improved, BP and HR were monitored before and after each session. All participants were required to establish proficiency in standing balance, weight-shifting, and sitting and standing transfers before proceeding to gait training. While standing, participants were required to demonstrate independent weight-shifting with corresponding crutch placement in a 360° circumference. A full-length free-standing mirror was used to provide participants with visual feedback to assist with postural adjustments. The shifting parameters were adjusted by the trainer according to the user's in-device walking competency and ability to weight-shift.

Walk tests, level of assistance, and gait observation

As soon as the participant was able to initiate a series of continuous steps without verbal cues, walk

tests for time and distance for the 10-meter (10MWT) and 6-minute (6MWT) walk tests were performed. Visual qualitative analysis was performed by 2 study team members with gait training expertise – a biomedical engineer and a physical therapist. Because the number of sessions to acquire minimal walking skill varied, each participant was initially tested at different sessions. Once initially tested, walking tests were performed for each session going forward. During the 6MWT, recording was initiated while the powered exoskeleton user was in motion, with a moving start. A trainer trailed behind the participant to observe gait quality, gait characteristic, and posture. Concurrently, another staff person with a stopwatch and a surveyor's wheel measured the distances traveled. The total time to walk every 10 meters during the 6MWT was recorded using the "lap" function on a stopwatch. The shortest time to walk 10 meters during a single 6MWT was reported as the best effort for the 10MWT. The total distance travelled during the 6MWT was recorded. All walk tests were conducted in the hospital hallways directly outside of the research center. The walk test measurements, LOA provided by the trainer during the walk tests, and observational gait analysis were documented at the end of each session. The participants were only permitted to operate the device with a trainer present. LOA was adapted from the Functional Independence Measurement (FIM) as one of the following: (a) moderate assistance (Mod) – participant performs 50% to 74% of the task and the trainer has both hands on the participant or device at all times to provide occasional guidance or balance support; (b) minimal assistance (Min) – the user performs 75% or more of the task and the trainer has one hand on the participant or device for infrequent guidance or balance support; (c) supervision (S) – the trainer is not touching the participant but is close enough to reach in to provide support for balance or guidance as needed; and (d) modified independence (MI) – the trainer does not provide any assistance, and the participant is fully independent while walking in device.

Statistical methods

Individual values for the demographic characteristics, the walk tests, LOA, and lower limb and tilt parameter settings are reported. Descriptive statistics for the mean plus or minus the standard deviation for duration of injury and age are reported. The median values and ranges are reported for the EAW device settings. Box plots were created for the EAW 10MWT velocity split by LOA groups. Normalcy of distribution of the 10MWT velocity split by LOA group was determined by kurtosis and skewness. 10MWT velocity was compared across LOA groups by a nonparametric analysis using the Spearman rank correlation coefficient.

Results

Of the 19 individuals consented, 7 either did not qualify or did not complete the study (**Figure 1**). The remaining 12 individuals (2 women and 10 men) who participated in the study had mean injury duration of 6.8 ± 5.4 years (range, 1.5-19 years) and were wheelchair users for indoor and outdoor mobility (**Table 2**). The age of the participants ranged from 24 to 64 years (mean, 46 ± 12) years old. All HR and BP values were within the expected ranges for rest, standing, and EAW.

The settings on the powered exoskeleton for each individual and the median values are reported (**Table 3**). Most participants were able to take steps in the device during the first or second session. On average, the first walking assessments began around session 6 and were repeated during each subsequent training session. Over a median period of 55 sessions (range, 12-102), 7 of the 12 participants were able to ambulate at a velocity ≥0.40 m/s. Five participants performed the 6MWT and 10MWT with MI, 3 with S, 3 with Min, and 1 with Mod (**Table 2**). Significant inverse relationships were noted between LOA and EAW velocity for both 6MWT (Z value = 2.63, Rho = 0.79, P = .0086) and 10MWT (Z value = 2.62, Rho = 0.79, P = .0088) (**Figure 2**).

Visual observation of the gait pattern in the MI group (ie, the most independent group) demonstrated balance and body positions of an upright trunk with shoulder girdles relaxed and scapulae mildly retracted. The hands were tension free and the elbows were slightly flexed to allow the hands to have contact with the crutches, which were used for balance stability but not for

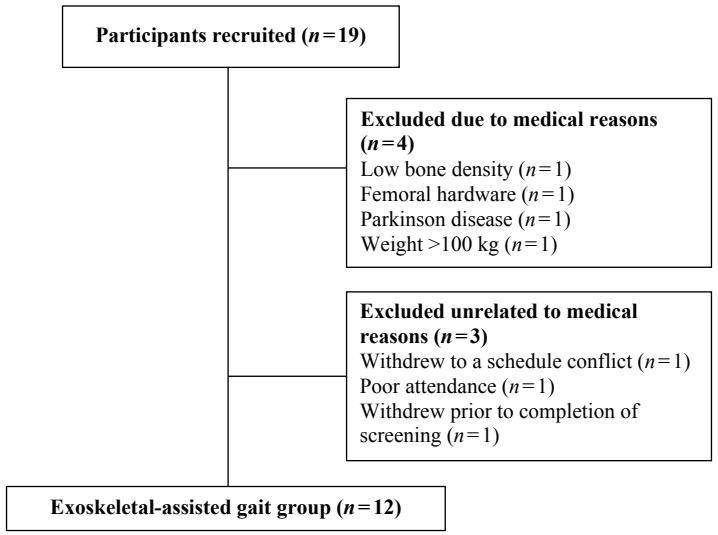

Figure 1. Study flow diagram. Nineteen participants were consented for screening eligibility. Seven participants were screening failures: one for low bone mineral density (BMD), one for metal implant, one for unrelated medical condition, one for being over the weight limit, one did not complete screening, one had schedule conflict due to travel issues, and one was discharged due to poor attendance compliance. Twelve participants have data on the walking tests.

Table 2. Characteristics of the study participants with best exoskeletal-assisted walking (EAW) performance and level of assistance

Demographic characteristics								Walk tests and levels of assistance						
PID	Age range, years	Height, cm	Weight, kg	Gender	DOI year, range	LOI	AIS	10MWT, s	10MWT, m/s	6MWT, m	6MWT, m/s	LOA[a]	Total session	Best performance session
A	31-45	173	66.7	M	6-10	T4	B	39	0.26	90.2	0.25	Min	94	89
B	46-60	168	68.0	M	1-5	T10	A	62	0.16	50.5	0.14	Min	18	18
C	31-45	183	77.1	M	1-5	T4	A	20	0.58	209.0	0.58	MI	63	63
D	46-60	160	64.4	F	1-5	C8/T8	A (NT)	24	0.42	139.0	0.39	MI	43	43
E	61-75	175	72.6	M	11-15	T11	A	23	0.44	137.4	0.38	MI	50	37
F	16-30	185	74.8	M	1-5	T5	A	56	0.18	60.2	0.17	Min	12	12
G	31-45	183	88.5	M	1-5	T1	B	61	0.16	50.8	0.14	S	120	102
H	46-60	175	83.9	M	1-5	T9	A	22	0.46	151.0	0.42	S	60	51
I	36-60	183	99.8	M	11-15	T7	A	17	0.59	208.2	0.58	MI	60	56
J	31-45	170	65.8	M	6-10	T2	A	22	0.46	150.0	0.42	S	60	59
K	61-75	173	72.8	M	1-5	T2	A	78	0.13	46.3	0.13	Mod	35	28
L	31-45	152	65.8	F	16-20	C8	C (NT)	14	0.71	255.9	0.71	MI	41	39

Note: PID = participant identification letter; DOI = duration of injury; LOI = level of injury; AIS = American Spinal Injury Association Impairment Scale; 10MWT = 10-meter walk test; 6MWT = 6-minute walk test; LOA = level of assistance; M = male; F = female; NT = nontraumatic SCI.

[a]LOA categories: Mod = moderate assistance: participant performs 50%-74% of the task. Min = minimal assistance: the user performs 75% or more of the task. S = supervision: trainer is close enough to reach in to provide support for balance as needed. MI = modified independence: participant does not need any physical assistance.

Table 3. ReWalk settings for lower limb and shift parameters

PID	Hip flexion, degree	Knee flexion, degree	Step time, ms	Delay between steps, ms
A	16	26	800	50
B	19	27	1,200	50
C	22	29	800	0
D	22	31	600	50
E	23	32	800	50
F	22	31	1,200	100
G	21	30	800	50
H	21	30	700	100
I	25	34	600	0
J	21	30	800	200
K	22	31	600	50
L	25	32	600	0
Median	22	31	800	50

Note: ms = milliseconds; PID = participant identification letter.

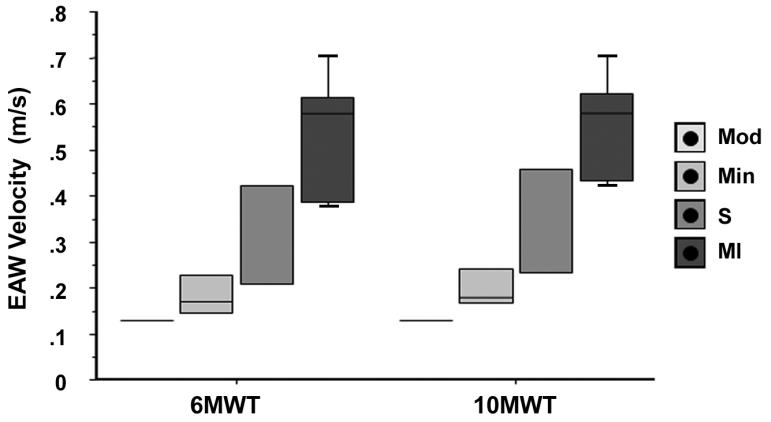

Figure 2. Boxplots of level of assistance and exoskeletal-assisted walking (EAW) velocity results from 6-minute walk test (6MWT) (*Z* value = 2.63, Rho = 0.792, *P* = .0086) and 10-meter walk test (10MWT) (*Z* value = 2.62, Rho = 0.790 = 0.790, *P* = .0088) where Mod = moderate assistance (*n* = 1); Min = minimal assistance (*n* = 3); S = supervision (*n* = 3); and MI = modified independence (*n* = 5). The horizontal lines sequentially represent the 10th (at the bottom), 25th, 50th, 75th, and 90th (top line) percentiles.

body weight support. MI and S groups favored the 2-point alternating crutch gait pattern. Min and Mod groups had difficulty maintaining an erect posture and balance during ambulation; a greater LOA was required. Individuals in the Min and Mod groups tended to lean forward to rely on their upper extremities for balance support. This action often led to an inconsistency in activating the tilt sensor, despite the exaggerated pelvic movement, and resulted in the exoskeleton timing out and return to the standing position. The Min and Mod groups favored ambulation with a dual crutch forward motion and then one foot, yielding a 3-point gait.

There were no serious study-related adverse events. Thirteen episodes of mild skin abrasions occurred. These abrasions were fully resolved with padding and equipment adjustments.

Discussion

This single-group observational study has 3 main findings. First, individuals who ambulated at a higher EAW velocity required less LOA, and

these individuals achieved a gait velocity self-selected for limited community ambulation. Second, individual's gait posture, anatomy, and ability to weight-shift in the device were associated with gait velocity. Finally, consistent with the findings of Esquenazi et al and Zeilig et al, EAW in the ReWalk was performed safely in a hospital setting.[23,24]

Walking velocity in individuals with a stroke or the elderly population has been shown to be closely associated with safety, functional independence, and quality of life.[25,26] Furthermore, a walking velocity of 0.40 m/s enables an individual to become a limited community ambulator.[2,25,26] Seven of the 12 participants were able to ambulate at least 0.40 m/s in the ReWalk. All individuals who ambulated at a velocity >0.40 m/s were able to do so with very little or no assistance (either S or MI). However, one participant (with T1 and more than 80 sessions) was able to ambulate with S LOA, but at a velocity <0.40 m/s. Therefore, this powered exoskeleton user was able to safely walk, albeit more slowly than the others who needed less assistance and for longer distances than were once possible without a motorized device. To further satisfy the requirement of community ambulation, a powered exoskeleton user should be able to walk outside the hospital setting and negotiate door thresholds, uneven surfaces, low curbs and ramps, as well as other potential obstacles. Future studies should examine the skills necessary to safely and efficiently navigate home/community conditions, the energy expenditure requirements, maximal walking distances achievable, length of time in the device that is safely tolerated, fall risks, and other potential considerations to better define categories unique to powered exoskeleton users.

Gait velocity is a product of step length and cadence.[27] An increase in either step length or cadence over time would increase the distance traveled.[27] Although increased lower limb length was related to maximal gait velocity, increased lower limb length was not an important factor in "comfortable" walking velocity in able-bodied individuals.[28] Among the powered exoskeleton users, the speed and precision to trigger the tilt sensor combined with a weight-shift onto the advancing foot determined step cadence for any given distance walked.[22-24] Participants I (height, 183 cm) and L (height, 152 cm) had identical step speed and delay between steps on their respective devices. However, participant L achieved higher EAW velocity despite having shorter leg length. This observation suggested that the user's anatomy and ability to weight-shift in the device contributed to EAW velocity variability. A slightly slower walking velocity from the 6MWT may be due to a variation in the walking consistency or fatigue. Continued efforts to study the effects of cadence and step length on gait velocity could help to improve gait efficiency and extrapolate a threshold velocity to serve as one of the clinical predictors of a modified independent powered exoskeleton user.

Balance is a requirement for efficient gait due to the strong relationship between gait velocity and balance.[29] Walking balance is a state of equilibrium that requires dynamic coordination of the somatosensory, vestibular, and visual systems. Individuals who ambulated at a higher velocity walked with better posture and fluidity. When the advanced users lost their balance, they were able to detect the weight-shift, recover early, and minimize their postural sway with the use of crutches. The ability to harness the somatosensory system of the upper extremities would become more significant when exoskeleton users ambulated in an outdoor environment. The crutches could help to detect changes in the surface level that were not visually obvious. The slower walkers tended to look down on the floor and lean more heavily onto their crutches, which made crutch placement and balance recovery difficult. A similar observation was made by Roquejo[30]; during weight acceptance on a weaker lower extremity of a person with SCI, there was an increase in extension moment in the contralateral wrist and need for a more stable gait pattern. Aside from a 3-dimensional gait analysis, defining characteristics of exoskeleton users can be further delineated through future trunk and upper extremity electromyography, kinematics, and crutch–ground reaction force studies.

No falls or serious injuries occurred for the duration of this study. If participants lost their balance, they used the Lofstrand crutches to catch themselves and shift their weight directly over their feet. During the initial training, trainers provided assistance or contact guard to ensure proper balance during weight-shifting. Although participants

progressed and did not require hands-on assistance during ambulation, a trainer was always within an arm's length from the participants as an added safety precaution. Minor skin abrasions were the most common adverse event encountered. All skin abrasions were adequately managed with small adhesive bandages. Additional padding to areas of high contact pressure was used to avoid new skin injuries. Users were taught to examine themselves for skin abrasions after each session. Regular monitoring of BP and HR was used to detect hemodynamic trends or potential spikes during each training session, however all HR and BP responses were within normal limits. Consistent with previously published data on the safety of the ReWalk,[23,24] the results from this study further support that participants from all 4 LOAs (MI to Mod) can perform EAW in the ReWalk safely in an outpatient, hospital setting.

To determine the mobility potential of the ReWalk and other exoskeletons of similar design in the community setting, it is important to distinguish functional versus recreational/exercise-related community ambulation. Functional community ambulation requires an individual to be able to walk and accomplish mobility-related activities of daily living safely within the environmental construct and within a practical time frame. For example, traversing across a parking lot to walk up and down the aisles inside a retail store may be viable; but at 0.40 m/s, mobility may be too slow to be convenient and the wheelchair would likely remain the modality of choice. On the other hand, the user's expectation for recreational or exercise-related ambulation may be less stringent. An individual may walk at a self-selected velocity and distance in a controlled setting to gain the benefits of being upright and physically active in a way that cannot be achieved from a wheelchair. Nonetheless, the EAW provides individuals with SCI an opportunity to perform consistent recreational or exercise-related ambulation outside of the hospital setting.

There are several limitations of this study. The sample size was relatively small and did not permit significant results relative to the relationship of level and completeness of injury with EAW velocity. Because each participant's total training session varied, walking performances were measured at varying time points in the training cycle. Those who completed fewer sessions had less opportunity to learn and gain walking proficiency, whereas those who finished more sessions had more exposure to EAW training.

Conclusion

In general, the less assistance a participant needed, the faster he or she achieved EAW velocity. Fifty-eight percent of the individuals with SCI who were studied were able to ambulate at a walking velocity ≥0.40 m/s. This velocity may be conducive for outdoor activity-related community ambulation. The results of this in-hospital study support the findings of others that the ReWalk powered exoskeleton is a safe device for ambulation. In-hospital sessions allow for researchers to study the potential medical and social benefits of regular upright ambulation in individuals with SCI. Future studies to investigate retention or improved outcomes with continued use in the home/community environment are the next step.

Acknowledgments

Financial support/disclosures: The funding was provided by the Department of Veterans Affairs, Office of Research and Development, Rehabilitation Research and Development Service, National Center of Excellence for the Medical Consequences of Spinal Cord Injury (VA RR&D #B9212-C), James J. Peters VA Medical Center, Bronx, New York.

Conflict of interest: ReWalk Robotics, Inc. provided 2 of the 4 units on loan for a portion of this study duration. The authors declare that they have no conflict of interest.

Ethical standards: The authors certify that this human study has been approved by the appropriate ethics and institutional review board (IRB) committees and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. They declare that all persons gave their informed consent prior to their inclusion in this study and that details that might disclose the identity of these subjects under study have been omitted.

Device status: ReWalk is approved by the FDA (June 24, 2014). The device is classified under the following:

Product Code: PHL
Device Type: Powered Exoskeleton
Class: II
Regulation: 21 CFR 890.3480

The device is approved for overground ambulation in home and community setting. The targeted users are individuals with paraplegia due to spinal cord injuries at T7 to L5. The user must be accompanied by a trained caregiver. The device can also be used by individuals with spinal cord injuries at levels T4 to T6 in rehabilitation institutions.

ClinicalTrials.gov Identifier: NCT02118194

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