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SCI

The ReWalk Powered Exoskeleton to Restore Ambulatory Function to Individuals with Thoracic-Level Motor-Complete Spinal Cord Injury

ABSTRACT

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Objective: The aim of this study was to assess the safety and performance of ReWalk in enabling people with paraplegia due to spinal cord injury to carry out routine ambulatory functions.

Design: This was an open, noncomparative, nonrandomized study of the safety and performance of the ReWalk powered exoskeleton. All 12 subjects have com- pleted the active intervention; three remain in long-term follow-up.

Results: After training, all subjects were able to independently transfer and walk, without human assistance while using the ReWalk, for at least 50 to 100 m continuously, for a period of at least 5 to 10 mins continuously and with velocities ranging from 0.03 to 0.45 m/sec (mean, 0.25 m/sec). Excluding two subjects with considerably reduced walking abilities, average distances and velocities im- proved significantly. Some subjects reported improvements in pain, bowel and bladder function, and spasticity during the trial. All subjects had strong positive comments regarding the emotional/psychosocial benefits of the use of ReWalk.

Conclusions: ReWalk holds considerable potential as a safe ambulatory powered orthosis for motor-complete thoracic-level spinal cord injury patients. Most subjects achieved a level of walking proficiency close to that needed for limited community ambulation. A high degree of performance variability was ob- served across individuals. Some of this variability was explained by level of injury, but other factors have not been completely identified. Further development and ap- plication of this rehabilitation tool to other diagnoses are expected in the future.

Key Words: Spinal Cord Injury, Paraplegia, Orthotic Devices, Walking, Ambulation, Robotics

Approximately 200,000 Americans currently live with a disability related to spinal cord injury (SCI).[1] Each year, there are approximately 11,000 new SCIs in this country. Advances in medical care for persons with SCI have resulted in increased rates of survival and longer life span. Many patients with SCI report reduced life satisfaction[2Y6]; nearly 70% of patients with new SCI have been shown to have reduced quality-of-life, significant levels of pain,[7] and long-term satisfaction score reduction. Factors associated with reduced life satisfaction among these patients include mobility limitations[6,8] and changes in occupational roles[6,8,9] or physical health.[3,5,6] Some of the major changes contrib- uting to reduced physical health stem from im- paired bowel and bladder function, pressure sores, pain, increased muscle tone, obesity, and decreased bone density. Singularly or in combination, these changes can contribute to reduced mobility and so- cial interaction.

Locomotion Options for Individuals with Thoracic-Level Motor-Complete SCI

Manual wheelchair propulsion is the most common mode of locomotion for those with a motor- complete thoracic-level SCI.[10] In wheelchairs, indi- viduals are often able to navigate around a properly modified home and workplace, perform many ac- tivities of daily living, and engage in some social and recreational activities. However, because of signifi- cant architectural and environmental restrictions, there are limitations associated with wheelchair use.[11] Furthermore, the typical seated wheelchair posture does not load the legs in a normal manner[12] and can lead to pressure sores[13,14] and promote joint contractures. Dependence on arms for propulsion can result in shoulder overuse

syndrome[15,16] as well as neuropathy. Finally, most wheelchairs do not provide a means for eye-to-eye social interac- tion with able-bodied adults.

Other modes of locomotion that have been previously used come up far short of even the standard set by the wheelchair. Classic knee-ankle- foot orthoses are heavy, cumbersome, and diffi- cult to don, with most patients discontinuing their use within a short time. Reciprocal gait orthosis, hip guidance, and isocentric reciprocal gait orthoses (IRGO) have brought about improvement over knee-ankle-foot orthoses, allowing increased ambu- lation for short distances, but long-term adoption is still limited because of high energy consump- tion from the inefficient gait pattern required and potential for increase upper limb overuse.[17] Other

obstacles to the use of this type of braces include difficulty donning/doffing, obesity, dependence on others for assistance guarding, and mechanical breakdown of the devices. These braces may also interfere with other functional situations, such as moving to/from a couch or car transfers.[18,19] The American Paraplegia Society has developed clinical practice guidelines for clinicians who work with patients having SCI. The guidelines suggest using a stander at 1 yr after injury for individuals with motor-complete SCI injuries above T1. For injuries between T1 and below, either a stander or orthoses for therapeutic or functional activities are an option.[20]

Functional electric stimulation systems may enable patients to ambulate for very limited dis- tances.[21] The first success in functional electric stimulationYassisted gait in paraplegia occurred in the 1970 s, with the systems of Kljajic and Bajd in Slovenia[22] and Graupe et al. in the United States.[23] Others used implanted electrodes to elicit a gait pattern.[24] The technique has many limitations, re- quiring functioning lower motor neurons for neu- romuscular excitability and complete sensory loss to tolerate the significant electrical stimulus needed to achieve an adequate muscular contraction. In ad- dition, the electrical stimulation differs greatly from the physiologic nerve impulse because in functional electric stimulation, all motor units in a muscle group are stimulated simultaneously. This rapidly induces muscle fatigue and results in high energy consumption. To try to overcome these limitations, a hybrid orthosis using swing phaseYonly functional electric stimulation to assist limb advancement[25] and allowing periods of no stimulation in stance phase where electromechanical actuators provide stability is in development.

The walking performances of all the above methods remain quite modest in comparison with normal gait. Speed is very low and energy utiliza- tion is high, thus limiting their functional use. The problem of afferent feedback and balance remains unsolved, requiring the use of a walker or crutches for stability, regardless of the system used.

Reduction in upright posture, reduced bone loading relative to functional bipedal walking, di- minished practicality, and the potential for a range of unwanted side effects are all factors that have been identified as having a significant negative impact on the overall health of individuals with SCI.[26Y30]

Impact of the Loss of Walking for the SCI Population

Nonrecreational walking accounts for a signif- icant fraction of activity for the average adult. Lower

physical activity levels have been observed after SCI[26] resulting from lost motor function, lack of training during acute rehabilitation, decreased access to exercise facilities and adequate adaptive fitness equipment, limited time, and psychologic factors.[31] The physical deconditioning resulting from largely sedentary lives of individuals with tho- racic or higher level SCI is well documented.[27,29] Lack of standing, ambulation, muscle activity, weight- bearing, and neuroendocrine changes all contribute to rapid and marked alteration in body composition such that muscle mass and bone density decline and adipose tissue increases. Additional complications such as muscle atrophy,[32] joint contractures, pres- sure sores, osteoporosis,[33] increased spasticity, pain, edema, urinary and intestinal stasis, and abnormali- ties of carbohydrate,[34] lipid, and protein metabo- lism[35] may be present.

Exercise has been shown to be an effective contributor to overall health, bone density, a proper level of muscle tone, cardiovascular fitness, regular bowel and bladder function, reduced risk for obe- sity, heart disease, and reduction in type II diabetes for patients with SCI.[28,29] Therapeutic exercise for individuals with SCI have several limitations, that is, difficulty in execution,[36,37] insufficient car- diovascular stimulus, potential for injury, and the need for specialized equipment. Upper body exer- cises including hand ergometry or weight lifting may increase the likelihood of overuse of already taxed upper limb joints, particularly for thoracic-

level injured individuals who rely on wheelchair propulsion for locomotion and their arms for transfers.[16,38,39] Having an SCI results in a 40% reduction in work and leisure time compared with preinjury status,[40] making the adherence to an ex- ercise routine that is separate from, rather than a part of, the activities of daily living more difficult. As an example, in one small study, individuals with SCI who reported relief from pain from a 9-mo exercise program showed a nearly 50% drop in adherence to the program and a resurgence of pain just 3 mos after study conclusion.[41] Functional walking is an excellent means to accomplish exercise without requiring extra time commitments. But this is a difficult option, particularly for those with motor- complete SCI at the thoracic or higher levels.

Description of the ReWalk

The ReWalk is a lower limb powered exoskeleton that allows thoracic or lower level motor-complete individuals with SCI to walk independently (Fig. 1). ReWalk contains independently controlled bilat- eral hip and knee joint motors, rechargeable bat- teries, and a computerized control system carried in a backpack. ReWalk users control their walking through subtle trunk motion and changes in cen- ter of gravity. A tilt sensor determines the angle of the torso and generates a preset hip and knee displacement

(angle and time) that results in a step. The ankles use a simple double-action orthotic joint with limited motion and spring-assisted dorsiflexion

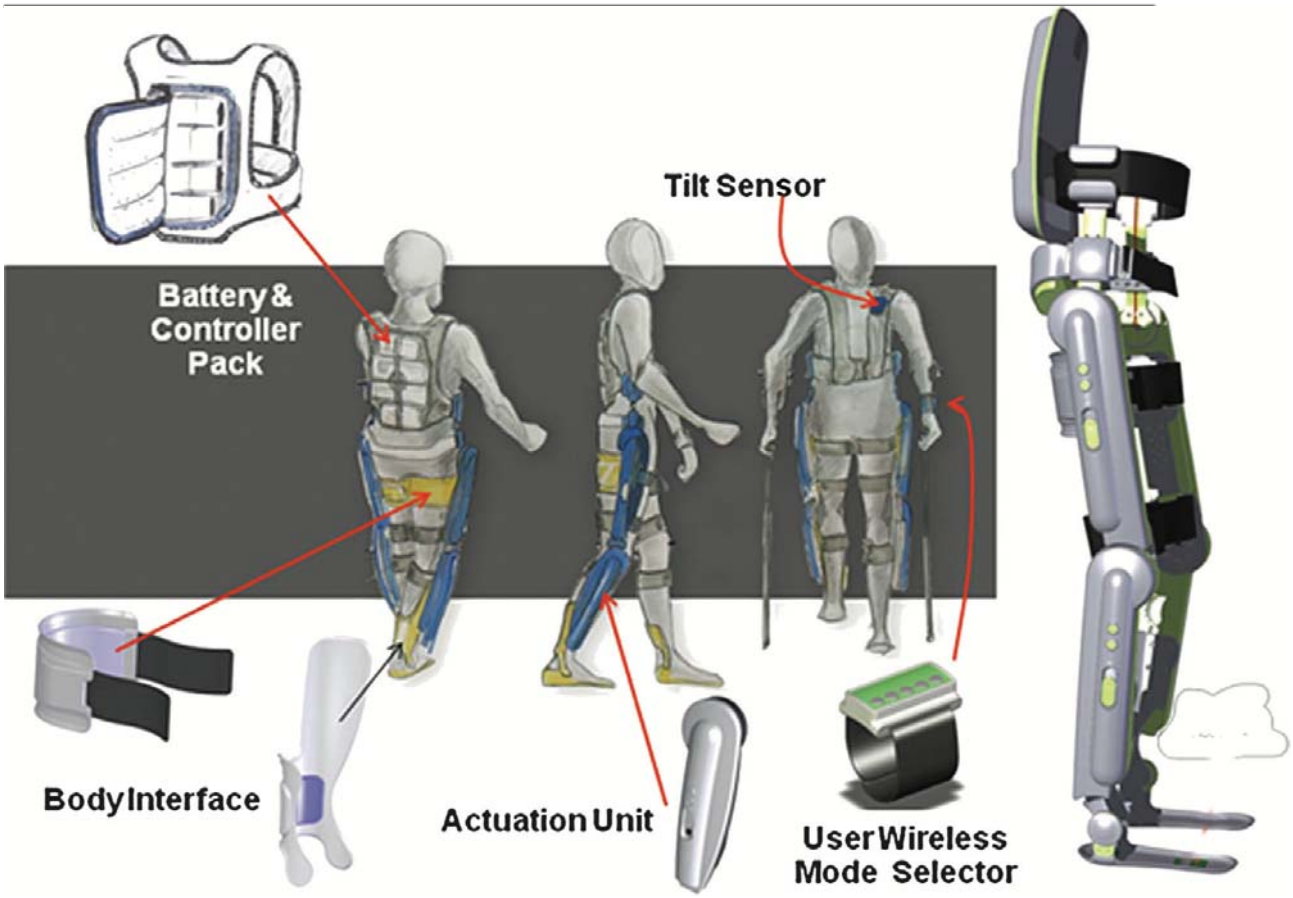

FIGURE 1 Schematic of the ReWalk I Exoskeleton System. The tilt sensor is used to signal the on-board computer when to take the next step. Body interface is adjustable and uses soft closures. Actuation unit has individual motors for each knee and hip. Wrist unit provides wireless remote access to selected functions in the system. Backpack contains microprocessor, main battery, and backup power supply.

adjustable through screw tension. The device is eas- ily adjustable in height and width and has padded interfaces for calves and thighs and a rigid pelvic frame linking the limbs. Velcro closures with pads, shoes, and a waist belt are used to secure the user in the exoskeleton. Crutches provide standing stability. The subject can interact remotely with the system with a user-operated wrist pad controller that can command sit to stand, stand to sit, and walk acti- vation. The novelty of ReWalk is in the unique manner in which the user is actively involved in controlling walking. The specially designed soft- ware algorithm interprets a signal from the torso tilt sensor and generates alternating limb-coordinated motion to produce bipedal walking. At the same time, the system prevents two sequential steps of the same leg. During training, joint angle displacements for the knee and hip can be adjusted using an ex- ternal computer to optimize the walking char- acteristics or implement a training mode. A manual mode of operation can

be used to trigger steps bypassing the tilt sensor. The same mode of opera- tion can be used to trigger sit-stand-sit transfers. ReWalk is suitable for adults who have preserved bilateral upper limb function as well as the capacity for assisted standing (such as with a standing frame or braces and crutches). Because the system is bat- tery powered and completely untethered and indi- viduals are fully in control of when they step, ReWalk offers a real option to improve upon the current ambulation standard for individuals with thoracic- level motor-complete SCI. Moreover, because walk- ing in ReWalk is similar to upright bipedal walking, it may offer the potential to overcome some of the physical and psychosocial problems caused by loss of natural walking. In this article, the authors report the findings of their 2-yr clinical trial to assess the safety and efficacy of ReWalk, along with insights into some of its other potential benefits.

METHODS

This was a prospective, single-intervention, open, nonrandomized, partially sponsored by in- dustry trial to evaluate the safety and usability of the ReWalk. The research was approved by the in- stitutional review board at the Albert Einstein Healthcare Network. Informed consent was obtained from all participating subjects before initiating any study-related activity. All subjects had gait train- ing using the ReWalk as the intervention. Subjects were trained for up to 24 sessions of 60- to 90-min duration over approximately 8 wks (target was three times per week). Near the conclusion of the training,

subjects had a performance evaluation visit that consisted of a 6-min walk test, a 10-m walk test, and a gait laboratory evaluation including three- dimensional motion capture and temporospatial data. Dynamic electromyogram was collected dur- ing walking from selected lower limb proximal muscles to confirm that no lower limb muscle ac- tivity was present. Twelve subjects completed the gait training portion of the study. All subjects who participated in the intervention portion of the trial were followed for approximately 1 yr after active intervention phase to assess any long-term effects; three subjects remain in the follow-up phase.

Subject Selection

Adults with chronic (at least 6 mos postinjury) motor-complete cervical and thoracic (C7YT12) SCI according to American Spinal Injury Associa- tion guidelines were targeted for recruitment into the study. Subjects were initially screened by tele- phone to determine potential eligibility to partici- pate; subsequently, subjects were scheduled to come to the facility to be consented for complete evalua- tion of their ability to participate. The intake evalu- ation included dual-energy x-ray absorptiometry, electrocardiography, and leg long bone and lumbar spine x-rays to confirm joint integrity and absence of unhealed fractures or heterotopic ossification that may impede walking. At the time of screening, sub- jects had to report a history of standing (either with lower limb bracing or a standing frame) on a frequent basis to proceed. Furthermore, a complete neuro- logic evaluation by a study coYprimary investigator (M.S.) was used to confirm injury level; skin integ- rity; hemodynamic stability; adequate hip, knee, and ankle range of motion; and a spasticity level of 3 or less using the Ashworth scale. The

above infor- mation, combined with the absence of osteoporosis on the basis of bone mineral density (BMD) measured from the right-limb femoral neck and the L2 to L4 spine. BMD t scores at the measured sites of greater than j2.5 were required based on the definition of osteoporosis from the World Health Organization.[42] To make a final determination of subject eligibility to participate, the primary investigator, a board-certified, practicing physiatrist experienced in bio- mechanics of gait and with understanding of the ReWalk technology, reviewed and considered all the available information. Table 1 summarizes inclusion/ exclusion criteria used for this study.

Intervention Phase

After measurement of the subject and fitting with the device, the training program commenced,

TABLE 1 Inclusion and exclusion criteria

Inclusion criteria
Motor-complete cervical (C7Y8) and thoracic
(T1YT12) spinal cord injury/damage according to
American Spinal Injury Association guidelines Male and nonpregnant, nonlactating woman Age 18Y55 yrs
At least 6 mos after injury
Regular use of RGO or KAFOs or able to stand using a standing device (e.g., Easy stand)
Ability to provide informed consent Height of 160Y190 cm
Weight of G100 kg
Exclusion criteria
History of severe neurologic injuries other than SCI
(MS, CP, ALS, TBI, etc.)
Severe concurrent medical diseases: infections,
circulatory, heart or lung, pressure sores Severe osteoporosis affecting the hip and spine
(t scores Gj2)
Severe spasticity (greater than Ashworth 3) or
uncontrolled clonus
Unstable spine or unhealed limb or pelvic fractures Heterotopic ossification that restricts functional
range of motion
Significant contractures (beyond 15 degrees at the

hips or 20 degrees at the knees)
Psychiatric or cognitive comorbidities that may

interfere with the trial

RGO indicates reciprocal gait orthosis; KAFOs, knee- ankle-foot orthoses; SCI, spinal cord injury; MS, multiple sclerosis; CP, cerebral palsy; ALS, amyotrophic lateral scle- rosis; TBI, traumatic brain injury.

following a protocol including sit-to-stand and standing activities in the parallel bars, stand-sit transfers, standing balance, and skills related to stepping (Table 2). Training progressed to crutch use placement for balance and advancement. After the acquisition of these underlying skills, the bulk of the training focused on improving and integrating walking performance with step triggering, coordi- nating step timing and foot clearance, safe and ef- fective stopping, and finally, full self-control using the wrist pad controller. Training sessions were in- dividualized, by the physiotherapist, to facilitate safe and efficient walking. Generally, sessions lasted 75 to 90 mins total, with actual standing and walking training times dependent primarily on equipment adjustment and subject need for rest periods. Heart rate, blood pressure, spasticity, self-reported pain (VAS scale), fatigue (VAS scale), and skin integrity were measured before and after each session by the same member of the research team. Subjects were continually supervised by at least one training staff member during all training. A physical therapist, physical therapist aide, and a biomedical engineer comprised the training staff. Staff received training in the symptomatic detection of autonomic dysre-

flexia and orthostatic hypotension and the initial interventions to manage it. Emergency medical staff was available on site to respond at all times during ReWalk use.

Follow-Up

Subjects completed a survey describing their experience at the conclusion of the active interven- tion phase. This survey included questions about subjects' overall comfort and confidence using ReWalk (Appendix 1) as well as specific inquiries about pain, fatigue, spasticity, intestinal function, and respiratory problems. They were also evaluated at approximately 12 to 15 mos after the intervention to determine whether there were any long-term physical and emotional effects of device use. This consisted of a physical examination, assessment of spasticity and pain, as well as the SF-36v2 Health Survey Questionnaire.

RESULTS

Seventeen subjects were screened, and 13 were considered eligible to participate in the study. Three of those ineligible had severe osteoporosis in the hip and spine and one was too large to comfortably use the ReWalk device. One eligible subject was not able to participate after screening was completed be- cause of study-unrelated personal reasons. Twelve subjects participated in this study. The demographics of these 12 subjects are shown in Table 3. All sub- jects in the study had thoracic-level motor-complete

TABLE 2 General training schedule Schedule of Gait TrainingVMajor Activities

Session 1: complete necessary measurements Session 1: fitting of device to subject
Session 1: sit to stand between parallel bars (manual

trigger mode)
Sessions 1Y4: putting on device
Sessions 1Y4: sit-to-stand and stand-to-sit within

parallel bars
Sessions 1Y4: stable standing between parallel bars

(without support)
Sessions 1Y4: walking between parallel bars (manual

trigger mode)
Sessions 2Y4: walking between parallel bars (subject

triggered tilt sensor)
Sessions 2Y4: sit-to-stand with help of assistant Sessions 2Y4: basic training in the use of crutches
Sessions 2Y5: walking with crutches (manual trigger

mode)
Sessions 3Y18: walking with crutches using tilt sensor Sessions 3Y18: sit-to-stand and stand-to-sit using

crutches

TABLE 3 Subject demographics
Age, Weight, Height,

Time Since Injury, yrs

4.8 1.0 2.4 3.3

24.3 13.7 2.1 3.1 19.6 6.0 2.9 6.0

Cause of Injury

Vascular MVA MVA Fall MVA Assault MVA MVA Fall MVA GSW MVA

Injury No. of Level Visits

T8 25 T3 22 T8 26

T11 24 T10 25 T10 24

T4 26

T6 13 T10 23 T12 25

T7 24 T4 26

Subject Code	1	2	3	4	5	6	7	8	9	10	11	12
yrs Sex kg cm												
49 Female 68.2 163 45 Male 79.1 183 36 Male 71.4 175 55 Male 81.8 180 46 Male 75.0 185 41 Male 88.6 183 18 Female 56.8 168 36 Male 86.4 185 40 Male 70.5 175 36 Female 56.8 168 20 Male 79.5 188 32 Female 70.5 175												

MVA indicates motor vehicle accident; GSW, gunshot wound.

SCI and were nonambulatory without wheelchair before initiating the study. By completion of the trial, all subjects had walked under their own control, without human assistance while using the ReWalk, for at least 50 to 100 m continuously and for a period of at least 5 to 10 mins. Velocities ranged from 0.03 to 0.45 m/sec (mean, 0.25 m/sec) (Table 4). Veloci- ties were considerably slower for the first 2 of the 12 subjects who participated. It is unclear to what extent the authors' own unfamiliarity with the device or not having a fully developed training protocol contributed to the limited outcomes of these first two subjects enrolled in the study. Differences in velocity and distance performance may also be related to level of injury; three groups appear when perfor- mance data are stratified by level of injury (Fig. 2).

During the thousands of steps taken through the authors' facility hallways and even outdoors, there was not a single study-related serious event: no falls, no bone fractures, or episodes of autonomic dysre- flexia occurred.

Of the 12 subjects, 5 had a definite or possible study-related mild to moderate adverse event. The events consisted of (1) skin abrasions in areas of contact with the device, (2) lightheadedness, and (3) edema of the lower limbs. They were all man- aged by the appropriate use of (1) foam and pad- ding, (2) caffeinated beverage intake and adjustment of blood pressure medication, (3) elastic stockings and rest, respectively.

There were no detrimen- tal changes in vital signs or complaints of light- headedness with prolonged standing. A summary of changes in spasticity for the bilateral knee and ankle were derived from all sessions for each sub- ject completing the trial (Table 5). The differences were measured from immediately before to imme- diately after each test session. The scores show

that, in general, spasticity seemed to be favorably impacted by using the ReWalk. Although not for- mally recorded, total time in standing and walk- ing per session ranged approximately between 20 and 60 mins. Furthermore, subjects 4, 8, and 10 reported in the survey at the end of the training intervention that their overall spasticity improved (noted in Table 5), whereas no subjects indicated that their spasticity had increased.

Pain was measured before and after each test session. Five of the subjects reported a combined 28 times that pain was noticeably reduced; one sub- ject indicated that pain was repeatedly increased immediately after the training intervention. The increased pain complaints were not dissimilar to that produced by standing with a standing frame and, as such, was not considered a ReWalk adverse effect.

TABLE 4 Objective walking performance measures

Subject Code	6-min 6-min Test 10-m Distance, Velocity, Time,				
	m	m/sec	min:sec		
	10-m Test Velocity, m/sec				
	0.03	0.03	0.25	0.42	0.40	0.45
1						
2						
3						
4						
5						
6						
7						
8						
9						
10	113.5	11	86.7	12	39.6
	15.3	0.04	5:10	10.8	0.03	5:25	63.4	0.18	0:40
	122.0	0.34	0:24	106.7	0.30	0:25	150.4	0.42	0:22
	54.3	0.15	0:55	0.18					
	aaaa								
	90.2								

[a]Subject was unable to participate in this test because of factors unrelated to the study.

0.25 0:39 0.26 0.32 0:31 0.32 0.24 0:36 0.28 0.11 1:09 0.14

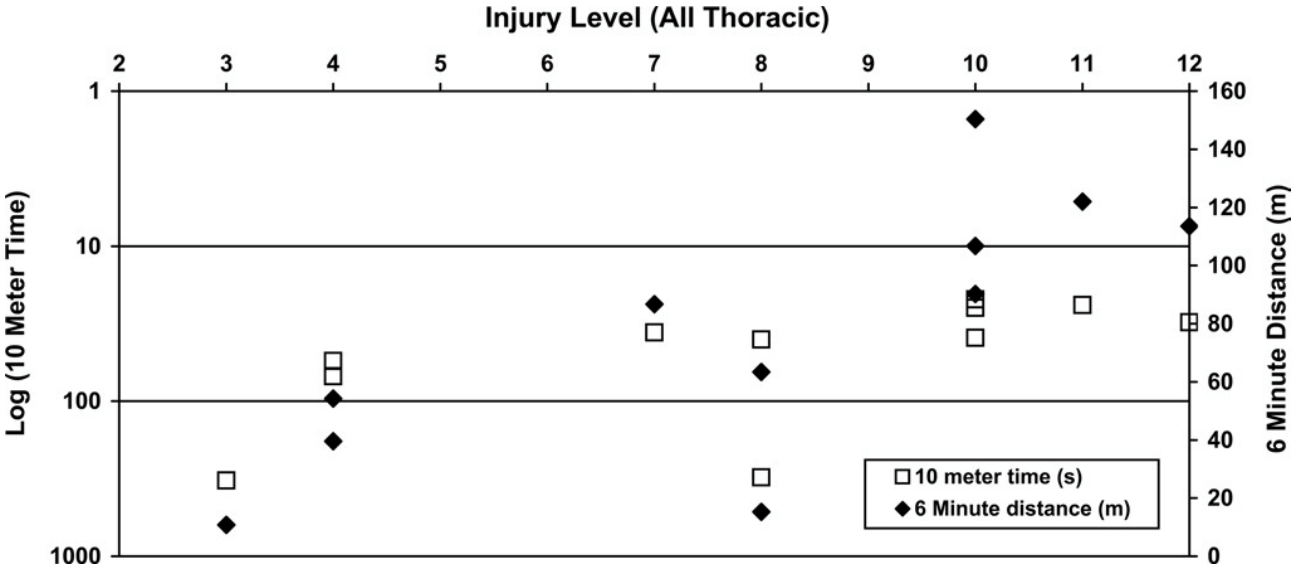

FIGURE 2 Walking performance across injury levels. Figure illustrates the performance on the 6-min and the 10-m walk tests by level of injury and suggests the effect of level of injury on performance (i.e., lower level of injury higher walking velocity and longer distance walked).

In addition to the above data obtained from each test session, self-reported data were collected upon trial termination. The following trends were observed: 3 of 11 subjects reported improved spasticity.
0 of 11 subjects reported that use of ReWalk caused

pain.
1 of 11 subjects reported that use of ReWalk caused

fatigue.
5 of 11 subjects reported improved bowel regulation.

The study therapist and investigators repeat- edly and consistently observed all study subjects perspiringVsometimes considerablyVduring initial training with the ReWalk. Moreover, cursory review of heart rate data support that elevated heart rates and a modest increase in blood pressure sometimes resulted from use of the ReWalk (Table 5). This im- proved over time as subjects' fitness and familiarity with using the ReWalk increased.

Finally, a follow-up examination and question- naire were administered approximately 12 mos after final device use. The general health status, as mea- sured by study clinicians, did not change. Two sub- jects reported study-unrelated complications in this

phase. One was a victim of stabbing and the other developed a grade 3 pressure sore that required surgery. Evaluation of long-term changes in Modi- fied Ashworth scores, spasm frequency, and inter- preted SF-36v2 scores is pending. All subjects had strong positive comments regarding the emotional/ psychosocial benefits of participating in the trial. The authors aim to further evaluate this aspect via the SF-36v2 when long-term follow-up is completed for all study subjects.

Two subjects had implanted medical devices at the time of enrollment: one had a spinal cord stimulation system and another had an intrathecal drug delivery system. Neither patient had device- related complications during the course of the ReWalk intervention. System parameters for both devices were not changed during the course of the training.

DISCUSSION

In a population of thoracic SCI subjects, the ReWalk was found to be safe and effective in allowing independent walking at different levels of ambulatory performance. With careful and regular

TABLE 5 Effect of ReWalk on leg spasticity (Ashworth score), HR, and BP

Subject Code	No. of Times Improved	Spasticity Got Worse	No. of Times Spasticity mm Hg	Average Change in BP, beats/min	Average Change in HR,
1	0	0	11/3	4 2	8 18
j3/j2	7	3	40	12	11/2
j5	4	12[a]	1	2/j3	7
5	0	0	9/16	19 6	18 33
0/2	6				
7	42	8	3[a]	9 6	10
1[a]	11	0	12	0	
0	11/10	26	02/37	1	
j3/j2	4	02/04	0	6/4	12
0	6/8	10			

[a]Subjects for whom self-reported overall spasticity improved. HR indicates heart rate; BP, blood pressure.

monitoring of walking as described by the manu- facturer, use of the ReWalk triggered no serious adverse events and only a relatively small number of minor adverse events. All of these events were straightforward to manage by padding of contact surfaces or physical measures and did not lead to any longer term issues or cause any more than a small delay in trial progress. Subjects did occasionally lose balance and either caught themselves with their crutches or were stabilized by the physical therapist or physical therapist aide. None fell to the ground at any time during walking, standing, or transfers. Subjects were not allowed to use the device unsu- pervised. Spasticity was not

considered an adverse effect because it is well documented that fatigue may increase this phenomenon and, as such, is a possible expected effect of the training.

With regard to the BMD screening measure- ments, the community standard for bone densito- metry includes the femoral neck and lumbar spine, and these were the locations used in this study. Although it is well recognized that the pattern of bone loss after SCI is different (i.e., the distal femur demonstrating the most profound loss), the authors selected the standard measurement sites because many subjects traveled long distance to participate in the study after obtaining their bone densitometry in their community. The observation that 13 of the 17 screened subjects had nearly normal or only osteopenic levels of BMD at the lumbar spine and femoral neck may not represent the data in the general paraplegic population. The frequent upright positioning required to participate in this study may have attenuated the BMD loss in these subjects. There was no consistent pattern of decreased BMD at either the lumbar spine or the femoral neck in the screened participants. The safety of ReWalk in individuals with osteoporosis has not been formally evaluated at this time, but its design does provide support to the distal femur.

The Bdifferent levels[of performance refers to the range of walking capacity varying from limited household to independent community functional walking. Two of the subjects were particularly limited and unable to sustain 0.1 m/sec walking speed over a 10-m span (Table 5). It is unclear to what ex- tent the authors' own unfamiliarity with the device or lack of a fully developed training protocol con- tributed to lower performance in these first two study subjects. In addition, several of the subjects were not able to obtain consistent and comfortable use of the remote wrist controller. They were still in control of their walking through self-triggering of steps; however, they were not able to consistently

change between the walking and sitting routines by themselves as they preferred to keep their hands on the crutches. Although many of the subjects were able to perform independently in the hospital setting, they all had limited ability to deal with ex- traneous factors, such as significant changes in the walking surface, being amidst excessive foot traffic, and the occasional device step misfire (e.g., device not taking a step even when patient commands one).

The authors do not believe that with the pro- totype device tested and the limited duration of practice allowed in the trial, the subjects would have been able to navigate all terrain situations independently. Additional training seems to be of benefit as improved performance has been noticed in subjects who have continued training beyond the trial. Future implementation of a more formalized user training program based on level of injury may result in higher functional mobility using ReWalk.

Subject performance in the ReWalk was likely influenced by injury level and seemed to fall into broad categories (Fig. 2). Generally, the T2YT4 sub- jects seemed to perform distinctly differently from those with lower level injuries. The varying levels of performance are reflected in walking speeds that ranged from 0.03 to 0.45 m/sec. Larger studies are needed to determine the validity of this trend. Ad- equate limb clearance and consistent stepping were the largest obstacles to successful use. Based on this study, having adequate trunk control seems to be a factor for subjects to consistently and re-

peatedly trigger steps to create a fluid gait. This result is not completely unexpected; use of conventional hip-knee-ankle-foot orthoses in patients with para- plegia is typically easier with more caudal levels of thoracic injury.[10] At the completion of this study, training methods and modifications of the device were still in development. The manufacturer has added several changes to the software not available during the trial, including the option of a marching- type gait to facilitate consistent stepping training.

Many subjects were able to walk fairly large distances independently and continuously by the end of the active use phase (9150 m). Although energy consumption was not measured during this safety trial, subjects appeared to work harder than able-bodied individuals walking at the same speeds. Fatigue did not seem to be a limiting fac- tor in performance, nor would it be expected to be the limiting factor in a more natural environ- ment. Subject walking skill level seems to be readily improved with additional training time. The test device required minor but important further devel- opment, including, but not limited to, (1) slightly

higher consistency of step trigger performance and (2) improved fail-safe modes if users lose balance and need to reset the device. Other improvements that may be welcomed by the target population include quieter motors and a streamlined appear- ance. The current commercially available Food and Drug AdministrationYapproved device has imple- mented many of these suggested improvements.

Both the measured and self-reported data seem to support the premise that consistent ReWalk use has a positive impact on pain, spasticity, and bowel and bladder function. None of the trends could be statistically analyzed because of the pilot nature of this trial. None of the observed benefits were reported to remain once active training stopped. The authors note that medication regimen was docu- mented but not controlled and no changes were made to implanted devices during the trial. The reported improvements cannot be unequivocally attributed to the use of ReWalk; however, it is the authors' expectation that more intense and longer term use of ReWalk may support sustained and statistically significant improvements along these and other health dimensions.

Subjects were positive about the ReWalk ex- perience and there was clear emotional well-being reported from walking. This was particularly evi- dent initially when several subjects were visibly overwhelmed with emotion upon initial walking. The follow-up survey indicated that these effects were not sustained after training discontinuation. However, ReWalk use by an individual in an ev- eryday setting may provide both the emotional and physical health benefits previously described, in addition to improving mobility and the oppor- tunity for increased social interaction. Taken to- gether, these changes may contribute to improved life satisfaction.[4,43] Neural repair and regeneration approaches, to the degree needed to restore func- tion to patients with complete SCI motor injuries and other neurologic conditions, seem far from being commonplace. The ReWalk and other similar technology may keep individuals with SCI ideally prepared to be candidates for more advanced medi- cal treatments as they are developed by

maintaining physical health, particularly neuromusculoskeletal health below the level of the injury.

The authors continue to explore the potential of ReWalk to restore independent walking function in patients with SCI. Future goals are to expand the use of ReWalk to noncomplete SCI and explore use in other neurologic causes of gait dysfunction such as stroke, brain injury, and cerebral palsy, either as an orthosis or as a gait training intervention.

CONCLUSIONS

The potential for ReWalk to be used as an ambulatory powered orthosis for motor-complete SCI patients is evident from this trial; long-term consistent use is promising as the device is devel- oped for personal home use. Subjects were able to safely participate in training sessions up to three times a week for a period of approximately 2 mos, with no falls or occurrences of autonomic dysre- flexia and relatively few minor adverse events re- lated primarily to pressure and irritation from the device or from being upright for prolonged periods of time, for those not used to that. Most subjects were able to achieve a level of walking proficiency that was close to that needed for limited commu- nity ambulation in an urban setting. The natural- istic mode of exercise provided by ReWalk may improve some of the health problems reported in this population, thereby possibly lessening the in- herent risks associated with their management. Data also suggest that immediate gains may be made in several key areas, including pain management, spasticity, and bowel and bladder function. Further- more, the use of the ReWalk can offer, in the near future, a greater level of independent upright mo- bility than currently exists for this population.

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APPENDIX 1
Participant Satisfaction Questionnaire

The 10 questions below were asked of each subject upon the completion of the active participation phase of the research project. Subjects were given the following five answer choices to each question:

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1. The ReWalk training process is easy.

2. Fitting and adjusting ReWalk is easy.

3. I felt comfortable using ReWalk.

4. Using ReWalk did not cause me any pain.

5. I didn’t feel especially fatigued when using ReWalk.

6. When I finished training, I felt comfortable using ReWalk.

7. Use of the device has lessened the spasticity in my lower limbs.

8. I didn’t experience any respiratory problems when using the device.

9. During the period when I was using the device I felt an improvement

in my intestinal activity.

10. At the end of the training period I felt confident using the device.

Strongly Disagree (1)

_____ _____ _____ _____

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_____
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_____ _____

Disagree (2)

_____ _____ _____ _____

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_____
_____ _____

Neither Agree or Disagree (3)

_____ _____ _____ _____

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_____ _____

Agree (4)

_____ _____ _____ _____

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_____ _____

Strongly Agree (5)

_____ _____ _____ _____

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_____
_____
_____ _____

Amaç:
Bu çalışmanın amacı, omurilik yaralanmasına bağlı paraplejisi olan kişilerin rutin ayakta fonksiyonel işlevleri yerine getirmelerinde ReWalk'un emniyet ve performansını değerlendirmektir.

Tasarı:
Bu, ReWalk ile çalışan dış iskeletin emniyetini ve performansını açıkça, karşılaştırılmayan, randomize olmayan bir çalışmaydı. 12 deneğin hepsi aktif müdahaleyi tamamladı; Üçü uzun vadeli izlemde kaldı.

Sonuçlar:
Eğitim sonrasında, tüm denekler, ReWalk'ı kullanırken insan yardımına gerek kalmaksızın, sürekli olarak en az 50 ila 100 m boyunca, en az 5 ila 10 dakika sürekli ve hızları 0.03 ila 0,45 m / sn (ortalama, 0,25 m / sn). Oldukça düşük yürüme özelliklerine sahip iki denek hariç tutulduğunda, ortalama mesafeler ve hızlar önemli ölçüde iyileşmiştir. Bazı kişiler deneme sırasında ağrı, bağırsak ve mesane fonksiyonlarında düzelme ve spastisiteyi bildirdiler. Tüm denekler, ReWalk kullanımının duygusal / psikososyal faydaları konusunda güçlü pozitif yorumlarda bulundu.

Sonuçlar:
ReWalk, motor tam torasik düzeydeki omurilik hasarı hastaları için güvenli bir ambulator ortez olarak önemli bir potansiyele sahiptir. Çoğu konu, sınırlı topluluk ambulasyonu için gereken seviyeye yakın düzeyde bir düzeyde yürüme yeterliliği elde etti. Bireyler arasında yüksek düzeyde bir performans değişkenliği gözlemlendi. Bu değişkenliği bazıları yaralanma seviyesine göre açıklanmıştır, ancak diğer faktörler tamamen tanımlanmamıştır. Gelecekte bu rehabilitasyon aracının diğer teşhislere daha da geliştirilmesi ve uygulanması beklenmektedir.