Mobility Outcomes Following Five Training Sessions with a Powered Exoskeleton

Clare Hartigan, MPT,[1] Casey Kandilakis, DPT,[1] Skyler Dalley, PhD,[2] Mike Clausen,[2] Edgar Wilson,[2] Scott Morrison,[2] Steven Etheridge,[2] and Ryan Farris, PhD[2]

[1]Virginia C. Crawford Research Institute, Shepherd Center, Atlanta, Georgia; [2]Parker Hannifin Corporation, Human Motion and Control, Macedonia, Ohio

Background: Loss of legged mobility due to spinal cord injury (SCI) is associated with multiple physiological and psychological impacts. Powered exoskeletons offer the possibility of regained mobility and reversal or prevention of the secondary effects associated with immobility. **Objective:** This study was conducted to evaluate mobility outcomes for individuals with SCI after 5 gait-training sessions with a powered exoskeleton, with a primary goal of characterizing the ease of learning and usability of the system. **Methods:** Sixteen subjects with SCI were enrolled in a pilot clinical trial at Shepherd Center, Atlanta, Georgia, with injury levels ranging from C5 complete to L1 incomplete. An investigational Indego exoskeleton research kit was evaluated for ease of use and efficacy in providing legged mobility. Outcome measures of the study included the 10-meter walk test (10MWT) and the 6-minute walk test (6MWT) as well as measures of independence including donning and doffing times and the ability to walk on various surfaces. **Results:** At the end of 5 sessions (1.5 hours per session), average walking speed was 0.22 m/s for persons with C5-6 motor complete tetraplegia, 0.26 m/s for T1-8 motor complete paraplegia, and 0.45 m/s for T9-L1 paraplegia. Distances covered in 6 minutes averaged 64 meters for those with C5-6, 74 meters for T1-8, and 121 meters for T9-L1. Additionally, all participants were able to walk on both indoor and outdoor surfaces. **Conclusions:** Results after only 5 sessions suggest that persons with tetraplegia and paraplegia learn to use the Indego exoskeleton quickly and can manage a variety of surfaces. Walking speeds and distances achieved also indicate that some individuals with paraplegia can quickly become limited community ambulators using this system. **Key words:** *mobility limitation, orthotic devices, robotics, rehabilitation, spinal cord injuries, walking*

There are about 276,000 individuals in the United States with spinal cord injury (SCI), with roughly 12,500 new injuries sustained each year.[1] Surveys of persons with SCI indicate that mobility concerns are among the most prevalent[2] and that chief among mobility desires is the ability to stand and walk.[3] In addition to limiting access to places not accessible by wheelchair, loss of legged mobility results in substantial adverse effects on health. These secondary impairments can include skin complications; increases in pain, muscle spasticity, and urinary tract infections; impaired digestive, lymphatic, and vascular functions; increased body mass index; decreased bone mineral density and respiratory and cardiovascular capacities; and depression.[4-6] The collective effect of secondary impairments is a potential decrease in quality of life and a substantial increase in the cost of health care for individuals with SCI.

Recently, lower limb exoskeletons have emerged on the clinical and commercial marketplaces. Such devices enable weight-bearing legged mobility for individuals with SCI. Although comprehensive studies on the health effects of exoskeleton walking have yet to be published, several studies have described health benefits associated with supported standing for nonambulatory individuals with SCI. These benefits include improvements in well-being, blood circulation, bowel and bladder function, skin integrity, and sleep and reductions in spasticity and pain.[7-9] If these benefits can be derived from the stationary nature of a standing frame, then similar or greater health benefits may result from walking with a lower limb exoskeleton. An exoskeleton provides a similar upright weight-bearing posture as a standing frame, while also allowing lower limb movement, coordinated upper body movement, and cyclic weight-bearing shifts from one leg to the other. Because exoskeletons offer mobility, the frequency and duration of use by persons with mobility limitations may be increased. More

Corresponding author: Ryan Farris, Parker Hannifin Corporation, Human Motion and Control, 1390 E. Highland Road, Macedonia, OH 44056; e-mail: ryan.farris@parker.com

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frequent or prolonged use could further enhance some of the benefits of upright weight bearing.

Few studies have been published on the potential health benefits of walking with exoskeletons for nonambulatory individuals. A pilot study of an exoskeleton for walking was conducted with 12 individuals with motor-complete thoracic-level SCI. Although the primary objective was to establish safety and efficacy, the study reported improvements in pain, bowel function, bladder function, spasticity, and emotional well-being.[10] A study of exoskeleton use by 6 subjects with motor-complete paraplegia found that all participants sustained a small but significant loss of fat tissue mass after 20 to 60 hours of use.[11] A reduction in fat tissue may decrease predisposition to diabetes or cardiovascular disease, as fat tissue mass increases the propensity for these conditions.[12]

To best obtain potential health benefits, individuals with SCI should be able to quickly achieve a nominal level of proficiency with the exoskeleton and without an undue amount of time training in the clinic. Further, exoskeletons should be usable by individuals with a wide range of personal and injury characteristics, including neurological level, completeness, age, and time since injury. If exoskeleton walking is shown to provide the health benefits previously mentioned, realization of the full potential to do so will entail use of the exoskeleton in the home and community. To assess the extent to which individuals of various injury levels are able to achieve a nominal level of proficiency in walking in a short period of time, a preliminary study was conducted in which 16 subjects with motor-complete SCI at levels C5 through L1 were given 5 sessions each to learn to walk in the Indego exoskeleton. These sessions encompassed an initial evaluation, fitting, adjustments, training, and practice. (There were no preliminary set-up sessions.) At the close of the fifth session, each subject performed a 10-meter walk test (10MWT) and a 6-minute walk test (6MWT) to characterize the level of proficiency achieved in walking over the 5-session course. The authors also characterized the extent to which, after the 5-session course of training, each subject could don/doff the device; walk outdoors, on ramps, on sidewalks, and over grass; and use elevators. This article presents the results of these preliminary studies and specifically describes the level of mobility achieved by 16 SCI participants with an exoskeleton after a total of approximately 7.5 hours of fitting and training per person.

Indego Powered Exoskeleton

The Indego exoskeleton (Parker Hannifin Corporation, Macedonia, OH), shown in **Figure 1**, was used in the study. The Indego incorporates 4 motors for powered movement of bilateral hip and knee joints in the sagittal plane, in addition to built-in ankle-foot-orthoses (AFOs) at both ankle joints to provide ankle stability and transfer the weight of the exoskeleton to the ground. The exoskeleton consists of 5 modular components: a hip segment, a right and left upper leg segment, and a right and left lower leg segment. These components assemble via quick-connects to enable easy donning, doffing, and transport and compact storage. The hip segment contains a swappable, rechargeable lithium ion battery pack that powers the exoskeleton, and each thigh segment contains a pair of brushless DC motors, which actuate the hip and knee joints through speed reduction transmissions. The knee joints are equipped with

Figure 1. The Indego powered exoskeleton.

normally locked brakes to preclude knee buckling in the event of a power failure. This essentially renders the orthosis as a pair of knee-ankle-foot orthoses (KAFOs) in the unpowered state. The total mass of the exoskeleton including the battery is 12 kg (26 lbs). The system is designed with a low profile and no backpack, allowing it to be worn and used by an individual while sitting in a rigid frame wheelchair, car seat, or armchair.

The powered lower limb exoskeleton enables sitting, walking, and standing as well as sit-to-stand, stand-to-walk, walk-to-stand, and stand-to-sit transitions. To allow the user to have autonomous control of these maneuvers, a user interface was developed based on the user's ability to affect his or her center of pressure via the use of the upper body in combination with a stability aid. Specifically, the control system estimates the location of the user's center of pressure (CoP), defined as the user's center of mass projection onto the horizontal ground plane, and uses the distance between the CoP and the location of the forward ankle joint as the primary command input. Thus, the user transitions from a given activity (sitting, standing, or walking) by tilting his or her body forward or backward such that the CoP moves in an anterior or posterior direction, which commands the controller to transition to a different activity mode. This approach enables the user to autonomously perform the various walking tests. An Apple iPod Touch is used with a custom Indego App and Bluetooth connection for clinician-adjustable settings. This provides an interface for adjusting various control, gait, and feedback settings, as well as a portal for viewing real-time device status information and current and past session reports. A more detailed description of the exoskeleton control architecture and user interface, including a more specific discussion of the conditions required to move between activities, has been previously reported.[13]

Methods

An exoskeleton was fitted to 16 individuals with SCI whose injury levels ranged from C5 complete to L1 incomplete. To assess how quickly each participant could achieve proficiency in walking, each participant was trained in the system for 5 sessions, each session lasting approximately 1.5 hours. Following these 5 sessions, each participant performed a 10MWT and a 6MWT. Depending on injury level and comfort level, participants used either a front-wheeled platform walker, front-wheeled walker, or forearm crutches as a stability aid. Although the 10MWT and 6MWT were conducted indoors, additional objectives during the 5-session training period were to walk outside (on concrete walkways and city sidewalks), up and down Americans with Disabilities Act (ADA)–compliant ramps (ie, 5° slope or less), and over grass. Other performance objectives included the ability to self-don and self-doff the device and the ability to enter an elevator, ride to another floor, and exit without requiring the elevator door to be held open.

Shepherd Center Institutional Review Board approval was obtained for this study, and informed consent was obtained from each participant. Inclusion criteria for the study required participants to be 18 years or older, with height between 155 cm and 191 cm and weight of 113 kg or less. Persons with SCI were eligible for the study if they were nonambulatory (used either a manual or motorized wheelchair) for home and community mobility, their injury was complete or incomplete (ASIA Impairment Scale [AIS] A, B, C, or D), and their neurological level was C4 or lower. No restrictions on time since injury were defined. The study allowed for individuals who exhibited spasticity up to and including a Modified Ashworth Scale score of 3. General requirements for gait training applied, including medical clearance from a physician, appropriate joint ranges of motion for safe gait, and ability to tolerate being upright without orthostasis.

The first day of the 5 sessions was used for initial evaluation. This entailed an assessment by a physical therapist of the subject's height, weight, range of motion, sensation, muscular strength, and ability to walk. Additional measurements were taken of the hips, upper legs, and lower legs to aid in fitting the user to the proper exoskeleton component sizes. Days 2, 3, and 4 of the trial were gait-training sessions during which participants learned to stand and walk with the exoskeleton while using an appropriate stability aid as determined by the physical therapist. During the

fifth and final session, participants performed the 10MWT and the 6MWT. For the 10MWT, the floor was marked with a 14-meter path and the middle 10 meters were timed for gait speed. Participants began walking 2 meters before the timed section and ended 2 meters beyond to ensure that the timed 10 meters captured constant gait speed. They were instructed to walk "as safe and as fast as you can from the start line to the finish line" (14 meters). Using a stopwatch, the physical therapist recorded the time the participants took to walk the middle 10 meters. Time started when any part of the body crossed the 2-meter mark and time stopped when any part of the body crossed the 12-meter mark. The 6MWT was performed in a straight hallway in which 2 cones were spaced 30 meters apart. The participants were instructed to "cover as much ground as possible in 6 minutes" by walking back and forth, turning around the cones as each was reached. The physical therapist recorded the total distance covered by each participant during the 6 minutes.

The level of therapist assistance required during walking was also recorded for each participant. All participants in this study required moderate assist, minimal assist, or supervision. Moderate assist was reported when a participant required assistance but was able to perform between 50% and 75% of the activity. Minimal assist was reported when a participant required assistance but was able to perform at least 75% of the activity. Supervision was reported when a participant was able to perform 100% of the activity but a therapist was present to ensure safety.

Throughout the study, all control of the exoskeleton was left to the participant (see previous description of the device). Additionally the device settings for step length, step height, and step speed were similar for each participant. Although the nominal setting for step speed was held constant, the participants were able to influence their walking speed based on how quickly they transitioned their posture to trigger stepping.

Results

The demographics and results of the study for the 16 enrolled participants are summarized in **Tables 1** and **2**. The participants ranged from age 18 to 51 years with injury levels from L1 to C5. For purposes of discussion, the participants are divided into 3 categories: tetraplegia (C5-C7), upper paraplegia (T1-T8), and lower paraplegia (T9-L1). The average walking speeds for each group during the 10MWT and the average distances traveled during the 6MWT are shown in **Figures 2** and **3**.

Table 1. Subject demographics

Level of injury	Subject no.	Sex	Age range, years	Height, cm	Weight, kg	Neurological level of injury
Tetra (C5-C7)	G2 04	Male	18-26	163	61	C5B
	G2 06	Male	18-26	191	91	C6B
	G2 14	Male	18-26	193	102	C6A
Upper para (T1-T8)	G2 02	Male	35-42	175	79	T5A
	G2 09	Male	27-34	180	66	T7A
	G2 16	Male	35-42	173	82	T5A
	G2 17	Male	43-51	185	84	T6A
	G2 18	Female	27-34	173	65	T7C
Lower para (T9-L1)	G2 01	Male	43-51	180	86	T12A
	G2 03	Male	43-51	188	80	T10A
	G2 05	Female	18-26	157	54	T10A
	G2 07	Male	18-26	173	61	T11B
	G2 10	Female	35-42	173	59	T 9A
	G2 11	Male	43-51	183	88	T12A
	G2 13	Male	43-51	170	64	L1C
	G2 15	Male	43-51	178	82	T12A

Table 2. Participant performance data from Indego pilot study

Level of injury	Subject no.	PRW, RW, or FCs	10MWT Speed, m/s	6MWT Distance, m	Assist to walk	Surfaces[a]	Don time,[b] m:s	Doff time,[b] m:s
Tetra (C5-C7)	G2 04	PRW	0.24	74.2	Min A of 1	I,O,R	D 8:00	D 5:00
	G2 06	PRW	0.19	46.9	Mod A of 1	I,O,R	D 15:00	D 5:00
	G2 14	PRW	0.22	71.2	Mod A of 1	I,O,R,G	D 10:00	D 2:00
Upper para (T1-T8)	G2 02	RW	0.25	62.1	Supervision	I,O,R	C 10:00	S 4:00
	G2 09	RW	0.32	92.8	Supervision	I,O,R	S 2:15	S 2:00
	G2 16	RW	0.22	74.8	Min A of 1	I,O,R	C 8:00	C 2:00
	G2 17	RW	0.25	81.03	Min A of 1	I,O,R	C 10:00	C 3:00
	G2 18	RW	0.24	69	Min A of 1	I,O	C 10:00	C 5:00
Lower para (T9-L1)	G2 01	FC	0.53	143.9	Supervision	I,O,R,G	S 2:30	S 2:00
	G2 03	FC	0.41	129.4	Supervision	I,O,R,G	S 12:00	S 6:00
	G2 05	RW	0.36	92.4	Min A of 1	I,O,R,G	S 13:00	S 3:00
	G2 07	RW	0.47	140	Supervision	I,O	S 5:00	S 3:00
	G2 10	RW	0.31	91.5	Min A of 1	I,O,R,G	C 3:30	S 4:00
	G2 11	RW	0.53	140.8	Supervision	I,O,R	S 13:00	S 12:00
	G2 13	FC	0.54	136.9	Supervision	I,O,R,G	S 11:00	S 3:00
	G2 15	FC	0.41	91.5	Supervision	I,O,R,G	S 3:30	S 2:30

Note: FC = forearm crutches; Min A = minimal assist; Mod A = moderate assist; PRW = platform rolling walker; RW = rolling walker; 10MWT = 10-meter walk test; 6MWT = 6-minute walk test.

[a]I = inside (thresholds, carpet, and hard flooring); O = outside; R = ramps; G = grass.

[b]Don/doff time: C = combined PT/subject; D = fully dependent on physical therapist; S = subject only.

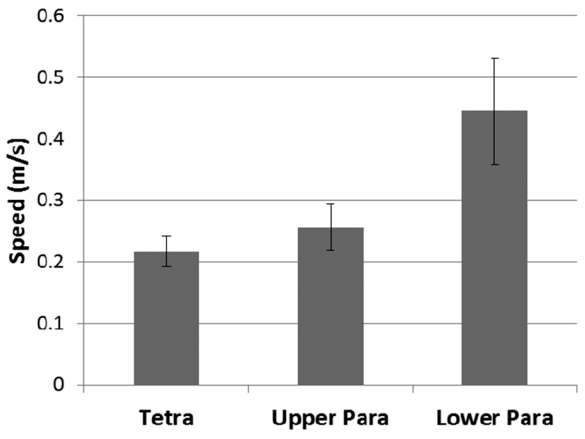

Figure 2. Average 10-meter walk test gait speeds with standard deviations shown for the 3 test groups: tetraplegia (Tetra), upper paraplegia (Upper Para), and lower paraplegia (Lower Para).

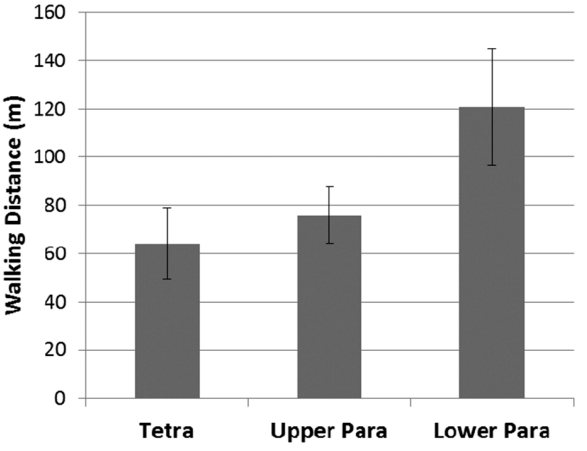

Figure 3. Average 6-minute walk test distances with standard deviations shown for the 3 test groups: tetraplegia (Tetra), upper paraplegia (Upper Para), and lower paraplegia (Lower Para).

Tetraplegia (C5-C7 injury level)

After 5 sessions, the 3 participants with motor complete tetraplegia were able to ambulate using a bilateral platform rolling walker with minimal or moderate assist of one therapist at an average speed of 0.22 m/s during the 10MWT. These participants were able to walk on indoor surfaces (including hard flooring, carpet, and thresholds), outdoor surfaces (sidewalks), elevators, and ADA-compliant ramps with the assistance of 1 or 2 persons for safety. One participant was able to walk over grass. Due to poor weather conditions,

the other 2 participants were unable to attempt walking on grass. During the 6MWT, participants covered an average of 64 meters. All participants in this category were dependent upon a physical therapist for donning and doffing the exoskeleton.

Upper paraplegia (T1-T8 injury level)

The 5 participants with upper paraplegia used a rolling walker and averaged 0.26 m/s during the 10MWT. Two walked with supervision and 3 required minimal assist of one therapist. All participants in this group were able to walk on indoor surfaces, outdoor surfaces, and in elevators. Four participants successfully negotiated ramps, whereas 1 participant did not due to time constraints. The average distance covered by these participants during a 6MWT was 76 meters. One participant was able to don and doff the system independently, while the remaining 4 required varying levels of assistance from the therapist during donning and doffing.

Lower paraplegia (T9-L1 injury level)

Eight participants with lower paraplegia participated in the study. Half used a rolling walker and half used forearm crutches. Six of the 8 were able to walk independently, and 2 required minimal assist from one therapist. This group averaged a walking speed of 0.45 m/s during the 10MWT and a distance of 121 meters during the 6MWT. Six of the 8 participants were able to ambulate on indoor surfaces, outdoor surfaces, elevators, ramps, and grass. The maximum level of assistance required for these participants is reported in the "assist to walk" column of **Table 2**. One participant did not attempt to walk on grass, and one participant did not attempt to walk on ramps or grass due to weather or time constraints. Seven participants were able to don and doff the system independently.

Discussion

The authors have examined the usability and efficacy of an exoskeleton with a small sample of persons with lower paraplegia, upper paraplegia, and lower tetraplegia. It is difficult to predict the possible performance achievable with long-term use of an exoskeleton; but based upon the results of 5 training sessions, the data suggest several trends. Users with tetraplegia are expected to require assistance with donning, doffing, and walking. Walking speeds for this population were below the thresholds for community or limited community ambulation. Therefore, the exoskeleton would be appropriate for use in individuals with tetraplegia primarily as a means for exercise or as a rehabilitative therapy intervention.

Several participants with upper paraplegia demonstrated the ability to use the system with supervision only. However, the average gait speeds and walking distances recorded for this group were only slightly higher than those of the group of participants with tetraplegia. This indicates that individuals with upper paraplegia may be capable of using the system outside of the clinic, but their use may be restricted to limited community distances, home, or exercise ambulation.

In contrast, the majority of participants in the lower paraplegic group were able to achieve supervision-only walking with the system and significantly higher gait speeds and longer walking distances. A recent study[14] on distance and velocity requirements for community ambulation suggests that a gait speed of 0.49 m/s is adequate for community ambulation, based upon the time required to cross the street as dictated by typical crosswalk signals. The average gait speed for the participants with lower paraplegia in this study was 0.45 m/s after 5 sessions. Therefore, individuals with lower paraplegia are likely to be capable of community ambulation or at least limited community ambulation outside the home with the assistance of powered exoskeletons.

During the course of the study, 2 minor adverse events were reported. One subject experienced bruising on the torso under one of the tensioning straps. Training was continued after additional padding was placed over the participant's ribcage. The bruising resolved in 4 days. Another participant experienced grade 1 skin redness along the lateral upper back. It was unclear whether this was related to pressure or friction created by the device or to the participant's abdominal binder. The redness resolved in 2 days.

Conclusion

The participants' proficiency after 5 sessions suggests that powered exoskeletons systems are capable of providing individuals with SCI the ability to ambulate in both indoor and outdoor environments. For individuals with higher level SCI (tetraplegia), the use of exoskeletons may be most appropriate for exercise purposes and rehabilitative training within a clinical setting. The results also indicate that some users will be capable of independent donning, doffing, and walking and will ambulate at speeds appropriate for use outside of the clinic, particularly in the case of lower paraplegia.

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