Initial Outcomes from a Multicenter Study Utilizing the Indego Powered Exoskeleton in Spinal Cord Injury

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Objective: To assess safety and mobility outcomes utilizing the Indego powered exoskeleton in indoor and outdoor walking conditions with individuals previously diagnosed with a spinal cord injury (SCI). **Methods:** We conducted a multicenter prospective observational cohort study in outpatient clinics associated with 5 rehabilitation hospitals. A convenience sample of nonambulatory individuals with SCI (N = 32) completed an 8-week training protocol consisting of walking training 3 times per week utilizing the Indego powered exoskeleton in indoor and outdoor conditions. Participants were also trained in donning/doffing the exoskeleton during each session. Safety measures such as adverse events (AEs) were monitored and reported. Time and independence with donning/doffing the exoskeleton as well as walking outcomes to include the 10-meter walk test (10MWT), 6-minute walk test (6MWT), Timed Up & Go test (TUG), and 600-meter walk test were evaluated from midpoint to final evaluations. **Results:** All 32 participants completed the training protocol with limited device-related AEs, which resulted in no interruption in training. The majority of participants in this trial were able to don and doff the Indego independently. Final walking speed ranged from 0.19 to 0.55 m/s. Final average indoor and outdoor walking speeds among all participants were 0.37 m/s (SD = 0.08, 0.09, respectively), after 8 weeks of training. Significant ($p < .05$) improvements were noted between midpoint and final gait speeds in both indoor and outdoor conditions. Average walking endurance also improved among participants after training. **Conclusion:** The Indego was shown to be safe for providing upright mobility to 32 individuals with SCIs who were nonambulatory. Improvements in speed and independence were noted with walking in indoor and outdoor conditions as well as with donning/doffing the exoskeleton. **Key words**: *ambulation, exoskeletons, gait, paraplegia, robotic devices, spinal cord injury, walking*

Damage to the spinal cord often results in lasting sensory and motor impairments that can significantly impact an individual's mobility and independence and lead to reduced life satisfaction.[1-3] There have been medical advancements in treating spinal cord injury (SCI), and rehabilitation services and technology are needed to address the often permanent functional limitations of SCI.

Return to walking is a priority for individuals in rehabilitation after SCI.[1] Recent technological advancements have resulted in the development of robotic exoskeletons with the goal of providing an energy efficient avenue for individuals to regain the ability to walk after neurologic injury. Multiple versions of robotic exoskeleton systems have been developed that rely on hip and knee joint motors, a computerized control system, and rechargeable batteries to promote walking for individuals who are otherwise unable to mobilize in an upright manner.

Current literature on exoskeletons includes pilot and case series studies that have suggested safety, feasibility, and potential improvements in independence, mobility, and even health; however, these results have been obtained using relatively small sample sizes.[4-8] Therefore, a more comprehensive investigation is warranted with a larger sample size to adequately investigate safety and feasibility for a nonambulatory SCI population

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in the indoor and outdoor environments. Due to the novelty of this technology and the inherent risk in this patient population, it is particularly important to appropriately position robotic exoskeletons in the continuum of rehabilitation care and community mobility when evaluating a larger SCI population with varying levels of injury and ability.

In June 2014, 5 rehabilitation centers in the United States specializing in the care of individuals who had sustained SCIs participated in a clinical trial sponsored by Parker Hannifin to evaluate the safety and feasibility of utilizing the Indego exoskeleton for upright mobility in individuals with SCI. The participating centers were Craig Hospital (Englewood, Colorado), Kessler Foundation and Kessler Institute for Rehabilitation (West Orange, New Jersey), Rehabilitation Institute of Chicago (now Shirley Ryan AbilityLab, Chicago, Illinois), Rusk Rehabilitation (New York), and Shepherd Center (Atlanta, Georgia). The primary purpose of this article is to report on the safety and feasibility outcomes utilizing the Indego device for standing and walking with 32 participants who previously sustained SCIs and are unable to walk independently.

The trial was registered with clinicaltrials.gov (#NCT02202538) and was designed with the intent to demonstrate safety and feasibility to the US Food and Drug Administration (FDA) as part of a submission for clearance of the device. Feasibility objectives were defined as the following: (1) Forty-four nonambulatory participants with SCI would complete an 8-week training protocol utilizing the Indego across 5 sites. (2) Participants completing the trial would experience limited device-related AEs. (3) Participants would demonstrate the ability to don/doff the device with limited to no assistance. (4) Participants would exhibit improvements in walking-related outcomes such as speed, endurance, independence, and sit-to-stand transitions. The sample size was chosen based on FDA feedback. This report will focus on the outcomes of the initial 32 participants who completed the trial.

Methods

Participants

Each participant was required to have a signed medical clearance from their physician signifying that they were appropriate for walking with full weight bearing and without undue risk for fracture. No formal bone health measurements were taken prior to enrollment. The criteria were evaluated by each participant's physician and the site-specific medical primary investigator (PI) before a participant was enrolled in this study. No restrictions were placed on time since injury. **Table 1** lists the specific inclusion and exclusion criteria.

Table 1. Inclusion and exclusion criteria for participation in the Indego exoskeleton trial

Inclusion criteria	Exclusion criteria
• 18 years or older • Height between 5'1" to 6'3" • Hip width no greater than 42 cm • Weight less than 250 lbs • Diagnosed with an SCI and a neurologic level of injury (NLI) T4 and lower • International Standards of the Neurological Classification of SCI (ISNCSCI) A, B, C, or D • Modified Ashworth Scale (MAS) score of 3 or less for the lower extremities • Sufficient upper extremity (UE) strength and range of motion (ROM) to use an appropriate assistive device (AD) for stability • Blood pressure and heart rate within established guidelines for locomotor training • Nonambulatory or poorly ambulatory (uses a wheelchair as primary means of mobility)	• Heterotopic ossification (HO) that was felt by the investigative team to put them at undue risk for fracture • Moderate to severe traumatic brain injury (TBI) • Inability to follow instructions • Women who were pregnant or attempting to become pregnant during the study intervention time period • Lower extremity joint limitations that exceeded 10° at hips, knees, or ankles • Deemed to have an increased risk for injury by medical personnel for any other reason.

Note: Inclusion height and weight was based on manufacturers' indications. Neurologic level of injury for enrollment was based on current US Food and Drug Administration guidelines.

Each center was responsible for obtaining their site-specific institutional review board approval and to consent all participants prior to study participation. Thirty-two participants were enrolled from October 2014 to April 2015 across all 5 clinical sites in the United States. After obtaining medical clearance and informed consent, each participant was fitted with the Indego exoskeleton and received training from study personnel on the appropriate use of the system. Participants completed initial and final evaluations along with 24 training sessions at a frequency of 3 times per week for 8 weeks (26 visits). Participants also received a follow-up phone call 1 week after their final evaluation (session 27) to inquire about potential adverse events after trial completion. Throughout the trial, participants were asked to perform various gait-related tasks, and outcome measures were captured and recorded. A summary of the 27 sessions and a breakdown of the dose and duration of treatment per session are provided in **Table 2**.

Table 2. Indego trial dose and duration summary

Session summary		
Timeframe	**Activity**	**Sessions count, *n***
Week 1	PT evaluation and 3 training sessions	4
Weeks 2, 3, 4, 5, 6, and 7	3 sessions/week	18
Week 8	3 sessions and final evaluation	4
Week 9	Follow-up phone call[a]	1
Total sessions		**27**
Duration summary		
Session	**Purpose**	**Duration, hours**
1	Subject consent and evaluation	4
2-23 (excluding 11, 12, 13)	Indego training sessions 3x/week	1.5 X 18 sessions = 27
11, 12, 13	Midway training assessments	2 x 3 sessions = 6
24	Outcome measures	2
25	Outcome measures	2
26	PT final evaluation	4
27	Follow-up phone call[a]	1
Total hours		**46**

Note: PT = physical therapy.

[a]Follow-up phone call completed to ensure no adverse events reported after study completion.

Device

The Indego consists of 5 modular components: a hip segment, a right and left upper leg segment, and a right and left lower leg segment (**Figure 1**). Powered movement at the hips and knees is provided by 4 motors contained in each upper leg component along with embedded sensors and controllers. The system has built-in carbon fiber ankle-foot orthoses (AFOs) that provide ankle stability and transmit the weight of the orthoses to the ground. The hip component houses a rechargeable lithium ion battery that provides power to the system.

On-board microprocessors receive signals from integrated sensors that provide feedback on the user's posture and tilt. When users transition between mobility activities, they move their center of pressure (COP) in an anterior or posterior direction; this signals the controller to switch to a different activity mode. The Indego controls are self-contained, which allows the user to utilize an assistive device (walker or crutches) solely for stability while standing and walking. The exoskeleton weighs 26 pounds and is used in conjunction with an Apple iPod Touch via a Bluetooth connection. A more detailed description of the exoskeleton along with the user interface has been previously reported.[9]

Adverse events

AEs monitored during this trial included skin health and cardiovascular health. Skin checks were completed before, during, and after each session with any abnormalities clearly documented.

Outcomes

Outcomes assessed in this study include mean time for donning/doffing the Indego device and 10-meter walk test (10MWT), 6-minute walk test

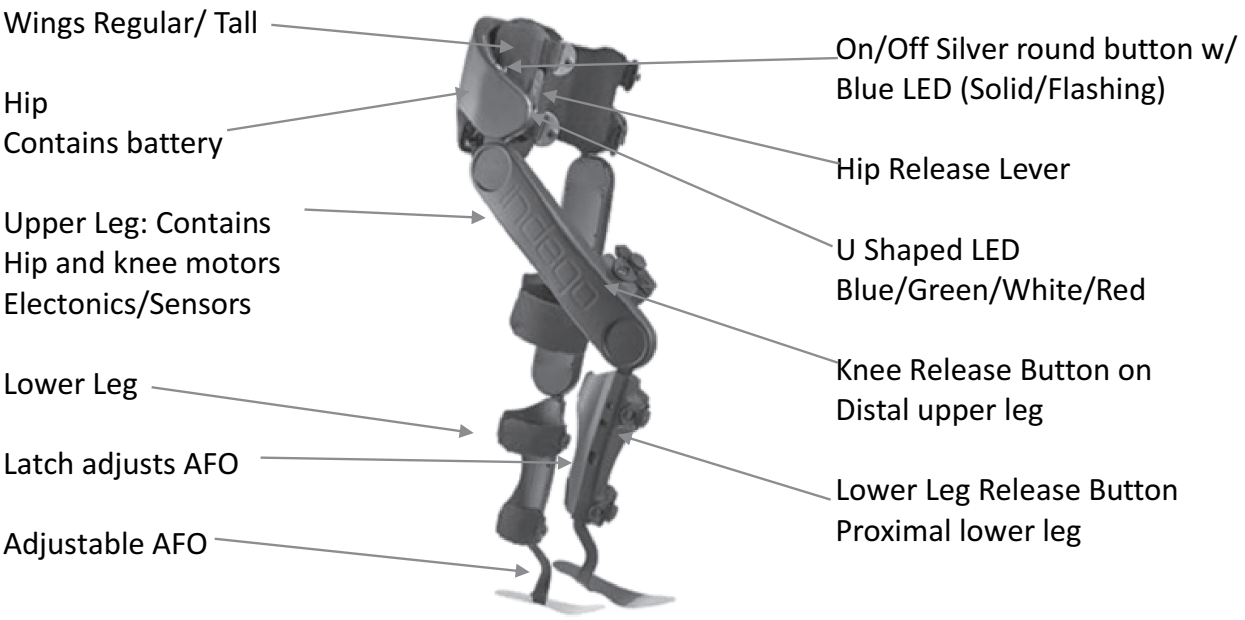

Figure 1. Indego exoskeleton. AFO = ankle-foot orthosis.

(6MWT), Timed Up & Go (TUG), and 600-meter walk test. The 10MWT has been shown to be a valid and reliable tool to assess walking speed in both the acute and chronic SCI populations.[10,11] Indoor assessments were completed on level smooth surfaces, and outdoor assessments were completed on sidewalks or pavement. Three trials of the 10MWT were completed at each assessment and were averaged to obtain an overall gait speed. The 6MWT has been shown to be valid and reliable in the SCI population when measuring walking speed over a longer period of time and distance.[10-13] Participants were asked to walk as far as possible during a 6-minute period with standing rest breaks given as needed. The 10MWT and 6MWT were completed midway (session 11, 12, or 13) and during the final walking sessions (session 24 or 25) utilizing the device and an appropriate assistive device (AD). The 600-meter walk test was completed once during the trial on indoor surfaces between the midway and final assessments. The 600-meter walk test was developed specifically for this trial based on recent literature suggesting that 600 meters is the minimum walking requirement for full community ambulation.[14] The TUG is a timed assessment that incorporates sit to stand, stand to sit, walking, and turning; it has demonstrated excellent reliability in community-dwelling elderly individuals and is highly sensitive for predicting falls in that population.[15,16] Three trials of the TUG were recorded with participants using the device and appropriate AD during the midway (session 11, 12, or 13) and the final walking sessions (24 or 25). Therapists began training participants on the appropriate technique for donning/doffing during the initial training session, and the time and amount of assistance required to complete both activities were recorded during each training session. The goal of each session was to move toward the participant gaining greater independence with donning/doffing until the therapist was no longer needed.

Statistical analysis

Descriptive statistics were utilized to evaluate age, height, weight, level of injury (LOI), and American Spinal Injury Association Impairment Scale (AIS) classification. Mean donning and doffing times and standard deviations were calculated at midway and final evaluations. Mean walk speeds along with standard deviations were calculated at midway and final evaluations in both

indoor and outdoor conditions. Mean walking endurance and standard deviations were calculated at midway and final evaluations. Mean TUG times and standard deviations were also calculated at midway and final evaluations. Paired samples *t* tests were calculated to determine pre/post differences in walking speed and endurance with a significance level set at $p = .05$.

Results

Participant demographics are described in **Table 3**.

Adverse events

All 32 participants enrolled in the trial were able to complete the 8-week protocol. A total of 864 walking sessions were completed among the initial 32 participants with a combined total of 66 AEs reported across the 5 sites. Eleven of these events were directly device related and were reported on 6 participants. The majority (9/11) of the device-related AEs were skin redness, small abrasions, mild joint edema, or mild bruising on the lower legs and hips that were resolved with improved padding and pressure relief. Sixty-four of 66 AEs were minor and were not device-related, with the majority being minor skin abrasions that occurred outside of training. Two events were categorized as moderate on a severity scale. One participant determined to have a moderate AE presented with a right greater trochanteric blister due to pressure and friction while walking in the device. Another participant sustained an ankle sprain while walking in the device. There was no interruption in training for either participant experiencing a moderate AE, and both participants completed the trial on schedule.

Table 3. Participant demographics in the Indego exoskeleton trial

Gender, *n*	female (5), male (27)
Age, years	range, 18-64; mean, 37
Height, cm	range, 152.4-190.5; mean (*SD*), 174.6 (9.4)
Weight, kg	range, 52.1-104.8; mean (*SD*), 72.1 (12.8)
Level of injury	T4-L2
AIS classification, *n*	AIS A (21), AIS B (5), AIS C (6)

Note: AIS = American Spinal Injury Association Impairment Scale.

Outcome results

Table 4 depicts the time and independence associated with donning and doffing the Indego device for the participants in this study. Reduction in the average time to don and doff the device was demonstrated by all participants and illustrates that with practice individuals have the ability to improve their efficiency with donning/doffing the device.

Midpoint indoor walk speed average among all participants was 0.31 m/s ($SD = 0.08$), while the outdoor average walk speed at this time point was 0.32 m/s ($SD = 0.08$). Final indoor and outdoor walking speeds among all 32 participants improved to 0.37 m/s ($SD = 0.08$ and 0.09, respectively). Utilizing a paired samples *t* test, no significant differences were noted between midpoint indoor and midway outdoor or final indoor and final outdoor 10MWT ($p = .081$ and $p = .627$, respectively). Significant ($p < .05$) improvements were noted between midpoint and final indoor 10MWT times as well as between midpoint and final outdoor 10MWT times among participants. For all participants, average distance completed during the initial 6MWT was 92.0 m and an average distance of 107.5 m ($SD = 28.3$) was completed during the final evaluation period. TUG improved from a midpoint average of 102.1 seconds ($SD = 28.3$) to a final of 83.6 seconds ($SD = 19.8$). The average time it took all 32 participants to walk 600 meters was 35 minutes 24 seconds ($SD = 13.44$ seconds). **Table 5** shows walking speed based on AIS classification.

Table 4. Donning/doffing Indego exoskeleton

Activity	Midway assessment	Final assessment	*p*
Donning time, mean (*SD*) min:sec	10:46 (4:11)	9:01 (3:56)	.005
Doffing time, mean (*SD*) min:sec	3:08 (1:25)	2:44 (1:32)	.016
Independent donning	Not assessed	20/32	
Independent doffing	Not assessed	27/32	

Table 5. Gait speed based on AIS classification

			Speed, m/s		
Assessments	**AIS (NLI)**	***n***	**Minimum**	**Maximum**	**Mean (*SD*)**
Mid indoor	A (T4-L1)	22	0.19	0.54	0.32 (0.07)
Mid outdoor	A (T4-L1)	22	0.22	0.54	0.34 (0.07)
Final indoor	A (T4-L1)	22	0.19	0.55	0.38 (0.08)
Final outdoor	A (T4-L1)	22	0.20	0.57	0.38 (0.08)
Mid indoor	B (T4-T5)	5	0.18	0.27	0.27 (0.09)
Mid outdoor	B (T4-T5)	5	0.20	0.32	0.26 (0.06)
Final indoor	B (T4-T5)	5	0.23	0.43	0.36 (0.08)
Final outdoor	B (T4-T5)	5	0.21	0.54	0.36 (0.12)
Mid indoor	C (T4-T12)	7	0.16	0.42	0.30 (0.11)
Mid outdoor	C (T4-T12)	7	0.22	0.42	0.32 (0.08)
Final indoor	C (T4-T12)	7	0.29	0.42	0.36 (0.04)
Final outdoor	C (T4-T12)	7	0.19	0.43	0.34 (0.08)

Note: AIS = American Spinal Injury Association Impairment Scale; NLI = neurologic level of injury.

On average, participant indoor walking speed improved from midpoint to final 10MWT by 0.06 m/s (*SD* = 0.07) and outdoor speed improved by 0.05 m/s (*SD* = 0.08). All participants were able to increase the distance they walked during the 6MWT from midpoint to final evaluations and the average improvement for the group was 15.5 m.[12] During the midpoint evaluations, 6 out of the 32 participants chose to rely on forearm crutches for a stability aide while the 26 individuals utilized a rolling walker. For the final walking evaluations, 8 individuals chose to rely on forearm crutches for balance while 24 continued to prefer a rolling walker. Two participants chose what is considered a less restrictive AD after completing the 8 weeks of training.

Discussion

Overall, the safety objectives proposed in this trial were met with the Indego exoskeleton walking device when utilized with 32 participants who had sustained SCIs and were nonambulatory, as the training yielded limited device-related AEs. There were no severe device-related AEs reported and all AEs were reversible. The majority of AEs were minor skin issues that resolved during the trial and did not interrupt training.

The majority of participants in our study were able to independently don (22/32) and doff (29/32) the device during their final evaluations. All were able to decrease the amount of time required to don and doff the devices from the initial training to the final evaluation, demonstrating that this process can become less time consuming and more efficient with appropriate training and practice.

The majority of participants in this study demonstrated the ability to learn and become more proficient with the device with statistically significant improvements in walking speed from midpoint to final evaluations. However, large variability was noted among training response to speed in both indoor and outdoor conditions, and pooled results did not meet the threshold for minimal detectable change. The participants

in this trial were nonambulatory prior to the trial so these thresholds may not be relevant, as any opportunity to have upright mobility may be a clinically relevant and important difference for this population. The final average indoor and outdoor walking speed was 0.37 m/s, which is significantly slower than normal walking speed of 1.3 to 1.4 m/s.[17] However, the range of walking speed for all 32 participants was 0.19 m/s to 0.55 m/s, demonstrating that several participants were walking at household ambulation speeds (≥0.4 m/s).[18] These results were consistent with those published by Esquinazi et al[5] for 12 participants using the ReWalk powered exoskeleton who achieved walking speeds of 0.03 to 0.45 m/s. They were also in line with results by Hartigan et al[7] who reported walking speeds of 0.29 m/s to 0.45 m/s for individuals with thoracic and lumbar SCIs using the Indego exoskeleton.

Indoor and outdoor walking speeds were not significantly different in this trial, demonstrating that participants were as confident walking in the community as they were inside a rehabilitation center. However, there were statistically significant differences noted in walking speed between midpoint and final evaluations; participants were able to improve walking speed with training across both indoor and outdoor conditions.

It is important to note that the majority of the initial 32 participants finishing this trial continued to require close supervision or minimal assistance for ambulation at the end of 8 weeks of training. Several factors may have contributed to the continued need for assistance during this study, including the therapists' lack of comfort with the device given that very few therapists had experience with the Indego prior to starting this study. Additionally, independent ambulation and walking speeds may have demonstrated greater progression if they had been the primary aims of this study, as the training approach would have focused on these outcomes rather than safety and feasibility.

Study limitations

There were several limitations to this study. First, it was a feasibility study so there was no comparison group to determine whether these participants would have responded better to walking training in an alternate exoskeleton system. Also, the focus of the training was on safety so further studies need to be completed which focus on the goal of improving walking speed and independence to understand the capacity of these systems to improve mobility.

Future directions

Future publications from this multicenter trial will focus on the final outcomes of all 44 individuals who completed this study. Outcomes to be reviewed will include quality of life, spasticity, perceived exertion, and functional outcomes.

Conclusion

The Indego exoskeleton was shown to be safe when providing upright mobility for nonambulatory or poorly ambulatory individuals who had sustained SCIs at T4 and below. Many individuals with thoracic and lumbar SCIs demonstrated the ability to don and doff the Indego exoskeleton independently and were able to achieve walking speeds close to those associated with currently accepted household ambulation speeds. Many individuals demonstrated significant progress toward independence while utilizing the device for walking and some did not require physical assistance after 8 weeks of training. Although this is an exciting new aspect of rehabilitation, there are still many questions to answer before exoskeletal devices become realistic options for the majority of individuals with severe mobility impairment. Further research and clinical integration will give rehabilitation professionals greater insight into the benefits and limitations of these devices and determine the technological advances that must be made to meet the demands of individuals with severe mobility impairment.

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