Safety and Feasibility of using the Ekso™ Bionic Exoskeleton to Aid Ambulation after Spinal Cord Injury

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Abstract

Objective: Evaluate feasibility and safety of Ekso™ to aid ambulation in individuals with SCI.

Design: Prospective pilot study.

Setting: SCI Rehabilitation Center Outpatient Gym.

Participants: Eight individuals, at least 18 years of age, with complete T1 SCI or below, within 2 years of injury, completed initial inpatient rehabilitation. All participants signed informed consent, had been cleared from requiring spinal orthoses, met inclusion criteria, and were pre-screened based on device requirements and medical stability.

Intervention: Six weekly sessions with graduated time and less assistance in the Ekso™ device.

Outcome Measures: Skin evaluation, blood pressure, pain level, spasticity, time and level of assistance needed to transfer into and don device; time ambulating; time up in device; assistive devices used during ambulation; step length; distance walked; level of assistance during use; losses of balance; number of falls and level of assistance needed to doff and transfer out of device.

Results: No major skin effects, minimal pain reports, no known fractures, swelling, or other adverse events. Level of assistance ranged from dependent to moderate independent, average set up time was 18.13 minutes, loss of balance and falls were infrequent.

Conclusions: Bionic exoskeletons such as Ekso™ are safe for those with complete thoracic SCI in a controlled environment, in the presence of experts, and may eventually enhance mobility in those without volitional lower extremity function. There appears to be a training effect in the device but further trials are needed. Future studies of bionic exoskeletons as gait training devices are warranted. Future studies of bionic exoskeletons as a clinical tool to alleviate secondary complications should be considered.

Keywords: Exoskeleton; Spinal cord injury; Feasibility studies; Safety; Locomotion; Orthotic devices

Introduction

The sudden inability to walk is one of the most glaring impairments following spinal cord injury (SCI). Regardless of time since injury, recovery of walking has been found to be one of the top priorities for those with SCI as well as their rehabilitation professionals [1]. Despite clinical management and promising basic science research advances, a recent multicenter prospective study revealed that 59% of those with SCI are unable to ambulate without assistance from others at one year following injury [2]. The worldwide incidence of SCI is between 10.4-83 per million [3], and there are approximately 265,000 persons with SCI living in the United States [4]. Thus, there is a tremendous consumer demand to improve ambulation outcomes following SCI.

Multiple rehabilitation strategies have been implemented. Traditional over ground (TOG) therapy has been used for decades. For over 20 years, there has been considerable attention in SCI rehabilitation on utilizing body weight supported training (BWST) to improve ambulation. This movement was spurred by an animal model focusing on complete low thoracic spinalized cats that demonstrated recovery of hindlimb stepping following treadmill training with assisted hindlimb loading [5]. Since, there have been several studies evaluating a similar intervention in persons with SCI utilizing BWST [6-12].

A recent systematic review was published evaluating the effectiveness of BWST compared with TOG in restoring walking in those with motor incomplete SCI [13], finding the group who had TOG reached higher levels of independence in walking than those who underwent BWST. Conversely, a randomized clinical trial of individuals with incomplete SCI demonstrated gradual improvements in lower extremity motor score, Functional Independence Measure (FIM) motor score, and walking speed [14] for individuals using BWST and TOG. While the study found no significant differences between groups, there did appear to be an influence of time to rehabilitation. Individuals, who entered rehabilitation earlier, had better outcomes. Another study, evaluating the effectiveness of therapy-assisted BWST in comparison to robotic-assisted BWST, also revealed no significant difference between groups in achieving improved walking [15].

Interest remains in BWST as a therapy tool, but there is a lack of evidence that it is superior to TOG in improving ambulation for those with SCI. There are spatial and financial burdens of BWST, particularly if robotic-assisted. In addition, one difficulty with clinical implementation is the labor-intensiveness for therapists [16]. A newer, promising rehabilitative tool for assisting those with SCI achieve ambulation is the robotic exoskeleton [17-28], particularly those that are wearable. While

there has been little published on clinical implementation of these devices, they do offer a few potential advantages to treadmill training. Wearable robotic exoskeletons are relatively lightweight, small, and may function essentially as an orthosis. In doing so, these devices can allow for over ground ambulation, potentially with sole control by the user. Thus, the ultimate goal for some using the exoskeleton would be to use them outside direct therapy supervision as a mobility aid.

There are several wearable mobile exoskeletons currently in development and early clinical evaluation, including Ekso™, HAL™ (Hybrid Assistive Limb robot), ReWalk™, and Rex™. All require the user to have at least some upper extremity function. There is kinematic support for HAL™, [21] in the form of a case study of one person with chronic incomplete paraplegia that demonstrated improved step length and gait stability with ambulation over short distances (5-7 meters). A pilot study on ReWalk™, in individuals with SCI > 6 months post-injury, demonstrated no adverse outcomes when using the device for 100 meters with therapy assistance [27].

The purpose of the current study was to evaluate the feasibility and safety of using Ekso™ to aid ambulation in a group of individuals with SCI who had completed their initial SCI rehabilitation. Secondarily, training effects in terms of time tolerated, distance traveled, and assistance needed while in Ekso™, with progressive use were evaluated. Efficacy was not a direct goal of this pilot.

Methods

Participants

Participants included persons with SCI over 18 years of age. All participants had a complete injury with a single neurological level of T1 or below by American Spinal Injury Association (ASIA) definition [29]. Each had completed their initial SCI inpatient rehabilitation and were within 2 years of injury. The study was approved by the Institutional Review Board (FWA# 00001437), and all study participants signed approved Informed Consent Forms and HIPAA documents. Given the need for informed consent and the ability to follow instructions on use of the device, participants had to be able to read/speak English. All participants had been using a standing frame on a routine basis prior to enrolment. At the time of our study, the safety specifications for device use by Ekso™ were height 5'2"- 6'2" and weight limit of under 220 pounds.

Exclusion criteria included known spinal instability; history of long bone fracture below the neurological level of injury; known lower extremity joint instability; history of other neurological disorder (e.g. CVA, TBI, peripheral neuropathy); psychiatric or cognitive impairment that would interfere with accurate feedback during device use; ongoing skin breakdown at areas that would interface with Ekso™; or pregnancy. In addition, participants with poorly controlled spasticity, orthostasis, or autonomic dysreflexia were excluded.

Procedures

Each participant was recruited for six weekly sessions with the device. All participants had been cleared from requiring spinal orthoses by their spine surgeon. A Pre-Screening Tool (Figure 1) was utilized to evaluate basic characteristics and eligibility of participants prior to study enrolment. Demographic data included ASIA Impairment Scale (AIS) status, Neurological Level of Injury (NLI) as defined by ASIA, age, gender, and date of injury. Other baseline data included spasticity, range of motion (ROM), upper and lower extremity motor function, proprioception, level of functional mobility (e.g., transfers), and measurements to screen for Ekso™ device appropriateness.

Figure 1: Prescreening tool used to determine study eligibility.

Prior to application of the device, each session began with the Physical Therapist (PT) assessing the participant's skin, baseline pain utilizing the Subjective Pain Scale (SPS), and spasticity using the Ashworth scale. The participant's subjective feedback from the previous session was also recorded by the therapist. The total set-up time, which included the time it took for the therapist to set up the device, transfer the participant into the device, and for the device to be donned, was recorded. The level of assistance needed by the participant to transfer into and don the device were also recorded. Blood pressure sitting and standing in the device were measured prior to ambulation.

While in the device, total time ambulating, total time up in the

device, assistive devices used during ambulation, step length, distance walked, number of people needed to assist the participant, number of times the participant lost balance, number of falls, and level of assistance were recorded. Following ambulation, level of assistance needed to doff and transfer out of the device were noted along with any abnormalities upon skin inspection. Adverse events were recorded by the PT during each session as well as the participants' and clinicians' qualitative feedback.

The study protocol indicated a graded progressive guideline of total ambulation time from 20 minutes in the first session, 40 minutes in the second session, and then up to 60 minutes in the remaining sessions, if tolerated by the participant and session time permitted. All participants started out standing and ambulating in the device with the use of a front-wheeled walker (FWW). If deemed appropriate by the PT, participants were then progressed onto Loftstrand forearm crutches (FC). Finally, when Ekso™ use with FC was mastered, participants could be advanced onto the Human Machine Interface crutches (HMIC) developed by Ekso™. The HMIC was a modified forearm crutch that utilized pressure sensors in the arm and footpad to trigger a step in the contralateral leg when the HMIC was placed on the ground.

As this was the first study of Ekso™ in SCI, we chose to incorporate the use of an overhead tether at all times for participant safety. Additionally, our protocol required two trained individuals to assist with ambulation at all times. While the first person was hands-on, the second person, a PT or Ekso™ engineer, was primarily hands-off, activating the next step by remote, and managing the overhead tether. Loss of balance (LOB) and falls were recorded as the primary safety outcomes. LOB was defined as any disturbance of balance requiring hands-on assistance from the PT to correct the participant's balance without requiring the engagement of the overhead tether. Falls were defined as a LOB which engaged the overhead tether (e.g. became taught).

Results

Participant demographics

Enrolled participants included eight individuals with AIS A SCI with NLI ranging from T4-T12 within two years of injury. Six of the eight individuals completed all six sessions with one individual completing only five sessions. The eighth participant was dropped from the study due to failure to follow-up for the third and subsequent visits due to transportation issues and other participant commitments, but not due to issues with the Ekso™ device, medical issues, or adverse events. Participant demographics and injury characteristics are presented in Table 1. On average, participants were 29.86 (SD=6.87) years of age, mostly male (75%), with a mean of 311.29 (SD=217.60) days post injury. Participants were mostly injured as a result of motor vehicle accidents.

Clinical evaluation

Upon enrolment to the study and prior to application of the device, participants were evaluated on a variety of clinical measures including pain, spasticity, range of motion (ROM), upper and lower extremity motor function, proprioception, level of functional mobility (e.g., transfers), and measurements to screen for Ekso™ device appropriateness. One participant did not meet the height requirements for the Ekso™, with a height of 5'1", but was deemed appropriate to participate in the study due to leg measurements and joint alignment in the device. This inclusion decision was made by the PT, the Ekso™ clinical team and the MD overseeing the study. In general, participants did not report much pain at baseline and spasticity levels did not preclude anyone from using the device (Table 2).

Skin, pain, and fracture assessment

There were no major skin effects from Ekso™. All of the skin changes were superficial and found to be a Stage 1 on the Braden Scale for Predicting Pressure Sore Risk [30,31]. The most common areas of redness were in skin overlying the anterior tibia, greater trochanter,

Participant	Level of Injury	ASIA* Classification	Age at Enrollment	Gender	Time Post Injury (days)	Etiology
P1	T†11	A	24	F	65	MVA‡
P2	T10	A	19	F	486	MVA
P3	T11	A	40	M	186	MVA
P4	T7	A	29	M	111	MVA
P5	T12	A	34	M	578	MVA
P6	T4	A	30	M	546	MVA
P7	T8	A	33	M	207	Fall

* American Spinal Injury Association
† Thoracic
‡ Motor Vehicle Accident

Table 1: Demographic and Injury Characteristics.

Participant	Pain Assessment*	Pain Location	Spasticity† Right	Spasticity† Left	Sitting Blood Pressure	Standing Blood Pressure
P1	0	n/a	7	7	145/100	160/92
P2	0	n/a	7	7	123/89	120/82
P3	0	n/a	7	7	132/96	140/100
P4	3-4	buttock	7	7	152/86	143/69
P5	2	left elbow	7	7	137/93	143/84
P6	0	n/a	11	11	114/77	112/72
P7	0	n/a	19	20	148/87	141/92

* as measured with the Subjective Pain Scale
† as measured with the Ashworth

Table 2: Summary of Clinical Assessment at Baseline.

sacrum, abdomen, and dorsum of the foot. Recurring sites of skin changes were discussed with Ekso™ engineers, and this assisted in device modifications to further minimize pressure at these sites.

Overall, there were minimal pain reports during and after use of Ekso™. The most common areas of pain/soreness were upper extremities, decreasing as participants became more proficient with Ekso™. A few participants reported minimal low back pain after using Ekso™, but did not impact participants' interest to continue in the pilot. One participant (P5) had a premorbid lateral epicondylitis which was occasionally aggravated with use of the forearm crutches while in Ekso™.

There were no reported or clinician identified fractures throughout the pilot. There was no gross asymmetric lower extremity swelling noted before, during, or after Ekso™ use. Further, no other adverse events were reported by participants or identified by clinicians throughout the pilot.

Level of assistance and safety

The amount of assistance to transfer into the device, don, doff, and transfer out of Ekso™ were recorded (Table 3). In general, participants either remained at a similar level of assistance throughout all training sessions or progressed a single level over time. Most progress was seen transferring in and out of Ekso™. Doffing appeared to be much easier for participants than doning. Total set up time (including device preparation, participant transferring into, and doning the device) ranged from 10 to 30 minutes, with an average of 18.13 minutes. Total set up time did not include any of the pre-screen time or the instruction to the patient.

Across all 41 sessions, loss of balance was infrequent (Figure 2). In looking at each participant over time, loss of balance generally decreased despite decreasing stability from assistive devices, as the participants transitioned from a walker to forearm crutches.

Participants 2, 5, 6, and 7 had no falls that engaged the tether (Figure 3). Participant 1 experienced two falls, one during her fifth session and one during her sixth session with both falls occurring during the sit to stand transition. Each fall was related to mechanical programming errors which caused the device to malfunction during the site to stand transition. The tether was involved on both occasions so they were denoted as "falls" and the participant was manually assisted to sit back down with no harm to the participant or the staff. Mechanical errors continued to occur with participants 4, 6, and 7 during the sit to stand transition but they did not result in falls and the participants were always able to continue sessions.

Participant 3 had two falls in the second session and three falls in the third session as the participant was learning to weight shift and ambulate with FC. This participant subsequently had 2-3 falls in each of the final 3 sessions after he had been advanced to the HMIC. The HMIC was supposed to trigger a contralateral step, based on positioning of the HMIC; rather than the step being initiated via remote by a second PT/engineer. Each of the falls by participant 3 during use of the HMIC was due to a combination of factors, including errors in the programming of the HMIC (e.g. the left leg would step first when it was programmed for the right leg to step first), difficulty turning while using HMIC, and a mechanical error causing the device to buckle at the knee joint which led to participant 3 falling backwards. Software for this type of interface was in the development phase and was deemed unsafe, in part due to these issues. Therefore, the use of this HMIC was stopped

Participant	Transfer In						Don						Doff						Transfer Out					
Session	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6
P1	‖	§	‖	§	‖	§		¶	¶	¶	‖	‖	¶	¶	¶	¶	‖	§	‖	‖	‖	‖	§	‡
P2	‡	‡	‡	†	§		**	¶	‖	¶	¶		§	§	§	§	§		†	†	†	‡	‡	
P3	‡	*	†	‡	‡	*	¶		¶	¶	¶	‖	¶	¶	¶	¶	‖	‖	§	‡	‡	‡	§	‡
P4	‡	†	†	†	†	†	**	¶				¶	‖	†	¶	†	‖	‖		‡	†	†	†	†
P5	‡	†	‡	†	†	§	¶	‖	‖	‖	¶	§	¶	‖	‖	‖	‖	§	‡	†	‡	†	†	§
P6	‡	‡	‡	†	§	‡	**	¶	¶	¶	¶	‖	¶	¶	¶	‖	¶	‖	‡	‡	‡	†	‡	†
P7	‡	‡	†	‡	‡	‡	**	¶	¶	¶	¶	¶	**	¶	¶	¶	¶	¶	‡	§	†	‡	‡	‡

Levels of Assistance: *Moderate Independent; †Supervised; ‡Standby; §Minimal; ‖Moderate; ¶Maximum; **Dependent
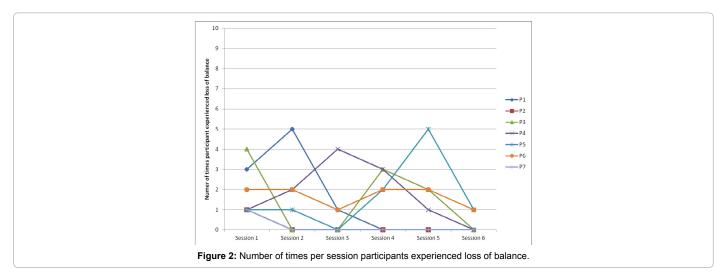Note: blank space = session not completed

Table 3: Level of Assistance.

Figure 2: Number of times per session participants experienced loss of balance.

after participant 3 and removed from the planned release of the first professional version of Ekso™.

Participant 4 experienced a fall during the fifth session after progressing to forearm crutches. For participant 4, the machine was accidentally powered off causing the patient to lean backwards and engage the tether. The participant returned to sitting with assistance. After the device was powered back on, the participant finished the remainder of that session with no further issues.
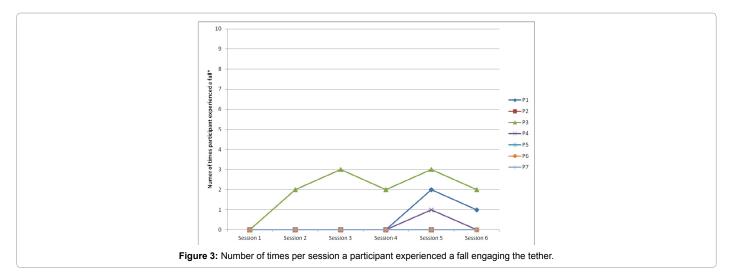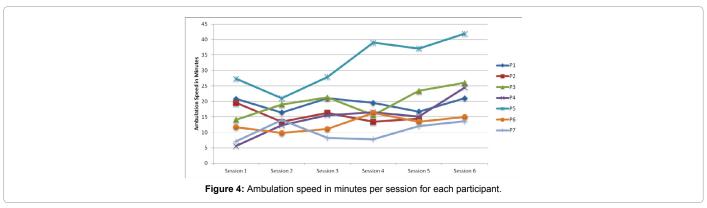
Time up and ambulating

Participants were up in the device a total of 2387 minutes, of which 1230 minutes were spent actively walking. Data is provided in Table 4 regarding individual participant progression. Mean time spent up across all 41 sessions was 58.22 minutes with a mean walking time of 30 minutes per session. The ratio of time ambulating while upright versus time up but not ambulating in the device for each participant across individual sessions is also included in Table 4.

Over time, participants were generally able to increase relative time ambulating while in Ekso™. The average step length/ten foot walking distance, distance ambulated, and type of assistive device used were recorded for each participant (Table 5). An estimate of ambulation speed was calculated by dividing time up and ambulating by distance covered during each session (Figure 4).

Discussion

Regarding skin, there were two areas of concern with the Ekso™

Figure 3: Number of times per session a participant experienced a fall engaging the tether.

Figure 4: Ambulation speed in minutes per session for each participant.

	Session 1 Walking/ Upright (ratio)	Session 2 Walking/ Upright (ratio)	Session 3 Walking/ Upright (ratio)	Session 4 Walking/ Upright (ratio)	Session 5 Walking/ Upright (ratio)	Session 6 Walking/ Upright (ratio)
P1	15/47 (0.32)	19/63 (0.30)	26/68 (0.38)	20/40 (0.50)	28/64 (0.44)	26/57 (0.46)
P2	16/45 (0.36)	29/79 (0.37)	24/43 (0.56)	29/72 (0.40)	27/52 (0.52)	*
P3	22/51 (0.31)	37/64 (0.57)	22/55 (0.40)	35/68 (0.51)	60/78 (0.77)	54/75 (0.72)
P4	14/35 (0.40)	38/69 (0.55)	45/76 (0.59)	52/71 (0.73)	31/54 (0.57)	35/49 (0.71) †
P5	20/51 (0.39)	26/50 (0.52)	28/48 (0.48)	32/66 (0.48)	40/80 (0.50)	41/60 (0.68)
P6	20/45 (0.44)	28/70 (0.40)	14/28 (0.50)	24/48 (0.50)	35/57 (0.61)	26/53 (0.49)
P7	11/29 (0.38)	25/62 (0.40)	43/81 (0.53)	34/71 (0.48)	26/63 (0.41) ‡	23/50 (0.46)

*Session not done
† Ekso™ powered off during session
‡ Ekso™ arrived at center late and session cut short

Table 4: Minutes upright and ambulating each session.

Participant	Session 1			Session2			Session 3		
	Step Length*	Distance†	Device	Step Length	Distance	Device	Step Length	Distance	Device
P1	1.05	312	FWW	1.05	312	FWW	0.77	546	FWW
P2	1	312	FWW	0.91/1	156/234	FWW/FC	0.83/0.83	156/234	FWW/FC
P3	1	312	FWW	0.77/0.83	234/468	FWW/FC	0.83/0.83	156/312	FWW/FC
P4	1	78	FWW	0.91/1	234/234	FWW/FC	0.91/0.91	234/468	FWW/FC
P5	1/1	156/390	FWW/FC	1/0.91	156/390	FWW/FC	1.25	780	FC
P6	0.83	234	FWW	0.91/0.91	234/39	FWW/FC	1	156	FWW
P7	1	78	FWW	1.11/1.11	273/78	FWW/FC	0.91/0.91	312/39	FWW/FC
Participant	Session 4			Session 5			Session 6		
	Step Length	Distance	Device	Step Length	Distance	Device	Step Length	Distance	Device
P1	0.91/0.91	156/234	FWW/FC	0.83/0.83	234/234	FWW/FC	0.91/0.91	234/312	FWW/FC
P2	1/1/1	156/78/156	FWW/FC/HMIC	1.11/1	156/234	FWW/FC	#	#	#
P3	0.83	546	FC	0.91	1404	FC	0.83	1404	FC
P4	0.91/1	78/780	FWW/FC	1	468	FC	1	858	FC
P5	1.25	1248	FC	1.25	1482	FC	1.25	1716	FC
P6	1	390	FWW	1	468	FWW	0.83	390	FWW
P7	0.91/1	234/30	FWW/FC	0.91/1	234/78	FWW/FC	1.11/1	78/234	FWW/FC

*Step length in feet was derived from the number of steps taken across a 10 foot space; e.g. 9 steps over 10 feet = .9
†Distance in feet was initially recorded as the number of 78 foot laps traveled and subsequently multiplied by 78;
#Session not done; FWW – Front Wheeled Walker; FC-Forearm Crutches; HMIC – Human Machine Interface Crutches

Table 5: Step Length, Distance Traveled, and Assistive Device Used.

prototype. One was an area in the hip joint/lateral thigh which was pinched by one participant when the device's legs were locked into place during the doning process. The engineers created a hip guard which greatly decreased this problem. One participant scratched his sacrum on the Ekso™ leg when transferring into the device. The was corrected when Ekso™ engineers created a rotating hip joint allowing the leg to be swung out of the way for transfers.

There were no significant pain reports while using the Ekso™. Most of the areas of discomfort were reported in participants' upper extremities, as might be expected in individuals who begin a new gait training program using upper extremities assistive devices. Two participants reported minimal low back pain while ambulating with Ekso™. The current device has stricter hip extension ROM guidelines and modifiable hip extension ROM settings which may have benefited these participants in deterring low back pain. Since all but one of our participants had no lower extremity sensation it is inconclusive of whether they would have had more subjective pain reports in their lower extremities if they had had sensation.

The set up time for the therapist getting the participant into the device did not always decrease with more repetitions as would be expected. We believe this is partially due to the fact the device was a frequently changing prototype requiring therapists to reacquaint to new updates. Accurate estimations of set-up time should be investigated now that a standard version of the Ekso™ is available. In addition, although the participants' level of assist to don/doff Ekso™ was assessed, there was not a heavy focus on participants' learning how to don the device independently. It may be beneficial to evaluate participants' ability to be independent in doning/doffing and if differences exist amongst varying levels of SCI.

Participants' frequency of LOB increased with progression from FWW to FC; a finding expected as one progresses to a less stable and more dynamic assistive device. Most FWW LOB were during the first session as the participants learned to ambulate with the new device. Later session LOB was primarily machine induced. The only two falls which occurred with the FWW were due to the mechanical sit to stand errors discussed earlier.

There were several falls that occurred during use of the HMIC, and ultimately this HMIC was not included as part of the first professional version of Ekso™. It is noteworthy insofar as we had only one fall in the device after use of the HMIC was abandoned and this fall was due to the machine accidently being powered off by one of the assistants. Ekso™ appeared overall to be safe when utilized under supervision of trained personnel, particularly when used with FWW or FC. No participants sustained any injuries, though any potential participant trauma from losses of balance and falls were minimized due to the overhead tether. While aiding participant 3 during a fall while utilizing HMIC one PT sustained impact to her hip which resulted in a sacroiliac joint sprain. This was another reason the use of the HMIC was abandoned after participant 3.

Distance traveled per session was based on the number of laps traveled in our gym, thereby was not an exact measurement. Speed was a relative estimate based on distance traveled during the time up and ambulating in the device. There were general trends of improvement in distance traveled/speed for most participants which suggests a training effect and progress in terms of time efficiency in Ekso™. The percentage of time that participants actually ambulated while they were up was influenced by several factors including the amount of training instructions each participant required as they switched from one assistive device to another, how much experience the PT had with the device, and the number of device errors.

As this device was a prototype, as to be expected with any evolving device, there were quite of bit of mechanical errors and changes in the device from session to session. By regularly getting our participants into the device we were able to help the engineers test out the software and hardware of the device to help minimize errors and safety issues. The last participant used the Ekso™ device with far fewer errors, only two LOB, and no falls over all six sessions.

As this study represented the initial clinical application of Ekso™ for those with SCI, close communication between our center and Ekso™ personnel was necessary. Discussion between participant, PT, and Ekso™ personnel during the study assisted with device alterations which deterred some of the skin complications at the sacrum and lateral hip. The HMIC was abandoned during this study after real-time analysis by our staff and Ekso™ personnel led to an acknowledgement

of risk to the device user and PT. Ultimately, the collaboration between our group and Ekso™ team seemed to have led to progress in device safety and utility.

There are several methodological weaknesses in this study. In addition to the small sample size, clinicians did not have proven guidelines for removing layers of stability from assistive devices as participants progressed. Due to the fact that the device was new to the PTs, they were learning the device from the Ekso™ personnel and had to rely on the experience of the Ekso™ personnel to suggest progression to a different assistive device as well as when to change Ekso™ parameters and settings. With the device being a prototype, which was constantly changing and developing, some of the parameters and devices (i.e., HMIC) were relatively new even for the Ekso™ personnel. Future studies should include a clear algorithm for assistive device progression.

Pain and spasticity were measured at baseline prior to initial Ekso™ use, and at the start of each session. While none of the participants had reported high levels of pain, it would have been interesting to have seen if the participants' upper extremity pain decreased as they became more proficient at ambulating with the device. It would also have been beneficial to assess the participants' spasticity level after each session due to the fact that the two participants who had spasticity subjectively reported a reduction in spasticity after using the Ekso™. This would have allowed for an initial evaluation on the effect of Ekso™ on spasticity.

The recording of distance and estimate of speed were gross measurements, as detailed previously. Time up in the device was not stopped and restarted for brief exchanges between the participant and PT, nor was it stopped during turns. While participants appeared to have consistent speed over straight distances, turning in Ekso™ required slower speeds. Pilot methodology could not account for variations in speed within sessions, but allowed only session averages. The pilot focused on evaluating safety, and did not deliberate on more advanced methods to monitor distance and speed. Use of an accelerometer to track distance and record speed would certainly be an improvement, and appears feasible. Future prospective studies could include such a device or Ekso™ may track internally with more advanced software.

Conclusion

Ekso™ is one of several wearable exoskeletal devices that appear to have potential in those without volitional lower extremity function. It is safe for those with complete thoracic SCI, when utilized in a controlled environment with hands-on assistance by trained personnel. Use of an overhead tether should be considered, particularly as staffs develop expertise with the device and while decreasing a device user's stability from other assistive devices (e.g. transition from FWW to FC). There appears to be a training effect in the device, as participants were able to spend more relative time walking and move faster in the device over time. It would be interesting to evaluate whether Ekso™ is able to reduce therapy time toward achieving therapeutic goals. Further trials are also needed to determine whether other populations, including those low or incomplete cervical SCI may also be able to safely use Ekso. It would also be beneficial to look at the efficacy in using the Ekso™ as a gait training device in the incomplete SCI population or others with mobility disorders such as hemiparesis post stroke. In addition, based on participant anecdotal feedback, certain clinical parameters including spasticity, pain, fatigue, and bowel and bladder function should be evaluated for possible improvements secondary to Ekso™ use by those with SCI.

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