	Protocol Name:	**Investigational Study of the Ekso Bionics Powered Exoskeleton for High-Dosage Use by Individuals with Spinal Cord Injury in a Non-Clinical Environment**
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Investigational Study of the Ekso Bionics Powered Exoskeleton for High-Dosage Use by Individuals with Spinal Cord Injury Walking in a Non-Clinical Environment

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2. Date Revised

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3. Objectives

3.1 To determine the physiological effects of high-dosage use of the Ekso device over a 12- 36-month period.

3.2 To documents the quality of life benefits of using an Ekso device in a non-clinical setting.

3.3 To define the safety and efficacy of using the device in a home environment.

3.4 To determine the safety and efficacy of a non-medical professional spotting the subject.

3.5 To determine inclusion/exclusion criteria for an Ekso Bionics device used in a home setting.

4. Background

The incidence of spinal cord injury is estimated at 1.5-5.3 million worldwide.[1] "Will I walk again?" is often cited as one of the more common questions, with the decreased ability to walk as one of the most difficult challenges to live with.[2,3] Over the last 10 years more research has focused on the ability for the spinal cord to" heal" itself, i.e. undergo plasticity,[4,5] by task-specific, high-

intensity activities.[4,6] Two major groups of task specific activities for ambulation have been developed. The first option is conventional over the ground training (CONT), where a number of therapists help support the subject while the others assist in moving the limbs in a reciprocal gait pattern. The other option, body weight supported training (BWST), involves partial support of the subjects weight via a harness while a therapists moves the lower limbs in a reciprocal gait pattern either over ground, in water or over a treadmill. A subset of BWST uses a robotic device in place of a therapist to move the limbs in a reciprocal gait pattern. The advantages of BWST include starting training before the subject can fully bear weight, prior to developing adequate motor control, and with greater safety and less fear of falling.[7] The effort required of the therapists to assist and guide limb movement was the major challenge that resulted in development of robotic assisted devices.[6,8]

Overall a number of studies have reported improvements in various gait parameters including walking speed, amount of physical assistance needed, and the degree and type of assistive devices needed.[7,9, 10-13] Previously it was thought that CONT and BWST were equivalent in outcomes [7,14]. More recent reviews suggest that BWST whether therapy assisted or robotically assisted does not produce greater return in walking independence or velocity of gait.[11,15] However the greatest benefit of CONT was seen among individuals with incomplete SCI while those with more severe impairments (i.e. complete motor paralysis) benefited from BWST[13].

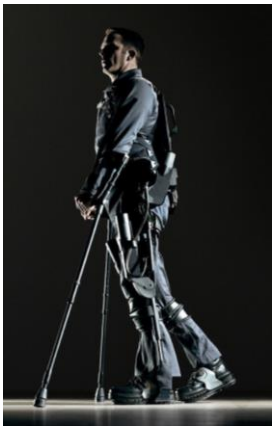
In addition to the potential for spinal cord plasticity and recovery of walking function, ambulation after SCI may also offer secondary health benefits. Kohout and colleagues [16] reported that the ability to walk more than 1000 feet was related to a decreased need for pain and spasticity medications. Similarly, BWST has been associated with decreased spasticity of the plantar flexors and quadriceps muscles [17]. In contrast, Giannantoni and coworkers [18]

found a worsening of urodynamic function following ambulation in a reciprocating-gait orthosis. A recent review on the physiological benefits of ambulation following SCI provided 2 conclusions from the literature: 1) the current evidence is controversial and mostly anecdotal; 2) physiological benefits of walking after SCI were most evident when ambulation was performed for at least 4-5 hours per week and over a long period of time [19].

Currently there is no cure for spinal cord injury [20] however there have been improvements in therapies that promote a greater chance for neurological recovery. The evidence supporting gait training in spinal cord injuries suggests that starting early, utilizing task specific activities, and continuing the activities for long durations are beneficial.[20] CONT training offers task specificity , however is labor intensive, time consuming, and requires a high degree of expertise to avoid injury. Moreover, those that are more severely impaired cannot begin CONT training early or safely offering a potential benefit of BWST in this subpopulation. BWST requires larger physical space for the treadmill can only be found at specialty centers and cannot be utilized at home. Therefore there is an opportunity to develop a "hybrid" of these 2 training paradigms. One that can allow for early participation despite severity of injury, can reduce the intensity of therapy assistance, can optimize the benefit of over ground training, and has the potential to be utilized in the home setting.

Recently the benefit of body weight supported training, either therapy assisted or robotically, has been questioned to be no greater than conventional over the ground training.[21] However, traditional training for those subjects with severe injuries is very labor intensive and difficult. Technology that blends the "labor reduction" benefit of BWST and the task specific benefit of over the ground training may provide the optimal solution. Therefore development of technologies that are easier to use, cheaper to implement and more

readily accessible by the general spinal cord injured population is important.



One such device recently developed is the Ekso. The Ekso is an anthropomorphic mobile exoskeleton that is intended for rehabilitation and increased mobility for those suffering from muscular and neurological conditions affecting their lower extremity. The device is used to drive the subject's lower extremity joints through a desired trajectory in order to obtain a user specified motion. The device is mobile and holds all necessary batteries and processing on board for at least 2 hours of consistent use. The batteries are also interchangeable allowing for fully charged batteries to be swapped into the machine whenever required. The device is designed to adjust easily to fit a wide range of users. This adjustment is made using adjustments at the thigh and shank to adjust length and at the hips to adjust frontal plane width. The device is attached to the user's torso with backpack style shoulder harnessing and a torso brace. The other harnessing on the device are upper thigh straps, shin guards on the shank and secure foot binding.

The device is electrically powered by four electric motors at the user's knee and hip joints in the sagittal plane. The flexion and extension directions at the hip and knee are the only actuated degrees of freedom on the device. The device is equipped with mechanical hard stops at the limits of healthy subject ranges of motion to prevent powering the joint of the user to a position that the joint cannot reach. The actuated range of motion at the hip is -20° to 135° and the actuated range for the knee is 0° to 120°. Not all of this range of motion is needed in normal walking; however the ranges of these joints were selected to provide for other necessary functions such as standing and sitting. At the ankle the device is passive, with springs to resist sagittal plane motion and locked in the other degrees of freedom. The range of motion provided at the

ankle is from -10° to 20° dorsiflexion with hard stops at the limits of this range to protect the user. The final degree of freedom is a manual lock for abduction at the hip. When released, the device is free to swing in the abduction direction (used for donning/doffing purposes) but when locked the device prevents motion in both the abduction and adduction directions.

The device operates using a number of important sensors. There are foot pressure sensors at the heel and toe of both feet to determine the forces between the user and the ground at those locations. Multiple position sensors determine the angle of each actuated joint. A body tilt sensor is used to find the lean of the torso in space. Finally, temperature sensors are used to monitor the motor and drive temperatures.

The control code in the device operates by creating an internal estimate of the subject's current position and then coordinating the motion of the four actuated degrees of freedom to take the desired motion. The desired motion is specified through an attached user interface that can be controlled by the user or a therapist. The device can stand from a seated position, walk and sit down. In actual operation the device is triggered by various modes. The first mode is used early in training where the therapist manually triggers the steps with the user interface. For advanced users the machine can operate in a different mode and interpret their posture to determine when steps are desired.

The Ekso provides full weight bearing, over ground reciprocal gait training. The robotic exoskeleton reduces the need for therapy guidance and can free the therapists up for safety spotting and feedback, ultimately reducing the number of therapists required. In addition the low profile allows for use in varied environments both indoor and outdoor, and the size of the device can potentially allow for ease of transport for use at home. As such subjects can continue to utilize the principle of "start early" as the robotic components

allow for utilization of more severely injured subjects; "task-specific" as the robotic limb trajectory mirrors a normal gait pattern, and "keep it going" as the ability to use the device out of the classic rehabilitation setting will allow for greater duration of use.

It is anticipated that modifications to the hardware and software will be developed and implemented throughout the testing of the device as required to better meet the needs of subjects. Some of these modifications that already exist include a sagittal plane actuated ankle, a passive hip frontal plane degree of freedom, a passive hip rotation degree of freedom, and a leg with reduced actuation for higher functioning subjects. Each of these modifications maintains the current safety features included in the existing manufactured device. These safety features include mechanical hardstops to limit the range of motion to less than a non-disabled person's range of motion, redundant position sensing at all actuated joints, monitoring of sensors to identify device failures prior to injury, and padding at all points where the subject and device make contact. All future device modifications will hold to these design safety features.

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5. Setting of the Human Research

This Investigative study will be conducted primarily in the homes of the subjects. The location could be anywhere in the United States but must meet the parameters defined in this protocol. Some preliminary training may take place at Ekso Bionics, 1414 Harbour Way South, Suite 1201, Richmond, CA 94804.

6. Study Design

This is a 36 month exploratory Investigational Study compliant with the NSF Human Subjects regulations (45 CFR 690) trialing a new device for the SCI populations to aid in ambulatory function in a home setting. Ekso Bionics will enable up to twelve (12) subjects with SCI to use an Ekso device in their home for a 12-month period. Qualified subjects will help Ekso Bionics determine the practical use of the device in the home environment and will enable Ekso Bionics to gather data to develop a device for use in a home environment. The study will require a trained spotter to be present at all times that the device is being used. The study will also evaluate the effectiveness of a non-medically licensed spotter to assist the subject.

6.1. The study will measure and evaluate the following to enable Ekso Bionics to determine the physiological benefits of high-dosage use of the device in the home. Baseline measures will be recorded at the beginning of the study and reassessed a minimum of every three months over a twelve month period (+/- 2 weeks) and every 6 months after (+/- 2 weeks). The metrics include:

6.1.1. The number of Ekso sessions completed

6.1.2. Number of steps taken in device (per week, average per session, whole time)

6.1.3. Time spent walking in device (per week, average per session, whole time)

6.1.4. Duration of training session in each walking mode (FirstStep, ActiveStep, ProStep)

6.1.5. Perceived rate of exertion (PRE) – Borg Perceived Rate of Exertion Scale

6.1.6. Bowel function - Modified International SCI Bowel Function Basic Data Set

6.1.7. Bladder function - Modified International SCI Lower Urinary Tract Basic Data Set

6.1.8. Frequency of secondary health conditions (urinary tract infections, pressure ulcerations, respiratory conditions)

6.1.9. Quality of life (QOL) – International SCI Quality of Life Basic Data Set

6.1.10. Functional abilities – Spinal Cord Independence Measure II (SCIM II)

6.1.11. Pain – International SCI Pain Basic Data Set (between session pain) and Modified International SCI Pain Basic Data Set (within session pain)

6.1.12. Spasticity – Modified Asworth Scale (MAS) at initial, 3, 6, 9 12 months and every 6 months thereafter

6.1.13. Strength – Upper and lower extremity motor scores (UEMS, LEMS) based on the ISNCSCI exam (Initial and 12 month and every 6 months thereafter)

6.1.14. Bone Density - DEXA Scan (Initial and 12 month)

6.2. The subject will identify an individual to spot them for safety during every moment of device use. The individual may be a relative, friend or an individual hired by the subject. The spotter will not likely be a medical professional although Ekso Bionics will consider a medical profession as a spotter. The spotter must meet the Inclusion/Exclusion criteria listed below. Ekso Bionics clinicians will train the spotter with the subject in the device over a three day period in the subject's home environment (Appendix A). The spotter must be certified as

competent by Ekso Bionics' clinicians in order for the device to be used without an Ekso Bionics clinician present. If the spotter is not approved, the subject may locate another spotter. Due to the time commitment required of the spotter, each subject may choose to train up to two spotters during the initial spotter training sessions.

6.3. Subject training will include but is not limited to:

6.3.1. Informing of device functions, failure modes and common characteristics.
6.3.2. Safety and how to respond to various conditions including being off balance, uneven surfaces.
6.3.3. Device set-up and take-down
6.3.4. Operating the device.
6.3.5. Putting the device on and taking the device off.
6.3.6. Sitting/Standing
6.3.7. Walking
6.3.8. Balance
6.3.9. Using hands when in the device

6.4. Spotter training will include but is not limited to:

6.4.1. Informing of device functions, failure modes and common characteristics.
6.4.2. Safety and how to respond to various conditions including being off balance, uneven ground.
6.4.3. Device set-up and take-down
6.4.4. Operating the device.
6.4.5. Putting the device on and taking the device off.
6.4.6. Sitting/Standing
6.4.7. Walking
6.4.8. Supporting the subject

6.4.9. Helping the subject safely perform simple daily tasks inaccessible to the subject while in the device (e.g., bend down to get a plate from a cabinet or open a door)

6.5. Ekso Bionics will:

6.5.1. Evaluate the efficacy of a spotter in a home environment.

6.5.2. Evaluate the safety of using the device in a home environment.

6.6. After initial training at either Ekso Bionics or at the participant's home, a follow-up evaluation device operation may be conducted either in-person or by video at weeks 3 and 7. Review meetings will be held every three months from the time the device is delivered to the subject's home (or more frequently) to evaluate safety and efficacy. Information gathered from the study and status meetings will be used by Ekso Bionics to further the product development. Information may also be used by Ekso Bionics Marketing to determine the most appropriate market for the device and by Clinicians to aid in training future clinical staff.

Schedule of study measure.

	Baseline	**3 months**	**6 months**	**9 months**	**12 months**	**Every 6 months after**
Device measures (6.1.1 – 6.1.4)		√	√	√	√	√
Physiological measures (6.1.5 – 6.1.7)	√	√	√	√	√	√
Frequency of secondary health conditions (6.1.8)	√	√	√	√	√	√

Quality of Life measures (6.1.9)	√	√	√	√	√	√
Functional ability (6.1.10)	√	√	√	√	√	√
Pain (6.1.11)	√	√	√	√	√	√
Spasticity (6.1.12)	√	√	√	√	√	√
Strength testing (6.1.13)	√	√	√	√	√	√
Bone Density (6.1.14)	√				√	

7. Inclusion and Exclusion Criteria

7.1. Subject Inclusion Criteria:

Participants must have a spinal cord injury between C7-L3 resulting in motor paralysis.

Participants must meet each of the remaining criteria:

7.1.1. be an experienced user of the Ekso device with a minimum of 20 hours and no more than 50 hours of device use and require no greater than minimal assist (support of up to 25% body weight) for safe and consistent walking.

7.1.1.1 no more than 2 episodes of balance loss per 1 hour training session that require no more than moderate assistance (support of 26% to 50% of body weight)

7.1.1.2 participants with more than 50 hours of device experience must agree to a 1 month period of non-use prior to acquisition of baseline measures

7.1.2. be between 18-65 years of age.

7.1.3. be able to physically fit into the exoskeleton device.

7.1.4. be able to tolerate upright standing for up to 60 minutes.

7.1.5. have sufficient joint range of motion to fit safely within Ekso: Hip flexion contracture ≤ 15o; knee flexion contracture ≤ 10o; ankle dorsiflexion to neutral with no more than 10o of knee flexion.

7.1.6. have sufficient upper body strength to balance themselves with two arms

7.1.7. be fluent in English

7.2. Subject Exclusion Criteria:

7.2.1. Height below 60 inches or above 76 inches or with physical characteristics incompatible with device and testing procedure.

7.2.2. Weight above 220 lbs.

7.2.3. Lower extremity joint contractures that exceed device capacity for safe use.

7.2.4. Any medical issue that precludes full weight bearing and ambulation (e.g. osteoporosis that prevents safe standing, orthopedic injuries, pain, severe spasticity)

7.2.5. Skin integrity issues that would prevent wearing the device.

7.2.6. Cognitive and/or communicative disability inappropriate for testing as determined by Ekso Bionics clinician. Subjects must be able to follow directions well and demonstrate learning capability.

7.2.7. Pregnancy (Self-reported)

7.2.8. Colostomy

7.2.9. Medical or environmental conditions arising after the start of the study that are deemed unsafe per Ekso Bionics discretion.

7.3. Spotter Inclusion Criteria:

Spotters must meet each of the remaining criteria:

7.3.1. be between 18-65 years of age.

7.3.2. be physically fit and

7.3.3. able to lift and carry the Ekso device (50 pounds).
7.3.4. able to support the subject if off balance.
7.3.5. able to guide the subject to a safe position in case of a fall.
7.3.6. be certified in First Aid
7.3.7. be available at least four days per week for at least five out of every six weeks throughout the duration of the study. If more than one spotter will be working with the subject, then spotters together must meet these criteria.
7.3.8. be fluent in speaking and reading English
7.3.9. be able to read the LCD display
7.3.10. be able to hear device alarms and tones

7.4. Spotter Exclusion Criteria:

7.4.1. Known muscular-skeletal or other medical condition that could cause regular delays of the study if spotter is injured or impaired.
7.4.2. Pregnancy (Self-Reported)

Environmental Condition Requirements

Use of the device must adhere to the following conditions:

Environment	
General Specifications	• Not for use in damp areas • Solid, flat terrain with less than 2% slope • Not for use on deep pile carpet (over ½" pile), ice, loose dirt or gravel, grass, rubber or high friction flooring, and other similar • surfaces
Conditions of Visibility	**For Control Pad:** • Ambient luminance range: 100lx to 1500lx • Viewing distance: 20-30 cm • Viewing angle: normal to display +/- 45 deg
Physical Conditions	• Temperature range 10-30 deg C • Relative humidity range 20-95%, non-condensing • Background sound pressure level: <70 dBA in the range of 100 Hz
Frequency of Use for Operator	
Maximum Frequency	6 hours per day

8. Recruitment Methods

8.1. Ekso Bionics will locate interested subjects from an existing group of prior test subjects. Additional networking for the purpose of identifying potential subjects will occur through rehabilitation hospitals currently using the Ekso Bionics device as well as non-for-profit organizations interested in supporting the individual use of Ekso. Since all recruitment will be verbal,

recruitment flyers of other marketing materials are not necessary. Hospitals acting as recruiting centers to locate Ekso Bionics test subjects may have their own IRB for recruiting only.

8.2. Ekso Bionics Clinical team members will perform the initial screening of potential participants. The team will determine study eligibility based on a clinical evaluation, home site evaluation, interviews with the prospective non-clinical spotter(s) and the experience and capability of the subject. They will discuss in detail the objectives, complete protocol, and its risks and potential benefits.

8.3. Once volunteers agree to participate they will be required to provide a medical release from their physician. Potential participants will read the Ekso Bionics informed consent and have an opportunity to ask questions and discuss the study with their physician, family, and friends before agreeing to enter the study. The informed consent and medical release (Appendix B) also include contact information should the participant or his/her associates have any questions. The original signed informed consent will be given to the participant, and a copy will be kept in a locked cabinet at Ekso Bionics accessible only by Investigators.

9. Number of Subjects

The study will consist of a minimum of two (2) subjects and a maximum of twelve (12).

10. Study Timelines

The Investigational study will take place over the course of 36 months. Each subject will be evaluated for a minimum of 12 months during the 36 month period.

If at any point during the study, the subject must take a break from regular walking for medical or personal reasons, if the break is less than 2 month, they will be able to restart the study by notifying the principal investigator of the break and resuming use. If the break is greater than 2 months, the subject will need to be re-evaluated by an Ekso Bionics physical therapist to restart the study. In the case of a break of more than 2 months, the study clock will be considered "paused" at this point and the next evaluation after the initial re-evaluation will be 3 months later (+/- 2 weeks) if in the first year of the study and 6 months (+/- 2 weeks) after beyond the first year of the study.

11. Endpoints

11.1. At the conclusion of the 12-month training period, final measurements will be taken, both the subject and the non-clinical spotter will be interviewed or a questionnaire (Appendix C) will be provided to obtain information that will assist Ekso Bionics with further development of the device. Measurements will continue to be collected every 6 months for up to the conclusion of the study or the subject terminates his/her enrollment.

11.2. Sessions will be ended for any of the following reasons:

11.2.1. Subject decides to stop participation in the study at any time and for any reason.

11.2.2. An Ekso Bionics staff member stops the subject from taking part in this study at any time if he believes it is in the subject's best interest or if the subject does not follow the study protocol.

11.2.3. Equipment is operating inconsistently or is deemed unsafe

11.2.4. A therapist/researcher involved feels that the subject's performance or continued usage places them at risk for injury.

11.2.5. The subject is experiencing any adverse medical condition as evaluated by the subject, clinician or spotters.

11.2.6. The subject or assistants to the subject (spotter or otherwise), deliberately or not, does not follow the study protocol or uses or permits use of the device in an unsafe manner.

11.3. If the subject, deliberately or not, does not follow the study protocol or uses or permits use of the device in an unsafe manner, the device may be returned to Ekso Bionics without financial reconciliation to the subject.

11.4. If the subject does not walk in the Ekso for a period of more than 21 days for any reason, they will be withdrawn from the investigation.

11.4.1. If the subject wishes to resume participation in the study, additional training of the subject and baseline assessments may be necessary.

12. Procedures Involved in the Human Research

12.1. The study is designed to enable Ekso Bionics to evaluate the high-dosage use of a robotic exoskeleton in the home environment by persons with spinal cord injury. The study is based on the existing Ekso device. Features will include devices and controls to emulate proper gait training, stability and walking for common daily function. The device will not allow all daily functions including bending over, squatting, toilet use, climbing up or down stairs or ramps, side stepping or backward stepping.

12.2. Since the study involves periodic observation and data collection for evaluation by Ekso Bionics clinical, engineering and marketing personnel, the testing procedures includes:

12.2.1. Periodic evaluations by trained Ekso Bionics clinicians according to general inclusion/exclusion criteria.

12.2.2. A minimum of weekly electronic data transfer to Ekso Bionics of the data collected on the Ekso on-board computer. These data includes but are not limited to

12.2.3. Number of steps.

12.2.4. Length of steps

12.2.5. Speed

12.2.6. Walking mode used

12.2.7. Battery usage

12.2.8. A minimum monthly transmittal of a usage log completed daily by both the subject and the spotter. The log will include subjective and objective data including (Appendix D):

12.2.8.1. Amount of sleep the previous night

12.2.8.2. Any deviations from typical daily activity (e.g., medications, exercise, travel, illness)

12.2.8.3. Description of physical activity other than using the Ekso.

12.2.8.4. Subjective rating of quality of life

12.2.8.5. General impressions in relation to the experience of using Ekso on a daily basis

12.2.9. The participant will be asked to use the device in their own discretion as long as the use adheres to the safety protocols outlined. Device features such as step length, swing time, and assist mode (maximum assist vs. variable assist) can be locked to prevent inadvertent or intentional manipulation of device settings which may create unsafe walking.

12.3. Notable observations by Ekso Bionics will include:

12.3.1. Donning/doffing the device

12.3.2. Standing/sitting

12.3.3. Walking
12.3.4. Balance and stability
12.3.5. Maneuverability
12.3.6. Duration of sessions
12.3.7. Device reliability
12.3.8. Physical and psychological deviations
12.3.9. Human factors and usability

13. Cost and Compensation

13.1. Equitable access plan:

There is a substantial cost to enrolling a subject in the study. The costs fall into four categories:

1. Training cost
2. Testing costs
3. Subject/Spotter costs
4. Device cost

Ekso will entirely bear the training cost (1) and cost associated with data acquisition (e.g. Dexa scan)(2). The subject will be responsible for the potential cost of obtaining a medical release from their physician. The subject will also be responsible for providing a spotter since this will often be an unpaid family member and therefore have no associated cost (3). The Ekso device ($130,000-160,000 retail depending on features) is a substantial cost which some subjects will not be able to pay, nor can Ekso afford to provide enough devices for the desired number of subjects (4). Since Ekso Bionics' objective is to study the objectives in Section 3, the device will be equally accessible to all qualified subjects at cost. This will be achieved by one of the following options.

13.1.1. Subjects may purchase their own Ekso device which they may then keep at the end of the study. This will enable a prompt start to their participation in the study.

13.1.2. Ekso will introduce subjects to non-profit organizations specifically available to fund robotic medical devices. These organizations include but are not limited to the Bridging Bionics Foundation (https://www.facebook.com/bridgingbionics?ref=stream, https://twitter.com/bridgingbionics) and SoldierSocks (http://www.facebook.com/pages/Soldier-Socks/147478454297?ref=stream&hc_location=timeline). SoldierSocks has already committed to donating ten Ekso devices to veterans of war (Appendix E).

13.1.3. Ekso Bionics will assist the subject to establish a fundraising program under the Ekso Hope program (http://www.eksobionics.com/eksohope). Ekso Hope has successfully raised hundreds of thousands of dollars to enable the purchase Ekso devices. The foundation set up a program and assist individuals reach their goal.

14. Data Management and Confidentiality

14.1. Data may be collected manually, on video, on a computer embedded in the device or transferred to an Ekso Bionics computer.

14.2. The subject will be assigned an ID number so Ekso Bionics can keep all of the data collected during the duration of the study. Only the subject's ID number will be associated with the test session, not the subject's name. Only the Investigators will have access to the subject's identifying name and number. The identifying information will be kept in 1) a secure, password protected computer file on a server and 2) hard copies stored in

a locked cabinet located at the Ekso Bionics facility in Richmond, CA.

14.3. Data obtain remotely from the device will include but is not limited to number of steps taken during the session, the total distance travelled, the distance between steps, the force on various device components including pressure and torque, the location of the subject in relation to the device to evaluate balance and stability.

14.4. Physiological and psychological data will be gathered per Section 6.1.

14.5. Data will be stored for ten years.

14.6. An authorized Ekso Bionics staff member will transfer the data to the Ekso Bionics server at least once during the duration of the study. Data will be cleared from the device upon transfer; although, a portion of the data can be reviewed by the subject on the Ekso Pulse website. Ekso Pulse is a website designed specifically for users to review the data associated with their walking sessions. The Ekso Pulse site is protected by a user specific login. The server is under the same security measures as the primary Ekso server.

14.7. Data security and subject privacy measures will be taught at clinical training sessions to all clinicians, engineers or any Ekso Bionics staff responsible for testing and capturing data. Ekso Investigators will agree upon a secure password, file location and locked cabinet prior to the start of any testing. Keys to the cabinet will be in the sole, personal possession of the Investigators.

14.8. The data are intended to guide the development of the Ekso device for home use and to analyze the clinical effect on the subjects. Much of the analysis will be subjective in nature where the researchers will ignore outliers and be able visually

verify the data quality. Any suspicious data will be ignored or verified by comparing it with the videos and pictures.

14.9. The computer data, video and written notes will be evaluated and analyzed based on the needs of the Ekso Bionics engineering, marketing and business requirements. Analysis may include observation, statistical deviation, or other methods to enable results.

14.10. Written data, including subject questionnaires, will be given to study personnel at each checkup. This data will be transferred to the principal investigator by physical handoff or certified mail where physical handoff is not possible.

15. Provisions to Monitor the Data to Ensure the Safety of Subjects

15.1. This study does not require a Data and Safety Monitoring Committee or Board. This is a pilot study. It is considered an intervention, behavioral, learning-based training study with minimal risk to subjects.

16. Risks to Participants

16.1. The risk of falling: This could be caused by loss of control of the ambulation activity by the participant or spotter as well as malfunction of the Ekso device itself. The risk of falling will be minimized by having a trained spotter with the subject at all times. The risk of falling is further mitigated by allowing only very experienced subjects who have been approved by the Ekso Bionics Clinical Team walk in the device during the study. This risk is similar to any gait therapy in which subjects with lower extremity disorders are standing and walking.

16.2. Risk of exceeding subject range of motion: This would be caused if the Ekso moved the subject beyond their normal range of

motion, resulting in a strain, sprain and/or fracture. This risk is mitigated by mechanical hard stops that prevent the device from exceeding a normal human range of motion even in the event of a failure in the electrical or software systems. Software systems are also in place to further reduce range of motion to improve fit and comfort for subjects during walking. Subjects will be evaluated by trained Ekso Bionics clinicians who will eliminate any subjects from participation if they cannot meet the required range of motion.

16.3. Discomfort, skin pressure/friction, bruising, pain, or unusual swelling caused by the exoskeleton which has the potential to lead to skin breakdown or abrasions. All locations where the subject contacts the exoskeleton are padded to prevent bruising or skin irritations. Also all pinch points are covered and protected from catching either skin or clothing. Adjustments to the harness placement and additional padding will be assessed to decrease the risk of skin breakdown as well.

16.4. Blood pressure instability during use of the device related to standing or activity as well as reflex bowel or bladder activity or autonomic instability during use of the device. This risk will be reduced with frequent assessment of subject's symptoms as well as assessment of blood pressure, heart rate, and oxygen saturation during initial device training by research physical therapists. Activity will be stopped in the event of instability of vital signs and as recognized by experience research personnel. Spotters will be trained to recognize signs and symptoms associated with blood pressure instability and to stop activity if present.

16.5. Spasms triggered by joint movement in the device. This risk will be reduced through screening prior to enrollment in the study with exclusion of subjects with severe spasticity.

16.6. There is a risk of device malfunction causing injury from falling or unintended motion of Ekso. Testing the device with Ekso Bionics employees without disability prior to a subject wearing the device will minimize risk of malfunction of the Ekso. Device malfunction is also mitigated through numerous safety features of the device. Redundant position sensing on all of the actuated joints ensures that the motors are always controlled using reliable sensor information. If the redundant sensors ever do not agree then the device shuts down. An emergency disable button is always available to the spotter to instantly shut down the device. This is implemented via hardware, so it is effective even during a software malfunction. The device is equipped with fail-safe brakes on the actuated knee joints, so if the device loses power or is shut down for any reason the knees will continue to support the subject. Finally there are numerous sensor, motor, and software monitoring systems in place. If any abnormality is detected (such as excess joint speed or force) the software shuts down the device in a safe manner.

16.7. The risk of fractures with use of the device: this will be minimized by requiring medical clearance for all participants and requiring all participants to be actively involved in a standing program.

16.8. The risk of musculoskeletal injury for the spotter: This could be caused by an attempt to correct a significant loss of balance during ambulation by the Ekso user as well as malfunction of the Ekso device itself causing a need for additional support to prevent a fall from occurring. The risk of musculoskeletal injury may also occur when lifting and moving the device. This risk will be minimized by providing the spotter with training related to safe body-mechanics during all aspects of device use. The risk of musculoskeletal injury for the spotter is further

mitigated by allowing only experienced subjects who have been approved by the Ekso Bionics Clinical Team walk in the device during the study.

16.9. The use of the Ekso system may involve risks that are currently unforeseeable as this is a trial to assess safety and efficacy of the Ekso device.

17. Provisions for Research Related Harm/Injury

17.1. If medical resources are required, the identified spotter must immediately contact appropriate medical services or call 911. Ekso Bionics principal investigator should also be contacted as soon as the subject is medically stable. For minor injuries, a local hospital emergency room will be identified as part of an emergency plan established prior to allowing use of the device.

17.2. This device has been determined to be NSR (non-significant risk) by Ekso Bionics due to the spotting requirement.

18. Potential Benefits to Subjects

18.1. There may be no direct benefit to the participants. The main benefit of this study is to determine the progression of technology to enhance functional ambulation, improved health and independence of people with spinal cord injuries. The feedback obtained from the participants and therapists will provide insights to the company for the next iteration of the design of the Ekso device.

19. Provisions to Protect the Privacy Interests of Subjects

19.1. Each participant will be assigned a coded identification number to designate all evaluations. Data will be stored by the coded identification number without information identifying the individual. All data, written and electronic, will be stored on

the Ekso Bionics server with password protection. Data will only be available to the researchers involved in the studies.

20. Payments to Subjects

No payments will be provided.

21. Consent Process

21.1. Ekso Bionics will require all participants to sign an Ekso Bionics Medical Release/Consent Form and Permission to Obtain Medical Treatment prior to the preliminary evaluation. Spotters will be required to sign an Ekso Bionics Consent Form:

21.1.1. All consent information will be provided to the subject in advance of their clinical screening.

21.2. There will be no waiting period required between the subjects being informed of risks and their providing of consent for participation in the study. Payment for the device must be received in most cases prior to starting the study.

22. Informed Consent Process for Research

22.1. The consent process will be directly conducted by a member of the Ekso Bionics clinical team who is under the direct supervision of Darrell Musick, Ekso Bionics' Clinical Director. The consent process typically takes 30-60 minutes for the subject to understand and consent to participate in the study.

22.2. Only test subjects capable of comprehending and acknowledging the consent form will be included in the test.

	Protocol Name:	**Investigational Study of the Ekso Bionics Powered Exoskeleton for High-Dosage Use by Individuals with Spinal Cord Injury in a Non-Clinical Environment**
	Principal Investigator:	Katherine Strausser, PhD, Sr. Controls Engineer
	Primary Contact Name/Contact Info:	Katherine Strausser, PhD, Sr. Controls Engineer KStrausser@EksoBionics.com 510-529-2529
	Date Revised:	9/28/2015
	Study Number:	13098-01

Appendices

Appendix A

- 103218 - Ekso Non-Clinical Spotter Training Schedule
- 103217 - Ekso Non-Clinical Spotter Use Training Checklist
- 103215 - Ekso Non-Clinical Spotter Competency Signoff Sheet

Appendix B

- 103213 - Ekso Participant Informed Consent Form
- 103316 - Ekso Spotter Informed Consent Form
- 103214 - Ekso Medical Release Form

Appendix C

- 103223 - Ekso Non-Clinical Spotter Questionnaire

Appendix D

- 103212 - Ekso Case Report Form - Subject Daily Log

Appendix E

- SoldierSocks Letter of Intent to Ekso Bionics