ISCRR
Institute for Safety, Compensation and Recovery Research

HORIZON SCANNING

July 2016

BRIEF

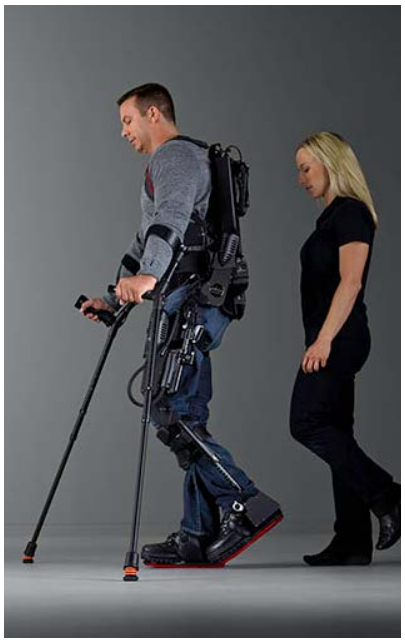
Powered Lower Limb Exoskeletons for Spinal Cord Injury

Background

In Australia between 300 and 400 new cases of spinal cord injury occur each year. By 2021, it is estimated that between 10,500 and 12,000 Australians will be living with spinal cord injury.[1] A significant proportion of these people will experience a loss of mobility with approximately 60% - 80% of individuals likely to be dependent on the use of mobility aids such as wheelchairs.[2]

Wheelchairs, both manual and powered, are the primary mobility aids used by people who have sustained a spinal cord injury resulting in paraplegia (loss of the use of the lower limbs). However, long-term wheelchair use is associated with thinning bones, pressure sores, and problems with the urinary, cardiovascular, and digestive systems. The primary limitation of wheelchair use reported by users is the inability to walk or climb stairs. Wearable powered exoskeletons have the potential to overcome this limitation by providing greater mobility and freedom to individuals with paraplegia from spinal cord injury.[3]

Over the past decade there have been significant developments in the area of lower limb exoskeletons with several exoskeletons now available commercially. This brief has been prepared to provide an overview of the current exoskeletons that have been identified through ISCRR's Horizon Scanning program and provide a quick reference guide detailing their features and potential clinical application.



Ekso GT Image: Ekso Bionics

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ReWalk Personal 6.0 Image: ReWalk Robotics

Potential for Impact

Powered exoskeletons have potential for a number of applications, including:

- During early rehabilitation to support gait training and to promote development of new nerve pathways
- During late rehabilitation and in the community as an exercise tool to promote physical, mental and social wellbeing
- Community use as a wheelchair alternative for improved mobility.[4]

Exoskeletons address an unmet need for an alternative to prolonged wheelchair use.[3] Using an exoskeleton could lead to improved independence, improved mobility and improved quality of life.[5] Additionally, exoskeletons can reduce the complications associated with prolonged wheelchair use such as:

- Pain
- Bowel and bladder dysfunction
- Muscle spasticity
- Risk of skin breakdown
- Reduced bone density.

The suitability of use of the various exoskeletons may be limited by personal factors such as the users' level and severity of spinal cord injury, fit within the device and upper body strength.

Other potential limitations include the need for assistance to put on and take off the device, the need to be under the supervision of a specially trained healthcare professional or the need to be accompanied by a specially trained companion and the amount of time needed for a user to learn to use the exoskeleton.

Technology Overview

Lower-limb powered exoskeletons are prescription devices comprising an external, powered, motorised brace-like structure that is placed over a person's paralysed or weakened limbs for the purpose of facilitating standing, walking, climbing stairs and performing activities of daily living.[6] Two types of exoskeletons are available:

- Those designed for use as a therapeutic tool in the rehabilitation setting
- Those used as a personal assistive walking device for use at home or in the community.[7]

There are several powered exoskeletons at various stages of development; some of which are currently commercially available. Each of these exoskeletons include an external support skeleton, electric motors for the lower limb joints, batteries to supply power to the motors, a computer to control the device and all are designed to be worn on top of clothing. The exoskeletons differ in design, appearance, size and other characteristics such as the need for assistance to put on and take off the device, the need for stability aids, how movement is controlled and the intended patient population.[4] *Table 1* summarises the characteristics of the exoskeletons that are currently available internationally which include:

- ReWalk
- REX
- Ekso (formerly eLegs)
- Indego (formerly Vanderbilt)
- Hybrid Assistive Limb (HAL)
- Keeogo.

Clinical Indication

Powered exoskeletons are designed for individuals with lower limb paralysis or weakness to provide mobility and other health benefits. Lower limb paralysis or weakness can be due to disease or injury including spinal cord injury, stroke, multiple sclerosis or cerebral palsy. The ReWalk, Ekso, REX, Indego and HAL exoskeletons are designed to be used by individuals diagnosed with paralysis. In comparison the Keeogo exoskeleton requires a base level of mobility and is therefore targeted towards patients who can walk and is not intended for individuals with spinal cord injuries causing paralysis. The use of the various exoskeletons may be limited by personal factors such as the users' level and severity of spinal cord injury, fit within the device and upper body strength. Personal factors affecting the use of ReWalk, REX, Ekso, Indego, HAL and Keeogo exoskeletons are summarised in *Table 2*.

ReWalk Personal 6.0 Image: ReWalk Robotics

Clinical Effectiveness

Powered exoskeletons for individuals with spinal cord injury

A systematic review with meta-analysis of the effectiveness and safety of powered exoskeletons in individuals with spinal cord injury was published in March 2016. The analysis included a total of 14 studies representing 111 patients. The studies ranged in size from 3 to 16 patients. The ReWalk was evaluated in eight studies, Ekso in three, Indego in two studies and an unspecified exoskeleton in one study.[6]

Powered exoskeleton training programs were typically conducted three times per week for 60 – 120 minutes per session over a duration of 1 – 24 weeks. Ten of the studies utilised training programs conducted exclusively on flat indoor surfaces, while four incorporated more complex forms of training including walking outdoors, navigating obstacles, climbing stairs and performing activities of daily living. The analysis showed that following the training program 76% of individuals were able to walk using the exoskeleton with no therapist assistance.

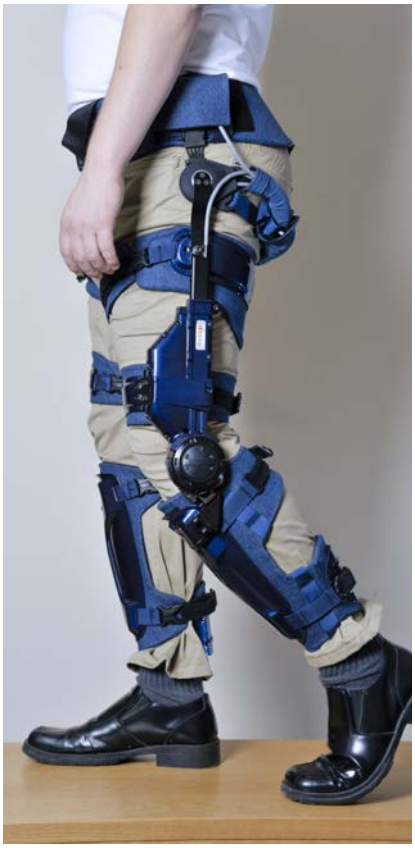
REX Image: REX Bionics plc

The average distance covered during a 6-minute walk test was 98m (0.27 metres per second). The physical exertion required to walk with an exoskeleton was reported to be at an intensity that can convey health benefits but not result in early fatigue.[6]

A separate systematic review of walking speed with powered exoskeletons (including ReWalk, Ekso and Indego) reported an average walking speed of 0.26 metres per second. Individual participant walking speeds ranged from 0.31 to 0.71 metres per second. The walking speed that was achieved was related to the level of injury and the amount of time spent practicing.[8] The average walking speed achieved with the exoskeletons did not reach the threshold required to cross a road in the time of a walk signal which varies from 0.44 to 1.32 metres per second.[9]

Health benefits related to exoskeleton use are reported inconsistently in trials. In the effectiveness and safety analysis, five of the included studies assessed muscle spasticity (involuntary muscle activation) and found that 38% of users reported decreased spasticity. In the three studies that assessed bowel function, 61% of exoskeleton users reported improvements in bowel movement regularity.[6]

A search of the ClinicalTrials.gov registry (searched 14 June 2016) identified nine ongoing trials further evaluating powered exoskeletons in persons diagnosed with spinal cord injury, including ReWalk in three studies, Ekso in four studies, ReWalk and Ekso in one study and REX in one study. Two additional trials one involving ReWalk and the other the Indego device are expected to commence in mid-late 2016. Some of the outcomes being assessed include the number of sessions and level of assistance required to achieve advanced indoor and outdoor walking skills, changes in muscle volume and structure of the lower limbs and quality of life including effects on pain and bowel and bladder function.

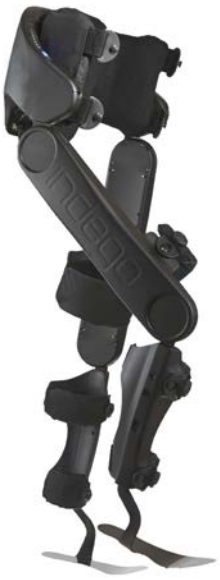


Keeogo Image: B-TEMIA

Keeogo assistive walking device for individuals with limited walking capacity

The Keeogo is the only powered exoskeleton which is intended for individuals with limited walking capacity. The benefits of Keeogo are currently under investigation and have not yet been clinically proven. The manufacturers claim that the intended functional benefits for individuals with mobility impairments wearing Keeogo on a regular basis include: ability to remain active, ability to work, improved safety and stability, improved accessibility, possibility to prolong the onset of wheelchair use, overall independence and freedom. Intended clinical benefits include: improved endurance, musculoskeletal health, balance, posture, bladder/bowel function, bone health, mental health and increased circulation.[10]

The manufacturers report that a multi-centre clinical trial to assess the effectiveness and safety of Keeogo for community and home mobility use is currently underway.[11]



Indego Image: Parker Hannifin Corporation

Safety

The risks associated with the use of this type of device include:

- Instability, falls and associated injuries
- Bruising, skin abrasions, pressure sores, soft tissue injury
- Changes in blood pressure and heart rate
- Interference with other electrical equipment/devices
- Burns, electrical shock and device malfunction (e.g. device stoppage or unintended movement).[12]

The safety of exoskeleton use was assessed recently in a systematic review and meta-analysis published in March 2016. There were no reported serious adverse events. The incidence of a fall at any time during the training program was 4.4% and the incidence of bone fracture during training was 3.4%. The risk of falls and fractures has been lessened with newer generation exoskeletons and refinements to patient eligibility characteristics.[6]

The continuous expert supervision provided during the clinical trials of powered exoskeletons may underestimate the risk of falls and fractures in the community or home setting.[13]

Setting for Technology Use

Powered exoskeletons are available for two care settings; those used as a therapeutic tool for use in a rehabilitation setting and those used as a personal assistive walking device for use at home or in the community. Some exoskeletons including the ReWalk, REX, Indego and Keeogo are available for use in both care settings.

Clinical use in the rehabilitation setting	Personal use in the community or home setting
ReWalk Rehabilitation	ReWalk Personal 6.0
REX	REX P
Indego Therapy	Indego Personal
Keeogo	Keeogo
Ekso GT	
HAL for Medical Use - Lower Limb Model	

Indego Image: Parker Hannifin Corporation

Regulatory Approval

ReWalk was the first of the powered exoskeletons to be approved for rehabilitation and personal use. It was cleared by the United States Food and Drugs Administration in June 2014 and by the Australian Therapeutic Goods Administration (TGA) in December 2014. REX is currently the only other powered exoskeleton approved for use in Australia. REX was approved by the TGA for clinical use in May 2015 and home use in February 2016.

As at the time of publication, the status of lower limb powered exoskeleton approval in Australia, Canada, the United Kingdom and the United States is shown below.

Model	ReWalk Personal 6.0 ReWalk Rehabilitation	Ekso GT	REX P REX	Indego Personal Indego Therapy	HAL for Medical Use - Lower Limb Model[4]	Keeogo
Australia	Yes		Yes			
Canada	Yes	Yes				Yes
United Kingdom	Yes	Yes	Yes	Yes	Yes	
United States	Yes	Yes	Yes*	Yes		

**Rehabilitation use only*

Table 1: ***Exoskeleton Features***

Model	ReWalk Personal 6.0 [14,15] ReWalk Rehabilitation [14,15]	Ekso GT [16]	REX P [17,18,19] REX [19,20,21]	Indego Personal [22,23,24] Indego Therapy [24,25,26]	HAL for Medical Use - Lower Limb Model[4]	Keeogo[27,28]
Manufacturer	ReWalk Robotics Inc. (formerly Argo Medical Technologies)	Ekso Bionics	REX Bionics PLC	Parker Hannifin Corporation	Cyberdyne Inc.	B-TEMIA
Battery life per charge	2 hours (plus 15 minutes using auxiliary battery)	1 hour (two interchangeable batteries provided)	1 hour (two interchangeable batteries provided)	1.5 hours	1.5 hours	Not specified
Battery charge time	Minimum 4 hours	1 hour	90 minutes	Maximum 4 hours	Not specified	Not specified
Weight	30kg 25kg	23kg	45kg	12kg	15kg	6kg
Stability aid required (walker or crutches)	Yes	Yes	No	Yes	Yes	No
Initiation of movement	Remote control worn on the wrist to change modes, postural changes for stepping	Remote control used by the physical therapist to select mode, weight shift to initiate stepping	Joystick / T-Bar	Changes in posture	Remote control and body movement initiated	User initiated
Motions supported	Sit, stand, walk and turn	Sit, stand, walk and turn	Sit, stand, walk, turn, shuffle sideways	Sit, stand, walk and turn	Sit, stand, walk and turn	Sit, stand, walk, run, turn, crouch, squat, kneel
Supports stair climbing	Yes*	No	No	Yes*	Not specified	Yes
Environment for use	Level surfaces and mild slopes	Indoor, smooth surfaces	Flat, horizontal, stable, dry surfaces	Even or uneven terrain up to 5 degrees of inclination	Not specified	Flat or uneven surfaces
Special design features		Can provide adaptive amounts of power to either side of the users' body	Completely self-supporting, giving freedom to use hands	Modular design consisting of 5 snap together components Can be worn while seated in most standard-frame wheelchairs	In a voluntary control mode incorporates myoelectric biofeedback to facilitate gait	Classified as a dermoskeleton (sub-class of exoskeleton)
Conditions of use		For use in rehabilitation institutions under the supervision of a trained physical therapist	For use with the assistance of a trained buddy (REX P) For use under the supervision of a trained healthcare professional (REX)	Can only be used in coordination with a specially trained companion. Only individuals who participate and successfully pass the clinical training program requirements are allowed to operate or assist in the use of the device.	Not specified	Not specified
Minimum expected useable life	5 years	4 years	5 years	5 years	Not specified	Not specified

**Not approved for stair climbing in the United States*

Table 2: ***User Characteristics***

Model	ReWalk Personal 6.0 [14,15] ReWalk Rehabilitation [14,15]	Ekso GT [16]	REX P [17,18,19] REX [19,20,21]	Indego Personal [22,23,24] Indego Therapy [24,25,26]	HAL for Medical Use - Lower Limb Model[4]	Keeogo[27,28]
Therapeutic population	Individuals with spinal cord injury at levels T7 to L5. It may also be used with higher-level injuries (T4 to T6) in rehabilitation settings	Individuals with spinal cord injury at levels T4 to L5. It may also be used with higher-level injuries (C7 to T3) with acceptable muscle control (diagnosed as ASIA D) Individuals with hemiplegia due to stroke	Individuals with mobility impairment	Individuals with spinal cord injury at levels T7 to L5. It may also be used with higher-level injuries (T4 to T6) in rehabilitation settings (United States) Individuals with lower limb weakness or paralysis (Europe)	Individuals who have disorders in the lower limb and people whose legs are weakening	An assistive walking device for individuals experiencing a lack of endurance, reduced muscle strength or pain as a result of an injury or chronic illness
User height range	160 – 190cm	158 – 188cm	142 -193cm	155 – 191cm	145 – 185cm	Not specified
User maximum weight	100kg	100kg	100kg	113kg	85kg	No weight restriction
User maximum hip width	Not specified	Not specified	38cm	42.2cm	Not specified	Not specified
Other conditions for use	Users must meet the following prerequisites: -Hands and shoulders can support crutches -Healthy bone density -Free from skeletal fractures -Able to stand using a device such as a walker -In good general health		Manual dexterity and cognitive ability to use a joystick / T-bar on a right hand mounted controller. No skin integrity issues that may affect ability to use REX / REX P	Sufficient upper body strength to balance and advance with forearm crutches, front-wheeled walker or platform walker		The user should have the ability to: -Initiate all movements in walking, sit-stand, stand-sit, squatting, crouching, kneeling and stair climbing -Walk without assistance from another person (with or without an assistive device) -Maintain necessary balance and core strength to remain upright

Costs

The cost of individual powered lower limb exoskeletons could be as much as $130,000 - $150,000 [29]. Additional costs associated with the use of these devices include training (healthcare professionals, users, companions) and post-warranty service contracts. In some countries the devices can be leased for a monthly fee, for example, in Canada the Keeogo can be leased for $1000 (CAD) per month.[30]

In its latest robotics report, ABI Research predicts the robotic exoskeleton market will reach $1.9 billion in 2025 up from $68 million in 2014. Lower body exoskeletons, employed as rehabilitation or quality of life enablers, currently lead the sector however industrial systems that amplify abilities are expected to see the strongest growth.[33] One of the challenges the market faces is the high price of exoskeleton systems.[34]

ReWalk Personal 6.0 [31] ReWalk Rehabilitation [31]	Ekso GT	REX P [32] REX [32]	Indego Personal Indego Therapy	HAL for Medical Use (Lower Limb Type)	Keeogo
ReWalk Personal $89,000 (USD) ReWalk Rehabilitation $96,500 (USD) (includes a 2-year service warranty)	Not available in Australia	$200,000 (AUD) Including on-site training, shipment and first year service and parts. Price reviewed quarterly.	Not available in Australia	Not available in Australia	Not available in Australia

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