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. 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.

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.

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.
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.

Exoskeletons address an unmet need for an alternative to prolonged wheelchair use. Using an exoskeleton could lead to improved independence, improved mobility and improved quality of life. 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.

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.

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.

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, HAL and Keeogo exoskeletons are summarised in Table 2.
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.¹

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.

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 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
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).

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. 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.

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.

<table>
<thead>
<tr>
<th>Clinical use in the rehabilitation setting</th>
<th>Personal use in the community or home setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>ReWalk Rehabilitation</td>
<td>ReWalk Personal 6.0</td>
</tr>
<tr>
<td>REX</td>
<td>REX P</td>
</tr>
<tr>
<td>Indego Therapy</td>
<td>Indego Personal</td>
</tr>
<tr>
<td>Keeogo</td>
<td>Keeogo</td>
</tr>
<tr>
<td>Ekso GT</td>
<td></td>
</tr>
<tr>
<td>HAL for Medical Use - Lower Limb Model</td>
<td></td>
</tr>
</tbody>
</table>

Indego Image: Parker Hannifin Corporation
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.

<table>
<thead>
<tr>
<th>Model</th>
<th>ReWalk Personal 6.0</th>
<th>ReWalk Rehabilitation</th>
<th>Ekso GT</th>
<th>REX P REX</th>
<th>Indego Personal Therapy</th>
<th>Indego Therapy</th>
<th>HAL for Medical Use – Lower Limb Model$</th>
<th>Keeogo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Australia</strong></td>
<td>Yes</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
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</tr>
<tr>
<td><strong>Canada</strong></td>
<td>Yes</td>
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<td>Yes</td>
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<td></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>United Kingdom</strong></td>
<td>Yes</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>United States</strong></td>
<td>Yes</td>
<td></td>
<td>Yes</td>
<td>Yes$</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Rehabilitation use only
### Table 1: Exoskeleton Features

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

*Not approved for stair climbing in the United States
### Table 2: User Characteristics

<table>
<thead>
<tr>
<th>Model</th>
<th>User Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ReWalk Personal 6.0</strong></td>
<td>Individuals with spinal cord injury at levels T4 to L5. It may also be used with higher-level injuries (T4 to T6) in rehabilitation settings.</td>
</tr>
<tr>
<td><strong>ReWalk Rehabilitation</strong></td>
<td>Individuals with spinal cord injury at levels T7 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.</td>
</tr>
<tr>
<td><strong>Ekso GT</strong></td>
<td>Individuals with mobility impairment.</td>
</tr>
<tr>
<td><strong>REX</strong></td>
<td>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).</td>
</tr>
<tr>
<td><strong>Indego Personal</strong></td>
<td>Individuals who have disorders in the lower limb and people whose legs are weakening.</td>
</tr>
<tr>
<td><strong>Indego Therapy</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>HAL for Medical Use - Lower Limb Model</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Keeogo</strong></td>
<td>Not specified.</td>
</tr>
</tbody>
</table>

#### Therapeutic population
- **ReWalk Personal 6.0**: 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.
- **ReWalk Rehabilitation**: 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.
- **Ekso GT**: Individuals with mobility impairment.
- **REX**: 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).
- **Indego Personal**: Individuals who have disorders in the lower limb and people whose legs are weakening.
- **Indego Therapy**: 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.
- **HAL for Medical Use - Lower Limb Model**: 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.
- **Keeogo**: Not specified.

#### Costs

The cost of individual powered lower limb exoskeletons could be as much as $130,000 - $150,000. 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.

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. One of the challenges the market faces is the high price of exoskeleton systems.
References


18. REX Bionics Ltd. REX P instructions for use. V1.0, 2016


21. REX Bionics Ltd. TM-01 REX instructions for use. V4.0, April 2016


Have you heard about a new health technology you think will have an impact on people injured on the roads or at work? Please let us know by contacting us at:
iscrr.horizon.scanning@monash.edu

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