ReWalk: Robotic Exoskeletons for Spinal Cord Injury
Summary

- ReWalk is a powered exoskeleton— an external brace-like, lower-limb orthotic device.

- ReWalk may allow adults with mobility impairment to stand, sit, walk, turn, and navigate stairs.

- Four small, uncontrolled studies suggest that the supervised use of ReWalk is safe.

- ReWalk costs US$71,600 for a personal device and US$85,500 for an institutional device, with additional annual service fees. The lifespan of the device is approximately five years.

- ReWalk may lead to an increase in the need for health care aids.

- ReWalk may represent an important advance for those with mobility impairment whose condition imposes substantial physiological and psychological burdens.

- Larger comparative studies are needed to understand the potential impact of ReWalk and similar devices in rehabilitation and community settings.

The Technology

ReWalk (ReWalk Robotics, Marlborough, Massachusetts) is a powered gait orthosis for lower-limb mobility-impaired adults. It is also sometimes referred to as an exoskeleton—a term that generally describes a variety of supportive, brace-like orthotic devices that are external to the body.¹

ReWalk consists of fitted, metal braces that support each leg and part of the upper body. With joints running parallel to the hip, knee, and ankle, ReWalk is considered a full lower-limb orthosis. Unlike mechanical orthoses, ReWalk incorporates battery-powered bilateral hip and knee joint motors, a computerized control system, and a wireless remote control worn on the wrist. In addition to walking, the device also facilitates standing from a sitting position, sitting from a standing position, and navigating stairs.

Walking is initiated through minor trunk motions and changes in the centre of gravity, which are detected by a torso-mounted sensor. A software algorithm analyzes input from the sensor and generates pre-set hip and knee movements in alternating legs that result in stepping. Crutches are required to provide stability.²

Two variants of the ReWalk device are commercially available: an adjustable model intended for multiple users in rehabilitation settings and a customized version for use by individual users at home or in the community. Although other robotic exoskeletons are commercially available, ReWalk is the first such device approved for personal use in North America.

Regulatory Status

ReWalk was licensed by Health Canada as a Class II device (#91986) in September 2013. However, in December 2014, Health Canada reclassified the ReWalk device as a Class I device (John Hamilton, ReWalk Robotics, Marlboro, MA: personal communication, 2015 April 3). It now holds a Medical Devices Establishment Licence (#6595) as a Class I device.³

In the United States, the ReWalk institutional-use system was registered by the Food and Drug Administration (FDA) in 2011 and the personal-use system was issued a marketing clearance in June 2014. The personal-use system is to be used under the supervision of a trained companion, and navigation of stairs is
Components of ReWalk system.

Image courtesy of ReWalk Robotics
Standing and walking have been shown to produce positive physiological and psychological effects for individuals with paraplegia.

In February 2015, the FDA issued a rule making all powered exoskeletons Class II devices. Class II devices are considered higher risk than Class I devices and require greater regulatory controls to provide reasonable assurance of safety and effectiveness prior to US marketing.

Patient Group

Although lower-limb impairment can arise in a wide variety of clinical circumstances, ReWalk is specifically approved in the US for use by individuals with paraplegia due to spinal cord injury (SCI) at levels T7 (seventh thoracic vertebra) to L5 (fifth lumbar vertebra). It may also be used with higher-level injuries (T4 to T6) in rehabilitation settings.

To use ReWalk, individuals must have hand, arm, and shoulder function. Contraindications include a history of neurological injuries other than SCI, severe spasticity, significant contractures, unstable spine, and unhealed limb or pelvic fractures. Concurrent medical issues such as infection, cardiovascular or respiratory conditions, or pressure sores also rule out the use of the device.

Published prevalence and incidence estimates for SCI in Canada vary widely, as does the detail available regarding the origin and severity of SCI. SCIs can have traumatic origins (e.g., accidents, falls, violence) or non-traumatic origins (e.g., infections, tumours, vascular diseases) and the consequences can be quadriplegia or paraplegia. SCIs are further classified as complete or incomplete depending on whether there is a total or partial motor and/or sensory deficit below the level of the injury.

A recent report estimated the number of Canadians living with SCI in 2010 at 85,556; of this total, an estimated 48,243 (56%) were individuals with paraplegia. Of those SCIs resulting in paraplegia, 40% (19,232) were associated with trauma, while the balance (29,011) had non-traumatic origins. No information is presented concerning the number of complete versus incomplete injuries. The annual incidence for SCIs is estimated at 3,675, the majority (58%) of which are non-traumatic SCIs. Non-traumatic SCIs are expected to grow significantly as the population ages. Prevalence and annual incidence are expected to grow to 121,000 and 5,000 respectively by 2020.

The inability to walk is associated with an increased risk for osteoporosis, cardiovascular disease, pressure ulcers, muscular spasticity, and contractures. Other potential complications include chronic pain and urinary, sexual, and digestive dysfunction. According to one study, individuals with SCI are hospitalized 2.6 times more often, require 2.7 times more physician contacts, and use 30 times more home care services than the non-SCI population. Standing and walking have been shown to produce positive physiological and psychological effects for individuals with paraplegia.

Current Practice

Individuals with paraplegia have a number of locomotion options available to them, including wheelchairs, orthoses, and neuroprosthetic functional electrical stimulation systems. All of the options have some limitations. The wheelchair remains the most common mode of locomotion for people with paraplegia. While they provide users with mobility that allows them to perform many activities of daily living, wheelchairs are limited by numerous architectural and environmental barriers, their risk of causing shoulder and arm injuries, and the height restrictions for eye-to-eye interaction with non-SCI adults. More importantly, by not allowing the user to put weight on his or her legs, wheelchairs do not mitigate the adverse clinical conditions associated with SCI.

Mechanical (non-powered) orthoses have been used to support standing and walking in some individuals with paraplegia. These
Table 1: Study Participant Injury Level and Degree of Impairment

<table>
<thead>
<tr>
<th>ReWalk FDA-Approval Status</th>
<th>Injury Level</th>
<th>Number of Study Participants</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Complete</td>
<td>Incomplete</td>
</tr>
<tr>
<td>Not approved</td>
<td>C7</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>C8</td>
<td>2(^a)</td>
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<tr>
<td></td>
<td>T1</td>
<td>1</td>
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<tr>
<td></td>
<td>T2</td>
<td>2</td>
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<tr>
<td></td>
<td>T3</td>
<td>1</td>
</tr>
<tr>
<td>Rehab settings</td>
<td>T4</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>T5</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>T6</td>
<td>1</td>
</tr>
<tr>
<td>Personal/community use</td>
<td>T7</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>T8</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>T9</td>
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<td></td>
<td>T11</td>
<td>2</td>
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<tr>
<td></td>
<td>T12</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>L1</td>
<td>1(^b)</td>
</tr>
</tbody>
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C = cervical (neck); L = lumbar; T = thoracic.

\(^a\)One of these injuries is described as a C8-T8 injury and the other as a C8-T2 injury.

\(^b\)Benson et al.\(^18\) include one patient with an L1 spinal cord injury, which is a deviation from their inclusion criteria of C7-T12.

Table 2: Walking Performance Measures for ReWalk

<table>
<thead>
<tr>
<th>Study Author</th>
<th>Timed Up-and-Go (Mean sec ± SD; Range)</th>
<th>6-Minute Walk Distance (Mean m ± SD; Range)</th>
<th>6-Minute Walk Velocity (Mean m/sec ± SD; Range)</th>
<th>10-Metre Walk Time (Mean sec ± SD; Range)</th>
<th>10-Metre Walk Velocity (Mean m/sec ± SD; Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zeilig et al.(^15)</td>
<td>101 ± 27.3 sec.; 72 to 156</td>
<td>47 ± 20.8 m; 18 to 72</td>
<td>0.131 ± 0.063 m/sec.; 0.050 to 0.200 (^a)</td>
<td>66 ± 22.3 sec.; 42 to 103</td>
<td>0.168 ± 0.058 m/sec.; 0.097 to 0.238 (^b)</td>
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<tr>
<td>(n = 6)</td>
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<td>Esquenazi et al.(^12)</td>
<td>N/A</td>
<td>77.5 ± 44.9 m; 10.8 to 150.4</td>
<td>0.216 ± 0.126 m/sec.; 0.03 to 0.42</td>
<td>88.7 ± 114.0 sec.; 22.0 to 325.0</td>
<td>0.251 ± 0.145 m/sec.; 0.03 to 0.45</td>
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<td>(n = 11)</td>
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<tr>
<td>Benson et al.(^18)</td>
<td>48.8 ± 8.7 sec.; 39 to 59</td>
<td>140.8 ± 41.1 m; 91 to 174</td>
<td>0.391 ± 0.114 m/sec.; 0.253 ± 0.483 b</td>
<td>24.4 ± 3.4 sec.; 22 to 30</td>
<td>0.415 ± 0.051 m/sec.; 0.333 to 0.455 b</td>
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<td>(n = 5)</td>
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<tr>
<td>Yang et al.(^19)</td>
<td>N/A</td>
<td>129.0 ± 70.9 m; 46.3 to 255.9</td>
<td>0.359 ± 0.197 m/sec.; 0.13 to 0.71</td>
<td>36.5 ± 21.9 sec.; 14.0 to 78.0</td>
<td>0.379 ± 0.196 m/sec.; 0.13 to 0.71</td>
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<tr>
<td>(n = 12)</td>
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</table>

m = metres; N/A = not available; SD = standard deviation; sec = seconds.

\(^a\)Walking velocity and/or mean and SD were calculated using published individual participant outcome data.

\(^b\)All numbers are presented to one decimal place, unless the authors did not report to the decimal place.
devices are often challenging to put on and take off, and they are widely recognized as requiring high energy expenditure on the part of users. Upper-limb overuse is also a risk with these devices. Published reports show that users abandon the use of these orthoses at high rates.\textsuperscript{12,13} Functional electrical stimulation has also been used successfully but is known to quickly induce muscle fatigue.\textsuperscript{12}

Additional gait-training options exist within rehabilitation facilities, such as treadmill systems, some of which incorporate powered exoskeletons. However, the inability to receive or continue the therapy at home may limit the frequency and intensity of walking.\textsuperscript{14}

The Evidence

Six small observational studies published as medical journal reports\textsuperscript{12,15-19} and a conference presentation/research report\textsuperscript{14} make up the available evidence base on the ReWalk technology. Two reports\textsuperscript{16,17} focus primarily on the mechanics of walking (e.g., body motion, weight distribution) with the ReWalk device, while six address, directly or incidentally, safety and/or walking performance.\textsuperscript{12,14-16,18,19} Among the reports, three\textsuperscript{14,17,19} include overlapping study populations (i.e., reporting on the same patients), thus leaving four studies of primary relevance to this report.\textsuperscript{12,15,18,19}

All of the relevant studies received financial or in-kind support from the device manufacturer. The study size at enrolment ranged from eight to 14 participants (n = 44) and none included a comparator therapy or device.

Inclusion and exclusion criteria were similar across the studies. Men and women with SCI and weighing less than 100 kilograms were eligible for enrolment. Females were required to not be pregnant and not be lactating. Individuals with a history of neurological disorders other than SCI, as well as those with concurrent medical conditions (e.g., infections, circulatory or respiratory disease), unhealed or recent (within the past two years) lower extremity fractures, psychopathology, or other cognitive issues were excluded. All but one study\textsuperscript{15} also had similar exclusion criteria related to osteoporosis, severe spasticity, range of motion, and contractures.

Participants who completed the studies (n = 35) were predominately male (83%) and ranged in age from 18 to 64 years. The time since injury ranged between one and 24 years. Regarding impairment, most participants had complete SCIs (91%), with the majority (57%) of the injuries located between the T7 and L1 vertebrae. Table 1 summarizes the injury level and degree of impairment in the study participants. The choice of walking performance measures was similar across the four studies, and those results are summarized in Table 2.

The training programs varied across the studies — in particular, by the number of training sessions and their intensity. Participants in the study by Zeilig et al. trained on a level surface, with the goal of walking 100 metres unassisted before walking performance was measured. Training sessions averaged 50 minutes, and an average of 13.7 sessions (range 7 to 24) were required to meet the 100-metre goal.\textsuperscript{19} Esquenazi et al. did not define a required performance threshold, but they also deferred performance measurement until the conclusion of the program. Participants trained for 60 to 90 minutes for an average of 24 sessions (range 13 to 26).\textsuperscript{12}

Benson et al. measured performance at multiple points during the training period. Training sessions lasted 120 minutes and were intended to occur twice per week over a 10-week period. The mean number of weeks to achieve 20 sessions was 19 (range 10 to 31).\textsuperscript{18} Participants in the study by Yang et al. initially trained for 60 minutes, but this time increased to 120 minutes as participant tolerance permitted. The average number of training sessions was 55 (range 12 to 120).\textsuperscript{19}

Although all study participants were able to walk using the ReWalk device, the ability to perform the different tests varied. Two studies reported that participants did not achieve a level of proficiency to support functional daily use or fell just short of the proficiency required to be mobile in the community setting.\textsuperscript{12,15} The basis for these conclusions is not clear, but one study noted that the number of training sessions was not sufficient to support the skill development necessary to achieve more rapid walking.\textsuperscript{15} The other study noted that it was difficult for participants to manage changes in walking surfaces and deal with heavy foot traffic.\textsuperscript{12} Benson et al. described the ambulatory improvements in participants with complete SCIs as profound, but they also reported that no participants achieved walking velocities close to those necessary to safely cross a road.\textsuperscript{18}

In contrast, Yang et al. noted that seven of 12 participants in their study were able to walk at a velocity of greater than or equal to
0.40 m/sec., a speed they characterized as sufficient for limited community ambulation. Velocity may ultimately be correlated to the SCI level. Zeilig et al. found that performance was influenced by the location of the SCI. Participants with lower-level injuries (to thoracic vertebrae T9 to T12) walked longer distances than those with higher-level injuries (to thoracic vertebrae T5 to T7).

In the 10-metre walk test, participants with lower-level injuries walked significantly faster than those with higher injuries. Similar but less specific observations were made in two additional studies, but others caution that variation in walking speed is not entirely explained by injury level.

Overall, the studies offer limited insight into the use of the ReWalk device in situations other than walking on even surfaces. The training program offered by Benson et al. incorporated navigating obstacles and stairs, as well as other activities of daily living performed in an upright position. The published study offers no details regarding participant performance in these sub-categories of activity other than noting that four of the five participants who completed the training program were able to navigate stairs and an obstacle course. Some additional insight may be gleaned from Spungen et al., whose study population is a subset of the population in the study by Yang et al.

Spungen et al. examined participants’ ability to perform an extensive list of primary and secondary standing or walking skills. In addition to basic skills such as standing, sitting, use of the remote wristband, and walking, the authors also assessed the ability to stop walking on command, manoeuvre to a wall to rest, walk on carpet, and other irregular surfaces, as well as to navigate electric doors, elevators, revolving doors, and stairs. All seven participants in the study were able to transfer into and out of the device, but six individuals required assistance to put on shoes. Five participants were able to independently use the wrist-mounted control device and four were able to independently retrieve an object from overhead while standing in the device.

All participants achieved standing and walking skills within 15 training sessions, although three participants still required minimal assistance (with the trainer placing one hand on the user) to moderate assistance (with the trainer having both hands on the user). The skills needed to use stairs were acquired by all four participants who attempted this task within 25 training sessions, but all required moderate assistance. The ability to arrest one’s gait, manoeuvre to a wall to rest, and navigate a push-button door either independently or with assistance was achieved by all participants. Independent or assisted walking on carpet was accomplished by four of the six participants who attempted this task; and on outdoor surfaces, four out of the five who attempted this task were successful. Navigating elevators and revolving doors was attempted by four and three participants respectively, and all were successful without assistance.

In terms of tolerance and satisfaction, participants in two studies were generally positive about the training. Some studies reported positive impacts on pain and spasticity, but not all studies reported positive impacts on bowel or bladder function. In one study, the authors noted that positive findings cannot be unequivocally attributed to the device. Another study indicated that most participants reported a slight increase in pain after using the exoskeleton and that, overall,
the device did not meet participant expectations regarding perceived benefits and impact on quality of life.\textsuperscript{18} Two studies concluded that larger trials are needed to confirm the efficacy of the device or address other outstanding questions.\textsuperscript{15,16} As to the feasibility of larger trials, one study reported significant challenges in recruiting participants.\textsuperscript{18} Although the recruitment difficulties are not attributed to any single issue, the time commitment associated with training is mentioned. Pre- or post-enrolment withdrawal for logistical reasons (e.g., time availability, transportation, work relocation) were reported in three studies.\textsuperscript{15,18,19} Of 36 eligible participants in the study by Benson et al., 16 opted not to enrol because of limited interest in committing to a 10-week training program.\textsuperscript{18} This study also noted 19 interruptions in the training program stemming from participant logistical issues.

### Adverse Events

No serious adverse events, including death and hospitalization, were reported in the ReWalk studies. Esquenazi et al. reported skin abrasions in areas of contact with the device, light-headedness, or lower-limb swelling in five users.\textsuperscript{12} Yang et al. reported 13 episodes of mild skin abrasions, all of which were successfully resolved with padding and equipment adjustments.\textsuperscript{19} Benson et al. reported a high incidence of skin issues. Five grade 1 skin aberrations occurred in three participants, and 10 grade 2 aberrations occurred in five participants. All of the skin aberrations resulted in interruptions to the training program, and two participants were forced to withdraw because of recurring skin issues. An additional study participant was required to withdraw because of what the authors describe as a near-serious fracture of a bone in the ankle.\textsuperscript{18}

No falls were reported in any of the studies, but Esquenazi et al. mentioned instances where users lost their balance and either saved themselves from falling or were stabilized by staff.\textsuperscript{12} The same authors also reported instances where the device misfired and failed to step, a situation that might lead to an adverse event. This deficiency has reportedly been addressed by the manufacturer. Benson et al. cautioned that the continuous expert supervision characteristic of clinical environments may underestimate the real risk of falls and fractures in community settings.\textsuperscript{18}

### Administration and Cost

ReWalk is currently used primarily in rehabilitation centres. Published trials have targeted training frequency of two to three times per week, for periods of up to 120 minutes. Spungen et al. have shown that basic standing and walking skills can be acquired in 15 training sessions or less, but other skills may not be acquired by some users even after 25 sessions.\textsuperscript{14} Regarding the physiological benefits that might be associated with using ReWalk, no data on its effects on this type of outcome have been published.

The institutional version of ReWalk is priced at US$85,500. A 2.5 day training program for four clinicians and two technicians costs an additional US$4,000. The device comes with a two-year warranty, after which an annual service contract costs US$8,000 per year. The contract includes servicing three times per year. The personal-use system costs US$71,600 and the post-warranty service contract costs US$4,000 per year. The life expectancy of the device is five years (Loren Wass, ReWalk Robotics, Marlborough, MA: personal communication, 2015 Mar 12).

Anecdotal evidence suggests that powered exoskeletons may reduce staffing requirements in rehabilitation settings.\textsuperscript{20} Whether this observation extends to all powered exoskeletons and all rehabilitation settings, especially those already using treadmill systems incorporating a powered gait orthosis, is unknown.

### Concurrent Developments

In addition to ReWalk, three other robotic exoskeletons are commercially available in Australia, Europe, Japan, and/or North America. Although similar in purpose, the devices vary in appearance, size, and other factors, such as the presence or absence of functional electrical stimulation. Only one of the other devices is currently marketed for personal use. At least eight powered exoskeletons are reported to be under development, including one by Canadian company Bionik Laboratories.\textsuperscript{21}

Advances in power supplies, microprocessors, sensors, and other components are expected to result in changes to the appearance and capabilities of powered exoskeletons in the future. Further developments, such as direct brain interfaces, may lead to even more sophisticated devices. Despite these potential advances, wheelchairs are likely to remain the most important mobility technology for people with SCI for at least the next decade.\textsuperscript{1}
Rate of Technology Diffusion

Powered exoskeletons, including ReWalk, are in the early stages of diffusion. The three vendors whose public reporting includes sales figures have approximately 560 devices in use worldwide. A single vendor (Cyberdyne, Tsukuba, Ibaraki Prefecture, Japan) has reportedly sold 363 devices in Japan.

As of early 2015, ReWalk Robotics reported 99 devices in service worldwide, with sales increasing threefold in 2014 compared with 2013. There are currently two ReWalk devices in Canada: one at the University of Alberta and another at a private, not-for-profit rehabilitation centre in Nova Scotia (Loren Wass, ReWalk Robotics, Marlborough, MA: personal communication, 2015 Mar 12).

ReWalk may represent an important advance for some mobility-impaired individuals whose condition imposes substantial physiological and psychological burdens.

Ekso Bionics (Richmond, California) has 96 devices in use worldwide, including five in Canada. The devices at Canadian sites include two at public facilities in Vancouver, one in Edmonton, and one in London, as well as one at a private facility in London (Heidi Darling, Ekso Bionics, Richmond, CA; personal communication, 2015 Mar 10).

A Rex Bionics (Auckland, New Zealand) exoskeleton is in use at Able Bionics, in London, Ontario.

There are no significant barriers to the diffusion of powered exoskeletons in Canadian health care facilities other than awareness and cost. Diffusion of personal-use devices will be affected by cost and/or public reimbursement practices.

Expanded indications for use may also influence diffusion. Most vendors see the market for this type of technology expanding beyond SCI and rehabilitation (estimated to be the smallest markets in the US). Other conditions, such as stroke, may offer larger marketing opportunities. Industry reports estimate the powered exoskeleton market may grow to US$1.9 billion by 2020.

Implementation Issues

It is unlikely that the ReWalk device or similarly powered exoskeletons face any policy or reimbursement barriers to their diffusion into publicly funded rehabilitation centres in Canada. The ReWalk device and some competitor devices are already in place in a small number of facilities. Other related but stationary technologies — such as treadmill gait-training systems, some of which incorporate powered exoskeletons — are also becoming more common. The challenge facing public sector service providers is in determining the appropriate place for ReWalk within the rehabilitation technology continuum and its relative effectiveness. In the absence of comparative studies, these questions are difficult to answer.

The situation is more complex in relation to the placement of personal-use devices in the community. There are significant knowledge gaps regarding the role of powered exoskeletons in community settings: will they primarily extend rehabilitation capabilities to the home and will they fundamentally change the ability of persons with SCI to move around their communities? Clear evidence has yet to emerge regarding many questions, including who is most likely to benefit from the technology, how long it can be comfortably worn, and what is the rate at which users might abandon the technology? ReWalk and other exoskeletons are very costly relative to wheelchairs, but currently there is no indication they can replace wheelchairs or positively affect public funding arrangements for mobility devices that are already in place. In addition, the life expectancy of the ReWalk device is relatively short, virtually matching that of wheelchairs, thus eliminating the need for any major extension of the replacement cycle currently supported by payers.

Despite these barriers to implementation, payers need to be aware that robotic exoskeletons may be an important advance for a portion of a population whose condition imposes significant physiological and psychological burdens.
References


