

Ekso exoskeleton for rehabilitation in people with neurological weakness or paralysis

Medtech innovation briefing
Published: 18 January 2017

www.nice.org.uk/guidance/mib93

Summary

- The **technology** described in this briefing is the Ekso GT robotic exoskeleton. It is a motorised orthosis device for use in rehabilitation activities for people who have weak or paralysed legs and sufficient arm strength to use crutches. It is intended to help people to relearn to stand and walk.
- The **innovative aspect** is the SmartAssist software that is incorporated in the device. This allows physiotherapists to set the power for each leg independently to best suit the user. Multiple patients can use each Ekso GT robotic exoskeleton, with it being adapted to their specific needs.

- The intended **place in therapy** would be instead of, or in addition to, existing rehabilitation activities including physiotherapy, exercise, strength training, walking therapies with or without support, and functional electrical stimulation.
- The **key points from the evidence** summarised in this briefing are from 1 systematic review and 5 case series, involving a total of 41 patients in a rehabilitation setting. After using Ekso, these patients were able to walk without assistance from physiotherapists and their walking speed and distance increased. No serious adverse events were reported.
- **Key uncertainties** around the evidence are that the included studies were done outside the UK so the results may not be generalisable to the NHS. Also, the studies were small and non-comparative.
- The **cost** of the Ekso GT exoskeleton is £98,000 per unit (excluding VAT), which includes staff training, software and all supporting equipment but not ongoing maintenance and support costs. The **resource impact** is currently unclear because of a lack of evidence.

The technology

The Ekso GT robotic powered exoskeleton is for use in people with weak or paralysed legs caused by stroke, spinal cord injury or other neurological conditions. It is placed over the legs to help with standing and walking ([Miller 2016](#)), using battery-powered motors to drive the legs. As the user shifts their weight, sensors are activated that initiate steps ([Sale 2016](#)). Functional gait training using powered exoskeletons helps people to relearn step patterns and weight shifts, with the ultimate aim of helping them regain as much of their natural gait as possible.

Ekso is made up of an exoskeleton frame for the legs, passive ankle joints, a foot plate and an electric motor. There is also a backpack that contains a computer, battery and a wired controller ([Kozlowski 2015](#)). The exoskeleton is attached to the body by a series of straps set at a specific distance to ensure stability according to the patient's weight (Nitschke 2013). Ekso incorporates proprietary SmartAssist software, which allows the physiotherapist to set the power for each leg independently to best suit the user. Ekso can be used for more than 1 user and can be adapted to individual patients' specific needs. Settings for each user can be saved for use at their next session.

A physiotherapist initially supports the user to help prevent falling ([Kozlowski 2015](#)). Ekso

is fully weight-bearing, which can reduce the physical load on the physiotherapist who is supporting the user. Physiotherapist support becomes less necessary over time with use of Ekso, but one should always be present when the device is used. Ekso should be used with assistive devices, such as a walker or crutches, to ensure balance ([Kressler 2014](#)).

During a treatment session, patients walk for increasingly longer periods and progress from using a front-wheeled walker to crutches for stability ([Kozlowski 2015](#)). The parameters of gait, such as stride length and height, can be changed as the patient progresses within training sessions. However, when walking with Ekso it is difficult to overcome obstacles or compensate for uneven ground. Because of this, Ekso is specifically a therapy device for gait training and not a device for independent walking ([Nitschke 2013](#)).

Regaining a natural gait helps people to overcome the practical and social issues related to not being able to stand or walk. Moreover, regular walking may also lead to an improvement in secondary medical problems associated with a lack of weight-bearing activity, such as osteoporosis, cardiovascular disease, respiratory problems and pressure ulcers ([Miller 2016](#)).

The innovation

Several wearable exoskeletons are available ([Kolakowsky-Hayner 2013](#)). However, the SmartAssist software incorporated in Ekso is potentially novel in allowing physiotherapists to strategically target aspects of a patient's gait by providing different amounts of support to each leg.

Current NHS pathway

The NICE guideline on [stroke rehabilitation in adults](#) recommends a number of treatment options for people with muscle weakness following a stroke. This includes strength training and walking therapies with or without support. Strength training focuses on progressive strength building through a combination of body weight activity repetitions, weights and resistance exercises. Walking therapies, such as using treadmills, aim to increase mobility and walking endurance. Ankle-foot orthosis devices and functional electrical stimulation are options for people who have difficulty walking following a stroke because of poor swing phase foot clearance. These interventions are also used for people with muscle weakness because of other neurological conditions.

Wheelchairs, hip-knee-ankle-foot orthosis devices, reciprocating gait orthosis devices and powered exoskeletons are also options for people with muscle weakness or paralysis. Using hip-knee-ankle-foot orthosis and reciprocating gait orthosis devices is tiring and many patients stop using them over time (Miller 2016). Powered exoskeletons may allow safe walking at a sustainable intensity of physical activity, although it is still labour-intensive for the physiotherapist administering the device (Miller 2016, Nitschke 2013).

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to Ekso:

- HAL (Hybrid Assistive Limb robot; Cyberdyne)
- ReWalk (ReWalk Robotics)
- Rex (Rex Bionics)

Population, setting and intended user

Ekso should be used in a rehabilitation setting for adults with weakness or paralysis in their legs because of stroke, spinal cord injury or other neurological condition, but who still have strength in their arms and can use assistive walking devices. It is not expected that Ekso would be used in the home or long term.

Usually, physiotherapists will be responsible for therapy sessions using Ekso, once they have completed a training programme. Initial training on the device takes 1 week and allows physiotherapists to learn its basic features and use it under the supervision of a physiotherapist who is already familiar with Ekso. Training progresses to using Ekso's advanced features and eventually the second physiotherapist is not needed.

Use of the device is restricted to adults who are between 5 feet 2 inches and 6 feet 2 inches tall and who weigh less than 100 kg (220 pounds).

Costs

Device costs

The manufacturer provides Ekso to the NHS in a package costing £98,000 (excluding

VAT). This package includes the Ekso GT robotic exoskeleton with the SmartAssist software, training for up to 4 physiotherapists, a 2-year warranty and all supporting equipment (1 walker, 2 crutches, 1 control unit, 1 seat cushion, 1 kit bag, 2 battery sets and 1 charger). There is also a 'try before you buy' option (including the Ekso GT robotic exoskeleton with SmartAssist software and training but not the supporting equipment) for £1,650 per month. This option can be used for 3 to 5 months. Use of the device during this period counts towards the full purchase of the device within 12 months of the first training session.

Ekso CARE is a technical support and maintenance package, which can also be purchased from the manufacturer for £19,000 (excluding VAT). This includes coverage for 4 years for service and repair costs, access to software and limited hardware updates, technical support by phone and access to usage statistics through an online interface. Ekso CARE is provided at no additional cost when the 'try before you buy' option is chosen.

One Ekso exoskeleton device, including rechargeable batteries, is expected to have a 4-year lifespan if routine maintenance is done. This estimate is based on Ekso being used 6 to 8 times a day, with a mean use time of 1 hour. Routine maintenance can be done by physiotherapists who use the device and doesn't need any manufacturer input.

Ekso could be used an estimated 1,500 times each year, assuming that it is used 50 weeks per year, 5 times per week and 6 times per day. Assuming that users have 15 to 20 hourly sessions, the device cost per patient is between £245 and £327.

Each session using Ekso must be done under the supervision of a physiotherapist, and in many sessions 2 therapists will be needed particularly during the initial period of physiotherapist training. The average cost of a physiotherapy visit, as an outpatient appointment, is £46 ([Department of Health 2015](#)).

Costs of standard care

A number of options are available on the NHS for people for whom Ekso may be considered. These include wheelchairs, hip-knee-ankle-foot orthosis devices, reciprocating gait orthosis devices and other exoskeletons. The cost of a wheelchair is based on patient need (low, medium or high) with the average cost of equipment ranging from £241 to £1,320 ([Department of Health 2015](#)). Relevant prices for all other options could not be identified. Patients would also need to visit a physiotherapist outpatient clinic when using Ekso, but the frequency and length of these visits is not known.

Resource consequences

The manufacturer states that Ekso is currently used in 1 NHS trust.

If adopted further, it is not expected that Ekso would lead to any significant changes in infrastructure but it may require extra outpatient clinics and physiotherapy services.

The use of Ekso may help patient mobility and reduce pain, so it could reduce subsequent resource use and costs in NHS and social care settings. However, there is currently no evidence for this so the resource and cost consequences are currently uncertain.

Regulatory information

The Ekso GT exoskeleton was CE marked as a class IIa device in 2012 and this certification was renewed in 2016. The current version of Ekso has been developed from older versions that did not have the SmartAssist software, and these are also CE marked under the same certification.

A search of the Medicines and Healthcare products Regulatory Agency (MHRA) website revealed that no manufacturer Field Safety Notices or Medical Device Alerts have been issued for this technology.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Ekso may be used in people who have had a stroke. The risk of stroke increases with age and is also higher in men and people of African and Caribbean family origin ([Wang 2013](#)). Ekso is also contraindicated for people less than 5 feet 2 inches or more than 6 feet 2 inches tall, people who weigh more than 100 kg (220 pounds) and pregnant women. Age,

disability, race, pregnancy and sex are also protected characteristics under the Equality Act 2010.

Ekso can only be used by people with enough strength in their arms to use crutches. Because of this, people with weak or paralysed arms will not be able to use the device.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the published process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises the results of 1 systematic review and 5 case series including a total of 41 patients. Three of these case series were included in the systematic review and have been summarised separately in this briefing to highlight relevant outcome measures that were not reported in the systematic review.

Results indicated that Ekso enabled patients to stand, walk and sit with minimal assistance and using light to moderate effort. The increased mobility may have contributed to reduced pain, less muscle tightness, fewer involuntary movements, and improved bowel function in some patients.

One meta-analysis of a range of exoskeleton devices was also identified ([Miller 2016](#)). This included 14 studies of various exoskeleton devices, 3 of which included Ekso. The meta-analysis reported that across all studies 76% of patients were able to walk with an exoskeleton without physical assistance, and that patients had decreased spasticity and improved bowel movements. These results were not specific to Ekso and so this study has not been summarised in the evidence table.

Strengths and limitations of the evidence

The evidence base is currently very limited with outcomes only reported for 41 patients across 5 clinical studies. However, there are a large number of ongoing trials that may help

to improve the evidence base.

The currently available evidence is from non-randomised, non-comparative observational studies, which limits any accurate assessment of Ekso's effectiveness. All 5 studies were single-centre trials done outside of the UK, which limits the generalisability of the results to NHS settings. Moreover, 2 were pilots for an earlier version of the device and a third was a pilot for a management protocol. The largest case series ([Stampacchia 2016](#)) only evaluated a single walking session, which lasted from 7 to 25 minutes.

The available studies report on short-term outcomes, and no longer-term outcomes have been reported. Study length ranged from 1 session per patient (approximately 40 minutes per session, including rest time) to up to 24 sessions at a rate of 1 or 2 sessions per week (up to 2 hours per session).

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Table 1 Summary of selected evidence

Study	Intervention and comparator(s)	Outcomes	Strengths and limitations
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<p><u>Louie 2015</u> Systematic review. 15 studies (ranged from single-subject case studies to prospective trials comparing orthoses); 102 patients in total. Number of centres not stated. Countries not stated.</p>	<p>Intervention: HAL (1 study) Custom-powered IRGO (1 study) ReWalk (5 studies) Ekso (3 studies; earlier versions of the device) Indego (3 studies) Mina (1 study) WPAL (1 study) Comparator: No studies had a control group; however in 2 studies the participants trialled both the device and a standard rigid orthoses.</p>	<p>Mean (SD) gait speed of non-ambulatory patients using Ekso at the end of training 0.14 (0.07) m/s.</p>	<p>The search included multiple databases and hand-searching, although it was limited to articles published in English. There was heterogeneity in the study characteristics (device, control of stepping, training duration, outcome measurement), which reduces generalisability. The outcome presented here (mean gait) was only reported in 1 (n=3) of the 3 included studies on Ekso.</p>
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<p><u>Kolakowsky-Hayner 2013</u> Case series. 8 patients with complete SCI within 2 years of injury (only 7 completed therapy). Single rehabilitation outpatients centre. USA</p>	<p>Intervention: Ekso: 6 weekly sessions with graduated time and less assistance in the Ekso device.</p>	<p>There were no major adverse events and minimal pain reports during and after use. Loss of balance and falls were infrequent. Over the training period, patients needed less help to transfer into and out of the device, and increased their time walking.</p>	<p>This was a small feasibility study using a prototype device and without a control. Clinicians did not have set algorithms for progression through training. Therefore, results are not generalisable. The pilot focused on evaluating safety, and did not use advanced methods to monitor distance and speed, which were only shown graphically.</p>
<p><u>Kozlowski 2015</u> Case series. 7 patients with neurological weakness due to SCI. Single rehabilitation outpatient centre. USA</p>	<p>Intervention: Ekso: up to 24 weekly sessions, each up to 2 hours long.</p>	<p>Heart rate changes and reported perceived exertion were consistent with light to moderate exercise. All but one patient was able to stand, walk and sit with minimal assistance when using Ekso at end of training. Secondary benefits were also reported for some patients with regard to sitting balance and bowel habit.</p>	<p>This was a small convenience sample of men only so results may not be generalisable to a wider population. There was no control group and the study had a high drop-out rate. The study used a first-generation device, before a software upgrade.</p>

<p><u>Kressler 2014</u> Case series. 3 patients with complete SCI between T1 and T10 for ≥ 1 year. Single academic research centre. USA</p>	<p>Intervention: Ekso: 3 days (1 hour per session) per week for 6 weeks.</p>	<p>Outcomes were measured in the first and last sessions when using Ekso and increases in steps taken, distance travelled and walking speed were recorded. The energy expenditure needed was similar to walking in people without disability but there were no changes in clinical measures of spasticity. All participants reported reduced pain severity.</p>	<p>Very small case series so extremely low patient numbers and no control. The study did not report which generation of the device was used, but the manufacturer has stated that this was the first-generation Ekso.</p>
<p><u>Sale 2016</u> Case series experimental A-B design study. 3 patients with spinal cord injury. Single rehabilitation outpatient centre. Italy</p>	<p>Intervention: Ekso: robot walking sessions for 45 minutes daily over 20 sessions.</p>	<p>All 3 patients showed substantial improvements in functional outcomes, including walking speed and step length. Improvements in spatiotemporal measures were also reported. No adverse events, clinical instability or falls were reported.</p>	<p>Very small pilot study to evaluate a new rehabilitative protocol in patients who are not representative of the wider SCI population; no control group. The study did not report which generation of the device was used but the manufacturer has stated that this was the second-generation Ekso.</p>

<p><u>Stampacchia 2016</u> Case series. Single rehabilitation outpatient centre. Italy</p>	<p>Intervention: Ekso: a single exercise session of about 40 minutes; total time of walking ranged from 7 to 25 minutes.</p>	<p>After the walking session, a significant decrease in muscle spasticity and pain intensity were observed.</p>	<p>Small study evaluating only a single short session with Ekso; no comparator.</p>
<p>Abbreviations: HAL, Hybrid Assistive Limb; HKAFO, hip-knee-ankle-foot orthosis; IRGO, isocentric reciprocal gait orthosis; PCI, physiological cost index; RCT, randomised controlled trial; RGO, reciprocating gait orthosis; SCI, spinal cord injury; SD, standard deviation; WPAL, Wearable Power Assist Locomotor.</p>			

Recent and ongoing studies

- [EKSO Trial: Powered Exoskeleton for Ambulation in Subjects With Spinal Cord Injury \(EKSO\) NCT01701388](#). This study is ongoing but not recruiting patients. It is an observational study on the first-time use of a robotic exoskeleton; it aims to test the safety and efficacy of Ekso in people with spinal cord injuries and similar neurological weakness. Estimated study completion date: April 2017. Location: Illinois, USA.
- [Investigational Study of the Ekso Bionics Powered Exoskeleton for High-Dosage Use by Individuals With Spinal Cord Injury in a Non-Clinical Environment NCT02566850](#). This study is enrolling patients by invitation only and aims to measure the safety and health effects of using Ekso in a home setting over 12- to 36-month period. Estimated study completion date: January 2017. Location: California, USA.
- [Performance Attributes and User Progression While Using Ekso NCT02132702](#). This study is enrolling patients by invitation only and aims to evaluate the performance attributes and user progression of people with motor complete and incomplete spinal cord injuries while using Ekso in an 8-week training programme. Estimated study completion date: January 2017. Location: several countries in Europe.

- Locomotor Training With Exoskeleton Ekso GT in Patients With Incomplete Motor Spinal Cord Injury in a Hospital Setting NCT02600013. This study is currently recruiting patients. The aim of this observational, non-controlled study is to describe the safety, tolerability and responses to inpatient intensive rehabilitation with Ekso in patients with incomplete motor spinal cord injuries. Estimated study completion date: February 2017. Location: Italy.
- Mobility Training Using Exoskeletons for Functional Recovery After Stroke NCT02128152. This study is currently recruiting patients who have had a severe stroke. It aims to assess the safety and effectiveness of Ekso. Estimated study completion date: September 2017. Location: Illinois, USA.
- Safety Study of Outdoor and Indoor Mobility in People With Spinal Cord Injury (Robotics Spinal Cord Injury Ekso, ROBOSCIEKSO) NCT02065830. The recruitment status of this study is unknown because the information has not been verified recently. Its aim is to evaluate the safety and the efficacy of Ekso in patients with spinal cord injuries and with other neurological disease. Estimated study completion date: March 2016. Location: Italy.
- Exoskeletal-assisted Walking to Improve Mobility, Bowel Function and Cardio-Metabolic Profiles in Persons With Spinal Cord Injury (EAWSCI) NCT02314221. This study is currently recruiting patients. Its primary aim is to achieve successful walking skills using 2 exoskeletal walking devices (Ekso and ReWalk) in 36 sessions over 3 months in patients with chronic spinal cord injury who use wheelchairs. Secondary aims include determining if this amount of exoskeletal walking is effective in improving bowel function and body composition in this patient population. This is a crossover randomised controlled trial comparing supervised exoskeletal-assisted walking training with usual activities. Estimated study completion date: January 2019. Location: USA (Maryland, New Jersey, New York).
- Wearable Lower Extremity Exoskeleton to Promote Walking in Persons With Multiple Sclerosis NCT02519244. This study is currently recruiting patients. Its aim is to investigate whether Ekso can help people with multiple sclerosis to walk again. Estimated study completion date: March 2018. Location: Texas, USA.

- Non-Ambulatory Spinal Cord Injury Walk Using a Robotic Exoskeleton: Effect on Bone and Muscle NCT02324322. This study is currently recruiting patients. It aims to examine the effectiveness of Ekso to improve muscle volume and structure in the legs during walking (5 hours per week, 100 sessions, 20 weeks = 100 hours) in patients with spinal cord injuries. Estimated study completion date: December 2016. Location: New Jersey, USA.
- The WISE Trial – Walking Improvement for Spinal Cord Injury With Exoskeleton (WISE) NCT02943915. This study is currently recruiting patients. It aims to assess the effectiveness of Ekso compared with standard gait training or no gait training during 36 sessions over 12 weeks, in people living at home with spinal cord injuries. Secondary outcomes include economic factors and an analysis of the physical burden on therapists supervising training. Estimated study completion date: December 2019. Location: New York, USA.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

One of the 3 specialist commentators who provided comments has used this technology in their department for 2 years.

Level of innovation

One commentator stated that Ekso is a new innovation that incorporates existing technologies. Another commentator added that it is difficult to compare the different commercially available exoskeletons and stated that although Ekso is emerging as a useful rehabilitation tool, its use is limited to a rehabilitation setting. A third expert added that Ekso's main claim to innovation is the software that allows different power to be applied to each leg and that this might be useful for people with stroke and cerebral palsy. However, they also noted this is likely to be a relatively minor addition to current options.

Potential patient impact

Commentators noted that Ekso helps patients with incomplete spinal cord injuries improve

mobility more quickly by providing a means for repetitive controlled practice. For people with complete spinal cord injuries (where the whole width of the spinal cord is damaged causing a full loss of muscle control and sensation below the injury), it provides a tool for exercise and health benefits associated with ongoing upright exercise if regular access is available. One commentator also added that there is a clear training effect, with patients able to walk faster and for longer after a few sessions. Another commentator noted that the device has the potential to improve outcomes by allowing people to relearn how to walk but there are currently no controlled, longer-term trials to confirm this.

Two commentators agreed that there were psychological benefits associated with users being able to stand and walk, and that this could have a positive effect on their overall health. One of these stated that it was often difficult to separate the psychological benefits from physical benefits of rehabilitation and this made it difficult to assess the total patient benefit.

Two commentators advised that Ekso would be limited to a rehabilitation setting and to patients with enough arm strength to use the device, which may mean that some stroke patients may not be able to use Ekso if their arm function is not sufficient. They added that for patients with complete spinal cord injuries there is no clear point at which to stop using the device, but for patients with incomplete spinal cord injuries (where a portion of the spinal cord is still intact and so they have some function below the injury), Ekso may increase their recovery speed.

One commentator noted that the physical benefits are still unclear, and all commentators felt that further research and evidence is needed. The first commentator also advised that a study assessing the effect of Ekso on bone mineral loss in patients with spinal cord injuries has just been approved.

No commentators reported any safety concerns with Ekso.

Potential system impact

One commentator noted that sites adopting Ekso would need extra physiotherapy services, outpatient clinics and exercise space, so its adoption may mean changes to infrastructure. A second commentator suggested that no changes in infrastructure would be needed.

One commentator noted that it does not appear that cost savings to the NHS would be

generated immediately, but that they may be realised in future as the technology is refined and costs are lowered. Nevertheless, both noted that more research is needed to assess the resource and cost impact for the NHS.

A third commentator noted that the number of physiotherapy appointments could be reduced if Ekso allows people to walk sooner, but the evidence for this is not yet clear. Similarly, it is not clear how many people would be suitable for the device. They added that Ekso is expensive and the overall costs may be high.

General comments

Commentators remarked that Ekso can be used in both inpatient and outpatient settings, as part of initial rehabilitation, and as an ongoing exercise tool.

All 3 commentators agreed that further evidence is needed to show patient benefit from Ekso.

One commentator clarified that standard care for patients with complete spinal cord injuries consists of exercise and physical activity, with the ultimate aim of independent wheelchair use. Standing frames, assisted technologies and ongoing physiotherapy may all be used. For patients with incomplete spinal cord injuries, functional electrical stimulation, partial body support treadmill training and other interventions are used to speed recovery and encourage exercise in partially paralysed muscles.

Commentators agreed that although hip-knee-foot orthosis and rigid gait orthosis devices have been used in patients with spinal cord injuries, they are rarely used consistently and long-term use is not sustained.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr Kidangalil Mathew, Consultant in Spinal Injuries, Sheffield teaching hospitals
- Mrs Dot Tussler, Physiotherapist, National Spinal Cord Injury Centre, Stoke Mandeville
- Professor Jonathan Cole, Consultant in neurophysiology, Poole Hospital NHS Foundation Trust

Representatives from the following patient organisations were contacted in the production of this briefing:

- The Stroke Association
- Brain and Spinal Injury Charity
- Spinal Injuries Association
- Muscular Dystrophy UK

Development of this briefing

This briefing was developed for NICE by Newcastle and York assessment centre. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-2296-3