

# ReStore Soft Exo-Suit for gait rehabilitation

Medtech innovation briefing

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## Summary

- The **technology** described in this briefing is the ReStore Soft Exo-Suit. It is a powered exosuit worn by adults who are having gait rehabilitation to relearn to walk after a stroke or brain injury.
- The **innovative aspects** are that the real-time data from sensors in the shoes and on the affected leg are used to adjust the mechanical assistance to match the user's natural gait and to enhance propulsion symmetry.
- The intended **place in therapy** would be in rehabilitation clinics, in addition to standard care, for people who are having physiotherapy after a stroke or brain injury that has affected the movement in one of their legs.
- The **main points from the evidence** summarised in this briefing are from 3 non-comparative feasibility and safety studies, including a total of 53 adults recovering from stroke, in physiotherapy clinics in the US. They show that while wearing ReStore some gait metrics were improved.

- **Key uncertainties** around the evidence are that it is at an early stage in evidence generation and there is currently no comparative evidence or studies showing the long-term impact on gait rehabilitation outcomes. Two of the studies used early versions of ReStore, and so may not reflect outcomes from the current version.
- The **cost** of ReStore is £22,995 per unit (excluding VAT) with around £4,000 per year in consumables (when used by 10 patients per month and both cartridges are replaced yearly). As an add-on intervention, the **resource impact** would be greater than standard care.

## The technology

The ReStore Soft Exo-Suit (ReWalk Robotics) is a device designed to help people having walking gait training after a stroke or brain injury that has affected the movement in one of their legs. It is intended to be used during physiotherapy sessions to help the user relearn the movements needed for walking. The system comprises:

- a waistbelt that holds the powerpack and an actuator attached to a pulley cartridge
- a fabric-based calf-wrap to secure the device to the person
- a shoe insole for the foot needing assistance that attaches to the mechanical cables
- sensors that clip to the shoes of both feet to monitor gait
- mechanical cables connecting the different pieces of the system together to assist the person's ankle in motion (plantarflexion and dorsiflexion)
- a handheld controller with the integrated therapist interface app to enable therapists to control the mode and amount of assistance from ReStore.

The system weighs around 5 kg in total. The actuator in the waistbelt produces movement, which is conveyed through the pulley cartridge to mechanical cables attached to the calf-wrap and the insole. The system can move the foot in 2 ways. When the cable near the heel (the posterior cable) is shortened, the heel is pulled up to create plantarflexion which gives forward propulsion. When the cable on the top of the foot (the anterior cable) is shortened, the top of the foot is pulled up to create dorsiflexion which allows ground clearance of the foot as it moves forward.

Force sensors in the calf-wrap and motion sensors clipped onto the user's shoes record

movement of the feet and the forces delivered with each step. A proprietary algorithm is used to process the data in real time, to build a picture of the user's gait cycle. This information is used to match the timing and level of mechanical assistance to the affected foot, to synchronise movement to the user's natural gait. If the user's gait speed, step length or walking direction changes, the system detects this change and adjusts the level of mechanical assistance accordingly. Stance time ratio (the ratio of time spent in stance on each foot) and step count are also recorded.

The foot movement data can be viewed on the handheld controller, which is linked to the suit via Bluetooth. This information can be used by healthcare professionals to adjust the level of mechanical assistance applied, and to monitor each user's progress during therapy. The software on the controller includes pre-programmed walking tests such as 10-metre, 2-minute and 6-minute walking tests.

The handheld controller can also be used to quickly change ReStore's mode:

- In assist mode, data from the motion sensors calculates the level and timing of mechanical assistance to the affected foot.
- In slack mode, data from the motion sensors can be viewed on the handheld controller but the cables are released so that no mechanical assistance is applied. This allows the user to practice walking without assistance, without having to interrupt the training session to remove the device.
- In brace mode, the cables are locked into position to provide continuous ankle support. Data from the motion sensors can be viewed on the handheld controller.

The modes can be switched to help with gait training, and gait data can be collected in any mode, so that data from different sessions can be compared. ReStore can be used alongside aids such as hoists, walking sticks and frames, and can be used on a treadmill.

The company notes that ReStore should not be used with ankle foot orthosis because it would restrict ankle movement and prevent rehabilitation.

## Innovations

The company says that the ReStore Soft Exo-Suit is innovative for the following reasons:

- The system creates 2 directions of flex in the ankle, which helps to avoid compensatory issues such as hip hiking and circumduction.
- The technology can be used to train the plantarflexion movement, which is not well addressed by other treatment options.
- The real-time data analytics allow the foot movement to be adaptive to the user's natural gait and level of need.
- The mechanised foot movement reduces the need for physiotherapists to manually move the user's foot while they walk. The company says that up to 3 physiotherapists are needed per patient for gait training with manual foot movement but only 1 is needed with ReStore.

There are technologies that appear to fulfil a similar function to ReStore. [NICE has published a medtech innovation briefing on Ekso exoskeleton](#). Ekso exoskeleton uses battery-powered motors to drive the legs and help people to relearn step patterns and weight shifts, to try to regain their natural gait. ReStore provides plantarflexion and dorsiflexion assistance to the affected leg, taking feedback from a sensor on the unaffected leg to improve speed and symmetry in the walking gait.

## Current care pathway

Standard care for managing movement difficulties after stroke includes physiotherapy and fitness, strength and repetitive task training. Walking therapy is recommended for people who have had a stroke and who are able to walk, with or without assistance. Treadmill training, with or without body weight support, should be considered as one option for walking therapy. Electromechanical gait training should only be used as part of a research study, according to NICE's guideline on stroke rehabilitation in adults.

The medium- to longer-term care of people who have had a traumatic brain injury may include rehabilitation to improve mobility and independence. Rehabilitation plans should be goal-oriented and be tailored to each person's needs, taking account of their views, cultural background and lifestyle before the injury. When offering movement and motor control therapy to people with an acquired brain injury, partial bodyweight treadmill training, strength training, gait re-education to improve walking ability, and exercise to improve fitness should be considered (British Society of Rehabilitation Medicine, 2003).

The following publications have been identified as relevant to this care pathway:

- [NICE guideline on stroke rehabilitation in adults](#)
- [The British Society of Rehabilitation Medicine national clinical guideline on rehabilitation following acquired brain injury, 2003.](#)

## Population, setting and intended user

The ReStore Soft Exo-Suit is intended to be used in physiotherapy clinics, in a secondary care, outpatient or community care setting.

ReStore would be used by people who have hemiplegia or hemiparesis resulting from stroke, who are 142 cm to 192 cm tall and weigh less than 120 kg. It is contraindicated in pregnancy and in people who have serious comorbidities that may prevent ReStore from being used safely, including:

- severe peripheral artery disease
- unresolved deep vein thrombosis
- restricted range of ankle movements that may prevent safe walking
- cognitive disabilities or mental health conditions that may prevent the user following instructions
- open wounds or broken skin where the exosuit touches the body
- urethane allergy.

Additional monitoring and support may be needed for people who have:

- severe aphasia that limits their ability to express their needs or discomfort
- uncontrolled muscle spasticity
- mild to moderate peripheral artery disease
- a need for more than moderate assistance from a therapist to walk a short distance.

In clinics the use of ReStore would be supervised by physiotherapists or neurological physiotherapists. The company says that typically 1 to 3 physiotherapists are needed to supervise each patient at a gait training session. ReWalk Robotics trains physiotherapists

to use ReStore. Training usually takes about 4 hours and is in person. It includes a presentation, hands-on training with ReStore, and an exam. A physiotherapist can become a 'lead therapist' through another training session including an extra hour of training, clinical use of the ReStore with at least 5 patients, and an exam. The company says that all training is included in the device purchase cost.

## Costs

### Technology costs

The ReStore Soft Exo-Suit costs £22,995 per unit (excluding VAT). The company estimates that the annual cost of using ReStore Soft Exo-Suit would be around £4,000, assuming 10 new users each month and assuming that both cartridges are replaced every year. It is expected to last 2 to 3 years. The cost includes a 2-year warranty, servicing and maintenance.

Calf-wrap liners and cable cartridges are additional costs. A calf-wrap liner is similar to a prosthetics sleeve and is worn on the calf as a barrier to protect the user's skin. The liners come in 4 sizes and are not intended to be shared between users. Each user can wash and re-use their own liner multiple times. Each liner costs £24 and they are sold in packs of 10. Twenty calf-wrap liners (5 of each size) are included in the purchase price. Cable cartridges are the mechanical cables that provide the lifting forces to the user's foot. The cables can be re-used between users but need to be replaced every 600,000 total steps (300,000 paretic steps) in assist mode, which is approximately 1 year of moderate to heavy usage. The cable cartridge can be refurbished for £524 or replaced for £1,277. A starter kit of 2 cable cartridges (1 of each size) is included in the purchase price.

### Costs of standard care

Gait rehabilitation therapy is provided by physiotherapists in the NHS. The cost of outpatient physiotherapy is from £55 to £66 per session ([National Cost Collection data 2018/2019](#)).

## Resource consequences

The ReStore Soft Exo-Suit is currently being used by 2 private physiotherapy practices. The company is in discussions about trialling it at 1 NHS site.

If ReStore is adopted in the NHS it would be an additional cost to standard care. If it is shown to have long-term benefits such as improved gait retraining in people recovering from stroke, then costs could be saved from the reduced costs of treating falls. There is currently no evidence to support this, however. Savings could also be made if using ReStore reduces staffing costs by reducing the number of physiotherapists needed in gait rehabilitation sessions. There was no published evidence on how ReStore affects staffing but the experts suggested that it could reduce the number of staff needed in therapy sessions. ReStore can be used alongside other gait training aids and would not require any additional changes in facilities or infrastructure.

## Regulatory information

The ReStore Soft Exo-Suit and handheld controller system is a CE marked class IIa medical device.

## Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

The ReStore Soft Exo-Suit should not be used by some people who could be considered to be disabled, such as people with a restricted range of ankle movements that may prevent safe walking, or with cognitive disabilities or mental health conditions that may prevent the user following instructions. Disability is a protected characteristic under the 2010 Equalities Act.

## Clinical and technical evidence

A literature search was carried out for this briefing in accordance with [NICE's interim 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](mailto:mibs@nice.org.uk).

## Published evidence

Three studies are summarised in this briefing, including a total of 53 people who were having gait training during their recovery from stroke.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

## Overall assessment of the evidence

The ReStore Soft Exo-Suit is at an early stage of evidence generation and there is currently no evidence on its longer-term effects on gait training.

The current evidence suggests that ReStore is safe and that using it for gait training would be feasible.

There is limited reporting of the activities and staffing at the physiotherapy sessions in the studies so the relevance to standard NHS care is not clear. The 2 studies from 2017 by Awad et al. may include some overlap in the patient cohorts.

### Awad et al. (2020)

#### Study size, design and location

A multisite, non-comparative evaluation using the ReStore Soft Exo-Suit in post-stroke rehabilitation sessions for 44 people recovering from stroke. Thirty-six of the 44 people completed the evaluation and were included in the analysis. All of the study sites were in the US.

#### Intervention and comparator(s)

Over a maximum of 4 weeks, people had a walking evaluation then 5 physiotherapy sessions, at a rate of at least 2 per week, and then a second walking evaluation. Each physiotherapy session consisted of up to 20 minutes of walking on the ground and 20 minutes walking on a treadmill, both while using ReStore. There was no comparator.



## Key outcomes

The primary outcome of the study was the frequency of device-related adverse events and falls. Device-related adverse events occurred in less than 10% of study visits and were mostly mild in severity, such as pain in the lower extremity and skin abrasions. Part way through the study the manufacturer implemented mandatory training on fitting ReStore and the rate of adverse events then fell. No device-related falls or serious adverse events were reported.

Secondary outcomes were clinician safety (device-related injuries to the physiotherapists) and device reliability. No clinician injuries were reported. Device malfunctions were reported in 11.6% of physiotherapy sessions in the study.

An exploratory assessment of changes in maximum walking speed was included in the study. Overall, there was an average increase in ReStore-assisted walking speed of 0.1 m/s. Approximately 61% of 36 people had a 'small meaningful change' in their ReStore-assisted walking speed (0.05 m/s or more faster than baseline) and 44% had a 'large meaningful change' (0.1 m/s or more faster than baseline). The average increase in non-assisted walking speed was 0.07 m/s.

## Strengths and limitations

This study was designed to show the ReStore's safety. The reported patient outcomes were described as a secondary, exploratory assessment only. The study is non-comparative. Long-term outcomes were not investigated.

## Awad et al. (2017a)

### Study size, design and location

An evaluation of the feasibility of using ReStore Soft Exo-Suit to restore normal gait mechanics and energetics after stroke. The study included 9 adults in the chronic stage of stroke recovery and was in the US.

### Intervention and comparator(s)

Two versions of ReStore were used in this study: one used an 'off-board' actuation unit, meaning that it was on a trolley and connected by cables rather than being built into the

suit; the other was the commercial version with the actuator worn on the waistbelt. People in the trial completed 2 treadmill walking trials using ReStore. There was no comparator.

## Key outcomes

The study aimed to demonstrate the feasibility of using the ReStore in gait training, and to evaluate immediate outcomes in terms of gait symmetry and metabolic burden, which can contribute to inactivity in older adults.

Interlimb peak propulsion asymmetry during treadmill walking using the off-board actuator suit with mechanical assistance was 20% lower (range 4%) than using the suit without mechanical assistance. The energy cost of walking was 10% lower (range 3%) than with no mechanical assistance.

Propulsion asymmetry in overground walking using the commercial version of ReStore with mechanical assistance was 16.3% lower (range 6.8%) than wearing the suit without mechanical assistance. The energy cost of walking was not reported.

## Strengths and limitations

Long-term outcomes for gait or mobility were not reported. It was a small, non-comparative study. Results from trials using the off-board actuator exosuit (weighing around 1 kg) may not reflect the commercial, actuator-bearing version of ReStore (weighing around 5 kg).

## Awad et al. (2017b)

### Study size, design and location

A single session study comparing walking with and without the ReStore Soft Exo-Suit. It included 8 adults in the chronic phase of stroke recovery and was in the US.

### Intervention and comparator(s)

Eight adults who were recovering from a stroke (which had happened at least 6 months before the study) completed 2 treadmill walking trials lasting 8 minutes each. In 1 trial the suit was worn unpowered, with no mechanical assistance. In the other trial the suit was powered with mechanical assistance to support walking. In both trials the off-board

actuator version of ReStore was worn rather than the commercial version with the actuator on the waist. There was no comparator.

## Key outcomes

Post-stroke gait-compensation was assessed by measuring circumduction (a walking style in which the leg is unbent as it swings forward so it rotates forward in a circular movement) and hip hiking (the angle of the pelvis when the affected leg is in mid-swing).

Hip hiking with mechanical assistance was lower by an average of 27% (standard error 6%) on the affected leg than without mechanical assistance. Circumduction was lower by an average of 20% (standard error 5%) on the affected leg. No change in either measure was recorded in the unaffected leg.

## Strengths and limitations

Long-term outcomes for gait or mobility were not reported. It was unclear whether there is overlap in the patient cohorts between the 2 studies by Awad et al. in 2017. Results from trials using the off-board actuator exosuit (weighing around 1 kg) may not reflect the commercial, actuator-bearing version of ReStore (weighing around 5 kg).

## Sustainability benefits

The company notes that all components of the system except the calf-wrap liner are reusable and designed to be used on multiple individuals.

## Recent and ongoing studies

Ankle exosuit training in the clinic to community. ClinicalTrials.gov identifier: NCT04251091. Status: recruiting. No interim results published. Indication: Observable gait deficits following stroke event occurred at least 6 months ago. Devices: ankle exosuit training. Country: US. Last update on 17 September 2020.

## Expert 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.

Three experts provided their comments, including 2 who were familiar with or had used this technology before.

## Level of innovation

All experts thought that the ReStore Soft Exo-Suit was a novel concept compared with current standard care. One expert noted that most exoskeletons designed to improve walking completely cover both legs and usually have a 'cage' around the pelvis. But ReStore is designed to improve movement of the paretic ankle joint (dorsiflexion and plantarflexion). One expert suggested that some robotic devices are available in the private clinics that are similar to ReStore with minor variations.

## Potential patient impact

The ability to help restore a pre-stroke gait pattern was identified as an important benefit for people with gait deficits after stroke. ReStore helps people who lack correct movement in the affected ankle have a more normal walking pattern. It can feed back to people about their gait pattern and this could help their rehabilitation. One expert suggested that ReStore helped people walk more efficiently and improved their confidence in their abilities because they were able to walk a longer distance and practice more steps. The expert added that ReStore could be used in the community, depending on the availability of the service. Two experts considered that people who would benefit most from using the technology are those:

- with paralysis on one side of their body (hemiplegia)
- who have had a stroke
- with a multilevel deficit who would need several therapists to help rehabilitate their standing and gait.

## Potential system impact

All experts agreed that ReStore is likely to cost more than current standard care, but also that it could improve outcomes by, for example, reducing falls and improving balance and confidence. Two experts also suggested that ReStore could reduce the number of staff

needed in therapy sessions because fewer would be needed to assist people. One expert thought that if there was evidence that ReStore improved neuromuscular recovery more than standard care, the resource impact of using the device would be lower, and the technology could be cost effective compared with standard care.

## General comments

All experts considered that ReStore could be used as an addition to standard care. They thought skin and joint irritation were likely side effects. One expert reported 2 anecdotal adverse events: 1 person with pre-existing biomechanical issues who had pain from the footplate and another who had exacerbating hyperextension of the knee. Both stopped the ReStore session. Two experts noted the set-up time of ReStore was expected to be more than that of standard care; for instance, the initial assessments could take around 1.5 to 2 hours, and subsequent sessions could last about 1 hour.

## Expert commentators

The following clinicians contributed to this briefing:

- Mr James Benson, neurological physiotherapist, James Benson Physiotherapy. Used the device in the private clinic. Had occasional paid work to assist the ReWalk team as a clinician on assessments for the ReWalk device.
- Mr Thomas McGregor, clinical lead and neurological physiotherapist, Hull and East Yorkshire NHS Trust and MOTIONrehab. Did not declare any interests.
- Professor Valerie Pomeroy, professor of neurorehabilitation, University of East Anglia. Did not declare any interests.

## Development of this briefing

This briefing was developed by NICE. [NICE's 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.

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