NICE advice

RT300 for spinal cord injury rehabilitation

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is RT300, a functional electrical stimulation (FES) integrated cycling system. It is used to start muscle contraction to stimulate trunk and limb muscles in people with spinal cord injury.
- The **innovative aspect** is that the RT300 combines FES with a cycle ergometer, allowing stimulation of muscles in the trunk and arms or legs during a cycling motion as part of rehabilitation or physical activity for people with spinal cord injury. The combined motor and electrical stimulation system adjusts resistance and speed to make sure stimulation is safe for optimal treatment. The system links to a database to store and monitor performance data.
- The intended **place in therapy** would be as well as standard rehabilitation care for people with spinal cord injuries. This would start in specialist spinal injuries units but can be given in any setting.

- The **main points from the evidence** summarised in this briefing are from 6 studies (3 randomised trials and 3 observational studies), including a total of 103 patients (43 adults and 60 children) in the US and Canada. Limited evidence shows that using RT300 may be associated with an improvement in quality of life and an increase in muscle volume compared with passive cycling systems or pre-treatment baseline.
- **Key uncertainties** around the evidence or technology are that the study results may not be generalisable to the NHS. The studies were small and the comparative studies used a passive cycling system from the same manufacturer.
- The **cost** of RT300 ranges from £14,995 to £21,995 per unit with 6-channel stimulations (exclusive of VAT) plus an annual service charge of £495. An extra 6-channel stimulation unit costs £6,995. The **resource impact** is unclear because of a lack of evidence and uncertainty in the standard care pathway and which people may benefit.

The technology

The RT300 combines functional electrical stimulation (FES) with a motorised ergometer that allows repetitive cycling activity as part of a rehabilitation programme for people with a spinal cord injury.

It stimulates muscles with electrodes attached to the skin, producing muscle contractions and patterned activity. It can stimulate muscle groups in 1 or both arms or legs and trunk in a coordinated cycling motion. The standard configuration stimulates 6 muscle groups with 1 stimulator. Another 6 muscle groups can be stimulated by an extra stimulator and 4 more can be stimulated by individual Bluetooth stimulators. Training plans vary in clinical practice. The typical training session can range from 15 to 60 minutes per session, 3 to 4 times per week. The training can last from 6 weeks up to lifetime use depending on the severity of spinal injuries.

RT300 has systems configurable for different muscle groups (arms, legs) and can be used while in a wheelchair, chair or bed. It can be used by children.

During a therapy session, the technology starts by passively cycling muscles and prepares them for exercise. Electrical stimulation then gradually activates the muscles to work up to a target speed or until muscle fatigue is detected. Different parameters can be changed depending on the person's progress, such as current amplitude and frequency, pulse

width and resistance. The RT300 has an automatic setting which adjusts the ergometer resistance or the stimulation to safely get to the target speed and avoid excessive muscle movement. RT300 will stop if it detects too much muscle spasm to avoid injury. All functions of the RT300 are controlled by a tablet computer.

Innovations

The RT300 system has a motor built into the stimulation system to automatically adjust the stimulation and the ergometer resistance. This is not available in other FES systems. The company claims this allows therapy to respond to individual patient performance, to maximise muscle contractions and to give consistent and reliable outcomes.

RT300 systems use software that sends data through a secure Wi-Fi connection from the tablet computer to a cloud-based database. This means data can be monitored by therapists and therapy can be customised. Data collected in treatment sessions can be exported as documents in formats such as Excel and PDF, which can be included in individuals' NHS electronic records.

Current NHS pathway

NICE's guideline on spinal injury covers early management in pre-hospital settings (including ambulance services), emergency departments and major trauma centres but does not cover rehabilitation. The British Society of Rehabilitation Medicine guideline on chronic spinal cord injury also does not include rehabilitation.

NICE's interventional procedures guidance on functional electrical stimulation for drop foot of central neurological origin supports the use of FES for drop foots from conditions such as stroke, cerebral palsy, multiple sclerosis or spinal cord injury provided that normal arrangements are in place for clinical governance, consent and audit.

The current standard care after a spinal cord injury involves acute care after the injury, rehabilitation and reintegration into the community, lifelong follow-up of people living with spinal cord injury, and further admission if necessary for medical or surgical management (NHS England 2013). Rehabilitation following spinal cord injury starts as soon as the patient is medically stable after injury, and focuses on increasing functional independence (Harvey 2016). A range of rehabilitation measures can be used to improve function or compensate for loss of function, such as exercise (WHO 2013).

NICE is aware of the following CE-marked FES-assisted cycling systems that appear to fulfil a similar function to RT300:

- Rehamove: FES cycling system for weakened or paralysed arms or legs
- BerkelBike: FES-assisted outdoor leg cycling.

Population, setting and intended user

RT300 would be used in a rehabilitation setting with standard rehabilitation care for adults or children with weakened or paralysed muscles in their arms or legs because of spinal cord injury. The technology can also be used in the home.

A trained therapist would set up the RT300 system after a complete assessment of the patient. The therapy could then be given by a therapy assistant or carer at home. Physiotherapists would need training to use RT300.

Costs

Technology costs

Table 1 Cost of RT300

Description	Cost[1]
RT300 leg cycle (6 channels)	£14,995 (ex VAT)
RT300 leg and arm cycle (6 channels)	£21,995 (ex VAT)
Additional 6 channels	£6,995 (ex VAT)
Delivery, installation and clinical follow-up	£495 (ex VAT)
RT300 service charge	£495 annually
Electrodes[2]	£528 annually
[1]The technology has an 8 year lifespan. The cost may vary depending on the number of channels available. [2]The cost is based on a single patient using the RT300 3 times per week for 1 year.	

Costs of standard care

No estimate for the complete cost of rehabilitation care for people with spinal cord injuries could be identified. One expert noted the cost of other passive FES equipment varied from £50 to £3,500. The number of rehabilitation (physiotherapy) sessions during which treatment with RT300 would be used varies between patients. The estimated cost of a hospital physiotherapist is £32 per hour.

Resource consequences

The company states that 7 of the 12 UK specialist spinal cord injury units offer RT300 as part of standard care, particularly for people with incomplete spinal cord injuries.

If used more widely, it is not expected that RT300 would lead to any major changes in infrastructure, but extra physiotherapy services (such as staff) may be needed.

Using RT300 may help strengthen muscles and improve patient mobility, so it could reduce subsequent resource use and costs in NHS and social care settings. However, there is no evidence to support this, and variability in the standard care pathway and uncertainty in the population who may benefit mean the resource impact is uncertain.

Regulatory information

The RT300 functional electrical stimulation integrated cycling system was CE-marked as a class IIa device in 2005.

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).

RT300 can be used in people with spinal cord injuries whose muscles are weakened or paralysed, and they are likely to be described as disabled. The technology should not be used for people with a cardiac pacemaker, unhealed fracture in lower extremities or pregnant women. It is also contraindicated for people with a grade 3 tear in upper extremities, shoulder subluxation that cannot be corrected, or unhealed fractures in upper extremities, shoulder girdle or upper ribs.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the 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.

Published evidence

The evidence for RT300 includes 17 studies, of which 6 relevant studies (3 randomised trials and 3 before–after cohort studies) that reported key outcomes (such as secondary complications and quality of life) are summarised in this briefing. Table 2 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence for the effectiveness of the RT300 functional electrical stimulation (FES) cycling in people with spinal cord injuries is limited, with outcomes only reported for a total of 43 adults and 60 children.

The available evidence is from 2 randomised studies in children, 1 randomised trial and 3 before–after observational studies in adults. All 6 studies were done in the US and Canada, which may limit the generalisability of the results to NHS settings.

Two randomised controlled trials were based on the same cohort of children with spinal cord injury. They showed that there was a statistically significant increase in lower limb muscle volume and muscle strength but no change in bone mineral density after the 6-month FES cycling (Johnston et al. 2011, Lauer et al. 2011). One randomised trial involved adults with spinal cord injury and also showed a statistically significant increase in

lower limb muscle volume (Johnston et al. 2016).

Three observational studies of adults with spinal cord injury showed a statistically significant improvement in lower limb exercise performance compared with baseline (Allison et al. 2016) but a non-significant change in upper limb exercise performance (Ptasinski et al. 2013) after the 12-weeks FES cycling. The studies also suggest that RT300 FES cycling is associated with a statistically significant improvement in quality of life (Dolbow et al. 2013) and cardiovascular function (Ptasinski et al. 2013; Allison et al. 2016) compared with pre-treatment baseline.

Table 2 Summary of selected studies

Allison et al. 2016	
Study size, design and location	A before–after cohort study of 10 adults with SCI for more than 6 months. Canada.
Intervention and comparator(s)	Intervention: RT300 FES-LE cycle (FES system for legs and core muscles) 3 times per week. No comparator.
Key outcomes	All patients experienced improvement in exercise performance because they were able to exercise for a longer distance before experiencing fatigue and needing fewer breaks after the 12-week FES cycling ($p<0.01$). There was a statistically significant increase in peripheral cardiovascular function, with a 34% increase in pulse volume within the femoral artery from an average of pre-intervention 4.25 ml to 5.69 ml ($p=0.04$). No changes in any molecular indices of cardiovascular risk such as cholesterol measures were seen.
Strengths and limitations	The study included adults (age ranged 26 to 55 years) with chronic SCI but this was a very small sample size (n=10). All patients had SCI with levels ranging from C5 to T11, and time since injury ranged from 6 months to 20 years.
Johnston et al. 2016	

Study size, design and location	A randomised pilot study of 17 adults with SCI for more than 6 months. USA.
Intervention and comparator(s)	Intervention: RT300 FES cycle (FES system for legs and core muscles), low cadence cycling at 20 RPM (n=9). Comparator: RT300 FES cycle (FES system for legs and core muscles), high cadence cycling at 50 RPM (n=8).
Key outcomes	After the 6-month programme, both low and high cadence groups increased muscle volume compared with the baseline (low cadence cycling by 19%, p<0.01; high cadence cycling by 10%, p=0.56). Low cadence cycling showed a statistically significant decrease in bone-specific alkaline phosphatase, suggesting less bone formation after 6 months (15.5% decrease for low cadence cycling, p=0.04; 10.7% increase for high cadence cycling, p=0.74). Low cadence cycling group also had statistically significantly less bone resorption compared with the baseline (34.5% decrease for low cadence cycling, p=0.04; 16.7% decrease for high cadence cycling, p=0.34).
Strengths and limitations	The study recruited a total of 17 people with SCI, and 15 people completed the study. All patients had the intervention. There was no non-intervention control in the study.
Dolbow et al. 2013	
Study size, design and location	A before–after cohort study of 11 male adults with SCI for more than 6 months. USA.
Intervention and comparator(s)	Intervention: RT300 FES-LE cycle (FES system for legs and core muscles). No comparator.
Key outcomes	There was an increase in all World Health Organisation QOL scores including physical, psychological, social, and environmental domains, with the physical and environmental domains sustaining a statistically significant increase. Physical QOL scores increased by 2.3 units (p=0.01) and the environmental QOL scores increased by 1.9 units (p=0.03) from before to after the programme.

Strengths and limitations	Only a small number of people were recruited to take part in the study, and there were no female patients.
Ptasinski et al. 2013	
Study size, design and location	A before–after pilot study of 5 adults with SCI for more than 1 year. Canada.
Intervention and comparator(s)	Intervention: RT300 FES-arm ergometry (FES system for arms and core muscles). No comparator.
Key outcomes	There was a statistically significant decrease in resting MAP from 91.1 mmHg at the baseline to 87.7 mmHg following the 12-week FES cycling programme, but there was no change in resting heart rate. There were no statistically significant changes in exercise performance but a trend towards improvement in both time to fatigue and distance to fatigue after the programme.
Strengths and limitations	This is a pilot study that only included 5 patients. Functional outcomes were collected using a self-reported questionnaire.
Johnston et al. 2011	
Study size, design and location	A prospective RCT of 30 children aged between 5 to 13 years with SCI. USA.
Intervention and comparator(s)	Intervention: RT300-P FES cycle (FES). Comparator: RT100 motorised cycle (PC) or a 2-channel surface stimulation unit to create lower limb muscle contractions (ES).
Key outcomes	There were statistically significant improvements in overall quadriceps muscle volume (24.4%, p=0.001) and muscle strength (42.4%, p<0.001) in FES groups after the 6-month intervention. Of 3 interventions, the ES group (27.2%) gained statistically significantly more in quadriceps muscle volume compared with the FES (24.4%, p=0.042) and PC (7.7%, p=0.001) groups. The FES (142.4%) gained statistically significantly more strength than the PC group (41.8%, p=0.015).

Strengths and limitations	Patients were randomised. All 30 children who took part in the study completed the training, with 24 having muscle volume data and 27 having stimulated strength data. There were statistically significant differences between groups in characteristics baseline including height, weight, and age, with more older and larger children in the ES group, and there were more patients with tetraplegia in the PC group compared with the FES and ES groups. But there was no difference between groups for outcome measures at baseline. The study did not define the minimally clinically important difference, so the changes seen may or may not be clinically meaningful in practice.
Lauer et al. 2011	
Study size, design and location	A prospective RCT of 30 children aged between 5 to 13 years with SCI. USA.
Intervention and comparator(s)	Intervention: RT300-P FES cycle (FES). Comparator: RT100 motorised cycle (PC) or a 2-channel surface stimulation unit to create low limb muscle contractions (electrically stimulated exercise, ES).
Key outcomes	There were no statistically significant increases in BMD between or within intervention groups after 6 months.
Strengths and limitations	Patients were randomised. 28 of 30 children who took part in the study completed baseline and 6-month assessment. The developmental changes in BMD for children with SCI are not known.
Abbreviations: BMD, bone mineral density; ES, electrical stimulation; FES, functional electrical stimulation; MAP, mean arterial blood pressure; PC, passive cycling; QOL, quality of life; RCT, randomised controlled trial; RPM, revolutions per minute; SCI, spinal cord injury.	

Recent and ongoing studies

No recent or ongoing studies were identified.

Specialist commentator comments

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

Three specialists were familiar with or had used this technology before.

Level of innovation

One expert said the RT300 was highly innovative by allowing quick multichannel stimulation, but noted that other functional electrical stimulation (FES) bikes with similar advantages are on the market. Another commentator, who works in a specialised spinal unit, said FES cycling is now considered standard practice for inpatient spinal cord injury rehabilitation and had used it for over 10 years. They added that it could still be considered novel in other spinal units or clinical specialities where there was less familiarity with FES technology. One commentator said the main innovation is being able to stimulate multiple muscles against a resistance in the same treatment session, which saves therapist time. A further commentator noted the RT300 was innovative because it can be used with the patient in a supine position. Some people with spinal cord injury have autonomic dysfunction, resulting in exercise-related hypotension. Other technologies did not offer this innovation.

Potential patient impact

Experts noted that RT300 allows muscles to be exercised that otherwise could not be in people with spinal cord injury. Two experts considered that RT300 could help recovery of voluntary muscle power if the patient has the neurological potential to improve. Such improvement in muscle power could have a positive effect on patients' functional ability to improve their independence. An expert stated that the use of the RT300 in children with spinal cord injury could help to develop awareness of their limbs and provide patterned muscle activities that maintain muscle bulk while the child learns to move voluntarily. This expert also noted that the RT300 ability to link to a database allowed people to access

treatment at home.

Experts considered that the use of the technology could potentially reduce secondary complications and hospital admissions. They also considered that RT300 allowed people with spinal cord injury to exercise their unused muscles, and provided them an opportunity to improve their cardiovascular fitness. This then reduces the risk of secondary cardiovascular conditions. One expert felt the FES cycle could be the most effective way to maintain the health of paralysed limbs in people with spinal cord injury. They added that the muscle torque generated can be enough to stimulate bone growth, which will help maintain a healthier bone density if training is set at a high level.

Potential system impact

Two experts considered that more staff would be needed to support patients during treatment sessions. Another expert felt there would be a need for staff training to allow them to fully understand the potential applications and benefits of RT300. One expert noted sites adopting RT300 would need extra space to accommodate the devices in rehabilitation settings.

One expert considered that the technology would reduce hospital admission by reducing secondary complications of spinal cord injury. However they did not feel there would be real cost benefits for some time because of the availability and uptake of the technology in rehabilitation settings. Another expert noted the technology would add extra cost compared with standard care, and did not feel it would have a substantial effect on overall length of stay for a patient in a spinal injuries unit.

General comments

One expert considered that RT300 has become core to spinal cord injury rehabilitation in their practice but the adoption of the technology may be limited because of funding availability for rehabilitation care. This expert also noted that FES cycling would not be suitable for all people with spinal cord injury, and an assessment including people's ability to respond to electrical stimulation should be made before treatment. One expert felt the adoption of RT300 may be delayed because of a lack of knowledge of how to use the technology.

Specialist commentators

The following clinicians contributed to this briefing:

- Kirsten Hart, clinical specialist physiotherapist, National Spinal Injuries Unit, Buckinghamshire Healthcare NHS Trust, did not declare any interests.
- Claire Lincoln, specialist physiotherapist, Queen Elizabeth National Spinal Injuries Unit, NHS Greater Glasgow and Clyde, did not declare any interests.
- Dr Ellen Merete Hagen, consultant in neurology, the National Hospital for Neurology and Neurosurgery, did not declare any interests.

Development of this briefing

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.

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