

The STAK tool for preventing and treating knee stiffness

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is the STAK tool. It is for people who have had knee trauma or surgery, to prevent and treat knee stiffness (arthrofibrosis).
- The **innovative aspects** are that it uses a person's own leverage and gravity to achieve higher increases in the range of knee movement.
- The **intended place in therapy** would be after knee trauma or surgery as an alternative to physiotherapy in people who have had knee surgery or suffered from a knee trauma such as a fracture or dislocation.
- The **main points from the evidence** summarised in this briefing are from 1 block-randomised prospective observational study including 35 adults after knee surgery in an NHS trust. It shows that the STAK tool can be more effective at improving range of movement and patient-reported quality-of-life measures than physiotherapy alone in people who have had knee surgery and have knee stiffness.
- **Key uncertainties** around the evidence or technology are that there is currently 1 published study from 1 NHS trust. It is unclear if this is representative of the whole NHS.

- The cost of the STAK tool is £250 per unit (excluding VAT). The cost of standard care is around £55 per group session.

The technology

The STAK (self-treatment assisted knee flexion) tool (Orthopaedics Ltd) is a high-intensity medical stretching device for use in hospital or in the community. It is used to treat and prevent knee stiffness (arthrofibrosis) in people who have had knee trauma or surgery, such as knee replacement. It can be used daily at home or in hospital.

Arthrofibrosis sometimes happens after knee trauma or surgery as a result of an exaggerated inflammatory response, leading to the formation of dense scar tissue. The STAK tool enables a person to generate (using their own body weight) the high-intensity stretch needed to break down scar tissue, and to control and finely adjust the intensity of any stretch.

The device consists of an adjustable footplate that is placed on the ground and secured to a foot of the chair. While seated in a chair, the person places their foot into the STAK tool, which is set to the limit of their current knee flexion ability. They then apply force using their body weight and leverage to stretch the knee to the limit of their pain threshold at their end range of movement.

The STAK tool can be used independently at home so individuals are engaged and in control of their treatment. A programme is also provided that uses telephone calls, texts or Skype. This reduces the need for face-to-face physiotherapy appointments.

Innovations

The company claims the STAK tool is the only stretching device that uses the individual's own leverage and gravity to achieve higher increases in the range of movement in their knee.

Current care pathway

There is currently no NICE guidance on knee arthrofibrosis.

The [NHS overview on knee replacement](#) notes that surgery is usually needed when the knee joint is worn or damaged so that mobility is reduced, and there is pain even while resting. The most common reason for knee replacement surgery is osteoarthritis. Complications are rare but can include stiffness of the knee (arthrofibrosis).

NHS University Hospitals of Leicester self-treatment assisted knee flexion tool states that revision surgery for arthrofibrosis is both expensive for the NHS and traumatic for the patient. However, the alternatives are limited. Manipulation can be done, but this requires general anaesthetic, is not always successful and has risks attached to it. Improved range of movement has been noted from using continuous passive motion, but these devices are typically expensive and cumbersome, and need clinic appointments for treatment by trained staff.

NICE's guideline on joint replacement (primary): hip, knee and shoulder has been identified as relevant to this care pathway, in particular the section on postoperative rehabilitation.

Population, setting and intended user

The technology would be used by people who have had knee trauma or replacement and subsequently have knee stiffness.

Stiffness after total knee arthroplasty, defined as limited range of movement that affects activities of daily living, is a common problem happening in 5% to 30% of people.

In 2019, 103,617 partial knee replacements were done in the UK (National Joint Registry, 17th Annual Report 2020).

US data suggest that arthrofibrosis is responsible for the majority (28%) of hospital readmissions after total knee replacement.

Costs

Technology costs

The technology costs £250 (excluding VAT), including a supporting chair. The device is reusable.

Costs of standard care

Currently people would expect to get information before discharge about self-directed recovery exercises and physiotherapy, and face-to-face physiotherapy from the NHS on a more ad-hoc basis.

The company estimates that on average people would have 8 physiotherapy sessions from the NHS at a cost of £55 per group session. The more expensive one-to-one physiotherapy sessions at £64 are done on an ad-hoc basis (Personal Social Services Research Unit, 2020). Alternatively, an hour of staff costs for a mid-point band 5 physiotherapist is around £20 and a mid-point band 6

physiotherapist is around £25.

Resource consequences

The technology is not currently used in the NHS outside of research.

The company estimates that the technology could save the NHS around £11.7 million a year. This estimate is based on 30,671 people having treatment every year for arthrofibrosis using the STAK tool.

Most of the estimated savings, £7.36 million, arise from reducing the number of physiotherapy sessions from 8 to 3, and a further £5.27 million of savings by reducing numbers of people requiring manipulation under anaesthetic (estimated to cost £4,317) from 5% to 1%. The company assumes 20 STAK tools will be needed at each of the 168 NHS hospitals that carry out total knee operations in the UK. There is no published evidence to support these claims.

The company provided a manuscript of an unpublished economic evaluation of the STAK tool, using data from [Aspinall et al. \(2020\)](#). This reports that the STAK tool has a 96% probability of being cost effective based on a quality-adjusted life year (QALY) threshold of £20,000 to £30,000, and an incremental cost-effectiveness ratio of about £1,200 per QALY gained.

The STAK tool is expected to have a minimum lifespan of 10 years and is reusable. Training is provided at initial adoption and it is not expected that further training will be needed, but it is available on request at no cost. The remote monitoring, treatment and support through Skype and Zoom can be provided by the treating physiotherapist.

The company claims that the STAK tool could be easily incorporated into the physiotherapy pathway identified by the [NICE guideline on joint replacement \(primary\): hip, knee and shoulder](#).

Regulatory information

The STAK tool is a CE-marked class 1 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.

No equalities issues were identified.

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

One study of 35 people is summarised in this briefing.

Further unpublished evidence was identified or provided by the company, including presentations, conference abstracts, patient testimonies, and manuscripts prepared or submitted for publication. These contain limited information but support the evidence in the 1 published study.

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

Overall assessment of the evidence

The limited evidence is supportive of the STAK tool. It shows that it can improve range of movement and patient-reported outcome measures. The study was done in the UK and is relevant to the NHS. However, it involves 1 NHS trust and a small number of patients. It is unclear how representative findings are and if they would be replicated across the NHS. The comparative evidence is limited to 8 weeks follow up. Further evidence generation could help to address these points.

Aspinall et al. (2020)

Study size, design and location

[Prospective observational study in the UK of 35 adults after knee surgery who were prescribed intensive physiotherapy for stiffness by their surgeon](#). People were recruited consecutively in block allocations.

Intervention and comparator

STAK tool and physiotherapy compared with physiotherapy alone.

Key outcomes

The STAK tool made significant gains compared with control during the 8-week treatment period in mean range of movement (30° compared with 8°, $p < 0.0005$). It also improved Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC; 19 points compared with 3 points, $p < 0.0005$), and Oxford Knee Scores (8 points compared with 3 points, $p < 0.0005$).

After the 8-week treatment period using the STAK tool, people were followed up for varying lengths of time, up to 15 months. During this follow-up period there was a small decline of 2° in range of movement and continued improvements in the remaining Oxford Knee Scores and WOMAC scores. These changes were not statistically significant, and suggested improvements were maintained in the follow-up period.

Study feedback found that both groups followed their treatment. But, individuals were more actively engaged with the STAK tool (an average of 3 times a day at a 'very intense' level of stretch for an average of 13 minutes per session for 7 days a week compared with on average twice a day at a 'moderate intensity' level of stretch for 14 minutes per session for 4.8 days a week). People who used the STAK tool reported high acceptability for the intervention (mean score, 6.8/7); 98% were extremely likely to recommend it to a friend, and 93% considered that the STAK tool was wholly responsible for their change in knee range of movement.

Strengths and limitations

A randomised trial, even though randomisation was in blocks, with well-matched groups at baseline. People could not be blinded to treatment, and while the assessors were, it is possible that treatment details were disclosed to them. Only the STAK tool group was followed up after 8 weeks, so it is not possible to be certain that gains against controls were maintained. People in the STAK group were telephoned once a week to check that there were no problems using the device. This could constitute a further intervention that could have favoured the intervention group.

The study author is the inventor of the STAK technology.

Sustainability

The company claims the technology is reusable and the components of the device are stable for a

minimum of 10 years. The materials used have been tested and proven to withstand chloro-clean, and have suitable mechanical strength for all intended purposes. The device was used by different patients in the published study.

Recent and ongoing studies

The company has informed NICE that it has submitted a manuscript to the Medicine in Novel Technology and Devices journal (patient experience of a new treatment (STAK) for arthrofibrosis following total knee replacement surgery: a qualitative analysis).

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.

Two of 3 experts were familiar with or had used this technology before.

Level of innovation

All of the experts considered the device to be innovative. They thought the device would be a useful addition to standard care or that they would need further information before determining if it could replace standard care. Three experts mentioned passive motion or other active devices as alternatives to the technology. But, they noted that these were bigger devices that are more expensive and cumbersome, and may not be reusable or provide the same level of functions.

Potential patient impact

All of the experts mentioned the ability to use the device at home or less need for hospital visits as potential patient benefits, particularly because of the COVID-19 pandemic. They also mentioned, as further patient benefits, the fact that it is non-invasive, care can be self-directed, it is easy to learn how to use and is likely to have few side effects.

Potential system impact

The experts identified fewer hospital visits, the relative cheapness of the treatment and the fact that it is non-invasive as potential system benefits. The benefits of a reduced need for visits during the COVID-19 pandemic were highlighted. But there was a concern raised that some patients,

particularly those with cognitive difficulties, or with low adherence with exercise regimes, could be disadvantaged by having fewer hospital visits.

General comments

Two experts stated that the technology was likely to reduce costs, and 1 stated that it would be cost neutral and cost incurring at worse. All the experts considered the technology to be safe and the potential for harm to be low. One expert who had not used the device speculated that if the technology does not work it may delay effective treatment in some patients. They considered that further research was needed.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Toby Smith, senior researcher in rehabilitation, University of Oxford, and associate professor in physiotherapy, University of East Anglia, did not declare any interests.
- Professor Robert Ashford, consultant musculoskeletal tumour and joint reconstruction surgeon, University Hospitals of Leicester, did not declare any interests.
- Mr Steven Godsiff, consultant orthopaedic knee surgeon, University Hospitals of Leicester, co-authored a publication showing the advantages of the STAK tool.

Development of this briefing

This briefing was developed by NICE. 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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