NICE advice

Mobi-C for cervical disc replacement

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Summary

Mobi-C is a prosthetic device used for 1- or 2-level cervical disc replacement. It is designed for people with cervical disc degeneration. The evidence from 1 systematic review and 3 additional studies summarised in this briefing includes 1,675 individual patients and is of mixed quality. The systematic review concluded that Mobi-C is non-inferior to anterior cervical discectomy and fusion (ACDF). The studies found that Mobi-C (at 1 or 2 levels) was more effective than ACDF for overall success and for reducing limitations of daily activity as a result of neck pain, and allowed a greater range of motion with less adjacent-segment degeneration and less need for subsequent surgery. Each Mobi-C prosthesis costs £1,750 (excluding VAT).

Product summary and likely place in therapy	Effectiveness and safety
• Mobi-C is a prosthetic device designed for 1- or 2-level cervical intervertebral total disc replacement for people with cervical disc degeneration. • It is an alternative to conservative treatment options (such as rest, analgesic medication, physical therapy and local corticosteroid injections) or to anterior cervical discectomy and fusion (ACDF), and alternative disc replacement systems.	• The published evidence summarised in this briefing comes from 1 systematic review and 3 randomised controlled trials of mixed quality. None of the studies were done in the UK. All 3 trials used ACDF as a comparator. • In the systematic review which included 1,319 patients, 1-level Mobi-C was found to be non-inferior to ACDF, but had high rates of heterotopic ossification (bone formation in soft tissue). • In 1 randomised controlled trial of 2-level Mobi-C included in the systematic review (n=330), the subsequent 4-year follow-up found that 66% of the Mobi-C group and 36% of the ACDF group achieved a composite end point of overall success. • A similar trial of 1-level Mobi-C (n=245) found that at 5 years, the composite overall success was 61.9% with Mobi-C and 52.2% with ACDF (statistically non-inferior). • Another randomised controlled trial of 1-level Mobi-C (n=111) found a statistically significantly greater range of motion with Mobi-C than ACDF. None of the patients who had Mobi-C needed adjacent-segment reoperations compared with 7.1% of those having ACDF at 4 years.

Technical and patient factors	Cost and resource use
• The manufacturer states that Mobi-C may be used if a person's cervical disc degeneration has not responded to at least 6 weeks of conservative treatment, or if they have shown progressive signs or symptoms despite non-operative treatment. • The prosthetic disc is delivered pre-assembled on a disposable cartridge, which allows the position of the prosthesis to be checked using X-rays. • The device is suitable for skeletally mature adults. Treatment should be carried out by spinal surgeons in specialist centres.	• A single Mobi-C prosthesis costs £1,750 (excluding VAT). Two Mobi-C devices are needed for 2-level cervical disc replacement. • A US cost-effectiveness analysis found that the average cost per patient in the 5 years after surgery was $23,459 (about £16,515) for Mobi-C, and $21,772 (about £16,031) for ACDF. The incremental cost-effectiveness ratio was $8,518 (about £6,000) per quality-adjusted life year in favour of Mobi-C.

Introduction

Cervical disc replacement may be used to treat the symptoms of cervical myelopathy or radiculopathy, associated with cervical disc degeneration. Cervical myelopathy is a narrowing of the spinal canal and can cause pressure on the spinal cord (Coughlin et al. 2012). It may occur as a result of age-related wear and tear of the cervical spine. To compensate for damage to the joints, extra bone may develop within the spine, leading to the symptoms of spondylosis (NHS Choices 2014). Cervical radiculopathy is defined as pain caused by pressure on spinal nerves which can result from a slipped disc, degeneration of the spine from wear and tear, or trauma (Caridi et al. 2011).

Cervical disc degeneration may have no symptoms, but people most commonly present between the ages of 40 and 60. It has been previously shown that 25% of adults under the age of 40 have some evidence of disc degeneration, and this number increases to 85% in people aged 60 and over (Kelly et al. 2012). In the studies included within NICE interventional procedure guidance on prosthetic intervertebral disc replacement in the

cervical spine, between 52 and 60% of people with cervical disc degeneration were women, with a mean age ranging from 43 to 46 years.

NICE interventional procedure guidance on prosthetic intervertebral disc replacement in the cervical spine states that damage to the cervical discs may lead to pain and stiffness in the neck, as well as pain, pins and needles, numbness or weakness of the limbs. Pain arising from degenerative changes in the cervical spine can be very debilitating (Hisey et al. 2016). Cervical myelopathy can also lead to further problems if left untreated, including bowel and bladder dysfunction (Todd 2011). People with symptoms that cannot be resolved through conservative management, including rest, painkillers and physiotherapy, may need surgery. The aim of treatment is to relieve radicular arm pain and/or prevent progression of cervical myelopathy.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

CE marks (class III implants; Medical Device Directive 93/42/EEC amended 2007/47/EC) were awarded to LDR Medical in October 2004 for Mobi-C and in November 2007 for Mobi-C Plug and Fit, which includes the 'Plug and Fit' implantation system. The CE marks were renewed in September 2015.

Description

Mobi-C is a prosthetic device for cervical intervertebral disc replacement (C3/C4, C4/C5, C5/C6, C6/C7) intended to restore disc height and retain movement in the cervical spine. It can be used for either the replacement of 1 (1-level) or 2 (2-level) cervical discs; 2-level replacement requires 2 Mobi-C devices. The prosthesis consists of a superior spinal plate, an inferior spinal plate and a mobile insert. The plates are made of chromium cobalt

molybdenum alloy with a pure titanium and hydroxyapatite coating, and the insert is made from polyethylene. Mobi-C is delivered pre-assembled on a disposable PEEK cartridge, with jaws keeping the 2 plates and the insert together. This aims to make inserting the prosthesis easier and replaces the previous version of the device. The cartridge allows the prosthesis to be viewed under X-ray for optimal positioning. The device has an accompanying instrument kit that contains all equipment needed to complete procedures with Mobi-C.

The prostheses come in various sizes, which are detailed on the product website. Before surgery, an X-ray is taken to check that the affected disc size is at least 14 mm from front to back and that disc height is adequate for disc replacement. During surgery, the correct prosthesis is selected under fluoroscopy ensuring it does not exceed the height of healthy adjacent discs. The depth of the disc is verified during surgery by direct measurement with a depth gauge, supplied by the manufacturer in the instrument kit. All measurements must take into consideration any osteophytes (bony projections) that will be removed at the beginning of the procedure.

The surgical approach for implanting Mobi-C is similar to that of an anterior cervical discectomy and fusion (ACDF), involving a number of steps:

- partial discectomy
- width gauge and positioning of a centring pin (with fluoroscopy to confirm correct positioning)
- distraction of the disc space
- complete discectomy
- parallel distraction
- depth measurement
- insertion of trial prostheses (screwed onto a holder) to assess the final prosthesis size
- loading the prosthesis
- millimetre adjustment of the stop setting
- prosthesis insertion
- position checking

- removal of the prosthesis holder and clamps
- anchorage optimisation.

As well as the potential adverse events arising from any surgery, some adverse events are specific to the anterior approach to the cervical spine (such as recurrent laryngeal nerve palsy or nerve root injury leading to arm weakness or numbness), or to cervical disc replacement itself (for example, the prosthesis becoming displaced or components failing, allergy to materials or degeneration in adjacent discs).

People who have discs replaced with Mobi-C should be advised that they can return to normal activities 3 to 6 months after surgery in most circumstances, but that any excessive loading or movement of the neck (for example, gymnastics or rugby) should be avoided.

Contraindications include:

- known or suspected sensitivity to the materials
- degenerative arthrosis of the facet joint
- neck pain without radiculopathy
- systemic spinal or local infection
- fever
- any local condition that could compromise the stability of the prosthesis (such as a tumour or osteoporosis)
- significant cervical anatomical deformity (for example ankylosing spondylitis or rheumatoid arthritis).

Setting and intended use

Mobi-C is designed to be used to replace cervical spine discs in adults who need cervical disc replacement because of radiculopathy or myelopathy. For people with myelopathy, the presence of at least 1 of the following conditions should be confirmed by radiographic imaging before the procedure: spondylosis, herniated nucleus pulposus or visible loss of disc height compared with adjacent levels. Cervical discs C3 to C7 can be replaced using Mobi-C, and 1 or 2 discs may be replaced during the procedure. For 2-level procedures,

2 Mobi-C devices are needed. People may be suitable for surgery if their cervical disc degeneration has not responded to at least 6 weeks of conservative management, or if they have shown progressive signs or symptoms despite non-operative treatment.

The surgical procedure for cervical disc replacement with Mobi-C is technically demanding, with a risk of serious injury to the person having the procedure comparable to ACDF. Because of this, the prosthesis should only be implanted by experienced spinal surgeons who are trained in using Mobi-C and who understand the mechanical limitations of the cervical disc prosthesis.

Current NHS options

NICE interventional procedure guidance on prosthetic intervertebral disc replacement in the cervical spine notes that conservative treatment options include rest, analgesic medication, physical therapy and local corticosteroid injections. If these conservative options fail, or if a person is at risk of permanent neurological damage, surgery may be offered. The guidance recommends that the procedure may be used with normal arrangements for clinical governance, consent and audit. It also encourages further research including long-term outcomes on the preservation of mobility, occurrence of adjacent segment disease and the avoidance of revision surgery.

A number of surgical treatment options are available. ACDF is a well-accepted treatment option to relieve symptoms caused by spinal cord or spinal nerve compression (that is, myelopathy or radiculopathy). During the procedure, cervical disc material that is compressing the spinal cord or nerve is removed. The space is then generally filled with a bone graft taken from a separate site in the body, or with a synthetic 'cage' to encourage bone fusion. ACDF has a high success rate, but can be complicated by recurrent neck pain and adjacent segment disease (Delamarter and Zigler 2013).

Prosthetic intervertebral discs may be used as an alternative to ACDF. NICE interventional procedure guidance on prosthetic intervertebral disc replacement in the cervical spine notes that the aim of prosthetic disc surgery is to preserve mobility in the affected area of the spine, reducing the risk of long-term adjacent segment degeneration. More than 1 disc can be replaced during the same procedure and various devices may be used. The guidance states that cervical disc replacement procedures should only be done in specialist units where cervical spine surgery is common.

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

Mobi-C:

- BRYAN Cervical Disc (Medtronic)
- PCM Cervical Disc (NuVasive)
- PRESTIGE LP Cervical Disc (Medtronic)
- ProDisc-C Total Disc Replacement (DePuy Synthes).

Costs and use of the technology

The cost of a single Mobi-C prosthesis, including the jaws and screw needed for the procedure, is £1,750 (so £3,500 for a 2-level procedure; excluding VAT). Cervical disc replacements with Mobi-C also require the accompanying instrument kit that the manufacturer provides at no extra cost. The instruments can be reused following sterilisation. Intraoperative fluoroscopy will also be needed throughout the procedure to ensure accurate instrument and prosthesis positioning.

The manufacturer provides onsite training, staff and technical support in the operating room, and user meetings at no extra cost.

In practice, hospitals that use Mobi-C are reimbursed through the NHS National Tariff Payment for cervical disc replacement (table 1). The total difference between disc replacement and fusion procedures, at usual NHS prices, is expected to be £1,622 for 1-level replacement and £3,511 for 2-level replacement (British Association of Spine Surgeons 2011, NHS England 2016). This is similar to the cost of the Mobi-C device (£1,750 for 1-level and £3,500 for 2-level replacement).

Table 1 Tariff payments: cervical disc replacement and ACDF

Intervention	HRG code		PbR tariff value	
	1 level	More than 1 level	1 level	More than 1 level
Cervical disc replacement	HC02C	HC01Z	£7,607	£11,118
Anterior cervical discectomy and fusion	HC03C	HC02C	£5,985	£7,607

Difference	£1,622	£3,511
Tariff payments for spinal surgery are currently adjusted to account for specialised services commissioning, which increases the tariff by 32%. The adjusted prices are shown.		

Likely place in therapy

The Mobi-C prosthesis would be used as an alternative to ACDF and other prosthetic discs.

Specialist commentator comments

One commentator stated that Mobi-C may have advantages over other prostheses because it is only semi-constrained, which means it provides excellent mobility when inserted optimally, and is perhaps more forgiving than other devices if the placement is not perfect. They added that constrained devices offer only limited height variation, whereas Mobi-C prostheses are available in a range of heights. For example, Mobi-C can even replace a disc of 4 mm to 5 mm in height, making it suitable for people with smaller discs.

One commentator stated that ACDF is the gold-standard procedure for people with cervical myelopathy or radiculopathy, but that it has the disadvantage of adjacent segment disease and the possibility of further surgery. They noted that cervical disc replacement procedures aim to address these disadvantages. A second commentator considered that Mobi-C should be used instead of ACDF for certain indications, specifically in people who have had previous fusion surgery and develop adjacent disc disease; people with symptomatic multi-level disc disease; and young adults with a soft disc prolapse causing compression who also have a degenerate disc not causing compression. They added that Mobi-C results are likely to be more favourable in people with 2-level procedures when compared with ACDF. This is because 2-level fusion procedures have a more detrimental effect on cervical movement and biomechanics than 1-level ACDF. A third commentator noted that Mobi-C should be used for the same indications as other prosthetic replacement devices.

One commentator remarked that all procedures with Mobi-C should be done by surgeons competent in anterior cervical disc replacement, and that because of this the procedure is likely to be restricted to neurosurgical units or spinal surgery centres with orthopaedic

surgeons who do anterior neck surgery. They added that the procedure with Mobi-C should not be more technically demanding than fusion procedures, and in both types of surgery the main risk arises from the decompression process. They estimated the risk of serious injury with both procedures to be approximately 1 in 400 to 1 in 800, which they deemed to be low. The commentator was of the opinion that revision procedures were no more risky than initial placement. A second commentator considered that revision procedures are likely to be more risky and that there are limited long-term data regarding failure rates with cervical disc replacement. They added that cervical disc replacement can be associated with major complications such as paralysis, and these complications can have a significant effect on the cost-effectiveness of the procedure. A third commentator stated that it is particularly important to explain the expected outcomes to people considering both options so that they can make an informed decision about treatment. One commentator stated that cervical disc replacement procedures require spinal joints to be in a relatively good condition (for example, low levels of osteoarthritis and disc height of at least 50%), and this often limits the procedure to younger people.

One commentator noted that heterotopic calcification is an important consideration with the Mobi-C procedure because most people will develop evidence of anterior osteophytes over time after surgery. Depending on their severity, osteophytes can limit movement, and when osteophytes fuse together this can stop movement altogether. However, even if patients experience fused osteophytes at 10 years after surgery, the commentator considered that retention of movement up until that point would still deliver significant benefits. The commentator also noted that the rate of calcification is likely to be comparable across different prostheses and is not unique to Mobi-C. A second commentator remarked that there have been reports of spontaneous fusion with cervical disc replacement procedures. This usually occurs anteriorly or due to heterotopic ossification, and will restrict movement leading to similar outcomes to ACDF procedures.

One commentator noted that people are more regularly requesting cervical disc replacement over fusion procedures based on research they have done themselves, with 1 person also specifically requesting disc replacement with Mobi-C.

One commentator stated that people with cervical disc degeneration are commonly given neuropathic medication, or even no treatment.

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, 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).

People with cervical degeneration may be considered to have a disability if their symptoms have an adverse and long-term effect on their ability to carry out daily activities, for example as a result of pain and reduced mobility. Mobi-C may enable people with cervical disc degeneration to become more mobile and, therefore, partake in more everyday activities. Cervical disc degeneration becomes more common with age, so the device may be used more regularly in older people. Age and disability are protected characteristics under the Equality Act (2010).

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device.

A search of the US Food and Drug Administration (FDA) database Manufacturer and User Device Facility Experience (MAUDE) found 3 reports of adverse events. These were:

- Revision surgery of a patient with hypermobility at 1 level of the cervical disc replacement site; devices were removed and replaced with fusion treatment.
- Revision surgery to remove an implanted device due to alleged pain.

- Patient developed severe neck and arm pain 7 years after implant; device was removed and replaced with anterior cervical discectomy and fusion with cage and plate.

Clinical evidence

The published evidence summarised in this briefing comes from 1 systematic review and 3 randomised controlled trials of mixed quality. None of the studies were done in the UK. All 3 studies used ACDF as a comparator.

One systematic review (Alvin et al. 2014), with a search date of 1 September 2014, included any studies that presented clinical results associated with the Mobi-C cervical disc prosthesis. Complications or adverse outcomes assessed included heterotopic ossification, adjacent segment degeneration and adjacent segment disease (defined clinically by symptoms). Results were not combined statistically but were presented in a narrative format and in tables. The review included 15 studies: 1 randomised controlled trial, 5 prospective studies and 9 retrospective studies, involving a total of 1,319 patients. Most of the included studies compared 1-level Mobi-C with 1-level ACDF. One study analysed outcomes of 1-level Mobi-C compared with 2-level Mobi-C, and another compared 2-level Mobi-C with 2-level ACDF. Alvin et al. (2014) concluded that 1-level Mobi-C is non-inferior, but not superior, to 1-level ACDF for patients with cervical disc degeneration. For 2-level Mobi-C procedures, the authors concluded that it may be superior to 2-level ACDF, but insufficient evidence exists. Therefore, unbiased, well-designed prospective studies are needed to confirm these findings. Furthermore, the authors concluded that Mobi-C is associated with high rates of heterotopic ossification. However, the authors also noted that exact definitions of heterotopic ossification were not provided in each study, meaning the complication rates may not be fully comparable across studies.

The report by Davis et al. (2015) was based on the 1 randomised controlled trial included in the systematic review (Davis et al. 2013), and includes 48-month follow-up data. At 48 months, 66.0% of the Mobi-C group and 36.0% of the ACDF group achieved overall success ($p<0.0001$). Overall success rates were defined as a combination of improvement in the Neck Disability Index (NDI) score, adverse events or subsequent surgery, improvement in neurological function and radiographic success. Four types of surgical procedure may have been needed: reoperation, prosthesis removal, prosthesis revision or supplementary fixation. The criterion for radiographic success in the Mobi-C group was defined as non-fusion of both treated levels. Radiographic success in the ACDF group was

defined as fusion of both treated levels, less than 2° of angular motion in flexion and extension, evidence of bridging bone across the disc space and radiolucent lines at no more than 50% of the graft vertebral interfaces. The mean improvement in NDI score was 36.5±21.3 with Mobi-C and 28.5±18.3 with ACDF (p=0.0048). Subsequent surgical intervention was needed in 4.0% of patients having the Mobi-C procedure (9 of 225, a total of 10 surgical procedures), compared with 15.2% of patients having ACDF (16 of 105, a total of 18 surgical procedures; p<0.0001). Adjacent-segment degeneration occurred in 41.5% of Mobi-C patients compared with 85.9% of ACDF patients (p<0.0001). The authors concluded that the 48-month results indicate that Mobi-C is a safe, effective and statistically superior alternative to ACDF.

Another RCT (not included in the systematic review; reported in Hisey et al. 2014 and 2016) was very similar to the Davis et al. (2013 and 2015) study, but included people treated at a single level rather than 2 levels. At 60 months (reported in Hisey et al. 2016), the composite overall success was 61.9% with Mobi-C compared with 52.2% with ACDF; however, the difference was not statistically significant. Subsequent surgery was carried out in 8 people (4.9%) with Mobi-C and 14 people (17.3%) with ACDF (p<0.01). Patients who had Mobi-C had a statistically significant lower rate of adjacent segment degeneration compared with ACDF patients (p<0.03, results presented graphically). Improvements in NDI, visual analogue scale (VAS) for neck and arm pain, and SF-12 scores were similar between groups. There was no significant difference between Mobi-C and ACDF in adverse events or major complications. The authors concluded that the 60-month results demonstrate that Mobi-C is a safe and efficacious alternative to ACDF for 1-level cervical disc replacement. It may also lower the rate of subsequent surgical procedures and adjacent segment degeneration.

The trial described in Zhang et al. (2014) compared Mobi-C with ACDF in 111 patients with degenerative cervical spondylosis of 1 segmental level in China. In both treatment groups, there was a significant improvement in the Japanese Orthopaedic Association (JOA), VAS and NDI scores 48 months after surgery compared with scores taken before surgery (p<0.05). There were no statistically significant differences between the groups. The range of motion in the ACDF group decreased at 1 month after surgery (to around 45°; shown graphically) and increased to around 50° at 3 months, remaining at a similar level throughout the 48 month follow-up. In the Mobi-C group, the range of motion was significantly greater than with ACDF from 1 month to 48 months, reaching around 50° at 1 month and increasing to around 60° at 3 months. It then remained at a similar level throughout the 48 month follow-up (p<0.0005 between groups at each time point from 1 to 48 months). In the Mobi-C group, 33% of patients (18/55) had heterotopic ossification

at 48 months; this outcome was not reported for the ACDF group. Pseudarthrosis rates in treated segments were 10.7% (6/56) at the 6-month follow-up and 1.8% (1/56) at 48 months for the ACDF group; this outcome was not reported for the Mobi-C group. There were no adjacent-segment reoperations in the Mobi-C group but 7.1% (4/56) of patients in the ACDF group had further surgery within 4 years (1 replacement procedure with Mobi-C, 1 ACDF and 2 posterior cervical open-door laminoplasties). The authors concluded that both Mobi-C and ACDF were reliable surgical options, but ACDF may increase the risk of reoperation. Patients who had disc replacement with Mobi-C showed statistically superior radiographic outcomes.

Recent and ongoing studies

One relevant ongoing or in-development trial of the Mobi-C device was identified in the preparation of this briefing:

- NCT00554528: The Arthroplasty Versus Fusion in Anterior Cervical Surgery: Prospective Study of the Impact on the Adjacent Level (PROCERV). The aim of this phase IV trial is to evaluate Mobi-C cervical disc replacement compared with ACDF, with a primary outcome measure of adjacent disc degeneration 3 years after surgery. In total 200 people were enrolled in the trial. The study was listed as completed in September 2015.

A second trial, NCT00640029: The Evaluation of the Prosthetic Disc Replacement (EVA) trial, was identified; however, this was terminated due to insufficient recruitment.

Costs and resource consequences

NHS Hospital Episode Statistics (HES) data indicate that in all English NHS hospitals in 2014/15, there were 4,642 finished consultant episodes relating to 'primary decompression operations on cervical spine' and 168 for 'revisional decompression operations on cervical spine' (revision rate of around 3.6%). The former description also includes 1,976 episodes of 'primary anterior decompression of cervical spinal cord and fusion of joint of cervical spine' (that is, discectomy plus fusion). This compares with 308 episodes of 'prosthetic replacement of cervical intervertebral disc' representing a ratio of discectomy plus fusion to cervical disc replacement of about 6:1 (Health and Social Care Information Centre 2015).

The manufacturer notes that Mobi-C has been used for more than 2,000 procedures in the

UK. The procedure is done in specialist spinal units, and more widespread use of the device is not expected to change service delivery if limited to these centres. The cost of prosthetic cervical disc surgery is greater than alternative ACDF surgery, so overall costs may increase if fusion surgery is replaced by Mobi-C procedures. However, the use of Mobi-C may result in savings if it can lead to a reduction in the number of adverse events, a reduction in the number of revision surgery procedures, and a reduction in the number of adjacent-segment reoperations.

Health economic evaluations

One cost-effectiveness analysis was identified (Ament et al. 2015). The authors used a Markov model to determine the incremental cost-effectiveness ratio (ICER) of cervical disc replacement using Mobi-C compared with ACDF. Costs were calculated from both US healthcare system and societal perspectives over a 5-year time horizon. The analysis used further 5-year follow-up data from the study by Davis et al. (2015). Direct medical costs used in the analysis were from a healthcare system perspective and included operative time, hospital stay, medication use, adverse event rates and follow-up office visits.

The average cost per patient in the 5 years after surgery was $23,459 (converted to £16,515) for patients having Mobi-C and $21,772 (converted to £15,327) for patients having ACDF. Effectiveness was measured using quality-adjusted life years (QALYs). Over 5 years, the use of Mobi-C resulted in an estimated 3.574 QALYs per patient compared with 3.376 QALYs per patient for ACDF. The study reported an ICER for Mobi-C of $8,518 per QALY. Using the converted cost per patient values (£16,515 and £15,327) and original QALY scores (3.574 and 3.376), this equates to an ICER of £6,000 per QALY gained for Mobi-C compared with ACDF.

When the authors incorporated Mobi-C's effect on the wider healthcare system and potential productivity loss/savings, total costs were estimated to be $80,906 (about £56,956) for Mobi-C and $113,596 (about £79,969) for ACDF. Therefore, in the model Mobi-C both cost less and worked better than ACDF.

Sensitivity analyses showed that the ICER remained fairly consistent regardless of the age of patients entering the model (varied between 30 and 70 years, from 44 years in the base case) or time horizon of the model (varied from 2 to 8 years). Probabilistic sensitivity analyses found Mobi-C to be cost effective compared with ACDF in over 95% of cases (up to an ICER of $20,000 per QALY gained). The results showed that from a US healthcare system perspective, Mobi-C was the dominant technology compared with ACDF. It is not

clear how generalisable these results are to the NHS.

Strengths and limitations of the evidence

The systematic review by Alvin et al. (2014) was evaluated using the systematic review and meta-analyses checklist recommended by the NICE guidelines manual. The systematic review was deemed to be of a relatively poor quality. The search strategy used was unsophisticated, given that only a basic set of search terms appeared to have been used (full strategy not reported) and only 1 database (MEDLINE) was searched. It was also unclear what process was adopted for sifting and data extraction, and whether 2 independent reviewers were involved in this process. For the studies that were included, no assessment of study bias took place, with the exception of a check for conflicts of interest. Within the review, included studies were classified by 2 independent reviewers according to the level of evidence. This assessment incorporated criteria defined by Sackett et al. (2000), which included an analysis of study factors such as length of follow-up, percentage of subjects available at follow-up, and reporting of outcome measures. Alvin et al. (2014) also addressed an appropriate and clearly defined question, and included relevant studies.

The 3 randomised controlled trials were evaluated using the checklist recommended in the NICE guidelines manual. Davis et al. (2015) presented 48-month follow-up results of an RCT in which the study design had been reported previously (Davis et al. 2013). Similarly, Hisey and colleagues (2016) presented 60-month follow-up results of an RCT in which the study design had been reported previously (Hisey et al. 2014). For both Davis et al. (2015) and Hisey et al. (2016), information from the underlying studies was used to assess the bias within each paper.

The risk of selection bias in Zhang et al. (2014) was unclear. The paper did not report the method of randomisation, and it was unclear whether there was adequate concealment of allocation for investigators and patients. Furthermore, although the authors noted that the demographics were similar between the 2 treatment groups, they did not report the numerical values for the different characteristics or whether tests for statistical significance were done. It was therefore unclear whether the groups were comparable at baseline. The risk of selection bias in Davis et al. (2013 and 2015) and Hisey et al. (2014 and 2016) was deemed to be low. In both studies an interactive voice randomisation system was used to appropriately randomise patients and divide them into subgroups based on NDI score. It was unclear whether there was adequate concealment of allocation for investigators and patients in both studies. In both studies the treatment groups were

comparable at baseline, with no statistically significant difference in all characteristics reported.

All 3 studies were deemed to be at high risk of performance bias. In each study, the 2 treatment groups did not receive the same care aside from the intervention. In Zhang et al. (2014) the comparator group received a neck-encumbering brace 48 to 72 hours after surgery, whereas the Mobi-C group did not. The authors did not justify the difference between treatment groups, and it was unclear if this was a bias or if it accurately reflected standard practice. However, it appears likely that the difference could affect long-term patient outcomes. Furthermore, it was not clear if patients were kept blind to their treatment. In both the Davis et al. (2013 and 2015) and Hisey et al. (2014 and 2016) studies, the care given after surgery was at the discretion of the surgeon, and this included a prescribed rehabilitation programme. Therefore, it is likely that the care differed depending on the surgeon who did the original procedure.

The Hisey et al. (2016) study included 25 surgeons across 23 sites. Davis et al. (2015) did not report exact surgeon numbers, but the trial took place over 24 sites so a similar number of surgeons may have been involved. It was not clear in either study how patients from the 2 treatment groups were allocated across the sites. In both studies the patients were blinded to allocation before surgery; however, allocation was revealed after surgery. It is not clear how this may have affected long-term outcomes. Surgeons were not blinded to the allocation of treatment, but this was not possible due to the nature of the procedures.

The risk of attrition bias was low in Zhang et al. (2014) and unclear in Davis et al. (2015) and Hisey et al. (2016). Zhang et al. (2014) reported that all included patients were evaluated after surgery for a minimum of 48 months (the last time point assessed within the paper), so no drop-outs were reported. In Davis et al. (2013 and 2015), both treatment groups were followed-up for 28 months. However, 17 patients who were initially randomised did not have surgery, and outcomes data were unavailable at 48 months for 25 patients in the Mobi-C group (11%) and 20 patients in the ACDF group (18%). It is not clear if this difference was statistically significant or not, because p-values were not reported. The presence of any systematic differences between groups was also not reported, both in terms of those who did not have surgery compared with those who did, and those who were not followed up for the full 48 months compared with those who were. It appeared that all patients who were randomised in the Hisey et al. (2014 and 2016) study subsequently had surgery. Following surgery, 24 patients in the Mobi-C group (14.5%) and 18 patients in the ACDF group (22%) did not remain in the trial for the full

5 year follow-up period. It was not clear if the drop-out rate was statistically significantly different between groups, as p values were not reported. Similarly, it was not reported if there were any systematic differences between the 2 groups.

The risk of detection bias in the 3 studies was unclear. All 3 had an appropriate follow-up time that enabled patient outcomes to be recorded. Similarly, they each used precise outcomes definitions. In Zhang et al. (2014), 3 specific outcome measures were used to determine clinical outcomes and patient improvement: the Japanese Orthopaedic Association questionnaire, a visual analogue scale and the NDI. However, it should be noted that all 3 measures are questionnaire-based and are therefore subjective. This makes them more susceptible to the introduction of bias because patients may consciously or unconsciously misreport their symptoms or outcomes. In both the Davis et al. (2015) and Hisey et al. (2016) studies, the overall rate of success was determined using a composite end point of 5 outcome measures: change in NDI from baseline, re-operation rates, adverse event rates, neurological outcomes and radiographic success. Because positive results were needed for all 5 measures in order for the surgery to be considered a success, the risk of bias was very low. Within Davis et al. (2015) and Hisey et al. (2016) a number of secondary outcomes were also presented. For all 3 studies it was not clear if investigators were blinded to patient allocation. If investigators were not blinded they may have been able to influence patient responses on subjective measures, such as the NDI.

All 3 studies were done outside of the UK: Zhang et al. was based in China, and both Davis et al. (2013 and 2015) and Hisey et al. (2014 and 2016) were done in the US. The results may therefore have limited generalisability to the NHS. Furthermore, in both the Davis et al. and Hisey et al. studies the manufacturer of Mobi-C contributed to the design and conduct of the study. The authors of the papers also disclosed financial interests, such as owning shares in the manufacturer or receiving research grants from the manufacturer. Therefore, funding bias may have been present.

Relevance to NICE guidance programmes

NICE has issued the following guidance that is relevant to this briefing:

- Musculoskeletal conditions (2016) NICE pathway
- Prosthetic intervertebral disc replacement in the cervical spine (2010) NICE interventional procedure guidance 341

- Percutaneous endoscopic laser cervical discectomy (2009) NICE interventional procedure guidance 303

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Appendix

Contents

Data tables

Table 2 Overview of the Alvin et al. (2014) systematic review

Study component	Description
Objectives/ hypotheses	To critically assess the available literature on CDA with the Mobi-C prosthesis, with a focus on 2-level CDA.
Study design	Systematic review.
Setting	Search date: September 1, 2014.
Inclusion/ exclusion criteria	Any studies (randomised controlled, retrospective, and prospective studies) that presented clinical results associated with the Mobi-C cervical disc prosthesis were included. Exclusion criteria: biomechanical studies, radiographic studies, animal studies and articles dealing with nucleus replacement.

Primary outcomes	Complications and/or adverse outcomes assessed included HO, ASDG (defined radiographically), adjacent segment disease (defined clinically by symptoms), or other, such as dysphagia or reoperation.
Statistical methods	Results were not combined statistically but presented as a narrative and in tables.
Patients included	Fifteen studies were included: 1 RCT, 5 prospective studies and 9 retrospective studies, involving a total of 1,319 people receiving Mobi-C.
Results	All included studies showed non-inferiority of 1-level Mobi-C CDA to 1-level ACDF. In comparison with other cervical disc prostheses, the Mobi-C prosthesis is associated with high rates of HO. In the 1 RCT identified (Davis et al. 2013; n=330), 225 patients underwent 2-level CDA, and 105 underwent 2-level ACDF. Both groups experienced statistically significant improvements in NDI and VAS arm/neck scores versus preoperative values. The Mobi-C group experienced significantly greater improvement in NDI score than the ACDF cohort ($p<0.05$). ROM was maintained at both treated segments. The reoperation rate was significantly higher with ACDF (11.4%) versus Mobi-C (3.1%). Lower adverse events were reported with Mobi-C. ASDG occurred in 16% with Mobi-C and 51% with ACDF ($p<0.03$). The authors provided only the Grade IV HO rate for Mobi-C at 2 years (4.9%, 11 patients). Overall study success rates were superior with CDA cohort versus ACDF (69.7% vs 37.4%; $p<0.01$).
Conclusions	One-level Mobi-C CDA is non-inferior, but not superior, to 1-level ACDF for patients with cervical degenerative disc disease. Mobi-C is also associated with high rates of HO. Two-level Mobi-C CDA may be superior to 2-level ACDF however, insufficient evidence exists.
Abbreviations: ACDF, anterior cervical discectomy and fusion; ASDG, adjacent segment degeneration; CDA, cervical disc arthroplasty; HO, heterotopic ossification; NDI, Neck Disability Index; RCT, randomised controlled trial; ROM, range of motion; VAS, visual analogue scale.	

Table 3 Overview of the Davis et al. (2015) study

Study component	**Description**

Objectives/ hypotheses	To evaluate the safety and effectiveness of 2-level TDR using Mobi-C at 48 months' follow-up.
Study design	RCT. This is a follow-up to the Davis et al. 2013 study described in Alvin et al. (2014).
Setting	24 centres in the US. Patients underwent surgery between April 2006 and March 2008. This paper reports outcomes at 48 months.
Inclusion/ exclusion criteria	Inclusion: people aged 18–69 years with a diagnosis of degenerative disc disease with radiculopathy or myeloradiculopathy at 2 contiguous levels from C3 to C7 that was unresponsive to non-operative treatment for at least 6 weeks or demonstrated progressive symptoms calling for immediate surgery. Other inclusion criteria included: NDI score ≥30, physically and mentally able, signed informed consent and willingness to discontinue all use of NSAIDs from 1 week before surgery until 3 months after surgery. Exclusion included: more than 2 vertebral levels requiring treatment, any prior spine surgery, metabolic bone disease, marked cervical instability, diseases that would preclude accurate clinical evaluation, use of high-dose steroids, use of other investigational drug or medical device within 30 days before surgery, pending personal litigation relating to spinal injury, smoking >1 pack of cigarettes per day, reported to have mental illness.
Primary outcomes	The primary endpoint was "overall success", that is a composite endpoint including: 1) ≥30-point improvement for patients with baseline NDI ≥60 or 50% improvement for patients with baseline NDI <60; 2) no subsequent surgical intervention at either treated level; 3) no AEs assessed as major complications; 4) maintenance or improvement in neurological function; and 5) radiographic success. Other outcome measures included: VAS for neck and arm pain, the SF-12 MCS and PCS, subsequent surgical intervention, complications, neurological function, return to work, patient satisfaction, ROM, HO, and adjacent-segment degeneration.

Statistical methods	The study included a non-inferiority hypothesis of the overall success rate of Mobi-C compared with that of the control procedure. Non-inferiority was assessed using an exact 95% 1-sided confidence bound. A post hoc test was pre-planned to test for superiority in the event of non-inferiority. Superiority was assessed using a 97.5% 1-sided confidence bound in the event a 10% non-inferiority margin could be excluded. Two-sided t-tests were used to determine statistical significance for all continuous outcome measures between groups at each time point. Fisher's exact tests were used to determine success or incident rates. Wilcoxon signed-rank tests were used to compare the change from baseline within treatment groups. A p value <0.05 was considered significant.
Patients included	225 people received treatment with a Mobi-C cervical artificial disc and 105 with corticocancellous allograft and an anterior cervical plate using the standard ACDF technique, for disease at 2 levels.
Results	66.0% of the TDR group and 36.0% of the ACDF group achieved 'overall success' (p<0.0001).
Conclusions	The authors concluded that 4-year results support TDR as a safe, effective, and statistically superior alternative to ACDF for the treatment of degenerative disc disease at 2 contiguous cervical levels.
Abbreviations: ACDF, anterior cervical discectomy and fusion; BMI, body mass index; CI, confidence interval; HO, heterotopic ossification; MCS, Mental Component Summary; n, number of patients; NDI, Neck Disability Index; NSAID, nonsteroidal anti-inflammatory drug; PCS, Physical Component Summary; RCT, randomised controlled trial; ROM, range of motion; SF-12, 12-item Short Form Health Survey; TDR, total disc replacement; VAS, visual analogue scales.	

Table 4 Summary of results from the Davis et al. (2015) study

	Mobi-C cervical artificial disc	ACDF	Analysis
Randomised	n=225	n=105	
Efficacy	n=200	n=85	

Primary outcome: overall success at 4 years	66.0% (132/200)	36.0% (31/85)	p<0.0001
Selected secondary outcomes:			
Improvement in NDI score at 4 years (Mean±SD)	36.5±21.3	28.5±18.3	p=0.0048
Improvement in VAS neck pain score from baseline at 4 years (Mean±SD)	53±30	48±29	NS
SF-12 MCS score improvement at 4 years (Mean±SD)	11±12	10±12	NS
SF-12 PCS score improvement at 4 years (Mean±SD)	13±12	10±12	p<0.05
Time to return to work (for those working; mean±SD)	46±101 days (n=191)	67±113 days (n=86)	NS
Very satisfied or somewhat satisfied with treatment	96.4%	89.0%	p=0.03329
Safety	n=234	n=105	
Neurological deterioration at 4 years	6.2%	7.6%	NS
Major complications at 4 years	4.0%	7.6%	NS
Subsequent surgical intervention	4.0% (9 of 225 patients, having a total of 10 surgeries).	15.2% (16 of 105 patients, having a total of 18 surgeries).	p<0.0001

Problems identified radiographically at 4 years	Clinically relevant HO (grades III and IV): 25.6%; includes 10.2% at grade IV.	Failed fusion in 14.8% (12 of the 81 patients with available radiographs; 7.8% of treated levels).	N/A
Adjacent-segment degeneration at 4 years	41.5%	85.9%	p<0.0001
Abbreviations: ACDF, anterior cervical discectomy and fusion; HO, heterotopic ossification; MCS, Mental Component Summary; n, number of patients; NDI, Neck Disability Index; N/A, not applicable; NS, non-significance; PCS, Physical Component Summary; ROM, range of motion; SF-12, 12-item Short Form Health Survey; TDR, total disc replacement; VAS, visual analogue scales.			

Table 5 Overview of the Hisey et al. (2016) study

Study component	Description
Objectives/ hypotheses	To compare clinical outcomes 5 years after TDR surgery using Mobi-C or ACDF to treatment single-level symptomatic disc degeneration.
Study design	RCT. This is a follow-up to the Hisey et al. 2014 study.
Setting	Surgery was performed between April 2006 and March 2008; this paper reports results at 5 years.
Inclusion/ exclusion criteria	Symptomatic DDD with radiculopathy or myeloradiculopathy at 1 level from C3 to C7, disc height of at least 3 mm, not osteoporotic, no previous cervical fusion, and failure of at least 6 weeks of non-operative care.
Primary outcomes	The primary outcome measure was a composite endpoint that required patients to meet all of the following criteria: 1) minimum 30/100 point improvement in NDI scores compared to baseline; 2) no device-related subsequent surgery; 3) no AEs classified as possibly or probably device-related by an independent CEC; 4) no neurological deterioration; 5) no intraoperative changes in treatment if randomised to Mobi-C.

Statistical methods	This study was designed as a non-inferiority trial with the primary study hypothesis testing the non-inferiority of TDR with Mobi-C against ACDF using a 10% margin with respect to patient success at 60 months. Non-inferiority in the overall success rate was assessed using an exact 95% 1-sided confidence bound. Statistical significance in success criteria and incidence rates was determined using Fisher's exact test. Statistical significance of continuous outcome measures was assessed by 2-sided t-tests at each time point. Changes from baseline within treatment groups were evaluated by Wilcoxon signed-rank test to determine significance. Statistical significance was indicated by a p-value less than 0.05.
Patients included	People with single-level symptomatic cervical disc degeneration; Mobi-C (n=164) or ACDF (n=81).
Results	The composite overall success was 61.9% with Mobi-C compared with 52.2% for ACDF, demonstrating statistical non-inferiority.
Conclusions	Five-year results demonstrate the safety and efficacy of TDR with Mobi-C as a viable alternative to ACDF in the treatment of 1-level symptomatic cervical disc degeneration, with the potential advantage of lower rates of re-operation and adjacent segment degeneration.
Abbreviations: ACDF, anterior cervical discectomy and fusion; AE, adverse event; CEC, Clinical Events Committee; DDD, degenerative disc disease; n, number of patients; NDI, Neck Disability Index; TDR, total disc replacement.	

Table 6 Summary of results from the Hisey et al. (2016) study

	Mobi-C	**ACDF**	**Analysis**
Randomised	n=164	n=81	
Efficacy	n=140	n=64	
Primary outcome: overall success at 5 years	61.9%	52.2%	NS
Selected secondary outcomes:			
SF-12 PCS final score at 5 years	47.6	48.3	NS

Subsequent surgery within 5 years	8 people (4.9%)	14 people (17.3%)	p<0.01
Patient satisfaction (very satisfied)	92.0%	83.9%	Not stated
Safety	n=179	n=81	
Failure based on radiographic evaluation	5.5%	3.7%	NS
Adjacent segment degeneration at the superior level	37.1%	54.7%	p<0.03
Abbreviations: ACDF, anterior cervical discectomy and fusion; AE, adverse event; CEC, Clinical Events Committee; DDD, degenerative disc disease; n, number of patients; NDI, Neck Disability Index; NS, non-significance; SF-12 PCS, Short Form-12 Health Survey Physical Component Score.			

Table 7 Overview of the Zhang et al. (2014) study

Study component	Description
Objectives/ hypotheses	To compare cervical disc replacement using Mobi-C disc prostheses with ACDF.
Study design	RCT.
Setting	11 separate medical institutions across China; participants enrolled from February 2008 to November 2009.
Inclusion/ exclusion criteria	Patients aged 18–68 years with a diagnosis of degenerative cervical spondylosis of 1 segmental level, supported by clinical symptoms and imaging data and with no significant improvement after conservative treatment for at least 3 months. Patients were excluded if they had multi-segmental-level cervical diseases, severe facet-joint degeneration, osteoporosis, cervical instability, spinal-canal stenosis, ossification of the posterior longitudinal ligament, tumour, infection or metal allergies.

Primary outcomes	Clinical and neurological outcome was determined by measuring the JOA scores, VAS and NDI. Static and dynamic radiographs were obtained of the cervical curvature, the FSU angle and ROM of the cervical spine, FSU angle and treated and adjacent segments.
Statistical methods	Statistical analysis was determined using a single-factor analysis of variance with Bonferroni's post hoc tests for multiple comparisons of baseline within the treatment groups at each follow-up time-point. For between-treatment group comparisons, paired t tests were performed.
Patients included	111 patients with single-level symptomatic cervical spondylosis were included; n=55 with Mobi-C disc replacement and n=56 with ACDF using plate/cage.
Results	JOA, VAS and NDI showed statistically significant improvements 48 months after surgery ($p<0.05$). ROM, FSU angle, treated segment and adjacent segments in the Mobi-C group were not significantly different before and after replacement ($p>0.05$). ROM in the ACDF group was significantly reduced at 1 month and remained so throughout the follow-up. By 48 months, more ACDF patients required secondary surgery (4 of 56 patients).
Conclusions	The authors concluded that although ACDF may increase the risk of additional surgery, clinical outcomes indicated that both Mobi-C artificial cervical disc replacement and ACDF were reliable. Radiographic data showed that ROM of the cervical spine, FSU angle and treated and adjacent segments were relatively better reconstructed and maintained in the Mobi-C group compared with those in the ACDF group.
Abbreviations: ACDF, anterior cervical discectomy and fusion; CI, confidence interval; FSU, functional spinal unit; JOA, Japanese Orthopaedic Association; n, number of patients; NDI, Neck Disability Index; ROM, range of motion; VAS, visual analogue scale.	

Table 8 Summary of results from the Zhang et al. (2014) study

	Mobi-C	ACDF	Analysis
Randomised	n=55	n=56	
Efficacy	n=55	n=56	

JOA score	Before surgery: 10.86 7 days: 12.80 1 month: 13.86 3 months: 14.58	Before surgery: 10.84 7 days: 12.54 1 month: 13.64 3 months: 14.44	NS
VAS score	Before surgery: 6.72 7 days: 4.20 3 months: 2.04	Before surgery: 6.64 7 days: 4.44 3 months: 2.24	NS
NDI score 48 months post-operation	19.60	20.10	NS
ROM	Around 60° (shown graphically)	Around 50° (shown graphically)	p<0.0005
Safety	n=55	n=56	
Number of patients with post-operative pharyngeal discomfort or hoarseness	15	13	NR
Other complications at 4 years	33% (18/55) had HO at 4 years	Pseudarthrosis rates in treated segments were 10.7 % (6/56) at the 6-month follow-up and 1.8 % (1/56) at 48-month follow-up.	NR
Adjacent-segment reoperations	0	7.1% (4/56)	NR
Abbreviations: ACDF, anterior cervical discectomy and fusion; CI, confidence interval; FSU, functional spinal unit; HO, heterotopic ossification; JOA, Japanese Orthopaedic Association; n, number of patients; NDI, Neck Disability Index; NR, not reported; NS, non-significance; ROM, range of motion; VAS, visual analogue scale.			

Search strategy and evidence selection

Search strategy

The search strategy was designed to identify evidence on the clinical and cost effectiveness of the Mobi-C cervical disc. To maximise sensitivity the strategy comprised of 1 concept only; the intervention. The title, abstract, author keyword and address fields were searched for the brand name of the device and the name of the manufacturer. A broader search to capture studies of interest which may not explicitly name the device in the title, abstract or other fields of the database record was not feasible within the context of this project. A search for all studies describing the use of artificial cervical discs or cervical disc replacement procedures would have returned a volume of literature requiring full text review beyond that which could be assessed within the scope of a medtech innovation briefing. This reflects the relatively large evidence base and number of competitor devices in this field. To test the 1 concept search strategy, the results using this strategy were compared against the 5 known relevant studies identified by NICE, and all 5 studies were retrieved in MEDLINE and EMBASE. Searching using only the device and manufacturer's name also found all of the relevant 14 studies included in a 2014 review of Mobi-C (Alvin et al. 2014).

The strategy excluded animal studies using a standard algorithm. Non-English language publications were also excluded from the search results. The search was restricted to studies published from 2004 to date. This reflects the date the device was CE marked. The following databases were searched:

- Cochrane Central Register of Controlled Trials (Cochrane Library, Wiley)
- Cochrane Database of Systematic Reviews (Cochrane Library, Wiley)
- Database of Abstracts of Reviews of Effects (Cochrane Library, Wiley)
- Embase (Ovid SP)
- Health Technology Assessment Database (Cochrane Library, Wiley)
- MEDLINE and MEDLINE in Process (Ovid SP)
- NHS Economic Evaluation Database (Cochrane Library, Wiley)

- PubMed.

Evidence selection

A total of 261 records were retrieved from the literature search. After de-duplication, 182 records remained for assessment. One recently published study, not included in any of the resources searched as of 2 March 2016 due to its publication date, was additionally provided by the device manufacturer, taking the total number of records to 183. The title and abstracts of all 183 records were screened independently by 2 reviewers, against the inclusion and exclusion criteria listed below:

Inclusion criteria:

- Includes the 1 level or 2 level Mobi-C cervical disc.
- Comparative studies, including systematic reviews and meta-analysis.
- Paper records at least 1 outcome measure (for example, not an opinion piece), including, but not limited to: patient mobility score, occurrence of adjacent segment disease, rate of adjacent segment degeneration, rate of revision surgery.

Exclusion criteria:

- Non-English language studies.
- Conference abstracts.
- Review protocols.
- Low patient numbers (that is n<15).

During the first sift 136 papers were excluded, with initial disagreements resolved following discussions between the 2 reviewers. Following the first sift a further 28 papers were excluded as they were identified to be conference abstracts. Full records were retrieved for the remaining 19 papers and a second sift was undertaken against the same inclusion and exclusion criteria. Again, disagreements between the 2 reviewers were resolved through discussion, with a further 7 papers were excluded for:

- No data specific to Mobi-C (n=3).

- Low patient numbers (n=2).
- Non-comparative study (n=1).
- Not a clinical evaluation (n=1).

Of the remaining 12 papers, 5 were selected for inclusion in this briefing. One of the papers was a systematic review and 2 reported on long-term follow-up data of 2 RCTs, whose shorter term data had been published previously. The other 7 papers were excluded for the following reasons:

- Study assessed in the included systematic review (n=5).
- Longer term follow-up data presented in included RCT (n=1).
- Comparison of 1-level vs 2-level Mobi-C, rather than Mobi-C vs comparator (n=1).

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by Newcastle & York External 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.

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The following specialist commentators provided comments on a draft of this briefing:

- Mr Roger Strachan, Consultant Neurosurgeon, South Tees NHS Foundation Trust
- Mrs Elaine Buchanan, Consultant Physiotherapist, Oxford University NHS Foundation Trust
- Mr Ashley Cole, Consultant Spinal Surgeon, Sheffield Teaching Hospitals NHS Foundation Trust

Declarations of interest

Mr Ashley Cole has received a fellowship sponsored by DePuy Synthes, which produce devices used in anterior cervical discectomy and fusion procedures and also a prosthesis that can be used for cervical disc replacement.

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