NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis

Osteoarthritis of the inner aspect of the knee can cause pain and inflammation especially when the knee joint bears too much weight.

Implantation of a shock or load absorber involves attaching a device between the thigh bone and the shin bone, alongside the knee joint, to share some of the load on the knee when standing. No tissue or bone is removed during the procedure, allowing further surgery if needed. The device can be removed.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in March 2014.

Procedure name

- Implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis

Specialist societies

- British Association Surgery of the Knee (BASK).

Description

Indications and current treatment

Osteoarthritis of the medial compartment of the knee is the result of progressive deterioration of the articular cartilage and menisci of the joint. This leads to exposure of the bone surface and chronic excessive joint loading during movement. Symptoms include joint pain, stiffness, local inflammation, limited movement and loss of knee function.

Treatment depends on the severity of the osteoarthritis. Conservative treatments include: analgesics and corticosteroid injections to relieve pain and inflammation; physiotherapy and exercise to improve function and mobility; and weight loss for people who are overweight or obese, as recommended in NICE's guideline on osteoarthritis. When symptoms are severe, surgery may be indicated. Options include high tibial osteotomy and unicompartmental or total knee arthroplasty.

What the procedure involves

The aim of this procedure is to lighten the load on the knee when the person is standing by inserting a load absorber. This reduces pain and potentially delays the need for further surgery. The device is implanted subcutaneously outside the knee joint, along its medial aspect. It is secured to the femur and tibia. It is intended to keep surrounding structures including bone, muscle and ligaments intact, allowing subsequent surgery to be performed if necessary. The device can be removed at a later date.

The procedure is performed with the patient under general anaesthesia and supine. Fluoroscopy is used to confirm alignment of the knee joint. Two incisions, over the medial aspect of the femoral and tibial condyles, are made. A femoral base plate is inserted through the proximal incision and attached to the medial femoral cortex using surgical screws; a tibial base plate is similarly attached to the medial tibial cortex. A tunnel is created between the 2 incisions beneath the skin using blunt dissection and the load absorber is implanted in this tunnel. The load absorber is attached to the 2 base plates. Its function is checked and the wounds are closed.

Osteoarthritis classification

Kellgren–Lawrence grading system

The Kellgren–Lawrence grading system employs radiographic images from X-rays to classify osteoarthritis according to the degree of joint space narrowing and the presence of osteophytes, which are small bony projections that form around joint margins that limit joint mobility and cause pain. The system consists of 5 categories:

- Grade 0: normal cartilage.
- Grade 1: possible osteophytes and unlikely joint space narrowing.
- Grade 2: small osteophytes and possible joint space narrowing.
- Grade 3: multiple, moderately sized osteophytes, definite joint space narrowing, some sclerotic areas, possible deformation of bone ends.
- Grade 4: multiple large osteophytes, severe joint space narrowing, marked sclerosis and definite bony end deformity.

Outcome measures

Western Ontario and McMaster Universities Osteoarthritis Index

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a standardised questionnaire that is extensively used to assess patients with osteoarthritis of the knee or hip. The questionnaire evaluates 3 domains – 5 pain-related activities (score range 0–20); 2 stiffness categories (score range 0–8) and 17 physical function activities (score range 0–68) of the lower extremities – and is based on recall over the previous 48 hours. The total score ranges from 0 to 96 with lower scores indicating better outcomes.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis. Searches were conducted of the following databases, covering the period from their commencement to 26-03-2014: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with mild to moderate symptomatic medial knee osteoarthritis.
Intervention/test	Implantation of a shock or load absorber.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 103 patients from 1 case series and 3 case reports.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis

Study 1, 2 London NJ (2013)

Details

Study type	**Case series**
Country	UK, Australia
Recruitment period	Not reported
Study population and number	Patients with symptomatic medial knee OA pain and dysfunction refractory to conservative treatments (from 3 prospective studies – OASYS [n=30], OAKS [n=30] and COAST [n=40]) trials) **n=99**
Age and sex	Mean 52 years (range 31–75 years) 75% (74/99) male; mean BMI 30 kg/m^2; disease severity grade: 3.0±0.7
Patient selection criteria	Primary common inclusion criteria were age 25 years and older and symptomatic, radiographically confirmed medial knee OA resistant to non-operative care. Common exclusion criteria included symptomatic lateral compartment or patellofemoral OA, varus alignment >10 degrees, inflammatory joint disease, prior traumatic knee injury, moderate to severe osteoporosis, previous surgery at the target knee, symptomatic instability, current smoking, active infection and clinically significant comorbidity (e.g. uncontrolled diabetes).
Technique	A joint sparing, extracapsular implant (KineSpring knee implant system) was implanted. General anaesthesia used in 77% patients.
Follow-up	**Mean 17 months [range, 1.5–48 months]**
Conflict of interest/source of funding	Authors disclose no funding sources. 3 authors received financial support from Moximed Inc.

Analysis

Follow-up issues: follow-up recorded as per protocol. Patient follow-up is ongoing through 5 years.

Study design issues: study entry criteria were similar among the 3 clinical trials.

Magnetic resonance imaging was performed at 1 and 2 years in the OASYS and OAKS trials only.

Patients from each study with a minimum of 6-week post-operative data (n=99) were included in the analysis.

Validated knee-specific patient-reported outcome tools were used to measure clinical outcomes.

Study population issues: disease severity was comparable to patients undergoing total knee arthroplasty (TKA).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **99**

Clinical outcomes

Technical success (defined as successful implantation and activation with no operative complications): 100%

Mean operative time: 67±17 minutes

Mean hospital stay: 1 day (range 1–13 days)

Knee-specific patient-reported outcomes

	Baseline	**6 weeks**	**1 year**	**p value and mean % decrease**
Knee pain severity* (mean±SD)	59±19	33±22	23±22	p<0.001 (60% improvement)

*assessed using a 0–100 visual analogue scale

The percentage of patients achieving the MCID for pain severity increased throughout the follow-up period, from 60% at 6 weeks to 76% at 1 year.

Knee joint mean range of motion decreased from $119^0 \pm 13^0$ to $105^0 \pm 19^0$ at 6-week post-operative period. It gradually increased to baseline levels at 1 year follow-up.

Clinical success (changes in WOMAC pain, function and stiffness scores)*

WOMAC domain	**Baseline**	**Final follow-up**	**p-value and mean % decrease**
Mean pain score	45±17	20±18	p<0.001 (56% improvement)
Mean function score	44±18	22±18	p<0.001 (50% improvement)
Mean stiffness score	52±21	32±24	p<0.001 (38% improvement)

*Clinical success for each WOMAC domain was defined as a ≥20% improvement from baseline.

Regardless of age group, gender, BMI or K–L grade (disease severity), all WOMAC domain scores significantly improved during the post-operative follow-up period (p<0.01).

Obese patients experienced significantly greater improvements in all WOMAC scores than non-obese patients (for pain 60% vs 48%; for function 58% vs 39%; for stiffness 47% vs 24% – all time-by-group p values <0.001).

WOMAC clinical success rates (≥20% improvement)

	Pain (%)	**Function (%)**	**Stiffness (%)**
Patients (n=99)	77.8	77.8	68.7

Neither gender, age, BMI, nor disease severity predicted clinical success in any WOMAC domain.

Patient characteristics had little association with post-operative clinical outcomes.

Safety

Adverse event	**% (n)**
Wound infection (hospitalised for 13 days), resolved with conservative treatment	1 (1/99)
Additional surgery for failure to improve symptoms (4 TKA, 2 HTO)	6 (6/99)
Device explanted between 2 and 10 months post-implant (due to no pain resolution)	4(4/99)
Recurring pain (within 6 months of implant)	2 (2/99)

Abbreviations used: BMI, body mass index; HTO, high tibial osteotomy; MCID, minimal clinically important difference; OA, osteoarthritis; TKA, total knee arthroplasty; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index questionnaire.

Study 3 Hayes DA (2012)

Details

Study type	**Case report**
Country	USA
Recruitment period	Not reported
Study population and number	Patients with bilateral knee OA, each with 1 knee previously and unsuccessfully treated with high tibial osteotomy. Severe pain and dysfunction in contralateral knee (K–L grade 2) for 2 years in case 1 and (K–L grade 1) for 1 year in case 2 that was resistant to conservative treatments. Subsequently treated with a joint sparing system. **n=2**
Age and sex	Case 1: 51-year-old female Case 2: 53-year-old obese male (BMI 39 kg/m^2)
Patient selection criteria	Dissatisfaction with previous surgical intervention (HTO), prolonged recovery and potential for compromised TKA outcomes by HTO and reluctance to undergo HTO procedure on the contralateral knee.
Technique	Contralateral knee treated with a joint sparing, extracapsular implant (KineSpring knee implant system).
Follow-up	**Case 1: 3 years; case 2: 1 year**
Conflict of interest/source of funding	2 authors are consultants to Moximed Inc.

Analysis

Study design issues: validated knee-specific questionnaires were used.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **2** **Case 1:** At 3 years' follow-up, all patient-reported outcomes were significantly improved compared with baseline: WOMAC pain score improved by 90% (50 to 5); WOMAC function score improved by 76% (41 to 10); WOMAC stiffness score improved by 100% (50 to 0); KSS knee score improved by 27% (79 to 100). **Case 2:** At 1-year follow-up, WOMAC pain score improved by 38% (40 to 25), WOMAC function score improved by 43% (44 to 25), WOMAC stiffness score improved by 50% (50 to 25), KSS knee score improved by 42% (62 to 88) and KSS function score improved by 138% (40 to 95).	No device- or procedure-related complications were reported during the procedure or in the follow-up period in both cases. No adverse radiographic findings have been reported through 1 year in case 2.
Abbreviations used: BMI, body mass index; HTO, high tibial osteotomy; KSS, knee society score; TKA, total knee arthroplasty; WOMAC questionnaire, Western Ontario and McMaster Universities Osteoarthritis Index questionnaire.	

Study 4 Bowditch M (2012)

Details

Study type	**Case report**
Country	USA
Recruitment period	2010
Study population and number	Patients with symptomatic knee OA (medial pain and catching in the left knee while playing tennis, intermittent mild medial pain with weight bearing over 2 years). Weight-bearing radiograph demonstrated moderate narrowing of the medial joint space, MRI showed a medial meniscal tear, herniation from the joint space with bone oedema within the medial tibial plateau, and osteochondral damage on the medial femoral articular surface. **n=1**
Age and sex	46-year-old male
Patient selection criteria	Not applicable
Technique	Patient underwent a joint sparing, extracapsular implant (KineSpring knee implant system) in July 2011, remained in hospital for 2 days, instructed to walk with crutches for 2 weeks to encourage wound healing, engage in light activities until 6 weeks and slowly resume physical activity as tolerated. Subsequently a novel 2-stage revision procedure was done because of local infection (first stage 3 months after initial implant procedure). The femoral and tibial wounds reopened, both bases of the KineSpring system remained in situ, and the absorber was removed in the first phase. Intravenous antibiotics administered for 48 hours and oral antibiotics for 6 weeks. A new absorber was placed 3 months after the infection resolved onto the pre-existing bases and activated. Post-operatively the patient was advised to gradually increase movement using crutches with minimum knee bending.
Follow-up	**5.5 months**
Conflict of interest/source of funding	Moximed Inc provided financial support for the development of the paper.

Analysis

Study design issues: no validated questionnaires were used to measure pain and knee function. Patient underwent arthroscopy and menisectomy before the joint sparing implant procedure.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **1** The first implantation procedure was uneventful. Patient reported immediate arthritic pain relief in the post-operative period. At 2 weeks, follow-up wounds were healed and range of motion was 90^0. At 5 weeks, patient expressed satisfaction with his progress (knee range of motion was 110^0, wounds healed, arthritic symptoms were non-existent). Local infection: at 6 weeks, patient reported redness and inflammation at the tibial wound following prolonged physical activity. Suspected bursitis was diagnosed and treated with 2-week course of antibiotics. At 8 weeks, the wound settled with minor inflammation. At 10 weeks, necrotic fat from a small sinus at the proximal end of the tibial wound discharged. Patient readmitted and necrotic tissue down to the tibial base was debrided. Antibiotic sensitive coagulase-negative staphylococci confirmed. Results after first stage revision procedure: after removal of the load absorber, patient reported arthritic medial knee pain with weight bearing. At 6 weeks, there was no evidence of infection. At 3 months, patient reported no wound problems, complete resolution of arthritic pain, 120^0 range of motion with normal ambulation, engaged in moderate physical activities with no complications, pain or joint dysfunction. No device- or procedure-related complications were reported during the initial or revision procedures.	
Abbreviations used: MRI, magnetic resonance imaging; OA, osteoarthritis.	

Study 5 Citak M (2013)

Details

Study type	**Case report**
Country	Germany
Recruitment period	2013
Study population and number	Patients with sudden knee pain and failed joint sparing, extracapsular implant system (due to breakage of the mechanism spring) in the treatment of medial knee OA, 7 months after implantation. **n=1**
Age and sex	75-year-old female, BMI 24.7 kg/m^2
Patient selection criteria	Not applicable
Technique	Patient underwent 2-step revision surgery for removal of the broken KineSpring knee implant system) for a painful right knee. In the first step, diagnostic arthroscopy was performed and in the second step femoral and tibial scars were excised and the device completely removed. Full weight bearing was allowed after surgery and the patient was discharged after 3 days. An elective TKA was planned.
Follow-up	**Post-procedure**
Conflict of interest/source of funding	None

Analysis

Study design issues: patient underwent arthroscopic menisectomy before 4 years and autologous osteochondrial mosaicplasty 3 years before the joint sparing implant procedure.

Patient was active in daily and sporting activities.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **1** 7 months after system implantation: patient had sudden onset of pain in the right knee without any trauma. Clinical examination revealed a swollen right knee, on the medial side, with concomitant soft tissue tenderness. No evidence of infection or neurological defects. Radiographs revealed a breakage of the spring. Outcome after revision surgery: arthroscopy in the first step revealed severe cartilage damage within the medial compartment with concomitant changes in the lateral and patellofemoral compartments. Extensive metallosis noted and the broken implanted system was removed entirely without any further complications.	
Abbreviations used: BMI, body mass index; OA, osteoarthritis; TKA, total knee arthroplasty.	

Efficacy

Implantation success

A case series of 99 patients with symptomatic medial knee osteoarthritis refractory to conservative treatment who received a shock load absorber reported that all devices were successfully implanted and activated[2].

Clinical success

Changes in WOMAC pain, function and stiffness scores

The case series of 99 patients reported improvements in the Western Ontario and McMaster Universities Osteoarthritis Index questionnaire (WOMAC). Statistically significant mean improvements of 56%, 50% and 38% were observed for the WOMAC pain, function and stiffness scales respectively (all $p<0.001$) during a mean follow-up of 17 months. All WOMAC domain scores significantly improved during this follow-up period ($p<0.01$), independent of age, gender, BMI or disease severity (K–L grade). WOMAC clinical success rates (defined as ≥20% improvement from baseline) were 78% for pain, 78% for function and 69% for stiffness[1,2].

Changes in knee pain severity scores

The case series of 99 patients reported that knee pain severity improved significantly after the procedure, from 59±19 at baseline, 33±22 at 6 weeks and gradually improved through 1 year (23±22) representing a 60% reduction in pain ($p<0.001$). The authors reported that the percentage of patients achieving the 'minimal clinically important difference' for pain severity increased throughout the follow-up period, from 60% at 6 weeks to 76% at 1 year[2].

Changes in knee joint range of motion

The case series of 99 patients reported that the mean range of motion of the knee decreased from $119^0 \pm 13^0$ to $105^0 \pm 19^0$ at 6 weeks after the operation. It gradually increased to baseline levels at 1-year follow-up[2].

Safety

Device failure and explantation

Device fracture 7 months after implantation was reported in a case report of 1 patient. The patient developed sudden knee pain and radiographs revealed that this was due to a breakage of the mechanism of the implant system. Two-step revision surgery was performed and the device was completely removed without any further complications[5].

In the case series of 99 patients[2], devices were explanted in 4% (4/99) of patients between 2 and 10 months post-implant because of no pain resolution.

Local infection

Wound infection after implantation was reported in 1 patient in the case series of 99 patients. The patient was hospitalised for 13 days and the infection resolved with conservative treatment[2].

Infection of the tibial wound due to prolonged physical activity was reported 6 weeks after implantation of the shock load absorber in a case report of 1 patient. The patient was initially treated with a 2-week course of antibiotics but at 10 weeks necrotic fat discharge was noted and antibiotic-sensitive coagulase-negative staphylococci were confirmed. The patient underwent a 2-stage revision procedure involving removal of the load absorber and antibiotics for 6 weeks and insertion of a new absorber 3 months after the infection was resolved. The patient reported arthritic medial knee pain after the removal of the load absorber. This resolved 3 months after the revision procedure[4].

Additional surgery

Additional surgery for failure to improve symptoms was needed in 6% (6/99) of patients in the case series of 99 patients. Four patients underwent total knee arthroplasty and 2 patients underwent high tibial osteotomy[2].

Recurring pain

Recurring pain within 6 months of implantation was reported in 2 patients in the case series of 99 patients. Further details were not reported[2].

Validity and generalisability of the studies

- One case series and 3 case reports were published on this topic.
- There is a lack of long-term data on this procedure.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Mini-incision surgery for total knee replacement. NICE interventional procedure guidance 345 (2010) (replaces IPG117). Available from http://www.nice.org.uk/guidance/IPG345
- Individually magnetic resonance imaging-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee. NICE interventional procedure guidance 317 (2009). Available from http://www.nice.org.uk/guidance/IPG317
- Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis. NICE interventional procedure guidance 230 (2007). Available from http://www.nice.org.uk/guidance/IPG230
- Mosaicplasty for knee cartilage defects. NICE interventional procedure guidance 162 (2006). Available from http://www.nice.org.uk/guidance/IPG162

Clinical guidelines

- Osteoarthritis: Care and management in adults. NICE clinical guideline 177 (2014) (replaces CG59). Available from http://www.nice.org.uk/guidance/CG177

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their specialist society or royal college. The advice received is their individual opinion and does not represent the view of the society.

Mr William Jackson, Mr David Johnson, Mr Nick London, Mr Andrew Porteous, British Association for Surgery of the Knee (BASK).

- One specialist adviser performs the procedure regularly and 3 advisers have never performed it.
- Three advisers consider the procedure definitely novel and of uncertain efficacy and safety for early knee osteoarthritis and think that it may be efficacious in delaying the need for joint replacement in young patients. One adviser considers it as the first in a new class of procedure.

- Two advisers considered that the title should state whether the device is intra- or extra-articular. They suggest adding the term ‘extra-articular’ to the existing title.
- Conservative treatments (for example, braces, lateral wedge insoles, exercise programmes or pain management) or surgical procedures (for example, high tibial osteotomy, medial unicompartmental knee replacement or total knee replacement) are the best comparators for this procedure.
- Advisers stated that fewer than 10% of specialists are currently engaged in this area of work in the UK.
- Theoretical adverse events listed include risk of surgical intervention; thrombotic events (deep vein thrombosis leading to pulmonary embolism); infection (most likely superficial but potentially deep within bone and/or knee joint); implant dislocation; implant loosening; breakage of implanted components; mechanical irritation of adjacent soft tissues (skin causing breakdown, medial collateral ligament causing potential attrition); stiffness of the knee; failure of device to alleviate symptoms due to failure in design concept or malpositioning during implantation; bone loss adjacent to anchoring sites that could compromise future salvage surgery including joint replacement; need for further surgical interventions or revision to joint replacement.
- Anecdotal adverse events reported include infection, soft tissue irritation, impingement, dislocation, breakage or uncoupling of the device needing removal.
- Key efficacy outcomes listed include reduction in knee pain due to off-loading of medial joint osteoarthritis, improved function and activity, patient-reported outcomes (for example, Oxford Knee Score, WOMAC scores, Knee Society Score, University of California Los Angeles activity score, EQ-5D, patient satisfaction scales) and delayed need for knee replacement. Advisers stated that the long-term efficacy of this procedure is unknown (especially if revision surgery is needed) and there is a lack of studies comparing the procedure against other standard treatments. A European multicentre comparative study

– GOAL (shock or load absorber versus high tibial osteotomy) – is currently in progress.

- One adviser suggested that data should be collected and submitted to the Knee Osteotomy Register, which is currently being set up with the approval of BASK.
- Specialist advisers stated that cadaveric surgical training organised by the manufacturer and the opportunity to observe experienced surgeons performing the procedure are needed.
- Advisers stated that the speed of diffusion for this procedure is likely to be slow unless efficacy is proved superior to other current treatments, it is likely to be carried out in a minority of hospitals in the UK and the potential impact on the NHS is moderate to minor in the long term.
- One adviser stated that the patient population that may be indicated for the procedure is large. If shown to be safe, cost effective and superior to current treatments, then its use could be significant.

Patient commentators' opinions

NICE's Public Involvement Programme sent 19 questionnaires to 1 clinician carrying out this procedure. NICE received 11 completed questionnaires. The completed questionnaires represented patients aged between 42 and 64 years (mean=55 years, median=56 years). One patient (9%) was female and 10 patients (91%) were male.

In summary more people were positive about the procedure than negative, saying that it helped them with their day-to-day activities and their general wellbeing. However some reported a limit in bend or flexibility in the knee, some could feel the device, and those who do sports tended not to regain their full sporting capacity. Nearly all would recommend the procedure but a number pointed out the longer than anticipated recovery time.

Issues for consideration by IPAC

- Currently clinical studies investigating the shock or load absorber are ongoing in Australia, Europe and the USA. These include:
  - ISRCTN63048529: COAST study: a multicentre open-label interventional study of patients with medial compartmental knee osteoarthritis symptoms treated with the KineSpring Unicompartmental Knee Arthroplasty (UKA) System; study type: prospective non-randomised uncontrolled study; location: Belgium, UK; estimated enrolment: 40; primary outcome: KSS function score 6 months post-implantation. (Study completed; results included in study 2, 3.)
  - NCT01738165: SOAR study: a prospective, multicentre pilot study to evaluate symptom relief in patients with medial knee osteoarthritis treated with the KineSpring knee implant for load reduction; study type: prospective uncontrolled study; location: USA; estimated enrolment: 60; estimated completion date: February 2019; primary outcome: rate of individual patient success at 24 months.
  - NCT01610505: GOAL (post-marketing) study: a global, prospective, multicentre, non-randomised, controlled non-inferiority trial to evaluate symptom relief in patients with medial knee osteoarthritis treated with the KineSpring knee implant for load reduction compared with HTO; study type: non-randomised parallel assignment; location: Belgium, Germany, Luxembourg, UK; estimated enrolment: 225; estimated completion date: June 2018; primary outcome: WOMAC pain and function subscales at 24 months, procedure- and device-related complications.
- The implant system has specific indications and contraindications for use that limit the applications of this implant.
- The KineSpring knee implant system is not approved by the Food and Drug Administration in the USA.

References

1. London NJ, Smith J, Miller LE, and Block JE (2013). Midterm outcomes and predictors of clinical success with the KineSpring knee implant system. Clinical Medicine Insights: Arthritis and Musculoskeletal Disorders.6.
2. London NJ, Smith J, Miller LE, and Block JE (2013). Bridging the osteoarthritis treatment gap with the Kinespring knee implant system: early evidence in 100 patients with 1-year minimum follow-up. Orthopedic Research and Reviews 5, 65-73.
3. Hayes DA, Miller LE, and Block JE (2012). Knee Osteoarthritis Treatment with the KineSpring Knee Implant System: A Report of Two Cases. Case Reports in Orthopedics 2012 297326.
4. Bowditch M, Miller LE, and Block JE (2012). Successful two-stage revision of a KineSpring joint unloading implant: a case study. International Medical Case Reports Journal 5 91-95.
5. Citak M, Kendoff D, PF et al (2013). Failed joint unloading implant system in the treatment of medial knee osteoarthritis. Archives of Orthopaedic & Trauma Surgery 133 (11) 1575-1578.

Appendix A: Additional papers on implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Clifford A, O'Connell M Gabriel, S et al (2011). The KineSpring load absorber implant: rationale, design and biomechanical characterization. Journal of Medical Engineering & Technology 35:65-71.			Preclinical testing
Clifford AG, Gabriel SM et al (2013). The KineSpring Knee Implant System: an implantable joint-unloading prosthesis for treatment of medial knee osteoarthritis. Medical Devices Evidence and Research 6 69-76.	KineSpring System, (implant characteristics, principles of operation, indications for use, patient selection criteria, surgical technique, postoperative care, preclinical testing, and clinical experience)	Preclinical and clinical studies have demonstrated excellent prosthesis durability, substantial reductions in medial compartment and total joint loads, and clinically important improvements in OA-related pain and function.	Review
Elizabeth A et al (2014). Early knee osteoarthritis management should first address mechanical joint overload. Orthopedic Reviews 6:5188.			Review
Farr J, Crawford DC et al (2013). Prospective, multi-center, pilot study to evaluate symptom relief in patients with medial knee osteoarthritis (OA)	Subjects with symptomatic osteoarthritis of the medial compartment of the knee KineSpring Knee Implant System.	Will collect data on the safety and effectiveness of the KineSpring in patients with primarily unicompartmental medial knee osteoarthritis through 24 months of postoperative follow-up.	Protocol

treated with the KineSpring knee implant for load reduction - the SOAR protocol. Journal of Long-Term Effects of Medical Implants 23 (2-3) 161-173.			
Ferdick A (2012). An alternative unloading implant for medial knee OA in the young and active patient. Journal of Bone Joint Surgery. vol 94-B no. suppl XL 4.	n=79 Patients with isolated medial knee OA. Follow-up-2.5 years mean age -52 years BMI>30kg/m2	Mean surgical time 72 minutes. Patients recovered rapidly and achieved full weight bearing within 1-2 weeks and normal range of motion by 6 weeks. Significant pain relief and functional improvement by 6 weeks, sustained beyond 2 year follow-up. WOMAC pain improved from 43 at baseline to 13 at 2 years ($p<0.001$), function 43 to 11 ($p<0.001$) stiffness from 52 to 18 ($p<0.001$). Patients reported satisfaction with implant.	Conference abstract Belgium
Gabriel SM, Clifford AG et al (2013). Unloading the osteoarthritic knee with a novel implant system. Journal of Applied Biomechanics 29 (6) 647-654.	6 cadaver knees with Outerbridge Grade I-II medial OA. Knees were tested with and without the medial knee implant.	Significant medial compartment load reductions (134 + 53 N [P = .002]) were found throughout the stance phase of gait, significant total joint load decreases (91 + 40 N [P = .002]) were observed without substantial changes in lateral compartment loads in treated knees. These reductions are within clinically effective ranges of other unloading systems.	Preclinical testing
Hak A, Li CS, and Bhandari M (2013). Cost-effectiveness and economic impact of the KineSpring Knee Implant System in the treatment of knee osteoarthritis in the United Kingdom. Journal of Long-Term Effects of Medical Implants 23 (2-3) 199-210.		Assuming lifetime durability, the cost-utility ratios of surgical treatment, total knee arthroplasty (TKA), the KineSpring System, and conservative treatments, compared to no treatment are 1,303+22/QALY, 821+175/QALY, 796+73/QALY and 11,096+1188/QALY, respectively. Assuming a treatment durability of 10 years, the cost-utility ratio of surgical treatment, TKA, the KineSpring System, and conservative treatments, compared to no treatment are 4,153+95 per QALY, 2,698+768 per QALY, 2,848+345 per QALY, and 10,624+1528 per QALY, respectively. KineSpring System is a cost-effective treatment for knee OA and is comparable to current standard-of-care treatments.	Costs, not in IP remit
Li CS, Ayeni OR, Sprague S et al	Systematic reviews on	Medications and viscosupplementation show	Overview of systematic

(2013). Conservative treatments, surgical treatments, and the Kinespring Knee implant system for Knee osteoarthritis: A systematic review. Journal of Long-Term Effects of Medical Implants. (2-3) 105-149.	treatment strategies for knee OA. We pooled results for each treatment in three categories: pain, function, and stiffness. Then we compared this data to that available for the KineSpring System.	promising initial pain relief for knee OA. Aerobic and resistance training, unicompartmental knee arthroplasty (UKA), and total knee arthroplasty (TKA) showed a reduction in pain scores. High tibial osteotomy (HTO) generally improves pain and function at 6 weeks, but long-term results are lacking. The KineSpring System demonstrated significant improvements from baseline to 24 months, but direct comparative data are lacking.	reviews for different knee treatments and indirect comparison with OASYS trial data.
Li CS., Poolman RW, and Bhandari M (2013). Treatment preferences of patients with early knee osteoarthritis: a decision board analysis assessing high tibial osteotomy versus the KineSpring Knee Implant System. Journal of Long-Term Effects of Medical Implants 23 (2-3) 175-188.	n=81 questions on treatment preferences, willingness to pay KineSpring Knee Implant System	Of 81 respondents, the KineSpring System was preferred by 60% (n = 49). Individuals selecting KineSpring would be willing to pay an average of $2,700 to receive it over HTO.	Decision board analysis
Li CS, Path R et al (2013). Is the treatment gap in knee osteoarthritis real? A qualitative study of surgeons' perceptions. Journal of Long-Term Effects of Medical Implants 23 (2-3) 223-240.	n=10 focus group and semi-structured interviews KineSpring Knee Implant System	Orthopedic healthcare professionals are enthusiastic about the prospect of the KineSpring System as an option to help close the treatment gap in knee OA. Focusing only on clinical trials with long-term data may be impractical and deprive patients and society of benefits that can be gained while trial data are maturing.	Qualitative study
Li CS., Seeger T et al (2013). Cost-effectiveness and economic impact of the KineSpring Knee Implant System in the treatment for knee osteoarthritis. Knee Surgery, Sports Traumatology, Arthroscopy 21 (11) 2629-2637.		Assuming the durability of 10 years, the cost-utility ratio of the KineSpring System, surgical treatments and conservative treatments compared to no treatment in 2012 was euro>3,402/QALY, euro 4,899/QALY and euro 9,996/QALY, respectively. With even a lesser durability of 5 years, the cost-utility ratio of the KineSpring System maintained superiority over surgical treatments and conservative treatments (euro 7,327/QALY, euro 9,706/QALY and euro 10,467/QALY, respectively). The KineSpring System is a highly cost-effective alternative for knee osteoarthritis compared with the current accepted cost-effective threshold (willingness to pay) of $50,000 US/QALY gained. Our models	Costs, not in IP remit

		suggest KineSpring System, if adapted widely could save up to 2.0 + 0.07 million QALY assuming it has a 5-year durability and save up to 3.9 + 0.1 million QALY assuming it has a 10-year durability.	
Li CS. and Bhandari M (2013). Cost-effectiveness of unicompartmental knee arthroplasty, high tibial osteotomy, and KineSpring Knee Implant System for unicompartmental osteoarthritis of the knee. Journal of Long-Term Effects of Medical Implants 23 (2-3) 189-198.		Cost-effectiveness of UKA, HTO and the KineSpring System in terms of QALY gained compared to patients without treatment yielded gains of approx. $5150/QALY, $6754/QALY, and $7010/QALY, respectively. Using the accepted standard willingness-to-pay threshold of $50,000 US/QALY gained, the UKA, HTO, and the KineSpring System are economically favorable. Our analysis demonstrates that the KineSpring System, despite a greater initial cost in surgery, has significantly smaller conversion and complication costs compared to UKA and HTO. The 10 years overall expected cost for the KineSpring System ($12,559) is significantly less compared with that of UKA ($17,570) and HTO ($22,825).	Costs, not in IP remit
London N et al (2011) Treatment of medial compartment knee osteoarthritis using an implantable load absorber: UK and Australian experience. Orthopaedic proceedings.	n=58 Follow-up: 24 months	Mean WOMAC pain (0-100 scale) improved from 42.4 to 16.1 (p<0.001); mean WOMAC function (0-100 scale) improved from 42.0 to 14.7 (p<0.001). Most patients reported “no or mild” pain (85%) or “no or mild” functional impairment (90%) at last follow-up (9.5 ± 3.5 months). Patients reported high satisfaction with the implant. Complications arising in the early surgical experience were resolved through revised surgical technique and minor design modifications.	Conference abstract.
Marcacci M, Zaffagnini S et al (2013). Cost-effectiveness and economic impact of the KineSpring Knee Implant System in the treatment of knee osteoarthritis in Italy. Journal of Long-Term Effects of Medical Implants 23 (2-3) 211-222.		Assuming lifetime durability, the cost-utility ratios of total knee arthroplasty (TKA), unicompartmental knee arthroplasty (UKA), high tibial osteotomy (HTO), the KineSpring System, and conservative treatments, compared to no treatment were 2348+70 per QALY, 2040+61 per QALY, 2281 + 68 per QALY, 1669+268 per QALY, and 11,688+2185 per QALY, respectively. Assuming a treatment durability of 10 years, the cost-utility ratio of TKA, UKA, HTO, the KineSpring System and conservative treatments, compared to no treatment were 4,884+323 per QALY, 4243+280 per QALY, 4,744 +313 per QALY, 3757+1353 per QALY, and 10,575+4414 per QALY, respectively.	Costs, not in IP remit
Stiebel M, Miller LE et al (2014). Post-			Review

traumatic knee osteoarthritis in the young patient: therapeutic dilemmas and emerging technologies Open Access Journal of Sports Medicine, 5 73–79			

Appendix B: Related NICE guidance for implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis

Guidance	Recommendations
Interventional procedures	**Mini-incision surgery for total knee replacement. NICE interventional procedure guidance 345 (2010) (replaces IPG117)** 1.1 Current evidence on the safety and efficacy of mini-incision surgery for total knee replacement is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Mini-incision surgery for total knee replacement should only be carried out by surgeons with specific training in the procedure. 1.3 Surgeons should submit details on all patients undergoing mini-incision surgery for total knee replacement to the National Joint Registry. **Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis. NICE interventional procedure guidance 230 (2007)** 1.1 Evidence on the safety and efficacy of arthroscopic knee washout with debridement for the treatment of osteoarthritis is adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance. 1.2 Current evidence suggests that arthroscopic knee washout alone should not be used as a treatment for osteoarthritis because it cannot demonstrate clinically useful benefit in the short or long term. **Mosaicplasty for knee cartilage defects. NICE interventional procedure guidance 162 (2006)** 1.1 Current evidence suggests that there are no major safety concerns associated with mosaicplasty for knee cartilage defects. There is some evidence of short-term efficacy, but data on long-term efficacy are inadequate. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and audit or research. 1.2 Clinicians wishing to undertake mosaicplasty for knee cartilage defects should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and the options for alternative treatments. They should provide them with clear written information. In addition, use of the Institute's information for the public is recommended.

	• Audit and review clinical outcomes of all patients having mosaicplasty for knee cartilage defects. The Institute may review the procedure upon publication of further evidence. **Individually magnetic resonance imaging-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee, IPG317 (September 2009)** **http://guidance.nice.org.uk/IPG317** 1.1 Current evidence on the safety and efficacy of individually magnetic resonance imaging (MRI)-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research studies. These should include clear descriptions of patient selection; and should report both objective and patient-reported outcomes and the length of time before joint replacement is required. 1.2 NICE may review the procedure on publication of further evidence.
Clinical guidelines	**Osteoarthritis: care and management in adults (replaces CG59) NICE clinical guideline 177 (2014)** 1.4 Non-pharmacological management *Invasive treatments for knee osteoarthritis* 1.4.10 Do not refer for arthroscopic lavage and debridement[3] as part of treatment for osteoarthritis, unless the person has knee osteoarthritis with a clear history of mechanical locking (as opposed to morning joint stiffness, 'giving way' or X-ray evidence of loose bodies). **[2008, amended 2014]** [3] This recommendation is a refinement of the indication in Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis (NICE interventional procedure guidance 230 [2007]). The clinical and cost-effectiveness evidence for this procedure was reviewed for the original guideline (published in 2008), which led to this more specific recommendation on the indication for which arthroscopic lavage and debridement is judged to be clinically and cost effective. 1.5 Pharmacological management *NSAIDs and highly selective COX-2 inhibitors* Although NSAIDs and COX-2 inhibitors may be regarded as a single drug class of 'NSAIDs', these recommendations use the two terms for clarity and because of the differences in side-effect profile. 1.5.6 Where paracetamol or topical NSAIDs are ineffective for pain relief for people with osteoarthritis, then substitution with an oral NSAID/COX-2 inhibitor should be considered. **[2008]** 1.5.7 Where paracetamol or topical NSAIDs provide insufficient pain relief for people with osteoarthritis, then the addition of an oral NSAID/COX-2 inhibitor to paracetamol should be considered. **[2008]** 1.5.8 Use oral NSAIDs/COX-2 inhibitors at the lowest effective dose for the shortest possible period of time. **[2008]** 1.5.9 When offering treatment with an oral NSAID/COX-2 inhibitor, the

	first choice should be either a standard NSAID or a COX-2 inhibitor (other than etoricoxib 60 mg). In either case, co-prescribe with a proton pump inhibitor (PPI), choosing the one with the lowest acquisition cost. **[2008]** 1.5.10 All oral NSAIDs/COX-2 inhibitors have analgesic effects of a similar magnitude but vary in their potential gastrointestinal, liver and cardio-renal toxicity; therefore, when choosing the agent and dose, take into account individual patient risk factors, including age. When prescribing these drugs, consideration should be given to appropriate assessment and/or ongoing monitoring of these risk factors. **[2008]** 1.5.11 If a person with osteoarthritis needs to take low-dose aspirin, healthcare professionals should consider other analgesics before substituting or adding an NSAID or COX-2 inhibitor (with a PPI) if pain relief is ineffective or insufficient. **[2008]** *Intra-articular injections* 1.5.12 Intra-articular corticosteroid injections should be considered as an adjunct to core treatments for the relief of moderate to severe pain in people with osteoarthritis. **[2008]** 1.5.13 Do not offer intra-articular hyaluronan injections for the management of osteoarthritis. **[2014]**

Appendix C: Literature search for implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)//	14/10/2014	Issue 10 of 12, October 2014
Database of Abstracts of Reviews of Effects – DARE (Cochrane Library)	14/10/2014	Issue 3 of 4, July 2014
HTA database (Cochrane Library)	14/10/2014	Issue 3 of 4, July 2014
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	14/10/2014	Issue 9 of 12, September 2014
MEDLINE (Ovid)	14/10/2014	1946 to October Week 1 2014
MEDLINE In-Process (Ovid)	14/10/2014	October 13, 2014
EMBASE (Ovid)	14/10/2014	1974 to 2014 Week 41
PubMed	14/10/2014	n/a
JournalTOCS	14/10/2014	n/a

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

# ▲	Searches
1	arthritis/ or arthritis, rheumatoid/
2	Knee/ or Knee Joint/
3	1 and 2
4	Osteoarthritis, Knee/
5	((Inner* or inside* or symptomatic* or medial*) adj4 knee* adj4 (osteoarthrit* or arthrit*)).tw.
6	(Medial* adj4 (compartment* or unicompart*) adj4 (osteoarthrit* or arthrit*)).tw.
7	(Knee* adj4 (osteoarthrit* or arthrit* or degenerat* or deteriorat* or injur* or damag* or weak*)).tw.
8	(Symptomatic* adj4 medial* adj4 OA).tw.
9	MKOA.tw.
10	Gonarthros*.tw.

11	or/3-10
12	Orthotic Devices/
13	knee prosthesis/
14	(Unload* or load* or shock* or absorb* or bypass* or by-pass* or by pass*).tw.
15	Biomechanical Phenomena/
16	(biomechanical* adj4 (phenomen* or device* or system* or treat* or tech* or therap*)).tw.
17	or/12-16
18	"Prostheses and Implants"/ or Bone Screws/
19	(Implant* or attach* or screw*).tw.
20	or/18-19
21	11 and 17 and 20
22	KineSpring.tw.
23	"Knee Implant System".tw.
24	Moximed.tw.
25	21 or 22 or 23 or 24
26	animals/ not humans/
27	25 not 26
28	**limit 27 to english language**
29	**limit 28 to ed=20140730-20141031**