NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of individually magnetic resonance imaging-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee

Osteoarthritis of the knee can cause pain, stiffness, swelling and difficulty in walking. In this procedure, an individually designed implant is inserted at the knee between the thigh and shin bones to realign the knee and prevent bone-on-bone rubbing. This aims to reduce pain and delay the progression of osteoarthritis and the need for further, more invasive surgery, such as knee replacement.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this 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 overview was prepared in December 2008.

Procedure name

- Individually magnetic resonance imaging-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee

Specialty societies

- British Association for Surgery of the Knee
- British Orthopaedic Association

Description

Indications and current treatment

Osteoarthritis of the knee is the result of progressive degeneration of the menisci and articular cartilage of the joint, leading to exposure of the bone surface. It causes pain, stiffness, swelling and difficulty in walking.

Treatment options depend on the severity of the osteoarthritis. The condition is usually chronic, and different treatment strategies may be required at different stages. Conservative treatments include medication to relieve pain and inflammation, physiotherapy and/or prescribed exercise, and corticosteroid injection.

If these therapies do not adequately relieve symptoms, patients may be offered surgical options, such as upper tibial osteotomy or unicompartmental or total knee replacement. Upper tibial osteotomy works by realigning the leg to reduce the pressure on the damaged part of the knee. Unicompartmental knee replacement involves replacing either the inner or outer side of the knee where arthritis affects only part of the joint. The patient may need a total knee replacement following either of these procedures. All of these operations are major procedures that involve significant rehabilitation time for the patient, and joint replacements are likely to need revision over time, particularly in younger patients.

What the procedure involves

The aim of this procedure is to manage pain and increase function in a way that preserves the bone and delays the need for a knee replacement.

Before the operation, the knee is scanned using magnetic resonance imaging (MRI). A metallic implant is then designed based on the surface measurements of the patient's joint and the level of cartilage loss, which is determined from the MRI scan.

The operation is usually performed with the patient under general anaesthesia and often as day surgery. Before implantation, the patient may have an arthroscopic procedure to remove osteophytes. The implant is inserted through a 4–6 cm incision placed either medially or laterally depending on the change in leg axis required. The prosthesis is then slid into position between the femur and the tibia. Its position may be confirmed using fluoroscopy. Bone cuts and articular cartilage removal are not needed in this procedure.

Efficacy

A case series of 27 patients with early to mid-stage unicompartmental knee osteoarthritis treated by arthroscopic removal of osteophytes followed by MRI-designed implant insertion reported that the average correction of leg axis from was from -4.4° preoperatively to -0.9° postoperatively. Successful leg axis correction to 0° and/or slight undercorrection of up to 2° was reported

in 85% (23/27) of patients[1]. The authors considered this to be a successful correction (preoperative leg axis measurements not given).

The remaining 4 patients were reported to have had overcorrections of leg axis of 0.2°, 0.5°, 0.9° and 0.9°. MRI showed a low average correction loss of 0.5° (range 0–1°) at random check-ups of 12–22 months.

The same study reported the correlation coefficient between implant offset (minimal thickness of the implant) and extent of axis correction to be 0.838 (a value of 0.80 was considered 'good').

The study reported a mean operating time from incision to suture of 47 minutes.

Safety

The case series reported that there were no dislocations intra- or postoperatively. It did not report any other safety data.

Two consultation respondents reported unpublished safety data.

One respondent reported that the rate of revision in a clinical trial of 84 patients was approximately 5% (absolute number and time of revision surgery not given).

A second respondent reported implant dislocation in 7% (4/60) of patients treated with the MRI-designed implant (time of occurrence not stated).

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to insertion of individually MRI-designed unicompartmental interpositional implant in osteoarthritis of the knee. Searches were conducted of the following databases, covering the period from their commencement to 06/11/08 and updated on 26/06/09: 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).

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 unicompartmental osteoarthritis of the knee.
Intervention/test	Insertion of individually MRI-designed unicompartmental interpositional implant.
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 overview

This overview is based on 27 patients from one case series[1] and unpublished safety data.

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

- Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis. NICE interventional procedures guidance 230 (2007). Available from www.nice.org.uk/IPG230
- Artificial trapeziometacarpal joint replacement for end-stage osteoarthritis. NICE interventional procedures guidance 111 (2005). Available from www.nice.org.uk/IPG111

Clinical guidelines

- Osteoarthritis: the care and management of osteoarthritis in adults. NICE clinical guideline 59 (2008). Available from www.nice.org.uk/CG59

Table 2 Summary of key efficacy and safety findings on Individually MRI-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee

Study details	Key efficacy findings	Key safety findings	Comments
Koeck F et al (2008)[1] **Case series** Germany Study period: June 2005 – April 2007 Study population: early to moderate-stage unicompartmental knee osteoarthritis (Kellgren-Lawrence grade 3 or below); all patients underwent at least one preliminary arthroscopic procedure to remove osteophytes with partial and/or subtotal meniscus resection. n = **27** Average age: 55.3 years (range 38–57) Sex: 56% female, 44% male Inclusion criteria: all sequential cases included Technique: MRI was performed before surgery (to design implant) with anteroposterior single-leg stance and 6 weeks postoperatively. An MRI-designed implant (iForma manufactured by ConforMIS) was inserted through incision (average size: 5.2 cm, range: 3.8–7.2 cm). Follow-up: **6 weeks** Conflict of interest: none	***Correction of leg axis*** Average correction in leg axis was from –4.4° (SD: 0.81°) preoperatively to –0.9° postoperatively (SD: 1.12°). Leg axis was corrected as intended (to 0° and/or slight undercorrection of up to 2°) in 85% (23/27) of patients (preoperative figures not given). The remaining four cases had a slight overcorrection in leg axis of 0.2°, 0.5°, and two patients with 0.9°. Correlation coefficient between implant offset (minimal thickness of the implant) and extent of axis correction: r = 0.838 (previous author Lienert was quoted to consider a 0.8 value as 'good'). New axis images performed in random check-ups of 12–22 months in the four patients with overcorrection in leg axis showed a low correction loss average 0.5° (range 0–1°). ***Mean operative time***: 47 minutes (range: 34–102) (from incision to suture). (Operating time was occasionally longer in some cases [exact number not stated] where a difficult meniscetomy required careful removal of osteophytes – this explains the operation that ran for 102 minutes.)	The study reported that there were no dislocations of the implant (intraoperative or postoperative).	The objective of this study was to correct leg axis. The authors noted that optimal leg axis correction is still uncertain. They also noted that the self-fixating feature of this implant aims to overcome the problem of dislocations in earlier non-customised implants.

Study details	Key efficacy findings	Key safety findings	Comments
Unpublished reports from consultation respondents Technique: insertion of MRI-designed implant (iForma). Follow-up = not stated Conflict of interest: not stated	n/a	Two consultees reported safety data: - An unpublished clinical trial including 84 patients reported that the rate of revision was approximately 5% (exact number and time of occurrence not stated). - Implant dislocation in 7% (4/60) of patients (time of occurrence not stated).	These reports are not published, but are included in accordance with the Interventional Procedures Programme Methods Guide regarding inclusion of evidence on safety.

Validity and generalisability of the studies

- Only one study was identified; it presents data on a small case series of patients (there are no comparative data).
- The study looked specifically at the use of this procedure for leg axis correction; it did not include patient-specific or patient-reported outcomes that have been highlighted by the Specialist Advisers as important (such as pain relief).
- The study had minimal follow-up.
- All patients involved in the study had arthroscopy before the procedure.
- One patient had a prior matrix-associated chondrocyte transplantation – it is not clear whether this could have had a significant effect on the functioning of the implant.
- Data on the safety of this procedure were reported by two respondents at consultation. These data have been included in accordance with the Interventional Procedures Programme methods guide, which states that data on safety may be considered by the Committee regardless of its source and publication status.

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 Simon Donell, Mr Phil Hirst and Mr Tim Wilton (British Association for Surgery of the Knee)

- None of the Specialist Advisers has performed this procedure; two of the three Advisers have undertaken bibliographic research.
- All Advisers believed this procedure to be novel and of uncertain efficacy and safety, and stated that less than 10% of specialists are engaged in this area.
- They considered comparators to include unicompartmental knee replacement (fixed to the bone) and high/upper tibial osteotomy.

- One Adviser stated that this is an experimental procedure that is a modern version of a McKeever or MacIntosh interpositional implant that ‘fell out of favour’ because of poor mid- to long-term results.
- One Adviser noted that limited literature has been published on this procedure, and what has been published was largely produced by the device developers. Another stated that there have been no comparative studies, despite US Food and Drug Administration approval.
- All Specialist Advisers thought that there is likely to be relatively slow diffusion of this procedure until adequate clinical outcomes are proven and unless there is major marketing of the procedure. All Advisers agreed that surgeons will need convincing that this procedure is beneficial and safe in the long term, by properly conducted trials that have a follow-up of at least 5 years.

Efficacy

- The Specialist Advisers considered key efficacy outcomes to include reduced pain, ability to return to work and perform activities of daily living and sports and the length of time before revision to another type of knee implant or joint replacement.
- Two Advisers considered the uncertainties about the efficacy of the procedure to be similar to the uncertainties about the implants that preceded the MRI-designed implant. These include poor improvement in pain and a high revision rate compared with other standard types of knee replacement (which may also have been caused by dislocation or subluxation of the devices).
- Another Adviser stated that there are concerns about the long-term benefit of a procedure that will need revision. This Adviser noted that the main problem is loosening of the implant resulting in further wear of the joint, which may make a standard knee replacement more difficult and make the patient more susceptible to infection.

Safety

- The Advisers considered theoretical adverse events to include implant dislocation, infection, persistence of pain, general knee-related complications such as fracture and infection, general medical complications such as venous thromboembolism, cerebrovascular accident, and myocardial infarction.
- Two Advisers stated that there are no uncertainties or concerns about the safety of this procedure. One Adviser stated that the procedure is not much less safe than comparative procedures and that the issue is the relative safety compared with the efficacy.

Training

- Two Advisers considered that training was particularly important for this procedure, even for an experienced knee surgeon, either by attending a skills laboratory or observing a surgeon trained in this technique. They considered that training would be needed for both the surgery and the use of MRI scanning. A third Adviser considered that little training was needed for experienced knee surgeons.

Issues for consideration by IPAC

- There were no other studies identified that used an MRI-designed interpositional implant. We are aware of other devices (which are not MRI-designed) that have been used in a similar procedure but we have been informed that surgeons have stopped using them because of limited efficacy.
- The procedure is intended to preserve the bone and cartilage; it has been stated that it could be beneficial to young and active patients in whom it may be considered too early to perform a traditional knee replacement.
- As stated above, the outcomes reported are solely biomechanical; the study does not address the key efficacy outcomes considered by the Specialist Advisers to be important (such as pain relief, return to work, length of time until further surgery).

Reference

1. Koeck FX, Perlick L, Luring C et al. (2008) Leg axis correction with ConforMIS iForma^{TM} (interpositional device) in unicompartmental arthritis of the knee. International Orthopaedics 33: 955 – 960. Available from www.springerlink.com/content/k3747845t571g558/

Appendix A: Additional papers on individually magnetic resonance imaging-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee

There were no additional papers identified.

Appendix B: Related NICE guidance for individually magnetic resonance imaging-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee

Guidance	Recommendations
Interventional procedures	**Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis. NICE interventional procedures 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. **Artificial trapeziometacarpal joint replacement for end-stage osteoarthritis. NICE interventional procedures guidance 111 (2005).** 1.1 Current evidence on the safety and efficacy of artificial trapeziometacarpal (TMC) joint replacement for end-stage osteoarthritis appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2 Most of the evidence was based on a single type of joint prosthesis. The range of prostheses used is continually changing and clinicians are encouraged to submit their results to the appropriate joint replacement registry for evaluation of long-term outcomes of different types of prosthesis.
Clinical guidelines	**Osteoarthritis: the care and management of osteoarthritis in adults. NICE clinical guideline 59 (2008)** **1.5.1 Referral criteria for surgery** 1.5.1.1 Clinicians with responsibility for referring a person with osteoarthritis for consideration of joint surgery should ensure that the person has been offered

	at least the core (non-surgical) treatment options (see recommendation 1.1.5 and figure 2). 1.5.1.2 Referral for joint replacement surgery should be considered for people with osteoarthritis who experience joint symptoms (pain, stiffness and reduced function) that have a substantial impact on their quality of life and are refractory to non-surgical treatment. Referral should be made before there is prolonged and established functional limitation and severe pain. 1.5.1.3 Patient-specific factors (including age, gender, smoking, obesity and comorbidities) should not be barriers to referral for joint replacement surgery. 1.5.1.4 Decisions on referral thresholds should be based on discussions between patient representatives, referring clinicians and surgeons, rather than using current scoring tools for prioritisation.

Appendix C: Literature search for individually magnetic resonance imaging-designed unicompartmental interpositional implant insertion for osteoarthritis of the knee

Database	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	03/11/2008	Issue 4, 2008	1
Database of Abstracts of Reviews of Effects – DARE (CRD website)	05/11/2008	-	4
HTA database (CRD website)	05/11/2008	-	0
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	03/11/2008	Issue 4, 2008	15
MEDLINE (Ovid)	03/11/2008	1950 to October Week 4 2008	38
MEDLINE In-Process (Ovid)	05/11/2008	November 04, 2008	4
EMBASE (Ovid)	05/11/2008	1980 to 2008 Week 44	78
CINAHL (NLH Search 2.0/)	03/11/2008	1981 – present	14
BLIC (Dialog DataStar)	06/11/2008	-	6
National Research Register (NRR) Archive	06/11/2008	-	8
UK Clinical Research Network (UKCRN) Portfolio Database	06/11/2008	-	0
Current Controlled Trials *meta*Register of Controlled Trials - *m*RCT	06/11/2008	-	6
Clinicaltrials.gov	31/10/2008		A Study to Evaluate the DePuy Minimally Invasive Unicompartmental Knee NCT00734084 Ongoing 2002-2012 Oxford Partial Knee Replacement. A Randomized Clinical Trial of Three Implant Types NCT00679120

			May 2008 A Clinical Investigation of the Oxford® Meniscal Unicompartmental Knee System NCT00578994 July 2008 Oxford® Partial Knee Kinematics Gait Analysis Study NCT00576966 July 2008 Local Infiltration Analgesia Following Unicompartmental Knee Arthroplasty NCT00653926 April 2007 Pre-Operative Rehabilitation Exercise Program for Total Knee Arthroplasty (PREP) NCT00493142 May 2008 Fast-Track vs Conventional for UKA NCT00284635 July 2007

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

1 (Interposition$ adj3 (Arthroplast$ or Device$ or implant$)).tw. (394)
2 IFORM$.tw. (3)
3 ConforMIS.tw. (36)
4 UNISPACER.tw. (9)
5 ZIMMER.tw. (316)
6 ORTHOGLIDE$.tw. (0)
7 "Prostheses and Implants"/ (31006)
8 (menis$ adj3 (insert$ or tibial$)).tw. (131)
9 (MRI adj3 (interposit$ or device$)).tw. (130)
10 or/1-9 (31976)
11 Osteoarthritis, Knee/ (4876)
12 Unicompartment$.tw. (683)

13 11 and 12 (204)
14 ((knee or patella$) adj3 (arthrit$ or osteoarthrit$)).tw. (4847)
15 (unicompartmental$ adj3 (arthrit$ or osteoarthrit$)).tw. (129)
16 UKA.tw. (105)
17 or/14-16 (4982)
18 Arthritis/ (21105)
19 Knee/ (8812)
20 Knee Joint/ (29723)
21 19 or 20 (37622)
22 21 and 18 (1548)
23 22 or 13 or 17 (6424)
24 23 and 10 (42)
25 Animals/ (4369324)
26 Humans/ (10765890)
27 25 not (25 and 26) (3279216)
28 24 not 27 (38)
29 from 28 keep 1-38 (38)