NICE National Institute for Health and Care Excellence

NICE guidance

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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg317

1 Guidance

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.

2 The procedure

2.1 Indications and current treatments

2.1.1 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.

2.1.2 Treatment options depend on the severity of the osteoarthritis. Conservative treatments include medication to relieve pain and inflammation, physiotherapy and/or prescribed exercise and corticosteroid injection. Surgical options include upper tibial osteotomy to realign the leg and unicompartmental knee replacement. Patients with severe osteoarthritis may need total knee replacement.

2.2 Outline of the procedure

2.2.1 The aim of this procedure is to relieve pain, increase function and prevent damaging eccentric loading of the knee, thereby delaying progression of osteoarthritis and the need for total knee replacement. This procedure aims to correct the leg axis so that the line that passes through the centre of the hip to the centre of the ankle joint also passes through the centre of the knee joint (as in people without eccentric knee loading). This is achieved by insertion of an individually MRI-designed metallic implant into either the medial or lateral compartment of the knee joint (whichever is required).

2.2.2 An MRI scan of the knee is performed to enable bespoke design of a metallic implant. The operation is usually carried out with the patient under general anaesthesia, and may be done as day surgery. Before implantation, the patient may have an arthroscopic procedure to remove osteophytes. The individually designed metallic implant is inserted into either the medial or lateral compartment of the knee joint, depending on the change in leg axis required. Fluoroscopy may be used to confirm the position of the implant.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 In a case series of 27 patients with early- to mid-stage unicompartmental osteoarthritis of the knee treated by arthroscopic removal of osteophytes followed by insertion of an MRI-designed implant, the average correction in leg axis was –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 (preoperative leg axis measurements not given). The remaining 4 patients were reported to have had overcorrections of leg axis of 0.2°, 0.5° and 0.9° (2 patients). The follow-up MRI showed a low average loss of correction of 0.5° (range 0–1°) at 12–22 months. For all 27 patients, the correlation coefficient between implant offset (minimal thickness of the implant) and extent of axis correction was reported to be 0.84 (a value of 0.80 was considered 'good').

2.3.2 The Specialist Advisers listed key efficacy outcomes as reduced pain, ability to return to work and ability to perform activities of daily living and sports. They considered uncertainties about the efficacy of the procedure to be similar to the uncertainties relating to the non-customised implants that preceded the MRI-designed implant. These include failure to provide good pain relief, dislocation or subluxation of the device and a high revision rate compared with standard types of knee replacement.

2.4 Safety

2.4.1 The case series reported that there were no dislocations during or after the procedure but did not report any other safety data. Implant dislocation was reported in 7% (4/60) of patients after insertion of an MRI-designed implant in an unpublished case series.

2.4.2 A revision rate of approximately 5% after insertion of an MRI-designed implant was reported in an unpublished trial of 84 patients (absolute number and time of occurrence not stated).

2.4.3 The Specialist Advisers considered theoretical adverse events to include implant dislocation, infection, persistence of pain and venous thromboembolism. One Specialist Adviser expressed concern that loosening of the implant may cause further wear to the joint, which may make knee replacement more difficult.

3 Further information

3.1 NICE has published interventional procedures guidance on arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis and artificial trapeziometacarpal joint replacement for end-stage osteoarthritis. NICE has also published a clinical guideline on the care and management of osteoarthritis in adults.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

5 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation