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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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment

or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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 magnetic resonance imaging (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.

2.3 Efficacy

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.

2.3.1 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 out of 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° to 1°) at 12 to 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 out of 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 guideline on osteoarthritis in over 16s.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.