NICE guidance

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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg512

1 Recommendations

1.1 Current evidence on the safety and efficacy of implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 Further research into implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis should include comparative studies against existing forms of management. Studies should record patient selection, functional outcomes, quality of life and complications. They should also report the nature and timing of any further surgery on the knee and the effect of removing the device. A minimum follow-up period of 2–3 years is needed. NICE may update the

guidance on publication of further evidence.

2 Indications and current treatments

2.1 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.

2.2 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.

3 The procedure

3.1 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.

3.2 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 aspects 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.

4 Efficacy

This section describes efficacy 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 interventional procedure overview.

4.1 A case series of 99 patients with symptomatic medial knee osteoarthritis refractory to conservative treatment who received a load absorber 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 period of 17 months. All WOMAC domain scores improved significantly 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% or more improvement from baseline) were 78% for pain, 78% for function and 69% for stiffness.

4.2 The case series of 99 patients reported that knee pain severity improved significantly after the procedure, from 59±19 at baseline to 23±22 (assessed on a 0–100 visual analogue scale) at 1 year, 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.

4.3 The case series of 99 patients reported that the mean range of motion of the knee decreased from 119°±13° at baseline to 105°±19° at 6 weeks after the operation. It gradually increased to baseline levels at 1-year follow-up.

4.4 The case series of 99 patients reported that all devices were successfully implanted and activated.

4.5 The specialist advisers listed key efficacy outcomes as reduction in knee

pain, 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.

5 Safety

This section describes 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 interventional procedure overview.

5.1 Device fracture 7 months after implantation was reported in a case report of 1 patient. A 2-stage revision procedure was performed and the device was completely removed without any further complications.

5.2 Infection of the tibial wound attributed to prolonged physical activity was reported 6 weeks after the procedure in a case report of 1 patient. The patient was initially treated with antibiotics but the infection did not resolve. The patient subsequently had a 2-stage revision procedure involving removal of the load absorber with antibiotics for 6 weeks followed by insertion of a new absorber 3 months after the infection was resolved.

5.3 Persistent pain led to the removal of the device in 4% (4/99) of patients in the case series between 2 and 10 months after implantation.

5.4 Surgery was done for failure to improve symptoms in 6% (6/99) of patients in the case series of 99 patients: 4 patients had total knee arthroplasty and 2 patients had high tibial osteotomy.

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

5.6 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse

events: soft tissue irritation, impingement, dislocation, or uncoupling of the device needing removal. They considered that the following were theoretical adverse events: thrombotic events (deep vein thrombosis leading to pulmonary embolism); stiffness of the knee; and bone loss adjacent to anchoring sites that could compromise future salvage surgery including joint replacement.

6 Committee comments

6.1 The Committee was advised that there are few treatment options for younger patients with osteoarthritis of the knee. Implantation of a shock or load absorber may offer an option for these patients, and may delay the need for joint replacement.

6.2 The Committee noted comments from patients describing benefit. The time to recovery was relatively long for these patients: up to 1 year. Some patients noted that the device was bulky.

7 Further information

7.1 For related NICE guidance, see the NICE website.

Information for patients

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

About this guidance

NICE interventional procedures 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.

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

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

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Changes after publication

March 2015: 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 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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

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