

Mini-incision surgery for total knee replacement

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg345

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.

This guidance replaces IPG117.

1 Guidance

- 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.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 The most common indication for a total knee replacement is symptomatic degenerative arthritis (osteoarthritis) of the knee joint.
- 2.1.2 Conservative treatments for arthritis include medications for pain and inflammation, and physical therapies. Corticosteroids may be injected into the knee joint to relieve inflammation. If these therapies are insufficient, a partial or total knee replacement may be necessary.

2.2 Outline of the procedure

- 2.2.1 The aim of mini-incision surgery is to improve both cosmesis and recovery time by reducing the length of incision and minimising damage to tendons and muscles. The procedure is carried out with the patient under general anaesthesia or spinal/epidural block. Specially designed instruments enable the surgeon to work through a small incision and avoid eversion of the patella or dislocation of the knee joint. The same types of joint prostheses are used in mini-incision procedures as in standard knee replacement. Computer-guided navigation may be used to improve placement of the prostheses.

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 A randomised controlled trial (RCT) of 108 patients treated by computer-assisted mini-incision (n=52) or conventional knee replacement (n=56) reported that 34 patients from each group were pain free at 6-month follow-up (denominator not stated; p=0.15).
- 2.3.2 A non-randomised controlled trial of 200 knees reported that mean pain score (using a 10-point visual analogue scale; high score indicates worse pain) was significantly better in the mini-incision group (3.2 points) than in the conventional surgery group (3.8 points) at 1-year follow-up (p<0.01).
- 2.3.3 The RCT of 108 patients treated by mini-incision or conventional knee replacement reported no difference in mean Knee Society knee scores (on a scale from 0 to 100; high score indicates less pain and better functional mobility) of 84 points and 85 points respectively at 6-month follow-up (p=0.06).
- 2.3.4 In a case series of 237 patients undergoing revision surgery for reasons other than infection (not otherwise described) the mean time to revision surgery was significantly shorter in patients initially treated by mini-incision surgery than in patients treated by a standard approach (15.4 months and 79.2 months

respectively; $p < 0.0001$).

- 2.3.5 A non-randomised controlled study of 747 knees reported that achievable flexion was significantly greater in knees treated by mini-incision surgery (124°) than following conventional surgery (113°) at 24-week follow-up ($p < 0.001$).
- 2.3.6 The Specialist Advisers listed key efficacy outcomes as recovery time, functional long-term outcome and implant survival at 10 years.

2.4 Safety

- 2.4.1 Deep wound infection requiring 2-stage revision surgery and haemarthrosis requiring evacuation were reported in less than 1% (2 out of 725, and 1 out of 725 respectively) of knees treated by mini-incision surgery in a non-randomised controlled study of 732 knees (mean 25-month follow-up). Deep infection requiring 2-stage reimplantation was reported in less than 1% (2 out of 335) of patients in a case series of 335 patients at a median 2-year follow-up.
- 2.4.2 Tibial component failure (requiring revision) was reported in less than 1% (2 out of 725) of knees treated by mini-incision surgery in the non-randomised controlled trial of 732 knees (more than 12-month follow-up).
- 2.4.3 Periprosthetic femur fracture after a fall was reported in 1 of 725 knees treated by mini-incision surgery at 2-week follow-up in the non-randomised controlled trial of 732 knees.
- 2.4.4 Patella tendon rupture (requiring surgical repair) was reported in 1 of 725 knees treated by mini-incision surgery in the non-randomised controlled trial of 732 knees (timing of event not stated).
- 2.4.5 In a non-randomised controlled study of 137 knees, patella tendon shortening of greater than 5% occurred in significantly more knees treated by conventional surgery (37% [21 out of 57]) than knees treated by mini-incision surgery (12% [9 out of 74]) at 2-year follow-up ($p = 0.001$).
- 2.4.6 The non-randomised controlled study of 747 knees reported that 'patella clunk'

occurred significantly more frequently following mini-incision surgery (6% [17 out of 275] of knees) than following conventional surgery using the same type of prosthesis (less than 1% [1 out of 222] of knees) at 1-year follow-up ($p < 0.001$).

- 2.4.7 In the non-randomised controlled study of 137 knees, secondary manipulations for reduced range of movement at 6 weeks were reported in 3% (2 out of 68) of patients treated by mini-incision surgery and 7% (4 out of 61) of patients treated by conventional surgery (significance not stated).
- 2.4.8 The Specialist Advisers listed anecdotal or published adverse events as increased operative time and malpositioning of the implant. They considered theoretical adverse events to include inadequate removal of bone cement from the back of the knee which may lead to early failure.

2.5 Other comments

- 2.5.1 The Committee noted that there is no generally accepted definition of a 'mini-incision' approach to knee replacement.
- 2.5.2 The Committee recognised that although concerns have been expressed about an increased revision rate after mini-incision surgery for total knee replacement, this may reflect the learning curve of a new procedure. The 2009 annual report of the Swedish Knee Arthroplasty Register stated that there was no increase in the revision rate of the procedure compared with standard arthrotomy at up to 8-year follow-up.

3 Further information

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](#).