NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of mini-incision surgery for total knee replacement

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making 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 April 2004.

Procedure name

- Mini-incision surgery for total knee replacement.

Specialty society

- British Orthopaedic Association.

Description

Indications:

The most common indication for a total knee replacement is osteoarthritis of the knee joint.

Current treatment and alternatives

Conservative treatments for arthritis symptoms include medications for pain and inflammation, and physical therapy. Corticosteroids may be injected into the knee joint to relieve inflammation. If these therapies do not work, a partial or total knee replacement may be necessary.

A conventional total knee replacement involves an incision 20 to 30 cm long over the knee. The kneecap is inverted and retractors are used to expose the knee joint. The end surface of the femur is removed and replaced with a metal shell. The end surface of the tibia is removed and replaced with a plastic component joined to a metal stem. The underside of the kneecap is also removed and replaced with a plastic button. Special glue, or cement, may be used to bond the artificial joint components to the bones (cemented procedure) or the artificial parts may be made of a porous material that allows bone to grow into the pores to hold the parts in place (uncemented).

What the procedure involves:

The mini-incision total knee replacement involves an incision 10 to 12 cm long over the knee. A padded bolster to flex the hip or a knee holder to support the leg is used, allowing the weight of the leg to open the joint and push the tissue away. The surgeon can extend or flex the joint, to expose different parts of the knee. The surfaces of the tibia and femur are removed using specially designed instruments. The same prostheses that would be used in a standard knee

replacement are inserted but specialised instruments are used to move around the soft tissue rather than cut through it. There is less need to cut the leg muscles and the kneecap can be moved to one side rather than inverted.

Some surgeons are combining minimally-invasive total knee replacement surgery with computer-guided navigation to assist in the accurate placement of the prostheses.

The potential advantages of the mini-incision total knee replacement over a conventional total knee replacement are a faster and less painful rehabilitation, less scarring, less blood loss and shorter hospital stay.

Efficacy:

Two non-randomised controlled trials and three case-series were identified. Two studies were reported from the same centre, but the extent of the overlap in the patient groups is unclear. In one study, 50 patients with a mini-incision total knee replacement were compared with 20 patients given a standard total knee replacement.[1] At 6 weeks, patients with the mini-incision procedure had a greater range of movement than patients with standard surgery, but the difference was not statistically significant. One case series of 166 patients (216 knees) with a minimum two-year follow up reported that 98% (195/216) of knees had ‘’good” or ‘’excellent” objective patient satisfaction indices.[5]

A recent Health Technology Assessment reported that the revision rate for a conventional total knee replacement through five years or more was 2%.[6]

The Specialist Advisors stated that long term durability of the prostheses needs to be established.

Safety:

There was limited information on safety outcomes for most of the studies. In a case series of 66 patients, 4.5% (3/66) patients had a complication arising from the procedure.[2] These complications were a pulmonary embolism, a transient peroneal nerve palsy and an intraoperative myocardial infarction. In a case -series of 20 patients, 10% (2/20) of patients had painful crepitus and 5% (1/20) of patients had haemarthrosis.[3] In a case series of 166 patients, 2.3% (5/216) of knees required re-operation.[5]

A recent Health Technology Assessment reported that the perioperative complication rate of a conventional total knee replacement was 5% when the unit of analysis was the number of knees operated on, and 8% when the denominator was the number of patients.[6]

The Specialist Advisors stated that poor positioning of the components was the main safety concern.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to mini-incision surgery for total knee replacement. Searches were conducted via the following databases, covering the period from their commencement to April 2004: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these 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 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, laboratory or animal study.
Patient	Patients with degeneration of the knee joint.
Intervention/test	Mini-incision surgery for total knee replacement.
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 five reports from three different centres, including two unpublished conference abstracts. One non-randomised controlled study published in full was identified. [1] Four case series studies were found, one of which reported on patients from the same centre as the non-randomised controlled study. [2] Two of the other case series were reported from the same centre. [3,5]

Table 2 Summary of key efficacy and safety findings on mini-incision surgery for total knee replacement

Study details	Key efficacy findings	Key safety findings	Comments
Tria AJ (2003)[1] Retrospective non-randomised controlled study New Jersey, USA 2001 – 2003 70 patients • 50 mini-incision total knee replacements (8 patients had bilateral procedures) • 20 standard total knee replacements Mean age for mini-incision group: 67 years (range 51 to 86 years)	Average preoperative range of motion: Mini-incision surgery = 119° of flexion Standard surgery = 130° of flexion Average range of motion at first postoperative visit (2-4 weeks postoperative): Mini-incision surgery = 112° of flexion Standard surgery = 91° of flexion Average range of motion 6 weeks postoperatively: Mini-incision surgery = 126° of flexion Standard surgery = 115° of flexion (p = not significant) Overall valgus Mini-incision surgery = 4° Standard surgery = 4°	**Complications** Pulmonary embolism = 2% (1/50) Intraoperative myocardial infarction with an associated postoperative cardiogenic stroke = 2% (1/50) Transient postoperative arrhythmia = 4% (2/50) 2 procedures were converted to the standard approach. One was changed because of soft bone in an obese patient with rheumatoid arthritis and the second was changed because of posterior capsular bleeding.	No randomisation. Short follow-up. Comparison group patients were selected because of their unusually high preoperative range of motion. Patients are also likely to be included in Tria AJ, 2003.[2]
Tria AJ (2003)[2] Case series New Jersey, USA 66 patients (4 patients had bilateral procedures) Mean age: 67 years (range 51 to 84 years) Inclusion criteria: good medical health, knee deformity should not exceed 10° anatomic varus, 15° anatomic valgus and 10° flexion contracture.	Postoperative average distal femoral valgus = 6° Postoperative average tibial varus = 2.5° Postoperative average overall alignment = 4° valgus Radiographs were compared with a matched group of patients given conventional total knee replacements and there were no statistically significant differences. Range of motion at first follow-up was 20° greater than that of a matched group of patients with conventional total knee replacements ($p < 0.05$).	**Complications** Transient peroneal nerve palsy = 1.5% (1/66) Pulmonary embolism = 1.5% (1/66) Intraoperative myocardial infarction with an associated postoperative cardiogenic stroke = 1.5% (1/66) Two procedures were converted to the standard approach. One was changed because of limited exposure in an obese patient with rheumatoid arthritis and the second was changed because of posterior capsular bleeding.	Not consecutive patients. Short follow-up. No description of how patients were matched. Patients are also likely to be included in Tria AJ (2003).[1]

Study details	Key efficacy findings	Key safety findings	Comments
Bonutti PM (2003)[3] Case series Illinois, USA 20 patients Mean follow -up: 8 months (range 6 months to 1 year)	Postoperative hospital stay = 2 days Postoperative average range of motion = 118° (range 96° – 128°) "Radiographs demonstrate excellent alignment in the coronal and sagittal plane."	**Complications** Haemarthrosis = 5% (1/20) Painful crepitus = 10% (2/20)	Unclear whether patients were recruited consecutively. Small patient numbers. Short follow-up.
Laskin RS (2004)[4] Non-randomised controlled study New York, USA 102 patients • 51 mini -incision • 51 standard incision	Mean surgical time: • mini-incision = 63 minutes • standard incision = 60 minutes Patients with mini-incision surgery were discharged "18% faster than the standard incision patients". Patients with mini-incision surgery had a statistically shorter time until they could leg raise, used less epidural analgesia, used less overall analgesics, and had a more rapid regaining of flexion than the standard incision patients.	**Complications** Mini-incision surgery: • conversion to standard incision = 3.9% (2/51)	Consecutive patients. Unpublished conference abstract.
Bonutti PM (2004)[5] Case series Illinois, USA 166 patients (216 knees) Follow -up: 2 – 4 years	98% (195/216) knees have good and excellent objective Knee Society scores and patient satisfaction indices.	**Complications** Requirement for manipulation under anaesthesia = 2.8% (6/216) Reoperation = 2.3% (5/216)	Consecutive patients. Unpublished conference abstract.

Validity and generalisability of the studies

- None of the studies reported a long-term follow-up. The longest mean follow-up reported was 8 months. [3]

- All three studies were small. Two of the three studies were based at the same centre and it is difficult to ascertain how many patients were included in both reports.[1,2]

- One study stated that the inclusion criteria were more restrictive because the procedure was still under development. [2]

- Two studies were reported in unpublished conference abstracts.[4,5] Results from these studies must be considered as preliminary and may be less reliable than those published in peer-reviewed journals.

Specialist Advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

- There are a number of different approaches being used for this procedure.
- Computerised navigation may be useful to ensure accurate placement of the components.
- Long-term data is needed to establish the durability of the prostheses.
- Surgeons need to be properly trained in the technique.

Issues for IPAC consideration

- A European multicentre randomised controlled trial is currently underway (including one UK centre), comparing computer-assisted minimally invasive total knee replacement with conventional open total knee replacement. Approximately 250 patients will be included and enrolment is expected to continue until December 2004.

References

1 Tria AJ. Advancements in minimally invasive total knee arthroplasty. *Orthopedics* 2003; 26: S859 – S863.

2 Tria AJ and Coon TM. Minimal incision total knee arthroplasty. *Clinical Orthopaedics and Related Research* 2003; 416: 185 – 190.

3 Bonutti PM, Neal DJ, and Kester MA. Minimal incision total knee arthroplasty using the suspended leg technique *Orthopaedics* 2003; 26: 899 – 903.

4 Larskin RS, Phongkhunakorn A, and Davis JP. TKR through a mini midvastus MIS approach and comparison to standard approach TKR. *American Academy of Orthopaedic Surgeons 2004 Annual meeting conference abstract No. 285.* March 2004.

5 Bonutti PM, McMahon M, and Mont MA. Minimally invasive total knee arthroplasty – two year follow-up. *American Academy of Orthopaedic Surgeons 2004 Annual meeting conference abstract No. 284.* March 2004.

6 Kane RL, Saleh KJ, Wilt TJ, et al. Total knee replacement. Evidence Report / Technology Assessment No. 86 (Prepared by the Minnesota Evidence-based Practice Center, Minneapolis, MN). AHRQ Publication No. 04-E006-2. Rockville, MD: Agency for Healthcare Research and Quality. December 2003.

Appendix A: Literature search for mini-incision surgery for total knee replacement

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

1. knee replacement.mp. [mp=ti, ab, ot, rw, sh]
2. knee arthroplasty.mp. [mp=ti, ab, ot, rw, sh]
3. 1 or 2
4. minimally invasive.mp. [mp=ti, ab, ot, rw, sh]
5. minimal incision.mp. [mp=ti, ab, ot, rw, sh]
6. mini incision.mp. [mp=ti, ab, ot, rw, sh]
7. 4 or 5 or 6
8. 3 and 7