### NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

#### INTERVENTIONAL PROCEDURES PROGRAMME

# Interventional procedures overview of minimally invasive two-incision surgery for total hip 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 May 2004.

#### Procedure name

• Minimally invasive two-incision surgery for total hip replacement.

#### Procedure number

240

#### Specialty societies

• British Orthopaedic Association

#### Indication(s)

The most common indication for a total hip replacement is degenerative arthritis (osteoarthritis) of the hip joint. Other indications include rheumatoid arthritis, injury, bone tumours, and necrosis of the hip bone.

#### **Current treatment and alternatives**

Conservative treatments for arthritis include medications for pain and inflammation, and physiotherapy. If conservative treatments fail, a hip replacement may be necessary.

A traditional hip replacement involves making a large incision (20 to 30cm) above the hip joint and cutting through the muscles, ligaments and tendons to access the joint. The head and neck of the femur is removed by cutting it with a saw and replaced with a metal ball and stem. The surface layer of the socket is removed and an artificial socket is attached to the hip bone. Special glue, or cement, may be used to bond the artificial joint to the existing bone (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

Two small incisions (3 to 6 cm in length) are made, one at the front of the hip directly over the femoral neck and one at the back in line with the femoral canal. Fluoroscopy may be used to define the femoral neck before the incisions are made and to confirm the position of instruments and prostheses during the procedure. The muscles are retracted to expose the joint capsule. After the capsule is divided and retracted, using specially designed illuminated retractors, a saw is used to remove the femoral head and neck. Specially designed reamers are used to prepare the socket and a specially designed inserter is used to prepare the femoral canal before the stem is inserted through the posterior incision. The prosthetic head is placed on the stem, gently impacted in place and the incisions are closed.

This procedure uses the same prostheses that would be used in a conventional hip replacement. The minimally invasive two-incision surgery entails less muscle and tendon trauma than conventional surgery. The potential advantages include a faster and less painful recovery, reduced blood loss, less scarring and a shorter hospital stay.

#### Efficacy

Results on this procedure have been published from five centres, describing a total of 517 patients.<sup>1-4</sup> Efficacy outcomes were poorly reported and mainly focused on the operating time and length of hospital stay, rather than the function of the prosthesis. One study reported on 30 patients after a minimum follow-up of one year and found that 91% of the implanted femoral stems were in a neutral alignment.<sup>2</sup> All the prostheses (30/30) had tissue ingrowth and had not migrated. In one study of 142 patients followed up for between 6 weeks and 2 years, the acetabular components were satisfactory in 99% (141/142) of patients.<sup>1</sup> The mean operating time was reported by all five centres and ranged from 62 minutes to 101 minutes. In four studies, the proportion of patients discharged from hospital within 24 hours of the surgery ranged from 77% (58/75) to 90% (90/100).<sup>2,3</sup>

There are no published studies comparing the efficacy of the minimally invasive twoincision hip replacement with a conventional total hip replacement. A large UK study of 1198 conventional total hip replacements reported a failure rate of approximately 9% (44/499), with clinical and radiological assessment, after a follow-up period of five years.<sup>5</sup> 3% (35/1080) of prostheses had undergone revision for loosening, infection, and recurrent dislocation.

An American study reported a median hospital stay of 5 days for 58,521 elective primary total hip replacements performed in 1995 and 1996.<sup>6</sup> The median length of hospital stay for all patients with a total hip replacement in NHS hospitals in England during 2002 and 2003 was 9 days.<sup>7</sup>

Specialist Advisors stated that there was some uncertainty about the long term outcome of this procedure, compared with a conventional total hip replacement.

#### Safety

Femoral fracture was reported as a complication in all five studies, affecting between 1% (1/100) and 3.5% (5/142) of patients. One study reported that 21% (16/75) of patients suffered from hypoesthesia of the anterior part of the thigh.<sup>3</sup> Other less common complications that occurred in less than 1% of patients across all five

studies included hip dislocation (5 people), infection (4 people), deep vein thrombosis (3 people), heterotopic bone formation (3 people), partial femoral nerve palsy (2 people), stem subsidence (2 people), haematoma (1 person) and bowel obstruction (1 person).

There are no published studies comparing the safety of the minimally invasive twoincision hip replacement with a conventional total hip replacement. A large UK study of 1198 conventional total hip replacements reported a femoral fracture in 2% (20/1130) of operations.<sup>5</sup> Postoperative complications in 1080 patients included urinary retention (6%), dislocation (5%), pulmonary embolism (3%), wound infection (3%), deep vein thrombosis (3%), loosening of the prosthesis (2%), deep infection (1%), and upper gastrointestinal haemorrhage (1%).

Specialist Advisors stated that malposition of components, nerve damage, vascular damage and femoral fracture were theoretical adverse events which may potentially be associated with this procedure.

#### Literature review

#### Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to minimally invasive two-incision surgery for total hip replacement. Searches were conducted via the following databases, covering the period from their commencement to May 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.

| 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 hip joint                               |
| Intervention/test | Minimally invasive two-incision surgery for total hip 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.       |

#### Table 1 Inclusion criteria for identification of relevant studies

#### List of studies included in the overview

Three published articles and a conference abstract were identified, describing the results of case-series from five centres. <sup>1,2,3,4</sup>

A Health Technology Report on minimally invasive hip arthroplasty was published in 2003. <sup>8</sup> This report did not identify any publications with outcome data on the minimally invasive two-incision procedure in the peer-reviewed literature.

| Study Details  | Key efficacy findings  | Key safety findings  | Comments   |
|--|--|--|--|
| Irving JF, 2004 <sup>1</sup>   | Mean operating time = 65 minutes   | Complications<br>Intraoperative proximal femoral cracks =                  | All patients with osteoarthritis<br>undergoing total hip replacement |
| Case series  | Discharged home on postoperative day 3 or $4 = 28\%$ (23/82)   | 3.5% (5/142)<br>Deep vein thrombosis = 1.4% (2/142)                        | were treated with this procedure during the study period.            |
| 2001 – 2003  | Using a cane by hospital discharge = $50\%$ (71/142)<br>Using a cane by $3^{rd}$ week = $98\%$ (135/142) | Superficial infections = 2.1% (3/142)<br>Haematoma requiring readmission = | 25 patients had simultaneous   |
| USA  | Not using a cane after 1 month = 75% (107/142)   | 0.7% (1/142)<br>Grade 4 heterotopic bone = 0.7%                            | bilateral procedures during the same time period. Results for        |
| 142 patients   | No components were revised for loosening.  | (1/142)<br>Transient numbness = 2.1% (3/142)                               | these patients were not presented.                                   |
| Mean weight: 78.7 kg (range 45.9 –<br>159 kg)                              | Acetabular component angles were satisfactory in 99% (141/142) patients.                                 | Anterior dislocations = 2.1% (3/142)                                       | Fluoroscopy was not used for<br>implant positioning.                 |
| Follow-up: 6 weeks to 2 years  |  |  | 19 cemented stems, 123   |
| Indications: Osteoarthritis  |  |  | uncemented stems.  |
| No patients were excluded based on BMI, age, physical or social situation. |  |  | No details of follow-up compliance.                                  |
|  |  |  |  |
|  |  |  |  |

Table 2 Summary of key efficacy and safety findings on minimally invasive two-incision surgery for total hip replacement

| Study Details  | Key efficacy findings   | Key safety findings   | Comments  |
|--|---|---|---|
| Berger RA, 2003 <sup>2</sup>   | Patients electing to go home the same day as surgery = 85% (75/88)                            | <b>Complications</b><br>Femoral fracture = 1% (1/100)                   | Consecutive recruitment.  |
| Case series  | Patients electing to go home the day after surgery = 15% (13/88)                              | (stem removed and replaced without                                      | The first five patients were lean with relatively normal anatomy of |
| 2001   | Mean operative time for the last 88 patients = 101  | extending the incisions. 1.5 years postoperative – stem has ingrown and | the hip. As experience was gained, the procedure was done           |
| USA  | minutes (range 80 to 120 minutes)   | fracture healed)  | successfully on heavier patients.                                   |
| 100 patients   | Radiographic analysis after minimum 1-year follow-up  | No dislocations, infections or<br>reoperations were reported.           | Paper presents radiographic<br>analysis of first 30 patients only,  |
| Mean age: 55 years (range 30 to 76 years)  | (n = 30):<br>Femoral stems in neutral alignment = 91%   |   | followed up for a mean of 18 months.                                |
| Mean weight: 176 lb  | Stems between neutral and 3° valgus = 100%<br>Ingrowth of prostheses without migration = 100% |   | Uncemented.   |
| 30 patients with minimum 1-year follow-<br>up  | Mean abduction angle = 45° (range 36° - 54°)  |   |   |
| Indications: osteoarthritis,<br>developmental dislocation of the hip,<br>osteonecrosis   |   |   |   |
| Exclusion criteria: patients with morbid<br>obesity, marked abnormal hip anatomy,<br>prior surgery (other than core<br>decompression), or complete hip<br>dislocation. |   |   |   |

| Study Details  | Key efficacy findings  | Key safety findings   | Comments                    |
|--|--|---|-----------------------------|
| Duwelius PJ, 2003 <sup>3</sup>   |  |   |                             |
| Case series  |  |   |                             |
| USA (four centres)   |  |   |                             |
| Centre 1: 100 patients   | Patients discharged home with 24 hours = 90%<br>(90/100)                                 | <b>Complications</b><br>Posterior hip dislocations = 2% (2/100)                                       | Selected group of patients. |
| Mean age: 57 years for men, 60 years for women   | Patients discharged on 2 <sup>nd</sup> postoperative day = 10% (10/100)                  | (treated with closed reduction and use<br>of a brace for 6 weeks)<br>Stem subsidence and loosening of | Uncemented.                 |
| Mean weight: 184 lb for men, 141 lb for women  | Mean operating time = 90 minutes (range 80 – 120<br>minutes)                             | femoral component, requiring revision =<br>1% (1/100)<br>Femoral fracture = 1% (1/100) (healed        |                             |
| Follow-up: 1 year  | Mean Harris hip score improved from 52 points<br>preoperatively to 90 points at one year | without incident)<br>Infection around prosthesis = 1%   |                             |
| Indications: osteoarthritis, osteonecrosis, rheumatoid arthritis   | postoperatively (maximum score possible 100)   | (1/100) (9 months postoperatively,<br>probably due to haematogenous<br>infection from a lung abscess) |                             |
| Inclusion criteria: weight less than<br>220lb, <75 years old, no major<br>comorbidities, osteoporosis, or cognitive<br>impairment and no prior surgery on<br>ipsilateral hip |  |   |                             |
| Centre 2: 100 patients (56 men, 44 women)  | Patients discharged home within 24 hours = 77% (77/100)                                  | <b>Complications</b><br>Femoral fractures = 2% (2/100)  | Selected group of patients. |
| Mean age: 56 years   | Mean operating time = 62 minutes (range 38 – 140 minutes)                                | Deep vein thrombosis = 1% (1/100)<br>Bowel obstruction = 1% (1/100)                                   | Uncemented.                 |
| Mean weight: 194 lb for men, 148 lb for women  |  |   |                             |
| Mean follow-up: 1 year (range 3 months to 18 months)   |  |   |                             |
| Indications: osteoarthritis,<br>developmental hip dysplasia,<br>osteonecrosis, trauma.   |  |   |                             |
| <b>Centre 3</b> : 100 patients (see reference 1 for details)   |  |   |                             |

| Study Details   | Key efficacy findings   | Key safety findings  | Comments  |
|---|---|--|---|
| Duwelius PJ, 2003 <sup>3</sup> (continued)  |   |  |   |
| Centre 4: 75 patients, 3 with a bilateral<br>procedure<br>Mean age: 58 years for men, 62 years<br>for women<br>Mean weight: 229 lb for men, 184 lb for<br>women<br>Indications: osteoarthritis, post-<br>traumatic arthritis, developmental hip<br>dysplasia, rheumatoid arthritis. | Patients discharged on day of surgery = 9% (7/75)<br>Patients discharged within 24 hours of surgery = 77%<br>(58/75)<br>Mean operating time = 85 minutes (range 55 – 125<br>minutes)  | <b>Complications</b><br>Femoral fracture = 3% (2/75)<br>(treated with a cerclage wire, healed<br>uneventfully)<br>Asymptomatic stem subsidence = 1%<br>(1/75)<br>Grade I heterotopic bone = 3% (2/75)<br>Partial femoral nerve palsies= 3% (2/75)<br>(fully resolved within 8 weeks)<br>Hypoesthesia of the anterior part of the<br>thigh = 21% (16/75) (9 had full recovery,<br>7 had partial resolution) | Consecutive patients.<br>Uncemented.  |
| Berger RA, 2004 <sup>4</sup><br>Case series<br>USA<br>30 patients<br>Mean age: 54 years (range 29 to 68<br>years)<br>Mean follow-up: 25 months  | Mean time on crutches = 5 days<br>Mean time using a cane = 8 days<br>Mean time to be off all narcotics = 6 days<br>Mean time to return to work = 8 days<br>Radiographic analysis:<br>Femoral stems in neutral alignment = 91%<br>Mean abduction angle = 45° (range 36° - 54°) | Complications<br>Femoral fracture = 3.3% (1/30)<br>No dislocations, no failure of ingrowth,<br>no reoperations.  | Conference abstract.<br>Patients likely to also be included<br>in Berger, 2003. <sup>2</sup><br>No patients were lost to follow-<br>up. |

#### Validity and generalisability of the studies

- The longest reported mean follow-up was 25 months.
- Two of the study centres excluded patients with morbid obesity and those with prior hip surgery.
- There are differences in the techniques used to perform this procedure; fluoroscopy may or may not be used for implant positioning.

#### Specialist advisors' opinions

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

• The procedure is technically challenging and training is important.

#### Issues for consideration by IPAC

None.

#### References

- 1 Irving JF. Direct two-incision total hip replacement without fluoroscopy. *Orthopaedic Clinics of North America* 2004; 35: 173 181.
- 2 Berger RA. Total hip arthroplasty using the minimally invasive two-incision approach. *Clinical Orthopaedics and Related Research* 2003; 417: 232 241.
- 3 Duwelius PJ, Berger RA, Hartzband MA, and Mears DC. Two-incision minimally invasive total hip arthroplasty: operative technique and early results from four centers. *Journal of Bone and Joint Surgery* 2003; 85: 2240 2242.
- 4 Berger RA. Minimally invasive total hip arthroplasty using a two incision technique. *American Academy of Orthopaedic Surgeons 2004 Annual Meeting conference abstract 207*. March 2004.
- 5 Fender D, Harper WM, and Gregg PJ. Outcome of Charnley total hip replacement across a single health region in England. *Journal of Bone and Joint Surgery* 1999; 81: 577 581.
- 6 Phillips CB, Barrett JA, Losina E, Mahomed NN, Lingard EA, Guadagnoli E, et al. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *Journal of Bone and Joint Surgery* 2003; 85: 20 – 26.
- 7 Department of Health. Hospital Episode Statistics. London: HMSO, 2003. Available from <u>www.dh.gov.uk</u> (accessed 05/08/2004).
- 8 Hailey D. Minimally invasive hip arthroplasty. HTA Initiative # 8. Calgary Health Region and Alberta Heritage Foundation for Medical Research, 2003.

## Appendix A: Literature search for minimally invasive two-incision surgery for total hip 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.

| #  | Search History                             |
|----|--|
| 1  | hip arthroplasty.mp. [mp=ti, ab, rw, sh]   |
| 2  | hip replacement.mp. [mp=ti, ab, rw, sh]    |
| 3  | 1 or 2                                     |
| 4  | total.mp. [mp=ti, ab, rw, sh]              |
| 5  | 3 and 4                                    |
| 6  | 2 incision.mp. [mp=ti, ab, rw, sh]         |
| 7  | two incision.mp. [mp=ti, ab, rw, sh]       |
| 8  | 6 or 7                                     |
| 9  | 5 and 8                                    |
| 10 | minimally invasive.mp. [mp=ti, ab, rw, sh] |
| 11 | 3 and 10                                   |