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Australia and New Zealand Horizon Scanning Network

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Horizon scanning technology Prioritising summary

Minimal incision hip arthroplasty

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**Australian
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of New
Interventional
Procedures -
Surgical**



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College of Surgeons**

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Enquiries about the content of the report should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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This horizon scanning prioritising summary was prepared by Miss Deanne Leopardi from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

PRIORITISING SUMMARY

REGISTER ID S000074

NAME OF TECHNOLOGY MINIMAL INCISION HIP ARTHROPLASTY

PURPOSE AND TARGET GROUP PATIENTS WITH HIP CONDITIONS, INCLUDING ARTHRITIS, FRACTURES AND TUMOUR, REQUIRING RESTORATION OR REPLACEMENT OF ALL OR PART OF THE JOINT

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input checked="" type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|--|-------------|-----|
| <input type="checkbox"/> Yes | ARTG number | N/A |
| <input type="checkbox"/> No | | |
| <input checked="" type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia		✓	
Ireland		✓	
Japan		✓	
Korea		✓	
Netherlands		✓	
United Kingdom		✓	
United States		✓	

IMPACT SUMMARY

Minimal incision (MI) hip arthroplasty, performed through mini-incision (< 12 cm in length), is a potential alternative to traditional hip arthroplasty, performed through larger incisions (15 to 40 cm in length), for the correction of hip joint disorders. This technique is currently in the investigational stage in Australia.

BACKGROUND

The most common indication for hip arthroplasty in Australia is primary osteoarthritis (Australian Institute of Health and Welfare 2005). Osteoarthritis causes loss of cartilage in the load-bearing joints of the body, including the hips, which leads to pain and disability. Other indications for hip arthroplasty include rheumatoid arthritis, ankylosing spondylitis (chronic inflammatory arthritis effecting the spine and adjacent structures), neglected congenital dislocation, protrusio acetabuli (defect of the hip socket or acetabulum), fracture dislocation, previous operation failure, late aseptic necrosis, dysplasia, benign tumours and slow growing malignant tumours (Campbell & Rothman 1971).

Hip arthroplasty, or hip replacement, describes the surgical procedure of replacing all or part of the hip joint with an artificial device or prosthesis (MedlinePlus 2007). Total hip prosthesis includes a cup which replaces the acetabulum located in the pelvis, and a ball which replaces the head of the femur, that may cover the heads surface or be attached to a stem secured in the shaft of the femur (MedlinePlus 2007). Total hip arthroplasty (THA) begins with an incision in the skin and surrounding muscle to expose the hip joint. The hip is then dislocated so that the head of the femur can be cut out and removed. The remaining cartilage and arthritic bone is removed from the acetabulum using a tool known as a reamer. The acetabular and femoral prostheses are fixed to their respective bones by acrylic cement (Campbell & Rothman 1971). Traditionally these procedures are performed via large incisions from 15 to 40 cm in length (Wright et al 2004). In order to continue the progression of hip arthroplasty and optimise its safety and effectiveness a minimally invasive surgical approach has been introduced.

MI hip arthroplasty is defined by an incision of 10 to 12 cm, or less, in length (Dorr et al 2007). The overall aim of MI hip arthroplasty is to reduce soft tissue damage and minimise damage to tendons or muscles during dissection (Levine et al 2007). The potential benefits of reducing incision size include shorter intraoperative time, less perioperative blood loss and postoperative pain, more rapid rehabilitation, earlier hospital discharge and improved cosmetic appearance due to reduced scarring (Dorr et al 2007). Conversely, decreased operative visibility, increased risk of neurovascular complications, a higher prevalence of dislocation, excessive skin trauma due to stretching, compromised implant fixation and positioning and the steep learning curve associated with the procedure have led to controversy and uncertainty surrounding the use of MI (Levine et al 2007). As well as this, the long-term success rates of MI hip arthroplasty are not yet documented.

CLINICAL NEED AND BURDEN OF DISEASE

Osteoarthritis is the most common form of arthritis in Australia and it is estimated 1.4 million Australians have this long-term condition (Australian Institute of Health and Welfare 2005). People who are severely overweight are up to three times more likely to require THA as a result of osteoarthritis (Australian Bureau of Statistics 2001).

According to the 2003 Survey of Disability, Aging and Carers, 14% of people with disability report arthritis and related disorders as the main disabling condition responsible for restricting their daily activities and consequently impairing their quality of life (Australian Institute of Health and Welfare 2005). From 2003-04, 16,913 unilateral THA procedures were carried out in Australia, which is 21.8% of all the surgical procedures performed as a result of osteoarthritis (Australian Institute of Health and Welfare 2005). The procedure is more commonly performed in 70- to 74-year old men (Australian Institute of Health and Welfare 2005). Hospitalisation rates for hip replacements were similar for both men and women and increased from approximately 70 separations per 100,000 individuals in 2000-01 to approximately 83 separations per 100,000 in 2004-05 (Australian Institute of Health and Welfare 2008).

DIFFUSION

Minimally invasive orthopaedic surgery has been increasingly popular over the last two to three years (Dutka et al 2007). As a result clinical studies have been carried out to compare the efficacy of MI hip arthroplasty with conventional hip arthroplasty techniques. Trials have been conducted throughout Europe, Asia, the UK and the US, where the procedure appears to be in limited use.

MI hip arthroplasty appears to be in the investigational stage in Australia.

COMPARATORS

Cemented low-friction THA, described in the 1970s by John Charnley, remains the 'gold standard' in hip replacement technology (Zuckerman & Kubiak 2003), and is the main comparator of minimally invasive hip arthroplasty performed via mini-incision.

There have been modifications to the conventional hip arthroplasty system, including refinements in cementing technique, specific instruments to aid implantation, femoral stem design, and the development of cement-free acetabular and femoral component designs (Zuckerman & Kubiak 2003). The most commonly used variations of standard hip arthroplasty include: anterior hip arthroplasty, anterolateral, direct lateral (with multiple modifications), transtrochanteric and posterior (Levine et al 2007).

SAFETY AND EFFECTIVENESS ISSUES

Five studies were identified for inclusion. Four were randomised controlled trials (RCTs) and one was a pseudorandomised controlled trial. All five studies compared minimally invasive hip arthroplasty with conventional hip arthroplasty through a standard incision. The blinded RCT by Chimento et al (2005) included 60 patients with a body mass index (BMI) of less than 30 (obesity is defined as a BMI > 30) who required primary THA. Twenty-eight patients were randomly assigned at the time of surgery to undergo a modified posterolateral MI THA via an 8 cm incision, while 32 patients received standard posterolateral THA through a 15 cm incision. The patients' baseline characteristics were comparable ($p > 0.3$). The mean age of patients in the MI and standard incision group was 67.2 years (SD 8.6 years) and 65.6 years (SD 10.5 years), respectively. The Harris

hip score for each group was 54.2 (SD 9.4) and 53.4 (SD 7.9), respectively. Follow-up was two years (the mean follow-up for each group was not provided).

The randomised, blinded study conducted by Dorr et al (2007) compared the results of patients treated with small posterior incision THA with those treated with long posterior incision. Treatment allocation was concealed from patients and all medical staff, with the exception of the operating team, for six months by increasing the incision before closure so that all patients had the same incision length. Thirty patients received incisions of 10 cm (SD 2 cm), and 30 received incisions of 20 cm (SD 2 cm). Patients were comparable in baseline characteristics: mean age was 70.3 years (range: 44 - 84 years) for the MI group and 63.9 years (range: 34 - 87 years) for the long-incision group. Preoperative Harris hip score was 64.4 (SD 12.8) and 63.33 (SD 14.15), respectively. Overall BMI ranged from 18.9 - 49.4 BMI, therefore there was no restriction on obese or morbidly obese patients in eligibility for treatment. Follow-up was six months (the mean follow-up for each group was not provided).

In the study conducted by Ogonda et al (2005) 219 patients (BMI < 34) were randomly assigned to receive either unilateral THA using a single incision posterior approach with posterior capsular repair (incision of ≤ 10 cm, n = 109) or a standard incision of 16 cm (n = 110). Treatment allocations were concealed from patients, hospital staff and assessors by using the same size bandage for all patients. Mean age for the MI and standard incision groups was 67.42 years (SD 9.84 years) and 65.85 years (SD 10.33 years), respectively. Preoperative Harris hip score for each group was 29.04 (SD 11.65) and 27.41 (SD 13.23), respectively. Overall, patients' characteristics were comparable at baseline ($p > 0.21$). Mean follow-up was six weeks.

In a RCT conducted by Kaneko et al (2005) 64 patients over the age of 75 with femoral neck fractures were randomised equally into one of two treatment groups to compare the outcomes of MI (mean length 7 cm) bipolar hemiarthroplasty (only the head of the femur is replaced with prosthesis) with standard incision (mean length 15.2 cm) bipolar hemiarthroplasty. The mean age of all of the patients was 79.1 years (range: 72 - 85 years) and the mean follow-up duration was 16 months (range: 10 - 24 months).

In a pseudorandomised single-blind study conducted by Dutka et al (2007) patients (with a BMI < 30) received THA through either a MI direct lateral approach (incision 6 - 8 cm) or a standard direct lateral approach (incision 20 - 25 cm). Of 120 patients, 60 were randomly assigned to each group based on the day of the week their surgery took place. The mean age of the MI and standard incision group was 46 years (range 40-67 years) and 44 years (range: 32 - 61 years), respectively. The Harris hip score for each group was 44.5 (range: 42 - 48) and 45 (range: 43 - 48), respectively. Patient characteristics at baseline were comparable between the groups ($p > 0.05$). Mean follow-up was also comparable at 8.5 months (range: 6 - 12 months) for the MI group and 10.5 months (range: 10 - 16 months) for the standard incision group.

Safety

In the RCT by Chimento et al (2005) there were no cases of nerve injury, infection or thrombotic events in either treatment group. Of the patients who underwent MI THA, one experienced a postoperative atrial flutter, one patient had sciatic pain in the contralateral leg that interfered with rehabilitation and one patient reported visual hallucinations while on the patient controlled epidural anaesthesia (PCEA) pump (all in the MI group). In the standard THA group, one patient had a rash and another developed analgesic-related confusion. All complications resolved spontaneously. During the 2-year follow-up period, two patients in each group sustained dislocations ($p = 0.2$). One patient who sustained dislocation developed instability and required revision to a constrained liner. The other dislocation occurred early in the postoperative period as a result of hip movement outside the suggested range and internal rotation. An uncomplicated closed reduction was performed to resolve the situation. At two years follow-up, one patient from each group was unreachable and two patients from the standard THA group had died from unrelated causes.

In the study carried out by Dorr et al (2007) there were no incidences of intraoperative complications in either group. There were a total of four reoperations required, two in each group. Three of these reoperations were to treat periprosthetic fractures caused by falls once the patient had returned home. The remaining re-operation was to treat infection in a patient from the MI group. One patient in the long-incision group suffered a symptomatic deep venous thrombosis in the calf, which was diagnosed three months after the surgery. There were no dislocations in either group within the first year of follow-up.

In the study conducted by Ogonda et al (2005) two patients from the standard incision group died early in the postoperative period. One of the deceased patients had a history of ischaemic heart disease and suffered acute myocardial infarction; and the other, had an extensive bowel infarction from mesenteric vessel thrombosis. Intraoperatively, two patients in the standard incision group acquired fractures, one of the greater trochanter; and the other, of the medial acetabular wall during the insertion of the press-fit acetabular component. Both fractures were treated conservatively. Postoperative complication in the MI group included deep infection, superficial wound infection and early dislocation in one patient each. Complications in the standard incision group included early dislocation and proximal deep infection, which was treated by irrigation and debridement and six weeks of intravenous antibiotics, in one patient each. The patient suffering proximal deep infection from the standard incision group required the only re-operation; in addition the C-reactive protein levels remained normal at eight weeks following the subsequent surgical intervention.

Kaneko et al (2005) reported two femoral calcar fractures in the MI group, which were treated conservatively. No other complications were observed in either group.

In the study by Dutka et al (2007), there were no intraoperative or late complications in either group. Six months after the surgery, there was no incidence of infection, venous thrombosis or hip dislocation among the 120 patients enrolled. One patient in each group

experienced early complications; these were prolonged discharge from tube port (MI THA) and extended subcutaneous hematoma (standard THA).

Effectiveness

In the study conducted by Chimento et al (2005) no mini-incision was converted to standard length due to technical difficulties. There was no difference between the treatment groups with respect to mean operative time, length of hospital stay, volume of blood collected from wound drainage tubes and transfusion, PCEA or oral pain medication requirement ($p \geq 0.3$). However, mean intraoperative blood loss (127 mL versus 170 mL, $p = 0.003$) and total blood loss (378 mL versus 504 mL, $p = 0.009$) were significantly lower in the MI group, compared to the standard THA group. Although preoperative and postoperative interleukin (IL)-6 levels were not significantly different between the two patient groups, there was a significant increase in IL-6 levels from baseline to posttreatment for each group ($P < 0.001$). Thus, the increase was not related to incision length ($P = 0.3$). There was no significant difference in the overall cement grading or the number of C grades between the groups ($P \geq 0.3$). There were no significant differences in the prosthesis position or fixation between the groups. Although 21.4% (6/28) of MI patients and 46.8% (15/32) of standard incision patients had a persistent limp, by one-year follow-up all limps had resolved. At two years the mean Harris hip score was 94.5 for both groups.

In the study carried out by Dorr et al (2007) mean incision length was significantly different between the MI group and the standard incision group ($p = 0.0001$). No mini-incision was converted to standard length due to technical difficulties. The duration of surgery and total blood loss was not significantly different between the two groups ($p > 0.12$). Haemoglobin (g/L) and haematocrit (%) levels were also not significantly different between the groups both pre- and postoperatively, however there was a significant reduction in their levels within each group from baseline to follow-up ($p = 0.001$). Patients in the long-incision group were generally in more pain before medication was given on each postoperative day, this difference was only significant on day one and discharge day ($p = 0.002$). Intravenous narcotics were required by significantly more patients in the long-incision group (23%) than the MI group (3%) ($p = 0.03$). On the first and second postoperative days patients in the MI group were significantly less reliant on an assistive device to ambulate ($p < 0.048$). Significantly more patients from the MI group (97% of patients versus 67% of patients) achieved the goal of discharge on the second postoperative day ($p = 0.003$) and mean hospital stay was shorter for the MI group (63.2 hours [SD 13.3 hours] versus 73.6 hours [SD 23.5 hours]) ($p = 0.04$). Upon discharge significantly fewer patients from the long-incision group (53%) required the use of a single assistive device (i.e. cane, single crutch) compared with the MI group (87%) ($p = 0.005$). At six months follow-up the mean Harris hip score for the mini and long-incision group was 96.8 and 96.0, respectively.

In the study conducted by Ogonda et al (2005) mean total operative time was not significantly different between the groups; however when the operation was separated into three phases (incision to insertion of acetabular liner, insertion of acetabular liner to reduction of hip and reduction to wound closure) the first and last phases were

significantly longer for the standard incision group ($p < 0.001$). No mini-incision was extended to full length during surgery due to technical difficulties. In muscular or morbidly obese patients acetabular exposure was subjectively more difficult through MI. Subgroup analysis found patients with a BMI >35 had a significantly longer operation time compared with patients with a BMI <30 ($p < 0.001$), independent of incision length ($p = 0.48$). Intraoperative blood loss was significantly higher in the standard incision group ($p = 0.03$). Postoperative swelling and inflammation in response to surgery was measured as an increase in mid-thigh circumference and C-reactive protein levels, respectively, neither of these parameters were significantly different between the two groups ($p < 0.30$). Radiographic results of prosthesis position and fixation were also not significantly different.

Functionality tests showed no significant difference between the groups in their ability to move from the supine position to the sitting position, from the sitting position to standing, walk with an aid, negotiate stairs and complete a 10 m walk ($p > 0.27$). Mean hospital stay and the number of patients discharged on the second postoperative day were also not significantly different between the groups. Patient variables which determined the ability for early discharge (< 3 days) included age, preoperative haemoglobin levels and the availability of adequate family support ($p < 0.001$). At six week' follow-up both groups displayed substantial improvement from their baseline analyses. Harris hip score for the MI group had increased to 84.15 (SD 10.56), and for the standard incision group to 83.36 (SD 8.33) (Ogonda et al 2005).

In the study carried out by Kaneko et al (2005) mean incision length and the time taken to complete full weight bearing on the affected leg were the only outcomes significantly dissimilar between the MI group and the standard incision group ($p < 0.05$). Total blood loss, operation duration and the time taken to reach postoperative rehabilitation goals were not significantly different between the groups ($p > 0.05$).

In the study by Dutka et al (2007) the mean duration of surgery in the MI group (118 minutes) was significantly longer than the control group (133 minutes) ($p < 0.05$). Mean total blood loss was also reduced in the MI group (640mL) compared with the control group (835 mL) ($p < 0.05$). The remaining characteristics were not significantly varied between two groups; including pain, radiographic outcomes, postoperative haemoglobin drop, the volume of blood transfused, analgesic use and the length of hospitalisation ($p > 0.05$). At three months' follow-up the Harris hip score for the MI group increased to 92 (range: 87 - 95), and for the control group increased to 88 (range: 80 - 93).

COST IMPACT

With increasing life expectancy and an aging population, it is estimated that there will be an increase in hip dysfunction and an increased need for THA (Lawlor et al 2005), resulting in greater financial pressure on the Australian healthcare system. Over 32,000 total hip and knee replacements were performed in Australian hospitals during 2000-01, costing on average \$12,500 to \$26,400 per procedure in the public sector (Department of Health and Aging 2002, in Australian Institute of Health and Welfare 2006). By 2003-04,

the number of hip and knee procedures had increased to 42,000, with an estimated per procedure cost of AU\$13,600 to AU\$30,600 (Department of Health and Aging 2005, in Australian Institute of Health and Welfare).

Evidence indicates that operative parameters related to MI hip arthroplasty, such as operative time, transfusion and analgesic requirement and duration of hospital stay, are similar to those of standard hip arthroplasty. Therefore, any cost savings to the healthcare system is likely to come from reduced complication rates and shorter rehabilitation time. However, there is no evidence to suggest these factors are improved in MI hip arthroplasty compared with the standard technique. Therefore, MI hip arthroplasty does not appear to offer a potential economic benefit.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

The term ‘minimally invasive’ may allude to two different surgical techniques of hip arthroplasty (Dutka et al 2007). One being THA performed utilising one of the traditional approaches, but with minimal skin and soft tissue dissection (minimal incision technique), and the other using two separate approaches of installation for both prosthesis components (two-incision technique) (Dutka et al 2007). Therefore, it is important these techniques are differentiated before conclusions in respect to their effectiveness are made.

SUMMARY OF FINDINGS

From four randomised controlled trials and one pseudorandomised controlled trial minimally invasive hip arthroplasty appears to be analogous with conventional hip arthroplasty performed through long-incision, in regards to safety and effectiveness. These five studies generally found the two approaches to have similar outcomes, including: operation time, length of hospitalisation, postoperative functionality, perioperative and postoperative complications and patient satisfaction. Some of the studies found the early postoperative results of mini-incision to be slightly superior to the standard technique; however, it is unknown whether differences in postoperative pain management and physical therapy regimen or the mini-incision technique itself is responsible for this. In addition, there are currently no studies reporting on long-term outcomes for mini-incision THA.

It was noted in the studies that minimally invasive hip arthroplasty may not be suitable in patients who are muscular or morbidly obese (BMI > 35) because of increased difficulty in exposing the hip joint. Also, patients with hip conditions that necessitate careful reconstruction (including pre-existing non-union fractures and bone destroyed by osteoarthritis) may not be candidates for mini-incision.

The factors responsible for the pull towards minimally invasive surgical techniques are the promise of reduced pain and rehabilitation time and improved postoperative function. It is possible that patient demand for minimally invasive THA may drive further diffusion of the technique, despite a lack of evidence showing superior benefit compared with standard THA.

HEALTHPACT ACTION

Based on the inconclusiveness of the available literature, minimally invasive hip arthroplasty will be archived. Long-term outcomes of this procedure would be evident from the Joint Replacement Registry.

NUMBER OF STUDIES INCLUDED

Total number of studies	5
Level II evidence	4
Level III-1 evidence	1

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SEARCH CRITERIA TO BE USED

Minimally invasive

Mini incision

Hip arthroplasty

Hip replacement