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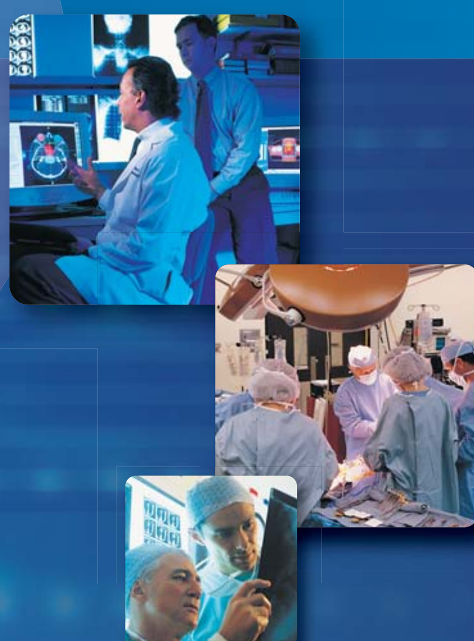
Minimally Invasive Arthroplasty in the Management of Hip Arthritic Disease: Systematic Review and Economic Evaluation



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Minimally Invasive Arthroplasty in the Management of Hip Arthritic Disease: Systematic Review and Economic Evaluation

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Conflicts of Interest

No conflicts of interest were declared by the authors.

REPORT *IN BRIEF*

February 2008

Minimally Invasive Arthroplasty in the Management of Hip Arthritic Disease: Systematic Review and Economic Evaluation

Technology

Minimally invasive total hip replacement (MI THR) procedures that involve single- and double- incision techniques.

Condition

Patients who are eligible for THR due to degenerative, rheumatoid, or other arthritic diseases of the hip.

Issue

Emerging minimally invasive surgical techniques for hip replacement require specialized equipment. There is uncertainty regarding the clinical and economic arguments about the adoption of these techniques.

Methods and Results

Fifty-five articles describing 42 studies [12 randomized controlled trials (RCTs), 22 non-randomized comparative studies, and eight case series (including registry data)] were identified through a systematic literature review. Thirty-two compared single mini-incision with standard incision, including nine RCTs. One RCT compared double incision to single mini-incision. A cost-utility analysis of single incision procedures from the perspective of the Canadian public health care system and a 40-year time horizon was conducted. A value of information analysis was also conducted.

Implications for Decision Making

- **Differences between minimally invasive and standard techniques exist, but the clinical significance is unknown.** MI THR techniques may have some peri-operative advantages (less blood loss and shorter operative time), although these may be of limited clinical significance. Of particular concern is the absence of evidence on the rates of revision after a primary procedure.
- **Single-incision MI THR is unlikely to be cost-effective.** Single-incision techniques are associated with higher costs (C$20,400 versus C$19,100) and quality-adjusted life-years (7.48 versus 7.47) compared to standard THR resulting in an incremental cost per QALY gained of $148,300. The probability that MI THR is more cost-effective than standard THR for a decision maker willing to pay $50,000 for a QALY is 47%. These results are most sensitive to the cost of initial hospitalization and patient utility values in the first year post-treatment.
- **Collecting long-term comparative information may be of value.** Compared to expanding funding for single-incision MI THR, it would be cost-effective to spend up to C$480M on gathering additional data through field evaluation, to remove uncertainty regarding the effect of MI THRs on revision rates.

This summary is based on a comprehensive health technology assessment available from CADTH's web site (www.cadth.ca): Coyle D, Coyle K, Vale L, de Verteuil R, Imamura M, Glazener C, Zhu S. *Minimally Invasive Arthroplasty in the Management of Hip Arthritic Disease: Systematic Review and Economic Evaluation.*

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EXECUTIVE SUMMARY

The Issue

Minimally invasive total hip replacement (MI THR) is a continuation in the trend towards the use of less invasive approaches to surgery. In 2002, there were 19,977 total hip replacements in Canada, of which 86.9% were primary procedures and 13.1% were revisions. This review assesses the clinical effects and cost-effectiveness of minimally invasive approaches to THR for arthritis of the hip from the perspective of the Canadian health care system.

Objective

The aim of this technology assessment is to examine the impact of adopting MI THR into the Canadian health system by answering the following questions:

- What are the known clinical effects of MI THR techniques compared to standard THR for patients undergoing primary THR?
- What is the cost-effectiveness of MI THR techniques compared to standard THR?
- What is the potential financial impact of increased adoption of MI THR techniques?

The study was conducted in collaboration with the United Kingdom's National Institute for Health Research (NIHR) and includes a systematic review of the clinical evidence and a cost-utility analysis.

Clinical Review

Methods: A comprehensive literature search was conducted involving electronic databases (1966 to 2007) and relevant web sites, contact with experts in the field, and the scrutiny of retrieved papers to identify reports of published and ongoing studies. Systematic reviews and selected conference proceedings were also searched. The clinical review adopted the same methods as those in the NIHR health technology assessment (HTA) report.

Results: Fifty-five reports were identified describing 42 studies [12 randomized controlled trials (RCTs), 22 non-randomized comparative studies, and eight case series including one report from a registry]. The RCTs were of moderate quality, with the number of participants varying between 20 and 219.

MI THR techniques may have some peri-operative advantages (less blood loss and shorter operative time), although these may be of limited clinical significance. There was limited evidence on long-term outcomes. Of particular concern is the absence of evidence on the rates of revision after a primary procedure.

Economic Analysis

Methods: The economic implications of the adoption of MI THR was assessed through a review of existing economic studies and the conduct of a cost-utility analysis comparing MI THR to standard THR.

A systematic review of economic evaluations was performed comparing the minimally invasive approach to standard THR.

A Markov simulation model was created to estimate the long-term costs and quality-adjusted life-years (QALYs) for patients undergoing standard THR and MI THR. The economic evaluation assessed the cost-effectiveness of a single mini-incision procedure compared with a double mini-incision procedure because evidence was lacking for the latter. The model was populated with the most appropriate estimates of transition probabilities, costs, and utilities. Short-term cost and utility data were obtained from a recent Canadian RCT. Clinical transition probabilities were obtained from the literature, and where no significant differences were found in the clinical review, a relative risk of long-term events of one was assumed with a wide degree of uncertainty around these estimates. Long-term Canadian costs were obtained from the literature and from Canadian administrative databases. Utilities associated with revision procedures were obtained from the literature. For the primary analysis, a deterministic analysis was used to estimate expected costs and QALYs. In addition, a stochastic analysis was conducted to determine the degree of uncertainty surrounding the cost-effectiveness of MI THR. A value-of-information analysis was conducted to determine which area of research focus would be the most valuable and the value of further research in this area. The economic evaluation in this report was also used in the UK NIHR HTA report, but in this report, data that were more relevant to the Canadian system were used.

Results: Two existing economic evaluations were identified. These studies were of poor quality, given the strong assumptions of the study authors, and, therefore, had limited applicability to Canada. Our Canadian economic evaluation found a single-incision MI THR technique to be associated with higher costs ($20,400 versus $19,100) and higher QALYs (7.48 versus 7.47) compared to standard THR. The incremental cost per QALY gained was $148,300. If a decision maker adopted a threshold of $50,000 per QALY, the probability that MI THR was more cost-effective than standard THR, based on current knowledge, is 47%.

The value of information analysis explored the degree of uncertainty regarding whether or not to adopt MI THR, and the maximum value from conducting further research to reduce this uncertainty. This analysis found that uncertainty around the relative effect of MI THR on future revision rates contributes most to the overall level of uncertainty, with a maximum value of research of $480 million. Compared to funding single-incision MI THR, it would be cost-effective to spend as much as $480 million to remove all uncertainty regarding the effect of MI THRs on revision rates. Other areas of study that would reduce the uncertainty of the results include improving the estimates of short-term cost and utilities.

A sensitivity analysis that was conducted confirmed the high degree of uncertainty around these results. It found that the results were particularly sensitive to changes in the cost of the initial hospitalization, and the utility values for the first year post-treatment.

Health Services Impact

In 2002, there were 19,997 THRs in Canada, of which 86.9% were primary procedures. Assuming a 1% increase in procedures per annum, the number of primary THRs in 2007 can be forecast as 18,246. From the economic evaluation, the incremental cost of initial hospitalization for MI THR compared to standard THR is $1,300, primarily due to the requirement for additional staff and other resources. In 2002, 9% of THRs were MI THRs. Thus, if 25% of THRs were MI, the increased cost in 2007 would be $3.8 million. If the rate of MI THR were higher or lower, there would be a proportional budget impact.

Conclusions

Despite the number of studies identified, there was little evidence of any longer-term differences between MI THR and standard THR. This is mainly because of the lack of data available. In addition, surrogates for longer-term outcomes provided insufficient information with which to make judgements about longer-term performance. Overall, it seems likely that the MI approach offers some peri-operative advantages regarding blood loss and operative time, although these may be of limited clinical significance. The MI approach may also offer a shorter recovery period, as identified by the shorter length of hospital stay and time to return to usual activities.

Two economic evaluations of MI THR were identified. Both were of poor quality and did not provide useful information.

The economic analysis found little difference between therapies in costs and QALYs. Single-incision MI THR was more expensive with more QALYs. The incremental cost per QALY gained was $148,000. The results were sensitive to changes in parameters, and value of information analysis confirms the benefit from conducting more research.

In conclusion, given the level of clinical evidence available and the results of the economic evaluation, greater value seems to be gained from conducting a larger definitive RCT focusing on long-term revision rates rather than providing funding for the expansion of MI THR.

ACRONYMS AND ABBREVIATIONS

BMI	body mass index
CI	confidence interval
DVT	deep venous thrombosis
EVPI	expected value of perfect information
EVPPI	expected value of partial perfect information
ICER	incremental cost-effectiveness ratio
MCS	Monte Carlo simulation
MI	mimimally invasive
OR	odds ratio
PE	pulmonary embolism
QALY	quality-adjusted life-year
RCT	randomized controlled trial
THR	total hip replacement surgery
UK NIHRHTA	UK National Institute for Health Research Health Technology Assessment
WMD	weighted mean difference

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1 INTRODUCTION

1.1 Background and Setting in Canada

Current treatments for arthritis of the hip include weight loss, analgesic or anti-inflammatory medication, and physiotherapy. If conservative management should fail, a hip replacement may be indicated. A total hip replacement (THR) or arthroplasty is most commonly required when a patient has degenerative arthritis (osteoarthritis) of the hip joint. Other indications include rheumatoid and other inflammatory arthropathies, injury, deformity, bone tumours, and avascular necrosis of the femoral head.

In Canada, in 2002, there were 19,977 THRs.[1] Based on a sample of procedures, it was estimated that 86.9% of procedures were primary procedures and 13.1% were revisions; 81% of primary THRs were due to osteoarthritis. Age-standardized rates of THR are higher for females than males (60.1 versus 53.8 per 100,000 in 2002). The increase in rates from 1994 to 2002, however, was greater in males (6% compared to 4%). Of THRs, 66% were conducted on patients over age 65 years. The mean length of stay in hospital ranged from 8.2 days in Ontario to 14.2 days in Newfoundland and Labrador.[1]

1.2 Overview of Technology

A THR is a surgical procedure whereby a surgeon removes the diseased cartilage and bone of the hip joint, replacing it with an artifical joint. The normal hip joint has a socket from the pelvis, and a ball, which is the head of the femur. Standard procedures require an incision that is large enough to remove and replace the diseased ball and socket without a need for additional instrumentation or computer guidance.

Specially designed instruments are used for some of the minimally invasive (MI) surgical techniques that have been developed for inserting standard replacement hips through one or two smaller incisions. In 2002, 9% of THRs were MI procedures.[1] The move towards the consideration of MI THR mirrors moves in other surgical specialties, such as knee athroplasty.[2]

MI THR is not a uniform procedure. It is performed with significant variations between surgeons. There are three types of MI THR. The "double incision", or two-incision approach, can be regarded as new and specific to MI surgery, while the anterolateral and posterior approaches are developments of traditional approaches performed through smaller incisions.

The two-incision technique is performed with the patient supine, and unlike other MI approaches, x-ray fluoroscopy is needed throughout the procedure.[3] A short incision is made anterior to the femoral neck and the hip, approached via medial retraction of the sartorius and rectus femoris muscles, and lateral retraction of the tensor fascia lata. The lateral circumflex vessels are coagulated, and the femoral head and neck resected after a capsulotomy. Lighted Homan retractors are used to obtain acetabular bone exposure, allowing for preparation and cup implantation. A second incision is then made laterally above the greater trochanter and deepened to form a track through which the femoral instrument can be inserted. After femoral preparation and trial reduction, the definitive femoral component is implanted.

The posterior (or posterolateral) approach is a MI adaptation of the approach originally described by Moore.[4] The patient is positioned laterally, and one incision made along the posterior edge of the greater trochanter and deepened through the gluteal fascia. The obturator internus and gemelli muscles are divided close to their insertions, with or without piriformis superiorly and part of quadratus femoris inferiorly.

Finally, MI anterolateral (or anterior) approaches are usually derivatives of the Hardinge or Watson-Jones approaches.[5,6] The patient may be positioned supine or, more commonly, laterally. One incision is made over the anterior part of the greater trochanter and deepened through the fascia lata.

The same staff is needed for MI THR and for standard THR. The single-incision approaches can be performed using the same equipment as standard THR, although specialized customized equipment may be used. This would lead to a one-time cost of approximately $6,000 – a minimal unit cost per patient.

2 THE ISSUE

The increased adoption of MI surgical techniques for certain procedures has led to the exploration of its use in other surgical areas. Thus, there is increasing interest in the adoption of MI THR. The issue is whether there is sufficient clinical evidence and economic arguments for the adoption of such techniques in the Canadian health system.

3 OBJECTIVES

The aim of this health technology assessment was to examine the impact of adopting MI THR on the Canadian health system by answering the following questions:

- What are the known clinical effects of MI THR compared to standard THR for patients undergoing primary THR?
- What is the cost-effectiveness of MI THR compared to standard THR?
- What is the potential financial impact of increased adoption of MI THR?

4 CLINICAL REVIEW

4.1 Methods

A protocol for the systematic review was written a priori. The review was conducted initially as part of a concurrent United Kingdom National Institute for Health Research (NIHR) Health Technology Assessment (HTA) study, and the initial methods and reporting were the same for both reports. Different editorial processes, including peer review, have been applied to the two reports. These may account for differences in the final versions.

4.1.1 Literature search strategy

The search strategy involved searching electronic databases and relevant web sites, contacting experts in the field, and scrutinizing bibliographies of retrieved papers. Electronic searches were conducted to identify reports of published and ongoing studies on the effectiveness of MI THR. Searches were performed for full papers and conference abstracts, and there were no language restrictions. The databases searched were MedLine (1966 to February, 2007, week 3), MedLine In-Process (March 1, 2007), EMBASE (1980 to 2007 week 8), BIOSIS (1985 to March 1, 2007), Science Citation Index (1985 to March 2, 2007), the Cochrane Central Register of Controlled Trials, and current research registers [National Research Register (Issue 4, 2006), Current Controlled Trials (December 2006), and Clinical Trials (December 2006)]. Additional databases that were searched for systematic reviews and other background information included the Cochrane Database of Systematic Reviews (Cochrane Library, Issue 1, 2007), the Database of Abstracts of Reviews of Effects (December 2006), the Health Technology Assessment database (December 2006), and the Health Management Information Consortium (1979 to January 2007). Full-text searching of key surgical journals (American and British editions of *Journal of Bone & Joint Surgery, Journal of Arthroplasty,* and *Clinical Orthopaedics & Related Research* (all 2000 to February 2007) was undertaken. Relevant conference proceedings and reference lists of all included studies were scanned to identify additional potentially relevant studies. We searched the web sites of national orthopedic registries, professional organizations (including the American Association of Orthopaedic Surgeons, the British Orthopaedic Association, and the British Hip Society), and manufacturers (DePuy International, Smith & Nephew, Stryker Howmedica Osteonics, and Zimmer). The search strategies and web sites are documented in Appendix 1.

4.1.2 Selection criteria

A study was eligible for inclusion only if it satisfied each of the following criteria.

a) *Study design*

All randomized controlled trials (RCTs) and quasi-RCTs were included. Prospective non-randomized studies with concurrent comparisons and matched-pair studies, irrespective of the duration of follow-up, were included. Retrospective comparative studies were eligible only if there was evidence of prospective design, consecutive series, or total population recruitment. In addition, case series or single cohort studies with two or more surgeons and a minimum follow-up of one year were selected for inclusion. Single-surgeon case series were included if there was a minimum follow-up of three years, and the full text was available. Data from national registries were included when these registries provided long-term outcomes such as revision rates. Studies or reports in languages other than English and Chinese were excluded after full-text copies of all potentially relevant reports were obtained.

b) *Study populations*

All adults eligible for standard THR for arthritis were included. Studies that solely or primarily focused on patients undergoing total hip arthroplasty for other reasons – such as osteoporosis, fracture, or tumour – were excluded.

c) *Interventions*

Studies of single mini-incision primary THR compared with standard primary THR were included. Studies of two-incision primary THR compared with standard primary THR, or single mini-incision primary THR, were considered. Studies of revision surgery, hip resurfacing, or computer modelling surgery were excluded.

d) Outcomes

Table 1 outlines the outcome measures that were sought.

4.1.3 Selection method

All titles and abstracts obtained were assessed to identify potentially eligible studies. Two reviewers (MI and SZ) independently assessed them for inclusion, using a study eligibility form developed for this purpose (Appendix 2). Any disagreements were resolved by discussion.

Table 1: Outcome measures

Category	Outcomes
Clinical performance	• Revision rates • Time to revision • Dislocation • Surrogates for long-term outcomes o Implant position (radiographic analysis) o Implant migration (radiostereometric analysis) o Heterotopic ossification o Cement quality • Limb length inequality
Harm	• Blood loss • Intra-operative fracture • Peri-prosthetic fracture • Wound infection • Nerve injury • Vascular injury • Deep venous thrombosis and pulmonary embolism
Resource utilization	• Duration of surgery* • Length of hospital stay†
Patient-relevant measures	• 30-day mortality • Long-term mortality • Pain relief • Post-operative pain • Long-term pain • Time to return to usual activities • Functional result (e.g., Harris hip, Mayo, Oxford hip, and Charnley scores) • Health-related quality of life • Patient satisfaction
Other	• Operating theatre throughput • Opposite method initiated (pre-operatively)‡ • Conversions to alternative procedure (intra-operatively) and reasons for conversion§

*Time from first incision to last suture or, where this was unavailable, time in theatre or duration of anesthesia
†Time from admission to discharge
‡A MI hip arthroplasty started when a standard THR was randomly allocated or vice-versa
§A procedure initiated as MI but converted to a standard THR intra-operatively

4.1.4 Data extraction strategy

Two reviewers (MI and SZ) independently screened the literature search results and reviewed the full-text articles of all reports that seemed to meet the selection criteria. Articles were then selected independently by the two reviewers, who systematically applied the selection criteria. They then independently extracted data using a standard data extraction form (Appendix 3). Discrepancies in report selection or data extraction were resolved by discussion, with involvement of a third reviewer (CG) when necessary. The reviewers were not blinded to authors, institutions, or publication. If there was insufficient information in the published report, attempts were made to contact the authors for clarification.

4.1.5 Strategy for quality assessment

The methodological quality of RCTs, quasi-RCTs, and comparative studies of other designs was assessed using the Delphi criteria list (Appendix 4).[7] Each study was assessed independently by two reviewers (MI and SZ). Any disagreements were resolved through discussion.

4.1.6 Data analysis methods

Quantitative data syntheses were performed with the randomized control trial data only. For trials with multiple publications, only the most up-to-date or complete data for each outcome were included. The data from the comparative studies were not formally combined in data synthesis to avoid the risk of accentuating any possible systematic bias inherent in non-randomized studies.[8] To estimate a summary measure of effect on relevant outcomes in the trial data, dichotomous outcome data were combined using the Peto odds ratio (OR) method, because there were relatively few events reported for many of the dichotomous outcomes.[9] The Peto OR is an alternative to the Mantel-Haenszel method for pooling ORs when conducting meta-analyses. It is better than the other approaches at estimating ORs when there are many trials with no events in one or both arms. Continuous outcomes were combined using the inverse variance weighted mean difference (WMD) method, and 95% confidence intervals (CI) and p values were calculated for the estimates of OR and WMD. The results were reported using a fixed effects model. Chi-squared tests and I-squared quantities were used to explore statistical heterogeneity across studies. Where there was evidence of heterogeneity, random effects models were applied for continuous outcomes, and possible reasons for heterogeneity were explored by re-performing analysis under different conditions. Quantitative syntheses were performed using the standard Cochrane software RevMan 4.2 (Cochrane Collaboration, Copenhagen).

Because of a lack of uniformity in the data of many studies, a qualitative review looking for consistency between studies was performed. For continuous variables, this was supplemented by two additional analyses.

In the first, where standard deviations (SDs) were not reported by the authors, they were estimated on p values (calculated SDs) based on available information. This approach made the assumption that SDs are the same in both arms of the trial. Where studies reported only p values less than a certain value (e.g., $p<0.05$), SDs were calculated on the basis of a p value equal to that value (i.e., $p=0.05$).

In the second, where information on p values was also unavailable, SDs were estimated as the weighted means of SDs reported in the other studies that reported data on the same outcome (dummy SDs). A judgment was made for each outcome as to which of the three analyses – reported means and SDs, reported means and SDs with calculated SDs, reported means and SDs with calculated and dummy SDs – should be used as the base case. This judgment was based on consideration of the nature and pattern of missing data. The other analyses are reported in Appendices 10 and 11. Where a quantitative synthesis was considered to be inappropriate or not feasible, a narrative synthesis of results was provided.

4.2 Results

4.2.1 Quantity of research available

The results of the searches are summarized in Tables 2 and 3. The number of papers retrieved from the searches in the Science Citation Index, BIOSIS, Cochrane Central Register of Controlled Trials, and full-text journal searches include only the additional reports found after excluding those identified from the MedLine-EMBASE multi-file search. A total of 887 reports were identified, of which 186 were selected for full assessment.

Table 2: Search results

Database	Number Retrieved	Number Selected for Assessment
MedLine-EMBASE-MedLine In-Process multi-file search (after deduplication in Ovid)	552	104
Science Citation Index	61	11
BIOSIS	28	3
Cochrane Central Register of Controlled Trials Full-text journals	4 19	0 4
National Research Register	22	8
Current Controlled Trials	24	3
Clinical Trials	4	4
Database of Abstracts of Reviews of Effects	35	7
Health Technology Assessment database	35	11
Health Management Information Consortium	0	0
Conference abstracts	96	24
Registry reports	7	7
Total Retrieved	**887**	**186**

Table 3: Articles selected for full assessment

Assessment	Number of Articles
Included in review	55
Kept for background information	42
Excluded	81
Unobtainable	8
Total	**186**

Fifty-five articles including 44 full articles[3,10-50] and 11 abstracts [51-61] met the inclusion criteria for the review. Relevant data were supplemented by a published registry report [62] and extra information from the registry holders (Dr. Birgitte Espehaug, the Norwegian Arthroplasty Register: personal communication, 2007 January 5).

In total, 55 articles describing 42 studies [12 randomized trials, 22 non-randomized comparative studies, and eight case series (including registry data)] were determined to be relevant to the review. Of these, 32 studies were useful for the comparison of single mini-incision with standard incision, including nine randomized trials,[13,14,23,26,29,41,51,57,59] 17 comparative studies,[3,11,12,15-18,25,27,28,31,35,37-39,56,60] and six case series or registry reports.[22,24,32-34,62] One trial was used for the comparison of double incisions with standard THR,[40] and nine were relevant to the comparison of double incisions to single mini-incision, including two trials,[54,55] five comparative studies,[21,30,36,53,61] and two case series.[10,19] The list of included studies and associated references appears in Appendix 5.

A total of 81 other reports were obtained, but they did not meet the inclusion criteria and were subsequently excluded. Of these, four studies did not use concurrent comparisons (i.e., had historical controls), 10 were retrospective studies, and 18 were descriptive studies. Five studies included only participants who received THR for reasons other than arthritis (e.g., fracture), and five studies focused primarily on revision surgery. Seventeen did not report relevant outcomes or did not have a sufficient length of follow-up. The remaining 22 studies were excluded because they were reported in languages other than English. A few studies were ongoing and were therefore excluded. A list of these studies appears in Appendix 6.

a) *Study quality*

Table 4 summarizes the methodological quality of the 12 trials and 22 comparative studies by type of intervention and study design. Details of the quality assessment are shown in Appendix 7.

b) *Single mini-incision procedure*

Regarding the studies examining the single mini-incision procedure, randomization was performed in nine studies. This was considered to be adequate in three of these studies (e.g., a computer-generated sequence, random number tables, or a card drawn by the anesthetist at the time of surgery)[13,29,41] The methods used for randomization and allocation concealment were considered to be inadequate (e.g., alternation, sealed envelopes) in five studies[13,14,23,26,29] and unclear in a further three (which were abstracts or a poster).[51,57,59]

Six of the nine randomized trials reported that the intervention and comparison groups were similar at baseline,[13,26,29,41,51,57] two groups were not balanced in one study,[59] and it was unclear for the other two whether or not the groups were balanced.[14,23] The criteria by which patients were assessed as eligible for inclusion were not described in three trials.[26,51,59] All but one trial[57] reported that the outcome assessors were blinded. It is questionable whether blinding care providers and patients is possible, given the nature of the intervention. Nevertheless, four trials[26,29,51,59] reported that care providers and patients were blinded, and one further trial suggested that care providers were unaware of the incision length.[41] One of these studies reported that blinding was achieved by using a standard-length wound dressing.[29] Point estimates and measures of variability were presented for the primary outcome measures in four studies.[13,14,29,41] Four trials included an intention to treat analysis;[13,14,29,41] it was unclear if this was the case in four others.[26,29,57,59]

Of the 17 (non-randomized) comparative studies examining the single mini-incision procedure, six reported that the intervention and comparison groups were similar at baseline.[15,16-18,27,56] The groups were dissimilar in seven studies,[11,25,28,31,35,38,39] and group similarity was unclear in a further four.[3,12,37,60] The eligibility criteria were not described in five studies.[3,18,31,56,60] In 11 studies, the outcome assessors were not blinded,[12,15,16,25,31] or it was unclear if they were blinded.[3,18,28,39,56,60] One study reported that care providers and patients were blinded: this was done by using a standard-length wound dressing.[11] One further study suggested that patients were unaware of the incision length.[35] Point estimates and measures of variability were presented for the primary outcome measures in 10 studies.[12,16,18,25,27,28,35,37-39] An intention-to-treat analysis was included in nine.[11,16-18,27,28,31,35,38]

Table 4: Methodological quality of included trials and comparative studies

Criteria		One Incision		Two Incisions	
		Trials	Comparative	Trials	Comparative
1a. Was a method of randomization performed?	Y N U	9 0 0	0 17 0	3 0 0	0 5 0
1b. Was a method of sequence generation adequate?	Y N U	3 3 3	0 17 0	2 0 1	0 5 0
2. Was treatment allocation concealed?	Y N U	1 5 3	0 17 0	0 0 3	0 5 0
3. Were the groups similar at baseline regarding the most important prognostic indicators?	Y N U	6 1 2	6 7 4	3 0 0	3 1 1
4. Were eligibility criteria specified?	Y N U	6 3 0	12 5 0	1 2 0	3 2 0
5. Was outcome assessor blinded?	Y N U	8 0 1	6 5 6	0 0 3	1 1 3
6. Was care provider blinded?	Y N U	5 2 2	1 7 9	0 0 3	0 2 3
7. Was patient blinded?	Y N U	4 1 4	2 10 5	0 0 3	0 3 2
8. Were point estimates and measures of variability presented for primary outcome measures?	Y N U	4 4 1	10 7 0	1 2 0	1 4 0
9. Did analysis include intention-to-treat analysis?	Y N U	4 1 4	9 0 8	0 0 3	1 0 4

N=no; U=unclear; Y=yes.

c) Two-incision procedure

Among the eight studies examining the two-incision procedure, an adequate method of random sequence generation (computerized randomization) was performed in two studies.[54,55] One further study reported that patients were randomized, but did not provide information on the method of randomization that was used.[40] No information was available about whether treatment allocation was concealed in these studies. In all three randomized studies[40,54,55] and most of the non-randomized studies,[21,30,53] the intervention and comparison groups were similar at baseline, but this was not the case for one[36] and unclear in another.[61] Half the studies described the patient eligibility criteria.[21,30,36,40] One study reported that the outcome assessor was blinded,[36] but no study reported blinding of the care provider or patient. Point estimates and measures of variability for the primary outcome measures were presented in two studies,[36,40] and one study included an intention-to-treat analysis.[30]

4.2.2 Study characteristics

Table 5 summarizes the baseline characteristics of the participants in the included trials, comparative studies, and case series and registry. Study characteristics are described in Appendix 8.

In the nine trials and 17 comparative studies comparing single mini-incision and standard incision, there were 27 comparisons, because one non-randomized comparative study divided the participants into three groups post-operatively according to the incision length; i.e., mini-incision (<10 cm), midi-incision (10 cm to 14 cm), and standard incision (>14 cm).[35] The results of this study are presented as two comparisons; i.e., mini-incision versus midi-incision, and mini-incision versus standard incision. Hip replacements were performed through several approaches, including anterolateral, lateral, posterolateral, anterior, and posterior. In four trials[14,41,57,59] and one comparative study,[31] the mini-incision procedure (intervention) and the standard incision procedure (comparator) were performed through different approaches (e.g., mini-incision anterior approach versus standard incision lateral approach). A further three comparative studies did not provide information on the operative approaches used.[37,56,60] This is a possible confounder when comparing the potential effects of different surgical approaches and length of incision.

The sample sizes ranged from 20[31,60] to 219,[29] with one trial[29] and one comparative study[3] having 200 or more participants. The total number of participants was 979 in the trials (recruited between November 1999 and June 2004) and 1,686 in the comparative studies (recruited between October 1998 and January 2005). The range of average age of participants was comparable between the trials and comparative studies, from 55.6 years[26] to 72.4 years [23] in the trials and 57.0 years[35] to 71.0 years[16] in the comparative studies. There were more female than male participants across both trials (334 males versus 375 females) and in the comparative studies (510 males versus 567 females), excluding those studies that did not provide information about gender distributions.[3,35,37,39,51,56,57,59] In the trials, participants' body mass index (BMI) was similar in the mini-incision group and the standard incision group, except in one trial, where it was higher for the mini-incision group.[59] In nine comparative studies, however, the BMI in the mini-incision group was lower,[11,15,17,25,27,28,35,38,39] and all but two reported this to be statistically significant.[15,17]

The nine trials were conducted in eight countries: two in the UK,[29,59] and one each in Canada,[51] US,[13] Australia,[14] Czech Republic,[23] Korea,[26] Austria,[57] and China.[41] Eight comparative studies occurred in the US,[3,11,15,17,18,37-39] three in Canada,[16,25,28] two in China,[12,27] and one each in Hungary,[35] Japan,[60] the Netherlands,[31] and Spain.[56] Five trials[13,14,23,26,41] and five comparative studies[11,17,27,37,39] had a follow-up period of one year or longer. In four trials[13,14,26,29] and eight comparative studies,[11,15,17,25,28,35,37,39] it was reported that all surgeries had been performed by, or directly supervised by, one surgeon, while two trials[51,57] and four comparative studies[16,18,31,38] reported that two or more surgeons performed surgeries in one institution, and a further trial involved two surgeons from two institutions.[23]

For case series and registries regarding the single mini-incision procedure, 1,175 participants (551 males and 624 females) were identified between 1988 and July 2004 with the sample size in each study ranging from under 100[22] to over 900.[33,34] The participants' average age was between 60 years[32] and 73 years.[22] One study[34] provided information on participants' BMI at 26.5, which is comparable to the value reported in the trials and comparative studies examining the same mini-incision procedure. The case series and registry data were sourced from five countries, including Germany,[22] Italy,[32] France,[33] US,[24,34] and Norway.[63] All studies were based on single surgeon experience, except for the French study (which involved two surgeons)[33] and the registry data.[64] The duration of follow-up ranged from one year to 10 years.[22,24,32-34,63]

Table 5: Patient baseline characteristics						
Study	**Comparator (Operative Approach, Average Incision Length)**	**Number of Participants**	**Age***	**Sex (Male/ Female)**	**BMI**	**Comments**
One Incision						
RCT and quasi-RCT						
Charles, *et al.*[51]†	milateral	20	66.6	NR	25.8	
	silateral	20	70.8	NR	25.2	
Chimento, *et al.*[13]	miposterolateral, 8 cm	28	67.2	16/12	25.2	
	siposterolateral, 15 cm	32	65.6	13/19	24.8	
Chung, *et al.*[14]	miposterolateral, 9.2 cm	60	61.0	24/36	NR	
	siposterior, 20.0 cm	60	64.0	28/32	NR	
Hart, *et al.*[23]	miposterolateral, 9-10 cm	60	72.4	40/80	27.6	
	siposterolateral, 20 cm	60				
Kim[26]	miposterolateral, 8 cm	70	55.6	53/17	25.6	bilateral THRs (mi on one hip, si on other)
	siposterolateral, 15-20 cm	70				
Ogonda, *et al.*[29]	miposterior, 9.5 cm	109	67.4	49/60	28.2	
	siposterior, 15.8 cm	110	65.9	58/52	28.9	
Rachbauer, *et al.*[57]†	mianterior	60	NR	NR	NR	
	silateral	60	NR	NR	NR	
Sharma and Bharma[59]†	miposterior	20	67.0	NR	26.5	
	siposterolateral, 12 cm	20	68.6	NR	24.4	
Zhang, *et al.*[41]	mianterior, 7.9 cm	60	61.0	25/35	NR	
	siposterolateral, 16.3 cm	60	62.5	28/32	NR	
Comparative Studies						
Asayama, *et al.*[11]	milateral, 8-10 cm	52	64.3	24/28	26.1	
	silateral, 15-20 cm	50	65.1	25/25	28.7	
Berger[3]	mianterolateral, 8.3 cm	100	57.0	NR	NR	
	sianterolateral, 15-20 cm	100	59.0	NR	NR	
Chen, *et al.*[12]	miposterior, ≤10 cm**	51	68.1	28/23	NR	
	siposterior, 15-20 cm	95	69.8	54/41	NR	
Ciminiello, *et al.*[15]	mianterolateral, <12.7 cm	60	69.8	15/45	23.8	matched-pair study
	sianterolateral, ≥12.7 cm	60	70.2	15/45	24.1	
de Beer, *et al.*[16]	milateral, 7.7 cm	30	71.0	10/20	32.4	matched-pair study
	silateral, 13.9 cm	30	69.0	10/20	31.7	
DiGioia, *et al.*[17]	miposterior, 11.7 cm	33	65.0	19/14	27.0	with image navigation; matched pairs
	siposterior, 20.2 cm	33	65.0	19/14	28.0	
Dorr, *et al.*[18]	miposterior, 9.6 cm	109	63.5	52/57	26.7	
	siposterior, 17.9 cm	56	65.6	26/30	26.4	
Howell, *et al.*[25]	mianterolateral	46	59.8	34/16	26.2	
	sianterolateral	56	62.3	27/30	28.8	
Li, *et al.*[27]	miposterolateral, 9.3 cm	18	NR	13/5	24.6	
	siposterolateral, 16.8 cm	18	NR	14/4	26.1	
O'Brien and Rorabeck[28]	milateral, 10cm	32	67.0	19/13	27.0	
	silateral, >10 cm	51	67.0	25/26	30.0	

Table 5: Patient baseline characteristics						
Study	**Comparator (Operative Approach, Average Incision Length)**	**Number of Participants**	**Age***	**Sex (Male/ Female)**	**BMI**	**Comments**
Panisello, *et al.*[56]†	mi	40	NR	NR	NR	
	classic approach	40	NR	NR	NR	
Pilot, *et al.*[31]	mianterior, 8.6 cm	10	67.9	4/6	29.1	
	siposterolateral, 17.4 cm	10	67.5	2/8	26.4	
Szendroi, *et al.*[35]§ (mi/md)	milateral, 8.8 cm	38	64.0	NR	26.0	
	mdlateral, 12.6 cm	43	62.0	NR	28.0	
Szendroi, *et al.*[35]§ (mi/si)	milateral, 8.8 cm	38	64.0	NR	26.0	
	silateral, 16.1 cm	21	57.0	NR	29.5	
Takahira, *et al.*[60]†	mi 7.5 cm	10	NR	3/7	NR	
	si 13.8 cm	10	NR	1/9	NR	
Teet, *et al.*[37]	mi 10 cm	73	NR	NR	NR	
	si 17-22 cm	54	NR	NR	NR	
Woolson, *et al.*[38]	miposterior, ≤10 cm¶	50	60.0	29/21	25.1	
	siposterior, 15-25 cm¶	85	63.0	31/54	28.2	
Wright, *et al.*[39]	miposterolateral, 8.8 cm	42	64.2	NR	24.4	
	siposterolateral, 23 cm	42	65.0	NR	28.3	
Case Series and Registries						
Flören and Lester[22]	miposterior	79	73.0	31/48	NR	participants with minimum 10-year FU only
Hartzband[24]	miposterolateral	100	M61, F65	41/57	NR	
Pipino[32]	milateral, 8-10 cm or 12-15 cm	368	60.0	220/148	NR	1 surgeon in 2 locations
Siguier, *et al.*[33]	mianterior, <10 cm	926	67.8	336/590	NR	
Swanson[34]	miposterior, 8.8 cm	759	62.3	415/585	26.5	
Norwegian Arthroplasty Register[62]	mi	200	NR	NR	NR	
Two-incision						
RCT and quasi-RCT						
Pagnano, *et al.*[54]†	2 mi	10	NR	NR	NR	
	mi posterior	10	NR	NR	NR	
Pagnano, *et al.*[55]†	2 mi	36	66	20/16	NR	
	miposterior	36		20/16	NR	
Yan, *et al.*[40]	2 mi	15	63.0	6/9	NR	
	siposterolateral, 12 cm	15	61.0	7/8	NR	
Comparative Studies						
Duwelius, *et al.*[21]	2 mi	43	57.4	24/19	NR	matched-pair study
	miposterior	43	59.1	24/19	NR	
Greidanus, *et al.*†[53]	2 mi	66	NR	NR	NR	
	mi	99	NR	NR	NR	
Pagnano, *et al.*[30]	2 mi	26	69.0	10/16	NR	staged bilateral THRs (2 mi on 1 hip, mi on other)
	miposterior, 6-9 cm	26				
Tanavalee, *et al.*[36]	2 mi	35	53.0	8/27	25.0	
	miposterior, 9 cm	35	54.9	20/15	24.2	

Table 5: Patient baseline characteristics						
Study	**Comparator (Operative Approach, Average Incision Length)**	**Number of Participants**	**Age***	**Sex (Male/ Female)**	**BMI**	**Comments**
Yoon, *et al.*[61]†	2 mi	100	NR	NR	NR	
	mi, 7.5 cm	118	NR	NR	NR	
Case Series						
Archibeck and White[10]	2 mi	831	61	435/396	26	159 trainee surgeons
Duwelius, *et al.* [19]	2 mi	375	30-76	188/112	NR	4 centres (4 surgeons)

BMI=body mass index; FU=follow-up; md=midi-incision, mi=single mini-incision procedure; 2 mi=two-incision procedure;NR=not reported; RCT=randomized controlled trial; si=single standard incision procedure; THR=total hip replacement
*Age is mean or as reported by individual studies
†Abstract only
‡Includes two-incision surgeries in 29% of mini-incision group
¶Three-arm trial presented as two analyses
§Incision length measured before operation began

In eight studies comparing the two-incision procedure with the single mini-incision[21,30,36,53-55,61] or standard incision [40] procedure, there were 713 participants (122 in the trials and 591 in the comparative studies) recruited between 2002 and 2004. The sample sizes ranged from 20[54] to 218.[61] Where reported, there were more females than males (139 versus 204) with the average age between 53 years and 69 years. Information on participants' BMI was largely unavailable. Four studies occurred in the US,[21,30,54,55] and one each in China,[40] Canada,[53] Thailand,[36] and Korea.[61] Four studies had an average follow-up of one year or longer.[21,36,54,55] Three studies[21,30,36] reported that one surgeon performed all surgeries.

Two case series examined the two-incision procedure.[10,19] Both studies were multi-centred and conducted in the US. The first study involved 159 surgeons who attended corporate-sponsored training on the two-incision THR, and who were asked to report to the company on the first 10 cases.[10] A total of 851 cases from 831 patients were reported between October 2002 and April 2004. The second study involved four surgeons in four institutions performing 375 procedures followed for one year.[19] In both studies, the number of male participants was higher than that of female participants (435 versus 396 and 188 versus 112, respectively).

4.2.3 Data analysis and synthesis

The selected outcomes reported in the included studies are described in Appendix 9. Detailed results of the meta-analyses performed appear in Appendix 10, with summarized results shown in Appendix 11.

4.3 Discussion

Despite the number of studies identified, there was little evidence of long-term differences. This is mainly because of the lack of data available. Surrogates for longer-term outcomes also provided insufficient information with which to make judgements about longer-term performance.

Overall, it seems likely that the mini-incision approach offers some peri-operative advantages in terms of blood loss and operative time, although these may be of limited clinical significance. The mini-incision approach may also offer a shorter recovery period as identified by the shorter length of hospital stay and time to return to usual activities. Patients also seem to be more satisfied with the operation and the appearance of the scar (although this finding may be more influenced by the scar's location than its size). Limited data are available for other outcomes, and the level of uncertainty is such that clinically important differences may favour either treatment. Nevertheless, until new data become available, it may be sensible to assume that the two methods are comparable. The effect sizes based on the meta-analyses of trial data are summarized in Table 6.

It is not possible to make firm conclusions about the two-incision procedure because of the small number of studies identified from our searches and the poor quality of the data reported. At best, the data suggest that the two-incision procedure may offer a possible short-term benefit in terms of earlier discharge from hospital and better quality of life (Harris hip score) compared to single incision (Table 7). Although there were more cases of nerve injuries with the two-incision operation, CIs were wide and did not rule out clinically important differences that could favour two-incision or single-incision procedures. Blood loss and operation time tended to be more favourable in single-incision versus two-incision surgery. For longer-term outcomes, there was no discernible difference according to the type of surgical procedures in the available data.

Table 6: Effect size from meta-analysis of trial data for single mini-incision THR versusstandard THR

Outcome (WMD and Peto OR Based on Trials)	Number of Trials (Number of Comparative Studies)
Favours mini-incision	
Blood loss (mL)* WMD −56.59 [−71.63, −41.55], p<0.00001	7 (11)
Duration of operation (minutes)* WMD −3.70 [−5.67, −1.74], p=0.0002	9 (15)
Length of hospital stay (days)* WMD −0.50 [−0.83, −0.18], p=0.002	6 (12)
Return to usual activities after operation: • Time to return to normal activities: no trial data • Use of walking aids (days): WMD −3.40 [−5.23, −1.57], p=0.0003 • Use of walking aids (number of patients): Peto OR 0.55 [0.20, 1.53], p=0.25 • Limp (number of patients): Peto OR 0.31 [0.11, 0.91], p=0.03	 0 (1) 1 (0) 1 (1) 1 (1)
Patient satisfaction WMD not estimable	1 (3)
No evidence of difference or insufficient information	
Revision rates Peto OR 7.96 [0.16, 402.02], p=0.30	3 (6)
Post-operative dislocation rates Peto OR 1.72 [0.43, 6.92], p=0.45	6 (11)
Surrogates for long-term outcomes: • Implant position (cup): Peto OR 0.93 [0.50, 1.74], p=0.83 • Implant position (stem): Peto OR 0.70 [0.35, 1.40], p=0.31 • Implant migration: Peto OR not estimable • Heterotopic ossification: no trial data • Cement quality: Peto OR 1.26 [0.70, 2.27], p=0.45	 3 (6) 5 (9) 1 (1) 0 (2) 3 (4)
Limb length inequality (number of patients with unequal length) No trial data	0 (1)
Intra-operative fractures Peto OR 0.14 [0.01, 2.18], p=0.16	2 (3)
Post-operative fractures	2 (3)

Table 6: Effect size from meta-analysis of trial data for single mini-incision THR versusstandard THR	
Outcome (WMD and Peto OR Based on Trials)	**Number of Trials (Number of Comparative Studies)**
Peto OR not estimable	
Infections Peto OR 7.48 [0.78, 72.16], p=0.08	7 (9)
Nerve injury Peto OR 1.95 [0.20, 18.89], p=0.56	6 (9)
Vascular injuries Peto OR not estimable	1 (0)
Deep venous thrombosis Peto OR 0.39 [0.12, 1.30], p=0.12	5 (6)
Pulmonary embolism Peto OR not estimable	1 (2)
30-day mortality Peto OR 0.14 [0.01, 2.18], p=0.16	1 (2)
Long-term mortality Peto OR 0.15 [0.01, 2.45], p=0.18	1 (2)
Analgesic use: • Narcotic (days): WMD not estimable • Patient-controlled anesthesia (mg): WMD −4.41 [−29.18, 20.36], p=0.73 • Total narcotic received (mg): no trial data	 1 (0) 3 (0) 0 (3)
Short-term pain: Pain (number of patients): no trial data Pain score: WMD −0.06 [−0.56, 0.44], p=0.81	 0 (3) 4 (2)
Long-term pain: Pain score: WMD not estimable	 1 (0)
Long-term difference in usual activities: Limp: Peto OR not estimable	 1 (0)
Short-term condition-specific quality of life: • Harris hip score:* WMD −1.25 [−3.75, 1.24], p=0.33 • WOMAC: WMD 0.45 [−3.13, 4.03], p = 0.81 • Oxford Hip Score: WMD −0.91 [−2.74, 0.92], p=0.33 • Merle d'Aubigné-Charnley score: WMD not estimable	 2 (3) 2 (0) 1 (1) 1 (0)
Long-term condition specific quality of life: • Harris Hip Score:* WMD 0.35 [−0.13, 0.83], p=0.15 • Merle d'Aubigné-Charnley score: WMD not estimable	 4 (6) 1 (0)
Short-term general quality of life: • SF-12 physical component: WMD −0.75 [−3.38, 1.88], p=0.58 • SF-12 mental component: WMD 0.50 [−2.39, 3.39], p=0.73 • SF-36 physical function: WMD not estimable	 1 (0) 1 (0) 1 (0)
Long-term general quality of life: • SF-36 physical function: no trial data • SF-36 mental function: no trial data	 0 (1) 0 (1)
Favours standard incision	
No outcomes	

OR=odds ratio; THR=total hip replacement; WMD=weighted mean difference; WOMAC=Western Ontario and McMaster Universities Index of Osteoarthritis.
*Based on published data supplemented with calculated SDs. All other values (WMD and Peto OR) are based on published data

Table 7: Evidence for two-incision THR versus single mini-incision or standard THR	
Outcome	**Number of Studies**
Favours two incisions	
Length of hospital stay: 2 mi versus si: 1 favours two incisions (significant difference) 2 mi versus mi: 3 favour two incisions (2 significant differences)	 1 3
Short-term condition-specific quality of life (Harris hip score): 2 mi versus si: 1 favours two incisions (significant difference) 2 mi versus mi: 1 favours two incisions (no significant difference)	 1 1
No evidence of difference or insufficient information	
Revision rates: 2 mi versus si: no studies 2 mi versus mi: no events	 1 1
Post-operative dislocation rates: 2 mi versus si: no events 2 mi versus mi: no studies	 1 0
Surrogates for long-term outcomes: • Implant position (cup): 2 mi versus si: no studies 2 mi versus mi: 8/78 cases versus 8/78 cases • Implant position (stem): 2 mi versus si: no events 2 mi versus mi: 8/78 cases versus 7/78 cases • Implant migration: 2 mi versus si: no studies 2 mi versus mi: no events	 0 2 1 2 0 2
Limb length inequality: 2 mi versus si: no studies 2 mi versus mi: 6/39 cases versus 6/38 cases	 0 1
Intra-operative fractures: 2 mi versus si: no studies 2 mi versus mi: 5/78 cases versus 1/78 cases	 0 2
Post-operative fractures: 2 mi versus si: 1/15 cases versus 1/15 cases 2 mi versus mi: 2/35 cases versus 0/35 cases	 1 1
Infections : 2 mi versus si: no events 2 mi versus mi: no studies	 1 0
Short-term pain: • Narcotics use: 2 mi versus si: no studies 2 mi versus mi: 2 favour 2 mi (1 significant difference), 1 favours mi (significant difference) • Pain score: 2 mi versus si: no studies 2 mi versus mi: 1 favours 2 mi (no significant difference)	 0 3 0 1
Long-term pain (pain score): 2 mi versus si: no studies 2 mi versus mi: no significant difference	 0 1
Return to usual activities after operation (various measures): 2 mi versus si: no studies 2 mi versus mi: 1 favours 2 mi (significant difference), 1 favours si (no significant difference), 1 no difference	 0 3

Table 7: Evidence for two-incision THR versus single mini-incision or standard THR	
Outcome	**Number of Studies**
Long-term difference in usual activities (gait analysis): 2 mi versus si: no studies 2 mi versus mi: no significant difference	 0 1
Long-term condition-specific quality of life (Harris hip score): 2 mi versus si: no significant difference 2 mi versus mi: no significant difference	 1 2
Short-term general quality of life (SF-36): 2 mi versus si: no studies 2 mi versus mi: 1 favours 2 mi (no significant difference)	 0 1
Long-term general quality of life (SF-36): 2 mi versus si: no studies 2 mi versus mi: 1 favours mi (no significant difference)	 0 1
Favours single incision	
Blood loss: 2 mi versus si: 1 favours si (significant difference) 2 mi versus mi: 1 favours 2mi (significant difference), 1 favours mi (significant difference)	 1 2
Nerve injury: 2 mi versus si: 1/15 cases versus 0/15 cases 2 mi versus mi: 10/78 cases versus 0/78 cases	 1 2
Duration of operation : 2 mi versus si: 1 favours si (significant difference) 2 mi versus mi: 3 favour mi (2 significant difference)	 1 3

mi=single mini-incision procedure; 2mi=two-incision procedure; si=single standard incision procedure; THR=total hip replacement.

5 ECONOMIC ANALYSIS

5.1 Review of Economic Studies: Methods

This section reports the findings of a review of economic evaluations that compared the use of MI THR to standard THR. The initial methods and reporting of the review of economic studies were the same for the UK NIHRHTA report and this report. Different editorial processes, including peer review, that were applied to the reports may account for differences in the final versions.

5.1.1 Literature search strategy

Studies that reported both costs and outcomes of single mini-incision or two mini-incision techniques compared to standard THR surgery for the treatment of arthritis of the hip were sought from a systematic review of the literature. No language restrictions or limitations to searches were imposed.

Databases searched were MedLine (1996 to February week 3 2007), EMBASE (1980 to Week 8 2007), MedLine In-Process (March 1, 2007), Science Citation Index (1985 to March 2, 2007), National Health Service Economic Evaluation Database (December 2006), Health Technology Assessment database (December 2006), and Health Management Information Consortium (1979 to March 2006). Conference proceedings and reference lists of all included studies were scanned to identify additional potentially relevant studies. Other sources of information included references in relevant articles and selected experts in the field. The search strategies are documented in Appendix 1.

5.1.2 Selection criteria

To be included, studies had to compare, in terms of both costs and outcomes, strategies involving single- or two mini-incision surgical techniques compared to standard THR for the treatment of arthritis of the hip. Studies were included even if they made no formal attempt to relate cost to outcome data in a cost-effectiveness or cost-utility analysis. One reviewer (RdV) assessed all abstracts for relevance, and full papers were obtained for those that appeared to be potentially relevant.

5.1.3 Selection method

The literature search strategy identified 118 studies. The abstracts and titles of these studies were reviewed, and 23 were identified as potentially relevant. Full papers and reports for the 23 studies were examined, and one study was found to be relevant for inclusion in the literature review. One unpublished study was obtained from the manufacturer (Appendix 13).

5.1.4 Data extraction strategy

The following data were extracted for each included primary study using the framework provided for abstracts prepared for the UK National Health Service Economic Evaluation Database:[65]

a) Study identification information
- author and year
- interventions studied
- type of economic evaluation
- country of origin and currency reported

b) Intervention, study design, and main outcomes
- fuller description of treatment
- numbers receiving, or randomized to receive, each intervention
- outcomes studied

c) Sources of data
- effectiveness data
- mortality and co-morbidity (if measured)
- cost data
- quality of life (if measured)

d) Methods and study perspective

e) Results
- costs
- outcomes
- incremental cost-effectiveness utility ratio (ICER)
- sensitivity analyses

f) Additional comments relating to the design and reporting of the economic evaluation.

For reviews of economic evaluations, data were extracted on the nature of the methods used, the inclusion criteria for studies, the number of studies identified, the method of quality assessment for individual economic evaluations, and the conclusions drawn on the relative efficiency of the alternative methods.

5.1.5 Strategy for assessing validity of included studies

One economist (RdV) assessed the included studies using the National Health Service Economic Evaluation Database guidelines for reviewers.[65]

5.1.6 Data analysis methods

No attempt was made to synthesize quantitatively the primary studies identified. Data from all included studies were summarized and appraised to identify common results, variations, and weaknesses between studies.

5.2 Review of Economic Studies: Results

5.2.1 Number of studies identified

The results of the literature search appear in Table 8. The number of reports retrieved from the search in the Science Citation Index is the total after deduplication against the results of the MedLine-EMBASE multi-file search.

Table 8: Results of searching for studies on cost-effectiveness

Database	Hits Screened	Selected for Full Assessment
MedLine-EMBASE-MedLine In-Process multi-file search (after deduplication in Ovid)	56	16
Science Citation Index	12	1
National Health Service Economic Evaluation Database	5	5
Health Technology Assessment Database	35	1
Health Management Information Consortium	10	0
Selected from conference abstracts	0	0
Total	**118**	**23**

Twenty-three articles were selected from the searches, and one[66] met the inclusion criteria. An unpublished paper was obtained from a manufacturer of hip prostheses.[20] Nineteen of the remaining 22 papers were selected for background information or for possible utilities data. The remaining three were excluded because one contained no cost information,[20] procedures that followed a care pathway dissimilar to usual care in Canada (standard THR was treated as an inpatient procedure while MI THR was an outpatient procedure) were used in the second study,[67] and the final study compared standard THR with a "do nothing" approach rather than a MI THR technique.[68]

5.2.2 Study identification and key elements

a) Comparators, type of study, dates for collection, prospective study from sample

Duwelius' unpublished paper compared single mini-incision and two mini-incision THR with standard THR on a group of non-randomized patients in the US.[20] Straumann *et al.*'s study, which was set in Switzerland, used a model-based analysis to assess the consequences to Switzerland of MI THR compared to standard THR at the aggregate level. For the Swiss study, MI THR was assumed to include the mini-incision and two mini-incision surgical techniques.[66]

The unpublished study was classified as a cost-utility analysis; i.e., the consequences of programs are adjusted by generic health state preference scores to allow the quality-adjusted life- years (QALYs) gained to be assessed rather than the crude number of years of extended life.[69] The Swiss study was classified as a modelling study, with a retrospective costing exercise of standard THR. Effectiveness data and the cost difference between standard and MI THR were based on Duwelius' unpublished US study.[20] Both papers took a societal perspective, i.e., they took into account the cost of productivity losses in addition to hospital and community costs. The characteristics of the included studies appear in Table 9.

Table 9: Characteristics of included studies

Study	Design	Sample	Follow-up	Perspective
Duwelius unpublished[20] (US)	Multi-centred, prospective non-randomized, unmatched cohort	Two-incision THR: 235 Mini-incision THR: 325 Standard THR: 31	6 weeks	Societal
Straumann[66] (Switzerland)	Modelling with retrospective costing exercise of standard THR	13,101 primary THRs performed in Switzerland in 2003	NA	Societal

THR=total hip replacement

The unpublished US study collected its effectiveness data prospectively from 2002 to 2005. The costing was undertaken retrospectively on the same sample as that used for the effectiveness study.[20] In relation to the Swiss study, the baseline costs were estimated for 2003.

5.2.3 Patient group, study sample, and study design

The sample size of the US study was 591 patients, although patients were not distributed equally between the three interventions: 235 patients were treated using the two mini-incision technique, 325 using the single mini-incision technique, and 31 patients were treated with standard THR. For this multi-centred unmatched cohort study, 14 surgeons at 10 hospitals provided data on the 591 patients. It seems that no eligibility criteria were specified, and patients were recruited to each intervention based on surgeon preference. As a consequence, significantly different ($p \leq 0.05$) demographics between groups were identified at the time of operation, i.e., patient selection tended towards younger and healthier patients for the two mini-incision and single mini-incision techniques.[20] Patients were followed for a maximum of six weeks.

Regarding patient groups and study sample, Straumann *et al*.'s Swiss paper is difficult to quantify.[66] This study is classed as a simple, model-based analysis, which used a retrospective costing exercise of standard THR. It is assumed, from published literature, that 13,101 primary THR operations were performed in Switzerland in 2003. The average hospital cost of a primary THR was estimated from one hospital in Zurich. From the total number of primary THRs performed, it was assumed that potentially 30% (conservative) up to 50% (optimistic) of these might have been performed as a MI technique. Therefore, the costs (and potential cost savings) of the minimally invasive surgery (MIS) techniques were calculated at the aggregate level, assuming the indication rates of 30% and 50%, by applying the definitive cost difference in percentage terms between the standard and MI techniques from the unpublished US study.[20]

The main clinical outcome measures for the included studies appear in Table 10.

Table 10: Outcome measures used in included studies	
Study	**End Points**
Duwelius unpublished[20] (US)	• Time to walking without support • Psychometric health status (SF-36) • Post-operative recovery (approximated by WWOS, Harris hip score, and health-related quality of life) • Various complications
Straumann[66] (Switzerland)	• None specified (assumed equal)

5.2.4 Methods of economic analysis

Both papers provided details on which items were included in cost calculations, although no unit cost data was presented for either.[20,66] What is unclear is whether a consistent base-year has been applied to all costs.[20] Indirect costs were calculated for both studies using the human capital approach (time off paid work). In terms of summary measures of health benefits, none were presented for Straumann *et al*.'s study, which assumed that outcomes were equal,[66] while the unpublished US paper presented QALYs as its main measure of health benefit.[20]

Two-way sensitivity analysis was performed by Duwelius for all costs and utility values.[20] Furthermore, community costs such as those of an inpatient rehabilitation facility, skilled nursing facility, home health care, home only (no rehabilitation), and physicians were all varied by +30% and −30% of the base-case values. Wages and hospital cost-to-charge ratios were also varied by +10% or −10% of base-case values. Inflation rates were varied by +5% to −5% of base-case values to see what effect this might have on results.[20] The only sensitivity analysis performed in relation to the Swiss paper was changes to the indication rate of MI techniques from 30% (assumed to be conservative) to 50% (optimistic).[66]

5.2.5 Results

The results of the included studies appear in Table 11. In Duwelius' unpublished study, total costs including productivity costs were lowest for the MIS two-incision technique and highest for the standard technique (two mini-incision $16,085; single mini-incision $16,615; and standard incision $21,705).[20]

Table 11: Cost and outcome data reported in included studies				
Study	**Finding**	**Two Mini-incision**	**Single Mini-incision**	**Standard**
Duwelius[20] unpublished	Total cost*	$16,085	$16,615	$21,705
(US)	Total costs, excluding productivity losses*	$14,651	$14,825	$19,451
	6 week QALYs*	0.053	0.039	0.016
Study	**Finding**	**MIS (Single and Two Mini-incision)**		**Standard**
Straumann[66]	Total cost per patient*	€13,511		€11,534.40
(Switzerland)	Aggregate hospital cost savings assuming 30% MIS indication rate*	€7.8 million saving		NA
	Aggregate hospital cost savings assuming 50% MIS indication rate*	€12.9 million saving		NA
	Aggregate community cost savings assuming 50% MIS indication rate*	€10.9 million saving for two mini-incision and €10.1 million saving for single mini-incision		NA
	Aggregate community cost savings assuming 50% MIS indication rate*	€18.1 million saving for and two mini-incision €16.9 million saving for single mini-incision		NA
	Aggregate indirect cost savings assuming 30% MIS indication rate*	€23.8 million saving		NA
	Aggregate indirect cost savings assuming 50% MIS indication rate*	€39.7 million saving		NA

MIS=minimally invasive surgery; NA=not applicable; QALY=quality-adjusted life-year

When the total cost was divided into hospital costs, rehabilitation costs, and indirect costs, the cost for the two mini-incision and single mini-incision techniques were consistently lower than that of standard THR, with double mini-incision remaining the least costly option. It is unclear whether the differences in costs were tested for significance, and no CIs were reported. In terms of benefits, six-week QALYs were calculated for the three interventions, and the reported incremental effectiveness of the two mini-incision and single mini-incision techniques compared to standard incision were 0.037 and 0.023 QALYs gained, respectively. The authors reported that the same pattern of outcomes and costs were observed after varying input parameters to test the sensitivity of the base-case assumptions.

No measure of health benefit was included in Straumann *et al.*'s study.[66] Average hospital costs per patient were higher for standard THR compared to MI THR (€13,511 versus €11,534.40 per patient). At the aggregate level, it was assumed that by using MI THR in place of standard THR for 30% or 50% of cases, hospital and rehabilitation costs would be reduced and many millions would be saved over the one-year time horizon. In terms of indirect costs, it was assumed that 36 fewer work days were lost per employed patient with MI THR, as opposed to standard THR. From this, it was estimated that the effective reduction of productivity losses ranged between €23.8 million and €39.7 million.

5.2.6 Discussion

The two studies that met the inclusion criteria of the economic review estimated that MI THR (including single and double mini-incision) is likely to be less costly than standard THR. This is because the unpublished US study found that length of stay was statistically significantly shorter for the MI procedures ($p \leq 0.05$). The study also found that the need for community rehabilitation was reduced for the MI procedures in comparison to standard THR. Furthermore, it was reported that short-term outcomes were improved for the MI techniques in comparison with standard THR, although differences in six week QALYs were not statistically significant.[20] A statistically significant difference, however, was found in case-mix between the groups in the unpublished US study, i.e., younger and healthier patients were being selected for the double and single mini-incision approaches compared to standard THR. The authors tried to compensate for this bias by using propensity scoring.[20] As the relative difference in costs and effects were taken from Duwelius' unpublished paper[20] and applied to Swiss data in Straumann *et al.*'s study,[66] it is unsurprising that the same conclusions regarding costs were found. Both studies concluded that the adoption of MI techniques in THR would likely reduce health care costs and provide better short-term outcomes.

Many issues should be taken into account when interpreting the results of the two studies that are contentious. In relation to the unpublished US-based study, the most important limitation relates to the case mix of patients who are recruited to undergo the three surgical approaches. Patients were non-randomized and unmatched. As a result, all reductions in necessity for post-operative care and improved outcomes are likely to be affected by the fact that younger and healthier people were consistently selected to receive the MI techniques. As a result, the fact that these patients were discharged from hospital sooner, were less likely to use rehabilitation facilities in the community, and had higher quality of life in terms of QALYs gained is of little surprise. The authors used propensity scoring when calculating health-related quality of life to counteract the potential biases that might arise from differences in case mix, although the use of this method in the calculation of QALYs is not standard, and its validity is unclear. Further limitations of this study related to the costing method. A retrospective costing exercise estimated surgeon costs from the Medicare unadjusted national average rates for primary THR, hospital costs from charge data converted to costs using a hospital cost-to-charge ratio, and rehabilitation costs from inpatient hospital discharge and Medicare reimbursement schedules. It is unknown whether such costs would be appropriate to Canada and to THR because charges were converted using hospital level cost-to-charge ratios. Furthermore, it is unclear whether a consistent base-year has been applied to all costs as is usual good practice when conducting an economic evaluation.

Little useful information is presented in the Swiss paper,[66] and this study cannot be classified as a typical type of costing exercise. The paper assumes that MI THR is associated with at least equal effectiveness in outcomes and only considers the potential cost savings from the introduction of MI techniques. By applying the definitive cost difference between MI THR and standard THR to the average cost of a standard THR in Switzerland, the authors make several strong assumptions. First, the authors assume that data from the unpublished US study are correct, even for the US, and that MI THR is likely to have equal or better outcomes than standard THR. The authors also assume that US data are likely to be applicable to Switzerland. Given the difference in standard surgical practice across health care systems, this is a strong assumption to make.

5.2.7 Conclusions

This section presents the overall evidence available on the cost-effectiveness of single and double mini-incision THR compared to standard THR in the treatment of arthritis of the hip, based on a systematic review of the literature. The two studies that met the inclusion criteria for the review of economic evaluations add little, if any, value to the evidence base. The studies conclude that MI techniques are likely to be cost saving and provide better outcomes in the immediate post-operative period. Strong assumptions, however, were made by the authors of the two included studies, and techniques that are likely to produce biased and unreliable results were used, thereby limiting the applicability to Canada. Results suggest that the short-term benefits of MI THR for shorter recovery, and consequently a faster return to paid employment, make MI techniques appear less costly. These are strong conclusions to make given the poor quality of the studies. The measurement and inclusion of such costs (indirect costs), however, in an economic evaluation is contentious. A well-designed Canadian-based economic evaluation with long-term follow-up of costs and outcomes is warranted to answer questions about the potential cost-effectiveness of MI THR.

5.3 Primary Economic Evaluation: Methods

The objective of the study was to determine the cost-effectiveness of a MI surgical technique for hip replacement as compared with the standard technique, which involves a larger incision.

5.3.1 Type of economic evaluation

The analysis took the form of a cost utility analysis, given that treatment mainly affects patients' quality of life.

5.3.2 Target population

The base case analysis assumed that patients underwent a total hip arthroplasty at the age of 68 years using one of the two surgical techniques. Aside from the need for hip surgery, the patients were assumed to be otherwise healthy.

5.3.3 Comparators

Two surgical techniques for hip replacement were compared. A single mini-incision technique for primary total hip replacement was compared with a standard surgical technique in which a larger incision is used.

5.3.4 Perspective

The analysis was conducted from the perspective of a provincial ministry of health.

5.3.5 Effectiveness

For the cost utility analysis, effectiveness took the form of QALYs.

5.3.6 Time horizon

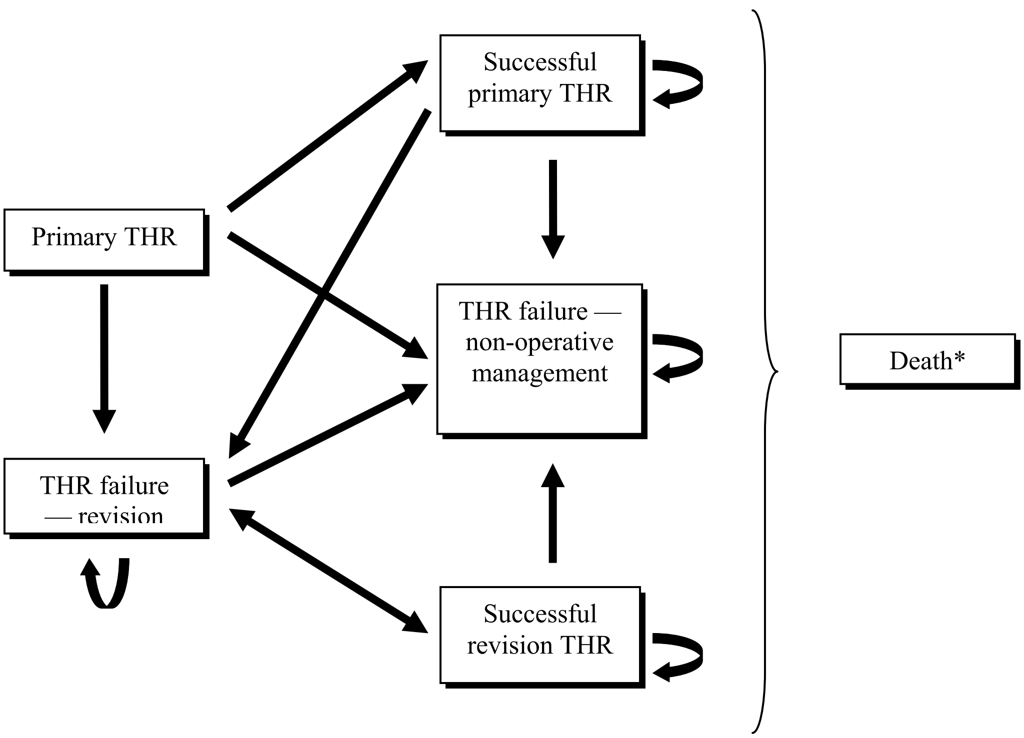
A time horizon of 40 years was used. This reflects the maximum life expectancy of the population.

5.3.7 Modelling

A Markov model was developed, using Microsoft Excel, to predict the outcomes of the two surgical procedures. Analysis was based on a time horizon of 40 years, with costs and benefits discounted at 5% per annum.[70] The Markov model has a cycle length of one year.

It is assumed that the cohort of patients enter the model upon undergoing THR. One year after surgery, patients are assumed to enter one of the following health states: successful THR, failed THR requiring revision, failed THR to be treated by non-operative management, and death. In subsequent years, an additional health state of successful revision is incorporated in the model (Figure 1).

Figure 1: Simplified Markov model



*All states in the model may lead to death

a) Transition probabilities for no treatment

The transition probabilities for the model, where available, were taken directly from the literature included in the systematic review. For the base case analysis, the transition probabilities are the same as those used in the UK NIHRHTA study.

All patients are assumed to enter the model upon undergoing THR via the MI technique or the standard incision technique. As with all surgical procedures requiring general anesthetic, there is a risk of death during the operation. A transition probability of 0.0091 for operational mortality was used in the base case analysis, derived from the Trent regional hip replacement register.[71] As patients transitioned through the 40 years of the model, Canadian annual rates of mortality were applied to the study population.[72]

Outcome states to which patients may transition upon completion of the original operation include successful THR or failed THR. Although the original operation may be considered to be successful, the complications of surgery must be considered. Although they generally do not require revision, they do affect resource use and patients' quality of life. Four complications that were considered in the model include deep venous thrombosis (DVT), pulmonary embolism (PE), dislocation, and deep infection. For all four complications, it is assumed that patients would receive treatment and, upon resolution, would continue to be considered to have undergone successful THRs. The risk of DVT and PE were factored into the initial operation state only with transition probabilities derived from the Scottish Intercollegiate Guidelines Network's Prophylaxis of Venous Thromboembolism guideline.[59] The risk of dislocation and deep infection, which may require reoperation but not revision, were derived from the Swedish National Hip Arthroplasty Register (2004).

Patients with a failed THR may transition to one of two states: revision or non-operative management. For the base case analysis, all patients with failed THRs were assumed to continue to revision rather than to non-operative management. The baseline annual rate of revision was derived from the Swedish registry 2004,[73] which shows that the risk of revision increases from one year to the next until year 24. After this time, it remains constant for the 40-year duration of the model.

b) Treatment effect

To incorporate the effect of the surgical technique on the transition of patients, the transition probabilities for revision and the risk of dislocation, DVT, PE, and infection were weighted by relative risks associated with each procedure. Given the paucity of data in the systematic review, the calculated risks were generally implausible because the Confidence Intervals (CIs) surrounding the values were unreasonably large. Consequently, the difficult decision was taken not to assume any differences between procedures and long-term outcomes. This led to the assumption for the base case analysis that all relative risks would be 1. Thus, the transition probabilities for all health states, including intra-operative mortality, non-operative management, and failure of THR, were assumed to be the same for both procedures.

Estimates of relative risks for dislocation and DVT after MI THR compared to standard THR obtained from the meta analysis, although not statistically significant, were not implausible, unlike the estimates for other relative risks. Thus, a sensitivity analysis was conducted using these relative risks (1.72 CI for the risk of post-operative dislocation and 0.39 for DVT). Further analysis did use all relative risks (including PE, infection, revision rates, and 30-day mortality), although most of these estimates are implausible (e.g., relative risk of almost 8 for revision rates).

5.3.8 Resource use and costs

Canadian costs for the original THR operation and the costs associated with complications, including revisions, were incorporated in the model. The costs of the original operation were estimated from the hospital costs associated with each arm of a Canadian clinical trial comparing the MI technique with the standard technique for THR (n=40, 20 in each group, re-analysis of data from Charles *et al.*[51]). Costs were obtained from the Ottawa Hospital case-costing system, which details patient-specific inpatient costs divided by cost category; e.g., pharmaceuticals, allied health, operation room, equipment, and non-physician personnel. From this, the mean hospital cost of the MIS and the standard surgery were calculated. Physician costs were incorporated by including fees for operations and for ward visits on each day during the patient's hospitalization. These fees were obtained from the Ontario Schedule of Benefits and Fees (2005).[74]

All revision surgeries were assumed to have been conducted using a standard THR technique because they are considered to be too complex for MI techniques. The costs of revisions were estimated from the Ontario Case Costing Initiative for 2006.[50]

The cost of complications were incorporated into the model because they were thought to significantly affect the overall cost estimate and the difference between surgical techniques. The cost of DVT and PE were incorporated in the original THR operation and revision operations. It was assumed that 5% of all DVTs would result in hospital admission and that 95% could be managed on an outpatient basis. DVT costs were derived from a 2003 Canadian study and inflated to 2006 Canadian dollars using the retail price index.[75] The costs of PE, dislocation, and infection were obtained from the same source as the costs of revisions.[50] The costs of dislocation and infection were incorporated in each of the 40 years of follow-up after the original, and any revisional THR.

In some cases, failed THRs are managed through non-operative management rather than revision surgery. It is expected that the costs of non-operative management would be the same in both treatment groups. For the base case scenario, the costs were estimated as $2,084.75 for failed THRs. This incorporates weekly home care visits, two physician consultations per annum, and daily drug costs.

5.3.9 Discount rate

In the base case analysis, costs and outcomes were discounted at 5% per annum.

5.3.10 Valuing outcomes

Utility values in the first year post-surgery were calculated from SF-36 raw data in the same Canadian clinical trial from which cost data were derived (Appendix 12).[51] For MI THR and standard THR, we estimated utilities using the SF6D scoring algorithm for baseline, three months, six months, and twelve months post-surgery.[76] Utilities for the first year of the model were obtained using the area under the curve method. For subsequent years with successful THR, the utility value for twelve months after standard THR is used for both arms.

For patients requiring revisions and for disease complications, utility values were derived from the literature by searching the Harvard Cost Utility Database. Utility values were obtained for surgical failures (dislocation or other complications or for just before revision) and for successful revision from Dawson's study, which was the only identifiable study that focused on patients undergoing revision surgery.[77]

5.3.11 Base analysis

The model allows the conduct of cost utility analysis, where outcomes are expressed in QALYs. Analysis is presented in terms of the incremental cost per outcome gained. Base analysis was conducted through a deterministic analysis whereby point estimates for each parameter are entered into the model, and an estimate of the cost-effectiveness of the two surgical techniques is obtained.

5.3.12 Variability and uncertainty

a) Analysis of uncertainty

A sensitivity analysis was conducted to assess the robustness of the study's results to changing assumptions in the model:

- using median costs rather than mean costs
- applying differences in treatment-specific operating room costs while assuming all other costs are equivalent between surgical techniques
- incorporating the utility values after primary THR, as in the UK National Institute for Health Research Health Technology Assessment report
- applying discount rates of 0% and 3%
- using the Peto ORs obtained from the clinical review
- assuming 25% of patients receive non-operative management rather than revision surgery after failed THR.

b) Monte Carlo simulation

Monte Carlo simulation (MCS) provides estimates of the uncertainty surrounding the incremental cost-effectiveness ratio.[78] MCS involves obtaining several estimates of outcomes by re-running the model using different values for each data input randomly selected from that variable's probability distribution.

For this analysis, the MCS involved obtaining 5,000 estimates of the incremental costs and QALYs associated with MI THR. Crystal Ball, a Microsoft Excel plug-in tool (Decisioneering Inc., Denver, CO), was used to conduct the MCS.

The degree of uncertainty around the estimates were expressed in terms of 95% CIs, and as a cost-effectiveness acceptability curve, which presents the probability that each procedure is optimal given different willingness to pay for an additional QALY.

c) Value of information analysis

In addition to the estimates of uncertainty around the ICER, MCS can provide estimates of the value of conducting further research in this area, given the underlying uncertainty. Thus, a Bayesian value of information analysis was conducted.[79]

Value of information analysis allows identification of the parameters that contribute most to the uncertainty of the study results and, therefore, for which there is most value from conducting further research. Value of information analysis provides an estimate of the maximum value of information gained from additional research. Estimates can be obtained for the whole model, which would give us the maximum value from reducing all uncertainty in the model. This is known as the expected value of perfect information (EVPI). Of more interest is to identify which parameter(s) contribute most to the uncertainty over the study's results. This is obtained by estimating the expected value of perfect partial information (EVPPI).[79]

In this study, analysis was conducted for the overall model (i.e., all the uncertain parameters) and for subsets of input parameters (e.g., costs, utilities, and clinical parameters). Further analysis explored the EVPPI of subsets of parameters that could relate to alternative study designs: a short-term study of one year's duration focusing on costs and utilities; a long-term study looking at all clinical parameters, costs, and utilities beyond one year; and a simple long-term study looking at short-term costs and utilities and long-term effects on revision rates.

The method used to calculate the value of information was the single MCS method.[80,81] This method has been shown to produce results that are comparable to more computationally complex methods such as a two-stage MCS method.[80,81] The single MCS method involves conducting a MCS by sampling from the probability density function of the parameters of interest with all other parameters fixed at their expected value. The EVPPI is the expected value of the difference between the net benefit of the optimal treatment and the maximum net benefits across all treatments.

5.4 Primary Economic Evaluation: Results

5.4.1 Analysis and results

a) Transition probabilities

Tables 12 to 16 show the data inputs for the economic model. Table 12 contains the model transition probabilities with the probability distributions and distribution parameters used in the MCS. Distributions were not incorporated for non-operative management because no patients entered this state for the base case analysis. They were also not incorporated for dislocation and infection because these estimates were derived from a large number of observed events in the Swedish registry. Table 13 presents the annual revision rates and annual mortality as they vary with each cycle of the model.

Table 12: Transition probabilities and other probabilities for Markov model

Parameter	Probabilities	Distribution	Distribution Parameters
Annual revision rates after MI, standard, and revision surgery	Vary by year (Table 13)		
Probability of going into non-management	0	Fixed	
Operative mortality of MI, standard, and revision surgery	0.0091	Beta	alpha=21, beta=2,234
All-cause mortality	Vary by year (Table 13)		
Annual probability of dislocation	0.01	Fixed	
Annual probability of DVT	0.0189	Beta	alpha=22, beta=1,137
Annual probability of infection (first 5 years)	0.011	Fixed	
Annual probability of PE	0.012	Beta	alpha=16, beta=1,302

DVT=deep venous thrombosis; MI=minimally invasive; PE=pulmonary embolism

Table 13: Annual transition probabilities for revision, non-operative mortality, and revision rates after MI, standard, and revision surgery			
Years Post-surgery	**Probability of Revision**	**Age**	**Non-operative Mortality Rate**
0	0	68	0.01996
1	0.007	69	0.02176
2	0.013	70	0.02375
3	0.017	71	0.02599
4	0.02	72	0.02854
5	0.028	73	0.03138
6	0.035	74	0.03441
7	0.042	75	0.03774
8	0.05	76	0.04145
9	0.06	77	0.04563
10	0.073	78	0.05022
11	0.085	79	0.05513
12	0.097	80	0.06046
13	0.113	81	0.06632
14	0.124	82	0.07280
15	0.136	83	0.07982
16	0.147	84	0.08734
17	0.163	85	0.09543
18	0.174	86	0.10422
19	0.186	87	0.11379
20	0.197	88	0.12413
21	0.204	89	0.13515
22	0.211	90	0.14691
23	0.218	91	0.15966
24 onward	0.222	92	0.17339
		93	0.18811
		94	0.20380
		95	0.22046
		96	0.23829
		97	0.25756
		98	0.27792
		99	0.29966
		100	0.32242
		101	0.34678
		102	0.37339
		103	0.39978
		104	0.43141
		105	0.45714
		106	1.00000
		107	1.00000
		108	1.00000

c) Costs

Tables 14 and 15 show the costs required for the model. Table 14 provides a breakdown of the costs associated with the initial THR operation. Costs in all categories (including operating room, recovery room, and implant costs) were higher for MI THR compared to standard THR, except for the surgeon's fees, which are the same for both.

Table 14: Costs of initial operation and first-year follow-up

Parameter	Costs	Distribution	Distribution Parameters
Initial costs of operation* (includes hospital LOS, instrumentation, hip prosthesis, tests, personnel, and first year follow-up costs)			
Standard THR			
Allied health	$506		se=$49
Endoscopy	$0		se=$0
Imaging	$54		se=$3
Laboratory	$142		se=$21
Nursing	$2,517		se=$147
OR and recovery room	$2,483		se=$111
Implants	$3,067		se=$136
Medication	$238		se=$24
Ward visits	$97		
Surgical fee	$696		
Standard THR Total	**$10,158**	**Normal**	**mean=$10,158, se=$249**
MI THR			
Allied health	$776		se=$127
Endoscopy	$17		se=$17
Imaging	$118		se=$47
Laboratory	$169		se=$55
Nursing	$3,050		se=$560
OR and recovery room	$2,724		se=$150
Implants	$3,186		se=$216
Medication	$273		se=$42
Ward visits	$109		
Surgical fee	$696		
MI THR Total	**$11,474**	**Normal**	**mean=$11,474, se=$927**

LOS=length of stay; MI=minimally invasive; OR=operating room; se=standard error;THR=total hip replacement
*p values for all comparisons between standard THR costs and MI THR were all not statistically significant.

Table 15: Costs subsequent to first-year follow-up			
Parameter	**Costs**	**Distribution**	**Distribution Parameters**
Follow-up costs			
Annual follow-up costs for successful standard, MI, or revision THR	$21.10	Fixed	
Non-operative management costs for failed THR	$2,084.75	Fixed	
Cost of complications			
Revision THR	$15,127	Normal	mean=$15,127, se=$475
DVT (admitted to hospital)	$3,059	Fixed	
DVT (outpatient managed)	$248	Fixed	
Dislocation	$7,883	Normal	mean=$7,883, se=$2,066
Infection	$22,087	Normal	mean=$22,087, se=$2974
PE	$5,831	Normal	mean=$5,831, se=$452

DVT=deep venous thrombosis; MI=minimally invasive; PE=pulmonary embolism; se=standard error; THR=total hip replacement

d) Utilities

Table 16 shows the parameters used to derive utility values for each health state incorporated in the model. The methods for deriving the values that were used in the model appear in Table 17.

Table 16: Utility values			
Parameter	**Utility**	**Distribution**	**Distribution Parameters**
Primary standard THR			
Pre-operative	0.612	Beta	alpha=105, beta=66
3 months	0.763	Beta	alpha=234, beta=73
6 months	0.801	Beta	alpha=1,576, beta=392
1 year	0.814	Beta	alpha=157, beta=36
Incremental utility for MI THR			
3 months	0.045	Normal	mean=0.045, se=0.031
6 months	0.001	Normal	mean=0.001, se=0.003
12 months	-0.011	Normal	mean=-0.011, se=0.002
Other utility values			
Failure of THR or complications	0.32	Beta	alpha=309, beta=658
Successful revision	0.62	Beta	alpha=649, beta=398

MI=minimally invasive; THR total hip replacement

Table 17: Derivation of utility values		
Health State	**Method of Derivation**	**Value**
First year – standard THR	$0.125*U_{preop} + 0.25*U_{3mth} + 0.375*U_{6mth} + 0.25*U_{12mth}$	0.771
First year – MI THR	$0.125*U_{preop} + 0.25*(U_{3mth}+ I_{3mth}) + 0.375*(U_{6mth}+ I_{6mth}) + 0.25**(U_{12mth}+ I_{12mth})$	0.780
Successful primary THR	$(1 - P_{comp})* U_{12mth} + P_{comp}*U_{failure}$	0.794
First year – revision THR	$0.5*U_{failure} + 0.5*U_{revision12mth}$	0.47
Successful revision THR	$(1 - P_{comp})* U_{revision12mth} + P_{comp}*U_{failure}$	0.607
Non-operative management	$U_{failure}$	0.32

DVT=deep venous thrombosis; I_{3mth}= difference in utility value at 3 months between MI and standard; I_{6mth}=difference in utility value at 6 months between MI and standard; I_{12mth}=difference in utility value at 3 months between MI and standard; MI=minimally invasive; P_{comp} = probability of dislocation, pulmonary embolism, or deep venous thrombosis; THR=total hip replacement; U_{preop}=utility value before primary THR; U_{3mth}=utility value 3 months after standard; U_{6mth}=utility value 6 months after standard; U_{12mth}=utility value 12 months after standard; $U_{failure}$=utility value after revision failure; $U_{revision12mth}$=utility value 12 months after revision

e) *Base results*

The results of the base case economic analysis appear in Table 18. The standard incision technique for THR was less costly than the MI technique, with lifetime costs of $19,100 and $20,400, respectively. Both techniques resulted in similar lifetime QALYs, with a value of 7.47 for the standard incision technique and 7.48 for the MI technique. The incremental cost per QALY (ICER) gained for the MI technique versus standard therapy was $148,300.

Table 18: Base case analysis

	Costs	QALYs	Incremental Cost per QALY
Standard THR	$19,100	7.47	
MI THR	$20,400	7.48	$148,000

MI=minimally invasive; QALY=quality-adjusted life-year; THR=total hip replacement.

5.4.2 Results of uncertainty analysis

The sensitivity analysis (Table 19) found the results to be sensitive to changes in the costs of initial hospitalizations and utility values in the first year post treatment. Results were not sensitive for the relative effect size of MI THR compared to standard THR for DVT and dislocations. When all relative risks from the systematic review were included, standard THR was more expensive ($2,500), but with more QALYs (a gain of 3.85), leading to a cost per QALY of $700. This unlikely result highlights the limited usefulness of much of the clinical data.

Table 19: Sensitivity analysis

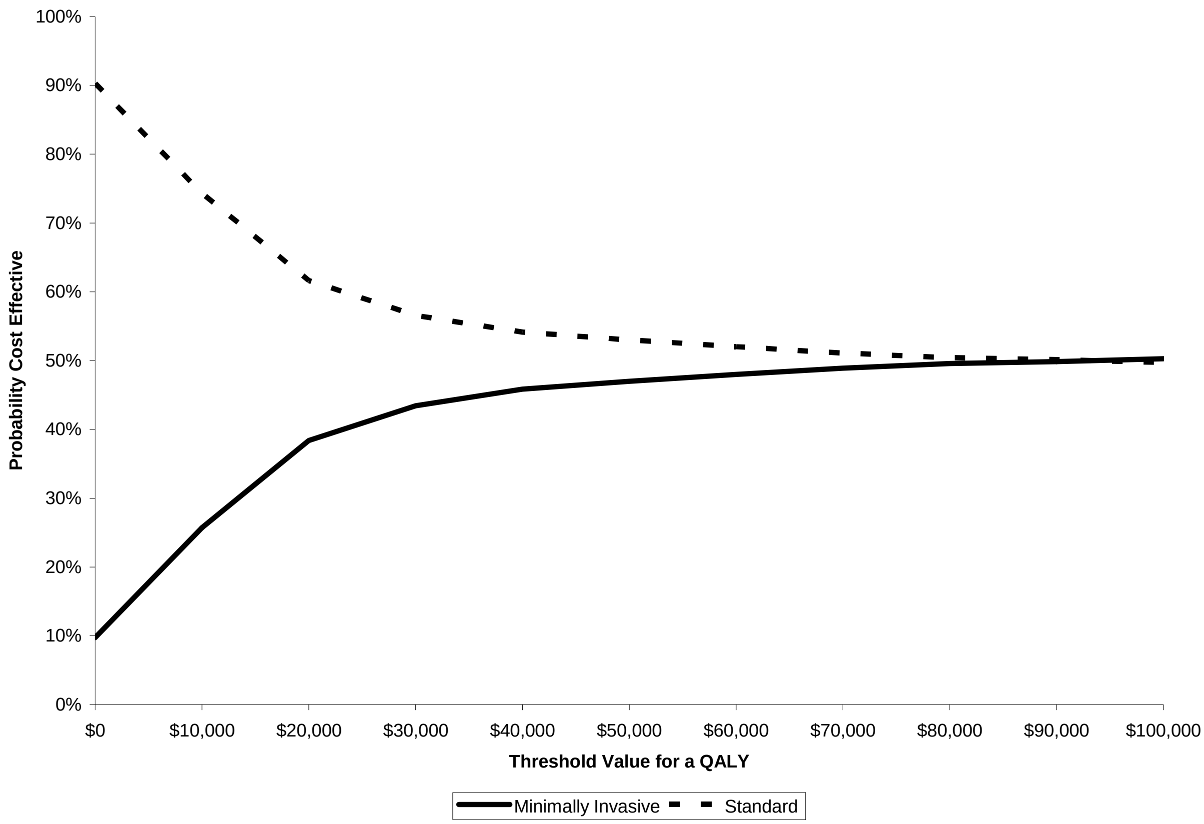
Scenarios where MI THR has higher QALYs	Incremental cost per QALY for MI versus Standard
Base case	$148,000
Increase percentage of DVT admissions from 5% to 25%	$148,000
Assume all costs same except operating room	$42,000
Use median rather than mean costs	$46,000
Utilities from UK NHS HTA report	$75,400
0% discount rate	$148,000
3% discount rate	$148,000
Peto ORs for DVTs and dislocations	$154,000
Use of UK infection costs (converted to Canadian dollars)	$148,000
Non-operative management 25% of failed THRs	$148,000
Scenarios where standard THR has higher QALYs	**Incremental cost per QALY for standard versus MI**
All Peto ORs	$700

DVT=deep venous thrombosis; HTA=health technology assessment; MI=minimally invasive; NHS=National Health Service; QALY=quality-adjusted life-year; THR=total hip replacement

a) *Monte Carlo simulation*

In the MCS, the incremental cost of MI THR was $1,300, with a 95% CI ranging from −$700 to $3,300. The incremental QALYs were 0.01, with a 95% CI of −0.36 to 0.37. For a QALY of $50,000, which is considered to be a common threshold for economic evaluations in Canada, the probability that MI THR is more cost-effective than standard THR is 47%, with the probability rising the greater the value of a QALY (Figure 2). Thus, the results of the MCS confirmed the great uncertainty concerning the cost-effectiveness of the alternative procedures.

Figure 2: Cost-effectiveness acceptability curve for MI THR versus standard THR



MI=minimally invasive; QAL =quality-adjusted life year; THR=total hip replacement.

5.4.3 Value of information analysis

Given the level of uncertainty, there is value to be obtained from further research in this area. Assuming a QALY of $50 000, the EVPI for the overall model is $3,247 per patient. Assuming that there are 18,246 primary THRs per annum, over a 10-year period, this would be $480M for all patients. Thus, it would be expected to be worth $480M to reduce all uncertainty in the model.

EVPPI was greater for clinical probabilities than costs or utilities, suggesting that most of the uncertainty in the model related to the relative effectiveness of the surgical procedures (Table 20). Further analysis exploring the clinical parameters found that one parameter did not have an EVPI of $0 — the relative risk of a revision with MI THR. For costs and utilities, there was no information value in obtaining more precise estimates of these parameters beyond one year.

The analysis of the EVPI of alternative study designs found that a useful design would likely be a simplistic comparative trial comparing MI THR and standard THR focusing on short-term costs and utilities and the long-term effect on revision rates.

Table 20: Expected value of perfect partial information for subsets of parameters		
	EVPI or EVPPI	
	Per Person	**Population* (Millions)**
All	$3,247	$480
Costs		
All costs	$97	$14
1-year data	$97	$14
Post 1-year data	$0	$0
Utilities		
All utilities	$16	$2
1-year data	$16	$2
Post 1-year data	$0	$0
Clinical probabilities		
All clinical probabilities	$3,221	$476
Relative risk for revisions	$3,220	$476
Study designs		
1-year data	$144	$21
Long-term data: after 1 year	$3,222	$476
Simple trial: 1 year costs and utilities and long- term revision rates	$3,246	$480

EVPI expected value of perfect information; EVPPI=expected value of partial perfect information; THR=total hip replacement
*Based on 18,246 primary THRs per annum

5.4.4 Discussion

The published economic evaluations were of insufficient quality to assist in determining the cost-effectiveness of MI THR relative to standard THR.

The economic analysis found little to differentiate between the single incision MI THR procedure and standard THR. In the base analysis, MI THR was moderately more expensive over the time horizon of the model ($1,300), but with an increase in QALYs (0.01). These differences translate into a cost per QALY of $148,300. Thus, the cost-effectiveness of MI THR will depend on a decision-maker's willingness to pay for a QALY.

There is much uncertainty in the analysis. The estimates of costs and utilities in the first year post-surgery are from a reliable source in terms of study quality — a well-conducted Canadian RCT. Therefore, cost data has a high degree of internal validity, but may be limited in external validity. This could be explored through further studies, although no other Canadian data are available. In addition, the number of patients in the study was relatively small, giving large degrees of uncertainty around the identified differences in costs and utilities. Furthermore, the data on the long-term effects of MI THR versus standard THR are sparse, leading to the assumption of no differences in the model.

The uncertainty is confirmed by the results of the sensitivity analysis and the MCS. Value of information analysis suggests there may be gain from conducting a further trial comparing standard THR and MI THR with respect to short-term costs and quality of life, and long-term effects on revision rates.

In the MCS, assumptions were made regarding the distributional form of the costs and utilities. The choice of distribution is complex and, regardless of which distribution is chosen, assumptions about the distributional form are needed. The choice of distribution has no impact on the expected value of costs, utilities, and net benefit, and will only have a modest impact on the estimates of EVPI.

The calculation of EVPI is complex, especially when the relationship between individual parameters and net benefit are non-linear. This would typically require complex methods involving double integration.[81] Although the model is a Markov model, the relationship between net benefit and individual parameters approximates a linear relationship. In previous studies, it has been shown that this is sufficient for the single MCS method to be a proxy to methods that require double integration. [80]

Another limitation of the analysis is that the limited quantity of data available regarding the surgical techniques did not allow for subgroup analysis. Future clinical trials, however, could provide information that would allow for a better understanding of the impact of patient factors such as age, sex, and current health state on outcomes, and whether or not surgical technique has a different impact in different patient populations.

As much as possible, Canadian data were used to populate the model. The extent of Canadian data regarding THR, however, was limited. Therefore, for a few estimates that were incoporated in the Markov model, data from other countries (e.g., Sweden, Scotland, and the UK) were used and assumed to be transferable to the Canadian situation. Should Canadian specific information become available, incorporation of these data in the model would improve its accuracy.

The results of this analysis differ from those of the UK report, which adopted a similar modelling framework, but found that MI THR was less costly and resulted in more QALYs than standard THR. This is mainly because of differences in the analyses relating to the short-term costs and utilities. In this report, we used Canadian data on utilities within the first 12 months post-surgery, and resource use and costs for hospitalizations for Canadian patients. In the UK report, patient-specific resource use was unavailable, so their analysis used differences in length of stay and operation time from clinical trials not necessarily pertaining to UK practice. Similarly, the UK report adopted an assumption relating to longer disutility after standard THR based on recovery times from clinical trials. In this report, a similar delay is noticed by the use of the utility values from the Canadian clinical trial,[51] but the impact of this delay is not as great on QALYs as the assumption in the UK report. The differences between the two reports highlight the uncertainty in this area.

5.4.5 Conclusions

MI THR could be considered to be cost-effective, only if a funder was willing to pay $148,300 per QALY, which is significantly higher than the $50,000 commonly used as a threshold in Canada.[82] Given the high degree of uncertainty over this result, however, more research – particularly into the impact of surgical procedure on revision rates – would improve the estimates and is likely to be of value based on the results of the value of information analysis. Conducting further research in this area would be a better return on investment than moving forward with the MI technique based on the current level of knowledge.

6 HEALTH SERVICES IMPACT

6.1 Population Impact

In Canada, in 2002, there were 19,977 THRs.[1] Based on a sample of procedures, it was estimated that 86.9% were primary procedures and 13.1% were revisions; and 81% of primary THRs were due to osteoarthritis. The age-standardized rates of THR was higher for females than males (60.1 versus 53.8 per 100,000 in 2002). The increase in such rates from 1994 to 2002, however, was greater in males (6% compared to 4%). Of THRs, 66% were conducted on patients over age 65 years. The mean length of stay in hospital ranged from 8.2 days in Ontario to 14.2 days in Newfoundland and Labrador.[1]

6.2 Budget Impact

6.2.1 Objective

The objective of the budget impact analysis was to estimate the impact of increasing numbers of MI THR on Canadian health care expenditures.

6.2.2 Methods

The analysis forecasted the impact, in 2007, of increased numbers of MI THRs. To do this, the following information was needed:

- number of primary THRs conducted in Canada
- percentage of primary THRs that are MI THRs
- incremental cost per MI THR.

6.2.3 Number of primary THRs in Canada in 2007

Of the 19,997 THRs conducted in 2002, in Canada, 86.9% were estimated to be primary procedures. Between 1995 and 2002, the number of THRs increased by 1% per annum. Thus, based on the same annual increase and proportion of primary surgeries, it is forecast that in 2007, the number of primary THRs was 18,246.

6.2.4 Percentage of primary THRs that are MI THR

Based on a sample of THRs conducted in 2002, 9% of THRs were MI THRs.

6.2.5 Incremental cost per MI THR

Based on the economic analysis, the incremental cost associated with a MI THR is $1,300.

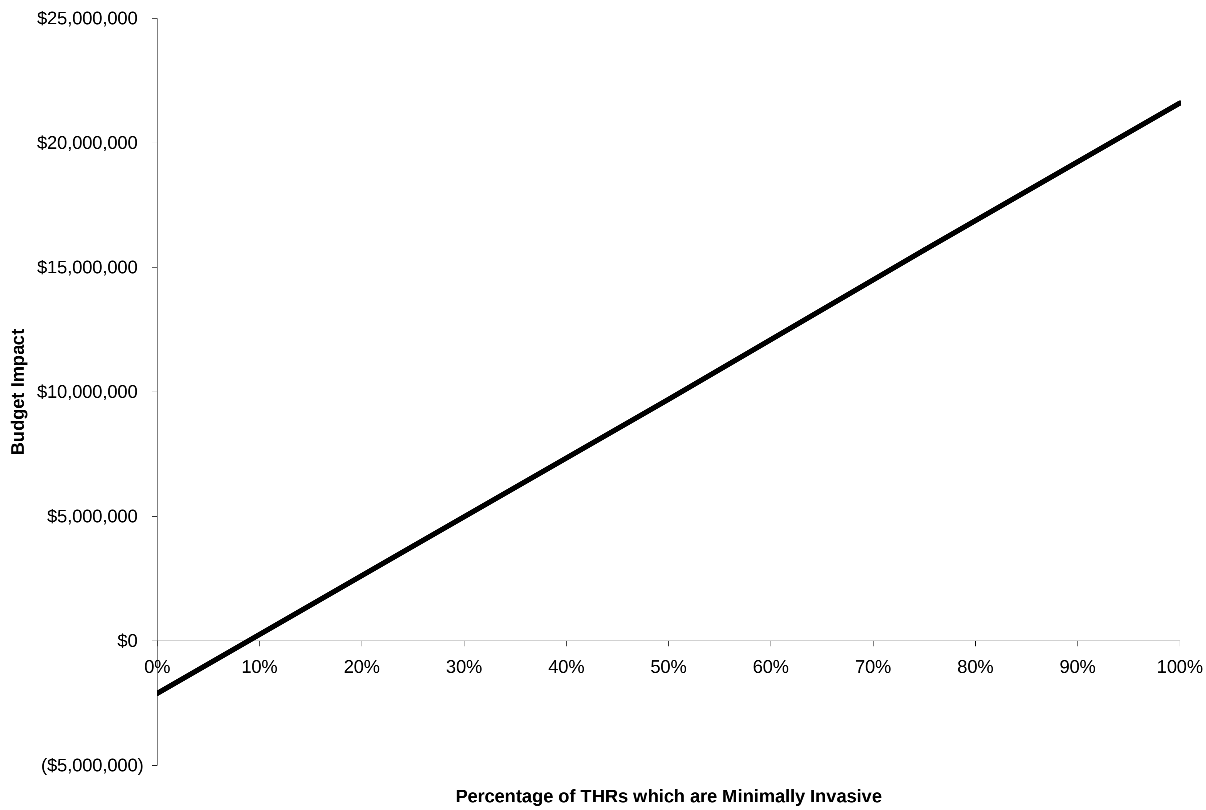
6.2.6 Results

Table 21 and Figure 3 detail the results of the budget impact analysis. If the percentage of primary THRs that were MI THRs was increased to 25%, the budget impact would be $3.8M. If no MI THRs were conducted, the budget impact would be a saving of $2.1 million.

Table 21: Budget impact analysis	
Percentage of THRs that are MI THRs	**Budget Impact**
0%	($2,100,000)
25%	$3,800,000
50%	$9,700,000
75%	$15,700,000
100%	$21,600,000

MI=minimally invasive; THR=total hip replacement.

Figure 3: Budget impact of MI THR by total percentage of THRs



6.2.7 Discussion

In 2002, there were 19,997 THRs in Canada, of which 86.9% were primary procedures. Assuming a 1% increase in procedures per annum, the number of primary THRs in 2007 can be forecast as 18,246. From the economic evaluation, the incremental cost for initial hospitalization for MI THR compared to standard THR is $1,316. Thus, if 25% of THRs were MI, the increased cost in 2007 would be $6 million. If the rate of MI THR was higher or lower, there would be a proportional budget impact. In addition, MI THR procedures may only be adopted for THRs due to arthritic causes because this was the focus of this analysis. This accounts for 81% of primary THR procedures.

6.3 Ethical, Equity, and Psychosocial Issues

The ethical, equity, and psychosocial issues associated with the choice of surgical procedures are limited because of the lack of well-designed clinical trials in this area, and the fact that the results of the available studies do not support a change in current practice.

The findings of this report indicate, however, some disparity between the evidence and the choice of surgical technique for total hip arthroplasty in Canada. The evidence of clinical efficacy and cost-effectiveness does not support a move away from the traditional surgical technique and towards MI techniques. In 2002, 9% of all THRs were performed using MI techniques. Given current knowledge, why are MI techniques being used? The most likely answer to this question is that there is a trend toward the use of MI techniques in other surgical areas such as surgery of the knee, which has led to success, especially from a time-to-recovery standpoint. Physicians' surgical techniques for THR are likely influenced by successes with MI techniques in other areas.

6.4 Planning, Implementation, Utilization, and Legal or Regulatory Considerations

Planning, implementation, utilization, and legal or regulatory considerations were not considered in this report, mainly because results tended not to favour any changes in current practice.

7 CONCLUSIONS

Despite the number of studies identified, there was little evidence of any longer-term differences between MI THR and standard THR. This is mainly because of the lack of data available. In addition, surrogates for longer-term outcomes provided insufficient information with which to make judgements about longer-term performance. Overall, it seems likely that the MI approach offers some peri-operative advantages regarding blood loss and operative time, although these may be of limited clinical significance. The MI approach may also offer a shorter recovery period, as identified by the shorter length of hospital stay and time to return to usual activities.

Two economic evaluations of MI THR were identified. Both were of poor quality and did not provide useful information.

The economic analysis found little difference between therapies in costs and QALYs. Single-incision MI THR was more expensive with more QALYs. The incremental cost per QALY gained was $148,000. The results were sensitive to changes in parameters, and value of information analysis confirms the benefit from conducting more research.

In conclusion, given the level of clinical evidence available and the results of the economic evaluation, greater value seems to be gained from conducting a larger definitive RCT focusing on long-term revision rates rather than providing funding for the expansion of MI THR.

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APPENDICES

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