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## **Treatment of Common Hip Fractures**

**Prepared for:**

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## Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. This report was requested and funded by AHRQ. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions, and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome written comments on this evidence report. They may be sent to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to [epc@ahrq.gov](mailto:epc@ahrq.gov).

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## Structured Abstract

**Objectives:** To conduct a systematic review and synthesize the evidence for the effects of surgical treatments for subcapital and intertrochanteric/subtrochanteric hip fractures on patient-focused outcomes for elderly patients.

**Data Sources:** MEDLINE<sup>®</sup>, Cochrane databases, Scirus, and ClinicalTrials.gov, and expert consultants. We also manually searched reference lists from relevant systematic reviews.

**Review Methods:** High quality quasi-experimental design studies were used to examine relationships between patient characteristics, type of fracture, and patient outcomes. Randomized controlled trials were used to examine relationships between type of surgical treatment and patient outcomes. Patient mortality was examined with Forest plots. Narrative analysis was used for pain, quality of life (QoL), and functional outcomes due to inconsistently measured and reported outcomes.

**Results:** Mortality does not appear to differ by device class, or by devices within a class. Nor, on the whole, do pain, functioning, and QoL. Some internal fixation devices may confer earlier return to functioning over others for some patients, but such gains are very short lived. Very limited results suggest that subcapital hip fracture patients with total hip replacements have improved patient outcomes over internal fixation, but it is unclear whether these results would continue to hold if the analyses included the full complement of relevant covariates. Age, gender, prefracture functioning, and cognitive impairment appear to be related to mortality and functional outcomes. Fracture type does not appear to be independently related to patient outcomes. Again, however, the observational literature does not include the full complement of potential covariates and it is uncertain if these results would hold.

**Conclusions:** Several factors limit our ability to definitively answer the key questions posed in this study using the existing literature. Limited perspectives lead to incomplete sets of independent variables included in analyses. Specific populations are poorly defined and separated for comparative study. Fractures with widely varying biomechanical problems are often lumped together. Outcome variables are inconsistently measured and reported, making it very difficult to aggregate or even compare results. If future high quality trials continue to support the evidence that differences in devices are short term at best, within the first few weeks to few months of recovery, policy implications involve establishing the value of a shorter recovery relative to the cost of the new device. As the literature generally focuses on community dwelling elderly patients, more attention needs to be directed toward understanding implications of surgical treatment choices for the nursing home population.



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Appendixes and evidence tables cited in this report are provided electronically at <http://www.ahrq.gov/clinic/epcindex.htm>

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# Executive Summary

## Introduction

Hip fractures rank in the top ten of all impairments worldwide in terms of loss in disability-adjusted years for people 50+ years old.<sup>1</sup> The absolute number of hip fracture hospitalizations in the United States is currently about 310,000,<sup>2</sup> and this number is expected to continue to rise due to increased life spans and an aging baby boom generation. Ninety percent of hip fractures result from a simple fall;<sup>3</sup> therefore, efforts to prevent hip fractures are unlikely to have a substantial impact on hip fracture incidence.<sup>4-7</sup>

The consequences for hip fractures in elderly individuals are significant in terms of lives lost and the associated negative impacts on hip fracture patients' functioning and quality of life.<sup>8</sup> One year mortality for patients after a hip fracture is approximately 20 percent, with men, patients older than 75 years, and nursing home patients at higher risk.<sup>4,9-11</sup> However, it is not clear how much of that mortality is due to the fracture and its sequelae and how much to the underlying frailty that may predispose a person to a fracture.<sup>12</sup> Morbidity associated with hip fractures may include serious complications, such as deep vein thrombosis and postoperative infection, muscular deconditioning, pain, and loss of mobility.<sup>4</sup> Among patients who were living independently prior to a hip fracture, only about half are able to walk unaided after fracture,<sup>13,14</sup> and about one-fifth require long-term placement in a care facility.<sup>15,16</sup>

Hip fractures are generally classified into three major types, depending on the specific location of the fracture: femoral neck, intertrochanteric, and subtrochanteric fractures. The term pertrochanteric hip fracture may also be used in hip fracture literature and refers to a more inclusive set of extracapsular fractures, including intertrochanteric, subtrochanteric, and mixed fracture patterns.<sup>6</sup>

Femoral neck fractures occur in the narrowed section of the upper femur between the rounded femoral head and bony projections called trochanters. Femoral neck fractures are grouped into *nondisplaced* and *displaced* fractures by the alignment of the fractured segments in relation to the original anatomic position of the femur.

Intertrochanteric hip fractures occur in the area between the greater and lesser trochanters. The trochanters are bony projections where major hip muscles attach. Intertrochanteric fractures may be further grouped into *stable* and *unstable* fractures, depending on the location, number, and size of the fractured bony segments.

Subtrochanteric fractures occur at or below the level of the lesser trochanter in the upper portion of the femur. Isolated subtrochanteric fractures occur in the area between the upper border of the lesser trochanter to 5 cm below it, toward the knee. Subtrochanteric fractures may include only a short, linear section of the proximal femur or may be part of a larger fracture pattern that involves both the intertrochanteric and subtrochanteric sections of the femur. Orthopaedic surgeons differ on their definition of subtrochanteric fractures, and may also consider fractures that extend further toward the knee to be subtrochanteric.

Michelson et al.,<sup>17</sup> found that the distribution of the types of hip fractures within the U.S. population is 49 percent intertrochanteric, 37 percent femoral neck, and 14 percent subtrochanteric, and these estimates are relatively consistent across authors.<sup>11,18,19</sup> The proportions are reliant on the classification system used and the preferences of surgeons in labeling fracture patterns.

The vast majority of hip fracture patients are treated with surgical repair. The short-term goal of surgical treatment is to stabilize the hip fracture enough to withstand early mobilization and weight bearing, which prevents complications due to prolonged bed rest and aids in fracture healing. The type of surgery is generally based on the fracture pattern and patient characteristics. Pertrochanteric fractures are generally managed with internal fixation, most often plate/screw devices or intramedullary nails. Femoral neck fractures are treated with either internal fixation or arthroplasty. Hemiarthroplasty replaces the femoral head segment of the upper femur with an artificial implant. The patient's own acetabulum is not replaced. Total hip arthroplasty is the prosthetic replacement of the entire hip joint, both the femoral head and the acetabulum within the pelvis.

The goal of treatment for hip fractures is to return patients to their pre-fracture level of function.<sup>6,20,21</sup> There is a growing body of literature on treatment options and their effects on intermediary and patient post-surgical treatment outcomes, including several systematic reviews; however, no comprehensive organization of the evidence across all types of geriatric hip fractures currently exists. The aim of the present project was to conduct a systematic review and synthesize the evidence of the effects of surgical treatments of fractures of the hip on patient post-treatment outcomes, which to date have received only modest attention, but which are central to the patient's experience.

## **Key Questions and Conceptual Model**

This review was asked to address the following key questions:

- Key Question 1 – What is the relationship between patient variables, the type of fracture and patient post-treatment outcomes, such as pain and functioning?
- Key Question 2 – What is the relationship between the type of fracture and patient post-treatment outcomes?
- Key Question 3 – What is the relationship between implant variables and patient post-treatment outcomes?
- Key Question 4 – What is the relationship between the type of intervention and patient post-treatment outcomes?

Key question 1 examines the larger question of how patient characteristics, including fracture type, relate to patient outcomes, while key question 2 focuses specifically on the relationship between fracture type and outcome, holding patient characteristics steady. Key questions 3 and 4 are differentiated by the level of analysis of device type, either at the level of specific device or whole classes of devices.

Fracture types and treatment choices are strongly correlated, so the ability to tease apart the separate effects of fracture type and surgical treatment on patient outcomes requires a comprehensive model that would account for the major variables that may impact patient post-treatment outcomes. These variables would include patient characteristics, factors that contribute to the surgical treatments, such as the hospital setting, surgeon factors, and factors related to operative procedures, and post-acute rehabilitation processes.

The review is focused on the patient population most likely to experience hip fractures due to low energy trauma, and the final patient outcomes of mortality, functional status, and quality of life. Patients younger than age 50, and fractures due to high energy trauma, are outside the scope

of this review. External fixators, or devices or surgical methods that are no longer in common use within the United States, are also outside the scope of this review.

## Methods

The search strategy included a list of terms intended to identify all research publications associated with intertrochanteric/subtrochanteric and subcapital hip fractures. Searches for trials were further limited by terms to identify types of surgical implant interventions. Electronic searches of MEDLINE<sup>®</sup>, Cochrane databases, Scirus, and ClinicalTrials.gov were conducted. We also manually searched reference lists from relevant systematic reviews.

The patient population inclusion criteria were age of 50 or older with a nonpathologic fracture that resulted from low energy trauma, and index fractures. Implantable devices must have been available for use in the United States or be similar enough to U.S. devices that the results were meaningful. Excluded devices were either experimental or no longer in clinical use in North America. All retained devices have characteristics that are generally the same as implants that remain in use in North America. All devices were reviewed by orthopaedic clinician authors for inclusion/exclusion status. Decisions were based on clinical experience and/or examining specifications and images of the device in question. Opinions from Technical Expert Panel (TEP) members were sought and TEP members vetted the final list. Because of overlapping clinical terminology within the studies, all types of femoral neck or intracapsular fractures were included.

Articles for key questions 1 and 2 were primarily observational cohort studies limited to those with prospectively collected data and some form of multivariate analysis. Included studies were required to specifically involve research questions aimed at understanding the relationship between patient characteristics, fracture type, and patient outcomes. We retained cohort studies that simultaneously evaluated patients that had either a femoral neck or pertrochanteric fracture, and the fracture type was entered as an independent variable in the multivariate analysis. Patient populations needed to be at least 200 to allow for sizeable enough numbers in each analysis group. Only full journal articles for randomized controlled trials (RCTs) were included because we were focused on a comprehensive approach to patient outcomes, utilizing all factors that might impact patient outcomes. Articles were not excluded based on country of research origin. Key questions 3 and 4 were limited to only RCTs.

Two independent reviewers screened and abstracted all articles using standardized forms. At least two researchers quality checked each evidence table. Differences were resolved through consensus.

The literature was mapped using decision-tree mapping techniques, and the literature was grouped into up to four levels of comparisons. The maps are not comprehensive of all possible decision sets regarding implantable devices for hip fractures as the literature itself does not include RCTs for all decision sets.

When measured patient outcomes were consistent across studies (e.g. mortality), quantitative analysis was performed. A qualitative approach was employed for all other patient outcomes. Results of the quantitative and qualitative analyses are compared to relevant published systematic reviews for consistency of findings. (See Appendix A for details of systematic reviews.)

Only one article focused exclusively on subtrochanteric fractures; therefore, we relied on the intertrochanteric literature where it included subtrochanteric fractures or intertrochanteric fractures with subtrochanteric extensions. As the classification systems do not by themselves provide adequate assurance of identification of subtrochanteric fracture, we relied on subtrochanteric involvement as defined by the study investigators.

We employed a threshold approach to determining which articles to retain. This threshold was set lower than may otherwise normally be applied for a systematic review. Study quality was assessed based on an item checklist,<sup>22</sup> with slight modifications. Since allocation concealment is not fully possible for surgical procedures, we placed a heavier weight on the randomization process and evidence of changes which might impact selection bias, whether the article provided sufficient information on the patient sample, and how carefully the patient sample was defined. Therefore, articles which excluded baseline information on the patient sample by group, or articles that did not provide exclusion criteria, were given lower quality ratings. Likewise, lack of information regarding attrition due to mortality and losses to followup was also weighted more heavily. With such large expected loss to mortality within the first year after a hip fracture, the total loss to followup can be substantial. Articles were retained for the review if they exceeded a minimum quality threshold that allowed for meaningful interpretations of patient samples. The body of evidence was rated according to the GRADE methods.<sup>23</sup> Although the extent of heterogeneity among studies and lack of patient outcomes precluded formal meta-analysis and pooling, we sought to explore the patterns across study groupings.

## Results

The search string for RCTs generated 625 unique references, of which 81 articles were retained representing 76 unique studies; 35 trials for femoral neck fractures, 40 trials for intertrochanteric fractures, and one trial for subtrochanteric fractures. The literature is overwhelmingly international, with only five published trials originating in the United States. Nine observational studies were retained for key questions 1 and 2.

### RCT Study Outcomes

For both femoral neck and intertrochanteric fractures, most head to head RCT comparisons of hip fracture treatments compared classes of fracture repair devices in the absence of supporting RCT literature to show equivalency of implants within classes. For example, a number of articles examined some form of internal fixation versus some form of arthroplasty for femoral neck fractures, but little RCT literature helped determine which forms of internal fixation yielded equivalent outcomes.

With the exception of mortality, there are few instances where similar patient outcomes were evaluated for similar patient populations undergoing the same device comparison, mainly due to inconsistent use of outcomes measures across studies.

### Key Question 1

In the observational literature, very little research specifically addressed the link between patient characteristics and outcome variables by fracture type. Increasing age, comorbidity, and lower prefracture functioning, were predictive of short-term (4 to 6 month) mortality and reduced

or delayed recovery of functioning as measured by ability to live independently, independence in activities of daily living (ADL)/independent activities of daily living (IADL), and mobility. Other identified predictors of recovery included lower American Society of Anesthesiologists (ASA) score, prefracture community residence, and femoral neck fracture. Dementia was also predictive if poor functioning and mortality were combined into an adverse outcome measure. Overall, the same pattern of predictors is found for functioning at 1 year. These results were consistent with observational research that controlled for fracture type as part of case mix, and those studies which dropped fracture type from the final analysis because of nonsignificance at the univariate level.

The observational literature set did not consistently adjust for fracture patterns or use treatment factors, such as hospital or perioperative factors or surgical devices, as model components. It is uncertain whether the reported results would differ, particularly with regard to functional outcomes, had the observational literature included such factors. Currently, the evidence suggests it is reasonable to treat age, prefracture functioning, comorbidities, and cognitive impairment as predictors of hip fracture treatment mortality and functional outcomes, but other predictors may yet be found to be important. The lack of comprehensive data collection within either the observational or RCT literature prevents a definitive answer about the relationship between patient characteristics, fracture types, and patient outcomes.

## **Key Question 2**

The observational literature provides a small amount of evidence that, holding all other factors constant, type of fracture does not independently predict long-term post-treatment patient outcomes. There is limited evidence that intertrochanteric fracture patients experience a delayed recovery period in the short term. However, the literature does not reliably differentiate between stable and unstable intertrochanteric fractures. Until the concern with regard to the reliability of classifying unstable intertrochanteric fractures is addressed, a definitive answer regarding the role of fracture types in post-surgical outcomes cannot be provided.

The RCT literature does not allow for an analysis of the impact of fracture type on post-treatment outcomes. In order to isolate the impact of fracture type, the analysis would need to hold constant other factors that might affect patient outcomes, and the literature is lacking in such covariates, such as patient characteristics, surgeon experience, or rehabilitation factors.. Although fracture stability and displacement within each of the main types of fractures can reasonably be expected to impact outcomes, the current RCT literature also does not allow for subtype analysis by fracture pattern, particularly for intertrochanteric hip fractures. While there is consistent classification of femoral neck fractures into displaced or nondisplaced subtypes across studies, there is great inconsistency in the classification of intertrochanteric fractures into stable and unstable subtypes.

## **Key Question 3**

In addition to the hospital setting factors discussed in key questions 1 and 2, surgeon and perioperative factors also contribute to the overall outcomes of a device-related surgical procedure and should be incorporated into analyses in order to isolate the effects of a device-specific procedure from the setting within which it was used. Unfortunately, few studies reported surgeon factors such as the surgeon's general level of training and experience, the surgeon's

experience with the specific devices being tested, the degree of orthopaedic resident participation in surgical procedures, or the quality of the surgical techniques. Only two used surgeon factors in analyses relative to outcomes.

Of the two articles that examined surgeon experience, one found that good positioning of the device was predictive of 1 year outcomes, and there was a trend for better implant positioning with greater surgeon experience.<sup>24</sup> The other study did not examine post-treatment outcomes, but found that experienced surgeons took less time, had better results for fracture reduction and implant positioning, and their patients experienced fewer complications than among inexperienced surgeons.<sup>25</sup>

Perioperative factors are frequently reported in the literature as intermediate outcomes, but no study used the perioperative factors further in analyses of patient outcomes.

Within the limitations of the literature using an incomplete set of covariates, overall, no major differences were found in mortality or other patient outcomes between different devices for either femoral neck or intertrochanteric fractures. Thus, there is insufficient evidence to support the use of one device over another within a class of devices for either femoral neck fractures or intertrochanteric fractures with regard to patient outcomes.

## Key Question 4

Similar to key question 3, within the limitations of the literature using an incomplete set of covariates, overall, no differences were found in mortality between different classes of devices. That is, there is insufficient evidence to support the use of plates/screws versus intramedullary nail devices for intertrochanteric hip fractures with regard to mortality. Likewise, there is insufficient evidence to support the use of different forms of arthroplasty, or arthroplasty versus internal fixation for femoral neck fractures.

For pain and functional outcomes for femoral neck fractures, on the surface it would appear that total hip arthroplasty (THA) tends to have improved outcomes over internal fixation, and authors of systematic reviews have suggested the evidence is strong enough to recommend THA for cognitively intact, independent elderly hip fracture patients.<sup>26,27</sup> However, one systematic review found no difference in pain or functioning between patients who received internal fixation and patients who received arthroplasty.<sup>28</sup> There also still remains the question of whether these positive findings for THA would continue to hold if the analysis included all the variables relevant to understanding patient outcomes.

The paucity of significant findings for pain and functional outcomes for intertrochanteric hip fractures suggests that neither plate/screw implants nor intramedullary nails can be claimed to produce superior patient outcomes. A few studies reported intramedullary nails were associated with higher pain but earlier improvements in weight bearing and mobility. However, these improvements were short lived, returning to nonsignificance within a few months to 1 year postoperatively. Further, there is also some disagreement within the systematic review literature, which tends to focus on intermediate outcomes such as complication rates. The Cochrane reviews have supported plate/screw devices as superior to intramedullary nails for both stable and unstable intertrochanteric hip fractures,<sup>29,30</sup> while there is some evidence that plate/screw devices have higher complication rates when used for certain unstable AO/OTA 31-A3 fracture subtypes.<sup>31</sup> The issue of implant superiority for intertrochanteric hip fractures may not be fully resolved until there is reliable agreement with regard to the classification of stable and unstable intertrochanteric fractures across orthopaedic studies. Kaplan et al.<sup>32</sup> also suggest there is

insufficient evidence to support specific internal fixation device recommendations for intertrochanteric hip fractures at this time.

The following table summarizes the research findings.

### Summary of Evidence

Patient Group	Strength of Evidence	Findings and Guidance
Femoral Neck – Displaced, generally independent or semi-independent, mobile elderly patients	Low 10 studies, N=1,968 Comparisons of IF	<ul style="list-style-type: none"> <li>No differences in patient outcomes between IF devices.</li> <li><i>No recommendation for type of IF based on patient outcomes.</i></li> <li>Surgeon experience and precision of implant placement may mediate intermediate outcomes.</li> </ul>
	Low 9 studies, N=1,374 IF vs. hemi	<ul style="list-style-type: none"> <li>No long-term differences in patient outcomes between IF and hemiarthroplasty. Possibly shortened recovery period, 4 month outcomes, for hemiarthroplasty.</li> <li><i>No recommendation for device based on patient outcomes.</i></li> </ul>
	Low 5 IF studies, N=526 IF vs. THA 3 hemi studies, N=332 Hemi vs. THA	<ul style="list-style-type: none"> <li>THA had better long-term improvements in pain and mobility than either IF or hemiarthroplasty.</li> <li><i>THA suggested based on patient outcomes for healthy elderly individuals most likely to gain from long-term functional improvements.</i></li> <li><i>Hemiarthroplasty reserved for patients with inadequate reduction and unlikely to see long-term functional benefits from surgical treatment.</i></li> </ul>
Femoral Neck – Displaced, age 70+ years with cognitive impairment	Low 2 studies, N=120 IF vs. hemi	<ul style="list-style-type: none"> <li>No differences in patient outcomes between IF and hemiarthroplasty.</li> <li><i>Hemiarthroplasty reserved for patients with inadequate reduction.</i></li> </ul>
Intertrochanteric – Unstable, all classifications, generally independent or semi-independent, mobile elderly patients	Low 32 studies, N=5,979 Comparisons of IF	<ul style="list-style-type: none"> <li>No differences in patient outcomes between IF devices.</li> <li><i>No recommendation for device based on patient outcomes.</i></li> <li>Surgeon experience and precision of implant placement may mediate intermediate outcomes.</li> </ul>
Intertrochanteric – Unstable, AO/OTA 31-A2, 70+ years of age	Low 2 studies, N=148 IF vs. arthroplasty	<ul style="list-style-type: none"> <li>No differences in patient outcomes between IF and arthroplasty.</li> <li><i>Arthroplasty should be reserved for patients with degenerative arthritis, severe comminution, or highly osteoporitic bone.</i></li> </ul>
Subtrochanteric – all classifications	Moderate 3 studies, N=148 Plate/Screw vs. IM	<ul style="list-style-type: none"> <li>No difference in patient outcomes between IF devices.</li> <li><i>No recommendation for device based on patient outcomes.</i></li> </ul>
Reverse Oblique/Transverse – AO/OTA 31-A3	Moderate 1 study, N=39 Plate/Screw vs. IM	<ul style="list-style-type: none"> <li>No difference in patient outcomes between IF devices.</li> <li><i>No recommendation for device based on patient outcomes.</i></li> </ul>

IF = internal fixation; IM = intramedullary device; THA = total hip arthroplasty

## Discussion

The surgical treatment of hip fractures improves patients' lives. In general, pain is reduced and function is restored after surgical treatment. About 75 percent of community dwelling elderly patients regain their prefracture independence by 1 year.<sup>33</sup> However, outcomes differ by the pre-fracture status of the patient. Older age, lower prefracture functioning, and cognitive impairment are consistently associated with higher mortality and worse functional outcomes for hip fracture patients. Fracture type does not appear to be independently related to long-term patient outcomes, although limited evidence suggests that intertrochanteric hip fracture patients may experience initial and short-lived delays in recovery relative to femoral neck fracture patients. It is unclear whether these results would continue to hold if the analyses included the full complement of relevant and important covariates.

The summary table above summarizes the surgical treatment guidance based on patient-focused outcomes that can be drawn from the evidence at this time. Overall, mortality does not appear to differ by class of device or by devices within a class. Nor, on the whole, do pain, functioning, and quality of life vary by device. Very limited results suggest that femoral neck fracture patients with THA have improved patient outcomes over internal fixation.

A strong case cannot be made for specific surgical treatments at this time for several reasons. Patient outcomes associated with different techniques produce only modest differences, if any. In addition, the literature does not include full complements of potential covariates that are necessary to draw clinically-relevant conclusions. Moreover, the overall strength of the evidence is generally low. Finally, the literature comparing devices within a class is scant compared with device class comparisons themselves, which provides a weak foundation for suggesting any device class guidelines for the treatment of particular hip fracture patient populations.

Since surgical choices are not clearly differentiated by patient-focused outcomes in the available literature, guidelines for surgical repair of hip fractures will need to rely on intermediate outcomes and expert opinion for the present time. The failure of the literature to provide guidance should not be viewed as an insurmountable problem, but rather as opportunities for research improvements.

The temporal nature of the recovery from hip fracture also bears more attention. The gain for patients seems to lie in the immediate post-treatment time spent in a better functional state. Among the two-thirds of patients who, on average, survive the first year after hip fracture, functional gains seemed to hit a maximum at 1 year.<sup>34</sup> Clinical trajectories converge by this point, or even earlier. Patients who were followed longer than 1 year generally showed functional declines. The policy implications thus involve putting a value on what can be thought of as the area under the curve. What is the value of an improved short-term recovery if the benefits for one device relative to another are short lived? This question takes on greater importance as the population ages and the fracture risks increase. At the same time, there are growing numbers of young elderly patients still working, for whom a shorter recovery period may have a direct impact on their income potential.<sup>35</sup>

Clinical trial quality within the past several years appears to be improving. Both the technical conduct of orthopaedic studies is improving and the outcomes perspective has been broadening to include patient input. We note both improvements in study conduct and improvements in the clarity of reporting, particularly in patient tracking and reporting post-discharge (better CONSORT compliance). This new initiative to improve outcomes reporting is likely to result in an increased ability to link fracture type, pattern, and implant to outcomes if well-designed,

sufficiently powered trials with adequate followup and consistently used outcome measures, are conducted. Yet, based on our review of the literature, the broader hip fracture outcomes questions of interest cannot be fully answered with the existing literature.

Two main factors limit our ability to definitively answer the key questions posed in this study using the existing literature. The first factor is the limited perspective of discipline-specific investigations, which tend to use incomplete sets of important independent variables in study designs and models. The second factor is the generally low quality of hip fracture outcome studies, where specific populations are poorly defined and separated for comparative studies, and inconsistent outcome variables impede aggregating, or even comparing, results.

While the clinical study quality has improved within the last several years, the literature that was available for this review reflects a problem common to studies of musculoskeletal functional outcomes, a lack of consistent outcomes measurement. Other problems that substantially limit the strength of study conclusions are high or unreported patient attrition, inadequate power, and inadequate or unreported randomization schemes.

## Future Research Recommendations

A number of recommendations can be made to improve future research so that it might contribute to improved surgical guidelines.

- Encourage collaboration between the research communities rooted in different research disciplines and methodologies. Bringing together the surgeon's perspective with regard to the importance of fracture types and patterns and device/surgery specifics and the epidemiologist's understanding of the importance of patient factors on functional outcomes would enhance our understanding of hip fracture patients and help match best treatments to the patient populations most likely to benefit from them. The Journal of Bone and Joint Surgery published a series of articles addressing research design and potential contributions that well designed observational studies can provide to orthopaedic research.<sup>36-43</sup>
- Continue focusing on rigorous study design, sufficiently powered RCTs that follow CONSORT recommendations, and relevant functional outcomes. Multicenter, well-designed RCTs are necessary to evaluate results among patients with uncommon fracture patterns. Firm inclusion and exclusion criteria should be specified before embarking on RCTs and be strictly followed throughout enrollment to minimize post-randomization exclusions.
- Establish consensus on consistent definitions of stable and unstable intertrochanteric hip fractures within the most commonly used classification system(s). The use of obsolete classification systems should be avoided. At a minimum, the frequency of each fracture subtype among all patients should be included in all manuscripts and analyzed in relation to outcomes. This would not preclude authors from recommending refinement or switching to other classifications systems. But if those recommendations are made in addition to, and perhaps compared with, a classification standard, the ability to leverage the information across research studies would be greatly enhanced.
- Develop more inclusive conceptual models and use these as the basis for analyses. Surgical repair of hip fractures is a necessary critical step in restoring function to patients, but viewed in isolation it is insufficient to relate intervention to outcomes in the context

of other critical factors. In order to isolate the effects of surgical treatments, research will need to incorporate measurements of all the major contributors to patient outcomes in order to control for them. Only a small portion of the published research for hip fracture surgical treatments collected such data, and even less incorporated the data into their analysis. Other patient characteristics important to understanding final outcomes may still need to be delineated. For example, fear of falling at 6 weeks post-surgery was a significant predictor of patient outcomes for hip fracture patients, in addition to cognitive impairment and depression.<sup>44</sup> Patient outcomes may be affected by the inference the patient draws from the pain and the larger experience.

- Enhance reporting of surgeon variables. Define and quantify the quality of surgical techniques. As a few studies have begun to do, surgeons can quantify the quality of the fracture reduction postoperatively.<sup>45-47</sup> Surgeons can also assess the technical quality of their implant placement immediately postoperatively.<sup>45,46,48,49</sup> It would also be appropriate to identify and report surgeons' level of experience with devices and procedures used for an RCT and, if possible, use this information in the analysis. The degree to which orthopaedic residents performed critical portions of surgical procedures should be identified.
- Consistently use validated quality of life and outcome assessment tools to improve comparability of outcomes across studies. A number of well-developed scales are available.<sup>50</sup> Investigators need to resist the urge to tweak outcome measures; measures idiosyncratic to their own study should be accompanied by validated measures that allow for validation and ensure their study results will be amenable to pooling.
- Consider funding data pools wherever possible. This is particularly important for assessing infrequent events such as low frequency fracture patterns, specific complications, or patients who represent a small proportion of the overall patient base. The observational literature has taken the lead to date on pooling data across studies. For example, enough research exists to demonstrate gender differences in hip fracture risk factors and outcomes.<sup>11,51,52</sup> Yet the research examined in this review found women to represent approximately 80 percent of the patient population across the studies. Within single studies this often does not provide sufficient power for subgroup analysis. Yet men that sustain a hip fracture are often sicker, at higher mortality risk than women, and differentially develop complications and respond to treatment.<sup>51</sup>
- Include and report on patients with cognitive impairments and dementia, with particular emphasis on patients admitted from nursing homes or other institutional residences. The issue of best treatments for the very frail elderly patients will continue to grow as the general population ages.

# **Evidence Report**



# Chapter 1. Introduction

## Overview

Hip fractures rank in the top ten of all impairments worldwide in terms of loss in disability-adjusted years for people 50+ years old.<sup>1</sup> Hip fracture rates in elderly population in the United States have decreased from 901 per 100,000 population in 1993 to 776 per 100,000 population in 2003; however, the absolute number of hip fracture hospitalizations increased 19 percent, from 261,000 to 309,500 during the same time period.<sup>2</sup> This number is expected to continue to rise due to increased life spans and an aging baby boom generation; by 2030, 71 million older adults will account for roughly 20 percent of the U.S. population.<sup>53</sup> The lifetime incidence of hip fracture is 17 to 22 percent for 50 year old women, 6 to 11 percent for men, and, while the rate for women stabilizes, there is an age-specific increase in incidence rates for men.<sup>54,55</sup>

Ninety percent of hip fractures result from a simple fall.<sup>3</sup> Although it might be argued that hip fracture incidence may change in the future due to recent drug interventions for osteoporosis,<sup>4</sup> efforts to prevent hip fractures are unlikely to have a substantial impact on hip fracture incidence.<sup>4,7</sup> In fact, many studies have found considerable overlap in bone mineral density and bone mass between hip fracture patients and their controls, suggesting that other factors are strong contributors to hip fracture risk. These factors include body size characteristics, decreased muscular strength, inactivity, impaired cognition, impaired perception and vision, environmental circumstances, chronic illnesses and drugs that may contribute to the propensity to fall, such as psychotropic anxiolytic/hypnotic drugs, barbiturates, opioid analgesics, antihypertensives, anticonvulsants, caffeine, tranquilizers, sedatives, antidepressants.<sup>4,56</sup>

Consequences of hip fractures are significant in terms of lives lost and the associated negative impacts on hip fracture patients' functioning and quality of life.<sup>8</sup> One year mortality for patients after a hip fracture is approximately 20 percent, with men, patients older than 75 years, and nursing home residents at higher risk,<sup>4,9-11</sup> as much as a three-fold increase in the first year after fracture.<sup>57</sup> However, it is not clear how much of that mortality is due to the fracture and its sequelae and how much to the underlying frailty that may predispose a person to a fracture.<sup>12</sup> Morbidity associated with hip fractures may include serious complications, such as deep vein thrombosis, muscular deconditioning, postoperative infection, pain, and loss of mobility.<sup>4</sup> Among patients who were living independently prior to a hip fracture, only about half are able to walk unaided after fracture,<sup>13,14</sup> and about one-fifth require long-term placement in a care facility.<sup>15,16</sup>

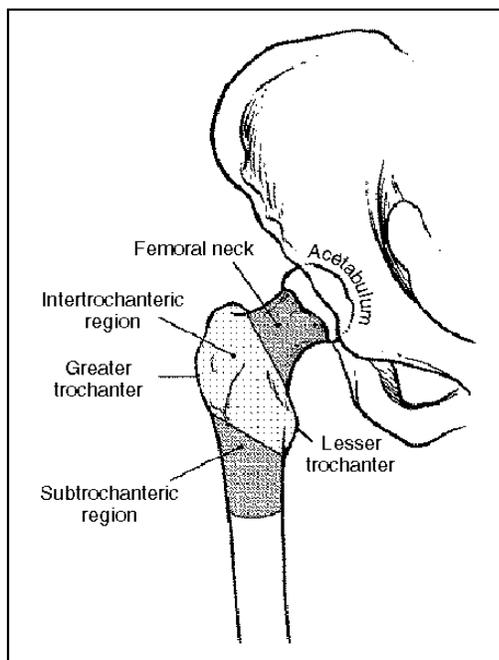
The goal of treatment for hip fractures is to return patients to their pre-fracture level of function.<sup>6,20,21</sup> Treatment options for hip fracture patients depend on the location and pattern of the fracture, patient characteristics, and available Food and Drug Administration (FDA) approved devices. There is a growing body of literature on treatment options and intermediary and patient post-surgical treatment outcomes, including several systematic reviews (see Appendix A). However, no comprehensive organization of the evidence as it specifically relates to patient outcomes currently exists. The current body of systematic literature reviews generally relies on intermediate outcomes such as complications, reoperation rates, and device failure in generating hip fracture treatment recommendations. The aim of the present project was to conduct a systematic review and synthesize the evidence of the effects of surgical treatments of

Appendixes and evidence tables cited in this report are available at <http://www.ahrq.gov/downloads/pub/evidence/pdf/hipfracture/hipfracture.pdf>

fractures of the hip on patient post-treatment outcomes, which to date have received only modest attention, but which are central to the patient's experience.

## Types of Hip Fractures

Hip fractures occur in the proximal (upper) portion of the femur, just outside the area where the femoral head (ball) meets the acetabulum (socket) within the pelvis. (Figure 1) Hip fractures are generally classified into three major types, depending on the specific location of the fracture: femoral neck, intertrochanteric, and subtrochanteric fractures. The term pertrochanteric hip fracture may also be used in hip fracture literature and refers to a more inclusive set of extracapsular fractures, including intertrochanteric, subtrochanteric, and mixed fracture patterns.<sup>6</sup> The term hip fracture describes fractures of the upper thigh or femur; fractures of the acetabulum (socket) and other pelvic fractures are not considered to be hip fractures and will not be discussed in this report.



**Figure 1. Diagram of right hip as viewed from the front**  
Fractures of the upper portion of the femur, are *hip* fractures. Hip fractures do not involve the acetabulum (socket).

From Zuckerman, 1996<sup>6</sup> Used with permission.

Femoral neck fractures occur in the narrowed section of the upper femur that lies between the rounded femoral head and bony projections called trochanters. Most femoral neck fractures occur within the capsule that surrounds the hip joint and are therefore termed intracapsular. The blood supply to the femoral head is entirely dependent upon a series of arteries that pass through the femoral neck region. Therefore, fractures of the femoral neck can entirely disrupt the blood supply to the femoral head, resulting in increased rates of major healing complications such as fracture nonunion, or death of the femoral head bone tissue, called osteonecrosis, or avascular necrosis. Femoral neck fractures are further grouped into nondisplaced and displaced fractures by the alignment of the fractured segments in relation to the original anatomic position of the femur.

Intertrochanteric fractures occur more laterally than femoral neck fractures, in the area between the greater and lesser trochanters. The trochanters are bony projections where major hip muscles attach. Intertrochanteric hip fractures occur outside of the joint capsule and are therefore extracapsular. Unlike the complicated blood supply through the femoral neck, intertrochanteric hip fractures involve bone with good local blood supply. However, these fractures are complicated by the pull of the hip muscles on the bony muscle attachments, which can exert competing forces against fractured bone segments and pull them out of alignment. Thus, the healing complications for intertrochanteric fractures are often different from those of femoral neck fractures, and are more likely to include shortening of the length of the femur or healing of the fracture in a misaligned position (malunion). Intertrochanteric fractures may be further grouped into stable and unstable fractures, depending on the location, number, and size of the fractured bony segments.

Subtrochanteric fractures occur at or below (distal to) the level of the lesser trochanter in the proximal portion of the femur. Isolated subtrochanteric fractures occur in the area between the upper border of the lesser trochanteric to 5 cm below it, toward the knee. Subtrochanteric fractures may include only a short linear section of the proximal femur or may be part of a larger fracture pattern that involves both the intertrochanteric and subtrochanteric sections of the femur. The blood supply to the bone of the subtrochanteric region is not as good as the blood supply to the bone of the intertrochanteric region and thus heals more slowly. Subtrochanteric fractures are also subject to competing forces exerted by muscular attachments on the femur that tend to pull the fractured fragments out of alignment.

Orthopaedic surgeons differ on their definition of subtrochanteric fractures, and may also consider fractures that extend further toward the knee to be subtrochanteric. There are at least 15 classification systems in the literature for subtrochanteric fractures, the Seinsheimer system being the most frequently used.<sup>58</sup>

Michelson et al.,<sup>17</sup> found that the distribution of the types of hip fractures within the U.S. population is 49 percent intertrochanteric, 37 percent femoral neck, and 14 percent subtrochanteric, and these estimates are relatively consistent across authors.<sup>11,18,19</sup> The proportions may change over time as demographics change,<sup>4</sup> and proportions are also reliant on the classification system used and the preferences of surgeons in labeling fracture patterns. This is a problem particularly for subtrochanteric fractures, where estimates of the percent of hip fractures that are subtrochanteric vary widely, depending on the classification system used.<sup>58</sup> Within the elderly population, the incidence of subtrochanteric fractures is estimated to be about 10 percent of all hip fractures.<sup>19,59</sup>

Table 1 summarizes the major differences in femoral neck and trochanteric fractures that are important to the management of these fractures. Nonoperative management of a hip fracture may be indicated for nonambulatory, institutionalized patients, patients with serious medical conditions, and where surgical intervention is considered too risky and nursing care can be accomplished without causing significant pain to the patient. However, the vast majority of patients with a hip fracture are treated surgically.

**Table 1. Hip fracture management characteristics**

<b>Characteristics</b>	<b>Femur Neck Fracture</b>	<b>Trochanteric Fracture</b>
Age group	60-80	Older
Orientation to capsule	Intracapsular	Extracapsular
Displacement and deformity	Lesser	Greater
Major determinant of severity	Degree of displacement	Number of fragments and medial calcar support
Major complications with treatment	Nonunion and osteonecrosis	Malunion
Device options	Screws/arthroplasty	Sliding hip screws/intramedullary hip nails/arthroplasty

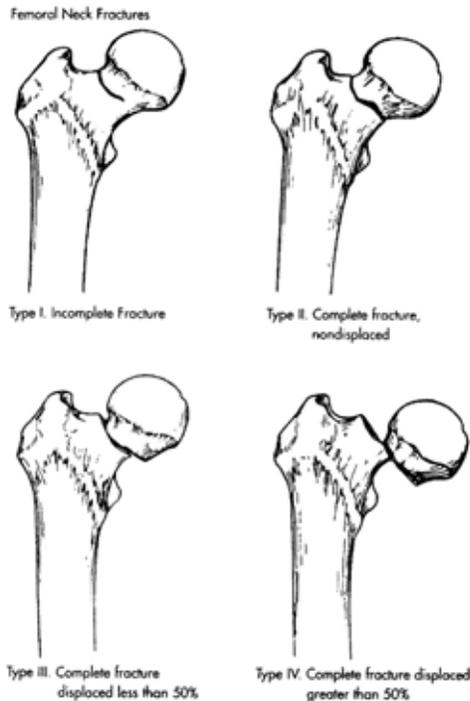
## Surgical Treatment of Hip Fractures

The short term goal of surgical treatment is to stabilize the hip fracture enough to withstand early mobilization and weight bearing, which prevents complications due to prolonged bed rest and aids in fracture healing. This type of surgery is generally based on the fracture pattern and patient characteristics.

Fracture healing is best accomplished when the edges of the fractured bone are perfectly realigned into a normal anatomic position (fracture reduction), and the fractured edges contact and press firmly upon each other (impaction) in good alignment, which stimulates bone healing. This is particularly important in elderly patients who are more likely to have low bone density and other medical issues that impair their ability to heal a fracture and recover hip function. Many hip fractures are treated with internal fixation, which is a general class of metal implants placed in or anchored directly alongside of bone to hold the fractured bony segments in alignment until the fracture can fully heal. Internal fixation devices are most often left in place after hip fractures heal, but they may be removed if painful. Severe complications in fracture healing are more likely to occur if the fracture was not sufficiently reduced before an internal fixation implant was placed, or if the implant was not placed and anchored properly.<sup>20</sup> If the optimal realignment of a fracture is not possible or practical for other reasons, then a partial or total hip replacement procedure (arthroplasty) is considered. An arthroplasty by its very nature replaces the function of the affected joint and is hence devoid of fracture healing complications. For arthroplasty, implant placement and surgical approach (where the incision is made) are important in predicting which complications are most likely to occur.<sup>20</sup>

### Femoral Neck Fractures

**Nondisplaced fractures.** Fractures of the femoral neck that are found on initial x-rays to be in normal or near-normal alignment are called nondisplaced femoral neck fractures by most surgeons (Figure 2). About one-third of femoral neck fractures are nondisplaced.<sup>60,61</sup> The treatment of nondisplaced femoral neck fractures is fairly uncontroversial and generally involves internal fixation.<sup>62</sup> Multiple stabilizing screws are placed from the outside (lateral) portion of the proximal femur through the fractured femoral neck, and anchored into the bone of the femoral head. With the fracture aligned and stabilized with screws, these fractures commonly heal without complications.



**Figure 2. Garden classification for femoral neck fractures**  
 Type I and II are considered nondisplaced fractures. Type III and IV are considered displaced. Used with permission.

**Displaced fractures.** Fractures of the femoral neck that are found to be moderately to severely misaligned on initial x-rays are called displaced femoral neck fractures. More controversy surrounds the treatment for displaced femoral neck fractures.<sup>63,64</sup> Elderly patients with displaced femoral neck fractures may be treated with internal fixation or arthroplasty, either hemiarthroplasty, or total hip arthroplasty.<sup>62,64</sup> Device selection depends on multiple factors, such as the patient's general health status, age, functional abilities, cognitive status, and surgeon preference.<sup>6,20,62</sup> When selecting the type of implant that is best for a patient, surgeons must simultaneously weigh the likelihood of achieving a satisfactory fracture reduction, the risk of nonunion of the fracture, the patient's medical condition and activity level, and the possibility of osteonecrosis of the femoral head if the blood supply through the femoral neck is damaged. Maintaining a patient's own femoral head through a satisfactory reduction is a treatment goal whenever possible.<sup>62</sup> Delays between sustaining a fracture and surgery may reduce the chance of uncomplicated healing of the femoral neck, and thus is also a consideration in treatment decisions.

*Internal fixation.* Internal fixation is often used in situations where the patient is relatively young, active, has a fracture pattern that is likely to be able to maintain reduction of the fracture, and has sufficient bone quality to anchor and hold the implant in place without allowing the fracture to re-displace during healing.<sup>62</sup> In addition to the screws mentioned for nondisplaced fractures, plate and screw combinations may be used as well, to hold the reduced fracture in position. However, no internal fixation device can compensate for an inadequately reduced fracture.<sup>20</sup>

*Arthroplasty.* Treatment choices shift to arthroplasty for displaced femoral neck fractures in the physiologically older patient with poor bone quality. Two types of arthroplasty are available: hemiarthroplasty and total hip arthroplasty (THA). Hemiarthroplasty is the replacement of the femoral head segment of the upper femur with an artificial implant. The patient's own acetabulum is not replaced, hence the term hemi-, or half of a new hip. THA is the prosthetic

replacement of the entire hip joint, both the femoral head and the acetabulum within the pelvis. Regardless of the type of hemiarthroplasty, hip pain as a result of acetabular erosion is likely to develop in due course of time (2-5 years or sooner). With this in mind, the patient's physiological status and likely life span are important factors in decisionmaking. Therefore, hemiarthroplasty is considered better suited to less active elderly patients who are expected to place low activity demands on their prosthesis, and whose acetabulum does not have extensive degenerative or arthritic type changes that could be aggravated by this type of implant. THA is used for patients who are more active at the time of their hip fracture, or whose hip joint already had severe degenerative changes.

Two types of hemiarthroplasty implants are available: unipolar or bipolar. Unipolar hemiarthroplasty consists of an implant with an artificial femoral head that acts as the ball of the hip joint, and a metallic rod, or stem, that is inserted into the innermost portion of the femur (intramedullary canal) to hold the entire device firmly in place. Some patients with early unipolar hemiarthroplasty designs experienced hip pain due to erosion of the acetabulum, or thigh pain due to loosening of the stem in the femoral canal. Later designs included cement to anchor the prosthetic stem into the mid-femur. Another design modification is the use of a bipolar hemiarthroplasty. The bipolar design incorporates a smaller femoral head which fits inside a second larger ball or shell, which together act as the artificial femoral head. Bipolar designs attempt to cut down on the amount of wear and tear the prosthesis causes to the patient's normal hip joint by allowing the smaller inside head to accomplish more movement than the outer rounded portion that contacts the patient's acetabulum. Bipolar hemiarthroplasty designs cost about \$1,000 more per implant than unipolar implants. Bipolar prostheses can also be converted to total hip replacements if required.

In THA, the artificial femoral head is attached to an anchoring metallic rod that extends down within the femur to the mid thigh area, similar to hemiarthroplasty. The prosthetic femoral head moves within the artificial socket to allow for near normal hip movements after healing. Various designs exist and design improvements are aimed at minimizing the amount of fine, particulate erosion that can occur within the artificial joint that can diffuse into the surrounding tissue and cause irritation or other undesirable changes. The same issues that can arise with the femoral stem component for hemiarthroplasty can also occur for total hip arthroplasty, since the stem component options are the same.

**Current issues.** Within these broad bounds, considerable controversy regarding which forms of surgical treatments are best for which patients remains.<sup>49,62,63</sup> Internal fixation saves the original femoral head but is more likely to require operative revision.<sup>28,65,66</sup> THA has a lower revision rate but is subject to dislocation, or slippage of the artificial femoral head out of the artificial socket. Dislocation is less common with hemiarthroplasty, but revision rates for hemiarthroplasty are somewhere between internal fixation and THA revision rates. However, technical failures and revision rates are affected by more than device design. A recent study that tested a physiologic status score as a decision support for whether internal fixation or hemiarthroplasty was used as surgical treatment found that neither age nor physiologic status was predictive of internal fixation failure.<sup>49</sup> However, when independent reviewers assessed the surgical treatments for technical failure, defined as inadequate reduction or improperly placed implants, technical failure was reported in 14 percent of internal fixations cases, in only 2 percent of hemiarthroplasties, and these errors in surgical technique correlated with worse clinical outcomes.<sup>49</sup>

## Pertrochanteric Fractures

Pertrochanteric fractures, which include intertrochanteric and subtrochanteric fractures, are typically treated with internal fixation. Since pertrochanteric fractures do not disrupt the blood supply to the femoral head, internal fixation is the treatment of choice, unless the entire hip joint is severely deformed due to advanced degenerative changes, or less commonly, when the fracture extends proximally into the femoral neck area.

**Types of internal fixation.** The two major forms of internal fixation for pertrochanteric fractures are extramedullary and intramedullary implants.

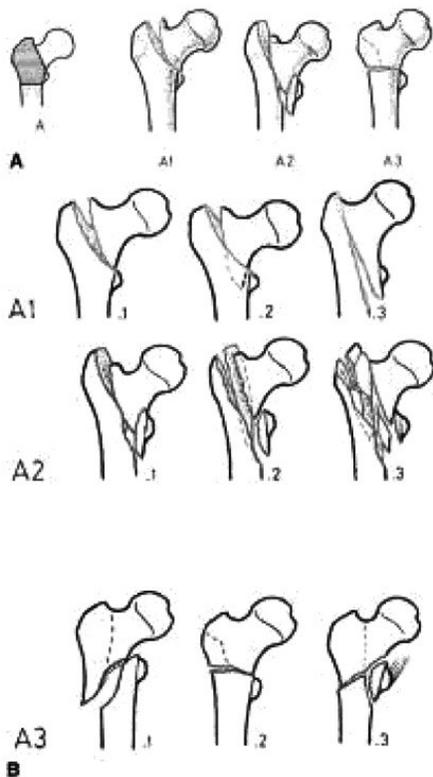
*Extramedullary.* Extramedullary devices attach externally along the outside of the upper femur. One of the earliest and most commonly used extramedullary devices is the sliding hip screw.<sup>67</sup> The term is somewhat misleading, since this category of devices actually has two main parts: a metal plate and multiple screws. The plate of a sliding hip screw is affixed along the outside of the femur with multiple screws that cross the upper femur to hold it in place. The upper portion of the device consists of a separate longer and thicker screw called a lag screw that is fit lengthwise from the outside, upper femur through the femoral neck into the hard bone of the femoral head. The term sliding hip screw describes the unique, intended action that allows the surgically-aligned fracture segments to impact firmly on each other to aid fracture healing, particularly when a patient stands or walks.

There are a number of versions of sliding screw/plate devices. Multiple modifications in designs have been engineered to address different forms of fixation failures and design flaws, such as the amount of sliding allowed where the lag screw meets the plate, the direction of sliding allowed, the length, design, and best placement of the lag screw, the number of nonlag screws needed and where to best position them, and variations in plate length and the number of anchoring screws needed. Fixation forms may vary in terms of rigidity of the device and the types and locations of the specific fixation to the femur in order to maintain optimal fracture reduction and necessary fracture impaction without the device failing or pulling out of the bone.

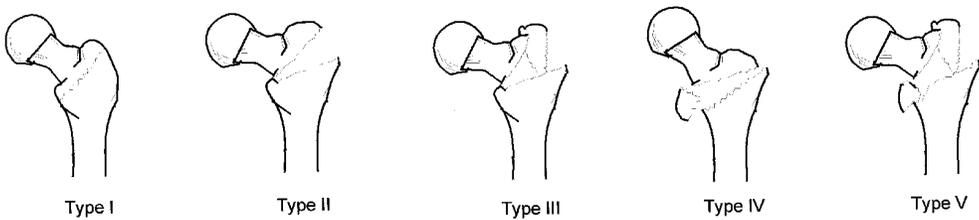
*Intramedullary.* Intramedullary internal fixation devices use the same type of anchoring lag screw that is used in the sliding screw/plate devices, and the controlled bony impaction at the fracture site is accomplished with the same dynamic motion as in the sliding hip screws. However, unique to this class of implants is the portion that controls the fracture, which is placed inside the canal of the femur, rather than alongside it, hence the term intramedullary. The devices are commonly called intramedullary nails (IMN), since the femoral portion of the device is essentially a very large surgical nail. The procedure requires a smaller incision than plate/screw procedures, near the top of the hip. Once the fracture is properly aligned by the surgeon, the IMN is slid into the central portion of the femur from the hip toward the knee, typically ending in the middle to lower third of the femur, but always above the knee.

The theoretical biomechanical advantage of IMN is that the central placement of the device within the femur leaves a shorter distance between the device and the weight bearing axis of the femur, thereby attempting to lessen the forces that pull fracture fragments out of alignment until the hip fracture heals. Because of the smaller incision, surgical procedures with IMN tend to have less blood loss. IMN devices have their own set of complications, including unintentional fractures intraoperatively as the surgeon places the nail, and later fracture of the femur at the distal end of the nail. As with plate/screws devices, multiple generations of IMN devices have been engineered, varying nail length, width, and curvature, among others, in attempts to improve treatment outcomes.

**Stable and unstable fractures.** Surgeons use multiple classification systems to identify intertrochanteric hip fracture patterns. The most commonly used are the AO/OTA (Arbeitsgemeinschaft für Osteosynthesefragen (Association for the Study of Internal Fixation)/ Orthopedic Trauma Association) classification (Figure 3) and the Evans classification, as modified by Jensen (Figure 4). The AO/OTA classification has nine distinct intertrochanteric subtypes, whereas the Evans-Jensen classification has five. Unlike bone in the mid portion of the femur, the bony anatomy of the intertrochanteric area is complex and fracture patterns vary widely. For randomized clinical trials, fracture classifications are used to group several fracture subtypes together that have similar treatment and healing issues in order to make general conclusions about which fracture patterns do better with which category of device. Typically, intertrochanteric fracture patterns are aggregated into stable and unstable groupings, and these fractures behave quite differently in terms of how they heal with an optimally placed device.



**Figure 3. AO/OTA classification of proximal femur fracture**  
 AO/OTA classification of proximal femur fractures. The A1 fracture would routinely be considered a simple, stable intertrochanteric femur fracture. The A2 fracture is characterized by a similar fracture pattern with an unstable medial buttress. The A3 fracture has a fracture line distal to the vastus ridge, and is therefore “unstable.” Used with permission.



**Figure 4. Evans/Jensen classification for stable/unstable intertrochanteric fractures.** Used with permission.

Isolated subtrochanteric fractures, or intertrochanteric fractures with subtrochanteric extension, are generally considered to be unstable fractures. Subtrochanteric fractures are complicated by the multiple strong muscular forces acting across the site of the fracture. Biomechanical studies have found the region one to three inches below the lesser trochanter, a small bony knob on the upper and inner portion of the femur, to be the most highly stressed region of the body,<sup>68</sup> which increases the possibility of implant failure and malunion of the fracture. Device options include similar internal fixation devices that are used for isolated intertrochanteric fractures. Intramedullary nails may be indicated for certain subtypes of fractures that are particularly unstable.<sup>69</sup> Sliding hip screw devices are not well suited for subtrochanteric and reverse oblique intertrochanteric fractures as they may allow unacceptable displacement of the femur shaft. Again, as for all surgical decisions, surgeon experience and familiarity with the devices must also be considered.<sup>68,70</sup>

**Current issues.** The choice between extramedullary or intramedullary devices for pertrochanteric fracture treatment among surgeons remains controversial,<sup>21,32,67,71</sup> and significant variation in surgeons' device choice for pertrochanteric fractures exists.<sup>19,67</sup> For stable fracture patterns, the literature suggests that the sliding plate/screw devices remain the treatment of choice,<sup>21,30,72</sup> although surgeon practice varies widely.<sup>19,67</sup> However, for unstable fractures, consensus has not been reached, with the possible exception of the reverse oblique fracture for which the intramedullary nail is better suited.<sup>21,32,69</sup> Intramedullary devices cost approximately \$1,000 more per implant than extramedullary devices.<sup>19,21,67</sup>

Additionally, there is no consensus among orthopedic surgeons internationally as to which subtypes of the current AO/OTA or Evans-Jensen classification systems are considered to be unstable fractures, and may therefore warrant special device considerations. This is not an issue with femoral neck fracture trials, since surgeons agree on the aggregation of femoral neck fracture subtypes into displaced or nondisplaced categories. For pertrochanteric fractures, this lack of consensus causes considerable challenges in the interpretation of implant-related outcomes within the existing literature, since investigators select different fracture pattern subtypes as unstable.

As with femoral neck fractures, surgeon skill has been found to be a strong predictor of fixation failure.<sup>73</sup> Accurate placement of the lag screw is one of the strongest predictors of whether or not the lag screw will pull out of the femoral head (cut-out) and result in implant failure.<sup>74,75</sup>

## Key Questions

This review was asked to address the following key questions:

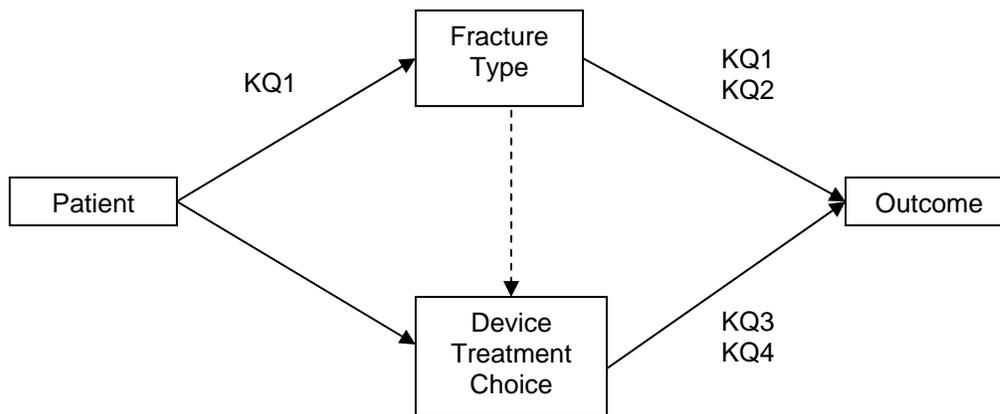
- Key Question 1 – What is the relationship between patient variables (e.g., demographic factors, comorbidities), the type of fracture (i.e., intertrochanteric, subtrochanteric, subcapital) and post-treatment outcomes (e.g., pain, mobility, mortality)?
- Key Question 2 – What is the relationship between the type of fracture (i.e., intertrochanteric, subtrochanteric, subcapital) and post-treatment outcomes (e.g., pain, mobility, mortality)?
- Key Question 3 – What is the relationship between implant variables (e.g., position, material, method, and design of implant) and patient post-treatment outcomes (e.g., pain, mobility, mortality)?

- Key Question 4 – What is the relationship between the type of intervention (e.g., internal fixation versus arthroplasty) and patient post-treatment outcomes (e.g., pain, mobility, mortality)?

Figure 5 graphically shows the linkages between the key questions. Key question 1 examines the larger question of how patient characteristics, including fracture type, relate to patient outcomes, while key question 2 focuses specifically on the relationship between fracture type and outcome, holding patient characteristics steady. Key questions 3 and 4 are differentiated by the level of analysis of device type, either at the level of specific device or whole classes of devices.

As shown earlier in this chapter, the device chosen to treat a hip fracture is highly reliant on the characteristics of the fracture in question. With fracture type and treatment choice so strongly correlated, the ability to tease apart the separate main effects of fracture type and surgical treatment on patient outcomes would require a more comprehensive model. While the key questions rely on basically the same analyses, the information to support them comes from two different literatures. Unfortunately, few studies provide detailed information on both patient characteristics and the procedure characteristics, and fewer include both sets of information in their analyses.

**Figure 5. Linkages between key questions**

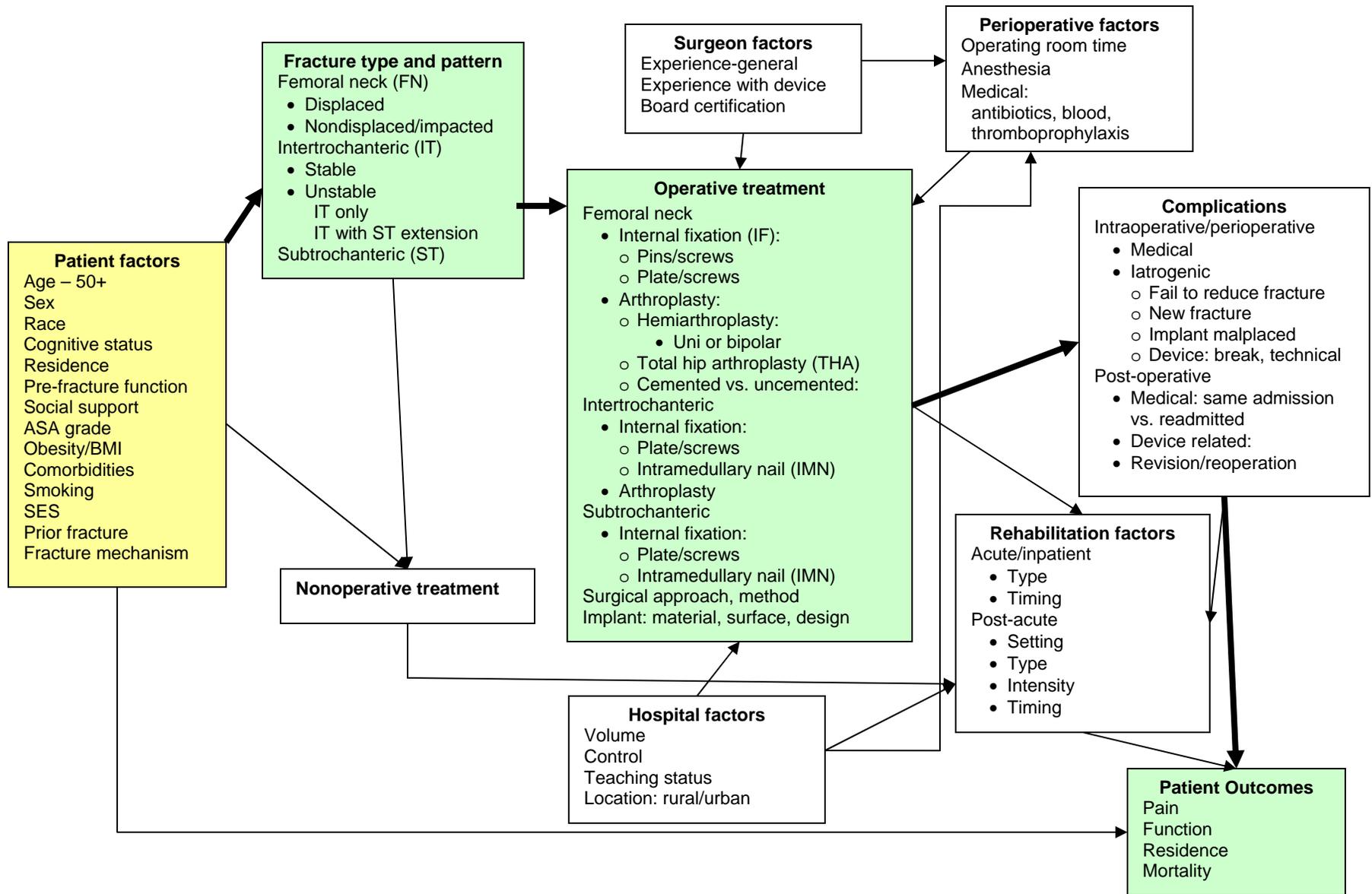


Therefore, a more comprehensive map of the elements which contribute to outcomes was developed and reviewed with the Technical Expert Panel (TEP) members (Appendix B).

## Conceptual Model

Figure 6 maps the major factors which impact the final outcomes hip fracture patients experience. These outcomes are influenced by patient characteristics, the specific characteristics of the sustained fracture, and elements of the treatment, including effects related to the hospital setting, the device, the skills and abilities of the surgeon, the operative processes, and post-acute treatment rehabilitation. The shaded boxes in the model represent variables directly related to the key questions and are the focus of the trials included in this review. The white boxes represent the other factors which must also be accounted for in order to isolate the main effects of the fracture

Figure 6. Conceptual model



type and treatment choice and are contained within this review only to the extent that they are relevant covariants. The bolded arrows are those relationships related to the key questions.

Patient factors important to hip fractures include demographic, medical, and other risk factors predictive of patient outcomes.<sup>4,6,51</sup> Many of these factors enter a surgeon's decision process when choosing specific device treatments, including the American Society of Anesthesiologists (ASA) score, used to recognize a patient's health status and presence of comorbidities. Characteristics that have been found to impact patient outcomes include age, gender, cognitive status, social support, marital status, pre-fracture function, and pre-fracture residence.<sup>13,76-78</sup> One would anticipate that studies would capture these patient factors at baseline in order to ascertain the comparability of patients with regard to patient characteristics that influence patient outcomes and the appropriateness of device choices.

As discussed previously in this chapter, types of hip fractures include femoral neck, intertrochanteric, and subtrochanteric fractures. The fractures are further classified as displaced or nondisplaced among femoral neck fractures, and stable or unstable for pertrochanteric fractures. Fracture types and patterns are often not well documented due to the multiple classification systems used by surgeons to identify fracture patterns and subtypes. Studies need to provide clear, reliable, and consistent reporting of fracture patterns in order to establish the relationship between fracture patterns and outcomes.

Studies should additionally include a full complement of non-patient factors that potentially impact outcomes in each analysis. Some covariates may be controlled for through a randomized controlled study design, but the ability to draw inferences from pooled studies is difficult without the full set of covariates that extends beyond patient factors alone. Hospital settings, surgeon factors, operative factors, recovery and rehabilitation factors all impact hip fracture outcomes and should all be accounted for as much as possible within clinical studies.

Hospital factors which can influence a patient's outcome trajectory include items such as annual volume of patients, specifically hip fracture patients, whether the hospital is a community hospital, teaching hospital or major trauma center, hospital location such as rural or urban, and the type of hospital ownership.<sup>79</sup>

A number of operative factors may relate to surgical outcomes, such as delay to surgical treatment,<sup>80</sup> need for blood transfusions,<sup>81</sup> and the duration of surgery.

Processes of care also differ by hospital location. Comprehensive processes of care can include prophylactic antibiotics and anticoagulants, urinary catheter protocols, mobilization and physical therapy, pain management, restraint protocols, and discharge processes for patients with active clinical issues.<sup>77</sup> Siu et al,<sup>77</sup> suggest that the benefit of any one intervention, such as thromboprophylaxis, is small or short-lived without timely followup with other elements of care, such as early weight-bearing. They found that combinations of processes of care were more predictive of patient functional outcomes than single interventions alone. However, the processes of care associated with lower mortality are not necessarily the same as processes of care associated with improved patient functionality.<sup>82</sup>

Treatment for hip fractures does not end with hospitalization. Patients typically receive post-acute rehabilitative services for several weeks beyond the initial hospitalization. These services may be provided by skilled nursing facilities, acute rehabilitation units, home health care programs, or some combination of the above.<sup>83-85</sup> Given the presence of home health care programs, using data from patient discharge alone is not a good proxy for the full rehabilitative processes a patient undergoes.

The patient outcomes assessed in clinical studies should be aligned with the stated treatment goal of returning patients to their pre-fracture functional status. Pain, mobility, and the use of walking aids are common outcomes but are difficult to fully interpret without comparison to baseline abilities.<sup>34</sup> Magaziner et al.<sup>34</sup> found that recuperation times were specific to the type of function regained, ranging from 4 months to 1 year.

The conceptual model shown in Figure 6 guided the data abstraction and analysis for this review. In addition to reviewing particular study results, we also collected data regarding the presence or absence of classes of covariates that were used in order to assess the general validity of the research findings as a whole.

## **Scope of the Review**

The review is focused on the patient population most likely to experience low energy traumatic fractures of the hip and the final patient outcomes of mortality, functional status, and quality of life. Patients younger than 50 and fractures due to high energy trauma are outside the scope of this review.

Many important factors noted in Figure 6 were not considered in this review. For example, we did not look at the direct effects of time delay to surgery, peri-operative monitoring, comprehensive perioperative medical management, or post-operative protocols. Attention to these items in this review was limited to examining whether such factors were accounted for when a study was looking for direct effects of surgical implants.

The review does not include analysis of devices at the level of specific manufacturers. The literature does not include sufficient information on manufacturers. Further, external fixators, devices that are affixed to the outside of the leg, or devices or surgical methods that are no longer in common use within the United States are outside the scope of this review. We also did not delve into broad classes of arthroplasty implants. For example, much of the literature on the topic of cemented versus cementless arthroplasty compares old technology uncemented implants (that would not be used for elective total hip replacement) to various cemented designs where technological advances have been less dramatic than for cementless designs.



## Chapter 2. Methods

### Search Strategy

Our study search plan included electronic and manual searching. We searched a variety of electronic sources, including MEDLINE<sup>®</sup>, Cochrane databases, Scirus, and ClinicalTrials.gov. The electronic searches were performed on April 28, 2008, and included English language articles from 1985 to the present. We also manually searched reference lists from published systematic reviews.

The main search strategy included a list of terms intended to identify all research publications associated with two domains; intertrochanteric/subtrochanteric and subcapital hip fractures and types of implant interventions. We used key words relevant to the two domains as the search basis for all key questions. (The search strategies are provided in Appendix C). Comparison to MeSH headings found that all references identified with MeSH headings were subsumed in the keyword searches. We used a tested search filter designed to identify methodologically high quality randomized controlled trials.<sup>86</sup>

For key questions 1 and 2 a search filter designed and tested for identifying observational studies was coupled with the hip fracture domain search terms.<sup>87</sup> Because observational articles are difficult to distinguish in electronic searches, this search was supplemented with additional searches using epidemiology, recovery, and odds ratio MeSH headings and keyword terms.<sup>88</sup> Articles were also contributed from personal files of the authors and TEP members.

### Eligibility

For the randomized controlled trial (RCT) literature, two investigators independently reviewed article abstracts for eligibility using screening forms developed on Trialstat's Systematic Review Software (SRS). (The forms are provided in Appendix D.) Screening was performed at two levels. The first screen used a more liberal approach and relied on title and abstract review. The second level examined full articles with a strict approach if (1) the article passed through the broad screening, (2) there were no abstracts, or (3) there was disagreement between the investigators on article eligibility. Differences of opinion regarding eligibility were resolved through consensus adjudication. We excluded external fixators as a class.

Patient population inclusion criteria were 50 years or older with nonpathologic fractures from low energy trauma, and an index fractures. Strict exclusion criteria were originally pathologic, bilateral, nonindex, and high energy trauma fractures. A more liberal approach to patient populations was allowed when we found that the literature is quite wide ranging in its use of exclusion criteria. The deviations a study made from the strict exclusion criteria for the review were noted.

Implantable devices for internal fixation used in included RCTs must have been available for use in the United States or be similar enough to U.S. devices that the results were meaningful. The excluded devices are either experimental or no longer in clinical use in North America. All retained devices have characteristics which are generally the same as implants which remain in use in North America. All devices were reviewed by clinician authors for inclusion/exclusion status. Decisions were based on clinical experience and/or examining specifications and images of the device in question. Opinions from TEP members were sought and TEP members vetted

the final list. Articles examining head to head comparisons of internal fixations must compare included devices to be retained. The final list of included devices is provided in Table 2 at the end of the chapter.

Because the studies generally do not differentiate type of femoral neck fracture, we included all types of intracapsular fractures, including subcapital, transcervical, and basicervical areas of the femoral neck and provide results both undifferentiated and differentiated where possible. By convention, fractures of the femur up to 5 cm below the lesser trochanter are subtrochanteric fractures. This category also includes hybrid intertrochanteric fractures with subtrochanteric extensions.

Based on a meta-analysis which showed nonrandomized studies generated biased estimates for mortality risk and relative benefits for hip fracture devices,<sup>89</sup> the review was limited to randomized controlled trials for key questions 3 and 4. Only full journal articles were included. Trial results reported in brief abstracts do not have the space necessary to report on all the factors a comprehensive approach to patient outcomes requires. Articles were not excluded based on country of research origin.

Quasi-experimental articles used for key questions 1 and 2 were limited to cohort studies with prospectively collected data and some form of multivariate analysis. Both femoral neck and pertrochanteric fractures needed to be included and fracture type entered as a factor in the multivariate analysis. Patient populations needed to be at least 200 to allow for sizeable enough numbers in each analysis group, which can be quite numerous when crossing multiple patient characteristics, fracture types and patterns, and outcome measures. Included studies were required to specifically involve research questions aimed at understanding the relationship between patient characteristics, fracture type, and patient outcomes. Titles and abstracts were screened using Endnote files; a file was coded only if it was potentially includable based on the inclusion criteria. This approach was utilized due to the significant size of the data files, over 6,700 articles. Full text was pulled for all potentially included articles and coded for inclusion or reason for exclusion. As this resulted in a very limited set of includable articles, the literature was supplemented with a comprehensive but not exhaustive representative set of articles aimed at understanding the relevant patient populations and outcomes through analysis of other factors of care.

## **Data Extraction**

At least two researchers independently abstracted each included article using a standard abstraction form created on SRS (Appendix D). We generated a series of detailed evidence tables (Appendix E) containing all the relevant information extracted from eligible studies. Results of the evidence tables were used to prepare the text of the report and selected summary tables. At least two researchers checked the quality of each evidence table. Differences were resolved through consensus.

## **Data Analysis**

Decision-tree/literature maps, shown in Figure 7 for femoral neck and Figure 8 for intertrochanteric/subtrochanteric fractures, were developed based on the available literature. Reading from left to right, the maps are very simplified decision trees modeling a surgeon's

possible decision choices regarding which device to use. Reading from right to left, the maps diagram the available comparative RCTs of devices represented in the literature. The maps are not comprehensive of all possible decision sets regarding implantable devices for hip fractures as the literature itself does not include RCTs for all decision sets.

Many articles reported findings on a mixed set of fracture patterns within a specific type of fracture. Some of these trials reported subgroups based on stability or displacement of the fractures, but many did not. Thus, the maps include branches that are inclusive of all fracture types. Where possible, outcomes are delineated by fracture subtypes in analyses.

Arrows with dotted shafts refer to additional decisions to be made rather than a discrete choice pair. For example, a surgeon can choose different distal locking techniques for an intramedullary nail. Without this form of identification the maps become unwieldy and difficult to use.

The decision nodes (Nodes), denoted by squares, are numbered to identify the level at which the decision is taking place, essentially between classes of devices, between types of devices within a class, and between modifications one may make to a type of device, such as using cement or changing the way a device is locked in place. The articles are organized within the evidence tables by the corresponding map node.

When measured patient outcomes were consistent across studies (e.g., mortality), quantitative summaries used forest plots. A qualitative approach was employed for all other patient outcomes. Trials at Nodes 2-4 compare specific device types, such as the general category of multiple device screws versus hook pins. Comparisons are not differentiated beyond the number of multiple device types used for fixation, i.e., two versus three femoral neck screws. Multiple devices are not differentiated by other characteristics, such as the size of the plate or the number of screws used to affix the plate to the femur. Node 1 analyses are made at the level of classes of devices. The one exception to this is Node 2 comparisons for hemi and total hip arthroplasty, which are treated as classes of devices. Results of the quantitative and qualitative analyses are compared to relevant published systematic reviews for consistency of findings. (See Appendix A for details of systematic reviews.)

As there was only one article focused exclusively on subtrochanteric fractures, we relied on the intertrochanteric literature where it included subtrochanteric fractures or intertrochanteric fractures with subtrochanteric extensions. We relied on subtrochanteric involvement as defined by the study investigators, since, as stated before, classifications systems do not by themselves provide adequate assurance of identification of subtrochanteric fracture.

## **Quality and Strength of Evidence Assessment**

In order to address the comprehensive model outlined in Chapter 1, we assessed the quality of each study reviewed, and employed a lower quality threshold than may be normally applied in systematic reviews when determining which articles to retain.

Two reviewers assessed the quality of all included studies. Differences of opinion were resolved by consensus adjudication of at least three reviewers. Completion of the checklist was based solely on what was reported in the articles. Studies were assigned a rating of Good, Fair, or Poor based on a 20 item checklist,<sup>22</sup> with some slight modifications. Since allocation concealment is not fully possible for surgical procedures, we placed a heavier weight on the randomization process and evidence of changes which might impact selection bias, whether the article provided sufficient information on the patient sample, and how carefully the patient sample was defined.

Therefore, articles that excluded baseline information on the patient sample by group, or articles that did not provide exclusion criteria, were given lower quality ratings. Likewise, lack of information regarding attrition due to mortality and followup losses was also weighted more heavily. With such large expected loss to mortality within the first year of a hip fracture, the total loss to followup can be substantial. Low patient numbers and loss to attrition, even if equally distributed, impact issues of power to find both Type I and Type II errors and are a major quality concern for hip fracture research as well. Articles were retained for the review if they exceeded a minimum threshold that allowed for meaningful interpretations of patient samples. Articles that did not include baseline patient characteristics by comparison group, information on randomization, exclusion criteria, or attrition, and low patient sample, were deemed not includable.

In looking across the body of evidence available, we judged both the quality and consistency of the material. We based our approach on the summarization methods advocated by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) group.<sup>23</sup> Although the extent of heterogeneity among the studies precluded formal meta-analysis and pooling, we sought to explore the patterns across study groupings.

## **Applicability**

Applicability of the results of this review is affected by the representativeness of the populations recruited to the studies. The evidence tables E2 and E4 in Appendix E identify details on the patient inclusion and exclusion criteria.

The literature was generally of two kinds, articles that looked at the overall elderly hip fracture patient populations and articles that selected an elderly patient population that was healthier, more mobile, and independent prior to the hip fracture. As noted earlier, the literature is predominantly international in origin. It has been found that patients with hip fractures have similar characteristics and are comparable across most nations.<sup>90</sup>

**Table 2. Included devices**

<b>Included Device</b>	<b>Included RCT Articles in which Device was Tested</b>
<b>Extramedullary</b>	
Sliding hip screw (SHS) includes Dynamic Hip Screw (DHS), Compression Hip Screw (CHS)	Papasimos, 2005, <sup>91</sup> Utrilla, 2005, <sup>92</sup> Mattsson, 2004, <sup>93</sup> Pajarinen, 2004, <sup>94</sup> Moroni, 2004, <sup>95</sup> Peyser, 2007, <sup>96</sup> Mattsson, 2005, <sup>97</sup> Pajarinen, 2005, <sup>98</sup> Ahrengart, 2002, <sup>99</sup> Saudan, 2002, <sup>100</sup> Brandt, 2002, <sup>101</sup> Harrington, 2002, <sup>102</sup> Kosygan, 2002, <sup>103</sup> Janzing, 2002, <sup>104</sup> Dujardin, 2001, <sup>105</sup> Adams, 2001, <sup>106</sup> Olsson, 2001, <sup>107</sup> Lunsjo, 2001, <sup>108</sup> Lunsjo, 1999, <sup>109</sup> Park, 1998, <sup>110</sup> Madsen, 1998, <sup>111</sup> Hardy, 1998, <sup>112</sup> Baumgaertner, 1998, <sup>47</sup> Watson, 1998, <sup>113</sup> Hoffman, 1996, <sup>114</sup> Elmeron, 1995, <sup>61</sup> Butt, 1995, <sup>115</sup> O'Brien, 1995, <sup>116</sup> Stappaerts, 1995, <sup>117</sup> Goldhagen, 1994, <sup>118</sup> Aune, 1994, <sup>119</sup> van Vugt, 1993, <sup>120</sup> Radford, 1993, <sup>121</sup> Leung, 1992, <sup>122</sup> Bridle, 1991, <sup>123</sup> Skinner, 1989, <sup>124</sup> Madsen, 1987, <sup>125</sup> Linde, 1986 <sup>126</sup>
SHS used in femoral neck studies	El-Abed, 2005, <sup>127</sup> Davison, 2001, <sup>128</sup> Ravikumar, 2000, <sup>129</sup> Benterud, 1997, <sup>130</sup> Kuokkanen, 1991, <sup>131</sup> Paus, 1986 <sup>25</sup>
DHS with Trochanter Stabilizing Plate (TSP)	Lunsjo, 2001, <sup>108</sup> Lunsjo, 1999, <sup>109</sup> Madsen, 1998 <sup>111</sup>
Gotfried Percutaneous Compression Plate (PCCP)	Peyser, 2007, <sup>96</sup> Brandt, 2002, <sup>101</sup> Kosygan, 2002, <sup>103</sup> Janzing, 2002 <sup>104</sup>
Medoff sliding plate (multiple versions with different numbers of holes)	Ekstrom, 2007, <sup>132</sup> Miedel, 2005, <sup>46</sup> Olsson, 2001, <sup>107</sup> Lunsjo, 2001, <sup>108</sup> Lunsjo, 1999, <sup>109</sup> Buciuo, 1998 <sup>133</sup>
Dynamic Condylar Screw (DCS) (95 fixed angle plate)	Sadowski, 2002, <sup>69</sup> Lunsjo, 2001, <sup>108</sup> Lunsjo, 1999 <sup>109</sup>
Minimally invasive percutaneous plate osteosynthesis (MIPPA) using DCS	Dujardin, 2001 <sup>105</sup>
<b>Intramedullary</b>	
Gamma nail (first, second, third generation)	Efstathopoulos, 2007, <sup>134</sup> Miedel, 2005, <sup>46</sup> Schipper, 2004, <sup>135</sup> Herrera, 2002, <sup>136</sup> Ahrengart, 2002, <sup>99</sup> Adams, 2001, <sup>106</sup> Fritz, 1999, <sup>137</sup> Madsen, 1998, <sup>111</sup> Hoffman, 1996, <sup>114</sup> Butt, 1995, <sup>115</sup> Goldhagen, 1994, <sup>118</sup> Aune, 1994, <sup>119</sup> Radford, 1993, <sup>121</sup> Leung, 1992, <sup>122</sup> Bridle, 1991 <sup>123</sup>
Asian Gamma nail, or Gamma AP	Vidyadhara, 2007, <sup>138</sup> Park, 1998 <sup>110</sup>
Intermedullary Hip Screw (IMHS)	Hardy, 2003, <sup>139</sup> Harrington, 2002, <sup>102</sup> Hardy, 1998, <sup>112</sup> Baumgaertner, 1998 <sup>47</sup>
Proximal Femoral Nail (PFN)	Ekstrom, 2007, <sup>132</sup> Papasimos, 2005, <sup>91</sup> Kim, 2005, <sup>140</sup> Pajarinen, 2004, <sup>94</sup> Pajarinen, 2005, <sup>98</sup> Schipper, 2004, <sup>135</sup> Herrera, 2002, <sup>136</sup> Saudan, 2002, <sup>100</sup> Sadowski, 2002 <sup>69</sup>
Gliding nail	Fritz, 1999 <sup>137</sup>
ACE trochanteric nail	Vidyadhara, 2007, <sup>138</sup> Efstathopoulos, 2007 <sup>134</sup>
<b>Femoral Neck Multiple Implants</b>	
Hansson hook pin (LIH pin) (6.5 mm smooth pin with hook extruded at tip)	Mjorud, 2006, <sup>45</sup> Lykke, 2003, <sup>60</sup> Elmeron, 1995, <sup>61</sup> Jonsson, 1996, <sup>141</sup> Hergren, 1992, <sup>142</sup> Olerud, 1991 <sup>143</sup>
Thornton nail (flanged trifin cannulated nail)	Jacobsson, 1985 <sup>144</sup>
Uppsala screws (8 mm cancellous screw with 6 mm shank)	Lagerby, 1998, <sup>145</sup> Hergren, 1992, <sup>142</sup> 662, 675
Von Bahr screws (7 mm cancellous screw with 5.5 mm shank)	Roden, 2003, <sup>146</sup> Rehnberg, 1989, <sup>24</sup> Paus, 1986 <sup>25</sup>
Mecron screws	Kuokkanen, 1991 <sup>131</sup>
AO screws	Mjorud, 2006, <sup>45</sup> Parker, 2002, <sup>147</sup> Parker, 2000, <sup>148</sup> van Dortmont, 2000, <sup>149</sup> Madsen, 1987, <sup>125</sup> Linde, 1986 <sup>126</sup>
Olmed screws (6 mm shank and 8 mm threads)	Mattsson, 2006, <sup>150</sup> Johansson, 2006, <sup>151</sup> Blomfeldt, 2005, <sup>152</sup> Mattsson, 2003, <sup>153</sup> Tidermark, 2003, <sup>154</sup> Tidermark, 2003, <sup>155</sup> Johansson, 2001, <sup>156</sup> Johansson, 2000, <sup>157</sup> Bachrach-Lindstrom, 2000, <sup>158</sup> Benterud, 1997, <sup>130</sup> Neander, 1997 <sup>159</sup>
Ullevaal screw (7 mm shank and 7 mm cancellous thread)	Lykke, 2003, <sup>60</sup> Puolakka, 2001, <sup>160</sup>
Scand pin (6.5 mm cancellous threaded screw)	Jacobsson, 1985 <sup>144</sup>

**Table 2. Included devices (continued)**

<b>Included Device</b>	<b>Included RCT Articles in which Device was Tested</b>
"Cannulated screws" (Depuy/J&J)	Blomfeldt, 2005 <sup>161</sup>
Richards screw (4.8 mm shaft 6.86 mm thread)	Lagerby, 1998 <sup>145</sup>
<b>Hemiarthroplasty</b>	
Thompson unipolar (cemented and uncemented)	Puolakka, 2001, <sup>160</sup> Davison, 2001, <sup>128</sup> van Dortmont, 2000, <sup>149</sup> Emery, 1991 <sup>162</sup>
Endo femoral head (Zimmer) with Zimmer CPT stem	Baker, 2006 <sup>163</sup>
Unitrax unipolar	Raia, 2003 <sup>164</sup>
Centrax bipolar	Raia, 2003 <sup>164</sup>
Moore unipolar (uncemented)	Skinner, 1989 <sup>124</sup>
Austin Moore unipolar (uncemented)	El-Abed, 2005, <sup>127</sup> Blomfeldt, 2005, <sup>161</sup> Parker, 2002, <sup>147</sup> Ravikumar, 2000, <sup>129</sup> Christie, 1994, <sup>165</sup> Emery, 1991 <sup>162</sup>
Monk bipolar (cemented)	Davison, 2001 <sup>128</sup>
Varikopf bipolar	Roden, 2003 <sup>146</sup>
Mallory head calcar replacement system	Kim, 2005 <sup>140</sup>
Vandeputte (VDP) endoprosthesis	Stappaerts, 1995 <sup>117</sup>
Bipolar Stanmore variocup	Van Vugt, 1993 <sup>120</sup>
Exeter modular stem (28 mm head, OGEE acetabular component) bipolar hemi or total hip replacement	Blomfeldt, 2007, <sup>166</sup> Blomfeldt, 2005, <sup>152</sup> Tidermark, 2003, <sup>154</sup> Tidermark, 2003 <sup>155</sup>
ODC modular femoral components	Cornell, 1998 <sup>167</sup>
<b>Total Hip Replacement</b>	
Charnley system	Jonsson, 1996 <sup>141</sup>
Zimmer system (acetabular cup with CPT stem)	Baker, 2006 <sup>163</sup>
Lubinus system	Johansson, 2006, <sup>151</sup> Johansson, 2001, <sup>156</sup> Johansson, 2000 <sup>157</sup>
BiMetric	Neander, 1997 <sup>159</sup>
Howse II	Ravikumar, 2000, <sup>129</sup> Skinner, 1989 <sup>124</sup>

Figure 7. Femoral neck decision tree/literature map

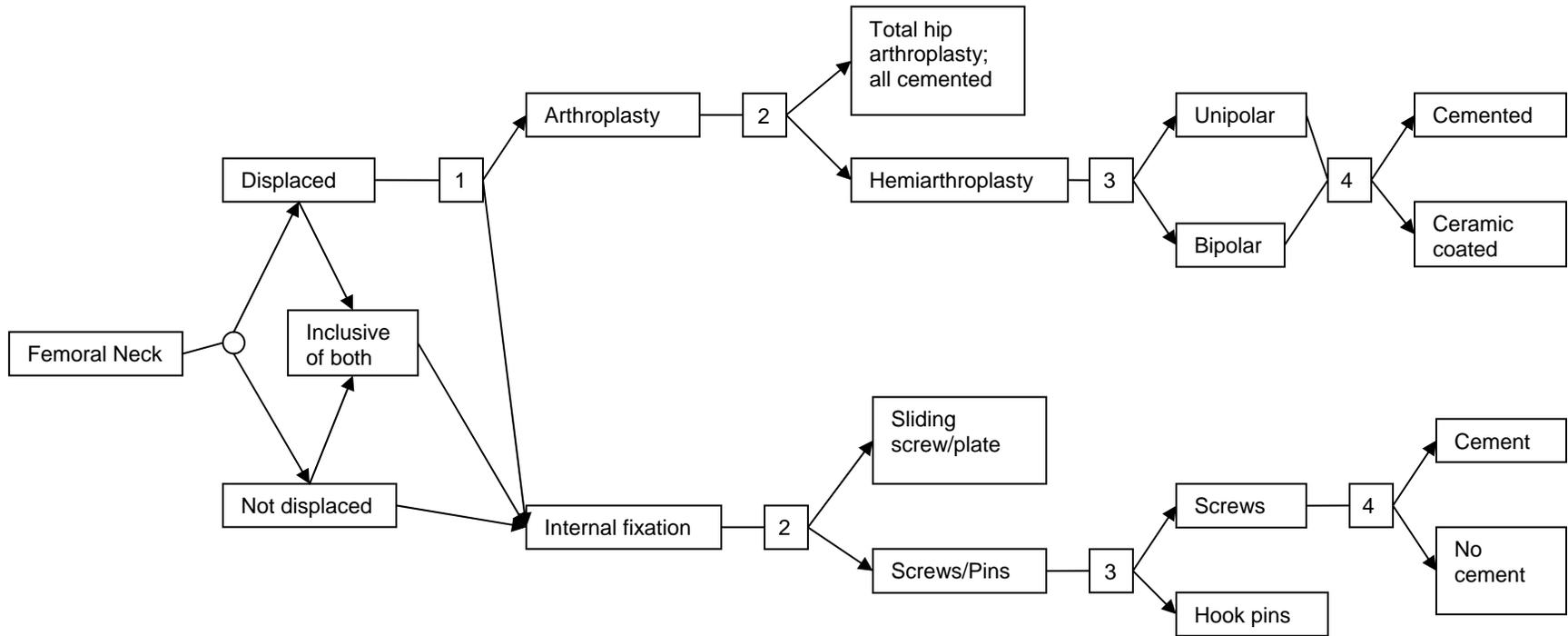
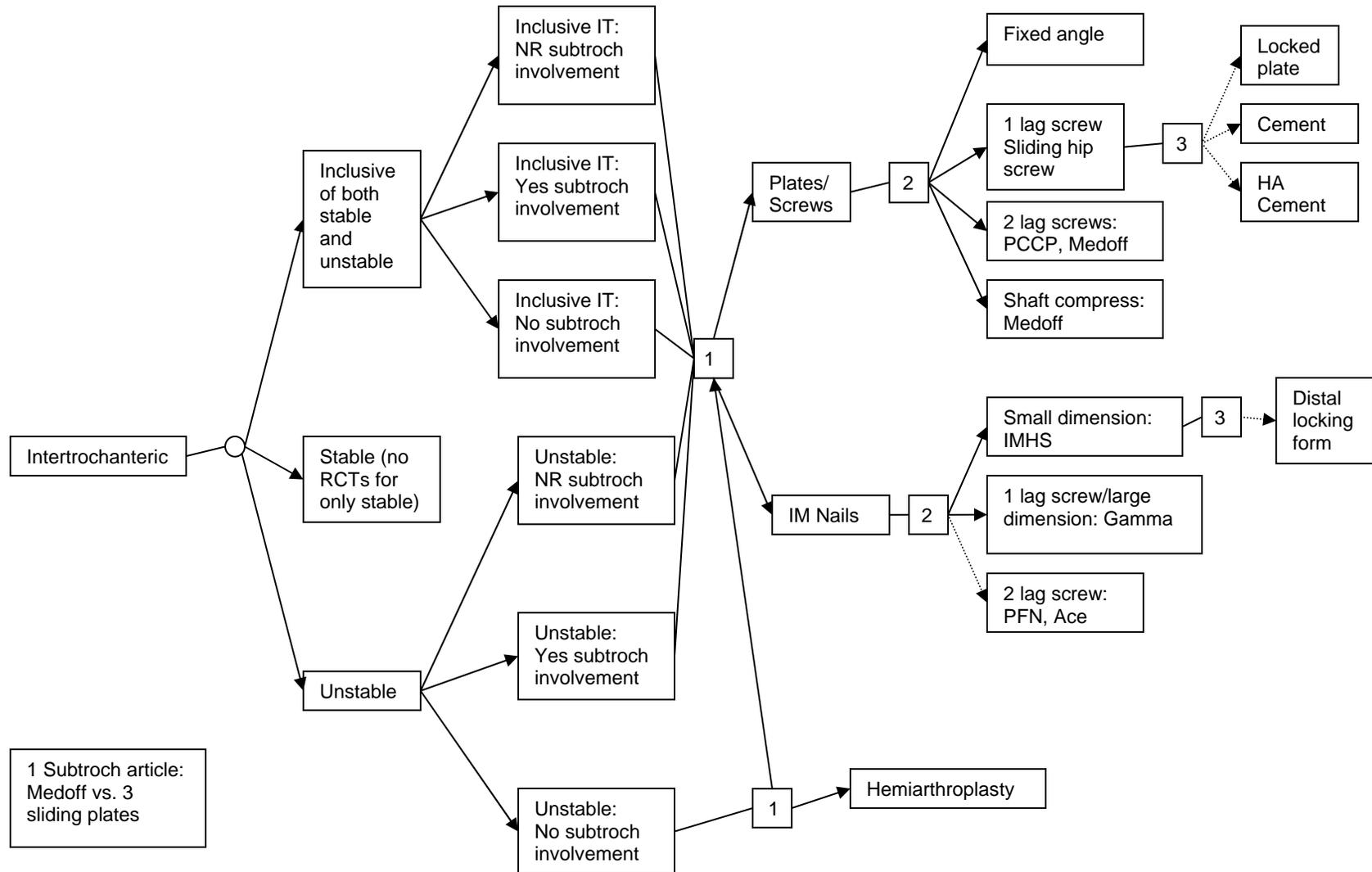


Figure 8 Pertrochanteric decision tree/literature map



NR = not reported, HA = Hydroxyapatite cement. IM Nails = intramedullary nails. PCCP = percutaneous compression plate. IMHS = intramedullary hip screw. PFN = proximal femoral nail. For further detail on types of devices, see Table 2.



## Chapter 3. Results

### Search Results

The search string for RCTs generated 625 unique references, of which 81 articles, representing 76 unique trials, were retained. The articles break down into 35 trials for femoral neck fractures, 40 trials for intertrochanteric fractures, and one trial for subtrochanteric fractures. The literature is overwhelmingly international, with only five published trials originating in the United States. Of the 6,773 articles generated with the observational study search string, 144 articles were reviewed at the full text level, and nine observational studies were retained for key question 1. Observational studies tended to originate in the United States. The quorum statement is available in Appendix E. Excluded studies are shown in Appendix F.

There is an interesting imbalance in the literature. For both femoral neck and pertrochanteric fractures, there are very small numbers of articles at the extreme right of the decision tree/literature maps shown in Chapter 2, and much larger numbers of articles at the level of class comparisons. In other words, most head to head comparisons for hip fractures compare different classes of fracture repair devices when there is not supporting RCT literature to show equivalency of implants within the broader device classes. For example, a number of articles looked at some form of internal fixation versus some form of arthroplasty for femoral neck fractures, but few studies helped determine which forms of internal fixation were equivalent relevant to outcomes.

All the key questions relate some set of variables to patient post-treatment outcomes. The most widely reported variable by far was mortality, although functional outcomes and pain may be seen as more important and relevant outcomes. Table 3 at the end of Chapter 3 lists the patient outcomes, in addition to mortality, available in the RCT literature. The outcomes are grouped into functioning, quality of life, residence, and pain. With the exception of mortality, there are few instances where similar patient outcomes are used for similar patient populations being tested with the same device comparison, mainly due to inconsistent use of outcomes measures. There was inconsistent reporting of the data required for quantitative analysis, such as the number and percent of patients with each target outcome. Several articles, noted in Table 3 provided no data at all or only a simple summary statement in the text, usually when no difference was found in an outcome between groups. Other studies did not report necessary information, such as the analytic sample size used for the outcome, or some measure of the variation of the mean score.

### **Key Question 1: What is the relationship between patient variables, the type of fracture, and post-treatment outcomes?**

Key Question 1 examines the larger question of how patient characteristics, including fracture type, relate to patient outcomes. Key Question 2, which will be discussed next, focuses specifically on the relationship between fracture type and outcome, holding patient characteristics steady. (See Appendix E Table E1 for details on included observational studies.)

Appendixes and evidence tables cited in this report are available at <http://www.ahrq.gov/downloads/pub/evidence/pdf/hipfracture/hipfracture.pdf>

## Observational Literature

Very little research specifically addressed the link between patient characteristics and outcome variables by fracture type. As noted above, of over 6,700 articles screened, 144 articles were reviewed at the full text level, and only nine were retained. Because the observational literature is not centrally located and easily identified, as discussed in Chapter 2, we chose to use a search strategy that emphasized sensitivity to potentially relevant literature. The large majority of articles were excluded because they did not include all major fracture types or involved research questions that were not within the scope of this review. The majority of the articles that advanced to full text screening either did not perform a multivariate analysis, failed to include fracture type as an independent variable in the analysis, or used too small a patient sample. (See Appendix E quorum statement for more details.) Of the included articles, three involved research questions directly focused on examining the relationships between patient characteristics, fracture type, and outcomes, and the remaining six examined predictors of outcomes in general, of which fracture type was one possible predictor. Appendix E Table E1 provides details on the included studies. An additional eight articles found fracture type to be nonsignificant at the univariate level and did not advance the variable to the multivariate regression model.

Similar to the RCT literature, mortality was a predominant outcome. Two of the studies with focused research questions<sup>168,169</sup> and two of the studies looked for general predictors of mortality as an outcome.<sup>82,170</sup> For short term (4 to 6 month) mortality, one found increasing age predictive of mortality,<sup>170</sup> two noted increased comorbidity,<sup>82,170</sup> and three found lower prefracture functioning to be predictive of mortality following hip fracture.<sup>82,169,170</sup> The only consistently reported predictor of short-term mortality was prefracture functioning. Age, male gender, heart failure, and intertrochanteric fracture were predictive of 10 year mortality.<sup>168</sup> However; this study did not adjust for functional or cognitive status of the patients.

Functional outcomes were also reported in the majority of observational studies. Six studies evaluated 3 to 6 month short-term functional outcomes. Lower patient age and higher prefracture functioning were consistent predictors<sup>13,14,33,169-171</sup> for recovery of functioning as measured by the ability to live independently, independence in activities of daily living (ADL)/independent activities of daily living (IADL), and mobility. Other identified predictors of functional recovery included lower ASA scores,<sup>33,170</sup> living in the community at the time of hip fracture,<sup>82,170,171</sup> and having a femoral neck, rather than intertrochanteric, fracture.<sup>171</sup> Hannan et al.<sup>82</sup> also found dementia to be a negative predictive factor if poor functioning and mortality were combined into an adverse outcome measure.

The same general pattern of predictive factors was found for functional outcomes at 1 year. Prefracture functioning<sup>14,33</sup> and age<sup>13,14,33</sup> remained consistently predictive. Koval et al.,<sup>13</sup> found that prefracture functioning, which was predictive for short-term functional recovery, dropped to nonsignificance at 1 year for recovery of ADL/IADLs. Intertrochanteric fracture type was found to be predictive of prefracture ambulatory patients becoming household or nonfunctional ambulators at 1 year.

These predictors for mortality and functional outcomes are consistent with observational studies that controlled for case mix variables, including fracture type.<sup>35,172-174</sup> Penrod et al. also found that patients of white race were more likely to survive and walk independently at 6 months than nonwhite patients and that dementia was negatively correlated with functioning and survival.<sup>173</sup> Studies that excluded fracture type from further analysis due to nonsignificance at the

univariate level consistently found that increased age,<sup>175,176</sup> male gender,<sup>11,176,177</sup> reduced prefracture functional status,<sup>175,176,178,179</sup> poor cognitive status,<sup>178,180</sup> and more comorbidities or worse health indexes,<sup>175,176,179,180</sup> were associated with higher mortality. Predictors of functional recovery included age,<sup>178</sup> female gender,<sup>178</sup> and prefracture functional status.<sup>178</sup> Other investigators of hip fracture patient heterogeneity used cluster analysis to empirically differentiate hip fracture patients into multiple subgroups, identifiable through age, pre-fracture functioning status, and dementia.<sup>168,181,182</sup>

We used the conceptual model in Chapter 1 to assess the potential validity of the predictors found in the observational literature. The literature set did not include full complements of variables which may potentially contribute to patient outcomes. The first variable to note is adjustment for fracture patterns. Only one study adjusted for stable/unstable intertrochanteric fractures,<sup>169</sup> one adjusted for number of fracture fragments for intertrochanteric fractures,<sup>170</sup> and three adjusted for displaced/nondisplaced femoral neck fractures.<sup>11,168,170</sup> The remainder of the studies used a dichotomous variable for femoral neck or intertrochanteric fractures.

There was inconsistent use of treatment factors as part of the overall modeling (see Table 4). Hospital factors tended to be addressed through the use of single hospital sites, although the assumption that patients were homogenous with regard to hospital factors would have been strengthened with the use of a measure of fidelity to inpatient treatment protocols. One study found slight differences in mortality and morbidity by hospital site, and suggested that hospitals may find the results a useful stimulus for quality improvement.<sup>170</sup> Another study controlled for hospital site but did not report its contribution to the model.<sup>82</sup> One study used detailed information on surgical treatment,<sup>170</sup> and one dichotomized patients to internal fixation or prosthetic replacement.<sup>14</sup> For the remaining two studies that reported surgical treatments for hip fracture patients,<sup>82,169</sup> the information was collected at the aggregate level of device class, i.e., internal fixation, hemiarthroplasty, and neither could use the information in the analysis due to an almost perfect correlation between fracture type and surgical treatment. One study captured and included in the analysis some perioperative factors such as type of anesthetic.<sup>169</sup> Neither surgeon factors nor rehabilitation factors appeared in any of the study analyses.<sup>11</sup>

**Table 4. Treatment covariates found in observational research**

Factors	Number of Articles that Collected the Factor	Number of Articles that Used the Factor in Analysis
Hospital factors	2	2
Surgical treatment factors	4	2
Perioperative factors	1	1
Surgeon factors	0	0
Rehabilitation factors	0	0

## RCT Literature

No RCTs were designed to assess the association between patient or fracture variables and outcomes. Obviously, one cannot randomly assign risk factors. At best, investigators of RCTs would need to collect and use the necessary covariates to perform multivariate or stratified subgroup analyses. Table 5 provides a breakdown of the major classes of covariates, the specific factors within those major classes that were collected by the trials, and the number of trials that incorporated those specific factors into their analyses.

**Table 5. Patient, hospital, and rehabilitation covariates from 81 RCT articles**

Covariate Class	Specific Factor	Number of Articles that Collected the Factor	Number of Articles that Used the Factor in Analysis
Patient Covariates	Age	65	4
	Gender	65	3
	Mental status	24	1
	Race	1	0
	Fracture pattern	51	2
	ASA status/health history	24	0
	Obesity	4	0
	Prefracture residence	26	0
	Prefracture functioning	44	0
	Prior fractures	4 (often exclusion criteria)	0
	Socioeconomic status	1	0
Smoking status	0	0	
Alcohol use history	1	0	
Hospital Covariates		11 trials were multisite trials; 4 femoral neck, and 7 pertrochanteric. Of these 11, only 2 trials reported details regarding the sites; 1 femoral neck, and 1 pertrochanteric.	None
Rehabilitation Covariates		None	None

Most hip fracture surgery RCTs are direct comparisons of implants, with minimum, if any, adjustment for patient characteristics. In a number of instances, potentially relevant information collected at baseline was not used further in the analyses. Only four articles adjusted their analysis by age,<sup>61,96,127,183</sup> three by gender,<sup>61,127,183</sup> one by the patients' mental status,<sup>157</sup> and two by fracture severity as determined by the number of bone fragments.<sup>61,108</sup>

Hospital factors within single trials are particularly important when the trial is a multicenter study. Of the 11 trials that were multisite,<sup>47,97,99,108,109,132,135,155,163,183,184</sup> only two reported details regarding the sites<sup>135,183</sup> and none used the data to adjust patient outcomes. One article provided an example of the importance of including other factors in analyses. Alho et al. performed a post-hoc analysis and found that the hospital site was more predictive of reoperations, an intermediate outcome, than the devices used in the trial treatment arms;<sup>185</sup> a "hard" outcome, carefully defined and incorporated into the study design and protocol, was subject to local variation.

Essentially all articles briefly described their inpatient post-operative mobilization protocol. Most articles mentioned that all patients were encouraged to engage in early mobilization, perhaps supervised by a physical therapist, and that this inpatient protocol was the same for both treatment groups. No article collected the data, including fidelity to the post-surgical inpatient protocol, and incorporated it into their outcome analyses. Few articles mentioned discharge destination. Among those that did, none identified which patients went to some type of rehabilitation nor any details about the duration, type, or intensity of post-acute rehabilitation as it related to outcomes. For most articles, there were no comments about any special care provided after the acute inpatient hospital discharge.

The lack of comprehensive data collection within either the observational or RCT literature prevents a definitive answer about the relationship between patient characteristics, fracture types, and patient outcomes. Currently, the evidence suggests it is reasonable to treat age, gender, prefracture functioning, and comorbidities as predictors of hip fracture treatment mortality and functional outcomes, but other predictors may yet be found to be important.

## Key Question 2: What is the relationship between the type of fracture and post-treatment outcomes?

One observational study looked directly at the type of fracture relative to patient mortality and long-term recovery. Fox et al.<sup>186</sup> examined mortality and recovery, defined as the return to prefracture level of independence, adjusting for significant prefracture characteristics, and found that patients with intertrochanteric hip fractures were less likely to recover functional abilities at 2 months, and had higher mortality at 2 and 6 months. However, by 1 year, recovery and mortality did not differ by fracture type. An increased likelihood of lower short-term 4 month recovery for patients with intertrochanteric fractures was also noted by Borgquist et al.<sup>171</sup> Karagiannis et al.'s study found a long-term association by fracture type that intertrochanteric fractures were more likely to be associated with higher mortality over 10 years.<sup>168</sup> However, the study did not adjust for prefracture functional status. Since functional status has been consistently found to be predictive of patient outcomes, the results of this study with regard to fracture type are questionable. In a subgroup analysis Koval et al.<sup>14</sup> also found evidence that intertrochanteric hip fracture patients who were functional prior to fracture were more likely to become household or nonfunctional ambulators after fracture.

The majority of the other studies did not find fracture type to independently predict patient outcomes.<sup>11,13,14,33,82,169,170,173</sup> Related observational research often found fracture type to be nonsignificant at the univariate or bivariate level and did not incorporate it further in the modeling.<sup>14,52,178,187</sup> Many observational studies did not characterize patients by type of hip fracture.<sup>34,57,76,77,181,182,188-190</sup>

The observational literature provides a limited amount of evidence that overall, holding all other factors constant, type of fracture is not an independent predictor of long-term post-treatment patient outcomes. Cornwall et al. suggested, based on their study, that future prospective studies could treat all fracture types as a homogenous group.<sup>169</sup> However, it is important to note that the authors acknowledge the uncertainty of stable and unstable intertrochanteric fracture classifications as a limitation. Until the lack of reliability in classifying unstable intertrochanteric hip fractures is addressed within the orthopaedic professional community, a definitive answer regarding the role of fracture types in post-surgical outcomes cannot be provided. Clarification of stable/unstable classifications should also help with confirming the limited evidence that intertrochanteric hip fracture patients experience delayed recovery patterns relative to femoral neck patients. The relative contribution of the impact of surgical treatment options on patient outcomes for intertrochanteric versus femoral neck fractures also remains unclear.

Similar to key question 1, the RCT literature does not allow for an analysis of the impact of fracture type on post-treatment outcomes. In order to isolate the impact of fracture type, the analysis would need to hold constant other factors which might affect patient outcomes, such as surgical treatment and both inpatient and outpatient rehabilitation protocols, and the literature is lacking in such covariates.

### Key Question 3: What is the relationship between implant variables and patient post-treatment outcomes?

Key question 3 relates to comparisons of devices at Nodes 3 and 4 of the decision tree/literature maps in Chapter 2. These nodes relate to differences between different devices within a device class, such as screws versus hook pins for internal fixation devices, or the choice to cement or not cement. (See Appendix E Tables E2-E5) for details on the included RCT studies.)

It is difficult to specifically separate the effects of the procedure/device from the setting/place of surgery without variables that account for factors closely related to the device and to the surgery itself. Results given in the sections for key questions 1 and 2 documented the limited use of hospital setting information. Surgeon and perioperative factors also contribute to the overall outcomes of a device and should be incorporated into analyses in order to isolate the effects of a device from the setting within which it was used. An example of this is a trial where two surgeons individually performed all surgeries for one arm of the study.<sup>105</sup> In this situation it becomes impossible to separate the effect of the surgeon from the device.

Table 6 provides information regarding the number of times a surgeon factor was addressed in the literature and the number of times the factor was used in post-surgical outcome analysis.

**Table 6. Surgeon factors reported in 81 RCT articles**

Factors	Number of Articles that Collected the Factor	Number of Articles that Used the Factor in Analysis
Surgeon training/experience	6 (4 FN, 2 IT)	2 <sup>24,25</sup>
Experience with device (learning curve)	2 (all FN)	None
Any descriptive comment in text	53 (22 FN, 31 IT)	None
Mentioned treatment arm is new	6 IT	None
Defined learning curve	4 (1 FN, 3 IT)	None
Study design well controlled for surgeons between arms (one or two experienced surgeons performed all operations)	9 (5 FN, 4 IT)	None

FN = Femoral neck fracture; IT = intertrochanteric fracture

The large majority of articles made some descriptive statement in the text, most often reporting the number of surgeons involved, less frequently the surgeon training level, and infrequently the extent of experience a surgeon had with the specific devices used in the treatment arms. Very few articles provided an operational definition for “experience” with a device or experience in general.

The lack of comment about the surgeons’ experience or learning curve with new treatments is important to note. The articles which provided an estimate of the learning curve give a range of two to five cases as an adequate learning curve for the trial.<sup>60,92,103,135</sup> Empirical data to support the claims are not provided. At least one author has suggested that the learning curve for second generation intramedullary nails is 25 cases.<sup>112</sup> Because devices may have different learning curves, the overall lack of information is of concern.

Of the two articles that examined surgeon experience, one found that good positioning of the device was predictive of 1 year outcomes, and there was a trend for better implant position with greater surgeon experience.<sup>24</sup> The other study did not examine post-treatment outcomes, but it also found that experienced surgeons took less time, had better results for fracture reduction and implant positioning, and their patients experienced fewer complications than among

inexperienced surgeons.<sup>25</sup> One study found that senior surgeons were more likely to have performed THA in one arm of the study, but did not adjust patient outcomes by surgical experience. In this study THA patients were found to have improved outcomes for displaced femoral neck fractures.

Ten studies also noted that large majorities of surgeries were performed by junior staff and residents.<sup>45,47,98,102,113,114,124,160,163,191</sup> Still other studies had large numbers of participating surgeons with little information on experience level.<sup>60,96,108,109,132,151,157,192</sup> When provided, the number of surgeons per study ran as high as 43.<sup>132</sup> Several studies took care to mention that the residents were supervised by senior staff, although the extent of resident involvement in operative cases was not specified.<sup>47,113,114</sup>

Unlike surgeon factors, perioperative factors, such as operating time and type of anesthesia used, are frequently found in the literature, due to the fact that they are often reported as outcomes. Major and minor medical and device related complications are collected in great detail. Table 7 provides a list of selected perioperative factors found in the literature.

**Table 7. Perioperative factors reported in 81 RCT articles**

<b>Factors</b>	<b>Number of Articles that Collected the Factor</b>	<b>Number of Articles that Used the Factor in Analysis</b>
Time in surgery	57 (16 FN, 41 IT)	None
Blood loss and transfusions	51 (9 FN, 42 IT)	None
Anesthesia	16 (2 FN, 14 IT)	None
Quality of surgical technique	31 (14 FN, 17 IT)	None

FN = Femoral neck fracture; IT = intertrochanteric fracture

Quality of surgical technique includes evaluation of the surgeon’s reduction of the fracture in relation to anatomic alignment both before and after implant placement, and postoperative quantification of proper implant positioning in relation to optimal positioning as determined by prior clinical and biomechanical studies. While no article used surgical technique when investigating patient post-treatment outcomes, three studies used regression analysis to investigate the relationship between surgical technique and intermediate outcomes. The quality of surgical technique was not found to be related to the number of infections<sup>149</sup> but inadequate fracture reduction and suboptimal implant position were associated with device failure<sup>130</sup> and radiographic healing complications,<sup>61</sup> and a higher need for revision surgery.<sup>46</sup>

We attempted to analyze the literature for final outcomes. Table 8 provides a breakdown of the number of studies within each comparison group that had extractable data. The table is organized by the levels of comparison illustrated in the decision tree/literature maps in Chapter 2. (See Appendix E Tables E6-E13 for specific outcomes by study.) Cells with relatively large numbers of reported functional outcomes include multiple forms of outcome measures (Table 3). Although the table is populated with only those studies that included extractable data, it should be noted that the number of empty cells and cells with low numbers in the table remains high even when including studies that provide insufficient or no data.

**Table 8. Outcomes reported in studies by comparison group**

Comparison	Pain (Categorical)	Pain (Continuous)	Functional (Categorical)	Functional (Continuous)
<b>Femoral Neck</b>				
Node 4 Arthroplasty – Hemi choices	1	0	2	0
Node 4 Internal fixation – Cemented vs. not	0	0	0	0
Node 3 Arthroplasty – Uni vs. bipolar hemi	0	0	1	1
Node 3 Internal fixation – Hook pins vs. screws	1	0	0	0
Node 3 Internal fixation – Screws vs. screws	1	1	2	1
Node 2 Arthroplasty – Hemi vs. THA	0	2	1	4
Node 2 Internal fixation – Pins/screws vs. plate and screws	0	0	0	0
Node 1 Internal fixation vs. hemi	2	1	5	2
Node 1 Internal fixation vs. THA	1	1	1	1
Node 1 Internal fixation vs. arthroplasty	1	0	1	0
<b>Intertrochanteric</b>				
Node 3 Plate/screw comparisons	0	0	0	0
Node 3 Intramedullary nail comparisons	1	0	0	0
Node 2 Plate/screw comparisons	0	2	3	2
Node 2 Intramedullary nail comparisons	0	1	2	3
Node 1 Plate/screw vs. Intramedullary nail	6	2	9	4
<b>Subtrochanteric</b>				
Node 1	0	0	1	0

## Mortality

Mortality was consistently gathered across the studies, and the relative risks for the studies reporting mortality data are provided here. The reader should recognize that mortality, while too frequent, is not necessarily a definitive outcome for hip fractures. The mortality data is followed by a brief narrative of the other patient outcomes based on what was reported in the literature.

**Femoral neck fractures.** For femoral neck fractures, Figures 9 through 11, provided at the end of the chapter, show forest plots of relative risks of mortality for unipolar versus bipolar hemiarthroplasties, screws versus hook pins, and sliding hip screws versus screws/pins, respectively. No significant differences are found in the relative risks for mortality in any comparison, nor are differences found across the different assessment periods. While the relative risk tends to be higher for patients receiving hook pins as compared to screws, the confidence intervals for all assessment periods still intersect the nonsignificance central line.

**Intertrochanteric fractures.** Figures 12 and 13 at the end of the chapter show forest plots of the relative risks of mortality among intertrochanteric hip fracture patients treated with types of implants within the same device class: various plate/screw models compared with each other (Figure 12) or different intramedullary nail models compared with each other (Figure 13). No significant differences were found between device subtypes within the broader implant classes for any assessment period. No differences were found in mortality for regular versus dynamic distal locking techniques (RR [relative risk] 1.35, CI [confidence interval] 0.56; 3.26),<sup>139</sup> or cemented screws (RR 0.64, CI 0.11; 3.69).<sup>97</sup>

## Pain and Functional Patient Outcomes

**Femoral neck fractures.** One small study (N=53) examined whether cemented or uncemented stems for hemiarthroplasties performed better for displaced fractures.<sup>162</sup> Only active,

pre-fracture independently mobile patients were included in the study. Identical stems were used for both treatment arms. More pain and use of walking aids continuing past 1 year after surgery was found among patients with uncemented stems. Miyamoto et al.<sup>27</sup> suggested that evidence is tending to support cemented devices. However, this must be weighed against the harm study by Christie et al., which found greater and more prolonged embolic cascades during surgery for cemented hemiarthroplasties as compared to uncemented.<sup>165</sup> This study involved only 20 patients with femoral neck fractures and provided little patient data with which to assess the appropriateness of the study. Since actual pulmonary embolism events are relatively infrequent, it would take considerably higher numbers of patients to understand the adverse event potential. A partial randomized study also switched its protocol from uncemented to cemented stems after complaints of hip pain.<sup>193</sup>

A comparison of hemiarthroplasty devices, one with a hydroxyapatite ceramic coated prosthetic stem versus a press-fit hemiarthroplasty (no ceramic coat) was examined in one study.<sup>194</sup> Hydroxyapatite ceramic is used to secure fixation because it incorporates directly into bone in an effort to avoid the use of cement for stem fixation within bone. The study found reduced pain, improved walking ability, and less use of walking aids in patients with displaced fractures treated with the ceramic coated stems when compared with uncemented hemiarthroplasty. A more telling comparison may have been against a cemented hemiarthroplasty device.

Two studies examined unipolar versus bipolar hemiarthroplasty.<sup>164,167</sup> No differences between the forms of hemiarthroplasty were found in mobility, functioning, or quality of life. Miyamoto et al.<sup>27</sup> suggests that there is some evidence for bipolar hemiarthroplasty to be superior to unipolar forms, but that the difference may not be sufficient to justify the increase in cost.

For internal fixation devices, cemented versus noncemented screws were addressed in two trials.<sup>150,153</sup> Both trials involved relatively healthy and active elderly patients with displaced fractures due to low energy trauma, but only one trial collected patient outcomes. No significant advantage was found for the cemented screws versus noncemented screws. Bajammal et al's. systematic review,<sup>195</sup> which included the two hip fracture trials in a larger set of more inclusive fractures, found that patients with cemented internal fixation devices had less pain during healing.

Comparisons of different forms of screws were addressed in two trials.<sup>24,145</sup> Both trials involved inclusive sets of femoral neck fracture patients, allowing both displaced and nondisplaced fractures, and very limited exclusion criteria. Pain, the use of walking aids, and residential status were measured. One study found that one form of screws was related to less pain and lower use of walking aids in the short term (4 months); however, the same study also found a trend in surgeon experience to be predictive of outcomes.<sup>24</sup> Published systematic reviews have not found superior performance related to specific numbers or forms of screws.<sup>196,197</sup>

Four trials compared two hook pins to two or three screws.<sup>45,60,142,143</sup> This literature set also used relatively liberal patient inclusion criteria. The three articles that reported patient age ranges included patients as young as their late 20s. High energy trauma and bilateral fractures were also noted. The most relevant exclusion criterion was the exclusion of fractures which could not be satisfactorily reduced. Pain, the use of walking aids, and living situation outcomes were reported. One of three studies found more pain with the hook pins and among institutionalized patients.<sup>143</sup> It should be noted that in the study which found more pain, the hook pin was a new device for the surgeons in that study, who also preferred the screws. Thus, neither screws nor hook pins were found to be consistently superior to the other,<sup>197</sup> although screws have been found to be superior to hook pins with regard to overall complication rates.<sup>196</sup>

Four trials compared sliding hip screws (SHS) to either hook pins or screws for femoral neck fractures.<sup>25,61,125,130</sup> Few patient exclusion criteria were used, although all but one article involved patient populations 50+ years of age. The only patient outcome reported across studies was mortality, and that was inconsistently reported across assessment periods. Neither SHS nor pins/screws were found to be superior with regard to patient outcomes in systematic reviews.<sup>196,197</sup>

Overall, the RCT literature for femoral neck fractures at comparison Nodes 3 and 4 does not offer evidence to suggest that a particular device is superior to other internal fixation devices with regard to patient post-treatment outcomes. This assessment supplements Parker et al's.<sup>196</sup> systematic review that recommended screws versus pins based on overall complication rates.

**Intertrochanteric fractures.** One study reported patient outcomes for a comparison of calcium phosphate cemented screws used to anchor a plate/screw system versus uncemented screws.<sup>97</sup> Pain, quality of life, functioning, and the use of walking aids were reported at 6 weeks and 6 months. Lower pain and better functioning and quality of life were reported at 6 weeks, but by 6 months, only quality of life remained significant. Likewise, hydroxyapatite cement was tested in another study as a way to affix a plate/screw system.<sup>95</sup> Harris hip scores and the SF36 were used to measure pain, mobility, and quality of life at 6 months for patients with unstable fractures. The augmented group had better Harris hip scores at 6 months.

One study examined static versus dynamic locking techniques for intramedullary hip screws (IMHS), a type of intramedullary nail.<sup>139</sup> Patients had hip fractures that involved the medial femoral cortex or reverse oblique fractures. No differences were found between the groups for mobility or pain within the first year after surgery.

Six studies compared various forms of extramedullary plate/screw devices.<sup>96,103,104,107,108,113</sup> The studies pitted SHS against a newer plate/screw device, such as the Medoff system. No differences were found in mobility, post-acute residential status, or ambulation. Pain was lower for percutaneous compression plates for 1 to 6 weeks after surgery in two studies,<sup>96,104</sup> but this difference became nonsignificant for later assessment periods. Likewise, in one study patients were quicker to weight-bear after surgery, but there were no differences between groups for walking ability or residential situation at any later assessment periods.<sup>108</sup>

Five studies compared Gamma nails against some other form of intramedullary nails, of which four studies examined patient outcomes.<sup>134,135,137,138</sup> None found any differences in mobility, functionality, or pain at any assessment period.

**Subtrochanteric fractures.** One study specifically examined extramedullary devices for subtrochanteric fractures.<sup>109</sup> The study randomized patients to receive either a SHS, SHS with a trochanteric stabilizing plater, or a dynamic condylic screw, based on the surgeon's decision, or the Medoff plate system. Outcomes were the use of walking aids and residential status, assessed at 4 and 12 months. Patients with the Medoff system were quicker to bear weight after surgery, but there were no differences in patient outcomes.

The findings of the studies are consistent with other systematic reviews which have not found evidence to suggest that one form of device within a class is superior to another, either plate/screw devices<sup>29</sup> or intramedullary nails.<sup>72</sup>

Overall, given the mortality analysis and narrative of other patient outcomes, there is no evidence to support the use of one device over another within a class of devices for either femoral neck fractures or intertrochanteric fractures with regard to patient post-treatment outcomes.

## Key Question 4: What is the relationship between the type of intervention and patient post-treatment outcomes?

Key question 4 relates to comparisons of devices at Nodes 1 and 2 of the decision tree/literature maps in Chapter 2. These nodes relate to differences between different device classes.

As Table 8 showed in the last section, except for mortality, there were too few consistently measured patient outcomes to allow a quantitative analysis of classes of implants. Reporting of mortality data is again followed by a narrative report of other patient outcomes found in the literature.

### Mortality

**Femoral neck fractures.** Figures 14 through 16 are forest plots of the relative risks of mortality for hemiarthroplasty versus THA, internal fixation versus hemiarthroplasty, and internal fixation versus THA, respectively. The studies included in Figure 17's forest plot include only those studies that randomized patients to an unreported set of arthroplasty options<sup>184</sup> or randomized patients to receive either internal fixation, hemiarthroplasty, or THA.<sup>124,129,192</sup> In all cases, there were no significant differences between groups in relative risk for mortality for any assessment period.

**Intertrochanteric fractures.** Figures 18 and 19 are forest plots of the relative risk for mortality among patients treated with plate/screw devices versus intramedullary nails. Figure 18 contains studies that included all intertrochanteric fracture types; Figure 19 has studies that included only unstable fractures. There were no significant differences between groups in the relative risk for mortality for any assessment period. Figure 20 shows that this conclusion holds true for internal fixation versus hemiarthroplasty comparisons for patients with unstable intertrochanteric fractures as well.

**Subtrochanteric fractures.** Figure 21 provides a forest plot of the relative risk for mortality for studies that explicitly included subtrochanteric fractures as defined by the study investigators. These studies compared plate/screw devices versus intramedullary nails,<sup>46,69,115,118,132</sup> or one specific form of plate/screw device against another.<sup>109</sup> Again, no significant differences were found in the relative risk of mortality between groups at any assessment period.

### Pain and Functional Patient Outcomes

**Femoral neck fractures.** Two studies compared hemiarthroplasty to THA for displaced femoral neck fractures.<sup>163,166</sup> One study used a followup period of 1 year and found that patients with THA had less pain than those who received hemiarthroplasty.<sup>166</sup> The second study used a longer followup period of 3 years and found that compared to patients who received hemiarthroplasty, patients who received THA continued to show better functioning at 3 years.<sup>163</sup> The patient populations in both studies were relatively healthy elderly patients living independently prior to the fracture.

Eight studies compared internal fixation with hemiarthroplasty, both cemented and uncemented versions, for displaced femoral neck fractures.<sup>120,127,128,146,147,149,160,161</sup> The studies were relatively long term, ranging from 2 to 5 year followup periods. All but two reported a wide

range of patient outcomes.<sup>149,160</sup> Three studies reported better patient outcomes for internal fixation, including functioning and quality of life.<sup>120,127,161</sup> Two studies reported that patients who received hemiarthroplasty were more likely to be satisfied with their recovery,<sup>128</sup> regained prefracture functioning, and were free of pain faster than those patients who received internal fixation, although the differences found in these two studies became nonsignificant in later years.<sup>146</sup> One study found no difference between groups.<sup>147</sup>

Two internal fixation versus hemiarthroplasty studies specifically focused on patients over age 70 with cognitive impairments.<sup>149, 161</sup> One study found a decrease in overall quality of life by the second year in hemiarthroplasty patients,<sup>149</sup> while no differences were found in the other.<sup>161</sup>

Four studies compared internal fixation to THA for displaced femoral neck fractures.<sup>141,151,152,198</sup> All studies found patients who received THA had better mobility, less pain, and better functioning and quality of life for at least 1 year following surgery. By the second year two studies found these differences to be moving to borderline significance,<sup>141,157</sup> and the one study that continued to follow patients for 4 years also found the difference to have returned to nonsignificance.<sup>152</sup>

Three studies compared all three major forms of implants, either in individual arms of internal fixation versus hemiarthroplasty versus THA,<sup>124,192</sup> or internal fixation versus an arthroplasty arm that included both hemiarthroplasty and THA.<sup>184</sup> In general, THA was found to perform better than internal fixation with regard to mobility and pain. One study also found that patients with THA scored higher on quality of life measures compared to patients who received hemiarthroplasty.<sup>192</sup>

The patient populations for internal fixation versus hemi or total arthroplasty studies were almost exclusively relatively healthy, independently living elderly patients. The one study that specified dementia patients as the study population did not report patient outcomes.<sup>149</sup>

Overall, on the surface it would appear that THA tends to have improved patient focused outcomes over internal fixation, and authors of systematic reviews have suggested the evidence is strong enough to recommend THA for cognitively intact, independent elderly hip fracture patients.<sup>26,27</sup> However, one systematic review found no difference in pain or functioning between patients who received internal fixation and patients who received arthroplasty.<sup>28</sup> The question remains whether these positive findings for THA would continue to hold if the analysis included all the variables relevant to understanding patient outcomes.

**Intertrochanteric fractures.** Twenty-two studies compared plate/screw fixations to intramedullary nails for intertrochanteric hip fractures; 16 studies included both stable and unstable fracture patterns,<sup>47,92,98-100,106,110,112,114-116,118,119,121-123</sup> and six studies included only fractures labeled as unstable by authors.<sup>46,69,91,94,102,132</sup> Of these, five studies did not report any patient outcomes beyond mortality.<sup>94,115,116,119,121</sup> The large majority of studies followed patients for 1 year or less. Two studies found reports of higher pain for intramedullary nails at final followup.<sup>99,112</sup> Four studies found improved early mobilization or early weight bearing for intramedullary nails, but these gains were only in the very short term.<sup>112,114,122,132</sup> Two other studies found improvements in mobility at 4 months,<sup>98</sup> or 1 year<sup>92</sup> for intramedullary nails, but these significant findings become nonsignificant when the appropriate Bonferonni significance corrections for multiple outcomes were conducted. The paucity of significant findings would suggest that with regard to patient outcomes, neither plate/screw implants nor intramedullary nails can be claimed to be superior over the other. There is some disagreement within the systematic review literature as well. The Cochrane reviews have supported SHS as superior to intramedullary nails for both stable and unstable fractures,<sup>29,30</sup> while Kregor et al.<sup>31</sup> argue that

intramedullary nails are preferable for unstable fractures, specifically AO/OTA A3 fracture patterns. This may well be unable to be fully resolved until there is reliable agreement with regard to the classification of stable and unstable fractures. Kaplan et al.<sup>32</sup> suggest there is insufficient evidence to support recommendations at this time.

**Table 3. Patient outcomes used in literature**

<b>Outcome</b>	<b>Articles in Which Outcome was Used</b>
<b>Functioning – Femoral Neck</b>	
6 minute walk	Cornell, 1998 <sup>167</sup>
Walking distance in miles	Baker, 2006 <sup>163</sup>
Walking distance 1 kilometer or more	Jonsson, 1996 <sup>141</sup>
Walking ability: no aid, with aids, not walking, unknown	Mjorud, 2006 <sup>45</sup> (no data)
Walking: 1 cane or less outdoors	Jonsson, 1996 <sup>141</sup>
Walking: 1 or no aids, 2 canes or more, not ambulatory	Lagerby, 1998 <sup>145</sup>
Walk without or 1 stick, walk with aid, not walking	Olerud, 1991 <sup>143</sup> (no data), Rehnberg, 1989 <sup>24</sup>
Return to same walking aid use: none, walking stick, walking frame (Zimmer), immobile	Parker, 2002, <sup>147</sup> Parker, 2000, <sup>148</sup> Paus, 1986 <sup>25</sup> (no data)
Return to prefracture walking	Roden, 2003 <sup>146</sup>
Independent of aids (no specifics)	Emery, 1991 <sup>162</sup>
Mobility: Independent (does shopping), independent with aids, housebound unless accompanied, uses aids indoors, chair or bedbound	Ravikumar, 2000 <sup>129</sup> (insufficient data), Skinner, 1989 <sup>124</sup> (no data)
"Get up and go"	Cornell, 1998 <sup>167</sup>
Activities of Daily Living (ADL) (no specifics)	Mattsson, 2006 <sup>150</sup>
ADL independence on at least 5 functions	Blomfeldt, 2005, <sup>152</sup> Blomfeldt, 2007, <sup>166</sup> Blomfeldt, 2005 <sup>161</sup>
Able to do own shopping	Jonsson, 1996 <sup>141</sup>
Able to go shopping	Livesley, 1993 <sup>194</sup>
Home assistance less than 4 hours weekly	Jonsson, 1996 <sup>141</sup>
Oxford hip (global)	Baker, 2006 <sup>163</sup>
Merle D'Aubigne mobility scale (passive, 6 increments of mobility)	Mattsson, 2006 <sup>150</sup> (no data)
Musculoskeletal functional assessment: mobility and ADL	Raia, 2003 <sup>164</sup> (insufficient data)
Parker/Palmer mobility score	Parker, 2002, <sup>147</sup> Parker, 2000 <sup>148</sup> (insufficient data)
Harris hip score (global)	Johansson, 2006 <sup>151</sup> (insufficient data), Davison, 2001 <sup>128</sup> (insufficient data), Johansson, 2000 <sup>157</sup> (insufficient data), Ravikumar, 2000 <sup>129</sup> (insufficient data), Kuokkanen, 1991 <sup>131</sup>
Harris hip score subscales: pain, function, absence of deformity, range of motion	Blomfeldt, 2007 <sup>166</sup>
Hip rating questionnaire. 100 point scale equal weight to global, pain, walking, function.	Keating, 2006 <sup>192</sup>
Charnley score: pain, movement, walking	Blomfeldt, 2005 <sup>152</sup> (insufficient data), Blomfeldt, 2005 <sup>161</sup>
Matta scoring system: (global) pain, ambulation, range of motion - surgeon rated	El-Abed, 2005 <sup>127</sup>
Barthel index (based on ADLs, maximum score-20)	Davison, 2001 <sup>128</sup>
Johansen hip score	Cornell, 1998 <sup>167</sup>
PRRAFSSWAO: patient's opinion of hip, rest pain, pain rising from chair, activity pain, hip flexion, ability to climb stairs, assistance walking, activity	Livesley, 1993 <sup>194</sup>
Return to preinjury state (no specifics)	Davison, 2001 <sup>128</sup>
<b>Functioning - Petrochanteric</b>	
Walking: able to walk without aids or 1 stick, walk with aids, walk when assisted by another person	Vidyadhara, 2007, <sup>138</sup> Pajarinen, 2005 <sup>98</sup>
Walking aids (no specifics)	Ahrengart, 2002 <sup>99</sup>
Walking: no aid or 1 stick (%)	Adams, 2001 <sup>106</sup>
Walking: no aids, aids, nonwalker	Lunsjo, 1999, <sup>109</sup> Leung, 1992 <sup>122</sup>
Walking: without help, with aid, wheelchair/bedridden	Janzing, 2002 <sup>104</sup>
Walking: 0 - 6 scale from no support to bedridden/wheelchair	Park, 1998 <sup>110</sup>
Walking 15 miles	Ekstrom, 2007 <sup>132</sup>
Ambulation: community, community with aid, household	Goldhagen, 1994 <sup>118</sup>
Recovery of walking to pre-op status (%)	Efstathopoulos, 2007, <sup>134</sup> Pajarinen, 2005 <sup>98</sup>

**Table 3. Patient outcomes used in literature (continued)**

<b>Outcome</b>	<b>Articles in Which Outcome was Used</b>
Return to pre-injury living (ambulation) status: community, household, nonambulatory	Harrington, 2002 <sup>102</sup>
Return to independent walker (no specifics)	Olsson, 2001, <sup>107</sup> Lunsjo, 2001 <sup>108</sup>
Rise from chair without arm support	Ekstrom, 2007, <sup>132</sup> Mattsson, 2005 <sup>97</sup>
Climb a 15 cm curb	Ekstrom, 2007, <sup>132</sup> Mattsson, 2005 <sup>97</sup>
Katz ADL: A independent in all; B independence in all but one, C-G dependence in bathing and at least one other function	Miedel, 2005 <sup>46</sup>
ADL scale (global)	Kim, 2005 <sup>140</sup>
ADL individual components	Mattsson, 2005 <sup>97</sup> (no data)
Weight-bearing score (single leg)	Peyser, 2007 <sup>96</sup>
Mobility scores (no specifics)	Efstathopoulos, 2007 <sup>134</sup>
Harris hip score (global)	Vidyadhara, 2007, <sup>138</sup> Kim, 2005 <sup>140</sup> Moroni, 2004, <sup>95</sup> Schipper, 2004, <sup>135</sup> Adams, 2001 <sup>106</sup> (insufficient data)
Salvati & Wilson score: pain, walking ability, muscle power-motion, overall function	Papasimos, 2005 <sup>91</sup> (insufficient data)
Parker & Palmer mobility score (global)	Utrilla, 2005, <sup>92</sup> Hardy, 2003 <sup>139</sup> (insufficient data), Saudan, 2002, <sup>100</sup> Sadowski, 2002, <sup>69</sup> Hardy, 1998 <sup>112</sup>
Parker & Palmer mobility subscales: hip pain, thigh pain, walking	Utrilla, 2005 <sup>92</sup>
Charnley: pain, movement, walking ability (subscales)	Miedel, 2005 <sup>46</sup> (insufficient data)
Merle d'Aubigne: pain, walking, mobility subscales	Fritz, 1999 <sup>137</sup> (insufficient data)
<b>Quality of Life – Femoral Neck</b>	
SF36	Baker, 2006, <sup>163</sup> El-Abed, 2005, <sup>127</sup> Raia, 2003 <sup>164</sup> (insufficient data)
EQ-5D Euro-QoL	Keating, 2006, <sup>192</sup> Blomfeldt, 2005 <sup>152</sup> (no data), Blomfeldt, 2007 <sup>166</sup> (no data), Blomfeldt, 2005 <sup>161</sup> (no data)
<b>Quality of Life - Pertrochanteric</b>	
SF36 (global)	Moroni, 2004 <sup>95</sup>
SF36 (subscales)	Mattsson, 2005 <sup>97</sup> (insufficient data)
EQ-5D (subscales)	Miedel, 2005 <sup>46</sup> (insufficient data)
Jensen social function	Hardy, 2003 <sup>139</sup> (no data), Saudan, 2002, <sup>100</sup> Sadowski, 2002 <sup>69</sup>
<b>Residence – Femoral Neck</b>	
Residence: home, sheltered home, NH, hospital	Livesley, 1993 <sup>194</sup>
Living condition: independent vs. NH	Mjorud, 2006 <sup>45</sup> (no data), Blomfeldt, 2007 <sup>166</sup>
Living in own home	Lykke, 2003, <sup>60</sup> Parker, 2002, <sup>147</sup> Parker, 2000, <sup>148</sup> Olerud, 1991 <sup>143</sup> (no data), Rehnberg, 1989 <sup>24</sup>
Living situation: alone, with family, sheltered home	Emery, 1991 <sup>162</sup>
Return to original residence	Roden, 2003 <sup>146</sup>
<b>Residence - Pertrochanteric</b>	
Living condition: own home, NH, institution	Ekstrom, 2007 <sup>132</sup> (insufficient data), Pajarinen, 2005 <sup>98</sup>
Living condition: own home, not at home/institution	Utrilla, 2005, <sup>92</sup> Ahrengart, 2002, <sup>99</sup> Saudan, 2002, <sup>100</sup> Sadowski, 2002, <sup>69</sup> Adams, 2001, <sup>106</sup> Fritz, 1999 <sup>137</sup> (insufficient data)
Recovery of ability to pre-op level (%)	Pajarinen, 2005 <sup>98</sup>
Accommodation (no specifics)	Hardy, 2003 <sup>139</sup> (no data)
Residence: independent, family/old people's home, NH/hospital	Janzing, 2002, <sup>104</sup> Lunsjo, 2001, <sup>108</sup> Lunsjo, 1999 <sup>109</sup>
Returned to own home	Ekstrom, 2007 <sup>132</sup> (insufficient data), Olsson, 2001 <sup>107</sup>
<b>Pain – Femoral Neck</b>	
VAS pain score	Mattsson, 2006 <sup>150</sup>
Charnley pain score	Parker, 2002, <sup>147</sup> Parker, 2000 <sup>148</sup> (insufficient data)
Little or no pain (no specifics)	Lykke, 2003 <sup>60</sup> (no data), Parker, 2002, <sup>147</sup> Parker, 2000 <sup>148</sup> (insufficient data)
Degree of walking or passive joint motion pain (no specifics)	Lagerby, 1998 <sup>145</sup>

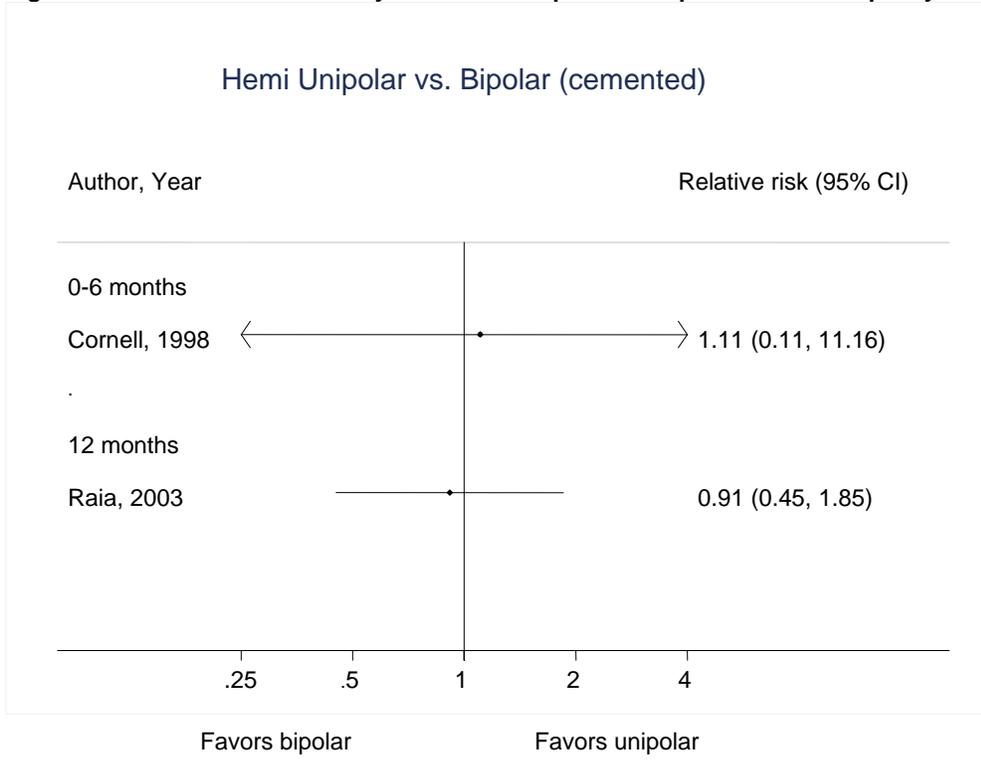
**Table 3. Patient outcomes used in literature (continued)**

<b>Outcome</b>	<b>Articles in Which Outcome was Used</b>
No pain at rest	Jonsson, 1996 <sup>141</sup>
No pain when walking	Jonsson, 1996 <sup>141</sup>
No use of analgesics	Roden, 2003, <sup>146</sup> Jonsson, 1996 <sup>141</sup>
Pain/no pain (no specifics)	Emery, 1991 <sup>162</sup>
Pain: none, on weight-bearing, constant	Olerud, 1991, <sup>143</sup> Rehnberg, 1989 <sup>24</sup>
Pain: no analgesics, occasional use, regular use	Ravikumar, 2000 <sup>129</sup> (insufficient data), Skinner, 1989 <sup>124</sup>
<b>Pain - Pertrochanteric</b>	
Hip pain (no specifics)	Vidyadhara, 2007, <sup>138</sup> Utrilla, 2005, <sup>92</sup> Baumgaertner, 1998, <sup>47</sup> Leung, 1992 <sup>122</sup>
Hip pain while walking (no specifics)	Hardy, 1998 <sup>112</sup>
Thigh pain (no specifics)	Vidyadhara, 2007, <sup>138</sup> Utrilla, 2005, <sup>92</sup> Hardy, 2003, <sup>139</sup> Leung, 1992 <sup>122</sup>
Thigh pain while walking (no specifics)	Hardy, 1998 <sup>112</sup>
Visual analog score (VAS) pain at rest	Ekstrom, 2007 <sup>132</sup> (insufficient data), Mattsson, 2005 <sup>97</sup>
VAS pain initiating walking	Ekstrom, 2007 <sup>132</sup> (insufficient data)
VAS pain while walking (10, 50 feet)	Ekstrom, 2007 <sup>132</sup> (insufficient data), Mattsson, 2005 <sup>97</sup>
VAS pain in single-leg stance	Peyser, 2007 <sup>96</sup>
Hip or thigh pain: 4 levels, no pain to severe pain at rest requiring meds (continuous)	Saudan, 2002, <sup>100 69</sup>
Resolution of hip pain	Hoffman, 1996 <sup>114</sup>
Lateral pain over femoral head screw	Ahrengart, 2002 <sup>99</sup>
Pain at top of greater trochanter	Ahrengart, 2002 <sup>99</sup>

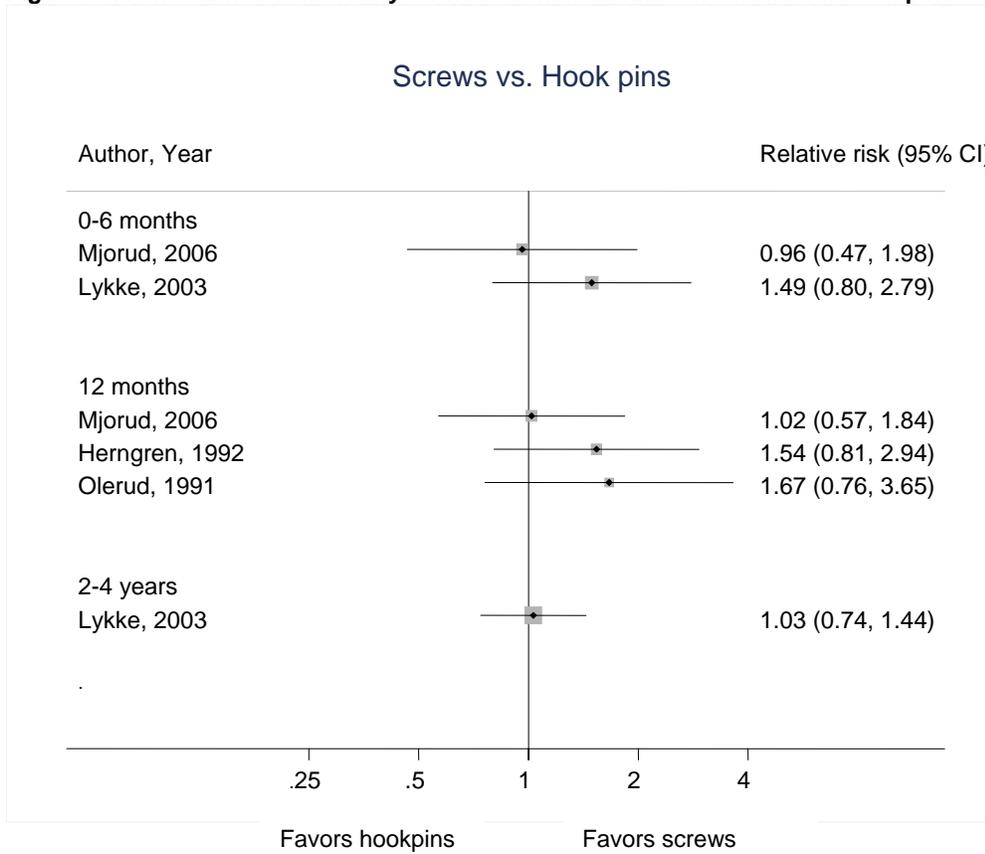
No data = article provided a summary statement regarding significance for the outcome, but did not provide supporting data

Insufficient data = article did not provide the full complement of data necessary for quantitative-analysis

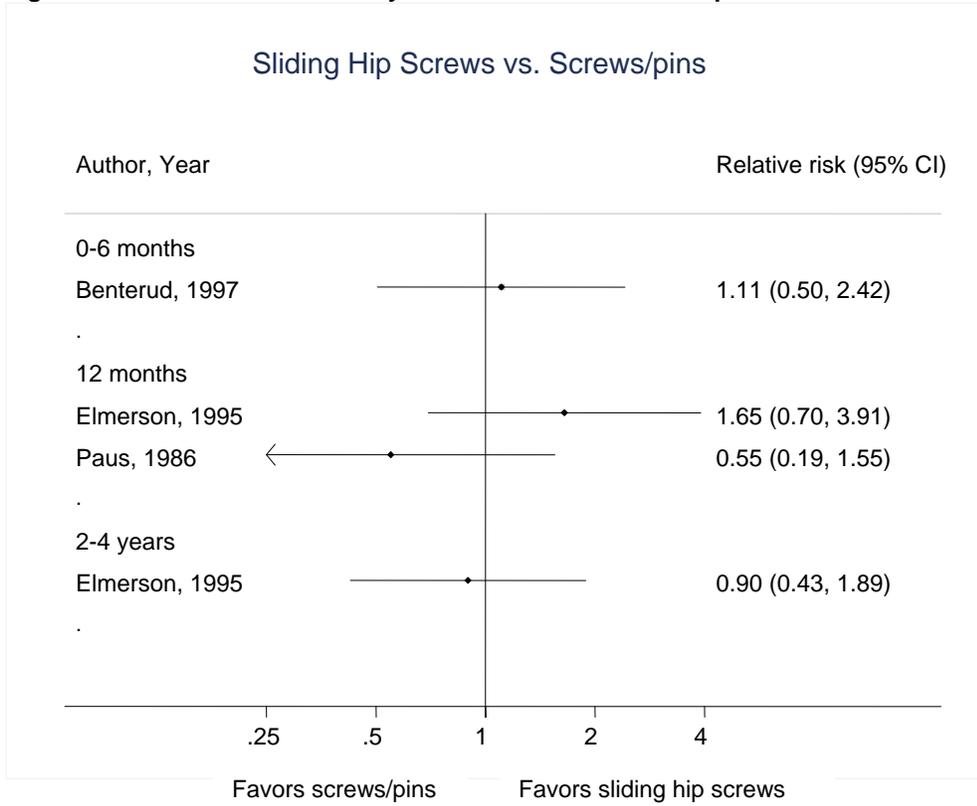
**Figure 9. Femoral neck - mortality for node 3 unipolar vs. bipolar hemiarthroplasty**



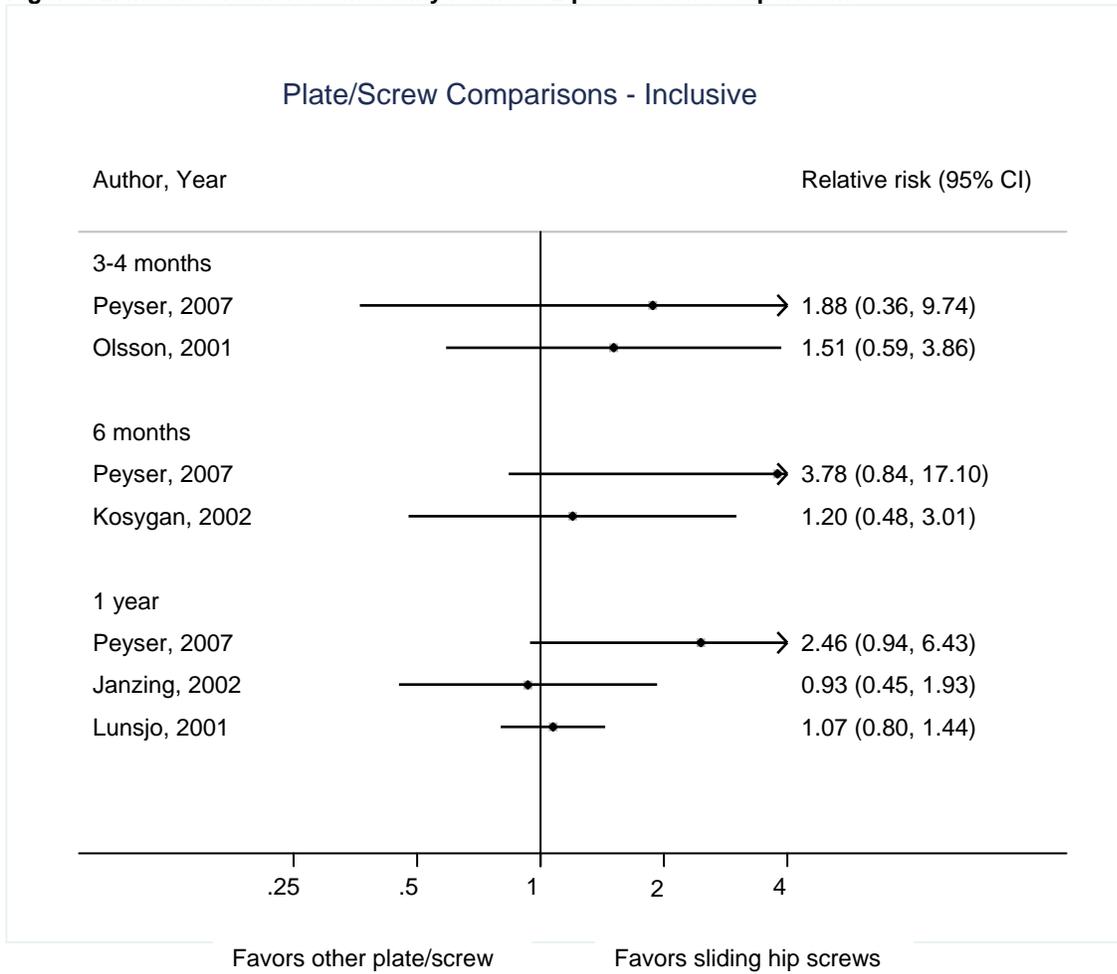
**Figure 10. Femoral neck - mortality for node 3 internal fixation screws vs. hook pins**



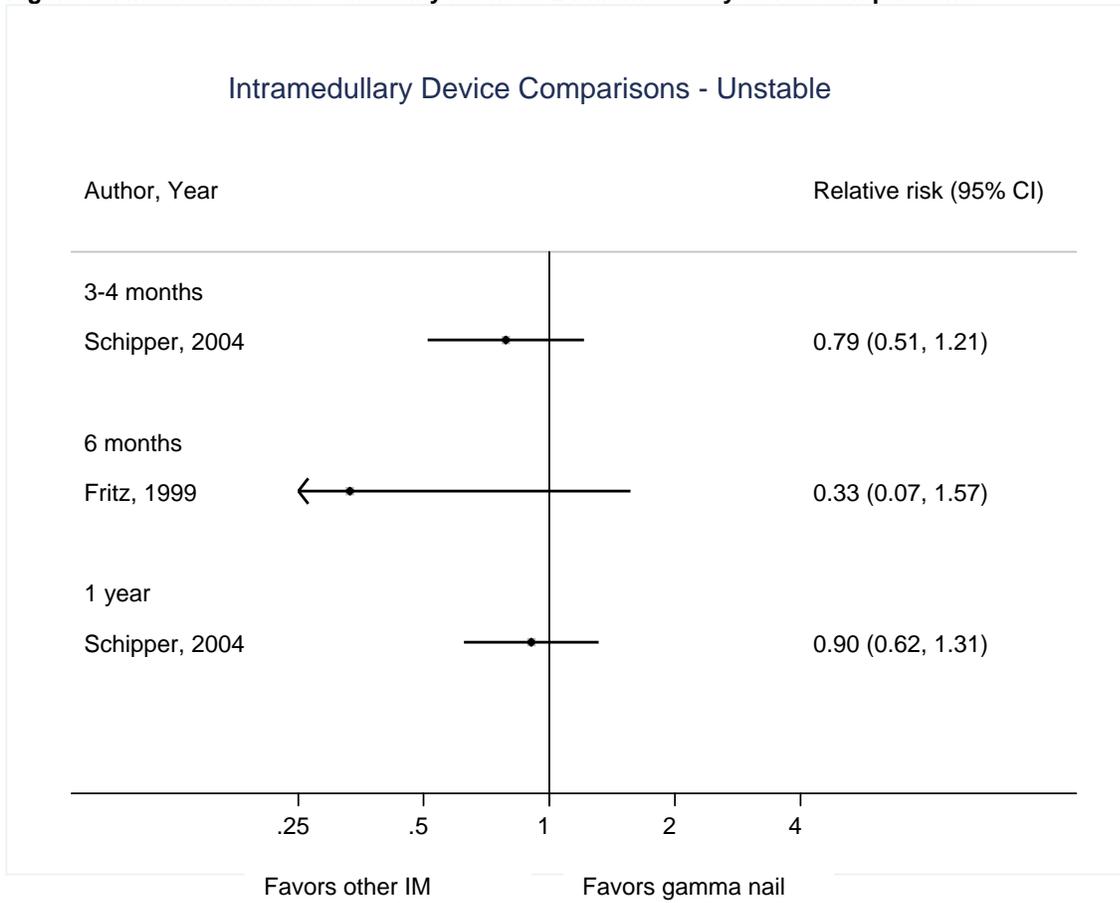
**Figure 11. Femoral neck - mortality for node 2 internal fixation plate and screw vs. screw/pins**



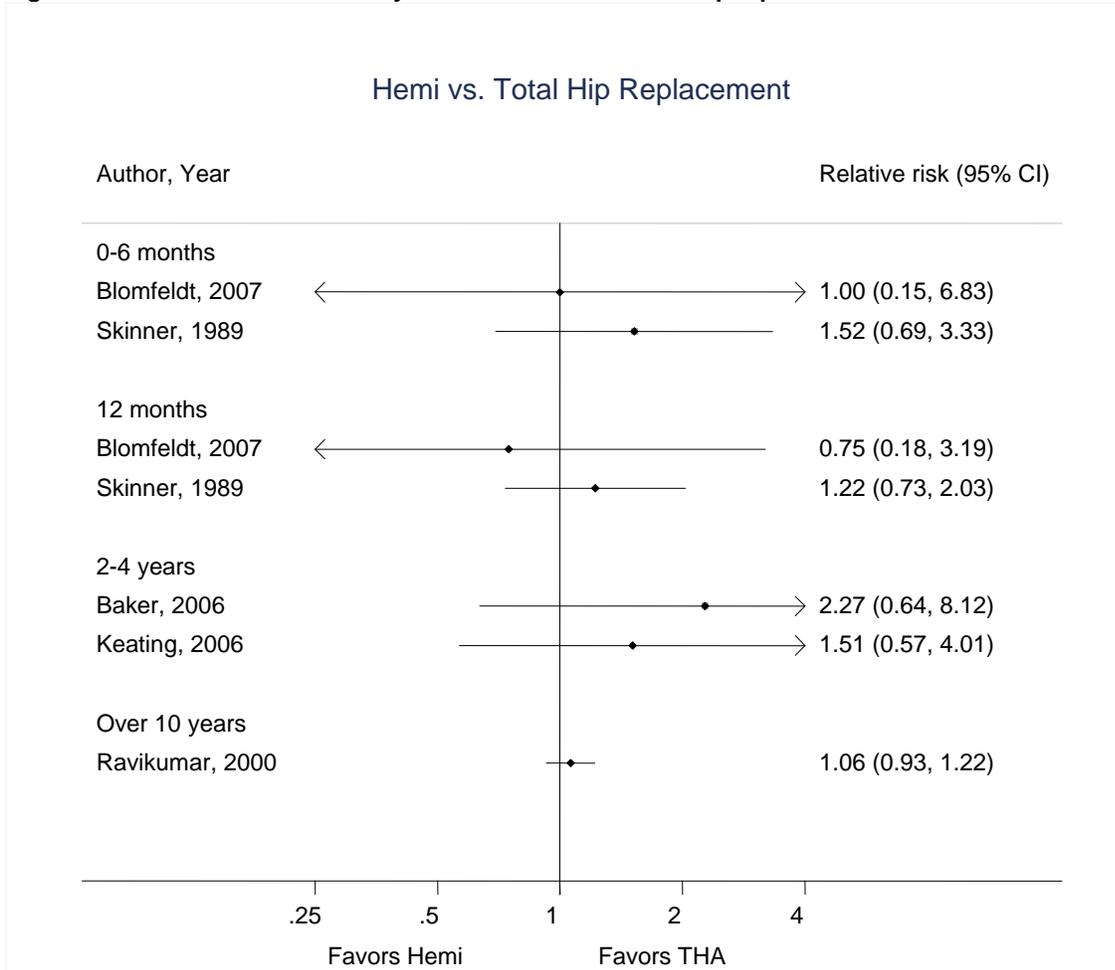
**Figure 12. Intertrochanteric – mortality for node 2 plate/screw comparisons**



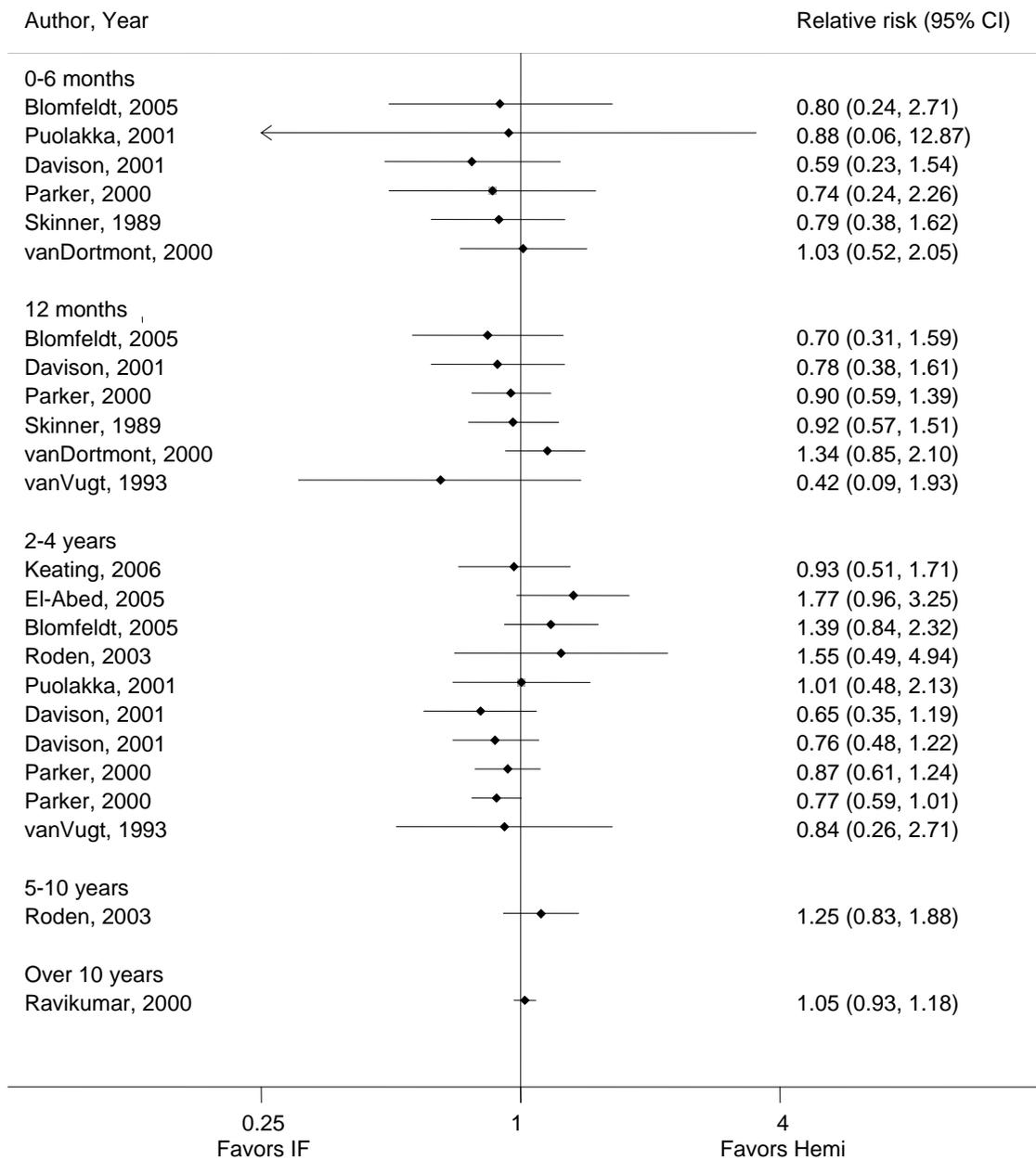
**Figure 13. Intertrochanteric – mortality for node 2 intramedullary device comparisons**



**Figure 14. Femoral neck – mortality for node 2 hemi vs. total hip replacement**



**Figure 15. Femoral neck – mortality for node 1 internal fixation vs. hemiarthroplasty**



**Figure 16. Femoral neck – mortality for node 1 internal fixation vs. total hip replacement**

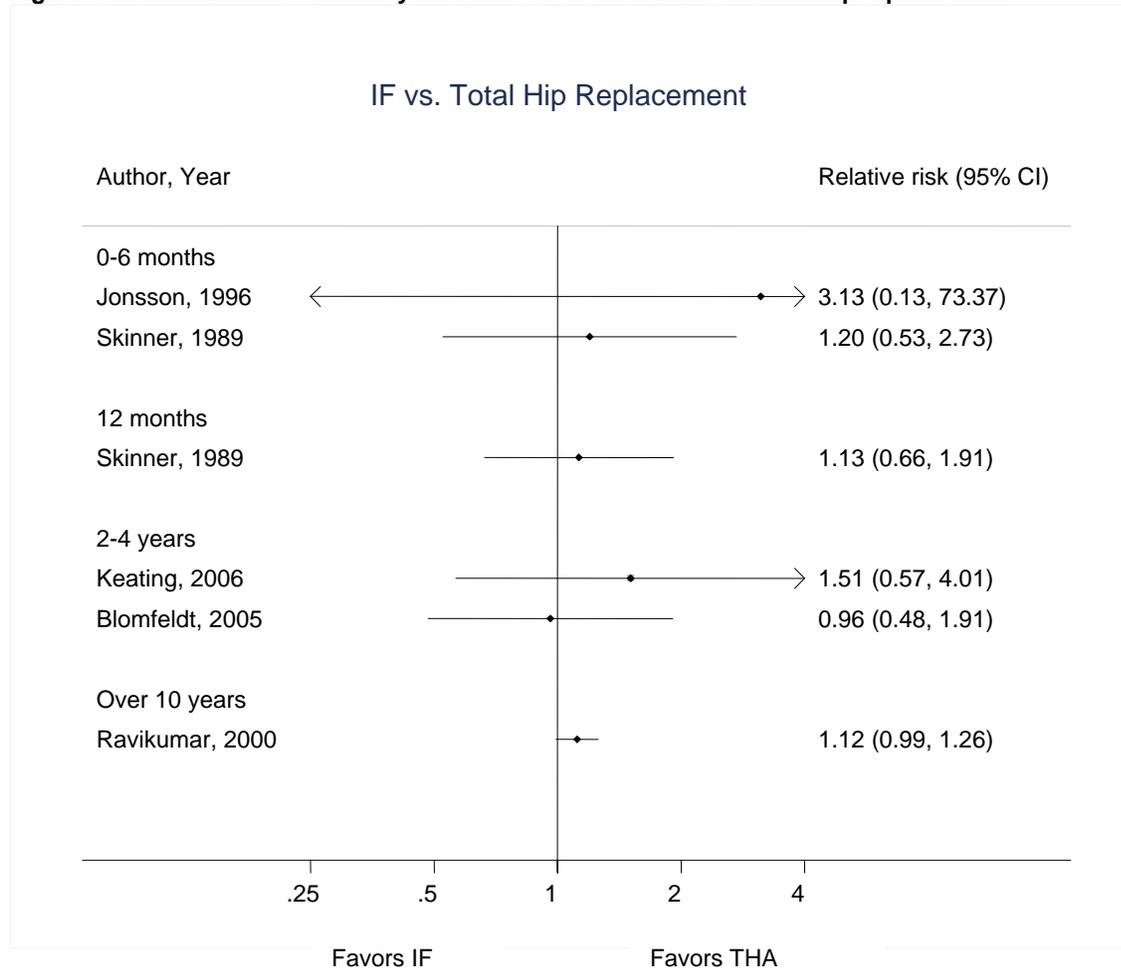


Figure 17. Femoral neck – mortality for node 1 internal fixation vs. arthroplasty

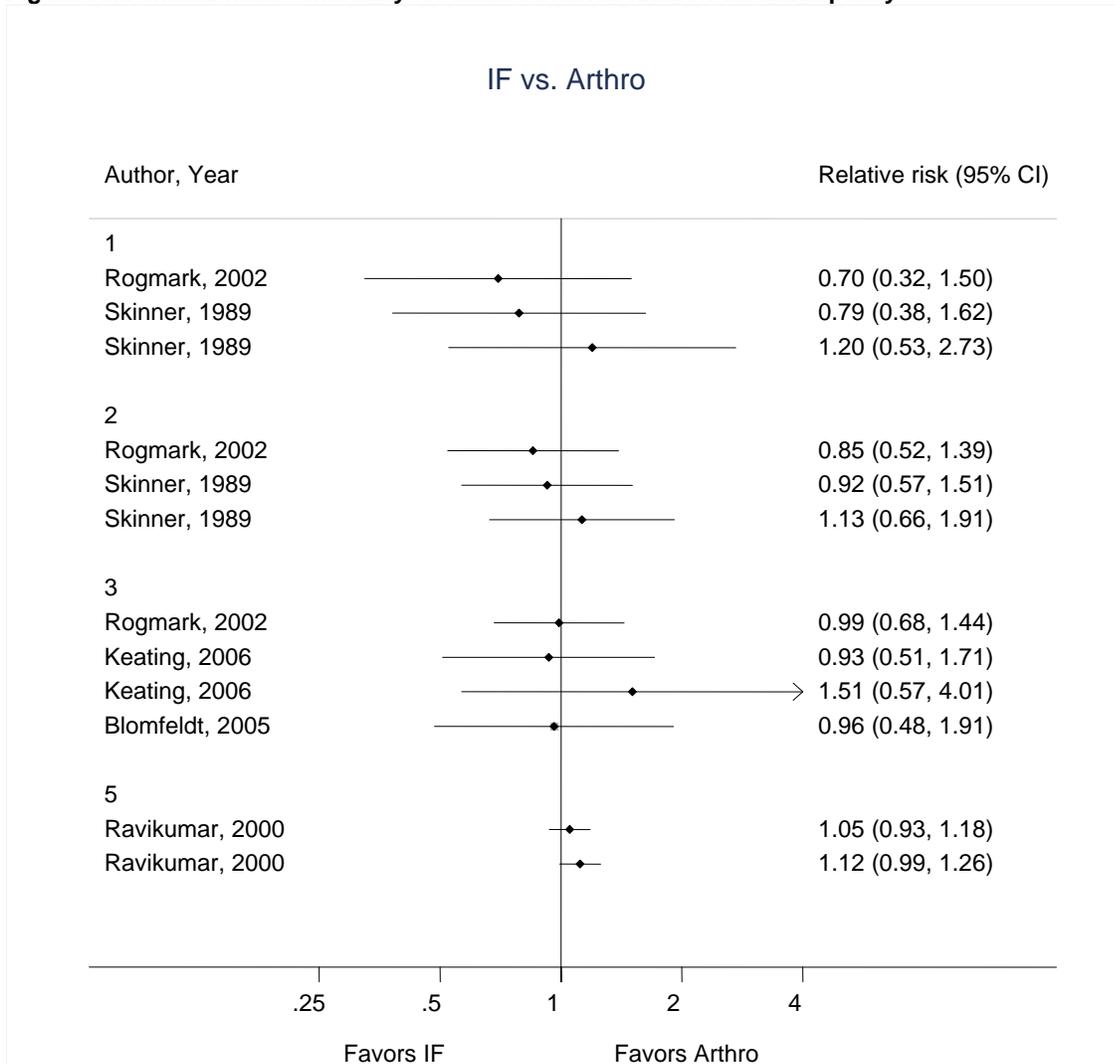
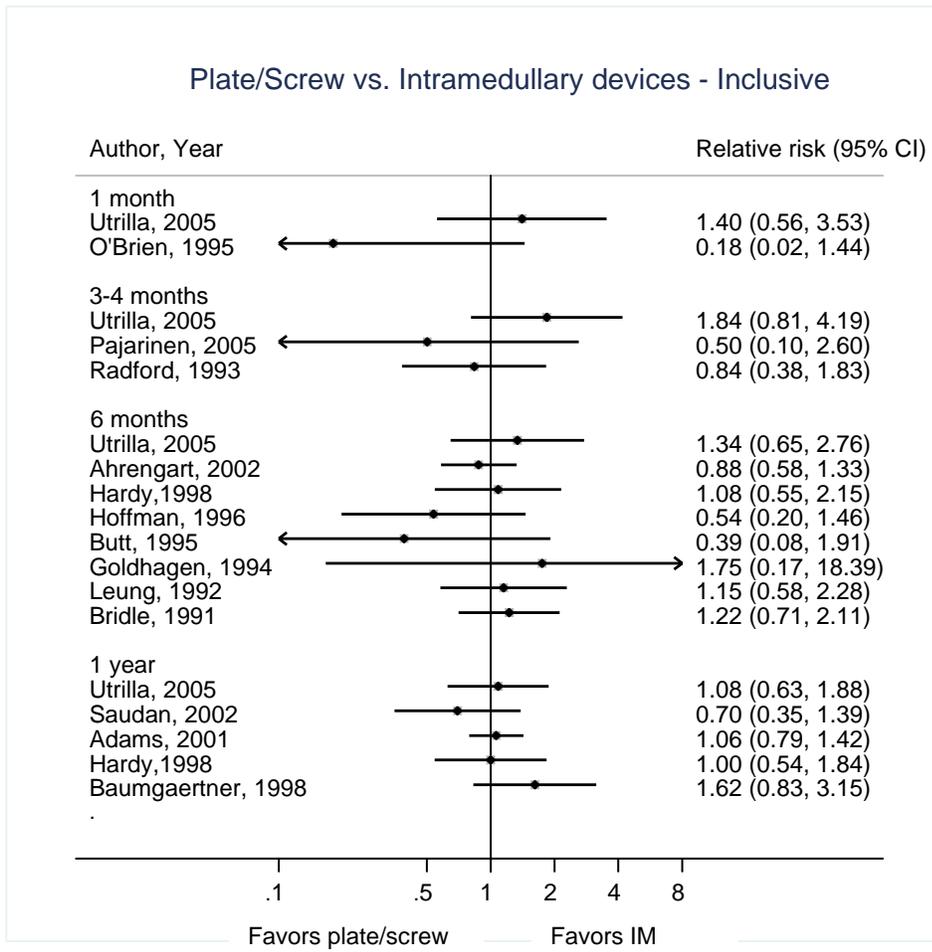
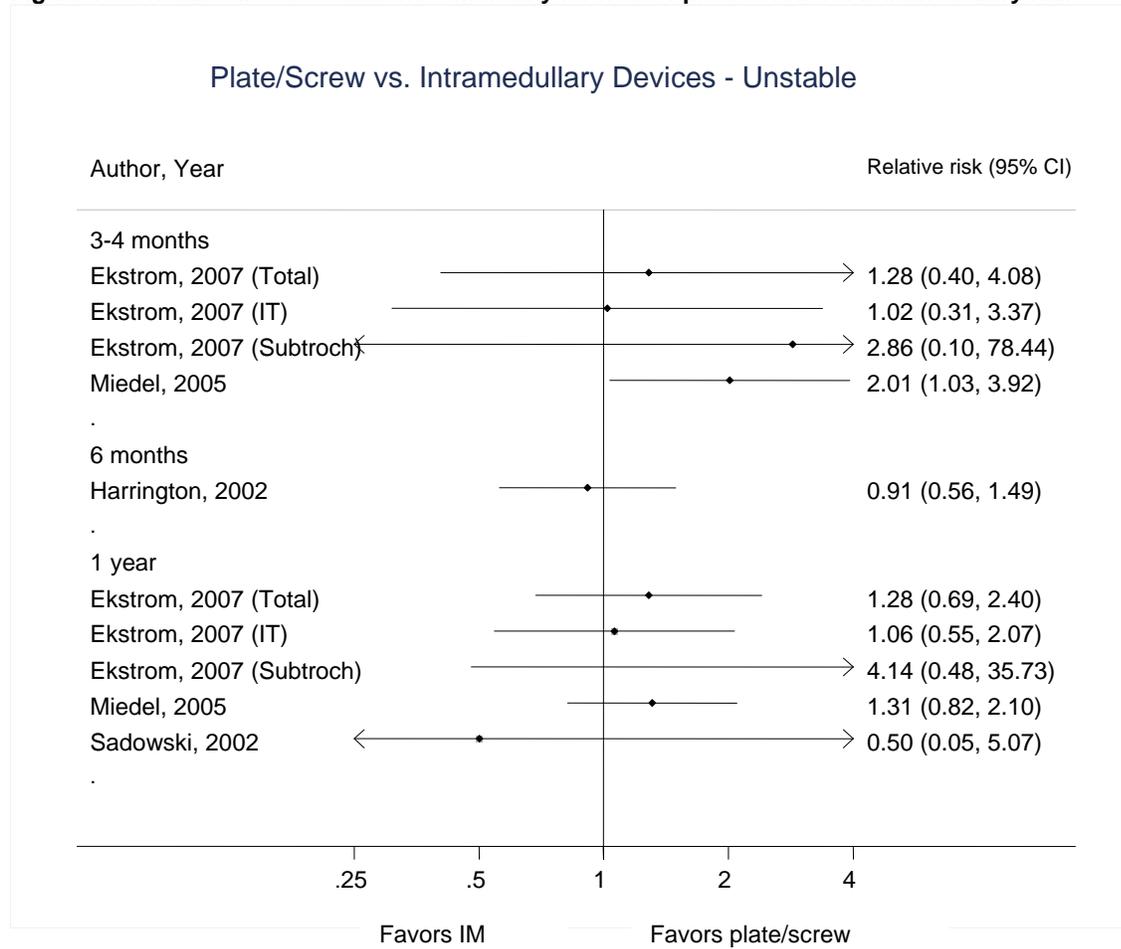


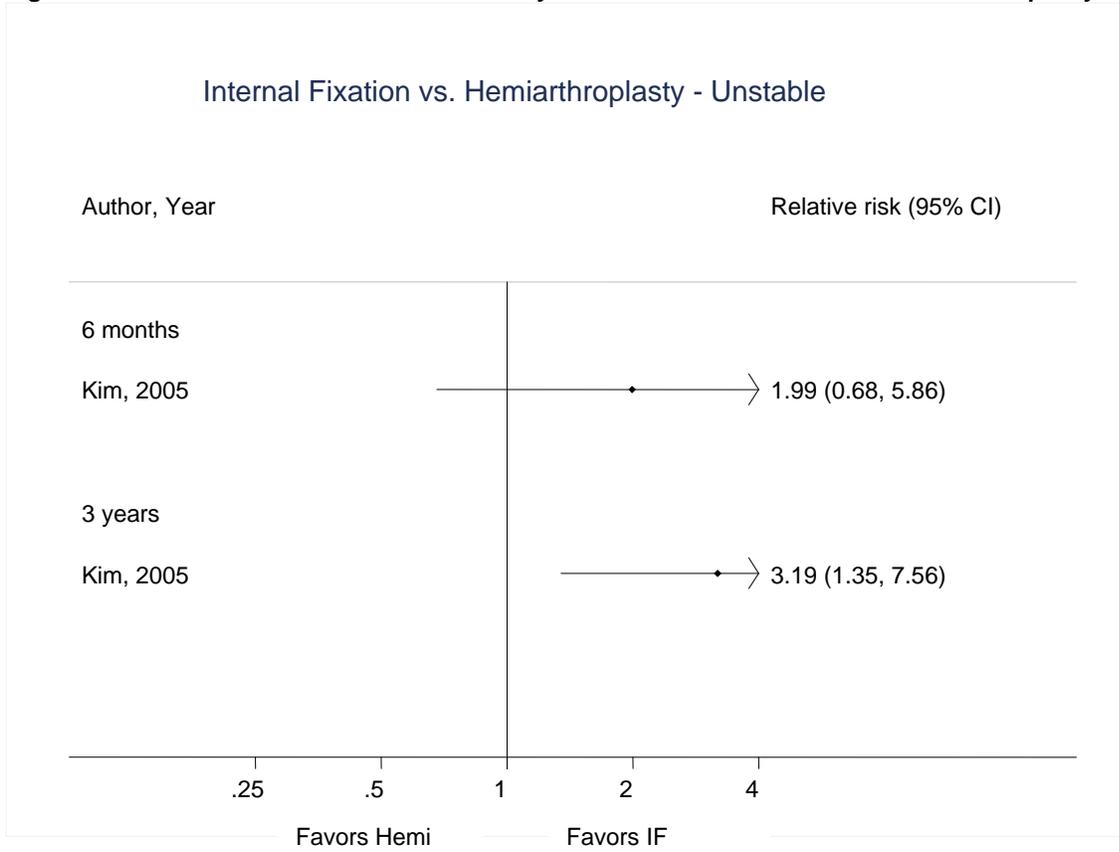
Figure 18. Intertrochanteric – mortality for node 1 plate/screw vs. intramedullary nail



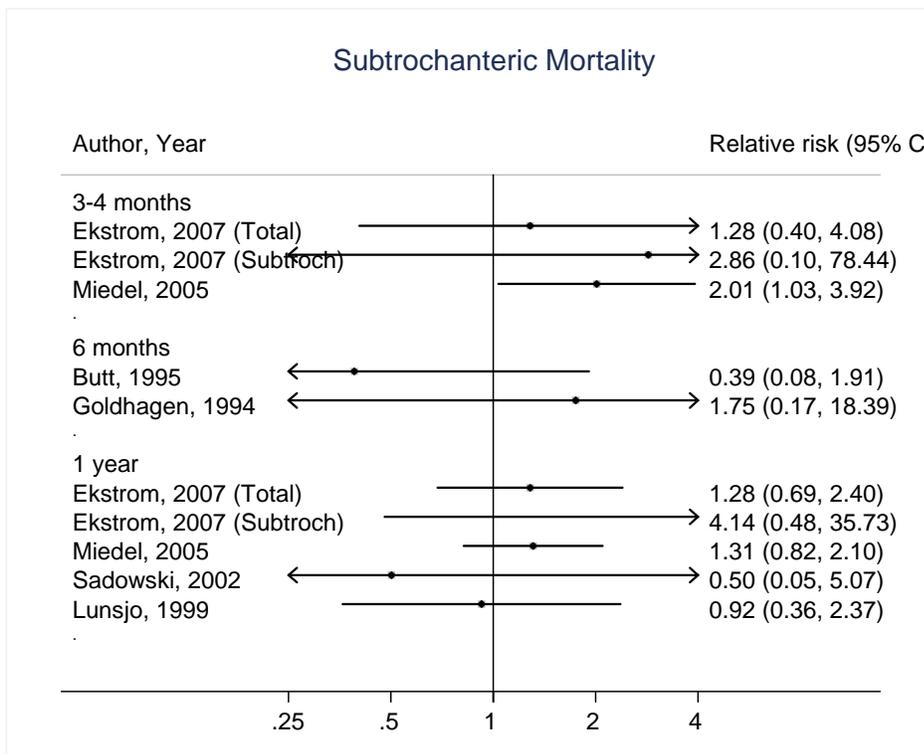
**Figure 19. Unstable intertrochanteric – mortality for node 1 plate/screw vs. intramedullary nail**



**Figure 20. Unstable intertrochanteric – mortality for node 1 internal fixation vs. hemiarthroplasty**



**Figure 21. Subtrochanteric – mortality for plate/screw comparisons**





## Chapter 4. Discussion

### General Discussion

Overall, surgical treatment of hip fractures improves patients' lives. In general, pain is reduced and functionality is restored after surgical treatment. About 75 percent of community dwelling elderly patients regain their prefracture independence by 1 year.<sup>33</sup> However, outcomes differ with the underlying status of the patient. Older age, lower prefracture functioning, and cognitive impairment are consistently associated with higher mortality and worse functional outcomes for hip fracture patients. Fracture type does not appear to be independently related to long-term patient outcomes, although limited evidence suggests that intertrochanteric hip fracture patients may experience initial and short lived delays in recovery relative to femoral neck fracture patients. It is unclear whether these results would continue to hold if the analyses included the full complement of relevant covariates. Patient characteristics should matter to surgeons when choosing surgical treatments.

Table 9 summarizes the surgical treatment guidance based on patient focused outcomes that can be drawn from the evidence at this time. Overall, mortality does not appear to differ by class of device or by devices within a class. Nor, on the whole, do pain, functioning, and quality of life. Very limited results suggest that femoral neck fracture patients with THA have improved patient outcomes over internal fixation.

A strong case cannot be made for specific surgical treatments at this time for several reasons. Patient outcomes associated with different techniques produce only modest differences, if any. In addition, the literature does not include full complements of potential covariates which are necessary to draw clinically relevant conclusions. Moreover, the overall strength of the evidence, which we discuss in greater detail later in this chapter, is generally low. Finally, the literature comparing devices within a class is scant compared with device class comparisons themselves, which provide a weak foundation for suggesting any device class guidelines for the treatment of particular hip fracture patient populations.

Since surgical choices are not clearly differentiated by patient focused outcomes in the available literature, guidelines for surgical repair of hip fractures will need to rely on intermediate outcomes and expert opinion for the present time. The failure of the literature to provide guidance should not be viewed as an insurmountable problem, but rather, opportunities for research improvements. Later in this section we discuss recommendations for future research that, if followed, would provide firmer ground for future guideline updates.

The temporal nature of the recovery from hip fracture also bears more attention. The gain for patients seems to lie in the immediate post-treatment time spent in a better functional state. Among the two-thirds of patients who, on average, survive the first year after hip fracture, functional gains seemed to hit a maximum at 1 year.<sup>34</sup> Clinical trajectories converge by this point, or even earlier. Patients who were followed longer than 1 year generally showed functional declines. The policy implications thus involve putting a value on what can be thought of as the area under the curve. What is the value of an improved short-term recovery if the benefits for one device relative to another are short lived? This question takes on greater importance as the population ages and the fracture risks increase. At the same time, there are

growing numbers of young elderly patients still working, for whom a shorter recovery period may have a direct impact on their income potential.<sup>35</sup>

There is continuing focus in the surgical community on how best to treat displaced femoral neck fractures and unstable intertrochanteric fractures. Less investigation is directed toward nondisplaced femoral neck fractures, stable intertrochanteric fractures, particularly beyond early new implant investigations. Very little research has been aimed specifically at subtrochanteric fractures. The current femoral neck inquiries are somewhat more refined than those noted among intertrochanteric hip fracture patients in that the greatest controversy appears to be how to best treat displaced femoral neck fractures in the moderately old elderly patient.<sup>64</sup> Surgeons appear to have a preference by device category for femoral neck fracture treatment, preferring internal fixation for physiologically young elderly patients, and arthroplasty for moderately healthy older patients (80 years or older), with no device consensus in between. Within those broad categories, there is no agreement on the use of specific devices. Surgeons need comparative outcomes information to inform their decisionmaking process about the implants they select, and their relationship to quality of life and mortality.<sup>64</sup>

## Applicability

Hip fracture has been deemed a marker of frailty. Given the high mortality rate in some patients, short-term gains in function within 3 to 6 months may be most pertinent in this elderly population. After 1 year, other comorbid factors may be primarily responsible for the functional declines noted. Although there is considerable interest in the lifespan of arthroplasty implants for elective joint replacement procedures, the questions of functional outcomes among elderly hip fracture patients treated with either arthroplasty or internal fixation may be best focused on shorter-range outcomes improvements.

Most orthopaedic study patients were community dwelling, cognitively-intact, independent ambulators prior to their hip fracture, making us unable to comment on how study factors relate to outcomes in nursing home patients. Other studies indicate that 20 to 30 percent of elderly patients who undergo surgery to treat a hip fracture in the United States fracture their hip while residing in a nursing home.<sup>9,65,199,200</sup> Yet, few studies included nursing home patients, and all were non-U.S. study sites. Less than one-fourth of the studies included nursing home patients, who constitute at least 20 percent of all hip fractures patients,<sup>55</sup> but did not distinguish them from non-nursing home patients in the analyses.

Patients with cognitive impairments, including dementia, were most often excluded from studies. Only three studies of femoral neck fracture patients included individuals with dementia. One was primarily a cost comparison of internal fixation versus THA.<sup>151</sup> The authors suggested that reoperation rates were lower in patients with dementia due to lower functional demands, but mortality was higher among those with dementia, which is consistent with other nonorthopaedic studies. The other two studies had small patient samples (N=60 each) of cognitively impaired patients with displaced femoral neck fractures. The authors recommended, based on perioperative findings and failure rates, that internal fixation is the treatment of choice for patients with dementia, unless adequate reduction cannot be achieved. We cannot comment about which treatments are best for intertrochanteric hip fracture patients with at least moderate cognitive impairments from the existing literature.

A large proportion of patients were treated by surgeons in training at teaching hospitals. Since we cannot distinguish which cases were performed by residents in the existing literature,

we cannot comment on any differences in mortality, function, or even intermediate outcomes such as reoperation or infection rates that may exist between patients of resident versus nonresident surgeons, given the current orthopaedic RCTs. Also, since studies tend to be conducted in high volume teaching centers, functional outcomes and mortality may differ among patients treated at nonacademic and lower volume centers that we are unable to account for within the current literature.

## Strength of the Evidence

Based on our review of the literature, the broader hip fracture outcomes questions of interest cannot be answered with existing RCT literature. Two main factors limit our ability to definitively answer the key questions posed in this study. The first factor is the limited perspective of discipline-specific investigations which commonly use an incomplete set of independent variables in study designs and models. The second factor is the generally low quality of hip fracture outcomes studies, where wide variability in the outcomes reported impedes aggregating, or even comparing, results.

The proliferation of outcome measures is not unique to hip fracture research. It can be found in other efforts that use musculoskeletal or neuromuscular function as an end point. For example, a recent Agency for Healthcare Research and Quality (AHRQ) technology assessment report on stroke rehabilitation also found a plethora of functional measures.<sup>201</sup> Functional measures differ on several levels. They may be created by a discipline to assess condition-specific aspects. They may be generic. In either case, they may be used as a composite score (in which the internal value of components has been calculated statistically (psychometrically) or empirically, with or without a formal basis for item weighting) or subscales may be used. In some cases individual items are used to assess issues of specific interest, such as pain or walking ability. The scores may be derived from patient reports or professional assessments; the source can influence the result.<sup>202</sup> Ultimately, the efforts to create consensus in the various research communities around generally accepted measures that adequately capture critical and relevant functional concepts will be broadly useful.

## Perspective

The key questions of this study involve broad analyses that should encompass several model components simultaneously, to determine how model factors affect outcomes among medically complex geriatric hip fracture patients. Current hip fracture outcomes conclusions are drawn largely from information derived from only a few model components at a time. Therefore, the resulting outcomes information lacks context and applicability within the greater realm of salient hip fracture outcomes. Moreover, the most commonly studied outcome is mortality, while perhaps more important and relevant outcomes, such as pain and function, are less frequently and more inconsistently addressed.

RCTs conducted by the orthopaedic surgeon community often focused on short-term process factors that were of interest to surgeons and the manner in which operations are carried out. Factors such as the type of fracture, operative treatment details, and short-term implant-related complications were often descriptively reported, with much less emphasis placed upon functional outcomes that are meaningful to patients. Very few outcomes were assessed from the patient's perspective. Baseline patient data was often collected, but it was often an incomplete set of

patient characteristics and subsequently not used in the analysis. Further, the full complement of other factors relevant to patients' functional outcomes, such as inpatient protocols and rehabilitation, were not collected. Therefore, conclusions from the RCT literature regarding patient outcomes are tenuous at best.

Conversely, the observational literature, although replete with patient factors, often disregarded fracture type, fracture stability, and type of implant and assumed a homogeneous effect of these factors on functional outcomes. While these studies laid a solid foundation for further inquiry of patient factors because they relate to functional outcomes, the existing observational studies tend to overlook a large segment of U.S. hip fracture patients who are physically dependent, cognitively impaired, or both. Indeed, it is important to distinguish the clinical course of patients who fracture their hips in nursing homes, and are destined to return there, from those admitted from the community. The Mayo Clinic population-based studies were exceptions to this observation.<sup>9</sup>

## Study Quality

In general, although the orthopaedic study quality was low, it is improving, specifically within the last several years. We note both improvements in study conduct and improvements in the clarity of reporting, particularly in patient tracking and reporting post-discharge including better compliance with CONSORT recommendations.

This new initiative to improve outcomes reporting will likely result in the ability to link fracture type, pattern, and implant to outcomes only if well-designed, sufficiently powered trials with adequate followup and consistently used outcome measures are conducted. Better effort needs to be made to reassess debilitated elderly patients after acute inpatient stays in order to minimize nonmortality losses to followup. Unfortunately, the literature that was available for this review reflects a period of research prior to this effort and underlines the reasons for which the research community undertook improving research quality. The following discussion of the limitations of the literature can be used in a constructive manner to encourage the research community to continue the improvement trajectory that has already begun.

The most important factors within the RCTs that substantially limit the strength of the study conclusions are high and ambiguous patient attrition, inadequate power, inadequate or unreported randomization schemes, and poor comparability of outcome measures across studies.

**High and ambiguous patient attrition.** Attrition imposes two problems: (1) bias and (2) sample loss, which can affect power. Although mortality is known to be high among elderly hip fracture patients, it is important to distinguish death from sample loss. Mortality is an important outcome in its own right. It may be the ultimate functional outcome. Given a high mortality rate, many treatment advantages may be measured in terms of time in various functional states (i.e., months of improved function).

The reporting of losses to followup was poor and often difficult or impossible to determine. Studies commonly included inpatient mortality, but most lacked the number of patients analyzed per group at each followup time point after the acute inpatient stay. Few studies included the number of patients who followed up at intermediate assessment points, and many studies did not report the number of patients per treatment group that were assessed at the final followup. Instead, authors often reported intermediate and final outcomes as percent of cases, without clearly stating the actual number of patients examined per time point. The reasons for loss to followup were often vaguely reported, if at all, commonly mentioning "ill-health" as the reason

for nonassessment. In other cases, the flow of patients through a study was reported by CONSORT statements, a very welcome recent improvement to study reporting in this literature. However, frequently the number of patients for whom functional outcomes were reported was not equivalent to the number of patients reported in the CONSORT statement, and the reason for the discrepancy was not reported. While mortality as a source of attrition is difficult to address, some investigators did take measures to minimize loss to followup through employing telephone interviews for patient assessed functional outcomes.

Another issue was investigator selection of analysis samples. Investigators often chose to exclude patients with implant failure or fracture nonunion from any further assessments and from all subsequent analyses. Analyses by subsamples of patients may be necessary to assess technical aspects of a device. However, if these subsamples are used for functional assessments, it may lead to biased results. Any subgroup analysis must be determined in advance and cannot be based on the outcomes.

**Randomization issues.** Randomization for surgical procedures for hip fractures, especially when many of the procedures are handled as emergency surgery events, is complicated by the fact that the surgeon may not have the full set of information necessary for clinical decisions until the surgery has begun. While an unavoidable complication, even with the best intentions, it leaves the door open for systematic bias to enter the randomization process. A number of studies reported randomization of patients prior to full application of exclusion criteria. For example, in some cases patients whose fractures were unable to be satisfactorily reduced were excluded after having been randomized to a study arm. Further, reporting of the randomization process itself was often cursory. About half of the studies reported the randomization scheme to be closed or in sealed envelopes. Only approximately one-quarter of included studies had information about sequence determination and implementation, which included randomization processes not recommended, such as basing randomization on medical record numbers or days of the week.

**Other patient population issues.** A large proportion of studies contained liberal inclusion criteria and minimal exclusion criteria, if any. Investigators with the stated or implied study focus of geriatric hip fracture patients often enrolled at least 10-20 percent of high energy trauma patients, those younger than age 50. Except in only a few studies, these patients were often not isolated in the analysis or by treatment group, likely due to problems with low power. A significant number of studies, particularly those prior to 1996, made no attempt to exclude patients with pathologic, cancer-related fractures, nor distinguish them in the analysis.

One important factor for determining inclusion criteria is identification of the fracture type and pattern. Surgeons used multiple fracture classification systems to identify fracture patterns, and the mapping of these patterns across classifications is not consistent. Additionally, surgeons show little reliability in their own ability to use these classification systems, which varies with surgeon experience and classification scheme.<sup>203</sup> Since hip fracture patterns are varied and complex, nearly all studies aggregated multiple fracture subtypes based on the general stability of the collective fracture patterns to enable them to state conclusions about categories rather than subtypes of fractures. Often, this aggregation was needed, since certain fracture patterns are uncommon and few cases were available of some fracture subtypes despite long enrollment periods. For femoral neck fractures, the aggregation of subtypes into displaced or nondisplaced was highly consistent across studies, where Garden III-IV patterns were consistently labeled as displaced fractures.

In contrast, the aggregation of fracture patterns into stable or unstable categories within the intertrochanteric fracture studies was highly inconsistent and undermines many of the

conclusions drawn that were based on fracture stability. Within the AO/OTA fracture classification system, (Figure 9 in Chapter 1) there are nine patterns of pertrochanteric fractures, and the frequency of each of fracture subtype is not evenly distributed. In the Fung et al. study, there was no consensus among surgeons about how to dichotomize the classifications into stable and unstable patterns.<sup>203</sup> Thus, it is difficult to conclude if there was consistency in the stable versus unstable grouping of fractures within the existing RCTs, particularly among fractures in the mid-range of the intertrochanteric fracture classifications, the OA/OTA 31-A2 subtypes. Surgeons' decisions to label fractures as unstable in RCTs when other surgeons would label them as stable fractures (i.e., AO/OTA 31-A2.1) artificially increases sample sizes when studying unstable fractures. Such sample size augmentation served to buffer the complication rates among fractures labeled as unstable, since the unstable treatment groups subsequently consisted of what other surgeons consider to be both stable and unstable fractures. In one study of unstable intertrochanteric fractures that included only AO/OTA 31-A2 fractures (three subtypes), two-thirds of patients had AO/OTA 31-A2.1 fractures, which are commonly considered to be stable fractures.<sup>117</sup> This aggregation pattern was common among studies of unstable intertrochanteric hip fractures, and subtype grouping within any of the classification systems appeared to be investigator dependent.

Inconsistent baseline data were collected across trials, and even less were reported. The patient factors that were described in the methods section of each study often far exceeded what was included in the patient baseline information table. Patient age and gender were consistently reported. However, other factors known or believed to impact functional outcomes and mortality, such as level of pre-fracture function, race or ethnicity, fracture pattern, pre-fracture residence, cognitive impairment, injury mechanism, and comorbidities, were often not reported. Of particular note is the lack of race or ethnicity in patient baseline information.

**Sample size and power.** Few orthopaedic outcomes studies reported a sample size calculation or discussed power in relation to their primary study outcome. The average number of patients per study arm was approximately 75 patients prior to attrition, and the final number of cases analyzed was often not accompanied by a sample size calculation. The majority of studies lacked a sufficient number of cases to detect a clinically important difference between two treatment groups for a given outcome, even if one existed. In general, it appeared from discussion comments that many authors underestimated the magnitude of the attrition from high mortality and other losses to followup among frail, geriatric hip fracture patients. Also, the numbers of patients enrolled in RCTs are frequently too small to control for other factors (surgeon and hospital factors, rehabilitation site) on outcomes (function, mortality, pain, residence).

**Inconsistency in functional outcomes.** Table 3 in Chapter 3 clearly illustrates the idiosyncratic nature of outcome reporting that has historically predominated in the literature. Most of the outcomes reported in trials published prior to 2000 used only surgeon-reported outcomes. Many RCTs in this analysis did not report any functional patient outcomes. Of those with functional outcomes, many did not report group scores in a useable manner. Outcomes tables frequently lacked the number of patients in the analysis sample by group, or any identifiable measure of variation (range, standard error of the mean, standard deviation), impairing comparisons.

**Other quality issues.** We note a recent, positive shift in the style of outcomes reported in trials from exclusively surgeon-reported outcomes to both patient- and surgeon-reported outcomes. The benefits of using validated quality of life and outcomes assessment tools such as

the SF-36, EQ-5D, WOMAC, and others is not yet fully reflected in the existing literature. Although we find this an encouraging sign, this trend is not yet consistent and appears to be investigator dependent.

Despite considerable efforts in the RCT literature to describe the technical aspects of performing hip fracture procedures, factors known to be both critical to the success of a procedure and surgeon dependent were often not reported. The degree to which fractures were realigned or reduced in relation to anatomic alignment, the extent to which the reduction held while an implant was placed, and the proximity of the final implant position to optimal were reported in a minority of studies. While the studies that included such details were explicit in doing so, few attempted to associate the quality of the reduction and implant position to implant failure or reoperation. None attempted to associate fracture or implant position to functional outcomes.

Surgeries performed by orthopaedic residents were common. A number of studies reported that residents performed all or most of the operative cases in the study.<sup>45,47,102,114,124,160,162,163</sup> Another fifth of the studies used large numbers of surgeons, where experience level undoubtedly varies widely, or explicitly stated the staff included both junior and senior surgeons. When both experienced surgeons and residents performed cases, we most often could not tell which surgeries were performed by residents. Few studies separated outcomes by surgeon seniority.

General levels of surgical experience are commonly not reported, or are only reported descriptively and collectively, and not by treatment group. Surgeons' experience with each device in a given study was rarely reported. This was particularly common in the intertrochanteric hip fracture studies, where intramedullary nails had previously been used for long bone fractures but were newly used for fractures of the hip. Many surgeons had no experience with intramedullary nails or only two to five cases prior to study participation, yet were reported to be accustomed to the plate/screws devices used in the other treatment arm. Specific familiarity with each device per surgeon was rarely reported.

Many RCTs tested newly introduced devices. However, once the initial new implant questions of complication rates, implant failures, and other post-operative complications, such as infection, were moderately addressed in comparison to an existing device, studies often failed to inquire further with additional studies to evaluate outcomes that are meaningful to patients. Equivalent complication rates do not necessarily equate to equivalent functional outcomes. Also, followup data can be misleading if critical groups are eliminated. Followup among patients who experienced implant failure was often incomplete or fully excluded from analyses. Not all patients with nonunion, implant failure, and device related pain underwent another surgery. Therefore, reoperation rates, particularly in this elderly patient population, likely underreport actual complication rates, since many older patients are too frail to undergo an additional procedure after their hip fracture surgery. Reoperation rates have also been shown to be subject to local variation, even within study protocols.<sup>185</sup> It is important to report on the outcomes of patients who had postoperative orthopaedic complications but did not have additional surgery to correct the problem, since the RCT literature lacks information as to which complications most adversely affect postoperative function, particularly ambulation.

The effects of post-hospital therapy, including rehabilitation, were often excluded entirely from hip fracture RCT analyses. Most studies that briefly listed in-hospital mobilization protocols indicated that protocols were the same for both treatment groups but provided no further information regarding patients' post-acute care. Most studies did not report the type, intensity, and duration of post-acute rehabilitation. Inpatient stays have shortened considerably in the United States in recent years, accompanied by an increased use of post-acute rehabilitation,

which is not reflected in the RCT literature we reviewed. Also, nearly all RCTs were conducted in Europe, which reduces comparability to U.S. populations.

Current analysis practices allow too much room for both Type I and Type II errors in relating clinical characteristics and interventions to outcomes. Significance levels were often not corrected for multiple outcome comparison, which opens the door for finding significant differences in devices that could be purely due to chance. The study by Utrilla et al. is an example.<sup>92</sup> Only one outcome was found to be significant at an unadjusted level. Had the outcome been adjusted to account for the possibility of significant difference in one out of seven outcomes purely by chance, there would have been no differences found between the devices. On the other hand, the small patient numbers previously mentioned, compounded with loss due to mortality and attrition, increase the likelihood of a Type II error, not finding a difference when there was one. While reporting of power calculations has been disappointingly low, the frequency of power calculation reports has increased in recent years.

Among studies that used existing assessment tools for THA patients, such as the Harris Hip Score, many patients scored below the lowest possible category (<70=poor) at all followup time points. Differences across treatment groups were often nonsignificant, which may be due to a lack of instrument sensitivity to minimal differences in highly disabled patients. Differences in mean values across treatment groups that were reported as statistically significant most often would not be expected to show relevant clinical differences.

Outcomes assessors were generally not blinded to the treatment, which increases the opportunity for biased assessment and reporting. Several recent studies identified that the functional assessors were not directly involved with the study, but only one study indicated that the patients remained clothed during functional assessment so the examiner could not determine from the incision which surgery a patient had undergone.

Finally, it was difficult or impossible to determine the degree of industry funding for many studies, particularly those prior to 2000. After that time, formal funding disclosure statements started to appear in articles from several major journals. Many studies appeared to be entirely unfunded works performed within one hospital or one academic center. Still, despite some disclosures of study funding, most did not contain specific details about the presence or absence of individual author's consulting or design arrangements with device or bone cement companies.

## **Recommendations for Future Research**

Given the preceding discussion of the limitations of the current research literature, there are a number of recommendations which can be made to improve future research so that it might contribute to improved surgical guidelines in the treatment of hip fracture patients. Table 10 at the end of the chapter provides a summary of the research recommendations.

- Encourage collaboration between the research communities rooted in different research disciplines and methodologies. Bringing together the surgeon's perspective with regard to the importance of fracture types and patterns and device/surgery specifics and the epidemiologist's understanding of the importance of patient factors would move forward our comprehensive understanding of hip fracture patients and help match best treatments to the patient populations most likely to benefit from those treatments. A recent issue of *The Journal of Bone and Joint Surgery* published a series of articles addressing research

design and potential contributions that well designed observational studies can provide to orthopaedic research.<sup>36-43</sup>

- Continue focusing on rigorous study design, sufficiently powered RCTs that follow CONSORT recommendations, and focus on patient relevant functional outcomes. Multicenter, well-designed RCTs are necessary to evaluate results among patients with uncommon fracture patterns. Firm inclusion and exclusion criteria should be specified before embarking on RCTs and be strictly followed throughout enrollment to minimize post-randomizations exclusions.
- Establish consensus on consistent definitions of stable and unstable intertrochanteric fractures within the most commonly used classification system(s). The use of obsolete classification systems should be avoided. At a minimum, the frequency of each fracture subtype among all patients should be included in all manuscripts and analyzed in relation to outcomes. This would not preclude authors from recommending refinement or switching to other classifications systems. But if recommendations are made in addition to, and perhaps compared with, a standard, the ability to leverage the information across research programs would be greatly enhanced.
- Develop more inclusive conceptual models. Surgical repair of hip fractures is a necessary critical step in restoring function to patients, but viewed in isolation it is insufficient. In order to isolate the effects of surgical treatments, research will need to incorporate measurements of all the major contributors to patient outcomes in order to control for them. Only a small portion of the published research for hip fracture surgical treatments collected such data, and even less incorporated the data into the analysis. Other patient characteristics important to understanding final outcomes may still need to be delineated. For example, fear of falling at 6 weeks post-surgery was a significant predictor of patient outcomes for hip fracture patients, in addition to cognitive impairment and depression.<sup>44</sup> Patient outcomes may also be affected by the inference the patient draws from under-controlled pain and the contextual experience.
- Enhance the reporting of surgeon related variables. Define and quantify the quality of surgical techniques. As a few studies have begun to do, surgeons can quantify the quality of the fracture reduction postoperatively.<sup>45-47</sup> Surgeons can also assess the technical quality of their implant placement immediately postoperatively.<sup>45,46,48,49</sup> It would also be appropriate to identify and report surgeons' levels of experience in general, and their specific experience with the devices and procedures used for an RCT and, if possible, use this information in the analysis.
- Consistently use validated quality of life and outcome assessment tools to improve comparability of outcomes across studies. A number of well-developed scales are available.<sup>50</sup> Investigators do not need to resist the urge to tweak outcome measures if they discipline themselves to ensure that the measures idiosyncratic to their own study are accompanied by validated measures that ensure their studies will be available for pooling.
- Consider funding data pools wherever possible. This is particularly important for assessing infrequent events such as low frequency fracture patterns, specific complications, or patients who represent a small proportion of the overall patient base. The observational literature has taken the lead to date on pooling data across studies. For example, enough research exists to demonstrate gender differences in hip fracture risk factors and outcomes.<sup>11,51,52</sup> Yet the research examined in this review found women to represent approximately 80 percent of the patient population across the studies. Within

single studies this often does not provide sufficient power for subgroup analysis. Men that sustain a hip fracture are often sicker and are at higher mortality risk than women, and differentially develop complications and respond to treatment.<sup>51</sup>

- Include and report on patients with cognitive impairments and dementia, with particular emphasis placed on patients admitted from nursing homes or other institutional residences. The issue of best treatments for very frail elderly patients will only continue to grow as the general population ages.
- Include all patients in the analysis sample for functional outcomes, particularly patients who experienced device failures. Whether and how early failure affects long term outcomes remains an empirical question that cannot be answered if such patients are excluded.

**Table 9. Summary of evidence**

Patient Group	Strength of Evidence	Findings and Guidance
Femoral Neck – Displaced, generally independent or semi-independent, mobile elderly patients	Low 10 studies, N=1,968 Comparisons of IF	<ul style="list-style-type: none"> <li>No differences in patient outcomes between IF devices.</li> <li><i>No recommendation for type of IF based on patient outcomes.</i></li> <li>Surgeon experience and precision of implant placement may mediate intermediate outcomes.</li> </ul>
	Low 9 studies, N=1,374 IF vs. hemi	<ul style="list-style-type: none"> <li>No long-term differences in patient outcomes between IF and hemiarthroplasty. Possibly shortened recovery period, 4 month outcomes, for hemiarthroplasty.</li> <li><i>No recommendation for device based on patient outcomes.</i></li> </ul>
	Low 5 IF studies, N=526 IF vs. THA 3 hemi studies, N=332 Hemi vs. THA	<ul style="list-style-type: none"> <li>THA had better long-term improvements in pain and mobility than either IF or hemiarthroplasty.</li> <li><i>THA suggested based on patient outcomes for healthy elderly individuals most likely to gain from long-term functional improvements.</i></li> <li><i>Hemiarthroplasty reserved for patients with inadequate reduction and unlikely to see long-term functional benefits from surgical treatment.</i></li> </ul>
Femoral Neck – Displaced, age 70+ years with cognitive impairment	Low 2 studies, N=120 IF vs. hemi	<ul style="list-style-type: none"> <li>No differences in patient outcomes between IF and hemiarthroplasty.</li> <li><i>Hemiarthroplasty reserved for patients with inadequate reduction.</i></li> </ul>
Intertrochanteric – Unstable, all classifications, generally independent or semi-independent, mobile elderly patients	Low 32 studies, N=5,979 Comparisons of IF	<ul style="list-style-type: none"> <li>No differences in patient outcomes between IF devices.</li> <li><i>No recommendation for device based on patient outcomes.</i></li> <li>Surgeon experience and precision of implant placement may mediate intermediate outcomes.</li> </ul>
Intertrochanteric – Unstable, AO/OTA 31-A2, 70+ years of age	Low 2 studies, N=148 IF vs. arthroplasty	<ul style="list-style-type: none"> <li>No differences in patient outcomes between IF and arthroplasty.</li> <li><i>Arthroplasty should be reserved for patients with degenerative arthritis, severe comminution, or highly osteoporitic bone.</i></li> </ul>
Subtrochanteric – all classifications	Moderate 3 studies, N=148 Plate/Screw vs. IM	<ul style="list-style-type: none"> <li>No difference in patient outcomes between IF devices.</li> <li><i>No recommendation for device based on patient outcomes.</i></li> </ul>
Reverse Oblique/Transverse – AO/OTA 31-A3	Moderate 1 study, N=39 Plate/Screw vs. IM	<ul style="list-style-type: none"> <li>No difference in patient outcomes between IF devices.</li> <li><i>No recommendation for device based on patient outcomes.</i></li> </ul>

IF = internal fixation; IM = intramedullary device; THA = total hip arthroplasty

**Table 10. Future research recommendations**

Key Question	Results of Literature Review	Types of Studies Needed to Answer Question	Future Research Recommendation
1. What is the relationship between patient variables, the type of fracture) and post-treatment outcomes?	Age, gender, prefracture functioning, and cognitive impairment appear to be related to mortality and functional outcomes.	Comprehensive studies that include variables that describe salient patient characteristics, fracture type, and surgical factors	<ul style="list-style-type: none"> <li>• Include nursing home or dementia patients and distinguish them in analysis.</li> <li>• Include comprehensive set of predictor variables.</li> </ul>
2. What is the relationship between the type of fracture and post-treatment outcomes?	Fracture type is not independently related to patient outcomes in observational literature, but the literature has not generally examined stable and unstable intertrochanteric fractures.		<ul style="list-style-type: none"> <li>• Collaborate with surgeon investigators.</li> <li>• Include stable/unstable intertrochanteric subtypes in analyses, as well as surgical treatments; does outcome depend more on reduction than implant?</li> </ul>
3. What is the relationship between implant variables and patient post-treatment outcomes?	Few studies show dramatic effects on patient level outcomes.	Well-designed RCTs. Likely multicenter studies will be necessary to attain adequately powered sample sizes.	<ul style="list-style-type: none"> <li>• Consistent use of validated outcome measures.</li> <li>• Quantify and report quality of surgical technique.</li> </ul>
4. What is the relationship between the type of intervention and patient post-treatment outcomes?			<ul style="list-style-type: none"> <li>• Reliable reporting of stable/unstable intertrochanteric fracture subtypes.</li> <li>• More inclusive conceptual models.</li> <li>• Data pooling.</li> <li>• Collaborate with observational investigators.</li> </ul>



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(Note that there are separate sets of references in some of the appendixes. The reference numbers there are different from those in the text of the report.)

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## List of Acronyms/Abbreviations

ADL	Activities of daily living
AHRQ	Agency for Healthcare Research and Quality
AO/OTA	Arbeitsgemeinschaft für Osteosynthesefragen (Association for the Study of Internal Fixation)/Orthopedic Trauma Association
ASA	American Society of Anesthesiologists
BMI	Body mass index
CI	Confidence interval
EPC	Evidence-based practice center
FDA	Food and Drug Administration
FN	Femoral neck
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
IADL	Independent activities of daily living
IF	Internal fixation
IM	Intramedullary device
IMHS	Intramedullary hip screws
IMN	Intramedullary nails
IT	Intertrochanteric
NH	Nursing home
NR	Not reported
QoL	Quality of life
RCT	Randomized controlled trial
RR	Relative risk
SHS	Sliding hip screws
SRS	Systematic review software
ST	Subtrochanteric
TEP	Technical expert panel
THA	Total hip arthroplasty
TSP	Trochanteric stabilizing plate
VAS	Visual analog score

## Appendix A: Previously Published Systematic Reviews and Meta-analysis

First Author, Year	Title Fracture Pattern Patient Population	# of Studies Patient N Hip N	Devices	Outcomes Addressed	Reported Results
<b>Femoral Neck: Displaced/Not Displaced</b>					
Bhandari, 2003 <sup>1</sup> Searched 1969 to 2002	Internal fixation compared with arthroplasty for displaced fractures of the femoral neck	14 RCTs N=1,933	Internal fixation (plate-screw or screw only) vs. arthroplasty, (hemi and THA)	Mortality, pain, good function (based on independent ADLs), revisions, infections, blood loss, time in surgery	Arthroplasty for displaced femoral neck fracture reduces risk of revision, but has greater infection rates, blood loss, operative time, and possibly increase in early mortality rates. No differences in pain or function. Larger trials needed. Hemiarthroplasty and THA populations pooled for analysis.
Rogmark, 2006 <sup>2</sup> Searched 1966 to 2004	Primary arthroplasty is better than internal fixation of displaced femoral neck fractures	14 RCTs N=2,289	Internal fixation (plate-screw or screw only) vs. arthroplasty, (hemi and THA)	Mortality, reoperations, major method-related complications	Update of Bhandari, 2003 review. Recommended THA for healthy, lucid 70-80 year old and hemi for older, impaired, or institutionalized patients based on reoperations and complications.
Parker, 1998 <sup>3</sup> Search period NR	Choice of implant for internal fixation of femoral neck fractures Displaced and not displaced	25 RCTs N=4,925	Multiple IF devices	No final patient outcomes. Overall complication rate	Screws superior to pins. No advantage to side-plate. Not able to determine optimum number or types of screws.
Varley, 2004 <sup>4</sup> Searched "last 40 years"	Stability of hip hemiarthroplasties Femoral neck fractures, subtypes not specified	133 RCTs to case series N=23,107	Unipolar, bipolar hemis	No patient final outcomes. Dislocations of prosthesis	Overall dislocation rate was 3.4%. No difference in dislocation rate between uni and bipolar hemiarthroplasties if account for posterior surgical approach and use of cement. Increased risk of open reduction of dislocations for bipolar.
Parker, 2006 <sup>5</sup> Searched 1966 to 2005	Internal fixation versus arthroplasty for intracapsular proximal femoral fractures in adults Both displaced and undisplaced	17 RCTs N=2,694 patients N=2,697 hips	Devices not specified; internal fixation, hemiarthroplasty, total arthroplasty	Operative details, complications related to type of surgery, post-op complications, post-op care outcomes, anatomical restoration, mortality, pain, residence at final followup, mobility, HRQoL	Internal fixation has less initial operative trauma, but increased risk of reoperations. There still exists a need for studies which define which devices best serve different patient groups.
Parker, 2001 <sup>6</sup> Searched 1966 to 2003	Internal fixation implants for intracapsular proximal femoral fractures in adults Both displaced and undisplaced	28 RCTs and quasi experimental N=5,547 patients N=5,552 hips	22 devices; nails, pins, screws, plates	Primary: non-union rate. Other: operative details, fracture fixation failures, post-op complications, anatomical restoration, mortality, pain, residence	Inconclusive. Sliding hip screw took longer to insert, with increased blood loss, compared to multiple screws or pins.

Previously Published Systematic Reviews and Meta-analysis (continued)

First Author, Year	Title Fracture Pattern Patient Population	# of Studies Patient N Hip N	Devices	Outcomes Addressed	Reported Results
Khan, 2002 <sup>7</sup> Search period NR	Cemented or uncemented hemiarthroplasty for displaced intracapsular fractures of the hip - a systematic review	18 RCTs to comparative N=NR	Unipolar and bipolar hemis	Pain, mobility, mortality, revision rate, blood loss, time in surgery	Tend to support use of cement for displaced fractures. Radiographic differences were variable and frequently did not correlate with clinical outcomes.
Parker, 2006 <sup>8</sup> Searched up to Dec 2005	Arthroplasties (with and without bone cement) for proximal femoral fractures in adults	17 RCTs N=1,920	Unipolar and bipolar hemis, THA	Operative details, complications related to type of surgery, post-op complications, post-op care outcomes, anatomical restoration, mortality, pain, residence at final followup, mobility, HRQoL	Limited evidence that cementing a prosthesis may reduce post-op pain and improve mobility. Insufficient evidence for the roles of bipolar and total hip arthroplasty.
Miyomoto, 2008 <sup>9</sup> Search period NR	Surgical management of hip fractures: an evidence based review of the literature for femoral neck fractures	35 RCTs to retrospective comparisons N=NR	Multiple forms of IF and arthroplasty	Complications, union, mortality, pain, functional outcomes, perioperative outcomes	No clear evidence for any one IF procedure. Some evidence for bipolar superior to unipolar, but may not justify cost. Less pain with cementing. THA for cognitively intact is well supported, especially compared to IF.
<b>Extracapsular/Stable and Unstable Intertrochanteric and Subtrochanteric</b>					
Chinoy, 1999 <sup>10</sup> Search period NR	Fixed nail plates versus sliding hip systems for the treatment of trochanteric femoral fractures: a meta analysis of 14 studies Stable or unstable intertrochanteric, and mixed fractures	14 RCTs to Comparative studies N=2,855 patients	Jewett, Thornton fixed nail, McLaughlin, or sliding hip screw	Cut-out, non-union, total complications, implant breakage, reoperation, mortality, pain, mobility	Sliding hip screw superior to fixed nail plates. (Many articles too old for inclusion in current review. Jewett and McLaughlin nails not included devices in current review.)
Schipper, 2004 <sup>11</sup> Searched 1990 - present	Unstable trochanteric femoral fractures: extramedullary or intramedullary fixation.	18 RCTs N=2,326	SHS, Gamma nail, IMHS, Static Nail, PFN, Gliding Nail	Failure rate, reoperation, other non-patient outcomes	Intramedullary implants biomechanically superior for unstable fractures. SHS is a safe and simple alternative for stable fractures. Evidence for either treatment class is still incomplete.
Audige, 2003 <sup>12</sup> Searched up to Dec 2002	Implant-related complications in the treatment of unstable intertrochanteric fractures: meta-analysis of dynamic screw-plate versus dynamic screw-intramedullary nail devices	17 RCTs N=2,431	Dynamic screw intramedullary devices vs. dynamic screw-plate devices	No final patient outcomes. Device complications, iatrogenic fractures	No differences in frequency of implant-related complications; DSIN tended to have less cut-outs, but persistent, if rare, risk of iatrogenic fracture.

Previously Published Systematic Reviews and Meta-analysis (continued)

First Author, Year	Title Fracture Pattern Patient Population	# of Studies Patient N Hip N	Devices	Outcomes Addressed	Reported Results
Jones, 2006 <sup>13</sup> Searched up to June 2004	Are short femoral nails superior to the sliding hip screw? A meta-analysis of 24 studies Stable, unstable, and subtrochanteric fractures	24 RCTs N=3,202 N=3,279	IMN, SHS	No final patient outcomes. Failure rate, reoperations, cut-out, fracture healing complications	Total failure rate and reoperation rate were greater for femoral nails. No evidence of reduced failure rate for nails in unstable tranchanteric fractures.
Kregor, 2005 <sup>14</sup> Searched 1996 - 2004	Unstable pertrochanteric femoral fractures. 31-A3 fractures	8 studies, RCT to case series	IMN, 95 plate, SHS, and SHS with TSP	Union rates, reoperation, mobility	Failure rates for SHS are too high for recommendation. More trials needed to compare IMN to 95 plate.
Parker, 1996 <sup>15</sup> Search period NR	Gamma vs. DHS nailing for extracapsular femoral fractures Trochanteric and subtrochanteric fractures.	10 RCTs N=1,794 N=1,797	Gamma nail vs. DHS	Mortality, reoperations, infection, iatrogenic fracture, cut-out	Gamma nail had increased risk of fracture of femoral shaft and reoperation rate. Not recommended until fracture problem is resolved. Larger trials needed.
Parker, 2006 <sup>16</sup> Searched up to Dec 2005	Replacement arthroplasty versus internal fixation for extracapsular hip fractures in adults Unstable intertrochanteric fractures, 70+ yrs	2 RCTs N=148	Hemi, PFN, CHS	Operative details, device complications, post-op complications, anatomical restoration, mortality, loss of independent status, Harris hip score	Insufficient evidence for replacement arthroplasty vs. internal fixation for extracapsular hip fractures. Larger, well-designed trials needed.
Parker, 2006 <sup>17</sup> Searched up to March 2006	Intramedullary nails for extracapsular hip fractures in adults Stable and unstable	6 RCTs and quasi N=1,071	PFN, Gliding Nail, Gamma Nail	Operative details, fracture fixation complications, post-op complications, anatomical restoration, early and long term mortality, pain, mobility, failure to return to living at home	Insufficient evidence for whether different IMN designs for extracapsular hip fractures matter. Ranking designs is not a priority given the evidence superiority for sliding hip screws over IMNs.
Parker, 2000 <sup>18</sup> Searched up to Sept 2004	Condylocephalic nails vs. extramedullary implants for extracapsular hip fractures	11 RCTs and quasi N=1,667	7 devices 2 intramedullary nails, 5 extramedullary implants	Operative details, fracture fixation complications, post-op complications, anatomical restoration, early and long-term mortality, pain, mobility, failure to return to living at home	Use of condylocephalic nails (Ender nails) is not supported due to increase in fracture healing complications, reoperation rate, residual pain, limb deformity, compared to extramedullary implant.
Parker, 2004 <sup>19</sup> Searched up to June 2005	Gamma and other cephalocondylic intramedullary nails vs. extramedullary implants for extracapsular hip fractures in adults Stable and unstable trochanteric and subtrochanteric	32 RCTs and quasi N=5,116 patients N=5,118 hips	7 devices; 5 intramedullary nails, 2 extramedullary implants	Operative details, fracture fixation complications, post-op complications, anatomical restoration, mortality, pain, mobility, failure to return to pre-fracture residential status	Sliding hip screw superior for trochanteric fractures compared to intramedullary nails. Further research required if intramedullary nails have advantages for other fracture types or if different intramedullary nails produce similar results.

**Previously Published Systematic Reviews and Meta-analysis (continued)**

<b>First Author, Year</b>	<b>Title Fracture Pattern Patient Population</b>	<b># of Studies Patient N Hip N</b>	<b>Devices</b>	<b>Outcomes Addressed</b>	<b>Reported Results</b>
Parker, 2006 <sup>20</sup> Searched up to July 2005	Extramedullary fixation implants and external fixators for extracapsular hip fractures in adults Unstable intertrochanteric, subtrochanteric Adults	14 RCTs N=2,222 patients	7 devices, fixed nail plates, various sliding hip screws, and others	Operative details, fracture fixation complications, post-op complications, anatomical restoration, mortality, pain, failure to return home, mobility and function	Sliding hip screw is superior to fixed nail plated due to increased fixation failure. Other comparisons were inconclusive.
Kaplan, 2008 <sup>21</sup> Search period NR	Evidence-based review of literature for surgical treatment of intertrochanteric fractures Stable and unstable fractures Adults	25 RCTs retrospective comparative N=NR	Multiple IMN, extramedullary fixation, hemi, THA	Complications, union, mortality, functional outcomes	Neither plate/screw fixation nor IM are superior for stable fractures. Unstable fractures theoretically would benefit from IM, but insufficient evidence to support recommendation. Comminuted fracture in osteoporotic bone can be treated with arthroplasty in select patients.

ADL – Activities of daily living  
 CHS – Compression hip screw  
 DHS – Dynamic hip screw  
 IF – Internal fixation  
 IMN – Intramedullary nail  
 IMHS – Intramedullary hip screw  
 NR – Not reported  
 PFN – Proximal femoral nail  
 RCT – Randomized controlled trial  
 SHS – Sliding hip screw  
 THA – Total hip arthroplasty  
 TSP – Trochanteric stabilizing plate

## References for Appendix A

(Note that there is a separate set of references at the end of the report and reference numbers are different than those in the appendixes)

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21. Kaplan K, Miyamoto R, Levine BR, et al. Surgical management of hip fractures: an evidence-based review of the literature. II: intertrochanteric fractures. *Journal of the American Academy of Orthopaedic Surgeons* 2008 Nov; 16(11):665-73.

## Appendix B: Technical Expert Panel

Michael Baumgaertner, MD

Yale University School of Medicine  
New Haven, CT

Ken Koval, MD

Dartmouth Hitchcock Medical Center  
Lebanon, NH

Hans Kreder, MD

Sunnybrook Health Sciences Center  
Toronto, Ontario

Jay Magaziner, MD

University of Maryland at Baltimore  
Baltimore, MD

Mark Sokolowski, MD

Trinity Orthopaedics, SC  
Oak Park, IL

Charles Turkelson, PhD

American Academy of Orthopaedic Surgeons  
Rosemont, IL

## Appendix C: Search Strings

### Search string for hip fracture literature:

1. ((hip\$ or femur\$ or femoral\$ or \$capsular\$ or \$trochant\$) adj4 fracture\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
2. limit 1 to yr="1985 - 2008", English language, humans

### Search string for device-related literature:

3. (pin\$1 or nail\$ or screw\$1 or plate\$1 or arthroplast\$ or fix\$ or prosthes\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]

### Search for RCTs

4. 2 and 3
5. (randomized controlled trial or clinical trial).pt.
6. (randomized controlled trials or random allocation or double blind method or single blind method).sh.
7. 5 or 6
8. clinical trial.pt.
9. exp Clinical Trial/
10. (clin\$ adj25 trial\$).ti,ab.
11. ((singl\$ or doubl\$ or trebl\$ or trip\$) adj25 (blind\$ or mask\$)).ti,ab.
12. (research design or placebos).sh.
13. (placebo\$ or random\$).ti,ab.
14. 8 or 9 or 10 or 11 or 12 or 13
15. 7 or 14
16. 4 and 15

### Search for observational literature

17. Cohort studies/ or comparative study/ or follow-up studies/ or prospective studies/ or risk factors/ or cohort.mp. or compared.mp. or groups.mp. or multivariate.mp.
18. 2 and 17
19. limit 18 to not (comment or editorial or historical article or interview or letter)
20. limit 19 to (addresses or bibliography or biography or classical article or clinical
21. "United States"/ep [Epidemiology]
22. 4 and 21
23. recovery.mp.
24. 4 and 23
25. odds ratio
26. 4 and 25

## Appendix D: Abstraction Forms

Study and Devices.....	D-2
Populations and Settings.....	D-6
Categorical Final Outcomes.....	D-10
Continuous Final Outcomes.....	D-12
Categorical Intermediate Outcomes.....	D-13
Continuous Intermediate Outcomes.....	D-14

Previewing Only: You cannot submit data from this form



Previewing at Level 3

Reviewer Comments ( Add a Comment )

On 10 May 2008, mary.forte said: DVT prevention

Prevention of pulmonary embolism and deep vein thrombosis with low dose aspirin: Pulmonary Embolism Prevention (PEP) trial.[see comment]  
 Lancet 355 9212, 1295-302- 2000:  
 Abstract. BACKGROUND: Previous trials of antiplatelet therapy for the prevention of venous thromboembolism have individually been inconclusive, but a meta-analysis of their results indicated reductions in the risks of deep-vein thrombosis and of pulmonary embolism in various high-risk groups. The aim of this large randomised placebo-controlled trial was to confirm or refute these apparent benefits. METHODS: During 1992-1998, 148 hospitals in Australia, New Zealand, South Africa, Sweden and the UK randomised 13,356 patients undergoing surgery for hip fracture, and 22 hospitals in New Zealand randomised a further 4088 patients undergoing elective arthroplasty. Study treatment was 160 mg daily aspirin or placebo, started preoperatively and continued for 35 days. Patients received any other thromboprophylaxis thought necessary. Follow-up was of mortality and of in-hospital morbidity up to day 35. FINDINGS: Among the patients with hip fracture, allocation to aspirin produced proportional reductions in pulmonary embolism of 43% (95% CI 18-60; p=0.002) and in symptomatic deep-vein thrombosis of 29% (3-48; p=0.03). Pulmonary embolism or deep-vein thrombosis was confirmed in 105 (1.6%) of 6679 patients assigned aspirin compared with 165 (2.5%) of 6677 assigned placebo, which represents an absolute reduction of 9 (SE 2) per 1000 and a proportional reduction of 36% (19-50; p=0.0003). Similar proportional effects were seen in all major subgroups, including patients receiving subcutaneous heparin. Aspirin prevented 4 (1) fatal pulmonary emboli per 1000 patients (18 aspirin-group vs 43 placebo-group deaths), representing a proportional reduction of 58% (27-76; p=0.002), with no apparent effect on deaths from any other vascular cause (hazard ratio 1.04 [95% CI 0.86-1.26]) or non-vascular cause (1.01 [0.84-1.23]). Deaths due to bleeding were few (13 aspirin vs 15 placebo), but there was an excess of 6 (3) postoperative transfused bleeding episodes per 1000 patients assigned aspirin (p=0.04). Among elective-arthroplasty patients, rates of venous thromboembolism were lower, but the proportional effects of aspirin were compatible with those among patients with hip fracture. INTERPRETATION: These results, along with those of the previous meta-analysis, show that aspirin reduces the risk of pulmonary embolism and deep-vein thrombosis by at least a third throughout a period of increased risk. Hence, there is now good evidence for considering aspirin routinely in a wide range of surgical and medical groups at high risk of venous thromboembolism.

State: Disagreement, Level: Strict Screening

Save to finish later

Submit Data

1. First Author (last name only)

Text input field for First Author (last name only)

Enlarge Shrink

2. Publication year

Text input field for Publication year

Enlarge Shrink

3. Country where study was conducted.

Text input field for Country where study was conducted

Enlarge Shrink

4. Multicenter study?

Yes

No

Clear Selection

5. Study design

RCT

Non-randomized controlled clinical trial

Observational case-control

- Prospective cohort
- Retrospective cohort
- Cross-sectional study
- Other

Clear Selection

6. Study design - crossover or parallel

- Crossover
- Parallel
- Unclear
- Not applicable
- Not applicable

Clear Selection

7. Study aim or hypothesis

Enlarge Shrink

8. How was project funded?

Enlarge Shrink

9. Ethical approval of study reported?

- Yes
- No

Clear Selection

10. Consent of participants?

- Yes
- No
- Not reported

Clear Selection

11. Were researchers/clinicians collecting outcomes blind to assignment?

- Yes
- No
- Not reported

Clear Selection

12. Length of follow-up (in months, numeric only)

Enlarge Shrink

13. Type of fracture

- Femoral Neck
- Intertrochanteric
- Subtrochanteric (only)
- Not identified

14. Specify type/location of femoral neck fracture (e.g. unspecified, subcapital, etc.)

Enlarge Shrink 

15. Specify femoral neck fracture pattern

- Displaced
- Non-displaced
- Unclear

16. Specify type of intertrochanteric fracture pattern

- Stable
- Unstable - IT only
- Unstable - IT with Subtroc extension
- Unstable - otherwise undefined
- Unclear

17. AOS (or other) classification codes identified.

Enlarge Shrink 

18. Name comparison group 1

Enlarge Shrink 

19. List all devices or ancillary material, name, location, used for comparison group 1 (e.g. Palacos cement (Schering-Plough, Hertfordshire, UK), CPT collarless polished tapered stem (Zimmer, Warsaw, Indiana), etc.)

Enlarge Shrink 

20. Name comparison group 2.

Enlarge Shrink 

21. List all devices or ancillary material, name, location, used for comparison group 2 (e.g. Palacos cement (Schering-Plough, Hertfordshire, UK), CPT collarless polished tapered stem (Zimmer, Warsaw, Indiana), etc.)

Enlarge Shrink 

22. Name comparison group 3

Enlarge Shrink 

23. List all devices or ancillary material, name, location, used for comparison group 3 (e.g. Palacos cement (Schering-Plough, Hertfordshire, UK), CPT collarless polished tapered stem (Zimmer, Warsaw, Indiana), etc.)

Enlarge Shrink 

24. Name comparison group 4

Enlarge Shrink 

25. List all devices or ancillary material, name, location, used for comparison group 4 (e.g. Palacos cement (Schering-Plough, Hertfordshire, UK), CPT collarless polished tapered stem (Zimmer, Warsaw, Indiana), etc.)

Enlarge Shrink 

26. Name comparison group 5

Enlarge Shrink 

27. List all devices or ancillary material, name, location, used for comparison group 5 (e.g. Palacos cement (Schering-Plough, Hertfordshire, UK), CPT collarless polished tapered stem (Zimmer, Warsaw, Indiana), etc.)

Enlarge Shrink 

Click a link below to review this article at these other levels.

[4. populations and setting](#)

[5. cat final outcomes](#)

[6. cont final outcomes](#)

[7. cat intermediate outcomes](#)

[8. cont intermediate outcomes](#)

Form took 0.2617188 seconds to render

Form Creation Date: Not available

Form Last Modified: Jul 30 2008 9:41AM

Previewing Only: You cannot submit data from this form



Previewing at Level 4

Reviewer Comments ( Add a Comment )

On 10 May 2008, mary.forte said: DVT prevention

Prevention of pulmonary embolism and deep vein thrombosis with low dose aspirin: Pulmonary Embolism Prevention (PEP) trial.[see comment]. Lancet 355 9212, 1295-302: 2000.

Abstract: BACKGROUND: Previous trials of antiplatelet therapy for the prevention of venous thromboembolism have individually been inconclusive, but a meta-analysis of their results indicated reductions in the risks of deep-vein thrombosis and of pulmonary embolism in various high-risk groups. The aim of this large randomised placebo-controlled trial was to confirm or refute these apparent benefits. METHODS: During 1992-1998, 148 hospitals in Australia, New Zealand, South Africa, Sweden and the UK randomised 15,356 patients undergoing surgery for hip fracture, and 22 hospitals in New Zealand randomised a further 4088 patients undergoing elective arthroplasty. Study treatment was 100 mg daily aspirin or placebo, started preoperatively and continued for 35 days. Patients received any other thromboprophylaxis thought necessary. Follow-up was of mortality and of in-hospital morbidity up to day 35. FINDINGS: Among the patients with hip fracture, allocation to aspirin produced proportional reductions in pulmonary embolism of 43% (95% CI 18-60; p=0.002) and in symptomatic deep-vein thrombosis of 29% (3-48; p=0.03). Pulmonary embolism or deep-vein thrombosis was confirmed in 105 (1.6%) of 6679 patients assigned aspirin compared with 165 (2.5%) of 6677 assigned placebo, which represents an absolute reduction of 9 (SE 2) per 1000 and a proportional reduction of 36% (19-50; p=0.0003). Similar proportional effects were seen in all major subgroups, including patients receiving subcutaneous heparin. Aspirin prevented 4 (1) fatal pulmonary emboli per 1000 patients (18 aspirin-group vs 43 placebo-group deaths), representing a proportional reduction of 58% (27-76; p=0.002), with no apparent effect on deaths from any other vascular cause (hazard ratio 1.04 [95% CI 0.86-1.26]) or non-vascular cause (1.01 [0.84-1.23]). Deaths due to bleeding were few (13 aspirin vs 15 placebo), but there was an excess of 6 (3) postoperative transfused bleeding episodes per 1000 patients assigned aspirin (p=0.04). Among elective-arthroplasty patients, rates of venous thromboembolism were lower, but the proportional effects of aspirin were compatible with those among patients with hip fracture. INTERPRETATION: These results, along with those of the previous meta-analysis, show that aspirin reduces the risk of pulmonary embolism and deep-vein thrombosis by at least a third throughout a period of increased risk. Hence, there is now good evidence for considering aspirin routinely in a wide range of surgical and medical groups at high risk of venous thromboembolism.

State: Disagreement, Level: Strict Screening

Save to finish later Submit Data

1. Sampling procedure (Most will be convenience, such as consecutive patients, or simply not reported.)

- Random
- Convenience
- Self-selection
- Selection from clinical or admin database
- Not reported

Clear Selection

2. Eligibility criteria regarding Diagnosis (example: fracture classification)

Enlarge Shrink

3. List exclusion criteria

Enlarge Shrink

4. Intention to treat analysis?

- Yes
- No
- Not reported

Clear Selection

5. Was allocation concealment adequate? (Adequate is up to point of treatment. Surgery is different, but may include situations where the surgeon determines whether patient will be randomized or not.)

- Adequate
- Not adequate
- Unclear

Clear Selection

6. Randomization scheme

Enlarge Shrink 

7. Was baseline data of subjects reported?

- Yes
- No

Clear Selection

8. Based on Q6, was randomization adequate? (Adequate: computer generated, random number tables, tossed coins, shuffled cards. Inadequate: alternate assignment, odd/even birth date, hospital number. Check "no" if scheme was not reported.)

- Yes
- No

Clear Selection

9. Was there adjustment for confounding factors from inadequate baseline randomization? (Were the groups significantly different at baseline on some factor, like ASA, and did analysis adjust for it?)

- Yes
- No
- Not reported
- No adjustment required

Clear Selection

10. Was there a power calculation for any outcome? (Check yes even if outcome not stated.)

- Yes
- No

Clear Selection

11. Did recruitment meet target-justified sample size?

- Yes
- No
- No target given

Clear Selection

12. Number recruited (if reported)

- Reported
- Not reported

Clear Selection

13. Number enrolled (if reported)

- Reported
- Not reported

Clear Selection

14. Was number lost to follow-up reported? (If mortality is not outcome, patient death should be included. Withdrawal or drop outs defined as any patient included in study but did not complete observation period or were not included in analysis.)

- Yes
- No
- No withdraw or drop out reported

Clear Selection

15. Describe loss of followup.

Enlarge Shrink 

Number of patients fracture Race ASA Obesity Residence Prefracture SES Prior Smoker EtOH Other Gender Age Mental

	pattern	functioning	fractures	Status
16. What baseline data was reported for comparison group 1?	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. What baseline data was reported for comparison group 2?	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. What baseline data was reported for comparison group 3?	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. What baseline data was reported for comparison group 4?	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. What baseline data was reported for comparison group 5?	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

21. Name and/or location of hospital(s) where surgery was performed.

Enlarge Shrink

22. Were hospital factors reported as covariates? (Check "Descriptive only" if reported but not used in analysis.)

Yes  
 No  
 Descriptive only

Clear Selection

23. Was time from injury to surgery reported? If yes, provide particulars.

Yes   
 No

Clear Selection

24. Did the same surgeon perform all surgeries within each comparison arm? If not, describe particulars.

Yes  
 No   
 Unclear

Clear Selection

25. Were surgeon factors reported as covariates? (Check "Descriptives only" if reported but not used in analysis.)

Yes  
 No  
 Descriptive only

Clear Selection

26. Were perioperative factors reported as covariates? (Check "Descriptive only" if reported but not used in analysis.)

Yes  
 No

Descriptive only

Clear Selection

27. Were rehabilitation factors reported as covariates? (Check "Descriptive only" if reported but not used in analysis.)

Yes

No

Descriptive only

Clear Selection

Click a link below to review this article at those other levels.

[3. study and devices](#)

[5. cat final outcomes](#)

[6. cont final outcomes](#)

[7. cat intermediate outcomes](#)

[8. cont intermediate outcomes](#)

Form took 0.453125 seconds to render

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 Previewing at Level 5

Reviewer Comments ( Add a Comment )

On 10 May 2008, mary.forte said: DVT prevention

Prevention of pulmonary embolism via deep vein thrombosis with low-dose aspirin - Pulmonary Embolism Prevention (PEP) trial [see summary]. Lancet 2002; 359: 995-1000.  
 Abstract BACKGROUND: Previous trials of aspirin as therapy for the prevention of venous thromboembolism have individually been inconclusive, but a meta-analysis of their results indicated reductions in the risks of deep-vein thrombosis and of pulmonary embolism. We conducted a multicentre randomised controlled trial to evaluate the effect of low-dose aspirin on the prevention of pulmonary embolism in patients undergoing elective orthopaedic surgery. STUDY DESIGN: Randomised controlled trial. SETTING: 11 hospitals. PARTICIPANTS: 1000 patients (500 in each group). INTERVENTIONS: Aspirin (100 mg daily) or placebo. MEASUREMENTS AND MAIN RESULTS: The primary end-point was the rate of pulmonary embolism. The secondary end-points were the rate of deep-vein thrombosis, the rate of mortality, and the rate of major bleeding. The rate of pulmonary embolism was significantly lower in the aspirin group (1.8% vs 4.3% in the placebo group; p=0.002). The rate of deep-vein thrombosis was significantly lower in the aspirin group (11.1% vs 15.8% in the placebo group; p=0.002). The rate of mortality was significantly lower in the aspirin group (1.8% vs 2.7% in the placebo group; p=0.002). The rate of major bleeding was significantly higher in the aspirin group (1.8% vs 0.7% in the placebo group; p=0.002). CONCLUSIONS: Low-dose aspirin significantly reduces the risk of pulmonary embolism and deep-vein thrombosis in patients undergoing elective orthopaedic surgery. The rate of mortality was significantly lower in the aspirin group. The rate of major bleeding was significantly higher in the aspirin group.

Date: Disagreement, Level: Strict Screening

[Save to finish later](#) [Submit Data](#)

1. Was prophylactic antibiotic used? (Described in methods section as part of protocol)

- yes
- no
- unclear/na

Clear Selection

2. Was thrombo-lytic used? (Described in methods section as part of protocol)

- yes
- no
- unclear/na

Clear Selection

3. Pain (pain rating, medication use)	N G1 analyzed	N G2 analyzed	N G3 analyzed	N G4 analyzed	# pain events G1	# pain events G2
Describe outcome measure	<input type="text"/>					
4. Pain	<input type="text"/>					
5. Pain	<input type="text"/>					
6. Pain	<input type="text"/>					

7. Functioning (range of motion, ambulatory, auditive devices, other)	N analyzed comparison group 1	N analyzed comparison group 2	N analyzed comparison group 3	N analyzed comparison group 4	Not of events for group 1	Not of events for group 2
Describe outcome measure	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
8. Functioning	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
9. Functioning	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
10. Functioning	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

11. ADLs	N analyzed comparison group 1	N analyzed comparison group 2	N analyzed comparison group 3	N analyzed comparison group 4	Not of events for group 1	Not of events for group 2
Describe outcome measure	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
12. ADLs	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

13. Mortality (in-hospital, short term, longer term)	N analyzed comparison group 1	N analyzed comparison group 2	N analyzed comparison group 3	N analyzed comparison group 4	Not of events for group 1	Not of events for group 2
Describe mortality outcome measurement	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
14. Mortality	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
15. Mortality	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
16. Mortality	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

17. Describe mortality issues

Emerg. Sinks

18. Return to same living situation	N analyzed comparison group 1	N analyzed comparison group 2	N analyzed comparison group 3	N analyzed comparison group 4	Not of events for group 1	Not of events for group 2
Describe outcome measurement	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
19. Discharged to nursing home/nursing hospital	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Describe outcome measurement	N analyzed comparison group 1	N analyzed comparison group 2	N analyzed comparison group 3	N analyzed comparison group 4	Nil of events for group 1	Nil of events for
20 Health related Quality of Life						

Click a link below to review this article at these other levels

- 1. study and devices
- 2. investigators and setting
- 3. local final outcomes
- 4. all intermediate outcomes
- 5. all intermediate outcomes

Form ID: 11, 12/11/11, 11/11/11 to 11/11/11  
Print Creation Date: Apr 25, 2014 3:34PM  
Form Last Modified: Oct 7, 2013 10:56AM

Previewing Only: You cannot submit data from this form  
 Previewing at Level 6

Reviewer Comments ( Add a Comment )

On 10 May 2008, mary.forte said: DVT prevention

Prevention of pulmonary embolism and deep vein thrombosis with low-dose aspirin. Pulmonary Embolism Prevention (PEP) trial (see comment) Lancet 365:1212-1295-300-2005.  
 Abstract. BACKGROUND: Previous trials of aspirin for the prevention of venous thromboembolism have individually been inconclusive, but a meta-analysis of their results indicated reductions in the rates of deep-vein thrombosis and/or pulmonary embolism. We conducted a randomised, controlled trial to assess the effect of aspirin on the rates of deep-vein thrombosis and pulmonary embolism in low-risk patients undergoing elective orthopaedic surgery. STUDY DESIGN: This was a randomised, controlled trial. SETTING: The trial was conducted in a tertiary care hospital. PARTICIPANTS: 1579 patients undergoing elective orthopaedic surgery were randomised to receive either 100 mg daily aspirin or placebo, started preoperatively and continued for 35 days. PRIMARY RESULTS: The rate of deep-vein thrombosis or pulmonary embolism was significantly lower in the aspirin group (1.6%) than in the placebo group (2.5%) (p=0.001). The rate of pulmonary embolism or deep-vein thrombosis was significantly lower in the aspirin group (0.8%) than in the placebo group (1.5%) (p=0.001). There was no significant difference in the rates of major bleeding between the two groups (1.0% in the aspirin group and 1.1% in the placebo group). There was no significant difference in the rates of death between the two groups (0.1% in the aspirin group and 0.1% in the placebo group). CONCLUSIONS: Low-dose aspirin significantly reduces the rates of deep-vein thrombosis and pulmonary embolism in low-risk patients undergoing elective orthopaedic surgery. The rate of major bleeding was not significantly higher in the aspirin group than in the placebo group. The rate of death was not significantly higher in the aspirin group than in the placebo group.

Date Disagreement Level: Strict Scrutiny

Outcome Measure	N analyzed for comparison group 1	N analyzed for comparison group 2	N analyzed for comparison group 3	N analyzed for comparison group 4	Outcome level group 1	SD (or 95% CI) g
1. Pain						
2. Functioning						
3. Functioning						
4. Functioning						
5. ADL/IADL						
6. Health related Quality of Life						

Click a link below to review this article at those other levels  
 3. study and devices  
 4. protocols and settings  
 5. outcomes  
 6. all intermediate outcomes  
 7. all intermediate outcomes  
 8. all intermediate outcomes  
 Form version Date: Oct 6 2005 2:10 PM  
 Form Last Modified: Oct 7 2005 10:04 AM

Previewing Only: You cannot submit data from this form.

Previewing at Level 7

Reviewer Comments (Add a Comment)

On 10 May 2008, mary.forte said: DVT prevention

**Question of pulmonary embolism and deep vein thrombosis with low dose aspirin: Pulmonary Embolism Prevention (PEP) trial** (see comment) Lancet 355:1212-1218 (2000)  
**Abstract** BACKGROUND: Previous trials of aspirin therapy for the prevention of venous thromboembolism have individually been inconclusive, but a meta-analysis of their results indicated reductions in the rate of deep-vein thrombosis and of pulmonary embolism in ambulatory patients undergoing surgery for hip fracture, and 22 hospitals in New Zealand conducted a further trial assessing ongoing prophylactic therapy. STUDY DESIGN: In 105 (1.8%) of 5873 patients assigned a aspirin compared with placebo, 43% (20/47) had deep-vein thrombosis (34% (3/9) in asymptomatic deep-vein thrombosis of 35% (3/9) in symptomatic deep-vein thrombosis) compared with 10% (1/10) in the placebo group. Pulmonary embolism or deep-vein thrombosis was confirmed in 105 (1.8%) of 5873 patients assigned a aspirin compared with placebo. Aspirin prevented 4 (1) fatal pulmonary embolism per 1000 patients (19 aspirin group vs 43 placebo-group deaths), representing a proportional reduction of 86% (27.7% (95% CI 15.2-38.2) with no observed effect on deaths from any other cause (p=0.04). Among elective orthopaedic patients, rates of venous thromboembolism were lower, but the prophylactic effects of aspirin were compatible with those among patients with hip fracture. INTERPRETATION: These results, across a wide range of surgical and medical groups at high risk of venous thromboembolism.

State Disagreement, Level, Blind Screening

	Save to finish later	Submit Data		N analyzed comparison group 1	N analyzed comparison group 2	N analyzed comparison group 3	N analyzed comparison group 4	Not of events for group 1	Not of events for group 2
1. Reduction (aspirin-based) qualify	<input type="checkbox"/>	<input type="checkbox"/>	Report on outcome measurement	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2. Reduction	<input type="checkbox"/>	<input type="checkbox"/>	Finalising outcome measurement	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3. Positioning of evidence (prioritised, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	Finalising outcome measurement	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4. Reoperations (removed, replacement with arthro, arthro revisions, total number of reoperations, other)	<input type="checkbox"/>	<input type="checkbox"/>	Finalising outcome measurement	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
5. Reoperation	<input type="checkbox"/>	<input type="checkbox"/>		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
6. Reoperation	<input type="checkbox"/>	<input type="checkbox"/>		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
7. Reoperation	<input type="checkbox"/>	<input type="checkbox"/>		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
8. Blood loss (removed, transfused, not patients transfused, total blood loss, haemoglobin)	<input type="checkbox"/>	<input type="checkbox"/>	Describe outcome measure	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
9. Blood loss	<input type="checkbox"/>	<input type="checkbox"/>		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
10. Union (time to union, non-union)	<input type="checkbox"/>	<input type="checkbox"/>	Describe outcome measure	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
11. Device complications	<input type="checkbox"/>	<input type="checkbox"/>	List complications	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
12. Local complications	<input type="checkbox"/>	<input type="checkbox"/>	List complications	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
13. General complications	<input type="checkbox"/>	<input type="checkbox"/>	List complications	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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Reviewer Comments (Add a Comment)

On 10 May 2008, mary.forte said: DVT prevention

Prevention of pulmonary embolism and deep vein thromboses with low-dose aspirin. Pulmonary Embolism Prevention (PEP) trial (see comments) Lancet 365:6912, 1995-079, 2005.  
 Abstract BACKGROUND: Previous trials of aspirin therapy for the prevention of venous thromboembolism have individually been inconclusive, but a meta-analysis of their results indicated reductions in the risk of deep-vein thromboses and of not undergoing surgery for hip fracture, and 22 hospital in New Zealand randomized a further 4568 patients undergoing elective orthopaedic surgery. Study treatment was 100 mg daily aspirin or placebo, started preoperatively and continued for 35 days. Patients in aspirin-treated deep vein thromboses of 20% (2/10; 95% CI 0-33). Pulmonary embolism or deep-vein thromboses was confirmed in 105 (1.6%) of 6679 patients assigned aspirin compared with 180 (2.7%) of 6677 assigned placebo, which represents an absolute patient-group relative risk reduction of 38% (95% CI 19-50), with no apparent effect on deaths from any other vascular cause (hazard ratio 1.04 [95% CI 0.88-1.20]) or non-vascular cause (1.01 [0.86-1.18]). Results are to be compared with those among patients with hip fracture. INTERPRETATION: These results, along with those of the previous meta-analysis, show that aspirin reduces the risk of pulmonary embolism and deep-vein thromboses by at least a third through

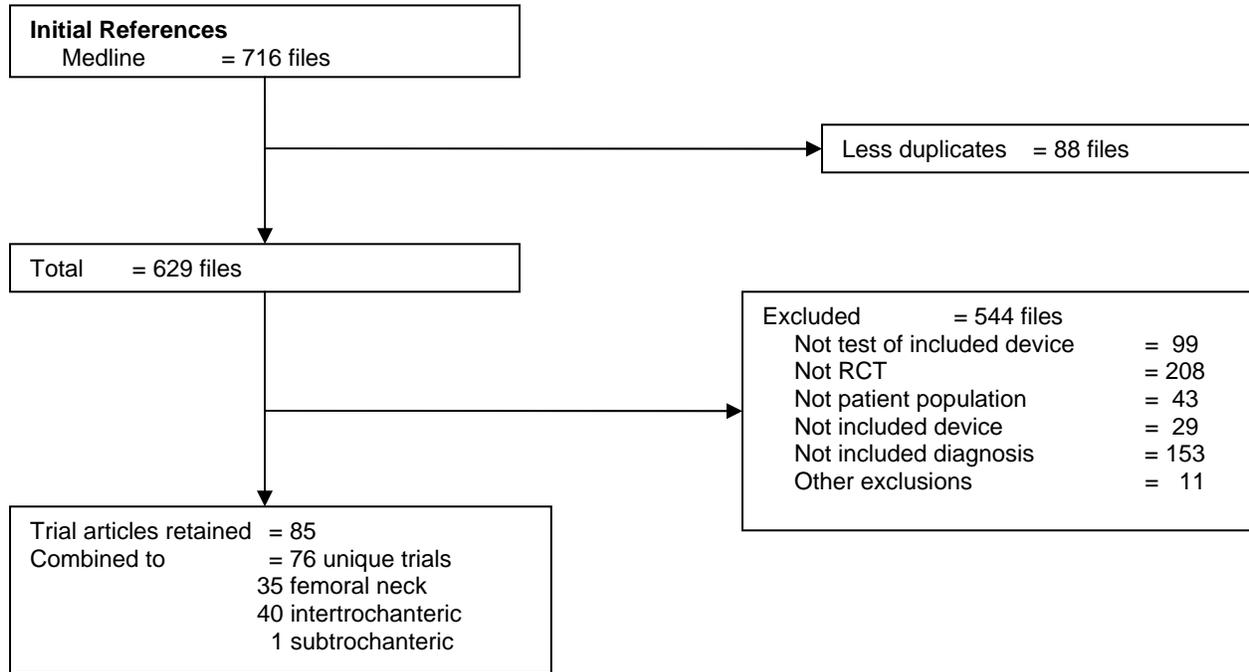
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4. Blood loss	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
5. Surgery time	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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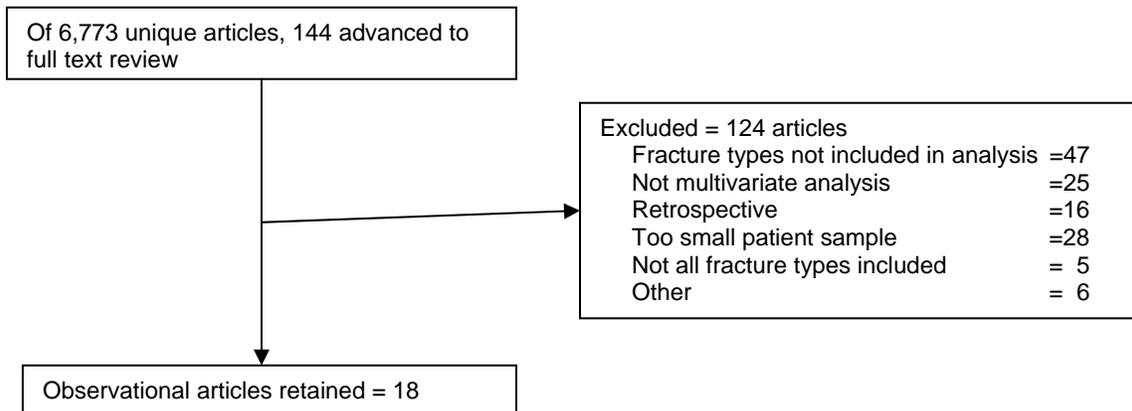
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# Appendix E: Quorum Statement and Evidence Tables

Appendix Figure E1. QUORUM statement data for RCT literature



Appendix Figure E2. QUORUM statement data for observational literature



**Appendix Table E1. Observational studies**

Author, Year, Country	Study Aim	Patient N Followup	Patient Population	Fracture Type	Surgical Treatment	Site	Reported Results
<b>Focused Research Question</b>							
Karagiannis, 2006 <sup>1</sup> Greece	Examine relationship between patient factors, fracture type, and long-term mortality	N=499 10 years	60+ years, excluded subtrochanteric, pathologic, nonindex, and high trauma fractures	FN, IT, no sub-types	None reported	Single hospital site	Age, sex, type of fracture, heart failure were independent predictors of 10 year mortality. IT had 1.37 times higher probability of mortality. Did not adjust for functional or cognitive status.
Cornwall, 2004 <sup>2</sup> United States	Examine the relationship between fracture type, patient characteristics, and mortality and functional outcomes	N=804 6 months	50+ years, excluding bilateral, pathologic, multiple trauma, non-index,	FN – displaced and not displaced; IT – stable and unstable	Yes, 100% correlated with type of fracture, IT and hemi	Single hospital site	Nondisplaced fractures more likely in younger patients. Preinjury functional dependence predicted mortality. Age, gender, fracture type, comorbidities, perioperative factors were not predictive. Age and preinjury functional dependence predicted functional outcomes.
Fox, 1999 <sup>3</sup> United States	Examine relationship between fracture type, patient characteristics and mortality and functional outcomes	N=923 12 months	65+ years, community dwelling, ambulatory.	FN, IT, no sub-types	Internal fixation, hemi, THA	7 hospital sites	IT had lower recovery at 2 months, higher mortality at 2 and 6 months. No differences between fracture types remained at 12 months. Surgical treatment did not affect the model when added.
<b>Generalized Research Question – Fracture type Included in multivariate analysis</b>							
Heikkinen, 2004 <sup>4</sup> Finland	Examine predictors of mortality and function after hip fracture	N=2,279 4 months	50+ years	Displaced/undisplaced FN, IT 2 or multi-fragment, subtroch	Multiple internal fixation, hemi, THA	6 hospital sites	Prefracture residence, mobility, morbidity, and age were predictive of 4 month mortality and function. Fracture type and surgical method were not predictive. Differences in hospital preferences for surgical treatment found. Potential effects of possible multicollinearity between variables not discussed.
Hannan, 2001 <sup>5</sup> United States	Examine patient factors for risk factors for 6 months mortality and functional status for hip fracture patients,	N=571 6 months	50+ years, no concurrent major injuries, pathological fractures, isolated pelvic or acetabular	Displaced and nondisplaced FN, IT without sub-types	Treatment 100% correlated with fracture type: IF, hemi	4 hospital sites. Outcomes adjusted by site.	Age, prefracture mobility, and nursing home residence predicted mobility. APACHE score, low prefracture mobility, and paid help at home were predictive of mortality. When the two outcomes were combined as adverse outcomes,

E-2

**Appendix Table E1. Observational studies (continued)**

Author, Year Country	Study Aim	Patient N Followup	Patient Population	Fracture Type	Surgical Treatment	Site	Reported Results
			fractures, bilateral fractures, nonindex fractures				dementia was also predictive. Fracture type was not a significant predictor.
Koval, 1998 <sup>b</sup> United States	Examine predictors of ADL/IADLs after hip fracture	N=338 12 months	65+ years, community dwelling, ambulatory, cognitively intact with nonpathological fractures	FN, IT, no sub-types	None reported	Single hospital site	Age and prefracture ADLs/IADLs predicted recovery at 3 and 6 months. Patient age was the only independent predictor at 1 year. Fracture type was not a predictor.
Koval, 1996 <sup>c</sup> United States	Examine predictors of dependency after hip fracture	N=431 12 months	65+ years, community dwelling, ambulatory, cognitively intact with nonpathological fractures	FN, IT, no sub-types	None reported	Single hospital site	Age, prefracture independence in ADL/IADLs, number of comorbidities were predictive at 3, 6, and 12 months of patient regaining prefracture independence. Fracture type was not significant
ECS Koval, 1995 <sup>b</sup> United States	Examine predictors of ambulatory ability after hip fracture	N=336 12-18 months	65+ years, community dwelling, ambulatory, cognitively intact with non-pathological fractures	FN, IT, no sub-types	Treatment 100% correlated with fracture type: IF, hemi	Single hospital site	Fracture type not predictive of a decline in ambulatory status for all patients or previous community ambulators. However, IT was borderline predictive of a patient becoming household or nonfunctional ambulators. Age, prefracture mobility, ASA rating were also predictors.
Borgquist, 1991 <sup>d</sup> Sweden	Examine predictors of independent ADLs after hip fracture in the elderly	N=827 4 months	50+ years, community dwelling prior to fracture	FN, IT, no sub-types	Yes, treatment reported 100% correlated with fracture type	Single hospital site	Age, gender, and living with someone predicted living at home at 4 months. Type of fracture, prefracture mobility and ADLs were not predictive. Age, FN fracture, gender predicted independent ADLs at 4 months.

FN = femoral neck fracture  
IT = intertrochanteric fracture

Appendix Table E2. Femoral neck evidence-1

Author, Year	Comparison	Country	N Enrolled	Inclusion	Exclusion	Average Age Range/SD % Female	Power Calculation Met Target
<b>Node 4 Displaced - Arthroplasty – Hemi Choices</b>							
Emery, 1991 <sup>10</sup>	Cement stem vs. not, bipolar hemi	England	53	Active, independently mobile with displaced femoral neck fracture	Admitted from NH, use more than one walking stick	79 61-96 87%	No
Livesley, 1993 <sup>11</sup>	Ceramic coated vs. not, bipolar hemi	United Kingdom	82	Displaced femoral neck fracture	None listed	81 SD 7.8 NR	No
<b>Node 4 Displaced – Internal Fixation - Cemented vs. Not Cemented Screws</b>							
Mattsson, 2006 <sup>12</sup>	IF - Calcium phosphate vs. no c.p.	Sweden	118	Displaced femoral neck fracture, ambulatory without walking aid (or with one cane) 60+ years of age, surgical procedure within 72 hours of admission, normal contralateral hip	Senility, earlier hip surgery, soft tissue infection at operative site, ongoing radiotherapy or chemotherapy due to malignancy, pathological fracture, clotting disorder, corticosteroid treatment exceeding 5 mg per day, concurrent fracture that would affect postoperative functional outcome, serious concomitant illness or mental instability, neurosensory, neuromuscular or musculoskeletal deficiency that might limit ability to perform objective functional tests	NR 60-98 81%	Yes Yes
Mattson, 2003 <sup>13</sup>	IF - Calcium phosphate vs. no c.p.	Sweden	40	Low energy trauma, pre- fracture ambulatory without aid (or with one cane)	Senility, pathological fracture, concurrent fracture, bilateral	78 62-92 83%	No
<b>Node 3 Displaced - Arthroplasty – Uni vs. Bipolar Hemi</b>							
Raia, 2003 <sup>14</sup>	Uni vs. bipolar hemi (cemented stems)	United States	115	65+ years with displaced femoral fracture, ambulatory	Dementia, pathologic fracture, concurrent lower extremity fracture, NH residence	82 65-101 72%	No
Cornell, 1998 <sup>15</sup>	Uni vs. bipolar hemi (cemented stems)	United States	48	65+ with displaced femoral neck fracture (early results but full study not reported)	Previous ipsilateral hip surgery, pathological fracture, mentally incompetent patients	78 62-97 75%	No

Appendix Table E2. Femoral neck evidence-1 (continued)

Author, Year	Comparison	Country	N Enrolled	Inclusion	Exclusion	Average Age Range/SD % Female	Power Calculation Met Target
<b>Node 3 Inclusive – Internal Fixation - Hook Pins vs. Screws</b>							
Mjorud, 2006 <sup>16</sup>	IF - 2 hook pin vs. 3 screws	Sweden	199	Cervical hip fracture	Non-healed bilateral, pathological fracture, combined with trochanteric component, joint disease, unable to reduce satisfactorily	U 79, D 81 U 28-101 D 53-101 76%	No
Lykke, 2003 <sup>17</sup>	IF - 2 hook pin vs. 3 screws	Norway	278	Femoral neck fracture	Bilateral, pathological fracture, concomitant or combined fractures, irreducible fractures	82 27-101 82%	No
Herngren, 1992 <sup>18</sup>	IF - 2 hook pin vs. 2 screws	Sweden	179	Femoral neck fractures	Pathologic fractures, unable to reduce satisfactorily	78 28-97 63%	No
Olerud, 1991 <sup>19</sup>	IF - 2 hook pin vs. 2 screws	Sweden	115	Femoral neck fractures	None listed	80 SD 9 84%	No
<b>Node 3 Inclusive – Internal Fixation - Screws vs. Screws</b>							
Lagerby, 1998 <sup>20</sup>	IF - 2 vs. 3 screws	Sweden	268	Femoral neck fractures	Pathological fractures	81 31-99 67%	Yes Yes
Rehnberg, 1989 <sup>21</sup>	IF - 2 vs. 2 screws	Sweden	222	Femoral neck fracture	Pathologic fractures, unable to reduce satisfactorily, fracture older than 1 week	80 55-98 75%	Yes
<b>Node 2 Displaced - Arthroplasty - Hemi vs. Total Hip</b>							
Baker, 2006 <sup>22</sup>	Hemi (cemented unipolar) vs. THA	United Kingdom	81	60+ years with displaced femoral neck fracture, walk >.5 miles living independently	Cognitive difficulty, pathological fracture, osteoarthritis, hip abnormality requiring THA (no bi-lateral, non-index)	75 63-86 80%	Yes Yes
Blomfeldt, 2007 <sup>23</sup>	Hemi (cemented bipolar) vs. THA	Sweden	120	70 to 90 years, acute displaced femoral neck fracture following a fall, no severe cognitive dysfunction, independent living status, pre-fracture ambulatory with or without aids.	Pathological fracture, fractured more than 48 hours prior, rheumatoid or osteoarthritis	81 70-90 84%	Yes Yes
<b>Node 2 Displaced – Internal Fixation – Pins/Screws vs. Plate and Screws</b>							
Benterud, 1997 <sup>24</sup>	IF - Sliding screw plate plus screw vs. 2 screws	Sweden	225	Displaced femoral neck fracture, 70+ years, but younger included	None listed	81 63-97 79%	No

Appendix Table E2. Femoral neck evidence-1 (continued)

Author, Year	Comparison	Country	N Enrolled	Inclusion	Exclusion	Average Age Range/SD % Female	Power Calculation Met Target
Madsen, 1987 <sup>25</sup> Linde, 1986 <sup>26</sup>	IF - Sliding screw plate vs. 4 screws	Norway	103	Displaced femoral neck fractures	Pathologic fractures, more than 24 hour delay to surgery for Garden stage 4	75 25-92 76%	No
Paus, 1986 <sup>27</sup>	IF - Hip compression screw vs. 2 screws	Denmark	131	<80 years with displaced femoral neck fractures	None listed	70 women, 64 men NR 82%	No
Elmerson, 1995 <sup>28</sup>	IF - Sliding screw plate vs. 2 hook pin	Sweden	248	Femoral neck fracture	Pathological fractures, unable to reduce fracture	77 NR, prior to exclusion 50-99 76%	No
<b>Node 1 Displaced – Internal Fixation vs. Hemi vs. Total Hip</b>							
Skinner, 1989 <sup>29</sup> Ravikumar, 2000 <sup>30</sup>	IF vs. hemi vs. THA	United Kingdom	278	65+ years with displaced femoral fracture (may not include THA)	None listed	81 NR 90%	No
Keating, 2006 <sup>31</sup> Keating, 2005 <sup>32</sup>	IF vs. hemi vs. THA (mixed bag)	Scotland	299	Mini-mental test score of >6, pre-fracture ability to be mobile independent of another person, no serious concomitant disease (or other clinical reason for exclusion), surgeon determination if treatment options suitable.	Undisplaced or valgus impacted intracapsular fracture. Surgeon decided clinical eligibility and whether to assign to 2 way or 3 way randomization (double counting of patients)	75 NR, 60+ years 78%	Yes Yes
Rogmark, 2002 <sup>33</sup> Rogmark, 2003 <sup>34</sup>	IF vs. arthro (mixed bag)	Sweden	409	70+ with displaced femoral neck fracture	Confusion, rheumatoid arthritis, bedridden, NH residence	82 SD 5.8 79%	Yes NR
<b>Node 1 Displaced – Internal Fixation vs. Hemi</b>							
El-Abed, 2005 <sup>35</sup>	IF (DHS) vs. uncemented unipolar hemi	Ireland	122	70+ with displaced femoral neck fracture	Non-displaced fractures, pathological fractures, and mental confusion, bedridden.	73 70-87 67%	Yes Unclear
Davison, 2001 <sup>36</sup>	IF (CHS) vs. hemi, cemented uni and bipolar	United Kingdom	280	Age between 65 and 79 years with displaced femoral neck fracture	Cognitive difficulty, pathological fracture, rheumatoid arthritis, long-term steroid therapy	75 70-78 76%	No
Blomfeldt, 2005 <sup>37</sup>	IF (2 screws) vs. uncemented unipolar hemi	Sweden	60	Displaced femoral neck fracture due to fall, 70+ years old, diagnosed dementia and/or severe cognitive dysfunction, mobile with or without aid	Pathological fracture, displaced fractures more than 24 hours, rheumatoid or osteoarthritis, inability to reduce	84 70-96 90%	No

Appendix Table E2. Femoral neck evidence-1 (continued)

Author, Year	Comparison	Country	N Enrolled	Inclusion	Exclusion	Average Age Range/SD % Female	Power Calculation Met Target
Roden, 2003 <sup>38</sup>	IF (2 screws) vs. cemented bipolar hemi	Sweden	100	70+, ambulatory, with displaced femoral neck fractures	Medical findings, senility, technical, fracture more than 12 hours previously, irreducible fracture and non-residence	81 70-96 71%	No
Parker, 2002 <sup>39</sup> Parker, 2000 <sup>40</sup>	IF (3 screws) vs. uncemented unipolar hemi	United Kingdom	455	71+, fit for surgery, with displaced femoral neck fracture	Rheumatoid or osteoarthritis, chronic renal failure, delay to surgery of more than 48 hours, pathological fracture	82 71-103 80%	No
Puolakka, 2001 <sup>41</sup>	IF (2 screws) vs. cemented hemi (Thompson)	Finland	32	75+ with displaced femoral neck fracture	Unable to walk independently, rheumatoid arthritis	82 76-90 84%	No
van Dortmont, 2000 <sup>42</sup>	IF (3 screws) vs. cemented hemi (Thompson)	Netherlands	60	70+ patients with GEM diagnosed dementia with displaced fracture	None listed	84 71-96 87%	No
van Vugt, 1993 <sup>43</sup>	IF (DHS) vs. cemented bipolar hemi	Netherlands	43	71-80 years, displaced femoral neck fracture, with a good degree of independence	None listed	76 SD 3 58%	No
<b>Node 1 - Displaced – Internal Fixation vs. Total Hip</b>							
Johansson, 2006 <sup>44</sup>	IF (2 screws) vs. THA	Sweden	146	75+ years displaced femoral neck fractures, prefracture walking ability	Non-index fracture, contraindications to surgery, malignancy, inflammatory arthritis	84 75-101 76%	No
Blomfeldt, 2005 <sup>45</sup>	IF (2 screws) vs. THA	Sweden	102	Displaced femoral neck fracture, 70+ years, independent living status, ability to walk independently with or without walking aids	Severe mental cognition dysfunction, pathological fracture, more than 24 hours before presentation, or rheumatoid or osteoarthritis	80 70-96 80%	No
Johansson, 2000 <sup>46</sup> Bachrach-Lindstrom, 2000 <sup>47</sup> Johansson, 2001 <sup>48</sup>	IF (2 screws) vs. THA	Sweden	100	75+, ambulatory prior to displaced femoral neck fracture	No major surgery contraindications, malignancy, rheumatic arthritis (anesthesiologist approval for THA before randomization)	84 75-101 74%	No
Jonsson, 1996 <sup>49</sup>	IF (2 hook pins) vs. THA	Sweden	47	Living in own home, fully ambulatory prefracture	>48 hours at admission, good candidate for THA surgery	80 67-89 77%	No

Appendix Table E3. Femoral neck evidence-2

Author, Year	Comparison	Patient Focused Outcomes	Assessment (Months)	Loss to Final Followup	Randomization Scheme	Blinded Assessment	Multivariate Adjustments
<b>Node 4 Displaced - Arthroplasty – Hemi Choices</b>							
Emery, 1991 <sup>10</sup>	Cement stem vs. not, bipolar hemi	Mortality, pain, use of walking aids, living arrangements	Mean 17 or 18 months (range 12-27 or 12-30)	26% mortality, no attrition	Randomized card in sealed envelope	No	No
Livesley, 1993 <sup>11</sup>	Ceramic coated vs. not, bipolar hemi	Mortality, complications, residence at 1 year, able to go shopping, functional assessment	12	38% mortality, no attrition	Week of hospital admission	No	No
<b>Node 4 Displaced – Internal Fixation - Cemented vs. Not Cemented Screws</b>							
Mattsson, 2006 <sup>12</sup>	IF - Calcium phosphate vs. no c.p.	Pain, walking aid, ADL, muscle strength, mobility scale, range of motion	6 weeks, 6, 12, 24	20% mortality, 21% attrition	Closed envelope system	No	No
Mattson, 2003 <sup>13</sup>	IF - Calcium phosphate vs. no c.p.	No patient outcomes	1 and 6 weeks	None	Sealed envelope system	No	No
<b>Node 3 Displaced - Arthroplasty – Uni vs. Bipolar Hemi</b>							
Raia, 2003 <sup>14</sup>	Uni vs. bipolar hemi (cemented stems)	Musculoskeletal functional assessment: mobility and ADL, SF36, Return to community ambulation	3, 12	21% mortality, 11% attrition	Closed envelope system	No	No
Cornell, 1998 <sup>15</sup>	Uni vs. bipolar hemi (cemented stems)	Range of motion, "get up and go", 6-minute walk, Johansen hip score	6	None	Random generated order, sealed envelopes, opened in operating room	Yes	No
<b>Node 3 Inclusive – Internal Fixation - Hook Pins vs. Screws</b>							
Mjorud, 2006 <sup>16</sup>	IF - 2 hook pin vs. 3 screws	Walking ability (short term only), mortality, living situation (incomplete data), re-operation	4, 12, 24	31% mortality, no attrition	Blocked randomization, sealed numbered envelopes	No	No
Lykke, 2003 <sup>17</sup>	IF - 2 hook pin vs. 3 screws	Mortality, discharge to living situation, pain (no data)	4, 12, 24	33% mortality, NR attrition	Computerized random number generation, using numbered, sealed, opaque envelopes in blocks of 50	No	No
Herngren, 1992 <sup>18</sup>	IF - 2 hook pin vs. 2 screws	Mortality, reoperations/time to complication, need for walking aid, degree of pain	1, 4, 12	18% mortality, 3% attrition	Random numbers sequence	No	No
Olerud, 1991 <sup>19</sup>	IF - 2 hook pin vs. 2 screws	Mortality, reoperations, pain when walking, pain during passive joint motion	4, 12	19% mortality, no attrition	Unclear	No	No

Appendix Table E3. Femoral neck evidence-2 (continued)

Author, Year	Comparison	Patient Focused Outcomes	Assessment (Months)	Loss to Final Followup	Randomization Scheme	Blinded Assessment	Multivariate Adjustments
<b>Node 3 Inclusive – Internal Fixation - Screws vs. Screws</b>							
Lagerby, 1998 <sup>20</sup>	IF - 2 vs. 3 screws	Mortality, reoperations/time to complication, need for walking aid, degree of pain	1, 4, 12	20% mortality, unclear attrition, at least 10%	Unclear	No	No
Rehnberg, 1989 <sup>21</sup>	IF - 2 vs. 2 screws	Mortality, pain, need for walking aids, living conditions	4, 12	26% mortality, 23% attrition	Random number table	No	No
<b>Node 2 Displaced - Arthroplasty - Hemi vs. Total Hip</b>							
Baker, 2006 <sup>22</sup>	Hemi (cemented unipolar) vs. THA	Oxford hip score, walking distance, SF36	3, 12, 36	10% mortality, 2% attrition	Sealed envelopes	No	No
Blomfeldt, 2007 <sup>23</sup>	Hemi (cemented bipolar) vs. THA	ADL, living condition	4, 12	6% mortality, 2% attrition	Sealed envelope technique	No	No
<b>Node 2 Displaced – Internal Fixation – Pins/Screws vs. Plate and Screws</b>							
Benterud, 1997 <sup>24</sup>	IF - Sliding screw plate plus screw vs. 2 screws	Mortality, reoperations/ complications	Average 29 (15-41) or average 27 (13-41)	26% mortality, unclear attrition	Unclear	No	No
Madsen, 1987 <sup>25</sup> Linde, 1986 <sup>26</sup>	IF - Sliding screw plate vs. 4 screws	Living at home, reoperations	3, 36	26% overall loss	Unclear	No	No
Paus, 1986 <sup>27</sup>	IF - Hip compression screw vs. 2 screws	Mortality, rate of union	3, 6, 12, 24	11% mortality, no attrition	Closed envelope system	No	No
Elmerson, 1995 <sup>28</sup>	IF - Sliding screw plate vs. 2 hook pin	Mortality, failure rate	6 weeks, 3, 6, 12, 24	19% mortality, 4% attrition	Random numbers table	No	No
<b>Node 1 Displaced – Internal Fixation vs. Hemi vs. Total Hip</b>							
Skinner, 1989 <sup>29</sup> Ravikumar, 2000 <sup>30</sup>	IF vs. hemi vs. THA	Mortality, pain, loss of prefracture mobility, Harris hip,	2, 12, follow up at 13 years	Mortality: 25% 1 year, 86% 13 years; Attrition 1 year, NR 13 years	Day of the week	No	No

Appendix Table E3. Femoral neck evidence-2 (continued)

Author, Year	Comparison	Patient Focused Outcomes	Assessment (Months)	Loss to Final Followup	Randomization Scheme	Blinded Assessment	Multivariate Adjustments
Keating, 2006 <sup>31</sup> Keating, 2005 <sup>32</sup>	IF vs. hemi vs. THA (mixed bag)	Hip rating questionnaire, EQ-5D, mortality, reoperation (hip outcomes also by >75 years), costs	4, 12, 24	14% mortality, 6% attrition	Allowed surgeon discretion to either 1 of 3 or 1 of 2 randomization options: a centralized, automated computer-based telephone service for randomization, stratified by surgeon with minimization on gender and age	No	Yes
Rogmark, 2002 <sup>33</sup> Rogmark 2003 <sup>34</sup>	IF vs. arthro (mixed bag)	Mortality, failure rate, outcome questionnaire	4, 12, 24	21% mortality, no attrition	Sealed, numbered, opaque envelopes	No	No
<b>Node 1 Displaced – Internal Fixation vs. Hemi</b>							
El-Abed, 2005 <sup>35</sup>	IF (DHS) vs. uncemented unipolar hemi	Matta function score, SF36, reoperation, mortality	Minimum of 36	22% mortality, NR attrition	Based on admission day	No	No
Davison, 2001 <sup>36</sup>	IF (CHS) vs. hemi, cemented uni and bipolar	Mortality, reoperation, return to pre-injury state, satisfaction, Harris hip score, Barthel home index	6 weeks, 12, 24, 36, 48, 60	23% mortality at 3 years, overall mortality and attrition 61% at 5 years	Computerized random number generation	Yes	No
Blomfeldt, 2005 <sup>37</sup>	IF (2 screws) vs. uncemented unipolar hemi	Failure/reoperation, mortality, Charnley - pain, movement, walking, ADL, EQ-5D, number with hip complications	4, 12, 24	42% mortality, 2% attrition	Sealed envelopes	No	No
Roden, 2003 <sup>38</sup>	IF (2 screws) vs. cemented bipolar hemi	Reoperations, mortality, return to pre-fracture walking, analgesic consumption	4, 12, 24, 60	NR	Sealed envelopes	No	No
Parker, 2002 <sup>39</sup> Parker, 2000 <sup>40</sup>	IF (3 screws) vs. uncemented unipolar hemi	Mortality, pain, mobility score, same walking aids, return to residential status, (some by phone, some by clinic visit), reoperations	Minimum of 12, also 24, 36	Approx 27% mortality, no attrition	Sealed, opaque, identical envelopes	No	No
Puolakka, 2001 <sup>41</sup>	IF (2 screws) vs. cemented hemi (Thompson)	Mortality, reoperations	24	47% mortality, NR attrition	Unclear	No	No

Appendix Table E3. Femoral neck evidence-2 (continued)

Author, Year	Comparison	Patient Focused Outcomes	Assessment (Months)	Loss to Final Followup	Randomization Scheme	Blinded Assessment	Multivariate Adjustments
van Dortmund, 2000 <sup>42</sup>	IF (3 screws) vs. cemented hemi (Thompson)	Mortality, wound complication	4, 12, 24	57% 1 year mortality, NR attrition	Unclear	No	No
van Vugt, 1993 <sup>43</sup>	IF (DHS) vs. cemented bipolar hemi	Clinical result score based on secondary intervention, loss of independence, pain, hip mobility score: excellent, good, moderate, poor	3, 6, 12, 24, 36	26% mortality, 2% attrition	Unclear	No	No
<b>Node 1 - Displaced – Internal Fixation vs. Total Hip</b>							
Johansson, 2006 <sup>44</sup>	IF (2 screws) vs. THA	Mortality, reoperation/dislocation, dislocation and mortality by mental impairment, Harris hip score, pain (no data) costs	3, 12, 24	29% mortality, 9% attrition	Unclear	No	No
Blomfeldt 2005 <sup>45</sup> Tidermark, 2003 <sup>50,51</sup>	IF (2 screws) vs. THA	Failure/reoperation, mortality, Charnley - pain, movement, walking, ADL, EQ-5D, number with hip complications	4, 12, 24, 48	25% mortality, 5% attrition	Sealed envelopes	No	No
Johansson, 2000 <sup>46</sup> Bachrach-Lindstrom, 2000 <sup>47</sup> Johansson 2001 <sup>48</sup>	IF (2 screws) vs. THA	Mortality, reoperation/complication, Harris hip score, dependence on help by Katz ADL	3, 12, 24	33% mortality, 9% attrition	Sequentially numbered, sealed envelopes	No	No
Jonsson, 1996 <sup>49</sup>	IF (2 hook pins) vs. THA	Use of walking aids, able to do own shopping, walking distance, pain, use of analgesics, home assistance less than 4 hours weekly	4, 12, 24	2% mortality, 26% attrition	Sealed envelopes	No	No

IF = internal fixation, THA = total hip arthroplasty

Appendix Table E4. Intertrochanteric evidence-1

Author, Year	Comparison	Country	N Enrolled	Inclusion	Exclusion	Average Age Range/SD % Female	Power Calculation Met Target
<b>Node 3 Plate/Screw Comparisons - Inclusive</b>							
Mattsson, 2005 <sup>52</sup>	EX - DHS with vs. no calcium phosphate cement	Sweden	112	65+ years, ambulatory with or without support, with unstable trochanteric fracture, 65+ years, less than 72 hours between fracture and surgery	Dementia, serious concomitant illness or mental instability, inability to perform functional tests, soft-tissue infection at operation site, cancer, pathological fracture, clotting disorder, corticosteroid treatment >5 mg/day, concurrent or bilateral fracture.	82 SD 7 or 6.3 81%	Yes Yes
Mattsson, 2004 <sup>53</sup>	EX - DHS with vs. no calcium phosphate cement	Sweden	26	Unstable IT fracture, walking without aid/one cane prior to fracture, normal contralateral hip	Senility, pathological fracture, concurrent fractures	83 66-95 85%	No
<b>Node 3 Plate/Screw Comparisons - Unstable</b>							
Moroni, 2004 <sup>54</sup>	EX - DHS with vs. no hydroxy-apatite cement	Italy	120	Osteoporosis (by DEXA analysis) with trochanteric fractures	History of previous hip fracture, open fracture, cancer, hard or soft tissue infection at fracture site, multiple fractures, poor positioning of device according to Baumgartner method.	81 SD 8 or 6 100%	Unclear
Sernbo, 1994 <sup>55</sup>	EX - CHS with vs. without locking lag screw	Sweden	200	Trochanteric hip fracture	Fractures older than 5 days, pathological fractures, subtrochanteric fractures	80 NR 82%	No
<b>Node 3 Intramedullary Nail Comparison - Inclusive</b>							
Hardy, 2003 <sup>56</sup>	IM - IMHS (1 screw) static vs. dynamic locking	Belgium	81	Fractures with loss of the medial buttress (J-M Type IV - V) or reversed oblique fracture	None stated	77 SD 11.8 and 13.1 63%	No
<b>Node 2 Intramedullary Nail Comparison - Inclusive</b>							
Efstathopoulos, 2007 <sup>57</sup>	IM - Gamma 1 screw vs. Ace Nail 2 screw construct	Greece	112	65+ with Evans-Jensen type I-IV (not specifically stated-determined from exclusion criteria)	Pathological fractures secondary to metastasis, non-ambulatory patients, ASA score V, previous ipsilateral or contralateral hip fractures	78 69-89 71%	No
Herrera, 2002 <sup>58</sup>	IM - Gamma 1 screw vs. PFN 2 screw	Spain	250	Petrochanteric fractures	None listed	79 NR 72%	No

Appendix Table E4. Intertrochanteric evidence-1 (continued)

Author, Year	Comparison	Country	N Enrolled	Inclusion	Exclusion	Average Age Range/SD % Female	Power Calculation Met Target
<b>Node 2 Plate/Screw Comparisons – Unstable</b>							
Lunsjo, 2001 <sup>59</sup>	EX - Medoff (shaft compression) vs. DHS, DHS+TSP, or DCS (by surgeon)	Sweden	569	Unstable intertrochanteric fracture	Pathological fractures, previous surgery of the proximal femur, 2-part fractures	81 42-99 67%	No
<b>Node 2 Plate/Screw Comparisons –Inclusive</b>							
Peysers, 2007 <sup>60</sup>	EX - CHS (1 screw) vs. PCCP (2 screw)	Israel	104	60+ with intertrochanteric fracture, amenable to closed reduction	AO/OTA 31.A3, pathological fractures, ipsilateral lower-limb surgery, bi-lateral hip fracture within last 12 months. Failure at closed reduction excluded 11 patients. Unavailable participating surgeons excluded another 7 patients.	82 62-95 67%	Yes Yes
Kosygan, 2002 <sup>61</sup>	EX - CHS (1 screw) vs. PCCP (2 screw)	United Kingdom	111	Extracapsular fracture	Pathological fractures, subtrochanteric fractures or subtroch extension	83 53-97 81%	No
Janzing, 2002 <sup>62</sup> Brandt, 2002 <sup>63</sup>	EX - DHS (2 screws, some with TSP) vs. PCCP	Belgium	115	60+ years with 31 A1 or A2 pertrochanteric fractures	Severe coxarthrosis of ipsilateral hip, multiple injuries, reverse or bifocal fractures	83 64-98 NR	No
Olsson, 2001 <sup>64</sup>	EX (CHS) vs. Medoff (shaft compression)	Sweden	114	Intertrochanteric fracture of the hip	Earlier surgery of the ipsilateral femur, pathological fractures	84 61-98 70%	Yes No
Watson, 1998 <sup>65</sup>	EX (CHS) vs. Medoff (shaft compression)	United States	178	Adults with acute intertrochanteric fracture	Pathological fracture, previous ipsilateral hip fracture or surgery, congenital or developmental anomaly	76 25-99 66%	No
<b>Node 2 Intramedullary Nail Comparison – Unstable</b>							
Vidyadhara, 2007 <sup>66</sup>	IM - Gamma 1 screw vs. Ace Nail 2 screw construct	India	73	60+ years with unstable trochanteric fracture	Inability to walk before injury; other fractures interfering with rehab; pathological fractures	69 61-89 49%	No
Schipper, 2004 <sup>67</sup>	IM - Gamma 1 screw vs. PFN 2 screw	Netherlands	424	60+ years with unstable trochanteric fracture, walking ability prior to fracture	Pathological fracture, other fractures interfering with rehabilitation	82 SD 8.4 or 8 82%	Yes Yes

Appendix Table E4. Intertrochanteric evidence-1 (continued)

Author, Year	Comparison	Country	N Enrolled	Inclusion	Exclusion	Average Age Range/SD % Female	Power Calculation Met Target
Fritz, 1999 <sup>68</sup>	IM - Gamma (130°) vs. Gliding Nail (125°)	Germany	80	Unstable intertrochanteric fracture	Intracapsular fractures, pathological fractures, coxarthrosis	82 NR 86%	No
<b>Node 1 Plate/Screw vs. Intramedullary Nail – Inclusive</b>							
Hardy, 1998 <sup>69</sup>	EX (CHS) vs. IM (IMHS)	Belgium	100	60+ years with an intertrochanteric fracture that allowed fixture by IHMS or CHS	Pathologic fracture, previous fracture/operation involving the ipsilateral hip, non-index fracture	81 SD 10.7 or 11.8 77%	No
Baumgaertner, 1998 <sup>70</sup>	EX (CHS plus side plate) vs. IM (IMHS)	United States	131	Intertrochanteric fracture	Pathologic fracture	79 40-99 66%	No
Utrilla, 2005 <sup>71</sup>	EX (CHS) vs. IM (T Gamma)	Spain	210	65+ years with a trochanteric fracture of the femur	Subtrochanteric fractures or subtrochanteric fracture extension, pathologic fractures, history of a previous injury involving the lower limbs, severe concomitant medical condition ASA grade V	80 65-104 69%	No
Adams, 2001 <sup>72</sup>	EX (CHS) vs. IM (Gamma - 2nd)	United Kingdom	400	Intertrochanteric fracture of the hip	Too frail for operation, residence outside hospital region	81 32-102 78%	No
Park, 1998 <sup>73</sup>	EX (CHS) vs. IM (Gamma AP)	Korea	60	Intertrochanteric fractures	None listed	73 NR 60%	No
Hoffman, 1996 <sup>74</sup>	EX (CHS) vs. IM (Gamma)	New Zealand	67	50+ years with intertrochanteric fracture	Pathologic fracture	81 SD 10.4 76%	No
Goldhagen, 1994 <sup>75</sup>	EX (CHS) vs. IM (Gamma - 2nd)	United States	75	Peritrochanteric fractures	Ipsilateral fracture or surgery of hip, congenital or developmental anomaly, fracture pattern not amenable to treatment by two methods	78 28-91 69%	No
Aune, 1994 <sup>76</sup>	EX (CHS) vs. IM (Gamma AP)	Norway	378	Trochanteric and subtrochanteric fractures	None listed	81 45-96 59%	No
Ahrengart, 2002 <sup>77</sup>	EX (CHS) vs. IM (Gamma)	Sweden/ Finland	492	Intertrochanteric fracture	Subtrochanteric fracture, pathologic fracture, previous fracture or operation on same hip, or surgeon unfamiliar with Gamma nail	80 32-99 72%	No

**Appendix Table E4. Intertrochanteric evidence-1 (continued)**

Author, Year	Comparison	Country	N Enrolled	Inclusion	Exclusion	Average Age Range/SD % Female	Power Calculation Met Target
Butt, 1995 <sup>78</sup>	EX (DHS) vs. IM (Gamma)	United Kingdom	95	Peritrochanteric fractures	Not listed	78 47-101 69%	No
O'Brien, 1995 <sup>79</sup>	EX (DHS) vs. IM (Gamma)	Canada	101	Intertrochanteric hip fractures	Fractures more than 1 week old, pathological fractures, subtrochanteric fractures	77 39-95 74%	No
Pajarinen, 2005 <sup>80</sup>	EX (DHS) vs. IM (PFN)	Finland	108	Low-energy extracapsular fracture	Pathological fracture, multiple injuries	81 SD 9.9 75%	No
Saudan, 2002 <sup>81</sup>	EX (DHS) vs. IM (PFN)	Switzerland	206	55+ years, all AO/OTA Type 31-A1 or A2 fractures caused by a low-energy injury	Pathologic fracture, fractures associated with polytrauma, previous ipsilateral hip or femur surgery, any fracture with extension five centimeters distal to the inferior border of the lesser trochanter.	83 SD 10 78%	No
Radford, 1993 <sup>82</sup>	EX (DHS) vs. IM (Gamma)	England	200	60+ years with peritrochanteric fractures	None listed	81 60-97 78%	No
Leung, 1992 <sup>83</sup>	EX (DHS) vs. IM (Gamma)	Hong Kong	225	65+ with peritrochanteric fractures	Purely subtrochanteric fractures	80 SD 9.46 71%	No
Bridle, 1991 <sup>84</sup>	EX (DHS) vs. IM (Gamma)	England	100	60+ with intertrochanteric fracture	None listed	82 NR 84%	No
<b>Node 1 Plate/Screw vs. Intramedullary Nail - Unstable</b>							
Ekstrom, 2007 <sup>85</sup>	EX (Medoff) vs. IM (PFN)	Sweden	203	Adult patients with a closed growth plate and an unstable trochanteric or subtrochanteric fracture	Two-part fracture, high-energy trauma, pathologic fracture, previous surgery of the proximal femur, an intake of daily steroid exceeding 10 mg of prednisolone, ongoing chemotherapy or irradiation treatment due to malignancy, and presence of degenerative osteoarthritis/arthritis in the injured hip.	82 48-97 76%	Yes Yes
Miedel, 2005 <sup>86</sup>	EX (Medoff) vs. IM (Gamma)	Sweden	217	Acute, unstable trochanteric or subtrochanteric fracture from a simple fall	Pathological fractures, rheumatoid or osteoarthritis, fractures extending more than 5 cm below lesser trochanter	84 SE 0.6 81%	No

**Appendix Table E4. Intertrochanteric evidence-1 (continued)**

Author, Year	Comparison	Country	N Enrolled	Inclusion	Exclusion	Average Age Range/SD % Female	Power Calculation Met Target
Papasimos, 2005 <sup>87</sup>	EX (DHS) vs. IM (T Gamma, PFN)	Greece	141	60+ years with extracapsular hip fractures	Prefracture inability to walk, pathologic fracture, previous ipsilateral hip or femur surgery, stable trochanteric fractures AO Type 31-A1, fractures with extension 5 cm distal to inferior border of lesser trochanter	81 NR 61%	No
Pajarinen, 2004 <sup>88</sup>	EX (DHS) vs. IM (PFN)	Finland	56	Unstable, low-energy pertrochanteric femoral fractures	Pathological fracture, polytraumatised patients, stable fractures (class A1) and subtrochanteric fractures (class A3)	79 49-94 80%	No
Sadowski, 2002 <sup>89</sup>	EX (DCS) vs. IM (PFN)	Switzerland	39	55+ years, 31-A3 fractures from low-energy injury	Pathological fractures, fractures from with polytrauma, a preexisting femoral deformity preventing hip screw osteosynthesis or intramedullary nailing, previous surgery on the ipsilateral hip or femur, and fractures extending 5 cm distal to the inferior border of the lesser trochanter	79 SD 14 69%	No
Harrington, 2002 <sup>90</sup>	EX (CHS) vs. IM (IMHS)	United Kingdom	102	65+ years with unstable intertrochanteric fracture	Dementia and incapable of providing informed consent, pathological fractures, concomitant fractures, previous proximal femoral fracture	83 SD 8.5 80%	No
<b>Node 1 Internal Fixation vs. Hemiarthroplasty – Unstable</b>							
Stappaerts, 1995 <sup>91</sup>	IF (CHS) vs. Endoprosthesis	Belgium	90	70+ years with unstable peritrochanteric fracture	Non-index, arthritis, fractures with subtrochanteric components	83 70-102 81%	No
Kim, 2005 <sup>92</sup>	IF (PFN) vs. uncemented calcar-replacement bipolar hemi	South Korea	58	75+ unstable comminuted intertroch fracture from low-energy injury	AO/OTA type 31-A1 or A3 fracture	82 SD 3.3 76%	No

**Appendix Table E4. Intertrochanteric evidence-1 (continued)**

Author, Year	Comparison	Country	N Enrolled	Inclusion	Exclusion	Average Age Range/SD % Female	Power Calculation Met Target
<b>Subtrochanteric Fractures</b>							
Lunsjo, 1999 <sup>93</sup>	EX - Medoff (shaft compression) vs. DHS, DHS+TSP, or DCS (by surgeon)	Sweden	107	Subtrochanteric fracture	Pathological fracture, previous surgery of proximal femur, fractures extending more than 5 cm distal	80 21-99 80%	No

See Table 2 in the report for more information about included devices

Appendix Table E5. Intertrochanteric evidence-2

Author, Year	Comparison	Subtroch Included / Classification	Patient Focused Outcomes	Assessments (Months)	Loss to Final Followup	Randomization Scheme	Blinded Assessment	Multivariate Adjustments
<b>Node 3 Plate/Screw Comparisons - Inclusive</b>								
Mattsson, 2005 <sup>52</sup>	EX - DHS with vs. no calcium phosphate cement	NR E/JM 4 - 5; AO 31 A1, A2	Pain, SF36, ADLs, strength, walking aids	1 and 6 weeks, 6	4% mortality, 13% attrition	Sealed envelope, randomization stratified by age, gender, pre-fracture mobility	No	No
Mattsson, 2004 <sup>53</sup>	EX - DHS with vs. no calcium phosphate cement	NR AO 31 A2	No patient outcomes	1 and 6 weeks, 6	NR	Closed envelope	No	No
<b>Node 3 Plate/Screw Comparisons - Unstable</b>								
Moroni, 2004 <sup>54</sup>	EX - DHS with vs. no hydroxy-apatite cement	NR AO A1, A2	Harris hip score, SF36	6	Replaced patients lost to followup	Computer generated random number list	No	No
Sernbo, 1994 <sup>55</sup>	EX - CHS with vs. without locking lag screw	Excluded Jensen; Hunter & Krajbick	No patient outcomes	4	NR	Sealed envelope	No	No
<b>Node 3 Intramedullary Nail Comparison - Inclusive</b>								
Hardy, 2003 <sup>56</sup>	IM - IMHS (1 screw) static vs. dynamic locking	NR E/JM 4-5, reverse oblique	Mortality, mobility score, pain	1, 3, 6, 12+	20% mortality, no attrition	Unclear	No	No
<b>Node 2 Plate/Screw Comparisons -Inclusive</b>								
Peysen, 2007 <sup>60</sup>	EX - CHS (1 screw) vs. PCCP (2 screw)	NR AO A1, A2	Pain, weight-bearing index, mortality	6 weeks, 3, 6, 12	NR	Computer generated, random number series, blocked in groups of 10; numbered, sealed, opaque envelopes	No	No
Kosygan, 2002 <sup>61</sup>	EX - CHS (1 screw) vs. PCCP (2 screw)	Excluded E/JM 1-5	Mortality, complications	6 weeks, 3, 6	15% mortality, no attrition	Sealed envelopes	No	No

Appendix Table E5. Intertrochanteric evidence-2 (continued)

Author, Year	Comparison	Subtroch Included / Classification	Patient Focused Outcomes	Assessments (Months)	Loss to Final Followup	Randomization Scheme	Blinded Assessment	Multivariate Adjustments
Janzing, 2002 <sup>62</sup> Brandt, 2002 <sup>63</sup>	EX - DHS (2 screws, some with TSP) vs. PCCP	NR AO A1, A2	Mortality, post-op pain, use of walking aids, living situation	1 week, 3, 6, 12	20% mortality, 8% attrition	Sealed envelopes	No	No
Olsson, 2001 <sup>64</sup>	EX (CHS) vs. Medoff (shaft compression)	NR Jensen 1 - 5	Mortality, complications, residential status, need for walking support	4	14% mortality, 7% attrition	Unseen card draw	No	No
Watson, 1998 <sup>65</sup>	EX (CHS) vs. Medoff (shaft compression)	NR E/JM 1-5 and reverse oblique	(Results by stable/unstable) Ambulation, living situation, pain, mortality, time to union	1 and 6 weeks, 3, 6, 12	10% mortality, 7% attrition	Medical record number	No	No
<b>Node 2 Plate/Screw Comparisons - Unstable</b>								
Lunsjo, 2001 <sup>59</sup>	EX - Medoff (shaft compression) vs. DHS, DHS+TSP, or DCS (by surgeon)	NR E/JM 3-5	Mortality, revision, fixation failure, residential situation, walking ability	4, 12	23% mortality, 8% attrition	Sealed envelopes	No	No
<b>Node 2 Intramedullary Nail Comparison - Inclusive</b>								
Efstathopoulos 2007 <sup>57</sup>	IM - Gamma 1 screw vs. Ace Nail 2 screw construct	NR E/JM I - IV	Mortality, mobility (also by stable/not)	1, 3, 6	17% mortality, 4% attrition	Sealed envelopes	No	No
Herrera, 2002 <sup>58</sup>	IM - Gamma 1 screw vs. PFN 2 screw	NR AO A1, A2, A3	No patient outcomes	1, 3, 6, 12	Unclear	Unclear	No	No
<b>Node 2 Intramedullary Nail Comparison - Unstable</b>								
Vidyadhara, 2007 <sup>66</sup>	IM - Gamma 1 screw vs. Ace Nail 2 screw construct	NR AO A2, A3	Harris hip score, pain, limp	1, 4, 12, 24	None reported	Computer generated random number table	No	No
Schipper, 2004 <sup>67</sup>	IM - Gamma 1 screw vs. PFN 2 screw	NR AO 31 A2, A3	Harris hip score, mortality, reoperations, complications	1, 4, 12	21% mortality, 5% attrition	Numbered, blind envelopes, computer generated randomly	No	No

Appendix Table E5. Intertrochanteric evidence-2 (continued)

Author, Year	Comparison	Subtroch Included / Classification	Patient Focused Outcomes	Assessments (Months)	Loss to Final Followup	Randomization Scheme	Blinded Assessment	Multivariate Adjustments
						permuted balanced blocks of 4 and 6 patients, stratified by participating center		
Fritz, 1999 <sup>68</sup>	IM - Gamma (130°) vs. Gliding Nail (125°)	NR AO A2, A3	Mortality, complications, living situation, Merle d'Aubigne subscale scores	6	13% mortality, 2% attrition	Unclear	No	Yes
<b>Node 1 Plate/Screw vs. Intramedullary Nail - Inclusive</b>								
Hardy, 1998 <sup>69</sup>	EX (CHS) vs. IM (IMHS)	NR E/JM 1-5	Mortality, mobility score, pain, social functioning (some by type of fracture)	1, 3, 6, 12	30% mortality, NR attrition	Medical record number	No	No
Baumgaertner, 1998 <sup>70</sup>	EX (CHS plus side plate) vs. IM (IMHS)	NR Evans/Kyle types I - IV	Mortality, return to pre-fracture living situation, return to pre-fracture mobility, pain (no group data provided)	6 weeks, 3, 6, 12, 24	22% mortality, 0% attrition	Sealed envelopes	No	No
Utrilla, 2005 <sup>71</sup>	EX (CHS) vs. IM (T Gamma)	Excluded E/JM 1-5	Pain, range of hip flexion, walking ability score, mortality, complications	1, 3, 6, 12	19% mortality, 3% attrition	Sealed envelopes	No	No
Adams, 2001 <sup>72</sup>	EX (CHS) vs. IM (Gamma - 2nd)	NR AO A1, A2, A3, B2; E/JM 1-5	Harris hip score (global), mortality, living in own home, walking independently (1 stick), reoperations, complications	3, 6, 12	30% mortality, 8% attrition	Closed, opaque envelopes	Yes	No
Park, 1998 <sup>73</sup>	EX (CHS) vs. IM (Gamma AP)	NR Tronzo II, III, IV	Time to union, complications, mobility	3	NR	Medical record number	No	No
Hoffman, 1996 <sup>74</sup>	EX (CHS) vs. IM (Gamma)	NR E/JM 1-5	Mobility, mortality, time to union, pain	6 weeks, 3, 6	19% mortality, NR attrition	Computer generated blocked	No	No

Appendix Table E5. Intertrochanteric evidence-2 (continued)

Author, Year	Comparison	Subtroch Included / Classification	Patient Focused Outcomes	Assessments (Months)	Loss to Final Followup	Randomization Scheme	Blinded Assessment	Multivariate Adjustments
Goldhagen, 1994 <sup>75</sup>	EX (CHS) vs. IM (Gamma - 2nd)	Yes Kyle; Seinsheimer	Ambulatory status, range of motion, pain, return to pre-injury functional level	6	4% mortality, 0% attrition	randomization, sealed, opaque numbered envelopes Medical record number	No	No
Aune, 1994 <sup>76</sup>	EX (CHS) vs. IM (Gamma AP)	Yes Jensen; Zickel	Reoperation	Median 17	NR	Drawing from envelopes	No	No
Ahrengart, 2002 <sup>77</sup>	EX (CHS) vs. IM (Gamma)	Excluded E/JM 1-5	Pain, use of walking aid, live at home (no outcome descriptions) (only perioperative by fracture stability)	6	Unclear	Sealed, numbered envelopes	No	No
Butt, 1995 <sup>78</sup>	EX (DHS) vs. IM (Gamma)	Yes AO (not provided)	No patient outcomes, time to union, complications	Followed until radiologic union	7% mortality, NR attrition	Week of admission	No	No
O'Brien, 1995 <sup>79</sup>	EX (DHS) vs. IM (Gamma)	Excluded Evans	No patient outcomes	12	7% mortality, NR attrition	Blind envelope selection	No	No
Pajarinen, 2005 <sup>80</sup>	EX (DHS) vs. IM (PFN)	NR AO 31 A1, A2, and "other"	Living situation, recovery to pre-fracture level, walking ability, recover walking to pre-fracture level, mortality	6 weeks, 4	6% mortality, 14% attrition	Unclear	No	No
Saudan, 2002 <sup>81</sup>	EX (DHS) vs. IM (PFN)	Excluded AO 31 A1, A2	Mortality, complications, reoperations, living situation, pain, social function, mobility score, consolidation	3, 6, 12	14% mortality, 4% attrition	Computer generated randomization	No	No
Radford, 1993 <sup>82</sup>	EX (DHS) vs. IM (Gamma)	NR Evans	No patient outcomes	3, 12	NR	Not reported	No	No
Leung, 1992 <sup>83</sup>	EX (DHS) vs. IM (Gamma)	Excluded (subtroch extension included) E/JM 1-5	Mean time to full weight bearing, mobility, hip range of motion, pain in hip or thigh	6-12	12% mortality, 7% attrition	Sequence of admission	No	No

Appendix Table E5. Intertrochanteric evidence-2 (continued)

Author, Year	Comparison	Subtroch Included / Classification	Patient Focused Outcomes	Assessments (Months)	Loss to Final Followup	Randomization Scheme	Blinded Assessment	Multivariate Adjustments
Bridle, 1991 <sup>84</sup>	EX (DHS) vs. IM (Gamma)	NR Evans	Mobility, mortality, pain, living situation	6	34% mortality, NR attrition	Unclear	No	No
<b>Node 1 Plate/Screw vs. Intramedullary Nail - Unstable</b>								
Ekstrom, 2007 <sup>85</sup>	EX (Medoff) vs. IM (PFN)	Yes E/JM 3-5; Seinsheimer 1-5; AO 31 A2, A3, 32 A1, B1	Mortality, mobility, pain, isometric abductor strength, living situation, union, complications (by inter/sub type)	6 weeks, 4, 12	16% mortality, 25% attrition	Numbered, sealed envelopes, computer generated list, stratified by intertroch/subtroch	No	No
Miedel, 2005 <sup>86</sup>	EX (Medoff) vs. IM (Gamma)	Yes E/JM 3 - 5, Subtroch S2B-C, S3A-B, S4, S5	(Some results by type of troch/sub) Mortality, revisions, ADL, EQ-5D, Charnley	4, 12	25% mortality, 10% attrition	Sealed envelopes	No	No
Papasimos, 2005 <sup>87</sup>	EX (DHS) vs. IM (T Gamma, PFN)	Excluded AO 31 A2, A3	Salvati & Wilson hip score, (return to pre-fracture ambulation level and independence - no data), Union	12	7% mortality, 8% attrition	Unclear	No	No
Pajarinen, 2004 <sup>88</sup>	EX (DHS) vs. IM (PFN)	Excluded AO 31A, A2	No patient outcomes	6 weeks 4	4% mortality, 11% attrition	Unclear	No	No
Sadowski, 2002 <sup>89</sup>	EX (DCS) vs. IM (PFN)	Yes AO 31 A3	Mortality, complications, reoperations, hip/thigh pain, social function, mobility score, residence	3, 6, 12	8% mortality, 3% attrition	Computer generated random numbers	No	No
Harrington, 2002 <sup>90</sup>	EX (CHS) vs. IM (IMHS)	NR E/JM 3-5	Ambulation, return to pre-fracture living situation	3, 5, 12	25% mortality, NR attrition	Sealed envelope	Yes	No
<b>Node 1 Internal Fixation vs. Hemiarthroplasty - Unstable</b>								
Stappaerts, 1995 <sup>91</sup>	IF (CHS) vs. endoprosthesis	Excluded AO A2; Evans/ Jensen 1C-1D	(Restricted to pre-fracture independent patients) Functional capacity	3	17% mortality, NR attrition	Unclear	No	No

Appendix Table E5. Intertrochanteric evidence-2 (continued)

Author, Year	Comparison	Subtroch Included / Classification	Patient Focused Outcomes	Assessments (Months)	Loss to Final Followup	Randomization Scheme	Blinded Assessment	Multivariate Adjustments
Kim, 2005 <sup>92</sup>	IF (PFN) vs. uncemented calcar-replacement bipolar hemi	NR AO A2; E/JM 3 - 4	Harris hip score, ADL, Mini mental status, ASA, mortality, reoperations/ complications	6 weeks, 3, 6, 12, average 35	36% mortality, no attrition	Computer generated random numbers	No	No
<b>Subtrochanteric Fractures</b>								
Lunsjo, 1999 <sup>93</sup>	EX - Medoff (shaft compression) vs. DHS, DHS+TSP, or DCS (by surgeon)	Sein-sheimer 1-5	Mortality, failure, walking aids, living situation	4, 12	15% mortality, 9% attrition	Sealed envelopes	No	No

Appendix Table E6. Femoral neck - categorical pain outcomes from studies with extractable data

Author, Year	Describe Outcome Measure	Group 1 N	% Group 1 with Outcome	Group 2 N	% Group 2 with Outcome	Assessment Period
<b>Node 4 Arthroplasty - Hemi - Cemented vs. Not Cemented</b>						
Emery, 1991 <sup>10</sup>	No pain in hip (no specifics)	19	Cement 68%	20	None 20%	17 months average
<b>Node 4 Arthroplasty - Hemi - Ceramic Coating vs. No Coating</b>						
None						
<b>Node 4 Internal Fixation - Cemented vs. Not Cemented Screws</b>						
None						
<b>Node 3 Arthroplasty - Hemi - Unipolar vs. Bipolar (Cemented)</b>						
None						
<b>Node 3 Internal Fixation - Screws vs. Screws</b>						
Lagerby, 1998 <sup>20</sup>	No pain, walk or passive (full group)	75	Richard 63%	86	Uppsala 64%	1 year
	No pain, walk or passive (not displaced)	25	64%	30	70%	1 year
	No pain, walk or passive (displaced)	50	62%	56	61%	1 year
<b>Node 3 Internal Fixation - Screw vs. Hook Pins</b>						
Herngren, 1992 <sup>18</sup>	No severe pain, walking or passive	96	Screw 89%	84	Hook pin 87%	4 months
<b>Node 2 Arthroplasty - Hemi vs. Total Hip</b>						
None						
<b>Node 2 Internal Fixation – Pins/Screws vs. Sliding Hip Screws</b>						
None						
<b>Node 1 Internal Fixation vs. Hemi (Cemented and Not) Arthroplasty</b>						
Roden, 2003 <sup>38</sup>	No use of analgesics	44	52%	44	86%	4 months
Parker, 2002 <sup>39</sup>	Little or no pain, hemi vs. IF	163	56%	160	45%	1 year
		105	79%	123	72%	2 years
		74	73%	91	74%	3 years
<b>Node 1 Internal Fixation vs. Total Hip Arthroplasty</b>						
Jonsson, 1996 <sup>49</sup>	No pain walking	23	39%	24	46%	4 months
		23	57%	24	33%	1 year
		23	57%	24	46%	2 years
		23	57%	24	58%	2 years
<b>Node 1 Internal Fixation vs. Arthroplasty</b>						
Rogmark, 2002 <sup>33</sup>	Hip pain: self-report	162	61%	170	34%	4 months
		116	43%	148	25%	1 year
		84	32%	125	25%	2 years

Appendix Table E7. Femoral neck - continuous pain outcomes from studies with extractable data

Author, Year	Outcome Measure	Group 1	Mean	SD (Range)	Group 2 N	Mean	SD (Range)	Assessment Period	Estimate
<b>Node 4 Arthroplasty - Hemi - Cemented vs. Not Cemented</b>									
None									
<b>Node 4 Arthroplasty - Hemi - Ceramic Coating vs. No Coating</b>									
None									
<b>Node 4 Internal Fixation - Cemented vs. Not Cemented Screws</b>									
Mattsson, 2006 <sup>12</sup>	VAS, pain with activity	Augmented 17	9	8	Control 26	7	9	24 months	NS
<b>Node 4 Internal Fixation - Screws vs. Screws</b>									
Rehnberg, 1989 <sup>21</sup>	Pain (no specifics), 4 point scale	Uppsala 88 64	1.12 1.02	0.36 0.12	vonBahr 77 51	1.4 1.24	0.59 0.42	4 months 1 year	p <.001 p <.01
<b>Node 3 Arthroplasty - Hemi - Unipolar vs. Bipolar (Cemented)</b>									
None									
<b>Node 3 Internal Fixation - Screws vs. Hook Pins</b>									
None									
<b>Node 2 Arthroplasty - Hemi vs. Total Hip</b>									
Blomfeldt, 2007 <sup>23</sup>	Harris hip pain score	Hemi 58 55	40 39.1	(20 - 44) (20 - 44)	THA 58 56	42 43.1	(20 - 44) (20 - 44)	4 months 1 year	p=0.121 p <.001
Keating, 2006 <sup>31</sup>	Hip rating questionnaire, pain	62 61 56	19.4 21.1 20.5	5 4 5	64 61 59	19.3 20.4 20.9	4 5 5	4 months 1 year 2 years	
<b>Node 2 Internal Fixation - Pins/Screws vs. Sliding Hip Screws</b>									
None									
<b>Node 1 Internal Fixation vs. Hemiarthroplasty (Cemented and Not)</b>									
Keating, 2006 <sup>31</sup>	Hip rating questionnaire, pain	111 101 92	16.8 18.8 19.7	6 6 6	102 97 86	19.2 21 20.6	5 4 5	4 months 1 year 2 years	
<b>Node 1 Internal Fixation vs. Total Hip</b>									
Keating, 2006 <sup>31</sup>	Hip rating questionnaire, pain	63 61 58	17.2 18.7 19.5	6 6 6	64 61 59	19.3 20.4 20.9	4 5 5	4 months 1 year 2 years	

Appendix Table E8. Femoral neck – categorical functional outcomes from studies with extractable data

Author, Year	Outcome Measure	Group 1 N	% Group 1 with Outcome	Group 2 N	% Group 2 with Outcome	Assessment Period
<b>Node 4 Internal Fixation - Cemented vs. Not Cemented Screws</b>						
	None					2 years
<b>Node 4 Arthroplasty - Hemi - Cemented vs. Not Cemented</b>						
Emery, 1991 <sup>10</sup>	No walking aids	19	Cement 58%	None 20	None 20%	17 months
	Living situation, home vs. institution	19	84%	20	75%	17 months
<b>Node 4 Arthroplasty - Hemi - Ceramic coating vs. No coating</b>						
Livesley, 1993 <sup>11</sup>	Able to go shopping	32	41%	20	20%	1 year
	Living at home	32	59%	20	75%	1 year
<b>Node 3 Arthroplasty - Hemi - Unipolar vs. Bipolar (cemented)</b>						
Raia, 2003 <sup>14</sup>	Return to community walker	31	Unipolar 74%	Bi 29	Bipolar 72%	1 year
<b>Node 3 Internal Fixation - Screws vs. Screws</b>						
Laberby, 1998 <sup>20</sup>	No (or 1) walking aid, total	74	Richards 47%	86	Uppsala 52%	1 year
	No (or 1) walking aid, stable	25	48%	30	67%	1 year
	No (or 1) walking aid, unstable	49	47%	56	45%	1 year
Rehnberg, 1989 <sup>21</sup>	Living in own home	88	Uppsala 77%	77	vanBahr 70%	4 months
		64	77%	51	84%	1 year
<b>Node 3 Internal Fixation – Screw vs. Hook Pins</b>						
Lykke, 2003 <sup>17</sup>	Return to own home	72	Screw 63%	98	Hook pin 60%	4 month
	Living in NH	131	37%	147	39%	1 year
<b>Node 2 Arthroplasty - Hemi vs. Total Hip</b>						
Blomfeldt, 2007 <sup>23</sup>	Independent living vs. NH status	58	Hemi 97%	58	THA 93%	4 months
		55	96%	56	96%	1 year
<b>Node 2 Internal Fixation – Sliding Hip Screws vs. Pins/Screws</b>						
None						
<b>Node 1 Internal Fixation vs. Hemi (Cemented and Not)</b>						
Blomfeldt, 2005 <sup>37</sup>	Independent living status		IF 11%	17	THA 35%	2 years
El-Abed, 2005 <sup>35</sup>	Matta score excellent/good	62	42%	60	70%	3 years
Roden, 2003 <sup>38</sup>	Walk as well as pre-op	40	43%	44	70%	4 months
Roden, 2003 <sup>38</sup>	Return to original residence	53	85%	47	79%	
Parker, 2002 <sup>39</sup>	Use same walking aid	166	37%	164	40%	1 year
	Same residential status	162	83%	164	82%	1 year
Van Dortmont, 2000 <sup>42</sup>	Retained mobility	19	37%	17	24%	4 months
		18	21%	17	18%	1 year

Table E8. Femoral neck – categorical functional outcomes from studies with extractable data (continued)

Author, Year	Outcome Measure	Group 1 N	% Group 1 with Outcome	Group 2 N	% Group 2 with Outcome	Assessment Period	
<b>Node 1 Internal Fixation vs. Total Hip</b>							
Jonsson, 1996 <sup>49</sup>	No (or 1) walking aid		OR	95% CI		4 months	
				(0.5-5)		1 year	
	Able to do own shopping				(2-88)		2 years
					(1.6-33)		4 months
	Walk 1 kilometer or more		1.5				1 year
							13
		7.1				4 months	
		1.7				1 year	
				(0.6-9)		2 years	
				(0.8-10)		4 months	
				(0.4-78)		1 year	
				(0.5-7)		2 years	
<b>Node 1 Internal Fixation vs. Arthroplasty</b>							
Rogmark,2002 <sup>33</sup>	Need walking aid: self-report		66%	170	47%	4 months	
				162	46%	1 year	
				116	54%	2 years	
	Reduced mobility: self-report		72%	170	44%	4 months	
				116	33%	1 year	
				84	25%	2 years	

Appendix Table E9. Femoral neck - continuous functional outcomes from studies with extractable data

Author, Year	Outcome Measure	Group 1 N	Mean	SD (Range)	Group 2 N	Mean	SD (Range)	Assessment Period
<b>Node 4 Arthroplasty - Hemi - Cemented vs. Not Cemented</b>								
None								
<b>Node 4 Arthroplasty - Hemi - Ceramic Coating vs. No Coating</b>								
None								
<b>Node 4 Internal Fixation - Cemented vs. Not Cemented Screws</b>								
None								
<b>Node 3 Arthroplasty - Hemi - Unipolar vs. Bipolar (Cemented)</b>								
Cornell, 1998 <sup>15</sup>	6 minute walk (average speed feet/second)	Uni 15	1.93	0.8	Bi 33	2.67	( 0.77-4.86)	6 months
	Johansen hip score	15	64.9	15	33	63.2	15	6 months
<b>Node 3 Internal Fixation - Screws vs. Screws</b>								
Rehnberg, 1989 <sup>21</sup>	Need for walking aid	Uppsala 88	1.52	0.64	vonBahr 77	1.96	1.35	4 months
		64	1.48	0.64	51	1.7	0.66	1 year
<b>Node 3 Internal Fixation - Hook Pins vs. Screws</b>								
None								
<b>Node 2 Arthroplasty - Hemi vs. Total Hip</b>								
Baker, 2006 <sup>22</sup>	Walking distance (miles)	Hemi 33	1.17	(0-4)	THR 36	2.23	(0-25)	3 years
	Oxford Hip Score (global)	33	22.3	(12-48)	36	18.8	(12-47)	3 years
Blomfeldt, 2007 <sup>23</sup>	Harris hip function scores	58	40	(20-44)	58	42	(20-44)	4 months
		55	39.1	(20-44)	56	43.1	(20-44)	1 year
Baker, 2006 <sup>22</sup>	SF36 physical	33	38.1	(16-58.8)	36	40.53	(16.2-56.5)	3 years
	SF36 mental	33	55.32	(39-66.6)	36	52	(24.2-68.4)	3 years
Keating, 2006 <sup>31</sup>	EQ-5D, worse health level	62		Adjusted OR	64	1.01	CI 0.40 - 2.53	4 months
		61		Adjusted OR	61	1.08	CI 0.44 - 2.64	1 year
		56		Adjusted OR	59	0.89	CI 0.37 - 2.13	2 years
<b>Node 2 Internal Fixation - Screws vs. Sliding Hip Screws</b>								
None								
<b>Node 1 Internal Fixation vs. Hemi (Cemented and Not)</b>								
El-Abed, 2005 <sup>35</sup>	SF-36 mean percentile score.	62	50	(26-77)	60	74	(39-90)	
Keating, 2006 <sup>31</sup>	EQ-5D, worse health level.	111		Adjusted OR	102	0.45	CI 0.23 - 0.86	4 months
		101		Adjusted OR	97	0.73	CI 0.38 - 1.41	1 year
		92		Adjusted OR	86	1.01	CI 0.52 - 1.97	2 years
<b>Node 1 Internal Fixation vs. Total Hip</b>								
Keating, 2006 <sup>31</sup>	EQ-5D, worse health level.	63		Adjusted OR	64	0.49	CI 0.21 - 1.17	4 months
		61		Adjusted OR	61	0.74	CI 0.32 - 1.74	1 year
		58		Adjusted OR	59	0.81	CI 0.34 - 1.93	2 years

Appendix Table E10. Femoral neck mortality

Author, Year	Group 1 N	% Group 1 Mortality	Group 2 N	% Group 2 Mortality	Assessment Period
<b>Node 4 Arthroplasty - Hemi - Cemented vs. Not Cemented</b>					
Emery, 1991 <sup>10</sup>	Cement		Control		
	27	7%	26	4%	3 months
	27	30%	26	23%	17 months average
<b>Node 4 Arthroplasty - Hemi - Ceramic Coating vs. No Coating</b>					
Livesley, 1993 <sup>11</sup>	Ceramic		Control		
	48	33%	34	41%	1 year
<b>Node 4 Internal Fixation - Cemented vs. Not Cemented Screws</b>					
Mattsson, 2006 <sup>12</sup>	Augmented		Control		
	58	17%	60	13%	6 months
	58	22%	60	17%	1 year
<b>Node 3 Arthroplasty - Hemi - Unipolar vs. Bipolar (Cemented)</b>					
Raia, 2003 <sup>14</sup>	Uni		Bi		
	60	20%	55	22%	1 year
Cornell, 1998 <sup>15</sup>		7%	33	6%	6 months
<b>Node 3 Internal Fixation - Screws vs. Screws</b>					
None					
<b>Node 3 Internal Fixation - Hook Pins vs. Screws</b>					
Mjorud, 2006 <sup>16</sup>	Screw		Hookpin		
	101	13%	98	13%	4 months
Lykke, 2003 <sup>17</sup>	101	19%	98	18%	1 year
	131	15%	147	10%	4 months
Herngren, 1992 <sup>18</sup>	131	34%	147	33%	2 years
	96	22%	84	14%	1 year
Olerud, 1991 <sup>19</sup>	59	24%	56	14%	1 year
<b>Node 2 Internal Fixation Pins/Screws vs. Sliding Hip Screws</b>					
Elmerson, 1995 <sup>28</sup>	SHS		Hookpin		
	100	11%	122	7%	1 year
	52	17%	78	19%	2 years
Benterud, 1997 <sup>24</sup>	SHS		Screw		
	108	10%	117	9%	3 months
Paus, 1986 <sup>27</sup>	66	8%	65	14%	18 months average
<b>Node 2 Arthroplasty - Hemi vs. Total</b>					
Baker, 2006 <sup>22</sup>	Hemi		THA		
	41	17%	40	8%	3 years
Blomfeldt, 2007 <sup>23</sup>	60	3%	60	3%	4 months
	60	5%	60	7%	1 year
Keating, 2006, <sup>31</sup> Keating, 2005 <sup>32</sup>	69	13%	69	9%	2 years
Ravikumar, 2000 <sup>30</sup>	91	15%	89	10%	2 months
	91	27%	89	22%	1 year
	91	86%	89	81%	13 years
<b>Node 1 Internal Fixation vs. Hemiarthroplasty (Cemented and Not)</b>					
Keating, 2006, <sup>31</sup> Keating, 2005 <sup>32</sup>	118	15%	111	16%	2 years
El-Abed, 2005 <sup>35</sup>	62	35%	60	20%	3 years
Blombeldt, 2005 <sup>37</sup>	30	13%	30	17%	4 months
	30	23%	30	33%	1 year
Roden, 2003 <sup>38</sup>	30	60%	30	43%	2 years
	53	13%	47	9%	2 years
Paulakka, 2001 <sup>41</sup>	53	53%	47	43%	5-6 years
	17	6%	15	7%	3 months
Parker, 2000 <sup>40</sup>	17	47%	15	47%	2 years
	102	5%	106	7%	1 months
	102	26%	106	29%	1 year
	102	34%	106	40%	2 years
	102	45%	106	58%	3 years

Table E10. Femoral neck mortality (continued)

Author, Year	Group 1 N	% Group 1 Mortality	Group 2 N	% Group 2 Mortality	Assessment Period
Ravikumar, 2000 <sup>30</sup>	91	12%	91	15%	2 months
	91	25%	91	27%	1 year
	91	90%	91	86%	13 years
Davison, 2001 <sup>36</sup>	IF		Uni+Bi		
	100	5%	200	9%	6 months
	100	9%	200	12%	1 year
	100	12%	200	19%	2 years
Parker, 2000 <sup>40</sup>	100	19%	200	25%	3 years
	106	7%	102	5%	30 days
	106	29%	102	26%	1 year
	106	40%	102	34%	2 years
Van Dortmont, 2000 <sup>42</sup>	106	58%	102	45%	3 years
	31	35%	29	34%	4 months
	31	65%	29	48%	1 year
Van Vugt, 1993 <sup>43</sup>	21	10%	22	23%	1 year
	21	19%	22	23%	2 years
<b>Node 1 Internal Fixation vs. Total Hip</b>					
Keating, 2006, <sup>31</sup> Keating, 2005 <sup>32</sup>	69	13%	69	9%	2 years
Blomfeldt, 2005 <sup>45</sup>	53	25%	49	24%	4 years
Jonsson, 1996 <sup>49</sup>	23	4%	24	0%	1 month
Ravikumar, 2000 <sup>30</sup>	91	12%	89	10%	2 months
	91	25%	89	22%	1 year
	91	90%	89	81%	13 years
<b>Node 1 Internal Fixation vs. Arthroplasty</b>					
Rogmark, 2002 <sup>33</sup>	217	5%	192	7%	4 months
	217	12%	192	15%	1 year
	217	21%	192	21%	2 years

Appendix Table E11. Intertrochanteric - categorical functional/pain outcomes from studies with extractable data

Outcome Measure (by Node and Comparison)	Author, Year	Group 1 N	% Group 1 with Outcome	Group 2 N	% Group 2 with Outcome	Assessment Period	Subtroch Involvement	
<b>Node 3 Plate/Screw Comparisons - Inclusive</b>								
None								
<b>Node 3 Plate/Screw Comparisons - Unstable</b>								
None								
<b>Node 3 Intramedullary Nail Comparisons - Inclusive</b>								
				Standard Locking				
Functional thigh pain (no specifics)	Hardy, 2003 <sup>56</sup>		20%	Dynamic Locking	34	6%	1 year	NR
<b>Node 2 Plate/Screw Comparisons - Inclusive</b>								
		SHS						
Mobility: walk without help	Janzing, 2002 <sup>62</sup>	39	54%	44	36%	1 year	NR	
Residence: independent	Janzing, 2002 <sup>62</sup>	39	59%	44	45%	1 year	NR	
		SHS		MSP				
Return to independent walking	Olsson, 2001 <sup>63</sup>	23	26%	21	24%	4 months	NR	
Return to living in own home	Olsson, 2001 <sup>64</sup>	36	69%	32	75%	4 months	NR	
<b>Node 2 Plate/Screw Comparisons - Unstable</b>								
		SHS group		MSP				
Return to independent walking	Lunsjo, 2001 <sup>59</sup>		36%	105	50%	1 year	NR	
Return to living in own home	Lunsjo, 2001 <sup>59</sup>		73%	150	77%	1 year	NR	
<b>Node 2 Intramedullary Nail Comparisons - Inclusive</b>								
Return to pre-fracture mobility	Efstathopoulos, 2007 <sup>57</sup>	41	66%	Ace TN	47	64%	8 months average	NR
<b>Node 2 Intramedullary Nail Comparisons - Unstable</b>								
		99		Ace TN				
Hip pain (not described)	Vidyadhara, 2007 <sup>66</sup>	140	11%	36	6%	1 month	NR	
Thigh pain (not described)	Vidyadhara, 2007 <sup>66</sup>	37	5%	36	1%	1 month	NR	
<b>Node 1 Plate/Screw vs. Intramedullary Nail - Inclusive</b>								
		SHS						
Recovery of abilities to pre-op status	Pajarinen, 2005 <sup>80</sup>	37	41	78%	42	81%	4 months	NR
Recovery of walking to pre-op status	Pajarinen, 2005 <sup>80</sup>		41	54%	42	76%	4 months	NR
Walking ability No aids needed	Pajarinen, 2005 <sup>80</sup>		41	29%	42	36%	4 months	NR
In need of aids, but independent	Pajarinen, 2005 <sup>80</sup>		41	54%	42	57%	4 months	NR
Residence: own home	Pajarinen, 2005 <sup>80</sup>		41	54%	42	57%	4 months	NR
Residence: own home	Saudan, 2002 <sup>81</sup>		89	56%	79	47%	1 year	Excluded
				Gamma				
Hip pain (not described)	Utrilla, 2005 <sup>71</sup>		81	54%	82	50%	1 year	Excluded
Thigh pain (not described)	Utrilla, 2005 <sup>71</sup>		81	56%	82	61%	1 year	Excluded
Lateral pain over femoral head screw	Ahrengart, 2002 <sup>77</sup>			26%	169	27%	6 months	Excluded
Pain at top of greater trochanter	Ahrengart, 2002 <sup>77</sup>			6%	169	20%	6 months	Excluded
Needs walking aid	Ahrengart, 2002 <sup>77</sup>			70%	169	71%	6 months	Excluded
Lives at home	Ahrengart, 2002 <sup>77</sup>			38%	169	65%	6 months	Excluded
Residence: own home	Adams, 2001 <sup>72</sup>	179	63%	126	60%	1 year	NR	
		179						
		179						
		179						
	SHS	179						

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Table E11. Intertrochanteric - categorical functional/pain outcomes from studies with extractable data (continued)

Outcome Measure (by Node and Comparison)	Author, Year	Group 1 N	% Group 1 with Outcome	Group 2 N	% Group 2 with Outcome	Assessment Period	Subtroch Involvement
Walking independently	Adams, 2001 <sup>72</sup>		45%	126	44%	1 year	NR
Walking: no support or 1 stick	Park, 1998 <sup>73</sup>	30	70%	30	80%	3 months	NR
Resolution of hip pain	Hoffman, 1996 <sup>74</sup>	31	71%	23	61%	6 months	NR
IT: Community ambulator with or without aid	Goldhagen, 1994 <sup>75</sup>	34	38%	28	36%	6 months	Included
Sub: Community ambulatory with or without aid	Goldhagen, 1994 <sup>75</sup>	4	50%	6	17%	6 months	Included
IT: Household ambulator	Goldhagen, 1994 <sup>75</sup>	34	15%	28	21%	6 months	Included
Sub: Household ambulator	Goldhagen, 1994 <sup>75</sup>		50%	6	50%	6 months	Included
Stable: hip pain	Leung, 1992 <sup>83</sup>	20	25%	30	27%	~7 months average	Excluded
Unstable: hip pain	Leung, 1992 <sup>83</sup>	73	37%	63	22%	~7 months average	
Stable: thigh pain	Leung, 1992 <sup>83</sup>	20	25%	30	13%	~7 months average	
Unstable: thigh pain	Leung, 1992 <sup>83</sup>	73	4%	63	11%	~7 months average	
Stable: independent mobility	Leung, 1992 <sup>83</sup>	20	40%	30	40%	~7 months average	
Unstable: independent mobility	Leung, 1992 <sup>83</sup>	73	32%	63	35%	~7 months average	
		SHS		IMHS			
Hip pain, walking	Hardy, 1998 <sup>69</sup>	35	6%	35	6%	1 year	NR
Thigh pain, walking	Hardy, 1998 <sup>69</sup>		6%	35	20%	1 year	NR
Hip pain (no specifics)	Baumgaertner, 1998 <sup>70</sup>	52	21%	53	28%	Latest followup	NR
<b>Node 1 Plate/Screw vs. Intramedullary Nail - Unstable</b>							
		SHS		IMHS			
Return to previous living status	Harrington, 2002 <sup>90</sup>	33	67%	30	63%	6 months	NR
		MSP					
Walk 15 meters without any aid	Ekstrom, 2007 <sup>85</sup>	56	88%	64	91%	12 months	Included
Rise from chair without any arm support	Ekstrom, 2007 <sup>85</sup>	56	54%	64	52%	12 months	Included
Walking aid: none or 1 crutch,	Ekstrom, 2007 <sup>85</sup>	56	38%	64	41%	12 months	Included
		DCS					
Living at home	Sadowski, 2002 <sup>89</sup>	17	29%	18	50%	1 year	Included
<b>Node 1 Plate/Screw vs. Hemiarthroplasty - Unstable</b>							
None							
<b>Subtrochanteric</b>							
				MSP			
Return to walking without aid	Lunsjo, 1999 <sup>93</sup>	23	35%	30		1 year	Included
Return to own home	Lunsjo, 1999 <sup>93</sup>	31	81%	36		1 year	Included

Appendix Table E12. Intertrochanteric - continuous functional/pain outcomes from studies with extractable data

Outcome Measure	Author, Year	Group 1 N	Mean	SD (Range)	Group 2 N	Mean	SD (Range)	Assessment Period	Subtroch Involvement
<b>Node 3 Plate/Screw Comparisons - Inclusive</b>									
			Control			HA coated			
Harris hip score (global)	Moroni, 2004 <sup>54</sup>	60	63	22	60	70	18	6 months	NR
SF 36 (global)	Moroni, 2004 <sup>54</sup>	60	56	24	60	62	20	6 months	NR
<b>Node 3 Plate/Screw Comparisons - Unstable</b>									
			Control			Cement			
VAS pain (global)	Mattsson, 2005 <sup>52</sup>	49	28	12	45	14	11	6 weeks	NR
VAS pain (global)	Mattsson, 2005 <sup>52</sup>		9	11	45	7	9	6 months	NR
VAS functional pain, walking 10 feet	Mattsson, 2005 <sup>52</sup>	49	32	15	45	17	10	6 weeks	NR
VAS functional pain, walking 10 feet	Mattsson, 2005 <sup>52</sup>	49	11	10	45	7	9	6 months	NR
VAS functional pain, walking 50 feet	Mattsson, 2005 <sup>52</sup> 49	49	31	17	45	17	12	6 weeks	NR
VAS functional pain, walking 50 feet	Mattsson, 2005 <sup>52</sup>	49	12	13	45	7	10	6 months	NR
<b>Node 3 Intramedullary Nail Comparisons - Inclusive</b>									
None									
<b>Node 3 Intramedullary Nail Comparisons - Unstable</b>									
None									
<b>Node 2 Plate/Screw Comparisons - Inclusive</b>									
			SHS			PCCP			
VAS pain score (range), single leg stance	Peyser, 2007 <sup>60</sup>	20	5.8	(0 to 10)	14	3.9	(0 to 10)	6 weeks	NR
		20	3.4	(0 to 7)	15	3.4	(0 to 7)	3 months	
		15	3.4	(0 to 10)	12	2.6	(0 to 6)	6 months	
<b>Node 2 Plate/Screw Comparisons - Unstable</b>									
None									
<b>Node 2 Intramedullary Nail Comparisons - Inclusive</b>									
			Gamma			Ace TN			
Parker mobility score (mean), total	Efstathopoulos, 2007 <sup>57</sup>	41	7	2.1	47	7.1	2.5	8 months mean	NR
Parker mobility score (mean), unstable	Efstathopoulos, 2007 <sup>57</sup>	32	5.4	2.5	39	5	1.9	8 months mean	NR

Table E12. Intertrochanteric - categorical functional/pain outcomes from studies with extractable data (continued)

Outcome Measure	Author, Year	Group 1 N	Mean	SD (Range)	Group 2 N	Mean	SD (Range)	Assessment Period	Subtroch Involvement
<b>Node 2 Intramedullary Nail Comparisons - Unstable</b>									
Harris hip score (global)	Vidyadhara, 2007 <sup>66</sup>	37	Gamma		36	Ace		4 months 1 year 2 years	NR
			91	2		93	3		
			95	2		96	1		
Harris hip score (global)	Schipper, 2004 <sup>67</sup>	139	Gamma	(SEM)	140	PFN	(SEM)	1 months 4 months 1 year	NR
			53.9	1.5		52.6	1.5		
			62	1.7		61.9	1.6		
		64	69.5	2	73	66.8	2.1		
<b>Node 1 Plate/Screw vs. Intramedullary Nail - Inclusive</b>									
Parker-Palmer scale: Total: walking ability	Utrilla, 2005 <sup>71</sup>	81	SHS 6.2	2.8	82	Gamma 6.4	2.8	1 year	Excluded
Parker-Palmer scale: Unstable: walking ability	Utrilla, 2005 <sup>71</sup>	81	5.8	2.7	82	7	2.1	1 year	Excluded
Parker-Palmer scale: Stable: walking ability	Utrilla, 2005 <sup>71</sup>	81	7.3	2.4	82	7.6	2.2	1 year	Excluded
Pain: 4 point scale	Saudan, 2002 <sup>81</sup>	89	SHS 1.31	0.63	79	PFN 1.36	0.63	1 year	Excluded
Palmer Parker mean mobility score	Saudan, 2002 <sup>81</sup>		5.07	2.97	79	4.94	3.33	1 year	Excluded
Jensen social function (mean)	Saudan, 2002 <sup>81</sup>	89	2.65	1.14	79	2.88	1.16	1 year	Excluded
Parker/Palmer mobility score (global)	Hardy, 1998 <sup>69</sup>	38 35	SHS 3.2 3.4	3.1 3.3	37 35	IMHS 4.6 4.8	3.1 3.2	6 months 1 year	NR
<b>Node 1 Plate/Screw vs. Intramedullary Nail - Unstable</b>									
Hip/thigh pain score: 0 none, 4: severe	Sadowski, 2002 <sup>89</sup>	10	DCS 1.77	PFN 0.73	18	1.44	0.86	1 year	Included
Jensen social function	Sadowski, 2002 <sup>89</sup>	10	2.5	1.3	18	2.6	1	1 year	Included
Parker/Palmer score	Sadowski, 2002 <sup>89</sup>		6	3.5	18	5	2.6	1 year	Included
<b>Node 1 Internal Fixation vs. Hemiarthroplasty - Unstable</b>									
Harris hip score (global)	Kim, 2005#108	29	PFN 80	9.7	29	Hemi 82	12.4	Latest	NR
<b>Subtrochanteric</b>		10							
None									

Appendix Table E13. Intertrochanteric mortality

Author, Year	Group 1 N	Group 1 % Mortality	Group 2 N	Group 2 % Mortality	Assessment Period	Subtroch Involvement
<b>Node 3 Plate/Screw Comparisons - Inclusive</b>						
Moroni, 2004 <sup>54</sup>						NR
Sernbo, 1994 <sup>94</sup>						Excluded
<b>Node 3 Plate/Screw Comparisons - Unstable</b>						
	Control		HA Cement			
Mattsson, 2004 <sup>53</sup>						NR
	NR by group					
Mattsson, 2005 <sup>52</sup>	57	4%	55	5%	6 months	NR
<b>Node 3 Intramedullary Device Comparisons - Inclusive</b>						
	Standard		Dynamic Locking			
Hardy, 2003 <sup>56</sup>		13%	41	10%	3 months	NR
		23%	41	17%	1 year	
<b>Node 2 Plate/Screw Comparisons - Inclusive</b>						
	SHS		PCCP			
Peyser, 2007 <sup>60</sup>	53	8%	50	4%	3 months	NR
		15%	50	4%	6 months	
		25%	50	10%	1 year	
Brandt, 2002 <sup>63</sup>	39 preliminary for 347					
Kosygan, 2002 <sup>61</sup>	56	16%	52	13%	6 months	Excluded
Janzing, 2002 <sup>62</sup>	62	19%	53	21%	1 year	NR
	SHS		MSP			
Olsson, 2001 <sup>64</sup>	60	17%	54	11%	4 months	NR
Watson, 1998 <sup>65</sup>	53 NR					NR
<b>Node 2 Plate/Screw Comparisons - Unstable</b>						
	SHS group					
Lunsjo, 2001 <sup>95</sup>	301	24%	268	22%	1 year	NR
<b>Node 2 Intramedullary Device Comparisons - Inclusive</b>						
Efstathopoulos, 2007 <sup>57</sup>	NR by group		MSP			NR
<b>Node 2 Intramedullary Device Comparisons - Unstable</b>						
Vidyadhara, 2007 <sup>66</sup>	NR					NR
	Gamma		PFN			
Schipper, 2004 <sup>67</sup>	213	15%	211	18%	4 months	NR
		20%	211	22%	1 year	
	Gamma		Gliding Nail			
Schipper, 2004 <sup>67</sup>	40	5%	40	15%	6 months	NR

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Table E13. Intertrochanteric mortality

Author, Year	Group 1 N	Group 1 % Mortality	Group 2 N	Group 2 % Mortality	Assessment Period	Subtroch Involvement	
<b>Node 1 Plate/Screw vs. Intramedullary devices - Inclusive</b>							
Utrilla, 2005 <sup>71</sup>	SHS 106	9%	Gamma 104	7%	1 months	Excluded	
		14%	104	8%	3 months		
		14%	104	11%	6 months		
		20%	104	18%	1 year		
Ahrengart, 2002 <sup>77</sup>	216	17%	210	20%	6 months	Excluded	
Adams, 2001 <sup>72</sup>	197	31%	203	29%	1 year	NR	
Park, 1998 <sup>73</sup>						NR	
Hoffman, 1996 <sup>74</sup>	106	36	31	26%	6 months	NR	
Butt, 1995 <sup>78</sup>	106	47	48	10%	Until satisfactory radiologic union		
	106						
O'Brien, 1995 <sup>79</sup>		49	53	11%	1 month	Excluded	
Goldhagen, 1994 <sup>75</sup>		40	35	3%	6 months	Included	
Aune, 1994 <sup>76</sup>						Included	
Radford, 1993 <sup>82</sup>		100	100	12%	3 months	NR	
Leung, 1992 <sup>83</sup>		113	113	12%	6 months	Excluded	
Bridle, 1991 <sup>84</sup>		51	49	31%	6 months	NR	
<hr/>							
Pajarinen, 2005 <sup>80</sup>	SHS 54	4%	PFN 54	7%	4 months	NR	
Saudan, 2002 <sup>81</sup>	106	12%	100	16%	1 year	Excluded	
<hr/>							
Hardy, 1998 <sup>69</sup>	SHS 50	26%	IMHS 50	24%	6 months	NR	
		30%	50	30%	1 year		
Baumgaertner, 1998	68	26%	67	16%	1 year	NR	
<hr/>							
<b>Node 1 Plate/Screw vs. Intramedullary Devices - Unstable</b>							
Ekstrom, 2007 <sup>85</sup>	MSP Total	98	18%	PFN 105	14%	1 year	Included
	IT	85	18%	87	16%	1 year	
	Subtroch	13	23%	18	6%	1 year	
	Total	98	6%	105	5%	4 months	
	IT	85	6%	87	6%	4 months	
	Subtroch	13	8%	18	3%	4 months	
Papasimos, 2005 <sup>87</sup>	NR						Excluded
Pajarinen, 2004 <sup>88</sup>							Excluded
<hr/>							
Miedel, 2005 <sup>86</sup>	MSP 108	20%	Gamma 109	10%	4 months	Included	
		29%	109	22%	1 year		
<hr/>							
Sadowski, 2002 <sup>89</sup>	DCS 19	5%	PFN 20	10%	1 year	Included	
<hr/>							
Harrington, 2002 <sup>90</sup>	SHS 52	37%	IMHS 50	40%	6 months	NR	

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**Table E13. Intertrochanteric mortality**

<b>Author, Year</b>	<b>Group 1 N</b>	<b>Group 1 % Mortality</b>	<b>Group 2 N</b>	<b>Group 2 % Mortality</b>	<b>Assessment Period</b>	<b>Subtroch Involvement</b>
<b>Node 1 Internal Fixation vs. Hemiarthroplasty - Unstable</b>						
Kim, 2005 <sup>92</sup>	PFN 29	28% 55%	Hemi 29	14% 17%	1 year 3 years	NR
Stappaerts, 1995 <sup>91</sup>	NR by group					Excluded
<b>Subtrochanteric</b>						
Lunsjo, 1999 <sup>93</sup>	SHS 52	13%	MSP 55	15%	1 year	Included

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## References for Appendix E

(Note that there is a separate set of references at the end of the report and reference numbers are different than those in the appendixes)

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## Appendix F: List of Excluded Studies

### Excluded from RCT Literature

1. Prevention of pulmonary embolism and deep vein thrombosis with low dose aspirin: Pulmonary Embolism Prevention (PEP) trial.[see comment]. *Lancet* 2000 Apr 15; 355(9212):1295-302. *Not test of device*
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## Excluded Observational Studies

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