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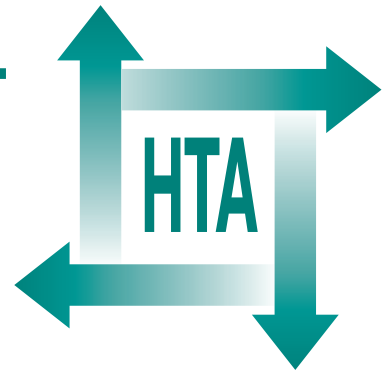

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Displaced intracapsular hip fractures in fit, older people: a randomised comparison of reduction and fixation, bipolar hemiarthroplasty and total hip arthroplasty

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The research reported in this monograph was commissioned by the HTA Programme as project number 94/24/03. The contractual start date was in June 1996. The draft report began editorial review in March 2003 and was accepted for publication in August 2004. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

Displaced intracapsular hip fractures in fit, older people: a randomised comparison of reduction and fixation, bipolar hemiarthroplasty and total hip arthroplasty

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Objectives: To compare internal fixation, bipolar hemiarthroplasty and total hip arthroplasty for the management of displaced subcapital fracture of the hip in previously fit patients of 60 years or older.

Design: A prospective randomised clinical trial.

Setting: This multicentre trial was carried out in 11 Scottish hospitals with acute orthopaedic trauma units.

Participants: The participants were 298 previously fit patients of 60 years or older with displaced subcapital hip fractures.

Interventions: The three surgical interventions for comparison were reduction and fixation, bipolar hemiarthroplasty and total arthroplasty (total hip replacement). Participating surgeons elected to randomise patients either among all three types of operation (three-way randomisation) or just between fixation and hemiarthroplasty (two-way randomisation).

Main outcome measures: Clinical outcomes were mortality rates, reoperation rates and the complication rates associated with each procedure. Functional outcome was measured using a hip specific questionnaire [Johanson Hip Rating Questionnaire (HRQ)] and a general health status questionnaire [EuroQol 5 Dimensions (EQ-5D)]. Economic analysis compared the costs in the randomised groups of hospital treatment for the initial and subsequent admissions for up to 2 years.

Results: Altogether, 207 patients were randomised among all three trial operations, and 91 between just fixation and bipolar hemiarthroplasty. There were no statistically significant differences in clinical outcomes, but confidence intervals (CIs) were wide. At 2 years fixation failure reached 37% among those allocated fixation and 39% had undergone further surgery. Further surgery rates after hemiarthroplasty and total hip replacement were 5% and 9%, respectively. The group allocated fixation had significantly worse HRQ and EQ-5D scores than both arthroplasty groups at 4 and 12 months. At 24 months the results still favoured arthroplasty, but the overall HRQ and EQ-5D scores were no longer statistically significant. Total hip replacement had the best patient-assessed outcome scores. At 24 months the overall HRQ and EQ-5D scores for total hip replacement were significantly better than for hemiarthroplasty. The mean costs for the initial episode ranged from £6384 for fixation to £7633 for total hip replacement. The cost differences were largely due to differences in theatre costs and the cost of protheses and hardware. The cumulative cost over 2 years of hemiarthroplasty was around £3000 lower than for fixation (95% CI £1227 to £7192). Compared with total hip replacement, both fixation and hemiarthroplasty were characterised by increased costs arising from hip-replacement admissions. When total (initial episode and subsequent hip-related admissions) hip-related costs are compared, total hip replacement conferred a cost advantage of around £3000 per patient (versus hemiarthroplasty, 95% CI –£1400 to £7420).

Conclusions: In fit, older patients the results of the study show a clear advantage for arthroplasty over fixation; arthroplasty was more clinically effective and probably less costly over a 2-year period postsurgery. The results suggest that total hip replacement has long-term advantages over bipolar hemiarthroplasty, but these findings are less definite. This study provided

support for the use of total hip replacement to treat displaced intracapsular hip fractures in fit, older patients. A larger trial comparing total versus hemiarthroplasty for these fractures could help to verify these findings. It would also be useful to know whether the findings of this study apply to patients aged 60 years or less who are usually treated with reduction and fixation. A clinical trial comparing arthroplasty versus fixation in patients older than 40 years would be a logical extension of the current study.

Contents

Glossary and list of abbreviations

Technical terms and abbreviations are used throughout this report. The meaning is usually clear from the context, but a glossary is provided for the non-specialist reader. In some cases, usage differs in the literature, but the term has a constant meaning throughout.

Glossary

Acetabulum Socket of the hip joint.

Arthroplasty Replacement of a joint.

Avascular necrosis Death of bone due to interruption of the blood supply. This complication occurs in association with fractures that, if displaced, endanger the blood supply to one of the fragments. In the case of hip fractures, a displaced intracapsular hip fracture will endanger the blood supply to the femoral head, which may result in avascular necrosis developing at a later stage, if the fracture is treated by internal fixation.

Bipolar hemiarthroplasty Type of hip hemiarthroplasty. The femoral component comprises an inner small diameter head and a larger outer head which articulates with the smaller head. In theory, this implant is supposed to function more like a total hip arthroplasty.

Cement Acrylic cement is widely used in orthopaedic surgery to anchor joint replacement components to bone.

Extracapsular The hip joint is enclosed in a layer of fibrous connective tissue termed a capsule. The capsule envelops the femoral neck to where it joins the trochanteric region of the femur. Fractures of the femoral neck occurring outside the capsule are termed intracapsular and involve the trochanteric region of the proximal femur. These fractures do not endanger the blood supply of the femoral head and can be successfully treated by internal fixation.

Girdlestone excision arthroplasty The hip joint is occasionally removed to deal with difficult complications such as infection. Girdlestone described a technique for excision of the hip joint to treat tuberculosis. The eponymous name is often used (incorrectly) to describe removal of hip implants after failed hip arthroplasty.

Hemiarthroplasty Replacement of one of the articulating surfaces of a joint. In the case of the hip this is commonly carried out after subcapital femoral neck fractures when the head of the femur is replaced. The acetabulum is not resurfaced.

Intracapsular The hip joint is enclosed in a layer of fibrous connective tissue termed a capsule. The capsule envelops the femoral neck to where it joins the trochanteric region of the femur. Fractures of the femoral neck occurring within the capsule are termed intracapsular and endanger the blood supply to the femoral head if displaced.

Non-union Failure of a fracture to heal within the expected time. Most fractures are healed by 6 months and fractures with no evidence of bone healing at 9 months are conventionally termed non-unions.

Protrusio Erosion of the acetabulum with translation of the femoral head in a proximal and medial direction. A recognised complication associated with the use of unipolar hemiarthroplasty.

Subcapital The area of the femoral neck adjacent to the articular surface of the femoral head. This area is the usual site of an intracapsular hip fracture.

Unipolar hemiarthroplasty A simple type of hip hemiarthroplasty with a single large metal femoral head replacement.

List of abbreviations

CI	confidence interval
CT	computed tomography
DVT	deep venous thrombosis
EQ-5D	EuroQol 5 Dimensions
HR	hazard ratio
HRQ	Hip Rating Questionnaire
IQR	interquartile range
Log.reg.	logistic regression
LREC	local research ethics committee
MI	myocardial infarction
MREC	multicentre research ethics committee
OR	odds ratio
SD	standard deviation
SHO	senior house officer
STARS	Scottish Trial of Arthroplasty or Reduction and fixation for Subcapital fractures
THR	total hip replacement

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Objective

The aim was to compare internal fixation, bipolar hemiarthroplasty and total hip arthroplasty for the management of displaced subcapital fracture of the hip in previously fit patients of 60 years or older.

Methods

Study design

The study was a prospective randomised clinical trial.

Setting

This multicentre trial was carried out in 11 Scottish hospitals with acute orthopaedic trauma units. The study involved five university teaching hospitals and six affiliated district general hospitals.

Subjects

The participants were 298 previously fit patients of 60 years or older with displaced subcapital hip fractures.

Interventions

The three surgical interventions for comparison were reduction and fixation, bipolar hemiarthroplasty and total arthroplasty (total hip replacement). Participating surgeons elected to randomise patients either among all three types of operation (three-way randomisation) or just between fixation and hemiarthroplasty (two-way randomisation).

Main outcome measures

Patients were followed up for 2 years. Clinical outcomes were mortality rates, reoperation rates and the complication rates associated with each procedure. Functional outcome was measured using a hip specific questionnaire [Johanson Hip Rating Questionnaire (HRQ)] and a general health status questionnaire [EurolQol 5 Dimensions (EQ-5D)]. Economic analysis compared the costs in the randomised groups of hospital treatment for the initial and subsequent admissions for up to 2 years.

Results

Altogether, 207 patients were randomised among all three trial operations, and 91 between just fixation and bipolar hemiarthroplasty. There were no statistically significant differences in clinical outcomes, but confidence intervals (CIs) were wide. At 2 years fixation failure reached 37% among those allocated fixation and 39% had undergone further surgery. Further surgery rates after hemiarthroplasty and total hip replacement were 5% and 9%, respectively.

The group allocated fixation had significantly worse HRQ and EQ-5D scores than both arthroplasty groups at 4 and 12 months. At 24 months the results still favoured arthroplasty, but the overall HRQ and EQ-5D scores were no longer statistically significant. Total hip replacement had the best patient-assessed outcome scores. At 24 months the overall HRQ and EQ-5D scores for total hip replacement were significantly better than for hemiarthroplasty.

The mean costs for the initial episode ranged from £6384 for fixation to £7633 for total hip replacement. The cost differences were largely due to differences in theatre costs and the cost of protheses and hardware. The cumulative cost over 2 years of hemiarthroplasty was around £3000 lower than for fixation (95% CI £1227 to £7192). Compared with total hip replacement, both fixation and hemiarthroplasty were characterised by increased costs arising from hip-replacement admissions. When total (initial episode and subsequent hip-related admissions) hip-related costs are compared, total hip replacement conferred a cost advantage of around £3000 per patient (versus hemiarthroplasty, 95% CI –£1400 to £7420).

Conclusions

In fit, older patients the results of the study show a clear advantage for arthroplasty over fixation; arthroplasty was more clinically effective and probably less costly over a 2-year period postsurgery. The results suggest that total hip

replacement has long-term advantages over bipolar hemiarthroplasty, but these findings are less definite.

Recommendations for research

This study provided support for the use of total hip replacement to treat displaced intracapsular hip fractures in fit, older patients. Although the total hip replacement group had a better functional and economic outcome than the hemiarthroplasty group, a larger trial comparing total versus hemiarthroplasty for these fractures could help to verify these findings. It would also be useful to know whether the findings of this study apply to patients ≤ 60 years who are usually treated with reduction and fixation. A clinical trial comparing arthroplasty versus fixation in patients >40 years would be a logical extension of the current study.

Chapter 1
Introduction

Hip fractures are a very common orthopaedic injury and the incidence is steadily increasing. This is due to changing population demographics, with an increasing proportion of the adult population reaching the age when hip fractures are common. Epidemiological studies predict that the incidence of these fractures will continue to increase in developed countries.[1] This will place an increasing demand on healthcare resources. It is important that the treatment selected is associated with the best outcome both for the patient and for the provider of healthcare.

Hip fractures may be divided into intracapsular and extracapsular types, depending on where in the femur neck the fracture is located. The capsule of the hip joint extends down to the base of the neck. Fractures outside this region are termed extracapsular hip fractures and are basal cervical, intertrochanteric or subtrochanteric. The most common is the intertrochanteric fracture. This region of bone has an excellent blood supply and fracture union occurs reliably, with a very low incidence of non-union. For these extracapsular fractures there is general agreement that internal fixation is the most effective treatment and there are implants available that have very satisfactory documented results with low complication rates.

Approximately half of all hip fractures are intracapsular[2] and occur just adjacent to the articular surface. In this location they are usually referred to as subcapital hip fractures. Blood supply to the femoral head reaches the area in capsular vessels running up on the inner surface of the hip joint capsule. The blood supply is more precarious and susceptible to disruption with displacement of fractures in this region. Undisplaced intracapsular fractures account for 10–15% of intracapsular fractures and the majority of these are treated by internal fixation with satisfactory results. The management of displaced intracapsular hip fractures continues to be a source of controversy. The displacement of the fractures can impair or destroy the blood supply to the femoral head. This damage to the blood supply may interfere with the rate of fracture healing, resulting in non-union or fixation failure. If the fracture heals despite damage to the blood supply avascular necrosis may occur at a later stage. The principal surgical options for the displaced subcapital hip fracture are reduction and fixation or some form of hip arthroplasty.

Reduction and fixation is the least invasive procedure. The displaced femoral head is realigned with the femoral neck by closed manipulation before being fixed in place. Fixation is most commonly carried out with cannulated screws designed for the purpose or a sliding hip screw with a short side-plate as an alternative. Acceptable clinical results have been reported with this method of treatment. It has been particularly favoured in Scandinavia, where in the past a high proportion of these fractures were treated in this way. The advantages are the short duration of surgery, the relatively small procedure performed and the low cost of the implant. Surgeons also believed that retaining the hip joint gave the patient the best possible chance of a return to normal function in the longer term. In recent years, however, there has been increasing recognition of problems associated with this procedure. In published series, the actual rate of failure due to non-union, fixation failure and later avascular necrosis has been quite high, varying from 16 to 33%.[3] Randomised comparisons have reported even higher rates, with levels of over 40%.[4–6] Later revision surgery is therefore relatively common following this procedure.

The alternative to reduction and fixation is some type of hip arthroplasty. There are several alternatives, including unipolar hemiarthroplasty, bipolar hemiarthroplasty and total hip arthroplasty. These implants are available in uncemented or cemented designs. For patients with limited functional demands, uncemented or cemented unipolar hemiarthroplasties have been most frequently used. Bipolar and total hip replacements have generally been reserved for patients who are considered medically fit with more normal functional expectations.

The majority of patients who present with displaced intracapsular fractures have limited prefracture mobility, impaired cognitive function or a combination of both, and are considered to have low functional demands. Randomised trials suggest that a unipolar uncemented

hemiarthroplasty is an acceptable treatment choice in these patients.[4–8] Although in certain parts of the world (notably Scandinavia) reduction and fixation has been widely used, the high complication rates described above have led to a decline in its use.

In previously fit active patients unipolar hemiarthroplasties are associated with a poor functional level and are not therefore considered a good choice of treatment, particularly if the implant is uncemented. They tend to loosen and cause disabling thigh pain. In the longer term there has also been a problem with acetabular erosion attributed to the presence of the large metal head articulating directly with the articular surface.

The bipolar hemiarthroplasty was developed to overcome these disadvantages. The stem design is similar to those used for total hip replacements. However, there is an articulating composite head that fits onto the small prosthetic head and fits into the acetabulum. The concept is that articulation occurs both between the inner head and outer shell and between the outer shell and the acetabulum. The prosthesis therefore should perform in a similar way to a total hip replacement, with a lower risk of acetabular erosion. However, this may not happen in practice.

Subsequent studies have demonstrated that many bipolar hemiarthroplasties actually function as unipolar prostheses, with all motion taking place between the outer shell and the acetabulum. In older patients a recent randomised trial has suggested that the bipolar hemiarthroplasty has no advantage over a cemented unipolar prosthesis.[5] Despite the limitations of the implant, the bipolar hemiarthroplasty has been a popular choice for fit, older patients with displaced subcapital fractures. The use of a cemented stem is associated with less thigh pain than an uncemented unipolar implant and the large head has been associated with a low dislocation rate, which in most studies has been under 5%. In addition, the implant avoids the need to resurface the acetabulum, which shortens the operation and eliminates this as a source of technical error. The bipolar cemented hemiarthroplasty has therefore been the most common choice of arthroplasty in fit, older patients with displaced intracapsular fractures.

Total hip replacement has been used to a much more limited extent in patients with displaced subcapital fractures. The majority of patients with limited functional demands simply do not require this type of more complex prosthesis. Of all the options, the total hip replacement is technically the most demanding. A high risk of dislocation with use of total hip replacement has also been reported, with rates of dislocation above 20% reported in some studies. However, a meta-analysis of the literature up to 2003 indicated that the actual rate of dislocation is less than 10%.[9] This is still much higher than the rate that would be expected following total hip replacement in a patient population with osteoarthritis, among whom total hip replacement is relatively common. Infection following total hip replacement is another complication that may have a higher incidence in patients with a hip fracture. While revision following failure of fixation is perceived to be a relatively straightforward problem to deal with, revision surgery to salvage complications of total hip replacement is a more formidable problem. This accounts for the reluctance of surgeons to choose this method of treatment, particularly in the absence of convincing evidence that it is a superior method of treatment.

A small percentage of patients with displaced intracapsular hip fractures are young. Most orthopaedic surgeons would choose to opt for reduction and fixation in patients who are aged 60 years or less at presentation to conserve the hip joint. This is on the basis that hip replacement may not last long enough in younger patients who, as a consequence, may require revision, which generally has poor results. However, only 5% of these injuries occur in patients under the age of 60 years.

Orthopaedic management remains controversial for patients aged 60 years and older who are otherwise fit.[10] Reduction and fixation, cemented bipolar hemiarthroplasty and total hip arthroplasty are the usual alternatives considered. These options are all used with considerable variation between different surgeons and centres. In general, surgeons have tended to favour reduction and fixation in patients aged 60–70 years and some form of cemented arthroplasty in older patients. Each has advantages and drawbacks and the evidence from formal randomised comparisons is limited. These have not specifically evaluated the outcome of treatments in fit patients, who constitute only a small proportion of the population who sustain this injury. It is therefore not possible to give clear guidelines on the optimal choice from the existing literature.

This is a report of a prospective multicentre randomised trial comparing the use of reduction and fixation with bipolar and total arthroplasty for displaced intracapsular hip fractures in previously fit, mobile patients aged 60 years or over, where the surgeon was uncertain which procedure to recommend. The aim was to determine the most effective and cost-effective treatment. The trial design incorporated clinical, functional, quality of life and economic outcomes, with final follow-up at 2 years after surgery.

Chapter 2

Materials and methods

The trial was mounted under the auspices of the Scottish Orthopaedic Trials Group, a collaboration involving the four Scottish university orthopaedic centres (Aberdeen, Dundee, Edinburgh and Glasgow), associated district general hospitals and the Scottish Health Services Research Unit in Aberdeen.

The trial was a pragmatic, open, multicentre, randomised trial designed to compare three policies for the initial surgical management of displaced intracapsular femoral neck fractures in the fit, older patient. The comparison of policies recognised that not every single patient would receive the allocated procedure; occasionally, a surgeon might revert to another procedure because of developments at the time of surgery. This design also recognised that an alternative operation may have been indicated later because the initial 'allocated' procedure had failed. Participants were analysed in the group to which they had been randomly allocated.

It was proposed that most participating surgeons would randomise eligible patients to any of the three options being compared. It was recognised, however, that this would not always be possible in some places and therefore surgeons were able to choose not to randomise their patients to the total hip replacement arm of the trial, provided this was agreed in advance with the trial coordinators. This flexible policy encouraged surgeon participation, but meant that larger numbers of participants contributed to the comparison of fixation with hemiarthroplasty than to the comparisons of fixation with total hip replacement and hemiarthroplasty with total hip replacement. To help orthopaedic surgeons to collaborate the trial protocol was designed to be as simple as possible; surgeons were asked to do the things that only they could do: identify eligible patients, arrange trial entry and randomisation, perform the operation allocated, provided it proved clinically sensible at the time, and complete a short section of the questionnaire describing the operation. All the subsequent data collection was performed by research assistants based in the four university departments and there were no special tests or follow-up visits to arrange. Reflecting the pragmatic nature of the study, participating surgeons were allowed to use their own judgement to manage care in other respects such as antibiotic and thromboembolism prophylaxis and anatomical approach to surgery. Dressing policies and mobilisation protocols followed local guidelines.

Participants

All patients with a displaced subcapital hip fracture who were admitted to the participating units were to be considered for trial entry. The aim was to recruit previously fit patients aged 60 years or older.

Inclusion and exclusion criteria

Inclusion criteria

- Displaced subcapital femoral neck fracture
- mobile before the fracture (as judged, for example, by being able to walk without the help of another person)
- capable of giving informed consent (not cognitively impaired, e.g. Mini Mental-Test score ≥ 7)
- no serious concomitant disease (e.g. known metastatic disease or terminal illness) or other reason for exclusion (e.g. contraindication to anaesthesia or clinically significant degenerative or inflammatory arthritis)
- aged 60 years or over: it was originally planned that only patients between 60 and 80 would be eligible; however, a decision was made to extend recruitment to those 80 and over who were otherwise eligible (see below)
- able to understand written English.

Exclusions

Patients were excluded if they did not satisfy the inclusion criteria or refused consent to participate.

Changes to protocol

In the development of the protocol from the original grant application, changes were made to the eligibility criteria, principally to the age range and mobility criteria (see Appendix 1). It was felt that the criteria specified in the proposal were too strict and that otherwise suitable patients would be excluded. In addition, the initial follow-up point after discharge was to have been at 3 months.

However, the Scottish Hip Fracture Audit has a follow-up point at 4 months. The first follow-up point in the trial was therefore changed to coincide with the Hip Fracture Audit follow-up and the two studies were dovetailed together to minimise requests for information made to participants. There were no significant alterations to the protocol after the trial began.

Ethics committee approval

Each university centre applied to their respective local research ethics committee (LREC) for individual ethics committee approval. When it was decided to proceed with enrolling additional centres from the district general hospitals, an application was submitted to the multicentre research ethics committee (MREC) which, by then, had been established to process applications involving five or more centres. MREC approval was granted in September 1997. The introduction of the MREC was intended to simplify and speed up multicentre research applications. However, in reality LRECs also had to approve the projects, requesting additional copies of all paperwork, making new stipulations and asking for various changes to the information sheet or consent form. The procedure was cumbersome and inconsistent, and the resulting time involved delayed the starting of the new centres. This not only shortened recruitment time but also resulted in a loss of impetus at the new centres. A complaint was lodged by the principal grantholder through the then Scottish Office, which resulted in guidelines being issued clarifying the role of the LRECs in relation to the MREC. The system subsequently improved and the final two applications for Falkirk and Law hospitals were processed quickly. Individual units obtained approval for the study from the relevant clinical directors and/or chief executives of the trusts (or health boards/district health boards) in which the study was to take part.

Once ethics committee approval had been obtained for a hospital to proceed, the unit was visited by the principal grantholder (JF Keating) and the principal research nurse (M Masson), to go over the trial protocol and randomisation procedure. This was timed to include as many of the relevant medical staff as possible and was particularly important for the units that did not have a research assistant on site.

Trial interventions

The three surgical interventions for comparison were reduction and fixation, bipolar hemiarthroplasty and total arthroplasty (total hip replacement). To facilitate participation, the implant and the surgical approach to be used were left to the discretion of the surgeon, reflecting the trial design of randomising to a policy rather than a specific implant. However, patients allocated to reduction and fixation were expected to have a closed reduction using a cannulated screw system or sliding screw and plate. In cases where it was impossible to perform a closed reduction, the subsequent management was left to the discretion of the operating surgeon. Patients allocated to either the bipolar hemiarthroplasty or total arthroplasty groups received a cemented prosthesis through the surgical approach preferred by the surgeon. Postoperative management (mobilisation, suture removal, etc.) was in accordance with local practice.

Outcomes

Previous randomised comparisons of management of subcapital fractures have concentrated on mortality and other clinical outcome measures. Although these are clearly important, the functional outcome and economic costs and consequences of treatment are key considerations in deciding optimal treatment. The outcome measurements were therefore designed to incorporate these aspects.

A decision had to be made regarding a reasonable follow-up interval. Clearly, in assessing arthroplasty, long-term follow-up is desirable. However, this had to be tempered by practical considerations that could render long-term follow-up impractical and unduly expensive. In addition, the long-term outcomes of the cemented implants used in the study have already been documented in clinical trials. The follow-up period adopted was 2 years. This period was chosen as in addition to allowing identification of all early postoperative complications, late complications (e.g. avascular necrosis, late infection) would be expected to manifest within this time-frame. The 2-year time interval was also considered to allow an adequate period for assessment of functional outcome, since surgical interventions to deal with complications would be completed within this period. Finally, the economic analysis would be able to include any subsequent hospital admissions for complications and further treatment, which are important cost drivers in the economic assessment of the individual treatment policies.

Clinical outcomes

All clinical outcomes were measured at four time-points (during acute postoperative stay, and up to 4, 12 and 24 months postoperatively).

Mortality rates

All deaths from any cause over the 2-year follow-up period were recorded. The date and cause of death were verified from death certificates.

Reoperation rates

The date of further surgical intervention to the affected hip was recorded for each patient for the total follow-up period. Further surgery was defined as any procedure requiring general or regional anaesthesia. This included manipulative reduction of prosthetic dislocations. The reason for further surgery and the type of operation performed were noted.

Readmission rates

All hospital readmissions over the 2-year follow-up were recorded. These were divided into those that could be directly related to the hip fracture (i.e. readmissions to treat complications) and those that were for unrelated medical indications. Patients were asked to state any readmissions or further surgery on the questionnaire booklet. All dates and details of surgery were clarified by viewing patient case notes. If the answer was omitted or unclear the patient was contacted by telephone. Where necessary, and for cases where the participant did not return a questionnaire, the data were sought from the patient's GP.

Postoperative complications

All postoperative complications that occurred were recorded. Complications that took place during the hospital admission were noted before discharge. Other complications were identified through the 4-, 12- and 24-month follow-up assessments.

Hip dislocation

Any dislocations of a bipolar or total hip prosthesis and the action required were recorded. This outcome can only occur following insertion of a hemiarthroplasty or total hip arthroplasty. However, a proportion of patients who had fixation underwent revision to an arthroplasty and these patients would then be at risk of this complication also.

Fixation failure

Fixation failure included all causes of fixation failure. It was anticipated that early failure of fixation would be due to redisplacement in patients with osteoporotic bone and non-union. Later failures were expected to include patients who developed avascular necrosis. Patients whose fractures had healed but who required removal of metalwork owing to discomfort were not included in this category. The designation of fixation failure is clearly one that can only apply to patients managed with reduction and fixation.

Proven wound infection

A proven wound infection was defined as the presence of a purulent wound discharge with bacterial pathogens identified on bacteriological culture. Any patients who returned to theatre for revision surgery owing to infection were also included in this category, irrespective of wound discharge or culture results.

Septicaemia

Clinical evidence of systemic infection in the presence of a positive blood culture was categorised as septicaemia.

Deep venous thrombosis

The trial design did not incorporate routine screening for deep venous thrombosis (DVT). This complication was therefore recorded in any patient who had the diagnosis confirmed on venogram or Doppler ultrasound.

Pulmonary embolism

Similarly, participants were considered to have had a pulmonary embolism if there was objective evidence of the condition on ventilation–perfusions scans, pulmonary angiography or computed tomographic (CT) angiography.

Confirmed stroke

A diagnosis of a cerebrovascular accident was made on the basis of positive physical signs with confirmation of the diagnosis by a consultant physician or a positive CT scan.

Confirmed myocardial infarction

The diagnosis of myocardial infarction (MI) was made on the basis of ECG changes, cardiac enzyme changes and confirmation by a consultant physician.

Other serious problems were categorised into three types: life-threatening intraoperative complications, serious local complication and life-threatening general complications

All hospital admissions reported during the 24-month follow-up period were checked with hospital records to verify or exclude events. Where necessary, and for participants who did not return a questionnaire, the data were sought from the patient's GP.

Functional and quality of life outcomes

Functional and quality of life outcomes were sought by a self-completed postal questionnaire at 4, 12 and 24 months following surgery [from the Scottish Trial of Arthroplasty or Reduction and fixation for Subcapital fractures (STARS); see Appendix 2]. A covering letter was sent with each questionnaire, which included the telephone number of the local research assistant, so that participants could contact a member of the research team if they had any questions. The questionnaire had three components:

- Hip Rating Questionnaire (HRQ)[11]
- EuroQol 5 Dimensions (EQ-5D)[12]
- supplementary questions asking the patient to record visits to orthopaedic outpatient departments, any admissions to hospital and any further surgical operations on the hip.

Hip Rating Questionnaire

There are no validated questionnaires designed specifically for patients with a displaced subcapital hip fracture. The majority of questionnaires have been designed for use in elective surgery for rheumatoid or osteoarthritis or following a total hip replacement. The Harris hip score, which has been used extensively for many years in the orthopaedic literature, was felt to be more suitable for patients achieving a higher functional level than that which might be expected following fracture of the femur. For this reason, the decision was taken to use a modified version of the HRQ,[11] which had originally been developed for the assessment of the outcome of total hip replacement. The scale gives equal weight to four domains (global or overall impact of hip problem, pain, walking and function). The maximum score is 100 points and the minimum 16 points. The global domain comprises a visual analogue scale where responders are asked to mark (X) on the scale for how well they are doing. The global assessment and the pain domain appear to account for most of the responsiveness, which makes it appropriate for use in this trial. The questionnaire was developed in the USA, so minor wording changes have been incorporated to accommodate UK usage and to replace the word 'arthritis' with 'hip problem' wherever it occurs (Appendix 3).

EuroQol

The EQ-5D[12] is a short, simple, acceptable, self-administered health status measure that has been developed for use in a multicultural European setting. Although a disadvantage is that, as a newer instrument, it does not have the international profile of the Short Form 36 (SF-36), it has been shown in arthritis studies[13,14] to have comparable sensitivity for locomotor problems, and it has the advantage of an established tariff of patient preferences to allow a cost–utility analysis. In addition to this, it has more recently been documented to be useful in patients with hip fractures.[15]

With only seven items to complete it is well suited for use with other questionnaires. Five dimensions give 243 unique health states. Full health scores 1.0. The minimum possible score is –0.59 and patients who have died are assigned a score of zero. Each health state can be weighted with reference to statistics derived from a population survey. A sixth question asks responders to rate their health on the day compared with just before they broke their hip, as better, much the same or worse. Using a visual analogue scale, drawn as a thermometer, responders are then asked to rate their health state on the day. The best state that they can imagine is marked by 100 and the worst state by 0.

Other information collected

Baseline data

Basic descriptive data were compiled for all patients, including age, gender, side of fracture, regular medication before fracture, date and time of injury (if known), and date and time of admission.

Hospitalisation data

The duration of hospital stay and the need for (and duration of) geriatric orthopaedic rehabilitation were both recorded. If the patient required any intensive care or high-dependency care this was also noted and differentiated from time spent on an orthopaedic acute ward. The timing and duration of all hospital admissions after discharge were recorded over the 2-year follow-up period.

Details of surgery

The date and start time of operation, the duration of surgery and time in theatre (both in minutes), and the type of procedure actually performed were noted. For internal fixation, the reduction was designated open or closed, and the implant in all cases was either a multiple cannulated screw system or a sliding hip screw with short side-plate.

For both types of arthroplasty, the name of implant and the surgical approach used were noted on the theatre data form. The direct lateral approach or standard posterior exposures were used in all cases.

The grade of surgeon performing the operation and the grade of the most senior surgeon present in theatre were noted. The type of anaesthetic administered was recorded (general/regional), as were the grade of anaesthetist and the grade of the most senior anaesthetist present in theatre. The use of antibiotic and DVT prophylaxis was also recorded on the theatre data form.

Economic outcomes

The trial design integrated measurement of survival, health-related quality of life and healthcare costs. All 298 patients enrolled in the trial were included in the economic evaluation. The economic evaluation used prospective measurement and valuation of direct health service costs from the perspective of the NHS.

Health service utilisation

The measurement of patient-specific health service utilisation was documented from the date of injury and initial hospital admission up to 2 years. This included all hospitalisation episodes (inpatient and day case), duration of inpatient stay and outpatient clinic attendances. All hospitalisation episodes, day-case and outpatient visits were valued on a centre- and speciality-specific basis using respective average costs per day or attendance calculated from the Scottish system of hospital cost statistics. Inpatient episodes after the initial episode were classified as hip related or non-hip related on the basis of information abstracted from the individual hospital patient records. Theatre costs were based on an analysis of theatre time, typical trauma team staff composition (numbers and grades), trays and consumables. The prosthesis and profile of hardware used by each patient were costed using unit costs derived from the four Scottish university orthopaedic centres. All costs are reported on the Scottish price base of the financial year 2000/01.

Statistical analysis of healthcare costs

Mean incremental costs

The full sample method was used to summarise the cumulative distribution of health service costs across care settings arising from the time of initial admission following injury up to 2 years using arithmetic mean costs observed for all patients. Confidence intervals for estimated untransformed arithmetic mean costs were estimated analytically and empirically using bootstrapping techniques to check for the adequacy of the assumptions made regarding the normality of the cost distributions. Standard *t*-tests and *t*-test-based confidence intervals were found to be very similar to those based on the bootstrap.

It had been intended to estimate an incremental cost-effectiveness ratio comparing the ratio of the mean values of the costs with the mean values of effectiveness estimated for the different policies for initial surgical management. This cost-effectiveness framework (potentially) allowed for combinations of incremental costs and incremental effects including the special case where the difference in effectiveness was zero or close to zero as measured by the primary trial end-points. In practice, because of uncertainties around the estimates for both effects and costs, the data were reported as a cost–consequence analysis.

Undiscounted mean incremental costs are presented. Although costs were recorded for up to 2 years following injury, discounting costs incurred in year 2 at conventional rates of 3–6% would have very little effect on the magnitude of cost estimates as most of the costs were incurred within 1 year of injury.

The study also considered how sensitive the findings were to the cost of key resource categories by allowing for different values of the total cost of hip-related admissions (following the index episode) and the cost of prostheses (and hardware). Reoperations, revisions and the need for hip-related admissions were assumed to be important cost drivers. It was also felt that the cost of the prosthesis could be a key element determining some of the cost differentials observed between the different management strategies. Both of these parameters were varied over a range from –50 to +100% around the baseline values recorded for the trial patients.

Sample size

The original intention was to identify at least a 7-point difference in the HRQ score (assuming a standard deviation of 13.5). The numbers needed to do this were erroneously overestimated in the original grant application. For this reason, revised sample size calculations were presented to, and accepted as a reasonable revision by, the data monitoring committee at its first meeting in 1998. To detect a difference of 7 points in the HRQ with 80% power ($p < 0.05$) required 60 participants per group. Because additional surgeons randomised just between fixation and hemiarthroplasty, the trial groups in this comparison were expected to be about twice as large. This would give 97% power to identify a 7-point difference and 80% power to identify a 5-point difference ($p < 0.05$).

Recruitment and consent

Recruitment of patients to the trial was the responsibility of the consultant orthopaedic surgeon under whose care the patient was admitted. In the majority of cases the patient was approached preoperatively after arrival in the orthopaedic ward, but occasionally this occurred in the casualty department. In units holding a morning 'trauma meeting', a patient's eligibility would be discussed there initially.

Once the patient had been identified as eligible, the trial was discussed with the patient, who was given a patient information leaflet to read and time to read a considered decision. Since the majority of patients with these fractures have surgery the day after admission it was envisaged that patients would have an adequate period to make a decision regarding trial participation. A copy of the information leaflet is included in Appendix 4. In general, informed consent for trial participation was obtained by the consultant in charge of the patient. If the patient agreed to participate he or she was asked to sign a consent form to that effect. The actual randomisation procedure (telephoning the centralised service) could be delegated to a more junior member of the medical team or the nursing sister.

Randomisation

Randomisation was performed by phoning a centralised 24-hour computerised service based within the Health Services Research Unit in Aberdeen. Before telephoning, basic identifying details of name, gender and date of birth were recorded on the surgeon's form, which also had an individual code for each surgeon. This form was used as an *aide-mémoire*. Once a telephone connection had been made these items of information were entered using the telephone keys. The patient's name was spoken and recorded. Once these details had been given and verified as correct by the caller, a study number and a random allocation were given in return. The surgeon code ensured that patients were correctly randomised between two or three procedures. The study number and treatment allocation were given recorded on the form. The allocation sequence had been concealed from the person randomising the patient until the final allocation had been assigned. In the event of computer failure, an emergency pager number allowed for manual randomisation. This was not required during the recruitment as the computerised randomisation proved reliable.

Following entry and allocation, arrangements were made for the patient to receive the allocated procedure. The surgeon's form and consent form accompanied the patient to theatre with the patient case notes. Details of the actual procedure performed were recorded on the surgeon's form as soon after surgery as possible. If forms were not completed the information was sought by the locally based research assistant as soon as possible after surgery.

The allocation process was stratified by surgeon code and minimised on age category (60–74 or 75+) and gender. As described above, some of the participating surgeons wished to randomise only to fixation or bipolar hemiarthroplasty. The randomisation sequence was designed to incorporate this and the patients of these surgeons were allocated only between these two treatment possibilities. At the end of the trial a decision was made to force the final three patients randomised between fixation and hemiarthroplasty to receive hemiarthroplasty, owing to a chance imbalance in the numbers in the groups in this comparison.

Data collection

Data collection was the responsibility of the local research assistants. A full-time assistant was based in Edinburgh and half-time assistants were based in Aberdeen, Glasgow and Dundee. The Edinburgh-based assistant coordinated the data collection and provided holiday cover when necessary. The Edinburgh-based assistant was responsible for following up patients in the Royal Infirmary of Edinburgh, Queen Margaret Hospital, Dunfermline, Falkirk Royal Infirmary, Law Hospital, and Dumfries and Galloway Royal Infirmary. The Glasgow-based assistant followed up patients in Western Infirmary Glasgow, Glasgow Royal Infirmary and Royal Alexandra Hospital, Paisley. The Dundee-based assistant followed up patients in Ninewells Hospital, Dundee, and Perth Royal Infirmary. The Aberdeen-based assistant followed up patients in Aberdeen Royal Infirmary. Following randomisation of a patient the Health Services Research Unit in Aberdeen notified the appropriate research assistant with the randomisation details.

Data were collected in hard copy on a series of forms that were subsequently sent to the Health Services Research Unit for data storage and subsequent analysis. (The data storage was later moved to Edinburgh.) The research assistant was

responsible for collecting the consent form and surgeon's form, checking them for completeness. On the next convenient working day the assistant visited the patient to go over arrangements for the trial and explain the follow-up procedure. Full contact details for the participant, likely place of convalescence, GP and a best contact person such as a relative or close friend were recorded on the nurse's form. The research assistant arranged to be notified of the patient's discharge in order to collect the outcome data during admission.

The local research assistants were responsible for posting out the questionnaires at 4, 12 and 24 months after surgery. The research assistant phoned the general practice to check the participant's whereabouts and circumstances before posting the questionnaire with an accompanying letter 2 weeks before the due date. A reminder was sent out after 3 weeks, followed by a telephone enquiry if there was still no response. Returned questionnaires were checked for completeness and where possible missing answers were obtained over the telephone. Patients were telephoned to thank them for their participation after the 24-month follow-up was completed. This also provided the opportunity to check on status at 24 months exactly. When this was not possible, the patient's GP was contacted.

Blinding

The three surgical treatments were sufficiently different that the postoperative management could not be standardised. It was therefore considered impractical to blind either patients or outcome assessors. Adequate concealment of the assigned treatment in the trial before allocation was considered the most important factor in the protection against bias. Therefore, particular attention was paid to the process of trial entry and randomisation.

Surgeons needed to know which operation they were performing. Before the operation the participating patients gave consent (independent of the consent for trial participation) for the actual operation that they had been allocated to receive. An explanation of the complications associated with each procedure was necessary. Precautions following surgery have a different emphasis for the three different treatment options.

When recording further surgery or operative complications it would usually be apparent to which group a patient was originally allocated, as different types of complication tended to occur in each arm of the trial.

Statistical methods

Comparisons between groups were made on a pairwise basis. For the fixation versus hemiarthroplasty comparison, data from both the two-way and three-way randomisations were used. For the other two comparisons, only data from the three-way randomisation were used. Analysis was performed on an intention-to-treat basis, that is, participants were analysed according to the allocated procedure and not by the operation actually performed. No adjustment was made for multiple significance testing.

For the prespecified primary outcome measures, an unadjusted analysis was followed by an adjusted analysis taking into account age, gender and (for the comparison of fixation versus hemiarthroplasty) whether randomised two-way or three-way. For the unadjusted analysis, continuous outcomes were compared using the independent samples *t*-test, dichotomous outcomes using the χ^2 test, and time-to-event outcomes using the log-rank test. Kaplan–Meier survival curves were also produced to enable the times until reoperation or death in each group to be examined. For the adjusted analysis adjustment was made for covariates using multiple regression, logistic regression and Cox regression, respectively. Depending on the type of data and the method of analysis used, differences between the groups were expressed as a difference in means, difference in proportions, odds ratio or hazard ratio, all with 95% confidence intervals.

Prespecified stratified analyses were conducted among those aged 60–74 years at the time of randomisation and those aged 75 years and over. An additional analysis based on the procedure actually used examined fixation failure and dislocation rates for different types of surgical approach.

Recruitment issues

The initial aim outlined in the grant proposal was to recruit 450 patients over 21 months equally between the three groups of reduction and fixation, bipolar hemiarthroplasty and total arthroplasty. Early monitoring of the recruitment rate and the reasons for exclusion and patient refusal to participate indicated that this number would be difficult to achieve within the proposed timetable. During the course of the trial several

strategies were implemented to encourage and improve recruitment.

At centre level

Recruiting additional centres was a slow process. There are around 20 units in Scotland of varying sizes dealing with adult trauma. The researchers identified and began approaching first the centres with the largest annual total of hip fractures. It was decided that it would not be feasible to include centres dealing with fewer than 150 hip fractures a year since the number of eligible patients would be very small. The initial approach was made by the principal grantholder to one of the surgeons at the identified units and a visit was arranged to give a formal presentation of the project to the orthopaedic consultants, as a group, at each hospital. Arranging a suitable date for the visit around the schedules of busy surgeons often meant a delay of some months. Some centres (e.g. Borders General Hospital, Southern General Hospital, Glasgow, and Victoria Infirmary, Glasgow) had no bipolar prostheses and were therefore not equipped to participate. Four centres were approached, but after consideration declined participation (Ayr General Hospital, Stirling Royal Infirmary, Raigmore Hospital, Inverness, and Crosshouse Hospital, Kilmarnock).

At surgeon level

After agreeing to participate, some centres recruited disappointing numbers of patients. In some cases there was a variable degree of enthusiasm among the group of surgeons about the trial. Initial enthusiasm may have been tempered by the practical difficulties in seeking consent and randomising patients to three markedly different surgical procedures. In some units the actual number of eligible patients was likely to be very small. In these units the level of awareness about the need to consider trial recruitment probably declined as so few eligible patients were seen.

At patient level

As described later in this report, about 30% of eligible patients refused participation. Refusal to participate was mainly due to the following reasons. First, the trial involved three very different surgical procedures and the rationale of randomisation in this setting was complicated to explain to patients. Second, the patient is often in pain at the time of admission. Depending on the circumstances of the fall the patient may also be dehydrated, exhausted and confused as a result of administration of opiate analgesic medication. This made informed consent difficult to achieve on occasion. Third, some patients had a firm view about treatment, often because of a previous hip fracture successfully (or unsuccessfully) treated by one of the options. Finally, some patients had a firm view about not participating in clinical trials.

Data monitoring committee

An independent data monitoring committee was established to assess accumulating data in confidence, hence avoiding biasing the participating surgeons. The committee comprised Peter Langhorne (Consultant Geriatrician and Senior Lecturer in Geriatrics, Glasgow University), Richard Morris (Statistician, London) and David Murray (Consultant Orthopaedic Surgeon, Nuffield Orthopaedic Centre, Oxford).

The three committee members first met on 17 November 1998. An interim analysis was considered on the first 154 patients randomised until the end of August 1998. The committee found no grounds for stopping or altering the trial, either on the basis of data presented and the observed comparisons between groups, or from information about other trials being conducted. A subsequent meeting occurred on 10 August 2000, which was after completion of recruitment. The committee recommended completion of the 2-year follow-up in all patients to maximise the volume of data collected and the applicability of the conclusions.

Extension of recruitment period

Owing to the slower than anticipated rate of patient recruitment the 21-month recruitment period was extended and a time extension for the trial was applied for and approved. The time from recruitment of the first to the last patient took 44 months. A number of other measures was taken to improve recruitment. Recruitment was extended to additional centres. The recruitment period was extended and the centres (especially where recruitment was slow) were revisited, and there was regular encouragement through telephone calls and newsletters. These probably helped to maintain recruitment at acceptable levels. An attempt was also made to include some English centres, but this proved unsuccessful owing to a lack of enthusiasm for participating in the study within the centres approached.

Chapter 3
Results

Recruitment to the trial started in September 1996 and ended in June 2000, during which time 299 participants were recruited. One participant withdrew consent before surgery, leaving 298 who had surgery in the trial. *Table 1* is a summary of the recruitment in the 11 centres. The four university hospitals started to recruit patients in 1996/97; other hospitals began recruitment in 1998 or 1999 and therefore were participating for a shorter period. One further participating hospital, Crosshouse, did not enrol any patients. In total, 207 patients were randomised among all three types of operation and 91 patients between just fixation and hemiarthroplasty. Surgeons in three centres (Aberdeen, Dundee and Perth) recruited patients to both the three-option comparison and the two-option comparison.

Figure 1 shows the pattern of recruitment over the course of the trial. The rate of recruitment was fairly constant throughout the entire enrolment period, despite the fact that additional centres became involved during the course of the trial. The typical rate of enrolment was around eight participants per month.

An audit of admissions for displaced subcapital hip fractures was carried out in the participating hospitals alongside the trial. This was difficult in some of the non-University centres where there was no designated research nurse. However, despite this, it was possible to collect this information for 203 centre-months out of a possible 293 centre-months. Complete information was available for Edinburgh Royal Infirmary throughout the recruitment period. *Table 2* describes the reasons for exclusion from the trial derived from this audit. Of the total of 2684 people documented in the audit, 2344 (87%) were judged ineligible. The most common reasons are listed in *Table 2*; some people had more that one reason for their exclusion. As can be seen, a failed mental test and poor prefracture mobility were common reasons for exclusion. The category of 'other reasons' included a range of clinical problems that individual surgeons considered made particular patients ineligible. Of the 340 considered eligible and included in the audit, 236 consented to be randomised. This meant that 9% of those identified in the audit were finally recruited, and this represented 69% of those eligible.

Figure 2 describes the flow of patients through the trial, giving details of completeness of follow-up in respect of both patient questionnaire data and clinical data at the three follow-up points in time: 4, 12 and 24 months. Of the 207 participants randomised among the three surgical options, 69 were allocated to each group; of the 91 randomised between the two options 49 were allocated to fixation and 42 to hemiarthroplasty. As can be seen, rates of completeness of data were high. Rates for postal questionnaire data were 85%

TABLE 1 *Summary of recruitment*

Centre	Start date of recruitment	No. of patients randomised to three-option comparison	No. of patients randomised to two-option comparison
Edinburgh	September 1996	110	–
Aberdeen	January 1997	23	29
Dundee	February 1997	29	11
Glasgow Western	June 1997	–	43
Glasgow Royal	February 1998	23	–
Dunfermline	February 1998	6	0
Dumfries	April 1998	–	1
Perth	May 1998	6	2
Paisley	June 1998	–	5
Falkirk	March 1999	7	–
Law	April 1999	3	–
Total		207	91

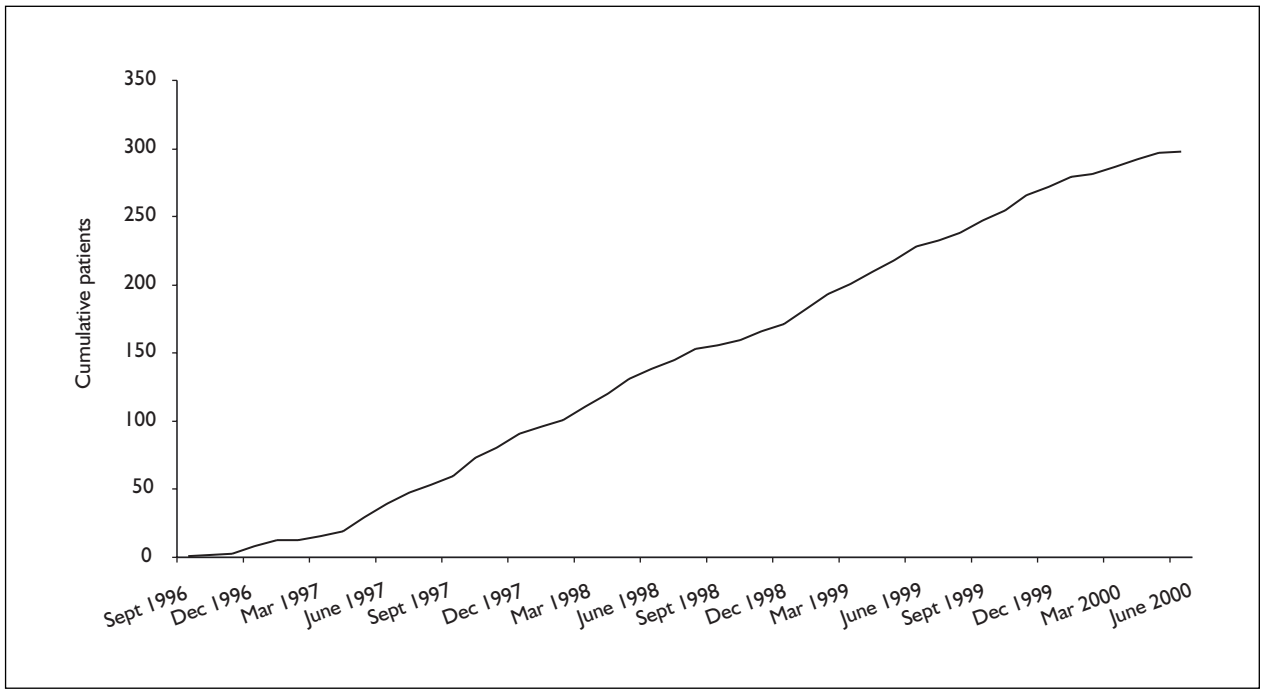

FIGURE 1 *Pattern of recruitment over the course of the trial*

TABLE 2 *Reasons for exclusion from the trial*

	n	%
Considered for the trial	**2684**	
Excluded because:		
Aged <60 years	100	4%
Judged too old	235	9%
Poor mobility	751	28%
Failed mental test	803	30%
Other reason	1121	42%
Any of above reasons[a]	2344	87%
Eligible	340	
Consented to be randomised	236	69%

Exclusions data were collected for 203 centre-months out of 293 (69%). This comprised all months for the main centre and selected months for other centres.
[a] Some people had more than one reason for exclusion.

or above, and most 95% or above. Clinical data were complete for all patients except for two at all three time-points. One patient allocated total hip replacement withdrew between the 4- and 12-month follow-up points.

Description and comparability of the groups at trial entry

Table 3 describes the groups at trial entry. These data, as are data in subsequent results tables, are presented as pairwise comparisons between the three options. The first pairwise comparison is between fixation and hemiarthroplasty. This includes larger numbers of participants because it draws on both those recruited by participating surgeons who randomised among all three options and those recruited by participating surgeons who randomised only between fixation and hemiarthroplasty. In contrast, the groups in the other two pairwise comparisons all have 69 participants, reflecting the numbers recruited by participating surgeons randomising among the

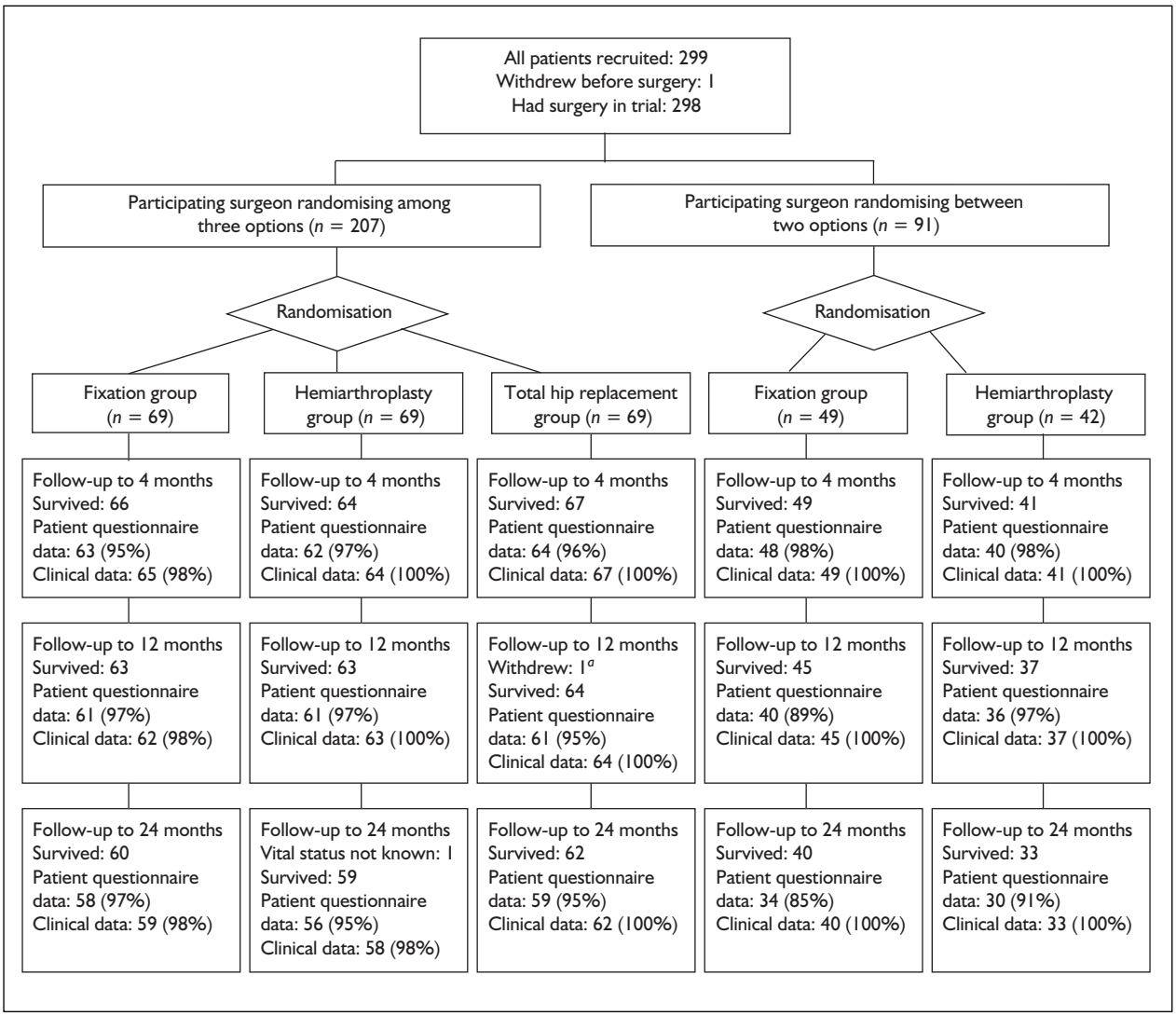

FIGURE 2 *Flow of patients through the trial. [a]Withdrew after 4-month follow-up.*

TABLE 3 *Description of groups at trial entry*

		Fixation (*n* = 118)	Hemiarthroplasty (*n* = 111)	Fixation (*n* = 69)	THR (*n* = 69)	Hemiarthroplasty (*n* = 69)	THR (*n* = 69)
Age (years)[a]		74.9 [7]	75.4 [7]	74.3 [7]	75.2 [6]	75.0 [6]	75.2 [6]
Gender	Female	89 (75)	92 (83)	51 (74)	52 (75)	54 (78)	52 (75)
	Male	29 (25)	19 (17)	18 (26)	17 (25)	15 (22)	17 (25)
Side of fractures	Left	59 (50)	66 (59)	33 (48)	38 (55)	40 (58)	38 (55)
	Right	59 (50)	45 (41)	36 (52)	31 (45)	29 (41)	31 (45)
On regular medication before trial entry	Yes	96 (82)	77 (70)	55 (80)	55 (80)	46 (67)	55 (80)
	No	21 (18)	33 (30)	14 (20)	14 (20)	23 (33)	14 (20)

THR, total hip replacement.
Data are shown as *n* (%) or [a]mean [SD].

three options, one of which was to total hip replacement. The participants ranged in age between 60 and 93 years. As can be seen in *Table 3*, the mean ages of the groups were similar and all around 75 years. As would be expected, the majority of participants were women; again, the trial groups were balanced: in most the proportion of women was 75%, although this was somewhat higher in the hemiarthroplasty group than in the fixation group. The groups were also balanced in respect of the side of the fracture and the numbers of participants on regular medication before trial entry. Overall, this applied to 73% of participants.

Details of the surgery actually received

Table 4(a) provides operative details of the procedures actually performed within the randomised groups. Amongst those allocated fixation, 86% actually had this procedure; most of the other 14% had bipolar hemiarthroplasty. All of those allocated bipolar hemiarthroplasty had some type of hemiarthroplasty procedure. All but four actually had a bipolar hemiarthroplasty and the other four had a unipolar hemiarthroplasty. Among those allocated total hip replacement, 84% actually had this procedure, 10% had a bipolar hemiarthroplasty and 6% had a unipolar hemiarthroplasty. Although not all participants received the procedure to which they had been allocated, all subsequent analyses are based on the intention-to-treat principle, that is comparing policies of an intention to use a particular procedure at the time of allocation, recognising that the allocated procedure may not prove to be appropriate when it comes to the time of surgery. In the group allocated fixation who actually had this procedure, a closed approach was used in about three-quarters, and 50% had multiple screws and 50% had a sliding hip screw or plate. For both types of arthroplasty, the majority were performed using a lateral approach. Within the pairwise comparisons, the proportions having general or regional anaesthesia were broadly similar for the operations, although those surgeons who only randomised between the two options of fixation and hemiarthroplasty were more likely to use a general anaesthetic.

Table 4(b) describes the grades and seniority of the surgeons and anaesthetists who operated or were present in the theatre. Most operations were performed by a specialist registrar. While around 20% of fixation and hemiarthroplasty procedures were performed by consultants, this applied to 42% of total hip replacements. This was also reflected in the finding that a consultant was nearly twice as likely to be present after allocation to total hip replacement than after allocation to one of the other procedures. There was no apparent difference in the grade of anaesthetist who gave the anaesthetic. About 40% of the anaesthetists were consultants and 40% specialist registrars. Similarly, there was no difference in the grade of the most senior anaesthetist present.

Table 4(c) shows that rates of antibiotic prophylaxis were around 95% in all groups. Rates for thromboprophylaxis were lower and between 60 and 80%. *Table 4(c)* also describes the duration of operation for those allocated to the procedure, together with the duration for the operation types actually received. The average duration in the groups as allocated was lowest for fixation and highest for total hip replacement, with hemiarthroplasty in between. It is noteworthy that the time taken to complete an allocated hemiarthroplasty was shorter than that for a hemiarthroplasty after allocation to fixation; this may reflect an attempt to perform fixation before converting to an arthroplasty. The pattern of theatre times was similar to that of duration of operation.

Trial events after surgery but before discharge from hospital

Table 5 describes postoperative complications and hospital stay following the index operation. Overall, only two participants received intensive care and eight received high-dependency care. Seven per cent allocated fixation had a blood transfusion, compared with 14% allocated hemiarthroplasty and 32% allocated total hip replacement. Adverse events were uncommon during the initial hospital stay and there were no clear differences between the trial groups in these respects. Four of the 298 participants died during the index admission.

Table 5 also describes the place to where survivors were discharged. About three-quarters went home and about one-fifth went to a rehabilitation centre. There was no apparent difference between the groups in this respect.

Clinical follow-up

Table 6 shows the adverse events that occurred between the operation and the 4-month follow-up.

TABLE 4 *Operative details*

(a) Procedures actually performed

	Fixation (*n* = 118)	Hemiarthroplasty (*n* = 111)	Fixation (*n* = 69)	THR (*n* = 69)	Hemiarthroplasty (*n* = 69)	THR (*n* = 69)
Internal fixation	**102 (86)**	**0**	**59 (86)**	**0**	**0**	**0**
Open/closed:						
Closed	77		46			
Open	25		13			
Screws/plate:						
Multiple screws	51		44			
Sliding hip screw/plate	51		15			
Bipolar hemiarthroplasty	**12 (10)**	**107 (96)**	**6 (9)**	**7 (10)**	**67 (97)**	**7 (10)**
Approach:						
Posterior	2	10	1	2	7	2
Lateral	10	97	5	5	62	5
Total hip replacement	**2 (2)**	**0**	**2 (3)**	**58 (84)**	**0**	**58 (84)**
Approach:						
Posterior	1		1	7		7
Lateral	1		1	51		51
Unipolar hemiarthroplasty	**1 (1)**	**4 (4)**	**1 (1)**	**4 (6)**	**2 (3)**	**4 (6)**
Girdlestones	**1 (1)**	**0**	**1 (1)**	**0**	**0**	**0**
Anaesthetic:						
General	67 (57)	54 (49)	27 (39)	21 (30)	26 (38)	21 (30)
Regional	51 (43)	57 (51)	42 (61)	48 (70)	43 (62)	48 (70)

(b) Details of surgeons and anaesthetists

		Fixation (*n* = 118)	Hemiarthroplasty (*n* = 111)	Fixation (*n* = 69)	THR (*n* = 69)	Hemiarthroplasty (*n* = 69)	THR (*n* = 69)
Grade of operating surgeon	Consultant	25 (21)	21 (19)	15 (22)	29 (42)	17 (25)	29 (42)
	Associate specialist	3 (3)	2 (2)	1 (1)	1 (1)	1 (1)	1 (1)
	Staff grade	6 (5)	2 (2)	4 (6)	1 (1)	0 (0)	1 (1)
	Specialist registrar	69 (59)	74 (67)	41 (59)	37 (54)	46 (67)	37 (54)
	SHO	15 (13)	11 (10)	8 (12)	1 (1)	5 (7)	1 (1)
	Not known	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Most senior surgeon present	Consultant	56 (48)	48 (43)	31 (45)	55 (80)	29 (42)	55 (80)
	Associate specialist	2 (2)	2 (2)	0 (0)	1 (1)	1 (1)	1 (1)
	Staff grade	3 (3)	2 (2)	2 (3)	1 (1)	1 (1)	1 (1)
	Specialist registrar	56 (48)	59 (53)	36 (52)	12 (17)	38 (55)	12 (17)
	SHO	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Grade of anaesthetist	Consultant	50 (42)	51 (46)	25 (36)	28 (41)	30 (44)	28 (41)
	Associate specialist	2 (2)	0 (0)	2 (3)	1 (1)	0 (0)	1 (1)
	Staff grade	3 (3)	5 (5)	1 (1)	2 (3)	4 (6)	2 (3)
	Specialist registrar	38 (32)	45 (41)	26 (38)	25 (36)	32 (46)	25 (36)
	SHO	24 (20)	10 (9)	15 (22)	13 (19)	3 (4)	13 (19)
	Not known	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Most senior anaesthetist present	Consultant	58 (49)	55 (50)	31 (45)	32 (46)	31 (45)	32 (46)
	Associate specialist	2 (2)	0 (0)	2 (3)	1 (1)	0 (0)	1 (1)
	Staff grade	3 (3)	5 (5)	1 (1)	3 (4)	5 (7)	3 (4)
	Specialist registrar	39 (33)	45 (41)	25 (36)	23 (33)	31 (45)	23 (33)
	SHO	15 (13)	6 (5)	10 (15)	9 (13)	2 (3)	9 (13)
	Not known	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	1(1)

continued

TABLE 4 *Operative details (cont'd)*

(c) Prophylaxis							
		Fixation (Max. *n* = 118)	**Hemiarthro-plasty (Max. *n* = 111)**	**Fixation (Max. *n* = 69)**	**THR (Max. *n* = 69)**	**Hemiarthro-plasty (Max. *n* = 69)**	**THR (Max. *n* = 69)**
Antibiotic prophylaxis	Given	112 (95)	105 (95)	66 (96)	65 (94)	68 (99)	65 (94)
Thrombo-prophylaxis	Given	71 (60)	76 (68)	46 (67)	54 (78)	55 (80)	54 (78)
Duration of operation (minutes)[a]	Received fixation	48.7 [20]	–	45.2 [18]	–	–	–
	Received hemiarthroplasty	84.9 [27]	62 [22]	85.7 [29]	64.3 [15]	58.9 [21]	64.3 [15]
	Received THR	70.5 [22]	–	70.5 [22]	82.4 [25]	–	82.4 [25]
	All operations	52.9 [23]	61.8 [21]	49.7 [22]	79.7 [26]	58.5 [21]	79.7 [26]
Theatre time (minutes)[a]	Received fixation	124.9 [44]	–	111 [35]	–	–	–
	Received hemiarthroplasty	170 [54]	137.8 [47]	181.7 [28]	130.7 [47]	130.9 [44]	130.7 [47]
	Received THR	200.5 [71]	–	200.5 [71]	156.7 [43]	–	156.7 [43]
	All operations	130.6 [48]	138.1 [47]	119.4 [43]	153.1 [44]	130.8 [44]	153.1 [44]

Data are shown as *n* (%) or [a]mean [SD].
GORU, geriatric orthopaedic rehabilitation unit; SHO, senior house officer.

TABLE 5 *Postoperative complications, and hospital stay and discharge*

	Fixation (*n* = 118)	**Hemiarthroplasty (*n* = 111)**	**Fixation (*n* = 69)**	**THR (*n* = 69)**	**Hemiarthroplasty (*n* = 69)**	**THR (*n* = 69)**
Patients who received intensive care	0	1 (1)	0	1 (1)	1 (1)	1 (1)
Patients who received high-dependency care	1 (1)	4 (4)	0	3 (4)	3 (4)	3 (4)
Patients who received blood	8 (7)	16 (14)	7 (10)	22 (32)	9 (13)	22 (32)
Adverse events						
Fixation failure	2 (2)	0	1 (1)	0	0	0
Hip dislocation	0	0	0	2 (3)	0	2 (3)
Proven wound infection	2 (2)	3 (3)	2 (3)	1 (1)	2 (4)	1 (1)
Septicaemia	0	0	0	0	0	0
Treated DVT	1 (1)	0	1 (1)	2 (3)	0	2 (3)
Treated pulmonary embolism	1 (1)	4 (4)	0	1 (1)	3 (4)	1 (1)
Confirmed stroke	1 (1)	0	0	1 (1)	0	1 (1)
Confirmed MI	0	2 (2)	0	1 (1)	2 (3)	1 (1)
Other serious problem[a]	1 (1)	3 (3)	1 (1)	2 (3)	2 (3)	2 (3)
Further surgery	1 (1)	2 (2)	1 (1)	2 (3)	2 (3)	2 (3)
Death during index admission	2 (2)	1 (1)	2 (3)	1 (1)	0 (1)	1 (1)
Survivors discharged to						
Home	86 (73)	81 (73)	53 (77)	50 (72)	49 (71)	50 (72)
Nursing home	1 (1)	1 (1)	0 (0)	0 (0)	1 (2)	0 (0)
GORU/other hospital rehabilitation	22 (19)	21 (19)	10 (14)	16 (23)	16 (23)	16 (23)
Convalescence	6 (5)	4 (4)	3 (4)	2 (3)	0 (5)	2 (3)
Other	1 (1)	1 (1)	1 (2)	0 (0)	1 (2)	0 (0)
Length of postoperative stay[b]	10.7 [7]	10.8 [7]	10.6 [6]	12.3 [10]	11.5 [8]	12.3 [10]

[a] Life-threatening intraoperative complications, serious local complications or life-threatening general complications.
Data are shown as *n* (%) or [b]mean [SD].

TABLE 6 *Cumulative events up to 4 months from operation date*

	Fixation (Max. *n* = 118)	Hemiarthro-plasty (Max. *n* = 111)	Fixation (Max. *n* = 69)	THR (Max. *n* = 69)	Hemiarthro-plasty (Max. *n* = 69)	THR (Max. *n* = 69)
Adverse events						
Fixation failure	24 (20)	0	13 (19)	0	0	0
Hip dislocation	3 (3)	3 (3)	2 (3)	2 (3)	2 (3)	2 (3)
Proven wound infection	7 (6)	4 (4)	4 (6)	3 (4)	3 (4)	3 (4)
Septicaemia	1 (1)	0	1 (1)	0	0	0
Treated DVT	4 (3)	0	3 (4)	4 (6)	0	4 (6)
Treated pulmonary embolism	2 (2)	5 (5)	0	1 (1)	4 (6)	1 (1)
Confirmed stroke	1 (1)	1 (1)	0	1 (1)	1 (1)	1 (1)
Confirmed MI	0	2 (2)	0	1 (1)	2 (3)	1 (1)
Other serious problem[a]	2 (2)	1 (1)	2 (3)	3 (4)	2 (3)	3 (4)
Hospital admission for serious problem[b]	25 (22)	6 (5)	13 (20)	4 (6)	5 (7)	4 (6)
No. with further surgery	26 (22)	6 (5)	14 (20)	5 (7)	5 (7)	5 (7)
Mortality	3 (3)	6 (5)	3 (4)	2 (3)	5 (7)	2 (3)

Date are shown as *n* (%).
[a] Life-threatening intraoperative complications, serious local complications or life-threatening general complications.
[b] Hip-related or following prespecified complications.

TABLE 7 *Cumulative events up to 12 months from operation date*

	Fixation (Max. *n* = 118)	Hemiarthro-plasty (Max. *n* = 111)	Fixation (Max. *n* = 69)	THR (Max. *n* = 69)	Hemiarthro-plasty (Max. *n* = 69)	THR (Max. *n* = 69)
Adverse events						
Fixation failure	34 (29)	0	20 (29)	0	0	0
Hip dislocation	3 (3)	3 (3)	2 (3)	3 (4)	2 (3)	3 (4)
Proven wound infection	8 (7)	4 (4)	4 (6)	3 (4)	3 (4)	3 (4)
Septicaemia	2 (2)	1 (10)	1 (1)	1 (1)	1 (1)	1 (1)
Treated DVT	4 (3)	0	3 (4)	4 (6)	0	4 (6)
Treated pulmonary embolism	2 (2)	5 (5)	0	1 (1)	4 (6)	1 (1)
Confirmed stroke	1 (1)	2 (2)	0	1 (1)	2 (3)	1 (1)
Confirmed MI	0	2 (2)	0	1 (1)	2 (3)	1 (1)
Other serious problem[a]	5 (4)	3 (3)	3 (4)	3 (4)	2 (3)	3 (4)
Hospital admission for serious problem[b]	37 (32)	8 (7)	21 (32)	5 (7)	7 (10)	5 (7)
No. with further surgery	37 (31)	6 (5)	22 (32)	6 (9)	5 (7)	6 (9)
Mortality	10 (8)	11 (10)	6 (9)	4 (6)	6 (9)	4 (6)

Date are shown as *n* (%).
[a] Life-threatening intraoperative complications, serious local complications or life-threatening general complications.
[b] Hip-related or following prespecified complications.

By this time, 20% of those allocated fixation had a fixation failure, and this was reflected in 22% being readmitted to hospital and having further surgery. This compared with 5% among those allocated arthroplasty and 7% among those allocated total hip replacement. There was no clear difference in respect of other adverse events.

Table 7 shows data about the same events but up to 12 months following the operation date. As can be seen, by 12 months, 29% allocated fixation had a fixation failure and 31% in this group had had further surgery. Rates of further surgery were still much lower in the other groups: 5% after hemiarthroplasty and 9% after total hip replacement.

Table 8 shows cumulative adverse events up to the final follow-up at 24 months. The rate of fixation failure had then reached 37% among those

TABLE 8 *Cumulative events up to 24 months from operation date*

	Fixation (Max. *n* = 118)	Hemiarthro-plasty (Max. *n* = 111)	Fixation (Max. *n* = 69)	THR (Max. *n* = 69)	Hemiarthro-plasty (Max. *n* = 69)	THR (Max. *n* = 69)
Adverse events						
Fixation failure	44 (37)	0	26 (38)	0	0	0
Hip dislocation	5 (4)	3 (3)	3 (4)	3 (4)	2 (3)	3 (4)
Proven wound infection	8 (7)	4 (4)	4 (6)	3 (4)	3 (4)	3 (4)
Septicaemia	2 (2)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)
Treated DVT	4 (3)	0	3 (4)	4 (6)	0	4 (6)
Treated pulmonary embolism	2 (2)	5 (5)	0	1 (1)	4 (6)	1 (1)
Confirmed stroke	4 (3)	3 (3)	1 (1)	2 (3)	2 (3)	2 (3)
Confirmed MI	1 (1)	4 (4)	0	2 (3)	3 (4)	2 (3)
Other serious problem[a]	7 (6)	3 (3)	4 (6)	4 (6)	2 (3)	4 (6)
Hospital admission for serious problem[b]	46 (40)	11 (10)	26 (39)	7 (10)	8 (12)	7 (10)
No. with further surgery	46 (39)	6 (5)	27 (39)	6 (9)	5 (7)	6 (9)
Mortality	18 (15)	18 (16)	9 (13)	6 (9)	9 (13)	6 (9)

Date are shown as *n* (%).
[a] Life-threatening intraoperative complications, serious local complications or life-threatening general complications.
[b] Hip-related or following prespecified complications.

allocated fixation and 39% had undergone further surgery. Further surgery rates in the other groups had not changed: 5% after hemiarthroplasty and 9% after total hip replacement. Death rates had risen, but there were no clear differences within the pairwise comparisons.

Table 9(a) is a summary of the main clinical results of the three pairwise comparisons. The table gives an estimate for the absolute difference between groups in respect of seven outcomes, together with 95% confidence intervals (CIs) and *p*-values. As indicated above, the duration of operation was shortest amongst those allocated fixation and longest among those allocated total hip replacement. This translates into a mean difference of around 9 minutes between fixation and hemiarthroplasty, 30 minutes between fixation and total hip replacement, and 21 minutes between hemiarthroplasty and total hip replacement. The differences in theatre time were in line with these. Length of hospital stay was not significantly different between groups. There were no clear differences between the groups in mortality, although the confidence intervals were wide and the data did not rule out clinically important differences. The differences in readmission for serious problems and further surgery to the hip reflected fixation failures in the groups allocated fixation.

Table 9(b) is a summary of the data related to the same main clinical outcomes, but this time adjusted for age, gender, and whether randomised between the two options or three options. The results are essentially the same as for the unadjusted analyses. The adjustments used logistic regressions and/or Cox proportional hazard regression, hence the use of odds ratios and hazard ratios in the bottom half of this table.

Figure 3(a–c) shows Kaplan–Meier diagrams for the three pairwise comparisons showing the time to first reoperation or death. In *Figure 3(a,b)* it can be seen that following allocations to fixation around half of the participants had either had a reoperation or died by the time of the follow-up at 24 months. This compares with around 15% among those allocated hemiarthroplasty or total hip replacement. *Figure 3(c)* is a direct comparison between hemiarthroplasty and total hip replacement and shows essentially the same outcome in respect of reoperation and death in these two trial groups.

Patient-assessed outcome

Table 10(a) describes patient-assessed outcome at 4 months in respect of the HRQ scale, first for the four subscales (global, pain, walking and function) and then overall. The mean scores are generally lowest in the fixation group and highest in the total hip replacement group. *Table 10(b,c)* gives a description of responses to the EQ-5D

TABLE 9 *Summary of main clinical results*

(a) Unadjusted

	Fixation vs hemiarthroplasty Difference in means (95% CI)	Fixation vs THR Difference in means (95% CI)	Hemiarthroplasty vs THR Difference in means (95% CI)
Index admission			
Duration of operation (minutes)	–8.92 (–14.75 to –3.09) $p = 0.003$	–29.97 (–38.05 to –21.89) $p < 0.001$	–21.25 (–29.13 to –13.37) $p < 0.001$
Theatre time (minutes)	–7.44 (–20.09 to 5.2) $p = 0.25$	–33.63 (–48.32 to –18.94) $p < 0.001$	–22.29 (–37.13 to –7.46) $p = 0.004$
Length of stay (days)	–0.15 (–1.99 to 1.7) $p = 0.87$	–1.72 (–4.49 to 1.04) $p = 0.22$	–1.60 (–4.01 to 2.30) $p = 0.59$
	Difference in proportions (95% CI)	**Difference in proportions (95% CI)**	**Difference in proportions (95% CI)**
Events within 24 months of surgery			
Mortality	–0.01 (–0.1 to 0.08) χ^2 $p = 0.84$ Log-rank $p = 0.78$	0.04 (–0.06 to 0.15) χ^2 $p = 0.41$ Log-rank $p = 0.43$	0.04 (–0.06 to 0.15) χ^2 $p = 0.41$ Log-rank $p = 0.40$
Readmission for serious problem	0.3 (0.19 to 0.41) χ^2 $p < 0.001$	0.29 (0.15 to 0.43) χ^2 $p < 0.001$	0.01 (–0.09 to 0.12) χ^2 $p = 0.83$
Further surgery to hip	0.34 (0.24 to 0.43) χ^2 $p < 0.001$ Log-rank $p < 0.001$	0.3 (0.17 to 0.44) χ^2 $p < 0.001$ Log-rank $p < 0.001$	–0.01 (–0.11 to 0.08) χ^2 $p < 0.75$ Log-rank $p = 0.73$
Further surgery to hip or death	Log-rank $p < 0.001$	Log-rank $p < 0.001$	Log-rank $p = 0.87$

(b) Adjusted for age, gender and whether randomised between two or three options[a]

	Fixation vs hemiarthroplasty Difference in means (95% CI)	Fixation vs THR Difference in means (95% CI)	Hemiarthroplasty vs THR Difference in means (95% CI)
Index admission			
Duration of operation (minutes)	–8.82 (–14.61 to –3.04) $p = 0.03$	–30.16 (–38.25 to –22.07) $p < 0.001$	–21.30 (–29.24 to –13.37) $p < 0.001$
Theatre time (minutes)	–8.21 (–20.65 to 4.23) $p = 0.20$	–34.66 (–49.28 to –20.03) $p < 0.001$	–22.15 (–36.98 to –7.33) $p = 0.004$
Length of stay (days)	–0.12 (–1.95 to 1.71) $p = 0.90$	–0.64 (–2.77 to 1.48) $p = 0.55$	0.14 (–2.46 to 2.75) $p = 0.91$

continued

TABLE 9 *Summary of main clinical results (cont'd)*

		OR/HR (95% CI)		OR/HR (95% CI)		OR/HR (95% CI)	
Events within 24 months of surgery							
Mortality	OR	**0.97**	(0.46 to 2.02)	**1.69**	(0.56 to 5.14)	**1.63**	(0.54 to 4.91)
		Log. reg. $p = 0.93$		Log. reg. $p = 0.36$		Log. reg. $p = 0.39$	
	HR	**0.97**	(0.5 to 1.88)	**1.66**	(0.59 to 4.68)	**1.62**	(0.58 to 4.56)
		Cox $p = 0.94$		Cox $p = 0.34$		Cox $p = 0.36$	
Readmission for serious problem	OR	**6.02**	(2.9 to 12.51)	**5.62**	(2.20 to 14.35)	**1.13**	(0.39 to 3.33)
		Log. reg. $p < 0.001$		Log. reg. $p < 0.001$		Log. reg. $p = 0.82$	
Further surgery to hip	OR	**11.82**	(4.74 to 29.44)	**6.68**	(2.12 to 17.67)	**0.81**	(0.24 to 2.81)
		Log. reg. $p < 0.001$		Log. reg. $p < 0.001$		Log. reg. $p = 0.74$	
	HR	**8.59**	(3.66 to 20.17)	**5.09**	(2.09 to 12.40)	**0.81**	(0.25 to 2.65)
		Cox $p < 0.001$		Cox $p < 0.001$		Cox $p = 0.73$	
Further surgery to hip or death	OR	**4.23**	(2.32 to 7.70)	**4.84**	(2.17 to 10.78)	**1.11**	(0.47 to 2.67)
		Log. reg. $p < 0.001$		Log. reg. $p < 0.001$		Log. reg. $p = 0.81$	
	HR	**3.18**	(1.94 to 5.20)	**3.39**	(1.75 to 6.58)	**1.08**	(0.49 to 2.37)
		Cox $p < 0.001$		Cox $p < 0.001$		Cox $p = 0.85$	

[a] Applicable to fixation versus hemiarthroplasty comparison only.
OR, odds ratio; HR, hazard ratio; Log. reg., logistic regression.

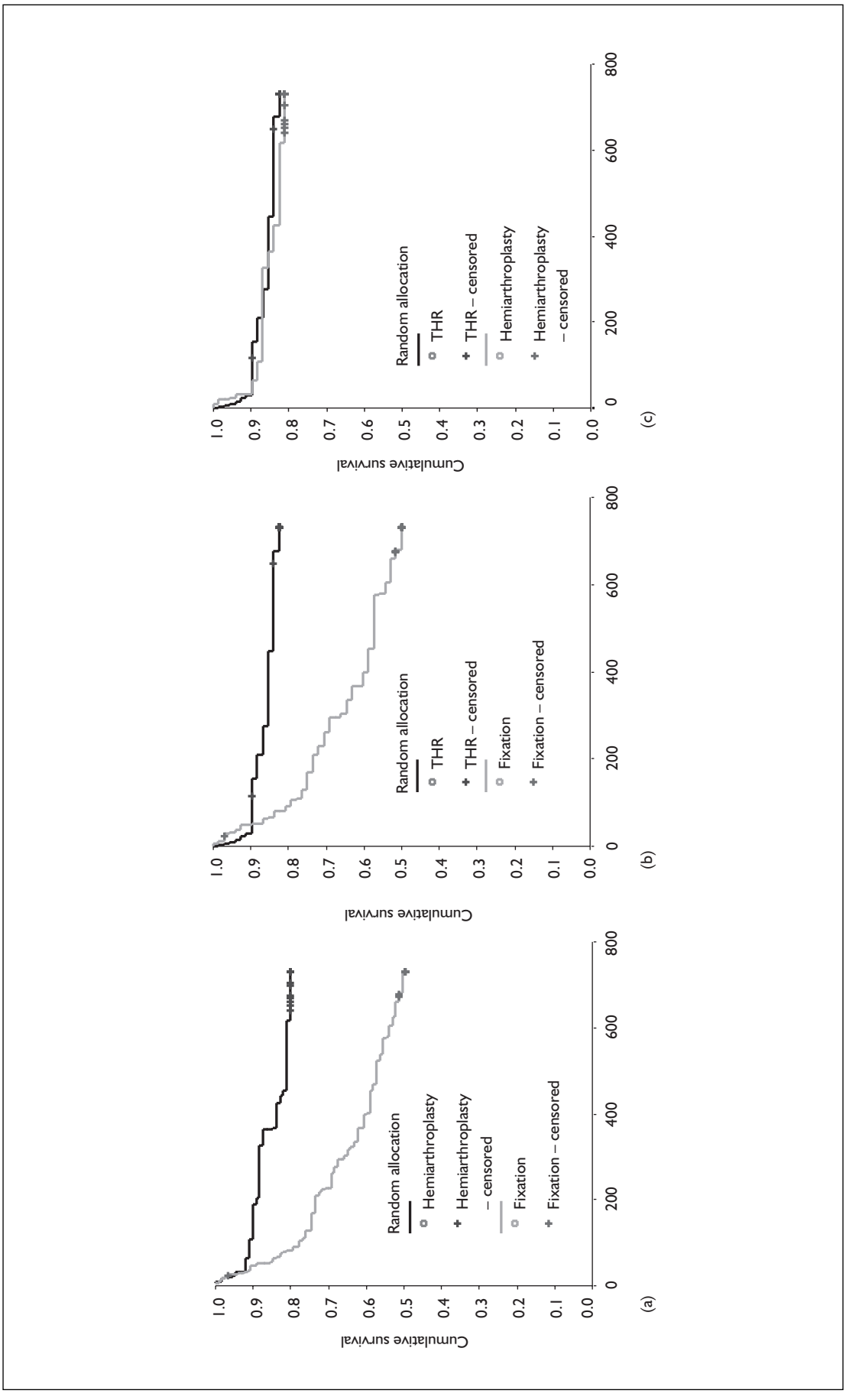

FIGURE 3 *Kaplan–Meier diagrams: time to first reoperation or death: (a) fixation versus hemiarthroplasty; (b) fixation versus total hip replacement (THR); (c) hemiarthroplasty versus THR*

TABLE 10 *Patient outcome at 4 months*

(a) HRQ[a]

	Fixation (Max. *n* = 93)	Hemiarthro-plasty (Max. *n* = 91)	Fixation (Max. *n* = 53)	THR (Max. *n* = 61)	Hemiarthro-plasty (Max. *n* = 58)	THR (Max. *n* = 61)
Global[b]	15.7 [5]	17.7 [5]	15.9 [5]	19.3 [5]	18.4 [5]	19.3 [5]
Pain[b]	16.8 [6]	19.2 [5]	17.2 [6]	19.3 [4]	19.4 [5]	19.3 [4]
Walking[b]	13.5 [5]	15.4 [5]	14.2 [5]	17.5 [5]	16.1 [5]	17.5 [5]
Function[b]	17.5 [4]	19.1 [4]	18.4 [3]	19.9 [4]	19.5 [4]	19.9 [4]
Overall[b]	63.6 [16]	71.4 [15]	65.7 [15]	75.9 [15]	73.4 [14]	75.9 [15]

(b) EQ-5D

	Fixation (Max. *n* = 110)	Hemiarthro-plasty (Max. *n* = 100)	Fixation (Max. *n* = 62)	THR (Max. *n* = 64)	Hemiarthro-plasty (Max. *n* = 62)	THR (Max. *n* = 64)
Mobility						
No problems in walking about	31 (29)	33 (33)	19 (31)	31 (48)	23 (37)	31 (48)
Some problems in walking about	76 (70)	66 (66)	43 (70)	33 (52)	38 (61)	33 (52)
Confined to bed	1 (1)	1 (1)	0 (0)	0 (0)	1 (2)	0 (0)
Self-care						
No problems with self-care	63 (58)	62 (62)	39 (63)	46 (72)	42 (68)	46 (72)
Some problems washing or dressing	44 (40)	35 (35)	23 (37)	18 (28)	19 (31)	18 (28)
Unable to dress	2 (2)	3 (3)	0 (0)	0 (0)	1 (2)	0 (0)
Usual activities						
No problems with performing usual activities	25 (23)	31 (32)	13 (21)	23 (36)	21 (34)	23 (36)
Some problems with performing usual activities	61 (55)	56 (57)	37 (60)	35 (55)	32 (53)	35 (55)
Unable to perform usual activities	24 (22)	11 (11)	12 (19)	6 (9)	8 (13)	6 (9)

(c) EQ-5D

	Fixation (Max. *n* = 109)	Hemiarthro-plasty (Max. *n* = 102)	Fixation (Max. *n* = 64)	THR (Max. *n* = 66)	Hemiarthro-plasty (Max. *n* = 64)	THR (Max. *n* = 66)
Pain/discomfort						
No pain or discomfort	25 (23)	31 (31)	15 (24)	19 (30)	19 (31)	19 (30)
Moderate pain or discomfort	77 (71)	68 (69)	43 (69)	44 (69)	43 (69)	44 (69)
Extreme pain or discomfort	7 (6)	0	4 (7)	1 (2)	0 (0)	1 (2)
Anxiety/depression						
Not anxious or depressed	65 (60)	67 (69)	39 (64)	50 (78)	42 (70)	50 (78)
Moderately anxious or depressed	39 (36)	25 (26)	21 (34)	14 (22)	14 (23)	14 (22)
Extremely anxious or depressed	4 (4)	5 (5)	1 (2)	0 (0)	4 (7)	0 (0)
EQ-5D utility score[b,c]	0.56 [0.29]	0.61 [0.29]	0.57 [0.29]	0.68 [0.24]	0.60 [0.31]	0.68 [0.24]
Compared with general level of health before breaking hip, health state today						
Better	3 (3)	7 (7)	2 (3)	6 (9)	6 (10)	6 (9)
Much the same	70 (64)	74 (74)	42 (68)	46 (72)	45 (73)	46 (72)
Worse	37 (34)	19 (19)	18 (29)	12 (19)	11 (18)	12 (19)
Thermometer[b,d]	66.0 [18]	69.1 [17]	67.4 [19]	73.3 [17]	72.8 [15]	73.3 [17]

[a] For each of the four subscales 25 represents the best outcome and 0 the worst outcome. The overall score is out of 100. Data are shown as *n* (%) or [b]mean [SD].
[c] A value of 1 indicates best possible health state, <0 worst health state. Patients who have died are assigned a value of 0.
[d] 0 = worst imaginable health state, 100 = best imaginable health state.

questionnaire at 4 months. Participants allocated fixation tended to have fewer responses in the 'no problem' categories, and this is reflected in lower mean EQ-5D utilities scores in this group. This was also reflected in a tendency to grade health state as worse than the general level of health before breaking the hip, and in lower visual analogue 'thermometer' scores.

Table 11 shows improvements in the HRQ and EQ-5D in comparison with the scores at 4 months. However, the pattern within the pairwise comparisons remains the same, with lower scores in the fixation groups than in the groups allocated hemiarthroplasty or total hip replacement.

Table 12 shows data for the same outcome variables at 24 months. While the overall hip rating questionnaire score has gone up in the fixation group and stayed the same in the total hip replacement group, it has gone down somewhat in the hemiarthroplasty group. The changes in the EQ-5D score reflect this, and the drop in the hemiarthroplasty groups is particularly marked relative to 12 months. There is now little difference between the fixation and hemiarthroplasty groups in the number of responses in the 'no problem' categories in the EQ-5D, whereas there are more in the total hip replacement group in comparison with both of the other groups.

Table 13(a) is a summary of the differences between the groups in the pairwise comparisons for the patient-reported outcomes at 4 months. The differences in the subscales and overall scale of the HRQ in respect of fixation versus hemiarthroplasty and fixation versus total hip replacement are all statistically significant. There are no clear differences between hemiarthroplasty and total hip replacement in these respects. In respect of the EQ-5D thermometer and utility score the differences go against fixation and this is significant for the utility score in the comparison of fixation with total hip replacement. *Table 13(b)* is a summary of the same analyses adjusted for age, gender and whether randomised to the two options or the three options. Adjustment makes little material difference to the findings.

Table 14 presents a similar summary of patient-reported outcomes, this time at 12 months. The pattern is broadly similar with poorer scores in the fixation groups. The overall difference in the HRQ now reflects predominantly the differences in the global and pain subscores. The EQ-5D utility score is again statistically significantly lower in the fixation group compared with the total hip replacement group. In the comparison of hemiarthroplasty with total hip replacement, there is now a marginally significantly lower score for walking. *Table 14(b)* is a summary of the same analyses, but adjusted for age, gender, and whether randomised to the two options or three options. Again, adjustment makes no material difference to the findings.

Table 15(a) is a summary of the patient-reported outcomes at the final follow-up stage of 24 months. Although the HRQ scores are still lower in the fixation group compared with hemiarthroplasty, the differences have narrowed and are no longer statistically significant; there is now no difference in the EQ-5D utility scores. Most differences between the fixation and total hip replacement group have also narrowed, although there is still a statistically significant difference in terms of the walking subscore of the HRQ. The main difference, however, at 24 months is in the comparison of hemiarthroplasty with total hip replacement. There is now a statistically significant difference in the overall HRQ score, reflecting significant differences in the walking and functions subscores. A highly significant difference has now emerged in the EQ-5D utility score. *Table 15(b)* shows the summary of the same analyses, adjusted for age, gender, and whether randomised to the two or three options. The findings are little changed by the adjustment.

Outcome according to surgical approach used

As mentioned earlier, surgeons varied in the actual way in which they performed a procedure. *Table 16* explores within observational analyses the possible impact that these variations might have had on outcome. There was no significant difference in the number having fixation failures after open or closed approaches had been used. The same applied to whether or not screws or a sliding hip screw/plate had been used. The risk of hip dislocation before 24 months appeared to be higher when a posterior rather than a lateral approach was used, although this was based on only 14 cases where the posterior approach had been used. There were too few hip dislocations after total hip replacement to address whether the approach had any impact on this outcome.

TABLE 11 *Patient outcome at 12 months*

(a) HRQ[a]

	Fixation (Max. *n* = 89)	Hemiarthro-plasty (Max. *n* = 82)	Fixation (Max. *n* = 55)	THR (Max. *n* = 54)	Hemiarthro-plasty (Max. *n* = 51)	THR (Max. *n* = 54)
Global[b]	15.9 [6]	18.7 [5]	16.3 [6]	18.6 [6]	18.1 [5]	18.6 [6]
Pain[b]	18.8 [6]	21.0 [4]	18.7 [6]	20.4 [5]	21.1 [4]	20.4 [5]
Walking[b]	16.0 [5]	17.0 [6]	16.6 [5]	19.3 [6]	16.9 [5]	19.3 [6]
Function[b]	19.9 [4]	20.4 [4]	20.2 [4]	21.1 [4]	20.4 [3]	21.1 [4]
Overall[b]	70.6 [16]	77.1 [14]	71.8 [17]	79.4 [17]	76.5 [13]	79.4 [17]

(b) EQ-5D

	Fixation (Max. *n* = 99)	Hemiarthro-plasty (Max. *n* = 95)	Fixation (Max. *n* = 61)	THR (Max. *n* = 61)	Hemiarthro-plasty (Max. *n* = 60)	THR (Max. *n* = 61)
Mobility						
No problems in walking about	35 (35)	42 (44)	25 (41)	29 (48)	26 (43)	29 (48)
Some problems in walking about	64 (65)	51 (54)	36 (59)	32 (52)	32 (53)	32 (52)
Confined to bed	0 (0)	2 (2)	0 (0)	0 (0)	2 (3)	0 (0)
Self-care						
No problems with self-care	69 (70)	71 (75)	42 (71)	49 (80)	46 (77)	49 (80)
Some problems washing or dressing	28 (29)	21 (22)	17 (29)	10 (16)	12 (20)	10 (16)
Unable to dress	1 (1)	3 (3)	0 (0)	2 (3)	2 (3)	2 (3)
Usual activities						
No problems with performing usual activities	37 (37)	37 (39)	23 (38)	25 (41)	24 (41)	25 (41)
Some problems with performing usual activities	45 (45)	47 (50)	29 (48)	31 (51)	29 (49)	31 (51)
Unable to perform usual activities	17 (17)	10 (11)	8 (13)	5 (8)	6 (10)	5 (8)

(c) EQ-5D

	Fixation (Max. *n* = 104)	Hemiarthro-plasty (Max. *n* = 105)	Fixation (Max. *n* = 65)	THR (Max. *n* = 65)	Hemiarthro-plasty (Max. *n* = 65)	THR (Max. *n* = 65)
Pain/discomfort						
No pain or discomfort	35 (35)	46 (48)	23 (38)	32 (53)	30 (50)	32 (53)
Moderate pain or discomfort	60 (60)	48 (51)	33 (54)	27 (44)	30 (50)	27 (44)
Extreme pain or discomfort	5 (5)	1 (1)	5 (8)	2 (3)	0 (0)	2 (3)
Anxiety/depression						
Not anxious or depressed	71 (71)	74 (78)	41 (67)	51 (84)	50 (83)	51 (84)
Moderately anxious or depressed	25 (25)	19 (20)	17 (28)	10 (16)	9 (15)	10 (16)
Extremely anxious or depressed	4 (4)	2 (2)	3 (5)	0 (0)	1 (2)	0 (0)
EQ-5D utility score[b,c]	0.58 [0.34]	0.64 [0.33]	0.58 [0.36]	0.70 [0.29]	0.66 [0.31]	0.70 [0.29]
Compared with general level of health before breaking hip, health state today						
Better	5 (5)	8 (8)	3 (5)	3 (5)	5 (8)	3 (5)
Much the same	67 (67)	67 (70)	41 (68)	45 (74)	44 (72)	45 (74)
Worse	28 (28)	21 (22)	16 (27)	13 (21)	12 (20)	13 (21)
Thermometer[b,d]	68.9 [19]	73.0 [18]	70.0 [20]	73.0 [17]	73.0 [19]	73.0 [17]

[a] For each of the four subscales 25 represents the best outcome and 0 the worst outcome. The overall score is out of 100. Data are shown as n (%) or [b]mean [SD].
[c] A value of 1 indicates best possible health state, <0 worst health state. Patients who have died are assigned a value of 0.
[d] 0 = wort imaginable health state; 100 = best imaginable health state.

TABLE 12 *Patient outcome at 24 months*

(a) HRQ[a]						
	Fixation (Max. *n* = 75)	**Hemiarthro-plasty (Max. *n* = 76)**	**Fixation (Max. *n* = 47)**	**THR (Max. *n* = 56)**	**Hemiarthro-plasty (Max. *n* = 50)**	**THR (Max. *n* = 56)**
Global[b]	16.9 [7]	18.2 [6]	17.9 [6]	18.4 [5]	17.7 [6]	18.4 [5]
Pain[b]	19.7 [6]	20.6 [5]	19.5 [6]	20.9 [5]	20.5 [5]	20.9 [5]
Walking[b]	16.5 [5]	17.3 [6]	17.3 [5]	19.3 [6]	16.2 [6]	19.3 [6]
Function[b]	20.1 [4]	20.0 [4]	20.4 [4]	21.2 [4]	19.3 [5]	21.2 [4]
Overall[b]	73.2 [19]	76.3 [17]	75.2 [19]	79.9 [17]	73.8 [16]	79.9 [17]
(b) EQ-5D						
	Fixation (Max. *n* = 90)	**Hemiarthro-plasty (Max. *n* = 85)**	**Fixation (Max. *n* = 58)**	**THR (Max. *n* = 59)**	**Hemiarthro-plasty (Max. *n* = 56)**	**THR (Max. *n* = 59)**
Mobility						
No problems in walking about	37 (41)	35 (42)	25 (43)	31 (53)	20 (36)	31 (53)
Some problems in walking about	53 (58)	47 (56)	33 (57)	27 (46)	34 (61)	27 (46)
Confined to bed	1 (1)	2 (2)	0 (0)	1 (2)	2 (4)	1 (2)
Self-care						
No problems with self-care	64 (71)	58 (69)	40 (70)	49 (83)	37 (66)	49 (83)
Some problems washing or dressing	22 (24)	22 (26)	13 (23)	7 (12)	15 (27)	7 (12)
Unable to dress	4 (4)	4 (5)	4 (7)	3 (5)	4 (7)	3 (5)
Usual activities						
No problems with performing usual activities	34 (38)	32 (38)	25 (43)	27 (46)	22 (39)	27 (46)
Some problems with performing usual activities	37 (41)	38 (45)	20 (35)	28 (48)	22 (39)	28 (48)
Unable to perform usual activities	19 (21)	15 (18)	13 (22)	4 (7)	12 (21)	4 (7)
(c) EQ-5D						
	Fixation (Max. *n* = 105)	**Hemiarthro-plasty (Max. *n* = 101)**	**Fixation (Max. *n* = 65)**	**THR (Max. *n* = 64)**	**Hemiarthro-plasty (Max. *n* = 65)**	**THR (Max. *n* = 64)**
Pain/discomfort						
No pain or discomfort	40 (44)	36 (42)	28 (48)	25 (43)	22 (39)	25 (43)
Moderate pain or discomfort	45 (49)	46 (54)	26 (45)	32 (55)	31 (55)	32 (55)
Extreme pain or discomfort	6 (7)	3 (4)	4 (7)	1 (2)	3 (5)	1 (2)
Anxiety/depression						
Not anxious or depressed	65 (74)	60 (71)	43 (77)	50 (85)	41 (73)	50 (85)
Moderately anxious or depressed	20 (23)	22 (26)	11 (20)	8 (14)	13 (23)	8 (14)
Extremely anxious or depressed	3 (3)	3 (4)	2 (4)	1 (2)	2 (4)	1 (2)
EQ-5D utility score[b,c]	0.55 [0.38]	0.53 [0.35]	0.58 [0.37]	0.69 [0.32]	0.53 [0.36]	0.69 [0.32]
Compared with general level of health before breaking hip, health state today						
Better	8 (9)	7 (8)	6 (10)	4 (7)	5 (9)	4 (7)
Much the same	58 (64)	54 (64)	37 (64)	41 (70)	37 (66)	41 (70)
Worse	25 (27)	24 (28)	15 (26)	14 (24)	14 (25)	14 (24)
Thermometer[b,d]	67.0 [17]	67.2 [22]	67.7 [18]	71.3 [19]	66.1 [23]	71.3 [19]

[a] For each of the four subscales 25 represents the best outcome and 0 the worst outcome. The overall score is out of 100. Data are shown as *n* (%) or [b]mean [SD].
[c] A value of 1 indicates best possible health state, <0 worst health state. Patients who have died are assigned a value of 0.
[d] 0 = worst imaginable health state; 100 = best imaginable health state.

TABLE 13 *Summary of patient-reported outcomes at 4 months*

(a) Unadjusted

	Fixation vs hemiarthroplasty Difference in means (95% CI)	Fixation vs THR Difference in means (95% CI)	Hemiarthroplasty vs THR Difference in means (95% CI)
HRQ: global	–1.81 (–3.2 to –0.41) $p = 0.01$	–2.86 (–4.71 to –1.02) $p = 0.003$	–0.93 (–2.78 to 0.92) $p = 0.32$
HRQ: pain	–1.97 (–3.41 to –0.53) $p = 0.007$	–1.76 (–3.5 to –0.02) $p = 0.05$	0.10 (–1.5 to 1.70) $p = 0.90$
HRQ: walking	–1.41 (–2.78 to –0.04) $p = 0.04$	–2.97 (–4.69 to –1.25) $p = 0.001$	–1.67 (–3.39 to 0.03) $p = 0.06$
HRQ: function	–1.31 (–2.41 to –0.20) $p = 0.02$	–1.58 (–2.89 to –0.27) $p = 0.02$	–0.76 (–2.1 to 0.57) $p = 0.26$
HRQ: overall	–6.42 (–10.77 to –2.08) $p = 0.004$	–9.04 (–14.45 to –3.63) $p = 0.001$	–3.53 (–8.92 to 1.86) $p = 0.20$
EQ-5D thermometer	–2.61 (–7.71 to 2.50) $p = 0.31$	–4.84 (–11.72 to 2.05) $p = 0.17$	–0.33 (–6.74 to 6.08) $p = 0.92$
EQ-5D utility score	–0.05 (–0.13 to 0.03) $p = 0.18$	–0.11 (–0.2 to –0.01) $p = 0.02$	–0.08 (–0.18 to 0.02) $p = 0.10$

(b) Adjusted for age, gender and whether randomised to two or three options[a]

	Fixation vs hemiarthroplasty Difference in means (95% CI)	Fixation vs THR Difference in means (95% CI)	Hemiarthroplasty vs THR Difference in means (95% CI)
HRQ: global	–1.77 (–3.17 to –0.36) $p = 0.003$	–2.91 (–4.76 to –1.07) $p = 0.002$	–1.03 (–2.87 to 0.81) $p = 0.27$
HRQ: pain	–1.83 (–3.26 to –0.39) $p = 0.01$	–1.75 (–3.49 to 0.01) $p = 0.05$	0.09 (–1.52 to 1.70) $p = 0.91$
HRQ: walking	–1.45 (–2.8 to –0.09) $p = 0.04$	–3.19 (–4.88 to –1.49) $p < 0.001$	–1.7 (–3.42 to 0.02) $p = 0.05$
HRQ: function	–1.39 (–2.47 to –0.32) $p = 0.01$	–1.71 (–3 to –0.41) $p = 0.01$	–0.78 (–2.11 to 0.55) $p = 0.25$
HRQ: overall	–6.34 (–10.67 to –2.01) $p = 0.004$	–9.41 (–14.8 to –3.97) $p = 0.001$	–3.7 (–9.1 to 1.70) $p = 0.18$
EQ-5D thermometer	–2.69 (–7.8 to 2.42) $p = 0.30$	–5.62 (–12.51 to 1.27) $p = 0.11$	–0.51 (–6.93 to 5.91) $p = 0.88$
EQ-5D utility score	–0.07 (–0.14 to 0.01) $p = 0.10$	–0.12 (–0.21 to –0.03) $p = 0.01$	–0.09 (–0.18 to 0.01) $p = 0.08$

[a] Applicable to fixation versus hemiarthroplasty comparison only.

TABLE 14 *Summary of patient-reported outcomes at 12 months*

(a) Unadjusted

	Fixation vs hemiarthroplasty Difference in means (95% CI)	Fixation vs THR Difference in means (95% CI)	Hemiarthroplasty vs THR Difference in means (95% CI)
HRQ: global	–2.37 (–3.95 to –0.78) $p = 0.004$	–1.90 (–4.05 to 0.26) $p = 0.08$	–0.14 (–2.09 to 1.81) $p = 0.89$
HRQ: pain	–2.17 (–3.67 to –0.66) $p = 0.005$	–1.89 (–3.85 to 0.08) $p = 0.06$	0.56 (–0.97 to 2.09) $p = 0.47$
HRQ: walking	–0.90 (–2.44 to 0.64) $p = 0.25$	–2.07 (–4.07 to –0.06) $p = 0.04$	–2.07 (–4.15 to 0.00) $p = 0.05$
HRQ: function	–0.62 (–1.71 to 0.46) $p = 0.26$	–0.91 (–2.32 to 0.50) $p = 0.20$	–0.74 (–2.18 to 0.71) $p = 0.32$
HRQ: overall	–5.86 (–10.38 to –1.35) $p = 0.01$	–6.64 (–12.84 to –0.44) $p = 0.04$	–2.29 (–7.88 to 3.31) $p = 0.42$
EQ-5D thermometer	–3.57 (–9.21 to 2.08) $p = 0.21$	–3.00 (–10.07 to 4.07) $p = 0.40$	–0.83 (–7.80 to 6.15) $p = 0.81$
EQ-5D utility score	–0.06 (–0.15 to 0.03) $p = 0.18$	–0.12 (–0.23 to –0.01) $p = 0.04$	–0.04 (–0.15 to 0.06) $p = 0.42$

(b) Adjusted for age, gender and whether randomised to two or three options[a]

	Fixation vs hemiarthroplasty Difference in means (95% CI)	Fixation vs THR Difference in means (95% CI)	Hemiarthroplasty vs THR Difference in means (95% CI)
HRQ: global	–2.40 (–4.01 to –0.79) $p = 0.004$	–2.02 (–4.15 to 0.11) $p = 0.06$	–0.21 (–2.15 to 1.72) $p = 0.83$
HRQ: pain	–1.92 (–3.45 to –0.40) $p = 0.01$	–1.62 (–3.56 to 0.33) $p = 0.10$	0.55 (–0.99 to 2.08) $p = 0.48$
HRQ: walking	–1.03 (–2.57 to 0.52) $p = 0.19$	–2.26 (–4.28 to –0.24) $p = 0.03$	–2.09 (–4.15 to –0.03) $p = 0.05$
HRQ: function	–0.77 (–1.85 to 0.32) $p = 0.17$	–0.99 (–2.41 to 0.43) $p = 0.17$	–0.68 (–2.10 to 0.73) $p = 0.34$
HRQ: overall	–5.82 (–10.40 to –1.25) $p = 0.01$	–6.79 (–13.03 to –0.56) $p = 0.03$	–2.45 (–8.00 to 3.09) $p = 0.38$
EQ-5D thermometer	–4.31 (–10.03 to 1.41) $p = 0.14$	–3.98 (–11.10 to 3.15) $p = 0.27$	–0.84 (–7.89 to 6.22) $p = 0.82$
EQ-5D utility score	–0.07 (–0.16 to 0.02) $p = 0.15$	–0.12 (–0.24 to –0.01) $p = 0.03$	–0.05 (–0.15 to 0.05) $p = 0.35$

[a] Applicable to fixation versus hemiarthroplasty comparison only.

TABLE 15 *Summary of patient-reported outcomes at 24 months*

(a) Unadjusted

	Fixation vs hemiarthroplasty Difference in means (95% CI)	Fixation vs THR Difference in means (95% CI)	Hemiarthroplasty vs THR Difference in means (95% CI)
HRQ: global	–1.37 (–3.24 to 0.51) $p = 0.15$	–0.51 (–2.66 to 1.65) $p = 0.64$	–0.92 (–2.99 to 1.15) $p = 0.38$
HRQ: pain	–1.04 (–2.68 to 0.61) $p = 0.22$	–1.24 (–3.29 to 0.82) $p = 0.24$	–0.57 (–2.35 to 1.21) $p = 0.53$
HRQ: walking	–1.35 (–3.07 to 0.37) $p = 0.12$	–2.38 (–4.48 to –0.28) $p = 0.03$	–2.72 (–4.98 to –0.47) $p = 0.02$
HRQ: function	–0.06 (–1.30 to 1.18) $p = 0.93$	–1.00 (–2.46 to 0.46) $p = 0.18$	–1.86 (–3.49 to –0.24) $p = 0.03$
HRQ: overall	–3.99 (–9.21 to 1.23) $p = 0.13$	–5.23 (–11.67 to 1.22) $p = 0.11$	–6.16 (–12.34 to 0.03) $p = 0.05$
EQ-5D thermometer	–0.51 (–6.66 to 5.64) $p = 0.87$	–4.34 (–11.55 to 2.86) $p = 0.24$	–5.29 (–13.20 to 2.62) $p = 0.19$
EQ-5D utility score	0.01 (–0.09 to 0.12) $p = 0.80$	–0.11 (–0.23 to 0.01) $p = 0.07$	–0.16 (–0.28 to –0.04) $p = 0.008$

(b): Adjusted for age, gender and whether randomised to two or three options[a]

	Fixation vs hemiarthroplasty Difference in means (95% CI)	Fixation vs THR Difference in means (95% CI)	Hemiarthroplasty vs THR Difference in means (95% CI)
HRQ: global	–1.22 (–3.11 to 0.67) $p = 0.21$	–0.67 (–2.76 to 1.42) $p = 0.52$	–0.98 (–3.03 to 1.08) $p = 0.35$
HRQ: pain	–0.91 (–2.59 to 0.78) $p = 0.29$	–1.22 (–3.28 to 0.84) $p = 0.24$	–0.58 (–2.37 to 1.22) $p = 0.53$
HRQ: walking	–1.48 (–3.22 to 0.27) $p = 0.10$	–2.65 (–4.70 to –0.61) $p = 0.01$	–2.82 (–4.97 to –0.66) $p = 0.01$
HRQ: function	–0.17 (–1.42 to 1.08) $p = 0.79$	–1.19 (–2.61 to 0.23) $p = 0.10$	–1.92 (–3.51 to –0.33) $p = 0.02$
HRQ: overall	–3.96 (–9.28 to 1.35) $p = 0.14$	–5.81 (–12.14 to 0.52) $p = 0.07$	–6.45 (–12.53 to –0.37) $p = 0.04$
EQ-5D thermometer	–0.95 (–7.22 to 5.32) $p = 0.77$	–4.99 (–12.31 to 2.32) $p = 0.18$	–5.50 (–13.32 to 2.32) $p = 0.17$
EQ-5D utility score	0.00 (–0.10 to 0.11) $p = 0.93$	–0.12 (–0.24 to 0.01) $p = 0.06$	–0.16 (–0.28 to –0.04) $p = 0.008$

[a] Applicable to fixation versus hemiarthroplasty comparison only.

TABLE 16 *Outcome by surgical approach*[a]

Fixation approach	No. having fixation failure before 24 months	
Open	35/77	(45%)
Closed	9/25	(36%)
Fixation approach	No. having fixation failure before 24 months	
Screws	23/51	(45%)
Sliding hip screw/plate	21/51	(41%)
Hemiarthroplasty approach	No. having hip dislocation before 24 months	
Posterior	4/14	(29%)
Lateral	1/103	(1%)
THR approach	No. having hip dislocation before 24 months	
Posterior	0/8	(0%)
Lateral	2/52	(4%)

[a] Results by actual procedure performed, not randomised group.

Exploration of whether age had an impact on differences in outcome between the treatments

Table 17 shows subgroup analyses based on strata of participants either aged 60–74 or aged 75 years and over, in terms of the principal measures of outcome. It can be seen that the differences in the overall trial results appear to reflect findings principally in the younger stratum of participants aged 60–74 years, particularly the later the follow-up. For example, in the comparison of fixation with hemiarthroplasty, at 4 months a difference in the HRQ is seen in both age strata (albeit somewhat larger in the 60–74 year-old group); this difference is sustained in the younger stratum but appears to disappear in the older age stratum. A similar pattern is seen in the comparison of fixation with total hip replacement. In the comparison of hemiarthroplasty with total hip replacement, statistically significant differences are seen at all periods for the HRQ overall score in the lower age group of participants aged 60–74 years, whereas there was no apparent difference in the older stratum aged 75 years and over.

Economic results

Mean costs and cost differences

Table 18 describes the arithmetic mean health service costs categorised by broad resource category and the actual procedure performed irrespective of the allocated management regimen. The mean costs for the initial episode ranged from £6384 for fixation to £7633 for total hip replacement. The cost differences were largely due to differences in theatre costs and the cost of protheses and hardware, with relatively little observed difference in the cost associated with the duration of initial inpatient hospitalisation.

Table 19(a) presents unadjusted mean costs and cost differences by resource category over 2 years for patients randomised to fixation or hemiarthroplasty. Although fixation is initially less costly than hemiarthroplasty, this short-term cost advantage is more than eroded by the significantly increased costs of hip-related admissions following fixation. No significant differences emerge in the costs of either the initial inpatient episode or non-hip-related admissions following the initial episode. The cumulative costs over 2 years of hemiarthroplasty were around £3000 lower compared than for fixation (95% CI –£1227 to £7192).

Table 19(a) also reports unadjusted mean costs and cost differences by resource category over 2 years for fixation versus total hip replacement and hemiarthroplasty versus total hip replacement. Compared with total hip replacement, both fixation and hemiarthroplasty were characterised by increased costs arising from hip-related admissions. When total (initial episode and subsequent hip-related admissions) hip-related costs are compared, total hip replacement was associated with a lower mean cost (mean cost difference versus fixation £2629, 95% CI –£1888 to £7146; mean cost difference versus hemiarthroplasty £3010, 95% CI –£1400 to £7420). This general pattern in cost differences was also confirmed when adjustments were made

TABLE 17 *Subgroup analyses based on participants aged 60–74 years and on participants aged ≥ 75 years*

	Age group (years)	Fixation vs hemiarthroplasty (Max. *n*, 60–74: 52 vs 46) (Max. *n*, ≥ 75: 66 vs 65)		Fixation vs THR (Max. *n*, 60–74: 32 vs 28) (Max. *n*, ≥ 75: 37 vs 41)		Hemiarthroplasty vs THR (Max. *n*, 60–74: 29 vs 28) (Max. *n*, ≥ 75: 40 vs 41)	
		HR	**(95% CI)**	**HR**	**(95% CI)**	**HR**	**(95% CI)**
Mortality	60–74	1.13	(0.30 to 4.22)	0.56	(0.09 to 3.36)	0.57	(0.09 to 3.44)
	≥ 75	0.93	(0.43 to 1.99)	2.72	(0.70 to 10.54)	2.64	(0.68 to 10.22)
Further surgery to hip or death	60–74	6.56	(2.52 to 17.10)	3.33	(1.20 to 9.22)	0.49	(0.12 to 2.08)
	≥ 75	2.23	(1.23 to 4.05)	3.36	(1.40 to 8.07)	1.48	(0.56 to 3.89)
		Difference in means (95% CI)		**Difference in means (95% CI)**		**Difference in means (95% CI)**	
4-month results							
HRQ: overall	60–74	–8.11	(–13.97 to –2.25)	–13.62	(–20.94 to –6.29)	–8.28	(–15.39 to –1.18)
	≥ 75	–5.00	(–11.29 to 1.29)	–6.30	(–14.28 to 1.68)	0.18	(–7.79 to 8.14)
EQ-5D utility score	60–74	–0.10	(–0.20 to 0.002)	–0.13	(–0.24 to –0.02)	–0.09	(–0.19 to 0.02)
	≥ 75	–0.04	(–0.16 to 0.08)	–0.11	(–0.24 to 0.03)	–0.09	(–0.23 to 0.06)
12-month results							
HRQ: overall	60–74	–11.44	(–18.27 to –4.61)	–14.79	(–24.51 to –5.06)	–8.27	(–15.95 to –0.58)
	≥ 75	–1.00	(–6.75 to 4.75)	0.10	(–7.76 to 7.96)	2.07	(–5.79 to 9.92)
EQ-5D utility score	60–74	–0.08	(–0.22 to 0.05)	–0.12	(–0.30 to 0.07)	–0.04	(–0.20 to 0.12)
	≥ 75	–0.05	(–0.18 to 0.08)	–0.14	(–0.29 to 0.02)	–0.06	(–0.20 to 0.08)
24-month results							
HRQ: overall	60–74	–8.15	(–15.73 to –0.56)	–12.78	(–22.09 to –3.47)	–12.45	(–20.93 to –3.97)
	≥ 75	0.16	(–6.98 to 7.30)	0.45	(–8.23 to 9.12)	–1.74	(–10.49 to 7.02)
EQ-5D utility score	60–74	–0.05	(–0.20 to 0.10)	–0.14	(–0.33 to 0.05)	–0.20	(–0.38 to –0.02)
	≥ 75	0.04	(–0.10 to 0.19)	–0.10	(–0.26 to 0.07)	–0.14	(–0.30 to 0.02)

TABLE 18 *Distribution of initial hospitalisation costs by resource category and actual procedure performed*

	Mean and median (IQR) costs[a] per patient			
	Fixation (*n* = 102)	**Hemiarthroplasty (*n* = 126)**	**THR (*n* = 60)**	**Non-trial procedure (*n* = 10)**
Resource category				
Mean	4801	5119	4871	5435
Median (IQR)	4019 (3282 to 5374)	4518 (3282 to 6303)	4475 (3800 to 5698)	4057 (3658 to 6778)
Theatre				
Mean	1307	1555	1907	1518
Median (IQR)	1218 (1028 to 1515)	1584 (1057 to 1867)	1739 (1602 to 2267)	1382 (1146 to 2008)
Prosthesis/hardware				
Mean	276	697	855	201
Median (IQR)	263 (238 to 338)	631 (434 to 973)	672 (672 to 898)	167 (141 to 193)
Total costs				
Mean	6384	7371	7633	7154
Median (IQR)	5607 (4693 to 6956)	6955 (5162 to 8590)	7319 (6396 to 9019)	5970 (4840 to 8979)

[a] UK £, 2000/01 values, undiscounted.
IQR, interquartile range.

TABLE 19 *Mean costs and cost differences (95% CI) by resource category over 2 years*

(a) Unadjusted

	Mean cost per patient[a]		
	Fixation (*n* = 118)	**Hemiarthroplasty (*n* = 111)**	**Mean cost Difference[b]**
Resource category			
Initial inpatient episode[e]	6524 (5904 to 7144)	7348 (6742 to 7954)	–824 (–1687 to 39)
Hip-related admissions[f]	5988 (4278 to 7699)	2483 (869 to 4098)	3504 (1159 to 5851)
Non-hip-related admissions[f]	4223 (1727 to 6718)	3966 (2016 to 5917	256 (–2921 to 3433)
Total-hip-related costs[f]	12,623 (10,768 to 14,478)	9897 (8062 to 11,732)	2726 (127 to 5325)
Total costs	16,846 (13,712 to 19,974)	13,863 (11,046 to 16,681)	2983 (–1227 to 7192)

	Mean cost per patient[a]			Mean cost per patient[a]		
	Fixation (*n* = 69)	**THR (*n* = 69)**	**Mean cost difference[c]**	**Hemiarthroplasty (*n* = 69)**	**THR (*n* = 69)**	**Mean cost difference[d]**
Resource category						
Initial inpatient episode[e]	6612 (5698 to 7527)	7593 (7012 to 8174)	–981 (–2054 to 93)	7914 (7009 to 8819)	7593 (7012 to 8174)	321 (–745 to 1387)
Hip-related admissions[f]	4551 (2836 to 6265)	1713 (789 to 2638)	2838 (908 to 4768)	3554 (984 to 6125)	1713 (789 to 2638)	1841 (–867 to 4548)
Non-hip-related admissions[f]	3613 (–117 to 7343)	2854 (1329 to 4379)	759 (–3235 to 4753)	3748 (1405 to 6090)	2854 (1329 to 4379)	893 (–1877 to 3663)
Total-hip related costs[f]	11,269 (9339 to 13,199)	9399 (8265 to 10,532)	1870 (–348 to 4089)	11515 (8621 to 14,409)	9399 (8265 to 10,532)	2117 (–963 to 5197)
Total costs	14,882 (10,799 to 18,964)	12253 (10,227 to 14,278)	2629 (–1888 to 7146)	15263 (11,300 to 19,225)	12253 (10,227 to 14,278)	3010 (–1400 to 7420)

continued

TABLE 19 *Mean costs and cost differences (95% CI) by resource category over 2 years (cont'd)*

(b) Adjusted for age, gender and whether randomised to two or three options

	Fixation vs hemiarthroplasty[a]	Fixation vs THR[a]	Hemiarthroplasty vs THR[a]
Resource category			
Initial inpatient episode[e]	–760 (–1620 to 100)	–905 (–1974 to 164)	339 (–730 to 1409)
Hip-related admissions[f]	3650 (1279 to 6021)	2863 (921 to 4804)	1839 (–884 to 4563)
Non-hip-related admissions[f]	445 (–2762 to 3654)	1030 (–2957 to 5017)	893 (–1896 to 3683)
Total-hip-related costs[f]	2931 (308 to 5554)	1966 (–252 to 4184)	2134 (–960 to 5229)
Total costs	3377 (–862 to 7615)	2996 (–1494 to 7487)	3027 (–1400 to 7455)

[a] UK £, 2000/01 values, undiscounted.
[b] Positive cost difference indicates that fixation is more costly than to hemiarthroplasty.
[c] Positive cost difference indicates that fixation is more costly than THR.
[d] Positive cost difference indicates that hemiarthroplasty is more costly than THR.
[e] From randomisation to end of initial inpatient episode.
[f] Includes service use recorded to 24 months postrandomisation, excluding initial episode.

TABLE 20 *Sensitivity analysis of mean cost differences (95% CI) between treatment options comparing a range of prostheses and hip-related admissions costs (UK £, 2000/01 values, undiscounted)*

	Prostheses cost			
Cost of hip-related admissions	**50% < baseline**	**Baseline values**	**50% > baseline**	**100% > baseline**
Fixation vs hemiarthroplasty				
50% < baseline	1361 (–2291 to 5012)	1185 (–2467 to 4836)	1009 (–2645 to 4662)	833 (–2822 to 4487)
Baseline values	3113 (–1099 to 7325)	2937[a] (–1276 to 7150)	2761 (–1454 to 6976)	2585 (–1632 to 6802)
50% > baseline	4865 (–125 to 9855)	4689 (–303 to 9681)	4513 (–480 to 9507)	4337 (–658 to 9333)
100% > baseline	6618 (717 to 12,518)	6442 (540 to 12,344)	6266 (361 to 12,170)	6090 (183 to 11,996)
Fixation vs THR				
50% < baseline	1427 (–2780 to 5635)	1197 (–3007 to 5402)	967 (–3235 to 5169)	737 (–3463 to 4937)
Baseline values	2847 (–1681 to 7374)	2616[a] (–1907 to 7140)	2386 (2134 to 6906)	2156 (–2361 to 6673)
50% > baseline	4266 (–750 to 9282)	4035 (–976 to 9047)	3805 (–1202 to 8812)	3575 (–1428 to 8578)
100% > baseline	5685 (55 to 11,314)	5454 (–169 to 11,078)	5224 (–394 to 10,843)	4994 (–620 to 10,608)
Hemiarthroplasty vs THR				
50% < baseline	2143 (–1500 to 5788)	2135 (–1513 to 5783)	2126 (–1526 to 5778)	2117 (–1541 to 5775)
Baseline values	3064 (–1346 to 7473)	3055[a] (–1358 to 7469)	3047 (–1371 to 7464)	3038 (–1384 to 7460)
50% > baseline	3985 (–1427 to 9396)	3976 (–1438 to 9390)	3967 (–1451 to 9385)	3958 (–1464 to 9380)
100% > baseline	4905 (–1636 to 11,446)	4896 (–1647 to 11,440)	4888 (–1659 to 11,434)	4879 (–1671 to 11,429)

[a] Baseline case.

for age, gender and whether randomised to two or three options (*Table 19b*).

These findings supporting an advantageous shift in the location and dispersion of costs for hemiarthroplasty compared with fixation, total hip replacement compared with fixation, and total hip replacement compared with hemiarthroplasty (*Table 20*) were robust across a range of assumptions varying the cost of hip-related admissions and prostheses. Not surprisingly, the cost differentials narrow when the cost of hip-related admissions is reduced by 50% and the cost of prostheses is doubled. Movement away from this perhaps unlikely combination of parameter values tends to widen the estimated cost differences, rendering fixation even less attractive from the perspective of NHS resource consequences over a 2-year horizon. Extreme and currently unrealistic assumptions regarding the frequency and cost of hip-related admissions and the cost of prostheses would have to be entertained for the estimated resource consequences of these alternative approaches to converge or reverse these general findings.

Chapter 4
Discussion

This is the first randomised trial to compare these three common surgical options for the management of the displaced subcapital fracture in previously fit older patients. It is also the first study to incorporate validated functional outcome measures and an economic assessment of the costs associated with each treatment method. The study found that reduction and fixation was followed by a high reoperation rate and poorer functional and health status outcome. When total hip replacement was compared with hemiarthroplasty, outcome tended to be better in the total hip replacement group, and this was statistically significant 24 months after the index operation.

Trial design

It is unlikely that the comparisons were distorted by significant bias. Randomisation was arranged through a fully automated, computer-based randomisation service, and participating surgeons were unaware of the allocation until an intervention had been assigned. Apart from the initial operative details, all subsequent data collection was organised or performed by research assistants, none of whom was directly involved in patient care. Reliance on busy clinicians to collect data has the disadvantage that data collection may be incomplete or that awareness of procedure and outcome may introduce the risk of bias. Data collection by research assistants worked well in the study with minimal loss to follow-up over the 2-year follow-up period, thus avoiding bias introduced by differential loss to follow-up. Data analysis was performed independently of participating surgeons in a free-standing research unit. All principal analyses were based on the intention-to-treat basis, hence avoiding bias introduced by differential cross-over to another form of surgery. The surgery was performed by whoever would normally do it within the hospitals taking part and hence evaluated surgical policies as they would be applied within the NHS.

The authors were concerned that the trial might not be large enough to identify with confidence clinically important but plausibly sized differences in outcome. This is why the sample size assumptions were reviewed by the data monitoring committee during the trial and why the recruitment period was extended to a longer period than originally planned. In the event, the differences observed in the primary end-points (hip function and health status) were highly statistically significant. Nevertheless, these results should be interpreted cautiously, as statistically significant differences in small trials tend to overestimate true treatment effects. Estimates of differences in some clinical events, such as pulmonary embolism, are particularly imprecise with wide confidence intervals because they are statistically rare.

A data monitoring committee reviewed accumulating trial data in confidence at two points during the trial to ensure that the trial was achieving its stated aims and to identify any ethical reason for changing the protocol (including discontinuing the study). No adjustment has been made to the analyses for this as their terms of reference indicated that only a difference of at least three standard deviations in a principal outcome would have been considered grounds for the data monitoring committee to suggest any change to the trial. The three types of surgery compared were fundamentally different. Some surgeons declined to participate because they were not comfortable with randomly allocating their patients among these options. Others were prepared to randomise, but only between fixation and hemiarthroplasty, and not to total hip replacement. Rather than lose these surgeons as collaborators in the trial, arrangements were made to allow them to randomise between the two procedures only, and this is the reason why there are more participants in the comparison of fixation with hemiarthroplasty than in the other two comparisons. Nevertheless, the fact that these surgeons were not prepared to randomise to total hip replacement reduced the statistical power of the comparisons involving total hip replacement and it is noteworthy that this was the option that apparently performed best.

Recognising that fit, older patients with displaced subcapital fractures are a relatively small subgroup, the trial was designed to maximise the chances of recruiting these patients. Several

previous trials of these fractures have been compromised by small numbers, limiting the power of the studies in question.[7,16–18] A multicentre trial was therefore planned which ultimately included 46 surgeons in 11 hospitals. Nevertheless, the trial also proved difficult to implement in practice, with the recruitment rate being lower than anticipated. Applying the criteria for trial entry to the study population, only 12% of those with displaced intracapsular fractures were considered eligible for participation. When eligible patients were asked to participate informed consent was not obtained in 31%. This was due in part to the difficulty in explaining the options and implications of the trial to relatively elderly, unwell patients. Furthermore, some patients had a history of a previous intracapsular hip fracture and had fixed ideas about the type of treatment that they wished to receive. Other patients made an informed decision about the operation they wanted based on the patient information sheet and declined to be randomised. In addition, a proportion of eligible patients could not be recruited because they failed the mental test. For some, this was due to an acute deterioration in mental function associated with the fracture. This is related to a number of factors. Patients who sustain these fractures often live alone and may wait for considerable periods before being discovered. This leads to dehydration. Following admission, administration of opiate analgesia is usual to control pain. The combination of these two factors can result in short-term deterioration in mental function, making it impossible to obtain informed consent.

The way in which the trial group was derived should be borne in mind when considering the generalisability of findings. Despite the difficulties with recruitment, a relatively large number of patients was eventually recruited. The loss to follow-up was small, and data collection was complete in 95% or more of patients entered into the trial at the 2-year final follow-up time-point.

The trial design was notably more rigorous than other randomised studies. Reports of some previous studies have not stated the method of randomisation,[7,16,17] and one trial was quasi-randomised,[19] allocating treatment by day of week. Some studies allowed for surgeon preference in deciding whether to use total hip arthroplasty or hemiarthroplasty in patients randomised to that treatment arm.[6] Only two previous studies used an intention-to-treat analysis.[4,18]

The use of the computerised randomisation system ensured an even distribution across treatment arms with well-matched groups in respect of clinical and demographic factors. Towards the end of recruitment, it was noticed that among the subgroup of patients recruited to the comparison of fixation versus hemiarthroplasty only, there was an overall imbalance in the numbers allocated to the procedures, with more in the fixation group. This reflected the use of minimisation within a number of relatively small strata characterised by the consultant surgeon. The balance within strata was good, but by chance there tended to be one or two more patients allocated to fixation in individual strata, hence the overall imbalance. For this reason, the last three patients recruited to this comparison were 'forced' into the hemiarthroplasty group, without the recruiting clinicians being aware of this. Subsequent methodological work on the advantages and disadvantages of approaches to minimisation, partly prompted by this experience, has recently been reported.[20] A proportion of patients in each group did not receive the allocated treatment (*Table 4a*). In the case of reduction and fixation this was most commonly because a satisfactory reduction could not be obtained at the time of surgery. In the case of hemiarthroplasty and total hip arthroplasty it was not always clear why the allocated procedure had not been performed. In some cases allocated to total hip replacement this was due to the lack of a sufficiently experienced surgeon to carry out a total hip replacement. The increased complexity of total hip arthroplasty was reflected in a higher rate of these procedures being performed by a consultant orthopaedic surgeon, although over half of the procedures in all groups were performed by trainee surgeons (*Table 4b*).

Owing to the multicentre design of the trial, it was not possible to standardise the implants used across the 11 participating centres. However, the implants used for fixation were of similar design and the arthroplasties were predominantly of the Charnley or Exeter type for both bipolar and total hip arthroplasties. There was no evidence that the variation in use of implants acted as an effect modifier (*Table 16*).

Clinical outcomes

Length of surgery

The group randomised to reduction and fixation had the shortest operative time: on average 9 minutes shorter than the group allocated hemiarthroplasty, which in turn had an operation time that was 21 minutes shorter than the group

allocated total hip replacement (*Table 4c*). This reflects the ascending technical difficulty of the three procedures. While a mean difference of 9 minutes is of questionable clinical or economic importance, the differences between fixation and total hip replacement (30 minutes) and between hemiarthroplasty and total hip replacement are significant. Other trials that have evaluated this point have also recorded longer operative times with arthroplasty.[4,6,7,16,18,21–23] In general, the mean differences have been between 20 and 30 minutes, although in the study by Rogmark and colleagues[6] the mean duration for screw fixation was 27 minutes compared with 80 minutes for the arthroplasty groups. These differences do not appear to have much importance in relation to outcome. The available evidence does not suggest that there is an increased risk of complications associated with the longer duration of surgery required for total hip replacement (although it does not rule it out). The main cost driver is the need for readmission and the extra duration of stay as a consequence. The lengths of stay after the initial procedure do not differ much and evidence from other surgical trials indicates that this often reflects hospitals' policies or preconceptions of how long people should stay after a particular operation.

Blood transfusion

Perioperative blood loss was not recorded; in other studies this has usually been higher with arthroplasty.[4,16,18,23] However, the requirement for postoperative blood transfusion during the acute hospital admission was evaluated. This was different in the three groups after the index operation, being lowest in the reduction and fixation group (7%), intermediate in the hemiarthroplasty group (14%) and highest in the total hip replacement group (32%). This difference is not surprising and is a reflection of the duration and magnitude of surgery.

Duration of hospital stay

There was little difference between the groups in the duration of hospital stay after the index procedure. Patients allocated total hip replacement stayed about 1 day longer on average than patients allocated the other two treatment options (*Table 5*), but the difference was not statistically significant (*Table 9a*). More than 70% in each group were discharged directly home (*Table 5*). Other studies have also reported the duration of stay as part of the outcome assessment. The results have varied, with most studies reporting no significant difference in duration of stay between arthroplasty and reduction and fixation.[4,16,18] Others have reported longer stays after arthroplasty,[6,24] although in general the actual differences have been small.

General complications

Major clinical complications were statistically rare in the trial and hence all estimates of differential effects are imprecise with wide confidence intervals. The ability to identify clinically important differences in these respects is therefore limited.

Thromboembolic complications

DVT was an identified complication in 3% of patients in the fixation group and 6% of patients who received a total hip arthroplasty. No patient in the bipolar hemiarthroplasty group was treated for DVT. The incidence of symptomatic pulmonary embolism also demonstrated no differences in the three treatment groups. Despite the fact that no symptomatic DVT was recognised in the bipolar hemiarthroplasty, five patients in this group were treated for pulmonary embolus. The incidence of asymptomatic DVT would presumably be much higher in all three groups. In terms of surgery, reduction and fixation is considered the procedure of least magnitude, but this did not manifest as a reduction in thromboembolic complications. These findings are reflected in other trials in the literature that reported thromboembolic complications as an outcome measure.[16,17,22,23] The present evidence therefore is that there is no difference in the incidence of symptomatic DVT and pulmonary embolism between the three treatments, although the wide confidence intervals do not rule out the possibility that a difference may actually exist.

Myocardial infarction

The incidence of MI was low in all treatment groups during the acute hospital stay and over the entire 24-month follow-up period (three and seven, respectively, out of the 298 participants). This complication is not reported in some studies.[5,18,23] In those studies that did report this as an outcome there were no differences in the incidence between arthroplasty and fixation groups, but again the numbers of events were small and the confidence intervals wide.[4,7,16,17,22]

Cerebrovascular accident

This complication affected only one patient in each of the three surgical treatment options at the 4-month follow-up point. This probably reflects the underlying fitness for surgery of the study cohort. By 24 months there had been a modest increase to 3% in each of the treatment groups.

The rate of this complication has been assessed in eight previous trials, which also noted no difference in rates between treatment options.

Miscellaneous general medical complications

Other general medical complications, including pressure sores, respiratory infection and urinary tract infection, affected between 3 and 6% of participants. There were no statistically significant differences between the groups in the incidence of these complications.

Mortality

Considering the differing magnitude of surgical procedure, it might be expected that reduction and fixation would be associated with a lower mortality rate in the early postoperative stages. In fact, there was no difference in mortality during the acute hospital stay, and the mortality at 4 months was 3% in the fixation and total hip replacement group, and 7% for patients who had been allocated bipolar hemiarthroplasty. There were no significant differences in mortality at any measurement point in the 24-month follow-up of the study and allocation to the procedure of greatest magnitude was actually associated with the lowest mortality (9%) at 2 years. In general, this is in line with the older published literature on the treatment of displaced intracapsular fractures.[3] A more recent review of the randomised trials[9] suggests that there is a (non-significant) lower early mortality with fixation. The mortality rates with longer term follow-up are no different. As for the other serious clinical complications, this may reflect a type II error because of the small numbers of deaths in the trials, but another explanation is that the incidence of mortality is more closely related to pre-existing medical co-morbidities than to the surgical procedure.

Local complications

Wound infection

The risk of wound infection is often cited as a reason for preferring reduction and fixation in this group of patients. This is because of the well-recognised difficulty in dealing with deep infection established in a cemented arthroplasty. Control of deep infection usually requires removal of the prosthesis with a single-stage exchange arthroplasty or interval arthroplasty at a later stage. The rate of infection in the present study was similar in all groups, with no significant differences being observed. In patients who received a total hip replacement there was only one case of established deep infection that required an excision arthroplasty. Similarly, only one patient of those who received a bipolar hemiarthroplasty had established deep infection that resulted in an excision arthroplasty. Three patients in the reduction and fixation group ultimately had an excision arthroplasty to control infection, a rate of 3%. In two cases this followed complications of a conversion to an arthroplasty. Data in the literature suggest that there is a reduced risk of infection with reduction and fixation. This may be true of the original procedure, but ignores the fact that a high percentage of patients will undergo revision surgery with a significant risk of further infection. Many previous studies have failed to report the rate of complications associated with later revision arthroplasties and this underestimates the number of patients treated by reduction and fixation who ultimately require excision arthroplasty. In the present study there was no significant difference observed at long-term follow-up and the rate of deep infection resulting in excision hemiarthroplasty was no lower in those patients initially treated with reduction and fixation.

Dislocation

Dislocation of an arthroplasty is an unwelcome complication, since it almost invariably results in readmission to hospital for relocation of the prosthesis. In most cases reduction of the dislocation needs to be carried out under anaesthesia or sedation and may be performed in an operating theatre, with possible disruption to planned theatre lists. Occasionally, it may not be possible to reduce the dislocation by closed manipulation, necessitating open reduction. These considerations have contributed to a lack of enthusiasm among some surgeons for the use of bipolar hemiarthroplasty and total hip arthroplasty for fit, older patients with displaced intracapsular hip fractures. This reticence has been reinforced by the findings in some studies of rates of dislocation following total hip replacement for these fractures in excess of 20%.[3] Dislocation of a bipolar hemiarthroplasty is known to be difficult to reduce by closed manipulation and often requires open reduction.

Some of these pessimistic views are misplaced. More recent data indicate that prosthetic dislocation rates with total hip replacement are much lower than previously thought, although still considerably higher than would be expected following the same operation performed for osteoarthritis.[9] Reported dislocation rates are much lower for hemiarthroplasty and are usually less than 5%.

The present study had a low rate of dislocation following total hip replacement (4%). This may be attributable to a number of factors. The patients were, by virtue of the entry criteria, fit with no cognitive impairment, and consequently may have been better equipped to cooperate with the standard postoperative rehabilitation regimen aimed at minimising the risk of dislocation. The majority of implants were inserted via the direct lateral approach, which is associated with a lower risk of dislocation. The rate of prosthetic dislocation was higher with implants inserted via the posterior exposure (*Table 16*), but this was based on only 14 operations performed using the posterior approach. The dislocation rate was also low in the bipolar hemiathroplasty group (3%). Three patients had dislocations and only one of these was recurrent. Although these implants have a reputation for being difficult to reduce by closed means, all of the dislocations were reduced without the need for open reduction. There were three dislocations in the total hip group, of which one recurred, but no patient had required revision surgery at the time of final follow-up. Based on this experience it is clear that although dislocation is a problem following arthroplasty, the incidence may be lower than previously reported and it seldom requires revision hip surgery.

Furthermore, this trial confirms that the belief that reduction and fixation avoid the problem is fallacious. As discussed below, revision surgery was required in a high number of these patients to deal with fixation failure. In the majority of these patients this was conversion to some form of arthroplasty. The dislocation rate in this group of patients was 10%, which contributed to the overall rate of dislocation for the fixation group over the 2 years of follow-up of 4%. The dislocation rate associated with revision surgery in patients being converted from fixation to arthroplasty is recognised to be higher than that associated with primary arthroplasty and the present results are consistent with this.

Fixation failure

By definition, fixation failure can only occur after reduction and fixation. It was, however, the most common complication encountered and accounted for the high rate of revision surgery in this group of patients. In this study the failure was due to early fixation failure in osteoporotic bone, non-union, malunion and avascular necrosis. Of these causes, early fixation failure and non-union accounted for the majority of cases. Avascular necrosis is a well-recognised complication of reduction and fixation of subcapital fractures, but was not a common cause of failure in the present study. The overall rate in the literature is 8%.[4–7,16,21,24,25] Fixation failure and non-union are now being increasingly recognised as the most common causes of failure and reoperation in these patients. As a consequence of these complications, 39% of the group allocated to reduction and fixation eventually required revision surgery. In the meta-analysis by Lu-Yao and colleagues,[3] the overall revision surgery rate after reduction and fixation was 33%. In more recent, larger trials reoperation rates of over 40% have been reported.[4,6,22,23]

Orthopaedic surgeons have tended to favour reduction and fixation for fit patients on the basis that the patients retain their hip joints and that the function would be satisfactory. However, it is apparent that between one-third and one-half of the patients treated in this way do not retain their hip and are obliged to undergo further surgery to deal with the complications of this method of treatment. Setting aside considerations of functional outcome and economics (see below), this is a very high level of revision surgery and would probably not be considered acceptable for most other orthopaedic conditions.

Functional outcome

Previous trials have had limited functional outcome data, preferring to concentrate on the rates of complications associated with each surgical procedure. Comparison of complication rates for displaced intracapsular hip fractures is not particularly enlightening, since the common complications of reduction and fixation (fixation failure and non-union) are quite different from the common, albeit less frequent, complications of arthroplasty (dislocation and infection). Most trials have used relatively crude outcome measures such as hip pain, residential status and an estimate of the level of mobility before injury and at the time of follow-up. The present study incorporated two validated outcome measures related to function (EuroQol and HRQ) to obtain a more objective measure of functional outcome and health status. When the trial was established there was no validated outcome measure for assessing function after surgical management of hip fracture. Therefore, the HRQ, originally designed for assessing hip function in arthritis, was adapted. The results have revealed a clear advantage for patients managed with arthroplasty, with statistically significantly better outcome at 24 months when total hip replacement was compared with hemiarthroplasty.

Reduction and fixation had the poorest outcome measures, particularly at the 4- and 12-month measurement points. This clearly reflects the high complication rate in this group of patients, which will naturally adversely affect function. In particular, the most notable differences were in relation to the pain component of the scores. Most of the failures following reduction and fixation occurred within the first year (see *Figures 3a*, *b*). This was reflected in a marked difference in the pain levels of patients in this group compared with the two arthroplasty groups.

Fixation failure and non-union usually result in the patients requiring revision surgery relatively urgently. Most of the failures in the fixation group would therefore have been revised, usually to an arthroplasty, once the complication had been recognised. This may be the reason why the outcome stayed at the same level between 12 and 24 months in the fixation group, but deteriorated in the hemiarthroplasty group. Perhaps most of the failures had been dealt with at that stage by conversion to arthroplasty and therefore the functional outcomes more closely matched the arthroplasty groups at that stage.

One unexpected finding was the deterioration in function in the bipolar hemiarthroplasty group between the 1- and 2-year follow-up stages. There is no obvious explanation for this. One concern about the use of hemiarthroplasty in fit patients is the risk of wear developing on the acetabular side of the joint with erosion of subchondral bone and the development of acetabular protrusio. However, this is usually treated by revision to a total hip replacement. Survivorship analysis shows little difference between the total hip replacement group and the bipolar hemiarthroplasty group, indicating that there was no late increase in failure of the bipolar hemiarthroplasty that could account for the decline in function. Longer term follow-up would be required to evaluate this change and determine whether it represents a true functional deterioration or whether the 2-year results are merely due to chance variation.

As already noted, most published trials have included limited functional outcome measures. Some trials have also shown functional advantages of arthroplasty over reduction and fixation for some outcome measures. Skinner and colleagues[19] noted that 12% of patients had residual pain at 1 year compared with none in the total hip arthroplasty group. Rogmark and colleagues[6] noted significantly less pain at 4 and 12 months, with improved walking ability in the arthroplasty group. As in the present study, the differences were less marked at 24 months, presumably owing to the improvement in the reduction and fixation failure group after conversion to arthroplasty. However, in another large recent trial[22] there was no significant difference in pain scores between hemiarthroplasty and fixation groups, although the data favoured fixation.

The numbers of participants returning to the same residence as they had been in before their injury were broadly similar in the trial groups (*Table 5*). Return to usual residence has been used as a measure of outcome in three published studies[4,21,22] where there was no statistically significant difference between hemiarthroplasty and fixation. Failure to regain the preoperative level of mobility has been reported in some studies[4,7,18,21] comparing hemiarthroplasty to fixation and there were no differences noted. Two studies[6,24] reported improved levels of mobility with total hip replacement.

Studies that have used functional scores have reported variable results. The Harris hip score has been used in two studies.[5,25] In the study by Davision and colleagues[5] hemiarthroplasty was compared with fixation in patients over the age of 65 years. There were no significant differences in the Harris hip scores between groups. Johansson and colleagues[25] reported significantly better Harris hip scores with total hip replacement than with reduction and fixation. Older studies have also reported conflicting outcomes. Using the Stinchfield classification, Søreide and colleagues[7] found more favourable outcomes in the arthroplasty group, whereas Jensen and co-workers[21] reported better outcome in the reduction and fixation group. Both studies had small numbers.

The final functional outcome assessments at 24 months in this trial suggest a clear advantage for the total hip replacement over the other two treatments. Secondary analyses stratified by a participant's age (*Table 17*) suggested that the benefit of arthroplasty over fixation and of total hip replacement over hemiarthroplasty was predominantly in the younger age stratum (60–74 years), which is contrary to current beliefs that fixation is the optimal management for these patients. It should be borne in mind, however, that current follow-up is only to 24 months and so does not address concerns about later prosthesis failure.

Economic evaluation

No previous randomised study has incorporated an economic analysis of treatment costs. There are previous studies that have estimated the potential cost of treating hip fractures,[26–28] but these have been general assessments and have not attempted to compare specific types of fracture or to differentiate between surgical treatment options. However, two published studies have estimated cost of different methods of treating subcapital femoral fractures.[29,30] These studies calculated costs on the basis of previously published data and predicted that arthroplasty would be cheaper for the management of these fractures.

The costs estimated in this pragmatic surgical trial accounted for the resource consequences of the initial procedure following injury, subsequent hip-related episodes, non-hip-related episodes and the use of other health services. It reflected contemporary techniques used by orthopaedic surgeons and the utilisation of health services by patients allocated to one of the three management strategies. Although the authors believe that their estimate of the differences in health service costs between these alternative approaches is robust, the absolute and relative differences are primarily a reflection of observed practice in Scottish centres between 1996 and 2002 and the specific resource unit costs recorded in this study. Both resource use and cost will vary across different healthcare systems and may change over time as novel techniques are adopted and a new pattern of service use is established.

The results of this study should be interpreted carefully against the background of a relatively small trial involving comparisons of resource use over a 2-year period for fairly small numbers of patients. This has the inevitable effect of making inferences less precise and reliable than would be ideal. In addition to the standard problems encountered when comparing distributions estimated with a (large) degree of imprecision, there is the attendant problem of censoring, as patients could not be followed up beyond 2 years of the date of their injury and randomisation.

This economic evaluation provides information that can be used to inform some of the arguments surrounding the choice of procedure. Given the disadvantages noted with fixation when measured against surgical and health-related quality of life end-points and the suggested attendant increase in resource consequences, it may be argued that either hemiarthroplasty or total hip replacement offers a more cost-effective approach. This conclusion should hold unless there is a dramatic convergence in revision rates across these surgical procedures. When compared with hemiarthroplasty, total hip replacement may be the preferred strategy. This study suggests that the costs of total hip replacement are lower, but the confidence intervals do not rule out the possibility that it may be more expensive.

Chapter 5
Conclusions

This is the first prospective randomised study to evaluate the three commonly selected treatment options for previously fit older patients with displaced intracapsular hip fractures. The results of the study show a clear advantage for arthroplasty over fixation; arthroplasty was more clinically effective and probably less costly over a 2-year follow-up period.

Total hip replacement performed better than hemiarthroplasty in terms of functional outcome and health status, and these differences were statistically significant at 2 years. In secondary analyses total hip replacement appeared to be particularly advantageous for younger patients (60–74-year-old age stratum). Total hip replacement was less costly than hemiarthroplasty (but the reverse could not be ruled out). However, total hip replacement is a more major procedure and might need revision, especially in younger patients. The findings of the study therefore provide strong evidence that fixation should no longer be used in the sorts of patients included in this trial. The trial also provides evidence to suggest that total hip replacement should be considered the treatment of choice for the fit patient with a displaced intracapsular hip fracture. The authors recognise that this conclusion is based on a small sample size and would encourage those who are not convinced to mount another, larger trial.

Chapter 6

Recommendations for further research

The present study has provided support for use of total hip replacement to treat displaced intracapsular hip fractures in fit, older patients. Although the total hip replacement group had a better functional and economic outcome than the hemiarthroplasty group, a larger trial comparing total versus hemiarthroplasty for these fractures could verify these findings. It would also be useful to know whether the findings of this study apply to patients under the age of 60 years who are usually treated with reduction and fixation. A clinical trial comparing arthroplasty versus fixation in patients aged over 40 years would be a logical extension of the current study.

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Contribution of authors

JF Keating (Consultant Orthopaedic Surgeon) was the principal grantholder and clinical investigator with responsibility for study design, patient and centre recruitment and coordination of the study, and was the main author of the text. A Grant (Director, Health Services Research Unit) a grantholder, was responsible for study design, administration of the study and data analysis, and was a co-author of the text. M Masson (Trial Manager) was the principal research nurse, responsible for patient recruitment in five centres, and was a co-author of the text. N Scott (Statistician) undertook statistical analysis and was a co-author of the text. JF Forbes (Senior Lecturer in Health Economics) was responsible for study design and economic analysis, and was a coauthor of the text.

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Appendix 1

Changes to eligibility criteria

Criterion	Original	Revised
Age	60–80 years	It is anticipated that most participants will be aged between 60 and 80 years, but this is not mandatory and the guiding principle is that the treatment options being compared are judged suitable by the surgeon responsible for care
Mobility	Were previously mobile (as judged, for example, by living independently and walking independently out of doors)	Were mobile before their fracture (as judged, for example, by being able to walk without the help of another person)
Consent	Are capable of giving informed consent (not seriously cognitively impaired, e.g. Mini-Mental score ≥ 7)	Are capable of giving informed consent (not cognitively impaired, e.g. Mini-Mental score ≥ 7)
Exclusion	No serious concomitant disease (e.g. known metastatic disease or terminal illness) or other reason for exclusion (e.g. contraindication to anaesthesia or clinically significant degenerative or inflammatory arthritis)	No changes

Appendix 2

Patient questionnaire

THE STARS HIP FRACTURE STUDY

Patient 4 month questionnaire

A questionnaire for people participating in the STARS study,
which aims to find out how best to manage displaced hip fractures.

Study number: ☐☐☐☐☐☐

Thank you in advance for completing this questionnaire.

The first set of questions is about your general health. By placing a (✔) in one box of each group below, please indicate which statements best describe your own health state today.

1. Mobility

I have no problems in walking about	☐ 1
I have some problems in walking about	☐ 2
I am confined to my bed	☐ 3

2. Self-care

I have no problems with self-care	☐ 1
I have some problems washing or dressing myself	☐ 2
I am unable to dress myself	☐ 3

3. Usual activities

I have no problems with performing my usual activities (e.g. work, study, housework, family or leisure activities)	☐ 1
I have some problems with performing my usual activities	☐ 2
I am unable to perform my usual activities	☐ 3

4. Pain/discomfort

I have no pain or discomfort	☐ 1
I have moderate pain or discomfort	☐ 2
I have extreme pain or discomfort	☐ 3

5. Anxiety/depression

I am not anxious or depressed	☐ 1
I am moderately anxious or depressed	☐ 2
I am extremely anxious or depressed	☐ 3

6. Compared with my general level of health just before I broke my hip, my health state today is:

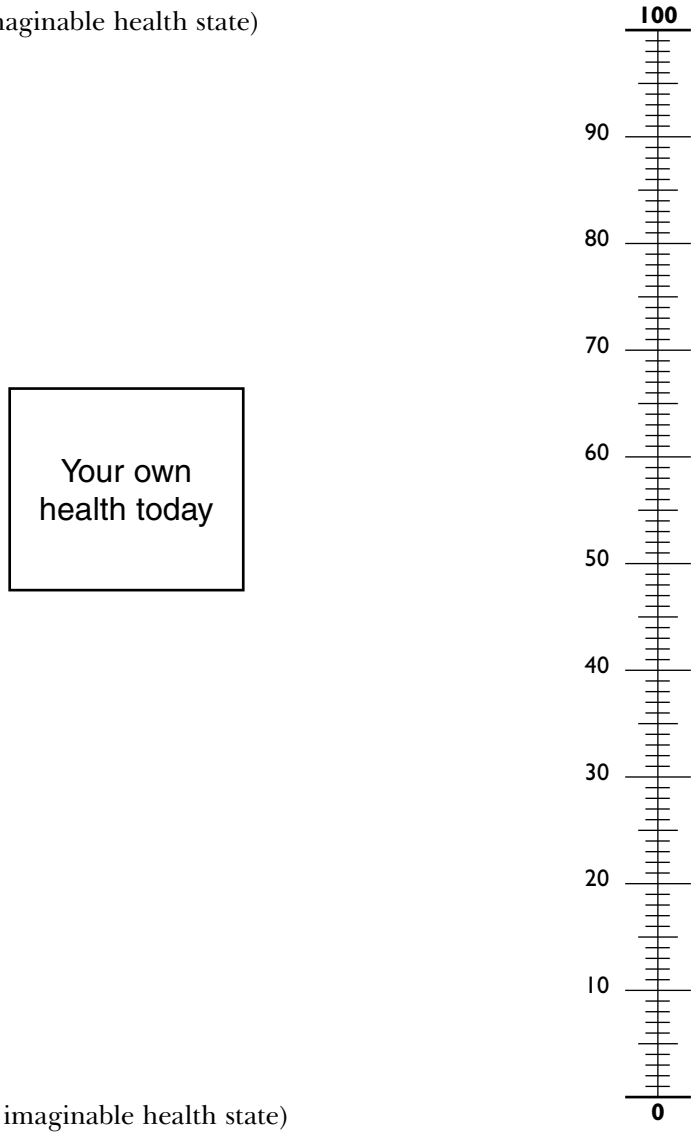
PLEASE TICK ONE BOX

Better	☐ 1
Much the same	☐ 2
Worse	☐ 3

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state is marked by 0.

We would like you to indicate on this scale how good or bad your own health is, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your heath state is.

(BEST imaginable health state)



(WORST imaginable health state)

This next set of questions is about the hip that you fractured.

Which hip(s) did you fracture? (circle one)

1 Left 2 Right 3 Both

Please answer the following questions about the hip(s) you have just indicated.

1. Considering all of the ways that your hip fracture still affects you, mark (X) on the scale for how well you are doing.

   _____

   Very well well fair poor very poor

Tick one response for each question

2. During the past month, how would you describe the pain in the hip that was fractured?

Very severe	☐	1
Severe	☐	2
Moderate	☐	3
Mild	☐	4
None	☐	5

3. During the past month, how often have you had to take medication because of the hip fracture?

Always	☐	1
Very often	☐	2
Fairly often	☐	3
Sometimes	☐	4
Never	☐	5

4. During the past month, how often have you had severe pain in the hip that you fractured?

Every day	☐	1
Several days per week	☐	2
One day per week	☐	3
One day per month	☐	4
Never	☐	5

5. How often have you had hip pain at rest, either sitting or lying down?

Every day	☐	1
Several days per week	☐	2
One day per week	☐	3
One day per month	☐	4
Never	☐	5

6. How far can you walk without resting because of pain in the hip that was fractured?

Unable to walk	☐	1
Less than 100 yards	☐	2
Between 100 yards and half a mile	☐	3
Between half and one mile	☐	4
Unlimited	☐	5

7. How much assistance do you now need for walking?

Unable to walk	☐ 1
Walk only with someone's help	☐ 2
Two crutches or walker every day	☐ 3
Two crutches or walker several days per week	☐ 4
Two crutches or walker once per week or less	☐ 5
Stick or one crutch every day	☐ 6
Stick or one crutch several days per week	☐ 7
Stick or one crutch once per week	☐ 8
Stick or one crutch once per month	☐ 9
No assistance	☐ 10

8. How much difficulty do you have going up or down one flight of stairs because of pain in the hip that was fractured?

Unable	☐ 1
Require someone's assistance	☐ 2
Require crutch or stick	☐ 3
Require banister	☐ 4
No difficulty	☐ 5

9. How much difficulty do you have putting on your shoes and socks because of your hip pain?

Unable	☐ 1
Require someone's assistance	☐ 2
Require long shoehorn and reacher	☐ 3
Some difficulty but no devices required	☐ 4
No difficulty	☐ 5

10. Are you able to use public transportation?

No, because of my hip fracture	☐ 1
No, for some other reason	☐ 2
Yes, able to use public transportation	☐ 3

11. When you bathe – either sponge, bath or shower – how much help do you need?

No help at all	☐ 1
Help with bathing one part of your body, like back or leg	☐ 2
Help with bathing more than one part of your body	☐ 3

12. If you had the necessary transportation, could you go shopping for groceries or clothes?

Without help (taking care of all shopping needs yourself)	☐ 1
With some help (need someone to go with you to help on all shopping trips)	☐ 2
Completely unable to do any shopping	☐ 3

13. If you had household tools and appliances (vacuum, mops, and so on), could you do your own housework?

Without help (can clean floors, windows, refrigerator, and so on)	☐ 1
With some help (can do light housework, but need help with some heavy work)	☐ 2
Completely unable to do any housework	☐ 3

14. How well are you able to move around?

Able to get in and out of bed or chairs without the help of another person	☐ 1
Need the help of another person to get in and out of bed or chair	☐ 2
Not able to get out of bed	☐ 3

Lastly, we would like to know about any medical problems that you have had with the hip that was fractured.

1. Since leaving hospital, have you been back to the hospital out-patients to see an orthopaedic surgeon?

   1 ☐ No 2 ☐ Yes *Please give (rough) date and surgeon's name and place, if possible*

   (i) _____ / _____ / _____ _____ _____
   day month year surgeon place

   (ii) _____ / _____ / _____ _____ _____
   day month year surgeon place

   (iii) _____ / _____ / _____ _____ _____
   day month year surgeon place

   (iv) _____ / _____ / _____ _____ _____
   day month year surgeon place

   (v) _____ / _____ / _____ _____ _____
   day month year surgeon place

2. Have you been readmitted to hospital for any reason?

   1 ☐ No 2 ☐ Yes *Please give (rough) date, place, doctor and reason, if possible*

   (i) _____ / _____ / _____ _____ _____ _____
   day month year place doctor reason

   (ii) _____ / _____ / _____ _____ _____ _____
   day month year place doctor reason

   (iii) _____ / _____ / _____ _____ _____ _____
   day month year place doctor reason

   (iv) _____ / _____ / _____ _____ _____ _____
   day month year place doctor reason

   (v) _____ / _____ / _____ _____ _____ _____
   day month year place doctor reason

3. Have you had any further surgical operations (other than the first operation to repair your hip fracture?

   1 ☐ No 2 ☐ Yes *Please give (rough) date, place, surgeon and reason, if possible*

   (i) _____ / _____ / _____ _____ _____ _____
   day month year place surgeon reason

   (ii) _____ / _____ / _____ _____ _____ _____
   day month year place surgeon reason

   (iii) _____ / _____ / _____ _____ _____ _____
   day month year place surgeon reason

Thank you for completing this questionnaire. It really will help us to find out how we can best help people who have hip fractures like the one you had.

We would like to contact you again in about eight months time. If your circumstances are likely to change, please let us know below:

New address: _____
_____
_____

New postcode: _____
New telephone number: _____
_____

Best person (such as a friend or relative) to contact if there are any difficulties

Name: _____
Address: _____
_____
_____

Postcode _____ Telephone _____

This questionnaire was produced by the Health Services Research Unit, University of Aberdeen, Polwarth Building, Foresterhill, Aberdeen AB25 2ZD

Appendix 3

Modification of Hip Rating Questionnaire

Changes are indicated in bold italics.

HRQ	Adaptation for STARS trial
1. Which hip is affected by arthritis? (circle one)	1. Which ***hip(s) did you fracture?***
2. During the past month, how would you describe the usual arthritis pain in your hip?	2. During the past month how would you describe the ***pain in the hip that was fractured?***
3. During the past month how often have you had to take medication for your arthritis?	3. During the past month how often have you had to take medication ***because of the hip fracture?***
4. During the past month, how often have you had severe arthritis pain in your hip?	4. During the past month, how often have you had severe ***pain in the hip that you fractured?***
5. How often have you had hip arthritis pain at rest, either sitting or lying down?	5. How often have you had hip ***pain at rest, either sitting or lying down?***
6. How far can you walk without resting because of your hip arthritis pain? A) Unable to walk B) Less than one city block C) 1 to <10 city blocks D) 10 to 29 city blocks E) Unlimited	6. How far can you walk without resting because of ***pain in the hip that was fractured?*** A) Unable to walk B) ***Less than 100 yards*** C) ***Between 100 yards and half a mile*** D) ***Between half and one mile*** E) Unlimited
7. How much assistance do you need for walking? A) Unable to walk B) Walk only with someone's help C) Two crutches or walker every day D) Two crutches or walker several days per week E) Two crutches or walker once per week or less F) Cane or one crutch every day G) Cane or one crutch several days per week H) Cane or one crutch once per week I) Cane or one crutch once per month J) No assistance	7. How much assistance do you need for walking? A) Unable to walk B) Walk only with someone's help C) Two crutches or walker every day D) Two crutches or walker several days per week E) Two crutches or walker once per week or less F) ***Stick*** or one crutch every day G) ***Stick*** or one crutch several days per week H) ***Stick*** or one crutch once per week I) ***Stick*** or one crutch once per month J) No assistance
8. How much difficulty do you have going up or down one flight of stairs because of your hip arthritis? A) Unable B) Require someone's assistance C) Require crutch or cane D) Require banister E) No difficulty	8. How much difficulty do you have going up or down one flight of stairs because of ***the pain in the hip that was fractured?*** A) Unable B) Require someone's assistance C) Require crutch or ***stick*** D) Require banister E) No difficulty
9. How much difficulty do you have putting on your shoes and socks because of your hip arthritis?	9. How much difficulty do you have putting on your shoes and socks because of your ***hip***?
10. Are you able to use public transportation? A) No, because of my hip arthritis B) No, for some other reason C) Yes, able to use public transportation	10. Are you able to use public transportation? A) No, because of my hip ***fracture*** B) No, for some other reason C) Yes, able to use public transportation
11. When you bathe – either a sponge bath or in a tub or shower – how much help do you need?	11. When you bathe – ***either sponge, bath*** or shower – how much help do you need?

Appendix 4

Patient information leaflet

THE STARS STUDY–
to find out how best to help people with a hip fracture like yours

An information leaflet describing

- what the STARS study is
- what it involves
- where to get further information

Your doctor will have told you that the top end of your thigh bone (femur) has broken (fractured) where it goes into the hip joint. We can understand that you must now be wishing it had never happened, but we will be doing everything we can to help you make a quick recovery. You should not hesitate to ask if you think we can help. Here in this hospital we are always trying to improve the care that we give, and this leaflet is to tell you about one way we are going to do this, and to ask if you would help us.

As you may know, many people who fracture their hips are old and less active than they were. Doctors generally agree about the best operation for them. Doctors also know that fit and active people like you also need an operation under anaesthetic when they fracture their hips. But they are not sure which of three types of operation allows the quickest return to normal, and is the best over the coming months and years.

The three operations

The top of the femur near where your break is, has a rounded end like a ball. It fits neatly into a space in the hip bone, called the socket.

One way of mending the break is with a type of screw sometimes with a plate on the side. The two parts of the bone are joined together, and no bone is replaced. The second way is using a hip replacement. The ball at the end of the femur bone is replace by an artificial 'ball' which is fixed into the top of the rest of the femur bone. The socket is not replaced.

The third method is also a type of hip replacement. Like the second method the ball of the femur is replaced. But now the socket in the hip bone is also replaced.

Your surgeon is experienced in all three methods, but is not sure which is the best one for you.

The study

Where there is doubt which is best, it means that the differences are probably fairly small. To find the answer needs a type of investigation called a randomised trial. In this the surgeon and patient agree to use whichever method of treatment is selected by a prepared list which gives you an equal chance of having one of the three methods carried out.

We are asking you whether you are willing to take part in this national study. If you agree, you will be asked to complete a questionnaire about your recovery from the operation, the function of your hip, and your general health at four months after the operation, one year after operation and again at two years.

However, there is no obligation to take part in the study. Should you decide not to participate you will have whichever one of the three treatments that is agreed between you and your surgeon. Also, if you do choose to take part, you can also withdraw from the study at any stage, and we assure you that doing so will not affect your treatment.

Further information

If you have any questions or require any more information about the study, please ask your surgeon or contact John Keating or Moyra Masson (Tel: 0131 536 3720).

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The Correspondence Page on the HTA website (http://www.ncchta.org) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

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