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Hemiarthroplasty versus internal fixation for displaced intracapsular hip fractures: A long-term follow-up of a randomised trial

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ABSTRACT

In a prospective randomised trial, 455 patients presenting to one hospital with a displaced intracapsular fracture were randomised to either closed reduction and internal fixation with three cancellous screws or replacement with an uncemented hemiarthroplasty. Follow-up of surviving patients was for between 9 and 15 years to determine the long-term outcome for the two treatment methods. 93% of patients died during this follow-up period. There was no difference in mortality between the two procedures. The need for revision surgery to the hip was increased for those treated by internal fixation (93% versus 62% implant survival rate; hazard ratio: 0.14, 95% CI 0.08–0.24). 91% of revision's operations occurred within 2 years from injury. There was no difference in the degree of residual pain between groups neither was there any difference in the number of patients requiring institutional care. These results demonstrate that both treatment methods produce comparable final outcomes but internal fixation is associated with an increased re-operation rate.

Introduction

The displaced intracapsular fracture has frequently been termed the unsolved fracture with continued debate as to whether the femoral head should be preserved or replaced.[5] A number of recently reported randomised trials comparing these two methods of treatment have tended to favor arthroplasty as this method of treatment was found to have a lower re-operation rate and a tendency to a better functional outcome.[6] We have undertaken the largest randomised trial to date on this topic and an earlier report presented the results with a 3-year follow-up for these patients.[7] This report presents the long-term follow-up for the patients recruited to this study with a mean follow-up for the surviving participants of 11 years.

Patients and methods

The full methodology of the trial has been previously reported.[7] All patients presenting to one hospital with a displaced intracapsular hip fracture between July 1991 and February 2001 were considered for inclusion. The inclusion criteria were a displaced intracapsular fracture in a patient aged over 70 years. Exclusion criteria were patients with undisplaced or minimally displaced fractures, patients with rheumatoid arthritis, chronic renal failure, significant arthritis of the hip, delay from fracture to surgery of more than 48 h, fractures secondary to tumours, Paget's disease or metabolic bone disease and those patients who were considered unfit for either of the procedures. All operations were undertaken or directly supervised by one surgeon (MJP). Randomisation was using identical sealed opaque and numbered envelopes. Once randomised all patients remained within the group to which they were allocated using an intention-to-treat analysis. Written consent was obtained from the patient or for those with mental impairment from the next of kin. The study was approved by the local ethical committee.

Internal fixation entailed a closed reduction using the fracture table and the image intensifier. Three 6.5 mm canullated cancellous screws were inserted percutaneously. Hemiarthroplasty was using an uncemented Austin Moore hemiarthroplasty inserted via an anterior-lateral approach. The same post-operative care was applied for both groups with unrestricted mobilisation and full weight bearing being allowed and no restriction on hip movements.

After discharge, follow-up of the patients was initially in a hip fracture clinic for up to 1 year from surgery and thereafter follow-up was by a phone assessment every year for 3 years, then every 2 years thereafter. For those patients who could not be contacted, enquiry was made to the patients' listed next of kin and via the patient's registered medical practitioner. Finally if the patient could not be contacted enquiry was made to the Office of Population Census Service. For the follow-up assessment pain was assessed on a scale of one (no pain) to six (constant and severe).[1]

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The patients walking ability was assessed using a scale of 0–9.[8] Nine represents full mobility indoors and outdoors without walking aids whilst zero represents a bed-bound patient. The patient was also asked what walking aids they normally used within their own home. Residential status was defined as living in their own home (including warden controlled accommodation), residential care (partial care within an institution) or nursing care (full nursing care or hospital inpatient).

Binary outcomes for the two groups were analysed using Fisher exact test and continuous outcomes with the unpaired *t*-test. Survival analysis was performed by the Kaplan–Meier method for all-cause mortality and for implant failure. For implant failure, deaths were treated as censored data and a sensitivity analysis was performed to determine if the results were altered by treating deaths as implant failures. The log rank method was used to compare the survival estimates calculated by the Kaplan–Meier method. A *p*-value of $p < 0.05$ was considered significant. The hazard ratio was calculated by the Cox regression analysis. The analysis was performed by an intention-to-treat analysis.

Results

There was no difference in the characteristics of the 455 recruited patients. The mean age was 82 years (range 71–103), 20% were male. The full characteristics and early outcomes of the two groups of patients has been previously described.[7] Of the 229 patients allocated to arthroplasty, 5 patients were treated with internal fixation as it was decided prior to surgery they were unfit for arthroplasty, in addition two of the arthroplasties were cemented in place. Of the 226 patients allocated to internal fixation 2 patients were treated with an arthroplasty because of a delay to surgery.

Follow-up of patients continued till a minimum of 9 years follow-up was achieved. The maximum follow-up was 15 years with the mean follow-up for the surviving patients being 10.6 years. By the date of the final follow-up, it was not possible to contact two patients. The follow-up for these patients was 1 year and 11 years. These patients were treated as censored at these times.

Regarding mortality, the median time to death was 3.5 years. In total 422 patients (93% of the study patients) were known to died during the follow-up period. The median survival after hemiarthroplasty was 2.7 years (95% confidence intervals (CI) 2.2–3.1 years) and 3.2 years after screw fixation (95% CI 2.5–3.9 years). The difference between these two groups was not statistically significant (rank test: $p = 0.424$; hazard ratio: 1.083, 95% CI 0.891–1.315). The mortality for the first 11 years from surgery is given in Fig. 1.

The fracture and surgery related complications are listed in Table 1. This includes complications encountered after revision surgery. Regarding re-operations for the two groups these are listed in Table 2. The implant survival rate for the hemiarthroplasty was 214/229 (93.4%), whilst that for internal fixation was 140/226 (61.9%). The time to revision is as detailed in Fig. 2. Those patients who just had removal of the internal fixation implant were excluded from this analysis. The difference between the two procedures was significant (log rank test: $p < 0.001$; hazard ratio: 0.14, 95% CI 0.08–0.24). This represents a 7.3 times increased risk of revision surgery for the screw fixation group. When deaths were treated as implant failures, the implant failure was still lower in the hemiarthroplasty group (log rank test: $p = 0.001$; hazard ratio: 0.732, 95% CI 0.604–0.887).

Fig. 3 details the mean pain scores at each assessment period for the two groups. None of the differences at any of the time points reached statistical significance. There were insufficient patients available to be assessed at 13 and 15 years for any valid data. Fig. 4 details the mean change in mobility score from the pre-injury score during the follow-up period. None of the differences between groups was statistically significant except that at 2 years after injury, with less reduction in mobility for those treated by internal fixation (*p*-value 0.03). Fig. 5 gives the percentage of patients using the same walking aids within their home as used at the time of the injury for the follow-up periods. There was no statistical significance between groups. Fig. 6 gives the percentage of patients who were living at the same residential state as immediately prior to the injury. There was no statistically significant difference between groups at any of the time periods.

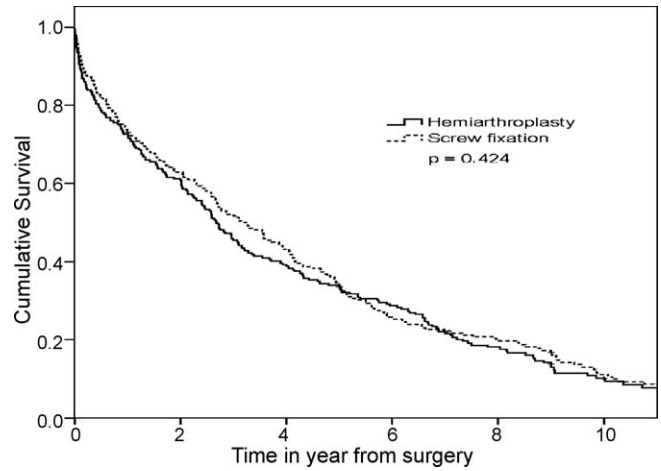

Fig. 1. Patient survival related to the two different treatment methods.

Table 1
Complications encountered for the two groups.

	Hemiarthroplasty	Internal fixation
Number of patients	229	226
Non-union of the fracture	2	78
Avascular necrosis	0	11
Loosening of the prosthesis	10	3
Fracture around implant	2	6
Dislocation	1	2
Acetabular erosion	1	0

Table 2
Types of re-operations for the two groups (some patients had more than re-operation).

	Hemiarthroplasty	Internal fixation
Removal of implant	0	19
Revision to hemiarthroplasty	2	78
Revision to total hip replacement	10	12
Fixation of fracture around implant	1	2
Reduction of dislocation	1	1
Acetabular cup augmentation	1	0
Drainage of haematoma	0	2
Excision arthroplasty	2	0

Discussion

To date there have been 17 published randomised controlled trials that have compared internal fixation with arthroplasty for intracapsular hip fractures.[6] This study is the largest to date and with this publication, the study with the longest and most complete follow-up of surviving patients. The aim was to continue follow-up until only 10% of the original participants were alive. This was to determine if there were any notable late complications with either of the treatment methods. The results of this study

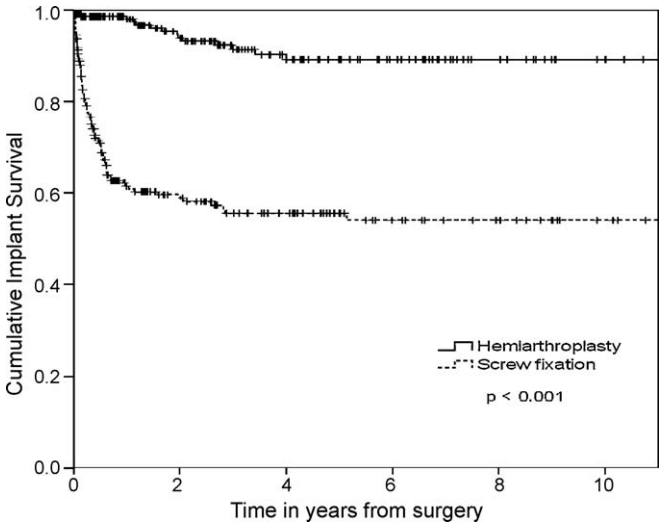

Fig. 2. Implant survival related to the two different treatment methods.

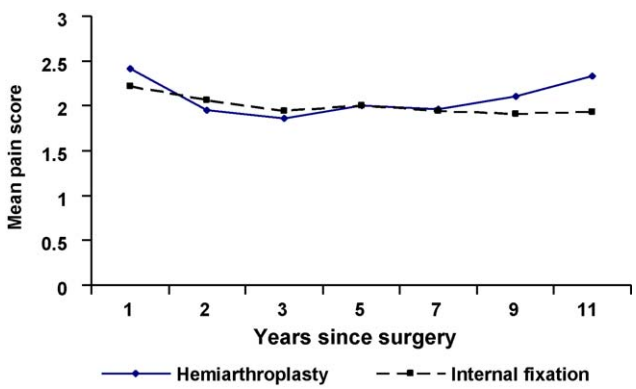

Fig. 3. Mean pain score for the two groups at the follow-up assessments.

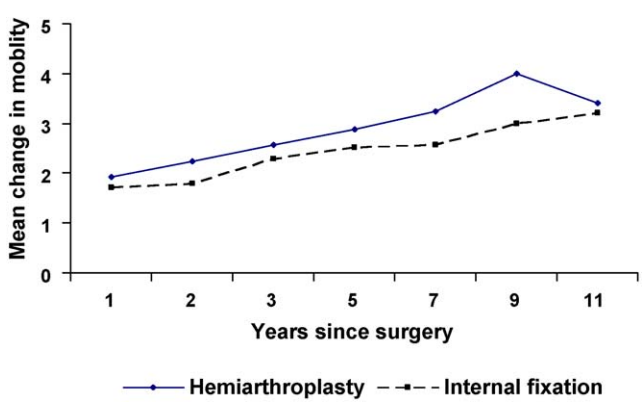

Fig. 4. The mean change in mobility score from the pre-injury score for the two groups.

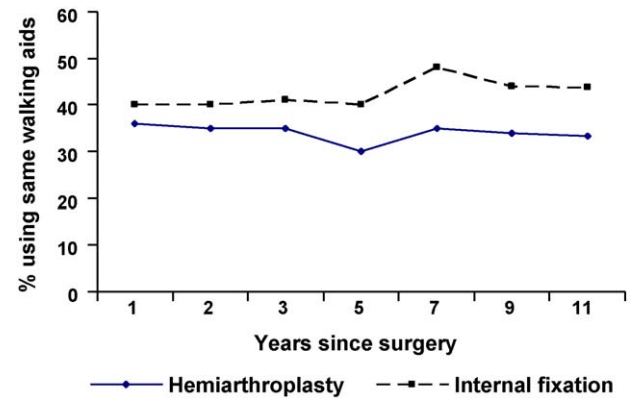

Fig. 5. Percentage of patients using the same walking aids as prior to the injury.

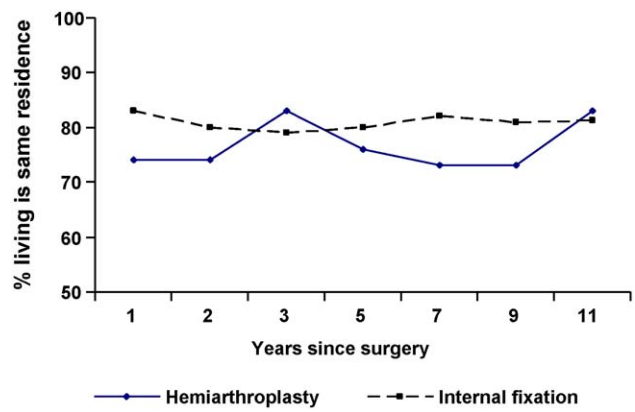

Fig. 6. Percentage of patients living at the same residential state as prior to the fracture.

clearly confirm that neither treatment method has any late sequel. As shown in Fig. 2, there were very few secondary operations after 3 years and for internal fixation the majority of revision operations were within the first year from injury. Figs. 3–6 clearly demonstrate that there was no notable change in hip function over the subsequent years.

A possible limitation of the study was the use of telephone follow-up instead of a clinic review of patients. For a study on intracapsular fractures to be able to include a representative sample of patients, it is essential that a randomised trial will have to include very elderly and frail patients. Clearly for this population repeated clinic visits are impractical and therefore an alternative method of review has to be used. Telephone follow-up is ideal as it enables all the important outcomes of residual pain, hip function, rate of revision surgery and mortality to be determined in a simple and cost efficient method. Repeated radiographs in this group of patients would only provide surrogate outcomes which may be of only limited clinical relevance.

When comparing two methods of treatment, the outcomes recorded can be divided into the final outcome measures and the process outcomes. The most important outcome measures in this study were mortality, residual pain and function. This study with its long follow-up period and minimal loss of patients to follow-up clearly demonstrated that there were no differences in the final outcome measures or mortality between the two groups. There was a small trend towards improved mobility and a lesser dependency on walking aids for those treated by internal fixation. The difference between groups however only reached statistical significance for the mobility score at 2 years from injury.

Regarding the process outcome's measures we have previously demonstrated within this study that internal fixation is associated with a shorter surgical time (24 min versus 46 min), a reduced operative blood loss (28 ml versus 177 ml) and a lower requirement for blood transfusion (2% of patients transfused versus 20%).[7] There was no difference in the overall occurrence of medical complications between the two groups. The mean hospital stay including re-admission for complication related to the hip fracture was 5 days longer for internal fixation although this difference was

not quite statistically significant (p-value = 0.087). This study confirmed the markedly increased re-operation rate for those patients treated by internal fixation with this difference persisting throughout the follow-up period.

This study was originally conceived in 1990 at a time when it was uncertain of the difference between a cemented and an uncemented arthroplasty. At this time the Austin Moore was the most frequent arthroplasty for intracapsular hip fractures in the UK.[2] For this reason it was chosen as the choice of arthroplasty for this study. Since this time a number of randomised trials have suggested that a cemented arthroplasty will lead to better mobility and less pain in comparison to an uncemented prosthesis,[3,4] it is therefore possible that had a cemented hemiarthroplasty been used in this study the functional outcomes and degree of residual pain would have been more favorable in the arthroplasty group.

A number of previous studies have compared internal fixation with arthroplasty. These have all been summarised within the Cochrane review on this subject.[6] The findings of this review were similar to the results of this study. The length of surgery, operative blood loss, requirement for blood transfusion and deep wound infections were all significantly less for internal fixation compared to arthroplasty. Arthroplasty had a significantly lower re-operation rate (11% versus 36%) in comparison with fixation. There was some limited information from some studies suggesting that there was better function and less pain for those treated with a cemented arthroplasty in comparison to fixation.

The conclusions of this study are therefore that both internal fixation and arthroplasty produce similar final outcomes of treatment. Internal fixation may have a slight tendency towards improved mobility in comparison to an uncemented arthroplasty but fixation incurs a markedly increased re-operation rate.

Conflict of interest

The authors have no conflict of interest for this paper.

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