Treatment for displaced intracapsular fracture of the proximal femur

A PROSPECTIVE, RANDOMISED TRIAL IN PATIENTS AGED 65 TO 79 YEARS

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We performed a prospective, randomised trial comparing three treatments for displaced intracapsular fractures of the hip in 280 patients aged 65 to 79 years.

The mean patient survival was significantly higher in the group undergoing reduction and internal fixation (79 months) compared with that with a cemented Thompson hemiarthroplasty or a cemented Monk bipolar hemiarthroplasty (61 months and 68 months, respectively). After three years, 32 of 93 patients (34.4%) who had undergone fixation had local complications, necessitating further intervention in 28 (30%). There were no significant differences in the functional outcome in survivors, who were reviewed annually to five years.

Either reduction and internal fixation or cemented hemiarthroplasty may be offered as alternative treatments for a displaced intracapsular fracture in a mobile and mentally competent patient under the age of 80 years. The choice of procedure by the patient and the surgeon should be determined by the realisation that the use of internal fixation is associated with a 30% risk of failure requiring further surgery. If this is accepted, however, hemiarthroplasty is avoided, which, in our study has a significantly

shorter mean survival time. The use of a bipolar prosthesis has no significant advantage.

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The choice of surgical treatment for a displaced intracapsular fracture of the proximal femur in the elderly remains as controversial now as it was almost 50 years ago when Speed¹ referred to it as "the unsolved fracture".

Our study was designed to compare the outcome after internal fixation, unipolar hemiarthroplasty and bipolar hemiarthroplasty, with particular reference to mortality and surgical morbidity, the rate of reintervention, functional recovery, level of dependency and subjective outcome. Few prospective, randomised trials have been performed which evaluate alternative treatments for displaced fractures of the femoral neck,² and to the best of our knowledge no such comparison of these three treatments has been reported.

Patients and Methods

All patients with a displaced intracapsular fracture of the proximal femur and aged between 65 and 79 years were considered for entry into the study. The patients were assessed by a research fellow, who recorded full details of health, mobility and dependency before the fracture occurred. We excluded patients who had a mental test score of less than 5/13 (Table I),³ uncontrolled Parkinson's disease, a pathological fracture or disseminated malignancy, Paget's disease, rheumatoid arthritis or were on long-term steroid therapy.

Patients were assigned by computer generation of random numbers to one of three treatments: 1) reduction and internal fixation using an 'Ambi' compression hip screw (AHS) and a two-hole plate (Smith & Nephew Richards, Cambridge, UK); 2) a cemented Thompson unipolar hemiarthroplasty (Corin Medical Ltd, Cirencester, UK); or 3) a cemented Monk (hard-top) bipolar hemiarthroplasty (Johnson & Johnson Orthopaedics, Bracknell, UK).

Between January 1, 1991 and January 31, 1996, 280 patients were recruited. There were 93 in the internal fixation group, 90 in the Thompson group and 97 in the Monk group.

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Table I. Abbreviated mental test score³

One point is given for each correct response. Maximum score = 13	
An address is given to the subject who is then instructed to memorise it (e.g. 42, West Street, Barkminster).	
Age in years	1
Time of day, to nearest hour	1
Current year	1
Name of the hospital	1
Recognition of 2 people	1
Date of birth:	
Day	1
Month	1
Year	1
Dates of World War II	1
Name of current monarch	1
Countdown from 10 to 1	1
Address:	
Partially recalled	1 point
Completely recalled	2 points

Operative technique

Internal fixation. The patient was positioned on the fracture table, and manipulative reduction was carried out under fluoroscopic control. After reduction, true postero-anterior and lateral radiographs were retained for formal measurement according to the criteria of Garden's index.⁴ A central guide-wire and one or two peripheral derotation wires were passed across the fracture to stabilise the reduction during fixation. A sliding lag screw and a 135° two-hole plate were used without a supplementary derotation screw. Further radiographs were obtained on completion of fixation.

Hemiarthroplasty. Replacement of the femoral head was carried out using a lateral (Hardinge) approach. The unipolar and bipolar prostheses had identical collar-and-stem profiles, and the surgical technique for implantation was the same. Methylmethacrylate cement of normal viscosity was inserted using a simple orthograde technique, with a vent and no cement restrictor.

All patients were mobilised after the operation bearing weight without restriction on the injured limb, under the direction of a physiotherapist.

All patients were invited to attend for assessment six weeks after surgery and annually for five years. Fractures which had been fixed internally were reviewed at intervals until they had united clinically and radiologically. At each attendance a verbally-conducted assessment questionnaire, which included subjective questions of function relative to the status before fracture and the level of satisfaction, was completed, as well as a formal Harris hip score.

Radiographs of the hip and pelvis were obtained at each attendance. Fractures which had been internally fixed were assessed for union, migration and cut-out of the screw, avascular necrosis and collapse, and degeneration of the joint. The pelvic radiograph was also assessed for evidence

of acetabular erosion.⁵ This was considered to have occurred if the prosthetic head had migrated by more than 3 mm in a medial or superior direction on serial radiographs. The radiographs of the patients with a hemiarthroplasty were also assessed for evidence of loosening and subsidence.⁶

From November 1994, a home assessment was carried out annually by a research occupational therapist who was blind to the patient's operative treatment. Data were collected by interview and direct observation. The level of mobility and dependency was assessed using the Barthel index⁷ which is a score based on activities of daily living (Table II).

Statistical analysis. The time to death, time to revision, time of return to the preinjury state and satisfaction were compared among the three groups by proportional hazards regression models. Time to revision and death were censored on July 1, 1997. For time of return to preinjury state and satisfaction, subjects with no review who were not known to have died were excluded from the analysis.

The minimum follow-up for all 280 subjects was two years. A maximum of 233 patients was eligible for three-year assessment, 179 at four years and 117 at five years.

Outcomes measured at each clinic review (Harris hip score, pain score and satisfaction with outcome) and the functional outcomes from home assessment (Barthel score) were analysed using MLN (Multilevel Number Modelling Software, Institute of Education, 1995) to allow for the variable numbers and times between reviews and assessments. Random-effects models were fitted, with each of the outcomes in turn as the dependent variable, and the operation group (AHS, Monk, Thompson) as the independent variable.

Results

The baseline details of the three operative groups were similar, although the AHS group was younger and more functionally independent before the fracture (Table III). All patients were Caucasian.

Initial surgery. Closed reduction was performed in all patients in the AHS group. In ten the reduction did not meet Garden's radiological criteria but was accepted. Of these, seven subsequently had a salvage procedure. An initially good reduction was lost in one patient during internal fixation and was revised to a hemiarthroplasty. Satisfactory reduction and fixation were achieved in the remaining patients. No surgical problems were encountered during any of the hemiarthroplasty procedures.

Mortality. Significant differences in survival were found among the three groups, with the mean survival time for the AHS group being 79 months compared with 61 months and 68 months in the Thompson and Monk groups, respectively (Wald chi-square = 9.58 on 2df, $p = 0.008$). The differences in early mortality to six months are shown in Figure 1a. The proportion surviving to various time points from the date of operation are shown in Table IV and Figure 1b by operative group.

Table II. The modified Barthel index⁷ based on the activities of daily living

Index score derived by grading each of the 10 activities below and adding the scores obtained
(full operational definitions required for use – see article)
Maximum score = 20

Bowels	0, incontinent 1, occasional accident (maximum 1 per week) 2, continent
Bladder	0, incontinent, or catheterised 1, occasional accident (maximum 1 per day) 2, continent
Grooming	0, needs help with personal care 1, independent
Toilet use	0, dependent 1, requires some help 2, independent
Feeding	0, unable 1, requires some help 2, independent
Transfer (bed to chair)	0, unable, no sitting balance 1, requires major physical help, able to sit 2, requires supervision or some minor physical help 3, independent
Mobility	0, immobile 1, wheelchair independent (including corners) 2, walks with assistance or supervision of one person 3, independent (but may use any walking aid)
Dressing	0, dependent 1, requires some help 2, independent
Stairs	0, unable 1, needs help (verbal, physical, carrying aid) 2, independent
Bathing	0, dependent 1, independent (or uses shower)

Table III. Details of the patients by operation group, by number and *percentage*

	AHS (n = 93)	Thompson (n = 90)	Monk (n = 97)
Female	70 (75.3)	71 (78.9)	72 (74.2)
Independent of aids	67 (72.0)	55 (61.1)	66 (68.0)
Independent in mobility	79 (85.0)	69 (76.7)	74 (76.3)
Incontinent	1 (1.1)	8 (8.9)	1 (1.1)
Marital status			
Single	9 (9.7)	9 (10.0)	10 (10.3)
Married	45 (48.4)	45 (50.0)	47 (48.5)
Widowed/Divorced	39 (41.9)	36 (40.0)	40 (41.2)
Living independently in the community	87 (93.6)	83 (92.2)	91 (93.8)
With any previous fracture	18 (23.1)	25 (28.8)	28 (31.1)
Median age (years (IQR*))	73 (70 to 77)	76 (72 to 77)	75 (71 to 78)
Median delay between fracture and admission (days (IQR))	0 (0 to 0)	0 (0 to 0)	0 (0 to 1)
Median delay between admission and operation (days (IQR))	2 (1 to 2)	2 (1 to 3)	2 (1 to 3)
Median inpatient stay (days (IQR))	14 (10 to 21)	15 (11 to 22)	15 (13 to 21)
Median mental test score (IQR)	13 (13 to 13)	13 (13 to 13)	13 (12 to 13)

* interquartile range

Table IV. Proportion surviving and proportion revision-free at various times after operation with 95% confidence intervals in parentheses

Time from operation (mth)	Survival (%)			Revision-free (%)		
	AHS	Monk	Thompson	AHS	Monk	Thompson
0	100	100	100	100	100	100
6	95 (90 to 99)	90 (84 to 96)	93 (88 to 98)	82 (75 to 90)	99 (97 to 100)	99 (97 to 100)
12	91 (86 to 97)	88 (81 to 94)	89 (82 to 95)	79 (71 to 87)	99 (97 to 100)	99 (97 to 100)
18	89 (83 to 96)	86 (79 to 93)	86 (78 to 93)	76 (67 to 84)	99 (97 to 100)	99 (97 to 100)
24	88 (81 to 95)	83 (76 to 91)	80 (71 to 88)	73 (64 to 82)	98 (94 to 100)	99 (97 to 100)
30	83 (75 to 91)	81 (73 to 89)	75 (66 to 84)	73 (64 to 82)	98 (94 to 100)	99 (97 to 100)
36	81 (73 to 90)	78 (70 to 87)	72 (63 to 82)	71 (61 to 81)	98 (94 to 100)	99 (97 to 100)

Fig. 1a

Fig. 1b

Figure 1a – Bar chart showing cumulative mortality over first 180 days after surgery by group. Figure 1b – Graph showing percentage survival over time after surgery.

Morbidity and revision surgery. Table V summarises the surgical complications and outcomes encountered in all three groups. The rates of revision for the three groups were substantially different, with 28 revision procedures being required in the AHS group compared with three in the Thompson group and five in the Monk group (Wald chi-square = 25.9 on 2df, $p < 0.0001$).

Internal fixation. There was a high incidence of failure of fixation and rate of reoperation after internal fixation (Tables IV and V). The rate of surgical complications was 21 of 93 (22.6%) at one year, and 19 of 93 patients (20.4%) had had a salvage arthroplasty procedure within one year for symptomatic failure of fixation. At two years, complications had occurred in 27 of 93 patients (29%), 21 (78%) resulting from the lag screw cutting out or penetrating the femoral head. At two years, 25 patients (26.8%) had been revised. Overall, 28 patients (30.1%) in the internal fixation

group required salvage surgery. Local complications occurred in 32 of 93 patients (34.4%).

Thompson hemiarthroplasty. There were no deep wound infections and the rate of dislocation was 1.1%. Two patients developed pain, with radiological evidence of acetabular erosion. In one, cement debris was identified within the acetabulum and total hip arthroplasty was performed at five months. The second patient required revision after three years. The surgical intervention rate was 3.3% in this group.

Monk hemiarthroplasty. Five patients (5.2%) have undergone revision surgery. One patient developed a deep wound infection (1%) and dislocation occurred in two (2.1%). One patient with persistent trochanteric pain had an exploration and excision of heterotopic bone after 18 months. The symptoms persisted but revision surgery was declined. One Monk prosthesis was revised at four years for persistent

Table V. Summary of complications by trial group over time

Number	Days after surgery	Complication/outcome	Revision procedure
Internal fixation			
138	9	Fixation failure; lag screw cut-out	THR
371	16	Fixation failure; lag screw cut-out	Hemiarthroplasty
121	17	Fixation failure; lag screw cut-out	THR
66	20	Early lag screw penetration. No intervention; ambulant and pain-free to 5 yrs in nursing home	Nil
482	21	Wound infection 3 weeks after surgery; chronic discharge	Nil
312	23	Fixation failure; lag screw cut-out after fall onto the hip	Hemiarthroplasty
585	34	Fixation failure; lag screw cut-out	THR
294	45	Fixation failure; lag screw cut-out	Hemiarthroplasty
608	45	Fixation failure; lag screw cut-out	Hemiarthroplasty
634	62	Fixation failure; lag screw cut-out	Hemiarthroplasty
466	63	Fixation failure; lag screw cut-out. THR complicated by recurrent dislocation	THR
298	69	Avascular necrosis and collapse with lag screw cut-out	THR
217	75	Fixation failure; lag screw cut-out	THR
305	82	Avascular segmental collapse	THR
46	96	Fixation failure; lag screw cut-out	THR
354	107	Fixation failure; lag screw cut-out	THR
29	107	Fixation failure; lag screw cut-out. 1st revision to Thompson, 2nd to THR at 4 yrs	Hemiarthroplasty, THR
264	110	Fixation failure; lag screw cut-out	THR
296	193	Nonunion with avascular collapse	THR
315	204	Avascular segmental collapse and lag screw cut-out	THR
274	259	Symptomatic nonunion	THR
685	393	Nonunion with screw penetration	Removal of fixation
453	498	Nonunion with screw penetration	THR
68	536	Avascular necrosis	THR
235	575	Nonunion with avascular collapse and cut-out	THR
67	581	Avascular necrosis	THR
251	696	Nonunion with screw penetration	THR
190	1790	Avascular necrosis with advanced arthritis	THR
256	670	Established nonunion, asymptomatic	Nil
309	1084	Avascular necrosis with arthritis, mild symptoms	Nil
160	1037	Avascular necrosis. Removal of fixation, followed after 2 yrs by THR	Removal of fixation, THR
194	1265	Nonunion with screw penetration	Removal of fixation
Thompson hemiarthroplasty			
554	1	Dislocation × 2	Closed reduction
290	165	Acetabular erosion	THR
493	1226	Acetabular erosion	THR
Monk hemiarthroplasty			
640	3	Dislocation. Recurrent pneumonia and died	Closed reduction
433	15	Dislocation	Open reduction
544	550	Refractory pain; heterotopic bone	Open biopsy and bone excision
161	1263	Deep infection, chronic recurrent discharging sinus	Excision arthroplasty
304	1460	Acetabular erosion	THR

groin pain. The origin of the pain was not established but it resolved after total hip arthroplasty.

Clinical review. The patients seen for review are summarised in Table VI. The three groups were similar in the proportions which had clinic reviews and home assessments. The baseline characteristics of those patients complying with the clinic and home reviews were similar among the three groups.

Return to preinjury state. The mean time of return to the

preinjury state for those receiving the Monk hemiarthroplasty was 24 months compared with 36 months in the AHS and Thompson groups. Two years after the operation, 51% of the Monk group had not returned to the preinjury state compared with 74% of the AHS patients and 71% of the Thompson group (Table VII).

These differences did not reach significance (Wald chi-square = 4.09 on 2df, $p = 0.09$).

Satisfaction. Significant differences in the rates of satisfac-

Table VI. Number of patients reviewed (*percentages* in parentheses) and place of review

	Clinic only	Clinic and home	Home only	No review
AHS	8 (9)	53 (57)	15 (16)	17 (18)
Thompson	16 (18)	47 (52)	11 (12)	16 (18)
Monk	11 (11)	59 (61)	10 (10)	17 (18)
Total	35 (12.5)	159 (56.8)	36 (12.9)	50 (17.8)

Table VII. Percentage failing to have returned to preinjury state and percentage unsatisfied at various times after operation, with 95% confidence intervals in parentheses

Time from operation (mth)	Not having returned to preinjury state			Unsatisfied		
	AHS	Monk	Thompson	AHS	Monk	Thompson
0	100	100	100	100	100	100
6	100	100	100	100	100	100
12	88 (80 to 96)	80 (70 to 89)	90 (83 to 98)	78 (68 to 89)	59 (48 to 71)	65 (53 to 76)
18	76 (67 to 88)	58 (46 to 70)	75 (64 to 87)	36 (23 to 48)	20 (10 to 28)	9 (2 to 17)
24	74 (62 to 85)	53 (41 to 65)	71 (59 to 83)	30 (18 to 42)	15 (6 to 23)	6 (0 to 12)
30	53 (38 to 68)	45 (33 to 58)	56 (41 to 70)	19 (8 to 30)	9 (2 to 15)	3 (0 to 8)
36	49 (38 to 68)	43 (31 to 56)	48 (33 to 63)	9 (0 to 19)	9 (2 to 15)	0 (0 to 0)

Table VIII. Mean Harris hip score by group at each annual review

	Annual review (year)				
	1	2	3	4	5
AHS	70.8	70.7	70.6	71.8	70
Thompson	71.1	70.7	72.4	68.4	71.8
Monk	73.2	77.6	74.8	77.4	73.6

tion were found among the three groups (Wald chi-square = 11.41 on 2df, $p = 0.003$). The level of satisfaction with recovery was lowest in the internal fixation group. By 18 months, only 9% of those receiving a Thompson prosthesis remained dissatisfied compared with 20% in the Monk group, and 36% in the internal fixation group (Table VII). *Home assessments.* No significant difference in the Barthel index score was found among the three groups (chi-square = 2.28 on 2df, $p = 0.32$).

Harris hip score. The mean Harris hip scores at each annual review by group are shown in Table VIII. No significant differences in score were identified among the groups.

Discussion

The age and exclusion criteria which we used led to the selection of patients in whom the choice of surgical treatment is the most controversial. Few prospective, randomised trials have been conducted for this fracture, and the large number of other reported studies often draw conclusions which conflict.²

The principal finding in this trial was the significant difference in the rate of reoperation between the internal fixation and hemiarthroplasty groups. The most common type of failure of internal fixation was redisplacement of the fracture with the lag screw cutting out of the femoral

head. The sliding hip screw and plate were selected for use in our study after a prospective, randomised trial carried out in our hospital had shown similar results compared with cannulated hip screws, but without the risk of subtrochanteric fracture associated with cannulated screws.⁸ Some surgeons prefer alternative methods of fixation of intracapsular hip fractures. A meta-analysis of fixation methods showed that the sliding compression screw and plate performs similarly to other methods.⁹

The difference in reoperation and rate of revision between internal fixation and hemiarthroplasty was similar to other reports.¹⁰⁻¹² Late failure and revision are most commonly associated with avascular necrosis and collapse of the femoral head, which is normally evident within two years of injury. All subjects in our study were assessed beyond that period.

A significantly longer mean survival in the internal fixation group seemed to conflict with the much higher rate of surgical reintervention in that group. The difference remained despite statistical correction for the slightly younger mean age and lower dependency level of the subjects randomised to this group. Previous reports noted that a transient increase in mortality after hemiarthroplasty compared with internal fixation was lost after one year.²

The number of patients who declined follow-up (out-patient or home assessment) was disappointing, although survivors who were successfully reviewed were evenly

distributed between the three groups and were found to be representative samples of each. No significant functional differences were identified among the three groups in patients reviewed by both outpatient clinic and home assessment. Subjective assessment of outcome also demonstrated no marked difference between the groups, although the internal fixation group fared least well.

No significant benefit was demonstrated from the use of the Monk bipolar implant during the follow-up period. We believe that a patient's own assessment of outcome is important.¹³ While the Monk group had the highest number claiming to have returned to their preinjury functional state, this was not statistically significant, and patients in the Thompson group were the most satisfied. Both acetabular erosion and loosening in hemiarthroplasty survivors will potentially lead to further cases requiring revision. Only extended follow-up will determine the scale of these problems, and demonstrate whether the theoretical advantage of the bipolar articulation over the Thompson implant proves to be of functional benefit.

We conclude that an informed choice between internal fixation and hemiarthroplasty can be made with the individual patient. The wish to avoid the risk of symptomatic failure of fixation requiring secondary surgery (approximately 30% in this study) will lead many patients to prefer replacement of the femoral head despite the potentially higher mortality. Most patients who are happy to accept this risk and undergo internal fixation will successfully retain their femoral head, although our study failed to demonstrate any clear advantage in terms of symptoms and function by doing so.

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