The results of arthroplasty in osteoarthritis of the shoulder

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We have undertaken a prospective clinical and radiological analysis of 124 shoulder arthroplasties (113 patients) carried out for osteoarthritis. The clinical results showed improvement in the absolute Constant score and the American Shoulder and Elbow Surgeons score of 22 and 43, respectively. Both were statistically significant ($p < 0.001$). There was no significant difference in the scores after hemiarthroplasty and total arthroplasty in those patients with an intact rotator cuff.

When revision was used as the end-point for survival at ten years, survival of 86%, or 90% if glenoid components made of Hylamer sterilised in air were omitted, was obtained in primary osteoarthritis. The most common cause for revision in the hemiarthroplasty group was glenoid pain at a mean of 1.5 years; in the total arthroplasty group it was loosening of the glenoid at a mean of 4.5 years. Analysis of pre-operative factors showed that the risk of gross loosening of the glenoid increased threefold when there was evidence of erosion of the glenoid at operation. Shoulder arthroplasty should not be delayed once symptomatic osteoarthritis has been established and should be undertaken before failure of the cuff or erosion of the glenoid are present.

The number of shoulder replacements for osteoarthritis has been increasing over the past 40 years with various changes being made to the earlier designs of prosthesis. However, many questions remain about the most appropriate procedure to be performed. While good functional improvement is usually gained,[1-4] this may be related more to relief from pain than improved movement. Relief from pain is generally expected although a few patients continue to have discomfort. The reason for this is not always clear.

There is still uncertainty as to whether replacement of the glenoid is associated with improved functional results.[1,2,5] There is a high incidence of radiological lucency and loosening of the glenoid component, despite improved techniques of fixation, which gives concern as to the long-term survival of the component. When only replacement of the humeral head is performed there is concern about adequate relief from pain and the potential for progressive erosion of the glenoid.

We have analysed these factors in a consecutive series of operations performed for osteoarthritic conditions using a single type of prosthesis since 1992, with at least a two-year follow-up period.

Patients and Methods

Between 1992 and 2002 the Global Shoulder replacement (DePuy International Ltd, Leeds, United Kingdom) was used in 124 shoulders in 113 patients for osteoarthritis. During this period no other type of prosthesis was used and no patient was excluded. The indications for surgery were increased levels of pain and reduced function of the shoulder. Radiological assessment included standard anteroposterior (scapular plane) and axillary views. Scanning was not routinely performed. Glenoid erosion was assessed on the radiographs and at surgery.

All the operations were performed by the senior authors (IAT, JFH) or under their supervision, using laminar air flow, body-exhaust suits and prophylactic antibiotic cover. The deltopectoral approach was used in all cases with division and release of the subscapularis tendon and anteroinferior capsule. The standard jigs for the implant at the time were used, which included in the more recent cases an intramedullary alignment guide.[6] Post-operative care involved an early active assisted mobilisation programme starting from the first post-operative day.

The mean age at operation was 66 years (SD 11.8; 35 to 89) with a male:female ratio of 1:3.

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Table I. Details of 124 Global Shoulder arthroplasties according to diagnosis and type of arthroplasty

Parameter*	OA†	AVN†	PTA†
Number of operations	95	14	15
Arthroplasty			
HHR	31	7	4
TSR	64	7	11

* HHR, humeral head replacement; TSR, total shoulder replacement
† OA, osteoarthritis; AVN, avascular necrosis; PTA, post-traumatic arthritis

Of the 124 shoulders, 42 had humeral head replacement and 82 had total shoulder replacement. Table I shows the diagnoses and the operations performed. The most common diagnosis was primary osteoarthritis. No cases of avascular necrosis were secondary to trauma and there were no cases of nonunion in patients with post-traumatic arthritis. The mean follow-up was for 5.1 years (SD 2.8; 2.2 to 11.6) unless there had been earlier revision. A glenoid component without metal backing was inserted in 82 shoulders, using the five-pegged device in 59 and the keeled in 23. The type of glenoid component used was the choice of the surgeon at the time of surgery. In all cases CMW cement with gentamicin (DePuy International Ltd) was inserted from a syringe and with finger pressure after the use of saline and hydrogen peroxide to remove as much blood as possible. In the presence of glenoid erosion bone grafting was not used but the glenoid was reamed to the correct alignment. Apart from two early cases, replacement of the humeral head was undertaken when there was a non-functioning or unrepairable rotator cuff, or when the glenoid bone was inadequate. A further group of patients had a humeral head replacement despite an adequate rotator cuff and glenoid, in line with the philosophy on appropriate treatment at that time. The humeral component was inserted without cement with the exception of seven cases.

The rotator cuff was intact in 95 shoulders and treated by a humeral head replacement in 20, in seven of which there was glenoid erosion. A small tear was present in ten shoulders, in five of which humeral head replacement was used; two of these had glenoid erosion. Large tears with a non-functioning cuff were present in 19 shoulders in which humeral head replacement was used 17 times; three had glenoid erosion (Table II).

The patients were assessed by the use of a visual analogue pain score (0 = no pain, 10 = worst possible pain), the American Shoulder and Elbow Surgeons score[7] and the absolute score of Constant and Murley.[8] These were initially obtained prospectively at the routine out-patient attendance, but since 1997 they have been collated by an independent research physiotherapist (AB) using special research clinics when necessary. The range of movement was assessed by a goniometer (Baseline, Chattanooga Group, Chattanooga, Tennessee) and strength was measured in kilograms of resisted abduction at 90° using an electronic myometer (MIE Medical Instruments, Leeds, United Kingdom).

Radiographs were obtained throughout the period of study and analysed after the latest review. Demarcation of the humeral components was assessed using the method of numbering described by Sperling et al.[9] Analysis of the glenoid components was carried out according to the method of Lazarus et al.[10] However, 15 of the 82 glenoid components were made of Hylamer (DePuy International Ltd.) which had been sterilised by gamma irradiation in air. This is now acknowledged to be associated with increased wear and loosening.[11] Late glenoid erosion in humeral head replacement was assessed by analysing the medial migration of the humeral component using a method previously described.[12] There was a measurement error of up to 2 mm and this proved to be unreliable in assessing the amount of movement seen on the radiographs.

The amount of glenoid bone was determined by either axial views on plain radiographs or CT scans and finally at surgery. At the time of the initial operation, 25 of the group who had total shoulder replacement had eroded glenoid bone which required corrective treatment. Using the classification of Walch et al,[13] these eroded glenoids were classified as ten of Type A1 and ten of Type B1. A further five showed anterior erosion, three of which had avascular

Table II. The mean values of movement and shoulder scores at two years or more after operation

	Number	Pain	Abduction (°)	Flexion (°)	External rotation (°)	ASES * score	Constant score
HHR†							
Rotator cuff							
Intact	20	2.5	91	106	30	55	52
Tear	5	3.8	67	73	39	35	38
Massive tear	17	3.3	66	76	29	47	40
TSR‡							
Rotator cuff							
Intact	75	1.8	101	114	42	71	60
Tear	5	0.7	108	120	46	72	54
Massive tear	2	2.0	68	70	35	39	35

* ASES, American shoulder and elbow surgeons
† HHR, humeral head replacement
‡ TSR, total shoulder replacement

Table III. Mean values of movement and shoulder scores before and after operation and the effect size for 113 patients (124 shoulders). All parameters were significant (Student's *t*-test, $p < 0.001$)

Variable	Pre-operative	Post-operative	Improvement	Effect size
Pain	7.4	2.4	5	1.9
Abduction (°)	53.0	92.0	39	1.2
Flexion (°)	64.0	103.0	39	1.1
External rotation (°)	11.0	39.0	28	1.4
ASES* score	25.0	68.0	43	1.6
Constant score	27.0	49.0	22	1.0

* ASES, American shoulder and elbow surgeons

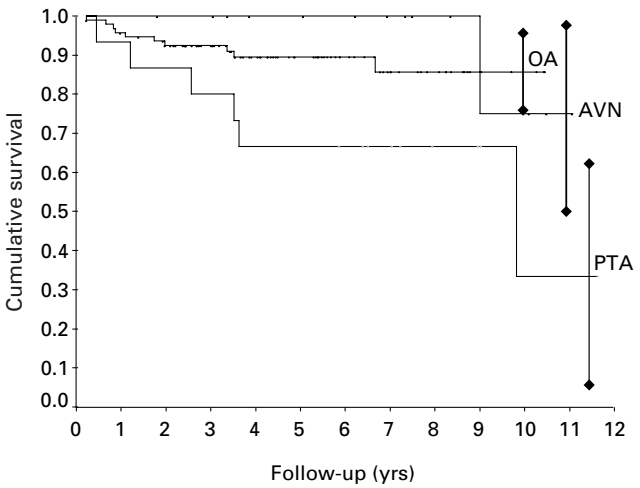

Fig. 1

Kaplan-Meier[15] survival curves for all revisions for each diagnosis (OA, osteoarthritis; AVN, avascular necrosis; PTA, post-traumatic arthritis).

necrosis. The presence or absence of corrected glenoid erosion was used as a pre-operative factor in multivariate analysis of loosening of the glenoid component.

Statistical analysis. The differences between the pre- and post-operative measurements of active movement, pain and both shoulder function scores, were tested using the Student's *t*-test at the last attendance or before revision. One-way analysis of variance (ANOVA) with a Bonferroni correction (SPSS Inc., Chicago, Illinois) was used to determine whether function changed over time. Sensitivity to change was also determined by calculating the effect size. Cohen[14] has suggested the guidelines for interpreting the magnitude, with an effect size > 0.8 indicating a large change, 0.5 a medium change and 0.2 a minor change. The power of the statistical tests was determined using the method described by Cohen.[14]

Survival curves were calculated using the Kaplan-Meier technique[15] for two terminal events, including revision and gross loosening of the glenoid component.

Proportional hazards analysis[16] (Cox's regression model) was used to model the hazard rates of two different terminal events, which were gross superior migration of the humeral head replacement, defined as an increase of 6 mm or more in the vertical distance between the centre of the glenoid and the centre of the humeral head on pre- and post-operative radiographs,[17] and gross loosening of the glenoid in total shoulder replacement.

Results

There was a significant improvement after operation in all parameters studied. Movement improved to give a good functional range. The effect size for all parameters was over 0.8 indicating a good magnitude of change (Table III). The results for the individual diagnoses showed significant improvement for those with osteoarthritis and avascular necrosis ($p < 0.001$), but in the post-traumatic arthritis group the Constant score did not show a significant change ($p = 0.057$). For those with a massive tear of the rotator cuff there was an improvement in all parameters, with the pain score improving by 4.6, the American shoulder and elbow surgeons score by 29 and the Constant score by 22 ($p < 0.001$).

The pre-operative pain and function scores improved significantly ($p < 0.001$) from each year up to eight years post-operatively with the mean differences at eight years for pain, American shoulder and elbow surgeons score and the Constant score being 4.9, 39 and 22, respectively. The sample size at nine years was too small to show a significant difference. There was no significant change in pain or function between any of the follow-up years.

Patients with an intact rotator cuff were treated by both humeral head replacement and total shoulder replacement. They were not randomised, but they were equivalent groups with no significant difference in their pre-operative scores. There was no significant difference in outcome between the two groups with regard to the post-operative scores or range of movement (Table II). In the humeral head replacement group, the results of pain, movement and outcome scores were better in patients with an intact cuff than in those with massive tears, but the only significant differences were in regard to abduction and flexion.

Kaplan-Meier survival curves,[15] with revision as the endpoint for the individual diagnoses, showed survival rates at ten years of 86% (95% confidence interval (CI), 76 to 96) for osteoarthritis, 75% (95% CI, 35 to 100) for avascular necrosis and 33% (95% CI, 0 to 80) for post-traumatic

arthritis (Fig. 1). If the Hylamer components used for osteoarthritis were excluded, the survival at ten years was 90% (95% CI, 83 to 97). The number of cases of avascular necrosis was small, with just one late revision having a large effect on cumulative survival.

The avascular necrosis and primary osteoarthritis groups had 11 revision procedures performed out of 109 operations. This included five humeral head replacements which had early revision at a mean of 1.5 years (SD 1.1; 0.8 to 3.5) because of persistent pain after the initial operation. Four patients were assessed as having glenoid pain because of the clinical finding of pain on passive movement in all planes, radiological evidence of bony erosion or change since operation best seen on the axial view and confirmed at surgery and the response to local anaesthesia. Other potential sources of pain such as loosening of the stem and infection were excluded. These patients were treated by insertion of a glenoid component. The diagnosis of glenoid pain was confirmed by a good response to surgery. The mean visual analogue pain score was 7.7 points before revision. After revision, at a mean of 6.2 years (SD 2.3; 0 to 4) pain was graded at 2.3 points, similar to the results of the series as a whole. Impairment and function also improved but this was not statistically significant, but the effect size values were all greater than 0.8, with the American shoulder and elbow surgeons function score having the highest effect size of 1.3. The patient who had a massive tear of the cuff was revised to a Delta-3 reversed geometry replacement (DePuy International Ltd).

Six total shoulder replacements were revised. One patient had a change in the version of the humeral component at one year because of instability. Another fell and sustained a fracture of the shaft of the humerus at the tip of the stem, requiring revision to a long-stemmed prosthesis with cerclage wires. The fracture subsequently healed. Four total shoulder replacements were revised at a mean of 4.5 years (SD 1.8; 2.6 to 6.7) because of loosening of the glenoid, although three had Hylamer components which had been sterilised in air.

There were six revisions of the 15 arthroplasties performed for post-traumatic arthritis. One humeral head replacement was revised to an arthrodesis because of ongoing pain, but continued to have a poor result. One total shoulder replacement had a rupture of the rotator cuff at six months. A component with a smaller humeral head was inserted. There was one revision at 1.2 years for infection and three for loosening of the glenoid at a mean of 5.3 years (SD 3.9). One of these glenoid components was made of Hylamer sterilised in air.

Cox regression analysis was used to determine whether gross superior migration (6 mm or more) of a humeral head replacement was associated with any pre-operative factors including age, gender, the presence of glenoid erosion, modification of the glenoid pegs, the state of the rotator cuff and the subacromial distance as measured on pre-operative radiographs. The state of the rotator cuff and the subacromial distance were the only factors to have a significant effect with p = 0.001 according to the following equation:

log hazard = 1.345 x rotator-cuff code – subacromial distance x 0.307

The rotator-cuff code (intact = 0, tear = 1, large tear = 2) had a positive function; the risk of superior migration increased nearly fivefold, according to the derived model equation, for each increment of the rotator-cuff code. Superior migration was identified in none of 20 intact cuffs, two of five with small tears and 13 of 17 with large tears. Subacromial distance had a negative function; the risk of superior migration decreased by 26% for each millimetre of increase in the pre-operative subacromial distance (Table IV).

Table IV. Radiological measurements obtained from Global Shoulder arthroplasties two or more years after operation

Parameter	Number	Incidence	Percentage
Humeral lucency			
2 mm at one zone	119	3	*2.5*
At risk (2 mm at 3 zones)	119	1	*0.8*
Glenoid lucency			
None	67	21	*31.0*
Grade 1, 2 or 3	67	37	*55.0*
Grade 4 to 5	67	9	*14.0*
HHR*			
Superior migration (> 5 mm)	42	14	*33.0*

* HHR, humeral head replacement

Radiological analysis of the 119 humeral components with adequate radiographs showed only one component with possible loosening when a line of 2 mm was visible in three of the seven zones. This was one of the seven cemented components (Table IV).

The 82 glenoid components were analysed for radiolucency. Grades four and five[10] had a lucency of at least 2 mm at all zones or there had been translation of the component. These were classified as 'at risk'. Of the 15 Hylamer components sterilised in air, there were two with no lucency, five with grades 1, 2 or 3 with lucency of less than 2 mm, but eight 'at risk' or revised for loosening of the glenoid. For the 67 standard glenoid components there were 21 with no lucency, 37 with grades 1, 2 or 3 and nine 'at risk' or revised for loosening (Table IV). A Kaplan-Meier survival curve[15] for these 67 prostheses with an endpoint of 'at risk' or revised showed survival of 78% (95% CI, 61 to 96) at seven years, but of only 46% (95% CI, 14 to 78) at ten years (Fig. 2).

A second Cox regression procedure with gross glenoid loosening ('at risk' or revised) as the terminal event found that only glenoid erosion at the time of operation (p = 0.017) had a positive function with the following prediction equation:

log hazard (of gross glenoid loosening) = 1.210 x glenoid erosion

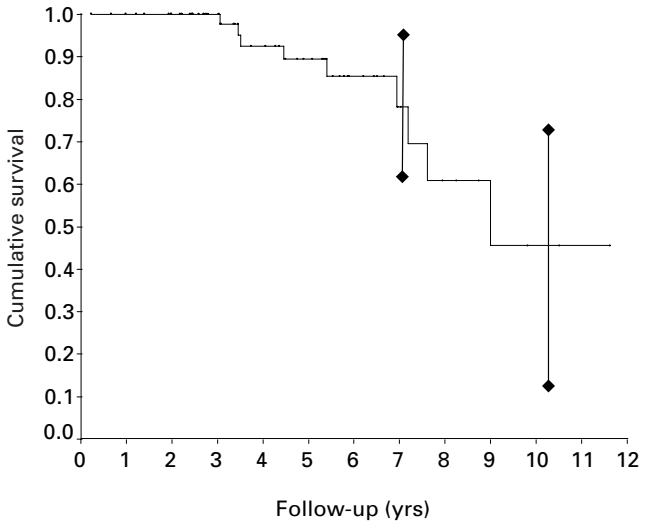

Fig. 2

Kaplan-Meier[15] survival curve for glenoid 'at risk' in 67 replacements, not including Hylamer components sterilised in air

The risk of gross loosening increased threefold when glenoid erosion was present at the time of operation. The equation was modelled as survival curves, including the presence and absence of glenoid erosion. At follow-up at ten years, gross loosening was seen in 87% of cases with glenoid erosion at the time of operation and in 46% of those in which the glenoid had been intact.

Complications. Two patients had post-operative haematomas, one of which required surgical drainage. There was also a case of delayed wound healing but none of the three patients involved have shown any clinical or radiological signs of late infection. One patient had a sensitive wound which was explored for excision of a neuroma, with a significant improvement in symptoms. Another had post-operative ipsilateral ulnar neuritis. This was decompressed at two months and recovered partially. On one occasion, the tendon of the long head of biceps was divided and a tenodesis performed. There were two fractures of the shaft of the humerus during operation. One was treated by insertion of a long stem with fixation by cerclage wires and the other by a splint. Both united satisfactorily. In two cases, the shaft was penetrated at operation. They were managed by delayed mobilisation. Penetration of the glenoid occurred seven times when drilling pegholes and once with a keel.

The operation was carried out without complication on 107 occasions (87%).

One patient had a cerebrovascular accident within one month of surgery. There were no recorded cases of pulmonary embolism or deep-vein thrombosis.

Discussion

The Global Shoulder replacement gives good results with significant functional improvement, which is subsequently maintained. The range of movement gained is sufficient to allow most activities. Kaplan-Meier survivorship[15] using the end-point of revision was 90% at ten years for primary osteoarthritis.

The results for post-traumatic arthritis were less good, in agreement with the findings of other authors,[18,19] and were probably related to the altered anatomy in this group. The group included 11 patients with a total shoulder replacement; in three of whom the glenoid component became loose. In this situation the rotator cuff was often compromised. Therefore it is probably better to treat post-traumatic arthritis by humeral head replacement.

The state of the rotator cuff plays an important role. The functional scores and ranges of movement were worse for the group with a cuff tear, but the difference did not show statistical significance except for the range of abduction and flexion. This may reflect the small numbers in each group. Even in the presence of massive tears of the rotator cuff, significant improvements in pain and functional scores can still be obtained by unconstrained shoulder arthroplasty.

The risk of progressive superior migration is greatest in those cases with the least function of the rotator cuff, presumably from erosion of the acromion. When the rotator cuff was intact, superior migration did not occur.

The humeral component is designed to be inserted without cement and this was shown to be safe and secure. There were two intra-operative fractures and two penetrations of the shaft, indicating the need to assess the size and configuration of the medullary cavity before operation. Proximal fixation is most important and excessive reaming to insert the largest possible stem is not appropriate.

There is continuing uncertainty about the need to replace the glenoid and we have not shown any statistical difference in overall scores or range of movement between the total shoulder replacement and humeral head replacement groups in which the rotator cuff is intact. There is little evidence in the literature to suggest improved function in total shoulder replacement compared with humeral head replacement, but the numbers of patients are often small and their status uncertain. The most controlled study to date is that of Orfaly et al[5] which compared total shoulder replacement with humeral head replacement in 65 shoulders with an intact cuff and concentric glenoid. They found no difference in the functional scores at 4.3 years, but there was a significantly greater improvement in the pre-operative, compared with the final scores in the total shoulder replacement group. The multicentre French trial[1] showed significant improvement in functional outcome of total shoulder replacement over humeral head replacement, but there were markedly different numbers between the two groups which were not fully controlled.

Some of our patients who were treated by humeral head replacement had persistent pain and gained benefit from revision by the insertion of a glenoid component. The modular nature of the implant aids such a procedure. These patients developed problems early, before the glenoid ero-

sion was severe. However, in humeral head replacement severe glenoid erosion and pain may develop over time when insertion of a glenoid component would become difficult or impossible because of erosion.

With glenoid replacement there is a risk of loosening and consequent revision may be difficult because of the poor quality of bone in the glenoid which may need grafting. Our figures show a worrying incidence of loosening of the glenoid which will increase. None of our patients were treated by bone grafting of the glenoid at their primary operation but when there was erosion of the glenoid, reaming was used to correct the alignment. We have shown that the presence of glenoid erosion is predictive of increased risk of loosening. Reaming of subchondral bone may cause structural weakness and it is also likely that the abnormal forces which caused the glenoid erosion remain, with unbalanced translation setting up a rocking-horse type of situation in an anteroposterior direction. The presence of glenoid erosion can be an indication for glenoid replacement for functional improvement, but our findings suggest that care must be taken when considering the insertion of a glenoid component in the presence of erosion. A recent study by Hettrich et al[20] has shown that for humeral head replacement the presence of glenoid erosion gives predictably worse short-term functional results. Although advances in cementing techniques give better results, they will not remove the risk of loosening completely. We advise that glenoid replacement should only be considered when there is a functioning rotator cuff, with adequate glenoid bone without significant erosion. Hylamer components sterilised in air should not be used.[11]

Glenoid erosion and a poor rotator cuff are related to poor results. If operation is indicated in the presence of early erosion of the glenoid or damage to the rotator cuff, consideration should be given to a total shoulder replacement rather than delaying surgery with the risk of progressive deterioration in the condition of the shoulder.

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