Clinical and radiological follow-up of the Aequalis third-generation cemented total shoulder replacement

A MINIMUM TEN-YEAR STUDY

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There are no long-term published results on the survival of a third-generation cemented total shoulder replacement. We describe a clinical and radiological study of the Aequalis total shoulder replacement for a minimum of ten years. Between September 1996 and May 1998, 39 consecutive patients underwent a primary cemented total shoulder replacement using this prosthesis. Data were collected prospectively on all patients each year, for a minimum of ten years, or until death or failure of the prosthesis. At a follow-up of at least ten years, 12 patients had died with the prosthesis intact and two had emigrated, leaving 25 available for clinical review. Of these, 13 had rheumatoid arthritis and 12 osteoarthritis. One refused radiological review leaving 24 with fresh radiographs.

Survivorship at ten years was 100% for the humeral component and 92% for the glenoid component. The incidence of lucent lines was low. No humeral component was thought to be at risk and only two glenoid components. The osteoarthritic group gained a mean 65° in forward flexion and their Constant score improved by a mean 41.4 points (13 to 55). The rheumatoid group gained a mean of 24° in flexion and their Constant score improved by 29.4 points. This difference may have been due to failure of the rotator cuff in 75% of the patients with rheumatoid arthritis.

Thus a third-generation total shoulder replacement gives an excellent result in patients with osteoarthritis and an intact rotator cuff. Patients with rheumatoid arthritis have a 75% risk of failure of the rotator cuff at ten years.

Fixation of the glenoid component is one of the limiting factors in both first- and second-generation total shoulder replacement (TSR).1-4 The rate of loosening seen with the second-generation Neer II modular TSR in long-term studies was 24% at 9.5 years5 and 40% at 7.7 years6 which was of considerable concern. This has led to the cautious use of a glenoid component even when the evidence points to the functional superiority of TSR over hemiarthroplasty in the short- and medium-term.7

The Aequalis TSR (Tornier Inc, St Ismier, France) is an unconstrained third-generation prosthesis with variable medial and posterior offset which replicates the complex shape of the proximal humerus. With its non-conforming anatomically pear-shaped glenoid component, this should, in theory, improve glenohumeral kinematics by restoring the mechanical lever arm of the abductors, thereby reducing excessive translation of the humeral head, eccentric loading and loosening.8,9

This study describes a third-generation modular posterior offset TSR performed using a contemporary cementing technique.

Patients and Methods

In September 1996 we began to use a third-generation prosthesis, the Aequalis (Tornier Inc). In 2008 we obtained approval of the Ethics Committee to review patients in whom this prosthesis had been implanted for more than ten years. Between September 1996 and May 1998, 39 consecutive Aequalis TSRs were implanted in 36 women and three men. Data were collected prospectively on all patients on an annual basis, for a minimum of ten years, or until death or failure of the prosthesis. During this period 12 patients died from unrelated causes at a mean of 5.75 years (1 to 10) from the initial operation. Two emigrated and were eventually lost to follow-up after one and six years, respectively. None of these patients showed signs of radiological loosening at the time of their last follow-up. The remaining 25 patients were reviewed by one of the authors (AK) who had not been
involved in the original surgery. The mean time to follow-up was 10.6 years (10 to 12). Obtaining 100% follow-up was difficult since many patients were in their ninth decade of life, and some had moved to live with younger relatives. For two of these, review was by telephone. One had radiography at his local hospital and the other refused to attend for this examination. Radiological data were therefore available for 24 patients and clinical information for all 25.

The pre-operative diagnosis of the 25 surviving patients was rheumatoid arthritis (RA) in 13 (52%) and osteoarthritis (OA) in 12 (48%). Two had a small tear of the rotator cuff seen at operation. There were 24 women and one man with a mean age of 78.6 years (38 to 84). The glenoid bone stock was assessed pre-operatively on anteroposterior (AP) and axial radiographs and again at operation. Of the 13 patients with RA, two had severe erosion of the glenoid, one extending to the base of the coracoid and the other causing severe retroversion. Of the 12 patients with OA, six had erosions. According to the classification of Walch et al,10 four were A1, one was A2 and the other B1. The state of the rotator cuff was assessed clinically before surgery and by direct inspection and palpation operatively.

Operative technique. The senior author (TDB) carried out all the operations using the same surgical approach and cementing technique. Each patient had a scalene block and general anaesthesia. An extended deltopectoral approach was used. The quadrilateral space was carefully dissected and the posterior circumflex humeral vessels and axillary nerve identified and marked with a silastic sling. This protected the neurovascular bundle during the release of the inferior capsule, which was believed to be the key to a good exposure of the glenoid and allowed the shoulder to move freely post-operatively. The superior capsule, including the coracohumeral and superior glenohumeral ligaments, was divided thereby allowing complete exposure of the margins of the glenoid. A biceps tenodesis to pectoralis major was performed, thereby allowing complete exposure of the margins of the glenoid. A biceps tenodesis to pectoralis major was performed in all cases.

A small tear of the rotator cuff was identified but not repaired in two patients with OA. All the others had an intact cuff, although this was attenuated in five of the 13 with RA. In the rheumatoid patient whose glenoid had been eroded to the base of the coracoid, osteotomy of the coracoid was needed to expose the margins of the glenoid. An allograft from a femoral head was screwed to the native glenoid before the implantation of a cemented glenoid component. In the other rheumatoid patient with a severely retroverted glenoid and posterior subluxation of the head of the humerus, the glenoid was reamed in an attempt to correct the retroversion before implanting the glenoid component. No bone graft was used. In the osteoarthritic patients, the glenoid was reamed according to the manufacturer’s recommendations (Tornier).

A standard cementing technique was used in each patient. The glenoid was irrigated using the Exeter lavage system (Howmedica International Ltd, London, United Kingdom) and the slot in the glenoid for the keel of the implant was dried with an adrenaline (1:200,000)-soaked swab. Palacos R bone cement with gentamicin (Schering-Plough Ltd, Welwyn Garden City, United Kingdom) was packed into the prepared, washed and dried bone and pressurised with the glenoid component. On the humeral side, an appropriately-sized Exeter cement restrictor (Howmedica) was inserted. The bone surface was washed using the Exeter lavage system (Howmedica), dried with suction and swabs, and Palacos cement with gentamicin was inserted down the intramedullary canal with digital pressure.

Implants. A keeled ultra-high-molecular-weight all-polyethylene flat-backed glenoid component was used in all cases. In 22 patients small components were used and in the other three, a medium-sized implant. In 13 patients a neck-stem angle of 130°, in three an angle of 125°, in seven an angle of 135°, and in two an angle of 140° was used and in 15 a head of 46 mm × 17 mm, in six a head of 43 mm × 16 mm, in one a head of 39 mm × 14 mm and in three a head of 50 mm × 19 mm was used. We used 9 mm humeral components in 22 patients and 6.5 mm components in the other three. These were implanted with 30° of retroversion in each case. Posterior offset was reproduced by rotation of the humeral head to the appropriate position.

Rehabilitation. A sling was used for 48 hours for comfort and to allow recovery from the scalene block. At this stage, patients were given gentle pendulum exercises. For the first six weeks the emphasis was on passive and then, at two weeks after surgery, active forward elevation and abduction to 90° and external rotation to neutral. Free movements were allowed after six weeks.

All the patients were assessed pre-operatively using the American Shoulder and Elbow Surgeons Score (ASES) and that of Constant and Murley. Follow-up assessment included ASES, the Constant and the Oxford shoulder score (OSS). The range of both pre- and post-operative movement in each direction was measured using a goniometer (Baseline, Chattanooga Group, Chattanooga, Tennessee). Strength was assessed with the arm at 90° of abduction in the plane of the scapula using the mean of three measurements with resistance against a calibrated 13 kg spring balance (Reuben Heaton Ltd, Warwickshire, United Kingdom) maintained for three seconds. This was recorded on the Constant score forms.

Radiological assessment. Standardised AP radiographs in the plane of the scapula and axillary views at a tangent to the glenoid, were taken throughout the study. At follow-up these were assessed for radiolucent lines by two authors not involved in the original surgery (AK, JBK). The glenoid was assessed according to the method of Lazarus et al as follows: grade 0, no lucent lines; grade 1, a lucent line under the base plate, but not affecting the keel; grade 2, an incomplete lucent line around the keel; grade 3, a complete lucent line around the keel which was non-progressive and less than 2 mm wide; grade 4, a complete lucent line around the keel greater than 2 mm wide; and grade 5, movement of the glenoid component relative to the native scapula and therefore considered to be loose. Glenoid components graded as 4 and 5 were deemed to be ‘at risk’.
The humerus was assessed by the method of Sperling et al.\textsuperscript{15} The stem was divided into thirds. Zones 1 to 3 referred to the cement-bone interface adjacent to the lateral three thirds, and zones 5 to 7 the interfaces adjacent to the medial three thirds. Zone 4 represented the tip of the stem and zone 8 the undersurface of the head. A radiolucent line > 2 mm wide in three or more zones or gross loosening indicated that the humeral component was at risk. Superior migration was recorded as movement of the centre of the humeral head with respect to the centre of the glenoid as described by Deutsch et al.\textsuperscript{16} An excursion of 5 mm or more was taken to represent failure of the cuff.\textsuperscript{5,16-18}

### Statistical analysis

Kaplan-Meier\textsuperscript{19} survival curves were constructed using loosening of the component and revision for any cause as endpoints. Pre- and post-operative measurements of active movement, pain and the Constant score were compared using the Friedman test. An unpaired \(t\)-test was used to compare the post-operative scores of groups of patients with intact and impaired rotator cuffs. A \(p\)-value \(\leq\) 0.05 was considered to be significant.

### Results

#### Clinical

There was significant improvement in the Constant score in each group after ten years. Pain, function and activity were all significantly better (\(p < 0.001\), Table I).

#### Patients with OA had the best results at follow-up. In this group the mean pain score on the visual analogue scale...
(VAS) improved markedly from 6.8 (4 to 10) to 1.0 (0 to 1). The mean flexion increased from 65° to 130° and the adjusted Constant score improved from 26.0% to 92.8%. By contrast, the two patients who had small tears at the initial operation had developed massive tears of the cuff with pseudoparalytic shoulders at follow-up. Their flexion was worse than before surgery, but the adjusted Constant score was better, 22.0% to 50.0%, because their pain was negligible. The VAS was reduced from 7.0 (4 to 10) to 4.0 (1 to 7). Despite the massive tears their glenoid components did not loosen.

The patients with RA also improved considerably. Their mean pain score (VAS) decreased from 7.7 (5 to 10) to 1.2 (0 to 9) at ten years. Flexion improved from a mean of 61° (30° to 100°) to 135° (50° to 180°) two years after surgery, but because of the deficiency in the cuff in nine of 12 of these patients, the mean flexion was only 84.6° (20° to 160°) at ten years. This was reflected in the Constant score which improved from a mean of 14.0 (8 to 36) to 67.2 (0 to 84) at two years, but decreased to 43.4 (8 to 71) at ten years (Table I).

**Radiolucent lines and osteolysis. Humerus.** The radiographs of 24 patients were reviewed. After ten years, radiolucent lines were present in a single humeral zone in 12 patients and in two humeral zones in four patients. In each case, they were less than 2 mm wide. There were no cases of revision for loosening of a ‘humerus at risk’ (Table II).

**Glenoid.** There were two revisions for glenoid loosening (Table II). Both patients had an unusual indication for TSR. The first had suffered a thalamic stroke which caused athetosis of her left arm and severe arthrosis. The athetoid movement could not be controlled by medication either pre- or post-operatively. She developed lucent lines around the glenoid keel and eventually displaced the glenoid component. This was removed eight years after the initial operation and a posterior bone block from the iliac crest was inserted in an attempt to keep her hemiarthroplasty located. In each of these cases, we assume that the cuff had failed since there was proximal migration of the humeral component of more than 5 mm.

At radiological review, two glenoids were thought to be loose (Table II). Both patients had severe RA and were satisfied with their TSRs ten and 12 years after the initial operation despite complete lucent lines (grade-4 lucency) around the keel of their prosthesis and obvious failure of the rotator cuff, with gross upward migration of the humeral head. One patient had a femoral head allograft screwed to her native scapula for gross medialisation. When followed up at 12 years she had severe failure of the cuff with erosion of the acromion and distal clavicle by the superiorly displaced humeral component. Despite the use of allograft we included her in our final analyses. Both patients felt that they were better than before surgery and did not need revision.

Incomplete radiolucent lines were seen around a further 11 glenoid components of which two were around the keel. All were less than 2 mm in width. These results are summarised in Table II.

**Integrity of the rotator cuff.** The rotator cuff was intact in 36 patients at the time of surgery. Of the three patients with a tear in the cuff, two had a small full-thickness tear with a cuff of poor quality, and one had a massive tear with arthrosis. She died six years after her operation. In each case the tears progressed with superior migration of the humeral component of more than 5 mm (Table II).

Of the 24 patients reviewed radiologically at least ten years post-operatively, nine of 12 with RA had clinical and radiological evidence of failure of the cuff. If the patient with the revision is excluded, they had a mean Constant score of 43.4 points (adjusted Constant score 62.8%); Table I. Two osteoarthritic patients, who had an intact cuff at surgery, developed a deficiency of the cuff after ten years. Overall, there was a rate of cuff failure of 54.2% (13 of 24) at a minimum of ten years. The groups were further subdivided according to the state of the cuff at ten years. Those with an intact cuff achieved a better Constant score (Table III). This difference did not, however, reach statisti-
In osteoarthritis, one patient developed failure of the cuff and two patients had tears of the cuff at the initial operation. The thoracic vertebra (T) and the lumbosacral junction (LSJ) were included. VAS is the visual analogue scale. Two patients were excluded from telephone review (one with rheumatoid arthritis and one with osteoarthritis). Mode values given for internal rotation declined a radiograph.

Rheumatoid arthritis with intact cuff

Rheumatoid arthritis with cuff failure

Table III. Mean shoulder scores at ten years or more comparing the effect of cuff failure.

<table>
<thead>
<tr>
<th>Pathology</th>
<th>Number of patients</th>
<th>Pain (VAS)</th>
<th>Constant pain score</th>
<th>Flexion (°)</th>
<th>External rotation (°)</th>
<th>Internal rotation (°)</th>
<th>Abduction (°)</th>
<th>Constant score (% adjusted)</th>
<th>OSS**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoarthritis with intact cuff</td>
<td>8</td>
<td>0.25 (0 to 1)</td>
<td>14.38 (10 to 15)</td>
<td>140 (90 to 180)</td>
<td>54.3 (40 to 70) T7</td>
<td>126 (90 to 180)</td>
<td>60.43 (94.4) (46 to 76)</td>
<td>19.88</td>
<td></td>
</tr>
<tr>
<td>Osteoarthritis with cuff failure</td>
<td>3</td>
<td>3 (1 to 7)</td>
<td>10 (0 to 15)</td>
<td>60 (30 to 90)</td>
<td>30 (10 to 50) LSJ</td>
<td>23 (0 to 50)</td>
<td>34.7 (54.1) (25 to 52)</td>
<td>33.67</td>
<td></td>
</tr>
<tr>
<td>Rheumatoid arthritis with intact cuff</td>
<td>3</td>
<td>3.3 (0 to 9)</td>
<td>8.3 (0 to 15)</td>
<td>93 (30 to 160)</td>
<td>38 (10 to 60) T12</td>
<td>60 (40 to 70)</td>
<td>42.0 (60.9) (8 to 71)</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Rheumatoid arthritis with cuff failure</td>
<td>8</td>
<td>0.375 (0 to 2)</td>
<td>11.25 (5 to 15)</td>
<td>85 (20 to 100)</td>
<td>43 (20 to 70) Thigh</td>
<td>34 (0 to 50)</td>
<td>43.9 (63.6) (35 to 53)</td>
<td>28.63</td>
<td></td>
</tr>
</tbody>
</table>

* data exclude the two revisions with failure of the cuff (one rheumatoid arthritis and one osteoarthritis patient) and a rheumatoid arthritis patient who declined a radiograph.
† excludes two patients from telephone review (one rheumatoid arthritis and one osteoarthritis). Mode values given for internal rotation.
‡ VAS, visual analogue scale.
§ T, thoracic vertebra; LSJ, lumbosacral junction.
¶ includes one patient with osteoarthritis who developed failure of the cuff and two with tears of the cuff at the initial operation.
** OSS, Oxford shoulder score.

A presumptive failure of the cuff was made if the patient was pseudoparalytic (marked weakness and restriction in active movements), or had a grossly positive Jobe and Moyner’s test (marked weakness and/or pain with resistance at 90° in the plane of the scapula with the upper limb internally rotated such that the thumb points to the floor), weakness of external rotation and marked weakness on strength testing for the Constant score at 90° of abduction, elevation of the humeral head on resisted cuff action and a radiograph which showed increased upward migration of at least 5 mm. Since advanced imaging modalities such as ultrasonography were not used there may be a degree of inaccuracy in our diagnosis.

Complications. There were only two revisions, both for aseptic loosening of the glenoid component, one of which was secondary to recurrent posterior dislocation. There were no other dislocations. This gave a revision rate of 8% from all causes. There were no peri-operative deaths. The mean age of the patients who died was 79.3 years (59 to 91). The 59-year-old patient died from chronic obstructive pulmonary disease and complications of a rheumatoid cervical spine including basilar invaginatio, causing vertebro-basilar insufficiency seven years after her initial operation. All 12 deaths were from unrelated causes. There were no cases of infection, neurovascular complications, thromboembolic event or peri-prosthetic fracture.

Survivorship. Survival of the humeral component for revision for any cause as an endpoint was 100%, with survival for aseptic or septic loosening of 100%. Survivorship curves of the glenoid with revision for any cause as an endpoint were constructed (Fig. 1) and survival of the glenoid at a minimum of ten years with revision for any cause as the endpoint was 92% (95% confidence interval (CI) 85.7 to 100). Survival of the glenoid with radiological loosening as the endpoint was 85.2% (95% CI 71.9 to 98.5; Fig. 2) at 12 years. In the worst-case analysis, in which the two shoulders lost to follow-up were regarded as failures, survival was 86.2% (95% CI 72 to 99) at 12 years.

Discussion

Loosening of the glenoid is one of the most common complications of TSR. Early studies the incidence of radiolucent lines at the glenoid cement-bone interface has ranged from 55% to 80%. This has improved with modern cementing techniques.

Several studies have shown anatomical variability in the proximal humerus, particularly in the diameter of the head and in the medial and posterior offset from its centre in relation to the longitudinal axis of the humerus. This resulted in a more anatomical third generation of shoulder prostheses with variable head size and offset such as the Tornier Aequalis. Roentgenographic stereometric analysis has shown that by translating and rotating less, offset humeral heads produce less eccentric loading of the glenoid than standard heads thereby potentially reducing the risk of loosening of the glenoid component.

Our study assesses the survival of such a third-generation prosthesis at a minimum of ten years. Our results are encouraging as far as survival is concerned but devastating in terms of failure of the rotator cuff in the rheumatoid patient. The 100% survival of the cemented humeral component, with none at risk, is a considerable improvement on the results of the uncemented Neer II implant which had rates of loosening of...
40% and 24% at 7.7 and 9.5 years, respectively.\textsuperscript{5,6} Our study suggests that a surgeon can be confident that a third-generation humeral component will survive for at least ten years.

Survival of 92% after ten years for the glenoid component is also reassuring. This is a better result than historical studies\textsuperscript{22,24} would have predicted. In retrospect, the two revisions in our study were as much a failure of indication as of technique. One glenoid component failed after being implanted into an athetoid patient and the other when severe retroversion of a posteriorly subluxed shoulder was not corrected at the time of the initial surgery. However, both patients would probably have suffered from marked erosion and pain in the glenoid had they been given a hemiarthroplasty.

Lucent lines around the glenoid component have been a concern in the past.\textsuperscript{22,24} In our study there were only two glenoids at risk and in both of these patients there was severe failure of the rotator cuff. One had a femoral head allograft between the glenoid component and the native scapula which had survived for 12 years. The relative paucity of glenoid lucent lines in the other patients at ten years is in sharp contrast to the high incidence of loosening seen in other series because of the ‘rocking-horse effect’\textsuperscript{2} not least considering that 53.8% of the patients showed radiological and clinical evidence of failure of the rotator cuff. These results are better than the medium-term multicentre results from the originators of the Aequalis prosthesis.\textsuperscript{27} This study reassures us that it is appropriate to replace the glenoid.

There are several potential weaknesses in our study. One was the relatively small number of patients available for review. However, these numbers were similar to those in the long-term studies of Sneppen et al\textsuperscript{28} and of Stewart and Kelly\textsuperscript{5} and to the mid-term studies of Raiss et al.\textsuperscript{29} We failed to follow up the two patients who had emigrated, but achieved complete clinical follow-up of those remaining in the country despite many being in their ninth decade of life. We used proximal migration of the humeral component as evidence of failure of the rotator cuff. Although an indirect parameter, its accuracy has been validated by numerous studies\textsuperscript{30-32} including its use in evaluating TSR.\textsuperscript{5,16-18}

The radiographs were not set up with image-intensifier control, but they were standardised and were performed by a dedicated musculoskeletal radiographer for all except one patient. Only films which were perpendicular to the glenoid were accepted.

The principal strength of our study was that it reviewed the survival of a third-generation TSR with a minimum follow up of ten years performed by a single surgeon, using the same prosthesis and technique at the same hospital.

Our study highlights a problem which we had not anticipated, that of failure of the cuff in 75% of the rheumatoid patients ten years after TSR. Paradoxically, this did not adversely affect the mean shoulder scores. Patients with an intact cuff had a mean Constant score of 42 whereas those with a tear scored 43.9. This was because one rheumatoid patient with an intact cuff scored poorly for function and had a VAS of 9. If she is excluded from the analysis, the mean Constant score for those with an intact cuff rises to 59 (47 to 71). In the osteoarthritic group those with an intact cuff had a Constant score of 60, whereas those with failure had a score of 34.7. None of the osteoarthritic group had radiological evidence of loosening of the glenoid.

Our study has shown that deficiency of the rotator cuff rather than loosening of the glenoid is the most common long-term complication of a third-generation TSR. Two
other studies confirm this. Sojbjerg et al showed failure of
the cuff in 43% of their 69 rheumatoid patients with a
mean follow-up of 7.7 years and Stewart and Kelly found
superior subluxation in 57% of 58 consecutive TSRs per-
formed for RA.

Our study found a survival of 100% for the humeral
component and of 92% for the glenoid component at a
mean follow-up of 7.7 years and Stewart and Kelly found
the cuff in 43% of their 69 rheumatoid patients with a
ten years.

The incidence of lucent lines and glenoid components at
risk is much less than reported in previous studies, but failure
of the rotator cuff occurred in 75% of rheumatoid patients by
years.

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