A multicentre study of the long-term results of using a flat-back polyethylene glenoid component in shoulder replacement for primary osteoarthritis

We report the long-term clinical and radiological outcomes of the Aequalis total shoulder replacement with a cemented all-polyethylene flat-back keeled glenoid component implanted for primary osteoarthritis between 1991 and 2003 in nine European centres. A total of 226 shoulders in 210 patients were retrospectively reviewed at a mean of 122.7 months (61 to 219) or at revision. Clinical outcome was assessed using the Constant score, patient satisfaction score and range of movement. Kaplan-Meier survivorship analysis was performed with glenoid revision for loosening and radiological glenoid loosening (SD) as endpoints. The Constant score was found to improve from a mean of 26.8 (SD 10.3) pre-operatively to 57.6 (SD 20.0) post-operatively (p < 0.001). Active forward flexion improved from a mean of 85.3° (SD 27.4) pre-operatively to 125° (SD 37.3) post-operatively (p < 0.001). External rotation improved from a mean of 7° (SD 6.5) pre-operatively to 30.3° (SD 21.8°) post-operatively (p < 0.001). Survivorship with revision of the glenoid component as the endpoint was 99.1% at five years, 94.5% at ten years and 79.4% at 15 years. Survivorship with radiological loosening as the endpoint was 99.1% at five years, 80.3% at ten years and 33.6% at 15 years.

Younger patient age and the curettage technique for glenoid preparation correlated with loosening. The rate of glenoid revision and radiological loosening increased with duration of follow-up, but not until a follow-up of five years. Therefore, we recommend that future studies reporting radiological outcomes of new glenoid designs should report follow-up of at least five to ten years.

A multicentre study has reported the mid-term results of 319 Aequalis (Tornier, Montbonnot, France) total shoulder replacements (TSRs) with a mean follow-up of 44 months (24 to 100), describing a rate of radiological loosening of 11.5% and a rate of revision of 1.3%. The glenoid component in that series comprised an all-polyethylene flat-backed keeled component. A study comparing the radiological appearances of flat-back and convex-back glenoid components (both Aequalis) in TSR showed a higher incidence of radiolucent lines with the flat-back component at a follow-up of two years. A recent mid-term survival analysis of the convex glenoid component demonstrated a survivorship of 100% with revision as the endpoint at nine years, but associated with an 87% incidence of radiolucent lines and a 33% incidence of radiological glenoid loosening.

We have analysed the long-term results of the flat-backed glenoid component in 308 TSRs implanted for primary glenohumeral osteoarthritis. Our hypothesis was that the rate of radiological loosening and glenoid revision would increase with time, but also that other specific pre-operative factors, such as age at time of operation, shape of the glenoid, gender and dominance, might significantly influence the development of radiological changes around the glenoid component.

Patients and Methods
Between September 1991 and December 2003, in nine European centres, 308 TSRs were performed in 292 patients for primary glenohumeral osteoarthritis, exclusively as described by Neer. All other diagnoses were excluded. Each centre contributed between 15 and 111 shoulder replacements to the study. Additionally, any shoulder with a history of trauma (fracture or soft-tissue injury), instability (surgically or non-surgically treated), prior shoulder surgery or shoulders with an associated massive tear of the rotator cuff diagnosed pre-operatively or at the time of surgery were excluded from the series. All TSRs were
performed with the third-generation Aequalis prosthesis (Tornier) with a cemented keeled all-polyethylene flat-back glenoid component. No other version of the glenoid component was included in this series, and no patients underwent bone grafting of the glenoid.

At review, 45 patients (45 TSRs) were either lost to follow-up or declined to participate in the study, leaving 263 shoulders in 247 patients available for study. Of these patients, 170 (68.8%) were female, comprising 182 (69.2%) shoulders; 16 patients (12 female, four male) underwent bilateral procedures. Of those undergoing a unilateral procedure, 142 (61.5%) were affected on the dominant side. Complete pre- and post-operative clinical data were available for 226 shoulders (210 patients), with a mean follow-up of 124.1 months (61 to 219) or until revision. The mean age at the time of operation was 66.9 years (40 to 90 years).

Clinical analysis. All patients were evaluated pre-operatively with a Constant score consisting of four individual components for pain (15 points), activity (20 points), range of movement (40 points) and strength (25 points). The absolute Constant score was subsequently adjusted to give a percentage of what is considered normal for a given age and gender. In addition, active pre-operative range of movement (ROM) for forward flexion in the plane of the scapula and external rotation with the arm at the side was recorded (Table I).

The post-operative evaluation was performed on all shoulders at the time of the latest follow-up and consisted of a Constant score, evaluation of ROM and a subjective assessment by the patient grading their outcome as very satisfied, satisfied, uncertain or disappointed. Clinical evaluation of patients undergoing revision was performed immediately prior to revision surgery and the results were included in the data analysis. Additionally, a subjective shoulder value was determined by asking the patient to score their TSR as a percentage of the function of their normal shoulder.

Radiological analysis. The pre-operative, initial post-operative and final follow-up radiographs were evaluated. A standardised radiological series was performed at final follow-up and included anteroposterior (AP) views in neutral, internal and external rotation, systematically performed under fluoroscopic control, and an axillary view. Radiographs at final follow-up were assessed by a consensus reached by a group of three shoulder surgeons (including two authors: AY and GW) who evaluated them to determine the presence of glenohumeral subluxation, peri-prosthetic loosening (radiolucent lines) and migration of the components. Glenohumeral subluxation was measured according to Torchia, Cofield and Settergren on the AP view in neutral rotation. Glenoid radiolucent lines were scored according to the Molé scoring system (0 for no radiolucency to 18 for radiolucent lines exceeding 2 mm in six zones). A score of 0 to 6 points was considered to indicate no loosening, 7 to 12 points possible loosening, and 13 to 18 points definite loosening. Any migration or shift of the component automatically resulted in a score of 18 points and was considered to indicate definite radiological loosening.

A pre-operative CT arthrogram was available in 170 cases and an MRI scan in 35 cases allowing for analysis of the glenoid shape in the horizontal plane and the state of the rotator cuff. A partial tear of the supraspinatus tendon was present in 19 (7.2%) of the 263 shoulders studied and a full thickness tear in 19 cases (7.2%). No tears of infraspinatus or subscapularis were detected. The shape of the glenoid was assessed according to the classification of Walch et al: 12 type A1, 48 type A2, 36 type B1, 51 type B2 and 4 type C. The glenoid was not classified in 18 cases.
operative data were analysed using paired Student t-tests. A subacromial decompression was performed in four shoulders (1.5%), a supraspinatus tendon repair in six shoulders (2.3%) and a tenotomy or tenodesis of the long head of the biceps in 136 cases (51.7%). Resection of the humeral head was performed at the level of the anatomical neck after removal of osteophytes under direct vision. The goal was to respect the original inclination and retroversion of each patient’s shoulder. The mean mismatch of radius of curvature between the glenoid and humeral components used in this series was 5.5 mm ± 1.5 mm. The stem of the humeral was cemented in 250 shoulders and press-fitted in 13.

Two techniques of glenoid preparation were used according to the surgeon’s preference: the curettage technique as described by Neer, Watson and Stanton,13 which consists of removing the cancellous bone with a curette, was used in 164 cases (62.4%), and a bone-preserving technique, whereby the slot for the keel is prepared with three small reamers to provide a flat surface for the glenoid component,14 was used in 96 cases (36.5%). In three shoulders the technique used was not clearly described. Removal of osteophytes under direct vision. The goal was to respect the original inclination and retroversion of each patient’s shoulder. The mean mismatch of radius of curvature between the glenoid and humeral components used in this series was 5.5 mm ± 1.5 mm. The stem of the humeral was cemented in 250 shoulders and press-fitted in 13.

Two techniques of glenoid preparation were used according to the surgeon’s preference: the curettage technique as described by Neer, Watson and Stanton,13 which consists of removing the cancellous bone with a curette, was used in 164 cases (62.4%), and a bone-preserving technique, whereby the slot for the keel is prepared with three small reamers to provide a flat surface for the glenoid component,14 was used in 96 cases (36.5%). In three shoulders the technique used was not clearly recorded. Reaming of the glenoid was performed with two small reamers to provide a flat surface for the glenoid component. In the majority of cases, the glenoid and keel slot were cleaned with saline solution and dried with a sponge, prior to insertion of rapid-setting cement into the slot with a syringe followed by the glenoid component.

**Statistical analysis.** Differences between pre- and post-operative data were analysed using paired Student t-tests. Differences among subgroups were tested by analysis of variance (ANOVA) for the quantitative variables, followed by post hoc Bonferroni, Kruskal-Wallis or Wilcoxon signed-rank tests if quantitative variables were not normally distributed and by chi-squared or Fisher’s exact test for categorical variables. Correlations between quantitative variables were analysed by the Spearman correlation coefficient. The level of significance was set at a p-value < 0.05.

Survivorship analysis was performed according to the method of Kaplan-Meier with right-censored data for no event or missing data15 and the 95% confidence intervals (CI) were calculated.

### Results

**Clinical.** The mean total Constant score improved from 26.8 (SD 10.3) pre-operatively to 57.6 (SD 20.0) post-operatively (p < 0.001). Mean active forward flexion improved from 85.3° (SD 27.4) pre-operatively to 125° (SD 37.3) post-operatively (p < 0.001) and mean active external rotation with the arm at the side improved from 7° (SD 6.5) pre-operatively to 30.3° (SD 21.8) post-operatively (p < 0.001). Subjectively 172 (76%) patients were either satisfied or very satisfied, 45 (20%) were uncertain and nine (4%) were disappointed. The post-operative clinical evaluation is presented in full in Table I.

The presence of a pre-operative tear of supraspinatus was not found to influence the clinical or radiological outcome significantly, as measured by the Constant score (Wilcoxon signed-rank test, p = 0.4407) and the subjective assessment (chi-squared test, p = 0.6106). Likewise, there was no statistically significant association between the presence of a supraspinatus tear pre-operatively and the radiolucent line score (Wilcoxon signed-rank test, p = 0.1343).

**Complications and revisions.** A post-operative complication was observed in 62 cases (23.5%) (Table II), and 38 of these (14.4%) required re-operation. A total of 24 shoulders (9.1%) were revised for glenoid loosening. The revision was performed at a mean follow-up of 122.7 months (25 to 192) at which stage the mean Constant score was 32.2 points (SD 15.1). The mean age at operation for those patients requiring a glenoid revision was significantly younger than that observed in the full series (60.4 years (43 to 80) versus 66.9 years (40 to 90); Wilcoxon signed-rank test, p = 0.0025). With the numbers available, we could not detect an association between the need for revision and gender or dominant arm (gender, p = 0.969 (chi-squared test); dominant arm, p = 0.387 (Fisher’s exact test)).

In all, 14 re-operations were conducted for reasons other than painful glenoid loosening. These included two shoulders with a humeral fracture distal to the stem, three shoulders with loosening of press-fitted humeral stems (revisions were performed at five, seven and eight years after the initial surgery), two shoulders with posterior dislocation (revised one and ten years after surgery), two with traumatic rupture of subscapularis (repaired at two and three months after surgery); one anterior dislocation (revised at three years); two infections (revised at three months) and two shoulders with severe stiffness (revised during the first post-operative year).

The survivorship of the glenoid component with the end-point being revision for glenoid loosening was 99.1% (95% CI 98 to 100) at five years, 94.5% (95% CI 91.4 to 97.7) at ten years, and 79.4% (95% CI 70.3 to 88.5) at 15 years (Fig. 1).

**Radiological analysis.** A total of nine shoulders had inadequate or incomplete radiographs leaving a total of 217 shoulders available for radiological analysis. The mean glenoid radiolucent line score was 11.3 (SD 6.4). No radio-
logical loosening, defined by a radiolucent line score between 0 and 6 was observed in 73 shoulders (33.6%), possible radiological loosening, defined by a radiolucent line score between 7 and 12, was observed in 45 shoulders (20.7%), and definite radiological loosening, defined by a radiolucent line score > 12 (Fig. 2), was observed in 99 shoulders (45.6%). Survivorship of the glenoid component with the endpoint being radiological loosening with a radiolucent line score > 12 was 99.1% (95% CI 98.1 to 100) at five years, 80.3% (95% CI 74.5 to 86.1) at ten years and 33.6% (95% CI 24.1 to 43.1) at 15 years (Fig. 3).

The duration of post-operative follow-up was found to have a statistically significant relationship with the presence of radiolucent lines (p < 0.001). The mean age at the time of surgery was significantly lower in shoulders with loosening of the glenoid component (64.4 years (43 to 84)) compared with those without loosening (68.3 years (40 to 90)) (p < 0.001). The influence of the surgical technique used for preparation of the glenoid keel on the radiolucent line score was also analysed. The compaction technique was found to be significantly better with a mean radiolucent line score of 9.5 (SD 6.2) compared with 12.6 (SD 6.3) for the curettage technique (p < 0.001). There was no statistically significant difference in the mean duration of follow-up of the two techniques of 120 months (34 to 189) for the curettage method and 125 months (61 to 219) for the compaction method (p = 0.978). Definite radiological loosening occurred in 26 of 84 shoulders (31.0%) with the compaction technique compared with 73 of 133 shoulders (54.9%) with the curettage technique (Fisher’s exact test, p = 0.0001). Finally, upward migration of the humeral head was also statistically correlated with radiolucent line score and radiological loosening (p < 0.001). We did not find a statistically significant relationship between glenoid loosening and either gender (Wilcoxon test, p = 0.465), pre-operative shape of the glenoid (i.e., type A versus type B glenoids; Wilcoxon test, p = 0.465) or mismatch of the glenohumeral prostheses (Spearman correlation coefficient: \( \rho = -0.06, p = 0.343 \)).

Regarding the effect of radiological loosening on clinical results, we found highly significant associations (ANOVA used for the following statistical analyses, except the chi-squared test for subjective outcome assessment; all p < 0.001) between radiological loosening and all of the following: pain, activity, active forward flexion, total
Constant score, adjusted Constant score, subjective outcome assessment and the subjective shoulder value. There was no statistically significant difference between the group with ‘no radiological loosening’ and the group with ‘possible radiological loosening’, whereas the difference was highly significant when comparing ‘definite radiological loosening’ against the other two groups (Table III).

 Superior subluxation of the prosthetic humeral head was observed in 101 (46.5%) of the 217 shoulders with full radiological follow-up, graded as: mild in 42 (19.4%), moderate in 29 (13.4%) and severe in 30 (13.8%).

**Discussion**

Loosening of the glenoid is recognised to be the weak link in TSR with cemented polyethylene glenoid components. The rate of revision for glenoid loosening in our series was 9.1% at a mean of 122.7 months, and these patients were found to be younger than those with definite radiological loosening who did not undergo revision. Others have reported revision rates for all-polyethylene keeled glenoid components of 5.6% to 8.5% with a similar follow-up, whereas Iannotti and Norris reported a rate of 4.2% at a follow-up three times shorter. Kasten et al recently reported a 100% survival in 87 TSRs at a mean follow-up of 89 months. With revision surgery for glenoid loosening as the endpoint, we observed survivorship of 99.1% at five years, 94.5% at ten years, and 79.4% at 15 years. With revision as the endpoint Fox et al reported a survivorship for the Cofield 2 all-polyethylene keeled glenoid (Smith & Nephew, Memphis, Tennessee) to be 99% at five years at ten years, 94% and 89% at 15 years.

While we have reported low rates of glenoid revision, our findings with regard to the radiological evidence of loosening were of concern. In our series, the rate of radiological loosening was 45.6% (99 of 217 shoulders) at a mean follow-up of ten years. In the literature, the incidence of radiological loosening varies from 0% to 15% after three years, increasing to 24% and 44% after nine years. Survivorship with the endpoint being radiological loosening has not generally been reported. Haines et al reported Kaplan-Meier survival curves with an endpoint of glenoid ‘at risk’ or revised and showed survival of 78% at seven years and only 46% at ten years. Kasten et al reported a rate of radiological glenoid loosening of 9% at five years and 33% at nine years, however, with regards to the presence of radiolucent lines the rates were 37% at five years and 87% at nine years. Other authors have reported high long-term rates of radiological loosening, about 40% at seven to ten years, but did not include survivorship analyses. Sperling, Cofield and Rowland in a minimum 15-year follow-up study of the Neer prosthesis, reported migration of the glenoid component in 24% and a complete radiolucent line of at least 1 mm in 40%. Overall, they found glenoid peri-prosthetic lucencies in 76% of TSRs. Our results demonstrated that radiolucent lines are progressive and lead to radiological loosening. While we found no significant difference in clinical outcome between those patients with no loosening and those with possible loosening, the development of radiological loosening was associated with deterioration in clinical outcome, leading to

**Table III. Relationship between radiolucent line (RLL) score and clinical results.** Differences between subgroups were tested with analysis of variance followed by t-tests with Bonferroni correction (if the global analysis was significant) for quantitative variables (active forward elevation, adjusted Constant score), or Fisher’s exact test for categorical variables (pain, activity, mobility, strength, Constant score and the subjective patient assessment).

<table>
<thead>
<tr>
<th>RLL score</th>
<th>0 to 6 vs 7 to 12</th>
<th>0 to 6 vs &gt; 12</th>
<th>7 to 12 vs &gt; 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>p = 0.4</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Activity</td>
<td>p = 0.25</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Mobility</td>
<td>p = 1</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Strength</td>
<td>p = 1</td>
<td>p = 0.0025</td>
<td>p = 0.025</td>
</tr>
<tr>
<td>Constant score</td>
<td>p = 1</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Adjusted Constant score</td>
<td>p = 0.98</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Active forward elevation</td>
<td>p = 1</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>Subjective patient assessment</td>
<td>p = 0.32</td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
</tr>
</tbody>
</table>

**Fig. 3**

Kaplan-Meier survivorship curve of the flat-back keeled glenoid component with the endpoint being radiological glenoid loosening (95% confidence interval).
revision. Glenoid revision was rare at five to ten years, but the preceding radiological changes demonstrated an earlier and more marked deterioration in terms of glenoid survival. These results support our recommendation that a minimum follow-up of five to ten years is mandatory for any new glenoid design hoping to provide improvement in radiological outcome.

We identified a number of factors, in addition to duration of follow-up, which were significantly associated with the development of radiological loosening. The bone compaction technique for preparation of the glenoid keel slot was found to be superior to the curettage technique with regard to loosening, which follows a previous report of superiority in terms of early radiolucencies. Younger patient age was also found to be significantly associated with radiological loosening. Fox et al. recently reported a trend toward lower rates of revision in patients aged 65 years or older. These observations suggest that greater activity in younger patients might be a contributing factor for glenoid radiological loosening and revision. In a recent report by Khan et al., the authors observed better radiological results at seven years than ours using the same prosthesis, however, the mean age of the patients at surgery was nearly 80 years compared to 67 years in our study. Lastly, we found secondary proximal migration of the head of the humeral component to be associated with radiological loosening. Franklin et al. reported a typical pattern of glenoid loosening in patients with a rotator cuff deficiency caused by a ‘rocking horse’ mechanism. Although none of our patients had a massive tear pre-operatively, there was evidence of secondary rotator cuff deficiency. Using moderate or severe superior subluxation of the humeral head as surrogate evidence of failure, we identified 59 TSRs in 217 available radiographs (27.2%) with this complication. For these patients we found a highly significant correlation with both the glenoid radiolucent line score and radiological loosening. While radiological assessment of proximal migration provides only an indirect measure of secondary cuff failure, its usefulness has been validated by a number of studies. Although our study was confined to patients with primary glenohumeral osteoarthritis, and therefore might be considered to have represented a best-case scenario for TSR, other authors describe superior results at seven and ten years with the same implants. The reasons for these differences are not clear.

There were a number of limitations to our study, including the inherent problems associated with performing a multicentre study. Specifically, there was the risk of selective exclusion of patients. There were also variations between surgical centres with regard to surgical experience, volume, technique, and post-operative rehabilitation. Additionally many different examiners participated in the pre- and post-operative clinical assessment and some variability was present in imaging protocols. However, the multicentre design allowed us to evaluate the results of a large number of patients from a more representative patient population from different geographical locations. Other advantages of this study were the long follow-up, single aetiology, and the use of the same prosthesis by each centre.

In conclusion, the flat-back all-polyethylene cemented glenoid component demonstrated a radiological loosening rate of 45.6% and a revision rate of 9.1% at a mean follow-up of 122.7 months. The rate of glenoid revision and radiological loosening increased considerably between five and ten years. The curettage technique, which sacrificed good bone, and a younger age at operation were demonstrated as significant adverse prognostic factors. Glenoid loosening significantly influenced all objective and subjective criteria of clinical outcome and continues to be the main problem affecting the longevity of non-constrained TSR with cemented all-polyethylene keeled glenoid components.

The authors would like to thank the following surgeons who contributed cases to this series and helped with the evaluation of clinical and radiological results: Ch. Levigne, B. Melis, R. Philippe, R. Assaad, JCh. LeHuec, G. Pape, K. Vaneva. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References