Revision surgery following total shoulder arthroplasty

ANALYSIS OF 2588 SHOULDERS OVER THREE DECADES (1976 TO 2008)

Our objective was to examine the rate of revision and its predictive factors in patients undergoing total shoulder arthroplasty (TSA). We used prospectively collected data from the Mayo Clinic Total Joint Registry to examine five-, ten- and 20-year revision-free survival following TSA and the predictive factors. We examined patient characteristics (age, gender, body mass index, comorbidity), implant fixation (cemented versus uncemented), American Society of Anesthesiologists class and underlying diagnosis. Univariate and multivariable adjusted hazard rates were calculated using Cox regression analysis. A total of 2207 patients underwent 2588 TSAs. Their mean age was 65.0 years (19 to 91) and 1163 (53%) were women; osteoarthritis was the underlying diagnosis in 1640 shoulders (63%). In all, 212 TSAs (8.2%) were revised during the follow-up period. At five, ten and 20 years, survival rates were 94.2% (95% confidence interval (CI) 93.2 to 95.3), 90.2% (95% CI 88.7 to 91.7) and 81.4% (95% CI 78.4 to 84.5), respectively. In multivariable analyses men had a higher hazard ratio of revision of 1.72 (95% CI 1.28 to 2.31) (p < 0.01) compared with women, and those with rotator cuff disease had a hazard ratio of 4.71 (95% CI 2.09 to 10.59) (p < 0.001) compared with patients with rheumatoid arthritis. We concluded that male gender and rotator cuff disease are independent risk factors for revision after TSA. Future studies are needed to understand the biological rationale for these differences.

The rate of revision following total shoulder arthroplasty (TSA) has been previously reported.2 Two recent systematic reviews of 23 studies including 1952 patients with a mean follow-up of 43 months,2 and 40 studies of Neer type II3 TSAs including 3584 patients with a mean follow-up of 59 months,4 have reported rates of revision of 6.5%2 and 6%,4 respectively. However, five- and ten-year revision rates of between 2% and 20%,5,8 and 3% and 27%,5,7 respectively, have been reported. The studies differed in setting, time period and length of follow-up, and most had sample sizes of < 200. Only one small study of 36 TSAs from our institution reported longer-term data, with a revision rate of 16% at a mean of 15 years.3 Thus, most robust data for revision rates following TSA are limited to a ten-year follow-up.

It is important to study risk factors for revision surgery, as recognition of modifiable factors can allow for specific measures to reduce the risk of revision and improve the outcome. To our knowledge, only three studies have examined the predictive factors for revision surgery after TSA. These studies reported four revisions in 34 TSAs (11%),3 16 revisions in 147 TSAs (11%)6 and 121 revisions in 1542 TSAs (8%).10 The presence of a rotator cuff tear,3 male gender,6,10 radiolucency adjacent to the flat tray,6 an underlying diagnosis of avascular necrosis or post-traumatic arthritis10 and a metal-backed glenoid design10 significantly increased the risk of revision. The main limitation of these studies was that they did not examine modifiable factors such as body mass index (BMI) and comorbidity. More unsatisfactory results have been reported in morbidly obese patients undergoing primary TSA.11 Additionally, two of these three studies had small sample sizes (< 200),3,6 leading to too few revisions (< 20) to perform meaningful multivariable-adjusted analyses. A small number of events in these studies raise serious concerns regarding a possible type II error, thus missing an important association due to lack of power.

Our objective was to examine the prevalence and predictors for revision in a large cohort of patients who had undergone TSA in a 33-year period from 1976 to 2008 at our centre. Our aims were to study revision rates at five, ten and 20 years, and whether higher BMI, comorbidity, age, gender, underlying diagnosis and type of implant (cemented versus uncemented) were associated with the risk of revision.
Patients and Methods

Study cohort. This study was approved by the Mayo Clinic Institutional Review Board and all investigations were conducted in conformity with ethical principles of research. The Mayo Clinic Total Joint Registry was used to conduct this study. This prospective registry has captured every arthroplasty performed at our institution since 1969, including all TSAs since 1976. Thus, our cohort consisted of all patients who had undergone TSA between January 1976 and December 2008. Each patient who undergoes TSA is followed prospectively with clinical follow-up at one, two and five years, and every five years thereafter. Patients failing to return follow-up are sent a questionnaire and asked to send in their radiographs. Patients failing to return the questionnaire receive a telephone call by trained registry staff, who interview them using the standardised shoulder questionnaire and enquire about any additional surgery. Data, including the indication for surgery and operative findings, are requested for subsequent operations performed at other hospitals.

Outcome and predictors. The outcome of interest was revision surgery for any reason. The Registry contains the date, indication and occurrence of revision surgery for every patient.

The main predictors of interest were BMI (kg/m²), comorbidity (using the Deyo-Charlson index) and gender. The Deyo-Charlson comorbidity index is a summative weighted scale of 17 comorbidities (including cardiac, pulmonary, renal, hepatic disease, diabetes, cancer, HIV, etc) and is the most commonly used measure of comorbidity in the medical literature. 13 Additional variables of interest included age, underlying diagnosis, American Society of Anesthesiologists (ASA) class and method of fixation. The ASA class is a validated measure of peri-operative mortality and morbidity 14,15 which was also obtained from electronic databases. Registry data were used to obtain the patients’ age at surgery, gender, underlying diagnosis (osteoarthritis, rheumatoid arthritis, rotator cuff disease, trauma, tumour and other) and method of fixation (cementing of humeral and/or glenoid component versus uncemented). All variables were available for the entire study duration, apart from the BMI, which was available from 1987, and the ASA class, which was available from 1988.

Statistical analysis. Summary statistics were calculated for patient demographic and clinical characteristics as means with standard deviation (SD) or proportions. We calculated revision-free survival at five, ten and 20 years using Kaplan-Meier survival analysis, censoring patients at death. We performed univariate analyses of each predictor of interest (age, gender, BMI, Deyo-Charlson index, ASA grade, underlying diagnosis, method of fixation) and the risk of revision using Cox regression analysis. Variables that were significant in univariate analyses were entered into a multivariable Cox regression model to adjust for confounding. Age and BMI were treated as continuous variables. ASA was categorised as grades 1 and 2 versus 3 and 4 (higher class representing worse physical status), as in previous studies. 16-18 The method of fixation was categorised as cemented versus uncemented, and underlying diagnosis as osteoarthritis, rheumatoid arthritis, tumour, trauma, rotator cuff disease or ‘other’ (comprising ankylosing spondylitis, psoriatic arthritis, dislocation, etc). The Deyo-Charlson index was categorised as none or one or more. Hazard ratios and 95% confidence intervals (CIs) were presented. A p-value < 0.05 was considered statistically significant.

Results

Clinical characteristics. The patients’ characteristics are summarised in Table I. A total of 2207 patients with a mean age of 65 years underwent 2588 TSAs. The mean Deyo-Charlson index was 1; osteoarthritis was the underlying diagnosis in 1640 shoulders (63%), rheumatoid arthritis in 452 (17%) and trauma in 374 (15%).

Rates of revision. A total of 212 TSAs (8.2%) were revised. At five, ten and 20 years the survival rates were 94.2% (95% CI 93.2 to 95.3), 90.2% (95% CI 88.7 to 91.7) and 81.4% (95% CI 78.4 to 84.5), respectively (Fig. 1). The number of patients under observation and the number of revisions at each five-year time point for the entire period are shown in Figure 1a. Survival curves by gender (Fig. 1b), age (Fig. 1c) and underlying diagnosis (Fig. 1d) are also shown.

Univariate and multivariable-adjusted predictors of risk of revision. On univariate regression analysis men were significantly more likely to undergo revision than women (Table II). Cemented implants were significantly less likely...
Patients who underwent TSA with an underlying diagnosis of rotator cuff disease or tumour were significantly more likely than those with rheumatoid arthritis to undergo revision. Younger age was associated with a higher revision risk ($p = 0.05$). Neither BMI nor comorbidity was associated with the risk of revision surgery.

In multivariable analyses that adjusted for gender, age, method of fixation and diagnosis, only gender and diagnosis were significantly associated with an increased risk of revision; fixation with cement and age were no longer significantly associated (Table III). Men were almost twice as likely as women, and those with rotator cuff disease or tumour were 3 to 3.5 times more likely than those with rheumatoid arthritis, to undergo revision surgery.

**Discussion**

In this study we reported up to 20-year survival rates for implants in patients who had undergone TSA at our institution over a 33-year period; 81% of TSAs had not required revision after 20 years. In multivariable-adjusted analyses we found that male gender and an underlying diagnosis of rotator cuff disease or tumour (including other diagnoses such as avascular necrosis, etc.) were significantly associated with a higher risk of revision. The association of method of fixation and age with the risk of revision noted in univariate analyses became non-significant in the multivariable-adjusted analyses.

An important finding is the association between the underlying diagnosis and the risk of revision risk. Rotator

Kaplan-Meier curves for unadjusted revision-free survival for a) the entire cohort, b) by gender, c) by age, and d) by underlying diagnosis. The number of shoulders under observation after primary total shoulder arthroplasty (TSA) were 1437 at five years; 810 at ten years; 365 at 15 years; and 120 at 20 years. The cumulative number of revision surgeries at five, ten, 15 and 20 years after TSA were 118, 165, 200 and 208, respectively. The unadjusted revision-free survival was significantly higher for women than men, significantly higher for older patients than younger, and significantly higher for diagnoses such as rotator cuff disease or tumour against other diagnoses (RA, rheumatoid arthritis; DJD, degenerative joint disease).
Rotator cuff disease and tumour were both significantly associated with a 3 to 5 times higher risk of revision than rheumatoid arthritis. This is a significant finding, given that an association between rotator cuff disease and an increased risk of revision was reported in one small study of 36 TSAs from our institution. Therefore, our study confirms this earlier finding in a much larger sample with a longer follow-up. The finding that patients with tumour and other diagnoses including avascular necrosis, ankylosing spondylitis, etc undergoing TSA had higher rates of revision than those with rheumatoid arthritis is not surprising. Invasion of bone by tumour leading to poor bone quality, the presence of osteoporosis, the effect of chemotherapy on bone remodelling or poor bone quality due to avascular necrosis may contribute to these differences. A higher risk of revision has been previously reported in patients with avascular necrosis undergoing TSA.

The association of male gender with almost twice the risk of revision confirms previous findings from two studies. Another previous study did not report this association in a sample of 36 TSAs with four revision cases. This is likely to be due to the small sample size rather than a true lack of association. The risk ratio for revision in men was 2.2 in a previous study, which is similar to our finding of a ratio of 1.8 for men. With three of the four previous studies reporting a higher risk of revision in men with the fourth study being underpowered, this finding is likely to represent a real difference by gender. Future studies should investigate whether this higher risk is due to differences in bone morphology, comorbidity or hormonal factors.

The lack of association between BMI and comorbidity and an increased risk of revision is also an important negative finding in our study. Our sample was large at > 2500 TSAs, and it is unlikely that this was due to type II error (i.e. missing an association because of a small number of cases). Morbid obesity (BMI > 40 kg/m²) was associated with less satisfactory results after TSA in our study suggesting that only patients with a very high BMI may be...
at risk of complications. To address whether revision rates are higher in this extreme obesity category an even larger sample of patients is needed. The lack of association between the Charlson comorbidity index and the risk of revision should reassure patients and surgeons. Considering that we found no significant differences in revision rates by comorbidity score, high comorbidity should not be cited as a reason not to undertake TSA.

In this paper we have presented the longest follow-up to date for revision-free survival after TSA, and have reported a 20-year survival rate of 81%. This is slightly better than a recently reported 15-year survival rate for the cemented Aequalis TSA of 79.4%, with revision of the glenoid component as the end point. Our five- and ten-year survival rates of 94% and 90% are slightly lower than or similar to the 98% and 97%, which have been reported for the Neer cemented metal-backed glenoid component and 98% and 95% for the all-polyethylene cemented glenoid component, and slightly better than our previously reported results of 87% and 79% for metal-backed bone-ingrowth glenoid components inserted between 1989 and 1994.

Our TSA failure rates are lower than those of 20% at five years and 27% at ten years in a study from the Norwegian Arthroplasty Register. Three failure rates after TSA can be put into perspective by comparing them with those following knee and hip arthroplasty, which are somewhat lower at < 1% per year.

Our study has several limitations. Despite our attempts to adjust for important factors such as BMI and comorbidity, because of the cohort study design residual confounding is possible. Some patients may have had revisions at other centres, and therefore our estimates of revision rates may be conservative. Despite intensive efforts to monitor all patients for post-arthroplasty complications and dedicated trained registry staff who systematically perform all follow-up assessments, some patients were probably lost to follow-up. We are unable to provide accurate estimations of under-reporting by loss to follow-up, since an attempt is made to contact every patient by multiple ways (clinic visit, mailed questionnaire and phone) at multiple times, and there is no single variable that can estimate ‘loss to follow-up’. If all events could be captured the revision rate might be higher, and therefore our estimates do not indicate the ‘worst-case scenario’. The strengths of this study are its large sample size, the long follow-up period, the availability of data on potential predictors and confounders, and robust estimates that did not change much with multivariable analyses.

In summary, we found that long-term revision-free survival following TSA was 81% at 20 years. Male gender and an underlying diagnosis of rotator cuff disease significantly increased the risk of revision surgery. BMI and comorbidity were not associated with an increased risk of revision. Future studies need to focus on the underlying biological rationale for the higher revision risk in men and with certain diagnoses.

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References