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Revision surgery following Total Shoulder Arthroplasty: Analysis of 2,588 shoulders over 3 decades (1976–2008)

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Abstract

Our objective was to examine the revision rates and its predictors in patients undergoing Total Shoulder Arthroplasty (TSA). We used the prospectively collected data from the Mayo Clinic Total Joint Registry to examine the 5-, 10- and 20-year revision-free survival following TSA and its predictors. We examined patient characteristics (age, gender, BMI, comorbidity), implant fixation (cemented versus not), American Society of Anesthesiologists class, and underlying diagnosis. Univariate and multivariable adjusted hazard rates were calculated using Cox regression analyses. Two thousand two hundred seven patients underwent 2,588 TSAs. Mean age was 65 years with 53% women, and osteoarthritis was the underlying diagnosis in 63%. Two hundred twelve TSAs were revised during the follow-up. At 5-, 10- and 20- years, implant survival rates (95% confidence interval) were 94.2% (93.2%–95.3%), 90.2% (88.7%–91.7%) and 81.4% (78.4%–84.5%). In multivariable analyses, men had higher hazard ratio of revision, 1.72 (95% confidence interval, 1.28–2.31) (p<0.01), than women, and those with rotator cuff disease had hazard ratio of 3.99 (95% confidence interval, 1.91–8.36) (p<0.01), compared to patients with rheumatoid arthritis. We conclude that male gender and rotator cuff disease are independent risk factors for revision. Future studies are needed to understand the biological rationale for these differences.

Keywords

revision; total shoulder arthroplasty; gender; predictors

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This study was approved by the Mayo Clinic Institutional Review Board and all investigations were conducted in conformity with ethical principles of research.

Author contributions
JAS- Study and protocol design, IRB application, review of data analysis and interpretation, manuscript preparation and revision
JS- Review of study and protocol design, review of data analysis and interpretation, critical revision of manuscript
RC- Review of study and protocol design, review of data analysis and interpretation, critical revision of manuscript

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Introduction

Several studies have reported revision rates following total shoulder arthroplasty (TSA), a common effective surgery for the treatment of refractory symptomatic shoulder disease (1). Two recent systematic reviews of 23 studies with 1,952 patients with mean follow-up of 43 months (2), and 40 studies of Neer type II shoulder prosthesis with 3,584 patients with a mean follow-up of 59 months (3), reported revision rates of 6.5% (2) and 6% (3), respectively. On the other hand, a wide range has been noted for 5- and 10-year implant revision rates, ranging 2–20% (4–8) and 3–27% (4–7) respectively. The studies differed in setting, time-period and follow-up durations; most had small sample sizes <200 (5) (6) (7) (8). Only one small study of 36 TSAs from our institution reported longer-term data at 15-year follow-up and the revision rate was16% (5). Thus, most robust data for revision rates following TSA are limited to a 10-year follow-up.

It is important to study risk factors for revision surgery, since recognition of modifiable factors can allow for targeted interventions to decrease the risk of revision and improve outcomes. To our knowledge, only three studies have examined the predictors of revision surgery after TSA (5) (6) (9). The studies reported 4 revisions in 34 TSAs (11%) (5), 16 revisions in 147 TSAs (11%) (6) and 121 revisions in 1,542 TSAs (8%) (9). Presence of rotator cuff tear (5), male gender (6) (9), radiolucency adjacent to the flat tray (6), an underlying diagnosis of avascular necrosis, or post-traumatic arthritis (9) and metal-backed glenoid design (9), significantly increased the risk of revision. The main limitation of these studies was that they did not examine important and modifiable factors, such as body mass index (BMI) and comorbidity. Emerging data suggests that higher BMI is associated with more unsatisfactory results in morbidly obese patients undergoing primary shoulder arthroplasty (10). Additionally, two of these three studies had small sample sizes <200 (5) (6), leading to too few revisions (<20) to perform meaningful multivariable-adjusted analyses. A small number of events in these studies raises serious concerns regarding overfitting and type II error, i.e., missing an important association due to lack of power.

Our objective was to examine the prevalence and predictors of revision in a large cohort of patients who had undergone TSA in a 33-year period from 1976–2008 at our medical center, Our aims were to study: (1) revision rates at 5-, 10-, 20-year follow-up after TSA; and, (2) whether higher body mass index, comorbidity, age, gender, underlying diagnosis and type of implant (cemented versus non-cemented) were associated with the risk of revision.

Methods

Study Cohort

The Mayo Clinic Total Joint Registry was used to conduct this study. This prospective registry has captured every arthroplasty performed at the Mayo Clinic, Rochester, Minnesota, since 1969. These include all the shoulder arthroplasties performed since 1976. Our cohort consisted of all patients who had undergone TSA at Mayo Clinic between January 1976 and December 2008. Each patient who undergoes shoulder arthroplasty is followed prospectively clinically with clinical follow-up visits at 1-, 2- and 5-years, and every 5 years thereafter. Patients failing to return for clinic follow-up are contacted with a mailed shoulder questionnaire (11) and requested to send their radiographs. Patients failing to return the questionnaire receive a telephone call by trained registry staff, who interviews them using standardized shoulder questionnaire, and enquires about any additional surgery. Data, including operative reports for indication and operative findings, are requested for surgeries at other hospitals. Since the follow-up is done 2- and 5-years post-arthroplasty and then every 5-years up to 20-years, patients are followed by a combination of these methods, clinic follow-up, questionnaires and telephone interviews. Most data is derived from the institutional operative reports and surgeon's notes in patients medical records, captured subsequently in the joint registry.

Outcome and Predictors

The outcome of interest was all-cause revision surgery for the index TSA. Total Joint Registry contains the date, indication and occurrence of revision surgery for every patient.

The main predictors of interest included BMI, comorbidity and gender. Additional variable of interest included age, underlying diagnosis, American Society of Anesthesiologist (ASA) class and implant fixation. BMI (in kg/m^2) and comorbidity, measured with Deyo-Charlson index, were obtained from institutional electronic databases for the study cohort. Deyo-Charlson comorbidity index is summative weighted scale of 19 comorbidities (including cardiac, pulmonary, renal, hepatic disease, diabetes, cancer, HIV etc.) and is the most commonly used comorbidity measure in the medical literaure (12). We used the Total Joint Registry to obtain data on patient‘s age at surgery, gender, underlying diagnosis (osteoarthritis, rheumatoid arthritis, rotator cuff disease, trauma, tumor and other) and implant fixation (cementing of humeral and/or glenoid component versus not). American Society of Anesthesiologist (ASA) class is a validated measure of perioperative mortality and morbidity (13–14), which was also obtained from institutional electronic databases. All variables were available for the entire study duration, except BMI (available since 1987) and ASA class (available since 1988).

Statistical Analyses

Summary statistics were calculated for patient demographic and clinical characteristics as mean (standard deviation) or proportions. We calculated revision-free survival at 5-, 10- and 20-years by using Kaplan-Meier survival analysis method, censoring patients at death.

We performed univariate analyses of each predictor of interest (age, gender, BMI and Deyo-Charlson index, ASA class, underlying diagnosis, implant fixation) and the risk of revision using Cox regression analyses. 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 categorized as class 1–2 versus 3–4 (higher class=worse physical status), as in previous studies. Implant fixation was categorized as cemented versus not, and underlying diagnosis as osteoarthritis, rheumatoid arthritis, tumor, trauma, rotator cuff disease and other diagnoses (anklyosing spondylitis, psoriatic arthritis, dislocation etc.). Deyo-Charlson index was categorized as none or 1 or more. Hazard ratios and 95% confidence intervals were presented. A p-value <0.05 was considered statistically significant.

Results

Clinical Characteristics

The patient characteristics are summarized in Table 1. 2,207 patients underwent 2,588 TSAs. For patients undergoing TSA, the mean age was 65 years with 53% women, mean Charlson index was 0.8; osteoarthritis was the underlying diagnosis in 63%, rheumatoid arthritis in 17% and trauma in 15%.

Revision Rates

Among 2,588 TSAs, 212 were revised during the follow-up. At 5, 10 and 20 years, survival rates were 94.2% (93.21%, 95.3%), 90.2% (88.7%, 91.7%) and 81.4% (78.4%, 84.5%). The KM curve depicts the survival rate during follow-up (Figure 1). The actual number of patients at observation and number of revisions at each 5-yeat time-point for the entire are shown in the figure legend (Figure 1a). K-M survival curves by gender (Figure 1b), age (Figure 1c) and underlying diagnosis (Figure 1d) are shown as well.

Univariate and Multivariable-adjusted predictors of risk of revision

In univariate regression analysis, men were significantly more likely to undergo a revision than women (Table 2). Cemented implants were significantly less likely to be revised. Patients who underwent TSA with underlying diagnosis of rotator cuff disease or tumor were significantly more likely than these with rheumatoid arthritis to undergo revision. Younger age was associated with higher revision risk (p=0.05). Neither BMI nor comorbidity was associated with the risk of revision surgery.

In multivariable analyses that simultaneously adjusted for gender, age, cement fixation and diagnosis, only gender and diagnosis were significantly associated with the risk of revision; cement fixation and age were no longer significantly associated (Table 3). Men were almost twice as likely as women, and those with rotator cuff disease or tumor were 3–3.5 times as those with rheumatoid arthritis to undergo revision surgery during follow-up.

Discussion

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

An important finding in our study is the association of underlying diagnoses with the revision risk after TSA. Rotator cuff disease and tumor (including other diagnoses such as avascular necrosis) were both significantly associated with 3–3.5 time higher hazard/risk of revision, compared to rheumatoid arthritis. This is a significant finding, given that association of rotator cuff disease with revision risk has been reported in one small study of 36 TSAs from our institution (5). Thus, our study, confirms this earlier finding in a much larger sample with a longer follow-up. The finding that patients with tumor/other diagnoses (including avascular necrosis, ankylosing spondylitis etc.) undergoing TSA had higher revision rate compared to rheumatoid arthritis is not surprising. Bone invasion by tumor leading to poor bone quality, osteoporosis due to paraneoplastic syndromes, the effect of chemotherapy on bone remodeling, or poor bone quality due to avascular necrosis may be contributing to these differences. Higher risk of revision has been previously reported in patients with avascular necrosis undergoing TSA (9).

The association of male gender with almost twice the hazard/risk of revision confirms previous similar findings from two studies that reported this association (6)(9). One of the previous studies did not report this association in a sample of 36 TSAs with 4 revision cases, which is likely due to small sample size with rate event rate, rather than lack of association (5). The hazard/risk ratio for revision in men was 2.2 in a previous study (9), which is similar to our finding of hazard ratio of 1.8 for men. With three of the four studies reporting higher revision risk in men (forth study being underpowered), this finding is likely a real difference by gender. Future studies should investigate whether this higher risk is due to difference in bone morphology, systemic disease/comorbidity, or hormonal factors.

The lack of association of BMI and comorbidity with risk of revision surgery is also an important negative finding in our study. Certainly, our sample was large at >2,500 TSAs; therefore, it is unlikely that this was due to type II error, i.e., missing an association due to small number of cases. Morbid obesity with BMI >40 kg/m^2 is associated with less satisfactory results after primary should arthroplasty in our recent study. This implies that only patients with very high BMI may be at risk of complications. To address whether revision rates are higher in this extreme obesity category, even a large sample of patients is needed. The lack of association of Deyo-Charlson comorbidity index with revision risk should reassure. patients and surgeons. Considering no significant differences in revision rates by comorbidity score, a high comorbidity should not be cited as a reason not to perform/undergo shoulder arthroplasty.

In this study, we have presented the longest follow-up for revision-free implant survival for TSA to-date. We reported 20-yr survival of 81% for TSA in our study. The 5- and 10-year implant survival rates of 94% and 90% in our study are slightly lower than/similar to the 98% and 97% for Neer cemented metal-backed glenoid (7), and 98% and 95% for all-poly ethylene cemented glenoid (9) and slightly better than our previously reported results of 87% and 79% for metal-backed bone-in growth glenoid from 1989–1994 (15). Our TSA failure rates are lower than those failure rates of 20% at 5-years and 27% at 10-years in a study using Norwegian Arthroplasty register (4). These failure rates after TSA can be put in perspective by comparing them to those following knee and hip arthroplasty, which are somewhat lower (16–17).

Our study has several limitations. Despite our attempts to adjust for important factors, such as BMI and comorbidity, due to cohort study design, residual confounding is possible. Some patients may have had revisions at other medical care centers, and, therefore, our revision rates are conservative. Despite our intensive efforts to monitor all patients for post-arthroplasty complications and dedicated trained registry staff who systematically perform follow-up assessments, some patients were likely lost of follow-up. If all events could be captured, the revision rate may be higher, and therefore our estimates do not indicate the “worst case-scenario”. The strengths of this study are a large sample size, a long follow-up period, availability of data on important 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-year follow-up. Male gender and underlying diagnosis of rotator cuff disease significantly increased the risk of revision surgery. BMI and comorbidity were not associated with the risk of revision. Future studies need to focus on underlying biological rationale for higher revision risk in men and in certain diagnoses.

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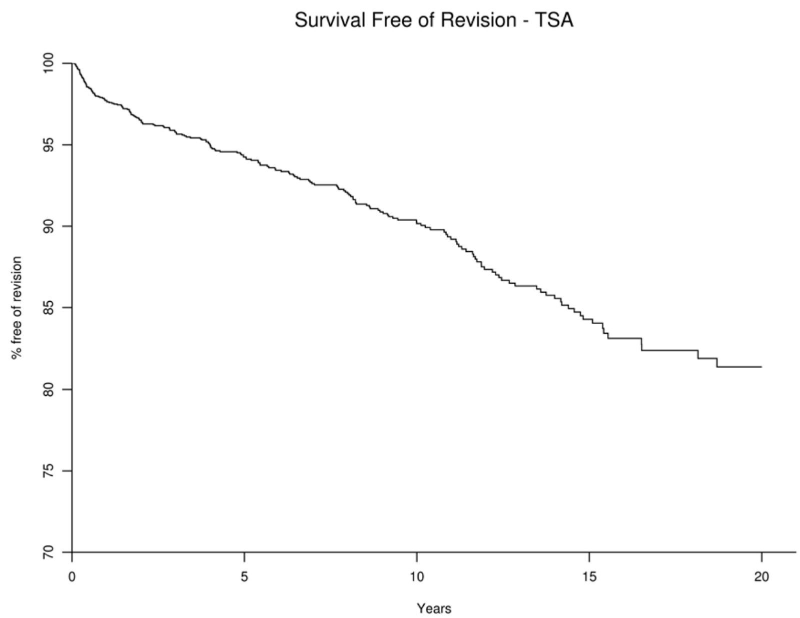
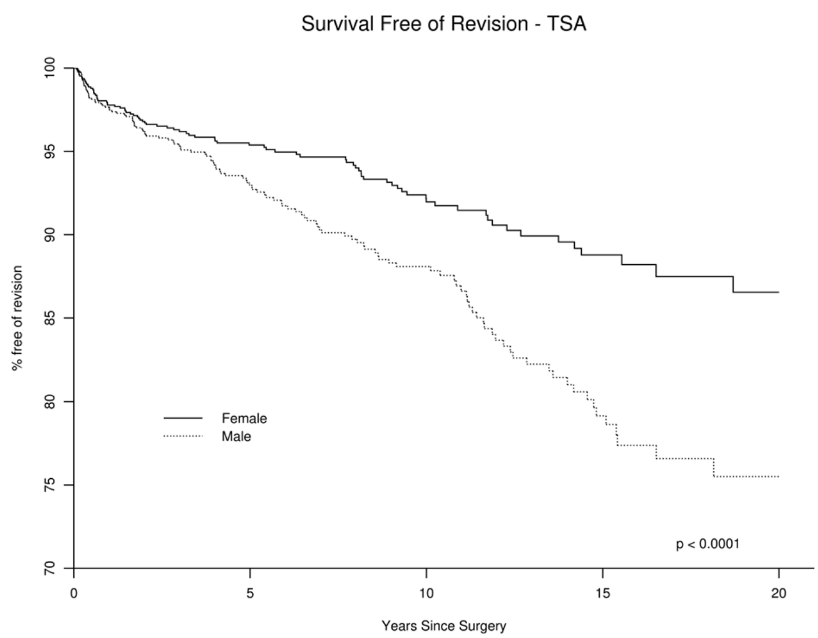
1A. Overall revision-free survival



1B. Revision-free survival by gender



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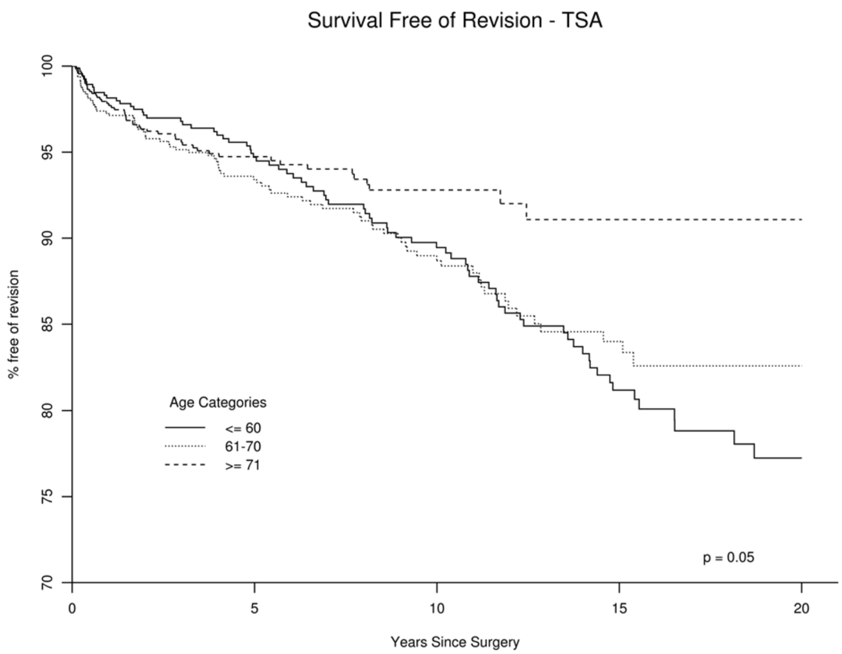
1C. Revision-free survival by age



1D. Revision-free survival by diagnosis

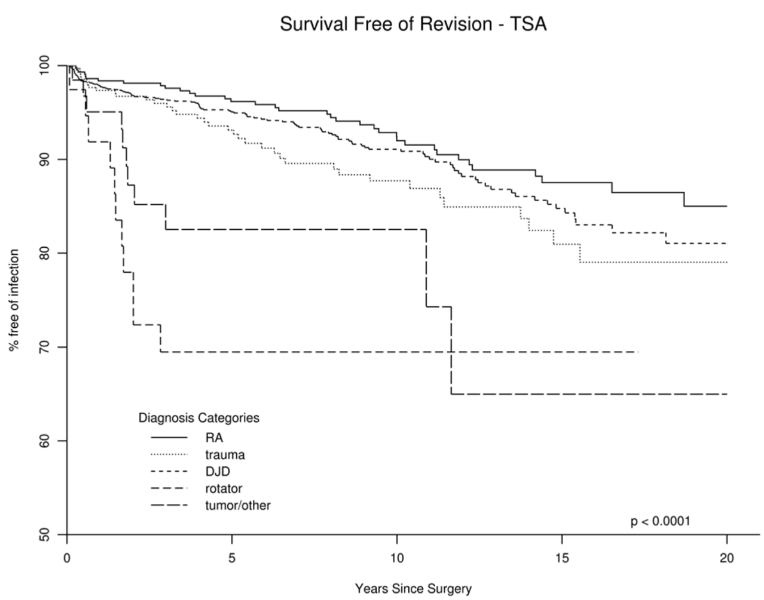


Figure 1. Kaplan-Meir curves for unadjusted revision-free survival for the entire cohort (1a) and by gender (1b), age (1c) and underlying diagnosis (1d)

1a: The number of shoulders under observation after primary TSA were as follows, respectively: 5-years 1,437; 10-years, 810; 15-years, 365; and 20-years, 120. The cumulative number of revision surgeries at 5-, 10-, 15- and 20-years were post-TSA, 118, 165, 200 and 208, respectively.

1b: The figure shows the unadjusted revision-free survival by gender, which was significantly higher for women than men

1c: The figure shows the unadjusted revision-free survival by age, which was significantly higher for older patients

1d: The figure shows the unadjusted revision-free survival by diagnosis, which was significantly higher for diagnosis such as rotator cuff disease or tumor

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Table 1

Clinical and Demographic characteristics of study population

	Total Shoulder Arthroplasty 2,207 patients with 2,588 shoulders
	Mean (Standard Deviation) or n (%)
Age (years)	65 (12)
Male/Female	1,044 (47%)/1,163 (53%)
Underlying Diagnosis	
Rheumatoid arthritis	452 (17%)
Trauma	374 (15%)
Tumor	37 (2%)
Osteoarthritis	1,640 (63%)
Rotator Cuff disease	40 (2%)
Other[a]	34 (2%)
Body Mass Index(kg/m^2)[b]	30 (6)
American Society of Anesthesiologist (ASA) class[c]	
1 or 2	1,236 (61%)
3 or 4	780 (39%)
Deyo-Charlson index	1 (1)
Implant fixation	
Cemented	2,485 (96%)
Uncemented	102 (4%)

[a]Other category for underlying diagnosis includes: avascular necrosis, ankylosing spondylitis, psoriatic arthritis, gout, Charcot arthropathy, dislocation, old injury, prior history of septic arthritis

[b]available from 9/1/1987 to present

[c]available from 11/1/1988 to present; for 9 patients with TSA and 7 patients with hemiarthroplasty, ASA class was missing Numbers and percents are rounded to the nearest digit, therefore the totals may not add up exactly to 100%

Table 2

Univariate association of patient and implant factors with risk of revision after total shoulder arthroplasty

			KM estimates (95% CI)			Cox proportional hazards		
variable	**# shoulders**	**# events**	**5 years**	**10 years**	**20 years**	**Hazard Ratio (95% CI)**	**p-value**	**overall p-value**
Female	1,352	84	95.4 (94.1,96.6)	92.0 (90.1,93.9)	86.5 (83.0,90.3)	1.0 (ref)		
Male	1,236	128	93.0 (91.4,94.7)	88.1 (85.7,90.5)	75.5 (70.6,80.7)	**1.77 (1.34,2.35)**	**<0.001**	
Age at surgery (years)						**0.99 (0.98,0.999)**	**0.03**	
Body Mass Index†						1.01 (0.99,1.04)	0.29	
ASA (1,2)‡	1,236	83	94.8 (93.3,96.3)	90.2 (87.8,92.7)	77.4 (70.5,85.0)	1.0 (ref)		
ASA (3,4)	780	56	93.7 (91.6,95.7)	89.4 (86.3,92.6)	80.0 (73.7,86.9)	1.21 (0.85,1.72)	0.29	
Deyo-Charlson index = 0	1,536	137	94.2 (92.8,95.5)	89.2 (87.1,91.2)	79.0 (74.8,83.5)	1.0 (ref)		
Deyo-Charlson index > 0	1,052	75	94.4 (92.8,96.0)	91.7 (89.5,93.9)	84.7 (80.5,89.0)	0.79 (0.59,1.05)	0.11	
No cement	103	22	89.6 (83.7,95.9)	82.2 (74.6,90.6)	69.5 (58.5,82.6)	1.0 (ref)		
Cement	2,485	190	94.4 (93.4,95.5)	90.6 (89.1,92.1)	82.3 (79.2,85.5)	**0.51 (0.32,0.81)**	**0.005**	
Diagnosis								
Rheumatoid arthritis	452	38	96.2 (94.3,98.1)	92.0 (89.0,95.1)	85.0 (79.8,90.5)	1.0 (ref)		**<0.001**
Trauma	374	38	93.1 (90.2,96.1)	87.7 (83.5,92.1)	79.0 (71.9,86.9)	0.80 (0.55,1.16)	0.23	
Osteoarthritis	1,640	114	95.1 (93.9,96.3)	91.1 (89.2,93.0)	81.0 (76.6,85.8)	1.26 (0.87,1.84)	0.22	
Rotator cuff	40	11	69.5 (55.9,86.3)	69.5 (55.9,86.3)	N/A	**3.45 (1.67,7.15)**	**<0.001**	
Tumor/other	82	11	82.5 (72.6,93.8)	82.5 (72.6,93.8)	65.0 (45.5,92.9)	**2.86 (1.56,5.26)**	**<0.001**	

† available from 9/1/1987 to present

‡ available from 11/1/1988 to present

N/A, Not applicable

Hazard ratios in bold represent those statistically significant with a p-value <0.05

Table 3

Multivariable-adjusted analyses of revision risk in patients with total shoulder arthroplasty

	Hazard Ratio (95% CI)	**p-value**	**overall p-value**
Female	1.0 (reference)		
Male	**1.72 (1.28,2.31)**	**<0.001**	
Age at surgery	0.99 (0.98,1.00)	0.07	
Diagnosis			**<0.001**
Osteoarthritis	1.0 (reference)		
Rheumatoid arthritis	0.85 (0.55,1.31)	0.46	
Trauma	1.26 (0.87,1.83)	0.22	
Rotator cuff	**3.99 (1.91,8.36)**	**<0.001**	
Tumor/other	**2.65 (1.40,5.02)**	**0.003**	
No cement	1.0 (reference)		
Cement	**0.62 (0.38,1.02)**	**0.06**	

Hazard ratios in bold represent those statistically significant with a p-value <0.05