

# Early revision in anatomic total shoulder arthroplasty in osteoarthritis: a cross-registry comparison

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## Abstract

**Background:** We evaluated anatomic total shoulders undergoing early revision (less than two years) in the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) and the Kaiser Permanente Shoulder Arthroplasty Registry (KPSAR).

**Methods:** A cross-sectional comparison of both registries was performed between the years of 2009 and 2012. Only patients who underwent anatomic total shoulder arthroplasty for a primary diagnosis of osteoarthritis were included. Aggregate-level data of patients undergoing early revisions done within two years of index arthroplasty were evaluated, and descriptive analysis was conducted.

**Results:** During the study period, 4614 patients were identified in the AOANJRR compared to 2036 in the KPSAR. Rotator cuff pathology, component loosening, and prosthetic instability were among the most common reasons for revision in both registries. A higher rate of revision in the AOANJRR was found to be secondary to the failure of one specific prosthesis, which has since been discontinued.

**Discussion:** Comparing reasons for early revision in total shoulder arthroplasty revealed several similarities between the AOANJRR and KPSAR. Differences were also noted, and this study served to highlight the importance prosthesis selection can play in determining outcomes. Cooperation among registries may allow for earlier identification of risk factors for failure in shoulder arthroplasty.

## Keywords

total shoulder arthroplasty, osteoarthritis, revision, registry

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## Introduction

Total shoulder arthroplasty (TSA) is increasingly being utilized in the management of glenohumeral osteoarthritis (OA).<sup>1–5</sup> In light of this increased demand, it is essential best practices are established for treating arthritic conditions about the shoulder. However, research evaluating outcomes is difficult, given the comparatively low overall volume of both primary and revision procedures.<sup>6</sup>

Established national and regional arthroplasty registries are beneficial for monitoring patient and prosthesis outcomes, aiding clinicians in determining evidence-based best practices.<sup>7</sup> Due to the relatively

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low numbers of TSA performed annually, collaboration among shoulder arthroplasty registries may be a strategy to investigate research questions regarding rare events or small effect sizes.<sup>6</sup> However, there is variation in diagnoses and outcomes across different shoulder arthroplasty registries.<sup>8</sup>

The purpose of this study is to compare (1) patient demographics, (2) early revision rates (less than two years), and (3) reasons for revision of anatomic TSA performed for OA for one national and one regional registry using data from both the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) and the Kaiser Permanente Shoulder Arthroplasty Registry (KPSAR), respectively.

## Methods

A cross-sectional comparison of the AOANJRR and the KPSAR was performed using summary-level data obtained from the two registries. This “distributed health data network” approach is previously shown to be successful in comparing registry data while allowing individual registries to maintain control of case-level data and protect patient privacy.<sup>9</sup> The AOANJRR commenced national-level shoulder arthroplasty data collection in 2007 and has information on 27,236 procedures through the end of 2014.<sup>10</sup> The KPSAR includes data on prostheses implanted since 2005 and by the end of 2014 has information on 10,983 procedures.<sup>11</sup>

For this study, each registry identified all anatomic TSA procedures performed for the diagnosis of OA from 1 January 2009 through 31 December 2012, with at least two years follow-up. Since the outcome of interest was time to first revision within two years of surgery, 31 December 2014 was the last date of follow-up. Data collection and validation for both registries are previously described.<sup>10,12</sup> During this period, the capture rate was 98.6% for the AOANJRR and 99.9% for the KPSAR.

Demographic information included age (continuous and by category: less than 50 years, 50–59 years, 60–69 years, 70–79 years, and 80 years or older) and gender (female and male). The primary outcome was revision within two years of primary surgery and reason for revision.

In the AOANJRR, multiple diagnoses for revision were managed using a revision diagnosis hierarchy, which identifies the single most important reason for revision.<sup>10</sup> Within the KPSAR, cases with multiple reasons for revision were manually chart reviewed (MTD and RAN), and a hierarchy was used to determine the best single reason for revision. Revision reason categories across registries were reviewed by three orthopedic shoulder surgeons (MTD, RSP, and

RAN) to harmonize categories between the two registries. Final harmonized categories included: arthrofibrosis, component loosening/lysis, component structural failure, implant malposition/incorrect sizing, infection, instability, other, periprosthetic fracture, and rotator cuff pathology.

Analysis was completed separately for the Australia and Kaiser Permanente (KP) cohorts. Frequencies and proportions for categorical variables and means and standard deviations (SD) for continuous variables were used to describe each cohort. Two-year revision incidence rates were calculated as the number of revisions within the first two postoperative years over the total population at risk. Revision rates were stratified by age and gender, including chi-square P values.

## Results

The study sample comprised 4614 TSA from Australia and 2036 from KP (Table 1). The mean age was 69.8 years (SD = 8.7) in the AOANJRR and 69.2 years (SD = 8.7) in the KPSAR; the age groups with the largest proportion of TSA was 70–79 years in the Australia cohort (38.1%) and 60–69 years in the KP cohort (37.3%). The majority of patients were female in the AOANJRR (58.4%); fewer patients were female in the KPSAR (48.4%).

**Table 1.** Demographics of Australian and Kaiser Permanente total shoulder arthroplasty patients from 2009 to 2012.

n (%)	Australia	Kaiser Permanente
Total	4614	2036
Age, in years, mean (SD)	69.8 (8.7)	69.2 (8.7)
Age category, n (%)		
Under 50	83 (1.8)	22 (1.1)
50–59	549 (11.9)	259 (12.7)
60–69	1743 (37.8)	759 (37.3)
70–79	1756 (38.1)	737 (36.2)
80 and over	483 (10.5)	259 (12.7)
Gender, n (%)		
Female	2695 (58.4)	986 (48.4)
Male	1919 (41.6)	1050 (51.6)

SD: standard deviation

**Table 2.** Frequency of early revision<sup>a</sup> of Australian and Kaiser Permanente total shoulder arthroplasty patients for all prostheses, within age and gender subgroups (2009–2012).

	Australia	Kaiser Permanente	P
Total	273/4614 (5.9)	31/2036 (1.5)	<0.001
Age category			
Under 50	11/83 (13.3)	1/22 (4.5)	0.254
50–59	39/549 (7.1)	5/259 (1.9)	0.002
60–69	108/1743 (6.2)	15/759 (2.0)	<0.001
70–79	99/1756 (5.6)	5/737 (0.7)	<0.001
80 and over	16/483 (3.3)	5/259 (1.9)	0.279
Gender			
Female	164/2695 (6.1)	11/986 (1.1)	<0.001
Male	109/1919 (5.7)	20/1050 (1.9)	<0.001

Note: Results presented as n/N (%).

<sup>a</sup>Early revision was defined as within the first two years of the primary procedure.

The overall two-year cumulative percent revision was 5.9% in Australia and 1.5% in KP ( $P < 0.001$ ) (Table 2). The age category with the highest frequency of revisions was those less than 50 years old (13.3% and 4.5% for Australia and KP, respectively,  $P = 0.254$ ); 80 years and over had the lowest frequency of revisions (3.3% and 1.9% for Australia and KP, respectively,  $P = 0.279$ ). More females had an early revision in Australia (6.1% vs. 5.7%), though males were more likely to undergo revision in KP (1.9% vs. 1.1%). Males and females both had a higher frequency of revisions in Australia compared to KP ( $P < 0.001$  for both).

The most common reasons for revision in the AOANJRR were instability/dislocation (31.1%), rotator cuff insufficiency (24.2%), and loosening/lysis and implant breakage glenoid insert (11.0% each), while the most common reasons in KP were rotator cuff tear (32.3%), glenoid component loosening (29.0%), and dislocation and infection (12.9% each) (Table 3). After harmonization, the most common revision reasons remained similar: instability (31.1%), rotator cuff pathology (24.2%), and component structural failure (16.5%) in Australia and component loosening/lysis and rotator cuff pathology (32.3% each) and instability and infection (12.9% each) in KP (Table 4).

**Table 3.** Reasons for early revision<sup>a</sup> of Australian and Kaiser Permanente total shoulder arthroplasty revision patients.

Reason for revision, n (%)	Australia	Reason for revision, n (%)	Kaiser Permanente
Total	273	Total	31
Arthrofibrosis	3 (1.1)	Dislocation	4 (12.9)
Dislocation	11 (4.0)	Glenoid component loosening	9 (29.0)
Fracture	4 (1.5)	Humeral component loosening	1 (3.2)
Implant breakage glenoid	4 (1.5)	Implant malposition	2 (6.5)
Implant breakage glenoid insert	30 (11.0)	Infection	4 (12.9)
Incorrect sizing/malposition	15 (5.5)	Periprosthetic fracture	1 (3.2)
Infection	15 (5.5)	Rotator cuff tear	10 (32.3)
Instability/dislocation	85 (31.1)		
Loosening/lysis	30 (11.0)		
Metal-related pathology	2 (0.7)		
Other	3 (1.1)		
Pain	5 (1.8)		
Rotator cuff insufficiency	66 (24.2)		

<sup>a</sup>Early revision was defined as within the first two years of the primary procedure.

**Table 4.** Harmonized reasons for early revision<sup>a</sup> of Australian and Kaiser Permanente total shoulder arthroplasty revision patients.

Reason for revision, n (%)	Australia	Kaiser Permanente
Total	273	31
Arthrofibrosis	3 (1.1)	0 (0.0)
Component loosening/lysis	30 (11.0)	10 (32.3)
Component structural failure	45 (16.5)	0 (0.0)
Incorrect sizing/ implant malposition	15 (5.5)	2 (6.5)
Infection	15 (5.5)	4 (12.9)
Instability	85 (31.1)	4 (12.9)
Other	10 (3.7)	0 (0.0)
Periprosthetic fracture	4 (1.5)	1 (3.2)
Rotator cuff pathology	66 (24.2)	10 (32.3)

<sup>a</sup>Early revision was defined as within the first two years of the primary procedure.

### SMR L2 glenoid prosthesis

During the study period, 1365 Shoulder Modular Replacement (SMR) L2 glenoid (Lima Orthopaedics, San Daniele, Italy) implants were registered by the AOANJRR, with a two-year revision rate of 13.1%; after the SMR were excluded, the two-year cumulative percentage revision was 2.9% in the Australia cohort, and revision rates across age and gender groups were more similar to the KP cohort, though still higher (Table 5). Instability (37.2%), component loosening/lysis (21.3%), and rotator cuff pathology (11.7%) were the most common harmonized revision reasons after excluding the SMR implants from the Australia cohort (Table 6). No SMR components were recorded in the KPSAR during the study period.

### Discussion

This work demonstrates how data can be harmonized across registries and provides baseline results of two international shoulder arthroplasty cohorts to understand where similarities and variation exist for consideration in future collaborations. It is the first collaboration of geographically distinct national and regional shoulder arthroplasty registries to date. One prior study on collaboration among shoulder arthroplasty registries included more racially homogenous

**Table 5.** Frequency of early revision<sup>a</sup> of Australian and Kaiser Permanente total shoulder arthroplasty patients after exclusion of the Shoulder Modular Replacement prosthesis, within age and gender subgroups (2009–2012).

	Australia	Kaiser Permanente	P
Total	94/3249 (2.9)	31/2036 (1.5)	0.001
Age category			
Under 40	5/56 (8.9)	1/22 (4.5)	0.513
50–59	14/381 (3.7)	5/259 (1.9)	0.202
60–69	41/1257 (3.3)	15/759 (2.0)	0.089
70–79	28/1214 (2.3)	5/737 (0.7)	0.007
80 and over	6/341 (1.8)	5/259 (1.9)	0.879
Gender			
Female	52/1916 (2.7)	11/986 (1.1)	0.005
Male	42/1333 (3.2)	20/1050 (1.9)	0.058

Results presented as n/N (%)

<sup>a</sup>Early revision was defined as within the first two years of the primary procedure.

**Table 6.** Harmonized reasons for early revision<sup>a</sup> of Australian and Kaiser Permanente total shoulder arthroplasty revision patients, after exclusion of Shoulder Modular Replacement prosthesis.

Reason for revision, n (%)	Australia	Kaiser Permanente
Total	94	31
Arthrofibrosis	3 (3.2)	0 (0.0)
Component loosening/lysis	20 (21.3)	10 (32.3)
Component structural failure	0 (0)	0 (0.0)
Incorrect sizing/implant malposition	7 (7.4)	2 (6.5)
Infection	10 (10.6)	4 (12.9)
Instability	35 (37.2)	4 (12.9)
Other	5 (5.3)	0 (0.0)
Periprosthetic fracture	3 (3.2)	1 (3.2)
Rotator cuff pathology	11 (11.7)	10 (32.3)

<sup>a</sup>Early revision was defined as within the first two years of the primary procedure.

patient populations.<sup>6</sup> We found similarities in the age distribution of anatomic TSA patients for OA across cohorts, with procedures most commonly performed in older individuals, although gender differences were observed. Most anatomic TSA were performed in patients aged between 60 and 79 years, in agreement with previously published reports.<sup>1,6,13</sup> Prior studies reported shoulder procedures to be performed more commonly in females,<sup>1,2,6,13,14</sup> though these studies included different types of procedures and/or additional indications other than OA. We too found females to comprise the majority of TSA for OA patients in the Australia cohort, however, not for the KP cohort. In another report using data from the KPSAR and including all shoulder procedures for all diagnoses, Dillon et al.<sup>12</sup> found the overall cohort to be mostly female (56%), but the frequency of females in the TSA subgroup was similar to those reported here.

Werner et al.<sup>13</sup> recently reported a one-year TSA revision frequency of 1.8% using the PearlDiver Patient Records Database, though this study included TSA for multiple indications. Similarly, we note early revision after TSA for OA to be an uncommon event. The Australia cohort had a higher frequency of revisions (5.9%) compared to the KP cohort (1.5%). This disparity highlights the role prosthesis selection can play in evaluating outcomes, as not all implants have equal revision rates. During the study period, the SMR L2 glenoid was identified by the AOANJRR as an implant with an increased risk of revision.<sup>15</sup> An early platform prosthesis, the SMR was designed to facilitate revision from anatomic TSA to reverse TSA. To this end, the L2 glenoid component was introduced in 2009 with a polyethylene liner on a metal backing that could be removed to more easily allow placement of a glenosphere on to the existing metal backing. Its use was discontinued in Australia by Lima Orthopaedics in 2012 due to a high rate of failure of the polyethylene liner separating from the metal backed portion as identified by the AOANJRR,<sup>15</sup> a finding also reported by the New Zealand National Joint Registry.<sup>16</sup> With the SMR excluded, the early revision rate of the Australia cohort was similar to that of the KP cohort.

It deserves noting that the AOANJRR has reported a high rate of reverse TSA utilization for OA,<sup>10</sup> a diagnosis for which reverse TSA was used sparingly at the time in the KPSAR.<sup>12</sup> Other than the exclusion of the SMR prosthesis, this study did not adjust for differences that may exist in prosthesis selection and utilization between the two registries. It may be that surgeon selection bias for TSA over reverse total shoulder arthroplasty (RTSA) in certain patient populations contributes to the differences in revision rates between the two cohorts.

In age-stratified results, patients under 50 years had the highest revision rate, which was most noticeably true in Australia. This reinforces the challenges inherent in performing shoulder arthroplasty in younger patients, a population where earlier studies have yielded inconsistent results.<sup>17–22</sup> Similarly, Werner et al.<sup>13</sup> found age younger than 65 years was associated with early revision in TSA, along with smoking, obesity, and morbid obesity. While patient factors certainly play a role in early revision, factors due to surgeon-related technical errors cannot be ignored, as has already been described in the knee arthroplasty literature.<sup>23</sup> Prosthesis selection also likely played a role in increased failures in younger patients in the Australia cohort, as 35% of the SMR prostheses implanted in this age-group required revision within two years (data not shown).

In a recent study evaluating the international differences in shoulder arthroplasty, Lubbeke et al.<sup>8</sup> stressed the need to harmonize data and outcomes among different registries to allow for future international collaboration. For the purposes of this study, we agreed upon a total of nine possible reasons for revision. In comparison, when the Nordic Arthroplasty Register Association (NARA) merged data from their registries into a common data set, it agreed to six reasons for revision for the purposes of data sharing and collaboration: infection, periprosthetic fracture, luxation and instability, loosening, rotator cuff problem, and others.<sup>6</sup>

During the harmonization process, we found similar reasons for revision existed between the two registries such as “instability/dislocation” in the AOANJRR and “dislocation” in the KPSAR. However, at times, it was necessary to combine multiple categories, such as “glenoid component loosening” and “humeral component loosening” in the KPSAR and “loosening/lysis” in the AOANJRR to make “component loosening/lysis.” We felt inclusion of “incorrect sizing/component malposition” was an important category. In these cases, it may be surgeon error that contributes to the revision, but it may also be that some prostheses have more burdensome instrumentation or limited component options that can compromise the operative technique and result in a higher likelihood of revision. Interestingly, all incidents of “component structural failure” involved the SMR and, with this component excluded, the reasons for revision in Australia were similar to KP.

Study strengths largely are attributed to the volume of procedures and the description of early revisions from two high-quality registries. Registry studies allow for generalizability of findings due to the many surgeons and hospitals included. Data derived from registries offer several advantages when compared to large scale database studies like those relying on



administrative claims,<sup>24</sup> as registry data can include additional detailed information such as laterality and specific implant-level data. This is also the first description comparing two geographically distinct TSA populations, showing where similarities and differences exist. We believe our work can help guide future registry collaborations. Future analyses investigating rare events and specific subgroups may be possible where previously an individual registry would be unable to undertake alone due to sample size constraints. This study helps to lay the groundwork for future registry collaborations into research questions where merging data from the two registries into a harmonized data set may allow us to better identify at-risk population subgroups and outlier implant devices (although we duly note that it was the astute surveillance of the AOANJRR alone responsible for the removal of the SMR implant from the Australian market). In an excellent example of the benefits of such cooperation, NARA recently demonstrated a higher risk of revision for the Delta III prosthesis (De Puy, Raynham, MA, USA) when compared to the Delta Extend (De Puy) after data from all member registries were combined. In comparison, this finding was not observed when that analysis was performed at the individual registry level.<sup>6</sup>

This study is not without limitations. As this study is largely descriptive comparing two international TSA cohorts, inferences regarding risk factors for revisions and reasons for revisions cannot be made. Although we present age and gender-stratified revision rates here, future cross-registry analytical studies will need to perform multivariable analysis including adjustment for other potential confounders. The AOANJRR reports a much higher rate of reverse TSA for OA than the KSPAR.<sup>10,12</sup> With the high rate of utilization of reverse TSA for OA in the AOANJRR, surgical indications for treating OA with anatomic TSA may be markedly different between the two countries, making comparison difficult. As a result, our study population underrepresents the total number of patients treated for OA in Australia, which might make comparing the populations of the two registries on the basis of TSA use alone misleading or biased. While the KP attrition rate is low (3.5% at two years postoperative), it is acknowledged some patients may undergo revision surgery after leaving the healthcare plan. However, we did restrict our study sample to patients with complete two-year postoperative follow-up for calculation of revision rates. It is also understood that not all revisions within the SMR group were due to the recalled L2 glenoid component, but discerning which revisions were due to that as opposed to a non-recalled glenoid component is not within the scope of this paper. Lastly, neither registry collects patient-reported outcomes, though it

should be noted their use is not agreed upon among the national shoulder registries.<sup>25</sup>

In summary, we identified several similarities, as well as some variation, across two geographically distinct registries and proved a cross registry comparison of these geographically distinct registries can occur and yield measurable and meaningful results. We were able to identify variation due to potential implant contributions, demonstrating the role that prosthesis selection can play in determining outcomes following shoulder arthroplasty and providing an opportunity to better understand factors contributing to differences in revision rates. This work may serve as the groundwork for future collaborative studies among registries, allowing for enhanced evaluation of outcomes of shoulder arthroplasty which can help the international orthopedic community better understand and treat operative glenohumeral OA on a global scale.

### Authors' Note

This study was accepted as a podium presentation at the Fifth International Congress of Arthroplasty Registries in Manchester, England (28–30 May 2016) and was later a poster presentation at the American Academy of Orthopedic Surgeons 2017 Annual Meeting in San Diego, CA, USA (14–18 March 2017).

### Authors' Contribution

MD, RP, and RN researched the literature and conceived the study. HP was involved in protocol development and data analysis. MD wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

### Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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### Ethical Review and Informed Consent

This study was approved by the Kaiser Permanente Institutional Review Board, study #5527. Informed consent was not sought for the present study, as it was deemed as unnecessary by the institutional review board.

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