Five-Year Results of the ASR XL Acetabular System and the ASR Hip Resurfacing System

An Analysis from the Australian Orthopaedic Association National Joint Replacement Registry

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Background: Articular Surface Replacement (ASR) hip prostheses, which have metal-on-metal bearing surfaces, were manufactured by DePuy Orthopaedics (Warsaw, Indiana) for use in both conventional total hip arthroplasty and hip resurfacing. Both the ASR XL Acetabular System and the ASR Hip Resurfacing System were recently recalled worldwide by the manufacturer. This report summarizes an analysis by the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) of the outcome of arthroplasties involving the ASR prostheses.

Methods: The first recorded use of the ASR XL Acetabular System in Australia occurred in 2004, and the Registry recorded 4406 procedures involving this system through December 31, 2009. The first recorded use of the ASR Hip Resurfacing System in Australia occurred in 2003, and the Registry recorded 1167 procedures through December 31, 2009. The Kaplan-Meier method and proportional-hazard modeling were used to compare the revision rate of primary total hip arthroplasties involving the ASR XL Acetabular System with that of arthroplasties involving all other conventional prostheses as well as with that of arthroplasties involving all other conventional prostheses with a metal-on-metal-articulation. In addition, the revision rate of primary arthroplasties involving the ASR Hip Resurfacing System was compared with that of arthroplasties involving all other hip resurfacing prostheses. Patient demographics, prosthesis characteristics, and information regarding the type of revision and the reason for revision were also compared.

Results: Arthroplasties involving both ASR designs had a significantly greater revision rate compared with those involving all other prostheses. The cumulative revision rate of arthroplasties involving the ASR XL Acetabular System at five years postoperatively was 9.3% (95% confidence interval [CI], 7.3% to 11.9%) compared with 3.4% (95% CI, 3.3% to 3.5%) for total hip arthroplasties involving all other conventional prostheses. The cumulative revision rate of arthroplasties involving the ASR Hip Resurfacing System at five years postoperatively was 10.9% (95% CI, 8.7% to 13.6%) compared with 4.0% (95% CI, 3.7% to 4.5%) for arthroplasties involving all other resurfacing prostheses. Arthroplasties involving the ASR XL Acetabular System had a greater rate of revision due to implant loosening and/or osteolysis and due to metal sensitivity compared with total hip arthroplasties involving all other conventional prostheses. Arthroplasties involving the ASR XL Acetabular System also had a significantly greater revision rate compared with total hip arthroplasties involving all other conventional metal-on-metal prostheses. Arthroplasties involving the ASR Hip Resurfacing System had a greater rate of revision due to metal sensitivity compared with total hip arthroplasties involving all other resurfacing prostheses.

Conclusions: ASR prostheses used in conventional hip arthroplasty and in hip resurfacing exhibited a greater revision rate compared with other prostheses in the AOANJRR. These results are consistent with those derived from other registries and from published studies of individual cohorts.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

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This study was performed by the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) to investigate the outcome of primary conventional total hip arthroplasties performed with use of the ASR (Articular Surface Replacement) XL Acetabular System (DePuy Orthopaedics, Warsaw, Indiana) and of primary hip resurfacing arthroplasties performed with use of the ASR Hip Resurfacing System (DePuy).

The ASR hip prosthesis, which has metal-on-metal bearing surfaces, was released worldwide for use in conventional total hip arthroplasty in 2003. The ASR Hip Resurfacing System was not approved for use in the U.S. but became available in other countries in 2003.

The ASR XL Acetabular System and the ASR Hip Resurfacing System were voluntarily recalled worldwide by the manufacturer in August 2010. The number of arthroplasty procedures performed with use of these prostheses was estimated by the manufacturer to be 93,000. The basis of the recall was unpublished 2010 data from the National Joint Registry of England and Wales that showed a five-year revision rate of 13% for arthroplasties involving the ASR XL Acetabular System and 12% for arthroplasties involving the ASR Hip Resurfacing System.

Prior to this recall, information from a variety of different sources had indicated that arthroplasties involving the ASR XL Acetabular System and the ASR Hip Resurfacing System were both being revised at a significantly greater rate compared with arthroplasties involving other prostheses in the same class[1-4]. Three publications regarding the ASR Resurfacing System identified a greater than anticipated revision rate at the time of short-term follow-up[1-3], and similar results were reported for a small number of ASR XL Acetabular Systems that had been used in primary conventional total hip arthroplasty[1]. The AOANJRR first identified the ASR Hip Resurfacing System as having a greater than anticipated revision rate in its 2007 Annual Report[5] and reported similar conclusions in the subsequent three annual reports[6-8]. The AOANJRR also identified the ASR XL Acetabular System as having a greater than anticipated revision rate in its 2008 Annual Report[6] and in the subsequent two annual reports[7,8]. The New Zealand Joint Registry first identified the ASR XL Acetabular System as having a greater than anticipated revision rate in 2009[9]. The present study presents the complete analysis of the ASR XL Acetabular System and the ASR Hip Resurfacing System performed by the AOANJRR with use of data through December 31, 2009.

Materials and Methods

The AOANJRR began data collection on September 1, 1999, and includes data on almost 100% of the arthroplasty procedures performed in Australia since 2002. Registry data is validated against patient-level data provided by each of the state and territory health departments in Australia with use of a sequential, multilevel matching process. A matching program is run monthly to search for all primary and revision arthroplasty procedures recorded in the Registry that involve the same side and joint of the same patient, thus enabling each revision to be linked to the primary procedure. Data are also matched annually with the Department of Health and Ageing's National Death Index to obtain information on the date of death.

The present analysis compared primary total hip arthroplasties involving the ASR XL Acetabular System with those involving all other conventional hip prostheses (regardless of the type of bearing surface) as well as with those involving all other conventional hip prostheses with metal-on-metal bearing surfaces. Primary arthroplasties involving the ASR Hip Resurfacing System were compared with those involving all other primary hip resurfacing prostheses. Patient demographics, prosthesis characteristics, and information regarding the type of revision and the reason for revision were also analyzed.

The first procedure involving the ASR XL Acetabular System was recorded by the Registry in 2004, and 4406 procedures were recorded through the end of 2009. The first procedure involving the ASR Hip Resurfacing System was recorded in 2003, and 1167 procedures were recorded through the end of 2009.

Statistical Analysis

The Registry uses Kaplan-Meier estimates of survivorship to describe the time to the first revision of an arthroplasty, with censoring at the time of death or closure of the database at the time of analysis. The unadjusted cumulative revision rate at the end of each of the first nine years after the primary arthroplasty, with an accompanying 95% confidence interval (CI), was calculated with use of unadjusted pointwise Greenwood estimates. The unadjusted cumulative incidence functions of the reasons for revision of primary conventional total hip arthroplasty and hip resurfacing were also calculated at the end of each of the first nine years.

Hazard ratios were calculated with use of Cox proportional-hazard modeling, adjusting for age and sex, and were used to make statistical comparisons of the revision rate between groups. The assumption of proportional hazards was checked analytically for each model; if the interaction between the predictor and the log of the postoperative time was significant in the standard Cox model, then a time-varying model was used. (Unless a time period is specified for a hazard ratio in the Results section, the reported hazard ratio pertains to the entire follow-up period.) If a time-varying model was necessary, a time point separating the postoperative period into two intervals was selected on the basis of the greatest change in hazard, weighted by the number of events. This process was repeated until the assumption of proportionality was met, and

TABLE I Reason for Revision of Primary Conventional Total Hip Arthroplasties

	ASR XL Acetabular System		Other Conventional Acetabular Component	
Reason for Revision	No. of Revisions	%	No. of Revisions	%
Loosening and/or osteolysis	92	44	1427	28
Infection	42	20	804	17
Metal sensitivity	26	12	36	1
Fracture	19	9	725	15
Dislocation of prosthesis	15	7	1385	29
Other	16	8	490	10
Total	210	100	4867	100

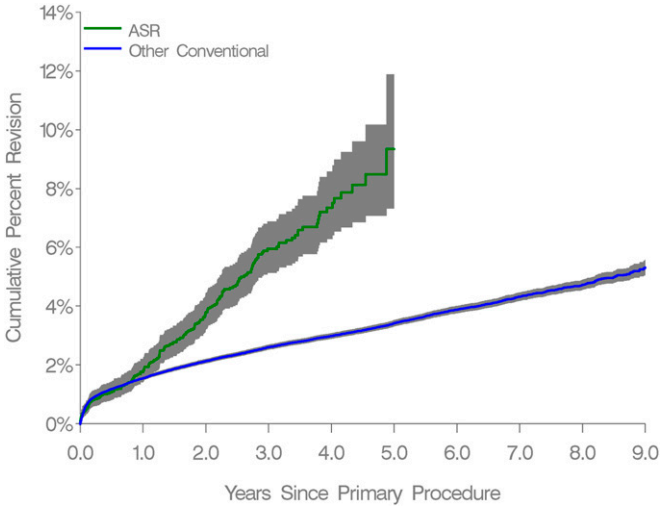

Fig. 1

Cumulative revision rate of primary conventional total hip arthroplasties.

the hazard ratio was then calculated for each of the resulting time intervals. All tests were two-tailed, and a p value of 0.05 was considered significant.

Source of Funding

The AOANJRR is funded entirely by the Commonwealth of Australia's Department of Health and Ageing.

Results

ASR XL Acetabular System

The most common diagnosis for patients treated with the ASR XL Acetabular System was osteoarthritis (90%). The mean patient age at the time of the index arthroplasty was sixty-four years (range, sixteen to 102 years), and 54% of the patients were men. The proportion of patients with osteoarthritis was similar to that of patients treated with primary total hip arthroplasty involving all other conventional prostheses (88%); however, the mean age of the patients treated with all other conventional total hip arthroplasty prostheses (sixty-eight years; range, twelve to 101 years) was slightly greater, and a smaller proportion (44%) were men. The ASR XL Acetabular System was widely used in Australia, and 136 of 303 hospitals that reported having performed conventional total hip arthroplasty performed arthroplasties involving this system.

The cumulative revision rate of arthroplasties involving the ASR XL Acetabular System at five years postoperatively was 9.3% (95% CI, 7.3% to 11.9%) compared with 3.4% (95% CI, 3.3% to 3.5%) for total hip arthroplasties involving all other conventional prostheses. The revision rate of arthroplasties involving the ASR XL Acetabular System between 1.5 and five years postoperatively, adjusted for age and sex, was four times greater than that of total hip arthroplasties involving all other conventional prostheses (Fig. 1). The revision rate of arthroplasties involving the ASR XL Acetabular System did not differ significantly according to sex (hazard ratio = 1.24 for the comparison of women with men, adjusted for age; p = 0.127). The proportion of revisions that involved the acetabular component (62%) was almost twice as great if an ASR XL Acetabular System was used than if another conventional hip prosthesis had been used (36%) (see Appendix).

The greater revision rate of arthroplasties involving the ASR XL Acetabular System resulted largely from the greater proportion of revisions due to loosening and/or osteolysis (Table I). The five-year cumulative rate of revision of arthroplasties involving the ASR XL Acetabular System due to loosening and/or osteolysis was 4.8% (95% CI, 3.1% to 7.0%) compared with 1.7% (95% CI, 1.6% to 1.9%) for arthroplasties involving all other conventional total hip arthroplasty prostheses. The rate of revision due to metal sensitivity (1.2% [95% CI, 0.7% to 1.9%] compared with 0.0% [95% CI, 0.0% to 0.1%]) and due to infection (1.5% [95% CI, 1.0% to 2.1%] compared with 0.7% [95% CI, 0.6% to 0.8%]) was also greater for arthroplasties involving the ASR XL Acetabular System than for total hip arthroplasties involving all other conventional prostheses (see Appendix).

The revision rate of arthroplasties involving the ASR XL Acetabular System was also significantly greater than that of total hip arthroplasties involving all other conventional prostheses with a metal-on-metal articulation. The revision rate of arthroplasties involving the ASR XL Acetabular System between one and five years postoperatively, adjusted for age and sex, was two and a half times greater than that of all other conventional total hip arthroplasties with a metal-on-metal articulation (Fig. 2).

The ASR XL Acetabular System was used with thirteen different femoral stems. In 98% of the procedures, a cementless stem was used. The femoral stems that were used most commonly in combination with the ASR prosthesis were the Corail (66%), the Summit (26%), and the S-ROM (6%) (all from DePuy Orthopaedics) (see Appendix), and the three-year cumulative revision rates for these combinations were 6.4% (95% CI, 5.3% to 7.6%), 4.9% (95% CI, 3.6% to 6.5%), and 5.9% (95% CI, 3.4% to 10.2%), respectively.

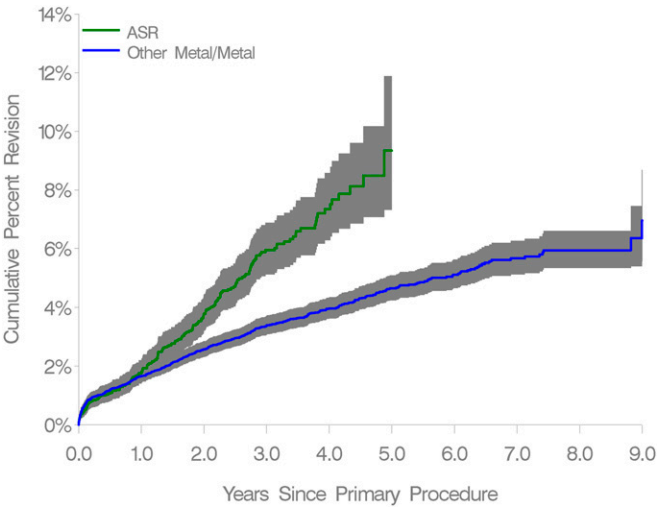

Fig. 2

Cumulative revision rate of metal-on-metal primary conventional total hip arthroplasties.

TABLE II Revision Rate of Primary Total Hip Arthroplasties Involving the ASR XL Acetabular System Compared with All Other Conventional Prostheses According to Femoral Component Head Size

Femoral Head Size *(mm)*	Time Interval	Hazard Ratio, ASR Compared with Other	95% Confidence Interval	P Value
≤44				
	0-2.5 yr	1.4	0.7 to 2.7	0.34
	2.5-5 yr	7.5	3.4 to 16.8	<0.01
45-49				
	0-0.75 yr	1.3	0.8 to 2.1	0.33
	0.75-1 yr	6.2	1.4 to 27.0	0.01
	1-1.5 yr	3.7	1.5 to 8.9	<0.01
	1.5-5 yr	2.8	1.7 to 4.4	<0.01
50-54	0-5 yr	1.3	0.9 to 2.0	0.18
≥55	0-5 yr	3.0	0.6 to 14.4	0.17

The revision rate of arthroplasties involving the ASR XL Acetabular System did not differ significantly according to the head size of the femoral component. For a femoral head size of <44 mm, the revision rate of arthroplasties involving the ASR XL Acetabular System between 2.5 and five years postoperatively was seven and a half times greater than that of total hip arthroplasties involving all other conventional prostheses of the same size (Table II and Appendix).

The revision rate of arthroplasties involving the ASR XL Acetabular System was greater than that of all other total hip arthroplasties involving conventional prostheses at both low-volume hospitals (≤100 hip arthroplasty procedures during the entire period) and high-volume hospitals (>100 procedures). The revision rate did not differ significantly between high and low-volume hospitals for either the ASR XL Acetabular System or all other conventional hip prostheses (Fig. 3).

ASR Hip Resurfacing System

The most common diagnosis for patients treated with the ASR Hip Resurfacing System was osteoarthritis (92%). The mean patient age was fifty-three years (range, sixteen to ninety-three years) at the time of the index arthroplasty, and 71% of the patients were men. Similarly, the most common diagnosis for patients treated with other hip resurfacing prostheses was osteoarthritis (95%), the mean patient age was fifty-three years (range, thirteen to eighty-two years), and 75% of the patients were men. The ASR Hip Resurfacing System was used in fifty-nine of 206 hospitals that reported having performed hip resurfacing.

The cumulative revision rate of arthroplasties involving the ASR Hip Resurfacing System at five years postoperatively was 10.9% (95% CI, 8.7% to 13.6%) compared with 4.0% (95% CI, 3.7% to 4.5%) for arthroplasties involving all other hip resurfacing prostheses. The revision rate of arthroplasties involving the ASR Hip Resurfacing System at five years postoperatively, adjusted for age and sex, was twice as great as that of arthroplasties involving all other hip resurfacing prostheses (Fig. 4). The revision rate of arthroplasties involving the ASR Hip Resurfacing System did not differ significantly according to sex (hazard ratio = 1.44 for the comparison of women with men, adjusted for age; p = 0.105).

The distribution of the types of revision procedures did not differ markedly between arthroplasties involving the ASR Hip Resurfacing System and arthroplasties involving all other hip resurfacing prostheses. However, the proportion of revisions of arthroplasties involving the ASR Hip Resurfacing System that were due to metal sensitivity (13%) was greater than that of arthroplasties involving all other hip resurfacing prostheses (6%) (see Appendix). The five-year cumulative rate of revision of arthroplasties involving the ASR Hip Resurfacing System due to metal sensitivity was 1.7% (95% CI, 0.9% to 3.1%) compared with 0.3% (95% CI, 0.2% to 0.5%) for arthroplasties involving all other hip resurfacing prostheses (see Appendix).

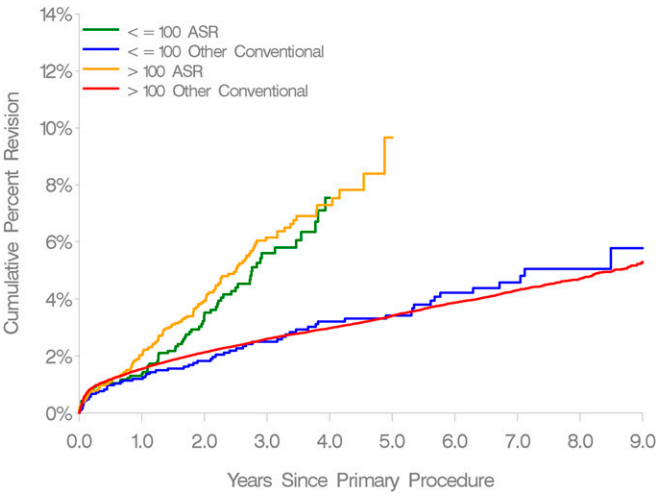

Fig. 3

Cumulative revision rate of primary conventional total hip arthroplasties according to hospital volume of conventional total hip arthroplasties.

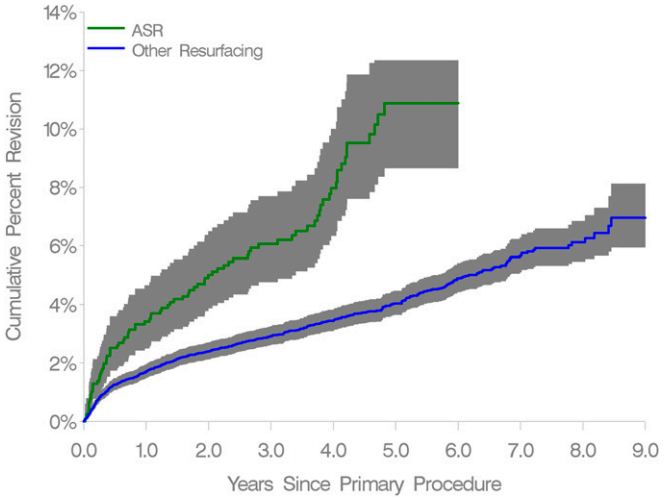

Fig. 4

Cumulative revision rate of primary hip resurfacings.

The revision rate of arthroplasties involving the ASR Hip Resurfacing System was five times greater if the head size of the femoral component was ≤44 mm than if it was ≥55 mm (hazard ratio = 5.1, adjusted for age and sex; 95% CI = 2.1 to 12.5; $p < 0.01$). For each femoral component head size range, the revision rate of arthroplasties involving the ASR Hip Resurfacing System was significantly greater than that of arthroplasties involving all other hip resurfacing prostheses and a femoral component of the same head size (see Appendix).

In contrast to the situation involving conventional total hip arthroplasty, the revision rate of hip resurfacings did differ according to hospital volume. The revision rate at hospitals that performed ≤100 hip resurfacing procedures during the entire period was greater than that at hospitals that performed >100 procedures. However, the revision rate of arthroplasties involving the ASR Hip Resurfacing System was significantly greater than that of arthroplasties involving all other hip resurfacing prostheses at both low and high-volume hospitals (Fig. 5).

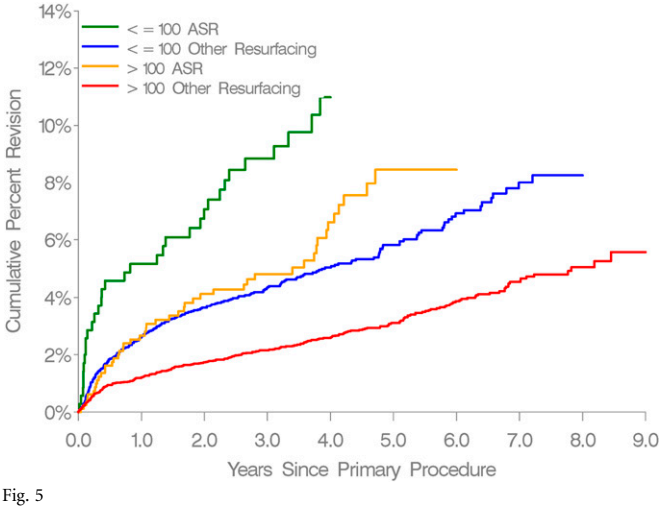

Fig. 5

Cumulative revision rate of primary hip resurfacings according to hospital volume of hip resurfacing arthroplasties.

Discussion

An important difference between national registry data and data from randomized controlled trials or cohort studies is that registry data can be used to compare the performance of prostheses within an entire population. This post-market surveillance ability is important because most prostheses are released onto the market without any supporting clinical data[10].

The present AOANJRR analysis of both the ASR XL Acetabular System and the ASR Hip Resurfacing System provides a good example of the type of comparative performance information that can be provided by a registry. This information includes the types of revisions, the reasons for revision, and the impact of a wide variety of factors (including the primary diagnosis, patient demographics, and hospital hip arthroplasty volume) on the revision rate. The comparative analysis of such data on different prostheses enables conclusions to be drawn regarding whether an observed difference in the revision rate was related to the prosthesis or to other factors. These other factors may include patient-related characteristics, surgical technique, usability of the device, and surgeon experience.

The AOANJRR analysis confirmed that patient selection was not responsible for the observed greater revision rate of arthroplasties involving either the ASR XL Acetabular System or the ASR Hip Resurfacing System compared with arthroplasties involving all other prostheses of the same type. The primary diagnosis of patients treated with the ASR XL Acetabular System or with the ASR Hip Resurfacing System was similar to that of patients treated with other conventional total hip arthroplasty prostheses or other hip resurfacing prostheses, respectively. The age and sex distributions of each pair of patient groups were also similar.

Siebel et al. reported that at a mean of 202 days of follow-up, eight (2.7%) of the first 300 arthroplasties involving the ASR Hip Resurfacing System had been revised[2]. The authors attributed this high early revision rate to a steep learning curve by the surgeons, and there was no suggestion in the paper that the high revision rate was potentially related in any way to the prosthesis itself.

Surgical experience is often cited as a cause of an elevated revision rate. However, data from the present study indicated that the greater revision rate involving both the ASR XL Acetabular System and the ASR Hip Resurfacing System was not surgeon-related. We used hospital volume as a surrogate for surgical experience in our analysis. The outcome of conventional total hip arthroplasty involving the ASR XL Acetabular System did not differ according to hospital volume; the revision rate was similar at high and low-volume hospitals and was much greater than that of total hip arthroplasties involving all other conventional prostheses. The outcome of hip resurfacing involving the ASR Hip Resurfacing System did differ according to hospital volume, with the revision rate being greater at low-volume hospitals than at high-volume hospitals. However, at

both high and low-volume hospitals, the revision rate was greater than that of arthroplasties involving all other hip resurfacing prostheses.

Since patient or surgeon factors did not account for the elevated revision rate of the ASR prostheses, this elevation in the revision rate is likely related to prosthesis-specific factors. The proportion of revisions that involved the acetabular component was greater if the acetabular component was an ASR XL Acetabular System than if it was another conventional acetabular component. This indicated that the acetabular component was contributing directly to the elevation of the revision rate. That conclusion was further supported by the fact that the elevation of the revision rate was independent of the femoral stem that was used. The revision rate of each of the three most common combinations of a femoral stem with the ASR XL Acetabular System was greater than that of the corresponding combination of that stem with all other acetabular components[7].

The reasons for revision of arthroplasties involving the ASR XL Acetabular System and of the ASR Hip Resurfacing System differed from those of arthroplasties involving all other prostheses of the same type. The greater rate of revision of arthroplasties involving the ASR XL Acetabular System due to loosening and/or osteolysis and due to metal sensitivity, compared with total hip arthroplasties involving all other conventional prostheses (including those involving all other conventional prostheses with metal-on-metal bearing surfaces), indicated a greater rate of metal particle generation. An elevated rate of revision due to metal sensitivity was also observed in association with use of the ASR Hip Resurfacing System.

The use of registry data in the present study introduced certain limitations, including the lack of radiographic measurements of prosthesis positioning and the lack of measurements of metal ion concentrations in serum and synovial fluid. Langton et al.[1,11] reported an elevated rate of revision of arthroplasties involving the ASR Hip Resurfacing System due to an adverse reaction to metal debris, and metal ion concentrations in serum and synovial fluid were significantly greater in patients who required revision than in patients who were pain-free.

The authors noted that both the inclination and the anteversion of the acetabular prosthesis were important factors in those requiring revision. In addition, a small head size of the femoral component used in combination with the ASR Hip Resurfacing System was an important risk factor for revision[3]. The AOANJRR data in the present study confirmed the association of a greater revision rate with a smaller femoral component head size in arthroplasties involving the ASR Hip Resurfacing System; however, the revision rate associated with a larger head size was also elevated compared with that of arthroplasties involving all other hip resurfacing prostheses. For a head size of ≤44 mm, arthroplasties involving either the ASR XL Acetabular System or the ASR Hip Resurfacing System had a significantly greater revision rate compared with that of arthroplasties involving all other prostheses of the same size and type. Although it was clear from our analysis of the AOANJRR data that the revision rate of arthroplasties involving either the ASR XL Acetabular System or the ASR Hip Resurfacing System was greater than that of arthroplasties involving all other prostheses of the same type, the mechanism responsible for this elevated risk of revision could not be identified with use of the Registry data. Implant retrieval studies should be able to provide further information regarding this mechanism.

Arthroplasty registries play a critical role in improving the outcome of joint arthroplasty by providing population-based comparative data[12]. The AOANJRR initially identified use of the ASR Hip Resurfacing System as resulting in a higher than anticipated revision rate in 2007 and identified use of the ASR XL Acetabular System as resulting in an elevated revision rate in 2008[5,6]. The Registry identified both prostheses as resulting in an elevated revision rate in each subsequent annual report[6-8]. The identification of these prostheses was associated with a substantial reduction in their use by surgeons in Australia and with the subsequent withdrawal of the prostheses from the Australian market in December 2009. Although these prostheses have now been withdrawn, the AOANJRR will continue to publish the outcome of the ASR XL Acetabular System and the ASR Hip Resurfacing System, and additional information on these prostheses as well as on other prostheses with a higher than anticipated revision rate will be provided on the AOANJRR website.

Appendix

eA Tables summarizing the types of revisions, the reasons for revision, and the revision rate according to the femoral component head size as well as figures showing the cumulative revision rate according to the reason for revision and according to the femoral component head size are available with the online version of this article as a data supplement at jbjs.org. ■

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