Original article

Medium term review of the ASR implant system: A single surgeon series

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ABSTRACT

Introduction: Both ASR hip resurfacings and stemmed ASR XL arthroplasties have failed at high rates in several published series. We assessed a single surgeon series of these arthroplasties looking to identify factors associated with their failure.

Methods: All surgeries were performed by one surgeon. Patients were evaluated clinically, radiologically and with serial cobalt and chromium ion analysis.

Results: 274 implants were analysed – 152 ASR resurfacings and 122 ASR XL implants. Thirty revisions were performed.

Conclusion: The failure rate of the ASR implant in our series is unacceptably high – its use in routine hip arthroplasty cannot be supported.

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1. Introduction

Both ASR hip resurfacings and stemmed ASR XL arthroplasties have failed at unexpectedly high rates in several published series and in multiple national arthroplasty registers including those of the UK Australia, New Zealand and Canada.^{1–3} The aetiology of these failures is multifactorial and includes design issues, underlying hip pathology, implantation technique and patient demography.^{4–7} Up to the time of the ASR recall in Ireland in 2010 our units experience with this implant and other MOM arthroplasties was anecdotally favourable. Revision rates of the ASR resurfacings and the ASR XL hip arthroplasties increased notably following the recall and the aim of our study was to assess the overall outcome of these arthroplasties and to identify those factors most commonly associated with their failure.

2. Materials and methods

All surgeries were performed by one surgeon between 2004 and 2010. ASR resurfacing were selectively used during this period for

the younger, more active patient where preservation of bone stock and enhanced stability were desirable. The ASR XL system was used from 2006 for arthroplasties that were unsuitable for resurfacing but where enhanced stability and the tribological benefits of hard on hard bearings were desirable. The posterior approach was used exclusively for resurfacing procedures. ASR XL arthroplasties were performed through the antelateral approach from 2004 to 2006. The posterior approach used thereafter (Figs. 1 and 2).

Under the recall protocol all patients were evaluated clinically, radiologically and with serial cobalt and chromium ion analysis. Patients were reviewed at 3, 6 or 12 monthly intervals according to their hip function, radiological findings or ion levels. On initial review patients were asked to objectively grade hip functionality through the 5-point Likert scale Western Ontario and McMaster Universities Index (WOMAC score). A database was created at the time of the ASR recall and was maintained prospectively to include patient demographics, implant type, ion levels, implant survival, and revision surgery details where appropriate. Statistical analyses were performed using R version 3.1.2 R Core Team (2014) (Figs. 3 and 4).

3. Results

3.1. Demographics

274 implants were sited in 245 patients – 219 hip implants in males and 55 implants in females, with a mean age at surgery of 57 years. Ninety per cent of surgeries were performed for

Abbreviations: ASR, articular surface replacement hip system; MoM, metal on metal.

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Fig. 1. Kaplan – Meier Curves for time until Revision Surgery by ASR Component.

Fig. 3. Kaplan – Meier Curves for time until Revision Surgery by WOMAC Score.

Fig. 2. Kaplan – Meier Curves for time to Revision Surgery by Gender.

Fig. 4. Kaplan – Meier Curves for time until Revision Surgery by Cobalt level.

osteoarthritis. The posterior approach was used in 78% of surgeries (Table 1).

Of the 274 primary implants, 152 were ASR resurfacings and 122 were ASR XL implants. In both cohorts, the majority of patients were males (76% in ASR and 84% in ASR XL). There was no significant difference in gender between the ASR and ASR XL

groups ($p = 0.26$). There was a significant difference in mean age between the ASR and ASR XL groups. ASR XL patients were 5 years older on average than ASR resurfacing patients ($p < 0.0001$). There was also a significant difference in mean cobalt levels between ASR and ASR XL groups, where mean cobalt levels in the ASR XL group

Table 1
Patient demographics, primary surgery details, and metal ion concentrations.

Variable	Overall	ASR	Modular	p-value
No. of primary hips	274	152	122	
No. of patients	245	132	113	
Male: Female (Implants)	219:55	117:35	102:20	0.26
Mean age in years (range)	57 (16–84)	55 (22–80)	60 (16–84)	<0.0001
Indication				
Osteoarthritis	247	141	106	
Other	27	10	17	
ASA Grade				
1	119	76	43	
2	135	68	67	
3	20	5	15	
Mean WOMAC (range)	21.3 (0–100) median = 10	19.0 (0–100) median = 7	24.3 (0–100) median = 12	0.032
Mean Modified WOMAC (range)	79.0 (0–100) median = 90	81.0 (0–100) median = 93	76.4 (0–100) median = 88	0.041
Mean Cobalt in nmol/l (range)	87.4 (0.65–1471) median = 38.5	66.4 (0.65–379) median = 31	113.0 (0.65–1471) median = 60	0.032
Mean Chromium in nmol/l (range)	48.2 (0.78–514) median = 23	46.9 (0.78–415) median = 25	49.9 (0.78–514) median = 22	0.51
Surgical Approach				
Anterolateral	53	1	52	
Lateral	2	2	0	
Posterior	144	80	64	
Posterolateral	1	1	0	
Extended Posterior	70	66	4	
TO & ETO	4	0	4	
Mean Cup inclination (range)	41.7 (23–62)	41.6 (23–62)	41.8 (25–62)	0.77
Mean Femoral head diameter (range)	52 (41–63)	50.9 (41–61)	53.4 (41–63)	<0.0001
Mean Femoral Stem Size (range)			12.5 (8–18)	
Mean Acetabular Component diameter (range)	58.8 (46–70)	57.6 (46–68)	60.3 (46–70)	<0.0001

Fig. 5. Kaplan – Meier Curves for time until Revision Surgery by Chromium level.

Fig. 6. Kaplan – Meier Curves for time until Revision Surgery by Cup inclination.

were higher than those in the ASR group by 46.6 nmol/L ($p=0.032$). WOMAC scores were also higher in the ASR XL patients by 5 points ($p=0.032$). Chromium levels, on the other hand, were not significantly different between the two groups ($p=0.51$) – see [Tables 4 and 5](#) for details ([Figs. 5 and 6](#)).

3.2. Revision surgeries

Thirty revision surgeries were performed – as outlined in [Tables 2 and 6](#). There were 14 revisions of ASR resurfacings (9%) while 16 ASR XL implants were revised. (13%). This difference in revision rates was not statistically significant (chi-squared = 0.70, p -value = 0.4043). The median time until revision surgery was 65 months (range: 23–99 months). The resurfacings had a longer median time until surgery (73 months) compared to the ASR XL hips (55 months). This difference, did not however reach statistical significance ($p=0.17$).

Twenty two revisions were performed for persistent, troublesome hip pain. Of these, 12 were resurfacings and 10 were ASR XL arthroplasties. Six of these demonstrated macroscopic gross

Table 4
Survival Analysis results for the ASR cohort.

Variable	Hazard Ratio	95% CI	p-value
Age (for every 5-year decrease in age)	1.02	0.77–1.36	0.90
Gender (Male as reference)	1.16	0.32–4.21	0.82
WOMAC Score (for every 5 units decrease)	1.18	1.09–1.29	0.0001
Cup Inclination (for every 5 mm increase)	1.57	1.10–2.23	0.013

Table 5
Survival Analysis results for the ASR XL cohort.

Variable	Hazard Ratio	95% CI	p-value
Age (for every 5-year decrease in age)	1.09	0.91–1.31	0.34
Gender (Male as reference)	6.96	2.32–20.89	0.0005
Cobalt (for every 5 units increase)	1.015	1.008–1.022	<0.0001
Chromium	1.034	1.015–1.054	0.0005

metallosis intraoperatively (2 ASR resurfacings, 4 ASR XL Acetabular System) which was later confirmed histologically. Histological data was retrieved in 27 cases of which 8 demonstrated histologic evidence of ALVAL.

Five patients (3 male, 2 female) were revised for component loosening. Of the 3 ASR XL Acetabular system revisions, one had a loose femoral stem and two demonstrated cup loosening. Of the two ASR resurfacings that were revised for loosening one had loosening of the femoral component and the other had loosening of the acetabular shell. One patient underwent a two stage revision for an infected prosthesis and one patient underwent revision following a traumatic periprosthetic fracture. One revision was performed in an asymptomatic female with the ASR Acetabular XL system on the basis of markedly elevated serum ion levels – see [Table 6](#).

Cox proportional hazards regression analysis was used to identify factors associated with a higher probability of revision surgery. All factors potentially influencing revision rate (age, gender, weight, metal ion levels, surgical approach in primary surgery, indication for primary surgery, ASA grade, femoral component (ASR/ASR XL), WOMAC score, acetabular inclination, femoral head diameter, and acetabular component diameter) were first entered into the model. Using backward elimination, it was

Table 2
Revision rates and details of failure mode.

Variable	Overall	ASR	Modular
No. of revisions (Rate)	30 (11%)	14 (9%)	16 (13%)
Male: Female	16: 14	7: 7	9: 7
Mean age (range)	54.0 (17–78)	53.9 (37–78)	54.2 (17–69)
Median Time to revision in months (range)	64.8 (23.5–99.0)	72.5 (23.5–99.0)	54.8 (25.1–94.0)

Table 3
Survival Analysis results for all patients.

Variable	Hazard Ratio	95% CI	p-value
Age (for every 5-year decrease in age)	1.01	0.86–1.18	0.90
Gender (Male as reference)	2.72	1.22–6.09	0.015
WOMAC (for every 5-unit increase)	1.12	1.06–1.18	0.0001
Cup Inclination (for every 5 mm increase)	1.32	1.04–1.68	0.020
Cobalt (for every 5-unit increase)	1.015	1.008–1.021	<0.0001
Chromium (for every 5-unit increase)	1.03	1.01–1.05	0.0004

Table 6
Analysis of revised implants.

Reason for Revision	Overall	ASR	ASR XL	Mean chromium (nmol/L)	Mean cobalt (nmol/L)
Pain	22	12	10	98.27 (5–514)	189.8 (11–1471)
Component Loosening/Progressive Osteolysis	5	2	3	144.8 (16–450)	186 (17–651)
Infection	1		1	6	19
Periprosthetic Fracture	1		1	22	30
Isolated elevated ion levels	1		1	77	52

found that gender, WOMAC score, cobalt and chromium levels, and cup inclination were the significant predictors. Details of this are shown in Table 3.

The hazard ratio (HR) for females compared to males was 2.72 (95% CI: 1.22–6.09). The HR for every 5 units increase in WOMAC score was 1.12 (95% CI: 1.06–1.18). Cobalt concentration was also found to be highly statistically significant in the model. For every 5 units increase in cobalt concentration, the risk for revision surgery increases by 1.5% (HR: 1.015, 95% CI: 1.008–1.021). Similarly, for every 5° increase in cup inclination, the risk of revision surgery increases by 32% (HR: 1.32, 95% CI: 1.04–1.68). The effect of chromium was examined in a different model that eliminated cobalt. In this model, for every 5 nmol/L increase in chromium levels, the risk for revision surgery increases by 3% (HR: 1.03, 95% CI: 1.01–1.05, $p=0.0004$) (Table 3).

4. Discussion

The results of this study show a high failure rate of the ASR in both its resurfacing and THR forms (9% and 13% respectively). While unacceptably high, this revision rate does not match the some extremely high rates quoted in other studies. Our results contrasts with a similar single surgeon study performed by Langton et al. in 2011.⁸ In 257 patients with a minimum follow up of two years, a failure rate of 25% was observed in the ASR resurfacing cohort with a failure rate of 48.8% for the ASR total hip replacement at 6 years. Langton initially attributed the increased rate of failure observed in patients with the ASR XL to the greater proportion of women in the ASR XL group (male:female, 40:60), believing that the prevalence of smaller bearings in these patients increased the likelihood of ARMD. Shemesh et al. analysed the outcomes of 57 ASR Total hip replacements under a single surgeon. They reported a 5 year revision rate of 17.5%. 40% of revisions were attributable to periprosthetic fractures.⁹

Hug et al. published a 13% revision rate of the ASR at 6 years – in 190 implants (149 THR, 41 Resurfacing) performed by two surgeons in a single institution. They reported a 12% revision rate in the XL cohort and 14.6% revision rate of the resurfacing cohort.¹⁰ They performed nine revisions for elevated metal ion levels and pain (4.7% of the 190 hips), eight for aseptic loosening of the acetabular component (4.2%), two for infection (1.1%), one for acetabular component malposition (inclination angle: 60°), one for aseptic femoral component loosening and one for heterotopic ossification (0.5%). They postulated that their high revision rates could be attributed to differences in surgical technique and that a learning curve was inherent in hip resurfacing. This learning curve was alluded to in a cohort of 300 ASR resurfacing prostheses by Siebel et al. They noted a reduction in revisions from 5 in the first 100 surgical procedures to 2 in the next 100 and 1 in the last 100.¹¹

The painful MOM hip replacement presents management challenges for Orthopaedic surgeons especially in the context of the withdrawal of the ASR implant and the close surveillance of other MOM arthroplasties. While there are review guidelines for these patients the decision on when to proceed with revision

surgery is largely made on a case by case basis.¹² In this study WOMAC score was a useful predictor of revision surgery and every 5 units increase in WOMAC score increased the risk of revision by 12%. A recent publication by Tibrewal et al. of 240 patients with metal on metal hip implants revised between 2008 and 2012 observed that 71 revisions occurred before the recall and 169 occurred after ($p=0.007$).¹³ We observed a similar but more obvious trend in our study with 29 of 31 revision surgeries (93.5%) performed following the ASR recall. This can be explained both by enhanced surveillance and sensitization of surgeons and patients towards revision in the aftermath of the recall.

The failure rate of the ASR implant in our series is unacceptably high and therefore its use as an implant for routine hip arthroplasty cannot be supported. However we recognise that a significant proportion of the cohort are functioning at a high level according to their WOMAC scores with few clinical symptoms, excellent radiographic findings, and ion levels suggesting low rates of component wear. Marshall et al. similarly demonstrated when the poorly designed devices are excluded, the well-performing MOM resurfacing devices have survivorships comparable to conventional THR.¹⁴ It is now generally accepted that females do poorly after hip resurfacing arthroplasty, as do those patients that require smaller implants including those with dysplastic hip joints.^{15–17} If, by careful patient selection the patient groups^{18,19} and technical requirements²⁰ which yield the most favourable outcomes are identified, then MOM resurfacing hip arthroplasty although presently out of favour, may still have a very select and much more narrowed indication in modern orthopaedic practice.²¹

Conflict of interest

The authors have none to declare.

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