

■ HIP

Independent predictors of revision following metal-on-metal hip resurfacing

A RETROSPECTIVE COHORT STUDY USING NATIONAL JOINT REGISTRY DATA

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Modern metal-on-metal hip resurfacing has been widely performed in the United Kingdom for over a decade. However, the literature reports conflicting views of the benefits: excellent medium- to long-term results with some brands in specific subgroups, but high failure rates and local soft-tissue reactions in others. The National Joint Registry for England and Wales (NJR) has collected data on all hip resurfacings performed since 2003. This retrospective cohort study recorded survival time to revision from a resurfacing procedure, exploring risk factors independently associated with failure. All patients with a primary diagnosis of osteoarthritis who underwent resurfacing between 2003 and 2010 were included in the analyses. Cox's proportional hazard models were used to analyse the extent to which the risk of revision was related to patient, surgeon and implant covariates.

A total of 27 971 hip resurfacings were performed during the study period, of which 1003 (3.59%) underwent revision surgery. In the final adjusted model, we found that women were at greater risk of revision than men (hazard ratio (HR) = 1.30, $p = 0.007$), but the risk of revision was independent of age. Of the implant-specific predictors, five brands had a significantly greater risk of revision than the Birmingham Hip Resurfacing (BHR) (ASR: HR = 2.82, $p < 0.001$, Conserve: HR = 2.03, $p < 0.001$, Cormet: HR = 1.43, $p = 0.001$, Durom: HR = 1.67, $p < 0.001$, Recap: HR = 1.58, $p = 0.007$). Smaller femoral head components were also significantly more likely to require revision (≤ 44 mm: HR = 2.14, $p < 0.001$, 45 to 47 mm: HR = 1.48, $p = 0.001$) than medium or large heads, as were operations performed by low-volume surgeons (HR = 1.36, $p < 0.001$). Once these influences had been removed, in 4873 male patients < 60 years old undergoing resurfacing with a BHR, the five-year estimated risk of revision was 1.59%.

In summary, after adjustment for a range of covariates we found that there were significant differences in the rate of failure between brands and component sizes. Younger male patients had good five-year implant survival when the BHR was used.

Metal-on-metal (MoM) resurfacing of the hip remains a contentious issue despite its evolution over more than 50 years. Uncertainties include the use of resurfacing as opposed to total hip replacement (THR) and the choice of resurfacing arthroplasty. Part of the concern may be historical: early resurfacing designs were flawed and had high failure rates.^{1,2} Modern resurfacing is based on learning experiences from the McKee-Farrar hip replacement, a pioneer MoM THR that provided reasonable long-term survival in some patients.³ The first of the current generation of resurfacing arthroplasties was introduced in the late 1990s with the evolution of the Birmingham Hip Resurfacing (BHR; Smith & Nephew, Memphis, Tennessee) in the United Kingdom. Encouraging early to mid-term results⁴ prompted many manufacturers to exploit the concept and introduce their own

versions, each with subtly differing interpretations of the fundamental design characteristics. Excellent ten-year results for the BHR have been reported from the designers' series and from independent units.⁵⁻⁷

At the peak of usage (2007) more than 6000 hip resurfacings were being implanted in England and Wales annually.⁸ The implant was intended for younger, more active patients for whom longevity was essential. Perceived benefits included low dislocation risk and preservation of femoral bone, permitting an uncomplicated revision when required.⁹ However, there are reports of excessive wear, high levels of circulating metal ions, local soft-tissue reactions and persistent pain in some patients.¹⁰⁻¹³

In 2010 the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) issued an alert, warning of problems with MoM implants and the need for regular

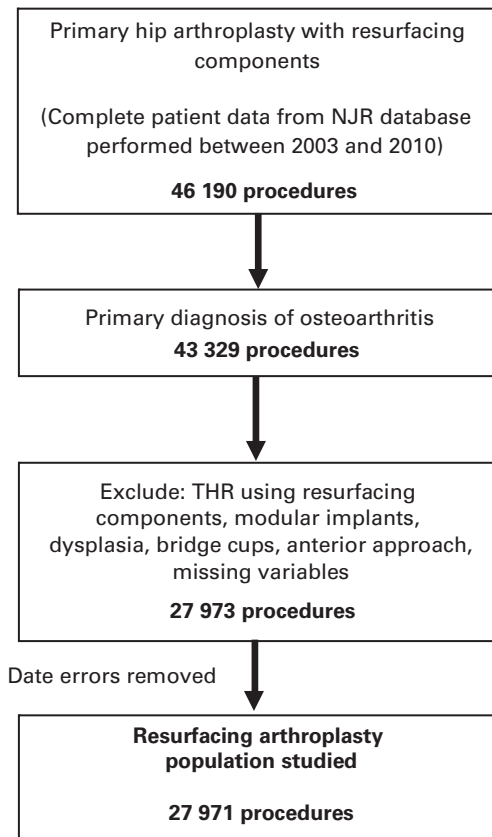


Fig. 1

Flowchart describing the inclusion criteria for this study (NJR, National Joint Registry for England and Wales; THR, total hip replacement).

follow-up.¹⁴ Later that year, the Articular Surface Replacement (ASR; DePuy, Leeds, United Kingdom) was withdrawn from distribution in the United Kingdom amid concerns regarding high failure rates, initially described in single-surgeon series and subsequently corroborated in registry data.^{8,15,16} Although specific design characteristics associated with the ASR may be important, other brands also perform poorly.¹⁷ Potentially, a range of surgical, patient and implant factors may contribute to the high rates of failure: implant position, component size, and female gender have all been implicated as risks for failure.^{18,19}

The aim of this study was to explore the risk factors for revision in a national cohort of patients who have undergone hip resurfacing, using data from the National Joint Registry for England and Wales (NJR).²⁰

Materials and Methods

This was a retrospective cohort study assessing NJR data for the survival time to revision from a first resurfacing procedure and exploring the risk factors independently associated with failure.

The NJR has assimilated data on patients, surgeons and implants performed in both the private sector and the NHS in England and Wales since 2003. Data were extracted for

all hip resurfacings for patients with a primary diagnosis of osteoarthritis (OA) submitted to the NJR until December 2010. Resurfacing components used with a femoral stem, modular resurfacing components, and complex resurfacings such as those using dysplasia or bridge acetabular components were excluded. The anterior approach was used for < 100 procedures and these were also excluded. A summary of the inclusion criteria is shown in Figure 1.

Covariate categories examined were patient age at the time of resurfacing, gender, American Society of Anesthesiology (ASA) grade,²¹ body mass index (BMI), brand of prosthesis, the size of the femoral component, the grade of the surgeon, the surgical approach and the volume of resurfacing procedures undertaken in the consultant's practice. Covariates used are summarised in Table I.

For an implant to have been recorded as revised (where one implant is exchanged for another, or removed as part of a staged procedure) on the NJR dataset, a complete record of the revision procedure (including the side of operation) is submitted from the treating hospital and linked to the original procedure by matching unique patient identifiers. A number of causes of revision can be recorded for each operation. In order to summarise these data effectively, infection or peri-prosthetic fracture were taken to be the primary reason when recorded. Soft-tissue reaction to metal debris and metallosis (including other free text terms such as the acronym ALVAL – aseptic lymphocytic vasculitis-associated lesions²²) were grouped together. Pain was only taken as a cause when no other reason was provided.

Information regarding the duration and severity of symptoms, radiological appearance and activity levels prior to and following the resurfacing procedure was not available in the NJR data, but may be available in due course as patient-reported outcome measures (PROMs) become linked to the NJR.

Statistical analysis. A revision procedure was considered to be a 'failure event', and the time between the index procedure and revision was a measurement of survival of the joint. Survival times for patients who had not undergone revision were censored at the study census date (31 December 2010). Event analysis was used to investigate the time to failure.²³ In this model, the contribution of potential factors to the risk of failure can be quantified. Cox's proportional hazard models were used to assess the extent to which the timing of failure could be explained in terms of the patient, surgeon and implant covariates. The Cox model assumes that there is an underlying unspecified baseline hazard that stays constant through time and which is influenced by covariates that mitigate or enhance the risk of failure.

Age and consultant volume were analysed as categorical data because of the greater clinical relevance of group comparisons. Age was partitioned into four groups based approximately on standard deviations from the mean. Consultant volume was partitioned into three groups, informed by spread of the data. As the distribution of head sizes differs between genders, the data were analysed in order to

Table I. Covariates used in the event analyses

| Category | Variable type | Covariate |
|---|---------------|---|
| Age | Continuous | Age at time of surgery |
| | Ordinal | ≤ 45 years 46 to 55 56 to 65 ≥ 66 years |
| Gender | Binary | Male Female |
| American Society of Anesthesiologists grade | Ordinal | Grade 1 Grade 2 Grade ≥ 3 |
| Body mass index (BMI) | Continuous | BMI at time of surgery |
| | Ordinal | Underweight (< 19 kg/m ²) Normal (19 < 25 kg/m ²) Overweight (25 < 30 kg/m ²) Obese (≥ 30 kg/m ²) |
| Brand | Nominal | Birmingham Hip Resurfacing (Smith & Nephew) Articular Surface Replacement (DePuy) Adept (Finsbury Orthopaedics Limited) Cormet (Corin Group plc) Conserve Plus (Wright Medical Technology Inc.) Durom (Zimmer Inc.) Mitch (Stryker Orthopaedics) Recap (Biomet Inc.) |
| Head size category | Continuous | |
| | Ordinal | Very small (≤ 44 mm) Small (45 mm to 47 mm) Medium (48 mm to 50 mm) Large (≥ 51 mm) |
| Surgical approach | Binary | Posterior Anterolateral |
| Primary surgeon | Binary | Consultant Other |
| Consultant resurfacing volume | Continuous | |
| | Ordinal | Low (≤ 50 cases throughout study period) Medium (51 to 200) High (≥ 201) |

partition into four groups containing both male and female patients in each. The categories for surgical approach on the data forms have evolved over the period of the study. For the purposes of this analysis the anterolateral, direct lateral, lateral and Hardinge²⁴ surgical approaches were grouped together ('anterolateral') and compared with the posterior approach. For categorical covariate hazard ratios (HR) the most frequent category was used as the baseline against which to compare hazards associated with other categories in that covariate; for example, the BHR was used as the baseline against which all other brands were compared. Exceptions to this were age (where the youngest group was used as the baseline) and head size (where the largest implant group was used). Kaplan-Meier survival

graphs were generated to display visual differences in unadjusted covariates. The log-rank (Mantel-Cox) test was used to perform paired comparisons between each of the covariates and the reference covariate in each of the following categories: gender, ASA grade, brand, femoral head size and consultant volume. Life tables were included to describe numbers in each covariate entering each year of the study.

All models were fitted using SPSS version 19.0 (SPSS Inc., IBM Corporation, Armonk, New York). When modelling determinants, any covariates found to have a non-statistically significant association were excluded from the model, based on statistical entry ($p < 0.05$) and rejection ($p > 0.1$) criteria. Results are presented as HR with 99% confidence

Table II. Demographic information on the hip resurfacing patients (England and Wales, 2003 to 2010)

| Characteristic | Hip resurfacing (n = 27 971) |
|--|------------------------------|
| Mean (SD) age (yrs) | 55.1 (8.48) |
| Age by category (n, %) | |
| ≤ 45 years | 3383 (12.1) |
| 46 to 55 | 9540 (34.1) |
| 56 to 65 | 12 215 (43.7) |
| ≥ 66 years | 2833 (10.1) |
| Gender (n, %) | |
| Male | 19 335 (69.1) |
| Female | 8636 (30.9) |
| American Society of Anesthesiologists (ASA) grade (n, %) | |
| 1 | 13 767 (49.2) |
| 2 | 13 381 (47.8) |
| ≥ 3 | 823 (2.9) |
| Mean (SD) body mass index (BMI) (kg/m ²) | 28.3 (4.60) |
| BMI by category (n, %) | |
| Underweight (< 20 kg/m ²) | 95 (0.3) |
| Normal (20 < 25 kg/m ²) | 1634 (5.8) |
| Overweight (25 < 30 kg/m ²) | 4088 (14.6) |
| Obese (≥ 30 kg/m ²) | 3021 (10.8) |
| No data | 19 131 (68.4) |
| Approach (n, %) | |
| Posterior | 20 048 (71.7) |
| Anterolateral | 5578 (19.9) |
| No data | 2345 (8.4) |
| Brand (n, %) | |
| BHR | 15 459 (55.3) |
| ASR | 2631 (9.4) |
| Adept | 2466 (8.8) |
| Conserve | 1173 (4.2) |
| Cormet | 3193 (11.4) |
| Durom | 1381 (4.9) |
| Mitch | 339 (1.2) |
| Recap | 1329 (4.8) |
| Head size (n, %) | |
| Very small (≤ 44 mm) | 3928 (14.0) |
| Small (45 mm to 47 mm) | 5295 (18.9) |
| Medium (48 mm to 50 mm) | 10 720 (38.3) |
| Large (≥ 51 mm) | 8028 (28.7) |
| Operator (n, %) | |
| Consultant | 26 166 (93.5) |
| Other | 1805 (6.5) |
| Number of consultants (n) | 722 |
| Consultant resurfacing volume (n, %) | |
| Low (≤ 50 cases over study period) | 7202 (25.7) |
| Medium (51 to 200) | 11 910 (42.6) |
| High (≥ 201) | 8859 (31.7) |
| Number of surgical units (n) | 376 |

intervals (CI); ratios > 1 indicate that risk is higher than the reference covariate category. Owing to the statistical methods used and the large population size, only covariates fitting models with $p < 0.01$ were considered significant

influences, to ensure that the chance of a type 1 error was reduced. The reliability of the models was explored by alternative stepwise procedures using the likelihood ratio test. The same covariates were fitted forward and reverse stepwise to ensure that findings were not qualitatively affected in the final model, and any inconsistency was reported. The final model was re-evaluated as a directly entered model (non-stepwise) to provide unconditional estimates, and was assessed by exploring two-way interactions between covariates and for the constant proportionality over time assumption. In addition, baseline entry and rejection criteria for the model were reduced to $p < 0.01$ and $p > 0.05$, respectively, to test covariate selection within the model.

Further analysis was then performed to compare brand differences in men < 60 years old. Operations were excluded if previously identified significant influences for implant failure were present. One-, three-, five- and seven-year revision rates (with 95% CIs) were then calculated for each brand and in total for the subgroup. Those brands with < 200 operations registered were excluded. Data were compared to the estimated revision rates for all patients in the study.

Results

A total of 27 971 hip resurfacings were available for analysis. The majority were in men (19 335, 69.1%), almost all had an ASA grade ≤ 2 (27 148, 97.1%) and the mean age was 55 years (15 to 108). The posterior approach was used in 20 048 cases (71.7%) and the BHR was the most commonly implanted prosthesis (15 459, 55.3%). Small or very small femoral components (≤ 47 mm) were used in 9223 hips (33%). Patients were under the care of 722 different consultants in 376 different surgical units, and most operations had been performed by a consultant (26 166 operations, 93.5%). A total of 7202 procedures (25.7%) were performed under the care of a consultant who had recorded < 50 resurfacing procedures during the study period. Demographic information is shown in Table II.

In all, 1003 patients (3.59%) underwent a revision procedure. The most common reason was aseptic loosening in 264 cases (26.3%), followed by peri-prosthetic fracture in 213 (21.2%) and pain without a recorded cause in 183 (18.2%). Revision due to a soft-tissue reaction to metal debris was undertaken in 71 patients (7.1%). Revision data are summarised in Table III. The 90-day mortality rate was 0.08%.²⁵ As of December 2010, 346 patients (1.24%) had died.

Patient-specific predictors of implant failure in the unadjusted data were female gender and ASA grades > 2. After risk adjustment using Cox's proportional hazards model, female gender (HR = 1.30 (99% CI 1.01 to 1.76); $p = 0.007$) and ASA grade ≥ 3 (HR = 1.74 (99% CI 1.17 to 2.61); $p < 0.001$) remained statistically significant (Table IV).

There were 19 133 entries (68.4%) without BMI data and 2345 (8.4%) without surgical approach data. Patient age, BMI, surgical approach and grade of operator did not significantly influence the risk of revision.

Table III. Reason recorded for revision following hip resurfacing (England and Wales, 2003 to 2010)

| Reason for failure (n, %) | Revision (n = 1003) |
|---|---------------------|
| Aseptic component loosening/lysis | 264 (26.3) |
| Femoral | 112 |
| Acetabular | 132 |
| Both | 20 |
| Peri-prosthetic fracture | 213 (21.2) |
| Femoral neck | 203 |
| Acetabulum | 6 |
| Both | 4 |
| Unexplained pain | 183 (18.2) |
| Technical error | 90 (9.0) |
| Component mismatch | 9 |
| Component malalignment | 81 |
| Adverse soft-tissue reaction to metal debris* | 71 (7.1) |
| Infection | 71 (7.1) |
| Dislocation/subluxation | 45 (4.5) |
| Component fracture | 37 (3.7) |
| Acetabular wear | 10 (1.0) |
| Other | 11 (1.1) |
| Avascular necrosis of the femoral head | 9 |
| Heterotrophic ossification | 1 |
| Leg-length discrepancy | 1 |
| No cause described | 60 (6.0) |

* including free text terms: metallosis, aseptic lymphocyte-dominated vasculitis associated lesion (ALVAL)

When the unadjusted data were analysed for brand, ASR, Cormet (Corin Group PLC, Cirencester, United Kingdom), Conserve (Wright Medical Technology Inc., Arlington, Tennessee), Durom (Zimmer Inc., Warsaw, Indiana) and Recap (Biomet Orthopedics LLC, Warsaw, Indiana) all had significantly higher revision rates than the BHR (Fig. 2). After risk adjustment, the same five brands were found to have a greater revision hazard than the BHR (ASR: HR = 2.82 (99% CI 2.24 to 3.54), $p < 0.001$; Conserve: HR = 2.03 (99% CI 1.42 to 2.91), $p < 0.001$; Cormet: HR = 1.43 (99% CI 1.10 to 1.86), $p = 0.001$; Durom: HR = 1.67 (99% CI 1.16 to 2.39), $p < 0.001$; Recap: HR = 1.58 (99% CI 1.03 to 2.42), $p = 0.007$) (Table IV).

Size of the femoral head < 48 mm was found to be a significant predictor of revision in both the unadjusted and the adjusted data (Fig. 3). Small femoral head sizes had significantly higher revision hazards than large heads (≤ 44 mm: HR = 2.14 (99% CI 1.53 to 3.00), $p < 0.001$; 45 to 47 mm: HR = 1.48 (99% CI 1.09 to 2.00), $p = 0.001$). There were no significant differences between the medium and the larger head sizes.

Surgeons who performed ≤ 200 resurfacings during the study period had a higher rate of revision in the unadjusted data. However, after risk adjustment, only patients operated on by low-volume surgeons (< 50 resurfacings) had a higher risk of revision (HR = 1.36 (99% CI 1.09 to 1.71), $p < 0.001$) than high-volume surgeons (Table IV).

Tests for interaction (multiplicative) between covariates and time-dependency were not statistically significant.

Forward and reverse stepwise model construction and varying significance thresholds led to the same final model.

When data for younger (< 60 years), fitter (ASA grades 1 and 2) male patients were analysed by brand, following resurfacing performed with head sizes > 48 mm by medium- to high-volume consultants, BHR patients ($n = 4873$) had a significantly lower five-year estimated revision rate (1.59% (95% CI 1.17 to 2.00)) than the poorest-performing brand (ASR ($n = 715$): 5.67% (95% CI 3.48 to 7.85)) and the entire subgroup (8172 patients: 2.47% (95% CI 2.04 to 2.91)) (Table V and Fig. 4). The estimated revision rate for the whole study population at five years was 4.76% (95% CI 4.44 to 5.08) (Table V).

Discussion

This retrospective cohort study provides the largest in-depth analysis of hip resurfacings to date. Significantly higher revision rates following resurfacing were independently associated with brand (ASR, Durom, Conserve, Cormet, Recap), female gender, smaller sizes of component, higher ASA grade and lower consultant volume. Increasing age was not associated with a greater risk of revision. This is most likely due to appropriate patient selection for resurfacing surgery across the population, mitigating the increased risk expected in older patients. Despite debate in the literature regarding the most appropriate surgical approach,²⁶⁻²⁸ in this analysis there was no significant difference between posterior and anterolateral approaches in terms of the risk of revision.

Although registries provide data from a vast number of patients, there are limitations. Revision is taken as a surrogate marker of failure, as other endpoints are unavailable. This does not take into account patients living with a painful hip, those with high metal ion levels, those with soft-tissue reactions, or those awaiting revision at the time of censoring. Thus the analysis assumes a common spectrum of, and progression to, failure regardless of brand or size of prosthesis. It is also apparent that poor positioning of the components may contribute to early failure.^{18,19} This analysis lacks data about positioning, but the relative performance of prostheses is likely to be robust within an analysis of such large numbers unless there are systematic differences in the ease of aligning different prostheses.

Several covariates are known to be associated, for example female gender and smaller prosthetic head size (females generally require smaller sizes than males). We explored multiplicative interactions between covariates and, in the final model, all significant covariate categories were independent of each other. The study design was observational and thus vulnerable to omitted variables, which may confound our findings. However, similarities between the unadjusted and adjusted models, robustness under different model fitting assumptions, and the independence of time support the stability of estimates.

NJR-linked PROMs are unlikely to contribute greatly to this type of analysis, as they report a single point in time (usually at around six months after surgery), and many of

Table IV. Independent predictors of revision. Age of patient, body mass index, operator and surgical approach were not selected for the final model (HR, hazards ratio; CI, confidence interval)

| Covariate | Simple (unadjusted) analysis | | Multiple variable (adjusted) analysis | |
|---|------------------------------|---------|---------------------------------------|---------|
| | HR (99% CI) | p-value | HR (99% CI) | p-value |
| Gender | | | | |
| Male | - | | - | |
| Female | 2.04 (1.74 to 2.41) | < 0.001 | 1.30 (1.01 to 1.67) | 0.007 |
| Age category (yrs) | | 0.368 | | |
| ≤ 45 | - | | | |
| 46 to 55 | 0.91 (0.70 to 1.19) | 0.375 | | |
| 56 to 65 | 0.85 (0.66 to 1.09) | 0.091 | | |
| ≥ 66 | 0.91 (0.64 to 1.27) | 0.452 | | |
| ASA [†] grade | | < 0.001 | | 0.001 |
| 1 | - | | - | |
| 2 | 1.19 (1.00 to 1.40) | 0.008 | 1.14 (0.96 to 1.35) | 0.045 |
| ≥ 3 | 1.74 (1.16 to 2.60) | < 0.001 | 1.74 (1.17 to 2.61) | < 0.001 |
| Body mass index | | 0.050 | | |
| Underweight (< 18.5 kg/m ²) | 2.07 (0.70 to 6.11) | 0.082 | | |
| Normal (18.5 < 25 kg/m ²) | 1.46 (0.97 to 2.19) | 0.016 | | |
| Overweight (25 < 30 kg/m ²) | - | | | |
| Obese (≥ 30 kg/m ²) | 1.19 (0.83 to 1.73) | 0.213 | | |
| Approach | | | | |
| Posterior | - | | | |
| Anterolateral | 1.26 (1.04 to 1.53) | 0.002 | | |
| Brand | | < 0.001 | | < 0.001 |
| BHR [†] | - | | - | |
| ASR [‡] | 2.80 (2.24 to 3.51) | < 0.001 | 2.82 (2.24 to 3.54) | < 0.001 |
| Adept | 1.32 (0.92 to 1.90) | 0.047 | 1.26 (0.87 to 1.81) | 0.107 |
| Conserve | 2.45 (1.73 to 3.47) | < 0.001 | 2.03 (1.42 to 2.91) | < 0.001 |
| Cormet | 1.74 (1.36 to 2.23) | < 0.001 | 1.43 (1.10 to 1.86) | 0.001 |
| Durom | 1.72 (1.20 to 2.45) | < 0.001 | 1.67 (1.16 to 2.39) | < 0.001 |
| Mitch | 1.50 (0.65 to 3.38) | 0.222 | 1.40 (0.61 to 3.20) | 0.298 |
| Recap | 1.73 (1.14 to 2.64) | 0.001 | 1.58 (1.03 to 2.42) | 0.007 |
| Head size category | | < 0.001 | | < 0.001 |
| Very small (≤ 44 mm) | 2.46 (1.95 to 3.11) | < 0.001 | 2.14 (1.53 to 3.00) | < 0.001 |
| Small (45 mm to 47 mm) | 1.60 (1.27 to 2.03) | < 0.001 | 1.48 (1.09 to 2.00) | 0.001 |
| Medium (48 mm to 50 mm) | 0.87 (0.68 to 1.01) | 0.118 | 0.99 (0.77 to 1.26) | 0.907 |
| Large (≥ 51 mm) | - | | - | |
| Operator | | | | |
| Consultant | - | | | |
| Other | 1.07 (0.76 to 1.49) | 0.624 | | |
| Consultant resurfacing volume | | < 0.001 | | 0.001 |
| Low (≤ 50) | 1.52 (1.22 to 1.88) | < 0.001 | 1.36 (1.09 to 1.71) | < 0.001 |
| Medium (51 to 200) | 1.24 (1.01 to 1.51) | 0.007 | 1.14 (0.92 to 1.41) | 0.110 |
| High (≥ 201) | - | | - | |

* ASA, American Society of Anesthesiologists

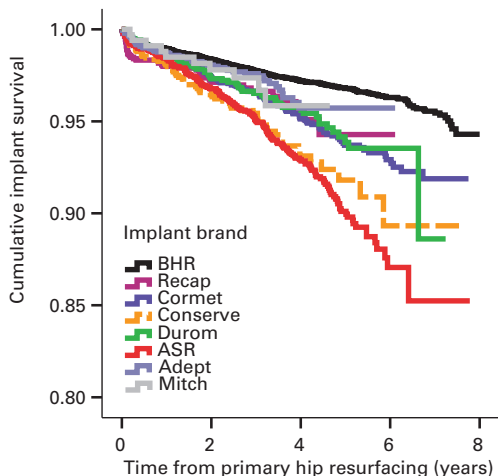
† BHR, Birmingham Hip Resurfacing

‡ ASR, Articular Surface Replacement

the problems resulting from a resurfacing procedure emerge over a longer period.

Despite evidence of good long-term survival in younger male patients,⁷ the use of hip resurfacing is now decreasing in England and Wales.⁸ It is accepted that there are now fewer indications for resurfacing. It has previously been

reported that men < 60 years of age undergoing resurfacing for osteoarthritis have a rate of revision at five-years of 6.05% (95% CI 5.55 to 6.60), significantly poorer than with hybrid (2.79% (95% CI 2.30 to 3.37)) and cemented THRs (3.25% (95% CI 2.83 to 3.73)) according to the NJR data.⁸ However, our own analysis found a five-year

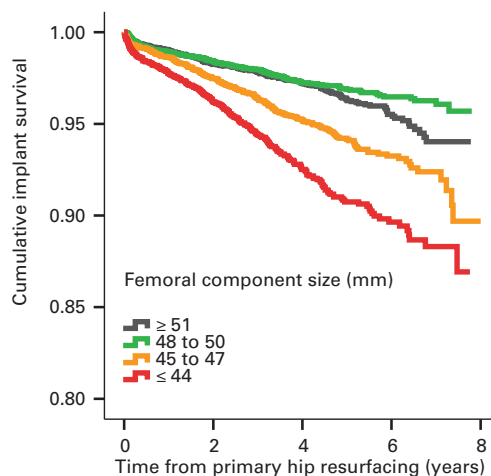


Life table showing numbers at risk in each year

| Brand | Year 0 | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 | Year 7 |
|----------|--------|--------|--------|--------|--------|--------|--------|--------|
| BHR | 15 459 | 14 172 | 12 314 | 10 069 | 7545 | 5092 | 2821 | 989 |
| ASR | 2631 | 2554 | 2314 | 1819 | 1201 | 586 | 135 | 1 |
| Adept | 2466 | 2049 | 1481 | 842 | 296 | 107 | 4 | 0 |
| Conserve | 1173 | 1037 | 850 | 610 | 332 | 127 | 52 | 10 |
| Cormet | 3193 | 3029 | 2590 | 1996 | 1334 | 883 | 463 | 159 |
| Durom | 1381 | 1318 | 1117 | 862 | 595 | 311 | 82 | 10 |
| Mitch | 339 | 314 | 272 | 151 | 39 | 0 | 0 | 0 |
| Recap | 1329 | 1120 | 818 | 488 | 189 | 44 | 2 | 0 |

Fig. 2

Kaplan-Meier unadjusted cumulative implant survival by resurfacing prosthesis brand (England and Wales, 2003 to 2010) (BHR, Birmingham Hip Resurfacing; ASR, Articulating Surface Replacement).



Life table showing numbers at risk each year

| Femoral size (mm) | Year 0 | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 | Year 7 |
|-------------------|--------|--------|--------|--------|--------|--------|--------|--------|
| ≤ 44 | 3928 | 3697 | 3178 | 2444 | 1613 | 966 | 474 | 167 |
| 45-47 | 5295 | 4075 | 4368 | 3522 | 2492 | 1534 | 786 | 245 |
| 48-50 | 10720 | 9674 | 8124 | 6166 | 4186 | 2644 | 1362 | 488 |
| ≥ 51 | 8028 | 7247 | 6086 | 4705 | 3240 | 2006 | 937 | 269 |

Fig. 3

Kaplan-Meier unadjusted cumulative implant survival by femoral component size (England and Wales, 2003 to 2010).

Table V. Estimated revision rates by brand of component following resurfacing for male patients aged < 60 years, with American Society of Anesthesiologists grade ≤ 2, using a femoral head size ≥ 48 mm, performed by a mid- to high-volume consultant, compared with the rates of the entire study population

| | Revision rates under optimal conditions* (% , 95% CI) | | | | | | | Revision rates for entire study population |
|--------------|---|-------------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|--|
| | Birmingham Hip Resurfacing | Articular Surface Replacement | Adept | Cormet | Durom | Recap | Total | |
| 1 year | 0.65 (0.43 to 0.88) | 0.99 (0.26 to 1.72) | 0.70 (0.09 to 1.31) | 0.26 (0.00 to 0.62) | 1.03 (0.03 to 2.03) | 0.96 (0.00 to 2.04) | 0.71 (0.52 to 0.89) | 1.29 (1.15 to 1.42) |
| 3 year | 1.18 (0.85 to 1.51) | 2.78 (1.51 to 4.04) | 1.06 (0.27 to 1.85) | 1.21 (0.37 to 2.04) | 2.85 (1.10 to 4.61) | 2.41 (0.44 to 4.38) | 1.51 (1.22 to 1.80) | 2.93 (2.72 to 3.25) |
| 5 year | 1.59 (1.17 to 2.00) | 5.67 (3.48 to 7.85) | 2.20 (0.45 to 3.96) | 2.79 (1.27 to 4.31) | 5.27 (2.33 to 8.22) | - | 2.47 (2.04 to 2.91) | 4.76 (4.44 to 5.08) |
| 7 year | 2.21 (1.51 to 2.91) | 6.42 (3.80 to 9.04) | - | 5.31 (1.94 to 8.69) | - | - | 3.34 (2.62 to 4.06) | 6.29 (5.76 to 6.81) |
| Total number | 4873 | 715 | 787 | 783 | 395 | 348 | 8172 | 27 971 |

* Conserve and Mitch brands had < 200 operations overall, so were excluded from this analysis

revision rate of 1.59% (95% CI 1.17 to 2.00) in men < 60 years who received a BHR compared with 4.76% (95% CI 4.44 to 5.08) for the entire study population. Thus, previous NJR analysis may have failed to reflect this heterogeneity, and revision rates for the BHR in young men may be considered more acceptable. Further evidence is required from comparison studies with stemmed implants and data from the PROMs project in order to ascertain whether resurfacing is superior to THR in this group.

Femoral neck fracture and reactions to metal debris are the most commonly reported reasons for revision following hip resurfacing.^{11,25,29} The major cause of revision in this

current study was component loosening or lysis. Metal debris and soft tissue reactions were uncommon, although descriptions of failure associated with debris have only been common in recent years, and the categories of revision in the NJR have evolved through modifications of the data collection forms. Many failures described in the component loosening, pain and infection categories may actually be a result of metal debris. Given these limitations, it is difficult to refute the evidence from in-depth reporting of revision in smaller studies.

Although several studies have found that higher failure rates in women are related to component size and

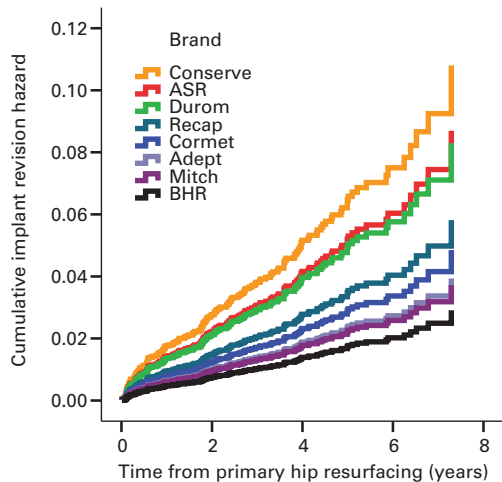


Fig. 4

Cumulative implant revision chart by brand (male patients < 60 years with American Society of Anesthesiologists grade ≤ 2 , using head size ≥ 48 mm by mid- to high-volume consultant (8172 procedures)) (England and Wales data, 2003 to 2010) (BHR, Birmingham Hip Resurfacing; ASR, Articulating Surface Replacement).

independent of gender,^{30,31} this current study identified that women have an increased risk of revision of 31% compared with men. A combination of factors may contribute to this, such as lower bone density (resulting in decreased cement penetration³² or an increase in risk of fracture), anatomical differences (leading to implant malalignment and impingement³³) and immunological responses.³⁴ It is not clear why higher ASA grade would result in greater implant failure, but there may be an association with poorer bone quality or immunological reserve.

Five brands have a significantly higher risk of revision than the most widely used device in the United Kingdom (BHR). There appears to be a brand influence after risk adjustment, suggesting that there are specific design features of some brands that may predispose to failure. This may relate to the characteristics of the acetabular component, such as its thickness and the ability to prevent deflection or lower head coverage, which has been implicated in the ASR and other sub-hemispherical designs.^{35,36} Lower clearance, as seen with the ASR, may also increase wear and subsequent failure. The BHR currently holds an Orthopaedic Device Evaluation Panel (ODEP) 10a rating in the United Kingdom – good evidence that this implant has > 90% survival at ten years.³⁷ However, these latest data show that smaller implants have significantly higher revision rates across all resurfacing brands, including the BHR. Smaller resurfacing components may function in boundary lubrication rather than mixed or fluid-film as intended, resulting in increased wear and reactions to metal debris, and this may explain the poorer results with these sizes. Even in patients with a BHR, survival will drop < 90% at ten years, based on current data. For resurfacing femoral

components < 47 mm a 10a rating may not be appropriate. Restricted to medium and large head sizes only (femoral head size > 48 mm) all resurfacing brands have an eight-year survival > 90% according to these current data.

Consultant volume conflates the number of years a surgeon has been working with their rate of surgery. Thus low-volume long-serving surgeons are grouped with higher-volume but less experienced surgeons. However, many authors have described a learning curve in hip resurfacing surgery related simply to the number of procedures performed.^{38,39} Our findings support the expert opinions from surgeons at the Ghent hip resurfacing meeting.⁴⁰

Female patients, those patients who require small components and surgeons performing low numbers of resurfacing procedures are associated with significantly higher failure rates. After adjustment for these covariates, there remain differences in the rates of failure between different brands of resurfacing prosthesis. For surgeons who undertake hip resurfacing, these data should guide their practice. However, further evidence is required to establish whether there is a true benefit of resurfacing devices over THR.

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