Orthopaedics & Traumatology: Surgery & Research 105 (2019) 943–948

Contents lists available at ScienceDirect

Orthopaedics & Traumatology: Surgery & Research

journal homepage: www.elsevier.com

Original article

Long-term comparative study of large-diameter metal-on-metal bearings: Resurfacing versus total arthroplasty with large-diameter Durom™ bearing

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ARTICLE INFO

Article history:
Received 8 December 2018
Accepted 16 April 2019

Keywords:
Metal-on-metal
Hip
Resurfacing
Arthroplasty
Metallic ions

ABSTRACT

Introduction: Short-term results in total hip arthroplasty (THA) with large-diameter metal-on-metal (MoM) bearings were encouraging, but high failure rates have been reported in the long term, notably implicating corrosion due to modularity. Several studies compared resurfacing (to which modularity does not apply) versus large-diameter MoM THA; but, to our knowledge, none compared the same bearing in the two situations with more than 10 years' follow-up. We therefore conducted a retrospective case-control study, using a single cup model (Durom™, Zimmer, Warsaw, USA) for both resurfacing (R) and large-diameter THA, to determine the role of modularity in failure of large-diameter MoM bearings. The study compared (1) metallic ion levels, and (2) survival, functional scores and complications rates between R and THA.
Hypothesis: Large-diameter MoM bearing failure implicates not bearing wear but head-neck junction modularity in larger-diameter MoM THA.
Material and method: Eighty-three THAs and 90 Rs were included between February 2004 and March 2006. All patients had clinical and radiologic follow-up with chromium (Cr) and cobalt (Co) ion blood assay.
Results: In the THA group, 24 of the 83 patients (28.9%) underwent revision for adverse reaction to metal debris (ARMD), versus none in the R group. Ten-year all-cause survival was significantly better in R (97.7%; 95% CI, 96.2–99.2) than THA (67.1%; 95% CI, 60.9–73.3). Median blood ion level was higher in THA (with a difference between Co and Cr: 5.75 μg/L (range, 3.82–19.2) versus 1.75 μg/L (range, 1.34–2.94) respectively) than in R (no difference: 0.89 μg/L (range, 0.67–2.89) and 1.07 μg/L (range, 0.67–1.65) respectively). In the THA group, there were positive correlations between Co and Cr elevation and implant revision (both $p < 0.0001$). Co/Cr ratio was significantly higher in THA (2.57) than R (0.88) ($p < 0.0001$), and higher again in the 24 cases of THA revision (4.67). There was no significant difference in mean PMA score (THA: 17.08 ± 1.82 (range, 7–18); R: 17.50 ± 0.74 (range, 15–18)), whereas mean Oxford score was better in R (14.32 ± 2.5 (range, 12–24)) than THA (18.17 ± 8.05 (range, 12–42)) ($p = 0.02$).
Discussion: The present study confirmed the incontrovertible implication of modularity in failure of large-diameter MoM THA, by analyzing the same bearing in THA and in resurfacing. Trunnionosis was observed in the 24 cases of revision, with the THA adaptation ring inducing serious metallic ion release (with dissociated Co/Cr ratio), accounting for the high rate of revision.
Level of evidence: III, case-control study.

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https://doi.org/10.1016/j.otsr.2019.04.006
1877-0568/

1. Introduction

In the 2000s, progress in tribology led to the use of 2nd-generation metal-on-metal (MoM) bearings in large-diameter arthroplasty (> 36 mm) to improve implant survival and reduce dislocation risk [1]. Resurfacing (R) thus gained a new lease of life. Large-diameter total hip arthroplasty (THR), initially developed exclusively for revision of resurfacing, came to be widely used in first line [1]. Application in THA allowed the advantages of a large diameter without the technical difficulties of resurfacing. Some 500,000 large-diameter MoM arthroplasties have been performed in the last 15 years worldwide [2]. Short- to medium-term results were encouraging [3–5], but national registries [6,7] reported high rates of bearing failure in the long term [8].

Many studies have compared THA and resurfacing, and some compared large-diameter THA and resurfacing [9–13], but either follow-up was no more than 10 years or the two implants were different [14–18]. We therefore conducted a retrospective case-control study with more than 10 years' follow-up, using the same cup (Durom™, Zimmer, Warsaw, Indiana, USA) in resurfacing (R) and large-diameter THA, to determine the role of modularity in large-diameter MoM bearing failure. The study compared:

- metallic ion levels;
- survival, functional scores and complications rates between R and THA.

The study hypothesis was that large-diameter MoM bearing failure is due not to bearing wear but to the excessive stress involved in large-diameter MoM THA head-neck junction modularity.

2. Material and method

2.1. Patients

A single-center retrospective comparative study included all patients undergoing hip arthroplasty, whether resurfacing or THA, with a Durom™ cup (Zimmer, Warsaw, Indiana, USA), between February 2004 and March 2006.

Inclusion criteria comprised: age < 70 years, with > 10 years' life-expectancy at surgery. Exclusion criteria comprised: known metal allergy, other concomitant metallic implants, and kidney failure; there were no contraindications regarding femoral head diameter in the resurfacing group.

The acetabular component consisted in all cases of a Durom™ cup. The femoral component was a Metasul™ Resurfacing Durom™ head in the resurfacing group and, in the THA group, a Metasul™ LDH Durom™ head, Protasul™ adaptation ring and Alloclassic™ Zweymüller stem (Zimmer, Warsaw, Indiana, USA). All procedures were performed on a posterolateral approach by the same team for both resurfacing and THA.

2.2. Assessment

All patients were assessed by a single examiner not involved in the surgery. Implant survival was defined by change for all causes. Clinical assessment comprised: Postel-Merle D'Aubigné (PMA)[19], Harris [20], Devane [21], Charnley [22] and Oxford-12 hip scores [23], and screening for cam effect [24], lower-limb length discrepancy and dislocation. All patients had AP weight-bearing pelvic X-ray. Cup inclination was measured against the radiologic U line.

Blood sampling for ion assay was from a peripheral vein, using a hollow BD Vacutainer Eclipse Blood Collection Needle with metal-free dry tube. The first 5 ml was discarded to avoid contamination. Chromium (Cr), cobalt (Co) and titanium (Ti) concentrations were measured on inductively coupled plasma (ICP) mass spectrometry (Varian 820-MS; Bruker, Wissembourg, France) with collision cell to eliminate spectroscopic interference. Any high levels were checked in the laboratory and, if confirmed, a second sample was taken a few weeks later. The detection threshold was 0.05 μg/L and the quantification threshold 0.1 μg/L.

2.3. Statistical analysis

Quantitative variables were reported as mean and standard deviation or median and interquartile range; distribution was checked graphically and on Shapiro–Wilk test. Qualitative variables were reported as number and percentage.

Ion concentrations and Co/Cr and Co/Ti ratios were compared between groups on multivariate linear regression with age [9], body-mass index (BMI) [25], gender [9], acetabular cup inclination [26] and femoral implant size [26] as adjustment factors. Ion concentration distribution was non-normal and was converted to log values so as to apply a parametric multivariate model. Survival was defined by all-cause revision surgery for implant change. The significance threshold was set at 5%. Analysis used SAS software, version 9.3 (SAS Institute, Cary, NC, USA).

3. Results

During the inclusion period, 103 large-diameter MoM THAs were performed; 20 hips were excluded from analysis (12 hips in 6 patients with bilateral arthroplasty, 7 deaths, 1 loss to follow-up), leaving 83 THAs. Ninety resurfacings were performed, with no exclusions (Table 1).

Median Co, Cr and Ti levels were significantly ($p < 0.0001$) higher in THA (Fig. 1): Co, 5.75 μg/L (range 3.82-19.20) versus 0.89 μg/L (range, 0.67–2.89); Cr, 1.75 μg/L (range, 1.34–2.94) versus 1.07 μg/L (range, 0.67–1.65); Ti, 5.70 μg/L (range, 4.10–6.80) versus 4.22 μg/L (range, 3.50–4.90).

Twenty-four patients showed Co > 7 μg/L and 4 showed Cr > 7 μg/L, all in the THA group (29% and 5%, respectively).

Co/Cr ratio was significantly ($p < 0.0001$) higher in THA: 2.57, versus 0.88 (i.e., close to 1); likewise, Co/Ti ratio was 1.04 versus 0.24 ($p < 0.0001$).

In the subgroup of 24 THA revisions for ARMD, mean Co level was 10.23 ± 3.98 μg/L (range, 0.36–16.8), and mean Co/Cr ratio 4.67 ± 2.91 (range, 0.36–11.26), with systematic macroscopic corrosion around the adaptation ring.

Twenty-four THA patients underwent revision for complications due to local ARMD, and none in the resurfacing group. Ten-year all-cause survival was significantly better ($p < 0.0001$) in resurfacing: 97.7% (95% CI: 96.2–99.2) versus 67.1% (95% CI: 60.9–73.3) (Fig. 2).

There was positive correlation ($p < 0.0001$) between Cr, Co and Ti ion elevation (taken separately) and/or dissociated Co/Cr ratio (with greater Co elevation) on the one hand and THA revision on the other. Median cup inclination was 49° (range, 46°–52°) in resurfacing and 50° (range, 46°–55°) in THA ($p = 0.12$), and < 50° in 63 resurfacings (70%) and 45 THAs (54%). There was no correlation between cup inclination and ion levels: Co ($p = 0.18$), Cr ($p = 0.19$), Ti ($p = 0.65$), Co/Cr ratio ($p = 0.56$).

All functional scores improved significantly in both groups ($p < 0.0001$), with no significant intergroup difference in PMA ($p = 0.92$) or Harris score ($p = 0.65$), while Oxford score was significantly better in resurfacing ($p = 0.029$) (Table 2). There were no cam effects in either group. There was 5–10 mm limb length discrepancy in 5% of THA patients and none with resurfacing. There were no dislocations; there were 2 periprosthetic fractures (1 Vancouver B2 in

Table 1
Demographic data.

	Durom™ THR	Durom™ R	*p*-value
Number of patients	83	90	
Follow-up (months)	108	99	$p < 0.001$
Gender			$p = 0.13$
Male	49	63	
Female	34	27	
Mean age (years) ± SD (range)	49.83 ± 10.21 (18–69)	44.51 ± 10.08 (18 -70)	$p = 0.0007$
Mean BMI (kg/m^2) ± SD (range)	27.7 ± 6.1 (17–46)	25.5 ± 5 (16–47)	$p = 0.01$
Mean weight (kg) ± SD (range)	82 ± 21 (47–165)	78 ± 18 (45–168)	$p = 0.01$
Mean height (cm) ± SD (range)	172 ± 10 (149–193)	174 ± 8 (156–189)	$p = 0.02$
Mean femoral head size (mm) ± SD (range)	46 ± 3 (38–54)	48 ± 4 (42-56)	$p = 0.0001$
Etiologies N/%.			
Primary osteoarthritis	34/41	61/68	
Dysplasia	14/17	16/18	
Epiphysiolysis sequelae	4/5	2/2	
Osteonecrosis	23/28	3/3	
Dislocation sequelae	3/4	1/1	
Septic arthritis sequelae	2/2	2/2	
Osteochondritis sequelae	1/1	4/5	
Post-traumatic	2/2	0/0	
Osteochondromatosis	0/0	1/1	
Devane score [21] (%).			$p < 0.0001$
1 and 2	8	89	
3	30	8	
4 and 5	62	3	
Charnley type [22] N/%.			$p = 0.0008$
A	28/34	55/61	
B	31/37	24/27	
C	24/29	11/12	
Cup inclination			
	50° (46–55)	49° (46–52)	$p = 0.12$

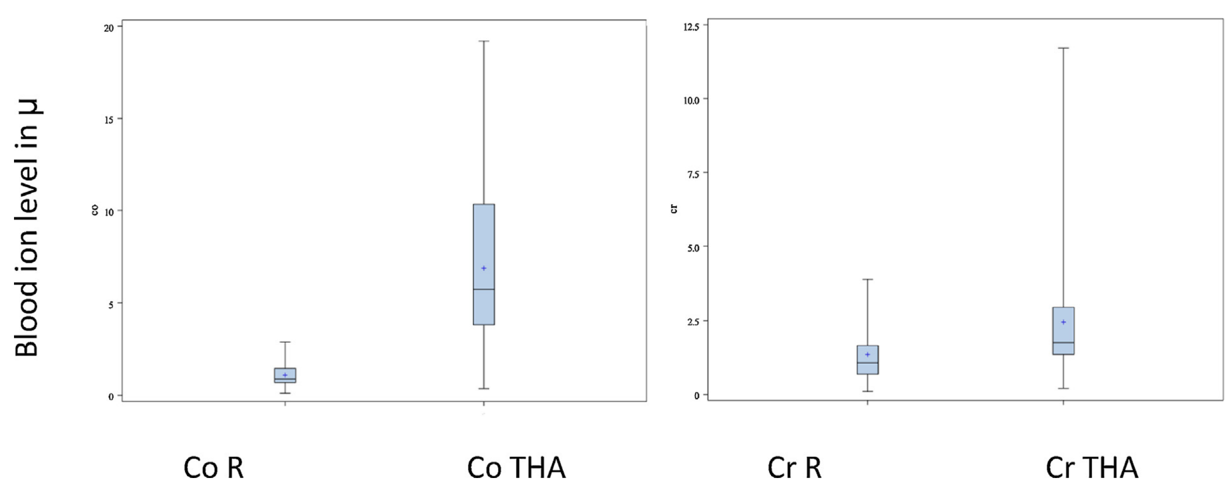

Fig. 1. Box-plot of Cobalt and Chromium levels in resurfacing (R) and total hip arthroplasty (THA).

Table 2
Progression in Postel Merle d'Aubigné (PMA) [19], Harris [20] and Oxford [23] scores (mean ± SD (range)).

	Durom™ THR	Durom™ R	*p*-value
Preoperative PMA score[19]	12.29 ± 2.06 (5–15)	11.37 ± 1.83 (4–15)	$p = 0.0012$
Last follow-up	17.08 ± 1.82 (7–18)	17.50 ± 0.74 (15–18)	$p = 0.92$
Gain	4.79 ± 2.42 (−3–10)	6.13 ± 1.96 (1–14)	$p < 0.0001$
Preoperative Harris score [20]	51.37 ± 14.92 (11–78)	51.31 ± 11.70 (27–83)	$p = 0.71$
Last follow-up	92.24 ± 13.64 (22–100)	95.48 ± 4.62 (82–100)	$p = 0.65$
Gain	40.86 ± 17.97 (−12–83)	44.16 ± 12.83 (9-73)	$p < 0.0001$
Preoperative Oxford score [23] (/60)	41 ± 3.3 (35–55)	40.3 ± 4.13 (25–55)	$p = 0.31$
Last follow-up (/60)	18.17 ± 8.05 (12–42)	14.32 ± 2.5 (12–24)	$p = 0.02$
Gain	22.83 ± 8.84 (1–43)	25.95 ± 4.27 (13–39)	$p = 0.0299$

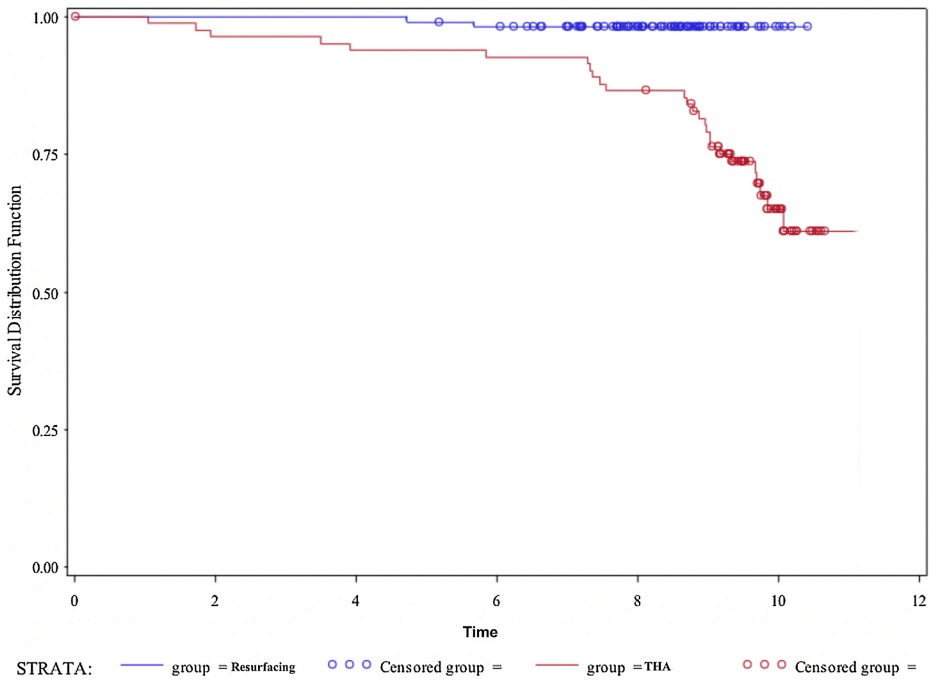

Fig. 2. Survival curves for resurfacing and total hip arthroplasty.

Table 3
Review of the literature. Comparison of MoM release between large-diameter THA and resurfacing, with identical implants.

Authors	THA	Resurfacing	Follow-up (months)
Garbuz et al. [27]	56 Durom	48 Durom	24
Vendittoli et al. [25]	29 Durom	53 Durom	12
Johnson et al. [14]	22 BFH/Conserve plus	110 Conserve plus resurfacing	62,2
Langton et al. [15]	138 ASR	19 ASR	12
Hug et al. [16]	78 ASR	15 ASR	40
Beaulé et al. [17]	26 BFH/Conserve plus	26 Conserve plus resurfacing	24
Lainiala et al. [18]	375 ASR82 BHR41 Durom	303 ASR 228 BHR 113 Durom	44 77 63
Present study	83 Durom	90 Durom	104

MoM: Metal on Metal.

THA, and 1 cervical fracture in resurfacing), 2 infections in THA, and 1 head collapse in resurfacing.

4. Discussion

The present study compared metallic ion release between two types of large-diameter MoM arthroplasty, with identical implants and long follow-up (Table 3). Survival was significantly better with resurfacing (97.7%) than THA (67.1%) (Fig. 2). High failure rates with Durom large-diameter MoM THA are also reported elsewhere: Althuizen et al. [28] reported a 10-year revision rate of 14.2% (range, 5.5–22.8%), and Ng et al. [29] 31%. With a 33% rate at around 9 years, and 28.9% of failures implicating the implant, the present results are in accordance with other studies at shorter follow-up [10,30–32] (Table 4). Survival in resurfacing was likewise comparable to literature reports (Table 5). Interestingly, the THA and resurfacing groups were comparable in terms of low dislocation rates and increased joint range of motion, commonly attributed to large-diameter arthroplasty.

Co, Cr and Ti ion levels were significantly higher in THA. Titanium is present on the THA femoral stem and in the cup coating, and passive surface corrosion [9] would explain ion release in both groups and the higher level in THA due to surface corrosion of the femoral stem (which does not exist in resurfacing). Cobalt and chromium are present in THA heads, cups and rings [32]; the higher level in THA with Co/Cr ratio dissociation argues for an implication

Table 4
Durom implant failure in large-diameter THA.

Authors	N hips	Follow-up (months)	Failure rate
Long et al. [30]	207	19	15%
Illgen et al. [31]	63	12	11.1%
Ng et al. [29]	297	120[a]	31%[a]
Lardanchet et al. [32]	24	24	8.3%
Althuizen et al. [28]	64	120[a]	14.2%[a]
Saragaglia et al. [33]	177[b]	81	7.3%
Present study	83	108	29%

[a] 10-year rate.
[b] 12% loss to follow-up.

of modularity by trunnionosis, in agreement with Goldberg et al. [39], who showed that cobalt and chromium were released in case of severe corrosion. The chromium remains localized around the Morse taper, whereas cobalt is released into the blood, whence the higher level of blood cobalt and dissociation of the Co/Cr ratio.

Implant design was identical in the two groups, as was cup inclination and femoral diameter: thus, these factors do not account for the observed differences. Release by prosthetic neck/cup contact is not implicated, as no impingement was seen and, biologically, the Co/Ti ratio was not lower, due to Ti release at the implant neck, in THA. There was a significant correlation in the present study between failure and elevated ion levels and Co/Cr ratio, although this is controversial in the literature [38,40]. Langton et al. [40]

Table 5
Durom implant failure in resurfacing.

Authors	N hips	Follow-up (months)	Failure rate
Vendittoli et al. [34]	64	24	0%
Goronzy et al. [35]	132	30	2.3%
Naal et al. [36]	100	60	11.8%
Leclercq et al. [37]	644	60	9%
Robinson et al. [38]	120	48	3.3%
Present study	90	99	2%

reported a correlation between ion elevation and failure, while other authors [38] found no significant correlation.

The present study had certain limitations. It was a level III retrospective study; however, all patients were examined by a single observer who had not performed the surgery. There may have been measurement biases in ion assay, with inter-individual differences in transportation time and time to analysis; however, the measurement protocol was routine for the follow-up of resurfacing and large-diameter MoM THA. There was also a risk of contamination of the probe in the ICP-MS apparatus if the previous sample contained a high metal concentration; however, this risk was slight, as a second analysis was made in case of abnormally high assay results. Adjustment was made for recognized sociodemographic confounding factors: age [9], gender [9] and BMI [25]. Finally, there was a significant difference in mean follow-up, but only of 9 months: the running-in phase for Metasul™ is between 1 and 4 years [9,10], and a 9-month difference should not affect ion levels, taking account of the running-in period.

5. Conclusion

The present study confirmed the importance of modularity in large-diameter MoM THA failure. Via trunnionosis, adaptation rings induce large ion release, accounting for the high revision rates. THA and resurfacing both target young active patients, with comparable functional scores and dislocation rates. Resurfacing now provides excellent clinical results and survival, and is logically indicated, whereas large-diameter THA, with its excessively high failure rate, has been abandoned.

Disclosure of interest

None of the authors have disclosures relating to the present article. Elsewhere, Henri Migaud is a consultant for Zimmer-Biomet, Corin, MSD and SERF and associate editor of Orthopaedics & Traumatology: Surgery & Research; Sophie Putman is a consultant for Corin; Charles Berton is a consultant for Corin; Julien Girard is a consultant for Smith & Nephew and Microport; and Gilles Pasquier is a consultant for Zimmer-Biomet. The other authors have no disclosures to make.

Funding

The study received no specific public, private or non-profit sector funding.

Authors' contributions

Pierre-Emmanuel Ridon: data acquisition, analysis and interpretation, article writing.

Henri Migaud: surgery, critical revision of article for intellectual content, final approval of version for submission.

Charles Berton: data acquisition.

Gilles Pasquier: critical revision of article for intellectual content, final approval of version for submission.

Sophie Putman: critical revision of article for intellectual content, final approval of version for submission, statistical analysis.

Julien Girard: surgery, critical revision of article for intellectual content, final approval of version for submission.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.otsr.2019.04.006.

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