What Are the Risks Accompanying the Reduced Wear Benefit of Low-clearance Hip Resurfacing?

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Abstract

Background Clearance is an important determinant of metal-metal bearing function. Tribologic theory and laboratory evidence suggest low clearance (LC) reduces wear but with a potential to increase friction and clinical reports show LC resurfacings have high implant failure rates. Thus, the role of LC is unclear.

Questions/Purposes We asked: is in vivo wear as reflected by cobalt (Co) and chromium (Cr) levels reduced

in LC bearings, and if so, is this benefit offset by increased friction as assessed by implant-bone interface changes?

Methods We retrospectively reviewed 26 patients with LC resurfacings. We assessed Co and Cr levels in blood and urine, hip function, and radiographic adverse features. These data were compared with those from 26 patients with a similar resurfacing but with conventional clearance (CC) from a previous study. Minimum followup was 4.0 years (mean, 4.1 years; range, 4.0–4.7 years).

Results Co and Cr ion comparisons showed three phases: in the first 2 months, there was no difference between the cohorts; at 2 to 24 months, the CC group showed higher levels; and subsequently, levels in the two groups converged. A mean Oxford hip score of 13 and step activity of 1.9 million cycles per year in the LC group were similar to those of the CC group. Cup radiolucencies were seen in three patients in the LC group and none in the CC group.

Conclusions Lower Co and Cr levels suggest lower wear in the LC resurfacings in the intermediate term, but the presence of radiolucencies raises the concern that higher bearing friction is affecting implant fixation. A larger clearance than the theoretically predicted ideal may be required to allow for minor manufacturing imperfections, component deformation, and progressive changes in the in vivo lubricant.

Level of Evidence Level III, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

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Introduction

Recently high failure rates have been reported with certain metal-metal (MM) hip resurfacing implants [4, 22, 32]. However, well-designed and properly positioned hip resurfacing implants continue to show 96% to 98% survival

at 10 to 13 years [30, 42]. Many surgeons believe resurfacing offers potential benefits [5, 9, 34], including femoral bone conservation [7], avoidance of stress shielding [21], reduced dislocation rates [17, 28], and more revision options [16, 27], which are of particular interest when treating young patients. However, systemic metal ion elevation [10] and local adverse reactions [23] continue to cause concern. These are related to bearing wear and are of concern in young people because of the expected long lifetime use.

Low wear and friction in large-diameter fluid-lubricated MM bearings are contingent on their ability to generate a fluid film greater in thickness than the composite surface roughness of the components. Wear and friction are influenced by several factors [20], of which load applied, lubricant viscosity, bearing diameter, and sliding speed are beyond surgeon or designer control in the resurfacing context. The potentially controllable factors include angle of articulation, surface roughness, sphericity, and diametral clearance (Fig. 1). In theory, a lower clearance generates a thicker fluid film and therefore should wear less [20], unless extremely low, when the risk of clamping occurs.

Laboratory results [1, 37] and clinical metal ion [3, 12, 31] studies relating to the effect of bearing diameter on wear and metal ions suggest conflicting conclusions, with some showing an inverse relationship between bearing diameter and wear and others showing no effect. Several in vitro studies relating to the effect of clearance [14, 20, 35, 36] on wear also reported conflicting results. Some [35, 36] report slightly lower wear with reduced clearance whereas others [13, 19] have shown the risk of higher friction and wear in low-clearance (LC) devices through cup deformation. We found no studies of in vivo metal ion release in patients implanted with MM bearings of different diametral clearances but similar in other characteristics.

We therefore compared (1) blood cobalt (Co) and chromium (Cr) levels in a cohort of patients with LC

resurfacings with the levels in historical controls with conventional-clearance (CC) resurfacings. Furthermore we compared (2) urine Co and Cr levels, (3) Oxford hip score (OHS) and UCLA activity levels, and (4) the incidence of radiologic adverse features including lucent lines, osteolysis, and component loosening between the two groups.

Patients and Methods

From August 2003 to December 2003, we performed 128 arthroplasties using the Birmingham HipTM Resurfacing system (BHR) (Smith & Nephew Orthopaedics UK Ltd, Warwick, UK). The indications for hip resurfacing included painful end-stage hip arthritis from any reason including primary and secondary osteoarthritis, inflammatory arthritis, and developmental dysplasia. Contraindications to resurfacing were (1) poor-quality femoral head bone, (2) severe cystic change or osteonecrosis of the femoral head, (3) severe hip dysplasia (Crowe IV), (4) renal failure, (5) known metal hypersensitivity, and (6) patients who owing to their age, activity level, or comorbidities were highly unlikely to outlive a conventional THA. The inclusion criteria in the study group were males with unilateral primary hip osteoarthritis who we judged suitable for a 50-mm-diameter bearing resurfacing based on preoperative and intraoperative templating. Only one head size was included to reduce variable surface corrosion and other confounding factors arising from different bearing diameters. Twelve-hour urine and whole-blood specimens were collected preoperatively after informed consent. We excluded 102 patients with bilateral disease, with need for any size other than a 50-mm-diameter bearing, with any other metallic device, with a history of renal impairment, or who lived abroad, leaving 26 patients for initial inclusion in the study. We excluded two patients between the 1- and 2-year followups. One patient with preexistent cystic change in the femoral head underwent revision of his arthroplasty to a THA with a modular-head MM implant for femoral failure and another patient underwent contralateral hip resurfacing. This left 24 patients in the LC group for evaluation at the 4-year stage. Minimum followup was 4.0 years (mean, 4.1 years; range, 4.0–4.7 years). No patients were lost to followup. No patients were recalled specifically for this study; all data were obtained from medical records and radiographs.

The results from the LC group were compared with those from 26 previously published [10] historical control patients with a CC (approximately 250 μ m) BHR of similar materials and design characteristics with either a 50- or a 54-mm-diameter femoral head. The primary objective of this study was to compare systemic Co levels as a

Fig. 1 Radial clearance is the difference between the inside radius of the cup and the outside radius of the femoral component ($R_2 - R_1$). Diametral clearance is twice radial clearance.

continuous response variable between independent study and control participants, with one control subject per study subject.

In that previous study [10], Co levels in the subject group with CC BHR implants were normally distributed with a mean of 1.26 and SD of 0.6. A 50% reduction in Co levels in study patients would be deemed clinically important. Assuming a true difference of 0.6 µg/L between the study and control means, 22 experimental subjects and 22 control subjects would be needed to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) of 0.9. The Type I error probability associated with this test of this null hypothesis is 0.05. We therefore needed to study 22 experimental subjects (LC resurfacings) compared with 22 controls (CC resurfacings). To allow for patient dropouts either because of revisions, subsequent arthroplasty in other joints, patient death, emigration, or any other reason, we decided to include 26 patients in the study group.

In the LC group, the mean age of the patients at the time of surgery was 55 years and mean height, weight, and BMI before the resurfacing procedure were 179 cm, 86 kg, and 26, respectively (Table 1). There were no differences between the LC and CC cohorts in terms of their demographics or preoperative hip scores (Table 1). Although the patients in the two groups were not actively matched, being drawn from a similar population of patients with the same diagnosis, using similar inclusion and exclusion criteria, they happened to have comparable characteristics. As the surgery was performed by the same experienced surgeon using the same operative technique, postoperative cup angles in the two cohorts also were in similar ranges (Table 1).

The manufacturer supplied 26 pairs of matched BHR components with known diametral clearance. They were Size 50 femoral heads and Size 56 acetabular cups

(nominal bearing diameter, 50 mm; clearance, 100 µm). All other features were those of a regular BHR implant, which is made of as-cast high-carbon Co-Cr alloy and is a hybrid fixed device with cemented femoral and uncemented hydroxyapatite-coated porous acetabular components. Its average surface roughness is 0.03 µm, mean deviation from roundness is 0.9 µm, and the angle of cover of the cup is 162°. The average diametral clearance in the whole group was 98 µm (SD, 3.8 µm; range, 94–109 µm).

At the preoperative consultation, the radiographs of all patients are templated and those who were found suitable for a BHR implant and likely to require a 50-mm femoral head component were provided information about the study. This was reiterated on the night before surgery and informed consent to participate in the study was obtained. Patients who consented provided blood samples and a 12-hour collection of urine (for metal ion analysis) passed directly into a metal-free container overnight.

All procedures were performed by the same surgeon (DM) using the same surgical technique as previously described [10]. Perioperative intravenous antibiotics were administered for 24 hours and antibiotic cement fixation was used for the femoral component, in addition to using a clean-air laminar flow enclosure and Charnley body exhaust suits. We did not use anticoagulants for thromboprophylaxis but administered a multimodal regime [8], which included hypotensive epidural anesthesia, antiplatelet medication, early mobilization, compression stockings, and pneumatic calf pumps. With the patient in the lateral decubitus position, a limited posterior approach was used [29]. If at surgery patients required a 50-mm resurfacing component as templated, they received those paired LC components and were included in the study. If on intraoperative templating it was found they required some other size, they received regular CC BHR components of that diameter and therefore were excluded from

Table 1. Demographics, hip function, activity levels, and cup inclination in the two groups

Parameter	Conventional-clearance hip resurfacing (n = 26)	Low-clearance hip resurfacing (n = 26)	p value
Age at operation (years)	52.9 (28–67)	54.9 (45–68)	0.3
Height (cm)	177 (165–187)	179 (167–196)	0.4
Weight (kg)	87 (59–119)	86 (70–102)	0.5
BMI	27.9 (21.5–36.3)	26 (24–32)	0.1
Preoperative Oxford hip score (points)	35 (25–48)	35 (25–48)	
4-year Oxford hip score (points)	12.7 (12–17, except for 1 outlier 42)	12.8 (12–17, except for 1 outlier 22)	0.4
4-year UCLA Activity Scale level	8 (6–10)	8.3 (6–10)	0.8
4-year step activity (Mcy/year)	2.1 (1–4.3)	1.9 (0.9–3.6)	0.3
2-month cup inclination (°)	43.3 (35–49)	41.9 (33–55)	0.2

Values are expressed as mean, with range in parentheses; Mcyc = million cycles per year.

the study. The preoperatively collected blood and urine specimens of such patients then were discarded. The femoral and acetabular components are available in 2-mm increments. Adequate exposure and full access to the periphery of the acetabulum were obtained before reaming for the acetabular cup. After reaming, a curette was used to rid the surface of all overlying articular cartilage or soft tissue. Antirotation flanges in the BHR cup were directed to lie against the ischium and the pubis. We aimed for 40° inclination and 20° anteversion. Bare metal was not exposed anteriorly so that the psoas tendon was not exposed to the cup edge. The soft tissue of the femoral neck was preserved. The proximal femur was always vented to help minimize local and systemic embolization. Notching of the femoral neck and varus placement were avoided. Femoral components were centered on the femoral neck rather than the femoral head. Within the constraints of the anatomy, we attempted to maximize anterosuperior head-neck offset to minimize impingement.

We reviewed patients clinically and radiographically at 2 months and then at 1, 2, and 4 years postoperatively. Urine specimens for metal ion assessment were collected preoperatively and at 5 days, 2 months, 6 months, and 1, 2, and 4 years postoperatively. A 12-hour urine collection was used rather than a 24-hour collection as patient compliance reportedly is better with a 12-hour collection [2, 15]. The 24-hour output of metal ions ($\mu\text{g}/24$ hours) was estimated as the product of the urinary concentration of metal ions and twice the 12-hour volume of urine. Whole-blood specimens were collected preoperatively and at the 1-, 2-, and 4-year followups. We chose the 1-year followup as the first time for combined whole-blood and urine measurements because we expected the run-in peak to occur at 1 year, based on a cross-sectional pilot study in patients with the BHR system. Except for the two excluded patients, hip function was assessed with OHS questionnaires and current occupational and leisure activities were assessed using the modified UCLA activity level assessment scale [9]. The StepWatchTM 2 system [10] (Prosthetics Research Study, now Cyma Corp, Mountlake Terrace, WA, USA) was used to monitor step rates in these patients at the 1-, 2-, and 4-year followups. The device was fitted on the leg above the ankle and patients were instructed to wear the device during all waking hours in the following 5 to 7 days.

High-resolution inductively coupled plasma mass spectrometry (HR-ICPMS) was used to analyze the urine and blood specimens. Details of specimen collection, analysis, and instrumentation have been described [10–12]. Metal ion assessment methodology and instrumentation used were similar in both cohorts and the details were described in a previous publication [10].

At each visit, we obtained an AP view of the pelvis centered on the symphysis pubis with a tube to film distance

of 100 cm and a horizontal shoot-through lateral film of the surgically treated hip. Two of us (JD, CP) assessed radiographs in three zones around the metaphyseal stem and four zones around the acetabular component, using established criteria [6] for lucent lines (> 1 mm thick line that was not present on the immediate postoperative film), osteolysis (geographic lucent lesions which have newly appeared or been progressively increasing), and loosening. Change of position or orientation of the components was classified as migration. Complete radiolucencies in all zones with or without migration was classified as loosening. The literature shows that these standardized assessments of adverse events at the implant-bone interface using plain radiography have an element of subjectivity, resulting in variable (0.3 to 0.8) intraobserver and interobserver reliability depending on observer experience [38], either with or without digital enhancement [26]. Acetabular cup inclination angle was assessed as the angle between the interteardrop line and the edge of the cup as described in a previous study [29].

We determined differences in Co and Cr levels in blood and urine between the LC and CC groups using box and whisker plots and Mann-Whitney U test, since normality was rejected for the data by the D'Agostino-Pearson test. The same test also rejected normality for the data relating to OHS and UCLA activity level scales. Nonoverlapping 95% CIs of medians and *p* values were used to test for differences. The differences in the radiologic findings were too few in the CC group for a statistical comparison of the two groups. We performed all statistical calculations using Excel[®] 2010 (Microsoft Corp, Redmond, WA, USA) and MedCalc[®] Version 12.2.1 (MedCalc Software bvba, Mariakerke, Belgium).

Results

Blood Co (Fig. 2) and Cr (Fig. 3) at all followups were higher than the corresponding preoperative level in each cohort. Blood Co and Cr levels were lower in the LC group than in the CC group at 12 months followup. Thereafter, in the LC group, there was no change. In the CC group, there was a reduction ($p < 0.001$) in Cr between the 12- and 48-month levels but no change in Co ($p = 0.85$). At 48 months, median Co and Cr levels continued to be relatively lower in the LC group compared with the CC group but the difference ($p = 0.048$) had considerably narrowed; blood Co levels at this stage showed overlapping 95% CIs suggesting the difference was not significant.

Urinary excretion of Co (Fig. 4) and Cr (Fig. 5) at all followups was greater than the corresponding preoperative levels in each cohort. In the LC group, compared with the 5-day Co output, the 2-month ($p = 0.02$), 6-month ($p = 0.02$) and 12-month ($p = 0.03$) outputs were higher. Compared with the 2-month Co output, the 48-month

Fig. 2 Box plots show whole-blood levels of Co in the LC and CC cohorts. The boxes represent interquartile ranges (IQRs) and the middle lines in them represent medians. The whiskers represent values within 1.5 times the IQR. The hollow circles are outliers. At 12 months we found differences, but at 4 years, 95% CIs of the medians overlap (CC: median, 1.04; 95% CI, 0.85–1.24; LC: median, 0.97; 95% CI, 0.60–1.08). Patients with CC BHR implants did not have a blood test at their 2-year followup.

Fig. 3 Box plots show whole-blood levels of Cr in the LC and CC cohorts. The boxes represent interquartile ranges (IQRs) and the middle lines in them represent medians. The whiskers represent values within 1.5 times the IQR. The hollow circles are outliers. Blood Cr was lower in the LC group than in the CC group at 12 months followup and remained lower at 4 years. Patients with CC BHR implants did not have a blood test at their 2-year followup.

Fig. 4 Box plots show 24-hour output of Co in urine in the LC and CC cohorts. The boxes represent interquartile ranges (IQRs) and the middle lines in them represent medians. The whiskers represent values within 1.5 times the IQR. The hollow circles are outliers. We found differences between the two groups at all followups after 2 months.

Fig. 5 Box plots show 24-hour output of Cr in urine in the LC and CC cohorts. The boxes represent interquartile ranges (IQRs) and the middle lines in them represent medians. The whiskers represent values within 1.5 times the IQR. The hollow circles are outliers. We observed differences between the two groups at all followups after 2 months.

output was lower ($p < 0.03$). We observed no other differences in the LC group. Compared with the CC group, the outputs of Co and Cr in the LC group between

6 months and 48 months were lower ($p < 0.001$), but we found no differences at the 5-day and 2-month followups. In the CC group, Co output peaked at 6 months followed by a declining trend until 4 years. In the LC group, this 6-month peak was absent, but three outliers at the 5-day stage led to a peak in the 90th percentile. This was followed by a small increase ($p = 0.0215$) in median Co at 2 months and then a declining trend until 4 years.

All patients with surviving implants in both cohorts had well-functioning hips. The median OHS in the LC group improved ($p < 0.001$) from 31 preoperatively to 12 postoperatively (reference range, 12 best possible to 60, worst score). The annual step activity and UCLA activity levels in the LC cohort were not different ($p = 0.8$) from those in the CC cohort (Table 1).

We observed no osteolysis, radiolucent lines, or aseptic loosening in any of the patients in the CC group and in 21 of the 24 patients in the LC group (Fig. 6). Radiolucencies around the cup were not seen in the CC Group but were seen in three patients in the LC group in socket Zones 1 and 2, one of which progressively worsened (Fig. 7) to 4 mm at 4 years. In the LC group, one patient had neck thinning greater than 10% and two others had tiny scalloping in the medial head-neck junction. Mean postoperative acetabular cup inclination was 41.9° in the LC group and 43.3° in the CC group with no change in the respective mean inclination angles at 4 years' followup (Table 1), indicating no component migration. The scatter of inclination angles was well controlled, with none greater than 55° in either group. None of the patients with radiologic adverse features has clinical symptoms or disability and none is awaiting revision surgery.

Discussion

Tribologic theory and simulator studies [36] suggested reducing bearing clearance reduces wear. However, cup deformation [13, 19, 20] (Fig. 8) during implantation

(circumferential) and during weightbearing (axial) can convert an LC bearing into negative clearance with high friction. Furthermore, an LC bearing makes less allowance for minor manufacturing imperfections in terms of surface

Fig. 7A–F A radiographic series shows the hip of a 55-year-old man (A) preoperatively, (B) 5 days postoperatively, and at (C) 2 months, (D) 1 year, (E) 2 years, and (F) 4 years after receiving a LC BHR prosthesis. A progressive radiolucent line in Zones 1 and 2 of the cup can be seen (arrows). This phenomenon was observed in three of 26 patients in the LC cohort but was not observed in any patients with the CC BHR implant.

Fig. 6A–D A radiographic series shows the hip of a 49-year-old patient (A) preoperatively and at (B) 2 months, (C) 1 year, and (D) 4 years after implantation with a LC BHR prosthesis. He had an

Oxford hip score of 12, UCLA activity level of 7, and no adverse radiographic appearances at his 4-year followup.

Fig. 8 When the cup is implanted in the pelvis, it is subject to deforming forces acting between the columns of the ischium and ilium leading to a two-point pincer effect (arrows). Some of this is plastic deformation and allows plastic recoil with time. Physiologically relevant loading of the bearing in an axial plane during walking further contributes to deformation.

roughness and out of roundness. A third problem relates to in vivo lubricant evolution. During the early postoperative period, macromolecules, blood cells, and clots in the joint fluid generate shear stresses and increase fluid friction in LC bearings [13]. The above factors can lead to increased friction and adversely affect fixation. We assessed blood Co and Cr levels, urine Co and Cr excretion, hip function scores and patient activity scale, and radiographic adverse findings in patients who received a LC hip resurfacing system and compared these with the same parameters in patients with a similar design CC bearing.

We acknowledge limitations in our study. First, being a prospective nonrandomized study without a concurrent control group introduces potential selection bias. However, we made an attempt to reduce it by being unselective and including all eligible consenting patients during the study period serially. The presence of an historical control group with matching demographics operated on by the same surgeon using a similar device provided a comparable cohort. Second, in the LC group, only one head size (50 mm) was used. In the CC group, although the majority had a 50-mm-diameter bearing, a few patients had a 54-mm bearing. If the CC bearings had shown lower metal ion levels, the advantage of the larger-diameter bearings could be considered a confounding factor. However, the CC cohort did not show lower metal ion levels in this study at any stage and therefore we believe this would not influence the findings. Third, we assessed only one specific hip resurfacing design and one aspect of the design, ie, clearance and how it affects the clinical, radiographic, and metal ion results. This limitation implies the results cannot

be applied to other designs or material combinations, but this strategy offers an advantage to the study inasmuch as it reduces confounding from other variables.

We found the metal ion differences between the two cohorts had three phases. In the early stage, there was no difference. In the medium term (6 months and 1 year), Co and Cr were lower in patients who had LC resurfacings. In the longer term, the differences in metal ion levels in the two groups tended to converge, with blood Co showing no difference at 4 years. The metal ion levels in LC and CC BHR resurfacing components compare well with results from the BHR [24] and Durom® (Zimmer, Inc, Winterthur, Switzerland) [43] from other centers (Table 2). Studies of the ASR™ (DePuy Orthopaedics, Inc, Warsaw, IN, USA) resurfacing system showed higher metal ion levels, in particular, in those [18] with cup inclination greater than 50°.

Hip function and patient activity in our patients compare well with those in other published cohorts [9, 10, 41]. Radiographic assessment showed the presence of progressive radiolucencies in three patients in the LC group, a phenomenon not seen in patients with the CC BHR system even at 6 years [10]. Although these patients are functioning well, they face a small risk of potential cup debonding after sudden forceful movement or injury. Thus, although LC appears to offer a benefit in terms of in vivo wear, the presence of radiolucencies and of outliers in Co output at the 5-day stage in some patients with the LC bearing raise the possibility that LC may lead to increased friction and wear during the very early phase. Raised friction, whether from deformation, manufacturing microimperfection, or lubricant shear, can lead to micromotion at the fixation surface. It is possible a larger clearance would tolerate these inadequacies better.

The ASR™ and Durom® were introduced to clinical practice as LC resurfacing devices with the deemed benefit of less wear. A recent study [32] of the Durom® resurfacing system reported a 17% revision rate in women and 9% in men at a mean followup of 5 years, of which more than ¼ (27%) underwent revision for component loosening. Among a combination of presumed factors, implant characteristics related to tribology, fixation, and implantation technique were included. Long et al. [25] reported 15% revisions for acetabular component loosening 2 years after resurfacing with the Durom® implant, despite implant positioning parameters of 41.3° mean radiographic cup inclination (range, 28°–52°); and 20.2° (range, 13°–36°) mean cup anteversion.

The Australian National Joint Replacement Registry [4] showed both of these bearings were performing worse than other resurfacing bearings. The National Joint Registry of England and Wales [33] recorded a 12% failure of ASR™ resurfacing systems and these high rates are confirmed by other reports, with up to 25% failure rates at 6 years [22–24].

Table 2. Comparison of data from the current study and the literature

Study	Device and diameter	Specimen	Analytic technique	Followup duration	Number of patients	Hip score	Activity scale	24-hour urine Co (μg/24 hours)	24-hour urine Cr (μg/24 hours)	Blood Co (ppb, μg/L)	Blood Cr (ppb, μg/L)
Daniel et al. [12]	28 mm Metasul MM THA	Blood	HR ICPMS	Minimum 1 year	20			11.6*	3.7*	1.7*	1.7*
	BHR (50–54 mm)	Blood	HR ICPMS	Minimum 1 year	26	12.7 (OH)	8.5 (UCLA)	12.3*	5.3*	1.3*	2.4*
Venditelli et al. [43]	Durom Resurfacing (40–58 mm)	Blood	HR ICPMS	3 months	50					0.9*	2.01*
	Durom Resurfacing (40–58 mm)	Blood	HR ICPMS	6 months	51					0.8*	1.89*
	Durom Resurfacing (40–58 mm)	Blood	HR ICPMS	1 year	53	8.9 (WOMAC)	7.8 (UCLA)			0.67*	1.61*
	Durom Resurfacing (40–58 mm)	Blood	HR ICPMS	2 years	27					0.59*	1.37*
Moroni et al. [31]	BHR 48 mm average	Serum	GFAAS	24 months	20	94 (HH)				1.4*	2.3*
	28 mm Metasul MM THA	Serum	GFAAS	26 months	26	91 (HH)				1.33*	1.73*
	Controls, no implants	Serum	GFAAS		48					0.29*	0.25*
Antoniou et al. [3]	28 mm Metasul MM THA	Blood	ICPMS DRC	6 months	28	86 (HH)	NS			2.5	0.35
	36 mm Ultamet MM THA	Blood	ICPMS DRC	6 months	58	80 (HH)	NS			1.8	0.25
	ASR Resurfacing	Blood	ICPMS DRC	6 months	70	92 (HH)	7.4 (UCLA)			2.3	0.5
	Prodigy MPE THA	Blood	ICPMS DRC	6 months	18	74 (HH)	NS			1.65	0.05
	Control	Blood	ICPMS DRC	6 months	40	49 (HH)	5.3 (UCLA)			1.75	0.05
	28 mm Metasul MM THA	Blood	ICPMS DRC	1 year	28	88 (HH)	6.4 (UCLA)			2.6	0.6
	36 mm Ultamet MM THA	Blood	ICPMS DRC	1 year	58	85 (HH)	6.4 (UCLA)			2.3	0.4
	ASR Resurfacing	Blood	ICPMS DRC	1 year	70	89 (HH)	7.5 (UCLA)			2.4	0.5
Langton et al. [23]	ASR XL THA	Blood	HR ICPMS	Minimum 2 years	51	76 (HH)				3.2	
	ASR Resurfacing	Blood	HR ICPMS	Minimum 2 years	206	94 (HH)				2.1	

Table 2. continued

Study	Device and diameter	Specimen	Analytic technique	Followup duration	Number of patients	Hip score	Activity scale	24-hour urine Co (µg/24 hours)	24-hour urine Cr (µg/24 hours)	Blood Co (ppb, µg/L)	Blood Cr (ppb, µg/L)
Current study	BHR 50–54 mm (CC)	Blood	HR ICPMS	1 year	26			11.9	4.8	0.96	2.43
	BHR 50 mm (LC)	Blood	HR ICPMS	1 year	26			5.3	2.4	0.66	0.68
	BHR 50–54 mm (CC)	Blood	HR ICPMS	4 years	26	12.7 (OH)	8.5 (UCLA)	3.6	3.6	1.04	1.12
	BHR 50 mm (LC)	Blood	HR ICPMS	4 years	24	12 (OH)	8.3 (UCLA)	2	2	0.96	0.7

BHR = Birmingham Hip Resurfacing; CC = conventional clearance; LC = low clearance; MM = metal-on-metal; MPE = metal-on-polyethylene; ASR = articular surface replacement; ICPMS = inductively coupled plasma mass spectrometry; HR = high resolution; DRC = dynamic reactor cell; GFAAS = graphite furnace atomic absorption spectrometry; HH = Harris hip score; OH = Oxford hip score; * = denotes means and the rest are medians; ppb = parts per billion; NS = not significantly different from controls; WOMAC = Western Ontario and McMaster Universities Arthritis Index; UCLA = University of California Los Angeles Activity Scale.

It is unclear whether friction from LC as described above, other factors such as their reduced angle of articulation, an as-yet-unrecognized factor, or a combination of these factors played a role in their high failure rate. It is noteworthy that some of the above LC bearing resurfacings failed with a high incidence of cup loosening. In the two devices mentioned above several design changes were introduced simultaneously which makes it difficult to identify which factor is responsible for the higher failures. In the current study all other factors are similar in the two cohorts allowing us to identify the exclusive effects of reducing bearing clearance.

Two studies [39, 40] reported the intraoperative cup implantation deforming force to be 412 N on average, varying with bone quality and increasing to 577 N in Dorr Type A bone. In vitro testing of resurfacing cups using 412 N produced deformations of 10 to 75 µm and 577 N produced 10 to 120 µm [39]. The higher values have the potential to clamp LC cups while allowing CC cups to function normally.

It also has been reported [39] stress relaxation occurs with time in modular Ti acetabular components over 25 days postoperatively, and this has an influence on initial wear properties and stress transfer to the bone-implant interface. Because bone ingrowth potential is greatest during the early weeks after implantation, we postulate micromotion at this stage could hamper ingrowth around the fixation surface. Subsequent relaxation leading to reduced bearing friction allowed some regions to reestablish ingrowth, leaving some regions better ingrown while others were less or not ingrown.

Our findings suggest metal ion levels are lower with the LC BHR implant than with a CC BHR implant, particularly in the intermediate phase of bearing life. However, the presence of progressive radiolucencies raises the concern that LC may lead to increased bearing friction and affect implant fixation. The search for a bearing design that would reduce in vivo wear and in vivo friction must continue, but until then CC appears to be more tolerant toward manufacturing and functional variability effects.

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