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Stable Midterm Fixation of ASR Hip Resurfacing Arthroplasty and M2a-Magnum Cup – 5-years Follow-up on Migration, Bone Mineral Density, and Metal Ion Levels

Ming Ding[1], Jeannette Penny[1,2], Carsten Jensen[3,4], Ole Ovesen[1] and Søren Overgaard[1,5]*

[1]Department of Orthopedic Surgery and Traumatology, Odense University Hospital, Department of Clinical Research, University of Southern Denmark, Denmark

[2]Department of Orthopedics, Zealand University Hospital, Naestved and Koege, Denmark

[3]Department of Orthopedics, Kolding Hospital, Denmark

[4]Institute of Regional Health Research, University of Southern Denmark, Denmark

[5]Department of Orthopedic Surgery & Traumatology, Copenhagen University Hospital, Bispebjerg and Department of Clinical Medicine, University of Copenhagen, Denmark

Abstract

Background: Preservation of bone tissues was one of the motivating factors for the introduction of Resurfacing Hip Arthroplasty (RHA). We investigated the implant fixation of ASR™ RHA compared to Large-Diameter Head arthroplasty (LDH) and standard Total Hip Arthroplasty (THA) over a 5-year follow-up.

Patients and Methods: The patients included had primary or secondary osteoarthritis (age 44 to 66 years): 19 patients in the RHA group, 15 in the LDH group and 17 in the THA group. These patients were assessed by radiostereometric analysis, dual-energy X-ray absorptiometry, and whole blood analysis.

Results: Total translation and rotation of cups were performed between 2 months and 5 years to allow for bedding-in. The within-group mean change for total cup translation after 5 years was 0.10 mm and 0.57 mm in the RHA and LDA groups, respectively. Small changes in Bone Mineral Density (BMD) were found for all regions of interest across the 5 years in the acetabulum and femur. A significantly decreased BMD by 1.36% annually in the RHA occurred only in the cup regions. The blood cobalt and chromium levels were significantly increased by 24 and 13 times in the RHA group.

Conclusion: We demonstrated relatively stable midterm fixation of RHA compared to LDH and THA during the 5-year follow-up. Although stable fixation and lack of clinical revision indications, the elevated metal ion levels and decreased BMD behind the cup in the RHA group should be followed up to assess whether these changes will affect implant stability.

Keywords: Resurfacing hip arthroplasty; Large-diameter head arthroplasty; Radiostereometric analysis; Bone mineral density; Blood ion level

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Correspondence:
Ming Ding, Department of Orthopedic Surgery & Traumatology, Odense University Hospital, J.B. Winsloewsvej 15, 3rd Floor, DK-5000 Odense C, Denmark, Tel: + 45 6541 3598; E-mail: ming.ding@rsyd.dk

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Background

Preservation of bone tissues, especially in patients younger than 60 years, was one of the motivating factors for the introduction of Resurfacing Hip Arthroplasty (RHA) [1]. Moreover, RHA and Large-Diameter Head (LDH) use in Total Hip Arthroplasty (THA) were introduced aiming to increase Range of Motion (ROM), reduce wear and prevent dislocation risk as an alternative to standard THA. However, RHA has been abandoned and withdrawn from the market due to an increased failure rate compared to THA [2]. Despite this, many patients had already received RHA and the safety of RHA is an increasing concern. Therefore, it is of importance to report the follow-up results.

Radiostereometric Analysis (RSA) is a screening tool to predict aseptic loosening failure [3]. Despite displaying RHA implant stability by RSA [4], several brands of Metal-On-Metal (MoM) implants have reported failure rates above average. Aseptic loosening is the major cause of revision [5]; initial implant stability as measured by RSA alone is not an adequate measure for MoM implant survival. Cup design and position, small head size, rim collision and taper fretting with

resulting metal particles, particularly cobalt, are thought to cause the local adverse reactions to metal debris of MoM implants [6], which increase their revision rates.

The primary outcome of this trial has been reported [4]. The 2-year study showed no continuous migration by RSA [4], as well as bone preservation according to Dual-Energy X-ray Absorptiometry (DEXA) [7].

This study aimed to explore the 5-year outcomes of the DePuy ASR™ hip-resurfacing cup and stem and the ReCap cup compared to the LDH and the standard THA assessed by RSA, BMD changes in the acetabulum and femur, and whole blood ion levels. We hypothesized that a combination of RSA, BMD and blood ion level could better assess the stability of RHA fixation, which was similar to LDH and THA during the 5-year follow-up.

Patients and Methods

Study design

The study was a randomized clinical trial registered at ClinicalTrials.gov (https://clinicaltrials.gov/ct2/show/NCT01113762). Recruitment and surgery were conducted at two hospitals using identical inclusion and exclusion criteria [7].

Patients

The patients eligible to participate had primary osteoarthritis or secondary osteoarthritis due to mild dysplasia, and their ages ranged from 44 to 66 years (Table 1, Figure 1).

Ethics

The patients were randomized following the approval of the ethical review board of Funen County, Denmark (Project ID: VF-20050133) and informed consent.

Surgery

The surgery was performed through a posterolateral approach. There were three groups. (1) The RHA group received an Articular Surface Replacement (ASR™; DePuy, Leeds, UK). (2) The standard THA group received a titanium Mallory-Head acetabular shell, a 28-mm Biolox delta modular ceramic head, an Arcom Ringlock Polyethylene Liner and a titanium Bi-metric stem (Biomet, Brigde End, UK). None of the Biomet components were Hydroxyapatite (HA)-coated. (3) The LDH group received an M2a Magnum/ReCap articulation made from cast high–carbon cobalt–chromium, the cup with porous plasma spray, in combination with cement less forged titanium Bi-metric stem.

Assessment time-points

The patients were assessed preoperatively. RSA was performed at 2 months as a baseline to allow for creep and settling in. Follow-ups were performed at 2 and 6 months and 1, 2 and 5 years. For BMD measurement, the baseline was established within 3 days of surgery. Follow-ups were done at 2 months and 1, 2 and 5 years. Two sequential RSA and BMD examinations were performed on the same day, with repositioning between scans to perform double measurements at the 1-year follow-up.

Outcomes

Primary outcome: ROM was the primary outcome in the original clinical trial, but as later studies have failed to demonstrate significant ROM differences between hip arthroplasty concepts, we have abandoned this outcome in this paper.

Secondary outcomes: Secondary outcomes included RSA, whole blood chromium and cobalt ions as markers for the wear or local particle load [8], BMD, patient-reported outcome measures, T-cell count, X-ray, steps, sick leave, blood loss, days in hospital, surgery time, complications, and incision length. RSA was only done for the RHA and LDH groups. A similar study of RSA for THA has been published previously [9]. Within the limited space of this paper, we focused on the most important outcomes of RSA, BMD and metal ions, and five-year was decided as the endpoint.

Radiostereometric analysis: The insertion of tantalum beads has been described [4]. All RSA images were obtained in the same department using the same setting. The patients were placed in a supine position over a uniplanar *UmRSA® Calibration Cage™* (cage 43; RSA Biomedical, Sweden) with two ceiling-mounted X-ray tubes at an angle of 35 degrees to each other. The exposure was set to 130 kV and 20 mAs. All X-ray images were stored electronically in GE PACS (GE Healthcare, Waukesha, WI, USA). The X-ray images were retrieved via a DICOM computer link. Image analysis was performed with the software Model-Based RSA *vs.* 3.33 (Medis Specials, Leiden, Netherlands) using Elementary Geometrical Shape implant models (EGS-RSA). This model allows tantalum bead marking of components or reverse engineering of cup models [10]. For marker stability, an upper limit of 0.35 mm was selected for the mean error of rigid body fitting and an upper Conditioning Number (CN) of 150 for distribution. At the 1-year follow-up, double examinations of 13 RHAs and 10 LHDs were performed to assess the precision of the RSA system.

Dual-energy X-ray absorptiometry: BMD was measured using a Hologic 4500A (Waltham, MA, USA) DEXA scanner, applying the Hologic metal-removal software (version V8.26A/3). Scans were performed with a resolution of 0.5-line pair/mm and a speed of 2.5 mm/sec. The radiation dosage was 20 μSv per examination. The patients were placed in a supine position, with the hip was 15° internally rotated and controlled by strapping the leg in a suitably sized hard plastic shell [7]. We measured the acetabular BMD around the metal cup in four regions [11]. The proximal femur of the THA group was divided into seven Gruen zones [12].

Metal ions: Blood was sampled between the hours of 9 AM and 1 PM. Whole blood was chosen for a complete characterization of the actual blood ion levels and was sampled in trace element 6/7 mL Plus K2EDTA tubes (368381). Sampling and handling were performed as described previously [13], discarding the first sample. The whole blood was transferred to 3.8-mL acid-washed Nunc tubes (Thermo Fisher Scientific, Denmark), stored at -80°C and analyzed for cobalt and chromium content on an ICP-SFMS Finnigan ELEMENT (Finnigan MAT, Bremen, Germany) in an independent ISO 17025/ ISO 9001:2000 accredited lab (ALS Scandinavia's laboratories, Luleå, Sweden).

Statistical analysis

Power and sample size considerations for the original trial used ROM as the primary outcome. If at least 16 patients from each group completed the trial, the trial would yield sufficient power (80.0%) to detect ($P<0.05$), a between-group difference of 45° with an SD of 42°. To allow for dropouts, 20 patients were recruited to each group. Initially, the data were checked for completeness and normality. Continuous outcome measures were analyzed using change values and repeated measures mixed linear models, with patient as a random effect, fixed factors for group (two levels, RHA *vs.* LDH or THA *vs.*

Table 1: Baseline demographics, median (range).

	RHA	LDH	THA
n=	19	17	19
Age, years	57 (46 to 64)	61 (44 to 66)	55 (44 to 64)
Females, n (%)	8 (42)	8 (50)	3 (16)
BMI, kg/m²	28 (19 to 36)	29 (23 to 35)	28 (23 to 36)
Head size, mm	51 (47 to 57)	50 (44 to 56)	28

RHA: Resurfacing Hip Arthroplasty; LDH: Large Diameter Head hip arthroplasty; THA: Total Hip Arthroplasty (Standard)

LDH/RHA) and time to follow-up (5 to 6 levels [baseline, months, and years]) and the corresponding interaction term (group × time). Continuous outcome measures were reported as between-group change values with 95% CI. Where no between-group comparison could be made, the within-group change (time) was reported with 95% CI. To evaluate the precision of the system, we calculated the 95% limits of agreement as 1.96 times the standard deviation of the difference between two repeated measurements [14]. The statistical analysis was performed using STATA 15.1 (StataCorp LLC, College Station, Texas).

Results

Patients

In total, 334 individuals were initially assessed for eligibility by orthopedic surgeons, and 76 were randomized (Figure 1). At Centre One, 20 patients were randomized to RHA and 19 to standard ceramic-on-polyethylene THA, and at Centre Two, 17 received LDH and 15 had standard ceramic-on-polyethylene THA. Of those 76 patients who were randomized, 71 had surgery between April 2007 and November 2009. However, the data from the standard THA group at Centre Two was not used in this study. The patients in each of the remaining three groups had similar baseline characteristics except for the gender distribution (Table 1).

Radiostereometric analysis

The comparisons of the total translation and total rotation of cups were performed between 2 months and 5 years to allow for bedding-in (Table 2, Figure 2). The within-group (effect of time) mean change (± SE) for total cup translation after 5 years was 0.10 mm (0.16) and 0.57 mm (0.17) in the RHA and LHA groups, respectively, corresponding to a statistically significant between-groups difference of 0.48 mm. The within-group mean change (± SE) for total cup rotation after 5 years was 5.5° (2.4) and 2.2° (2.5) in the RHA and LHA groups, respectively, with a non-statistically significant between-groups difference of -3.4°. Stem migration for the RHA group was 0.35 (0.22) mm and -0.55 (0.47) mm translation and rotation, respectively (Table 2, Figure 2). For ASR and ReCap, the respective mean error of rigid body fitting was 0.15 (0.07) mm and 0.19 (0.07) mm; the CN was 56 (59), and 110 (123).

The precision analyses of double measurements were very good. The variations of x-, y- and z-rotations of segment motion relative to baseline were -0.32°, -0.39°, and -0.12°, and the x-, y- and z-translations were 0.04, 0.02 and -0.07 mm, respectively.

Dual-energy X-ray absorptiometry

Generally, small changes in BMD were observed for all regions of interest across the 5-year, and a significant between-group difference was only observed for the cup regions, revealing a -3.8% (-7.2 to -0.5; *P*=0.004) larger reduction in BMD for the RHA group compared with the THA group. No statistically significant between-group differences were seen for the RHA femur regions or the LDH cup or femur regions. The neck regions could only be analyzed for RHA, but an 8.3 % (2.0) increase was present (P<0.001; Table 3).

Blood metal ions

Whole blood as a characterization of the actual blood ion levels was elevated in the patients who received RHA implants. At 5 years, the levels for the RHA patients were significantly greater than for those who received THA implants for both cobalt (2.5 µg/L; *P*<0.01) and chromium (2.4 µg/L; *P*<0.01; Table 4). Metal ion measures for the LDH group between base line and 2 years were not performed.

Discussion

This comprehensive study reports 5-year outcomes of the ASR RHA compared to LDH and standard THA. From 2 months to 5 years, the mean change in total cup translation was 0.10 mm and 0.57 mm in the RHA and LDH groups, respectively. Small changes in BMD were found for all regions of interest across the 5 years in the acetabulum and femur. The actual blood ion level was significantly elevated in the RHA group but within the usual range for MoM implants.

All the implants have press-fit cups, with each type of cup manufactured using different materials. On the acetabular side, both RHA and LDH have large metal heads and are made of a cobalt

Table 2: Total translation and rotation for cups and stems by group and time, mean (**SD**) and change at 5-year follow-up.

		Follow-up time-point					Within-group change (mean ± SE)	Between-group difference in change (mean [95% CI])	*P*-value
		2 months	6 months	1 year	2 years	5 years			
Total Cup Translation (mm)[1]	*n*=	**18/16**	**15/15**	**17/15**	**17/15**	**15/14**			
	RHA	0.62 (0.46)	0.65 (0.44)	0.58 (0.41)	0.83 (0.74)	0.70 (0.49)	0.10 ± 0.16		
	LDH	0.78 (0.45)	1.02 (0.75)	0.77 (0.49)	0.87 (0.50)	1.34 (0.88)	0.58 ± 0.17	0.48 [0.01 to 0.94]	0.043
Total Cup Rotation (⁰)[2]									
	RHA	9.8 (5.0)	8.7 (6.1)	10.0 (6.4)[3]	8.9 (5.4)	15.0 (16.6)	5.5 ± 2.4		
	LDH	6.8 (5.5)	6.6 (8.1)	5.5 (3.6)	6.2 (4.6)	8.9 (6.0)	2.2 ± 2.5	-3.4 [-10.2 to 3.5][4]	0.339
Total Stem	*n*=	**17/-**	**15/-**	**19/-**	**17/-**	**18/-**			
Translation (mm)	RHA	0.40 (0.24)	0.44 (0.44)	0.58 (0.41)	0.51 (0.52)	0.75 (1.22)	0.35 ± 0.22[5]		
Rotation (⁰)	RHA	1.80 (2.85)	1.62 (1.28)	1.40 (1.58)	1.25 (0.83)	1.23 (0.92)	-0.55 ± 0.47[5]		

[1,2]The total translation and rotation was calculated using the 3-D Pythagorean Theorem: √(x2 + y2 + z2);
[3]Outliner detected – without 17.3 (30.6)
[4]Analysed without outliner
[5]Within-group (time) change

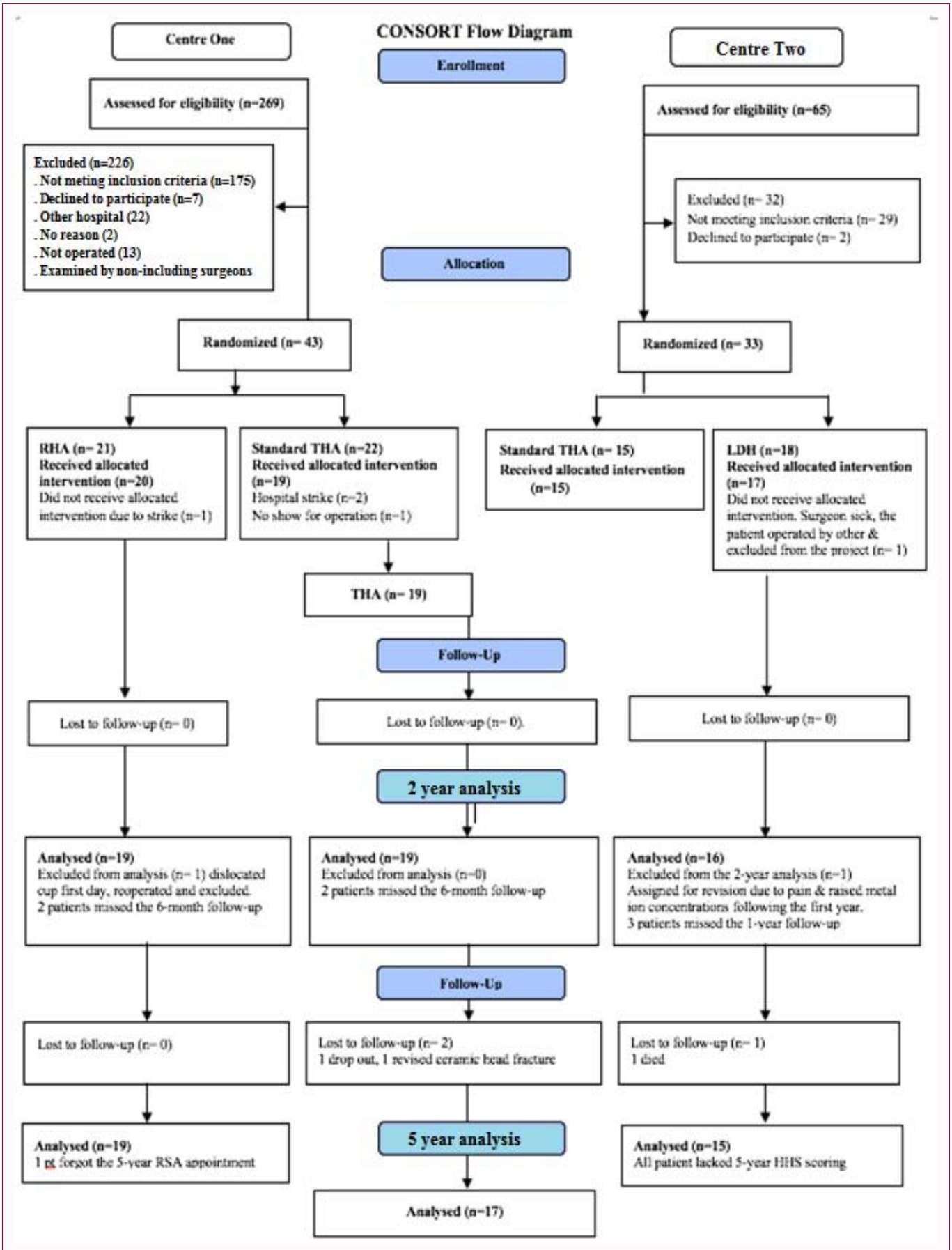

Figure 1: The Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing the inclusion and analysis process of the randomized controlled trial.

Table 3: Bone mass density (%) for cup, femur and neck by group and time, mean (SD) and change (95% CI) at 5-year follow-up.

	Implant	Follow-up time-points					Within-group Change (mean ± SE)	Between-group difference in change (mean [95% CI]))	*p*-value
		Base	2 months	1 year	2 years	5 years			
Cup, Wilkinsons [%][1]	*n*=	19/16/19	18/17/19	19/17/19	17/16/19	19/15/17			
	RHA	100	97.9 (3.3)	95.8 (3.9)	96.2 (4.7)	93.2 (7.5)	-6.8 ± 1.2	-3.8 (-7.2 to -0.5)[4]	0.026*
	LDH	100	99.3 (5.4)	101.5 (6.4)	100.2 (5.9)	98.9 (7.1)	-1.0 ± 1.3	2.0 (-1.5 to 5.4)[5]	0.267
	THA	100	98.3 (3.3)	96.9 (7.2)	97.6 (8.0)	96.5 (6.6)	-3.0 ± 1.2		
Femur, Grüen [%][2]	*n*=	-/-/-	13/17/18	15/17/19	13/16/19	15/15/17			
	RHA	100	98.6 (2.2)	101.8 (2.7)	103.2 (3.6)	102.0 (3.8)	2.0 ± 1.0	1.3 (-1.2 to 3.9)[4]	0.314
	LDH	100	94.4 (4.8)	97.8 (6.0)	98.5 (6.8)	99.5 (6.0)	-1.4 ± 1.2	-2.1 (-5.2 to 1.0)[5]	0.187
	THA	100	96.0 (3.3)	99.2 (4.3)	100.2 (4.9)	100.8 (5.6)	0.7 ± 0.9		
Neck, Kishida [%][3]	*n*=	-/-/-	19/-/-	19/-/-	17/-/-	19/-/-			
	RHA	100	97.8 (4.3)	105.3 (8.6)	109.6 (12.8)	108.3 (12.3)	8.3 ± 2.0		
	LDH	100	-						
	THA	100	-	-	-				

[1]Total for 4 Wilkinsons regions; [2] Total for 7 Grüen regions; [3] Total for 6 Kishida regions; [4] THA (ref) vs. RHA; [5] THA (ref) *vs.* LDH

Table 4: Whole blood ion content by group and time, mean (SD) and change (95% CI) at 5-year follow-up.

	Implant	Follow-up time-points						Between-group difference in change (mean [95% CI]))	*P*-value
		Base	2 months	6 months	1 year	2 years	5 years		
	n=	18/-/19	18/-/15	16/-/17	19/-/19	18/-/19	18/11/17		
Cobalt, [µg/L]	RHA	0.12 (0.13)	1.20 (0.71)	1.37 (1.12)	1.98 (1.54)	2.66 (2.32)	2.91 (3.00)	2.5 [1.6 to 3.3][1]	<0.01
	LDH	-	-	-	-		1.44 (0.99)		
	THA	0.07 (0.04)	0.12 (0.08)	0.09 (0.06)	0.10 (0.06)	0.12 (0.14)	0.37 (0.30)		
Chromium, [µg/L]	RHA	0.22 (0.33)	0.90 (0.54)	1.22 (0.77)	1.80 (1.74)	2.30 (2.04)	2.86 (2.95)	2.4 [1.5 to 3.2][1]	<0.01
	LDH	-	-	-	-		4.85 (10.3)		
	THA	0.21 (0.12)	0.18 (0.10)	0.29 (0.17)	0.29 (0.27)	0.31 (0.17)	0.51 (0.23)		

[1] THA (ref) *vs.* RHA

chrome alloy, where the standard THA is made from a softer titanium alloy. In addition, the RHA has an HA coating with aiming advantages in fixation and bone ingrowth [15]. But randomized studies between HA-coated and non-HA coated cups have revealed no differences in acetabular BMD within 3 years [16], and only minor changes occur after 8 years [17]. Our study reveals that RHA is relatively stable with no revisions over a 5-year follow-up. This study suggests that RHA is a viable concept; MoM bearings are well-suited for this procedure when a well-designed device is properly implanted [18].

For the cup region, reductions of BMD in all groups were observed, but only the BMD reduction around RHA implants was significant. For the femoral regions, there were no significant increases of BMD in the RHA and THA groups, and a non significant decrease in the LDH group. A similar study reported that acetabular BMD was better preserved behind a rigid press-fit convex cup in RHA compared to a titanium threaded cup in conventional but small-diameter metal-on-metal THA [1]. However, the increasing incidence of revisions for adverse reactions to metal debris among small-head MoM THA has been a concern [19]. Several studies have shown that LHD implants have a higher revision rate than both RHA and the standard THA, but the failure mechanism is under debate [19,20].

An attempt to group regions to fit the Wilkinson classification (Table 3) cannot support that cobalt–chromium shells shield the bone behind the cup to a greater degree than titanium. MoM cobalt–chromium shells with HA coating could seem to be a disadvantage. The stems in our study were identical, and apart from an unexplained increase in Gruen zone 1 for the THR, they identically affect the surrounding bone. A pattern similar to other THRs showed a postsurgical decrease of BMD especially pronounced in Gruen zone 7. The pattern seems to be a common feature independent of the resurfacing materials [21,22].

Regardless of head size and cup material and stiffness, proximally fixed uncemented. THAs transfer load to the proximal femur in a similar manner, resulting in stress shielding of the calcar. On the acetabular side, no drawbacks or advantages were observed for LDH, and only minor BMD percentages separated different press-fit cups, regardless of concept, coating and stiffness. None of the implants displayed evidence of failure during the study period.

Whole blood ion levels were significantly elevated in the patients who received the RHA implants. At 5 years, the levels of cobalt and chromium were 24 and 13 times greater compared to baseline and 7.8 and 5.6 times greater compared to the standard THA, respectively. Our results are similar to a recent study that reported the levels of metal ions in the blood increased significantly over the period until midterm follow-up in patients with both a MoM HRA and a MoM THA [23]. On the other hand, metal ion levels did not increase in patients with bilateral ReCap-M2A-Magnum THR with a mean 1.9-year measurement interval [24].

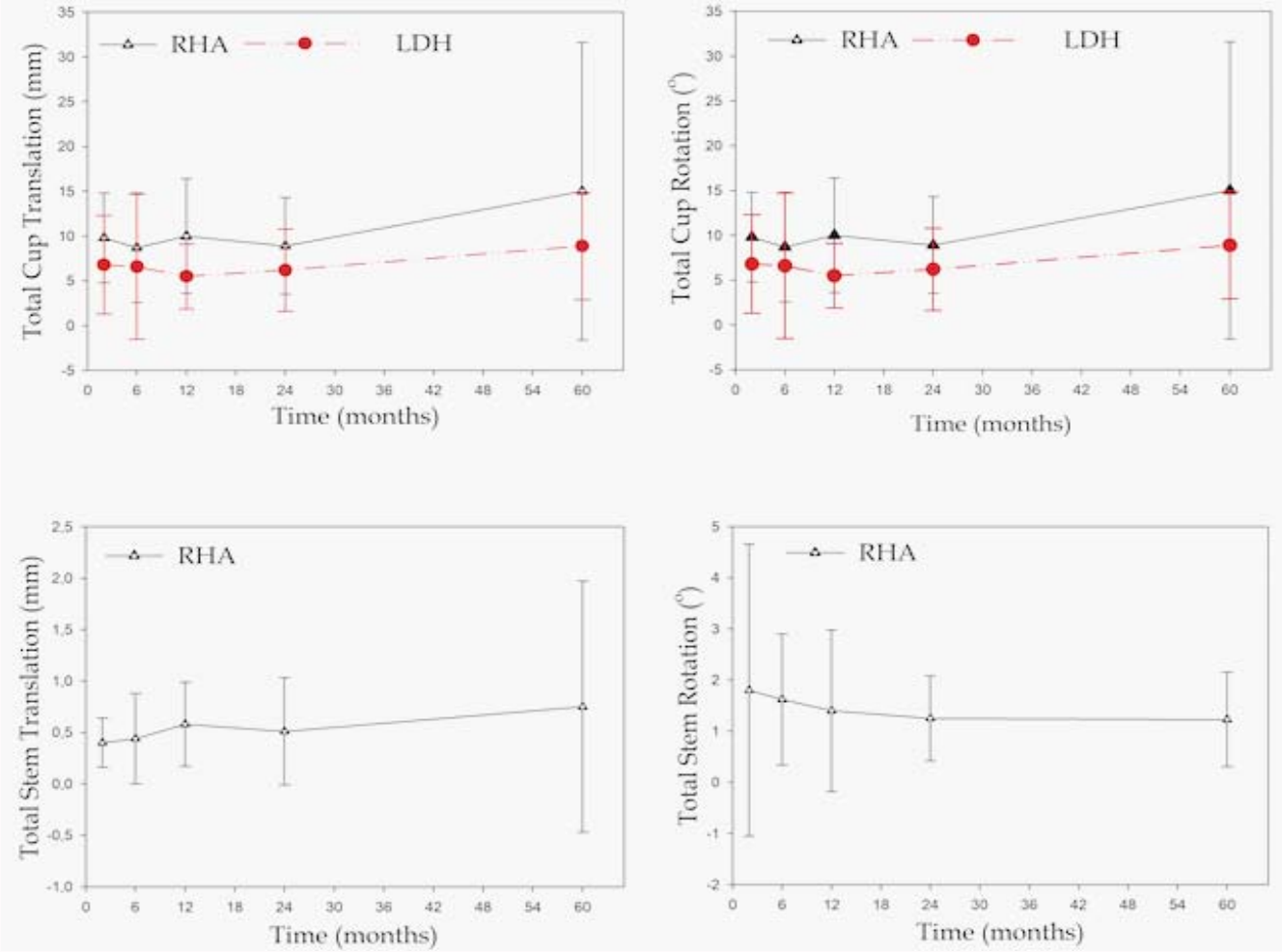

Figure 2: Total cup translation (a) and total cup rotation (b) of the RHA and LDH groups, and total translation (c) and rotation (d) of the RHA, between 2 months and 5 years by RSA.

This study has some limitation. Because a relatively limited number of patients were included, interpretation of the results should be cautious. The metal ion measures for the LDH group between base line and 2 years were not performed. Nevertheless, the study has several strengths. We compared RHA to LHD and standard THA in the same study design. Several well-validated methods were performed to quantify the migration, BMD, and blood iron levels over a follow-up of 5 years, which lead to convincing results. True randomized comparisons between RHA and the standard THA are scarce, so this study is valuable in the current debate about whether RHA should be abandoned or maintained.

Conclusion

This study demonstrated stable midterm fixation of ASR RHA compared to LDH and the standard THA during the 5-year follow-up. The changes in RHA were not similar to LDH and the standard THA over time. Small changes in BMD were observed for all regions of interest across the 5 years in the acetabulum and femur, and a significantly decreased BMD in the RHA by 1.36% annually was observed only for the cup regions. Whole blood ion levels were significantly elevated in RHA over time. Further follow-ups are necessary to investigate whether these parameters will change and affect implant stability over longer periods and whether it has clinical benefits in future revision surgery.

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Author contributions

MD: Collection of data, data analysis and interpretation, writing partial manuscript, and revising manuscript. JP: Study design, collection of data, data analysis and interpretation, writing and revising manuscript. CJ: Data analysis and interpretation, statistical analysis, and critical comments. OO: Study design, performing surgery, and critical comments. SO: Study design, performing surgery, and critical comments. All authors have proved the final version.

The authors have no conflict of interest to declare.

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