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Periacetabular Bone Mineral Density Changes After Resurfacing Hip Arthroplasty Versus Conventional Total Hip Arthroplasty. A Randomized Controlled DEXA Study

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ABSTRACT

A randomized controlled trial was performed to evaluate acetabular bone mineral density (BMD) changes after hip resurfacing (RHA) versus an established conventional total hip arthroplasty (THA). A total of 71 patients were allocated randomly to receive either an RHA press-fit cobalt–chromium cup ($n = 38$) or a THA with a threaded titanium cup and polyethylene-metal-inlay insert ($n = 33$). The BMD in five separate periacetabular regions of interest (ROI) was prospectively quantified preoperative until 24 months. We conclude that, in contrast to our hypothesis, periacetabular BMD was better preserved after RHA than after placement of a conventional THA. Long term follow-up studies are necessary to see whether this benefit in bone preservation sustains over longer time periods and whether it is turned into clinical benefits at future revision surgery.

One of the biggest concerns in total hip arthroplasty is long-term acetabular fixation and preservation of bone stock. According to the Swedish hip register 65% of all re-operations are because of an acetabular component revision [1]. A 30-year follow-up of the Charnley arthroplasty by Callaghan et al. [2] shows that revision of the cup is three times more common than stem revision. Polyethylene wear of acetabular components is a key factor in the development of periprosthetic osteolysis [3,4]. Periprosthetic osteolysis with loosening of the socket frequently opposes the orthopedic surgeon with challenging acetabular bone defect reconstructions. Metal-on-metal (MoM) hip arthroplasty was introduced as an alternative to overcome polyethylene wear related prosthetic failure. Proposed advantages are a reduction of wear, a subsequent lower incidence of periprosthetic osteolysis and eventually improved prosthetic survival [5]. On the other hand, a resurfacing hip prosthesis needs a rigid and thick shell press-fit socket. Such a relatively thick and rigid socket makes the implant stiffer and more susceptible to localized bone resorption caused by stress shielding behind the implant [6]. These press-fit cups transmit forces sideways to the peripheral cortical bone which induces stress shielding and a subsequent decrease of the cancellous bone mineral density (BMD) behind the cup [7–9]. The main theoretical benefit of resurfacing is the bone-preserving nature of the technique on the femoral side, however, when stress shielding results in osteolysis behind the cup, this benefit would be ineffective, if not detrimental. Finite element analyses predict medial bone loss up to 50% caused by stress shielding, and a bone gain near the prosthetic rim of press-fit cups (which is the main loading site of the pelvis) [10]. Clinical DEXA studies on metal-on-poly (MoP) conventional THA confirm these results [11,12]. Little is known about periprosthetic acetabular BMD changes around MoM implants and resurfacing hip arthroplasty (RHA) in particular. So far, only one study evaluated the acetabular BMD after RHA [13]. In that study the periacetabular BMD was evaluated 1 year after an RHA and compared to the BMD in the contralateral non-operated hip, no prospective changes in BMD were recorded in this study. A randomized comparison between RHA and conventional THA for periacetabular BMD changes has not been previously reported. For this reason, we performed a prospective randomized controlled trial of an RHA versus a conventional MoM THA and evaluated BMD changes in five periprosthetic regions of interest (ROI) of the acetabulum. We hypothesized that due to stress shielding behind the RHA cup a more profound BMD decrease would be encountered as compared to an established threaded conventional THA cup.

Materials and Methods

This randomized study was designed to compare, amongst other outcome parameters, the periprosthetic BMD changes in the acetabulum of patients who received an RHA against a conventional

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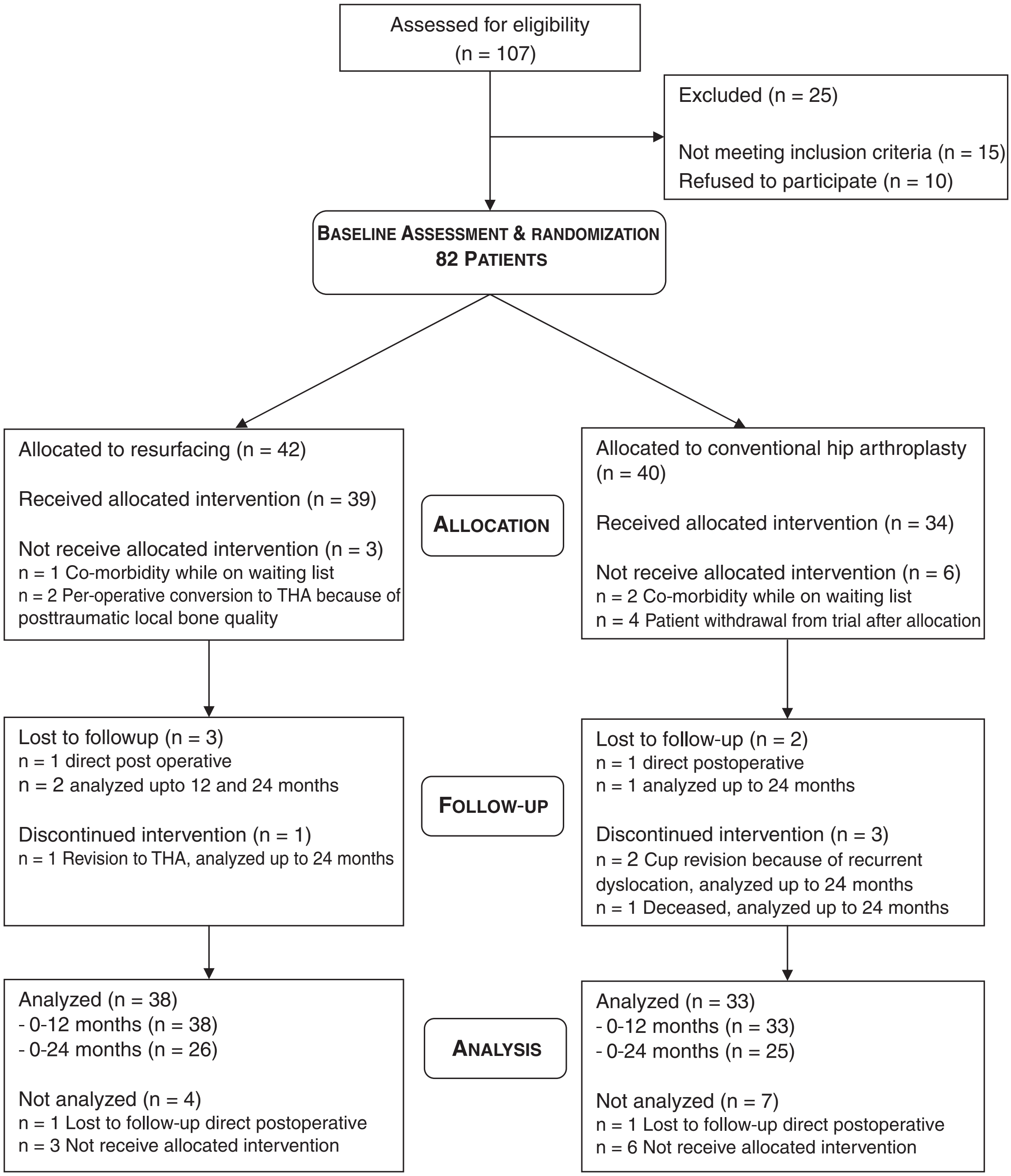

Fig. 1. Consort statement: flowchart of participants throughout the study.

uncemented MoM THA. The BMD of the femoral side of these patients has already been reported by our group [14], we now present a further recruitment of patients.

From June 2007 till January 2010 82 patients were randomly assigned to receive one of the two hip implants types (RHA versus THA). A computer-generated variable block schedule was used for randomization. The randomization list was generated by an independent statistician and the resulting treatment allocations were stored in sealed opaque envelopes. Randomization occurred at the outpatient consultation by the orthopedic surgeon at the time of planning the hip arthroplasty. Patient and the surgeon could not be blinded for the eventual type of implant, neither could they influence the randomization outcome. The criteria for inclusion were patients under 65 years, who needed a primary hip replacement for osteoarthritis. Patients were excluded if they had (previous) infection of the hip or other sites, hip fracture, avascular necrosis with collapse, osteoporosis,

Table 1
Clinical details of the patients in both groups.

	RHA ($n=38$)	THA ($n=33$)	*P*
Gender (women/men)	17/21	13/21	.637[a]
Mean BMI (SD)	26.1 (3.1)	28.0 (5.1)	.083[b]
Median acetabular cup size (range)	54 (48–60)	64 (58–68)	<.001[c]
Median age at operation in years (range)	57.5 (40.7)	59.1 (27.8)	.475[c]
Diagnosis (OA/AVN/CHD)	35/1/2	32/0/2	.639[d]
Median blood loss in mL (range)	300 (100–600)	250 (100–900)	.993[c]
Mean operating time in minutes (range)	75.0 (40)	54.0 (45)	<.001[b]

OA = osteoarthritis, AVn = vascular necrosis, CHD = congenital hip dysplasia.
[a] Fisher's exact probability test.
[b] Student's *t*-test.
[c] Mann–Whitney *U* test.
[d] Kruskal–Wallis test.

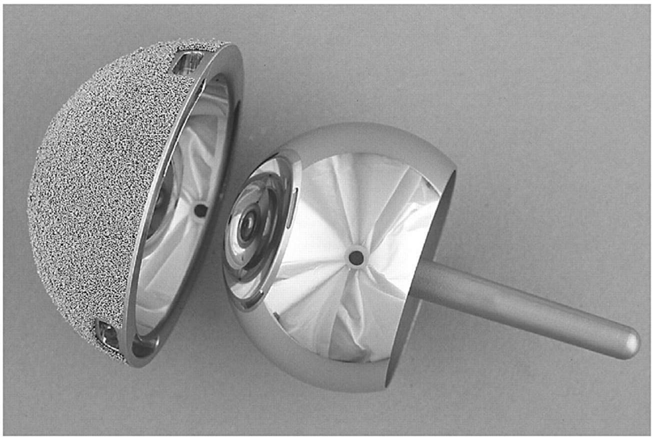

Fig. 2. Conserve plus hip resurfacing; Wright Medical Technology, Arlington, Tennessee, USA.

neoplasm, or renal failure. Inclusion and subsequent follow-up of patients is summarized in the consort statement (Fig. 1). Five patients (three RHA, two THA) were lost to follow-up; directly after operation ($n = 2$), after 12 months ($n = 1$) and after 24 months ($n = 2$). Three patients (one RHA, two THA) did not participate in all follow-up moments because of revision after 24 months, one patient passed away. One RHA was revised for unexplained pain and subtle signs of a periprosthetic adverse reaction to metal debris (ARMD) on MRI scan, in two patients with a THA a relatively simple insert exchange was performed for recurrent dislocation. Seventy-one patients had a follow-up of 12 months; 38 RHA patients, and 33 THA patients, 51 patients had a follow-up of 24 months (Table 3). There were no significant differences between both groups for age, gender and BMI (Table 1). Approval from the regional ethics committee from the Radboud University Nijmegen Medical Centre was obtained (LTC 419-071206). All patients agreed to sign an informed consent form. The study was performed in compliance with the Helsinki declaration, and is registered in EudraCT (2006-005610-12).

Surgical technique

Preoperative digital templating (Easyvision, Philips Medical Systems, Eindhoven, The Netherlands) for positioning of the implant was carried out for all patients. All surgeries were carried out by one of the authors (JvS) and two other experienced hip surgeons through a posterolateral approach. In the RHA group a resurfacing prosthesis was implanted with both components made of a cast, heat-treated solution-annealed Co–Cr alloy (Conserve plus; Wright Medical Technology, Arlington, Tennessee, USA) (Fig. 2). The femoral component was cemented with low-viscosity cement after preparation of the femoral head with multiple subchondral anchor holes, the 6-mm hydroxyapatite (HA)-coated acetabular component was press-fitted in the acetabulum (underreamed by 1 mm). The surgical technique has been described earlier [15]. In the THA group, an uncemented grit-blasted titanium alloy Zweymüller tapered stem was press-fitted in the femoral canal and a threaded solid backed titanium acetabular component was screwed in the acetabulum without additional screw fixation (Fig. 3). As this trial was designed to minimize confounding variables, a metal-on-metal bearing was also used for the THA together with a metal 28-mm head (Alloclasic

Fig. 3. Alloclasic Zweymüller CSF with Metasul inlay; Zimmer Orthopaedics, Warsaw, Indiana, USA.

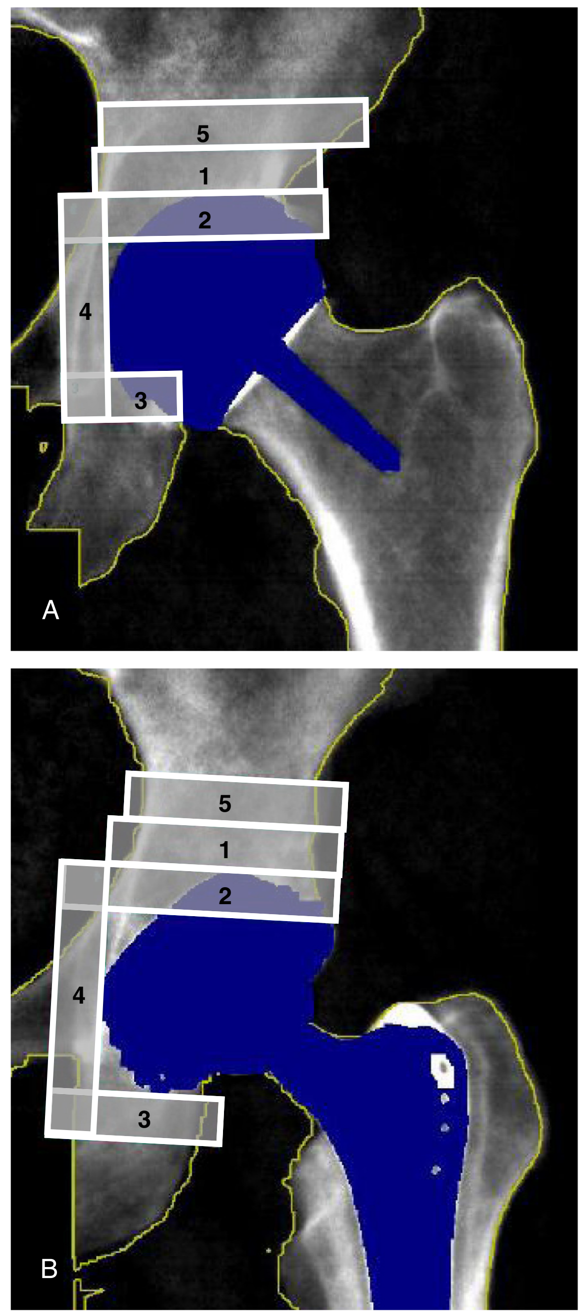

Fig. 4. Typical example of the measurement of BMD in the separate ROIs by dual energy x-ray absorptiometry of RHA (A) and THA (B).

Table 2
Percent coefficient of variation (CV%) in ROIs 1 to 5.

	ROI					
	1	2	3	4	5	Mean (SD)
CV%	1.3	2.2	3.0	4.0	2.5	2.6 (0.9)

Zweymüller CSF with Metasul inlay; Zimmer Orthopaedics, Warsaw, Indiana, USA). Both groups received identical antibiotic prophylaxis with Cephalosporin preoperative and 24 h postoperative, 3 days of Diclophenac for periarticular ossification prophylaxis, and thrombosis prophylaxis with Fraxiparine until 6 weeks postoperative. Patients were rehabilitated with immediate unrestricted weight bearing according to patient's tolerance [16].

Bone densitometry

BMD measurements and software have been described previously by our group [14]. Briefly, the BMD was measured by dual energy x-ray absorptiometry (DEXA) (Lunar Prodigy, GE Healthcare, United Kingdom) with software package 13.60.033. Measurements were performed 2 weeks preoperatively and then at 3, 6, 12 and 24 months after surgery. The patients were positioned supine with their feet attached to a positioning device to obtain a standardized reproducible 20° of internal rotation. Mortimer et al. [17] found that a range of 15° internal to 15° external rotation yields a precision of 1.7%. Five ROI were carefully defined, modified from the regions defined by Wilkinson et al. [18] (Fig. 4). For each patient standardized analysis of each ROI was obtained using the manufacture's metal exclusion software. Since the ROI could only be defined after implantation of the hip arthroplasty, these ROIs were imported in the preoperatively available DEXA scan to measure baseline BMD levels in the absence of the implant. Tests using phantoms have shown that DEXA is accurate for the determination of periprosthetic BMD with an error below 1% [19]. In addition, precision and reproducibility of the DEXA measurements for each region in this study were assessed on 15 patients (11 male, 4 female; 8 RHA and 7 THA) with a mean age of 53 years (range 34–63). They underwent two sequential DEXA examinations of the involved hip, taken on the same day and measured twice by two independent laboratory assistants, with repositioning between each scan. The precision error was expressed as the coefficient of variation percentage, calculated according to Aldinger et al. [20]. The precision in our study (Table 2) was adequate and consistent with the literature [18,20,21]. Additional quality controls for the DEXA equipment were undertaken daily according to the manufacturer's guidelines to verify the stability of the system. No change was observed during the entire study period.

Statistical analysis

We conducted a power analysis based on the article of Lian et al. [22]. The minimal number of participants needed in each group, to obtain a power of 80%, was determined at 34 patients, with a calculated difference of 2.98 percent (SD 6.14) in mean relative BMD. All BMD data were normally distributed and the differences in each ROI between the two groups preoperatively and at 3, 6, 12 and 24 months after surgery were analyzed using a Student's *t*-test. The change of the BMD in each ROI over each observation period was assessed by repeated analysis of variance for the two groups. To compare the changes between the time intervals, the mean relative BMD as a percentage of the baseline value (presented as 100%) was calculated. All normally distributed data are expressed as group means ± SD. When not normally distributed a median and a range are given. Differences were considered statistically significant at $P<.05$ All statistical analyses were performed using SPSS software (version 18.0).

Results

Patient characteristics are presented in Table 1. The mean operating time for the RHA group was significantly longer than for the THA group ($P<.001$), demonstrating the inherent technical difficulty of the resurfacing procedure. The acetabular cup of the THA was significantly bigger than the RHA ($P<.001$). Preoperatively the BMD of ROI 3 (caudal zone) significantly differed between the two study groups with a higher BMD in the RHA group ($P=.006$) (Table 3). The mean relative BMD change for each ROI, obtained during the 24-month follow-up, is shown in Fig. 5.

For RHA patients, the mean relative BMD of the medial ROIs 2 and 4 showed a significant overall decrease ($P<.001$, $P=.022$) in time. Cranial and caudal ROIs 1, 3 and 5 remained stable around the preoperative baseline levels values until 24 months ($P=.356$, $P=.404$, and $P=.274$ respectively) (Fig. 5). After a THA the BMD of ROIs 1, 2, 3 and 4 showed a significant decrease ($P=.001$, $P<.001$, $P<.001$, and $P=.043$ respectively). This decrease was most significant at 3 months ($P=.004$, $P<.001$, $P=.006$, and $P=.023$ respectively). The mean relative BMD of ROI 5 remained stable for THA patients ($P=.055$).

There were significant differences between the two groups in mean relative BMD. Twelve months after surgery the mean relative BMD was significantly higher for RHA in all ROIs except for ROI 4 ($P=.028$, $P=.001$, $P=.040$, $P=.293$, and $P=.006$, for ROIs 1, 2, 3, 4 and 5 respectively). At 24 months a significantly higher mean relative BMD still existed for ROIs 1, 2 and 5 ($P=.030$, $P=.046$, $P=.013$). In ROIs 1

Table 3
Mean BMD (in g/cm^2) (SD) for both groups in the postoperative period.

		Cranial		Medial		Caudal
Group	Time (months)	ROI 1	ROI 5	ROI 2	ROI 4	ROI 3
RHA						
($n=35$)	0	1.78 (0.24)	1.71 (0.31)	2.01 (0.29)	1.48 (0.48)	1.48[a] (0.47)
($n=38$)	3	1.73 (0.29)	1.70 (0.36)	1.54 (0.35)	1.39 (0.52)	1.48[a] (0.47)
($n=38$)	6	1.76 (0.30)	1.72 (0.34)	1.53[a] (0.37)	1.39 (0.52)	1.45[a] (0.45)
($n=38$)	12	1.75 (0.33)	1.72 (0.36)	1.57[a] (0.41)	1.39 (0.49)	1.53[a] (0.51)
($n=26$)	24	1.77 (0.41)	1.73 (0.37)	1.54[b] (0.45)	1.40[b] (0.54)	1.45[a] (0.57)
THA						
($n=32$)	0	1.78 (0.33)	1.76 (0.39)	2.03 (0.35)	1.34 (0.60)	1.19[a] (0.35)
($n=33$)	3	1.67 (0.29)	1.64 (0.35)	1.46 (0.29)	1.23 (0.56)	1.08[a] (0.35)
($n=33$)	6	1.63 (0.32)	1.67 (0.38)	1.35[a] (0.28)	1.25 (0.54)	1.07[a] (0.31)
($n=33$)	12	1.61 (0.37)	1.61 (0.37)	1.31[a] (0.27)	1.21 (0.57)	1.07[a] (0.27)
($n=25$)	24	1.60[b] (0.35)	1.60[b] (0.39)	1.34[b] (0.29)	1.24[b] (0.46)	1.05[a,b] (0.24)

[a] Significant difference between RHA and THA ($P\leq.05$).
[b] Significant difference against baseline at repeated measures within each ROI ($P\leq.05$).

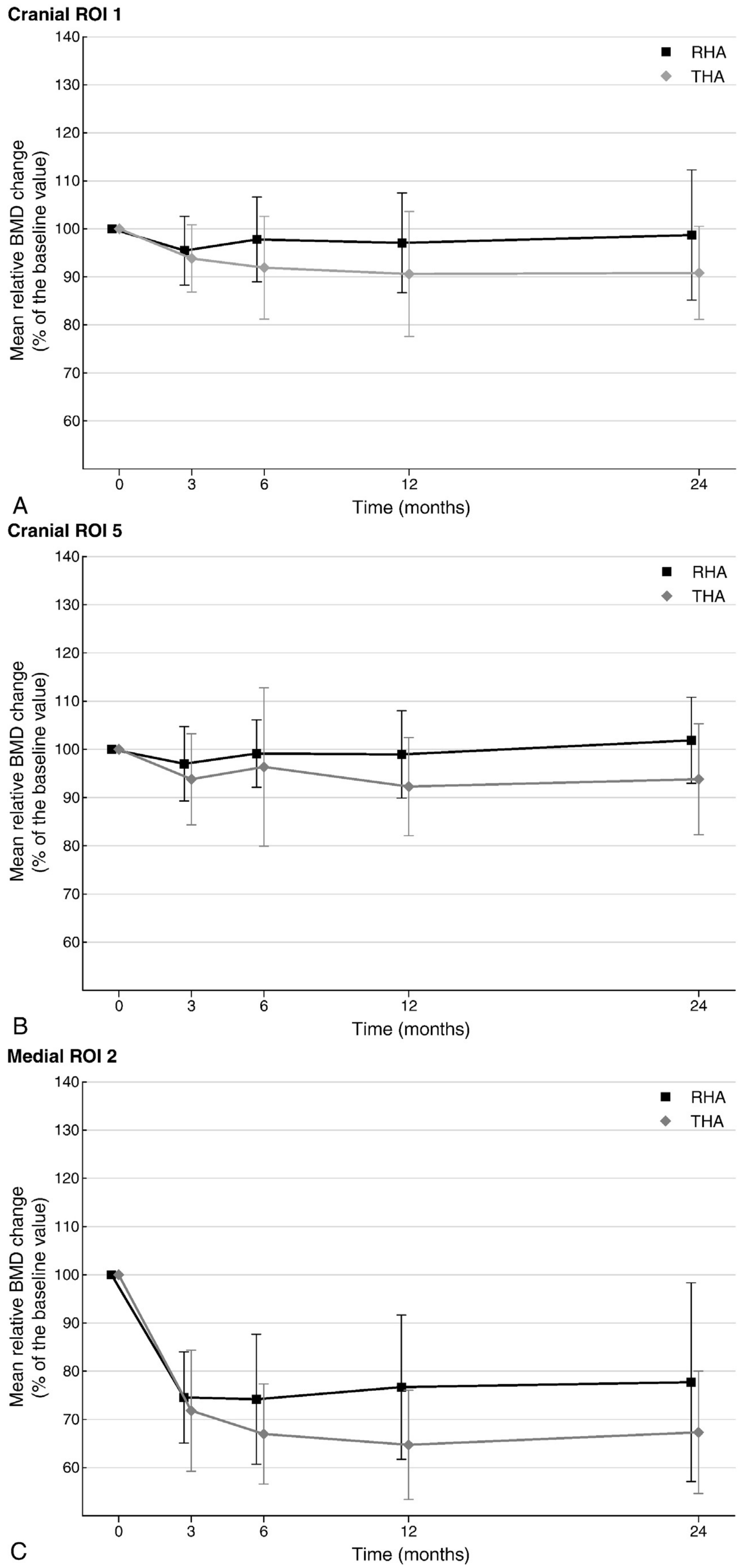

Fig. 5. Graph of the mean relative BMD change, as percentage of preoperative baseline values with error bars indicating one standard deviation for all ROI of RHA (black line) versus THA (gray line). (A) Cranial to the acetabular cup ROI 1. (B) Cranial to the acetabular cup ROI 5. (C) Medial to the acetabular cup ROI 2. (D) Medial to the acetabular cup ROI 4. (E) Caudal to the acetabular cup ROI 3.

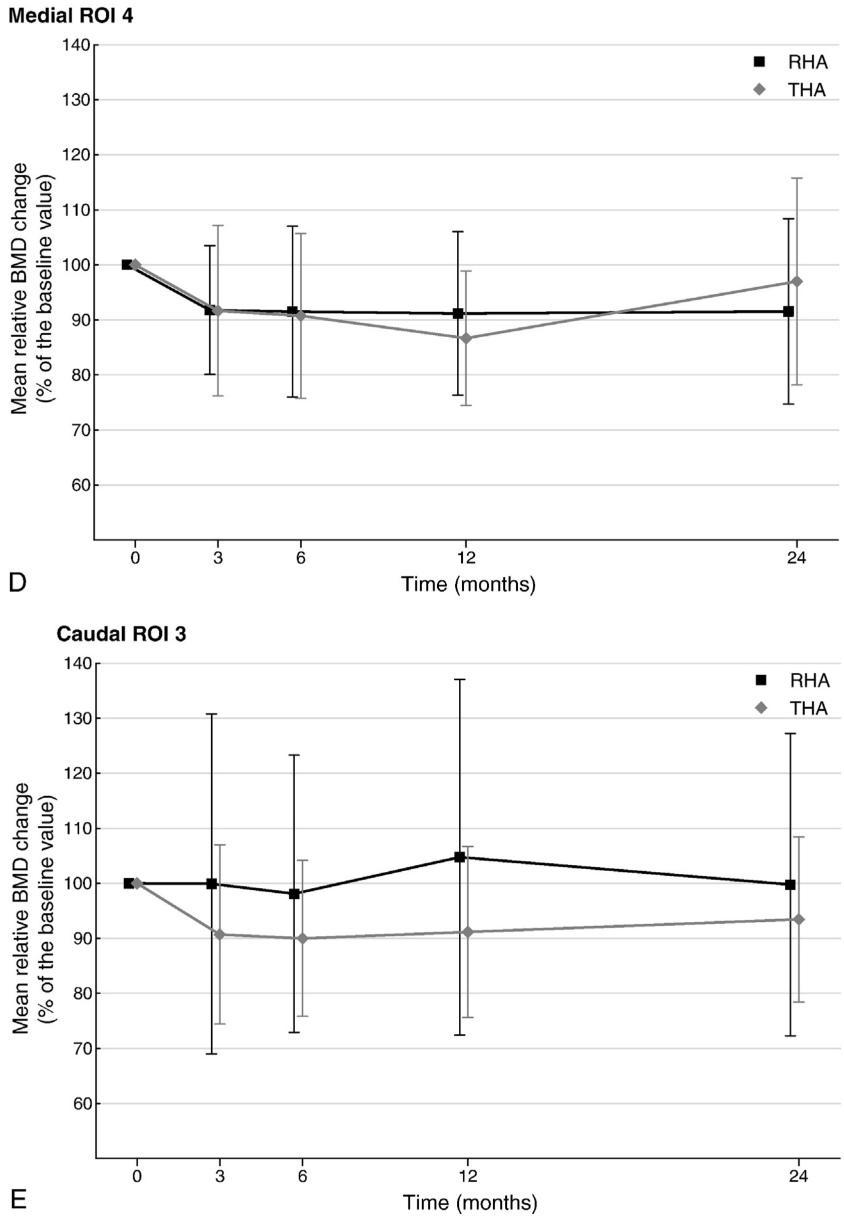

Fig. 5 (*continued*).

and 2 there was also a difference at 6 months in favor of RHA ($P=.017$, $P=.018$). The pattern of postoperative BMD decrease in ROI 2 was similar in both groups (Fig. 5) with a steep decline in BMD from baseline till the first evaluation at 3 months.

A difference of 13.6% between the two groups in mean relative BMD was obtained for the caudal ROI 3, at 12 months. In this region the BMD increased up to 105% for RHA versus a decrease up to 91% for THA ($P=.040$). At 24 months there were only significant differences between RHA and THA in ROI s1, 2 and 5; 7.9% ($P=.030$), 10.4% ($P=.046$) and 8.1% ($P=.013$) respectively, in favor of RHA.

Discussion

This prospective randomized controlled study shows that after an RHA both cranial ROIs remained stable around baseline levels whereas for one cranial ROI the BMD decreased significantly after THA. As for the two medial ROIs, the BMD decreased significantly for both implants ($P<.05$), in one of these ROIs this difference was in favor of the RHA group. BMD remained stable in the caudal ROI for RHA, whereas a significant decrease was found in the caudal ROI for THA.

These results suggest that, unlike our hypothesis, the acetabular bone was better preserved after the RHA with the rigid press-fit cup. The observed decrease in BMD medial to the cup (ROIs 2 and 4) of 23% and 8.5% for RHA and 32% and 3% for THA at 24 months are in concordance with earlier literature on BMD changes after press-fitted cups of a conventional THA. In clinical [12,23,24] and finite element [10,25] studies a 5% to 50% decrease was found in the ROI medial to the acetabular cup. The BMD preservation of RHA patients was most profound cranial to the cup (ROIs 1 and 5) for RHA patients. This is in accordance with the recent report from Yahia et al. [13] where similar results were found 2 years postoperative. In contrast to other studies, where a 3% to 35% decrease of cranial acetabular BMD was seen after the placement of a press-fit cup [7,9,23,26,27], we only found a significant decrease for one of the two cranial ROIs in the THA group. As confirmed in other studies we found the most rapid changes in BMD in the first 6 months after surgery, but (smaller) BMD changes still occurred until 24 months [27–29].

Wear and osteolysis are probably the most important factors that limit the survival of metal-on-poly THA. The articulation of the metal ball against the polyethylene cup of the acetabular component creates polyethylene wear debris. The macrophage-mediated response to these implant-derived particulate debris and probably other stimuli, results in local osteoclastic bone resorption [30]. Using a metal-on-metal bearing might prevent this wear-induced osteolysis, but does not overcome stress shielding and subsequent adaptive remodeling. Stress shielding is a major reason for periprosthetic bone loss after THA, because of changes in load distribution as a consequence of the rigidity of an implant [7,25]. Theoretically, the thicker and stiffer press-fit acetabular cup of an RHA may increase periacetabular bone stress shielding [7–9,13]. The rationale behind differences in stress shielding for press-fit or threaded cups is based on the elasticity modulus, whereas titanium is half as stiff as cobalt–chromium–molybdenum alloy (modulus of elasticity 114 vs. 214 GPa). Therefore, one would expect that the stiffer and more robust monoblock cobalt–chromium shell would show more bone loss because of increased stress shielding as shown “in vitro” [7]. We found the opposite, the monoblock shell preserved relatively more cranial acetabular bone compared to the titanium threaded cup. Possibly the differences in modulus of elasticity between the two bearings in vivo were insufficient to effect the same quantitative changes in the BMD over the 2 years of the study. In our observations that overall more BMD decline was encountered for THA patients as compared to RHA, we also have to realize that firm conclusions can only be drawn for the implants used in our study. The use of a metal-on-metal bearing with the THA may for example have stiffened the acetabular component leading to more profound stress shielding and BMD decline. On the other hand we do feel that this potential influence may have been minimal. What we know from our clinical data of these patients is that RHA patients reach a higher activity level then patients with a conventional THA [31], this might be a possible confounder. This higher postoperative activity level may have contributed to a reduced postoperative bone loss in the RHA group [32]. On the other hand the encountered difference in activity score in favor of RHA patients was only limited and we do not feel that the difference in BMD changes from can be explained by this phenomenon.

A remarkable finding in our study is the major decrease of BMD within the first 3 months of ROI 2 in both groups, whereas in other clinical studies [23,33] a more gradual medial BMD loss between 5% and 17% until 1-year postoperative has been described. All these studies, however, have their baseline measurements 1 to 6 weeks postoperative and therefore all measurements on BMD were performed on the postoperative situation with the implant in situ. One of the strengths of our study was the use of serial BMD measurements which are recorded truly against the preoperative baseline values, unlike the study of Yahia et al. [13] who compared with the contralateral non-operated side only at one time interval. We believe that the steep decline in BMD in the medio-cranial ROI 2 between the preoperative situation and 3 months after surgery can simply be explained iatrogenic by subchondral reaming and bone removal at the time of implantation and not by stress shielding. There are some remarkable findings in ROI 3 as well. At first, we found a lower preoperative BMD for the THA patients. We do not have an explanation for this difference, as all other patient characteristics appeared to be matched after randomization. It could have had an influence on the results as there is a significant relationship between periprosthetic femoral bone loss and the preoperative BMD [28]. Secondly, at 12 months we found an increase in BMD to 105% for RHA, this can be explained by an outlier of 260%. Without this outlier the mean relative BMD would be 100%. Lastly, at all time intervals the standard deviation in ROI 3 of the RHA groups is almost twice as large compared to THA. The reason might be the difficulty of ROI analysis, although the coefficient of variation is only 3%, which is relatively low.

Limitations of this study consist of the fact that patients and reviewing surgeons were not blinded. However, we do not see how these two factors can be overcome and are convinced that this has not biased our results. In RHA patients the cup size used appeared to be significantly larger than for THA patients. This can be explained by the fact that the acetabular preparation was different between the RHA and THA socket. In the THA group a threaded conical cup was screwed in the acetabular socket which mandated removal of a relatively large amount of subchondral acetabular bone. This difference in acetabular preparation and cup size between groups is a confounding factor that theoretically may have affected the subsequently observed change in periprosthetic BMD for both implants, however, we feel that since our change in BMD is recorded against preoperative baseline levels this influence can only be very limited. In addition the software used to calculate the actual change in BMD did correct for the iatrogenic bone removal and thus a potential influence from this phenomenon on our results was also avoided. Another limitation is the presentation of the results up to 2 years, whereas stress shielding is a process of years. Therefore we will continue to follow these patients in time, as these data are part of a larger randomized trial on this matter. On the other hand, we know from the literature that a decrease in BMD after various types of arthroplasty mainly occurs during the first 2 years [28,29]. Additionally, although DEXA remains a safe and reliable method to evaluate changes in BMD [19], the method only measures BMD and does not discriminate cancellous from cortical bone, and it is a two-dimensional projection instead of a three-dimensional measurement which can be performed with computed tomography.

Protection of bone stock after hip arthroplasty is important, especially for the relatively young population, since revision surgery is likely to occur. In this study we focused on periprosthetic BMD changes in the acetabulum after a bone-preserving RHA and the potential pitfall of gradual bone resorption due the effects of an acetabular cup implantation. We found that after placement of a thick press-fit resurfacing cup the supposed decrease of BMD seems not to be as critical as indicated in some finite element studies [10]. We can conclude that, on the short term, an RHA press-fit cup does not lead to more decline in periprosthetic BMD as compared to an established conventional threaded titanium acetabular component. The RHA used in this study thus appears to be relatively bone preserving, also on the acetabular side, however stress shielding is a process of years and this follow-up so far is limited to 24 months. RHA therefore does not appear to be more susceptible for periprosthetic acetabular bone loss from stress shielding as compared to an established titanium-threaded shell with a well-defined clinical track record. Similar findings were already recorded by us for the femoral side [14] and thus we believe that it is safe to conclude that RHA is indeed bone preserving on both the acetabular and the femoral sides. However, as these results are different from our hypothesis, clinical and biomechanical studies are necessary to assess why bone preservation is better around the RHA compared to the conventional THA. A better understanding of periprosthetic bone remodeling may lead to further improvements of hip replacement implants.

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