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Original Article

Comparison between component designs with different femoral head size in metal-on-metal total hip arthroplasty; multicenter randomized prospective study

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ABSTRACT

Backgrounds/Aims: We prospectively studied 78 prostheses with conventional femoral head and 86 prostheses with large head (Magnum) of metal-on-metal total hip arthroplasty (MoM THA) with two years follow-up.

Methods: Clinical outcomes and blood metal ion were evaluated.

Results: There were no significant differences of clinical outcomes between groups. $1.17 \pm 1.01 \mu\text{g/L}$ of blood cobalt ion in Magnum was significantly lower than $1.99 \pm 2.34 \mu\text{g/L}$ in conventional group. No dislocation was observed in Magnum while one dislocation in conventional group.

MoM THA with large head is useful if the implants are positioned in appropriate alignment, however longer follow-up will be necessary.

Clinical Trial Registration: NCT01010763 (registered on ClinicalTrials.gov)

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1. Introduction

Metal-on-metal total hip arthroplasty (MoM THA) were introduced to expect the reduction of the wear rate and the resultant loosening and osteolysis around the implants which has been one of the big complications of conventional metal-on-polyethylene THAs. The first MoM THA implants were introduced in 1938 with Wiles prosthesis made from stainless steel, but it failed early.¹ The McKee-Farrar prostheses made from cobalt and chromium alloys were then developed in the early 1960s and it also failed within 8 years in approximately 50% of cases² due to the imprecise clearance between the femoral head and acetabular component.³

The accumulated understanding of the tribology from hip-simulator studies led developing the second-generation metal-on-metal components. The volumetric wear rates of large head metal articulation were significantly decreased compared with conventional metal-on-polyethylene articulation.^{4,5} The metal-on-metal THA also allows the use of large-diameter femoral heads following the prospect for potential improvement in wear⁶ and reduction in the risk of dislocation.^{7,8}

However, the several concerns associated with metal-on-metal articulation for the formation of the symptomatic reactive periprosthetic soft tissues masses including adverse reaction to metal debris (ARMD),⁹ pseudotumor,¹⁰ and aseptic lymphocytic vasculitis-associated lesions (ALVAL),¹¹ have been recently reported. Measurement of metal ion levels from patients may be a powerful research tool in the evaluation of metal-on-metal hip arthroplasty systems.¹² Some of the metal-on-metal prostheses showed the early failure and showed the increased serum metal ion level.⁹

We designed a multicenter prospective randomized study with conventional (28 or 32 mm) and large femoral head metal-on-metal total hip arthroplasty 1) to investigate potential advantages of Magnum group compared to Conventional group in terms of range of motion, dislocation while maintaining the same function improvement and pain reduction and 2) to investigate metal ion release in Asian population.

2. Materials and methods

2.1. Study designs

Two types of different titanium plasma sprayed cementless acetabular component were used for this study. The M2a-Magnum Large Metal Articulation (Biomet, Warsaw, IN, USA) utilized one-piece cobalt–chromium–molybdenum acetabular shell allowing larger head sizes was used as a large head size group (Magnum group) in this study. Head diameter was 6 mm smaller than cup diameter. The M2a-Taper (Biomet) was modular cobalt–chromium–molybdenum inserts in the modular titanium alloy hemispherical shells. Head diameter of the M2a-Taper was 28 mm or 32 mm and was used as a conventional head size group (Conventional group). The stems that we used in this study were Bimetric XR (Biomet) Taperloc, (Biomet) or Taperloc Microplasty (Biomet).

The inclusion criteria were as follows; 1) Patients with inflammatory or non-inflammatory hip degenerative disease, and planned to be treated with primary THA, 2) Age was 20 years old or older with good compliance, 3) the American Association of Anaesthetists (ASA) score was I to III. Patients were excluded, if they met one of the following criteria; the presence of another metal implant in the body, infection, sepsis, abnormal bone metabolism including osteomalacia, pregnancy, rapidly destructive coxarthropathy, severe bone defect or not being willing to comply with the planned protocol. All patients gave written consent for inclusion in this study. This study was approved by the ethical committee in each institution.

2.2. Demographics

Sample size was calculated based on estimated dislocation rate at 5 year postoperatively. Alpha level was set at 0.025 one sided and Power was set as 80% for each calculation. The calculation revealed 150 patients per arm (including 7.5% lost to follow-up). Planned sample size was total of 330 patients. 1st patient was enrolled in December 2009, but we could not reach planned enrollment in 2 year period. So the enrollment had been stopped in December 2011.

Eligible patients were assigned to either Magnum or conventional group randomly (Fig. 1). Sequential numbers per site were allocated to all eligible patients and opaque envelope was opened before surgery. Sponsor prepared envelopes by block randomization (4-block) method before study implementation.

A total of 189 patients were eligible, but 4 patients withdrew before surgery. Resultant 185 patients were included in the study. Seventy four percent of patients were female (137 females), and there were no significant differences of age, height, weight and BMI between groups. Diagnosis was 160 patients 163 hips of osteoarthritis, 22 patients 23 hips of avascular necrosis of femoral head, 1 hip of traumatic osteoarthritis, 1 hip of Subcapital fracture and 1 hip of Perthes Disease. Twelve patients (12 hips) in Magnum group & 10 patients (10 hips) in conventional group were excluded from the analysis due to lack of 2 year blood cobalt ion data, and 3 patients died because of gall bladder cancer, cerebral infarction, and suffocation before 2 year follow up with components in situ were also excluded. This left 85 patients (86 hips) in Magnum group and 75 patients (78 hips) in conventional group for the current analysis. The patient demographics, surgical parameters and characteristics of implants were shown in Table 1.

All patients were scheduled to visit the clinic at three month, six month, one year and two year postoperatively. Clinical results were assessed using Harris Hip score.¹³ Post-operative activity level was assessed with use of the University of California, Los Angeles (UCLA) activity score.¹⁴ The EQ5D score was utilized for evaluation of patient reported health related quality of life.¹⁵ All intra-operative and post-operative complications were recorded.

For a radiological assessment, anterior and lateral radiographs of the pelvis were taken at each postoperative visit and analyzed for implant position, and signs of loosening and osteolysis. Acetabular cup inclination angle was quantified by

Fig. 1 – Study flow chart.

the angle formed between a line passing through the bilateral teardrop signs and a second line representing the greatest diameter of the acetabular component. Cup anteversion angle was evaluated using the method of a version angle on a cross-table lateral radiograph.¹⁶ Briefly, anteversion was quantified by the angle between the gravity line and a tangential line to the opening face of the acetabular component on a cross-table lateral radiograph.

Whole blood chromium and cobalt ion concentrations were measured with the use of atomic absorption spectrometry, and inductively coupled plasma mass spectrometry (ICP-MS) by a blinded independent laboratory (Chromium: BML, Tokyo, Japan, Cobalt: NMS, PA, USA, until 2012 & Toray Research Center, Tokyo, Japan from 2013), respectively. Also urine and serum Creatinine values were measured at SRL, Tokyo, Japan. For calculation of average ion concentration, in the case that the measurement results were reported as below detection limit with no value, “0” was imputed to those measurement results.

The results are presented as mean $\pm$ SD for continuous data. For comparison of the two groups, normally distributed continuous data (age, height, weight, metal ions) were analyzed by unpaired t-test, while non-normally distributed data (HHS, UCLA, EQ5D, metal ions) were analyzed by nonparametric Mann–Whitney U test. For comparison of ratio in two groups for the categorical data such as gender, either Fisher's exact test or Pearson's Chi-square test was used. SAS 9.2 (SAS Institute, Cary, NC) was used to perform the statistical calculations and significance level was set at $p < 0.05$ (two sides).

3. Results

3.1. Clinical outcomes and patient reported outcome measures

Harris Hip Score significantly improved from preoperative to postoperative in both groups, and there was no significant difference between the groups at any time points (Fig. 2a). UCLA activity score significantly improved postoperatively in both groups, and there was no significant difference between groups (Fig. 2b). EQ5D score significantly improved postoperatively in both groups, and there was no significant difference between groups (Fig. 2c).

3.2. Metal ion levels

MHRA in UK considers that whole blood metal ion level greater than $7 \mu\text{g/L}$ (=ppb) suggests potential soft tissue reaction after MoM procedure.¹⁷ Average whole blood chromium ion level of both groups was increasing postoperatively in time dependent manner and significant difference between both groups at 1 year postoperatively was observed (Fig. 3a). Average whole blood cobalt ion level of conventional group was increasing postoperatively in time dependent manner (Fig. 3b). That of Magnum group was also increasing postoperatively and reached to plateau at two years postoperatively. $1.17 \pm 1.01 \mu\text{g/L}$ (95% C.I. 0.95–1.39) of cobalt ion in Magnum group was significantly lower than $1.99 \pm 2.34 \mu\text{g/L}$ (95% C.I. 1.46–2.52) of cobalt ion in conventional group ($p = 0.0037$).

Table 1 – Patients demographics & surgery records.

	Magnum (n = 85 pts. 86 hips)	Conventional (n = 75 pts. 78 hips)	P value
Sex (Female/Male)	66/19	56/19	0.658
Side (Right/Left)	43/43	47/31	–
Age (year)	65.4 ± 8.6	66.2 ± 9.0	0.563
Height (cm)	154.5 ± 7.2	156.7 ± 6.9	0.054
Weight (kg)	57.2 ± 10.8	56.9 ± 10.0	0.854
BMI (kg/m ²)	23.9 ± 3.7	23.1 ± 3.6	0.196
Primary diagnosis			0.305
Osteoarthritis	71	72	
Osteonecrosis	12	6	
Perthes Disease	1		
Traumatic Arthritis	1		
Subcapital Fracture	1		
Approach			0.334
Posterolateral	51	47	
Direct Anterior	24	26	
Anterolateral	6	1	
Modified Watson-Jones	5	4	
Surgical time (min)	81.4 ± 31.0	79.7 ± 33.0	0.725
Blood loss (mL)	451.3 ± 271.7	450.3 ± 334.2	0.983
Femoral components			–
Taperloc Standard Length	12	6	
Taperloc Microplasty	56	61	
Bi-Metric XR	18	11	
Femoral head size			–
28 mm	–	18	
32 mm	–	60	
38 mm	1	–	
40 mm	1	–	
42 mm	14	–	
44 mm	40	–	
46 mm	16	–	
48 mm	10	–	
50 mm	2	–	
52 mm	2	–	

The whole blood cobalt level of all cases in each group was shown in Fig. 3c and d. The cobalt ion of five patients increased higher than 7 µg/L in conventional group, while that of no patients in Magnum group increased higher than 7 µg/L at two years postoperatively. One patient in Magnum group showed the 12.9 µg/L of cobalt ion at one year postoperatively, but such cobalt ion was decreased to 2.1 µg/L at two years postoperatively.

3.3. Radiographic outcomes and the relationship between the cup alignment and the whole blood cobalt ion concentration

At two years postoperatively, no radiographic signs of osteolysis and loosening were observed in both groups. Average cup inclination and anteversion angles were $37.7 \pm 5.0^\circ$ and $24.6 \pm 7.2^\circ$, respectively. Cup inclination and anteversion angles of all patients were plotted in Fig. 4. All cases were less than 50° of cup inclination angle and 95.1% (156 out of 164 hips) were less than 45° of cup inclination angle. The cobalt ion level of five patients increased to higher than 7 µg/L (Table 2). The cup alignment of these five patients was also shown in Fig. 4. The highest three among those five cups were positioned too large anteversion ($>34^\circ$). Average whole blood cobalt ion level of patients with cup aligned larger

than 35° of anteversion ($n = 12$) was 3.92 ± 4.00 µg/L (95%C.I. 1.65–6.18), and that of patients with cup aligned smaller than 34° of anteversion ($n = 148$) was statistically significantly lower ($p = 0.0499$, 1.36 ± 1.36 µg/L, 95%C.I. 1.15–1.58) than $\geq 35^\circ$ group.

3.4. Adverse events

No dislocation was observed in Magnum group while one dislocation was occurred in conventional group. Other adverse events including infection and nerve palsy had not observed in both groups.

3.5. Dislocated case

Dislocated case with increased cobalt ion level was in conventional group. She was dislocated at 8 days postoperatively. Whole blood ion was increasing continuously in time dependent manner (cobalt ion levels were 2.5 µg/L at 3 months, 8.9 µg/L at 6 months, 15.4 µg/L at 1 year and 11.0 µg/L at 2 years postoperatively). Cup alignment was 29° of inclination and 41° of anteversion. Dislocation might cause subluxation and/or edge loading after the hip reduced, those could be a cause of increased ion level. However, no hip pain and no clinical symptom were observed.

Fig. 2 – Clinical assessment. Average Total Harris Hip Score (a), Average UCLA Activity Score (b), and Average EQ-5D (c) were improved postoperatively in Magnum and conventional group, however, no significant differences were observed between both groups.

Fig. 3 – Average whole blood cobalt and chromium concentration and Individual cobalt concentration. Average whole blood chromium (a) and cobalt (b) ion concentration of both Magnum and conventional group was increasing postoperatively in time dependent manner. Cobalt concentration of Magnum group reached to plateau at two years postoperatively. Cobalt ion in Magnum group was significantly lower than that in conventional group ($p = 0.0037$). The individual whole blood cobalt level of Magnum (c) and conventional (d) group revealed that the cobalt ion of five patients increased higher than 7 µg/L in conventional group, while that of no patients in Magnum group increased higher than 7 µg/L at two years postoperatively.

4. Discussion

In this study, we compared the clinical and radiographic outcomes as well as whole blood metal ion level between the two different component designs with conventional and large femoral heads in MoM THA, and found that the MoM THA with large head showed the good clinical results including the low dislocation rate and did not increase the whole blood metal ion levels if the implants was positioned in appropriate alignment.

Recent several reports showed the unexpected high failure rate for some types of metal-on-metal articulation with large femoral head and the incidence of ARMD. MHRA issued the medical device alert for all metal-on-metal articulation and suggested a cut off level of 7 parts per billion (ppb) for ARMD in metal-on-metal THA.¹⁷ Some studies showed an association between blood cobalt and chromium ion concentration and increased failure after metal-on-metal hip replacement.^{18,19} In our study, five patients with conventional heads showed above 7 µg/L of cobalt ion level, while patients with large heads did not.

Lavigne et al reported the comparison of blood metal levels in four type of MoM THA with large head including Durom (Zimmer), Magnum (Biomet), ASR (Depuy) and BHR (Smith and Nephew). The cobalt Ion level of Durom was highest, while that of Magnum was lowest. It suggested the design of the metal-on-metal articulation is one of the important factors for metal-on-metal articulation. They also described that the sleeves of Durom and ASR were small and made of cobalt–chromium alloy, while that of Magnum were relatively large and made of titanium alloy and speculated the potential influence of the adapter sleeve on the metal ion release in MoM THA.²⁰ It was also reported that 18 of 358 patients with MoM articulations with 2 different type MoM bearings, M2a-38 (Biomet) and Magnum (Biomet) were revised at average 3.5 years (1.1–6.5) postoperatively and only one of 18 patients showed the pseudotumor.²¹ In current study, any patients did not show the clinical symptom at two years postoperatively and were not revised up to two year follow-up.

Hip simulator testing showed the effect of larger diameter bearing on reducing the wear in metal-on-metal hip implant.⁶ Smaller head diameters also increase the risk of rim contact, impingement, and edge loading, following to proceed the

Fig. 4 – Acetabular cup alignment and the cobalt ion. Cup inclination angle and anteversion angle of all patients were plotted. All cases were less than 50° of cup inclination angle and 95.1% were less than 45° of cup inclination angle. The cobalt ion level of five patients increased to higher than 7 µg/L and the cup alignment of these five patients was shown by large box. There were no patients showed above 7 µg/L cobalt ion level in Magnum group. The highest three among those five cups were positioned too large anteversion (>34°).

wear.²² In current study, the cobalt ion of the patients in the large head group was reached to the plateau at two years postoperatively and was significantly lower than that in the conventional group. Hallows compared serum metal ion level in small and large head with metal-on-metal articulations. Metal ion was significantly lower in the control metal-on-polyethylene group than in both small and large head group of MoM THA.²³ On the other hand, Bernstein reported that there was no difference in metal ion levels between patients with small- or large-diameter femoral heads and cup position had no effect on the metal ion levels at one year postoperatively.²⁴ In our study, we also did not detect the difference in whole blood cobalt ion level between two groups at one year postoperatively ($p = 0.0873$), but confirmed the significant difference at two years postoperatively ($p = 0.0059$). From these results, we suggest the efficiency of the lower ion release from large femoral head system.

In our cases, five patients showed increased metal ion level above 7 µg/L in conventional group. Hart et al identified 50°

cup inclination for the increase of metal ion level in metal-on-metal hip resurfacing as threshold.²⁵ They showed that cobalt and chromium levels positively correlated with cup inclination and negatively correlated with cup anteversion.²⁶ Our results were slightly different from their results, because all of our cups were aligned lower than 50° of inclination. Steepest cup inclination in our population was 50° in only one patient, so that we can evaluate the ion level in the safer cup positioning, which Hart et al found from their previous job.²⁵ Since cobalt ion concentration in whole blood exceeded 7 µg/L was only seen in conventional group, we stratified this patient group as follows. We set 35° as a threshold for anteversion and 7 out of 75 patients consisted of this group. Three patients in 7 excessive anteversion population (42.9%) showed above 7 µg/L cobalt ion and only two patients in 68 patients below 35° anteversion population (2.9%) showed above 7 µg/L cobalt ion, this difference in ratio of patients showed higher ion concentration was statistically significant ($p = 0.0030$) (Table 2). There are several differences between two groups in terms of

Table 2 – List of patients with increased Cobalt Ion Concentration in whole blood.

Case	Co (ug/L)	Component	Head size (mm)	Cup inclination (degree)	Cup anteversion (degree)
1	11	Conventional (M2a Taper)	32	29	41 ^a
2	10	Conventional (M2a Taper)	28	44	39 ^a
3	9.0	Conventional (M2a Taper)	32	39	42 ^a
4	8.2	Conventional (M2a Taper)	32	37	25
5	7.7	Conventional (M2a Taper)	32	37	15

^a Cup anteversion is above threshold (35°).

device configurations: 1) cup & liner (M2a Taper configures Hi-Carbon Forged CoCr Liner mating with titanium alloy cup, Magnum cup has Hi-Carbon As-cast CoCr monoblock cup substrate with commercially pure titanium porous plasma spray), 2) head (Heads of M2a Taper and 38 mm & 40 mm Magnum are Hi-Carbon Forged CoCr monoblock heads, whereas 42 mm and larger Magnum heads made of Hi-Carbon As-cast CoCr mate with titanium alloy sleeve adaptor), and 3) diametrical clearance (Diametrical clearance of M2a Taper is 25–75 µm and that of Magnum is 75–150 µm). As Lavigne stated,²⁰ difference of materials at taper junction might influence above referenced statistical difference of ion concentration in our series. Although specification of taper junction, which is called Biomet Type 1 taper, is same in both groups, but combinations of material is different. Titanium male taper of stem mates with CoCr female taper of M2a Taper head and 38 mm & 40 mm head of Magnum, and Titanium male taper of stems mates with Titanium female taper of Magnum taper sleeve (42 mm or larger).

One of the limitations with this multi-center study is that the patients were received surgery by the different surgeons with different surgical approaches. In our series, there was no dislocation within 2 years postoperatively in the large head groups in spite of the various surgical approaches, while one dislocation occurred in the patients with 32 mm heads. Berry et al reported the relative risk of dislocation being 1.7 for 22-mm compared with 32-mm heads and 1.3 for 28-mm compared with 32-mm heads in 21047 hips with ten years follow-up and concluded that a larger femoral head diameter was associated with a lower long-term cumulative risk of dislocation.⁸ It was reported that the clinical experience with 316 38 mm diameter femoral heads showed no dislocation within 3 months postoperatively compared with 2.5% of 78 patients receiving 28 mm diameter femoral heads.⁷ From these results, large diameter femoral heads were considered to be effective to reduce the risk of dislocation regardless of surgical approaches.

Current study does not have independent reviewer of radiographs, this might be one of limitations. Although, all radiographs were taken in accordance with aforementioned technique at each investigational site, inter-observer variances will exist.¹ And especially for Magnum group, it is difficult to detect contour of face of cup due to too small variances of diameters between cup and head. That was the reason why CT was not used for measurement.

Also, two different cobalt ion measurement laboratories were used during study period due to business issue of the vendor. Although different laboratories measured cobalt ion, same measurement method (ICP MS) was consistently used throughout the study period. So we believe that it didn't affect the interpretation of the results.

Another limitation of this study was that current study followed patients up to two years postoperatively and it was not clear how these results were related to the long-term results. Specifically, British national registries reported that revision rate of the MoM THA were increasing in time dependent manner.²⁷ In addition, Hart et al found similar prevalence of pseudotumor formation between well-functioning MoM THA and painful MoM THA.²⁸ We have a plan to follow-up current population up to 10 years and MRI

evaluations on available patients are also planned. However, based on the results of the present study, we might be able to address the advantage of the MoM THA with large femoral head under the appropriate selection of the metal articulation and its accurate positioning.

In conclusion, Large head MoM THA showed good clinical results with no dislocation case reported and showed significantly lower metal ion release than conventional MoM group if the implants were positioned in appropriate alignment at two years postoperatively.

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Conflicts of interest

All authors have none to declare.

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