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Serum Metal Ions in Contemporary Monoblock and Modular Dual Mobility Articulations

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ABSTRACT

Background: Questions exist about the release of cobalt and chromium ions from dual mobility (DM) cups. Modular implants, with potential backside wear between the cobalt-chromium liner and titanium cup, are of particular concern. This study compares the metal ion profile of patients with contemporary monoblock and modular DM articulations from two commonly used designs.

Methods: Cobalt and chromium serum levels were measured one year after surgery in a prospective cohort of patients undergoing total hip arthroplasty with a DM construct. Ion levels were detected above 1 μg/L. Clinical and surgical data were correlated with the ion levels for analysis.

Results: Overall, 29% of the patients had levels above 1 μg/L of either ion. More patients with modular cups had detectable ions than patients with monoblock cups (39% vs 20%, $P = .05$). Cobalt was more commonly detected in the monoblock group, and chromium was more commonly detected in the modular group ($P = .05$). There were no differences in the actual ion levels between the groups (1.35 μg/L vs 1.64 μg/L, $P = .44$, for cobalt and 1.35 μg/L vs 1.31 μg/L, $P = .77$, for chromium). No patient underwent revision during the follow-up period.

Conclusions: We found similar cobalt and chromium levels in patients with monoblock and modular DM cups. More patients in the modular group had detectable ions. Cobalt was more frequently detected in the monoblock group. These results suggest that both implants are performing well in the short term, but further follow-up is needed to determine whether the differences found are of clinical significance.

Introduction

Dual mobility (DM) acetabular components have been shown to increase stability in total hip arthroplasty (THA) [1-6]. By using a large polyethylene (PE) liner that articulates with a smooth metal surface, the effective femoral head size is increased, thus lowering the chance of dislocation [7].

While DM articulations have been used in Europe for more than 40 years, they became available in the United States only in 2009. They are currently indicated for primary and revision surgery, including conversion from a previous metal-on-metal (MoM) articulation [8]. There are several DM options on the market (Table 1), with monoblock and modular designs. Monoblock cups are a one-piece device, with an outside surface intended for osseointegration or cementation and a smooth inner surface for articulating with the PE liner. This inner surface is made of either stainless steel or cobalt-chromium (CoCr). Modular cups are regular titanium shells, capable of accepting either a standard PE insert or a DM insert. Most common DM inserts are made from CoCr even though other designs are available.

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Table 1
Dual mobility designs.

Name	Manufacturer	Modularity	Fixation	Main material	Inner surface material	Cobalt in articulating surface	Chromium in articulating surface
Bi-mentum	DePuy	No	Press-fit	Stainless steel	Stainless steel	No	Yes
Avantage*	Biomet	No	Press-fit	Stainless steel	Stainless steel	No	Yes
PolarCup	Smith&Nephew	No	Press-fit	Stainless steel	Stainless steel	No	Yes
Bi-mentum	DePuy	No	Cement	Stainless steel	Stainless steel	No	Yes
Avantage*	Biomet	No	Cement	Stainless steel	Stainless steel	No	Yes
PolarCup	Smith&Nephew	No	Cement	Stainless steel	Stainless steel	No	Yes
ADM	Stryker	No	Press-fit	CoCr	CoCr	Yes	Yes
Pinnacle	DePuy	Yes	Press-fit	Titanium	CoCr	Yes	Yes
G7	Zimmer-Biomet	Yes	Press-fit	Titanium	CoCr	Yes	Yes
MDM	Stryker	Yes	Press-fit	Titanium	CoCr	Yes	Yes
Delta	Lima	Yes	Press-fit	Titanium	CoCr	Yes	Yes
Trinity	Corin	Yes	Press-fit	Titanium	CoCr	Yes	Yes
OR3O	Smith&Nephew	Yes	Press-fit	Titanium	Zirconium alloy	No	Yes
Delta	Lima	Yes	Press-fit	Titanium	Ceramic	No	Yes

*Not available in the US.

The advantage of modular DM constructs is surgeon familiarity with a standard titanium cup, the option for supplementary screw fixation, and the possibility of an isolated insert exchange in instances such as infection or conversion to a constrained insert [9]. However, concerns have been raised regarding possible micromotion and galvanic reactions between the titanium shell and CoCr insert. This interface can potentially lead to fretting, corrosion, metal ion release, and possibly associated adverse local tissue reaction (ALTR) [10,11]. Several studies have analyzed the serum metal ion levels in patients with modular DM constructs [10-14]. Most report low metal ion levels and no adverse sequelae at short- and mid-term follow-up. One study evaluated metal ion levels in patients with a monoblock DM construct, but that design was cobalt-free [15]. We designed this study to report on the serum metal ion levels in a consecutive cohort of patients receiving either monoblock or modular contemporary CoCr DM articulations and compare the two. Our hypothesis was that ion levels would be higher in patients with modular DM devices because of the additional titanium-CoCr interface.

Material and methods

This was a prospective study of patients who underwent primary or revision THA with DM constructs in a single institution between February 2018 and May 2019. All surgeries were performed via the posterior approach. DM implants were used in primary THA in patients at increased risk for dislocation, having at least one of the following risk factors: male patients older than 75 years, female patients older than 70 years, body mass index of 30 kg/m^2 or greater, American Society of Anesthesiologists score 3 and higher, prior surgery on the same hip, reduced spinopelvic mobility (stiff spine from degenerative disc disease or prior lumbar fusion), or neuromuscular disease. In addition to the previous risk factors, prior hip instability or abductor insufficiency was an indication for a DM cup in revision THA [16-25]. All operations were performed by one of three fellowship-trained arthroplasty surgeons (P.K.S., D.J.M., T.P.S.) with prior experience in using these implants. One of the senior authors implanted all the primary monoblock devices while two others used the modular ones. All senior authors used modular DM cups for revision cases. During the study period, the authors also performed a total of 1678 non-DM THAs. All authors aimed for 40 degrees of inclination and 20-25 degrees of anteversion. Two authors consistently used navigation systems during primary THAs. All patients provided informed consent before study inclusion, and the study was approved by the institutional review board. To allow for implant bedding-in, a minimum follow-up period of 1 year, averaged across the cohort, was the only inclusion criterion applied. Patients with CoCr femoral heads, a well-functioning contralateral THA, or well-functioning hardware elsewhere in the body (such as prior or subsequent arthroplasty, spinal hardware, dental implants or a pacemaker) were not excluded. We did exclude those patients who had failing hardware or underwent revision for a previous failing MoM articulation. Patient demographics and implant characteristics were collected from our registry and combined with the ion level data. Correlative statistics were applied.

Monoblock cohort

The study cohorts and demographics are presented in Figure 1 and Table 2.

In the monoblock group, there were 49 patients with a mean age of 77.2 years (range: 51-93) at the time of THA. All surgeries were primary THA, and the anatomic dual mobility cup (Stryker, Mahwah, NJ) was implanted in all patients. The anatomic dual mobility

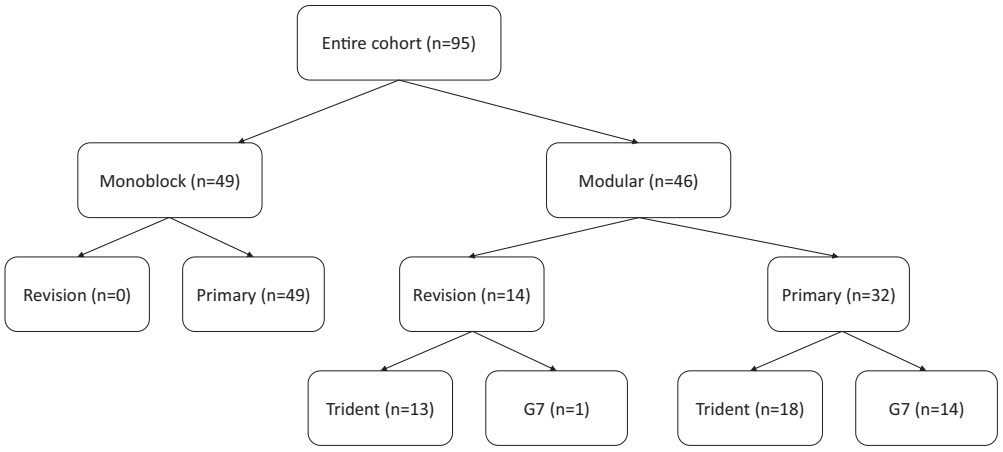

Figure 1. Study cohorts.

cup is a monoblock CoCr acetabular component, with titanium and hydroxyapatite coating on its outer surface and a polished CoCr inner surface for articulation with the PE liner. It has no screw holes, and thus, no screws were used. The most commonly implanted cup size was 48 mm, with a mean cup size of 50.9 mm for the entire cohort (range: 46-64). The manufacturer offers only one PE size per cup size (6 mm smaller than the cup outer diameter) and only a 28-mm head. Thus, the most commonly implanted PE size was 42 mm with a mean PE size of 44.9 mm for the entire cohort (range: 40-58). All patients received a 28-mm head. Forty-one patients (84%) received a CoCr femoral head while 8 patients (16%) received a ceramic femoral head (Delta Ceramic; CeramTec, Plochingen, Germany).

Modular cohort

There were 46 patients in this cohort, with a mean age of 70.5 years (range: 48-84) at the time of THA. Thirty-two (70%) were primary THAs while 14 (30%) were revision THAs. Cementless titanium acetabular components with a modular CoCr insert were used in all patients. There were 31 (67%) Trident acetabular components with a Modular Dual Mobility CoCr insert (Stryker) and 15 (33%) G7 acetabular components with an Active Articulation CoCr insert (Zimmer-Biomet, Warsaw, IN). Solid-back, cluster-hole, and multihole designs were used, with an average of 1.16 screws used per cup (range: 0-7). The most commonly implanted cup size was 52 mm with a mean cup size of 53.0 mm for the entire cohort

Table 2
Study cohort demographic and surgical data.

	Monoblock, no. (% or STDEV) (n = 49)	Modular, no. (% or STDEV) (n = 46)	Modular primary , no. (% or STDEV) (n = 32)	Monoblock vs modular, *P* value	Monoblock vs modular primary , *P* value
Age (y)	77.2 (7.8)	70.5 (9.4)	70.3 (8.4)	**<.01**	**<.01**
Sex (% female)	73%	74%	78%	.96	.68
BMI (kg/m^2)	26.3 (4.6)	25.9 (4.9)	26.0 (4.2)	.59	.76
ASA score				.44	.22
1	1 (2%)	3 (7%)	2 (6%)		
2	35 (71%)	34 (74%)	26 (82%)		
3	13 (27%)	9 (19%)	4 (12%)		
LOI (y)	1.1 (0.2)	1.2 (0.4)	1.2 (0.4)	.89	.31
Type of arthroplasty				N/A	N/A
Primary	49 (100%)	32 (70%)	32 (100%)		
Revision	0	14 (30%)	0		
Cup type				N/A	
ADM	49 (100%)	0	0		
Trident	0	31 (67%)	18 (56%)		
G7	0	15 (33%)	14 (44%)		
Cup size (mm)	50.9 (3.9)	53.0 (5.2)	51.2 (3.5)	**.03**	.71
Liner size (mm)	44.9 (3.9)	41.7 (4.0)	40.6 (2.9)	**<.01**	**<.01**
Head size (mm)	28.0 (0.0)	27.0 (2.3)	26.9 (2.4)	**<.01**	**<.01**
Head material				**<.01**	**<.01**
CoCr	41 (84%)	17 (37%)	11 (34%)		
Ceramic	8 (16%)	24 (46%)	16 (50%)		
Oxidized zirconium	0	8 (17%)	5 (16%)		
Stem material				.42	.41
Titanium	47 (96%)	41 (89%)	28 (88%)		
CoCr	2 (4%)	4 (9%)	4 (12%)		
Previous/other hardware	28 (57%)	27 (59%)	19 (59%)	.88	.84

ADM, anatomic dual mobility; ASA, American Society of Anesthesiologists; BMI, body mass index; LOI, length of implantation; N/A, nonapplicable; STDEV, standard deviation.
Bold values are statistically significant, with *P*-value <.05.

(range: 44-68). In contrast to the monoblock implant, modular implants accept a variety of liner and head options, depending on the specific model [26,27]. Thus, the most commonly implanted PE size was 42 mm with a mean PE size of 41.7 mm for the entire cohort (range: 32-52). The mean femoral head size was 27.0 mm (range: 22-28). There were 17 (37%) CoCr heads, 21 (46%) ceramic heads, and 8 (17%) oxidized zirconium heads (Smith & Nephew, Memphis, TN).

Modular primary cohort

As the modular group included both primary and revision patients, while monoblock cups were used only for primary cases, we isolated the modular primary cohort (32 patients) and compared it separately to the monoblock primary patients (see Fig. 1 and Table 2).

Serum metal ions

A 6-mL sample of whole venous blood was drawn from each patient at the 1-year follow-up visit. All instruments used for specimen collection were verified to be free of metal contamination. The specimens were placed in a transport tube free of trace elements and without any additives. Cobalt and chromium levels were measured using an inductively coupled plasma mass spectrometer by one laboratory (ARUP Laboratories, Salt Lake City, UT). Cobalt and chromium levels were detected at levels greater than 1.0 μg/L. Thus, the ion levels reported here represent only those patients for whom they were detected by the laboratory, rather than the entire cohort.

Statistical analysis

Statistical analyses were performed using chi-square tests for categorical variables and independent Student's t-tests for continuous variables. Differences in baseline demographics were assessed using the Mann-Whitney U test and Fisher's exact test. Differences in metal ion levels and implant types were compared using Fisher's exact test. All *P* values equal to or smaller than .05 were considered statistically significant.

Results

The overall metal ion detection rate in the study group was 29.5% (28 patients out of 95, with either cobalt or chromium [or both] levels above 1.0 μg/L; Table 3). Of the 28 detected patients, 18 patients (64.2%) had modular cups, and 10 patients (35.7%) had monoblock cups. This translates to a 39.1% detection rate in modular cups, compared to 20.4% in monoblock cups ($P = .05$).

Of the 10 patients with detectable ions in the monoblock group, 6 patients (60%) had cobalt detected, while 4 patients (40%) had chromium detected. In contrast, of the 18 patients with detectable ions in the modular group, only 3 patients (16.6%) had cobalt detected, while 13 patients (72.2%) had chromium detected ($P = .05$). Two patients had both ions detected.

The actual ion levels were similar for both groups (see Table 3). The mean cobalt level was 1.35 ± 0.31 μg/L in the monoblock group and 1.64 ± 0.72 μg/L in the modular group ($P = .44$). The mean chromium level was 1.35 ± 0.19 μg/L in the monoblock group and 1.31 ± 0.27 μg/L in the modular group ($P = .77$). It should be noted, again, that these levels represent only those patients who had ion levels above 1.0 μg/L, as that was the minimal detection level in the laboratory used for this analysis.

Examining only primary cases, the metal ion detection rate for all primary cases, monoblock and modular, was 28.4% (23 patients out of 81; Table 3). This translates to a 40.6% (13 out of 32) detection rate in primary modular cups, compared to 20.4% (10 out of 49) in primary monoblock cups ($P = .05$).

The actual ion levels were similar for both groups. The mean cobalt level was 1.35 ± 0.31 μg/L in the primary monoblock group and 1.33 ± 0.15 μg/L in the primary modular group ($P = .87$). The mean chromium level was 1.35 ± 0.19 μg/L in the primary monoblock group and 1.33 ± 0.30 μg/L in the primary modular group ($P = .89$).

No patient was revised or reoperated, either for ALTR or any other reason, during the study period.

Discussion

DM constructs are becoming increasingly popular in high-risk patients undergoing primary and revision THA [1-7]. With the recent introduction of modular DM articulations, concerns regarding the interface between the titanium shell and CoCr insert leading to fretting, corrosion, and the potential release of metal ions have been raised [10]. Limited studies have analyzed the serum metal ion levels in patients with modular DM constructs [11-15]; however, no direct comparisons between monoblock and modular DM implants have been performed. In this study, we found no difference in detectable metal ion levels between patients with monoblock and those with modular DM constructs at 1 year after surgery. However, we did find that significantly more patients with modular constructs had metal ion levels above 1.0 μg/L. In addition, we found that cobalt was more commonly detected in patients with monoblock cups while chromium was more commonly detected in patients with modular cups.

The normal range for cobalt and chromium ion levels in a primary DM THA remains unknown. A recent meta-analysis found a mean cumulative cobalt level of 0.47 μg/L and a mean cumulative chromium level of 0.53 μg/L in well-functioning DM hips [28].

Table 3
Metal ion levels and detection patterns in monoblock and modular dual mobility constructs.

	Monoblock , no. (% or STDEV) (n = 49)	Modular , no. (% or STDEV) (n = 46)	Modular primary , no. (% or STDEV) (n = 32)	Monoblock vs Modular, *P* value	Monoblock vs modular primary , *P* value
Patients with detectable ion levels	10 (20%)	18 (39%)	13 (41%)	**.05**	**.05**
1-y Co levels (mg/L)	1.35 (0.31)	1.64 (0.72)	1.33 (0.15)	.44	.87
1-y Cr levels (mg/L)	1.35 (0.19)	1.31 (0.27)	1.33 (0.30)	.77	.89
Ion detection pattern				**.05**	.21
Only Co (n, % of detected)	6 (60%)	3 (17%)	3 (23%)		
Only Cr (n, % of detected	4 (40%)	13 (72%)	9 (69%)		
Co + Cr (n, % of detected)	0	2 (11%)	1 (8%)		

STDEV, standard deviation.
Bold values are statistically significant, with *P*-value <.05.

Another study, not included in the meta-analysis, found a mean cobalt level of 0.85 μg/L and a mean chromium level of 0.61 μg/L [12]. In a study of patients who underwent *revision* arthroplasty with a DM implant, the mean cobalt level was 1.99 μg/L and the mean chromium level was 2.08 μg/L [29]. Notably, some of these patients in that study were revised for a failing MoM arthroplasty, thus, potentially skewing the results. The ion levels in our study are slightly higher than the ones quoted previously, yet it must be remembered that we could report only on patients who had ion levels above 1.0 μg/L, as that was the minimal detection level in the laboratory mentioned in this study. Assigning a value of 0.5 μg/L to all of our patients who had undetectable levels (ie, below 1.0 μg/L), as was done previously by Barlow et al. [12], would have yielded cobalt levels of 0.61 ± 0.30 μg/L for all patients with monoblock cups and 0.62 ± 0.42 μg/L for all patients with modular cups. Chromium ion levels would have been 0.57 ± 0.24 μg/L for monoblock cups and 0.74 ± 0.40 μg/L for modular cups, well in agreement with the literature.

Although the studies quoted previously may give an idea of what are considered normal mean metal ion levels, no single cutoff value exists above which a DM hip is considered abnormal, although a level of 1.6 μg/L is often cited as such. This number is taken from a work by Matsen Ko et al. who considered cobalt levels above this value to be "significantly elevated" [10]. Yet, 5 of the 9 patients in that study with cobalt levels above 1.6 μg/L had alternative cobalt sources in their bodies, such as other joint replacements. Moreover, 67% of their patients with cobalt levels above 4.5 μg/L had Oxford scores of 45-48 (ie, very well functioning hips) and had advanced imaging which was negative for ALTR. Thus, cobalt levels above 1.6 μg/L were not necessarily associated with poorly functioning hips. The authors chose 1.6 μg/L as a cutoff value based on a previous report by Cooper et al. that examined ALTR due to trunnionosis [30]. In that article, 1.60 μg/L was the lowest cobalt level in patients revised for trunnionosis. As that study looked only at revised patients, no data were available on cobalt levels in patients who did *not* undergo revision. Thus, it cannot be ruled out that there were patients with cobalt levels above 1.6 μg/L who had well-functioning hips. It should also be remembered that the interface between a titanium shell and modular CoCr insert is not necessarily mechanically similar to a trunnion. In light of all these, making a direct comparison between trunnionosis and DM articulations and setting 1.6 μg/L as a cutoff value for abnormal cobalt levels in DM hips should be done cautiously. Although it is probably prudent to have a closer follow-up when cobalt levels are above 1.6 μg/L, especially if they are rising, they are only one piece of the puzzle. Longitudinal studies are needed with patient-reported outcome measures, radiographs, metal ion levels, cross-sectional imaging, and revision data, including retrieval analysis, to map out the natural history of these implants and eventually devise an algorithm, such as a receiver operating characteristic curve, to set a cutoff value above which a DM hip would warrant further investigation.

We examined the role of the trunnion in our cohort. In the modular group, there were significantly less CoCr femoral heads than in the monoblock cohort (37% vs 84%, $P < .001$). The lower proportion of CoCr heads lessens the role of the trunnion in metal ion release in these patients. Yet, despite this *lower* proportion of CoCr heads, the modular group showed *higher* metal ion detection rates, suggesting that it was the junction between the CoCr insert and the titanium shell that could be the source of the higher metal ion detection rates. The ion levels in both our cohorts were lower than those reported for a cohort of well-functioning metal-on-poly hips [12], further suggesting that the trunnion did not have a significant role in our results.

Implant design may also have a bearing on metal ion release. In monoblock shells, the insert is an integral part of the cup. In contrast, modular shells are stand-alone titanium cups, and the CoCr inserts are assembled into them during surgery. This allows monoblock cups to be thinner than modular cups with the same outer diameter (as the modular cup and liner need to be thick enough to allow safe insertion during surgery). This, in turn, allows larger PE sizes in monoblock cups than in modular cups of the same size. For example, a size-52 monoblock shell used in this study accepted a 46-mm PE liner, while size-52 modular shells accepted only a 42-mm PE liner. Despite having this *larger* surface area for articulation with the PE liner, and thus, for potential wear, the monoblock cups in our study showed a *lower* metal ion detection rate than the modular cups, both in the overall analysis and when comparing only primary cases. One possible explanation for this is additional backside wear between the modular CoCr inserts and modular titanium shells.

Two retrieval studies have examined backside fretting and corrosion in modular DM hips [31,32]. Tarity et al. found evidence of fretting and corrosion in modular hips and noted that it was at lower rates than inserts retrieved from MoM articulations [31]. Kolz et al. examined 12 retrieved inserts of the same design and found a higher average qualitative corrosion score than that of Tarity et al. (2.7 vs 1.9) [32]. In addition, all the inserts examined in that study had a maximal linear material loss higher than 7 microns, which has been cited as being clinically significant [32]. Several other studies have detected backside fretting and corrosion in retrieved MoM hips, further implicating the taper junction between a metal insert and a metal shell as a source of metal ion release [33-35]. All these studies show that backside fretting and corrosion do exist in modular DM hips, which could explain the findings in our study, warranting further investigation.

We acknowledge several limitations to our work. First, no patient had preoperative serum metal ion testing. Second, we did not exclude patients with CoCr femoral heads, contralateral THA (with any bearing), or presence of hardware elsewhere in the body. Furthermore, the patients in the monoblock cohort were significantly older than those in the modular cohort (77.2 vs 70.5 years, $P < .001$). This was also true when comparing the monoblock cohort to the primary modular cohort (77.2 vs 70.3 years, $P < .001$). We could not find a good explanation for this, except that certain patients were gravitating toward certain surgeons, as most of the monoblock cups were implanted by one surgeon. This difference could introduce a certain bias to our results, as one could claim that at 70 years of age, patients were, on average, more active than they were at 77 years of age. Thus, they could be wearing out their implants more than the older patients. Although Tarity et al. did find higher levels of fretting and corrosion in younger patients than in older ones [31], they did not measure serum metal ion levels and did not have data on actual patient activity. In addition, most studies dealing with younger patients undergoing hip replacement define "young" as those aged than 65 years or even younger, and not those aged 70 years [11]. Furthermore, in a recent study focusing on DM implants in the young and active population, no patients were symptomatic at 2 years after surgery, and only one patient out of 43 had a cobalt level above 1 μg/L [13]. Thus, we believe that although this age difference was statistically significant, it was not clinically meaningful. Also, we were limited by the laboratory minimal detection level and could not measure metal ion levels below 1 μg/L. Thus, our results do not represent all our patients with DM hips, but only those for whom metal ions were detectable at a level above 1 μg/L. Moreover, as the monoblock designs were solid back, while the modular cups had holes with screws inserted in some of them, there was potentially larger effective joint space in the modular cases, allowing easier outflow

of ions from the hip. Yet, as ALTR was previously seen with solid-back MoM articulations [36], showing that the lack of holes did not prevent ion egression from the joint, this difference may not have been clinically significant. Finally, these data represent a short-term analysis, and long-term follow-up is needed.

Conclusions

In conclusion, we found that almost 30% of DM hips had metal ion levels above 1 μg/L 1 year after surgery. Monoblock cups had a 20% ion detection rate, while modular cups had a 39% detection rate. Cobalt was more commonly detected in monoblock designs, while chromium was more commonly detected in modular cups. Cobalt and chromium levels were comparable and uniformly low for both cohorts. To our knowledge, this is the first study to directly compare metal ion levels in monoblock and modular DM hips, and it is a further addition to the growing body of knowledge about these devices. While we support the selective use of monoblock and modular DM designs in primary and revision surgeries, a close clinical, radiological, and laboratory surveillance of patients with DM hips is warranted to further characterize the natural behavior of these implants.

Conflicts of interest

I. D. Martino is a paid consultant for Lima Corporate. D. J. Mayman received royalties from Smith & Nephew and Orthalign; is a paid consultant for Stryker; and has stock or stock options in Cymedica, Evolve Ortho, HS2, Imagen, Insight Global, Orthalign, and Stryker. P. K. Sculco is in the speakers' bureau of or gave paid presentations for DePuy, EOS Imaging, and Intellijoint Surgical; is a paid consultant for DePuy, EOS Imaging, Zimmer, Intellijoint Surgical, and Lima Corporate; has stock or stock options in Intellijoint Surgical and Parvizi Surgical Innovation; and receives research support from Intellijoint Surgical. T. P. Sculco received royalties from Exactech, is an unpaid consultant for Lima Orthopedic, is in the editorial or governing board of *American Journal of Orthopedics*, and is a board member in J. Robert Gladden Society and Orthopedic Research and Education Foundation.

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