



Early Post-operative Rises in Serum Metal Ion Levels in Total Hip Arthroplasty – A Prospective Cohort Study

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Abstract

Background: Serum Cobalt (Co) and Chromium (Cr) forms part of the diagnostic process for metallosis following Total Hip Arthroplasty (THA). While knowledge exists on longer term metal ion levels, expected early post-operative rises in serum Co and Cr in Metal-on-Polyethylene (MoP) THAs are currently unknown. This study aims to describe early rises in serum Co and Cr at 6 months post-operatively.

Methods: A prospective cohort study of 84 consecutive patients with an uncemented titanium stem from a single THA manufacturer was performed. Patients had either a metal (n=43) or ceramic (n=41) head articulating with a highly cross-linked polyethylene. Serum Co and Cr levels were measured six months post-operatively. Analysis compared mean values between groups and to determined baseline levels. Subgroup analysis investigated the effect of femoral head size and offset on metal ion levels.

Results: A mean difference of 0.002259 ppb (95% CI 0.000449-0.004069 ppb; p=0.015) was found when comparing 6-month serum Co in the metal head group compared to baseline. No significant differences were found in serum Cr (p=0.943) at six months post-surgery compared to baseline. Mean serum Co levels were higher in the MoP group compared to the CoP (Ceramic-on-Polyethylene) and auxiliary control group (p=0.012). There were no differences in serum Cr (p=0.976) between the MoP and CoP groups at 6 months post-surgery. Variations in femoral head size and offset did not impact metal ion levels.

Conclusion: At six months post-surgery, a higher magnitude of serum Co exists in metal heads when compared to baseline (p=0.015) and to ceramic heads (p=0.012). Further study is required to determine whether serum concentrations of metal ions will continue to increase over time which might leads to implant failure and revision.

Background

Trunnionosis in Total Hip Arthroplasty (THA) is the mechanical wear or corrosion occurring at femoral modular head-neck interfaces [1]. Trunnionosis has been attributed to elevated serum levels of cobalt and chromium in THAs [1,2]. The release of metal ions has the potential to lead to adverse local tissue reaction, persistent pain, increased wear, physiological dysfunction requiring revision surgery [3–5]. Its prevalence ranges between 0.023% to 2% accounting for 1.8% to 3.3% of the total THA revision burden [6–8].

The exact predisposing factors for trunnionosis are currently unclear. However, several aetiologies have been postulated. Shorter, narrower taper designs, longer neck, head size and femoral offset are factors suggested to increase edge loading at the bases causing local stress, micro-motion and subsequent damage [9–11]. Taper material

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and bearing surfaces have also been considered as factors affecting trunnionosis [12]. The impact of larger femoral head sizes is inconclusive although some studies associate it with higher metal ion levels in Metal-on-Polyethylene (MoP) THAs [13–15]. Ceramic-on Polyethylene (CoP) THAs have been a suggested solution. However, recent studies have suggested that taper corrosion still remains an issue [16,17].

There is currently no recommended single diagnostic tool to detect trunnionosis [18]. Serum cobalt (Co) and chromium (Cr) forms part of the diagnostic process; but consensus regarding its value in routine follow-up is lacking. The mean time from surgery to presentation with clinically significant trunnionosis is between 3.7 and 4.3 years [7]. In the absence of symptoms, many patients are not identified until revision surgery. It is not known whether metal ion levels alone should precipitate revision, however patients late to be diagnosed experience higher rates of complications [19,20].

Expected early post-operative rises in serum cobalt and chromium are currently unknown [21]. To date no studies in our search of the literature have evaluated the metal ion levels at intervals of less than 12 months in modern bearing couples. The best available evidence for levels of cobalt and chromium in well-functioning MoP bearing surfaces was demonstrated in a 10-year prospective follow-up study by Levine et al [22]. Their study measured metal ion levels at 12, 36, 60, 84 and 120 months post THA.

This study aims to determine whether there are early rises in serum cobalt and chromium at 6 months post MoP THA using pre-operative baseline and a CoP THA comparator groups. Additionally, we aimed to determine whether there was a difference in metal ion release based on variations in femoral head size and offset in MoP and CoP THAs.

Materials and Methods

A prospective study was performed to evaluate serum cobalt and chromium levels in patients undergoing primary elective THA for osteoarthritis in 2016 and 2017. Following institutional approval (HREC Approval Reference Number: 017105S), 100 consecutive patients aged 18 years or older were enrolled. All patients received an uncemented titanium femoral stem and acetabular component (MicroPort Orthopaedics Inc., Arlington, TN, USA; Dynasty Acetabular component, Profemur L Classic Monoblock Femoral component) using the Supracapsular Percutaneously Assisted Total Hip (SuperPATH) technique with in situ reduction of femoral head on trunnion under direct vi-

sion without impaction to avoid taper/trunnion damage as per the standard of care of a single surgeon (SQ) [23]. The PROFEMUR L Classic stem taper is made of Titanium Alloy (Ti6Al4V) with a 12/14 morse taper at the head-neck junction, Patients either had a metal (CoCr) (n=50) or ceramic (BioloX Delta, CeramTec North America Corp. Laurens, SC 29360, USA) (n=50) femoral head coupled with a High Cross-Linked Polyethylene (HCPE) liner. Choice of bearing surface was sequentially allocated with the first 50 consecutive patients receiving metal heads and the next 50 consecutive patients receiving ceramic heads.

Patients were deemed ineligible if they had undergone bilateral THAs, previous joint arthroplasty or underwent another arthroplasty procedure prior to follow-up (n=16).

Following exclusion criteria, of the 100 consecutive cases, eighty-four patients remained. These eighty-four cases with either a metal-on-polyethylene (n=43) or ceramic-on-polyethylene (n=41) were deemed eligible for inclusion.

Demographic data for each patient was collected including age, gender, BMI and previous joint arthroplasty. Implant specific information incorporating femoral head type, size, neck length, offset, trunnion taper design; and acetabular cup type and design were recorded.

The primary outcome was the serum level of cobalt and chromium levels at a single time point (6 months post-operatively). Baseline pre-operative serum Cobalt and Chromium values were determined from a separate group of pre-operative patients (n=50) (Auxiliary control group). Additionally, the CoP group served as a second comparator as its prosthesis (femoral head) does not contain cobalt or chromium. Patients were consented at their final pre-operative appointment and underwent pre-operative blood assessment of serum Cobalt and Chromium. Bloods samples were collected from patients into EDTA vacutainers test tubes using a stainless steel needle at the pathology collection centre. Blood samples were transported to the laboratory at ambient temperature for analysis. All blood samples were analysed for Serum Cobalt and Serum Chromium levels by Sullivan Nicolaides Pathology (Sullivan Nicolaides Pathology Pty Ltd, Queensland, Australia). At the standard six-month follow-up, enrolled patients were sent to the same centre for blood collection by trained phlebotomists. All specimens were prepared and transported to one laboratory for analyses.

Statistical Analysis

A priori, we hypothesized there would be no difference in serum cobalt or chromium at 6 months post-operatively between MoP and CoP THAs from a single manufacturer.

Additionally, we hypothesized that variations in femoral head size and offset would have no significant impact on metal ion levels at 6 months. With an alpha level of significance set to 0.05, a sample size of 32 patients in each group were required to detect a significant difference at a power level of 0.8. Differences in clinical characteristics between the two groups were evaluated using two-tailed sample T tests for statistical significance of continuous variables. All analyses were completed using Epitools Epidemiological Calculators (Ausvet, Australia).

Results

Patient Demographics

There were no significant differences observed between the metal and ceramic groups with respect to gender, mean age at time of surgery or BMI. Table 1 outlines the demographic data.

Serum Ion Comparisons with Baseline

A primary analysis was performed in which patients were grouped based on whether they had metal (MoP) or ceramic (CoP) heads. Significant difference was found in serum Co levels at 6 months post-surgery compared to baseline (auxiliary control group) in the MoP group (mean difference: 0.00226 ppb, SD 0.00438 ppb, 95%CI 0.000449 ppb – 0.00407 ppb ; $p=0.015$). No significant difference was found in serum Cr levels ($p=0.943$) compared to baseline (auxiliary control group) . In the CoP group, no significant difference was found in serum Co or serum Cr levels at 6 months compared to baseline ($p=0.833$ and $p=0.932$). Tables 2 and 3 outlines this data.

Metal-on-Polyethylene vs Ceramic-On-Polyethylene

A secondary analysis was performed comparing serum Co and Cr levels between MoP and CoP groups. Significant higher serum Co was found in the MoP group compared to CoP group (mean difference: 0.00211 ppb, SD 0.003774 ppb, 95% CI 0.000471-0.003749 ppb; $p=0.012$). However no significant difference was found in serum Cr levels between the two groups ($p=0.98$) at 6 months as well as baseline (auxiliary control group). Table 4 outlines this data.

Femoral Offset Comparison

The MoP cohort was further divided into standard ($n = 10$)_and extended offset groups ($n = 31$). There were no significant differences found in serum Co ($p=0.473$) or serum Cr ($p=0.398$) levels between these two groups. Table 5 outlines this data.

Table 1: Population demographic characteristics

	CoP THA group	MoP THA group	P value
Number of patients	41	43	
Males (%)	57%	56%	
Females (%)	43%	44%	
Age (mean)	62.5 ±12.8	66.2 ±9.46	0.13
BMI (mean)	28.3±4.6	30.3 ±5.4	0.07

Table 2: Baseline vs 6 months post MoP THA

	Baseline (n=43)	6/12 post MoP THA (n=43)	P value
Mean Cobalt (ppb)	0.00468	0.00694	0.015
Mean Chromium (ppb)	0.00981	0.00978	0.943

Table 3: Baseline vs 6 months post CoP THA

	Baseline (n=41)	6/12 post CoP THA (n=41)	P value
Mean Cobalt (ppb)	0.00468	0.00483	0.833
Mean Chromium (ppb)	0.00981	0.00976	0.932

Table 4: MoP vs CoP 6 months post surgery –serum chromium and cobalt comparison

	MoP THA group (n=43)	CoP THA group (n=41)	P value
Mean Cobalt (ppb)	0.00694	0.00483	0.012
Mean Chromium (ppb)	0.00978	0.00976	0.976

Table 5: All standard vs all extended offset

	All Standard Offset	All Extended offset	P-Value
Mean serum cobalt (ppb)	0.00726	0.00550	0.473
Mean serum chromium (ppb)	0.00995	0.00916	0.398

Significant difference was found only when comparing serum Co between MoP ($n = 9$) and CoP ($n = 10$)in those with extended offset ($p=0.016$). Table 6 outlines this data.

In further subgroup analyses, no other significant differences were found when comparing serum Co and Cr levels between MoP standard, MoP extended offset, CoP standard and CoP extended offset groups. Tables 6, 7, 8 and 9 outlines this data.

Femoral Head Size Comparison

Each cohort (MoP and CoP) were further divided by head size into small (<36 mm) and large (≥ 36 mm). There

Table 6: Extended Offset CoP vs MoP-serum chromium and cobalt comparison

	CoP group (n=10)	MoP group (n=9)	P value
Mean serum cobalt (ppb)	0.00420	0.00848	0.016
Mean serum chromium (ppb)	0.00940	0.0138	0.399

Table 7: Standard Offset CoP vs MoP-serum chromium and cobalt comparison

	CoP group (n=31)	MoP group (n=34)	P value
Mean serum cobalt (ppb)	0.00547	0.00653	0.360
Mean serum chromium (ppb)	0.00984	0.01040	0.650

Table 8: Extended vs Standard Offset in MoP-serum chromium and cobalt comparison

	MoP group Extended Offset (n=10)	MoP group Standard Offset (n=31)	P value
Mean serum cobalt (ppb)	0.00849	0.00653	0.280
Mean serum chromium (ppb)	0.00940	0.00984	0.774

Table 9: Femoral head size <36mm, MoP vs CoP

	MoP group femoral head <36mm (n=7)	CoP group femoral head <36mm (n=10)	P value
Mean serum cobalt (ppb)	0.0091	0.0058	0.07
Mean serum chromium (ppb)	0.0096	0.009	0.24

were no significant differences when comparing head sizes between MoP groups nor the CoP groups. Tables 9, 10, 11 and 12 outlines this data.

Discussion

In recent times there has been a growing clinic concern for metal ion release from trunnionosis in THAs [10]. Whilst not routinely measured, serum ion levels are important in the work-up of poorly performing THAs [18,24,25]. Currently, there exists minimal information on expected metal ion levels in patients with modern bearing coupled

Table 10: Femoral head size ≥36mm – MoP vs CoP metal ion levels

	MoP group (n=37)	CoP group (n=32)	P value
Mean serum cobalt (ppb)	0.008	0.005	0.11
Mean serum chromium (ppb)	0.0105	0.001	0.63

Table 11: CoP – femoral head size of <36mm vs ≥36mm metal ion levels

	CoP femoral head <36mm (n=10)	CoP femoral head ≥36mm (n=32)	P value
Mean serum cobalt (ppb)	0.0058	0.005	0.47
Mean serum chromium (ppb)	0.009	0.010	0.53

Table 12: MoP – femoral head size of <36mm vs ≥36mm metal ion levels

	MoP femoral head <36mm (n=7)	MoP femoral head ≥36mm (n=37)	P value
Mean serum cobalt (ppb)	0.0091	0.0079	0.75
Mean serum chromium (ppb)	0.0096	0.0105	0.63

THAs [26,27].

Results from this study showed a significant elevations in mean serum cobalt six months post-operatively in the MoP group but not in the CoP comparator group. Despite this, the mean short-term serum Co levels were within normal laboratory limits. No significant differences were found in serum Cr in either the MoP or CoP group compared to baseline levels. A differential elevation in cobalt has been attributed to greater solubility properties and localised head-neck modular precipitation of chromium orthophosphate [6,28]. This is consistent with literature suggesting that cobalt rises in a ratio of 1-5:1 in modular neck THAs [28–30]. Despite a lack of demographic difference between MoP and CoP groups, it is also important to consider ceramic heads more often being used in younger patients due to reports of improved wear rates [28,31].

The current evidence on femoral head size and offset variation in relation to serum metal ion levels remains inconclusive [19]. It has been speculated that increasing femoral head size would lead to increased tribocorrosion secondary to increased torque at the trunnion [11,32].

However, results from this study failed to identify any significant association with increased ion levels when stratifying based on head size regardless of bearing type. This might be a type 2 error as the subgroups used for head size analysis were relatively small (<10). Hence the result is inconsistent with prior studies [14,17]. White et al in their analysis of metal heads found a significant difference between serum cobalt levels in the 36mm group compared to the 32mm group. Similarly, Craig et al found a significant increase in serum cobalt levels in the 36mm group compared to the 28mm group. Interestingly there no significant differences between the 40mm group compared to 28mm group; although this lack of difference may be attributed to increased offset in the 28mm group. Bolland et al conducted a longer term study (mean follow up of 62 mths), they showed high rate of failure and high wear at the trunnion-head interface and passive corrosion of the stem, rising concern with using larger head on a conventional 12 taper [33]. The FEA simulation study by Lavernia et al. highlighted the potential influence of head size on trunnionosis. They showed that regardless of head material used, stress levels (underneath the junction between head and trunnion) had a direct correlation to head diameter. Therefore a larger head size could lead to high rate of trunnionosis [32].

There was a significant difference in serum Co levels only when comparing the MoP to CoP groups with extended femoral offset. There were no other significant differences in serum Co or Cr levels between MoP or CoP groups regardless of offset type. This result is in contrast to recent findings and laboratory-based studies demonstrating increased movement at the head-neck junction for higher offsets [11,19]. Martin et al found a significant increase in serum cobalt in those with increased offset. Significant differences in increased serum chromium were found only when comparing very high femoral offset (+7 to 9mm) to low offset (-2 to 1mm). However, it should also be noted that the average time to follow-up in this study was 28.7 (24.4-58.9) months. The differences in our study may not yet be apparent at six months.

There are a number of limitations to this study. Firstly, the baseline serum metal levels were taken from 50 pre-operative patients unrelated to our study cohort. Ideally pre-operative serum levels in our study cohort should have been used. Hence, a second comparator was found in the CoP group as the prosthesis was without any sources of Cobalt or Chromium. Secondly, this study did not account for potential confounders such as medical comorbidly such as renal insufficiency and level of daily activity level. Renal insufficiency is known to affect metal ion levels [34] although there were no patients with major renal disease

in our cohort. Differences in occupational exposure, diet and nutritional supplementation are also known to affect ion levels [6,35].

To our knowledge, this is the largest prospective study of metal ion levels concerning trunnionosis in a consecutive cohort based on sample size calculations and power analysis. However, subgroup comparisons concerning variations in implant components only included small numbers in each. The subgroup analyses were likely underpowered, leading to a type 2 error. A study with a larger sample size with adequate power would better reflect the impact of implant specific variations. It is unclear whether a “running-in” period exists as with older metal-on-metal implants where Co and Cr levels gradually stabilise [36]. Long term prospective cohort studies suggest that metal ion levels continue to increase with time and did not plateau [22,37]. Jacobs et al in a prospective longitudinal study found that at 36 months they were 5-8 times pre-operative levels [37]. Therefore, continued surveillance is necessary to determine if serum concentrations of metal ions will increase overtime in our cohort. Future research could focus on identifying those at risk of trunnionosis through detection of early post-operative serum metal ion rises.

Conclusions

This study allows a number of conclusions to be made. Rises in serum cobalt exist in the early stages post THA. At six months, increases were apparent in Metal-on-Polyethylene THAs when compared to baseline ($p=0.015$) and Ceramic-on-Polyethylene THAs ($p=0.012$). Serum metal ion levels were not affected by implant specific variations.

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AUTHOR DISCLOSURES

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