ARTICLE IN PRESS

The Journal of Arthroplasty xxx (2016) 1–6

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Original Article

A Comparison of Blood Metal Ions in Total Hip Arthroplasty Using Metal and Ceramic Heads

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A R T I C L E I N F O

Article history:
Received 28 December 2015
Received in revised form
29 February 2016
Accepted 11 March 2016
Available online xxx

Keywords:
metal
ceramic
THA
cobalt
chromium
adverse local tissue reaction

A B S T R A C T

Background: In recent time, metal ion debris and adverse local tissue reaction have reemerged as an area of clinical concern with the use of large femoral heads after total hip arthroplasty (THA).
Methods: Between June 2014 and January 2015, 60 patients with a noncemented THA using a titanium (titanium, molybdenum, zirconium, and iron alloy) femoral stem and a V40 trunnion were identified with a minimum 5-year follow-up. All THAs had a 32- or 36-mm metal (n = 30) or ceramic (n = 30) femoral head coupled with highly cross-linked polyethylene. Cobalt, chromium, and nickel ions were measured.
Results: Patients with metal heads had detectable cobalt and chromium levels. Cobalt levels were detectable in 17 (56.7%) patients with a mean of 2.0 μg/L (range: <1.0-10.8 μg/L). Chromium levels were detectable in 5 (16.7%) patients with a mean of 0.3 μg/L (range: <1.0-2.2 μg/L). All patients with a ceramic head had nondetectable cobalt and chromium levels. Cobalt and chromium levels were significantly higher with metal heads compared to ceramic heads ($P < .01$). Cobalt levels were significantly higher with 36-mm metal heads compared with 32-mm heads ($P < .01$). Seven patients with metal femoral heads had mild hip symptoms, 4 of whom had positive findings of early adverse local tissue reaction on magnetic resonance imaging. All ceramic THA was asymptomatic.
Conclusion: The incidence and magnitude of cobalt and chromium levels is higher in metal heads compared to ceramic heads with this implant system ($P < .01$). Thirty-six millimeter metal femoral heads result in larger levels of cobalt compared with 32-mm metal heads.

Modular femoral heads were introduced to total hip arthroplasty (THA) to provide greater intraoperative flexibility in restoring leg length, offset, and soft tissue tension. Other advantages include the ability to replace the femoral head at revision surgery and decrease implant inventory [1,2]. Despite an initial concern of fretting and corrosion at the head-neck interface [3], the advantages of modular heads and improved metallurgy ultimately led to its popularity. Although technologies have improved, there has been a remaining clinical concern over fretting and corrosion at modular junctions as a source of metal ion release especially with modular necks, larger head sizes, and narrow trunnions [4-7]. High metal ion levels have been associated with persistent pain, increased wear, metallosis, adverse local tissue reactions, and cognitive and cardiac dysfunction [5,8-12].

Most of the literature has focused on metal ion levels in articulating surface in both metal-on-metal hip resurfacings and metal-on-metal THAs, with little attention toward trunnionosis with polyethylene bearings [13,14]. Recent retrieval analyses have observed evidence of fretting and corrosion at the head-neck junction in both metal- and ceramic-on-polyethylene bearings, leading many to believe there may be a concern for metal ions release in these bearings [6,7,15]. However, few studies have evaluated metal ion levels with polyethylene bearings [3,16-20]. To our knowledge, the only prospective study measuring metal ions with highly cross-linked polyethylene bearings used 28-mm femoral heads [3].

In recent times, larger femoral head sizes are being used more frequently [21,22], largely due to the decreased risk of dislocations [23]. However, little is known about the effect large femoral heads

This study was IRB approved at our institution (IRB: 2015-119).

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to http://dx.doi.org/10.1016/j.arth.2016.03.024.

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http://dx.doi.org/10.1016/j.arth.2016.03.024

will have on metal ion release. Using computer modeling, Lavernia et al [24] showed that stresses at the head-neck junction increase proportionally to the diameter of the femoral head. However, to our knowledge, there have been no studies comparing metal ion release between larger (32 or 36 mm) metal and delta ceramic femoral heads.

Therefore, we sought to evaluate the incidence and magnitude of cobalt, chromium, and nickel ion release with contemporary noncemented THA using large ceramic and metal femoral heads coupled with highly cross-linked polyethylene (HXLPE). In addition, we aimed to determine if there was a difference in metal ion release based on head size and offset between the metal and ceramic femoral heads. Finally, we sought to determine if detectable cobalt and chromium ions are associated with pain, function, or satisfaction scores.

Materials and Methods

A study was performed to evaluate serum cobalt, chromium, and nickel ions in patients with large metal and delta ceramic femoral heads between June 2014 and March 2015. After institutional review board approval, all patients who had underwent primary THA with an Accolade TMZF (Stryker, Mahwah, NJ) and a large (32 or 36 mm) femoral head coupled with polyethylene were identified (n = 761) from our prospective database. All patients had either a metal (n = 370) or delta ceramic (n = 391) femoral head. Patients were deemed ineligible if they underwent bilateral THA with different head types, different head sizes, underwent revision THA, or underwent total knee arthroplasty before final follow-up (n = 109). Six hundred fifty-two THAs, with either a large delta ceramic (n = 361) or metal (n = 313) were eligible for inclusion in this study. Sixty-six patients were approached for enrollment during clinical follow-up at 5 years, 6 (9.1%) of whom declined to participate. A total of 60 patients were included in this study with large delta (n = 30) or metal (n = 30) heads.

At the time of surgery, all patients received a noncemented Accolade TMZF (Stryker) femoral stem as per the standard of care of the 2 senior authors (A.S.R. and C.S.R.). The Accolade TMZF stem is a tapered wedge design that has aV40 trunnion taper, 2 available neck angles (127° vs 132°), and a neck length that increases incrementally with stem size. The stem is composed of a titanium (12%) molybdenum (6%) zirconium (2%) iron (titanium, molybdenum, zirconium, and iron) β alloy, which is well known to have good biocompatibility [25,26], as well as provide increased flexibility, greater strength, and better surface stress resistance compared to other titanium-based alloys, especially titanium (6%) aluminum (4%) vanadium [26]. All patients received a ceramic (BIOLOX delta, CeramTec, Plochingen, Germany) or metal (low friction ion treatment; Stryker), cobalt-chrome femoral head. Based on reports of improved wear rates with ceramics [27,28], patients were indicated for a ceramic femoral head if they were young (<60-65 years); otherwise they received a metal femoral head. All femoral heads were coupled with a second-generation HXLPE (X3, Stryker), with a minimal polyethylene thickness of 5.9 mm. A Trident PSL (Stryker) acetabular component was used in all cases. Implant and head size were determined based off of preoperative templating with all final decisions made intraoperatively based on a patient’s anatomic features by the 2 senior surgeons (A.S.R. and C.S.R.).

Patients were consented at the time of their annual follow-up appointment (5 years or longer). At the annual office visit, anteroposterior and false profile radiographs were evaluated by one of the 2 senior authors for radiolucencies, component alignment, and osteolysis. After the office visit, enrolled patients were sent to the hospital laboratory for blood draw. All blood samples were attained as per our institution's standard of care. A patient's blood was drawn using a stainless steel needle and placed in a glass test tube, especially designed with no metal traces. Specimens were then centrifuged, refrigerated, and transported to ARUP Laboratories (Salt Lake City, UT) for analysis. ARUP Laboratories uses quantitative inductively coupled plasma mass spectrometry to measure serum ion levels, with a detection limit of <1.0 μg/L, <1.0 μg/L, and <10.0 μg/L, for cobalt, chromium, and nickel, respectively. Patients with detectable ion levels had blood work repeated to rule out the possibility of contamination.

All patients had clinical evaluations at their 6 weeks, 1-, 2-, and 5-year annual follow ups. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score (0-96, where 0 is the best and 96 is the worst) and subscores were used to evaluate pain (0-20, where 20 is worst), stiffness (0-8, where 8 is worst), and function (0-68, where 68 is worst). Patients were considered symptomatic if they reported a WOMAC pain subscore greater than 10. Activity level was measured using the University of California Los Angeles (UCLA) activity score (0-10, where 10 is the most active) and a patient-administered questionnaire (PAQ) [29] was used to measure pain and psychological symptoms (0-100, where 0 is the best). The PAQ also measures satisfaction by a visual analog scale (0-10, where is 10 fully satisfied). Hospital for Special Surgery hip score was also used to evaluate hip function (0-40, where 40 is the best) [30].

All patients with a cobalt level greater than 4.0 μg/L, or were symptomatic, were indicated for an magnetic resonance imaging to rule out adverse local tissue reaction. This value was chosen due to the improved sensitivity reported with a similar threshold [31]. Positive findings of adverse local tissue reaction were defined as an abnormal fluid, solid or mixed collection of soft-tissues around the hip.

Statistical Analysis

A priori, we hypothesized there would be no difference in metal-ion concentrations between the ceramic and metal groups. At a level of significance of 0.05, a total of 60 patients, 30 per group, were required to detect a significant difference at a power of 0.8. Differences in clinical characteristics between the 2 groups were evaluated using Mann-Whitney *U* tests for continuous variables and Fisher's exact tests for categorical variables. The Mann-Whitney *U* test was deemed appropriate, as the Shapiro-Wilk test determined continuous variables to be non-normally distributed. All analyses were performed with SAS 9.3 (Cary, NC) at a level of significance of 0.05. Metal ions below the given threshold detection limit (Co: <1.0 μg/L, Cr: <1.0 μg/L, Ni: <10.0 μg/L) were considered 0 for all statistical analyses. Pearson's correlation was used to assess the relationship between the incidence and magnitude of metal ions with the clinical evaluations. Descriptive statistics are shown as either means or medians with standard deviations (SDs) for continuous variables and frequencies and percentages for categorical variables.

Results

Demographics

The mean age for all patients in this study was 65.4 ± 9.2 years (range: 46.6-84.9) with a mean body mass index of 28.1 ± 5.6 kg/m^2 (range: 18.7-43.6). The ceramic group was found to be significantly younger than the metal group ($P < .01$). No differences were observed with respect to follow-up ($P = .55$), sex ($P = .30$), side ($P > .99$), body mass index ($P = .97$), UCLA score ($P = .28$), or head size ($P = .79$) between the metal and ceramic groups (Table 1).