The Journal of Arthroplasty xxx (2016) 1–5

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Original Article

Metal Ion Levels in Young, Active Patients Receiving a Modular, Dual Mobility Total Hip Arthroplasty

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ARTICLE INFO

Article history:
Received 24 September 2016
Received in revised form
23 November 2016
Accepted 10 December 2016
Available online xxx

Keywords:
total hip arthroplasty
dual mobility
metal ions
activity
clinical outcomes

ABSTRACT

Background: Dual mobility total hip arthroplasty (THA) components improve stability, yet use of a modular cobalt alloy acetabular liner may be associated with metal ion release. This study's purpose was to measure blood metal ion levels in young, active patients receiving a dual mobility THA prosthesis.
Methods: This is a prospective study of young, active patients undergoing primary THA. Twenty-six patients received a 22-mm cobalt alloy ($n = 10$) or a 28-mm ceramic ($n = 16$) femoral head, a modular cobalt chrome acetabular liner, with a highly cross-linked polyethylene insert (dual mobility). Seventeen control patients received a 32-mm cobalt alloy ($n = 6$), oxidized zirconium ($n = 5$), or ceramic ($n = 6$) femoral head and polyethylene acetabular liner (conventional). All patients received a cementless, titanium femoral stem. Blood metal ion levels (μg/L) were measured preoperatively and at 1 year postoperatively.
Results: No difference was present for age or body mass index ($P = .5$ and .9). At 1 year postoperatively, mean cobalt levels were greater in the dual mobility cohort (0.23 ± 0.39 vs 0.15 ± 0.07, $P < .001$). Four patients in the dual mobility cohort had a cobalt level outside the reference range (0.03-0.29), with values from 0.34 to 1.81 μg/L. One patient in the conventional cohort had a cobalt level outside the reference range with a value of 0.39 μg/L.
Conclusion: The presence and clinical significance of increased cobalt levels in 4 patients with the use of a modular dual mobility prosthesis demonstrates the necessity of continued surveillance.

Prosthetic dislocation following total hip arthroplasty (THA) remains a concern with a reported incidence of 0.2%-7% after primary and 10%-25% after revision THAs [1]. While the risk of dislocation following THA is multifactorial and includes both surgeon-related factors such as component position and surgical approach and patient-related factors such as gender and age [2], recent advancements in implant design have helped to decrease its incidence. While restoration of hip biomechanics and offset remains critical, the use of larger femoral head sizes has been associated with a lower incidence of postoperative dislocation following both primary and revision THAs [3-5]. Larger femoral head sizes increase the head-neck ratio, increasing range of motion before neck-socket impingement, while also increasing the jump distance necessary to displace the femoral head from the acetabulum [6]. However, the use of large-diameter cobalt alloy femoral heads has been associated with reports of adverse local tissue reactions secondary to metal ion release from not only a metal-on-metal bearing surface if present, but also the taper-trunnion junction between the head and stem [7-11].

Dual mobility articulations also increase femoral head size and have been shown to reduce the incidence of hip instability following THA [5,12-18]. They have been used in Europe for over 30 years, but have recently received an increased interest in the United States [19]. This prosthetic design consists of a large-diameter, highly cross-linked polyethylene insert articulating with an acetabular component with a polished inner surface or modular liner, and a smaller constrained articulation between a modular femoral head and the polyethylene. Thus, the polyethylene acts as a mobile-bearing

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.2016.12.012.

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http://dx.doi.org/10.1016/j.arth.2016.12.012
0883-5403/

articulating liner with both the femoral head and acetabulum [20]. Initial dual mobility designs consisted of an uncemented, hemispherical acetabular component with a highly polished metal inner bearing surface [21], but use of a monoblock acetabular component limits the ability to use acetabular screws for supplemental fixation and a conventional polyethylene acetabular liner [5]. Recently, modular dual mobility prostheses have been introduced in which a modular cobalt-chromium liner is inserted into a standard titanium acetabular component. While this modularity provides the familiarity of a standard titanium acetabular component and the ability for supplemental screw fixation, the potential for fretting corrosion between the cobalt-chromium liner and the titanium acetabular component remains a concern [5]. In a review of 100 consecutive patients undergoing primary THA using a modular dual mobility prosthesis (Modular Dual Mobility components; Stryker Orthopaedics, Mahwah, NJ), Matsen Ko et al [5] noted 21% of patients to have a serum cobalt level above the normal range, with 9% significantly above normal ($\geq$1.6 μg/L), at a mean of 27.6 months postoperatively. Patients in that investigation received the dual mobility prosthesis if perceived to have a high risk of instability due to increased age, neuromuscular disease, high Charlson comorbidity index, or American Society of Anesthesiology score [5]. However, preoperative serum metal ion levels were not obtained, a variety of testing laboratories were used, and no control population of conventional THAs were present for comparison in this investigation.

Thus, while modular dual mobility prostheses decrease the incidence of instability following primary and revision THA, concerns of fretting corrosion between a modular cobalt-chromium liner and titanium acetabulum remain. Prior investigations reporting on the use of a modular dual mobility prosthesis have mainly focused on primary THA patients deemed "high risk" for instability, or in the revision THA setting [5,15,22]. Thus, to our knowledge, the outcome of modular dual mobility prostheses in young, active patients has not been evaluated. Therefore, the purpose of this study is to prospectively compare whole blood metal ion levels and clinical outcomes in young, active patients undergoing primary THA with the use of a modular dual mobility prosthesis versus a conventional, highly cross-linked polyethylene acetabular liner. Our hypothesis is that while functional outcomes will be similar between the 2 cohorts, patients receiving a modular dual mobility prosthesis will have increased mean whole blood cobalt and chromium levels.

Materials and Methods

This is a prospective, Institutional Review Board-approved study of young, active patients undergoing primary THA at a single institution. All patients provided informed consent prior to study inclusion. Inclusion criteria for this investigation were patients between the ages of 18 and 65, with a body mass index of $\leq$35 kg/m^2, undergoing primary THA for a diagnosis of noninflammatory arthritis including osteoarthritis or avascular necrosis of the femoral head. In addition, patients were required to have a University of California at Los Angeles activity score of >6 prior to their hip becoming painful and/or limiting their activity, with the goal to capture a younger, more active patient population. Patients were also required to be willing to comply with regularly scheduled follow-up appointments up to 5 years postoperatively. Exclusion criteria for this study were the following: patients with an active hip infection or sepsis; bone stock considered inadequate based on radiographic evaluation for cementless acetabular and femoral fixation at the surgeon's discretion; any cardiovascular, immunological, or neuromuscular disorder severe enough to compromise implant stability and postoperative recovery; a history of renal disease; a contralateral hip arthroplasty; a prior open surgery on the affected hip; a history of metal hardware elsewhere in their body; and any patient pregnant or with plans to become pregnant during the course of the study.

All patients eligible and willing to participate received a modular, dual mobility acetabular prosthesis using a titanium, cementless acetabular component (Modular Dual Mobility; Stryker Orthopaedics), and a titanium, proximally coated, tapered cementless femoral stem (ACCOLADE II; Stryker Orthopaedics; "dual mobility: cohort"). All surgeries were performed by one of the 3 fellowship-trained arthroplasty surgeons with prior experience using this prosthesis. Femoral head size with this prosthesis is dictated by the size of the acetabular component as an acetabular component size of 48, 50, and 52 mm requires a 22-mm inner femoral head, and an acetabular component size $\geq$54 mm requires a 28-mm inner femoral head [5]. The 22-mm femoral heads were available in cobalt alloy only (LFIT CoCr; Stryker Orthopaedics). In the dual mobility cohort, 10 patients received a 22-mm cobalt alloy femoral head, while 16 patients received a 28-mm ceramic femoral head (Delta Ceramic; CeramTec, Plochingen, Germany). For comparison, patients meeting the same inclusion and exclusion criteria who received a conventional bearing with a highly cross-linked polyethylene liner were also reviewed ("conventional" cohort). These patients were part of a separate prospective investigation that had been performed to assess whole blood metal ion levels in primary THA using a conventional, highly cross-linked polyethylene liner. As with the dual mobility cohort, all patients in the conventional cohort received a titanium, cementless acetabular component and titanium, proximally coated, tapered, cementless femoral stem. Six patients received a 32-mm cobalt alloy femoral head (Zimmer, Inc, Warsaw, IN), 5 patients received a 32-mm oxidized zirconium femoral head (Oxinium; Smith and Nephew, Inc, Memphis, TN), and 6 patients received a ceramic femoral head (4 with 32 mm and 2 with 36 mm; Zimmer, Inc). Femoral stem and acetabular component combinations included 10 M/L Taper stems with Trilogy acetabular components (Zimmer, Inc), 2 VerSys Fiber Metal MidCoat stems with Trilogy acetabular components (Zimmer, Inc), 3 Synergy stems with R3 acetabular components (Smith and Nephew, Inc), and 2 Anthology stems with R3 acetabular components (Smith and Nephew, Inc).

All patients had radiographically well-fixed components at a minimum of 1-year clinical follow-up. Short-Form 12 (SF-12) [23] and Harris Hip Scores (HHSs) [24] were collected both preoperatively and at 1 year postoperatively. Blood samples from each patient were obtained for whole blood metal ion analysis (cobalt, chromium, titanium) prior to their THA and at 1 year postoperatively. All instruments used to collect specimens were verified to be free of metal contamination. All samples were processed by the London Health Sciences Department of Pathology and Laboratory Medicine. Metal ion levels were assessed using high resolution sector field inductively coupled plasma mass spectrometry as previously described by McMinn [25]. Reference ranges for metal ions tested were as follows: cobalt (0.032-0.290 ng/mL, parts per billion), chromium (0.40-1.60 ng/mL, parts per billion), and titanium (0.00-1.40 ng/mL, parts per billion) as recommended by the testing facility. In addition, blood urea nitrogen (BUN) and creatinine levels were measured as markers of renal function (mg/dL) both preoperatively and at 1 year postoperatively. There were no patients lost to follow-up in this prospective investigation.

Statistical analyses were performed using chi-square tests for categorical variables and independent Student's t-tests for continuous variables. All P values <.05 were considered statistically significant.

Results

Twenty-six patients were prospectively enrolled in the dual mobility cohort and 17 patients in the conventional cohort. There