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Changes in Early Serum Metal Ion Levels and Impact on Liver, Kidney, and Immune Markers Following Metal-on-Metal Total Hip Arthroplasty

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ABSTRACT

We retrospectively studied 32 consecutive patients (32 hips) who underwent THA with a Durom large-head, MOM articulation between January 2008 and December 2010. Of the patients who underwent THA using a Trilogy metal on polyethylene prosthesis during the same period, 32 were chosen to form the Trilogy group. 32 volunteers were chosen to form the control group. At the last follow-up, serum metal ion levels, liver and kidney function and host immunologic immune responses were evaluated. The mean Co and Cr levels in the Durom group were 4.33- and 1.95-fold higher than those in the Trilogy group. CD3+, CD4+ and CD8+ cell levels in the Durom group were significantly decreased. The INF- γ level in the Durom group was significantly higher than that in the Trilogy and control groups.

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Polyethylene particle-induced osteolysis has been confirmed as the most important factor in the reduced survivorship of patients following metal-on-polyethylene total hip arthroplasty (THA) [1,2]. To reduce wear-related osteolysis and improve long-term survivorship of prosthesis recipients, highly cross-linked polyethylene, metal-on-metal (MOM) articulation and ceramic-on-ceramic articulation have been introduced. With the improvement in metallurgy and manufacture design, MOM prostheses have been widely adopted because of superior wear performance, theoretically increased range of motion, and stability due to the large diameter femoral component [3–5]. Recent reports have shown good results of MOM THA [6,7].

However, because of the local and whole-body reaction due to metal ion release from MOM wear particles and the high revision rate of the acetabular component, the adverse effects and long-term results of MOM THA have recently become a concern [8]. Many studies have reported an elevated serum level of cobalt (Co) and chromium (Cr) ions in patients who received second generation MOM THA devices [9,10]. For example, Chandran et al [11] reported that the 9-year risk of developing chronic renal disease after primary MOM THA was 14% and severe or end-stage renal disease was 6%. Therefore, MOM articulation is not recommended for patients with inadequate renal function. On the contrary, Gröbl et al [7] found no renal insufficiency after 10-year follow-up of MOM THA. However, there are no reports in the current literature that have evaluated liver function in patients following MOM THA.

Diffuse and perivascular infiltration of T and B lymphocytes, and plasma cells in tissues surrounding prostheses in patients following MOM THA have been reported [12–14]. The immunological response pattern and cell composition in MOM patients were different from those in metal-on-polyethylene patients. A lymphocyte-dominated immunological response in correlation to metal wear product was suggested [12,14]. In vitro analyses have shown that metal ions may be toxic to lymphocytes and lead to cell necrosis or apoptosis [15,16]. Some hematological alterations, such as a reduction in the number of leukocytes and some subpopulations of lymphocytes, have been observed in patients with aseptic loosening of a MOM THA in which the metal component is worn [17]. However, the type and degree of immunological responses to well-fixed MOM prostheses remain unclear. The present retrospective, case-controlled study was performed to compare the clinical outcomes, serum metal ion levels, host immunologic responses, and renal, liver, and immune function in patients following different types of hip implants. Patients who received non-modular, large-head MOM acetabular component hip implants were compared with patients who received modern, modular titanium acetabular component hip implants using conventional head sizes and metal-on-highly cross-linked polyethylene articulations and healthy volunteers (controls) at a mean follow-up of 2 years.

Material and Methods

Implants

The Durom cup non-modular acetabular component hip implant (Zimmer Holdings Inc., Warsaw, IN, USA) is composed of a high-carbon, forged Cr–Co bearing surface with a cup diameter range of 44–66 mm and a corresponding head range of 38–60 mm. The Trilogy modular titanium acetabular component hip implant (Zimmer

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Holdings Inc., Warsaw, IN, USA) uses a 28-mm Cr–Co head on highly cross-linked polyethylene for articulation (Fig. 1).

Patients

The present study was approved by the ethical committee of the First Affiliated Hospital, Nanjing Medical University (Jiangsu, China) and informed consent was obtained from all patients prior to participation. We retrospectively analyzed 32 consecutive patients (32 hips; 18 women and 14 men; mean age, 57.4 years; age range, 37–75 years; mean body mass index (BMI), 24.7 ± 3.17) who underwent THA and received a Durom large-head MOM non-modular acetabular component hip implant (Durom group) between January 2008 and December 2010. The indications for the implantation of the Durom prosthesis were osteoarthritis in four patients (four hips), osteonecrosis in 16 (16 hips), and femoral neck fracture in 12 (12 hips). A total of 32 patients who underwent THA and received a Trilogy metal on polyethylene prosthesis implant during the same period were chosen to form the Trilogy group. From 100 healthy volunteers without history of metal implantation, 32 were chosen to form the control group. The three groups were matched on age, gender, and BMI and compared using analysis of variance (ANOVA) and the chi-squared test to ensure sample homogeneity.

Operative Technique

All THA procedures were performed using a modified Hardinge approach. The desired acetabular position was abduction of 45° and anteversion of 15° . All patients in the Durom group were implanted with large-diameter acetabulum (46–54 mm) and head (40–48 mm) components, whereas all patients in the Trilogy group were implanted with a conventional 28-mm metal head and highly cross-linked polyethylene liners. All procedures were performed by the two senior authors (Fan and Liu).

Assessment Methods

All patients underwent clinical examinations and the Harris Hip score was used to evaluate the physical function in hip and the Medical Outcome Study Short Form-36 (SF-36) score was used to measure physical health.

Anteroposterior supine radiographs of the pelvis and anteroposterior radiographs of the hip and femur were made preoperatively, immediately postoperatively, and at the last follow-up, and then evaluated by two observers. The osteolysis and radiolucent lines on the acetabular side were determined according to the method of Delee and Charnley [18], whereas component migration or radiolucent lines on the femoral side were determined using the method of Gruen et al [19].

Inductively coupled plasma mass spectrometry was chosen to measure serum ion levels. The detection limits were $0.1 \mu\text{g/L}$ for Cr and $0.01 \mu\text{g/L}$ for Co. Blood samples from all patients were collected by

the same nurse during the last follow-up examination. A 5-mL blood sample was collected from each patient in an individual syringe (Becton Dickinson & Company, Franklin Lake, NJ, USA) and centrifuged at 1000 g for 20 min to obtain serum, which was digested with nitric acid. The final serum sample was compared with aqueous standards and commercial blood controls to verify the results.

The circulating alanine aminotransferase (ALT), aspartate aminotransferase (AST), blood urea nitrogen (BUN), and serum creatinine levels of the three groups were determined at the last follow-up evaluation.

The circulating C3, C4, immunoglobulin (Ig)A, IgG, and IgM levels in all serum samples were determined at the last follow-up to evaluate the humoral immunity status of the patients. Thirty thousand cells were analyzed on a fluorescence-activated cell sorting (FACS) flow cytometer (FACSAria; BD Biosciences, San Jose, CA, USA) using FACSAria software (BD Biosciences). All plasma samples were thawed at room temperature and measured simultaneously on the FACSAria flow cytometer using Cytometric Bead Array Human Th1/Th2 kits (BD Biosciences) for the concentrations of interferon (IFN)- γ and IL-4. Data were analyzed using BD CBA software (ver. 1.4.2; BD Biosciences) and are expressed as pg/mL .

Statistical Analysis

The mean Harris Hip Score and SF-36 Score were compared using two-sided Student's *t*-test. The frequency distribution of lymphocyte subpopulations was calculated and the results were expressed as mean \pm standard deviation ($\bar{x} \pm s$). Serum levels of Co and Cr ions in the three groups were evaluated by ANOVA. The level of significance was set at $P = 0.05$ for all statistical tests. All analyses were performed using SPSS software (ver. 16.0; SPSS Inc., Chicago, IL, USA).

Results

All patients in the Durom and Trilogy groups completed the follow-up examinations. The mean postoperative follow-up time was 24.9 months (range, 15–34 months) in the Durom group and 25.53 months (range, 15–35 months) in the Trilogy group. In the Durom group, the mean age at the time of surgery was 57.44 ± 12.25 years, 18 patients were female, and the mean patient BMI was 24.70 ± 3.17 . In the Trilogy group, the mean age was 59.16 ± 13.97 years, 17 patients were female, and the mean BMI was 25.72 ± 3.27 . The control group was comprised of 17 females and 15 males with a mean age of 58.46 ± 13.25 years old and a mean BMI of 24.84 ± 4.41 . A comparison of the mean age and BMI among the three groups showed no significant differences by ANOVA ($F = 0.138$ and 0.733 ; $P = 0.871$ and 0.483). The Pearson test results showed no significant differences in gender ratio among the three groups ($P = 0.404$).

The mean Harris Hip Score at the last follow-up examinations was 94.93 ± 5.24 in the Durom group and 89.07 ± 7.32 in the Trilogy group, which were not statistically different ($t = 2.456$, $P = 0.084$).

The range of motion of the operated hips in abduction, adduction, internal rotation, and external rotation in the Durom group at the last follow-up was not different from that in the Trilogy group. However, the range of flexion in the Durom group was significantly higher compared to that in the Trilogy group ($111.33^\circ \pm 9.35^\circ$ vs. $94.23^\circ \pm 13.05^\circ$; $t = 4.027$, $P = 0.000$). The SF-36 satisfaction score in the Durom group at the last follow-up was significantly higher than that in Trilogy group (647.80 ± 87.19 vs. 600.70 ± 164.91 ; $t = 0.963$, $P = 0.011$).

There was no detectable radiological migration of the acetabular components or radiolucent lines in both groups.

At the last follow-up examination, the Co and Cr levels in the Durom group were $0.547 \pm 0.512 \mu\text{g/L}$ and $0.135 \pm 0.087 \mu\text{g/L}$ respectively. The Co and Cr levels in the Trilogy group were

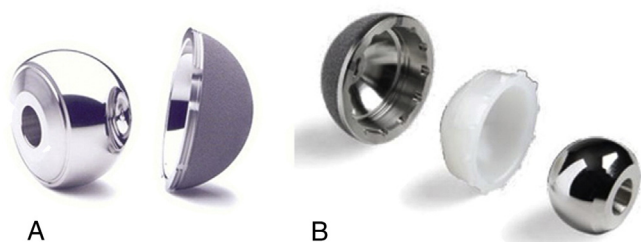


Fig. 1. The Durom cup (A) and Trilogy cup (B).

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