



# Serum Metal Ion Levels Following Total Hip Arthroplasty With Modular Dual Mobility Components



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## ABSTRACT

Dual mobility acetabular components can reduce the incidence of total hip arthroplasty (THA) instability. Modular dual mobility (MDM) components facilitate acetabular component implantation. However, corrosion can occur at modular junctions. Serum cobalt and chromium levels and Oxford scores were obtained at minimum two year follow-up for 100 consecutive patients who had THA with MDM components. Average Oxford score was 43 (range 13–48). Average serum cobalt and chromium values were 0.7 mcg/L (range, 0.0 to 7.0) and 0.6 mcg/L (range, 0.1 to 2.7), respectively. MARS MRI was performed for four patients with pain and elevated serum cobalt levels. Two of these studies were consistent with adverse local tissue reaction. We recommend use of MDM implants in only patients at high risk for dislocation following THA.

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Instability following total hip arthroplasty (THA) has been reported to be a common cause for subsequent revision surgery [1,2]. Use of larger femoral heads when performing THA is associated with a lower incidence of postoperative dislocation [3,4]. It is believed that this enhanced stability is due to greater range of motion (ROM) before neck to socket impingement and increased joint jump distance associated with use of larger femoral head [5]. Dual mobility components, recently introduced in the US, effectively increase head size and reduce the incidence of THA instability [6–12]. Increased head size, coupled with the potential for motion at two articulating surfaces leads to increased ROM prior to impingement and likely explains the low incidence of reported instability when this device is used [7,9,11].

However, the original dual mobility technology utilized a monoblock cobalt chromium acetabular component that does not have a central cup hole, and an implant insertion handle cannot be rigidly attached to the acetabular shell. Additionally, there are no screw holes in this implant for supplemental fixation of the acetabular component. These design limitations lead to difficulties controlling orientation during component insertion, inability to confirm full implant seating, and no potential for supplemental screw fixation if needed. In order to alleviate these issues, a modified dual mobility (MDM) device was recently developed. The modified implant combines a standard titanium acetabular

component and a modular cobalt chromium cup liner insert (Modular Dual Mobility components, Stryker Orthopaedics, Mahwah, NJ) (Fig. 1).

Fretting corrosion commonly occurs at modular interfaces following THA [13–15]. Release of metal ions associated with this form of corrosion, specifically cobalt, can lead to adverse local tissue reaction (ALTR) and the need for revision surgery [15]. MDM components consist of a male cobalt chromium cup liner, effectively acting as a trunnion that interfaces with a titanium female taper on the acetabular component. Conceptually, this relationship is analogous to a cobalt chromium femoral stem interfacing with a modular titanium femoral head. Therefore, fretting corrosion at this junction can occur. We attempted to determine if fretting corrosion and ALTR occurred at early follow-up (two years) following THA performed with MDM components.

## Patients and Methods

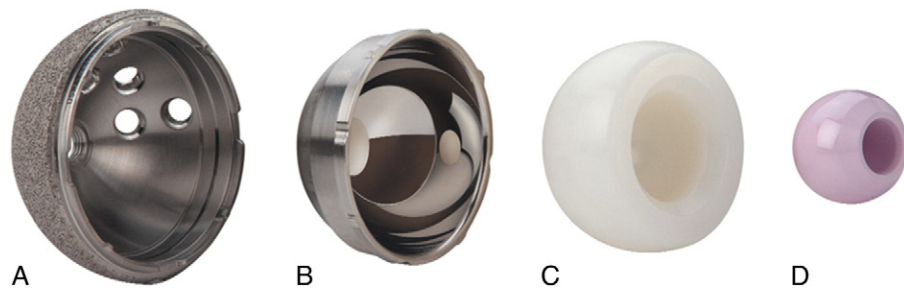
Routine surveillance evaluation included measurement of serum cobalt and chromium levels and patient-reported outcomes using the Oxford score (obtained approximately 2 years following the index procedure) for patients who had primary THA utilizing MDM components. The Oxford score is a joint-specific outcome measure tool designed to assess disability in patients undergoing THA, including assessment of pain, ability to walk and climb stairs, and difficulty with activities of daily life (such as self washing, using transportation, getting dressed, or household shopping) [16–19]. Following institutional review board approval, surveillance data from the first 100 consecutive patients undergoing THA utilizing MDM components for primary arthroplasty were evaluated. MDM implants were selected for those patients with surgeon-perceived increased risk of instability such as increased age [20], neuromuscular disease [10,20], higher Charlson comorbidity or

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**Fig. 1.** MDM components: (A) Titanium acetabular shell. (B) Cobalt chromium metal liner. (C) Mobile polyethylene bearing. (D) Inner femoral head (ceramic or metal options for 28 mm heads, metal only for 22 mm heads).

American Society of Anesthesiology score [20–22]. Patients who had trial reduction with standard components and impingement with intraoperative subluxation or soft tissue laxity also received MDM implants. It is the author's personal experience that flexible small patients (usually women) have demonstrable intraoperative subluxation (not dislocation) when full ROM is tested intraoperatively if standard 28 and 32 mm heads are used. Use of a DM cup (with improved head/neck ratio) eliminates this phenomenon in these patients. No patients were lost to follow-up and we were able to either evaluate them by in-office evaluation or by phone. All procedures were performed by a single fellowship-trained arthroplasty surgeon using Stryker Orthopaedic (Mahwah, NJ) components, specifically an Accolade 2 femoral stem, a Tritanium acetabular component, and a MDM articulation. When using MDM components, a 22 mm inner femoral head is required for Tritanium acetabular component sizes 48, 50, and 52 mm. For Tritanium acetabular components 54 mm or greater, the inner femoral head is only available in 28 mm size. Eighty-seven patients had THA with a 22 mm head and 13 had a 28 mm head. Only cobalt chromium 22 mm heads were available. For patients with a 28 mm head, 12 heads were composed of cobalt chromium and one was ceramic (Delta Ceramic, Ceramtec, Plochingen, Germany).

Complete data were obtained for all 100 subjects and none were lost to follow-up. Indications for use of the MDM device included identification of patient-related factors for increased incidence of postoperative instability, intraoperative determination of soft tissue laxity, or instability despite apparent leg length equalization. None of the patients had instability prior to surgery. Additionally, MDM component polyethylene thickness is greater when compared with a fixed bearing utilizing a 32 mm head combined with a 32 mm Tritanium acetabular polyethylene liner. The surgeon in this study commonly utilizes 32 mm heads combined with acetabular components of size 54 mm or less. Therefore, MDM components were also utilized for younger, active patients with smaller acetabular dimensions when additional polyethylene thickness was desired.

For reasons of patient convenience, multiple laboratory sites were utilized for performance of serum metal ion analysis. Since the normal reference value range of these laboratories varied, data were characterized as either within normal reference range or above normal reference range. Due to the lack of an established "safe" serum cobalt level and based on a previous report [13] that found that revision surgery was required for fretting corrosion-induced ALTR in a patient with a serum cobalt level of 1.6 mcg/L, any measurement above this value was considered significantly elevated. Fretting corrosion of the modular junctions is associated with serum cobalt levels elevated out of proportion to chromium values. Therefore, chromium levels were characterized as above normal reference range only and not as significantly elevated. No preoperative metal ion levels were obtained.

Additionally, a medical history was obtained for all patients, which included documentation of other joint arthroplasty surgery. For patients with significantly elevated serum metal ion levels, repeat laboratory analysis was recommended at six month intervals. A hip metal artifact reduction sequence (MARS) magnetic resonance imaging (MRI) was

recommended for any patient with a serum cobalt value  $\geq 4.5$  mcg/L. This recommendation was based on conservative analysis of the existing literature relating to ALTR, significant MRI findings, and serum metal ion values [13–15,20]. Two patients with a serum cobalt level greater than 4.5 mcg/L had imaging with MARS MRI. Two other patients with significantly elevated serum cobalt values, one symptomatic, were also evaluated with MARS MRI. The radiologist interpretations of these imaging studies are also reported in this manuscript. Patients who reported Oxford scores lower than 40 (consistent with at least mild to moderate hip symptoms and/or disability) who also had significantly elevated cobalt levels were clinically evaluated to determine if symptoms or signs of ALTR were present in the replaced hip.

## Results

Average follow-up following the index THA was 27.6 months (range, 21 to 38). The average serum cobalt and chromium values for all 100 patients were 0.7 mcg/L (range, 0.0 to 7.0) and 0.6 mcg/L (range, 0.1 to 2.7), respectively. Twenty-one patients (21%) had a reported serum cobalt level above the normal range with 9 (9%) of these values significantly above normal ( $\geq 1.6$  mcg/L). Four patients (4%) had a serum chromium level above normal range, but 3 of these had normal serum cobalt values. One patient (1%) had both serum cobalt and chromium values reported as above the normal range (Table 1).

The average Oxford score for all patients was 43 (range 13 to 48). Twenty-four patients reported an Oxford score of less than 40, but only 6 of these also had an elevated cobalt level. These 6 patients were clinically examined, and one was found to have signs suggestive of ALTR. Radiographs of the hip (anteroposterior and frog leg lateral) were evaluated for 8 of the 9 patients with significantly elevated cobalt levels, and these radiographs demonstrated bone ingrowth for both the acetabular and femoral components at a minimum of two years following the index THA. One patient refused to return for follow-up radiographs.

One patient required closed reduction surgery for a postoperative dislocation. The index THA had been performed for symptomatic developmental dysplasia of the hip (Crowe classification IV) and femoral shortening was required during the procedure. Following closed reduction, the hip remained stable. No patient required revision THA.

For the 9 patients with a significantly elevated serum cobalt level, a potential alternative explanation (other than fretting corrosion of the index arthroplasty) for elevated serum metal ion levels (eg, other joint arthroplasty) was possible in 5 patients. The average Oxford score for patients with elevated metal ion levels was 42 (range, 26 to 48). Repeat analysis of serum cobalt levels for the 3 patients with a value greater than 4.5 mcg/L revealed that all 3 were still significantly elevated above 4.5 mcg/L. Oxford scores for these 3 patients were 48, 48, and 45. Subsequent evaluation with MARS MRI of 2 of these patients failed to demonstrate findings consistent with the development of ALTR. For one symptomatic patient with a significantly elevated serum cobalt value (2.3 mcg/L), MARS MRI was interpreted as consistent with ALTR. Another patient was found to have an increase in serum cobalt

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