

Seven Years of Chronological Changes of Serum Chromium Levels After Metasul Metal-On-Metal Total Hip Arthroplasty

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Abstract: Although many authors have reported the serum concentrations of metal ions in patients who had metal-on-metal coupling prostheses, most of the studies were not longitudinal, and the follow-up periods were short. We evaluated the longitudinal changes of serum chromium levels in 44 patients who had undergone unilateral metal-on-metal total hip arthroplasty for a minimum of 7 years postoperatively. Although there was a consistent increase in the mean serum chromium level until 3 years after implantation, there was little difference in the levels from years 3 to 7 postoperatively. Although the serum chromium concentration was low throughout postoperative follow-up for 7 years in about 25% of patients, the serum chromium level stayed high or showed gradual elevation in 16.3% of our patients. **Keywords:** metal-on-metal total hip arthroplasty, serum chromium level, longitudinal study.

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Although metal-on-metal prostheses produce significantly less wear debris than metal-on-polyethylene prostheses, the debris generated expose the host to metal ions for a prolonged period, particularly in younger patients. Many authors have reported that serum concentrations of metal ions were significantly increased in patients who had metal-on-metal coupling prostheses [1-21], even if the implants were well fixed, and high ion levels were detected in some patients [8]. We have also reported that moderate to high serum chromium levels were found in patients who had undergone modern metal-on-metal total hip arthroplasty after follow-up period of 3 years [13]. In that study, we demonstrated that not all of patients had high serum chromium levels, and some patients had low chromium levels throughout the observation period. This suggested that a prospective longitudinal study was needed to assess the metal ion exposure of individual patients with metal-on-metal prostheses.

The purpose of the present study was to evaluate the chronological and longitudinal changes of serum chro-

mium levels in patients who had undergone modern metal-on-metal total hip arthroplasty for a minimum of 7 years postoperatively.

Patients and Methods

Between November 1997 and April 2001, 110 consecutive patients (116 hips) underwent primary total hip arthroplasty with the Metasul metal-on-metal prosthesis (Zimmer GmbH, Winterthur, Switzerland). Blood samples were collected from each subject every 6 months after implantation to investigate longitudinal changes of the serum chromium level after metal-on-metal total hip arthroplasty.

All of the prostheses were implanted without cement. Two types of acetabular component were used, which were the Wagner standard cup (Zimmer, Warsaw, Ind) (22 patients) and the APR cup (Zimmer) (22 patients). Because the APR cup for Metasul was only manufactured with a diameter of 49 mm or more, the Wagner standard cup was implanted when the diameter was less than 49 mm. Accordingly, these components were selected based on the outer diameter of the acetabulum, with the Wagner standard cup being used when this diameter was less than 49 mm and the APR cup being used when it was 49 mm or more. Both cups had a 2.4 mm thick CoCr alloy articular surface molded into ultra-high molecular weight polyethylene (UHMWPE) that was backed with titanium. The CoCr alloy was Protasul-21 wrought forged (Zimmer). The femoral head and stem were the same in all patients: the femoral

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Table 1. Patients Demographics

Sex	Male	7
	Female	37
Age	Mean (range)	61.5 (22-79)
Initial diagnosis	Osteoarthritis	39
	Osteonecrosis	3
	Rheumatoid arthritis	2
Duration from implantation	Mean (range) (mo)	102 (84-120)
Body weight	Male (mean \pm SD)	66.6 \pm 7.6
	Female (mean \pm SD)	53.4 \pm 9.4
BMI	Male (mean \pm SD)	24.7 \pm 2.4
	Female (mean \pm SD)	23.6 \pm 3.6
Implant Shell	APR	22
	Wagner standard cup	22
Stem	Natural hip stem	44
Lateral cup angle	Mean \pm SD (range)	45.2 \pm 5.9 (35-55)

head was made of Co-Cr alloy (Protasul-21 wrought forged) and was 28 mm in diameter, although the stem was a Natural Hip Stem made of titanium alloy (Ti6Al4V) with a proximal circumferential porous coating (Table 1).

Blood samples were collected and treated carefully to avoid contamination with other metal ions. The utensils used for blood collection were pre-tested to ensure that they were free of metal contamination. Blood samples were obtained by using a disposable intravenous cannula. Once the cannula had entered an appropriate vein, we immediately withdrew the central stainless-steel needle and only left the outer plastic tube in situ. The initial 10 mL of blood was discarded to exclude possible contamination by debris within the cannula. We subsequently withdrew a further 10 mL of blood and used this second sample for analysis. The serum concentration of chromium was measured by atomic absorption spectrophotometry, and all samples were tested twice at Mitsubishi Kagaku Biochemistry Laboratories (Tokyo, Japan). The detection limit was 0.2 $\mu\text{g/L}$.

Statistical analysis was performed with StatView Ver. 5.0 for Macintosh software (SAS Institute Inc, Cary, NC). Fisher's PLSD test was used to determine the significance of differences in the mean serum chromium level from 1 to 7 years postoperatively. All serum chromium values below the detection limit were defined as being the mean value of 0.1 $\mu\text{g/L}$ for statistical calculations. $P < .05$ was considered to be statistically significant.

Results

Of these 110 patients, 16 patients who had aseptic loosening of the acetabular component, 6 patients who had bilateral metal-on-metal total hip arthroplasty, 3 patients who died of unrelated causes, 18 patients who had already undergone metal-on-polyethylene total hip arthroplasty for the contralateral hip joint or had other metallic prostheses, 15 patients referred back to

their original hospitals, and 8 patients who had undergone surgery less than 7 years before the final examination were excluded from the study. The remaining 44 patients were investigated in this 7-year longitudinal study.

The mean age of the 7 men and 37 women was 61.5 years (range, 22 to 79 years). Thirty-nine hips had osteoarthritis due to acetabular dysplasia, 2 had rheumatoid arthritis, and 3 had osteonecrosis of the femoral head. The mean postoperative follow-up period was 102 months (range, 84 to 120 months) and none of the patients had renal dysfunction either preoperatively or postoperatively. There were no significant differences of body weight and body mass index (BMI) among these patients. The mean body weight and BMI of the men and women was 66.6 \pm 7.6 kg and 24.7 \pm 2.4 vs 53.4 \pm 9.4 kg and 23.6 \pm 3.6, respectively (Table 1). There were no patients with other metallic implants, dental prostheses containing chromium alloy, or exposure to metal during their daily activities. The activity level of all 44 patients was approximately the same, that is, all 44 patients could walk more than 6 blocks without assistance, and could ascend and descend stairs. None of the patients performed strenuous physical labor or contact sports. All of the prostheses were functioning well at the time of testing, as determined by a good or excellent Harris Hip Score, and there was no radiographic evidence of loosening, osteolysis, or infection during follow-up. There was no significant variation of the lateral cup angle among our patients. The mean lateral cup angle at implantation was 45.2° \pm 5.9° (mean \pm SD; range, 35°-55°) (Table 1).

In the patients with unilateral metal-on-metal total hip arthroplasty, the mean serum chromium level \pm SD ($\mu\text{g/L}$) at 6 months and 1 to 7 years after implantation was 6 months; 0.75 \pm 0.80 (range; 0.1-3.1), 1Y; 1.03 \pm 0.96 (range; 0.1-5.7), 2 years; 1.38 \pm 0.83 (range; 0.1-3.5), 3 years; 1.76 \pm 1.79 (range; 0.1-9.9), 4 years; 1.60 \pm 1.29 (range; 0.3-5.6), 5 years; 1.52 \pm 1.08 (range; 0.3-5.5), 6 years; 1.56 \pm 1.53 (range; 0.1-9.3), and 7 years; 1.68 \pm 1.28 (range; 0.3-5.3), respectively (Fig. 1). The mean serum chromium level increased between 6 months and third year after implantation, there were significant differences between the mean serum chromium level at the 6 months and the levels in years 2, 3, 4, 5, 6, and 7 (all $P < .01$), respectively. There were also significant differences between the level of postoperative 1 year and 3 ($P < .01$) and 4 ($P < .05$) years, respectively. The mean serum chromium level was stable after 3 years, and there were insignificant differences in the mean serum levels from years 3 to 7 postoperatively (all being approximately 1.6 $\mu\text{g/L}$).

The serum chromium level was not increased in all of the patients, since 2 men (59 and 62 years old) and 8 women (49-70 years old) showed 1.0 $\mu\text{g/L}$ and below throughout the 7 years of follow-up after implantation.

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