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Systemic Metal Ion Levels in Patients With Modular-Neck Stems: A Prospective Cohort Study

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ABSTRACT

Background: Recent registry data reveal that modular-neck hip prostheses are associated with increased revision rates compared to fixed-neck stems. Poor implant survival has been associated to corrosion at the neck-stem junction, inducing metal ion release and subsequently adverse local tissue reactions. Data on metal ion release on the neck-stem junction of such stems are scarce. The purpose of this study was to evaluate corrosion at this interface by determining metal ion release.

Methods: Serum and whole blood metal ion levels of 40 patients after 1 year of implantation of a modular-neck stem (titanium stem and cobalt-chromium neck) were compared with 10 patients with a monobloc version of the stem (all titanium) and 10 patients having no implant at all.

Results: Seven of 40 patients (18%) with a modular-neck stem had cobalt or chromium concentrations >2 μg/L. These patients underwent magnetic resonance imaging using metal artifact reduction sequences, which revealed a pseudotumor in 1 patient.

Conclusion: Corrosion at the neck-stem junction of modular-neck stems is a reported phenomenon, which is in part reflected by elevated systemic ion levels. The use of such implants should be restricted to a minimum, and screening algorithms of patients with such implants must be developed.

Modular-neck stems in total hip arthroplasty (THA) have been introduced to broaden the range of reconstructive options. However, disappointing clinical results have started to surface, reflected by an increased revision rate of such implants [1]. Some of them have had to be retracted from the market because of poor performance [2]. Complications related to corrosion at the neck-stem junction, including adverse local tissue reactions (ALTRs), pseudotumors, osteolysis, aseptic loosening, and cutaneous reactions, have been identified as frequent causes for revision [1,3-15].

Most national and international orthopedic associations have issued guidelines regarding the screening and treatment of patients with metal-on-metal (MoM) hip arthroplasties [16,17]. In general, these recommendations are (partially) based on serum or whole blood metal ion levels. In contrast, the situation regarding modular-neck stems remains even more vague, and little solid data are available to date [2,18]. Interpretation of data is complicated because of the heterogeneity of the implants. In contrast to MoM bearings, in which the 2 surfaces are always spherical, neck-stem connections vary considerably in design (round vs oval, conical angles) as well as alloy pairing (eg, titanium [Ti] vs cobalt [Co]-chromium [Cr] necks) and surface finish at the taper cone connection. In addition, for a given implant, various neck geometries are available (ie, neck length, caput-collum-diaphyseal angle, and version), each of them with particular loading pattern at the neck-stem junction, further confounding interpretation of outcome data. Finally, it remains unclear whether whole blood or serum metal ion levels are more indicative of mechanical failure at the neck-stem junction [19-22].

Some authors reported systemically elevated Co and Cr levels in patients after implantation of modular-neck stems [5,11-13,23]. However, some of these studies are flawed because of the small size

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of their cohort [12,13], a lack of control groups [12,13,24], or the possible presence of metal contaminants (Co-Cr heads, contralateral hip prosthesis, or other implants [eg, pacemakers, stents]) [5,11,12,24]. In addition, the study of Gill et al [5] evaluated blood samples after a minimum of 3 months after surgery, thereby possibly including effects of bedding-in at the neck-stem connection—a phenomenon which is well described for MoM bearing couples [25]. These 5 studies evaluated corrosion of stems, which meanwhile have all been retracted from the market (Stryker ABG II and Rejuvenate modular, Eska short stem modular).

The purpose of this study was to evaluate systemic metal ion levels in a homogenous series of patients at least 1 year after implantation of a mixed-alloy modular-neck hip prosthesis (Symbios SPS, Ti stems coupled to Co-Cr necks). These values were compared to those of 2 control groups: a group of patients having received the nonmodular-neck version of the same stem (Ti_6Al_4V) and a group of patients without any metal implant.

Patients and Methods

From September 2011 to February 2013, 285 total hip arthroplasties using the cementless anatomic SPS stem (Symbios Inc, Yverdon-les-Bains, Switzerland) were performed in 280 patients; 144 nonmodular stems and 141 modular-neck stems were used. These stems are made of Ti alloy (Ti_6Al_4V) with a hydroxyapatite coating. They exist in a modular-neck version, with 12 different necks made of Co-Cr-molybdenum alloy and in a standard version (ie, nonmodular, all Ti_6Al_4V).

To minimize other sources of metal ion release, only patients with ceramic-polyethylene or ceramic-ceramic bearing couples were included. Patients with metal heads were eliminated. Patients with other metal implants, including contralateral THA, osteosynthesis material, coronary stents, or pacemakers, with anamnestic use of metal containing nutritional supplements or medications, or suffering from renal insufficiency were excluded.

The study group (modular-neck group) consisted of 40 patients with a modular-neck stem. A first control group (nonmodular group) consisted of 10 patients with a nonmodular stem. A second control group consisted of 10 patients without any implants (no-implant group), admitted to hospital to undergo primary THA.

A preoperative planning was performed for all THAs using a computed tomography–based 3-dimensional templating tool (Symbios, Switzerland) [26], allowing preoperative selection of the appropriate implant size and neck type of modular stems, permitting dry assembly of the neck and stem on the back table without blood or debris contamination. All patients were operated by the senior author through a direct anterior approach as described elsewhere [26,27].

All patients were recalled to our outpatient clinic at a minimum of 1 year after surgery, to minimize potential run-in effects of the taper connections, which are effects well described for MoM bearings by Anissian et al [25]. Two blood samples (2 × 5 mL) were collected using trace element needles and tubes (BD Vacutainer; Becton Dickinson, Franklin Lakes, NJ). All specimens were analyzed within 48 hours using an inductively coupled plasma system coupled to mass spectrometry (7700 Series; Agilent, Palo Alto) for a complete elementary quantification in whole blood and serum separately. All patients were clinically examined, and an Oxford Hip Score (OHS) was obtained.

Accordingly with a recent consensus, patients having Co or Cr levels below the threshold value of 2 μg/L were considered at very low risk of ALTRs and were not further investigated [16]. The others were subjected to hip magnetic resonance imaging (MRI) using metal artifact reduction sequences (MARSs) to assess the presence of ALTRs.

The study protocol was approved by the institutional review board.

Statistics

Data analysis was performed using the STATA software (StataCorp. 2013, Stata Statistical Software: Release 13; StataCorp LP, College Station, TX). Age and metal ion levels were summarized by their means, standard deviations, and ranges, in each of the 3 studied groups. For sex, the ratio between men and women is reported. A 1-way analysis-of-variance was used to test the difference in metal ion levels between groups. In addition, the associations between metal ions levels and age, OHS, and delay between the operation and the blood test were checked using Pearson correlation and using a 2-sample *t* test for the neck geometry (long vs short, varus vs straight, retro vs neutral) and gender. The area under the receiver operating characteristic curves (AUCs) was calculated and compared between different ions.

Results

Patients' demographics and metal ion levels in serum and whole blood are detailed in Table 1 and illustrated in Figures 1-6.

Table 1
Demographics and Ion Levels in μg/L (Mean ± Standard Deviation; Range).

	Modular Necks	Nonmodular Necks	No Implant
Number of patients	40	10	10
Age	64 ± 12 (35-84)	63 ± 12 (47-83)	64 ± 6 (52-71)
Gender (male/female)	19/21	4/6	5/5
Interval surgery-examination (mo)	23 ± 4.6 (12-28)	20 ± 6.1 (12-28)	NA
Cobalt	Serum		
	1.54 ± 2.80 (0.19-16.90)	0.32 ± 0.20 (0.19-0.87)	0.30 ± 0.22 (0.16-0.90)
	Whole blood		
	1.28 ± 2.32 (0.16-12.36)	*0.22 ± 0.18 (0.10-0.73)*	*0.20 ± 0.16 (0.14-0.66)*
Chromium	1.12 ± 0.52 (0.59-3.51)	0.60 ± 0.17 (0.35-0.87)	0.92 ± 0.18 (0.65-1.20)
	1.03 ± 0.30 (0.69-2.59)	*0.75 ± 0.09 (0.62-0.89)*	*1.03 ± 0.17 (0.61-1.23)*
Molybdenum	0.96 ± 0.49 (0.27-2.46)	0.74 ± 0.24 (0.47-1.11)	0.75±0.30 (0.41 - 1.31)
	1.30 ± 0.48 (0.57-2.61)	*1.11 ± 0.20 (0.84-1.44)*	*0.90 ± 0.23 (0.60-1.31)*
Titanium	31.5 ± 10.0 (16.0-71.0)	22.3 ± 4.4 (18.0-33.0)	24.5 ± 3.7 (18.0-29.0)
	67.9 ± 18.3 (43.0-118.0)	*51.1 ± 8.0 (43.0-67.0)*	*62.5 ± 10.2 (46.0-77.0)*
Aluminum	10.3 ± 5.5 (3.9-25.7)	13.4 ± 5.6 (7.7-25.6)	9.1 ± 1.6 (6.8-11.8)
	13.7 ± 10.8 (4.6-45.4)	*30.0 ± 21.0 (9.9-64.0)*	*12.1 ± 5.9 (7.70-28.3)*
Vanadium	0.36 ± 0.10 (0.22-0.63)	0.39 ± 0.14 (0.23-0.66)	0.42 ± 0.15 (0.23-0.70)
	0.21 ± 0.04 (0.14-0.30)	*0.22 ± 0.04 (0.15-0.27)*	*0.24 ± 0.03 (0.17-0.29)*