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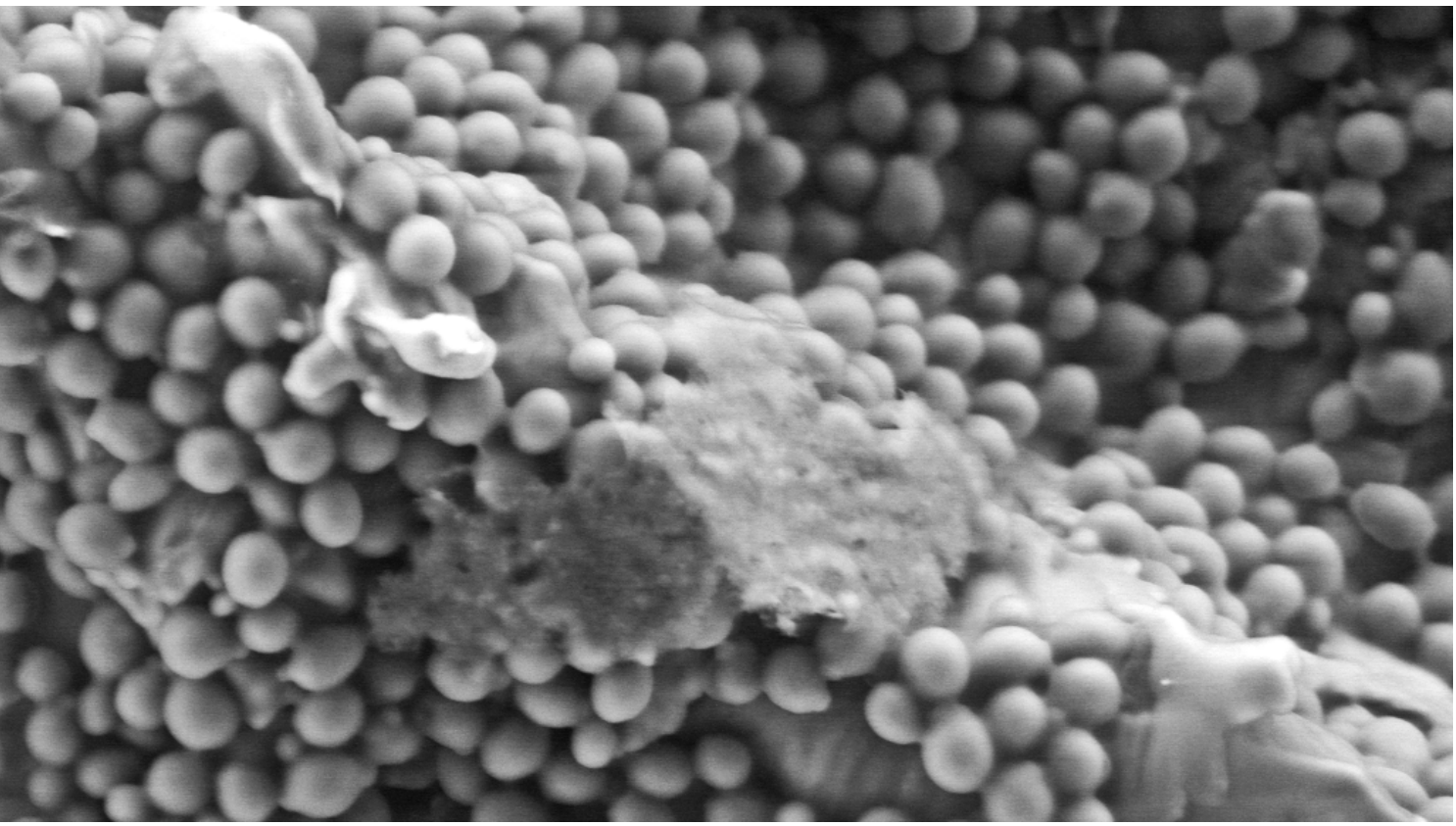
Focus:
Periprosthetic Joint Infection



Is Metal Ion Release also a Concern for Ceramic-on-Ceramic Couplings?

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- chromium ions
- ceramics
- ICP-MS
- tribology

Introduction

The latest member of the BIOLOX® family, BIOLOX® *delta*, is a ceramic composite material containing homogenously dispersed zirconia grains and strontium hexaaluminate platelets, which provide an increased level of fracture toughness, strength and wear resistance compared with monolithic alumina. It's an extremely popular choice for hip replacement devices; since its launch, 2.6 million BIOLOX®*delta* femoral ball heads and 1.1 million inserts have been implanted worldwide.
Some metal-on-metal hip devices that are known to release chromium and cobalt metal ions have been shown to produce toxicological effects. BIOLOX®*delta*, however, also contains trivalent chromium ions, which randomly replace the trivalent aluminum ions in the alumina matrix. Despite being strongly bound to the alumina lattice, it has yet to be experimentally proven if the chromium ions are eventually released into the body. If BIOLOX®*delta* is completely biocompatible in terms of ion release, it could offer an excellent alternative to metal-based bearing couples.

Objectives

This study aims to detect the in-vivo release of chromium ions in ceramic BIOLOX®*delta* bearings by analyzing patients' blood, erythrocytes and urine.

Methods

20 patients who had undergone the total hip arthroplasty with BIOLOX®*delta*-BIOLOX®*delta* couplings (patients) and 21 subjects with no implanted prostheses (controls) were enrolled once other forms of exposure to chromium had been ruled out. Blood samples were obtained from the radial vein using a butterfly needle. The first 3 ml was discarded and further samples were withdrawn in order to obtain whole-blood, serum and erythrocytes. Clean-catch urine samples (10 ml) were collected in universal sample pots. All samples were frozen and stored at -20°C until the analysis. Inductively coupled plasma mass spectrometry equipped with a dynamic reaction cell (DRC) was used for determination. The solutions of calibration curve and the sample solutions were pumped into the spray chamber using a peristaltic pump. Blank samples were used to correct for any contamination in each batch. The method's accuracy was determined on the basis of the mean values obtained from the certified reference materials (environmental and occupational) of G-EQUAS for blood, serum and urine.

Results

The patient group consisted of 10 females and 10 males, mean age 59.9, mean body weight 71 kg, 15 of which had a 32mm femoral ball head and 5 a 36mm femoral ball head. Follow-up took place between 6 and 63 months afterwards.
The control group consisted of 7 females and 14 males, mean age 57.2, mean body weight 75 kg, wearing no implants.
The Cr ion values in the patient group were as follows: 0.21 µg/l (SD 0.09) in mean blood, 0.21 µg/l (SD 0.12) in serum, 0.13 µg/l (SD 0.09) in normalized erythrocytes and 0.12 µg/l (SD 0.13) in normalized urine.
The Cr ion values in the control group were as follows: 0.22 µg/l (SD 0.14) in mean blood, 0.17 µg/l (SD 0.08) in serum, 0.13 µg/l (SD 0.11) in normalized erythrocytes and 0.07 µg/l (SD 0.08) in normalized urine.
The lab reference values were 0.1–5.0 µg/l for blood, 0.1–0.5 µg/l for serum, 0.14–4.58 µg/l for normalized erythrocytes and 0.05–2.2 µg/l for urine (Fig. 1a-d).

Conclusions

All of the blood, serum, urine and erythrocyte (marker for hexavalent chromium) samples in the patient and control groups contained chromium levels within the internal reference range, as set by the laboratory conducting the analysis. A power analysis was shown to be sufficient (95%).
This study has demonstrated that BIOLOX®*delta* ceramics is completely safe in terms of ion release. It is an excellent alternative to metal couplings. ■

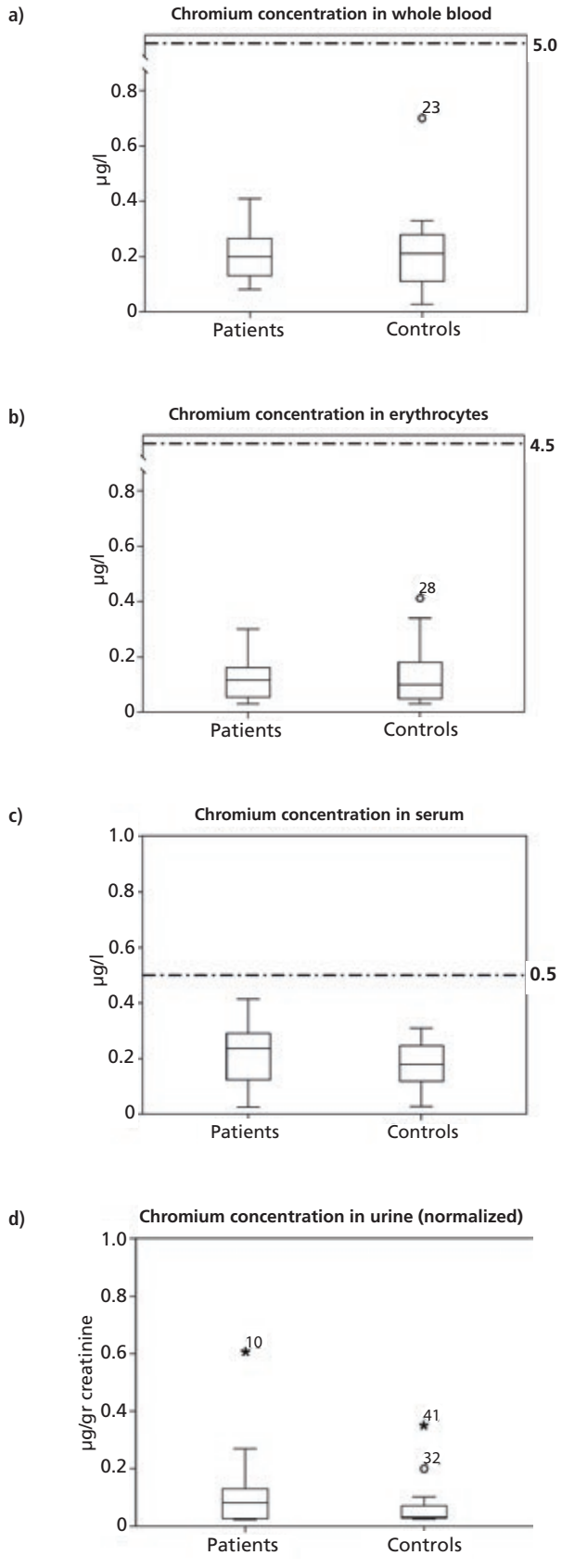

Fig. 1: The chromium ion levels in whole blood (a), erythrocytes (b), serum (c) and urine (d) for both patients and control group are within the internal reference range, as set by the laboratory conducting the analysis.

Laboratorio di Tecnologia Medica in Bologna

The mission of the Laboratorio di Tecnologia Medica (Medical Technology Laboratory) in Bologna, Italy, is to develop, validate and transfer into clinical practice every single innovative technology that could help to prevent, diagnose, treat, monitor or rehabilitate musculoskeletal diseases.
Together with the Department for Orthopaedic-Traumatology and Prosthetic Surgery and Revisions of Hip and Knee Implants, the laboratory forms a clinical and research unit directed by Dr. Aldo Toni.
The laboratory consists of approximately 40 members of staff, including senior and junior researchers as well as graduate and undergraduate students. It is organized into 5 research units.
Headed by Susanna Stea, PhD, the Biology Unit is conducting research on the following topics, some in co-operation with other research structures within and outside of the Rizzoli Institutes:

- Isolation of wear particles inside the synovial liquids and tissues of patients with a prosthesis using SEM-EDS and morphological analysis
- Dosage of metal ions using ICP-AES in the hair of patients with a prosthesis
- Bone histomorphometry
- Cytokine dosage inside the synovial liquids of patients with a prosthesis
- Histology of periprosthetic soft tissue – quantitative evaluation of wear
- Definition of crystallinity degree and oxidation products in ex-vivo polyethylene specimens
- Microhardness evaluation of healthy and pathologic bone tissue and different biomaterials related to the implant
- Bone cell culture for the in-vitro evaluation of bone homeostasis

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