Metal Ion Release In Urine And Blood From Titanium Cups Cith Different Surface.

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Introduction: Osteo-integration of non-cemented acetabular component in hip prostheses is a topic for survival of the implant. Intrinsic factors (bone quality) and extrinsic (implant shape and materials) participate to the achievement of a good primary stability. Among these, three-dimensional architecture and surface structure of the cups play a determining role in implant success. A new type of extremely porous biomaterial for the acetabular cups, the Trabecular titanium (Delta TT, Lima), was recently developed. The reticular structure similar to the cancellous bone, the high biocompatibility and the excellent mechanical properties (an elastic modulus similar to that of the bone and inferior to the modulus of conventional titanium cups (Delta, Lima) might provide great bone integration. The material offers a surface hundreds times wider compared to conventional full titanium. The aim of this study is to determine the eventual differences in metal ions release in blood and urine from acetabular cups in Trabecular titanium (D-TT) and in conventional full titanium (D).

Methods: A case-control study was carried out on 38 patients: 19 subjects (69 ±12 average age) implanted with the Delta (D) cup and 19 subjects (63 ±8 average age) implanted with the Delta-TT (D-TT) hip prosthesis. Aluminium (Al), Vanadium (V) and Titanium (Ti) in urine, Al in serum, V and Ti in whole blood were assessed on each patient before implantation (T0), at one week after implantation (T1), at 3 (T2) and 6 (T3) months after surgery. Clinical (Harris Hip Score) and radiological evaluation have been performed at the same intervals. SAMPLING ANALYSIS: The blood and urine samples were analysed by ICP/MS Inductively-coupled plasma mass spectroscopy. Agilent 7500. The calibration solutions of the instrument were prepared with AccuTrace multielement certified standard (referred to a primary standard solution NIST). in the analytical range of 0-100 µg/l and the 5 point calibration curve. The instrumental detection limits were: 0.05 µg/l (Aluminium); 0.5 µg/l (Titanium); 0.01 µg/l (Vanadium). The Mann-Whitney test was used for statistical analysis between the two groups, while the Friedman test was used to evaluate the variance within each group.

Results: The two groups were similar for age and characteristics of the patients. At T0 and T1 there were no relevant differences between the two groups and the limits for the general population. The clinical and radiological results did not show differences. The values obtained on blood and urine were compared between the two groups: no significant differences were observed for aluminium (in serum and urine), titanium (in whole blood and urine) and vanadium in whole blood. Concentration of vanadium in urine at T1 in group D-TT is higher than that of vanadium at the same time in group D; this difference is statistically significant (U-test, p=0.025). The variance of aluminium, titanium and vanadium both in serum or whole blood and urine within each group at different times was evaluated. Significant differences were not found in group D, or in group D-TT.

Discussion: The biocompatibility of titanium has been attributed to its oxide film, nevertheless some authors support the corrosion resistance of the titanium while others reported titanium release from
prosthetic devices in animals and humans. Deleterious effects of increased metal ion levels including bone loss, prosthetic loosening, local tissue toxicity, hypersensitivity reactions, and even malignant cellular transformation have been reported. Few studies, however, have examined whether fixed metallic implants, such as a locked volar distal radius plate, can also result in an increase in systemic metal ion levels and even less investigated is the release of metal ions from the bulk body of joint arthroplasties. Since new porous metals such as titanium or tivanium or similar used for hip implants have a wider surface compared to full titanium, the ion release might be dramatically increased. The evidence of this study pointed out that there is no correlation between a wider surface, trabecular titanium D- TT cups, and an increased ion level in blood, serum and urine, with respect to the traditional titanium D cups. The study has several limitations. First, the sample size is relatively small and therefore may be prone to type 1 error. However, power analysis of the data set showed relatively good sensitivity to detect small changes, and therefore lessens the likelihood of error and allows for identification of certain trends. Second, the study focuses on a short time period.

**Significance:** The absence of correlation between trabecular titanium cups and an increased ion levels, when compared to the traditional full titanium cups support the clinical application for acetabular cups of trabecular titanium, as new biomaterial with extremely high biomechanical properties. Continue monitoring of ion level for a possible increase over the years might be recommended.

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