Characterization of wear debris released from alumina-on-alumina hip prostheses: Analysis of retrieved femoral heads and peri-prosthetic tissues

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\textbf{ARTICLE INFO}

Keywords:
Alumina ceramic
Total hip arthroplasty
Wear debris
Hip joint prosthesis
Scanning electron microscopy
EDS
Polarization microscopy

\textbf{ABSTRACT}

We analyzed by SEM three alumina-on-alumina femoral heads obtained from three patients who underwent revision for an aseptic loosening of the acetabular component. In parallel, the peri-prosthetic tissues were analyzed histologically in search of wear debris coming from the ceramic. Stripe wears, abrasive streaks, craters, and areas with extensive biomaterial removal were evidenced on the three femoral heads by SEM. In the altered area, the structure of the ceramic composed of minute polyhedric grains packed together was evidenced. In the peri-prosthetic tissues, the alumina particles were present in different forms: large particles appeared transparent and birefringent, small particles engulfed by the macrophages had a light brown tint and were not birefringent. Large particles corresponded to the grains observed by SEM. EDS microanalysis confirmed the presence of aluminum oxide in these particles. Alumina debris are difficult to identify microscopically due to their pleomorphism.

1. Introduction

The placement of a total hip arthroplasty (THA) in patients with end-stage osteoarthritis intends to provide a pain-free and long-lasting functional hip joint in patients with an altered function. Other indications are represented by osteonecrosis of the femoral head and other destructive joint diseases. The total joint implants used to repair the articular surface include a metal component articulating against a polymeric component fabricated from ultra-high molecular weight polyethylene (the classical metal-on-polyethylene couple). This generates high amounts of wear debris in the joint cavity of patients responsible for aseptic loosening as the debris are capable to increase the osteoclastic activity (Massin et al., 2004a,b; Willert, 1977). In addition, these debris can migrate around the prosthesis stem and in the porosity of cortical and trabecular bone (Libouban et al., 2009). They can also accumulate in the lymph nodes at a considerable distance from the prosthesis (Baslé et al., 1996). Several alternatives have been proposed to combine materials with a low friction, good biocompatibility and low wear debris production to ensure a good ten year outcome. Among the different solutions proposed by several surgical groups, total hip prostheses using metal-on-metal (cobalt-chromium CoCr) have been proposed (Garbuz et al., 2010). However, the possibility to develop pseudo-tumors due to metal wear debris has been reported (Pandit et al., 2008). Total hip arthroplasty using alumina ceramic heads and cross-linked polyethylene cups has been proposed (Sugano et al., 1995; Zichner and Willert, 1992). The results in long term studies have reported the possibility for the ceramic head to penetrate in the polyethylene liner and metalback with massive foreign body granulomas (Simon et al., 1998). Zirconia femoral heads were proposed but this ceramic is largely unstable and phase changes resulted in a considerable decrease of biomechanical properties with fracture of the material (Hummer et al., 1995). The couple alumina-on-alumina couple have been used for several decades because of the high mechanical resistance and excellent biocompatibility of this ceramic (Hamadouche et al., 2002). The tribological properties of the alumina-on-alumina produce a friction torque generating 4000 times less wear particles than the metal-polyethylene couple and therefore a low peri-prosthetic osteolysis rate is reported (Bizot et al., 2001; Prudhommeaux et al., 2000). Analysis of alumina explants have shown that in vivo wear is very low, less than 1 μm/year under normal conditions (Dorlot et al., 1989).
The link between the wear of alumina heads and their presence in peri-prosthetic tissues has been seldom studied and only a few studies have concerned the histopathological analysis of peri-prosthetic tissues retrieved at the time of revision of an alumina-on-alumina prosthesis (Lerouge et al., 1996). The aim of our study was to report three patients with a histological analysis of peri-prosthetic tissues taken during revisions of total hip prosthesis with alumina-on-alumina couple and a scanning electron microscope analysis of the removed ceramic beads.

2. Patients and methods

2.1. Patients

2.1.1. Patient #1
This 48 y.o. female patient who presented an aseptic post-traumatic osteonecrosis of the femoral head underwent THA with a prosthesis composed of a hydroxyapatite-coated titanium acetabular component Cerafib T-titanium alloy (Ceraver, Roissy CDG, France) an alumina insert, and a short femoral neck (−3.5 mm) receiving an alumina head (28 mm in diameter). The patient presented mechanical hip pain in the postoperative period that were due to a defect in the anteversion of the femoral stem (Fig. 1A). The femoral stem was changed 22 months later; the alumina femoral head was sent for analysis with the peri-prosthetic tissues.

2.1.2. Patient #2
This 61 y.o. female patient underwent THA for an end-stage hip osteoarthritis. The prosthesis was composed of a hydroxyapatite-coated titanium acetabular component Cerafib T-titanium alloy (Ceraver), a long neck (+3.5 mm) with an aluminum head (28 mm in diameter). She reported progressive mechanical hip pain which started three years after the THA. X-rays, CT-scan and 99Tc-MBP scintigraphy showed an aseptic loosening of the acetabular component (Fig. 1B–C). The revision was done with unipolar change of the acetabular and head components five years after the primary THA.

2.1.3. Patient #3
This 62 y.o. female patient underwent THA for an end-stage hip osteoarthritis. The prosthesis was composed of a hydroxyapatite-coated titanium acetabular component Cerafib T-titanium alloy (Ceraver), a short neck (−3.5 mm) with an aluminum head (32 mm in diameter). She reported progressive mechanical hip pain which started five years after the THA. X-rays, CT-scan and 99Tc-MBP scintigraphy showed an aseptic loosening of the acetabular component (Fig. 1D–E). The revision was done with unipolar change of the acetabular and head components eight years after the primary THA.

After examining the transmitted documents and the Rapporteurs’ reports, the members of the Ethical Subcommittee of our university hospital approved the use of patient material as the work is retrospective from sampling of bone samples (complementary histological study). Consent was given oral, which is possible in non-interventional study cases. The members of the committee do not raise any objection to the implementation of this study which does not raise ethical questions.

2.2. Histological analysis

The prosthetic materials were carefully harvested at the time of revision, with special precautions being taken to avoid any mechanical damage of the ceramic femoral head during retrieving. The alumina heads were transferred to the laboratory without fixative. Digestion of the remaining organic phase present at the surface of the femoral head was done in a bath of sodium hypochlorite (50% in distilled water) during 24 h. The femoral heads were then extensively rinsed in successive baths of distilled water. They were allowed to dry at room temperature and were glued on brass stubs for scanning electron microscopy (SEM) with a Conductive Carbon Glue (Pelco, Agar Scientific, Stansted, United Kingdom). They were coated with a 20 nm layer of platinum by sputtering with a high vacuum coater (Leica EM ECA600, Leica, France). Examination was done on an EVO LS10 (Zeiss) field emission microscope equipped with an energy dispersive X-ray micro-analysis machine (EDS-INCA-Oxford). Images were captured in the secondary electron mode with an acceleration tension of 3 kV with a 30° tilt and 33 mm working distance. Energy Dispersive X-Ray Spectroscopy (EDS or EDX) is a microanalysis technique that detects X-rays emitted from a sample during bombardment by the electron beam.

Fig. 1. X-ray analysis of the three patients with aseptic loosening of an alumina-on alumina prosthesis. A) Patient #1 with anteversion of the femoral stem. B-C) Patient #2 CT-scan showing an aseptic loosening and 99Tc-MBP scintigraphy showing increased fixation in the iliac bone. D-E) Patient #3 with similar signs on the CT-scan and scintigraphy.
to characterize the elemental atomic composition present in an analyzed area. The data generated by EDS analysis consist of spectra showing peaks characteristic of the atomic elements of the sample (Goldstein et al., 2012).

In order to compare the surface of the retrieved femoral head with the native aspect of the ceramic, a new prosthesis (32 mm in diameter) from Ceraver was analyzed by SEM.

The peri-prosthetic tissues were harvested during the revision arthroplasty and fixed in formalin. They were embedded in paraffin and sectioned at 5 μm on a rotary microtome. Sections were stained with hematoxylin-phloxin-saffron for routine analysis under bright field and polarized illumination on a BX51 microscope (Olympus, France). The atomic composition of the particles was obtained by analysis of an unstained and dewaxed histological section by SEM and EDS. The sections were carbon-coated by sputtering with a high vacuum coater (Leica EM ECA600). To compare the debris found in peri-prosthetic tissues with true alumina particles, an alumina femoral head was grinded with a rasp. The particles were collected and mounted with NeoEntellan™ (Merck-France) on a histological glass slide. They were analyzed by SEM in the backscattered electron mode at 11 and 20 kV; an EDS analysis was done on the selected particles.

3. Results

3.1. Scanning electron microscopy

The alumina femoral heads from the three patients, made free from any cellular remnants, exhibited various signs of abrasion at their
surface. Fig. 2 reports the analysis at low magnification of the surface aspects of the ceramic prostheses. The new (unused) femoral head presented a smooth surface with minimal and randomly oriented striations (Fig. 2A). The implanted prostheses had focal areas with profound abrasive streaks, craters, and areas with extensive biomaterial removal (Fig. 2B–D). At higher magnifications, the structure of the ceramic, composed of compacted elementary grains became easily visible in the altered areas (Fig. 3).

3.2. Histological analysis

The alumina particles grinded from the test ceramic head presented a transparent and glossy appearance under bright-field microscopy. Under polarized light (with a ¼ waveplate) these particles were birefringent (Fig. 4A–B). In the peri-prosthetic tissues, the alumina particles were present in two different forms: i) large particles (i.e., 15–20 μm) had the same glossy appearance than the ground particles and were birefringent under polarized light. Smaller particles were also translucent but were not evidenced under polarized light (Fig. 4C–D); ii) small (1–3 μm) particles with a light brownish tint were observed in the cytoplasm of activated macrophages disposed in dense clusters between fibrotic areas (Fig. 4E). These particles were not birefringent under polarized light (Fig. 4F). In the three patients, the presence of black particles corresponding to wear metallic debris was also observed, sometimes associated with the alumina particles.

3.3. EDS analysis

Prosthetic alumina heads: EDS analysis confirmed the atomic composition of the ceramic biomaterial being made of aluminum oxide and gave similar results in the three cases (Fig. 5). The spectra from retrieved femoral heads were similar to those obtained on the new prosthesis. The spectra were similar in the different areas analyzed, at the smooth surfaces on in the altered areas.

Histological sections: EDS analysis performed on each type of particles (small or large) revealed their atomic composition made of aluminum oxide. EDS analysis also confirmed the presence of titanium particles (TA6 V alloy) (Fig. 5F).

4. Discussion

The alumina-on-alumina prostheses were proposed more than four decades ago as an alternative to the polyethylene-metal couple in hip joint surgery. Alumina is reported to be chemically inert and stable. A
number of study have confirmed that the wear debris production is reduced but not suppressed (Prudhommeaux et al., 2000). More recently, it was found that ceramic combining alumina and zirconium oxide had an improved mechanical resistance (Affatato et al., 2001; Massin et al., 2014; Moraes et al., 2004). However, an audible squeak is reported in some patients having an alumina-on-alumina prosthesis and friction of the different components is advocated (Jarrett et al., 2009; Mai et al., 2010). In our series, no patient reported this phenomenon and the revision was indicated after a malposition or an aseptic loosening in two cases. Alumina particles, and also titanium or polyethylene wear debris, can stimulate bone resorption in the vicinity of the prosthesis by inducing the production of inflammatory cytokines (Bylski et al., 2009).

In the present study, we could analyze the surface of three alumina femoral head obtained surgically at the time of prosthetic revision. They exhibited various aspects of erosion of their surface ranging from linear stripe wears to marked craters. Alumina particles, and also titanium or polyethylene wear debris, can stimulate bone resorption in the vicinity of the prosthesis by inducing the production of inflammatory cytokines (Bylski et al., 2009).

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1996). Alumina particles are abrasive and can provoke wear of the titanium stem of the prosthesis. Particles of metal are often observed together with the alumina debris and are phagocytized by activated macrophages. If the stem of the prosthesis is cemented, other types of particles can be encountered such as barium sulfate or zirconium oxide used to make the cement radio-opaque (Lerouge et al., 1996). In this small series of patients, the three stems were uncemented and only titanium particles were observed.

5. Conclusion

Alumina-on-alumina prostheses have been proposed in hip surgery. They can produce wear debris at the acetabulum and femoral head which can migrate in the prosthesis environment. Alumina debris are difficult to identify on microscopic sections due to their pleomorphism. Although the alumina-on-alumina couple is reported to be very stable, wear debris can be identified, polarization microscopy is able to identify large particles but smaller ones are not birefringent.

Conflict of interest

Authors have no conflict of interest.

Acknowledgments

This work was made possible by grants from the French Ministry of Research.

References


