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Ceramic-on-ceramic catastrophic liner failure in total hip arthroplasty: morphological and compositional analysis of fractured ceramic components

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Abstract

Surface bearing of total hip arthroplasty (THA) still is a strong subject of study due to the relatively high rate of failures caused by a multiplicity of factors including surgical technique, patient's attitude, and type/characteristics of the materials used (metal, ceramics, polyethylene) with their specific risk factors. Fractures of the ceramic components are rare but catastrophic events, with many concerns among the orthopaedic surgeons. Such complication is usually evaluated from a

clinical viewpoint; this study provides a materials scientist's complementary perspective and comprehensively evaluates the surface and the mechanism of rupture of the ceramic liner in two cases with different ceramics (Biolox Forte and Biolox Delta) after ceramic-on-ceramic THA. The morphological and compositional analyses of the ceramic components were performed by field-emission scanning electron microscopy (FESEM) and energy dispersive spectroscopy (EDS), along with macroscopic pictures. The SEM analysis of the ceramic liner showed many wear signs in all directions, while the EDS revealed the presence of titanium near to the fracture border, which might be interpreted as a consequence of the catastrophic contact between ceramic liner and metal back. Biolox Delta and Biolox Forte ceramic liners showed different patterns of fracture and surface modifications that are illustrated and discussed.

Keywords: Bioceramics; Total hip arthroplasty; Fracture; Scanning electron microscopy

1. Introduction

Total hip arthroplasty (THA) is effective, reliable and durable in relieving pain and improving function in patients with arthritis of the hip joint [1] thanks to the current bearing surfaces: ceramic-on-ceramic (CoC), ceramic-on-polyethylene (CoP), metal-on-metal (MoM) and metal-on-XLP (crosslinked polyethylene) [2]. However, all these materials have their own limitations: metal-on-metal THA has been largely abandoned after several reports of adverse tissue reactions associated with the metal ion release [3]. Despite an improvement in the wear resistance and properties of polyethylene, thanks to the crosslinking and the use of antioxidants [4-8], loosening remained a leading cause of failure in several large clinical series and worldwide registries concerning this material [9-11]. Ceramic bearing surfaces are probably associated with the best clinical results but still have a non-negligible risk of fracture [12]. With an increasing number of younger patients

undergoing THA along with expected increases in longevity of the population, there is a need to guarantee bearings survivorship beyond the second decade of service [13]. Ceramic bearings have been used in THA for over 3 decades thanks to some positive characteristics, including low wear, wettability, and low bioreactivity [14-17]. As of today, however, some concerns with component fractures and reliability still remain [18]. Moreover, the management of complications that arise from the fracture of a ceramic component can be a hard challenge for the surgeons. Particulate debris from broken ceramic components cause destructive and abrasive wear on the remaining components of the arthroplasty, therefore causing a damage to the trunnion at the level of the neck and the acetabular metal cup and ultimately making necessary a challenging revision surgery [19].

The purpose of this study was to analyze two cases of ceramic failure and describe the relevant mechanism of fracture when mixed ceramic combinations (Biolox Forte/Biolox Delta) are used in THA. The causes of the fracture of the components are reported and the ceramics have been studied in detail after the revision surgery by using both macroscopic and microscopic approaches (i.e. field-emission scanning electron microscopy (FESEM) combined with energy dispersive X-Ray spectrometry (EDS)).

2. Materials and methods

2.1 Collection and characteristics of samples

The prosthetic materials were explanted from two patients requiring hip revision surgery, as summarized below.

The Case 1 involved a male patient, born in 1944 and receiving an implant of THA in October 2010 for coxarthritis. The prosthesis comprised jump cup with diameter 54 mm, acetabular liner 36 mm Biolox Delta (morse taper angle 19°), Pegasus short stem, femoral head Biolox Delta 36 mm (Permedica Orthopaedics Corporate, Merate LC - Italy). The postoperative radiographic assessment

did not show any problem (Figure 1.a). Overall, good results were achieved until May 10th, 2016 when the patient felt sudden severe pain and heard "strange noises" at the implanted joint level. After clinical examination and X-ray radiographic imaging, the diagnosis of liner fracture was made. The patient underwent surgery for revision of the cup, where it was evidenced that the liner was placed in the acetabular metal back with an angle of approximately 7°. The broken liner and the metal shell were removed. A new cup Delta TT (Limacorporate, San Daniele, Italy) with a Biolox Delta ceramic liner (Ceramtec) and 2 additional screws were used. Since it was well positioned and well integrated, the previous stem was maintained to reduce the risk of femoral fracture, of bleeding and of surgical complications. In order to avoid trunion problems, the previous femoral head was maintained as well. The patient recovered with good clinical function without any residual pain. During the revision, pictures were taken and the broken liner was accurately analyzed.

The Case 2 involved a male patient, born in 1940 and receiving an implant of THA in February 2010 for left coxarthritis. The implant comprised plasma cup diameter 56 mm, acetabular liner 36 mm Biolox Forte (morse taper angle 20°), Metha stem N3 Aesculap, femoral head Biolox Delta 36 mm Aesculap B-Braun, Tuttlingen Germany), Figure 2. The patient complained of persistent pain over the years, most probably caused by his rather active lifestyle. On November 2016, the patient complained of a sudden severe pain after a big effort. Clinical examination and X-ray radiographic imaging proved a diagnosis of ceramic liner fracture. The patient underwent surgery for revision of the cup. The broken liner and the metal shell were removed. A new Delta-TT Limacorporate for revision, augmented with two screws, with a Biolox Delta ceramic liner was used. The previous stem and femoral head again were maintained for the same reasons as Case 1. The patient recovered a good clinical function. In this case, the radiographic assessment showed that the cup had a slightly vertical position; X-rays radiography also showed that the femoral head, after the fracture, was in contact directly with metal cup (Figure 2.a). Again, fragments of ceramic were collected during the revision surgery and studied, like in Case 1.

2.2 Characterizations

The ceramic fragments were studied to clarify the mechanism of fracture. First pictures collected during the surgery were used for the macroscopic analysis of the components. Then, morphological-compositional characterization of the fracture surfaces of the samples was performed by means of field-emission scanning electron microscopy (FESEM, SUPRATM 40, Zeiss) equipped with energy dispersive X-ray spectroscopy (EDS). After being sputter-coated with a thin layer of chromium (5 nm thick) to make them conductive, the specimens were placed on metal stubs by gluing them with a conductive compound; the analysis was performed under high vacuum (10^{-5} Torr) as the air would otherwise have prevented beam production (given the low electron energy).

3. Results

3.1 Case 1

The ceramic liner broke into two main fragments and few debris (Figure 1.b). Lots of fracture signals were found along the whole edge of the liner. Fragments of ceramic were collected during the revision surgery and studied: pictures collected during the surgery allowed performing the macroscopic analysis of the components, which were further analyzed by SEM-EDS after the preparation of the specimens as reported above. The results of SEM-EDS analyses are reported in Figures 3-5. The FESEM study (Figures 2-4) evidenced the clamping surfaces of the fracture, the composite nature of the ceramic, the progress of the crack, the zirconia particles, the gaps left by the zirconia particles during the intergranular break and the fracture onset. The presence of striations around the crack onset in Figure 2.a suggests progress of the crack and failure due to fatigue: this failure mode is compatible with zirconia-toughened alumina (Biolox Delta) [20].

3.2 Case 2

Similarly, as for the clinical Case 1, pictures collected during the surgery allowed the macroscopic analysis of the components, which were further analyzed by SEM-EDS after the preparation of the specimens as reported above. The pictures taken after surgery are reported in Figure 2.b-d. The ceramic liner, as shown in figure 2.b, failed due to the propagation of a sudden crack (brittle fracture), with no evidence of ductility or plastic deformation. This catastrophic fracture is usually associated with the formation of several fragments. The ceramic head (manufactured in Biolox Delta) showed several dark traces, probably due to the contact with the metallic cup (Figure 2.c). The dark colored traces on both ceramic head and fragments of the ceramic liner could be related to metallosis coming from the scrubbing of the metallic cup (Figures 2.b and 2.c). The pictures also revealed some scratches along the border (rim) of the titanium cup (Figure 2.d), suggesting that a mechanical interaction took place between the metallic cup and the ceramic head. This is in accordance with the observations reported by Tomek et al. [21], who detected metal transfer streaks on a ceramic femoral head resulting from discrete subluxations, which occurred intraoperatively during reduction and stability testing. The presence of metal on the prosthetic head surface may remain undetected if metal transfer occurs during final surgical reduction of the hip, and the metal can be further transferred from the femoral head to the inner bearing surface of the ceramic liner. Given the recurrent presence of metal transfer streaks on failed ceramic-on-ceramic hip prostheses that have been explanted, preventing the ceramic femoral head from contacting the acetabular rim intraoperatively is strongly recommended in order to avoid detrimental effects postoperatively.

The SEM analysis of the ceramic liner showed lots of wear signs in all directions and the presence of some bright debris in proximity of the fracture surface (Figures 6-7). The EDS analysis in this area revealed the presence of titanium, which might be interpreted as a consequence of the catastrophic contact with the metal back (Figure 7.c) The SEM analysis on the ceramic head

confirmed the hypothesis made on the basis of the macroscopic observation: the ceramic head showed several signs of wear, with different features depending on the area analyzed. These traces exhibited different brightness when the samples was inspected by SEM, i.e. a bright stain in the upper central area, a dark band apparently composed by several spots, some dark stains and a very sharp band across the upper central area (Figures 7-10).

4. Discussion

While the coupling and failure of the so-called "like-on-like" ceramic combinations (Biolox Forte/Biolox Forte and Biolox Delta/Biolox Delta) have been widely studied, there is a relative paucity of studies about mixed ceramic configurations, especially from a materials scientist's viewpoint. Castagnini et al. [22] recently reported a broad clinical follow-up study revealing that mixed ceramic combinations have mid to long-term outcomes comparable to those of like-on-like coupling, although the fracture rate of Biolox Forte-on-Biolox Delta coupling seemed to be a little higher. However, the features and mechanism of fracture were not considered in that study; therefore, the present work can provide important complementary information, despite the limitation of the low number of cases analyzed.

The morphological and compositional analyses performed suggest that a multitude of factors may have contributed to cause the failure of both the prosthetic implants examined. As the ceramic components apparently were consistent with the manufacturer's quality standard and did not exhibit any microstructural/morphological flaws or chemical anomaly, the reasons behind the unexpected failure must be sought among intra- or post-operative factors [23,24]. Possible reasons could be associated to the incorrect positioning of the ceramic liner during surgery (e.g. mis-centering with respect to the metal cup) and/or the mismatch between the mechanical properties of prosthetic femur head and acetabular liner, i.e. the prosthetic joint surfaces. In fact, Biolox Forte and Biolox Delta, being made of alumina and alumina/zirconia (75:25 wt.%) composite, respectively, exhibit

different hardness and toughness depending on their different chemical compositions [23,24]. Furthermore, mal-seating has been associated to patients with osteoarthritis who have an important bone sclerosis of approx. 25 mm [14]. Other processes involved in ceramic damage are impingement, subluxation and trauma, which can cause chipping of the ceramic liner [25]. In order to avoid these last complications, a cup abduction not higher than 45° has been suggested [25]. Titanium transfer in the taper interface between insert and cup is required to achieve a firm connection. In the present study the presence of titanium fragments has been noted and described; nevertheless this does not mean that it is a sign of catastrophic contact or the cause of the fracture. More likely, the titanium particles originated from the metal surfaces due to the friction against the ceramic fragments after the rupture.

It is interesting to underline the relationship that exists between the characteristics of the brittle fractures observed in the ceramic liners and the two different couplings considered. The liner made of Biolox Forte, coupled with an alumina/zirconia femur head, exhibited a sudden, very catastrophic fracture leading to the formation of many small fragments. Unstable crack propagation leading to fracture could be triggered by a high load, in good accordance with the patient's words ("sudden severe pain" – due to fracture of the alumina liner – "after a big effort"). In contrast, the liner made of Biolox Delta was less susceptible to crack propagation and its fracture, although being brittle, was associated to the formation of a lower number of fragments with larger size [26,27]. This different behavior can be associated to the higher toughness of Biolox Delta compared to Biolox Forte, which is due to the presence of yttria-stabilized zirconia grains embedded in the alumina matrix [12]. In fact, it was estimated that the fracture toughness of yttria stabilized zirconia is from two to three times higher than that of alumina [28].

The fracture of a ceramic component in total hip arthroplasty is a disastrous event, where the substitution of the broken component alone is not possible and that therefore requires the revision surgery of the whole implant (acetabular and femoral) [19]. Therefore, due to the increased number of ceramic-on-ceramic implants, more revision surgeries and reports on ceramic components failure

are expected in the future [29,30]. Although innovative ceramics have been developed to reduce the risk of fracture, this is not yet completely eliminated: a recent meta-analysis showed that the rate of ceramic fracture is 0.9/1000 patient/year in the Forte group and 0.5/1000 patient-year in the Delta group [31]. This is consistent with the higher toughness of Biolox Delta compared to Biolox Forte. If the risk of revision for CoC bearing fracture is very low, it is also possible that previous studies have underestimated this risk and there is evidence that the latest generation of ceramic has greatly reduced the head fractures but still there are concerns about the liner fractures [32,33]. In fact, it is known that ceramics can fracture under suboptimal implantation conditions such as edge loading or impingement and, therefore, further studies are necessary to validate ceramic bearings and understand the pattern of fracture [34,35]. Noise (Case 1) and pain (Case 2) can be associated with abnormal wear/malfunctioning implants and thus they may be the prelude/sign of a catastrophic ceramic failure, as suggested elsewhere [36]. While the technical error is clear in Case 1, radiographs and pictures of Case 2 show that there were no technical errors but failure could be associated to unstable crack propagation due to high load. Although it is impossible to draw conclusions by one case, based on the consideration that matching materials with different mechanical properties might cause problems, this study seems to suggest that hybrid couplings might be avoided. To the best of our knowledge, hybrid coupling in ceramics is unwarranted also by manufactures and like-on-like combinations are usually preferred. Nevertheless, when using a ceramic-on-ceramic "hybrid" couplings in THA (Biolox Forte vs Biolox Delta) it is recommendable to use Biolox Delta for the acetabular component in order to implant a tougher liner which can be less susceptible to sudden catastrophic failure.

5. Conclusions

This study described the different patterns of fracture for Biolox Forte and Biolox Delta prosthetic components in mixed ceramic combinations for THA by microscopic and compositional

investigations. Based on the cases analyzed, the results suggest that the fracture in modern ceramic liners is mainly due to mismatch of the components/surgical error rather than to inherent defects of the materials – which should virtually be nonexistent in certified commercial products.

Conflict of interest and Ethical statement

Authors declare that they have no conflict of interest: no employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding have been received for this study. The study was performed in accordance with the ethical standards and the patients gave their consent.

Figure legends

Figure 1. Case 1: (a) The postoperative radiographic image of the left THA: the implant is in position and there are no signs of fracture or mobilization. (b) The removed cup with the broken ceramic liner (Biolox Delta). It is evident that the liner was placed with a dis-alignment of approximately 7 degrees.

Figure 2. Case 2: (a) The postoperative radiographic image of the left THA: the cup has an excess in vertical position. (b) The fragments of the broken ceramic liner. (c)The removed ceramic femoral head. (d) The removed metal back cup.

Figure 3. Case 1: (a) FESEM image from the bigger of the two fragments (magnification 118×). The clamping surfaces are evident. They developed due to the progress of the crack. There is no laminating trace (the dark spots and stripes are in fact caused by chromium plating). (b) Image obtained through the back-scattering probe of the SEM (magnification 927×). On the fracture surface (right side of the picture) the composite nature of the ceramic is clearly observable (small bright zirconia granules embedded into the alumina matrix). On the border (dark gray) the fracture onset presents some dark, pore-like spots, probably due to the protrusion and detachment of zirconia particles.

Figure 4. Case 1: (a) FESEM image on the opposite side of the bigger of the two fragments (magnification 260×). The arrows indicate the fracture onset. (b) Detail of the bigger of the two fragments (magnification 556×). The arrow indicates the fracture onset.

Figure 5. Case 1: Comparison between two representative areas of the ceramic surface of the fracture zone (a) and of the smooth articular surface (b). In both images a uniform distribution of

the toughening zirconia particles is evident (bright granules that in Figure 4.b are evidenced by the back-scattering modality of data acquisition). It is well embedded in the alumina matrix. No agglomerates are evidenced, nor significant discontinuity at the interface between alumina matrix and zirconia granules; this finding confirms the good quality of the component and the absence of defective surface points due to the industrial fabrication process. The black spots observable also in this case on the fracture surface are the gaps left by the zirconia particles during the intergranular break; the clash has in fact caused the protrusion and detachment of these small crystals from the fractured surface. (Magnification 12160× and 15780× in (a) and (b), respectively)

Figure 6. Case 2: (a) SEM observation of the fracture surface of the biggest fragment of the ceramic liner (magnification 99×). (b) The surface exhibits a lot of wear signs in all directions, which can be interpreted as direct contact traces (magnification 93×).

Figure 7. Case 2: (a) Detail of a fracture surface observed on the biggest fragment (magnification 136×). The surface shows the typical morphology of a brittle fracture. (b) Detail of a bright debris on the observed surface of the ceramic liner (magnification 19290×). (c) EDS analysis performed on the bright debris in (b) revealed the presence of titanium, as further evidence of the interaction between the ceramic liner and the metal back.

Figure 8. Case 2: (a) SEM micrograph (magnification 1470×) of the femoral head surface (Biolox Delta), which is irregular and porous, apparently due to wear caused by the friction with the alumina liner (Biolox Forte). (b) SEM observation (magnification 23610×) of the bright region (morphological analysis). (c) SEM observation (magnification 50000×) of the bright region in back-scattering mode: the zirconia grains are embedded in the alumina matrix; some of them detached due to abrasion between the two surfaces.

Figure 9. Case 2: SEM observation of the femoral head surface (dark band): (a) several spots revealed the presence of pores, probably due to the mechanical detachment of zirconia granules (magnification 5000×). (b) Detail of one spot (magnification 55790×). The EDS analysis performed on a selected area of this surface (c and d) revealed the presence of Al and Zr, coming from the main oxides of the ceramic composite, as well as Cr, which can be ascribed both to the small amount of chromium oxide commonly present in the composite itself and to the ultrathin chromium coating needed for SEM observation. Therefore, no contamination or "foreign" elements were detected in this region of the sample.

Figure 10. Case 2: (a) Morphological analysis (magnification 159×) performed on the sharp band across the upper central area of the femoral head surface, revealed the presence of a lot of traces of material of different composition, which is adherent to the ceramic surface. (b,c) EDS analysis performed on a trace; it showed the presence of titanium, probably due to the interaction between the ceramic cup and the metal back after the liner failure, which caused adhesive wear. (d) EDS analyses performed on a single agglomerate adherent on the composite ceramic head revealed the presence of titanium and vanadium (see table), thereby confirming the interaction between the ceramic head and the Delta TT cup.

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