Chapter 7
Revision Surgery After Fractures of Ceramic Components

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Introduction

Ceramic on Ceramic (CoC) bearings for Total Hip Arthroplasty (THA) were introduced with the aim of reducing wear associated with polyethylene (PE) components, thus limiting osteolysis and increasing the longevity of the implant especially in young and active patients. The first attempts of utilizing a ceramic cup with a ceramic head were made in the 1970 by Pierre Boutin in France with cemented liners and in 1974 by Heinz Mittelmeier in Germany with cementless all ceramic threaded cups and skirted heads. Both systems were burdened by high failure rates related to poor mechanical properties of the first generation of alumina (low strength resistance due to the grain size), and to materials and design faults (direct contact of the ceramic to the bone, as alumina has no osseointegration capability, and skirted heads creating impingement). Since then, several new compounds with new generations of alumina (with smaller and more uniform grains) were introduced with good to excellent results [1–3]. Nowadays the most commonly used ceramics is the alumina matrix composite (AMC) (Biolox Delta™; CeramTech AG, Plochingen, Germany).

A brief explanation of the characteristics of the ceramics used in medical devices could be helpful to better understand the issues related to its utilization. Ceramics is defined, in material science, as a non-metallic, solid material comprising an inorganic compound of metal, non-metal and metalloid atoms primarily held in ionic and covalent bonds. Since the beginning, the ceramics used for medical purposes is composed of Alumina (Al), an oxide of Aluminum, the same material that composes the crystalline structure of Ruby and Sapphire. Al was chosen for its chemical inertness and biocompatibility: given its high oxidative state, the material does not tend to oxidize further in the body, and therefore its particles do not generate oxidative

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stress and inflammatory reaction. Moreover, thanks to its crystalline structure, Al ceramics has a very “smooth” surface, that provides a very low friction coefficient and an extremely low wear rate. Concerning its mechanical proprieties, as a covalently linked, crystalline structure, Al has the characteristics of a “hard” material: a high compressive strength (>4500 MPa) and a high Young’s (elastic) modulus (400GPa); on the other hand, it has a low flexural strength (around 600 MPa) and low deformation capacities [4]. Thus, in this material fractures tend to occur before any plastic deformation can take place. The intrinsic porosity of the material has a role in fracture generation: the pores act as a stress concentrator, thus reducing tensile stress and facilitating the crack propagation. Since mechanical fragility was clearly a weak point of this bearing, industry tried to overcome it with different technical solutions. To further increase the hardness and strength of the material, Zirconium oxide (ZrO), Strontium oxide (SrO) and Chromium oxide (CrO) were added to the Al matrix during the sintering process (Alumina Composite Matrix, AMC). In particular, ZrO particles play an important role in reducing the fracture propagation. These particles are less dense and are evenly distributed in the Al matrix; when a fracture appears, it propagates towards these less dense ZrO areas, that react to the fracture by changing their spatial phase (from tetragonal to monocyclic); this change is associated with an increase in density of the area, that in turn creates compressive forces that ultimately limit the fracture propagation. As a result, AMC ceramics almost doubles flexural strength (and hardness) compared to the Al ceramics, while maintaining the same elastic modulus and compressive strength [5].

While these technological advancements improved the mechanical properties of CoC bearings, dramatically reducing the fracture rates, nevertheless ceramic fracture remains a cause of concern as revision for ceramic fracture can lead to catastrophic failures and severe complications due to third body wear, caused by ceramic fragments [6, 7].

Epidemiology, Risk factors and Causes of Ceramic Fractures

According to the Australian Registry data, 99.8% of ceramics used in THA is CeramTech Biolox products [8]. However, this data may not reflect all the markets in different countries (such as in France or in Spain). Anyway, Manufacturer’s data on recorded events can help to understand the frequency of occurrence of ceramic fractures. Concerning Delta Ceramics, the reported fracture rate for the head is 1 in 100.000 (0.001%), while for the liner is 22 in 100.000 (0.022%). The fracture rate is higher for the old Forte™ Ceramics, being 21 in 100.000 (0.021%) for the head and 46 in 100.000 (0.046%) for the liner (CeramTech, Unpublished Data, 2017); while Forte Ceramics is no longer used for new THAs, it is important to know the risk of fracture of this material since it was widely used until few years ago. In a recent analysis of the National Joint Registry for England, Wales, Northern Ireland and Isle of Man (NJR), the percentage of ceramic fractures were found to be slightly higher than reported by the Company: 7 of 79,442 (0.009%) Biolox Delta heads, 38 of 31,982 (0.119%) Biolox Forte heads, 101 of 80,170 (0.126%) Biolox Delta liners and 35 of 31,258 (0.112%) Biolox Forte liners. Interestingly, regression analysis revealed that the two most important risk factors for fracture were smaller heads (in particular the 28 mm Forte head) and high BMI of the patient [9]. Most of the other published data reports similar fracture rates [10], the only outliers being single center studies [11, 12] that reported a prevalence of liner fracture of 0.9–1.1% with Delta Ceramics; however, since in both studies the same cup was used, it is possible that the higher fracture rates reported depends more on technical issues related to component design of the metal back rather than on the ceramic material itself [6].

Head fractures are nowadays less frequent than liner ones. Direct impact is a very rare cause of head fracture, while a more common mechanism is fatigue break due to taper mismatch, scratches on the taper and third bodies between the head and the taper. The only identified risk factor for head breakage in large clinical series is the 28 mm diameter head with short neck, as previously mentioned by NJR data and confirmed by a systematic review [13].

Liner fractures are almost never related to trauma as well, but rather depend on two main reasons: the former is the edge loading and the impingement due to the cup positioning, while the latter is the misalignment of the liner during insertion in the metal back or a metal back damage [14]. Edge loading occurs when the hip contact force vector moves over the edge of the liner or when the stress concentrates on a limited area; when this occurs, the increased stress both on the liner and on the head surfaces increases the risk of damage. A steep cup could reduce the contact area between components, therefore increasing the force transmitted at the edge. Another mechanism that provokes edge loading is neck impingement that causes a diametrically opposed sub-luxation of the head over the liner edge (Fig. 7.1). Poor orientation or bad rim design can create such a neck impingement and sub-

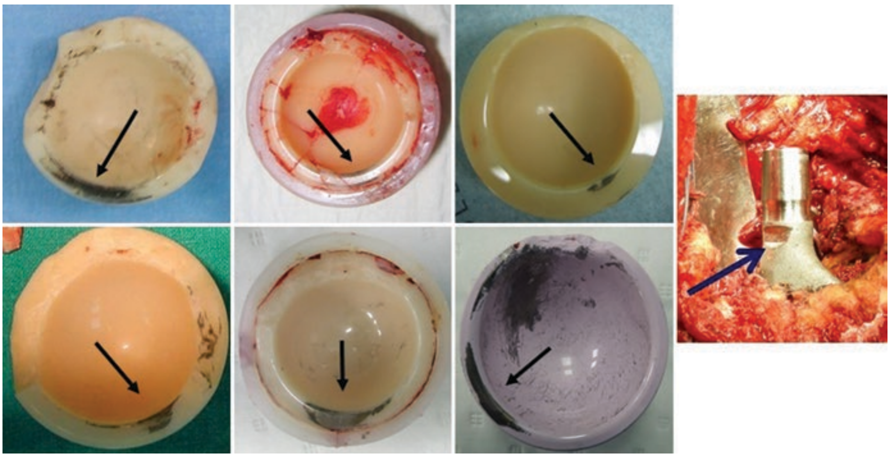

Fig. 7.1 Retrieval samples of fractured ceramic liners. Black arrows indicates the area of impingement against the neck of the stem, on the opposite side of the broken rim of the liner. In the last panel to the right, the blue arrow point to the damaged neck that impinged on the liner

dislocation on the opposite side of the liner with very small contact of the head on the rim as a consequence, leading to grain detachment, third body wear and crack propagation [14]. This model of fracture was confirmed by the clinical observation of Traina et al. that found a higher risk of fracture in cups with anteversion over the range [15], thus confirming previous studies [16] and finite element analysis [17]. Therefore clean positioning of the components is fundamental [18]. A particular situation of edge loading occurs when the acetabular liner is not correctly seated in the metal back. This could be due to a metal back rim damage or even a deformation during the insertion: titanium shell can deform by 0.6 mm during impaction, consequently generating a two-point support of the liner [19]. Another reason for that can be simply an incorrect handling of the ceramic liner during insertion jammed in a wrong position by the surgeon. Thus, a careful preparation of the acetabulum and assessment with trial insert is required when using a ceramic liner. Again, each implant must be checked intra-operatively for correct engaging of the liner into the metal back and of the head on the stem taper prior to the final reduction of the prosthesis [20]. Finally, screws protruding in the metal back have been described as a risk factor of the same phenomenon of incorrect seating of the ceramic liner, thus leading to the risk of later liner breakage [21].

Finally, a fracture of the liner can lead to a secondary breakage of the head. In any case the head is usually deeply damaged by the break of the liner.

Clinical Features and Diagnosis

The clinical picture of a fracture of ceramic head is straightforward. The breakage is usually sudden, complete and noisy. The patient immediately realizes that something has happened. X-Rays is mandatory, and the fragmented head is usually clearly visible and easy to be recognized.

The clinical picture of a ceramic liner fracture, differently, can be subtle and underestimated, thus a high level of consideration in suspicious events by the clinician is required to make the correct diagnosis. A careful history should be collected, with particular attention to pain, discomfort and noises. In patients with risk factors for ceramic fracture, such as cup malpositioning, a strict (i.e. yearly) follow up with X-Rays is suggested, and in case of new increasing noises a ceramic fracture should be suspected [22]. Onset of symptoms is not clear every time, so they could be underestimated both by the patient and by the physician. X-Rays are the first level of investigation, even if their diagnostic accuracy can be quite low. Fragments of the fractured liner could be visible on X-Rays as radiopaque areas that can be confused with heterotopic ossifications. Once the diagnosis of ceramic fracture is suspected, confirmative exam should be performed. CT-scan is helpful in this context: the fragments are usually visible in the soft tissues, and the liner can show cracks or chipping at the rim. Some studies suggested that the microanalysis by SEM (Scanning Electronic Microscope) of synovial fluid with the evaluation of ceramic particles can be useful in diagnosing ceramic fractures [23, 24]. However this exam is not readily available in most centers.

Revision Surgery

Timing

Once the diagnosis of ceramic fracture is made, the surgeon should be aware that the treatment cannot be postponed. Early revision is indicated for two main reasons: first, with time the ceramic fragments spread around into the soft tissues, and thus their complete removal becomes more and more difficult; retaining of fragments in the tissues could compromise the outcome of the revised prosthesis, because of third body wear. Secondly, the metal components, especially the titanium taper of the stem in case of head breakage, could be rapidly damaged with metallosis, leading to the need to revise a well-fixed stem (or even the cup), making the revision surgery much more complex and heavy for the patient (Fig. 7.2).

Planning

Despite the "relative urgent" condition of a ceramic fracture, the revision surgery should be carefully planned. Information about the prosthesis manufacturer, type and size, should be obtained. The timing of the fracture is also important, since more distant is the time of the fracture, more fragments could be found in the soft tissues. Preoperative X-Rays should be used to evaluate components orientation, in particular of the cup: if cup malpositioning is shown that can be the cause of failure, cup revision should be planned before surgery; if areas of osteolysis or cup/stem

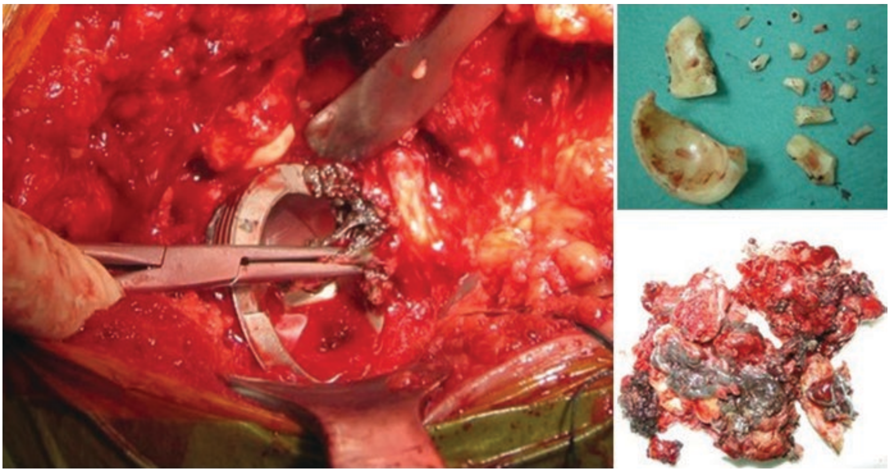

Fig. 7.2 Ceramic on ceramic fragments in soft tissues following a fracture of the liner. Left Panel: Removal of soft tissues with small ceramics fragments and metallosis due to Ti damage caused by AI. Top Right Panel: retrieved fragments of the liner; Bottom Right Panel: Removed soft tissues with metallosis

instability are suspected before surgery, a revision of the unstable component should be planned. The surgeon should be familiar with hip revision and with the approach that is intended to be used [25].

Surgical Technique

Surgical technique is of course of major importance. The goal of revision surgery is the positioning of a stable prosthesis that can have a long term survival without any early or late bearing problem. Therefore, the first step of the surgery is an aggressive soft tissue debridement and synoviectomy, with the ultimate goal of removing all the ceramic fragments or at least as much as possible (Fig. 7.2). For this purposes some Authors proposed in the past a double approach to the hip [26].

The second step is the removal of the broken head and/or liner, followed by the evaluation of stability, orientation and damage of the metal back and of the stem. If the metal back is in a satisfactory position and it is intra-operatively stable and not damaged, a new PE liner can be inserted (or cemented) if available for the cup in situ. Placement of a new ceramic liner in a previous metal back (even if well fixed, correctly oriented and apparently not damaged) is not acceptable as ceramic is too much sensitive to even small metal back damages, as outlined before. In case of isolated liner fracture, the change of the head is suggested in any case because, as mentioned before, a damage of the head surface is always relevant. If the taper is not damaged, according to manufacturer's recommendations, which is sometimes not so easy to be evaluated, a new head should be used without revising the stem. The decision between a major revision with removal of well-fixed components slightly damaged and retaining of those, should be anyway balanced on the age, general conditions, life expectancy and activity of the single patient. In case the stem is retained, the surgeon should be aware that nowadays when using a ceramic head it is mandatory to implant the one specifically developed for revision surgery (Biolox Option™, CeramTech, Plochingen, Germany). This type of head (Delta ceramic with a titanium sleeve) offers the possibility to select different head diameter and neck length, and can fit on different taper angles as provided by different prosthesis manufacturers. Anyway if the taper or the metal back damages have major damages, revision of those components is necessary to ensure long term survival of the implant.

Which Bearing Couple?

Few studies evaluated the outcomes of the various bearing surfaces in revision surgery after ceramic fracture [7, 26–30]. Several case reports highlighted massive wear of the metal head used after ceramic fracture including severe Co and Cr poisoning of the patients [7, 26, 29–33]. The hypothesis that metal is more susceptible to wear in presence of ceramic particles was confirmed in laboratory wear as well. Ceramic particles up to 5 mm of diameter were placed between the head and liner with three different couplings: Ceramic/Polyethilene, Ceramic/Cross-Linked Polyethilene (C/XLPE) and Metal/Cross-Linked Polyethilene (M/XLPE); while the two combination of ceramics showed a wear of 0.56 and 0.31 mg/million cycles, the wear of Met-XLPE coupling was 316 mg/million cycles, several magnitudes higher [34]. The use of Cer/Cer coupling after ceramic fracture was evaluated in a series of 30 cases by Traina et al., that reported a survival of 93.3% at a 3.3 years follow up [28]. While the use of a Cer/Cer bearing is a valid option after ceramic fracture, probably the most used for the scratch resistance to third body wear, Cer/PE is the Author's preferred option. Retrieval analysis showed how ceramics fragments can impact in PE liners (Fig. 7.3), rather than remaining free bodies between the two hard ceramic surfaces, thus probably causing less wear. Moreover, for the patient the proposal of a bearing that already failed could be not the most favorable option. In a series of 12 patients revised for ceramic fracture with Cer/XPE coupling, at a mean follow up of 6 years only one patient was revised again for PE wear, with an overall survival of 93.7% (Fig. 7.4). Interestingly, in this series the rate of early dislocation was very high (33.3%), probably because of the aggressive soft tissue release. Therefore we suggest to be very careful during surgery: to use a bigger diameter head possibly with longer neck, and in case of major instability, a dual mobility can be suggested with a ceramic liner instead of a metal one (construct composed by modular ceramic liner-mobile PE-ceramic head) that could reduce the risk of dislocation [27]. A judicious postoperative course is strongly recommended.

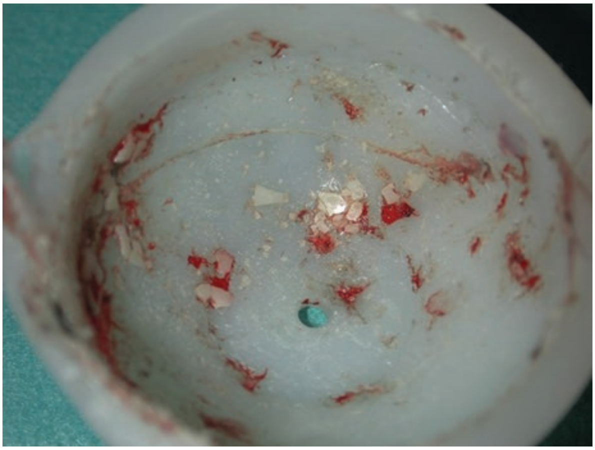

Fig. 7.3 Fragments of broken ceramics impacted in a PE par of a sandwich liner

Fig. 7.4 Panel A: male, 74 years, fracture of PE sandwich ceramic liner. Panel B: same patient, with a Cer-PE bearing, at 10-year follow up. No signs of wear or osteolysis can be found

Conclusions

Ceramic on Ceramic bearing is a good option in young and active patients due to the excellent wear resistance and the high biocompatibility of the material. Compared to soft bearings, Cer/Cer coupling is more sensitive to handling of the components and implant positioning. While rare, ceramic fracture is a catastrophic event, with high rate of complications. In case of ceramic breakage, accurate fragments removal and synoviectomy, replacement of damaged components and correction of malpositioning and impingement are the key points. At the moment there is no clear evidence on which is the bearing of choice in case of revision for ceramic breakage, but metal must be absolutely avoided. Revision using ceramic heads, with Ti sleeves in case of retained stem, on PE liners or on ceramic liners, can yield favorable results.

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