Strength and Reliability of Alumina Ceramic Femoral Heads:

Review of Design, Testing, and Retrieval Analysis

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Abstract

Ceramic components are used increasingly in total hip arthroplasty (THA). Compared with metallic components, ceramic femoral heads for THA have the potential advantage of lower wear rates in articulations with acetabular liners. However, the use of ceramic components is also associated with unique risks, including sudden fracture and intolerable bearing noise or squeaking. This review paper summarizes the published literature regarding alumina ceramic femoral heads and tries to identify areas where uncertainties remain. We will discuss the following topics: (1) the fracture mechanics of ceramic materials; (2) design-related stresses acting on the femoral head, especially at the interface between the stem trunnion and the head; (3) gradual loss of strength in service by fatigue or slow crack growth and simulation using a proof test; and (4) information that can be gathered from examination of fractured explants.

Key Words

Alumina, ceramic, femoral head, total hip arthroplasty, fracture, strength, proof testing, review

Introduction

Ceramic components have been used increasingly in total hip arthroplasty (THA) since their introduction in the 1970s (Boutin, 1971, 1972; Shikata et al., 1977). Compared with metallic components articulating with ultra-high molecular weight polyethylene, ceramic bearings have the potential advantage of lower wear rates in THA (Cuckler et al., 1995; Lancaster et al., 1997). However, the use of ceramic components is also associated with unique risks, including sudden fracture (Garino, 2005; Hannouche et al., 2003; Richter, 1998; Tateiwa et al., 2008), and, for ceramic-on-ceramic bearings, recent reports of intolerable bearing noise or squeaking (Walter et al., 2008). Although the fracture risk today is relatively low–on the order of 1 in 1,000 cases (Garino, 2005; Tateiwa et al., 2008)–it continues to be an important research topic, because when these ceramic components fracture, they tend to shatter in many pieces and require an immediate revision (Hannouche et al., 2003).

The brittle nature of ceramics makes it difficult to design implants that will not fracture. When a fracture does occur, it may be challenging to gather sufficiently detailed information to make a scientific analysis of the cause of the fracture. Furthermore, because ceramic component design, analysis, and testing is confidential in nature, engineering studies by third parties independent of manufacturers are often limited in scope and sophistication. In addition, case histories by surgeons and other medical investigators are hampered by limited experience with engineering principles and fracture analysis of ceramic materials.

In a review paper it is difficult to cover the issue of hip component design in a general manner. For this reason we contacted two international manufacturers of medical ceramic components, CeramTec Medical Products and Japan Medical Materials Corporation (JMM), as well as orthopaedic implant manufacturers, including Biomet Orthopedics, in order to gain further insight into this topic. Much of the design information of both the ceramic components and mating metal components is considered confidential information by the orthopedic implant manufacturers and is therefore not publicly available. Concerns over confidentiality, therefore, represent a limitation of the available scientific literature as it relates to ceramic fracture and reliability.

Although many of the details associated with the design and testing of ceramic implants are proprietary, CeramTec and JMM described an approach based on mutual exchange of technical information covering the full details of the metal taper and ball head design with the company that will integrate ceramics into their total hip system. Detailed design specifications are reviewed by both parties, and any concerns are resolved prior to product testing. Production samples of the metallic implant stem are sent to the ceramic producer for evaluation. Then, a battery of tests is performed in actual production components. These tests may include: burst, fatigue, post fatigue burst, rotational stability, lever out, push out, and hip simulator wear testing. All these tests should be successful for the ceramic component to be integrated into the orthopedic implant. Finally, the design of the complete total hip replacement system, including the ceramic head, must be reviewed and cleared by the national regulatory body for the country in which the implant will be marketed.

In this review, we have summarized the available published literature in light of engineering principles, and we suggest avenues for further analysis. This paper reviews the published information regarding ceramic femoral heads and tries to identify areas where uncertainties remain. Specifically we will discuss the following topics: (1) the fracture mechanics of ceramic materials; (2) design-related stresses acting on the femoral head, especially at the interface between the stem trunnion and the head; (3) gradual loss of strength in service by fatigue or slow crack growth and simulation using a proof test; and (4) information that can be gathered from examination of fractured explants. This review is limited to consideration of the strength and failure mechanisms of ceramic femoral heads, *i.e.,* to failure modes in which the head fractures in several pieces. We do not discuss other failure modes such as wear of the articulating surfaces or squeaking noise during a patient's normal daily activities. In addition, we have focused this review on alumina ceramics, which have the longest track record of ceramic biomaterials for hip arthroplasty.

Fundamentals of fracture mechanics

The failure of ductile materials such as metals is well understood in terms of stress and strength. The material has a characteristic strength, which may be a yield strength (elastic deformation limit) or an ultimate strength (fracture), depending on the failure mode considered. External loads on a component result in stresses, and failure occurs when the applied stress exceeds the material strength. For instance, a tension bar breaks when the axial stress exceeds the material ultimate tensile strength.

In the case of ceramics, however, this approach is not useful because the effect of cracks becomes important, but stresses cannot be computed accurately at a crack tip. Clearly, another criterion is needed to predict failure.

Fracture mechanics developed the relevant criterion, which is called "stress intensity factor" and is denoted K_I. In general, K_I is defined as

$$K_I = Y\sigma\sqrt{a}$$

where σ is the applied stress, a is the size of an initiating crack (usually its depth) and Y is a factor depending on the crack shape and the geometry of the part. This applied stress intensity factor K_I is the equivalent of stress. The equivalent of strength is the critical stress intensity factor, denoted as K_{Ic}. Failure occurs when K_I exceeds a critical value K_{Ic}, which is a material property also known as toughness.

Thus fracture of brittle materials depends both on applied stress and crack size. The stress at which failure occurs is not a characteristic of the material alone, it also depends on the size of the cracks that may be present. So when a strength value is quoted for a ceramic material, such as the strength of the alumina used for femoral head implants, this number reflects in part the flaw size distribution at the surface of the alumina sample used to measure the strength.

The fracture stress depends therefore on the location of the fracture origin. A given stress value may be acceptable at the outer surface of the femoral head, which is highly polished, but may cause fracture at the internal taper cone, where the surface is rougher.

Stress analyses of the femoral head

There are two locations of potentially high stresses in the head, namely at the taper interference between the head and the trunnion, and at the contact point between the head and the acetabular cup. Most field fractures appear to originate at the taper (Koo et al., 2008; Rhoads et al., 2008), so this location is the most important.

Design stresses at the taper interference

Femoral heads are held on the trunnion by a conical taper interference fit. The head has a female conical taper that is slipped over the male taper during surgery. The surgeon impacts the head onto the stem to force an interference fit between head and trunnion. This interference fit creates tensile stresses in the ceramic, which will remain constant during the life of the implant. External loads on the hip, from standing up, walking or other activities, will add cyclic stresses to these constant stresses.

The stresses depend strongly on fine details of the interference geometry. Ceramic femoral heads are specifically designed so that the load transfer takes place near the center of the ceramic head, which is their strongest part. The male stem trunnion has a slightly smaller included angle than the female head hollow cone. This places the maximum interference near the smaller end of the cones, which is closer to the center of the femoral head. This results in lower stresses than if the interference had been at the large end of the cones, where there is less material to resist the radial expansion of the femoral head.

The stresses due to interference fit will depend on several factors, including the assembly method, the magnitude of the impact, and the frictional characteristics at the metal-ceramic interface. The forces imparted to the ceramic head during the installation impact are variable (Nassutt et al., 2006). In a previous study, the impact force time history was recorded for a total of 39 surgeons as they impacted a ceramic head on a dummy cone taper in the laboratory (Nassutt et al., 2006). Each surgeon installed 3 to 5 heads and the average peak force was computed for each surgeon. These average peak forces ranged from 273 N to 7848 N, with a pulse duration of about 1 ms. This is a wide range, which will result in a wide variation in the interference stresses.

The frictional behavior between the ceramic and the trunnion is also very important. With less friction, the stem trunnion will be inserted further into the femoral head, resulting in higher tensile stresses in the head taper. Friction at the metal-ceramic trunnion interface depends on the trunnion material, the roughness of both the trunnion and the ceramic head, and on the lubricating effect of any fluid at the interface. Analyses aimed at computing the installation stresses on the ceramic heads should take into account the range of installation forces and friction coefficients.

Stress analyses

The design of total hip systems and the ceramic components are treated as confidential information by the manufacturers of the total hip system as well as the supplier of the ceramic components, which limits the availability of finite element stress analyses of the ceramic head. Those that are available usually do not provide enough details to enable an independent assessment of their accuracy, and they appear to contain oversimplifications that could render the results meaningless. For instance, two analyses published in the past few years (Aum et al., 2005; Lee et al., 2007) use modeling assumptions that seem to be significantly different from actual ball geometry and support. Both analyses do consider friction between the trunnion and the femoral head, but they both seem to use exactly the same taper angle for the male and female cones. This is generally not representative of actual service conditions because the tapers will never match exactly, either because of manufacturing tolerances or by design. Other boundary conditions may significantly alter the results. All nodes at the ball outer surface ("perimeter" in the articles) are fixed in three directions. This is clearly unrealistic and is likely to affect the stresses throughout the ball, since the entire periphery of the ball is rigidly constrained. In one study (Aum et al., 2005), the small end of the stem is also held rigidly, which according to the authors may affect the results but was necessary to ensure convergence of the model. The other study does not specify the boundary conditions at the small end of the trunnion, but in some load cases that small trunnion end seems to bear directly on the flat end of the female taper cone in the head. This condition is equally unrealistic and will significantly alter the results. In summary, the stress analysis results currently reported in the literature may be unreliable.

This is not meant to imply that proper stress analyses using finite elements are not available. These are generally required in the design control phase of the design of a total hip system and are a part of the information submitted by the orthopedic implant companies to the Food and Drug Administration as part of the approval process, but they are not made public. The overall goal of these analyses is to estimate the tensile stresses in the ceramic head *in vivo* in order to confirm the ability of the design to withstand the loads in service. The principal difficulty in computing these stresses is to determine the extent of interference at the taper lock between the stem taper and the ceramic ball head. One possible method for this may be to measure accurately the position of the femoral head with respect to the stem, before and after impacting the head onto the stem. This may be repeated for several values of the impacting energy or the coefficient of friction, to establish the effect of these variables on the interference stresses. Once an interference state has been chosen, external forces due to *in vivo* loading can be applied to the connection.

Testing of femoral heads

Ceramic femoral heads have undergone a broad based testing program before they are marketed by the orthopedic manufacturers. The standards test program includes wear, axial burst, axial fatigue, post fatigue, rotational stability, push out and of course proof testing. One of the most critical tests is the compression until failure (burst test) and results have been published (Dorre et al., 1983; Roy et al., 2005; Thomsen and Breusch, 2003). Burst tests are typically done in accordance with ISO 7206-10. This test method specifies that the femoral head be mounted on a stem and hydraulically loaded against a metal female cone with a 100° included angle. A copper ring may be placed between the head and the cone to reduce the local contact stresses (Figure 1).

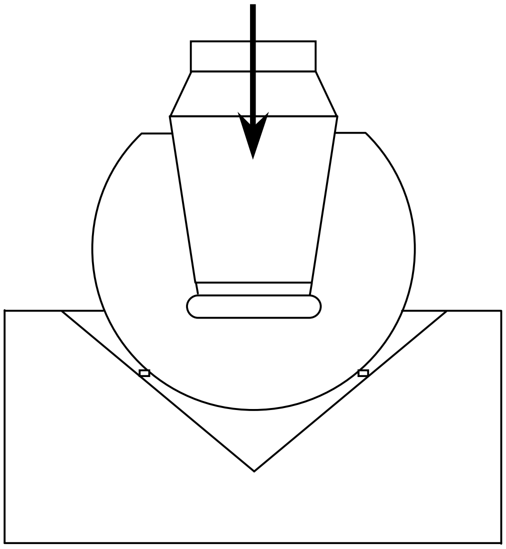

Figure 1. Axial compression or burst test set-up according to ISO 7206-10

The cone support and copper ring fixture are a part of the test method in part because the fracture patterns observed in the tests mimic those of fractures *in vivo*. In particular, test fractures originate at the taper interface. By contrast, in tests where the cone is replaced by a flat plate, the fracture typically originates on the outside surface of the head, at the point of contact with the plate. Such a fracture pattern is never observed *in vivo*.

The fracture force in these tests is typically very large, between roughly 50 kN and 100 kN. Such force levels are many times the expected force during normal activities, and likely much higher than forces experienced during falls and other impacts.

Many authors do not report the location of the fracture origin, which is an important parameter. The stresses in the ceramic during these tests are extremely non-uniform, so it is important to know the origin location to be able to make meaningful comparisons between tests. For instance, one study (Thomsen and Breusch, 2003) indicated that 14 out of 20 failures originated at the engraving at the bottom of the head and that five of the head fractures originated at the center. Of these five, four had laser signing rather than engraving (the ball heads with a fracture origin in the engraving were produced prior to 1995 with a previous generation material). This kind of detail is very useful to properly evaluate the test results and should be provided as often as possible. In particular, any indication that the fracture did not originate at the taper area should be mentioned, because such a test may not be as relevant to service life since most *in vivo* failures seem to originate from the taper region.

Effect of non-uniform taper contact

Debris at the taper interface

Weisse *et al.* have measured the effect of small debris trapped in the taper cone on the fracture load in compression (Weisse et al., 2009). Their tests show that very small debris trapped between the stem and the ceramic head cone tapers can significantly reduce the compression load. For instance, a 10 to 15 mg blood droplet placed on the stem and allowed to dry before assembling the femoral head reduces the compression fracture load to about 45 kN, compared to about 85 kN without any debris. Similar results are observed with bone chips of about 2 mg.

This result may explain some of the fractures observed in patients that do not report any strong trauma: it is possible that debris in the taper region reduced the fracture load significantly. Such debris may have left some imprint or other evidence on the fractured ceramic, which may be detected by a careful examination of the explant. For example, using elemental analysis Koo *et al.* (2008) linked two cases of fracture to contamination of the taper (Koo et al., 2008). The presence of sulfur, barium, and chloride were attributed to bone cement, while the presence of carbon, calcium, chloride and minimal sulfur were suggested to be soft tissue contamination.

By contrast, Weisse *et al.* found that scratches on the taper seem to have no effect on the compression fracture load. However, case studies in the literature have shown that implantation of a ceramic head on a stem damaged by ceramic fragments may result in a second fracture soon after revision (Koo et al., 2008). The prevailing recommendation is that in the event that the stem is left in place at revision a metal head should be utilized.

Mis-positioning of the femoral head

If the femoral head is not impacted hard enough on the trunnion, it may be partially dislodged in service, for instance as a result of minor trauma. When the interference fit between head and trunnion is different from design conditions, higher stresses may result, leading to failures in service.

Slow crack growth and its effects

The fracture load in axial burst tests is typically very high, even taking into account the reduction that may be due to entrapped debris between the taper cones. The fracture loads measured with debris at the taper interface are two to three times higher than maximum compression loads *in vivo*. There are also instances of ceramic head fractures in patients who do not report any trauma and for which there is no evidence of poor installation during surgery. Some of these fractures may be explained by subcritical crack growth in the ceramic during service.

Slow crack growth in alumina

The phenomenon of slow crack growth, or subcritical crack growth, in alumina under steady or cyclic load is well documented. Under constant stress, many glasses and ceramics are susceptible to stress-corrosion cracking, where the aggressive chemical species is simply water: the water molecule cleaves the metal-oxygen-metal bonds. This phenomenon occurs in alumina, as it does in many other oxides, and the crack growth rates in alumina have been measured (De Aza et al., 2002). De Aza *et al.* (2002) have published measurements of crack growth rates for alumina as a function of the applied stress intensity factor K_I. Their data shows that subcritical growth occurs for K_I greater than a threshold value $K_{th} = 2.5\ \mathrm{MPa \cdot m^{1/2}}$. For comparison, the critical stress intensity factor K_{Ic}, at which instantaneous fracture occurs, is about $4.2\ \mathrm{MPa \cdot m^{1/2}}$ for alumina. Therefore, small cracks for which K_I is above the threshold for subcritical crack growth but below K_{Ic} will grow slowly as long as the applied stress remains high enough. As these cracks grow, K_I increases as well, and sudden fracture occurs when K_I exceeds K_{Ic}. This results in unexpected fractures that are not associated with any particular trauma or excessive load.

The threshold value K_{th} is therefore a key design parameter, more important in a way than the fracture toughness K_{Ic}, since any crack for which the stress intensity factor exceeds this threshold value is likely to fail after some time if the stress does not decrease.

Proof testing

Since the strength of ceramic parts can be reduced as a result of imperfections in the material, an obvious method to ensure that parts are strong enough is to eliminate those that happen to have these imperfections. However, since there is no technology currently available to detect the imperfections, a proof test is performed at the end of the production process.

A proof testing protocol had been developed for ceramic femoral heads (Richter, 1996). It is essential that the proof test stress distribution be very close to the service stress distribution, so that the flaws most stressed in service are also stressed heavily during the proof test. In the case of ceramic femoral heads, the highest tensile stress in service is located at the taper cone. The proof test is conducted by pressurizing the cone cavity with a fluid, which will result in tensile stresses on the inside surface of the cone, where service stresses are expected to be maximum. The value of the proof pressure must be determined based on a variety of factors, which should include the possibility of subcritical crack growth both in service and during the test itself. For instance, here is a possible proof test protocol:

1. Estimate the maximum in-service stress, by finite element analysis or other means;
2. Compute the corresponding maximum flaw size a to keep the stress intensity factor below the threshold K_{th} for subcritical crack growth;
3. Compute the internal pressure at which a flaw of size a would propagate instantly;
4. Use this pressure as the proof pressure; decrease the pressure rapidly at the end of the test to ensure that there is no significant crack growth during the unloading period.

In this manner, cracks that survived the proof test are expected to be below threshold in service, thus they will not propagate and lead to failure.

Ceramic head manufacturers routinely subject their products to proof testing. Although the details are again confidential, the proof test protocol does involve stressing the taper cone area, which is the critical area where the service stresses are expected to be the greatest and where most of the service fractures seem to originate.

Slow crack growth in case studies

Slow crack growth has been suggested to be involved in component breakage in two separate case studies in which patients sustained a traumatic event, with delayed fractures occurring months later. In one case, the patient sustained an axial blow due to a fall without hip pain. One month later there was an acute onset of pain and crepitus (McLean et al., 2002). Similarly, in a second case, the patient fell from a height of 8 feet. Grinding in the hip with pain presented 6 months later after a slip without fall incident (Rhoads et al., 2008). In both cases, the authors suggested that the initial traumatic event led to increased hoop stresses in the head that promoted the propagation of subcritical cracks. Both fractures occurred in proof-tested components, indicating that subcritical cracks may form *in vivo* as a result of trauma. Over time, slow crack growth may occur under normal loading eventually leading to component fracture.

Explant fractography in case histories

Case histories are a useful tool to develop information about incidents or successes relative to hip implants and to attempt to understand the causes of premature fracture. However, many case histories reported in the literature do not include a detailed fractographic analysis. This reduces their value significantly, because the fracture surface contains a wealth of information about the causes of this particular failure. If the original fracture surface is still available and if it is properly interpreted, it can provide solid evidence regarding the causes of fracture. Also, the systematic analysis of fracture surfaces, from explants as well as from laboratory tests, builds up the fractographer's experience base and adds to examples of various failure modes, which are essential to proper interpretation.

The greatest impediments to the usefulness of a fractographic investigation are damage to the fracture surface after the initial fracture, and the lack of experience of the person conducting the analysis.

Post-fracture damage

After a fracture *in vivo*, there is often further damage caused by movements of the implant fragments before the revision surgery. The femoral stem is free to move among the various fragments of the ceramic head, causing additional breaking and chipping of the head fragments. Of course, during explant surgery, the surgeon should be careful to remove and save as much of the small fragments as practical, but the location of the fracture origin is often chipped away in very small pieces that are not available after surgery.

The fractographic analysis must proceed with the available pieces. Often, the larger fragments retrieved can be pieced together (taking care not to rub the fractures surfaces against each other). Typically, there will be one main fracture plane that bisects the head in two roughly equal halves. Experience has shown that this plane is often the primary fracture surface: it was created when the maximum tensile principal stresses were in the hoop direction, *i.e.* when the head was still intact and wedged on the stem. The primary plane should be examined closely for markings that indicate the direction of crack propagation. Fine features on the surface may appear to radiate from a spot, which is the area of origin. Sometimes the fracture surface shows some waviness, called cantilever curl, which is typically found towards the end of crack propagation.

Often, the general area of the origin has been damaged by chipping that occurred after the first fracture; the origin itself has been lost. In such a case, it is important to examine carefully both mating fracture surfaces, because one may be chipped but the other still intact. If the origin is available, it should be examined very closely for any evidence that may explain the failure.

Building experience in fractography

Some experience is required to conduct a good fractographic analysis. The explanted pieces are often heavily fragmented and damaged, making identification of typical fracture patterns difficult. Having examined several fractured heads makes it much easier to identify relevant markings and properly interpret the fracture. Implant manufacturers are thus in a better position than medical personnel to examine the explants, because they potentially have access to many more fractured items.

Experience can be built up by reviewing the published literature on fractography of ceramics. Standard references have been published (Fréchette, 1990; Quinn, 2007). While these texts are comprehensive, they do not specifically mention ceramic femoral heads. For a detailed discussion of the fracture of ceramic heads, including the expected stress state, the effect of debris entrapment at the taper cones, and other particular details, the reader is invited to refer to Richter (Richter, 2002) and Morrell (Morrell et al., 2001).

Case histories and detailed fractographic analyses can be very useful to determine the causes of specific failures and, by extension, identify the patterns that lead to the greatest number of failures.

Outlook for Contemporary Alumina Femoral Heads

As a result of stricter quality standards and improvements in manufacturing processes, the fracture rate of alumina femoral heads has declined over time. Whereas rates reported in the literature for first-generation alumina ceramic femoral heads range from 0.26% to as high as 13.4%, the rate for the current generation, or contemporary alumina femoral heads range from 0.004 to 0.015% today (Garino, 2005).

Current generation, or contemporary, femoral heads possess a higher density, smaller grain size, and decreased stress risers when compared to materials used during the 1970's. The implementation of improved processing of the raw material has reduced inclusions; the use of hot isostatic pressing (HIP) in the manufacturing process has increased density to $3.98 g/m^3$, and reduced the average grain size to less than 1.8 μm (Garino, 2005). In addition, improved tolerances for component mating and use of laser rather than mechanical engraving have decreased stress risers. Finally, the implementation of proof testing, as discussed previously, for 100% of manufactured components has increased the reliability of components in service.

However, *in vivo* fractures of alumina heads are still being reported, albeit with less frequency. Table 1 summarizes reports of contemporary, 3rd generation alumina fractures in the literature. For similar summaries of earlier generations of alumina the reader is referred to previous reviews (Fritsch and Gleitz, 1996; Meunier, 1998; Michaud and Rashad, 1995).

Table 1: Summary of Reported Current Generation Alumina Head Fractures

Author (Year)	**Bearing Type***	**Number of Head Fractures**	**Ceramic Brand**	**Head Size (mm)**	**Average Months to Fracture (range)**	**History of Trauma?**	**Proposed Cause of Fracture**
(McLean et al., 2002)	COP	1 (Case Study)	Biolox (Forte?)	28	41	Y#	Growth of subcritical cracks caused by trauma
(Rhoads et al., 2008)	COC	1 (Case Study)	Biolox Forte?	32	21	Y+	Growth of subcritical cracks caused by trauma
(Hwang et al., 2007)	COC	1 (Case Study)	Biolox (Forte?)	28	16	N	Impingement^
(Toran et	COC	1	(Biolox	28	10	N	Unknown

al., 2006)		(Case Study)	Forte?)				
(Koo et al., 2008)	COC	5/326	Biolox Forte	28	22.6 (12-31)	N	Unknown
(Yoo et al., 2006; Yoo et al., 2005)	COC	1/93	Biolox Forte	28	50	Y	Motor Vehicle Accident
(Park et al., 2006)	COC	2/357	Biolox Forte	28	7, 8	N	Unknown

* COC = Ceramic on Ceramic, COP = Ceramic on Polyethylene

\# Fall with axial trauma at 40 mo.; acute onset of grinding and pain at 41 mo.

\+ Fall from 8ft without pain at 15 mo.; acute onset of pain/crepitus after slip without fall at 21 mo.

^ Impingement in a Korean patient with frequent cross-legged sitting

Composite ceramic materials are the next step in the evolution of alumina femoral heads, and are currently produced by several international ceramic producers, including CeramTec and JMM. Additives such as zirconia are incorporated into alumina matrices to serve as toughening agents. The details of these mechanisms are beyond the scope of this review, but in short, controlled phase transformation of sub-micron zirconia particles within the alumina matrix prevents subcritical crack propagation, resulting in decreased fracture rates (De Aza et al., 2002; Insley, 2002; Maccauro et al., 2009). However, these materials have a relatively short clinical history, so further monitoring is necessary.

Conclusions

Component fracture continues to be a clinical concern with modern ceramic materials used in hip arthroplasty. Some fractures are due to technical difficulties or damage during implantation, others may be due to external trauma such as a fall, but some have no immediately apparent explanation. The role of the assembly of the components during surgery, the implant design, and the effect of trauma are not clearly elucidated in the available scientific literature.

Ceramic component design should be based on fracture mechanics considerations, including the effect of the subcritical crack growth threshold K_{th}. A well-designed proof test can assist in making sure that femoral heads will not fail in service, as long as they are assembled correctly at the time of surgery. The effect of debris entrapped in the taper engagement and of other abnormal contamination should not be overlooked. Finally, fractographic analysis should be performed on most of the fractured explants, to build an experience base leading to a deeper understanding of the failure modes found *in vivo* and their avoidance in the future.

Acknowledgements

Institutional support was received in part from NIH AR47904. The authors would like to thank Ricardo Heros, CeramTec; Masaru Ueno, Japan Medical Materials Corporation; and David Schroeder, Biomet Orthopedics, for providing insight into the ceramic implant design process and for many helpful discussions.

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