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ORIGINAL PAPER

# Emergence of the alumina matrix composite in total hip arthroplasty

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**Abstract** Pure alumina ceramic has been in clinical use in orthopaedics since 1971 and, currently, up to 5 million components have been implanted. Alumina offers advantages like stability, biocompatibility and low wear; however, it has limited strength. Applications are limited by design considerations. Engineers in biomaterials have worked on improving the performance of the material by optimising the manufacturing process. To fulfil surgeons' and patients' increasingly exacting requirements, ceramists have also developed a new ceramic composite, the alumina matrix composite (AMC). This material combines the great principles of the reinforcement of ceramics with its tribological qualities and presents a better mechanical resistance than alumina. The examination of the tribological situation of AMC, especially under the challenging conditions of hydrothermal ageing, shows the aptitude of this material in wear applications. The US Food and Drug Administration (FDA) has approved ceramic ball heads articulating against polyethylene inserts. Since its introduction, more than 65,000 ball heads and 40,000 inserts of AMC have been implanted. With a 6-year follow up, no complication has been reported to the manufacturer. Improved toughness and the excellent wear of AMC makes it a potentially more flexible alternative to the more traditional alumina for hip prostheses.

**Résumé** Les têtes en céramique d'alumine pure sont utilisées en orthopédie depuis 1971, plus de 5 millions de composants ont été implantés. L'alumine offre les avantages suivant: stabilité, biocompatibilité et usure minime cependant, sa fragilité peut être une limite. L'utilisation peut être limitée également du fait du type de design. Les ingénieurs en biomécanique ont travaillé de façon à améliorer les performances de ce type de matériau en optimisant le processus de fabrication. Ils ont également essayé de développer de nouvelles céramiques composites de type Alumina Matrix Composite (AMC). Ce matériel permet d'associer les grands principes de la céramique et d'améliorer sa résistance de même en ce qui concerne ses qualités tribologiques. Les conditions d'études tribologiques, en augmentant le vieillissement restent satisfaisantes. La FDA a approuvé l'utilisation de ces têtes céramiques avec un couple céramique/polyéthylène. Depuis son introduction plus de 60.000 têtes et 40.000 inserts d'AMC ont été implantés avec un suivi moyen de 6 ans sans complications rapportées. L'amélioration de la dureté et son excellente résistance à l'usure font de ce matériau une alternative satisfaisante à l'alumine traditionnelle pour les prothèses totales de hanche.

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## Introduction

In the last 20 years, applications for ceramics in orthopaedics have continuously increased in Europe and, more recently, in the United States. The first application of ceramics in this field was a commercially pure alumina [1, 9, 14]. This material has been in clinical use since 1971 and, currently, up to 5 million components have been implanted [8, 15, 17]. Engineers in biomaterials have worked on improving the performance of the material by optimising the manufacturing process in order to obtain an increase in reliability and performance. To fulfil surgeons' and patients' increasingly exacting requirements, ceramists have also developed a new ceramic composite, the alumina matrix composite (AMC). This material combines the great principles of the reinforcement of ceramics with its tribological qualities and presents a better mechanical resistance than alumina.

## Improvement of ceramics in orthopaedics

The optimisation of manufacturing processes has enabled alumina ceramic results to improve considerably.

In 1992, a first improvement appeared with a better quality alumina powder with much finer granulometry and a higher degree of purity.

The engraving process and the polishing of ceramics has been closely studied in order to guarantee better tribological results for the alumina-on-alumina bearing couple. The engraving of implants using a diamond fragilised the material and created tension on the surface [16, 22]. Today, laser engraving does not have this side effect. Numerous publications describe these former ceramics with obsolete designs (skirted heads) and, naturally, in these cases, complications were frequent [19].

The mechanical resistance of a ceramic component depends on the size of the minimal default in its microstructure [11, 18]. In other words, reducing the average size of the grains increases the material's resistance to flexion. The practical application of this reinforcement principle comes through hot isostatic pressing technology. This high-pressure fritting technique combined with a classical fritting technique has improved the mechanical resistance of alumina. The average size of the grains has been reduced from 3.2 µm to 1.8 µm and the bending strength values have been increased to 580 Mpa for alumina ceramics. The third-generation alumina ceramics commercialised today benefit from all of these improvements [12].

Table 1 summarises the different mechanical characteristics and their evolution.

## Alumina matrix composite material

In the 1970s, the basic foundation for the composite ceramic material was found when companies began investigating the principle of transformation toughening as a means to improve the strength of alumina materials.

Ceramic composite is a reinforced alumina. It is principally composed of alumina, which represents 82% of the volume of the overall material. Nano particles of zirconia oxide are added to the alumina matrix and represent 17% of the volume. The zirconia particles are stabilised in tetragonal phase, which is the phase that presents the best mechanical performance [13].

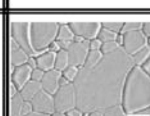
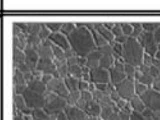
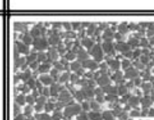
The three reinforcing mechanisms used today are:

- In situ formation of elongated oxide crystals, reinforcing the platelet
- The addition of homogeneously dispersed small zirconia particles in the alumina matrix, creating a transformation toughening
- The creation of a solid solution with chromium oxide hardening the matrix

### Platelet reinforcement

In situ grown platelets of strontium oxide (elongated grains) have a hexagonal structure and are dispersed homoge-

**Table 1** Mechanical characteristics and the evolution of different ceramic materials

| Properties of Ceramics | Alumina Ceramic ISO 6474 1994 | 1st and 2nd generation Alumina | 3rd generation Alumina (Hipped) | Alumina Ceramic Composite |
|---|---|---|---|---|
| 4-point bending strength | 400Mpa | 500Mpa | 580 Mpa | >1000 Mpa |
| Average Grain Size | < 4.5µm | < 3.2µm | < 1.8µm | < 1,5 µm |
| Density | 3.94g/cm3 | 3.96g/cm3 | 3.98g/cm3 | 4,37g/cm3 |
| Microstructure | |  |  |  |

neously within the microstructure [2]. This first mechanism's task is to deflect any subcritical cracks that could appear during the ceramics' lifetime. The composite stops the cracks from spreading through deviation, thanks to the shape of the crystal pins that act as barriers (Fig. 1).

## Metastability mechanism

The second mechanism is due to the presence of a small percentage of zirconia oxide (17% by volume) in the alumina matrix [7, 10]. The excellent structural stability, which is the principal characteristic of alumina, is maintained. Figure 2 shows the microstructure of the AMC.

Zirconia oxide is capital in the reinforcement of alumina. These Y-TZP grains are homogeneously distributed throughout the microstructure and, therefore, isolated from one another to provide an independent individual transformation ability. The metastable nano particles dispersed homogeneously in the alumina matrix will transform in case of the appearance of fissures between the alumina grains. When mechanical stress attempts to dissociate the alumina grains from one another, this metastability mechanism steps in.

The transformation from tetragonal phase to monoclinic phase is automatically accompanied by an increase in volume. In this precise case, the density of the monoclinic phase is inferior to the tetragonal phase. It, therefore, occupies a bigger volume. This transformation raises the compressive stress field in the vicinity of the particles because the volume expands by 4% in this process.

The spreading of the fissure will be stopped thanks to the increase in volume of the zirconia oxide grains transformed in the monoclinic phase. They act as an airbag, absorbing the energy of the fissure (Fig. 3).

The end result of this transformation toughening mechanism is an increase in the fracture toughness of the material.

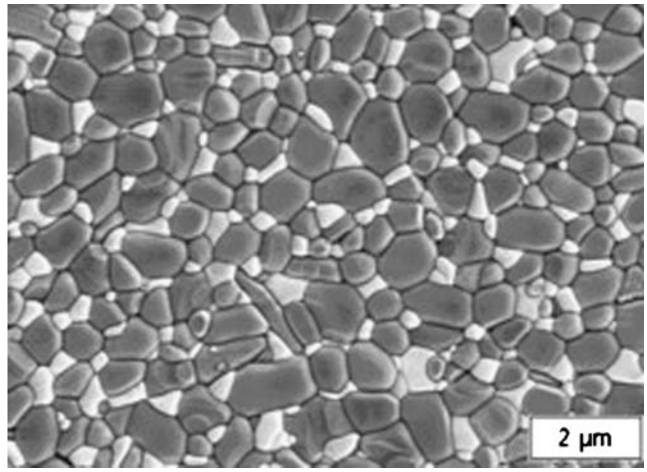



**Fig. 2** Typical microstructure of the alumina matrix composite (AMC)

## Hydrothermal stability

In the case of a composite ceramic, the zirconia oxide presents a double stabilisation mechanism.

The first stabilisation mechanism is a classical yttrium chemical stabilisation (3 mol%) in tetragonal phase. The second mechanism is a mechanical stabilisation of the zirconia grains, which are physically squeezed between the alumina matrix grains. The transformation phase cannot mechanically take place while a crack is freeing space between the alumina grains.

It is well known that the phase transformation of pure zirconia occurs under severe hydrothermal conditions [3] (e.g. water steam 100°C). The hydrothermal stability of the AMC has been demonstrated by several tests conducted on pre-aged samples. Pre-aging was accomplished by subjecting the samples to exposures of between 5 and 6 h in an autoclave (according to ASTM F 2345). After this pre-aging regime, the parts were tested and no significant differences were found in the mechanical properties from the non-aged

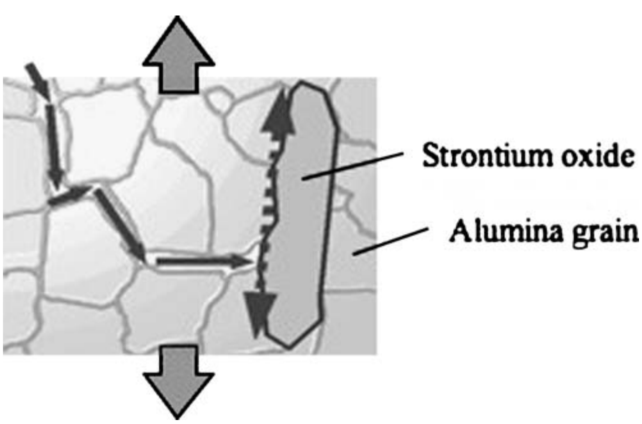



**Fig. 1** The mechanism of crack deviation

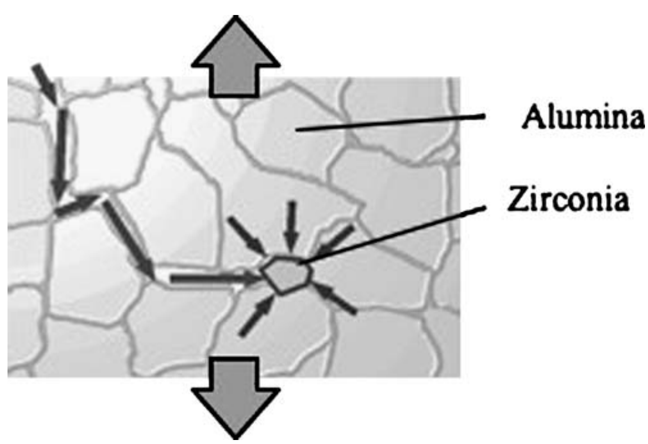



**Fig. 3** Metastability mechanism of zirconia grains inside the alumina matrix

**Fig. 4** Ceramic composite revision ball head (metallic sleeve)

and the pre-aged samples. The latter is not susceptible to hydrothermal conditions. As a consequence, the hydrothermal stability of the AMC is inherently superior in comparison to materials composed of pure zirconia.

Hardness

Finally, chromium oxide is added as a solid solution in the alumina matrix as a means to compensate for the drop in hardness caused by the addition of the lower hardness zirconia particles in the microstructure [4]. Finally, the hardness of these two sorts of ceramics are very close; 1,400 Vickers for classical alumina and 1,900 Vickers for AMC—they are perfectly compatible on the condition that they are produced by the same manufacturer. An alumina head can be used with a ceramic composite insert and vice versa [20, 21].

## Applications and clinical experience

The US Food and Drug Administration (FDA) has approved the material for use in ball heads articulating against polyethylene inserts. Its first clinical use in the United States was in June 2000. Today, we have 6 years of clinical experience of the material. More than 65,000 ball heads and 40,000 inserts of the AMC material have been implanted all over the world.

One of the first applications was ceramic ball heads for revisions (Fig. 4). These femoral heads have enabled the use of ceramic ball heads in a revision without having to remove the femoral stem, thanks to a metallic titanium sleeve. In the case of revision, it is risky to use a ceramic ball on a used or damaged taper. The surface deformation of the taper will create a stress concentration and increase the risk of ceramic fracture. The metallic sleeve will absorb the irregularity of the taper.

Several Investigational Device Exemptions (IDEs) are currently ongoing in the United States, some of them will end in 2008. These clinical studies will confirm the good behaviour of the material in vivo. Six years of clinical experience is not long enough for surgeons to have prepared sufficient series with the requested follow up and be published today in referenced journals. There are also many studies currently ongoing that they will be available soon. A few surgeons have already started to present their first clinical results with AMC/AMC bearings with at least 18 months follow up; the results are very promising [6]. A recent publication reported that no fractures occurred in the 6,500 AMC liners implanted from 2003 to 2007 [5].

Composite ceramics has enabled femoral ball heads to be manufactured in small diameters (22.2 mm), extra neck lengths, revision ball heads, new designs (new sizes for inserts, ceramic double mobility), knees and so on.

## Conclusion

The excellent hydrothermal stability, biocompatibility and tribology of ceramics establishes it as being particularly adapted for use in orthopaedics. For alumina ceramics, all of this information has a 30-year clinical follow up [23, 24]. The alumina matrix composite (AMC) ceramic material has been thoroughly evaluated and tested for use as an additional material in the total joint replacement area. The substantial improvement in mechanical properties and the excellent wear behaviour, even under severe micro-separation wear testing, serve to make this material a promising new addition to the orthopaedic surgical community and a possible solution to the existing longevity problems currently burdening many total joint systems in young and active patients.

No complications have yet been reported after 6-year follow up and with more than 100,000 components (heads and inserts) implanted.

New applications in orthopaedics are, therefore, possible. This ceramic is also becoming more and more commonly used for standard applications in the hip, for example, big-diameter femoral heads.

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