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Third-generation pure alumina and alumina matrix composites in total hip arthroplasty: What is the evidence?

Didier Hannouche[1]
Matthieu Zingg[1]
Hermes Miozzari[1]
Remy Nizard[2]
Anne Lübbeke[1]

- Wear, corrosion and periprosthetic osteolysis are important causes of failure in joint arthroplasty, especially in young patients.
- Ceramic bearings, developed 40 years ago, are an increasingly popular choice in hip arthroplasty. New manufacturing procedures have increased the strength and reliability of ceramic materials and reduced the risk of complications.
- In recent decades, ceramics made of pure alumina have continuously improved, resulting in a surgical-grade material that fulfills clinical requirements.
- Despite the track record of safety and long-term results, third-generation pure alumina ceramics are being replaced in clinical practice by alumina matrix composites, which are composed of alumina and zirconium.
- In this review, the characteristics of both materials are discussed, and the long-term results with third-generation alumina-on-alumina bearings and the associated complications are compared with those of other available ceramics.

Keywords: hip; arthroplasty; ceramic

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Introduction

Total hip arthroplasty (THA) is the most successful procedure used to treat end-stage degenerative conditions of the hip. Over 156.6 THAs per 100 000 population are performed each year in Europe, and the demand for primary THA is expected to grow by 174% by 2030 in some countries,[1] especially among adults in early middle age, between 45 and 65 years.[2]

With substantial improvements in prosthetic designs and surgical techniques, high success rates with THA have been achieved in the general population, but the outcomes of THA in young and active patients remain poorer than those in their older counterparts.[3-5] Poorer survivorships in young patients have been attributed to wear of conventional polyethylene (PE) that generates particles, which eventually lead to periprosthetic osteolysis.[6] The risk of osteolysis increases depending on the characteristics of the particles, including their number, composition, size and shape.

Bearing surfaces made of alumina (Al) ceramic were introduced in 1971, with the objective of reducing wear, limiting osteolysis progression and extending implant longevity in young and active patients. During the last 45 years, Al ceramics have continuously improved, resulting in pure Al material that fulfills clinical requirements.[7] Despite the track record of safety and the long-term results using third-generation Al ceramics, they are being replaced in clinical practice by Al matrix composites (AMCs) composed of Al and zirconium.[8,9]

In this review, the long-term clinical results with third-generation pure Al-Al bearings and their complications will be presented and compared with other available ceramics.

A brief history of Al ceramics in orthopaedics

Al is a chemically inert ceramic with very good biocompatibility, as evidenced by extensive clinical experience. Al implants used in orthopaedic surgery are subject to quality standards according to the ISO/DIS 6474-1[10] (updated in 2016) (Table 1). Al has a remarkable compressive strength (about 4500 MPa), although its flexural strength (about

Table 1. Comparison of the ISO/DIS 6474-1 standard specification characteristics of alumina (Al) ceramics and the characteristics of commercially available third-generation Al[10]

Characteristic	ISO/DIS 6474-1 (2016)	Third-generation Al
Density	$\geqslant$ 3.94 g/cm^3	3.98 g/cm^3
Al$_2$O$_3$ content (wt%)	$\geqslant$ 99.7%	$>$ 99.8%
Average grain size	$\geqslant$ 2.5 µm ± 25%	$<$ 1.8 µm
Bending strength	$\geqslant$ 500 MPa	580 MPa
Young's modulus	$\geqslant$ 380 GPa	407 GPa
Microhardness (HV1)	$\geqslant$ 18 GPa	20 GPa
Fracture toughness (K$_{IC}$)	$\geqslant$ 2.5 MPa·m$^{1/2}$	3.2 MPa·m$^{1/2}$

580 MPa) is low. It has a high elastic modulus (400 GPa), superior to that of cortical bone (300 GPa), and low deformation capacities.[11] Al exhibits mechanical fragility, which remains a weak point of this bearing, but offers several advantages over other sliding couples, such as extreme hardness, a low friction coefficient and excellent wear resistance, with a wear rate 4000 times lower than that of metal-on-PE.

Starting with the work of Boutin et al[12] in 1971, early implantations of Al-Al prostheses ended up with very disappointing results, due to a high rate of ceramic fractures and loss of fixation of the socket, which was initially either cemented or directly impacted into the acetabulum (Table 2).

From 1974 onwards, marked improvements were made in Europe [13-19] and Japan[20] in terms of prosthetic hip design, material quality and fixation methods. The introduction of Morse taper technology to orthopaedic surgery in 1974 was a key step for successful attachment of the ceramic head on the femoral component, as it was initially glued or screwed on the stem.[21] Later, modularity of the acetabulum allowed secure fixation of the Al insert by conical sleeving in a metallic shell (Fig. 1). Finally, in 1995, the introduction of hot isostatic pressing technology in the manufacturing process provided the so-called third-generation Al ceramic, with its high purity, high density (3.98 g/cm^3), fine grain and superior mechanical properties.[22]

In 2000, in order to increase the toughness of Al implants, biomaterial engineers developed an AMC made of 81.6% Al and 17% zirconium oxide (Zr), with the addition of Strontium Oxide (SrO) and Chromium Oxide (CrO) during the sintering process[9] (Table 2). AMC femoral heads and liners were marketed in Europe in 2000; Food and Drug Administration approval was obtained for femoral heads in 2000 (coupled with PE liners) and for liners in 2003.[23] Nano-sized Zr particles, which are homogeneously distributed within the material, play a major role in the reinforcement of AMCs. They are stabilised with yttrium oxide and exhibit a stable tetragonal phase at room temperature. When a crack appears, it propagates towards the less rigid Zr grains, which transform from tetragonal to monoclinic phase with a slight increase in volume. This phase transformation will increase the density, create significant compressive forces near a crack tip and help limit crack growth. Stiffness and hardness of AMCs are in the same range as Al ceramics, but their flexural strength and toughness are almost double, supposedly reducing the risk of fracture. The weak point of AMCs is their tetragonal crystalline phase that tends to transform into the monoclinic phase even under physiological conditions because of the presence of biological fluids and frictional heating.[24] When evaluated in the laboratory under severe microseparation test mode, the monoclinic content of 36 mm diameter heads increased considerably from 15% to 30%.[25] Monoclinic transformation is of concern, as it alters the phase integrity of the material and increases surface roughness, and potentially reduces sliding properties over time. Although AMCs are commonly used in THA, they have not yet firmly established a long-term track record in terms of wear and osteolysis, as compared with third-generation Al ceramics.

Fractures of third-generation Al and AMC ceramics

Al implants are brittle materials, which means they are sensitive to stress concentrations around areas of

Table 2. Overview of the development of ceramics in orthopaedics

Year	Type of ceramic	Head diameter	Comments
1971	Al	32	Non-modular ceramic heads/ cemented or impacted plain Al acetabular component
1973	Al	28,32	Modular ceramic heads
1977	Al	28,32	Modular ceramic heads
1983	Al	28, 32	Modular ceramic acetabular component: threaded, screwed
1989	Al	28, 32	Modular ceramic acetabular component: press-fit titanium grid
1989	Al	28,32	Approved by FDA for use with PE acetabular components
1995	Third-generation Al	28,32	Introduction of hot isostatic pressing
1997	Third-generation Al	28, 32	Modular ceramic acetabular component: press-fit titanium HA-coated
1997	Third-generation Al	36	Large heads approved by FDA for use with PE acetabular components
2000	AMC	28, 32	Marketed in Europe, approved by FDA for use with PE acetabular components
2003	AMC	28, 32	Ceramic liners approved by FDA
2006	AMC	36	Large heads approved by FDA for use with PE acetabular components

Al, alumina; AMC, alumina matrix composite; HA: Hydroyapatite; PE, polyethylene; FDA, Food and Drug Administration

Fig. 1 The design of the acetabular component has been modified over the last 40 years: a) impacted or cemented plain alumina socket; b) smooth titanium screwed-in shell with alumina liner; c) press-fit titanium shell with titanium grid; d) hydroxyapatite-coated titanium shell; e) hydroxyapatite-coated titanium shell entirely covered with a microstucture of ridges and grooves.

weakness of the material, including pre-existing cracks, scratches or pores.[26,27] The fracture toughness (K1c value) is used to evaluate the brittleness of the material, especially in the case of fast fractures. These fractures occur when the stress-intensity factor K1 at the crack tip becomes larger than the fracture toughness.[28] This situation is, however, rare, and most fractures occur by slow crack propagation at K1 values lower than K1c, under the effect of subcritical stresses.[29] Subcritical crack growth is extremely sensitive to applied loads but also depends on extraneous variables, such as temperature, the presence of body fluid and chemical concentrations. A high body mass index, high-impact physical activities, the presence of tissue interpositions between the Morse taper and the implant, and hammering during implantation are all important risk factors for head and acetabular liner fractures. The mechanical properties of Al ceramics depend on their purity, porosity, grain size and grain distribution, but also on machining processes that should be accurate to optimise surface finish and to avoid crack initiation.[30] Substantial improvements in the manufacturing process have significantly decreased the rate of femoral head fracture from more than 1% in the 1970s to 0.004% in the 2000s.[31,32] However, a retrospective study of 3710 ceramic prostheses implanted between 1993 and 2004 reported a fracture rate of the liner of 0.22%.[33]

The use of AMCs has been growing in the past 14 years because of their increased toughness, which is twice as high as third-generation Al ceramics. Very few studies, however, have compared the risk of fractures between these two ceramics. In a recent review, Massin et al[34] identified 58 studies reporting fractures of ceramic implants: 53 dealing with third-generation Al and five with AMC. They compared the reported fracture rates with the manufacturer's data and with the notifications provided by surgeons to the French National Agency for Safety of Drugs and Medical Products (ANSM). According to the manufacturer, the fracture rate of the femoral head was about ten times lower for AMC (0.002%), as compared with Al ceramics (0.021%). The figures provided by the ANSM showed an even greater difference, with a rupture rate of 0.18% for Al femoral heads and 0.0013% for AMC femoral heads. Interestingly, the rate of liner fracture did not differ significantly between third-generation Al ceramics and AMC, with an estimated fracture rate of 0.086% and 0.025%, respectively, according to the manufacturer. Similar findings have been reported by Howard et al[35] in the largest independent study on fractures of ceramic-on-ceramic bearings. The study included 111 681 ceramic-on-ceramic THAs (79 442 AMC and 31 982 Al femoral heads; 80 170 AMC and 31 258 Al liners) from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. Small 28 mm Al femoral heads had a significantly higher risk of fracture (0.382%). Body mass index was significantly associated with an increased risk of revision for both femoral head and liner fractures. Of note, the rate of fracture of AMC liners (0.126%) did not differ significantly as compared with third-generation Al liners (0.112%).

Recently, unacceptable rates of AMC liner fractures, i.e. between 1.1% and 3.8%, have been reported in the literature, warranting long-term monitoring of this specific complication.[36-39] It is still not known whether AMC liner fractures are related to the intrinsic properties of the material or to component design and technical issues related to the expanding use of this sliding couple. Ceramic liner fractures have been attributed to joint dislocation, micro-separation and malseating, which must be avoided by careful handling of the material, thorough cleaning and drying of the sleeve and proper positioning of the implants.

Squeaking of third-generation Al and AMC ceramics

Squeaking has been reported as an unpredictable complication of ceramic-on-ceramic sliding surfaces. It is a very annoying, high-pitched noise, similar to the creaking of a door hinge. It can be classified according to the loudness of the squeak, the perceptibility to others and the frequency of occurrence.[40] The incidence of squeaking varies considerably in the literature, at rates between 1% and 20%.[41] Mostly painless, it seriously affects quality of life, and might be responsible for social withdrawal.[42] Revision surgery is, however, rarely necessary, with an overall revision rate due to squeaking of 0.2%. Although no study compared the risk of squeaking between third-generation Al ceramics and AMC, it is noteworthy that the incidence of squeaking has greatly increased since the introduction of AMC, with reported incidence as high as 6% to 31%.[43-45] In a series of 336 AMC-AMC THAs, a noise was reported in 17% of the hips, and the noise was frequently heard in 48% of them.[45] In comparison, the incidence of squeaking was 2.6% in a cohort of patients who received a third-generation Al-Al bearing couple, and who were operated on between 2003 and 2004 and followed for up to three years after surgery.[46] No clear conclusion can be drawn from these series, as the aetiology of squeaking is likely to be multi-factorial, involving patient-related factors, anatomical factors and technical factors. As AMCs have come into widespread use, new prosthetic designs have been released and new technical issues have emerged regarding liner implantation and fixation within the socket. Consequently, there has been a noted increase in the diagnosis and reporting of noise problems after ceramic-on-ceramic THA, while this complication was seldom reported before.

The exact mechanism of squeaking remains unknown.[47] Squeaking can be reproduced experimentally. It might be related to lubrication problems,[48] third-body wear,[49] stripe wear,[50] impingement between the stem and the acetabular component,[51] excessive[52] or insufficient anteversion of the acetabular component,[53] head-neck ratio,[54] and microfractures of the liner.[55,56]

In a study reporting the results of 1486 THAs performed between 2003 and 2007, squeaking was reported in 6% of cases, but only nine patients had to be re-operated on for this complication.[44] No correlation could be found between the acetabular component position and the squeak.

Shah et al[57] recently compared the incidence of squeaking between navigated and conventional THAs. A total of 375 THAs were included (202 navigated, 173 conventional), all of which received an AMC femoral head and liner. The overall incidence of noise was 14.7%, including 7.7% with squeaking. The incidence of noise was significantly lower in the navigated hips, which had a 2.7× lower risk of making noise and a 1.9× lower risk of squeaking. In the navigated group, acetabular component anteversion was significantly higher and acetabular component inclination was lower, as compared with conventional THA. Conversely, a 3D scanographic study analyzed implant positioning in three squeaking hips, and showed a two-fold increase of combined anteversion (above 75°) in these patients as compared with those with non-squeaking hips.[58]

Sexton et al[59] reported that the risk of squeaking was higher in patients under 65 years of age, and in cases with increased femoral offset and lateralisation. Restrepo et al[54] pointed out the possible role of stem alloys, stem design and neck geometries that could act as a sound box for noise amplification. In a consecutive series of 304 THAs, the prevalence of squeaking was seven times higher with the use of titanium-molybdenum-zirconia-steel alloy femoral stems, as compared with titanium-aluminum-vanadium stems.

Recently, much emphasis has been placed on the possible role of micro-separation and subluxation occurring in extreme ranges of movement, thus responsible for edge-loading and abnormal stripe wear.[60] Taylor et al[50] explored the relationships between stripe wear, acetabular component inclination angle and clearance and their contribution to squeaking. Wear couples were composed of a 32 mm diameter femoral head and ceramic liner. The type of ceramic used was not described. In this experimental study, squeaking systematically occurred after the onset of stripe wear and was due to a combined phenomenon of edge-loading and lack of lubrication.

Optimal size of third-generation Al and AMC femoral heads

As for metallic heads, there has been a trend recently to increase ceramic femoral head diameter in order to improve hip range of movement, increase joint proprioception, delay cam-type impingement and reduce the risk of dislocation.[61] However, for a given acetabular component size, increasing head diameter results in a reduction in ceramic liner thickness, which should be at least 6 mm for Al implants and 3.5 mm for ACM to avoid ceramic liner fracture.[62]

The use of ceramic femoral heads with very large diameters would have several theoretical advantages. They may reduce the risk of femoral head fractures, seen in early generation implants, and may lower the risk of impingement, thus reducing the incidence of liner chipping.[63] Their use, however, raises several issues. They may increase wear by reducing fluid-film lubrication and increasing the friction coefficient; they may cause overload at the implant-bone interface and at the taper junction; and they may increase the risk of squeaking, although this explanation has been controversial. In a series of 208 AMC-AMC THAs with a femoral head of 32 mm to 48 mm, the incidence of noise was 31%, 66% of which was squeaking.[43] Noise occurrence was significantly more frequent in cases with excessive mobility, ligament laxity and small diameter femoral heads. More recently, Tai et al[64] explored the incidence of squeaking in 206 AMC-AMC THAs with a head diameter of 32 mm to 48 mm. They found no relationship between head diameter and the occurrence of squeaking, which was present in 7.3% of the cases.

Overall, given the reliability of the 32 mm and 36 mm ceramic heads, the low risk of dislocation with these diameters, and the available track record of these femoral head sizes, the authors recommend against exceeding 36 mm for Al and AMC heads.

Long-term results of ceramic bearings

Al ceramics are the only ceramics for which very long-term results (more than 20 years) are available. Importantly, publications on Al-Al bearing couples should be read carefully and interpreted with caution, since the development of a surgical-grade Al ceramic spanned three decades.[7] During this time, several designs of implants, modes of fixation, component materials and qualities have been tested, with some success. The purity and mechanical properties of Al ceramics are highly dependent on the period of implantation, which is almost always mentioned in the articles (Table 2). The high rate of failures reported in the literature in the early phase of clinical testing was mainly due to aseptic loosening of the acetabular component, which was initially a cemented plain Al socket.[65] The results were slightly improved with the use of cementless plain Al sockets. In a series of 106 patients (118 hips) operated on between 1978 and 1980 and followed up to 20 years, a plain Al socket was used in 33 hips.[66] At last follow-up, survivorship was 85.6% for impacted sockets and 61.2% for cemented acetabular components. No wear was detected on radiographs, and there was no osteolysis.

The results of Al-Al THA due to avascular necrosis of the femoral head were reported by Solarino et al[67] in a series of 61 patients (68 hips) with a mean age of 49.9 years. The acetabular component consisted of a pure titanium core with a titanium alloy mesh; the femoral component was a smooth and collared titanium cemented stem in 14 patients, a cementless anatomical stem with a trochanteric wing in 26 cases and a cementless straight tapered-wedge stem in 28 cases. No osteolysis was detected. The authors observed one aseptic loosening of a cementless anatomical femoral stem, and the Kaplan-Meier survivorship was greater than 95% at 180 months follow-up.

The most important series reporting the long-term results of modern third-generation Al-Al prostheses was published in 2016.[68] The authors examined the clinical and radiological results of 900 patients (1130 hips) who received a cementless femoral and acetabular THA and were less than 65 years old at the time of surgery. The Western Ontario and McMaster Universities Osteoarthritis Index score averaged 90 ± 9.9 at 20 years. No fracture of Al ceramics was observed and only three cases of revision due to recurrent dislocations were reported (0.3%). Implant survivorship was 99.7% at 20 years for all-cause revisions. CT evaluation at last follow-up showed good stability of the implants and no signs of osteolysis on either the acetabular or femoral sides.

Data from the Danish Registry at nine years are comparable. In a series of 1773 Al-Al THAs (81% of which were of third-generation Al on the acetabular side and 77% on the femoral side), Varnum et al[69] reported that 4% underwent revision. The causes of revision were dislocation (1.2%), aseptic loosening (0.6%), pain (0.5%), femoral bone fracture (0.5%), and implant failure (0.5%). No patient had signs of osteolysis on radiographs and two patients were re-operated on for squeaking (0.1%).

In the 2016 report of the Australian Orthopaedic Association National Joint Replacement Registry,[70] Al-Al prostheses were used in 72 139 cases. The 32 mm diameter Al femoral heads were associated with a lower risk of revision at ten years, as compared with 28 mm and 36 mm femoral heads. In patients under 55 years of age, the cumulative risk of revision of Al-Al THAs was 6.6% at 15 years *versus* 17.4% with metal-on-conventional PE. Results of ceramic on highly cross-linked PE were not available at this follow-up.

The results with modern Al-Al THAs in very young patients, who may want to perform strenuous activities and sports, have been promising. In a retrospective study, Hannouche et al[71] examined the results of 113 primary Al-Al THAs performed in 91 patients younger than 20 years at the time of surgery. The most common reason for THA was avascular necrosis of the femoral head in 56.2% of the cases. The revision-free survival rate at ten years was 90.3%, significantly lower than results reported in older patients; however, patient-reported outcomes and quality of life significantly improved. The revision-free survival rate for patients younger than 17 years was significantly lower than in patients older than 17.

Interestingly, all series reporting the results of third-generation Al-Al bearing couples pointed out the very low incidence of osteolytic lesions in the long term.[68,72-76] Hernigou et al[77] investigated peri-acetabular osteolysis in 28 bilateral THAs in patients who received an Al-Al couple on one side and Al on conventional PE in the contralateral hip. They found that the surface and volume of osteolysis at 20 years were significantly lower when an Al-Al bearing couple was used. The low incidence of osteolysis might be explained by the inert nature of Al material, which has a very low wear rate *in vivo*, and whose particles are very well tolerated, mainly triggering a fibroblastic reaction. It has been suggested that the capsule around Al-Al prostheses was less inflammatory and thicker than that around Al-PE bearings, which could protect the hip against late dislocations.[78] In a retrospective study of 126 patients who had bilateral hip arthroplasty and were followed up to 27 years, Hernigou et al[79] showed that the cumulative risk of dislocation was significantly lower when an Al-Al couple was used. To the authors' knowledge, there has been only one case of an important inflammatory foreign-body reaction due to an Al-Al articulation reported in the literature.[80] The prosthesis had been implanted nine years before. Cobalt and chromium ions were not elevated and there was no sign of trunnion corrosion. The pseudotumour observed in this patient was similar to the adverse local tissue reaction seen in patients with metal-on-metal bearings, and was assumed to be related to Al-Al wear debris.

Conclusion

The Al-Al bearing surface was introduced for THA due to its outstanding tribological properties. However, the first few implantations of Al-Al prostheses were accompanied by a set of unknown and initially unsuspected complications: implant fractures, femoral head fixation problems and aseptic loosening of the acetabular component. These issues were subsequently resolved in the late 1980s, almost 20 years later, due to incremental improvements in material design and quality, and the introduction of quality control procedures. Third-generation Al-Al couples have been accepted as a reliable alternative to metal-PE bearings and have even surpassed survivals of conventional implants in patients under 50 years of age.[81,82] Given their excellent wear performance and the inert nature of their debris, Al-Al bearings decrease the risk of osteolysis in the long term, and decrease the risk of late dislocations. New ceramics, such as AMC, show promising results in the short term, but further studies are needed to demonstrate their superiority and safety in the long term.

AUTHOR INFORMATION

[1]Department of Orthopaedic Surgery and Traumatology, Geneva University Hospital, Switzerland

[2]Department of Orthopaedic Surgery, AP-HP, Hôpital Lariboisière, Paris University, Paris, France

Correspondence should be sent to: D. Hannouche, Geneva University Hospital, Avenue Gabrielle Perret Gentil 4, Geneva 1205, Switzerland.
Email: didier.hannouche@hcuge.ch

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