Poor eight-year survival of cemented zirconia-polyethylene total hip replacements

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Between January 1988 and January 1991 we performed 100 consecutive cemented total hip replacements using a zirconia head, a titanium alloy stem and a polyethylene cup. We reviewed 78 of these hips in 61 patients in detail at a mean of 5.8 years (1 to 9).

Aseptic loosening was seen in 11 hips (14%). Eight needed revision. In total, 37 cups (47.5%) showed radiolucent lines, all at the cement-bone interface, with 18 (23%) involving all the interface. Of the 78 femoral implants, 17 (21.7%) showed radiolucent lines, and two, which had a complete line of more than 1 mm thick, definite endocortical osteolyses. There was also an abnormally high incidence of osteolysis of more than 2 mm at the calcar.

Survivorship analysis showed that only 63% were in situ at eight years. These worrying results led us to abandon the use of zirconia heads, since at the same hospital, using the same femoral stem, cement and polyethylene cup, but with alumina femoral heads, the survival rate was 93% at nine years. We discuss the possible reasons for the poor performance of zirconia ceramic.

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Alumina ceramic was introduced into orthopaedic surgery in the early 1970s^{1,2} because its biocompatibility³ and resistance to wear were greater than the alloys and polymers then in use.^{4,5} Good quality alumina worked satisfactorily in alumina-to-alumina couples and alumina-

polyethylene combinations.^{2,6-8} Its main drawback was its low resistance to fractures and to stress,^{4,9} making it vulnerable to microstructural damage and mechanical impact.¹⁰ For these reasons, the early alumina heads were no smaller than 32 mm in diameter,¹⁰ which gave difficulty with thin polyethylene in the smaller cups.¹¹

In 1988, zirconia ceramic heads 28 mm in diameter became available which allowed the use of thicker polyethylene cups. Experimental studies showed encouraging results as regards the tribological characteristics and biocompatibility of zirconia,¹²⁻¹⁸ but there have been no clinical and radiological reviews of hip replacements using a zirconia femoral head. We report 78 of our first 100 consecutive cases after a relatively short follow-up, because we have seen worrying radiological changes.

Patients and Methods

Between January 1988 and January 1991 we implanted 100 consecutive cemented total hip replacements with a 28 mm zirconia-polyethylene head. A total of 22 patients was lost to review before one year and was excluded. We studied 78 hips in 60 women and one man; 17 procedures were bilateral. Seven different surgeons were involved. The mean age of the patients at the time of operation was 56 years (23 to 77). Their mean weight was 66 kg (44 to 110) and mean height 162 cm (145 to 177). The indication for surgery was primary osteoarthritis in 45 hips (58%), osteoarthritis secondary to necrosis of the femoral head in 16 (21%), osteoarthritis secondary to dysplasia in 9 (12%), and rheumatic disease in 8 (10%). All except two were primary procedures. The mean follow-up was for 5.8 years (1 to 9).

The femoral implant. Unless stated all components were made by Ceraver, Roissy, France. The titanium alloy (TiAl6V4) implant had a polished surface covered with titanium oxide and included a flange resting on the calcar. The morse taper was 14 to 16 mm in diameter. The ultra-high molecular-weight polyethylene cup had outer diameters ranging from 44 to 54 mm, being 46 or 48 mm in 76%.

The 28 mm femoral head of zirconia ceramic was used directly from its commercial packaging with no second sterilisation. The mechanical properties of zirconium dioxide are better than those of alumina, with greater fracture

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Table I. Comparison of the mechanical properties of the surgical grade alumina heads, the non-reoxidised 'hipped' zirconia heads and the sintered reoxidised heads¹¹

	Heads		
	Alumina (ISO requirements)	Zirconia Pressureless sintering	Sinter and 'hipped'
Density (g/cc ³)	3.90	6	6.1
Mean grain size (µm)	<7	<1	<0.5
Microhardness (Vickers)	2000 to 3000	1000 to 1200	1000 to 1300
Young's modulus (GPa)	380	200	200
Bending strength (MPa)	400	900	1200

Table II. Comparison of roughness, wear rate and friction coefficients by pin-on-disc testing (linear speed of the disc, 0.24 m/s; constant 37° ± 1°C; applied load 80 N; contact area 19.6 mm²; contact load 4 MPa; lubricant deionised water, duration 384 hours; distance covered 331 776 m)

	Heads	
	Alumina	'Hipped' non-reoxidised zirconia
Arithmetical roughness (µm)		
Initial	0.02	0.01
Final	0.02	0.01
Wear rate (mm ³ /Nm)	0	0
Friction coefficient		
Final	0.025	0.01
Average	0.025	0.035

Table III. Comparison of roughness and friction coefficient by hip simulator (load minimum 800 N; load maximum 3500 N; flexion-extension 36°; mediolateral rotation 20°; lubricant deionised water; constant 37° ± 1°C; duration 1 million cycles)

	Heads		
	Alumina	'Hipped' non-reoxidised zirconia	'Hipped' reoxidised zirconia
Arithmetical roughness (µm)			
Initial	0.02	0.02	0.02
Final	0.02	0.02	0.02
Friction coefficient (flexion-extension)	0.03	0.01	0.04
Friction coefficient (medial and lateral rotation)	0.01	0.01	0.02

toughness and higher bending strength⁴ (Table I). Preparation involved hot isostatic pressure (HIP), in accordance with the 1997 ISO standard, but its unstable nature needs strict manufacturing processes.

Zirconia ceramic. Zirconium oxide ceramics can exist in three forms depending on temperature.^{4,10} The monoclinic form with submicronic grains is present at ambient temperature, while the hard, but unstable, tetragonal crystalline form appears at 1170°C, and the stable, but brittle cubic crystalline form at 2370°C. The transformation of the monoclinic phase into the tetragonal phase, at a rising temperature, is accompanied by a decrease in volume of 5%, but during cooling there is an increase in volume of 3%.¹⁰ These volume changes create stresses which are responsible for cracks which alter the mechanical properties.¹⁰ To prevent this, a stabilising oxide is added during the presintering stage. This is either calcium oxide, magnesium oxide or, commonly, yttrium oxide. A small amount of stabilising additive allows the tetragonal particles to be maintained in a stable state at a temperature below that of transformation from monoclinic to tetragonal phases, producing partially stabilised zirconia.⁴ Sintering is then carried out in a rare gas (argon) under HIP ('hipping') which increases the density of the zirconia without any major temperature variation. This sintering under argon causes a loss of oxygen molecules from the surface of the zirconia giving it a black colour. In our series, we used this non-reoxidised, but 'hipped', black zirconia. Manufacturers now reoxidise the zirconia after sintering, imparting a white or purple colour.

Tribological properties. The polyethylene cups which we used were all from the same batch of material. We compared three different bearing combinations:

- 1) polyethylene-to-hipped non-reoxidised zirconia;
- 2) polyethylene-to-hipped but reoxidised zirconia (Desmarquest, Vincennes, France); and
- 3) polyethylene-to-alumina.

We used a pin-on-disc apparatus for the combinations polyethylene-to-hipped non-reoxidised zirconia and polyethylene-to-alumina. The results are summarised in Table II. We used a hip simulator to compare all three bearing combinations, and the results are summarised in Table III.

Operative technique. We used a posterolateral approach, cementing both components after positioning a femoral plug with either Palacos (Schering Plough, Levallois-Perret, France) or Cerafix (CeraVer) cements. Both contain zirconium dioxide, as an opacifier, and gentamicin. The size of the femoral stem was chosen to fill the diaphysis as completely as possible.

Review of patients. The patients were either reviewed by the one examiner (SLM) who was not one of the operating surgeons, (68 hips) or they answered a questionnaire (10 hips) and provided a recent standing radiograph. Clinical assessment used the Merle d'Aubigné and Postel scoring system.¹⁹

We compared the radiological appearances of the acetabular and femoral implants on anteroposterior radiographs postoperatively and at follow-up. The position of the femoral stem was estimated by measurement of the distance between the flange and the lesser trochanter. Radiolucent

Fig. 1

Methods of measuring cup positions along vertical and horizontal axes: A, teardrop line; B, vertical line through the teardrop; 1, horizontal distance between the centre of the cup and the vertical line; and 2, vertical distance between the centre of the cup and the teardrop line.

lines at the stem-cement or cement-bone interfaces were recorded in each of the zones of Gruen, McNeice and Amstutz.²⁰ Calcar resorption was measured when present, and any femoral endocortical osteolysis noted.

The position of the cup relative to the pelvis was assessed by measuring the transverse and vertical distances between the centre of the cup and pelvic reference points²¹ (Fig. 1). Radiolucent lines about the acetabulum were noted in the

Fig. 2a

Fig. 2b

Anteroposterior radiographs showing movement of the cup. Figure 2a – In 1991 the horizontal distance is 30mm, and the vertical distance 28.5 mm (see Fig. 1). Figure 2b – In 1994 the horizontal distance is 30 mm, and the vertical distance 23 mm. Osteolysis of the calcar is indicated by an arrow.

Fig. 3

Radiograph showing femoral diaphyseal endocortical osteolyses.

Fig. 4a

Osteolysis of the calcar. Figure 4a – A postoperative radiograph. Figure 4b – Radiograph seven years later showing the osteolysis.

Fig. 4b

Table IV. Correlation between the presence of endocortical osteolysis and definite loosening of cup or stem

Femoral osteolysis	Number of hips (% of total)		
	Definite loosening	No loosening	Total
Yes	6 (37.5)	10 (62.5)	16 (100.0)
No	5 (8.0)	57 (92.0)	62 (100.0)

DeLee and Charnley zones.²² We recorded the width of the radiolucent lines as either less than 2 mm or 2 mm or more. Polyethylene wear was measured by the method of Livermore, Ilstrup and Morrey.²³ All measurements were corrected using an enlargement factor calculated by relating the radiological size of the head to the actual diameter, 28 mm.

We used the criteria of Harris, McCarthy and O'Neill²⁴ for assessing loosening of the femoral implant. Definite loosening was determined by evidence of migration, the appearance of a new radiolucent line at the stem-cement junction, a discernible shift in the position of the femoral component and/or the cement mantle, the appearance of a crack in the cement, or a fracture of the stem. We modified the criteria of Massin et al²¹ for cup loosening, using a variation of more than 5 mm or 5° between postoperative and latest radiographs or the presence of a cement fracture.

Statistical assessment used survival analysis with actuarial curves.^{25,26}

Results

Clinical assessment. At follow-up, the mean Merle d'Aubigné and Postel score for the 78 total hip prostheses was

16.8 out of 18. The objective results were excellent or very good in 74.4%, good in 14% and fair or poor in 11.6%.

Radiological assessment. There were no fractures of the zirconia femoral heads, but at follow-up ten cups (13%) showed loosening (Fig. 2) and 37 (47.5%) radiolucent lines, all at the cement-bone interface. In 18 hips (23%) this was global, with a width of 2 mm or more in 14. The mean wear of the polyethylene cup for the whole series was 0.09 mm/year, but loosened cups showed an average wear of 0.5 mm/year.

Two femoral implants (2.5%) had definite loosening, and 17 (21.7%) showed a cement-bone radiolucent line of under 1 mm. There were endocortical osteolyses in 16 (20%) (Fig. 3; Table IV), and an abnormally frequent incidence of over 2 mm of osteolysis of the calcar (Fig. 4). There were osteolytic lesions in zone 7 in 44 (51.3%) femoral implants with a mean height of 5.2 mm (2.5 to 12).

In total, 11 hips (14%) showed definite aseptic loosening involving the cups in nine, the femoral implant in one and both in one. Eight prostheses (10%) had already been revised. Survival analysis showed that only 63% of hips had no definite signs of aseptic loosening at eight years (Figs 5 to 10).

Discussion

There is considerable interest in ceramic implants because of increased awareness that wear debris from a metal-on-polyethylene articulation can cause osteolysis.²⁷ Ceramics show excellent mechanical and sliding characteristics and good

Fig. 5

Fig. 6

Fig. 7

Fig. 8

Fig. 9

Fig. 10

Survival curves for cup, stem and total arthroplasty compared for zirconia and alumina heads.

biocompatibility,²⁷⁻³¹ but their introduction in total arthroplasty of the hip, under Boutin's influence,³ has been delayed and difficult because of manufacturing problems. Early publications on alumina ceramic showed a high risk of fracture of the head, with serious consequences.^{8,32-36} Despite this, the theoretical excellent characteristics of ceramics promoted continued work to improve the quality of manufacture and to achieve a reliable alumina head with a 32 mm diameter. This large size caused problems¹¹ with cups of small diameter because of the thinness of the polyethylene.

In the 1980s, several publications on other ceramics showed interesting properties for zirconium dioxide, par-

tially stabilised by yttrium oxide (Table I).^{37,38} We introduced a zirconia-polyethylene combination in 1988 to give reduction of the diameter of the femoral head to 28 mm at a time when the quality of alumina did not allow this to be less than 32 mm.

We soon observed an abnormally high incidence of osteolysis in the area of the calcar and in the femoral diaphysis, and showed a statistical correlation ($p = 0.002$) between the appearance of femoral endocortical osteolyses and loosening of the cup (Table IV). This radiological deterioration was much worse than in a previous study⁶ of 156 cemented total hip prostheses, using an alumina-poly-

Fig. 11

Photomicrograph of an area of osteolysis. Muriform zirconia grains are indicated by small arrows and giant cells by large arrows (haematoxylin and eosin and Safranin $\times 25$).

ethylene combination at the same hospital, by the same surgeons, with the same cements, cups and femoral stems, but with alumina femoral heads of 32 mm in diameter. In this alumina series, we found an incidence of 30% of calcar osteolysis of mean height 2.9 mm at a mean follow-up of 8.6 years. The zirconia-polyethylene series showed 51.3% with a mean height of 5.2 mm at a mean follow-up of only 5.8 years. There were no femoral endocortical osteolyses in the alumina-polyethylene series. Survival analysis (Figs 8 to 10) of the 156 cemented alumina-polyethylene hips showed a rate of 93.0% at nine years⁶ as against 63% for the zirconia-polyethylene hips at eight years.

The cause of lysis of the calcar is not clear. Some have suggested a vascular origin^{39,40} but others found a higher incidence when the femoral implant is in a varus position, or there is reduced thickness of the cement at this level.^{41,42} Oh and Harris⁴³ blamed the decrease in constraints at calcar level. The femoral implant which we have used since 1979 has a flange resting on the calcar, but this did not prevent osteolysis as noted by Beckenbaugh and Ilstrup.⁴⁴ We feel that osteolysis of the calcar may result from local inflammatory changes caused by wear particles from the articular surfaces.^{9,45,46}

A warning from the French Ministry of Employment and Social Services dated 1996 (Reference: 967981) stated that "Studies have shown that a new (second) sterilisation with steam could trigger a change from the tetragonal to monoclinic form on the surface of zirconia crystalline structures. Such a transformation could bring about a release of zirconia grains and consequent premature wear associated with osteolysis". This sensitivity of zirconia to steam may derive from the stabilising oxide, yttrium oxide, which may be hydrolysed at 100°C in a wet atmosphere, yielding yttrium hydroxide and possibly affecting the stability of zirconia. No resterilised femoral heads were used in our series.

Our experience of a high incidence of femoral endocortical osteolysis led us to reconsider the biocompatibility of zirconia grains previously evaluated in rabbits and dogs with satisfactory results,^{14,47,48} but not yet well documented in clinical studies. Histological studies of the radiolucent lines of cemented implants⁴⁹⁻⁵¹ have suggested that the zirconia dioxide grains used as opacifiers in some cements may be responsible. Submicron grains of zirconia dioxide ($0.28 \pm 0.08 \mu\text{m}$ in diameter) are small enough to be scavenged by macrophages, and therefore could contribute to the inflammatory process and to osteolysis.⁵¹

Histological findings. The histological examination of biopsies of areas of osteolysis from our eight revision patients confirmed the presence of zirconia grains (Fig. 11). There were two forms: a compressed or wall-like structure found in the spaces where cement had dissolved during histological preparation, definitely derived from the opacifier (Fig. 11);⁵² and a micronic grain form (1 to 2 μm) found in intra- and extracellular sites scattered in areas of cell reaction. Even microprobe analysis could not define whether the origin of the zirconia grains was from the femoral head or the cement opacifier. Although their origin could not be defined it is of note that we did not see osteolyses in our alumina-polyethylene series despite using the same cement with zirconia dioxide as an opacifier.

It is possible that there may be a difference in ageing between the so-called 'black' zirconia which we used, which is not reoxidised after sintering, and the current 'white or purple' zirconia which is. There are no references in the literature to this unknown factor, but our pin-on-disc and hip simulator results (Tables II and III) showed no significant differences in tribological properties between the hiped non-reoxidised zirconia, hiped reoxidised zirconia and alumina.

In view of our findings, we have abandoned the use of zirconia heads, as have Hummer et al.³⁴ We now use alumina heads of 28 mm in diameter. Further studies are needed on the biocompatibility of zirconia and its components, including yttrium oxide.

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