Zirconia and alumina ceramics in comparison with stainless-steel heads

POLYETHYLENE WEAR AFTER A MINIMUM TEN-YEAR FOLLOW-UP

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Although alumina has been used in orthopaedic surgery since the 1970s, the long-term clinical results of zirconia have not been well documented in vivo. We studied hips with these two different ceramics during the same period and with a minimum follow-up of ten years. Because the size of the alumina and zirconia heads was different, hips with 32 mm alumina heads and those with 28 mm zirconia heads were compared with control hips with stainless-steel heads of the same size. Our aim was to compare the two ceramics.

There was an increased linear rate of penetration of the femoral heads into the liner between years five and 12 for the zirconia and the stainless-steel groups. This was severe in the zirconia group (0.4 mm/year compared with 0.13 mm/year for the stainless-steel group). During the same 12-year period there was, however, no significant change in the rate of wear in the alumina group (0.07 mm/year). The mean wear at the most recent follow-up was 1360 mm^3 for the 28 mm zirconia group, 683 mm^3 for the 28 mm stainless-steel group, 755 mm^3 for the 32 mm alumina group and 1314 mm^3 for the 32 mm stainless-steel group. The monoclinic content rose on the surface of three zirconia heads which were retrieved at revision. This change was associated with an increase in the surface roughness. A change in the roundness with an increase in the sphericity deviation was also observed both in the articular and non-articular parts of the femoral heads. The increase in rate of wear in the zirconia group was only evident after eight years and may be linked to a long-term biodegradation of zirconia in vivo, associated with the altered roughness and roundness which was observed on the retrieved heads.

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Polycrystalline aluminium oxide (Al_2O_3) or alumina was the first ceramic material to be used in orthopaedic surgery. Clinical studies have shown satisfactory results with an alumina-polyethylene combination and these results have been confirmed in hip arthroplasties.[1] However, in laboratory studies, alumina exhibits a brittle behaviour, with a low fracture toughness and low tensile strength and thus a susceptibility to fracture. This has been confirmed by clinical studies with sometimes serious consequences.[2,3]

Between 1970 and 1990 this limited the use of alumina to femoral heads with a large diameter (32 mm). Zirconia ceramic was introduced as an alternative to alumina ceramic for femoral heads.[4] Zirconia is harder and more resistant to fracture[4] and therefore can be used with smaller femoral heads (28 mm diameter). The main disadvantage of zirconia is that the crystal is not as stable as alumina. There are concerns that zirconia may deteriorate with time due to phase transformation from the tetragonal to the monoclinic crystal.[5,6] This has been studied in vitro but the long-term stability of zirconia in vivo is not known. Although it has been reported that over 350 000 zirconia heads have been implanted to date,[5] no study with a ten-year survival of zirconia-polyethylene total hip replacements has been reported.

We report a ten-year follow-up with radiological review of hips with two different ceramics implanted between 1988 and 1990. The femoral implant and the polyethylene were identical in the two groups. The femoral heads were of dense alumina with a diameter of 32 mm or of yttrium-oxide-partially-stabilized zirconia with a diameter of 28 mm.

Our aim was to compare the two ceramics. The sizes of ceramic femoral heads were different ten years ago. Alumina heads of 28 mm diameter were not available. We therefore used two control groups of 20 hips each, with stainless-steel heads of 28 and 32 mm in diameter. All were implanted during the same period and had the same follow-up. By comparing the ceramic and stainless-steel heads, an indirect comparison of the ceramics was obtained.

Patients and Methods

Between 1983 and 1988 only stainless-steel heads of 32 or 28 mm diameter or ceramic alumina heads of 32 mm diameter were available. The first generation of zirconia heads became available in 1988. Between 1988 and 1990, both zirconia and alumina heads were implanted in patients with osteoarthritis or osteonecrosis. Stainless-steel heads were also used during this period for the treatment of fractures of the femoral neck. The 28 mm zirconia or stainless-steel heads were used when the outer diameter of the cup was ≤48 mm; the 32 mm alumina or metal heads were used when the outer diameter of the cup was ≥48 mm. The polyethylene was the same and the outer diameter of the cups was 52 mm, 50 mm or 48 mm for the 32 mm diameter heads. With the 28 mm diameter heads, the outer diameter of the cups was 48 mm, 46 mm or 44 mm.

Between January 1988 and December 1990, 40 primary total hip replacements with a 28 mm zirconia-polyethylene combination were carried out by the same surgeon (PH). The zirconia was yttria tetragonal zirconium oxide polycrystal containing 5% by weight of yttrium oxide for stabilisation. The characteristics were measured on non-implanted femoral heads. The sphericity which is the difference between the largest and the smallest diameters was measured by an Indi-Ron radial measurement system (Precepion Devices, Milan, Italy). The spherical deviation was <5 μm in non-implanted femoral heads. The surface roughness (measured in Ra) of the femoral head before implantation was 0.005 mm of Ra. This is the arithmetic mean of the absolute value of the deviation of the profile height as measured from the graphical centre line, using a contact profilometer. These results were in agreement with the tolerance limits within which the manufacturers operated. The monoclinic content at the surface of the femoral head was analysed using x-ray diffraction, and was less than 4 mol% on the non-implanted femoral heads.

In the zirconia group the mean age of the patients at the time of operation was 68.2 years (52 to 76), the mean body-weight was 72.4 kg (58 to 95) and the mean follow-up was 10.6 years (10 to 12). Three zirconia heads were retrieved during the period of study. Their surface characteristics were analysed using light and scanning electron microscopy. Their roughness, sphericity and monoclinic content were also measured.

During the same period, 62 consecutive primary total hip replacements with a 32 mm alumina-polyethylene combination were carried out by the same surgeon (PH) and 56 were reviewed after ten years; six patients died between six and ten years after operation. None required a revision procedure and all were free from pain at the most recent follow-up. Using the same technique of measurement, the spherical deviation was <15 μm and the surface roughness of non-implanted alumina heads was 0.02 μm of Ra. The mean age of the patients at the time of operation for the alumina group was 63.9 years (51 to 74), the mean body-weight was 73.2 kg (59 to 94) and the mean follow-up was 10.8 years (10 to 12).

In the 32 mm stainless-steel group, the mean age of the patients at the time of operation was 67.4 years (60 to 75) and the mean body-weight was 74.6 kg (57 to 89). In the 28 mm stainless-steel group, the mean age was 69.7 years (58 to 78) and the mean-body weight was 71.5 kg (57 to 86). The stainless-steel femoral heads were manufactured by Ceraver Osteal (Roissy, France) and were made of Z_4 CNMD 21-9-4 (Norm ISO 5832-9). Their surface roughness was 0.07 μm of Ra before implantation and the spherical deviation was < 50 μm.

The femoral implant was the same in the four groups and was also manufactured by Ceraver Osteal as were the polyethylene liners. The femoral implant was of titanium alloy (TiAlV) with a polished surface covered with titanium oxide and had a flange which rested on the calcar. The operative procedure was the same in all patients and all the components were cemented using Palacos (Schering Plough) containing zirconium dioxide as an opacifier and gentamicin.

Each patient was evaluated clinically and radiographically at six weeks, three months, six months and then yearly. At each radiographic evaluation every patient had an anteroposterior radiograph of the pelvis and hip and a lateral view of the hip with the patient weight-bearing.

The measurements of wear were made on anteroposterior and lateral radiographs, with the central beam directed on the hip. Changes in the distances between the centres of the cup and prosthetic head were recorded. Ellipse markers were used to identify the centre of the cup. The measurement was made using a magnifier which enlarged the distance 20-fold. The technique used for measurement of wear of polyethylene was adapted from a three-dimensional technique used for metal-backed cups.[7] The Euclidean co-ordinates of a vector in space may be determined from measurements in two planes. Thus, the total displacement of the femoral head was calculated in space. The minimal volume of polyethylene debris generated by the displacement of the femoral head with time was calculated using a mathematical formula.[8]

Tests of accuracy for measurement of distances and angles were done in vitro with retrieved cups from patients who were not in the study and with new cups. The values obtained on radiographs were compared with those measured using a co-ordinate-measuring machine. The accuracy of this method was found to be 0.13 ± 0.12 mm for the distance of penetration and 8° for the angle. The discrepancy between the wear estimated by the formula of Kabo et al[8] and the wear measured by a co-ordinate measuring machine was between 25% and 50% with an underestimation using the formula.

Statistical methods. All 136 femoral heads (56 alumina, 40 zirconia, 20 stainless steel 32 mm and 20 stainless steel 28 mm) were included in the study. Multiple linear regression analysis was used to determine differences in the amount and rate of penetration of the groups of hips, while adjusting for any confounding effect of hip score, weight, and age of the patient. The thickness and abduction angle of the cup were also included as independent variables when analysing the amount of wear. Two separate regression analyses were performed for 32 mm and 28 mm heads. The dependant

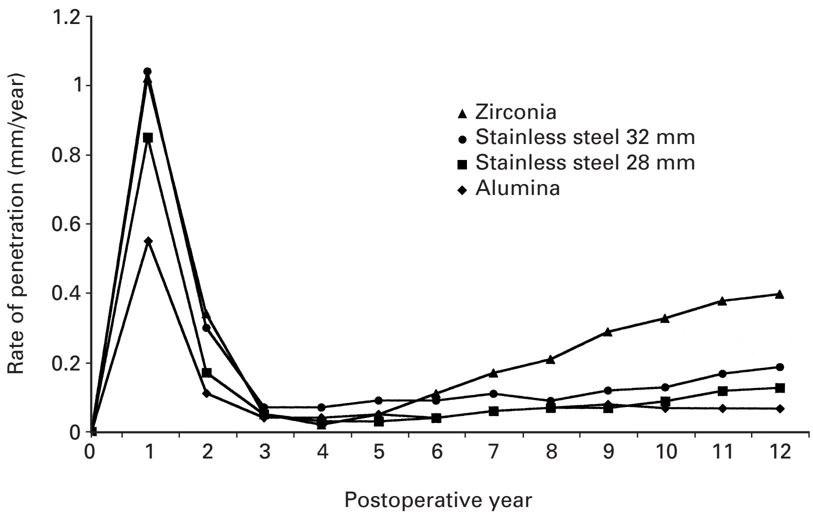

Fig. 1

Graph showing the mean temporal patterns of the rate of linear penetration for the four groups of patients. The mean penetration behaviour of the four groups differed before and after the fifth year of follow-up. The high initial rate of penetration during the first two years may not represent true loss of polyethylene by wear, but is probably creep and bedding in of the polyethylene.

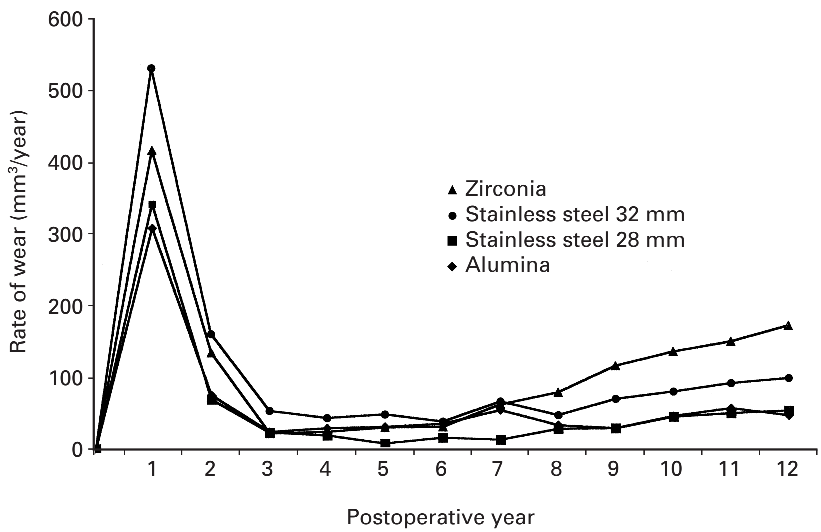

Fig. 2

Graph of the mean volume rate of wear during each postoperative year. The increase in wear during the third year was obtained from the difference between the volumes of wear calculated for the n and for the n-1 postoperative year. The rate of wear was greatest during the first two years, and decreased in subsequent years to aproach a constant value.

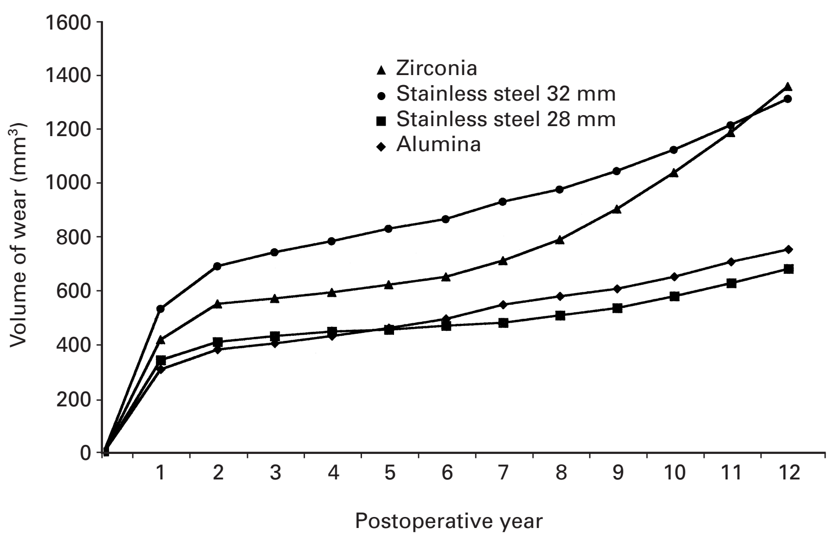

Fig. 3

Graph of the mean volume of wear related to the mean amount of penetration by the femoral head into the polyethylene liner during each postoperative year for the four different groups. The displacement of the femoral head as measured on the initial postoperative radiograph was assumed to be the zero position, and penetration was calculated as subsequent movement from this position. The volume of wear for each postoperative year was calculated from the amount of linear penetration using the formula of Kabo.

Table I. Data on mean (95% CI) rate of linear penetration (mm/year) for the different groups of arthroplasties at follow-up at five and 12 years

Type of head	Number of hips	5 years	12 years
Alumina	56	0.040 (0.031 to 0.049)	0.071 (0.041 to 0.101)
Stainless-steel 32 mm	20	0.072 (0.052 to 0.092)	0.192 (0.112 to 0.272)
Stainless-steel 28 mm	20	0.036 (0.029 to 0.043)	0.134 (0.074 to 0.194)
Zirconia	40	0.043 (0.035 to 0.051)	0.412 (0.252 to 0.572)

Table II. Data on mean (95% CI) volumetric rate of wear (mm^3/year; range) for the different groups of arthroplasties at follow-up at five and 12 years

Type of head	Number of hips	5 years	12 years
Alumina	56	30 (22 to 38)	46 (36 to 56)
Stainless-Steel 32 mm	20	47 (35 to 59)	98 (59 to 137)
Stainless-Steel 28 mm	20	25 (18 to 32)	53 (29 to 77)
Zirconia	40	29 (22 to 36)	171 (97 to 245)

Table III. Data on the mean (95% CI) volume of wear (mm^3) for the different groups of arthroplasties at follow-up at five and 12 years

Type of head	Number of hips	5 years	12 years	Amount of wear between the 5th and 12th years
Alumina	56	472 (314 to 630)	755 (534 to 976)	283 (187 to 379)
Stainless-Steel 32 mm	20	792 (648 to 936)	1314 (1007 to 1621)	522 (376 to 668)
Stainless-Steel 28 mm	20	484 (315 to 653)	683 (415 to 955)	199 (124 to 274)
Zirconia	40	586 (367 to 805)	1360 (802 to 1918)	774 (352 to 1156)

variables in the analysis were the amount and rate of linear penetration, and the amount and rate of volumetric wear.

Results

In the zirconia group three revisions for acetabular loosening were necessary at years 8, 10 and 11 of follow-up. In the alumina group, no revision was necessary and no loosening was apparent on radiographs. In the stainless-steel group one revision for acetabular loosening was necessary at year 9 of follow-up (a 32 mm head).

Linear wear was represented by the total displacement of the femoral head in space. As expected, there was great variation in the amount of penetration. At the most recent follow-up, it ranged from 0.4 to 4 mm. With multiple linear regression analysis, there was no significant relationship ($p > 0.05$ for all) between the weight, age, gender, hip score of the patient, the orientation of the cup and the amount of linear penetration or volumetric wear as measured on the latest radiograph. We included the thickness of the cup in the regression analysis of the penetration of the femoral head into the polyethylene and found no significant relationship ($p = 0.62$).

After high initial displacement of the femoral head, the rates of linear and volumetric wear settled to lower rates after about two years. The mean rates of penetration and volumetric wear, however, were different in the groups during the last five years of the study (Figs 1 to 3). The different groups were compared at two specific points, the five- and the 12-year follow-up (Tables I to III).

After adjusting for weight, age, gender, and thickness of the cup, the mean rate of linear penetration (Table I) was significantly less ($p = 0.045$) at the follow-up at five years for the 28 mm zirconia heads than for the 32 mm stainless-steel heads; the difference was not significant between the zirconia heads and the alumina heads or the 28 mm stainless-steel heads. At follow-up at 12 years this mean rate of linear penetration was significantly greater for the zirconia heads than for the 28 mm stainless-steel heads ($p = 0.024$), for the 32 mm alumina heads ($p = 0.014$) and for the 32 mm stainless-steel heads ($p = 0.028$). The same observations were made for the volumetric rate of wear (Table II). As a result, the mean increase in the amount of wear (Table III) between the follow-up at five and 12 years was significantly greater for the zirconia heads than for the other heads ($p = 0.021$ for alumina; $p = 0.042$ for 32 mm stainless-steel heads; $p = 0.024$ for 28 mm stainless-steel heads).

The three femoral heads retrieved in the zirconia group were analysed using x-ray diffraction. The transformation rate of the tetragonal to the monoclinic crystal was 19 mol%, 25 mol% and 30 mmol% respectively. By comparison, the percentage of monoclinic phase was 4 mol% on a non-implanted femoral head at its surface. The retrieved zirconia heads appeared to be glossy to the naked eye but different changes were observed. Their surface roughness was increased between 0.02 and 0.05 µm when compared with non-implanted heads (0.005 µm) but remained lower than that of the stainless-steel heads at the time of implantation. Scanning electron microscopy of the surface of the retrieved heads showed more craters than on the zirconia heads before implantation; these were more frequent in the regions around a 45˚ line above the equator of the heads and were related to the area of increased roughness. Changes were

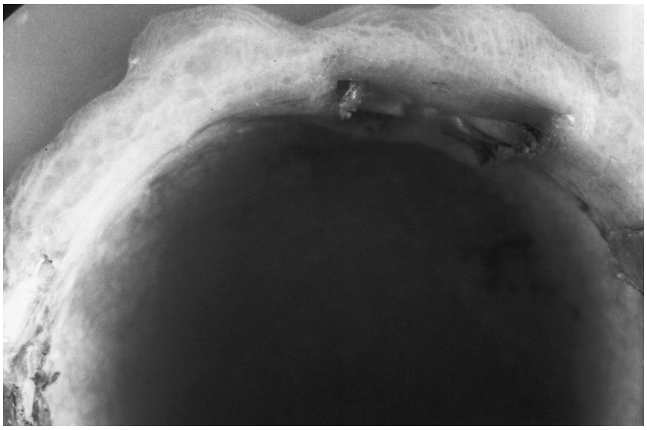

Fig. 4

Appearance of the polyethylene on a retrieved cup. It appears to have melted.

observed in the volume and sphericity of the retrieved heads. Their volume was measured by fluid displacement and had increased respectively by 0.5%, 0.7% and 1.1% compared with that of non-implanted heads. This variation was greater than that due to manufacturing tolerances (< 0.1%). The spherical deviation of the heads before implantation was <5 µm; on retrieved heads it was as high as 100 µm. Using microscopy, small smooth waves could be seen on the surface of the femoral heads. In these areas, the surface was locally deformed with small mounds giving spherical deviations which were present both above the equator of the heads on the articular surface and below the equator on the non-articular surface (the inferior aspect of the head, near the neck).

The morphological appearance of the surface of the retrieved cups was inspected. The most surprising change was found on the periphery of one cup with an increase in volume of the polyethylene on the non-articular surface of the liner as if the polyethylene had melted and then cooled (Fig. 4). The pattern of wear of this cup included cracking, delamination and deformation. For the other cups there was also cracking, pitting and deformation in the worn area, but not the peripheral changes related to heating.

Discussion

The zirconia-polyethylene combination was introduced in 1988 to allow reduction of the diameter of the femoral head to 28 mm at a time when the quality of alumina did not allow it to be less than 32 mm. In our series, at the most recent follow-up, three loosenings of the cup requiring revision were seen in the zirconia group. Greater wear was observed in the zirconia group, particularly after the fifth year. The total amount of wear in the zirconia group was significantly higher than the total amount of wear in the 28 mm stainless-steel group. With the method used in our study which involved digitisation of radiographs and the use of a computer, the accuracy was improved but was not precise enough to indicate changes in the year-by-year results during the first years; the expected annual wear results were the same during the first five years. However, it was sufficient enough to detect the increase in wear with zirconia which appeared between years five and eight of follow-up.

This greater wear was suspected at this length of follow-up but only became evident after the eighth year. It could be explained by time-dependent changes in the friction of the joint. This change in the friction after several years may be related to a change in the activity of the patients, or to changes in either the polyethylene liner or the femoral head. The increase in the rate of wear occurred after eight years and is unlikely to be due to an increase in activity of the patients whose mean age was 68.2 years in the zirconia group. It is more likely that their activity would have decreased during this time. All the liners were made of the same polyethylene during the same period by the same manufacturer and during this time the method of sterilisation of all the cups was the same. If the change in the friction couple had been related to the polyethylene liner, the increase in the rate of wear should have been observed in all the groups.

The poorer performance of zirconia in our series does not appear to be related to the initial tribological properties of the zirconia femoral heads. The roughness of the zirconia femoral heads before implantation was better than that of alumina heads and furthermore, wear was not higher during the first five years after implantation in the zirconia group than in the 28 mm stainless-steel group.

The retrieved femoral heads had a deterioration both of the surface sphericity and the roughness. Because the craters observed on the femoral heads were more frequent around the 45˚ line above the equator, they were probably related to the extraction of zirconia from the surface associated with third-body wear on the heads and an increased roughness. The surface roughness of zirconia heads after several years of implantation however, remained as good as the roughness of stainless-steel heads at the time of implantation. Therefore the increased roughness of the surface of the zirconia head was probably not sufficient solely to explain the increase in wear. The smooth waves or mounds giving spherical deviations and a change in sphericity may also have damaged the friction couple. Because these spherical deviations were associated with an increase in volume of the femoral heads and because they were observed both above the equator of the heads on the articular surface and below on the non-articular surface, they were not related to third-body damage due to debris in the friction couple. They were probably, however, related to transformation of the tetragonal phase to the monoclinic phase, transformation which is combined with an increase in volume from 3% to 5%. Since the transformation was probably not homogenously distributed at the surface of the zirconia, it may explain the formation of small mounds and alteration of the surface of the femoral head. We have implanted alumina femoral heads since 1983. Although, no alumina head was retrieved in this series, the deterioration of sphericity and roughness has not been observed on those heads which have previously been retrieved from other patients.

The rate of transformation of the tetragonal phase to the monoclinic phase observed on the retrieved femoral heads was greater than that expected from experiments in vitro at 37˚C. This transformation has been shown to depend on time and temperature. At 37˚ C over three years there is about a 5 mol% transformation rate of tetragonal to monoclinic zirconia.[9] However, at 50˚ C, from a theoretical point of view,[10] this transformation may be as high as 16 mol%, and at 95˚ C, 70 mol%. The consequences of this phenomenon gave rise to an official memorandum on the risks of autoclave sterilisation of zirconia and it is recommended that zirconia heads be sterilised by gamma irradiation or ethylene oxide. The monoclinic phase may contribute to a reduction in the cohesion of the ceramic particles, with the risks of liberation of small particles of zirconia or yttrium oxide. No femoral head which was sterilised by autoclave was used in our series.

In regard to the clinical relevance of the rate of change of phase transformation with temperature, it is possible to predict that if the temperature in the hip remains at 37˚C, the long-term ageing changes would be very small and probably without consequence.[5] However, one of the most important differences between alumina and zirconia is the thermal conductivity of the material. That of alumina is ten times higher than that of zirconia. The frictional heating of bearing materials was tested in a hip simulator by Lu and McKellop[11] and McKellop and Lu.[12] They found that the surface temperature of the polyethylene could be as high as 99˚C with zirconia heads but only 45˚C with alumina heads. This was explained by the surface heat generated by friction and the very low thermal conductivity of zirconia. A temperature of 45˚C for alumina heads was confirmed in patients by Bergman, Graichen and Fohlman[13] who implanted prostheses with temperature sensors in the neck and stem of the prosthesis. They found that with an alumina head, the increase in temperature at the surface of the polyethylene liner could be as high as 44˚C after walking for only six minutes. The temperature of a joint with a zirconia head is still speculative, but it is likely to be higher than this. This can be suspected from the cups retrieved and analysed in our series. For one patient the polyethylene on the rim of the cup appeared to have melted. The melting point of the polyethylene is 130˚C for large pieces of polyethylene, but may be lower for smaller pieces.[14] Therefore, it is possible that for this patient, the increase of temperature in the joint may have reached 90˚C due to the low thermal conductivity of zirconia and may have accelerated the phase transformation. The deflection temperature of the polyethylene is only 60˚C at 1.8 Mega pascals and 85˚C at 0.46 Mega pascals. This could also explain the deformation observed on the rim of the cup.

We conclude that although experimental studies have shown encouraging results with regard to the tribiological characteristics of zirconia,[15-18] our clinical report with long term follow-up demonstrates an increase in the rate of wear with zirconia heads which were manufactured between ten and 12 years ago, even if we have not observed catastrophic failures as others have.[19] The long-term reliability of zirconia femoral heads is not only dependent on the manufacturing process,[5] but also on the properties of zirconia. One other report[20] with a different manufacturing process has also recently demonstrated the phase transformation of zirconia heads after hip arthroplasty.

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