Comparison of Polyethylene Wear Associated with Cobalt-Chromium and Zirconia Heads After Total Hip Replacement

A Prospective, Randomized Study

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Background: A ceramic femoral head is an alternative to a metal femoral head for the bearing surface of total hip arthroplasty. The purpose of this study was to compare polyethylene wear in patients who had undergone bilateral total hip arthroplasty with implants that differed only with regard to the material used for the femoral head: a zirconia head was used on one side, and a cobalt-chromium head was inserted on the contralateral side.

Methods: A prospective, randomized study was performed to evaluate the outcomes in fifty-two patients who had undergone sequential bilateral primary total hip replacement. A zirconia head was used in one hip, and a cobalt-chromium head was used in the other. There were forty-eight men and four women; the mean age at the time of surgery was 44.2 years. The mean duration of follow-up was 7.1 years. Clinical and radiographic evaluations were performed preoperatively and at six weeks; three, six, and twelve months; and yearly postoperatively. Linear wear of the polyethylene liner was measured radiographically. Two femoral components with a zirconia head had aseptic loosening and were revised. The explanted heads were evaluated with use of interferometry, environmental scanning electron microscopy, and x-ray diffraction studies.

Results: The mean polyethylene wear rate was 0.08 mm/yr in association with the zirconia heads and 0.17 mm/yr in association with the cobalt-chromium heads ($p = 0.004$). The mean amount of volumetric polyethylene wear was 350.8 mm^3 in association with the zirconia heads and 744.7 mm^3 in association with the cobalt-chromium heads ($p = 0.004$). With regard to surface roughness, the Ra values of the two explanted zirconia heads were 15.87 and 17.35 nm and the Rpm values were 153.86 and 156.18 nm. Two identical zirconia heads that had not been implanted had Ra values of 5.31 and 5.48 nm and Rpm values of 65.27 and 66.35 nm. Four unimplanted cobalt-chromium heads that were identical to the ones implanted in this study had Ra values ranging between 25 and 50 nm and Rpm values ranging between 262.6 and 525.2 nm. Little phase transformation was noted in the two revised zirconia heads.

Conclusions: The mean amount and rate of polyethylene wear were significantly lower in the hips with a zirconia head than they were in the hips with a cobalt-chromium head, presumably because the zirconia heads had a smoother articulating surface.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

Despite the excellent wear characteristics of alumina ceramics, a historic problem has been that, under certain conditions, they are prone to fracture[1]. It has been claimed that zirconia ceramics have better mechanical strength than alumina ceramics, allowing the use of smaller zirconia heads with better wear performance[2]. However, several reports on total hip arthroplasty with a zirconia head have noted poor wear characteristics[3-6]. One cause is thought to be phase transformation of zirconia in vivo[3,7]. Zirconia ceramic has three phases of crystalline structure (monoclinic, cubic, and tetragonal), which vary with temperature. Such phase

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transformation can be accompanied by a 3% change in the volume of the ceramic head and may cause an increase in its surface roughness.

In a previous study, my colleagues and I reported the prevalence of polyethylene wear and osteolysis in association with implants with a cobalt-chromium femoral head and those with a zirconia head that articulated with a Hylamer liner (DePuy DuPont Orthopaedics, Warsaw, Indiana). We concluded that there was greater polyethylene wear with the zirconia heads[4]. I now present the results of a prospective, randomized study of the wear performance of zirconia and cobalt-chromium femoral heads articulating against a contemporary conventional ultra-high molecular weight polyethylene liner.

Materials and Methods

Patients

Between August 1996 and July 1999, I performed fifty-two consecutive primary bilateral total hip arthroplasties in fifty-two patients (104 hips) who had bilateral osteonecrosis of the femoral head and no other joint problems. All fifty-two patients (forty-eight men and four women) were enrolled in the present study, which was approved by the institutional review board at our institution. All patients provided informed consent. The average age of the patients at the time of surgery was 44.2 years (range, thirty-one to forty-eight years), and all were younger than fifty years of age. The average weight of the patients was 68.9 kg (range, 62 to 92 kg), and their average height was 168.3 cm (range, 158 to 184 cm). The mean duration of follow-up was 7.1 years (range, five to eight years).

The bilateral total hip arthroplasties were performed during the same anesthetic session, with one side treated immediately after the other. Randomization of the use of either a zirconia or a cobalt-chromium femoral head was determined from a sequential pool based on a table of randomized numbers. Insertion of the zirconia and cobalt-chromium heads was assigned alternatively to each side.

A cementless Duraloc acetabular shell (DePuy, Warsaw, Indiana) was used in all hips; ninety-two hips received a Duraloc 100-series acetabular component without screw holes, and twelve hips received a Duraloc 1200-series component with multiple screw holes. All acetabular components were press-fit after underreaming of the acetabulum by 2 mm. A 28-mm (inner diameter) ultra-high molecular weight polyethylene liner (Enduron; DePuy, Warsaw, Indiana) made of ram-extruded GUR 1050 polyethylene was used in all hips. The polyethylene was irradiated (with between 2.4 and 4 Mrad) in a vacuum and was packaged in a vacuum state.

A cementless Immediate Postoperative Stability (IPS) titanium-alloy femoral component (DePuy, Leeds, United Kingdom) was used in all hips[8]. The proximal, metaphyseal portion of the stem (about one-third of the stem) is porous-coated with sintered beads. The pore size is between 200 and 300 μm. The porous-coated surface has a circumferential hydroxyapatite coating of 30 μm in depth. The distal part of the stem is polished.

A 28-mm zirconia head was used in one hip and a 28-mm cobalt-chromium head was used in the contralateral hip in all patients. The zirconia was yttria tetragonal zirconium oxide polycrystal (Y-TZP) containing 3 mol% oxide for stabilization (DePuy, Leeds, United Kingdom).

All operations were performed through a posterolateral approach. The femoral component was inserted with a press-fit technique. The largest broach that would fill the femoral canal and leave little cancellous bone remaining was used.

The patients were allowed to stand on the second postoperative day, and they progressed to full weight-bearing with crutches as tolerated. The average time until full weight-bearing was ten days.

We performed a clinical and radiographic follow-up at six weeks, three and six months, and one year after the operation and yearly thereafter. Harris hip scores[9] were determined preoperatively and at each follow-up examination. Although several components of the Harris hip score (pain, limp, use of support, ability to put on socks and tie shoes, absence of deformity, and range of motion) were easily differentiated between the two hips in the same patient, distance walked, stair-climbing, sitting, and using public transportation were more difficult to differentiate between the two hips. However, if the patients had difficulties in these domains, they could always identify the hip that limited their activities.

A supine anteroposterior radiograph of the pelvis with both hips in neutral rotation and 0° of abduction was made for every patient. Consistent patient positioning was ensured with the use of an x-ray frame. This frame is constructed so that it can be placed at the end of a standard x-ray table. Plastic polypropylene orthoses are secured to a plastic backboard through a vertical slot. A wing nut allows adjustment for various limb lengths. Rotation and abduction remain constant. Cross-table lateral radiographs were also made of each hip.

The adequacy of the intramedullary fill by the stem was recorded as satisfactory when the stem filled >80% of the proximal part of the canal in the coronal plane and >70% in the sagittal plane, according to a previously described method[10]. The component was considered to be undersized if less of the canal was filled in either or both planes.

Definite loosening of the femoral component was defined as progressive axial subsidence of >3 mm or a varus or valgus shift[8]. A femoral component was considered to be possibly loose when there was a complete radiolucent line surrounding the entire porous-coated surface on both the anteroposterior and the lateral radiograph[8].

Anteversion of the acetabular component was measured on the true lateral radiograph of the hip as the angle between a horizontal line and a second line marking the plane of opening of the socket. To measure cup abduction, a line that joined the inferior margins of the two acetabular teardrops was drawn on the anteroposterior pelvic radiograph. The intersection of that line with a line marking the plane of opening of the socket determined the angle of abduction.

Definite loosening of the acetabular component was diagnosed when there was a change in the position of the com-

ponent (>2 mm vertically and/or medially or laterally) or a continuous radiolucent line wider than 2 mm on both the anteroposterior and the lateral radiograph[8]. A vertical change in the position of the cup was measured between the inferior margin of the cup and the inferior margin of the ipsilateral teardrop, and a horizontal change was measured between the Köhler line and the center of the outer shell of the acetabular component[11] (see Appendix).

The locations of areas of osteolysis in the acetabulum were recorded according to the system of DeLee and Charnley[12], and those in the femur were recorded according to the system of Gruen et al.[13]. The length and width of osteolytic lesions were measured, and the area was expressed in square centimeters[3].

Proximal femoral bone resorption was graded radiographically[14], with Grade 1 indicating atrophy or rounding off of the calcar; Grade 2, loss of density in the calcar region with preservation of the medial cortical wall to the level of the lesser trochanter; Grade 3, loss of density in the calcar region with loss of the medial cortical wall to the level of the lesser trochanter; and Grade 4, loss of density in the entire medial cortical wall distal to the level of the lesser trochanter.

To differentiate osteolysis resulting from polyethylene or metallic debris from stress-shielding-related bone resorption in the calcar region, three Craig-needle biopsy specimens were obtained under fluoroscopic control from the calcar region of four selected hips. Four patients who had had a total hip prosthesis in place for at least five years (five, 5.6, six, and 7.5 years) were randomly selected. The institutional review board approved this aspect of the study, and these four patients provided specific informed consent for this experimental procedure. Decalcified bone samples were embedded in paraffin wax and were stained with Mayer hematoxylin and eosin. The samples were then examined for evidence of polyethylene or metallic debris and/or macrophagic resorption of bone (osteolysis) or diminished trabeculae without macrophagic resorption of bone (stress-shielding).

Linear wear of the polyethylene liner was measured, with use of a software program (AutoCAD, Release 13; Autodesk, Sausalito, California)[4], by one observer who was blinded to the radiographic results. The observer made three measurements on each radiograph, and the intraobserver error was ±0.038 mm. A ScanMaker 9600XL flat-bed imaging scanner (Microtek, Carson, California) digitized the anteroposterior radiograph of the pelvis as two-dimensional gray-scale arrays of twelve-bit (256 gray level) integers. The scanning resolution was 600 psi (pixels per square inch). Wear, defined as penetration of the head into the liner, was determined at annual intervals from anteroposterior pelvic radiographs. The amount of penetration on radiographs made six weeks postoperatively was considered to be the "zero position."

Activity Level

The level of activity of the patients after the total hip arthroplasty was assessed with the activity score of Tegner and Lysholm[15]. This activity grading scale, with which work and sports activities are graded numerically, was used as a complement to the functional score. The patients were given a score, according to the activities in which they engaged in daily life, ranging from 0 points for a hip-related disability to 10 points for participation in competitive sports at a national level.

Analysis of Retrieved Femoral Heads

Two zirconia femoral heads, retrieved at the time of revision procedures due to aseptic loosening, were analyzed to determine the surface roughness (Ra and Rpm) and the phases of crystalline structure of zirconia heads. The ages of the two patients at the time of the revision surgery were forty-one and forty-eight years. One patient was 160 cm tall and weighed 55 kg, and the other was 170 cm tall and weighed 67 kg. The durations of implantation of these two zirconia femoral heads were five and six years.

The parameter Ra was the mathematical average of all deviations (peaks and valleys) from the mean line of the surface profile. The parameter Rpm (the mean leveling depth) was defined as the distance between the mean line and a line parallel to it that passed through the highest point. The intrinsic errors of the measurement of Ra and Rpm were 0.0215 and 0.163 nm, respectively.

The surface characteristics of the two explanted zirconia heads were evaluated with use of interferometry (Wyko RST 500 interferometer; Wyko, Tucson, Arizona) and environmental scanning electron microscopy. The monoclinic content of the surface of the zirconia head was calculated with x-ray diffraction. Interferometry, environmental scanning electron microscopy, and x-ray diffraction studies were also used to compare the two explanted zirconia heads with two identical zirconia heads that had never been implanted. The two unused zirconia heads had been sterilized and packaged by the same manufacturing company in a manner identical to that employed for the implanted ones. Four unused cobalt-chromium heads that were identical to those used in the study were also examined to determine their roughness values (Ra and Rpm).

The interferometry measurements were undertaken at two different magnifications with use of ×20 and ×40 lenses. The areas of analyses were 125 by 125 μm and 64 by 64 μm, respectively. The results are presented in terms of Ra and Rpm.

One investigator who had no knowledge of the clinical and experimental results performed additional analysis using a CamScan 4 environmental scanning electron microscope (University of Leeds, Leeds, United Kingdom), which is a special type of scanning electron microscope that works under controlled environmental conditions and requires no conductive coating on the specimen. This microscope makes it possible to examine specimens in their natural state. Secondary and back-scattered images were reviewed at various magnifications (particularly at ×250) to assess the pits and scratches on the zirconia head surfaces.

Statistical Analysis

The Student t test was used to determine possible correlations

between the rate of penetration and several specific variables, including age, gender, activity level, abduction angle of the acetabular component, and head type. Linear regression analysis was used to reveal any relationship between surface roughness values and age, gender, weight, activity, duration in vivo, and head type. The Kaplan-Meier curve method[16] was used in the analysis of the failure-free rate. Also, Greenwood's formula[17] was used to calculate confidence intervals of the failure-free rate at certain time-points.

Results

Clinical Results

Hip Score

The mean preoperative Harris hip score was 41 points (range, 8 to 48 points) in the zirconia head group and 43 points (range, 13 to 53 points) in the cobalt-chromium head group. The mean hip score at the final follow-up examination was 92 points (range, 63 to 100 points) in the zirconia head group and 94 points (range, 84 to 100 points) in the cobalt-chromium head group.

Functional Outcome

At the latest follow-up examination, forty-five patients had no detectable limp, five had a mild limp, and two had a severe limp due to aseptic loosening of the femoral component. The ability to use stairs and public transportation, to put on footwear, and to cut toenails was improved markedly after the operation.

Activity Score

Many patients were quite active despite our admonitions to avoid activities involving high impact after the total hip replacement. All but two patients had an activity score of 5 or 6 points after the total hip replacement, indicating participation in strenuous farm work (a score of 5 points) or playing tennis (a score of 6 points). The two patients with a loose femoral stem had a score of 1 point.

Radiographic Results

Stem Loosening

Two hips with a zirconia femoral head had aseptic loosening of the femoral stem and were revised with a larger stem. In these two hips, the femoral stem was undersized in both the coronal and the sagittal plane. The histopathological examination of the retrieved tissues around the two loose femoral stems revealed no evidence of infection or foreign-body reaction. There was no subsidence or aseptic loosening of any stem in the cobalt-chromium head group.

Position and Loosening of the Acetabular Component

The average lateral opening and anteversion of the acetabular component was 44.6° (range, 35° to 55°) and 21° (range, 16° to 24°), respectively, in the zirconia head group and 45.4° (range, 38° to 52°) and 23° (range, 18° to 26°), respectively, in the cobalt-chromium head group. All but two acetabular components were positioned in satisfactory abduction (35° to 45°) and anteversion (15° to 25°). The abduction angles of the acetabular components of the two hips that had loosening of the femoral component were 43° and 41°, and the anteversion angles were 24° and 25°, respectively. No acetabular component had aseptic loosening.

Fig. 1-A

Figs. 1-A and 1-B Environmental scanning electron microscopic images of one of the two unused and one of the two retrieved zirconia heads at six years after implantation. **Fig. 1-A** The surface of the unused zirconia head is smooth, with a combination of short and long randomly distributed voids.

TABLE I Surface Roughness of Explanted and Unused Zirconia Heads and Unused Cobalt-Chromium Heads

Surface Roughness	Explanted Zirconia Heads	Unused Zirconia Heads	Unused Cobalt-Chromium Heads
Ra *(nm)*	15.87, 17.35	5.31, 5.48	25-50
Rpm *(nm)*	153.86, 156.18	65.27, 66.35	262.6-525.2

Bone-Remodeling

At the latest follow-up evaluation, forty-seven hips in each group had Grade-2 bone loss and five hips in each group had Grade-3 bone loss in the calcar region. No hip in either group had Grade-4 bone loss. There was no evidence of polyethylene or metallic debris or macrophagic resorption of bone in any of the Craig-needle biopsy specimens. No hip had distal femoral or acetabular osteolysis. All hips in the cobalt-chromium head group and all but two hips in the zirconia head group had radiographic evidence of bone growth into the porous surfaces of the femoral stem (zones 1, 7, 8, and 14 as defined by Gruen et al.[13]).

Polyethylene Wear

The mean amount of polyethylene linear wear was 0.57 ± 0.035 mm in the zirconia head group and 1.21 ± 0.042 mm in the cobalt-chromium head group. The difference was significant (Student two-tailed t test, $p = 0.004$). The mean polyethylene linear wear rate per year (and standard deviation) was 0.08 ± 0.009 mm in the zirconia head group and 0.17 ± 0.011 mm in the cobalt-chromium head group. This difference was significant as well (Student two-tailed t test, $p = 0.004$). The mean amount of volumetric polyethylene wear was 350.8 mm^3 (range, 112.15 to 638.06 mm^3) in the zirconia head group and 744.7 mm^3 (range, 381.28 to 1018.21 mm^3) in the cobalt-chromium head group. This difference was also significant (Student two-tailed t test, $p = 0.004$). On the basis of the numbers available, there was no difference in the rates of polyethylene wear between the cups with and those without screw holes (Student two-tailed t test, $p = 0.88$). In both the cobalt-chromium and the zirconia head group, there was a significant relationship between polyethylene wear and the age of the patient ($p = 0.028$), male gender ($p = 0.042$), the activity of the patient ($p = 0.038$), and the abduction angle of the acetabular component ($p = 0.047$). With the numbers available, there was no significant correlation between polyethylene wear and the patient's weight, Harris hip score, anteversion of the cup, or range of motion of the hip.

Analysis of Retrieved Femoral Heads

The Ra values of the two explanted zirconia heads were 15.87 and 17.35 nm, and the Rpm values were 153.86 and 156.18 nm. The surface roughness values for the two zirconia heads that had not been implanted (the controls) were 5.31 and 5.48 nm of Ra and 65.27 and 66.35 nm of Rpm. The Ra values of the unimplanted cobalt-chromium heads were between 25 and 50 nm, and the Rpm values were between 262.6 nm and 525.2 nm (Table I).

Evaluation of the two unused zirconia heads with use of environmental scanning electron microscopy showed very

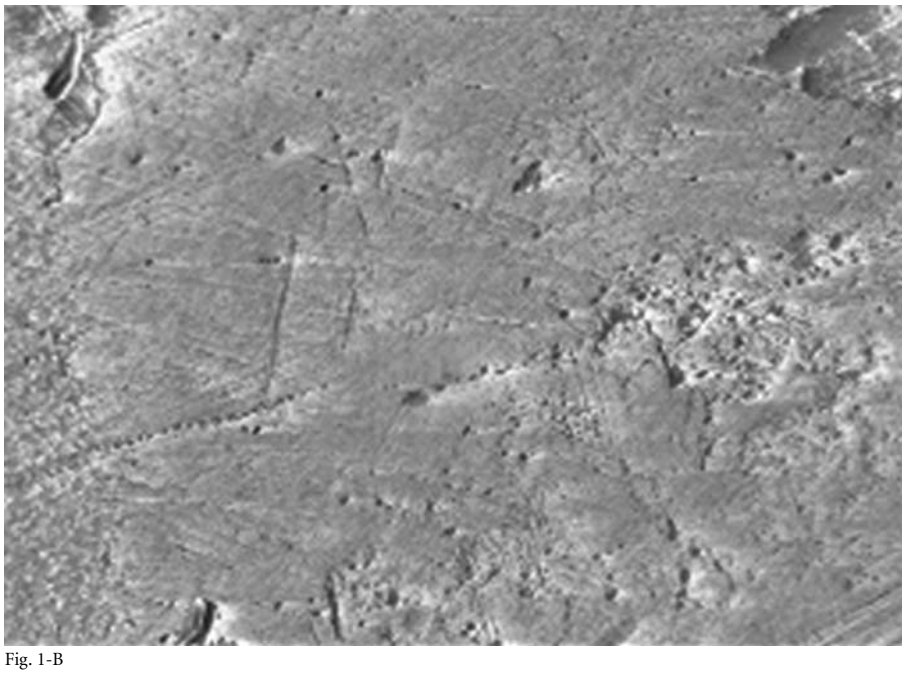

Fig. 1-B

The surface of the retrieved zirconia head reveals small pits and voids.

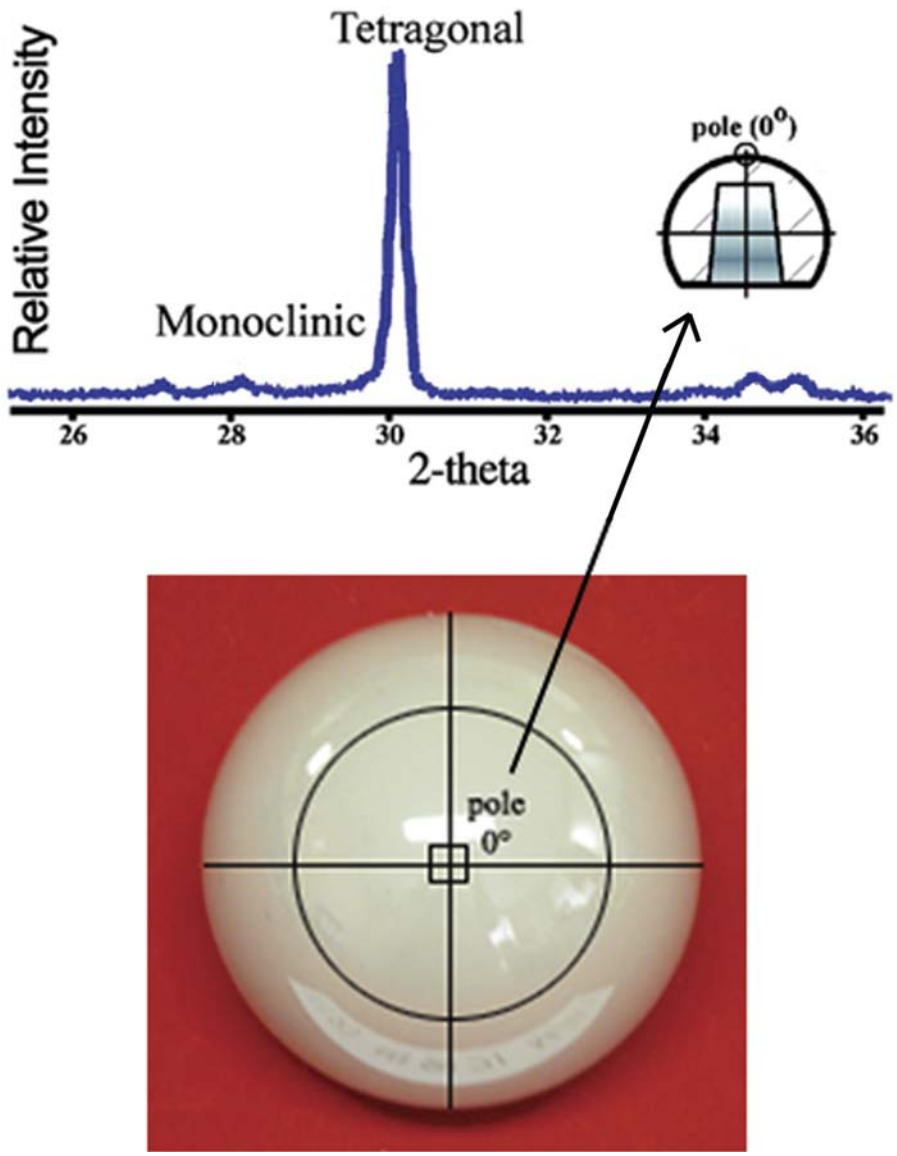

Fig. 2-A

Figs. 2-A and 2-B X-ray diffraction studies of an unused zirconia head and a zirconia head retrieved after six years of use. **Fig. 2-A** The study of the unused zirconia head reveals a high peak for the tetragonal phase and only a small amount of monoclinic phase transformation.

smooth surfaces with some short and long randomly distributed scratches (Fig. 1-A). The two retrieved zirconia heads revealed small pits and voids on the surface (Fig. 1-B).

X-ray diffraction studies showed similar high peaks for the tetragonal phase and only a small amount of monoclinic phase transformation on the pole areas of the two unused and the two retrieved zirconia heads (Figs. 2-A and 2-B).

Survivorship

Two femoral stems (4%) in the zirconia head group were revised because of aseptic loosening. These two stems were undersized in both the coronal and the sagittal plane. No acetabular component was revised in the zirconia head group, and no femoral or acetabular component was revised in the cobalt-chromium head group.

Discussion

Several studies have demonstrated good clinical results and a low wear rate of ultra-high molecular weight polyethylene cups used with a zirconia head[5,18], whereas others have shown no advantages with use of a zirconia head[3,4,6,19,20]. In a study of twenty-nine Charnley Elite total hip replacements with a 28-mm zirconia ball and a cemented Hylamer cup in younger patients, Norton et al. reported a five-year prosthetic survival rate of 32% and an average wear rate of >0.6 mm/yr for the failed cups[20]. Kim et al. performed simultaneous bilateral total hip re-

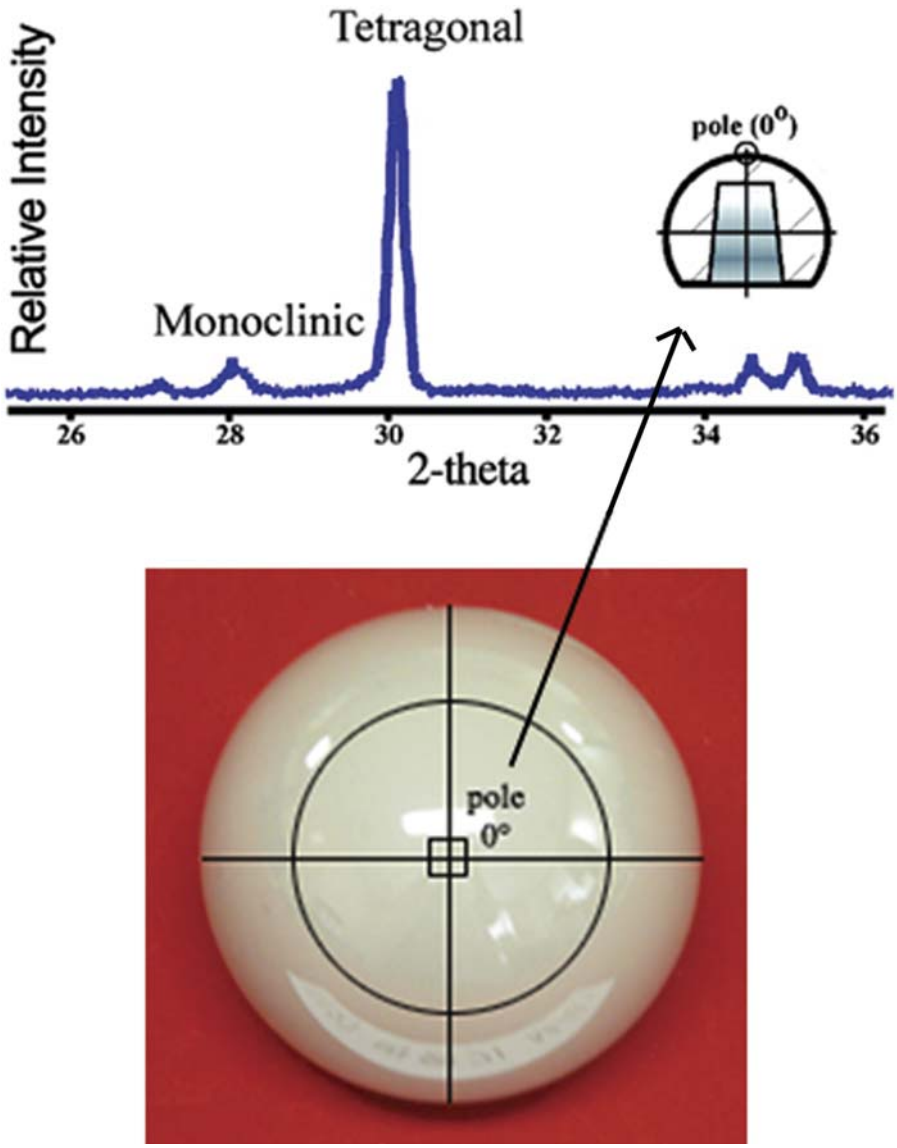

Fig. 2-B

The study of the retrieved zirconia head shows a pattern of the two phases that is similar to that seen for the unused zirconia head. The head appears pristine to the naked eye.

placement using a Hylamer liner and a cobalt-chromium ball on one side and a zirconia ball on the other side in seventy patients[4]. They observed greater wear with the zirconia head (0.21 mm/yr) than with the cobalt-chromium head (0.12 mm/yr). In contrast, Wroblewski et al. reported a wear rate of 0.02 mm/yr in a study of more than 1000 total hip replacements with a 22-mm zirconia head and a contemporary polyethylene cup[18]. The low wear rates seen by Wroblewski et al. and in the present study (0.08 mm/yr), in which the zirconia heads articulated with a contemporary polyethylene instead of Hylamer, suggest that the wear rates with zirconia heads might be even lower when they articulate with newer, improved surfaces such as highly cross-linked polyethylene.

One possible problem with the use of zirconia is in vivo phase transformation[7]. Zirconia ceramic has three phases of crystalline structure, which vary with temperature. The monoclinic phase transforms into a tetragonal phase at <1100°C, whereas the tetragonal phase transforms into the cubic phase at 2370°C. The tetragonal phase is the most unstable, but zirconia has the greatest mechanical strength in that phase. Transformation from the tetragonal phase into the monoclinic phase is accompanied by a 3% increase in the volume of the ceramic head. While this phase transformation plays an important role in increasing the mechanical strength of the zirconia head, it may cause an increase in the surface roughness and thereby may increase the polyethylene wear rate.

Such phase transformation in zirconia heads may be clinically relevant because it can be induced at relatively low

temperatures (as low as body temperature) in the presence of water and pressure[3,21]. Lu and McKellop reported that the surface temperature of the polyethylene articulation with a zirconia head rose to 99°C in a hip simulator[22]. Haraguchi et al. reported surface deterioration of two zirconia ceramic femoral heads associated with in vivo phase transformation after total hip arthroplasty[3]. The cause of the phase transformation of the zirconia head in their series was unknown.

Our x-ray diffraction study of two unused (control) and two retrieved zirconia heads demonstrated very little monoclinic phase content on the surface of the explanted heads. This finding suggests that the two retrieved zirconia heads underwent no deleterious volume expansion or delamination in vivo.

In summary, this study of patients treated with bilateral total hip arthroplasty showed that zirconia heads articulating with a contemporary polyethylene produced less radiographic evidence of polyethylene wear than did cobalt-chromium heads. While only two explanted zirconia heads were available for comparison with unimplanted zirconia heads and with unimplanted cobalt-chromium heads, the analysis of those components suggests that the zirconia heads that were implanted were smoother than the cobalt-chromium heads, and the radiographic wear data reflected those differences. Additional retrieval and tribologic studies are needed to confirm or refute these observations.

Appendix

A figure demonstrating the measurement of the change in the position of the acetabular component in the vertical and horizontal directions is available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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