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CERAMIC-ON-POLYETHYLENE BEARING SURFACES IN TOTAL HIP ARTHROPLASTY

SEVENTEEN TO TWENTY-ONE-YEAR RESULTS

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Background: Polyethylene wear debris, and the resulting inflammatory response leading to osteolysis and loosening, is the primary mode of failure limiting the longevity of total hip replacements. Alternative bearing surfaces, including ceramic-on-polyethylene, have been investigated in an effort to decrease the amount of polyethylene wear debris. The purpose of this study was to evaluate the seventeen to twenty-one-year results of the use of ceramic-on-polyethylene total hip prostheses.

Methods: Sixty-four total hip prostheses were implanted with cement, by one surgeon, in fifty-six patients from 1978 to 1981. The average age at the index arthroplasty was sixty-nine years (range, fifty-one to eighty-four years). The components consisted of a cemented Charnley-Müller stem with a 32-mm modular alumina femoral head and a cemented all-polyethylene acetabular component. All patients who retained the index prosthesis were assessed clinically with use of Harris hip scores and were evaluated radiographically at the time of the latest follow-up.

Results: At the time of this latest follow-up, of the original sixty-four implants, eighteen (28%) were still in place and five (8%) had been revised. The remaining forty-one implants were in patients who had died and were functioning well until the patient's death. No patient was lost to follow-up. Of the eighteen hips with an intact prosthesis in the surviving patients, seven had an excellent clinical result; nine, a good result; and two, a fair result. One asymptomatic hip had definite radiographic evidence of femoral loosening. No hip had definite signs of acetabular loosening or evidence of osteolysis. Survivorship analysis revealed that the probability of survival of the prostheses without revision was 95% at five years, 95% at ten years, 89% at fifteen years, and 79% at twenty years. The mean linear and volumetric polyethylene wear rates were 0.034 mm/yr and 28 mm³/yr, respectively. There were no fractures of the ceramic heads.

Conclusions: Outstanding long-term clinical and radiographic results were attained despite the use of what are now considered substandard techniques (an inferior stem design, a 32-mm head, and first-generation cementing techniques). The wear rates in this study are lower than previously reported metal-on-polyethylene wear rates and are consistent with the lowest reported *in vivo* ceramic-on-polyethylene wear rates. These findings support the consideration of ceramic-on-polyethylene bearing surfaces in total hip arthroplasty.

Aseptic loosening continues to be the primary mode of long-term failure after total hip arthroplasty¹. Particulate debris generated from the wear of the prosthetic components and the ensuing inflammatory response resulting in osteolysis have been implicated as the mechanism by which aseptic loosening occurs. Although wear debris from any of the components (metal, cement, or polyethylene) can stimulate the inflammatory response, wear of the polyethylene bearing surface has been recognized as the primary source of this debris². Efforts to limit the generation of polyethylene wear debris have focused both on improving polyethyl-

ene bearing surfaces (decreasing polyethylene oxidation and increasing polyethylene cross-linking) and on exploring alternative bearing surfaces (ceramic-on-polyethylene, ceramic-on-ceramic, and metal-on-metal).

Alumina ceramic was introduced as a bearing surface in the 1970s as an alternative to the metal-on-polyethylene couplings because of its inertness, coefficient of friction, wettability, and hardness. Subsequent hip-simulator trials of ceramic-on-polyethylene couplings demonstrated up to twenty times less wear compared with that of cobalt-chromium-molybdenum-polyethylene couplings. Ceramic-on-ceramic coup-



Fig. 1
Photograph showing the modular femoral component consisting of a 32-mm alumina ceramic head (Feldmuhle, Plochingen, Germany) and a stainless-steel Charnley-Müller stem (DePuy, Warsaw, Indiana).

lings showed even less wear—up to 100 times less wear—than their metal-on-polyethylene counterparts³.

The purpose of this investigation was to evaluate the seventeen to twenty-one-year results of total hip arthroplasties, performed by one surgeon, with a Charnley-Müller femoral prosthesis and an all-polyethylene cup, both cemented with use of first-generation cementing techniques. To our knowledge, we performed the longest follow-up to date of ceramic-on-polyethylene total hip prostheses.

Materials and Methods

From April 1978 to February 1981, the senior author (R.K.M.) performed sixty-four (sixty-one primary and three revision) nonconsecutive total hip arthroplasties using ceramic-on-polyethylene bearing surfaces in fifty-six patients. (Eight procedures were bilateral.) The availability of the ceramic head was the primary variable determining which femoral bearing surface was implanted. These sixty-four arthroplasties comprise the focus of this study.

There were twenty-five men (twenty-eight hips) and thirty-one women (thirty-six hips). The average age at the time of the index arthroplasty was sixty-nine years (range, fifty-one to eighty-four years). The average weight of the patients was 166 lb (75.3 kg), with a range of 100 to 286 lb (45.4 to 129.7 kg). The preoperative diagnosis was osteoarthritis in fifty-five hips (86%), avascular necrosis in four (6%), a failed

previous prosthesis in three (5%), and rheumatoid arthritis in two (3%). The arthroplasties were equally distributed between the left and right hips, with thirty-two performed on each side. The average preoperative Harris hip score was 55 points (range, 16 to 78 points).

The femoral component implanted in each patient (Fig. 1) consisted of a stainless-steel Charnley-Müller prosthesis (DePuy, Warsaw, Indiana) with a modular 32-mm alumina ceramic head (Feldmuhle, Plochingen, Germany) affixed to the trunion of the femoral component at the time of surgery. The nonmodular acetabular component (DePuy, Warsaw, Indiana) consisted of ultra-high molecular weight polyethylene that was sterilized by gamma irradiation in air. In this study, acetabular components of three different diameters (44, 50, or 54 mm) were inserted on the basis of intraoperative determinations of the diameter of the osseous acetabulum. Both the femoral and the acetabular components were inserted with



Fig. 2
Anteroposterior radiograph of the right hip, made eighteen years after a total hip arthroplasty, showing minimal wear of the polyethylene cup and stable components.

use of Simplex P cement. The cement for the femoral component was inserted by finger-packing, and no femoral canal plug was used (first-generation cementing technique).

For the latest follow-up evaluation, efforts were made to contact each patient or his or her family. Surviving patients were asked to return for clinical and radiographic evaluation. Those who had relocated and were unable to return to our institution were assessed, with use of the standard system of terminology for the reporting of results described by Johnston et al.⁴, by a local orthopaedist or physical therapist who was instructed to forward the clinical results and radiographs to us. The families of the patients who had died were interviewed to determine whether the patient had been satisfied with the result of the arthroplasty and whether he or she had undergone revision prior to death.

At the time of the latest follow-up, nineteen patients (twenty-two hips) were still alive and thirty-seven patients (forty-two hips) had died. No patient was lost to follow-up. Four of the twenty-two total hip prostheses in the surviving patients and one of the forty-two prostheses in the deceased patients had been revised. Therefore, eighteen hips had retained the index prosthesis and are the focus of this seventeen to twenty-one-year investigation.

Clinical evaluation consisted of quantifying, with use of Harris hip scores⁵, the functional level, pain, gait, limp, muscle strength, and range of motion of each surviving patient.

Standard anteroposterior radiographs of the pelvis and ipsilateral hip were made at the time of follow-up (Fig. 2) and were compared with the same views made within three months after the index arthroplasty. Each patient's radiographs were assessed for evidence of loosening, osteolysis, radiolucent lines, calcar resorption, heterotopic ossification, and wear.

Loosening of the acetabular and femoral components was categorized according to previously accepted criteria⁶⁻⁹. Definite loosening was defined as the presence of a radiolucent line at the interface between the acetabular or femoral component and the surrounding cement that had not been seen on the immediate postoperative radiograph, subsidence or migration of either component, or a fracture of the cement or component. Subsidence of the femoral component was determined with the method of Loudon and Charnley¹⁰, and migration of the acetabular component was determined with the criteria of Massin et al.¹¹. Probable loosening was defined as the presence of a continuous radiolucent line involving 100% of the cement-bone interface. Possible loosening was defined as a radiolucent line involving 50% to 99% of the cement-bone interface that had not been present on previous radiographs.

Osteolysis was defined as any area of progressive nonlinear radiolucency surrounding the prosthesis and measuring ≥ 2 mm in its greatest diameter⁹. Radiolucent lines were defined as progressive, linear, lucent areas surrounding the prosthesis, and generally parallel to it, measuring ≤ 2 mm in their greatest thickness⁹. The locations of these areas on anteroposterior radiographs were recorded with use of the femoral

zones described by Gruen et al.¹² and the acetabular zones described by DeLee and Charnley¹³. Calcar resorption was considered meaningful if the difference between the measurement between the undersurface of the collar of the prosthesis and the stump of the neck on the early postoperative radiograph and the same measurement on the latest radiograph was >3 mm¹⁴. Heterotopic bone, when present, was graded according to the classification system of Brooker et al.¹⁵.

Wear was determined with the technique described by Livermore et al.¹⁶. One independent observer with experience with the technique performed the measurements. The shortest distance between the center of the femoral head and the periphery of the acetabular component was measured. The difference between this length on the immediate postoperative radiograph and that on the most recent radiograph was divided by the time that had elapsed between the two radiographs to determine the linear wear rate. The volumetric wear rate was calculated by multiplying πr^2 by the linear wear rate. Measurements were made with a digitizing stylus and tablet (SigmaScan; Jandel Scientific, La Jolla, California) with a reported accuracy of 0.025 mm. Magnification was standardized against the known circumference of the femoral head.

The prevalence of revision was determined for all sixty-four hips initially entered into the study and for the twenty-two hips in the survivors at the time of the latest follow-up. The reasons for each revision were also documented. Survivorship analysis with use of the Kaplan-Meier method was performed with failure defined as revision of any component of the arthroplasty for any reason. Statistical analysis with use of the Pearson correlation coefficient, Spearman correlation coefficient, t test, and Fisher exact test was carried out to determine the correlation of linear wear rate with numerous variables. These variables included the age, gender, and weight of the patient; osteolysis; loosening; preoperative diagnosis; thickness of the acetabular component; radiolucent lines; heterotopic ossification; and calcar resorption.

Results

Patient Demographics

The average age of the nineteen patients (twenty-two hips) who were still alive at the time of the latest follow-up was eighty-two years (range, seventy-two to ninety-two years). The average duration of follow-up of these nineteen patients was 18.2 years (range, 17.2 to 21.3 years). The average age at time of death of the thirty-seven patients (forty-two hips) who had died was seventy-nine years (range, sixty-seven to ninety-three years). Ten patients (eleven hips) died within five years after the index arthroplasty; thirteen (fourteen hips), between five and ten years after it; six (eight hips), between ten and fifteen years after it; and eight (nine hips), between fifteen and twenty years after it.

Hip Scores

Preoperatively, the Harris hip scores for all fifty-six patients averaged 55 points (range, 16 to 78 points). The sixteen patients (eighteen hips) who were alive and had retained the in-

dex prosthesis at the time of the latest follow-up had had an average preoperative Harris hip score of 55 points (range, 35 to 78 points). At the time of the latest follow-up, the average Harris hip score was 88 points (range, 72 to 99 points). Of the sixteen patients available for this follow-up, seven had an excellent result, seven (nine hips) had a good result, and two had a fair result. The two patients with a fair result were nursing-home residents with advanced senile dementia and other medical comorbidities. These two patients had a limited range of motion and required assistance for activities of daily living but were pain-free and able to walk with the aid of assistive devices.

Satisfaction

Of the eighteen hips in the patients who were alive and had retained the prosthesis at the time of the most recent follow-up, sixteen were considered by the patient to have improved function, to be less painful, and to have a satisfactory result. The remaining two patients were unable to provide accurate subjective information. One of the deceased patients had undergone a revision and, therefore, no efforts were made to contact his family.

Information was obtained from a family member for thirty-two of the thirty-seven patients who died before the time

of the latest follow-up. All thirty-two patients were thought to have been satisfied with the overall result of the total hip arthroplasty before their death. The relatives of four patients could not be reached.

Aseptic Loosening and Radiolucent Lines

None of the eighteen unrevised hips in patients who were alive at the time of the latest follow-up had evidence of definite, probable, or possible loosening of the acetabular component. One of the femoral components was definitely loose according to the criteria of Harris et al.⁶. There was no probable or possible loosening of the femoral component.

Two hips had progressive radiolucent lines at the cement-bone interface of the acetabular component. These radiolucent lines were seen in zone III in one hip and in zones I and III in the other. In the hip with radiolucent lines in zones I and III, the lines did not involve $\geq 50\%$ of the cement-bone interface and, therefore, were not considered evidence of possible loosening.

Progressive radiolucent lines at the cement-bone interface of the femoral component were encountered in three hips. The radiolucent lines were in zones 1 and 7 in one hip and in zone 7 in the other two. These radiolucent lines did not

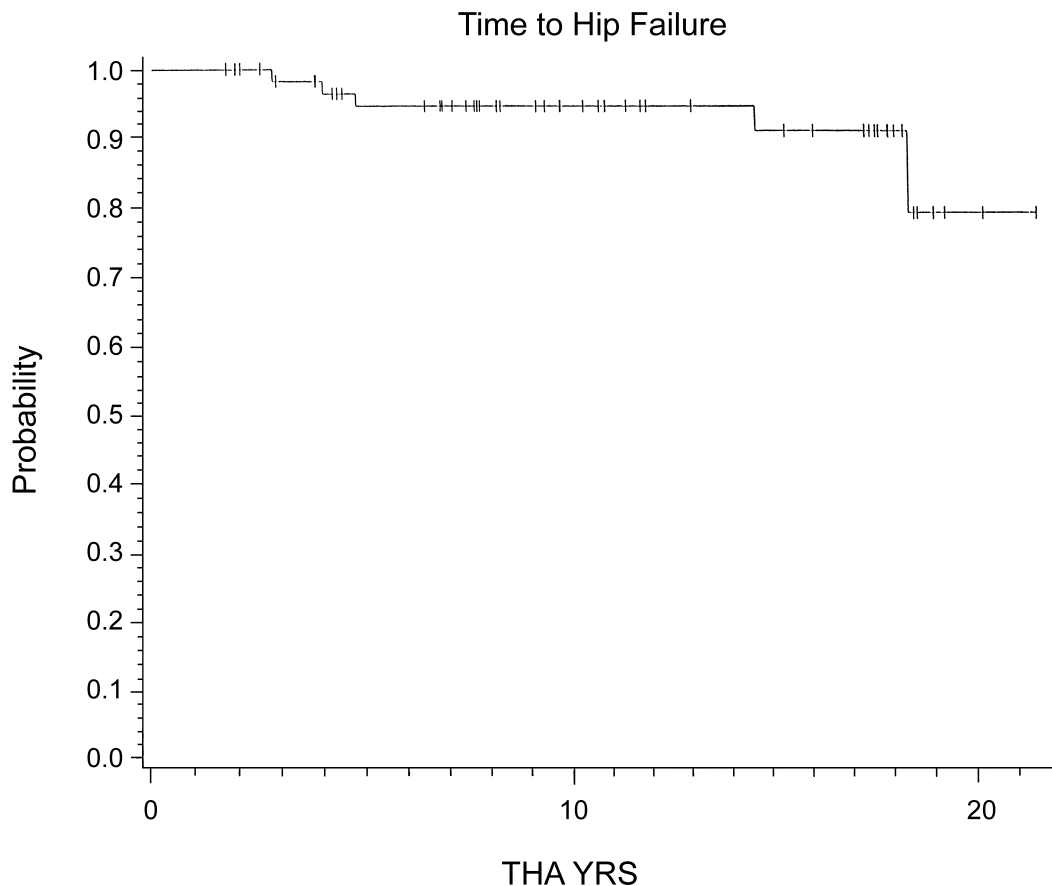


Fig. 3

Kaplan-Meier survivorship curve showing the probability of survival of the prosthesis over time, with use of revision as the end point. THA = total hip arthroplasty.

TABLE I Wear Rates from Studies of Metal-on-Polyethylene Total Hip Replacements

Study	Acetabular Bearing	Femoral Bearing	Femoral Head Diameter (mm)	Average Linear Wear Rate (mm/yr)
Woolson and Murphy ²⁹ (1995)	Polyethylene*	Cobalt-chromium	28	0.14
Okumura et al. ³⁰ (1989)	Polyethylene	Stainless steel	22	0.14
Livermore et al. ¹⁶ (1990)	Polyethylene	Stainless steel	22	0.13
		Cobalt-chromium	32	0.10
		Stainless steel	28	0.08
Madey et al. ²⁴ (1997)	Polyethylene*	Stainless steel	22	0.09
Bankston et al. ³¹ (1995)	Polyethylene*	Cobalt-chromium	28	0.05
Ohashi et al. ¹⁹ (1989)	Polyethylene	Cobalt-chromium	32	0.04
		Stainless steel	28	0.04

*Cemented all-polyethylene component.

encompass $\geq 50\%$ of the cement-bone interface, and therefore were not considered possibly loose.

Resorption of the calcar, as defined by Blacker and Charnley¹⁴, was encountered in two hips. Two other hips had 1.5 to 2.0 mm of calcar resorption. The remaining fourteen hips had no evidence of calcar resorption.

Wear and Osteolysis

The average rate of linear wear of the all-polyethylene acetabular component was 0.034 mm/yr (range, 0.00016 to 0.077 mm/yr) in the eighteen hips. The average volumetric wear was 28.012 mm³/yr (range, 0.13 to 62.09 mm³/yr).

Osteolysis was not encountered around either the femoral or the acetabular component in any of the eighteen hips at the time of the latest follow-up.

Heterotopic Ossification

Heterotopic ossification had developed in five of the eighteen hips at the time of the latest follow-up. According to the criteria of Brooker et al.¹⁵, three hips had grade-I ossification and two had grade-II ossification.

Revision Rates

Fifty-nine (92%) of the sixty-four original prostheses were

functioning or had been in place when the patient died. Of the twenty-two hips in the patients who were still alive at the time of the latest follow-up, four (18%) had been revised and eighteen (82%) had retained the original prosthesis. The remaining revision was in a patient who had died before the time of the latest follow-up. Revision of the index prosthesis was performed because of loosening of the acetabular component alone in one hip (at fourteen years), loosening of the femoral component alone in two hips (at four years and four and one-half years), and loosening of both the acetabular and the femoral component in two hips (at three and eighteen years).

No femoral stem or ceramic head fractured.

Statistical and Survivorship Analysis

The Kaplan-Meier survivorship analysis with 95% confidence intervals demonstrated that the probability of retention of the index prosthesis at five, ten, fifteen, and twenty years was 95% (89% to 100%), 95% (85% to 100%), 89% (81% to 100%), and 79% (57% to 100%), respectively (Fig. 3).

With the numbers available, no correlation was found between linear wear rates and age, gender, weight, osteolysis, loosening, preoperative diagnosis, thickness of the acetabular component, radiolucent lines, heterotopic ossification, or calcar resorption.

TABLE II Wear Rates from Studies of Ceramic-on-Polyethylene Total Hip Replacements

Study	Acetabular Bearing	Femoral Bearing	Femoral Head Diameter (mm)	Average Linear Wear Rate (mm/yr)
Saito et al. ²² (1992)*	Polyethylene	Alumina	28	0.10
Sugano et al. ²³ (1995)*	Polyethylene	Alumina	28	0.10
Okumura et al. ³⁰ (1989)	Polyethylene	Alumina	28	0.08
Schuller and Marti ²⁰ (1990)	Polyethylene	Alumina	32	0.03
Ohashi et al. ¹⁹ (1989)	Polyethylene	Alumina	28	0.03
Wroblewski et al. ²¹ (1996)	Cross-linked polyethylene	Alumina	22	0.03

*Same group of patients.

Discussion

Ceramics were introduced in the 1970s as an alternative bearing surface with superior wear characteristics compared with those of the established metal-on-polyethylene couplings used at that time for total hip arthroplasty. Nearly thirty years have passed, and metal-on-polyethylene couplings continue to be the most commonly used bearing surfaces. Although much knowledge has been gained and improvements have been made in the metals and polyethylene that make up the standard bearing surfaces used today, the failure of ceramic to supplant metal as the preferred femoral head material is principally due to the fact that fracture of the ceramic head has been reported in both ceramic-on-ceramic and ceramic-on-polyethylene couplings¹⁷. The rate of this devastating complication has been as high as 13.4%¹⁸. In the last decade, however, there has been renewed interest in ceramic bearing surfaces in total hip arthroplasty. It is now believed that many of the failures of ceramic femoral heads resulted from correctable manufacturing and material flaws. A lack of material standardization for the early-generation ceramics resulted in inferior material properties such as large grain sizes and increased porosity. This inferior quality of the ceramic coupled with imprecise taper mating surfaces (between the ceramic head and the trunion of the femoral stem) is believed to have created stress risers within the ceramic, leading to an increased susceptibility to fracture. Current-generation ceramics are manufactured with stricter standardization, increased strength of the ceramic (zirconium oxide), and a more precise Morse-type taper. These modifications have led to a substantial decrease in the prevalence of fractures of ceramic components (0% to 2.0%)¹⁷.

In this study, although early-generation alumina ceramic femoral heads were implanted in sixty-four hips, no femoral head fractured. We attribute the absence of ceramic fracture in our series to careful intraoperative handling of the ceramic component and the surgeon ensuring both a precise Morse-taper mating and that the taper mating surfaces of the femoral head and stem remained debris-free during impaction.

There have been numerous studies on the *in vivo* wear of metal-on-polyethylene total hip replacements. A wide range of linear wear rates has been reported, with the majority ranging from 0.08 to 0.10 mm/yr (Table I). In contrast, there have been only a few studies on the *in vivo* wear of ceramic-on-polyethylene total hip replacements. These too have demonstrated a relatively wide range of wear rates (Table II), with several as low as 0.03 mm/yr¹⁹⁻²¹. The average linear wear rate of 0.034 mm/yr in our study is consistent with the lowest previously reported ceramic-on-polyethylene wear rates and, correspondingly, compares favorably with the wear rates in historical studies of metal-on-polyethylene replacements.

A correlation between increased wear rates and calcar resorption was reported by Saito et al.²². Sugano et al.²³ reported similar findings with longer follow-up of the same group of patients. In our study, no correlation between increased wear and calcar resorption was identified, with the numbers available.

The 8% revision rate at an average of eighteen years in the present study compares favorably with the revision rates in previously reported long-term studies^{16,24-26}, despite the use in our study of what is now considered an inferior stem design (Charnley-Müller), first-generation cementing techniques, and a head size (32 mm) associated with greater volumetric wear.

The absence of osteolysis in association with low wear rates in our study support the finding of a direct correlation between wear rates and osteolysis in the study by Dowd et al.²⁷. In that study, hips with a wear rate of <0.1 mm/yr were found to have no osteolysis after ten years of follow-up. In contrast, osteolysis was encountered in 43% of hips demonstrating a wear rate between 0.1 and 0.2 mm/yr, in 80% of hips with a wear rate between 0.2 and 0.3 mm/yr, and in 100% of hips with a wear rate of >0.3 mm/yr.

Shortcomings of our study include the small number of patients available at the time of the latest follow-up and the inherent problems with the Livermore technique¹⁶. While the Livermore technique is commonly employed to measure polyethylene wear in total hip replacements, it only measures wear, or linear penetration, that occurs in the plane of the radiograph. Furthermore, the interobserver and intraobserver reliability of this technique has been reported to be poor²⁸. In an effort to minimize this potential source of error, one individual at an outside university who was experienced with the technique performed all of the wear measurements. Another shortcoming of our study is the nonconsecutive nature of the series of patients, which potentially introduces a selection bias. However, all patients presenting to the senior surgeon for total hip arthroplasty between 1978 and 1981 received a ceramic femoral head as long as one was available. The demographics of the nineteen hips that instead received a metal head during the same time frame did not differ with respect to age or diagnosis at the time of the index arthroplasty. The strengths of this study are that it represents one surgeon's experience, no patients were lost to follow-up, and to our knowledge it is the longest follow-up study of ceramic-on-polyethylene couplings in total hip arthroplasty.

In summary, this study demonstrates the value of ceramics as a femoral bearing surface in total hip arthroplasty. As the indications for total hip arthroplasty continue to expand to include younger, more active patients, the superior wear characteristics of ceramics provide an attractive alternative to contemporary metal-on-polyethylene designs. ■

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