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Total Hip Arthroplasty in Young Patients

8- to 13-Year Results Using an Uncemented Stem

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One hundred eight uncemented total hip arthroplasties were performed in 91 patients who were 50 years of age or younger using the Taperloc femoral component. The average age of the patients at time of surgery was 37 years (range, 20–50 years). The mean followup was 10.2 years (range, 8–13 years). No patient was lost to followup. Seven patients (eight hips) died before obtaining the minimum time of 8 years for inclusion in this study. All seven died with their femoral components in place. Of the remaining 100 total hip arthroplasties, no femoral component required revision for aseptic loosening. One femoral component was revised to correct a leg length discrepancy, and one well-fixed femoral component was revised for sepsis. In the 98 total hip arthroplasties that had not undergone femoral component revision, complete radiographic and clinical followup was obtained. Radiographically, 96 (98%) femoral components were determined to have fixation by bone ingrowth, two (2%) femoral components showed stable fibrous ingrowth, and no femoral component was unstable. Femoral cortical osteolysis occurred in seven (7%) hips; major lysis was present in only one (1%). Clinically, 91 (93%) total hip arthroplasties were rated good or excellent; six (6%) were rated fair, and one (1%) was rated poor. Thirty-nine patients with 47 total hip arthroplasties (48%) were engaged in moderate to strenuous manual labor. These results indicate that excellent fixation and minimal lysis can be achieved with an uncemented femoral component in young and active patients at 10 years.

The success of total hip arthroplasty in reducing pain and increasing function inevitably led to the expansion of this procedure to younger patients. Results using cement on the femoral side in young patients undergoing total hip replacement have shown substantial variability. The incidence of aseptic loosening and revision of the femoral component in several series has ranged from 8% to 55%, with femoral osteolysis occurring between 6% and 35%.[1,3,7,8,10,11,16,24,32–35] Changes in cementing technique, using a femoral plug, a cement gun, and a super alloy metal stem with rounded corners may explain these conflicting results.

There is now more than a decade of experience using biologic fixation in older patients requiring total hip arthroplasty. Although the results using several uncemented femoral components have been discouraging,[17,19,21,22] femoral components with a taper design have done well. McLaughlin and Lee[26] reported their results using the Taperloc (Biomet, Warsaw, IN) femoral component in older patients

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and found that 96% remained in place at 10 years' average followup. Femoral osteolysis occurred in 6%. Burt et al[6] evaluated their results using the Tri-lock (DePuy, Warsaw, IN) femoral component in patients with a mean age of 62 years. They reported a 95% survivorship at 10 years, with osteolysis occurring in 11%. Mulliken et al[28] reported their results using the tapered Mallory Head prosthesis (Biomet) in patients whose average age was 63 years. No femoral component required revision for pain, loosening, or osteolysis at 2 to 6.5 years.

The purpose of this study was to evaluate the 8- to 13-year results, with regard to osteolysis and durability of fixation, of total hip arthroplasty performed using an uncemented tapered Ti femoral component in patients whose average age was 37 years. These results are compared with those of arthroplasty performed with cemented and uncemented femoral components in the younger patients.

MATERIALS AND METHODS

Between October 1983 and September 1988, 108 consecutive primary total hip arthroplasties were performed without cement in 91 patients who were 50 years of age or younger. All procedures for this study were approved by the Institutional Review Board, and written informed consent was obtained from all patients. The average age of the patients at the time of surgery was 37 years (range, 20–50 years). The average weight was 81 kg (range, 50–134 kg). The outcome of every hip was determined. Seven patients (eight hips) died before obtaining a minimum 8-year followup. All seven patients died with their femoral components in place. This left 100 hips in 84 living patients. Among these, two femoral components have undergone revision. In the remaining 98 hips in 82 patients, complete clinical and radiographic followup was obtained. There were 43 women (51 hips) and 39 men (47 hips). The average followup was 10.2 years (range, 8–13 years).

The Taperloc femoral component was used in all patients (Fig 1). This implant is a noncollared

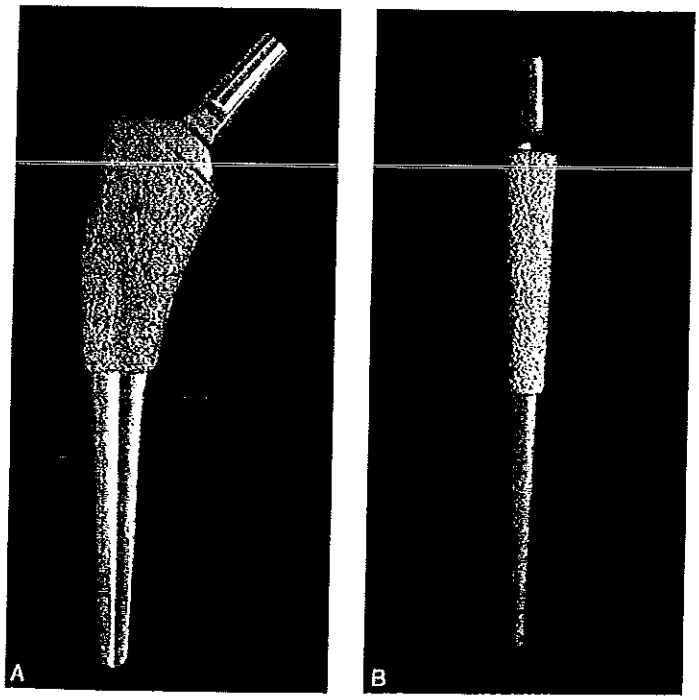

Fig 1A–B. (A) The Taperloc femoral component. Anteroposterior view shows the tapered geometry of the implant. (B) The lateral profile shows the narrow width of the component, which is designed to achieve fixation mediolaterally within the proximal femur.

stem made of wrought Ti alloy Ti-6Al-4V (Taperloc, Biomet Inc). The stem has a tapered wedge shape designed to achieve fixation mediolaterally within the proximal femur. The proximal 40% of the implant is coated with the identical Ti alloy (Ti-6Al-4V) applied with a pressure plasma spray technique. The plasma spray porous coating is between 635 to 889 μm thick. Pore diameter varies through the coating from 92.3 μm at the surface to 480.3 μm at the outermost points of the coating surface. All of the femoral components in this study had a 28-mm articulating head. Sixty-two femoral components were monoblock, and 38 had a modular design.

The preoperative diagnosis for the 98 anatomic joints was secondary osteoarthritis in 39 (40%) hips, developmental dysplasia of the hip in 29 (30%) hips, avascular necrosis in 20 (20%) hips, rheumatoid arthritis in eight (8%) hips, and Legg Perthes disease in two (2%) hips.

All surgeries were performed by one surgeon using a posterolateral approach to the hip. An intraoperative radiograph was obtained on every hip to assess component position. Antibiotics were administered before surgery and for 48 hours after surgery. The patients were allowed only partial weightbearing for 6 weeks and then were fully weightbearing thereafter.

Radiographic evaluation consisted of anteroposterior (AP) views of the hip and pelvis and a true lateral view of the hip. These were compared with the immediate postoperative radiographs and all subsequent followup radiographs. The femur was divided into seven zones, described by Gruen et al,[15] and the corresponding seven zones on the lateral radiograph. Radiographic evaluation is subject to interobserver variability or bias. All radiographs in this study were read by an independent orthopaedic surgeon (JRM) who was not the operating surgeon. Radiographic evaluation by one viewer eliminates interobserver variability; however, it can introduce bias. To reduce bias, all measurements were corrected for magnification based on the true size of the femoral head, and all measurements were made using a caliper.

All of the radiographs were assessed for radiolucencies in each of the seven Gruen zones and recorded in 0.5-mm increments. Progressive radiolucencies were identified and recorded. Radiolucencies with a scalloped or cystic appearance or greater than 2 mm in width were recorded as osteolysis.

Osteolysis was characterized by the criteria of Goetz et al.[14] Mild osteolysis was defined as a lesion involving one or two Gruen zones or occupying a total surface area less than 2.5 cm^2. Intermediate osteolysis occurred when a lesion involved three, four, and five Gruen zones or involved a total surface area of 2.5 to 10 cm^2. Extensive osteolysis involved a lesion involving six or more Gruen zones or occupying a surface area greater than 10 cm^2.

Femoral component stability was evaluated by the criteria of Engh et al.[12] A component was defined as having fixation by bone ingrowth when there was no subsidence. Stable fibrous ingrowth occurred when an implant showed no progressive migration with or without the presence of extensive radiopaque line formation around the stem. An implant with definite evidence of progressive migration was considered unstable.

Subsidence was determined by a comparison of two measurements between serial radiographs. The first measurement was the vertical distance from the tip of the greater trochanter to the distal tip of the implant. The second measurement was the vertical distance from the medial corner of the implant to the lesser trochanter. A difference greater than 4 mm on both of these measurements between radiographs was required for this determination.[30]

Stress shielding was determined by the classification of Engh et al.[12] First degree stress shielding was defined as a slight rounding of the proximal medial edge of the cut femoral neck. Second degree stress shielding occurred when rounding of the proximal medial femoral neck was combined with loss of medial cortical density at Level One on the AP radiograph. Third degree stress shielding involved more extensive resorption of the cortical bone extending from the cortical regions of Level One into the medial cortex of Level Two. Fourth degree stress shielding represented severe resorption of cortical bone extending below Levels One and Two into the diaphysis.

Patients were evaluated clinically by one author who was not the operating surgeon (JRM) in an office visit or by a telephone interview and questionnaire. The Harris hip score[18] was used to determine functional level. In addition, the presence or absence of thigh pain was recorded. At final followup, 79 patients with 95 hips (97%) were examined during an office visit, and three patients with three hips (3%) were evaluated by a questionnaire followed by a telephone interview.

Activity level was evaluated by the classification of Johnston et al.[20] Heavy manual labor was defined as frequently lifting 23 to 45 kg or engaging in vigorous sports such as singles tennis. Moderate manual labor indicated lifting 23 kg or less and involved in moderate sports, such as walking greater than 5 km. Light labor included heavy housecleaning, yard work, and walking less than 5 km. Semisedentary was defined as a white collar job or light housekeeping. A sedentary activity level indicated a minimum capacity for walking. Bedridden was determined as being confined to a wheelchair or bed.

The Kaplan-Meier survivorship analysis was used to estimate a cumulative survival function for the femoral component. The end point was defined as revision of the femoral component. Multivariate linear regression analysis by ordinary least squares was used to determine the statistical significance of the relationships between the variables. The analysis of residuals for the models was used to determine the magnitude and behavior of serial correlations. Chi square analysis and the Student's t-test also were performed.

Although not the focus of this review, the acetabular components also were evaluated. The acetabular component used in this series was a conically shaped, threaded ring Ti shell with a 28-mm articulating surface (T-Tap, Biomet Inc). In the first 35 acetabular components, ultrahigh molecular weight polyethylene powder (H1900, Himont, Wilmington, DE) was directly compression molded into the shell. In the next 65 acetabular components, a modular liner consisting of ram extruded bar stock polyethylene (GUR 415, Hoecht/Celanese Corp, Houston, TX) was used. The average followup of total hip arthroplasties performed using compression molded polyethylene was 12.2 years, compared with 9.6 years for those associated with ram extruded polyethylene.

RESULTS

At the time of final followup seven patients (eight hips) had died before obtaining the minimum followup of 8 years required for inclusion in this study. All of these patients died with their femoral component in place. Thus, 100 hips in 84 patients were observed for an average of 10.2 years (range, 8–13 years). No femoral component required revision for aseptic loosening. One (1%) femoral component required revision in the immediate postoperative period for a peroneal nerve palsy secondary to excessive leg lengthening. One femoral component was revised for sepsis. In the femoral components that have not undergone revision surgery, 96 (98%) were determined to have fixation by bone ingrowth and two (2%) showed stable fibrous ingrowth. No femoral component was unstable. At an average followup of 10.2 years, 98% of the femoral components were in place and well fixed.

Of the 100 total hip arthroplasties in living patients, two required revision of the femoral component. One femoral component was revised for a peroneal nerve palsy and was performed in the immediate postoperative period to correct excessive leg lengthening. The patient was a 33-year-old man with a preoperative diagnosis of rheumatoid arthritis. The one femoral component requiring revision for sepsis had revision surgery 9.5 years after the index procedure. This patient was a 50-year-old man who underwent total hip arthroplasty for avascular necrosis. Kaplan-Meier survivorship analysis with revision as the end point estimated a 98% chance of survival for the femoral component at 12.5 years (95% confidence interval, 0.96–1.00).

In this study, 56 (56%) total hip arthroplasties required revision of the acetabular component. In the hips requiring revision of the acetabular component, the average Harris hip score before revision was 55 (range, 32–82). The score increased to 89 (range, 54–100) after revision. The final average Harris hip score reported in this study uses the clinical score after revision of the acetabular component in those hips in which it was required. The use of assistive devices for walking reported in this review also represents the results after acetabular revision.

At final followup the average Harris hip score was 92 (range, 62–100). Fifty-seven patients with 66 hips (67%) had no pain, and 19 patients with 22 hips (22%) had only slight pain. Six patients with six hips (6%) had mild or occasional pain. Four patients with four

hips (4%) had moderate pain. No patient had severe pain. Thigh pain was present in two patients with two hips (2%). The clinical outcome of 74 hips (76%) were graded excellent, 17 (17%) were rated good, six hips (6%) were rated fair, and one hip (1%) was rated poor.

In the one patient (one hip) with a poor hip score, a decrease in function from an unrelated medical cause primarily was responsible. This patient currently is undergoing chemotherapy for metastatic cancer. Among the six patients (six hips) with a fair hip rating, a decrease in function from acetabular revision primarily was responsible in all six patients.

No support was required in 72 patients with 87 hips (89%). Eight patients with nine hips (9%) required a cane for long walks. One patient with one hip (1%) required a cane full time. One patient with a unilateral procedure (1%) required two crutches to ambulate as a permanent restriction secondary to acetabular allografting. Seventy-six patients with 90 hips (92%) could walk six blocks or greater. Six patients with eight hips (8%) could walk two to three blocks. At the time of last followup, nine patients with 12 hips were engaged in strenuous manual labor, 30 patients with 35 hips were involved in moderate manual labor, 29 patients with 32 hips were performing light labor, 12 patients with 17 hips were semisedentary, and two patients with two hips were sedentary.

Radiographs were obtained on all 98 total hip arthroplasties that had not undergone femoral component revision (Fig 2). Radiolucencies in the porous-coated region of the femoral component occurred in 16 (16%) hips, most commonly in Zone 1 on the AP radiograph (Fig 3). Stress shielding occurred in 72 (73%) hips. However, in 71 (99%) the stress shielding was first or second degree. In one (1%) hip, it was third degree. The immediate postoperative radiographs revealed 50 (51%) hips had a neutral stem position; 32 (33%) hips were in valgus, and 16 (16%) hips were in varus. No statistically significant relationship was found between osteolysis and initial femoral component alignment.

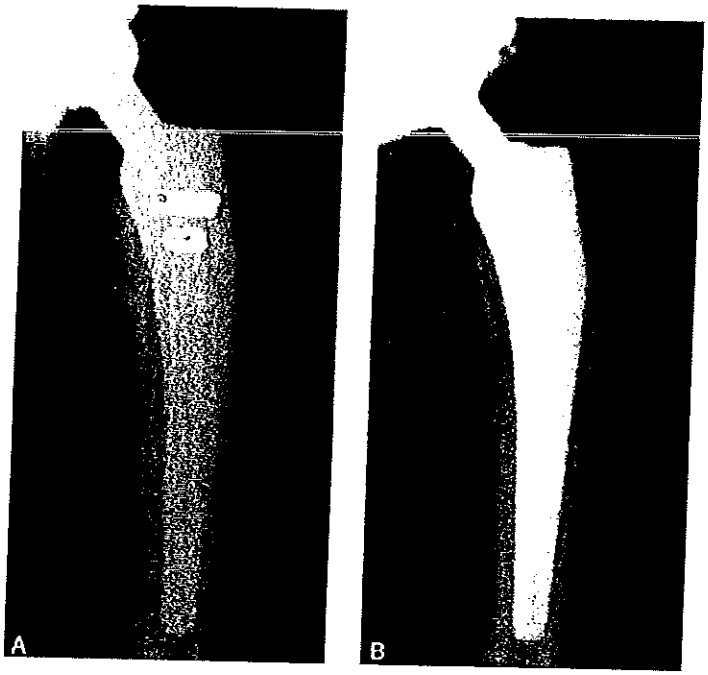

Fig 2A–B. (A) Anteroposterior radiograph of a 32-year-old woman shortly after surgery. (B) At 13 years, the femoral component remains well fixed and without osteolysis.

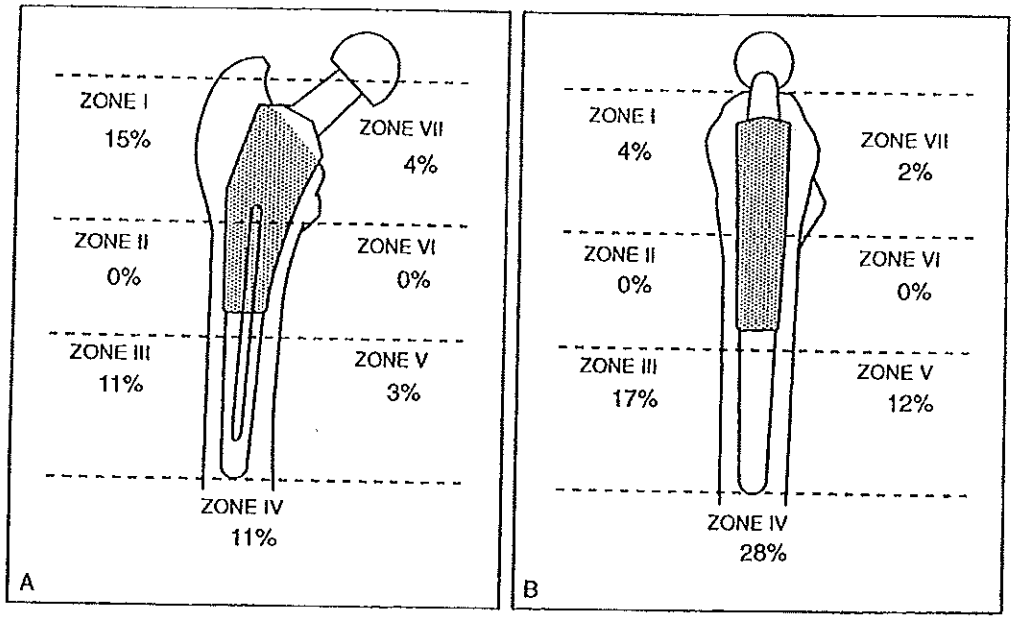

Fig 3A–B. (A) The prevalence and site of radiolucent lines in the porous and nonporous coated regions on the anteroposterior radiographs. (B) The prevalence and site of radiolucent lines in the porous and nonporous coated regions on the lateral radiograph.

In the 98 hips that had not undergone revision of the femoral component, femoral cortical osteolysis was present in seven (7%). Major osteolysis occurred in only one (1%) hip. Osteolysis involved one Gruen zone in five hips, two Gruen zones in one hip, and three Gruen zones in the one hip with major osteolysis (Fig 4). In the seven total hip arthroplasties (seven patients) in which femoral osteolysis occurred, five were in male patients and two were in female patients. This difference was not statistically significant. Three femoral components with osteolysis were in patients involved in strenuous manual labor. Four femoral components with osteolysis were in patients categorized as performing moderate manual labor. None of the total hip arthroplasties in patients who were sedentary, semisedentary, or involved in light manual labor had femoral osteolysis (Table 1). This difference was statistically significant ($p < 0.05$). The incidence of femoral osteolysis in hips associated with compression molded polyethylene was 0% (0 of 35). In the 63 hips in which ram extruded bar stock polyethylene was used, femoral osteolysis occurred in 11% (seven of 63). This difference was statistically significant ($p < 0.05$). The average followup of total hip arthroplasties performed with compression molded polyethylene was 12.2 years, compared with 9.6 years for those associated with ram extruded polyethylene. Thus, a greater incidence of femoral osteolysis occurred in a shorter time in total hip arthroplasties in which ram extruded polyethylene was used.

Pulmonary emboli developed in two patients after surgery; both were treated medically and resolved.

Although not the focus of this review, the acetabular components were evaluated. Fifty-six (56%) acetabular components required revision surgery and 44 (44%) remained in place. In the 44 acetabular components that

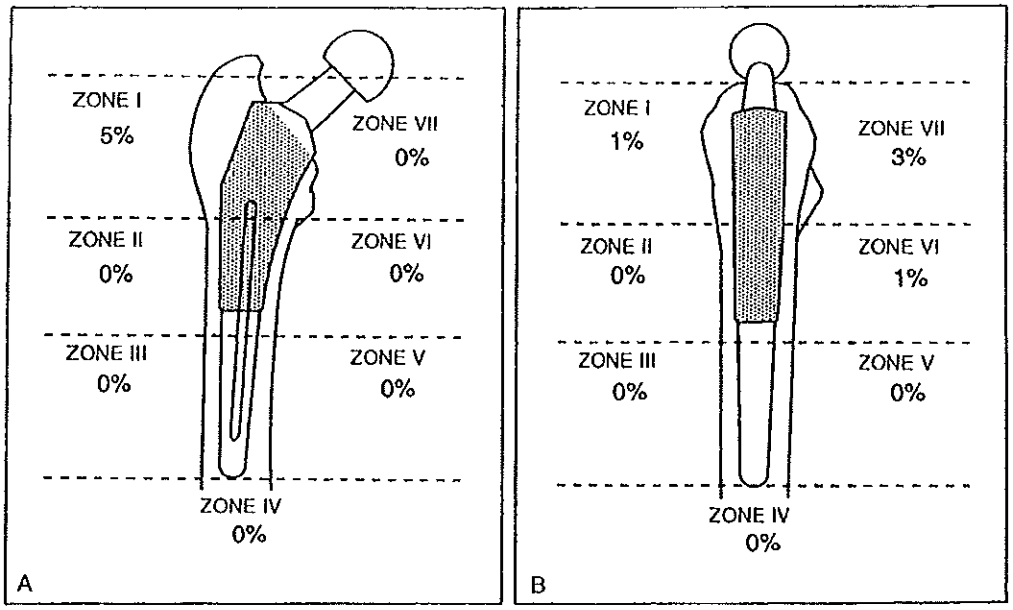

Fig 4A–B. (A) The prevalence and site of osteolysis in the porous and nonporous coated regions on the anteroposterior radiograph. (B) The prevalence and site of osteolysis in the porous and nonporous coated regions on the lateral radiograph.

had not been revised, osteolysis occurred in 11 (25%). No statistically significant relationship between acetabular revision and femoral component revision or osteolysis was found.

DISCUSSION

In this series using a femoral component inserted without cement, only 2% required revision for any reason, and lysis was present in 7%. Ninety-eight percent of the femoral components remained in place and rigidly fixed at 10 years. These results show that an uncemented femoral component with a taper design can achieve stable fixation and minimal lysis in young patients requiring total hip arthroplasty.

The initial results of cemented total hip arthroplasty in young patients were poor. Chandler et al[8] reported a 21% incidence of aseptic loosening of the femoral component in patients 30 years of age or younger followed up for only 5 years. Gustilo and Burnham[16] reported their results in patients 60 years of age and younger. They found a 22% incidence of aseptic loosening of the femoral component and a 10% incidence of revision at only 6.8 years.

TABLE 1. Level of Activity and Femoral Osteolysis

Classification	Number of Hips	Femoral Osteolysis (Number of Hips)
Heavy manual labor	12 (12%)	3
Moderate manual labor	35 (36%)	4
Light labor	32 (33%)	0
Semisedentary	17 (17%)	0
Sedentary	2 (2%)	0
Bedridden	0 (0%)	0

The advent of modern cementing techniques has significantly increased the duration of fixation of the femoral component in young patients. Barrack et al[3] reported their results in 50 patients 50 years of age or younger. Three (6%) femoral components had undergone revision and one (2%) femoral component was considered loose by radiographic criteria. Ninety-two percent remained in place and well fixed at 12 years. Callaghan et al[7] evaluated the results in patients younger than 50 years old and found a 5% incidence of aseptic loosening of the femoral component (five of 93) and an 8% incidence of revision (seven of 93) at 20 to 25 years. Lehtimaki et al[24] found a 91.9% survivorship of the femoral component at 15 years in patients whose average age was 31 years.

However, not all reports using improved cement technique in young patients have equaled these results. Analyzing the results using second generation cementing techniques, Smith et al[33] cited revision of eight of 51 (16%) femoral components in patients 50 years of age or younger at 17 to 20 years. Sporer et al[34] reported on the results at 8.2 years after using third generation cementing technique in patients younger than 50 years old. Eight (18%) of 45 precoated, grit blasted femoral components had been revised for aseptic loosening, and three (11%) were loose by radiographic criteria. Muldoon et al[27] evaluated their results using modern cementing technique in patients 40 to 60 years of age. At 10.5 years, six of 88 (7%) of the femoral components required revision for aseptic loosening, and 19% were loose by radiographic criteria. They reported a deterioration in femoral component fixation after the 10-year mark.

There are few reports available on the long-term results using uncemented femoral components in young patients. In a series of 242 hips using the Anatomic Medullary Locking (DePuy) femoral component, Glassman et al[13] reported a mechanical failure rate of 3.7% in patients 50 years of age or younger at an 8-year average followup. Femoral osteolysis occurred in 18%. The Tri-lock femoral component, which has a flat tapered shaped geometry nearly identical to the Taperloc, was evaluated by Olcott et al[29] at 10 to 15 years. In patients 60 years of age and younger, they found a 2% incidence of aseptic loosening and a 17.8% incidence of femoral osteolysis (Table 2).

The 7% incidence of femoral osteolysis in this series is low. The intermediate-term incidence of femoral osteolysis reported using several uncemented femoral components has ranged from 10% to 56%.[4,5,14,17,21,22,36,37] In the authors' opinion, two factors may be responsible for this low incidence of osteolysis. First, the stable fixation achieved with the taper design. This observation is based on the increased incidence of osteolysis found in total hip arthroplasties associated with aseptic loosening.[25,31] The second factor was the polyethylene. Direct compression molded polyethylene was used in 36% of the hips in this series. The incidence of femoral cortical osteolysis in those hips associated with compression molded polyethylene was 0%. The incidence of femoral cortical osteolysis in the hips that were associated with ram extruded bar stock polyethylene was 11%. In a retrieval study previously reported by Lee et al,[23] compression molded polyethylene showed significantly less wear than did ram extruded bar stock polyethylene. Compression molded polyethylene also was found to have a lower wear rate than did ram extruded bar stock polyethylene in studies performed by Bankston et al[2] and Clark et al.[9] The current authors think the decreased wear of compression molded polyethylene used in 36% of the hips in this series resulted in a lower overall incidence of osteolysis.

The results of the current study using the Taperloc femoral component in patients 50 years of age or younger are comparable with the best results reported using femoral components inserted with and without cement.[3,7,13,29] In addition, 39 patients with 47 hips (48%) were found to be in the moderate to strenuous manual labor activity classification. At 10 years' average followup in this young and active group, no femoral component required re-

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TABLE 2. Results of Cemented and Uncemented Femoral Components in Young Patients

Authors	Stem	Average Followup (Range)	Average Age (Range)	Number of Patients (Hips)	Femoral Revision (Percentage)	Radiographic Loosening (Percentage)	Osteolysis (Percentage)
Cemented Total Hip Replacement							
Barrack et al[3]	CAD HD2 Calcar	12 years (10–16.8)	40.9 years (18–50)	44 (50)	6%	2%	12%
Ballard et al[1]	Charnley Iowa	11 years (10–15)	41 years (18–49)	36 (42)	5%	12%	29% (26% in Zone 7)
Callaghan et al[7]	Charnley	23.3 years (20–25)	42 years (18–49)	69 (93)	5%	8%	20% (14% in Zone 7)
Chandler et al[8]	NR	5.6 years (4.8–7)	23 years (14–30)	29 (33)	15%	6%	NR
Dorr et al[10]	Charnley Charnley-Muller Aufrance Turner LeGrange-Letournel	16.2 years (13–20)	31.1 years 16–45)	35 (49)	49%	6%	NR
Sporer et al[34]	Precoated Iowa	8.2 years (5–11)	41 years (26–49)	37 (45)	18%	8%	3% Zone 1 5% Zone 3 8% Zone 4 5% Zone 5 35% Zone 7
Uncemented Total Hip Replacement							
Glassman et al[13]	AML	8 years (5–15.2)	NR (50 years and younger)	NR (242)	NR	3.7% MFR	18.1%
Olcott et al[25]	Trilock	NR (10–15)	48 years (NR)	NR (46)	2.2%	0%	17.8%
Current authors	Taperloc	10.2 years (8–13)	37 years (20–50)	84 (100)	2%	0%	7%

NR = not reported; MFR = mechanical failure rate.

vision for aseptic loosening, and none was loose by radiographic criteria. Femoral osteolysis occurred in 7%. Major lysis occurred in only 1%. These results support the continued use of this implant in young patients.

References

1. Ballard WT, Callaghan JJ, Sullivan PM, Johnston RC: The results of improved cementing techniques for total hip arthroplasty in patients less than fifty years old. A ten-year follow-up study. J Bone Joint Surg 76A:959–964, 1994.
2. Bankston AB, Keating EM, Ranawat C, Faris PM, Ritter MA: Comparison of polyethylene wear in machined versus molded polyethylene. Clin Orthop 317:37–43, 1995.
3. Barrack RL, Mulroy Jr RD, Harris WH: Improved cementing techniques and femoral component loosening in young patients with hip arthroplasty. A 12-year radiographic review. J Bone Joint Surg 74B:385–389, 1992.
4. Beauchesne RP, Engh CA, Knezevich S, Suthers K, Kukita Y: Roentgenographic evaluation of the AML porous coated acetabular component: A six year minimum follow-up study. Orthop Trans 16:834, 1992–1993.
5. Beauchesne RP, Kukita Y, Knezevich S, Suthers K: Roentgenographic evaluation of the AML porous

coated acetabular component: A six year minimum follow-up study. Orthop Trans 16:749, 1992–1993.
6. Burt CF, Garvin KL, Otterberg ET, Jardon OM: A femoral component inserted without cement in total hip arthroplasty. A study of the Tri-Lock component with an average ten-year duration of follow-up. J Bone Joint Surg 80A:952–959, 1998.
7. Callaghan JJ, Forest EE, Olejniczak JP, Goetz DD, Johnston RC: Charnley total hip arthroplasty in patients less than fifty years old. A twenty to twenty-five year follow-up note. J Bone Joint Surg 80A:704–714, 1998.
8. Chandler HP, Reineck FT, Wixson RL, McCarthy JC: Total hip replacement in patients younger than thirty years old: A five-year follow-up study. J Bone Joint Surg 63A:1426–1434, 1981.
9. Clark IC, Johnson SA, Philpatanakul W, Gustafson A: Hip simulator wear comparisons of UHMWPE cup processing: Extruded and gamma sterilized (air) vs molded and irradiated (Argon). Trans Orthop Res Soc 22:142, 1997.
10. Dorr LD, Kane TJ, Conaty JP: Long-term results of cemented total hip arthroplasty in patients 45 years old or younger. J Arthroplasty 9:453–456, 1994.
11. Dorr LD, Takei GL, Conaty JP: Total hip arthroplasties in patients less than forty-five years old. J Bone Joint Surg 65A:474–479, 1983.
12. Engh CA, Bobyn JD, Glassman AH: Porous-coated hip replacement. The factors governing bone ingrowth, stress shielding and clinical results. J Bone Joint Surg 69B:45–55, 1987.
13. Glassman AH, Engh CA, Culpepper Jr WJ: Cementless total hip replacement in patients fifty years of age and younger—A five year minimum follow up study. Orthop Trans 20:139, 1996.
14. Goetz DD, Smith EJ, Harris WH: The prevalence of femoral osteolysis associated with components inserted with and without cement in total hip replacements. J Bone Joint Surg 76A:1121–1129, 1994.
15. Gruen TA, McNeice GM, Amstutz HC: 'Modes of failure' of cemented stem-type femoral components: A radiographic analysis of loosening. Clin Orthop 141:17–27, 1979.
16. Gustilo RB, Burnham WH: Long-Term Results of Total Hip Arthroplasty in Young Patients. In Nelson JP (ed). The Hip. Proceedings of the Tenth Open Scientific Meeting of the Hip Society. St Louis, CV Mosby 27–33, 1982.
17. Haddad Jr RJ, Skalley TC, Cook SD, et al: Clinical and roentgenographic evaluation of noncemented porous-coated anatomic medullary locking (AML) and porous-coated anatomic (PCA) total hip arthroplasties. Clin Orthop 258:176–182, 1990.
18. Harris WH: Traumatic arthritis of the hip after dislocation and acetabular fractures: Treatment by mold arthroplasty: An end-result study using a new method of result evaluation. J Bone Joint Surg 51A:737–755, 1969.
19. Heekin RD, Callaghan JJ, Hopkinson WJ, Savory CG, Xenos JS: The Porous-Coated Anatomic total hip prosthesis inserted without cement. Results after five to seven years in a prospective study. J Bone Joint Surg 75A:77–91, 1993.
20. Johnston RC, Fitzgerald RH, Harris WH, et al: Clinical and radiographic evaluation of total hip replacement. A standard of terminology for reporting results. J Bone Joint Surg 72A:161–168, 1990.
21. Kim YH, Kim VE: Uncemented porous-coated anatomic total hip replacement. Results at six years in a consecutive series. J Bone Joint Surg 75B:6–13, 1993.
22. Kim YH, Kim VE: Cementless porous-coated anatomic medullary locking total hip prostheses. J Arthroplasty 9:243–252, 1994.
23. Lee KR, James SP, McLaughlin JR, Beauregard GP, Cox ED: Direct compression molded versus RAM extruded bar stock polyethylene: A wear rate analysis of surgically retrieved cementless acetabular components at 8 years. Orthop Trans 21:169, 1997.
24. Lehtimaki MY, Lehto MU, Kautiainen H, Savolainen HA, Hamalainen MM: Survivorship of the Charnley total hip arthroplasty in juvenile chronic arthritis. A follow-up of 186 cases for 22 years. J Bone Joint Surg 79B:792–795, 1997.
25. Maloney WJ, Jasty M, Harris WH, Galante JO, Callaghan JJ: Endosteal erosion in association with stable uncemented femoral components. J Bone Joint Surg 72A:1025–1034, 1990.
26. McLaughlin JR, Lee KR: Total hip arthroplasty with an uncemented femoral component. Excellent results at ten-year follow-up. J Bone Joint Surg 79B:900–907, 1997.
27. Muldoon MP, Berry DJ, Harmsen WS: Cemented total hip arthroplasty using contemporary cementing techniques in patients 40–60 years old: A 10–15 year follow-up study. Orthop Trans 21:85, 1997.
28. Mulliken BD, Bourne RB, Rorabeck CH, Nayak N: A tapered titanium femoral stem inserted without cement in a total hip arthroplasty. Radiographic evaluation and stability. J Bone Joint Surg 78A:1214–1223, 1996.
29. Olcott CW, Pellegrini Jr VD, Evarts CM: Long-term follow-up of total hip arthroplasty with a cementless femoral component in young patients at a minimum of 10 years: A clinical and radiographic analysis. Orthop Trans 21:86, 1997.
30. Pellegrini Jr VD, Hughes SS, Evarts CM: A collarless cobalt-chrome femoral component in uncemented total hip arthroplasty. J Bone Joint Surg 74B:814–821, 1992.
31. Perren SM: The Induction of Bone Resorption by Prosthetic Loosening. In Morscher E (ed). The Cementless Fixation of Hip Endoprostheses. New York, Springer 39–41, 1984.
32. Ranawat CS, Atkinson RE, Salvati EA, Wilson Jr PD: Conventional total hip arthroplasty for degenerative joint disease in patients between the ages of forty and sixty years. J Bone Joint Surg 66A:745–752, 1984.
33. Smith SE, Estok DM, Harris WH: Twenty year experience with cemented primary and conversion total hip arthroplasty using so-called second generation cementing techniques in patients 50 years of age or less. Orthop Trans 21:85, 1997.
34. Sporer SM, Callaghan JJ, Olejiniczak JP, Goetz DD, Johnston RC: The effects of surface roughness and polymethylmethacrylate precoating on the radio-

graphic and clinical results of the Iowa hip prosthesis. J Bone Joint Surg 81A:481–492, 1999.
35. Sullivan PM, MacKenzie JR, Callaghan JJ, Johnston RC: Total hip arthroplasty with cement in patients who are less than fifty years old. J Bone Joint Surg 76A:863–869, 1994.
36. Weidenhielm LR, Mikhail WE, Nelissen RG, Bauer TW: Cemented collarless (Exeter-CPT) versus cementless collarless (PCA) femoral components. A 2- to 14-year follow-up evaluation. J Arthroplasty 10:592–597, 1995.
37. Xenos JS, Heeken RD, Hopkinson WJ, Callaghan JJ: Osteolysis following uncemented total hip replacement. Orthop Trans 16:834, 1992–1993.

EFFECT OF FEMORAL OFFSET ON RANGE OF MOTION AND ABDUCTOR MUSCLE STRENGTH AFTER TOTAL HIP ARTHROPLASTY

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At a minimum of one year after operation, we studied 64 patients with 86 total hip arthroplasties (THA) by standard anteroposterior hip and pelvic radiographs and measurement of range of motion and of isometric abduction strength.

The femoral offset correlated positively with the range of abduction ($p = 0.046$). Abduction strength correlated positively with both femoral offset ($p = 0.0001$) and the length of the abductor lever arm ($p = 0.005$). Using multiple regression, abduction strength correlated with height ($p = 0.017$), gender ($p = 0.0005$), range of flexion ($p = 0.047$) and the abductor lever arm ($p = 0.060$).

Our findings suggest that greater femoral offset after THA allows both an increased range of abduction and greater abductor strength.

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There has been recent interest in femoral offset as a factor in total hip arthroplasty (THA) (Yanagimoto 1991; Abraham and Dimon 1992; Steinberg and Harris 1992; Davey et al 1993; Rothman et al 1993; Wong et al 1993). Femoral offset is defined as the perpendicular distance between the long axis of the femur and the centre of rotation of the femoral head. Charnley (1979) considered it to be a factor under the control of the surgeon at the time of hip replacement surgery; the more lateral position of the femur with greater offset was said to increase the range of motion and decrease the incidence of impingement of the femur on the pelvis. An increase in femoral offset (and consequently of the lever arm of the abductor muscles) will also, theoretically, increase the mechanical advantage and strength of the abductors. Finally, a greater femoral offset will increase stability by preventing impingement and improving soft-tissue tension.

Femoral offset has been shown to correlate with hip stability (Fackler and Poss 1980; Huk et al 1993), but we know of no clinical study which has related the range of motion or abduction strength to femoral offset after THA. We therefore reviewed 64 consecutive patients at a minimum of one year after surgery in an attempt to answer these questions.

PATIENTS AND METHODS

We reviewed 64 patients who had a total of 86 THAs by one of two surgeons (BFM, MEC) at a minimum of one year (mean one year nine months, range one year to three years two months) after surgery, by radiography, examination, and standard abductor strength testing. The number of joint replacements included was based on a power analysis calculation (see statistical section). The minimum follow-up was chosen because results for THA have been shown to stabilise at one year (Insall et al 1983; Schurman, Parker and Ornstein 1985; Parsley, Engh and Dwyer 1992). We excluded patients with a diagnosis of rheumatoid arthritis to avoid confounding factors in strength measurements. Patients who would have had to travel more than 500 miles were also excluded; the one-year assessment for such patients is often carried out locally.

The patients had been operated on over a two-year period, from 1988 to 1989, during which 263 THAs (excluding patients with a diagnosis of rheumatoid arthritis) had been performed by the two surgeons. Informed consent was obtained and the project and consent process were approved by the IRB of the Mayo Clinic.

There were 36 women and 28 men and the median age was 60 years (22 to 87). Their average weight and height were 77.7 kg (44.5 to 109.1) and 168 cm (140 to 190). All were seen in follow-up from April 1, 1989 to April 1, 1993 and no evaluations were excluded. The right hip had been replaced in 48 (55.8%) and the left in 38. The diagnosis was osteoarthritis in 57 (66.3%), post-traumatic deformity

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in nine (10.5%), developmental dysplasia in nine (10.5%), avascular necrosis in five (5.8%), Paget's disease in two (2.3%), arthritis following slipped capital femoral epiphysis in two, and systemic lupus erythematosus in two. There were 70 primary and 16 revision operations. Eighteen (20.9%) femoral components were cemented and 68 uncemented. An anterolateral approach was used in 32 (37.2%) and a posterior approach in 54; trochanteric osteotomy was not used. A variety of femoral prostheses was employed. There were 34 (39.5%) Osteonics Omnifit (Osteonics Corp, Allendale, New Jersey), 14 (16.3%) Osteonics Omniflex, 13 (15.1%) Zimmer Mayo-Morrey (Zimmer Inc, Warsaw, Indiana), 7 (8.2%) Zimmer Harris precoat, 5 (5.8%) Zimmer Harris-Galante, 5 (5.8%) Zimmer Bias, and eight other prostheses (9.3%) of varying design chosen by the surgeon.

Radiological assessment. Anteroposterior pelvic and hip radiographs were taken on the day of examination using a 100 mm magnification marker with the ankles 20 cm apart and the feet 15° internally rotated. The femoral offset and the abductor lever arm were measured by a single observer (BJM) from each radiograph (Fig. 1). In addition, the distance from the centre of rotation of the femoral head to a vertical line through the symphysis pubis was recorded as the body-weight lever arm. These measurements were then corrected for magnification.

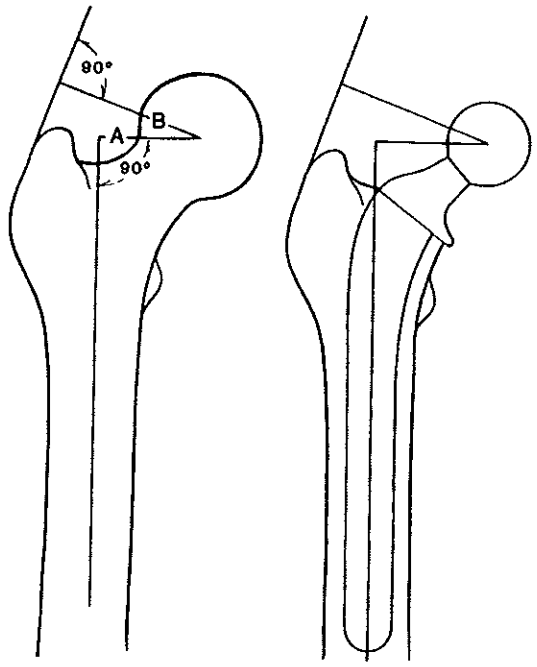

Fig. 1

Diagram showing measurements of femoral offset (A) and the abductor lever arm (B). Femoral offset is the perpendicular distance from the centre line of the femur to the centre of rotation of the femoral head. Abductor lever arm is the perpendicular distance from a line tangential to the greater trochanter to the centre of rotation of the femoral head. The tangential line corresponds to the abductor shadow on the radiograph (from Steinberg and Harris 1992, with permission).

Functional assessment. A complete examination included the recording of the patients' height, weight, and maximum thigh circumference on the affected side.

Motion. The ranges of motion in flexion, abduction, adduction, internal rotation, and external rotation were measured using a goniometer by a single observer (TDC).

Strength. Three measurements of isometric abduction strength at 0° (neutral) were made for each THA by the method previously described (Cahalan et al 1989). A Cybex II isokinetic dynamometer (Lumex, Ronkonkoma, New York) was modified to allow adjustment of the loading level arm to provide a comfortable position for the patient and maximal stability to produce optimal strength. A body stabilisation frame was developed and used to allow subjects to stand with support when testing abduction strength. The Cybex machine was calibrated at weekly intervals. We used the numerical average of three measurements as the abductor strength for data analysis.

Statistical analysis. A power analysis showed that a study of 84 THAs should provide at least an 80% chance (statistical power) of detecting any correlation between offset and range of motion or strength, accepting an r value of 0.30. Linear regression beta coefficients and corresponding probability using StatView software (Abacus Concepts Inc, Berkeley, California) were determined for femoral offset versus range of motion, and for abduction strength versus gender, age, diagnosis, revision, surgical approach, component fixation, height, weight, thigh circumference, offset, abduction lever arm, time from surgery, and body-weight lever arm. We then used multiple regression to determine which of the variables found to have significant interrelationships were the most important.

RESULTS

Radiological assessment. The corrected femoral offset averaged 3.9 cm (2.3 to 5.5), the abductor lever arm averaged 4.8 cm (3.4 to 7.1) and the body-weight lever arm averaged 9.2 cm (7.8 to 10.7).

Femoral offset correlated positively with the length of the abductor lever arm ($p = 0.0001$; $r = 0.43$; Fig. 2). The body-weight lever arm did not correlate with either offset or the abduction lever arm.

Functional assessment

Motion. The average range of motion with range and standard deviation is shown in Table I. Simple regression analysis showed that femoral offset was significantly and positively related to range of abduction ($p = 0.046$; $r = 0.22$; Fig. 3). We could demonstrate no significant correlation between femoral offset and hip flexion, adduction, or internal or external rotation.

Strength. There was a highly significant positive correlation between femoral offset (and consequently abductor lever

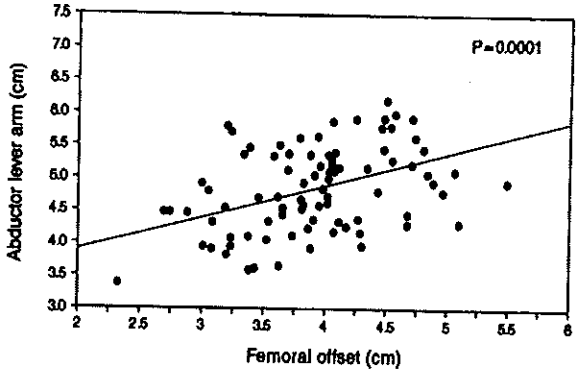

Fig. 2

Femoral offset related to length of abductor lever arm.

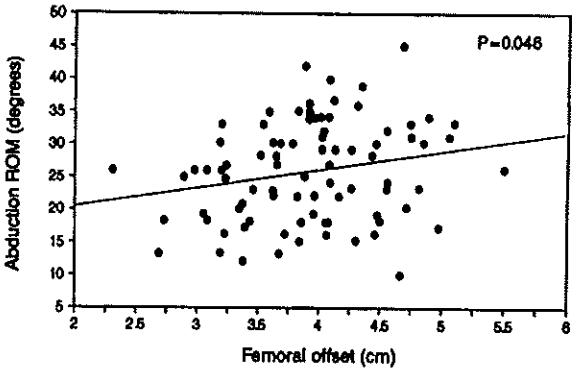

Fig. 3

Femoral offset related to range of abduction.

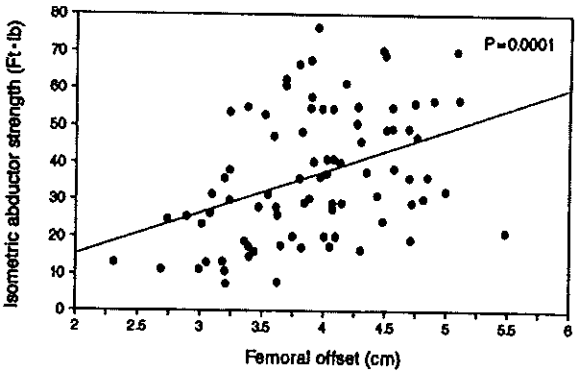

Fig. 4

Femoral offset related to isometric abductor strength.

Table I. Range of hip motion after THA in degrees

	Average	Range	Standard deviation
Flexion	99.8	48 to 121	15.3
Abduction	25.7	10 to 45	7.7
Adduction	19.8	8 to 35	5.7
Internal rotation	26.5	7 to 51	9.2
External rotation	24.9	6 to 48	8.1

Table II. Factors which correlated with strength of isometric abduction after THA by simple regression

	p value	r value
Patient height	0.0001	0.72
Patient gender (male > female)	0.0001	0.71
Femoral offset	0.0001	0.40
Abduction ROM*	0.0009	0.36
Patient weight	0.001	0.35
Flexion ROM*	0.004	0.32
Abductor lever arm	0.005	0.30
Patient diagnosis (OA† > others)	0.03	0.24

* range of motion
†osteoarthritis

arm) and abductor strength ($p = 0.0001$; $r = 0.40$; Fig. 4). The other factors which correlated with abductor strength are shown in Table II.

Additional variables and multivariate analysis. Abductor strength was not significantly related to side of arthroplasty, thigh circumference, use of cement for the femoral component, revision surgery, age, surgical approach, body-weight lever arm, and time from surgery. Multiple regression was used to determine the relative importance of each of the significant variables because a number of them were inter-related. The statistical data for each variable are presented in Table III. Of the four, only the length of the abductor lever arm is under the control of the surgeon.

DISCUSSION

The advantages of increasing femoral offset at THA are reported to include an increased range of motion, better mechanical advantage for the abductors and decreased instability because of better soft-tissue tension. Our study is the first, to our knowledge, to address the first two issues in a clinical setting.

Table III. Factors which correlated with strength of isometric abduction after THA by multiple regression analysis

	Standardised coefficient	p value	r value
Patient height	0.47	0.017	0.95
Patient gender (male > female)	0.44	0.0005	0.86
Femoral offset	0.030	0.74	0.67
Abduction ROM*	0.16	0.098	0.78
Patient weight	0.19	0.13	0.87
Flexion ROM*	0.18	0.047	0.74
Abductor lever arm	0.16	0.060	0.68
Patient diagnosis (OA† >others)	0.012	0.89	0.68

* range of motion
†osteoarthritis

The relationship between increasing femoral offset and stability after hip arthroplasty has been shown (Fackler and Poss 1980; Huk et al 1993). In our series there was a single postoperative dislocation (1.1%) in a patient with an absolute offset of 4.1 cm (series average 3.9 cm). We can therefore make no definitive statement on hip stability.

The lateral position of a hip with greater offset has been said to allow an increase in motion (Charnley 1979; Kelikian et al 1983) and we found that range of abduction was significantly greater in patients with greater femoral offset ($p = 0.046$). We could not, however, show any correlation with other planes of motion.

Charnley considered that the most effective method available to the surgeon to improve the abductor lever arm, and therefore the biomechanics, was to increase the offset. This should decrease the abductor force required for walking, and therefore decrease the energy requirement for gait as well as the overall joint reactive force.

Other authors have inferred that this relationship is true from apparent abductor weakness and lurch evident in patients with poor offset (Tauber et al 1980; Kelikian et al 1983; Rothman et al 1993). We identified a variety of factors that correlated with abductor strength after THA, among which were femoral offset ($p = 0.0001$) and the length of the abductor lever arm ($p = 0.005$). Multiple regression showed that the four most important factors in abductor strength after THA were height, gender, range of flexion, and abductor lever arm (Table III). All the other factors found to be significant by simple regression analysis were related to these four.

The advantages of increased stability, range of motion, and abduction strength are conferred by an increased femoral offset, but a possible disadvantage is an increase in the out-of-plane bending moment in the prosthesis. This effect in the stem is generally not important in modern THAs because of the increased fatigue resistance of currently used metals (Steinberg and Harris 1992). An increase in offset, however, could cause increased strain in the medial proximal femur, and more particularly in the medial proximal bone cement in cemented cases.

These potential concerns have been allayed by two recent scientific reports. Davey et al (1993) loaded cadaver femora containing cemented femoral components in simulated gait. Direct measurements of strain were made using strain gauges on the bone and the metal as well as in the cement mantle. It was possible to quantify the effect of changing offset on both abductor force and the resultant force, as well as on the strains in the cement, the bone and the prosthesis. Increased femoral offset gave substantial reductions in both abductor and resultant forces, and the strain in the proximal medial cement mantle was not significantly increased. Wong et al (1993) used finite-element analysis and a canine uncemented THA model to demonstrate that both the abductor force and hip reaction force were significantly reduced with an increase in offset. Although stress was slightly higher at the distal portion of the stem it did not produce an excessive increase in bone strains. In addition, the amount of bone ingrowth was not affected by a change in femoral offset. Both reports indicate that the adverse effect of an increasing bending moment was neutralised by a reduction in hip force.

Despite these experimental results, the clinical concern of increasing femoral component loosening has been expressed by Rothman et al (1993). They showed a 6% rate of loosening in femora with implant offset of 38 mm or more, against a 2% rate in those with less offset, in 146 patients followed for two to six years. These results must be interpreted cautiously; there were only five loose stems overall, there were significantly more males in the high-offset group, and the actual femoral offset was not reported, only the prosthesis offset. This is obviously important in that varus or valgus prosthesis positioning affects actual femoral offset.

Our data allow us to compare the abduction strength after THA with that for normal volunteers, previously reported (Cahalan et al 1989). We demonstrated the significant relationship of gender to strength, but could not identify the age-dependent relationship evident in normal volunteers. We believe that this was because all but one patient in our study would be in the 'older group' of the series by Cahalan et al (1989) (over 40 years of age). Of the anthropomorphic measurements reported in both studies, height had the greatest correlation. When gender-specific abduction strength is compared between normal volunteers and THA patients the latter have lower actual strengths by an average of 24.6% for men and 37.8% for women. This may be due to actual age difference, the effect of underlying diagnoses, the effect of surgery, or other factors.

Conclusions. We have shown that femoral offset correlated positively with increase in range of abduction and that objective strength of abduction correlated positively with both femoral offset and the length of the abductor lever arm.

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REFERENCES

Abraham WD, Dimon JH III. Leg length discrepancy in total hip arthroplasty. *Orthop Clin North Am* 1992;23:201-9.

Cahalan TD, Johnson ME, Liu S, Chao EY. Quantitative measurements of hip strength in different age groups. *Clin Orthop* 1989;246: 136-45.

Charnley J. Low friction principle. In: Charnley J. *Low friction arthroplasty of the hip.* New York: Springer-Verlag, 1979:3-15.

Davey JR, O'Connor DO, Burke DW, Harris WH. Femoral component offset: its effect on strain in bone-cement. *J Arthroplasty* 1993; 8:23-6.

Fackler CD, Poss R. Dislocation in total hip arthroplasties. *Clin Orthop* 1980;151:169-78.

Huk OL, Braun JT, Lieberman JR, Salvati EA, Ghelman B. Comparison of acetabular and femoral component alignment in dislocators versus nondislocators with total hip arthroplasties. Procs Canadian Orthopaedic Society, 48th Annual Meeting, Montreal, Quebec, June 1993.

Insall JN, Hood RW, Flawn LB, Sullivan DJ. The total condylar knee prosthesis in gonarthrosis: a five to nine-year follow-up of the first one hundred consecutive replacements. *J Bone Joint Surg [Am]* 1983;65-A: 619-28.

Kelikian AS, Tachdjian MO, Askew MJ, Jasty M. Greater trochanteric advancement of the proximal femur: a clinical and biomechanical study. In: Hungerford DS, ed. *The Hip.* Procs of the eleventh open scientific meeting of the Hip Society. St Louis: CV Mosby, 1983:77-105.

Parsley BS, Engh GA, Dwyer KA. Preoperative flexion: does it influence postoperative flexion after posterior-cruciate-retaining total knee arthroplasty? *Clin Orthop* 1992;275:204-10.

Rothman RH, Hearn SL, Eng KO, Hozack WJ. *The effect of varying femoral offset on component fixation in cemented total hip arthroplasty. Poster:* American Academy of Orthopaedic Surgery 60th Annual Meeting, San Francisco, CA, February 1993.

Schurman DJ, Parker JN, Ornstein D. Total condylar knee replacement: a study of factors influencing range of motion as late as two years after arthroplasty. *J Bone Joint Surg [Am]* 1985;67-A:1006-14.

Steinberg B, Harris WH. The 'offset' problem in total hip arthroplasty. *Contemp Orthop* 1992;24:556-62.

Tauber C, Ganel A, Horoszowski H, Farine I. Distal transfer of the greater trochanter in coxa vara. *Acta Orthop Scand* 1980;51:661-6.

Wong PKC, Otsuka NY, Davey JR, Fornasier VL, Binnington AG. The effect of femoral component offset in uncemented total hip arthroplasty. Procs Canadian Orthopaedic Society 48th Annual Meeting, Montreal, Quebec, June 1993.

Yanagimoto S. Basic study of cementless hip prosthesis design: analysis of the proximal femur in Japanese patients with osteoarthritis of the hip. *Nippon Seikeigeka Gakkai Zasshi* 1991;65:731-44.

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Minimum 10-Year Results of a Tapered Cementless Hip Replacement

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Seventy-one total hip arthroplasties with a cementless, wedge fit, cobalt chrome femoral component were reviewed in 60 patients at a minimum 10-year followup (mean, 11.5 years). For the femoral component, the mechanical failure rate was 5% and the revision rate for aseptic loosening was 0%. The mean Charnley scores for pain, function, and motion changed from preoperative mean values of 3.0, 2.7, and 3.2 to followup mean values of 5.7, 5.5, and 5.2, respectively. The followup mean Harris hip Score was 91. The incidence of thigh pain was 1.4% at 10-year followup. Ninety-five percent of femoral components showed radiologic evidence of stable, bone ingrowth fixation, whereas loosening was seen in 5% of stems. Despite the high incidence of acetabular osteolysis, no osteolysis was seen on the femoral side distal to the lesser trochanter. Nonmodularity of the femoral component led to unavoidable revision of stably fixed femoral components in seven (9.8%) hips during the revision of a loose socket. Design features (collarless, tapered, wedge fit, and circumferentially porous coated) were thought to be crucial to the superlative results with the cobalt chrome femoral component.

Despite the increasing use of uncemented total hip a rthroplasties during the last decade, no consensus exists regarding the ideal material of implant or ideal shape of the femoral component. Short term and midterm results of collarless, wedge fit, porous coated uncemented stem have been excellent regardless of type of metal.[14,16,17,23,27,31] However, only one report on long term experience with a wedge fit design is available using a titanium stem.[20] Long term, minimum 10-year results, with the use of a CoCr wedge fit, cementless femoral component for primary total hip arthroplasty are presented.

PATIENTS AND METHODS

Ninety total hip arthroplasties using the uncemented Trilock femoral component (DePuy, Warsaw, IN) were performed in 76 patients from 1983 through 1986 at one institution. The indications were younger, active patients and patients with good bone quality (Dorr Type A or B).[5] Nine patients (11 hips) died and seven patients (eight

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hips) were lost to followup before their 10-year followup, leaving 60 patients and 71 hips for review.

The demographics of this group included a mean age of 51.8 years (range, 25.2–69 years), mean weight of 177.2 pounds (range, 107–240 pounds), with 44 men and 16 women. Bone quality was classified as Dorr Type A in 21 hips and Type B in 50 hips. Of the 71 arthroplasties under review, 67 were primary, and four were conversion procedures (resurfacing arthroplasties). The mean followup was 11.5 years (range, 10–14 years). The preoperative diagnoses were osteoarthritis in 54, avascular necrosis in 16, and rheumatoid arthritis in one. Thirty-five cases were classified as Charnley Class A (involvement of only the ipsilateral hip); 31 were Charnley Class B (involvement of the contralateral hip); and five were Charnley Class C (involvement of other joints or systemic problems limiting activity).[3]

All acetabular components were cemented in place. The femoral component was monolithic and was available with only 32-mm heads. Femoral component insertion required minimal reaming. Only one reamer was used, which was of the size of the smallest broach in diameter. Its primary purpose was to sound the femoral canal. The femoral canal was prepared with hand driven broaches. The broaches were fully toothed and were designed to be slightly smaller than the size of the implant to provide a press fit. Testing of stability was not done scientifically. Rather, it was done by testing of the broach by rotating the broach handle. After a sequential broaching to a firm, snug fit, a trial smooth stemmed component was used to test for stability and leg lengths. Two neck lengths and a laterally offset femoral component were available. The final prosthesis, a straight stemmed collarless CoCr component, coated in proximal 60% was inserted with firm impaction. The Trilock Prosthesis (DePuy), which is made of CoCrMo alloy, has the proximal 60% of the stem circumferentially coated with CoCr sintered beads of average diameter of 150 μm (range, 100–250 μm) to form an irregular porous surface. The diameter of the empty spaces or pores ranged from 150 to 400 μm. The stem is flat in cross section anteroposteriorly with mediolateral wedging (Fig 1). After surgery, all patients were allowed only partial weightbearing for 6

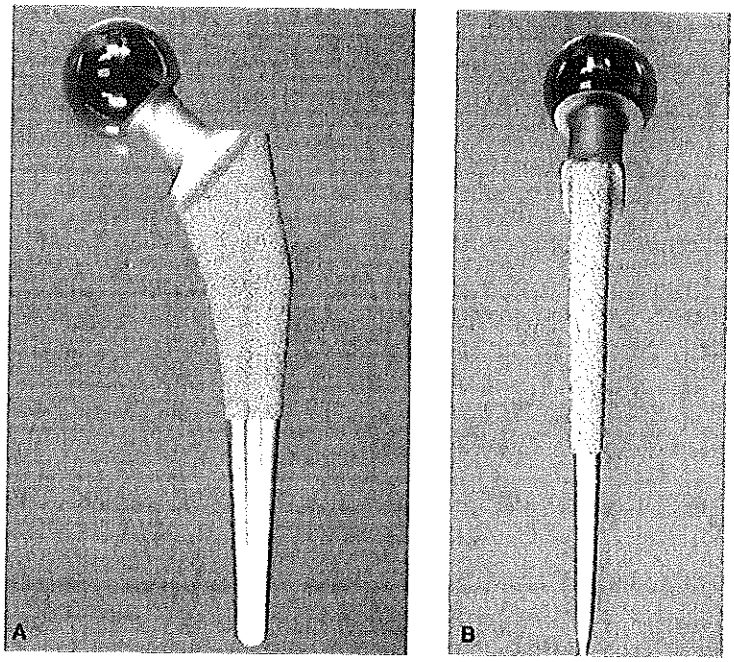

Fig 1A–B. (A) Front view of the monolithic Trilock femoral component (DePuy, Warsaw, IN). The circumferential porous coating made of CoCr sintered beads and the tapered shape with no collar can be seen. (B) Side view of the Trilock stem. The shape is thin and nonfilling.

weeks, and then were advanced to being fully weightbearing by 3 months.

Objective followup evaluation was performed by a specially trained research fellow. Clinical evaluations were performed before surgery, 6 weeks after surgery, and then yearly using the modified D'Aubigne and Postel scale.[9] Patients were questioned specifically regarding the level of pain, function, and motion using a grading system in which a score of six represents an excellent result, five a good result, and one a poor result. Patients were asked specifically about thigh or groin pain; the responses were recorded as present or absent. The presence of a limp also was recorded. More recently, the Harris hip scoring System has been incorporated into the clinical evaluation.[11]

The radiologic evaluation in this study was done independently by a research fellow and by an attending orthopaedic surgeon who was not involved in the patient's surgery. An analysis showed no difference between the two interpretations for parameters, such as bone ingrowth, loosening, and osteolysis. However, cup wear analysis was performed by one observer (research fellow). During the repetitive measurement of wear in another study at the authors' center, the intraobserver variability was found to be 0.06 mm, and the interobserver variability was found to be 0.11 mm. Anteroposterior (AP) radiographs of the pelvis and hip and frog leg lateral radiographs of the hip were evaluated at the same intervals of the clinical examinations. Leg holders were used to position the limb accurately for sequential radiographic review. Magnification correction factors were calculated for each film based on the ratio of the measured diameter of the prosthesis head versus the actual known diameter.[9] Postoperative films were evaluated for ectopic bone according to the classification of Brooker et al,[1] and the trochanter was evaluated for union, nonunion, and if applicable, degree of separation.

Acetabular component position was identified in reference to the teardrop. The horizontal reference line was drawn by connecting the points at the bottom of both teardrops. A vertical reference line was drawn perpendicular to this, passing through the center of the teardrop. The acetabular cup angle was measured from the horizontal reference line. Any change in component position from the horizontal or vertical reference line of 3 mm or more or any change in cup angle of 3° or more was considered migration of the cup, a sign of definite cup loosening.[13] Acetabular component coverage by bone was computed as a percentage. Component bone radiolucency greater than 1 mm was assessed in the three zones as defined by DeLee and Charnley.[4] If a complete radiolucent line was present, the cup was considered to be probably loose.[13] Cup wear was assessed according to the technique of Livermore et al.[18] Each radiograph was measured by one observer to the nearest 0.1 mm using a caliper. This technique has been validated by Cates et al.[2]

Femoral component position was assessed using a fixed point of reference on the prosthesis and on the femur (using the lesser trochanter). Subsidence was present if the component settled 3 mm or more. Component orientation was neutral if the center lines of the component and femur were within 3°; otherwise, the component was designated as varus or valgus.

All changes around the cementless femoral component were documented using a system modified from that suggested by Engh et al.[6-8] This femoral interface was divided in two zones. Zone 1 is defined as the area around the porous surface of the femoral component, and Zone 2 lies distally around the smooth part of the stem.[15] Calcar changes, atrophy or hypertrophy, radiolucent lines, endosteal new bone formation near the prosthesis (spot welds), the presence of a distal pedestal, and an intramedullary shelf of new bone changes were evaluated according to the definitions described by Engh et al.[8] Proximity of the component to within 1 mm of endosteal bone was identified in each zone, and AP fill of the medullary bone by the component was measured at the junction of Zones 1 and 2 and expressed as a percentage. The primary sign of component instability was subsidence of 3 mm or more.

Other signs suggestive of instability were calcar hypertrophy, distal pedestal formation, and the development of progressively divergent radiolucent lines around the component.[28] Stress shielding was determined as per the classification of Engh et al[6] as (1) first degree, slight rounding off the proximal medial edge of the cut femoral neck; (2) second degree, rounding off the proximal medial femoral neck combined with loss of medial cortical density at level one on the AP radiograph; (3) third degree, extensive resorption of cortical bone extending from level one into level

two; and (4) fourth degree, extensive resorption of cortical bone beyond levels one and two, extending into the diaphysis. Femoral components were classified into three categories using the classification system of Engh et al[8]: (1) stable, bone ingrown; (2) stable fibrous ingrown; and (3) unstable. Presence of osteolysis was classified as per the seven zones of Gruen et al.[10] Statistical analysis was performed using the SAS System (The SAS Institute, Cary, NC), a statistical software program.

RESULTS

Clinical Results

The mean preoperative Charnley score for pain was 3.0, for function 2.7, and for motion 3.2. At final followup the mean scores were 5.7, 5.5, and 5.2, respectively. The mean postoperative Harris Hip Score was 91 (range, 27.7–99.9). Thigh pain was present in one (1.4%) patient at the latest followup. At the 2-year followup in the same group of patients, four (5.6%) patients had thigh pain. Medical complications included deep vein thromboses (three patients), asymptomatic pulmonary embolisms (three patients), arrhythmia (one patient), gout (one patient), ileus (one patient), and urinary retention (two patients). Orthopaedic complications included two patients with hematomas, two with delayed wound healing, and one with temporary femoral nerve injury. There were no intraoperative femoral splits or fractures. Nonmodularity of the femoral component led to unavoidable revision of a well fixed femoral component in seven (9.8%) hips during revision of a loose socket.

Radiologic Results

Complete radiologic evaluation (minimum 10-year followup that correlated with the latest clinical followup) was possible in 62 of the 71 hips. Of the remaining nine hips, five had radiologic followup of a mean of 8.2 years (range, 7.5–9.5 years) and four had radiologic followup of a mean of 4.5 years (range, 3–5.7 years). These nine hips showed radiologic evidence of bone ingrowth fixation of the stem. Acetabular osteolysis, loosening of the cup, and femoral osteolysis were not seen in any of the nine radiographs. Although it is possible to predict the stability of the femoral component after having achieved bone ingrowth fixation, it is impossible to predict the status of the acetabular component and features such as osteolysis and cup wear. Thus, the radiologic data of these nine hips from the group of 71 hips were excluded.

Numerous radiologic changes occurred around the femoral component. Subsidence greater than 3 mm was observed in six hips, but three of them showed radiologic evidence of bone ingrowth with no additional subsidence. Fifty-eight (95%) hips were classified as stable, bone ingrown; three (5%) as unstable; and none were classified as stable, fibrous ingrown. Thus, the mechanical failure rate for this stem at 10 years was 5%. None of the patients with unstable stems needed revision surgery, and none of them had thigh pain. There were no femoral revisions for aseptic loosening. None of the hips showed any osteolysis distal to the lesser trochanter. Osteolysis was observed above the level of the lesser trochanter in two hips (3.2%) in Gruen Zone 7. Stress shielding was seen in 59 (95%) hips. It was first degree in 17 (27%) hips, second degree in 33 (54%), and third degree in nine (14%). Trochanteric separation was seen in one patient. Grade 4 heterotropic ossification was seen in one hip. Definite cup loosening and acetabular osteolysis was seen in 41 (66.1%) hips. The mean polyethylene wear was 1.22 mm (range, 0.11–2.71 mm). Twenty-three (37.1%) sockets required revision secondary to aseptic loosening.

Analysis of Patients Who Were Lost to Followup or Died

Eight patients (nine hips) died before the 10-year review, and one patient (two hips) died after the 10-year followup. This group included eight men and one woman, with a

mean age of 57.6 years (range, 36.5–72.3 years), mean weight of 194 pounds (range, 140–180 pounds), and the following diagnoses: osteoarthritis (nine) and avascular necrosis (two). The mean followup was 7.7 years (range, 4.5–10.7 years). At their latest followup all had mean pain and mean function scores above 5 points (Charnley scale), and none of the radiographs revealed loosening of the femoral or acetabular components.

Seven patients (eight hips) currently have not returned for their 10-year followup. The demographics of this group are five men and two women, with a mean age of 45.7 years (range, 25.5–59.6 years), mean weight 178 pounds (range, 100–222 pounds), and the following diagnoses: osteoarthritis (four), avascular necrosis (three), and failed endoprosthesis in one hip. However, five patients did return for 5-year followup and had mean pain and function scores of 5 points or greater. In addition, radiographs revealed no femoral loosening (definite or probable). Acetabular cup loosening was seen at 6 years in one patient who underwent socket revision. Thus, there were no revisions for aseptic loosening and no evidence of mechanical failure in the femoral components of the patients who either died before the 10-year visit or did not return for that visit.

DISCUSSION

This study showed excellent long term results with the Trilock femoral component. Although the mechanical failure rate was 5%, the revision rate for aseptic loosening was 0%, and thigh pain was present in 1.4% at a minimum of 10 years after surgery. These results surpass or equal those of cemented stems inserted with modern cementing techniques.[21,22,25] The success rate of the stem can be attributed to specific design features. Being flat, tapered, and collarless, the prosthesis can wedge into the femoral canal into a position of maximum rotational stability. If not attained at the time of implantation, axial and rotational stability can be achieved through weightbearing as the prosthesis can settle into a position of stability. This is what occurred in the three cases of initial subsidence, followed by bone ingrowth, long term stability, and good clinical outcome.

In one biomechanical study,[26] excellent rotational and axial stability with a tapered femoral component design was described. In their study, Sharkey et al[26] found no difference between the cemented stem and a tapered porous coated design regarding axial or rotational micromotion. However, the porous coated anatomic stem showed significant axial or rotational micromotion. The mediolaterally tapered Trilock femoral component, being flat anteroposteriorly, relies on its mediolateral wedging fit (taking advantage of prosthesis tapering) for stability, with no attempt being made to achieve AP fill (Fig 2). The design allows an interference fit with the medial and lateral endocortices as viewed in the AP radiograph (Fig 2). Another advantage of the tapered design is the ease of insertion and extraction. Because it requires minimal reaming for insertion, the deleterious effects of extensive reaming[24] are avoided.

Removal of a stable, fixed femoral component in seven cases was neither difficult nor caused any bone damage. All components that were removed in the seven cases were well fixed with bone ingrowth, which was visible at the time of surgical extraction. However, because the component did not fill the canal, it was relatively easy to remove this bone ingrown stem with high power instrumentation without damaging the cortical shell of the femur. Although this requires some care and precision in extraction, none of these patients required extended trochanteric osteotomies for removal and no cortical perforations were incurred during removal of the stems. All of these patients had radiologic evidence of osteopenia in the greater trochanter. Trochanteric osteotomy was not done because reattachment of the trochanter might have been difficult. Porous

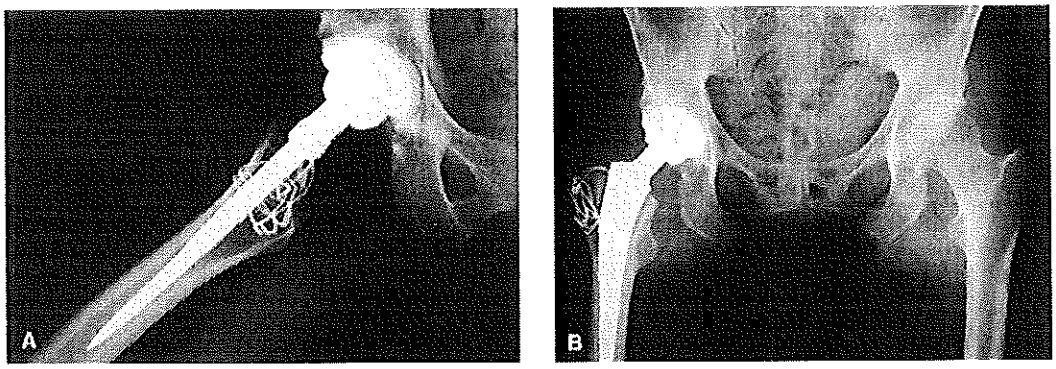

Fig 2A–B. (A) AP radiograph of implanted Trilock stem (DePuy). The tapering of the stem into the diaphysis with excellent mediolateral fit can be seen. (B) Lateral radiograph of implanted Trilock stem showing the lack of AP filling of the component within the canal.

coated components were used during the revision surgery. These implants were long stem and contained porous coating that extended past the metaphyseal and trochanteric region of the femur. However, none had extended porous coating.

The incidence of thigh pain in this study was 1.4% at the latest followup. This was much lower than the incidence of thigh pain at previous visits (5% incidence of thigh pain at 2 years of followup). Diminution in thigh pain is known to occur with continuing followup.[23] In a series of 57 hips replaced with the Trilock component, Pellegrini et al[23] reported thigh pain in 15 patients during the postoperative period; however, only two (3.5%) patients had thigh pain at the latest followup at a mean of 6.5 years (range, 5–8 years). Similar lower incidences of thigh pain have been reported with similar tapered wedge fit designs: 4% by Hozack et al,[16] and 6% by McLaughlin and Lee.[20] However, other uncemented femoral stems with different designs have been associated with higher incidences of thigh pain: 9.4% by Engh and Massin,[7] 15% by Heekin et al,[12] and 20% by Maloney et al.[19] In addition, even with modern cementing techniques Oishi et al[22] and Wixson et al[30] reported 3% incidence of thigh pain. The superlative results with the wedge fit prosthesis can be attributed partially to excellent initial stability with subsequent bone ingrowth. However, the tapered design likely plays a role; it allows for gradual transfer of stresses from the stem to the bone. An engineering analysis of the tapered design and stress transfer has been published that supports this effect.[29]

The circumferential porous coat of the prosthesis seems to prevent osteolysis. This hip system used cemented acetabular components and 32-mm heads with resultant high wear and loosening rates. However, no osteolysis was seen on the femoral side, probably because of the barrier effect of the circumferential porous coat. The porous coat of the Trilock Prosthesis is CoCr sintered beads (similar to the coating of the AML prosthesis[7]). However, the authors think the results of the current series are attributable to the component design, rather than the porous coat type, because similar excellent results have been achieved with a similar tapered, wedge fit, Ti prosthesis with a Ti plasma spray coating.[16,20]

The excellent results seen with the Trilock femoral component are related to its specific design features, such as collarless, wedge fit, mediolaterally tapered, and circumferential porous coating. However, the high failure rate of the acetabular component is related to the excessive polyethylene wear rate, with

acetabular lysis secondary to a 32-mm femoral head size.

References

1. Brooker AE, Bowerman JW, Robinson RA, Riley LH: Ectopic ossification following total hip replacement. Incidence and a method of classification. J Bone Joint Surg 55A:1629–1632, 1973.
2. Cates HE, Faris PM, Keating EM, Ritter MA: Polyethylene wear in cemented metal-backed cups. J Bone Joint Surg 75B:249–253, 1993.
3. Charnley J: Low Friction Arthroplasty of the Hip. Theory and Practice. New York, Springer 66–90, 1979.
4. DeLee JG, Charnley J: Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop 121:20–32, 1976.
5. Dorr LD, Abatz M, Gruen TA, Saberi MT, Dorzbacher JF: Anatomic porous replacement hip arthroplasty: First 100 consecutive cases. Semin Arthroplasty 1:77–86, 1990.
6. Engh CA, Bobyn JD, Glassman AH: Porous coated hip replacement. The factors governing bone in growth, stress sheilding, and clinical results. J Bone Joint Surg 69B:45–55, 1987.
7. Engh CA, Massin P: Cementless total hip arthroplasty using the anatomic medullary locking stem. Clin Orthop 249:141–158, 1989.
8. Engh CA, Massin P, Suther KE: Roentgenographic assessment of biological fixation of porous-surfaced femoral components. Clin Orthop 257:107–128, 1990.
9. Griffith MJ, Seidenstein MK, Williams D, Charnley J: Socket wear in Charnley low friction arthroplasty of the hip. Clin Orthop 137:37–47, 1978.
10. Gruen TA, McNeice GM, Amstutz HC: Modes of failure' of cemented stem-type femoral components: A radiographic analysis of loosening. Clin Orthop 141:17–27, 1979.
11. Harris WH: Traumatic arthritis of the hip after dislocation and acetabular fractures: Treatment with mold arthroplasty. An end result study using a new method of result evaluation. J Bone Joint Surg 51A:737–755, 1969.
12. Heekin RD, Callaghan JJ, Hopkinson WJ, Savory CG, Xenos JS: The porous coated anatomic total hip prosthesis, inserted without cement: Results after five to seven years in a prospective study. J Bone Joint Surg 75A:77–91, 1993.
13. Hodgkinson JR, Shelly P, Wroblewski BM: The correlation between the roentgenographic appearance and operative findings at the bone cement junction of the Charnley low friction arthroplasty. Clin Orthop 228:105–109, 1988.
14. Hozack WJ, Booth Jr RE: Clinical and radiological results with the Trilock femoral component: Wedge-fit porous ingrowth stem design. Semin Arthroplasty 1:64–69, 1990.
15. Hozack WJ, Rothman RH, Booth RE, Balderston RA: Cemented versus cementless total hip arthroplasty: A comparative study of equivalent patient populations. Clin Orthop 289:161–165, 1993.
16. Hozack WJ, Rothman RH, Eng K, Mesa J: Primary cementless hip arthroplasty with a titanium plasma sprayed prosthesis. Clin Orthop 333:217–225, 1996.
17. Huo MH, Martin RP, Zartoski LE, et al: Total hip arthroplasty using the Zweymuller stem implanted without cement. J Arthroplasty 10:793–799, 1995.
18. Livermore J, Ilstrup D, Morrey B: Effect of femoral head size on wear of the polyethylene acetabular component. J Bone Joint Surg 72A:518–528, 1990.
19. Maloney WJ, Jasty M, Harris WH, et al: Endosteal erosion in association with stable uncemented femoral components. J Bone Joint Surg 72A:1025–1034, 1990.
20. McLaughlin JR, Lee KR: Total hip arthroplasty with an uncemented femoral component: Excellent results at ten-year follow-up. J Bone Joint Surg 79B:900–907, 1997.
21. Mohler CG, Kull LR, Martell JM, et al: Total hip replacement with insertion of an acetabular component without cement and a femoral component with cement. J Bone Joint Surg 77A:86–95, 1995.
22. Oishi CS, Walker RH, Colwell CW: The femoral component in total hip arthroplasty: Six to eight year follow-up of one hundred consecutive patients after use of a third generation cementing technique. J Bone Joint Surg 76A:1130–1136, 1994.
23. Pellegrini VD, Hughes SS, Evarts CM: A collarless cobalt-chrome femoral component in uncemented total hip arthroplasty: Five to eight year follow-up. J Bone Joint Surg 74B:814–821, 1992.
24. Rhinelander FW, Nelson CA, Stewart RD, et al: Experimental reaming of the proximal femur and acrylic cement implantation. Clin Orthop 141:74–88, 1979.
25. Schmalzried TP, Harris WH: Hybrid total hip arthroplasty: A 6.5 year follow-up study. J Bone Joint Surg 74B:608–615, 1993.
26. Sharkey PF, Albert TJ, Hume EL, Rothman RH: Initial stability of a wedge-shaped prosthesis in the femoral canal. Semin Arthroplasty 1:87–90, 1990.
27. Smith SE, Garvin KL, Jardon M, Kaplan PA: Uncemented total hip arthroplasty: Prospective analysis of the Tri-Lock femoral component. Clin Orthop 269:43–50, 1991.
28. Vresilovic EJ, Hozack WJ, Rothman RH: The radiographic assessment of cementless femoral component stability: Correlation with intra-operative assessment. J Arthroplasty 9:137–141, 1994.
29. Vresilovic EJ, Hozack WJ, Rothman RH: Incidence of thigh pain after uncemented total hip arthroplasty as a function of femoral stem size. J Arthroplasty 11:304–311, 1996.
30. Wixson L, Stulberg SG, Mehlhoff M: Total hip replacement with cemented, uncemented and hybrid prostheses. J Bone Joint Surg 73A:257–270, 1991.
31. Zweymuller KA, Linter FK, Semlitsch MF: Biological fixation of a press-fit titanium prosthesis. Clin Orthop 235:195–206, 1988.

Primary Cementless Total Hip Arthroplasty in Octogenarians : Two to Eleven-Year Follow-up

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PRIMARY CEMENTLESS TOTAL HIP ARTHROPLASTY IN OCTOGENARIANS

TWO TO ELEVEN-YEAR FOLLOW-UP

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Background: Cementless total hip arthroplasty is an accepted alternative to total hip arthroplasty with cement in younger patients, but it remains controversial for elderly patients. The purpose of this study was to evaluate the clinical and radiographic outcomes of cementless total hip arthroplasty with use of a proximally coated stem in patients who were at least eighty years of age at the time of the operation.

Methods: One hundred and twenty-three cementless total hip replacements were performed for the treatment of osteoarthritis in 114 patients between the ages of eighty and eighty-nine years. Seven patients (eight hips) died within two years after the surgery, seventeen patients (eighteen hips) died more than two years postoperatively but were not followed for at least two years, and five hips were lost to follow-up; this left ninety-two hips in eighty-six patients for review. The mean duration of follow-up was five years (range, two to eleven years). For the clinical evaluation, the Charnley modification of the Merle d'Aubigné and Postel scale was used. In addition, preoperative and postoperative Harris hip scores were available for sixty-nine hips. Seventy-eight hips were followed radiographically for two years or more. The focus of the radiographic evaluation was the status of the fixation of the femoral and acetabular components as well as cup wear.

Results: Perioperative medical complications occurred in association with 24% (thirty) of the 123 operations, but there were no deaths. The mean Charnley scores for pain and function for the ninety-two hips that were followed clinically for at least two years improved by 3.0 and 1.4 points, respectively. The sixty-nine hips for which preoperative and postoperative Harris hip scores were available had a mean improvement of 42 points, with a mean score of 82 points at the last follow-up evaluation. Mild thigh pain was present in four patients, but it did not limit their activity. There were no femoral component revisions. All of the femoral components were radiographically stable and had bone ingrowth. No acetabular component failed by loosening, but 41% (thirty) of the seventy-three hips with radiographs available for measurement of wear showed polyethylene wear. Of the seventy-eight cups that were followed radiographically for two years or more, 4% (three) were associated with lysis, but none had been revised.

Conclusions: Cementless fixation in the elderly is safe, effective, and durable at the time of two to eleven-year follow-up.

Total hip arthroplasty with cement for patients older than eighty years of age has proven efficacy[1-5]. Cementless total hip arthroplasty is an accepted alternative in younger patients. Uncertainties regarding stem fixation, pain relief, demand on the implant, and cost are the basis for a widely held belief that the use of uncemented porous ingrowth total hip prostheses should be restricted to physiologically young patients[6-9]. However, because of the ever-increasing longevity and activity of the elderly, the value of a cementless implant in this population should not be dismissed. Additionally, fat embolism is potentially a serious problem for the elderly because of their lower level of physical reserves, and it could be partially prevented by the use of cementless implants[10-11]. Fat embolism has been most closely associated with total hip arthroplasties with cement, but it has also been seen with procedures in which cement was not used[12,15,16]. Elderly patients, who may be more fragile than younger patients, also may benefit from a reduction in surgical time. Eliminating the time required for the cement to harden can reduce the duration of the procedure by approximately twenty minutes. In this study, we reviewed the experience at a single institution in which cementless primary total hip arthroplasties were performed in octogenarians and the results were followed for a two to eleven-year period.

Materials and Methods

Between September 1987 and December 1993, a total of 2237 primary cementless total hip arthroplasties were performed for the treatment of osteoarthritis at our institution by the two senior authors (R.H.R. and W.J.H.). One hundred and twenty-three (5%) of these procedures were performed in 114 patients between the ages of eighty and eighty-nine years. To

TABLE I Demographic Characteristics	
No. of hips	92
No. of patients	86
Mean duration of follow-up (range) *(yr)*	5 (2-11)
Mean age (range) *(yr)*	83 (80-89)
Mean weight (range) *(kg)*	68 (49-109)
Gender (M/F) *(no. of hips)*	32/60
Initial diagnosis *(no. of hips)*	
Osteoarthritis	91
Avascular necrosis	1
Charnley class *(% of hips)*	
A	54
B	39
C	7

provide a more complete picture of the perioperative complications, this entire original group was analyzed. Of the 114 patients, seven (eight hips) died within two years (range, five to twenty-two months) after the surgery. None of these patients died of causes related to the hip surgery. Additionally, seventeen patients (eighteen hips) died more than two years postoperatively but had not returned for follow-up. Five hips were lost to follow-up. Thus, eighty-six patients (ninety-two hips) were available for review at two to eleven years (mean, five years) after the operation (Table I). (One patient with bilateral total hip replacement was followed for more than two years on only one side.) There was no significant difference regarding age ($p = 0.95$; t test), side ($p = 0.28$; chi-square test), or preoperative Charnley pain or function score ($p = 0.78$ and $p = 0.72$, respectively; chi-square test) between the twenty-nine patients (thirty-one hips) followed for less than two years (died or lost to follow-up) and the eighty-six patients (ninety-two hips) followed for two years or more. The only difference was that there were more men in the group followed for less than two years ($p = 0.01$; chi-square test).

The cementless acetabular component was the Universal cup I (Biomet, Warsaw, Indiana), which is a hemispherical titanium-alloy component with a plasma-spray coating. The peripheral flange has a flare to provide a press-fit. The plasma-spray coating increases the outer diameter by 1 mm compared with the reamed diameter, thereby further enhancing stability. The cup liner is a cylindrical shell with both standard and high-wall options. The technique for insertion of the acetabular cup included routine use of titanium screws inserted through the dome for supplemental fixation.

The cementless femoral component was the Taperloc femoral stem (Biomet). This component is composed of titanium alloy with a circumferential plasma-spray coating on its proximal third. It is a collarless, tapered, wedge-shaped implant and is available with a lateral-offset option. Insertion of the femoral component requires no endosteal reaming. Broaching achieves a solid cortical press-fit. The broach is used as a trial to check for stability and leg length. The permanent implant is then inserted with firm impaction. Stability of the prosthesis is manually tested by twisting the screwed-in handle used for insertion of the prosthesis. Excellent intraoperative stability was perceived in every patient, despite variation in bone stock.

All patients were instructed to bear approximately 10% of their weight on the treated extremity for six weeks, at which time they were advanced to a cane. A low-dose warfarin protocol was used, with 10 mg given on the night of the surgery and the dose subsequently adjusted daily to maintain the prothrombin time at fifteen seconds.

Objective preoperative and follow-up evaluation was performed by specially trained physical therapists or research fellows. Clinical evaluations were performed preoperatively, at six weeks postoperatively, and then yearly with use of the Charnley modification of the Merle d'Aubigné and Postel scale[17]. The Harris hip-scoring system[18] was incorporated into the clinical evaluation at our institution later in the study period, so a preoperative Harris hip score was not available for seventeen of the ninety-two hips. The patient was questioned specifically about thigh or groin pain, which was recorded as present or absent.

Leg-holders were used to position the limb accurately for sequential radiographic review, and the distance between the film and the x-ray tube was constant. The quality of the bone stock preoperatively was categorized radiographically with the method described by Dorr et al.[19]. Subsidence of the femoral component was defined as a change in position of more than 3 mm. All changes around the cementless femoral component were documented with a modification of the system suggested by Engh et al.[20-22]. The femoral component was classified as stable with bone ingrowth, stable with fibrous ingrowth, or unstable. Mechanical failure was deemed to have occurred if the femoral component was revised for loosening or was considered to be radiographically unstable.

The position of the acetabular component was determined according to the criteria of Massin et al.[23]. Any change in component position of either 3 mm or 3° was considered to represent migration of the cup, a definite sign of cup-loosening[24]. Radiolucency of greater than 1 mm in thickness at the component-bone interface was looked for in the three zones defined by DeLee and Charnley[25]. Cup wear was assessed according to the technique of Livermore et al.[26]. Briefly, the shortest distance between the center of the femoral head and the edge of the metal cup was used for this evaluation. Each radiograph was measured by a single observer to the nearest 0.25 mm with use of the X-caliper (Eisenlohr Technologies, Davis, California). This is an electronic caliper that automatically corrects for magnification on the basis of a known variable such as the actual femoral head size.

Statistical Analysis

Categorical variables were analyzed with use of a chi-square test[27]. Statistical comparison to test for differences between two groups was performed with the Student t test for uncorrelated means[27]. All analysis was done with StatView 5.0 (SAS Institute, Cary, North Carolina).

Results

Clinical Results

There was substantial improvement in pain relief, function, and motion following the total hip arthroplasties. At the last follow-up evaluation, the mean Harris hip score was 82 ± 13 points (range, 49 to 100 points). The Harris hip score was not determined for six patients (six hips) at the last office visit: two of them had died, and we were unable to contact the remaining four by telephone or letter. According to information recorded in the office charts, four of these six patients reported no pain, one had slight pain with tenderness over the greater trochanter, and one had moderate pain over an ununited greater trochanter. Neither of the latter two patients had radiographic signs of loosening of the prosthesis. As previously mentioned, because the Harris hip score was not incorporated into the clinical evaluation in the beginning of this study, preoperative scores were available for only seventy-five of the ninety-two hips; the mean score for these seventy-five hips was 40 ± 13 points (range, 15 to 78 points). The sixty-nine hips with both preoperative and postoperative Harris hip scores had a mean increase of 42 points.

The mean Charnley score for pain improved from 2.7 points (2, 3, or 4 points) preoperatively to 5.7 points (range, 3 to 6 points) at the time of the latest follow-up, the mean score for function improved from 2.8 points (range, 1 to 5 points) to 4.2 points (range, 1 to 6 points), and the mean score for motion improved from 4.0 points (range, 2 to 6 points) to 5.2 points (4, 5, or 6 points). Of the ninety-two hips, 77% (seventy-one) were not considered to be painful by the patients and 17% (sixteen) were considered to be mildly painful without limitation of activity. Four (4%) of the hips were associated with pain in the thigh. Each of these patients had radiographic evidence of osseous ingrowth, and each had a Charnley pain score of 5 points. Five (5%) of the ninety-two hips had pain that was considered limiting, and the location of the limiting pain was described as the groin (one hip), buttock (one hip), or trochanter (three hips).

At the time of the most recent follow-up, the eighty patients (eighty-six hips) with an available postoperative Harris hip score were evaluated with regard to whether they could walk six blocks or more without an assistive device (24% [twenty-one] of the eighty-six hips); could walk six blocks or more with support (10% [nine] of the hips); could walk outdoors for a distance of less than six blocks (31% [twenty-seven]), either with support (nineteen) or without support (eight); could walk only indoors (31% [twenty-seven]); or could not walk because of medical conditions unrelated to the hip surgery (2% [two, neither of which was painful]). They were also evaluated with regard to whether they required a walker for walking (20% [seventeen]), had difficulty putting on shoes and socks (43% [thirty-seven]), and could ascend and descend stairs (86% [seventy-four]).

There were no femoral or acetabular revisions.

Radiographic Results

Of the ninety-two hips that were evaluated after at least two years, 85% (seventy-eight) were followed radiographically for two years or more (mean, five years; range, two to ten years). Eleven hips were followed for less than two years, and we were unable to find the follow-up radiographs for three hips.

The acetabular cup angle averaged 42° (range, 27° to 60°). No socket demonstrated migration (definite loosening), and none showed complete bone-prosthesis lucency consistent with probable loosening.

Wear was measured on the immediate postoperative radiograph and on radiographs made at the time of the most recent follow-up. These radiographs were available for seventy-three of the seventy-eight hips. Of these, 41% (thirty) had a 22-mm femoral head and 59% (forty-three) had a 28-mm head. Forty-three percent (thirteen) of the thirty 22-mm sockets and 40% (seventeen) of the forty-three 28-mm sockets demonstrated measurable wear. Linear cup wear averaged 0.076 mm/yr for the hips with a 22-mm femoral head and 0.074 mm/yr for those with a 28-mm head. Volumetric wear was 29 and 46 mm^3/yr, respectively. Acetabular lysis was seen in 4% (three) of the seventy-eight hips; two had a 22-mm head and one, a 28-mm head.

According to the system of Dorr et al.[19], 17% (fifteen) of the ninety hips in which bone type was evaluated had type-A cortical bone; 58% (fifty-two), type-B; and 26% (twenty-three), type-C. Two hips did not have available radiographs for this evaluation. The clinical results were independent of bone type. According to the classification system of Engh et al.[20], all of the femoral components had radiographic evidence of bone ingrowth. No component was unstable, and no fibrous ingrowth was seen. None of these cementless femoral components had evidence of mechanical failure (that is, either a revision or radiographic evidence of failure) at a mean of five years (range, two to eleven years) after the arthroplasty. Despite the high prevalence of polyethylene wear and the presence of acetabular osteolysis, there was only one case of femoral osteolysis. This osteolysis was localized at the proximal-medial aspect of the femoral neck, proximal to the coating of the prosthesis.

Complications

In the original group of 123 hips, the rate of medical complications was 24% (thirty hips). The complications included femoral nerve palsy (associated with one hip [0.8%]), with total recovery by six months; urinary tract infection (five hips [4.1%]); pulmonary emboli (eight hips [6.5%]), none of which were symptomatic and all of which were detected on routine postoperative lung scans; cardiac abnormalities (three hips [2.4%]), consisting of one case of congestive heart failure, one case of angina, and one case of atrial fibrillation; gout attack (three hips [2.4%]); intestinal ileus (three hips [2.4%]); peptic ulcer (one hip [0.8%]); seizure (one hip [0.8%]); urinary retention (six hips [4.9%]); and enterocolitis (two hips [1.6%]). It is important to note that there were no perioperative deaths. Equally important are the results involving perioperative component-related complications. There were no femoral fractures, dislocations, or infections. One patient did eventually have recurrent dislocations (a total of nine dislocations treated by closed reduction) but declined operative in-

tervention. Two patients sustained a periprosthetic fracture at 1.5 and six years postoperatively. Both fractures were related to a fall. One was treated with traction, and the other was treated with open reduction and internal fixation.

Discussion

We are not aware of any other reports in the literature on the efficacy of primary cementless total hip arthroplasty in octogenarians. There are a few related reports on the use of cementless total hip arthroplasty in older patients. Engh et al.[22] reported good results with the use of the AML prosthesis (DePuy, Warsaw, Indiana) in patients older than sixty-five years. Survivorship probabilities with revision and mechanical failure as the end points were 98.6% and 92.5%, respectively, at eight years. There were three stem revisions, one because of stem breakage and two because of failure of biologic stabilization. The rate of revision because of failed biologic stabilization was only 0.6% at a mean of six years. McAuley et al.[28] reported a cumulative probability of prosthetic survival of 0.92 at twelve years, with any reoperation as the end point, in patients sixty-five years of age or older who were treated with different designs of the AML femoral component and a fully porous-coated acetabular component. The survival rate for the femoral component was 0.97, and that for the acetabular component was 0.92. At a mean of 8.5 years, 91% (139) of the 152 patients reported no or mild pain and had a normal activity level.

Concerns regarding cementless total hip arthroplasty in the elderly include persistent pain, failure of bone ingrowth, and cost[6,8,9,29,30]. Our data indicate no clinically adverse consequences of cementless fixation in terms of pain and function. Even patients with thigh pain had satisfactory clinical scores, and all patients had radiographic evidence of bone ingrowth. The decreased time required for insertion of an uncemented prosthesis in this physiologically frail age-group is an advantage over arthroplasty with cement. The time saved by avoiding curing of femoral and acetabular cement mantles decreases blood loss and operative time. Fat embolism is a well documented consequence of cement injection and pressurization[11-13]. Patterson et al.[31] reported seven cases of cardiac arrest during total hip replacement with cement and a long-stem femoral component. Three patients were successfully resuscitated, but four patients died. Factors that were common to all of these patients were advanced age, a previously undisturbed intramedullary canal, and osteoporotic bone. Cementless fixation is likely to reduce the chance of this serious complication.

Many authors[9,32] have based implant selection on an arbitrary age and bone quality because of the belief that initial implant stability may not be achievable in the elderly. In our series, no prosthesis was thought to be unstable when tested manually during surgery. Failure due to a lack of osseointegration is also of concern in these patients. There were no instances of loosening after a minimum two-year follow-up period in our patients. Therefore, we concluded that the bone of elderly patients can provide adequate initial stability for cementless implants, leading to subsequent bone ingrowth.

Cemented total hip components generally are considered to be a less expensive and therefore a more appropriate option for the elderly. The cost of the prosthesis alone is the usual basis of comparison, even though many additional costs are incurred in the implantation of a cemented stem and cup. For example, longer operative time as well as the cement, cement-mixing setup, cement pressurizers, cement restrictors, pulse irrigation, and cement guns are all associated with costs. Barrack et al.[33] examined the costs of total hip replacement with a cemented or uncemented stem and found the actual cost for a modern cemented stem to be greater than that for an uncemented stem.

Persons eighty years of age or older are, by percentage, the fastest growing segment of the American population, with their number estimated to increase to nine million by the year 2000 and to thirty-two million by the year 2050[34]. Because of their longevity, even this elderly group may require between ten and twenty years of service from their implants[35].

In conclusion, in the short term, cementless fixation for total hip replacement in octogenarians can decrease pain and improve function. Long-term biologic fixation may prove to be of benefit as these individuals lead longer and more active lives. ■

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References

1. **Boettcher WG.** Total hip arthroplasties in the elderly. Morbidity, mortality, and cost effectiveness. *Clin Orthop.* 1992;274:30-4.
2. **Brander VA, Malhotra S, Jet J, Heinemann AW, Stulberg SD.** Outcome of hip and knee arthroplasty in persons aged 80 years and older. *Clin Orthop.* 1997;345:67-78.
3. **Ekelund A, Rydell N, Nilsson OS.** Total hip arthroplasty in patients 80 years of age and older. *Clin Orthop.* 1992;281:101-6.
4. **Levy RN, Levy CM, Snyder J, Diglovanni J.** Outcome and long-term results following total hip replacement in elderly patients. *Clin Orthop.* 1995;316:25-30.
5. **Pettine KA, Aamlid BC, Cabanela ME.** Elective total hip arthroplasty in patients older than 80 years of age. *Clin Orthop.* 1991;266:127-32.
6. **Dorr LD, Wan Z, Gruen T.** Functional results in total hip replacement in patients 65 years and older. *Clin Orthop.* 1997;336:143-51.
7. **Grecula MJ, Grigoris P, Brown I, Dorey F, Amstutz HC.** The durability of cemented total hip arthroplasty in patients over sixty: a fifteen year survivorship analysis. *Orthop Trans.* 1994;18:875-6.
8. **Healy WL.** Economic considerations in total hip arthroplasty and implant standardization. *Clin Orthop.* 1995;311:102-8.

9. **Wixson RL, Stulberg SD, Mehlhoff M.** Total hip replacement with cemented, uncemented, and hybrid prostheses. A comparison of clinical and radiographic results at two to four years. *J Bone Joint Surg Am.* 1991; 73:257-70.

10. **Alexander JP, Barron DW.** Biochemical disturbances associated with total hip replacement. *J Bone Joint Surg Br.* 1979;61:101-6.

11. **Christie J, Burnett R, Potts HR, Pell AC.** Echocardiography of transatrial embolism during cemented and uncemented hemiarthroplasty of the hip. *J Bone Joint Surg Br.* 1994;76:409-12.

12. **Orsini EC, Byrick RJ, Mullen JB, Kay JC, Waddell JP.** Cardiopulmonary function and pulmonary microemboli during arthroplasty using cemented or noncemented components. The role of intramedullary pressure. *J Bone Joint Surg Am.* 1987;69:822-32.

13. **Pitto RP, Koessler M, Draenert K.** Prophylaxis of fat and bone marrow embolism in cemented total hip arthroplasty. *Clin Orthop.* 1998;355:23-34.

14. **Ries MD, Lynch F, Rauscher LA, Richman J, Mick C, Gomez M.** Pulmonary function during and after total hip replacement. Findings in patients who have insertion of a femoral component with and without cement. *J Bone Joint Surg Am.* 1993;75:581-7.

15. **Arroyo JS, Garvin KL, McGuire MH.** Fatal marrow embolization following a porous-coated bipolar hip endoprosthesis. *J Arthroplasty.* 1994;9:449-52.

16. **Hofmann S, Hopf R, Mayr G, Schlag G, Salzer M.** In vivo femoral intramedullary pressure during uncemented hip arthroplasty. *Clin Orthop.* 1999;360:136-46.

17. **Charnley J.** The long-term results of low-friction arthroplasty of the hip performed as a primary intervention. *J Bone Joint Surg Br.* 1972;54:61-76.

18. **Harris WH.** Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. An end-result study using a new method of result evaluation. *J Bone Joint Surg Am.* 1969;51:737-55.

19. **Dorr LD, Faugere MC, Mackel AM, Gruen TA, Bognar B, Malluche HH.** Structural and cellular assessment of bone quality of proximal femur. *Bone.* 1993;14:231-42.

20. **Engh CA, Bobyn JD, Glassman AH.** Porous-coated hip replacement. The factors governing bone ingrowth, stress shielding, and clinical results. *J Bone Joint Surg Br.* 1987;69:45-55.

21. **Engh CA, Massin P.** Cementless total hip arthroplasty using the anatomic medullary locking stem. Results using a survivorship analysis. *Clin Orthop.* 1989;249:141-58.

22. **Engh CA, Glassman AH, Suthers KE.** The case for porous-coated hip implants. The femoral side. *Clin Orthop.* 1990;261:63-81.

23. **Massin P, Schmidt L, Engh CA.** Evaluation of cementless acetabular component migration. An experimental study. *J Arthroplasty.* 1989;4:245-51.

24. **Hodgkinson JP, Shelley P, Wroblewski BM.** The correlation between the roentgenographic appearance and operative findings at the bone-cement junction of the socket in Charnley low friction arthroplasties. *Clin Orthop.* 1988;228:105-9.

25. **DeLee JG, Charnley J.** Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop.* 1976;121:20-32.

26. **Livermore J, Ilstrup D, Morrey B.** Effect of femoral head size on wear of the polyethylene acetabular component. *J Bone Joint Surg Am.* 1990;72:518-28.

27. **Daniel WW.** *Biostatistics: a foundation for analysis in the health sciences.* 5th ed. New York: Wiley; 1991.

28. **McAuley JP, Moore KD, Culpepper WJ 2d, Engh CA.** Total hip arthroplasty with porous-coated prostheses fixed without cement in patients who are sixty-five years of age or older. *J Bone Joint Surg Am.* 1998;80:1648-55.

29. **Barrack RL.** Implant matching has no clinical or scientific basis. *J Arthroplasty.* 1996;11:969-72.

30. **Maloney WJ, Harris WH.** Comparison of a hybrid with an uncemented total hip replacement. A retrospective matched-pair study. *J Bone Joint Surg Am.* 1990;72:1349-52.

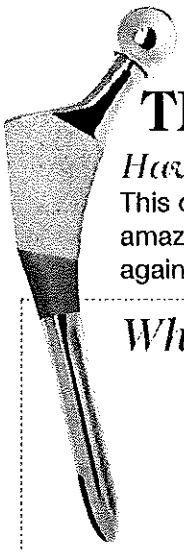
31. **Patterson BM, Healey JH, Cornell CN, Sharrock NE.** Cardiac arrest during hip arthroplasty with a cemented long-stem component. A report of seven cases. *J Bone Joint Surg Am.* 1991;73:271-7.

32. **Harris WH, Davies JP.** Modern use of modern cement for total hip replacement. *Orthop Clin North Am.* 1988;19:581-9.

33. **Barrack RL, Castro F, Quinn S.** Cost of implanting a cemented versus cementless femoral stem. *J Arthroplasty.* 1996;11:373-6.

34. **US Bureau of the Census.** http://www.census.gov/population/projections/nation/summary/np-t4-a.pdf, http://www.census.gov/population/projections/nation/summary/np-t4-g. pdf, and http://www.census.gov/prod/1/pop/p25-1130/p251130g.pdf, Table B-1. Accessed Jan 15, 2000.

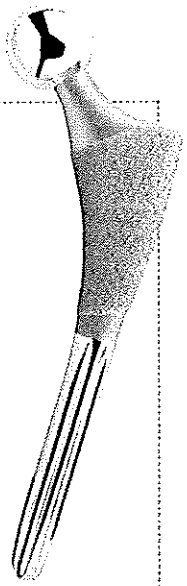
35. **Ritter MA, Albohm MJ, Keating EM, Faris PM, Meding JB.** Life expectancy after total hip arthroplasty. *J Arthroplasty.* 1998;13:874-5.



Meridian® TMZF® Stem

TMZF®: The Ultimate 5-Minute Primer

Have no time to read all the technical details on TMZF® alloy?
This quick, 5-minute primer is perfect for your skimming pleasure. Find out more about this amazing alloy, its growing role in the cementless product portfolio, and how to sell it against the competition!



Citation® TMZF® Stem

What is TMZF®?

TMZF® is a titanium alloy consisting mainly of the following elements

Titanium
Molybdenum
Zirconium
Ferrous (Iron)

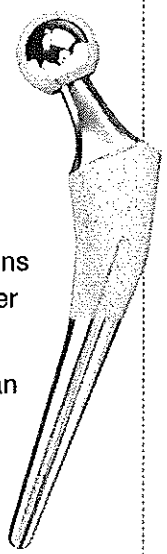
Note that this alloy does not include any aluminum or vanadium, as is the case for Ti-6Al-4V, the standard titanium alloy used in orthopaedic implants. Molybdenum, zirconium, and iron are added to "stabilize" and strengthen the alloy structure.

Why was TMZF® developed?

First, here's some history on Ti-6Al-4V. Although it's a great choice for orthopaedic applications because of its high strength, good corrosion resistance and tissue tolerance, it was actually originally developed for military and industrial applications. Since 1959, this alloy has been successfully used in many orthopaedic implant designs. But in 1986, Howmedica set out to improve it by developing a titanium alloy that was custom-tailored for orthopaedic applications: a titanium alloy that could optimize the key advantages of strength and flexibility.

Where has it been used?

Domestically, TMZF® alloy is currently used in the Meridian®, Citation®, and Accolade™ cementless stems.



Accolade® TMZF® Stem

How is TMZF® alloy an advantage?

Here are the three key points, which you should be able to chant in your sleep

- **Strength** TMZF® alloy is 20% stronger than Ti-6Al-4V. The higher strength means that we can incorporate smaller stems and cross sections into our designs. Smaller neck cross sections give the patient greater range of motion.
- **Flexibility** TMZF® alloy is 25% more flexible than Ti-6Al-4V and 62% more than cast cobalt chrome. Improved flexibility means better stress transfer to bone and potentially reduced thigh pain for the patient.
- **Notch Resistant** TMZF® alloy has 47% greater notch resistance than Ti-6Al-4V. Notch resistance is the ability of a material to resist fracture with the presence of a surface imperfection such as a notch, section, crack, or scratch.

Who else uses a titanium alloy other than Ti-6Al-4V?

Sulzer has an alloy containing titanium, aluminum, and niobium: Ti-6Al-7Nb. However this alloy is quite similar to Ti-6Al-4V and introduces no significant mechanical advantages over it. TMZF® alloy is still stronger by 20% and more flexible by 25%.

TMZF™
A Beta Titanium Alloy for Orthopaedic Implants

TMZF™*
A Beta Titanium Alloy for Orthopaedic Implants

Introduction

Since its introduction in the early 1950s, the use of titanium and its alloys in orthopaedics has been primarily limited to the alloy Ti-6Al-4V and to unalloyed commercially pure (CP) titanium. Both of these materials were originally developed for military or industrial applications, and later adopted for medical use due to their availability and desirable properties.[1]

CP titanium was first used clinically in 1951 by Doctors Jergensen and Leventhal for fracture fixation bone screws and plates. They observed that the material exhibited good corrosion resistance and tissue tolerance, but marginal strength.[2]

The alloy Ti-6Al-4V was first employed in the Soviet Union in 1959 in the Sivash total hip. During the early 1970s, Ti-6Al-4V replaced CP titanium to increase the strength of nails, plates, screws, and endoprostheses being manufactured in England. In the mid- to late-1970s, the extra low interstitial (ELI) grade of Ti-6Al-4V was introduced in the United States for total hip femoral components. In the 1980s, two variations on Ti-6Al-4V alloy were introduced in which vanadium was replaced to address concerns over vanadium toxicity. These alloys, Ti-6Al-7Nb and Ti-5Al-2.5Fe are metallurgically quite similar to Ti-6Al-4V, except for the absence of vanadium.[3]

In 1986, Howmedica R&D began a program to develop a titanium alloy specifically designed for use in orthopaedic implants. The goal was to optimize attributes such as strength and flexibility, while avoiding controversial alloying elements. The decision was made to pursue an alloy of the classification known as beta titanium alloys, as opposed to an alpha-beta alloy such as Ti-6Al-4V.

Beta titanium alloys generally can be processed to higher strength levels and exhibit better notch properties and toughness than alpha-beta alloys. By design, they contain bio-acceptable alloying elements, such as molybdenum, zirconium, niobium, tantalum, or iron, and can exhibit an elastic modulus lower than that of Ti-6Al-4V.[4,5]

The alloy developed by Howmedica R&D, Ti-12Mo-6Zr-2Fe, or TMZF™, is a beta titanium alloy that meets all of the design goals for an improved orthopaedic alloy. It is 25% more flexible than Ti-6Al-4V alloy, with a 20% higher yield strength and improved notched fatigue resistance. TMZF™ exhibits comparable corrosion resistance to Ti-6Al-4V, but has demonstrated superior resistance to wear and abrasion.

TMZF™ can be readily forged and cold-formed, making it an alloy well-suited to a range of implant applications from total hips to trauma devices. The alloy has been extensively tested and characterized by Howmedica R&D to define its mechanical, metallurgical, and physical properties. The results of this testing are presented in the following pages.

*US Patent Nos. 4,857,269 and 4,952,236.

Titanium Metallurgy

Unalloyed titanium exists in two crystallographic forms, or phases, depending upon temperature. Alpha titanium exists in a hexagonal close-packed (hcp) crystal structure below 882°C and transforms to the body-centered cubic (bcc) beta titanium above this temperature. This behavior of titanium provides the basis for the microstructural and property control of all titanium alloys.

Through elemental additions that elevate or lower the transformation (transus) temperature and strengthen the alpha and beta phases, plus heat treating and thermomechanical processing to alter the amount and form of the alpha and beta phases, titanium alloys with distinct metallurgical properties are created. Alloys, such as Ti-6Al-4V, exhibit a two phase microstructure of alpha plus beta phases and, hence, are referred to as alpha-beta alloys. Beta alloys, in contrast, consist of a single stabilized beta phase at room temperature.

Certain elements, such as aluminum, oxygen, and nitrogen, are soluble in the alpha phase. They strengthen alpha titanium and elevate the alpha-beta transformation temperature. Other elements, such as vanadium, molybdenum, zirconium, niobium, and iron, help strengthen and stabilize the beta phase and prevent the formation of the alpha phase on cooling through the transformation temperature range.[6]

TMZF™ Metallurgical Structure

TMZF™ Alloy retains a single phase beta microstructure on cooling to room temperature from its beta transus temperature of 754°C (**Figure 1**). In contrast, the alpha-beta alloy Ti-6Al-4V exhibits a two-phase microstructure upon metallographic examination (**Figure 2**).

The annealed all-beta TMZF™ microstructure has been found to provide the preferred combination of high strength, increased flexibility, and ductility desired for orthopaedic applications.

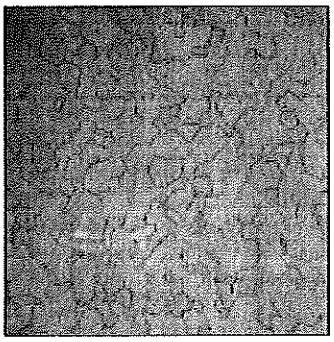


Figure 1
TMZF™ beta structure

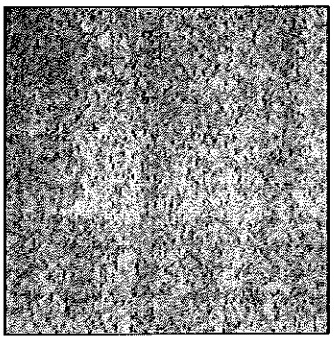


Figure 2
Ti-6Al-4V alpha-beta structure

TMZF™ Alloy Composition

The chemical composition requirements for TMZF™ Alloy are listed in **Table 1**. In addition to the major alloying elements – molybdenum, zirconium, and iron – which serve to stabilize the beta phase, there are also small amounts of oxygen, nitrogen, and carbon, which provide additional strengthening effects.

Table 1

Elements weight %	
Titanium	Bal.
Molybdenum	10-13
Zirconium	5-7
Iron	1.5-3.5
Oxygen*	0.28
Carbon*	0.05
Hydrogen*	0.020
Nitrogen*	0.05

*Maximum limits

While there have not been any clinically substantiated reports of problems stemming from the presence of the elements aluminum and vanadium in current titanium alloys, there are reported concerns based on potential toxicity, potential inhibition of apatite formation, and possible association with neurological disorders.[7] For these reasons, aluminum and vanadium were avoided in TMZF™ Alloy.

Corrosion Properties

TMZF™ Alloy exhibits the same excellent corrosion-resistant characteristic of titanium alloys, attributable to the spontaneous formation of a stable adherent surface oxide in the presence of only slight amounts of oxygen. It is the inertness of this surface oxide that accounts for the excellent corrosion resistance of titanium alloys.[1]

Anodic polarization testing, comparing annealed TMZF™ with annealed Ti-6Al-4V alloys, showed excellent corrosion resistance for both alloys (**Figure 3**).

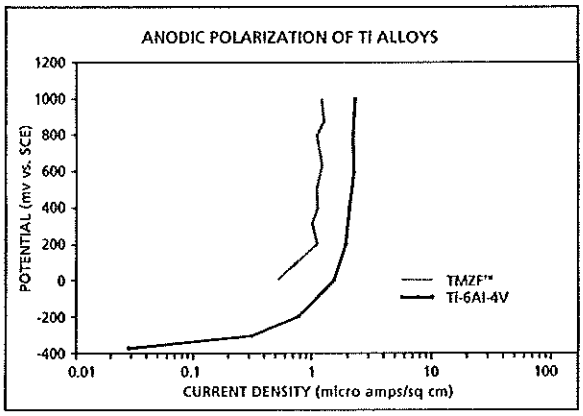


Figure 3

With increasing potential, each alloy reached a steady current density indicative of the presence of a stable passive protective oxide. Further increases in potential up to +1000mv vs. S.C.E. caused no further increase in current density for either alloy.

Mechanical Properties

Tensile Strength

Room temperature tensile testing was conducted on annealed TMZF™ and Ti-6Al-4V alloy bars in accordance with ASTM E-8. The results, shown in **Table 2**, demonstrate that TMZF™ has up to a 20% higher yield strength, an 80% improvement in elongation, and a 25% lower elastic modulus than Ti-6Al-4V alloy.

Table 2

Tensile Properties of TMZF™ vs. Ti-6Al-4V Alloys					
Alloy Type	Yield Strength (MPa)	Ultimate Strength (MPa)	%Elongation in Area	%Reduction in Area	Elastic Modulus (GPa)
TMZF™	1000-1060	1060-1100	18-22	64-73	74-85
Ti-6Al-4V	850-900	960-970	10-15	35-47	110

TMZF™ Alloy, with its increased yield strength and lower elastic modulus, (i.e., increased flexibility), permits the development of implant designs having increased flexibility, which increases implant/bone stress transfer without sacrificing component strength.

Fracture Toughness

Fracture toughness is a measure of a material's ability to resist the propagation of a crack under load. Generally, materials with higher fracture toughness are less sensitive to damage in service.

When tested for fracture toughness in accordance with ASTM standard E399 (Standard Test Method for Plane-Strain Fracture Toughness of Metallic Materials), TMZF™ Alloy exhibited toughness values 73% greater than those of Ti-6Al-4V alloy (90 versus 52 MPa$\sqrt{m}$).

Fatigue Strength

Rotating beam fatigue results for TMZF™ Alloy in the smooth and notched conditions are shown in **Figure 4**, and are compared against those for Ti-6Al-4V alloy. The smooth results are comparable for both alloys, with a fatigue strength of about 585 MPa at 10 million cycles.

Under notched conditions, TMZF™ proved to be superior. Results for notched samples having a stress concentration factor of 1.6 show Ti-6Al-4V with a drop in fatigue strength of 47%. TMZF™ tested under the same conditions was less affected, retaining 70% of its smooth strength.

Generally, improved notch fatigue resistance will provide a material with more tolerance of surface stress concentrations in service.

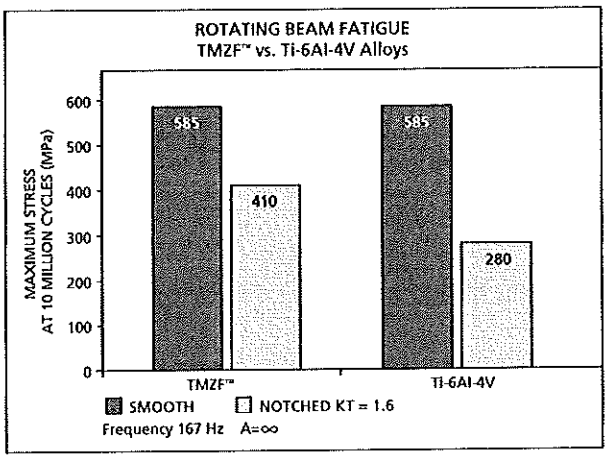


Figure 4

Modulus of Elasticity

Modulus of elasticity is a measure of a material's flexibility, that is, the degree to which a material can be deformed and still "spring back" to its original shape. Elastic materials will deflect more readily under load than will rigid materials.

In implant design, material elasticity is an important requisite for producing implants which will adequately transfer stress to surrounding bone to minimize bone atrophy due to stress shielding. More elastic materials allow for more flexible designs, which enhance implant to bone stress transfer (**Figure 5**).[8]

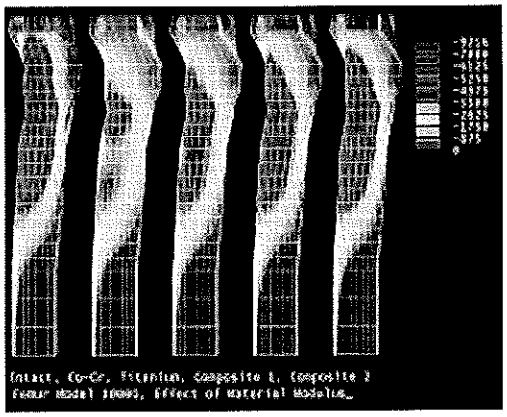


Figure 5
A finite element analysis (FEA) model of a hip stem in bone illustrates the increase in proximal stress transfer with decreasing material modulus (E). From left to right: intact femur; Co-Cr, E=220GPa; Ti-6Al-4V, E=110GPa; Composite 1, E=55GPa; Composite 2, E=14GPa. TMZF, with its low elastic modulus (80GPa), exhibits a flexibility approaching that of composite systems.

But, material elasticity is only useful when in combination with suitable material strength. Flexible materials without strength have limited utility, particularly in load-bearing applications such as orthopaedic implants.

TMZF™ Alloy has a preferred combination of strength and flexibility, offering designers the ability to increase implant flexibility (and stress transfer) without reducing component cross section and strength (**Figure 6**).

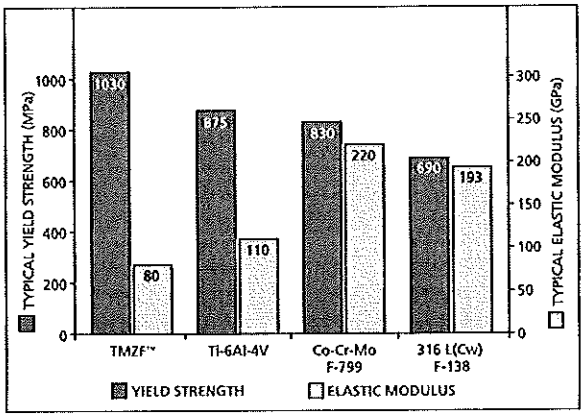


Figure 6
Elastic modulus and yield strength values for common implant alloys.

Admissible Strain

TMZF™ exhibits a low elastic modulus, nearly one third that of the widely used forged Co-Cr-Mo alloy, while maintaining a 20% higher yield strength. Compared with coldworked 316L stainless, TMZF™ Alloy has a 45% higher yield strength with a 60% lower modulus.

The ratio of yield strength to elastic modulus, referred to as "admissible strain," is a measure of a materials tolerance of deflection under load. The higher the ratio, the more "forgiving" the material is in use. TMZF™ Alloy's percent admissible strain of 1.25 is over three times that of Co-Cr-Mo and stainless steel alloys and over one and one half times that of Ti-6Al-4V alloy.[9]

Comparison of Beta Titanium Alloys Being Proposed for Orthopaedic Applications

In addition to TMZF™, five other beta titanium alloys have appeared in the literature as possible candidates for orthopaedic use. Based on published data, TMZF™ is superior in overall mechanical properties to each of these alloys. The comparative data is presented below in Table 3.

Optimal properties of an orthopaedic alloy include flexibility (demonstrated by a low elastic modulus), high yield and ultimate tensile strength, combined with good ductility (as measured in percent elongation).

While the other beta alloys may match some individual properties of TMZF™ Alloy, none has the equivalent combination of strength, flexibility, and ductility.

Table 3

Tensile Properties				
Alloy	Elastic Modulus (GPa)	UTS (MPa)	YS (MPa)	Elong. (%)
TMZF™	74-85	1060-1100	1000-1060	18-22
[10]Ti-13Nb-13Zr	79-84	973-1037	836-908	10-16
[11]Ti-15Mo-2.8Nb-0.2Si-0.26O	83	979-999	945-987	16-18
[12]Ti-15Mo	78	874	544	21
[9]Ti-16Nb-10Hf	81	851	736	10
[13]Ti-15Mo-5Zr-3Al	75-88	882-975	870-968	17-20

UTS – Ultimate Tensile Strength
YS – Yield Strength
Elong. – Elongation

Wear/Abrasion Resistance

The association of implant loosening with peri-implant bone loss due to biological reaction with implant wear debris has been well documented.[14] While wear of polyethylene articular surfaces is recognized to be the predominant source of debris in total joints, incidents of metallic stem wear in total hips have also been reported.[15,16]

Loosened cemented Ti-6Al-4V alloy stems have been found to generate significant amounts of black metallic wear debris, due to abrasion of the titanium alloy stem against the surrounding cement mantle.[17,18]

In view of the clinical reports of cement-stem abrasion, a pin-on-disc wear model, employing a metallic disc and Surgical Simplex P bone cement ball, was chosen to evaluate the wear resistance of TMZF™ Alloy. Five polished discs of Ti-6Al-4V and TMZF™ alloys (surface finish 1 micron) were individually tested against 12.7mm diameter bone cement balls under a 100 gram load in deionized water.

After 100,000 cycles, the TMZF™ discs exhibited only minimal change in surface roughness (0.01 to 0.06 microns) and no weight loss (**Table 4**). Only white bone cement wear debris was evident after testing (**Figure 7**). In contrast, severe wear of the Ti-6Al-4V samples was observed after only a few hundred cycles. Disc surface roughness increased on average over 5.0 microns with visible surface scratching. Significant black wear debris was generated, resulting in an average sample weight loss of 0.0145 grams (**Figure 8** and **Table 4**).

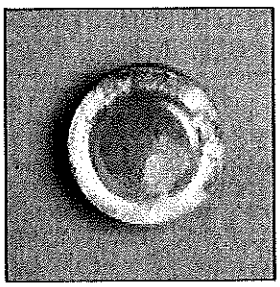


Figure 7

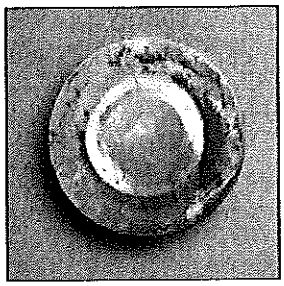


Figure 8

Table 4

Wear Test of TMZF™ and Ti-6Al-4V Against Bone Cement					
Disc Alloy		Surface Roughness (microns)		Weight Loss (grams)	
		Disc Samples		Disc (gain)	Cement
		Initial	Final		
TMZF™	*mean*	*0.036*	*0.072*	*(0.0005)*	*0.108*
	s.d.	0.021	0.022	(0.0004)	0.058
	n	5	5	5	5
Ti-6Al-4V	*mean*	*0.026*	*5.082*	*0.0145*	*1.214*
	s.d.	0.017	0.784	0.0017	0.142
	n	5	5	5	5

Coefficient of friction values for the Ti-6Al-4V samples were typically twice those for TMZF™, and exhibited a broad spread in value (**Figure 9**). This recorded spread in coefficient of friction is indicative of a sticking and sliding action between the bone cement ball and Ti-6Al-4V disc during testing, which likely accounts for the extreme wear and debris generation observed.

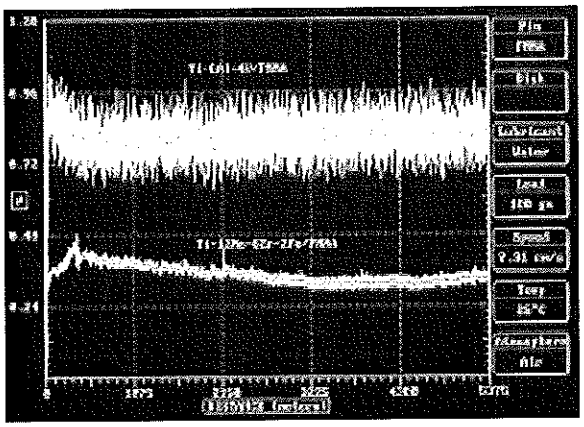


Figure 9

Biological Testing of TMZF™ Alloy

The safety of TMZF™ Alloy was tested in a series of assays based on the Tripartite Agreement, ASTM recommendations, and Howmedica's own standards for material safety. Contract laboratories conducted the following safety studies according to Good Laboratory Practice as summarized below in **Table 5.**

Table 5

Safety Test	Test Material	Control Material	Result
Agar Overlay Assay (ASTM F-898) (a) Direct Contact (b) Saline Extract	 TMZF™ TMZF™	 plastic extractant	 Passed Passed
Colony Suppression Assay	TMZF™	Ti-6Al-4V	Passed
USP Intracutaneous Toxicity Test (ASTM F-749) (a) Saline Extract (b) Cottonseed Oil Extract	 TMZF™ TMZF™	 extractant extractant	 Passed Passed
USP Mouse Systemic Test (ASTM F-750) (a) Saline Extract (b) Cottonseed Oil Extract	 TMZF™ TMZF™		 Passed Passed
In Vitro Hemolysis in Rabbit Whole Blood (a) Direct Contact (b) Saline Extract	 TMZF™ TMZF™	 Ti-6Al-4V Ti-6Al-4V	 Passed Passed
Guinea Pig Sensitization (Maximization)	TMZF™	Ti-6Al-4V	Passed
Ames Salmonella/Reverse Mutation Assay	TMZF™	Ti-6Al-4V	Passed
90 Day Muscle Implant study in the Rabbit	TMZF™	Ti-6Al-4V	Passed

Where appropriate, Ti-6Al-4V was the concurrent control. This battery of safety studies showed TMZF™ Alloy to be biocompatible. To determine if there was any difference in the tissue reaction to particulates of these materials, *in vivo* and *in vitro* studies were conducted. The particles used in these studies were <37 microns with average diameters of 27.0 microns for the Ti-6Al-4V alloy and 23.5 microns for the TMZF™ Alloy. They were produced via gas atomization and sieving. By using the same methodology to produce the particles and sieving them to the same maximum size, the only variable for this study was the alloy and not the particle shape or size. The size range used examined the ability for particles of either alloy to simulate cells from either surface or internal means.

In Vitro Particulate Assay

The objective of this study was to analyze the capability of particulate debris from potential implant materials (TMZF™ and Ti-6Al-4V) to affect the release of PGE_2, IL-1, and IL-6 by human peripheral blood macrophages in an *in vitro* cell culture system. Synovial cells from patients with rheumatoid arthritis retrieved at total joint arthroplasty were also used for this study, since this disease may affect the response of these cells to particulate materials. At concentrations ranging from 10^6 to 10^3 total particles, the peripheral blood macrophages and synovial cells did not respond to either the TMZF™ or Ti-6Al-4V alloy. Neither particle induced release of cellular mediators that are known to induce bone resorption.[19]

In Vivo Particulate Assay

A slight modification of the animal model used by Goodman et al.[20] was used to investigate the *in vivo* response by bone and marrow to 10^6 particles of TMZF™ or Ti-6Al-4V alloy after 8 and 16 weeks implantation. Undecalcified histology of the implantation sites showed that there was no difference in the bone or bone marrow response to TMZF™ particles or Ti-6Al-4V particles compared to each other or controls implanted with the carrier (hyaluronic acid) alone at either time period.

Summary

TMZF™ Titanium Alloy represents an advancement in the state of the art for implant titanium metallurgy. A beta titanium alloy with the composition Ti-12Mo-6Zr-2Fe, TMZF™ addresses many of the critical issues associated with implant materials:

- By design, the alloy composition avoids controversial alloying elements, such as aluminum or vanadium.
- Improved wear resistance reduces the potential for generation of particulate metallic wear debris.
- Increased strength combined with a low elastic modulus provides a material with the best combination of strength and flexibility of all titanium implant alloys.
- The unique metallurgical characteristics of TMZF™ Alloy's beta titanium structure permit hot or cold forming of a variety of implant designs.

References

1. Farthing TW. The Development of Titanium and Its Alloys. *Clinical Materials*, Vol. 2, No.1, Feb. 1987.
2. Laing PG. Clinical Experience with Prosthetic Materials; Historical Perspectives, Current Problems and Future Directions. *ASTM STP 684*, pp.199–211, 1979.
3. Semlitsch M. Titanium Alloys for Hip Joint Replacements. *Clinical Materials*, Vol. 2, No.1, Feb. 1987.
4. Duerig TW. Overview: Microstructure and Properties of Beta Titanium Alloys. *Beta Titanium Alloys in the 80's*, TMS of AIME, pp. 19–67, 1984.
5. Steineman SG. Titanium Alloys as Metallic Biomaterials. *Titanium Science and Technology*, Vol. 2, pp. 1327–1334, 1985.
6. *Titanium Alloys Handbook MCIC-HB-02*, MCIC 1972.
7. Buly RL et al. Titanium Wear Debris in Failed Cemented Total Hip Arthroplasty. *The Journal of Arthroplasty*, Vol. 7, No. 3, pp. 315–323, Sept. 92.
8. Mears DC. *Materials and Orthopaedic Surgery.* Williams & Wilkens, p. 194, 1979.
9. Steinemann SG et al. Beta Titanium Alloy for Surgical Implants. *Titanium '92 Science and Technology*, Vol. 3, pp. 2689-2696, TMS, 1993.
10. Mishra AK et al. "Mechanical and Tribological Properties and Biocompatibility of Diffusion-Hardened Ti-13Nb-13Zr: A Low Modulus Titanium Alloy for Orthopaedic Implants", Symposium on Medical Applications of Titanium and Its Alloys: The Material and Biological Issues, November 15-16, 1994.
11. Bhambri SK et al. "Optimization of Properties of Ti-15Mo-2.8Nb-3Al-0.2Si and Ti-15Mo-2.8Nb-0.2Si-0.26O Beta Titanium Alloys for Applications in Prosthetic Implants", ASTM Symposium on Medical Applications of Titanium and Its Alloys: The Material and Biological Issues, November 15-16, 1994.
12. Zardiackas LD et al. "Characterization of Ti-15Mo Beta Titanium Alloy for Orthopaedic Implant Applications", ASTM Symposium on Medical Applications of Titanium and Its Alloys: The Material and Biological Issues, November 15-16, 1994.
13. Teledyne Wah Chang Albany, Tiadyne 1610 Data Sheet, August 1993.
14. Clarke IC. Debris-Mediated Osteolysis - A Cascade Phenomenon Involving Motion, Wear, Particulates, Macrophage Induction and Bone Lysis. *ASTM STP 1144*, pp. 7–26, 1992.
15. McKellop HA et al. In Vivo wear of Titanium-Alloy Hip Prostheses. *JBJS*, Vol. 72-A, pp. 512–517, April 1990.
16. Black J. Metallosis Associated with a Stable Titanium-Alloy Femoral Component in Total Hip Replacement. *JBJS*, Vol. 72-A, No.1, pp. 127–130, Jan. 1990.
17. Lombardi AV et al. The Performance of Cemented Femoral Components as a Function of Their Metallic Composition. Scientific Exhibit, AAOS, Feb. 1992.
18. Agins HJ. Metallic Wear in Failed Titanium-Alloy Total Hip Replacements. *JBJS*, Vol. 70-A, No. 3, pp. 347–356, March 1988.
19. Lalor PA, Shortkroff S, Aberman HM, Viveiros C, Dumbleton JH, and Sledge CB. *In Vitro* Biocompatibility Studies of Ti-6Al-4V and Ti-Mo-Zr-Fe Particles. Transactions of the 40th Annual Meeting, Orthopaedic Research Society, February 21-24, 1994, p. 840.
20. Goodman SB, Fornasier VL, and Kei J. The Effects Of Bulk Versus Particulate Titanium And Cobalt Chrome Alloy Implanted Into the Rabbit Tibia. *Journal of Biomedical Materials Research*, Vol. 24, 1990, pp. 1539-1549.

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BASIC RESEARCH

Second-generation Highly Cross-linked X3™ Polyethylene Wear

A Preliminary Radiostereometric Analysis Study

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Abstract

Background First-generation highly cross-linked polyethylene liners have reduced the incidence of wear particle-induced osteolysis. However, failed acetabular liners have shown evidence of surface cracking, mechanical failure, and oxidative damage. This has led to the development of second-generation highly cross-linked polyethylene, which has improved wear and mechanical properties and resistance to oxidation in vitro. Owing to its recent introduction, there are no publications describing its clinical performance.

Questions/purposes We assessed early clinical wear of a second-generation highly cross-linked polyethylene liner and compared its clinical performance with the published results of hip simulator tests and with first-generation highly cross-linked polyethylene annealed liners.

Patients and Methods Twenty-one patients were enrolled in a prospective cohort study. Clinical outcome and femoral head penetration were measured for 19 patients at 6 months and 1 and 2 years postoperatively.

Results The median proximal head penetration was 0.009 mm and 0.024 mm at 1 and 2 years, respectively. The median two-dimensional (2-D) head penetration was 0.083 mm and 0.060 mm at 1 and 2 years, respectively. The median proximal wear rate between 1 and 2 years was 0.015 mm/year.

Conclusions The wear rate calculated was similar to the in vitro wear rate reported for this material; however, it was less than the detection threshold for this technique. Although longer followup is required for wear to reach a clinically quantifiable level, this low level of wear is encouraging for the future clinical performance of this material.

Level of Evidence Level IV, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

One or more of the authors (DGC) has received funding from Stryker Orthopaedics, Mahwah, NJ.
Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This work was performed at Wakefield Orthopaedic Clinic.

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Introduction

Component loosening is the most common reason for early to midterm revision of hip prostheses [2, 27]. A major contributor to the loosening observed at revision arthroplasty is osteolysis related to wear of UHMWPE [10, 17, 18, 23, 26, 40, 45, 46]. To overcome the problems of wear associated with conventional UHMWPE, highly cross-linked polyethylene (HXLPE) was introduced [11]. The first-generation HXLPEs in clinical use have exhibited markedly less wear than conventional UHMWPE [12, 14, 28, 30, 31]; however, there have been some reports of surface cracking, mechanical failure, and oxidative damage in failed acetabular liners [5, 22, 25].

The reduced mechanical properties of first-generation HXLPE can be attributed to the process of cross-link

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formation, which is achieved by irradiation and heating of the polyethylene [16, 37]. Materials that are heated above their melting temperature (remelted) have reduced fatigue strength [41, 42] owing to alteration of the material's crystalline structure [38]. Heating to just below the melting point (annealing) maintains the mechanical properties of the material; however, the ability to eliminate free radicals using this technique is reduced as a consequence of their limited mobility in the polymer, which increases the propensity for late oxidative damage to the material [42, 43]. To improve the efficiency of free radical elimination, a new process of sequential irradiation and annealing has been introduced in a new second-generation material X3™ (Stryker Orthopaedics, Mahwah, NJ). A hip simulator study has shown, in addition to excellent mechanical properties, acetabular liners made from this material have superior wear properties in comparison to conventional UHMWPE and clinically successful first-generation HXLPE [16].

Unfortunately, the ability to translate positive findings from hip simulator studies to equally good results clinically has proven challenging [29, 32, 39]. This highlights the importance of confirming the safety and wear performance of new materials in clinical studies using a sensitive evaluation technique. There is currently no published data describing the clinical performance of the second-generation highly cross-linked polyethylene X3™ acetabular liner. Therefore, we assessed the early clinical wear properties of the X3™ liner using radiostereometric analysis (RSA) to compare its clinical performance with the results of hip simulator tests and with those of first-generation annealed acetabular liners. We hypothesize the X3™ liner will have a clinical wear rate similar to that reported from hip simulator tests and less than that reported for first-generation annealed acetabular liners.

Patients and Methods

We recruited a prospective consecutive series of 21 patients with osteoarthritis of their hip for the trial. Inclusion criteria were the consultant surgeon selecting cementless components with the Trident® acetabular system (Stryker Orthopaedics) matched with an X3™ acetabular liner (Stryker Orthopaedics) as the preferred choice of implant and surgery scheduled at the Calvary Wakefield Hospital, which is equipped for RSA. Ethics approval was obtained for this study from the Wakefield Hospital ethics committee. All patients provided informed consent for the insertion of tantalum markers during surgery and the subsequent RSA radiographs. Exclusion criteria were residence outside the metropolitan area, abnormal gross anatomy of the hip, age older than 80 years, and inflammatory arthritis or severe osteoporosis. Two patients were excluded from the study owing to incomplete RSA evaluation at 12 months. Therefore, 19 patients were included in the study (10 men, nine women). Their median age was 63 years (range, 47–76 years); median male weight was 84 kg (range, 72–100 kg) and median female weight was 71 kg (range, 60–78 kg). Sixteen patients were Charnley grade A and three were Charnley grade B. The mean cup size was 54.6 mm (range, 48–62 mm). The mean inclination was 45.6° (range, 39°–58°).

All patients had a hemispheric, porous-coated, metal-backed shell (Trident® acetabular system) implanted with a HXLPE liner (X3™). The cross-link formation process of the liner involved three cycles of sequential irradiation and annealing. Each cycle consisted of gamma irradiation at a dose of 3 Mrad followed by annealing at 130°C for 8 hours [16]. The total cumulative radiation dose was 9 Mrad. Terminal sterilization was achieved through a gas plasma process. All patients received a cementless femoral stem (Accolade®; Stryker Orthopaedics) with a 32-mm cobalt-chromium femoral head.

Six tantalum markers (1.0-mm diameter; RSA Biomedical, Umeå, Sweden) were placed in the outer rim of the polyethylene liner at the time of surgery. Baseline RSA examinations were performed within 7 days of surgery and again at 6 months and 1 and 2 years postoperatively. Examinations were taken with each patient in a supine position. Bragdon et al. [8] and von Schewelov et al. [50] reported no statistical difference between the wear measurements made from standing and supine RSA radiographs; therefore, patients in our study were examined in the supine position.

A ceiling-mounted radiographic tube and a mobile radiographic tube were used simultaneously to take exposures of the hip with a calibration cage (Number 43; RSA Biomedical). Wear was measured by penetration of the femoral head inside the polyethylene liner with UmRSA® software (v6.0; RSA Biomedical). The program identifies the center of the outer ellipse of the femoral head and acetabular cup with an edge detection algorithm used in conjunction with tantalum markers placed in the outer rim of the polyethylene liner. This combined measurement technique using edge detection in conjunction with marker beads was proven to have the highest precision clinically in a study by Borlin et al. [4] with a conservative detectable limit for measuring wear of 80 μm.

Femoral head penetration into the polyethylene was calculated in three separate ways to enable comparison to other in vitro and in vivo studies. First, proximal head penetration was calculated from translations along the y axis (Fig. 1). Second, the amount of 2-D head penetration was calculated as the vectorial sum of medial-lateral (x axis) and proximal-distal (y axis) migrations. Third, the

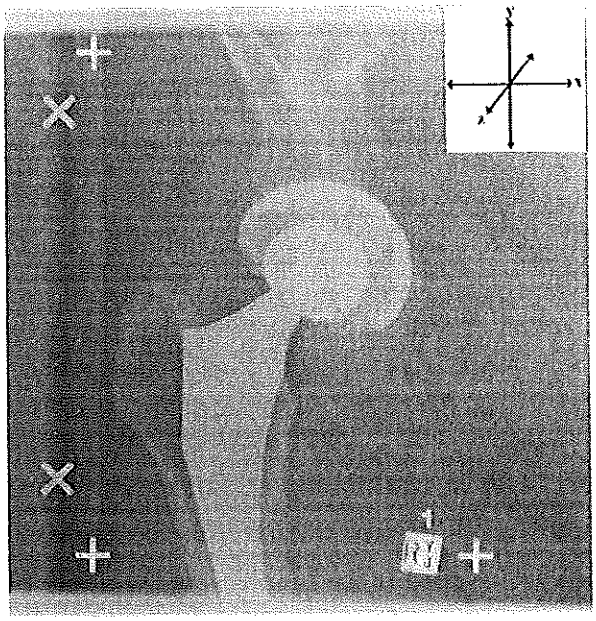

Fig. 1 A postoperative RSA radiograph of a right hip is shown, with an inset illustrating the three axes used to measure head penetration. Positive x-axis translations represent medial head penetration; positive y-axis translations represent proximal head penetration; and positive z-axis translations represent anterior head penetration.

amount of 3-D head penetration was calculated as the vectorial sum of medial-lateral, proximal-distal, and anterior-posterior (z axis) migrations. These measurements of femoral head penetration used the immediate postoperative radiograph as a baseline and therefore included "bedding-in" of the femoral head. The penetration recorded after 1 year was identified as true wear of the polyethylene liner, and consequently, the proximal wear rate was calculated between 1 and 2 years. Median wear rate was calculated as the difference in head penetration between 1 and 2 years for each individual.

To document that this series of patients achieved a typical outcome with usual physical activity after TKA, clinical outcome was measured using Oxford Hip and SF-12 scores recorded preoperatively and postoperatively.

Sample size was based on a power calculation made using the Altman normogram [1, 52]. Previous RSA studies [22, 41] showed wear of conventional polyethylene of 0.1 to 0.085 mm and a standard deviation less than 0.07. RSA studies on cross-linked polyethylenes support in vitro observations that wear would be less than the detection threshold of 0.80 mm. A power calculation indicated a total of less than 20 subjects was required to detect a target difference of less than 50% wear compared with published results of noncross-linked polyethylene ($\alpha = 0.05$, $\beta = 0.9$). A post hoc power calculation [33, 52] with 2-year results showed a β value greater than 90% for vertical, 2-D, and 3-D wear. Changes in clinical outcomes scores assessed preoperatively and at 1 year followup were compared using the Wilcoxon's matched pairs signed-ranks test. Significance was set at $p = 0.05$.

Results

There were no mechanical failures or reoperations in any of the patients. All patients showed improvement in preoperative and 1-year postoperative clinical scores ($p < 0.5$, Wilcoxon's matched pairs signed-ranks test). Oxford Hip Score improved from a preoperative median of 36 (range, 26–54) to a postoperative median of 18 (range, 12–30). The median preoperative SF-12 scores for pain and motivation were 30 (range, 21–43) and 42 (range, 31–61), respectively. Postoperatively, the median SF-12 scores for pain and motivation were 39 (range, 25–56) and 52 (range, 34–65), respectively. SF-12 scores were comparable to those of age-matched population normals [3]: in subjects aged 55 to 64 years, the mean physical component is 46.7 (range, 45.4–48.0) and the mean mental component is 53.4 (range, 52.4–54.5).

Femoral head penetration was observed during the initial 6 months, which plateaued with minimal wear at 1 and 2 years of followup. The median proximal head penetrations were 0.009 mm (range, −0.094–0.119 mm; SD, 0.063 mm) and 0.024 mm (range, −0.070–0.160 mm; SD, 0.061 mm) at 1 and 2 years, respectively (Fig. 2A). The median proximal wear rate calculated between 1 and 2 years was 0.015 mm/year. The median 2-D head penetration showed most of the migration occurred during the first 12 months. The median 2-D head penetrations were 0.083 mm (range, 0.017–0.152 mm; SD, 0.040 mm) at 1 year and 0.060 mm (range, 0.014–0.165 mm; SD, 0.040 mm) at 2 years (Fig. 2B). The median 2-D wear rate between 1 and 2 years was 0.009 mm/year. The median 3-D head penetrations were 0.159 mm (range, 0.017–0.317 mm; SD, 0.080 mm) and 0.156 mm (range, 0.067–0.256 mm; SD, 0.059 mm) at 1 and 2 years, respectively (Fig. 2C). The median 3-D wear rate between 1 and 2 years was −0.043 mm/year.

Discussion

As a consequence of its recent introduction to clinical use, there currently are no publications describing the clinical wear properties of the X3™ acetabular cup insert. One hip simulator study reports the in vitro wear of this insert [16], and therefore our purpose was to compare these in vitro wear results with those after clinical use during a 2-year period. Furthermore, as this is the first report of the clinical

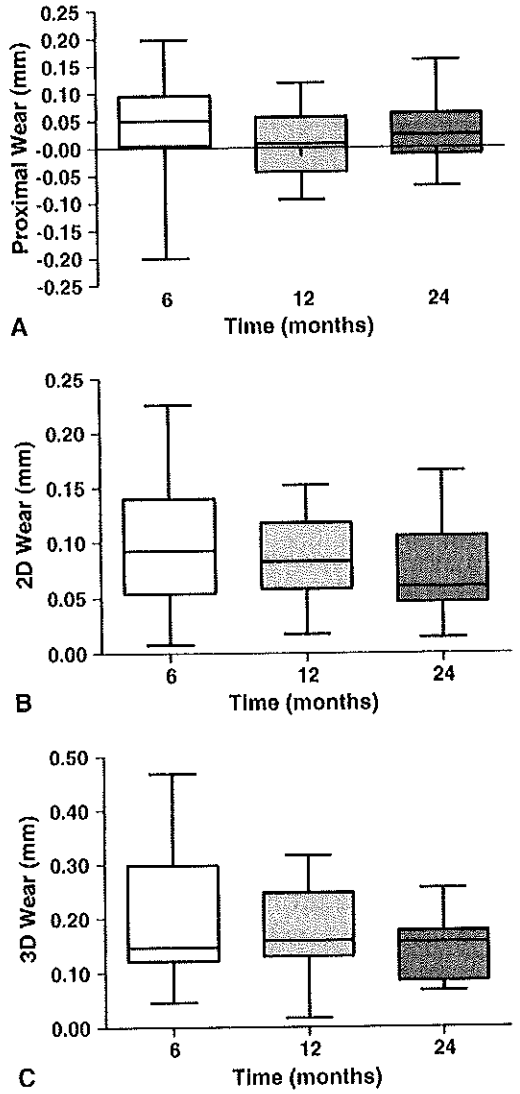

Fig. 2A–C Box-and-whisker plots show (A) proximal, (B) 2-D, and (C) 3-D head penetration measured at 6, 12, and 24 months. Horizontal bar = median; box = upper and lower quartiles; error bars = range.

wear characteristics of a second-generation HXLPE acetabular liner, we were interested in comparing the results from this study with literature reports of first-generation annealed highly cross-linked UHMWPE liners. We hypothesized the findings of this study would be consistent with the in vitro wear results and show clinical wear comparable or less than wear for first-generation HXLPE liners.

The high sensitivity of the RSA measurement technique, in conjunction with the ability to extrapolate results of short-term average linear wear rate to the average long-term linear wear rate for a population, makes this a useful tool for screening newly introduced prostheses [13, 29, 49]. Despite this, the RSA technique has limitations in accuracy and precision [4, 7, 51] that make it challenging to measure very small amounts of wear that are less than the detection threshold. In an optimal experimental setup, the accuracy of RSA is reported to range from 0.022 mm to 0.086 mm depending on the vector direction [7]. Our study is further limited in that no measurement of precision was made for this data set. The precision of our results should be similar to those validated previously for the combined liner and marker technique [4].

Dowd et al. [15] reported a linear increase in true wear with time is characteristic of polyethylene acetabular liners. However, we measured an uncharacteristic pattern of proximal femoral head penetration in that numerous patients had negative wear, particularly within the first year of the study. This finding has been reported previously [6, 20, 34–36] and is a result of femoral head penetration measurements lying within the accuracy limit of the technique and therefore being outside the limit of detection. The migration calculated between 1 and 2 years represents the actual rate of wear, but the numerical value of this should be interpreted with caution as it also lies within the detection threshold of the RSA technique.

The calculation of annual wear in this study was based only on wear that occurred between 1 and 2 years. Although the amount of head penetration was recorded at three times, the measurements were relative to the immediate postoperative radiographs and consequently included the initial creep and bedding-in of the liner. Studies have shown the majority of bedding-in occurs within 2.5 million cycles [21], which usually is complete after approximately 1 year [47]. This being the case, only wear measured between the first and second years was considered true wear. This is supported by the findings of Glyn-Jones et al. [24] in an RSA study of the creep and wear characteristics of HXLPE. They concluded femoral head penetration within the first 6 months was dominated by creep whereas penetration after 1 year was virtually all attributable to wear.

In the only published hip simulator study comparing the X3™ liner with conventional UHMWPE and a first-generation annealed HXLPE liner (Crossfire®; Stryker Orthopaedics), the X3™ liners had a markedly lower wear rate than the conventional and first-generation HXLPE liners [16]. Based on their findings, Dumbleton et al. [16] predicted the clinical wear rate of the X3™ liners should be 14 μm/year. The wear rate of 15 μm/year of median proximal wear measured in our study between 1 and 2 years is consistent with the predicted wear rate of 14 μm/year but should be considered a serendipitous result as this amount of wear is within the limits of accuracy for RSA and is not valid at this time. If we assume a conservative detectable limit for measuring wear of 80 μm, which is consistent with the precision measurements reported by Borlin et al. [4] for this technique (68 μm, 98 μm, 138 μm

in the x, y, z axes, respectively), it would take more than 5 years before there is evidence of measurable wear. Similar findings have been reported for first-generation HXLPE liners, which highlights the need to evaluate HXLPE over a period of at least 5 years [9, 35]. The annual 2-D wear rate calculated in our study was considerably less than for proximal wear; however, linear measurements of 2-D wear are thought to underestimate the true wear rate [17, 48] and therefore may not truly represent the wear rate for this type of polyethylene.

First-generation annealed Crossfire® liners are reported to have an annual wear rate of 36 μm/year based on a 5-year evaluation of plain radiographs [12]. The annual wear rate for the X3™ liner found in our study (15 μm/year) is 58% less than this, which is consistent with the hip simulator results of Dumbleton et al. [16], who found the X3™ material had 62% less wear than Crossfire® liners. Rohrl et al. [44] reported a mean wear of 23 μm between 2 and 24 months for Crossfire® inserts. This is similar to the mean proximal head penetration we found (28 μm) for the X3™ liner; however, an accurate comparison requires a longer study to quantify the potential differences in wear between these materials.

A low rate of polyethylene wear is advantageous as it reduces the likelihood of wear particle-induced osteolysis and the subsequent need for revision arthroplasty owing to aseptic loosening. Dumbleton et al. [17] have assigned an osteolysis threshold for wear of 0.1 mm/year, below which osteolysis occurs infrequently, and a rate of 0.05 mm/year, which is considered safe, as the occurrence of osteolysis is almost eliminated. The annual wear rate calculated in our study was well below this threshold. We can expect the need for revision arthroplasty attributable to wear particle-induced osteolysis to be unlikely at least in the short term. The functional biologic activity of this material is likely to be lower than conventional polyethylene owing to a combination of similar specific biologic activity and lower wear rate [16, 19].

Our study showed that wear of X3™ acetabular liners after 2 years is less than a clinically quantifiable level, making accurate comparison with first-generation Crossfire® liners challenging. A longer period of evaluation is required until wear reaches a level that is clinically detectable. However, it is clear X3™ liners have wear properties superior to those of conventional polyethylene. Our measurements between 1 and 2 years followup suggest wear is nearly undetectable, which is encouraging for the future clinical performance of this material.

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References

1. Altman DG. *Practical Statistics for Medical Research.* London, UK: Chapman and Hall; 1991.
2. Australian Orthopaedic Association National Joint Replacement Registry. *Annual Report.* Adelaide, Australia: AOA; 2008.
3. Avery J, Dal Grande E, Taylor A. *Quality Of Life in South Australia as Measured by the SF12 Health Status Questionnaire Population Norms For 2003 Trends From 1997–2003.* Population Research and Outcome Studies Unit Department of Human Services, Adelaide, South Australia; 2004.
4. Borlin N, Rohrl SM, Bragdon CR. RSA wear measurements with or without markers in total hip arthroplasty. *J Biomech.* 2006;39:1641–1650.
5. Bradford L, Baker DA, Graham J, Chawan A, Ries MD, Pruitt LA. Wear and surface cracking in early retrieved highly cross-linked polyethylene acetabular liners. *J Bone Joint Surg Am.* 2004;86:1271–1282.
6. Bragdon CR, Barrett S, Martell JM, Greene ME, Malchau H, Harris WH. Steady-state penetration rates of electron beam-irradiated, highly cross-linked polyethylene at an average 45-month follow-up. *J Arthroplasty.* 2006;21:935–943.
7. Bragdon CR, Malchau H, Yuan X, Perinchief R, Karrholm J, Borlin N, Estok DM, Harris WH. Experimental assessment of precision and accuracy of radiostereometric analysis for the determination of polyethylene wear in a total hip replacement model. *J Orthop Res.* 2002;20:688–695.
8. Bragdon CR, Thanner J, Greene ME, Malchau H, Digas G, Harris WH, Karrholm J. Standing versus supine radiographs in RSA evaluation of femoral head penetration. *Clin Orthop Relat Res.* 2006;448:46–51.
9. Campbell D, Mercer G, Nilsson K, Wells V, Field JR, Callary SA. Wear of a highly cross-linked polyethylene liner: a preliminary RSA study. *Eur J Orthop Surg Traumatol.* 2009; DOI 10.1007/s00590-009-0486-y.
10. Clohisy JC, Calvert G, Tull F, McDonald D, Maloney WJ. Reasons for revision hip surgery: a retrospective review. *Clin Orthop Relat Res.* 2004;429:188–192.
11. Collier JP, Currier BH, Kennedy FE, Currier JH, Timmins GS, Jackson SK, Brewer RL. Comparison of cross-linked polyethylene materials for orthopaedic applications. *Clin Orthop Relat Res.* 2003;414:289–304.
12. D'Antonio JA, Manley MT, Capello WN, Bierbaum BE, Ramakrishnan R, Naughton M, Sutton K. Five-year experience with Crossfire highly cross-linked polyethylene. *Clin Orthop Relat Res.* 2005;441:143–150.
13. Derbyshire B, Prescott RJ, Porter ML. Notes on the use and interpretation of radiostereometric analysis. *Acta Orthop.* 2009;80:124–130.
14. Dorr LD, Wan Z, Shahrdar C, Sirianni L, Boutary M, Yun A. Clinical performance of a Durasul highly cross-linked polyethylene acetabular liner for total hip arthroplasty at five years. *J Bone Joint Surg Am.* 2005;87:1816–1821.
15. Dowd JE, Sychterz CJ, Young AM, Engh CA. Characterization of long-term femoral-head-penetration rates: association with and prediction of osteolysis. *J Bone Joint Surg Am.* 2000;82:1102–1107.
16. Dumbleton JH, D'Antonio JA, Manley MT, Capello WN, Wang A. The basis for a second-generation highly cross-linked UHMWPE. *Clin Orthop Relat Res.* 2006;453:265–271.
17. Dumbleton JH, Manley MT, Edidin AA. A literature review of the association between wear rate and osteolysis in total hip arthroplasty. *J Arthroplasty.* 2002;17:649–661.
18. Dunbar MJ, Blackley HR, Bourne RB. Osteolysis of the femur: principles of management. *Instr Course Lect.* 2001;50:197–209.

19. Endo M, Tipper JL, Barton DC, Stone MH, Ingham E, Fisher J. Comparison of wear, wear debris and functional biological activity of moderately crosslinked and non-crosslinked polyethylenes in hip prostheses. *Proc Inst Mech Eng H.* 2002;216: 111–122.
20. Engh CA Jr, Stepniewski AS, Ginn SD, Beykirch SE, Sychterz-Terefenko CJ, Hopper RH Jr, Engh CA. A randomized prospective evaluation of outcomes after total hip arthroplasty using cross-linked marathon and non-cross-linked Enduron polyethylene liners. *J Arthroplasty.* 2006;21(6 suppl 2):17–25.
21. Estok DM II, Bragdon CR, Plank GR, Huang A, Muratoglu OK, Harris WH. The measurement of creep in ultrahigh molecular weight polyethylene: a comparison of conventional versus highly cross-linked polyethylene. *J Arthroplasty.* 2005;20:239–243.
22. Furmanski J, Gupta S, Chawan A, Kohm A, Lannutti J, Jewett B, Pruitt LA, Ries MD. Aspherical femoral head with highly cross-linked ultra-high molecular weight polyethylene surface cracking: a case report. *J Bone Joint Surg Am.* 2007;89:2266–2270.
23. Garcia-Cimbrelo E, Munuera L. Early and late loosening of the acetabular cup after low-friction arthroplasty. *J Bone Joint Surg Am.* 1992;74:1119–1129.
24. Glyn-Jones S, McLardy-Smith P, Gill HS, Murray DW. The creep and wear of highly cross-linked polyethylene: a three-year randomised, controlled trial using radiostereometric analysis. *J Bone Joint Surg Br.* 2008;90:556–561.
25. Halley D, Glassman A, Crowninshield RD. Recurrent dislocation after revision total hip replacement with a large prosthetic femoral head: a case report. *J Bone Joint Surg Am.* 2004;86:827–830.
26. Harris WH. The problem is osteolysis. *Clin Orthop Relat Res.* 1995;311:46–53.
27. Havelin LI, Engesaeter LB, Espehaug B, Furnes O, Lie SA, Vollset SE. The Norwegian Arthroplasty Register: 11 years and 73,000 arthroplasties. *Acta Orthop Scand.* 2000;71:337–353.
28. Heisel C, Silva M, dela Rosa MA, Schmalzried TP. Short-term in vivo wear of cross-linked polyethylene. *J Bone Joint Surg Am.* 2004;86:748–751.
29. Hopper RH Jr, Young AM, Orishimo KF, McAuley JP. Correlation between early and late wear rates in total hip arthroplasty with application to the performance of marathon cross-linked polyethylene liners. *J Arthroplasty.* 2003;18(7 suppl 1):60–67.
30. Krushell RJ, Fingeroth RJ, Cushing MC. Early femoral head penetration of a highly cross-linked polyethylene liner vs a conventional polyethylene liner: a case-controlled study. *J Arthroplasty.* 2005;20(7 suppl 3):73–76.
31. Leung SB, Egawa H, Stepniewski A, Beykirch S, Engh CA Jr, Engh CA Sr. Incidence and volume of pelvic osteolysis at early follow-up with highly cross-linked and noncross-linked polyethylene. *J Arthroplasty.* 2007;22(6 suppl 2):134–139.
32. Livingston BJ, Chmell MJ, Spector M, Poss R. Complications of total hip arthroplasty associated with the use of an acetabular component with a Hylamer liner. *J Bone Joint Surg Am.* 1997;79:1529–1538.
33. Lochner HV, Bhandari M, Tornetta P III. Type-II error rates (beta errors) of randomized trials in orthopaedic trauma. *J Bone Joint Surg Am.* 2001;83:1650–1655.
34. Manning DW, Chiang PP, Martell JM, Galante JO, Harris WH. In vivo comparative wear study of traditional and highly cross-linked polyethylene in total hip arthroplasty. *J Arthroplasty.* 2005;20:880–886.
35. McCalden RW, MacDonald SJ, Rorabeck CH, Bourne RB, Chess DG, Charron KD. Wear rate of highly cross-linked polyethylene in total hip arthroplasty: a randomized controlled trial. *J Bone Joint Surg Am.* 2009;91:773–782.
36. McCalden RW, Naudie DD, Yuan X, Bourne RB. Radiographic methods for the assessment of polyethylene wear after total hip arthroplasty. *J Bone Joint Surg Am.* 2005;87:2323–2334.
37. McKellop H, Shen FW, Lu B, Campbell P, Salovey R. Development of an extremely wear-resistant ultra high molecular weight polyethylene for total hip replacements. *J Orthop Res.* 1999;17:157–167.
38. Muratoglu OK, Bragdon CR, O'Connor DO, Jasty M, Harris WH. A novel method of cross-linking ultra-high-molecular-weight polyethylene to improve wear, reduce oxidation, and retain mechanical properties. Recipient of the 1999 HAP Paul Award. *J Arthroplasty.* 2001;16:149–160.
39. Norton MR, Yarlagadda R, Anderson GH. Catastrophic failure of the Elite Plus total hip replacement, with a Hylamer acetabulum and Zirconia ceramic femoral head. *J Bone Joint Surg Br.* 2002;84:631–635.
40. Oparaugo PC, Clarke IC, Malchau H, Herberts P. Correlation of wear debris-induced osteolysis and revision with volumetric wear-rates of polyethylene: a survey of 8 reports in the literature. *Acta Orthop Scand.* 2001;72:22–28.
41. Oral E, Malhi AS, Muratoglu OK. Mechanisms of decrease in fatigue crack propagation resistance in irradiated and melted UHMWPE. *Biomaterials.* 2006;27:917–925.
42. Oral E, Wannomae KK, Hawkins N, Harris WH, Muratoglu OK. Alpha-tocopherol-doped irradiated UHMWPE for high fatigue resistance and low wear. *Biomaterials.* 2004;25:5515–5522.
43. Ries MD, Pruitt L. Effect of cross-linking on the microstructure and mechanical properties of ultra-high molecular weight polyethylene. *Clin Orthop Relat Res.* 2005;440:149–156.
44. Rohrl S, Nivbrant B, Mingguo L, Hewitt B. In vivo wear and migration of highly cross-linked polyethylene cups: a radiostereometry analysis study. *J Arthroplasty.* 2005;20:409–413.
45. Saleh KJ, Thongtrangan I, Schwarz EM. Osteolysis: medical and surgical approaches. *Clin Orthop Relat Res.* 2004;427:138–147.
46. Schmalzried TP, Kwong LM, Jasty M, Sedlacek RC, Haire TC, O'Connor DO, Bragdon CR, Kabo JM, Malcolm AJ, Harris WH. The mechanism of loosening of cemented acetabular components in total hip arthroplasty: analysis of specimens retrieved at autopsy. *Clin Orthop Relat Res.* 1992;274:60–78.
47. Silva M, Shepherd EF, Jackson WO, Dorey FJ, Schmalzried TP. Average patient walking activity approaches 2 million cycles per year: pedometers under-record walking activity. *J Arthroplasty.* 2002;17:693–697.
48. Sychterz CJ, Engh CA Jr, Shah N, Engh CA Sr. Radiographic evaluation of penetration by the femoral head into the polyethylene liner over time. *J Bone Joint Surg Am.* 1997;79:1040–1046.
49. Valstar ER, Gill R, Ryd L, Flivik G, Borlin N, Karrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. *Acta Orthop.* 2005;76:563–572.
50. von Schewelov T, Onsten I, Markusson P, Carlsson A. Weight bearing radiographs are not necessary for measurement of polyethylene penetration in total hip prostheses: a radiostereometric study of 111 patients examined in weight-bearing and supine position. *Acta Orthop.* 2006;77:104–108.
51. von Schewelov T, Sanzen L, Borlin N, Markusson P, Onsten I. Accuracy of radiographic and radiostereometric wear measurement of different hip prostheses: an experimental study. *Acta Orthop Scand.* 2004;75:691–700.
52. Whitley E, Ball J. Statistics review 4: sample size calculations. *Crit Care.* 2002;6:335–341.

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Section 2. Total Knee Arthroplasty

Knee Bearing Technology

Where is Technology Taking Us?

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Abstract: A novel sequentially irradiated and annealed bearing material (X3), characterized for use in knee arthroplasty, has been developed. Attention was directed to mechanical strength properties, oxidation resistance, and the ability to reduce wear. Material properties such as ultimate tensile and yield strength were unaffected by the sequential cross-linking process. Elongation was reduced relative to GUR 1020 conventional polyethylene, but equivalent to that of direct compression molded 1900 material. In knee simulator testing for normal gait and stair climbing, measured wear rates for X3 polyethylene were reduced by 79% and 77% when compared to the same knee design using conventional polyethylene. Mechanical properties and wear characteristics of the X3 polyethylene were unaffected before and after exposure to accelerated aging; properties of conventional polyethylene were adversely impacted. **Key words:** polyethylene, highly crosslinked, knee arthroplasty, wear, mechanical properties, joint simulator.

Patient demographics are changing in ways that will create more challenges to total knee arthroplasty. Total knee recipients are nearly 20% heavier, more physically active, and have a life expectancy that is 25% longer when compared with patients from decades past [1]. The expectations of today's patients are often shaped by what they have been exposed to on the Internet; this Web-based information is rarely subjected to the peer review process. Consequently, patients may have lofty expectations for their arthroplasty, which, in turn, must be calibrated by the orthopedic surgeon. Nonetheless, implant manufacturers must continually seek to apply the results of responsible science to raise implant performance to meet or exceed the demands placed upon the replaced joints.

Polyethylene bearing failure has been cited as one of the leading causes of knee implant revision surgery; one investigation found polyethylene wear present in 25% of knee revision surgeries and listed this wear as the top reason for revision [2]. Certainly other mechanisms were present that may have contributed to the revision, but it is clear that polyethylene wear was a major clinical issue worthy of being addressed. From a bearing perspective, polyethylene needs to have sufficient strength, be resistive to oxidative breakdown, and not wear at a rate that would place a burden on the host. Patient factors such as weight and activity patterns can impact wear, mechanical, and fatigue behavior. Lastly, surgeon factors such as alignment and soft tissue balancing can also influence wear. Increased cross-linking has been shown to reduce hip wear in simulators [3,4]. The geometry of the bearing surfaces dramatically influences the kinematics of the joint, which can also impact the wear of the joint.

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The purpose of this article is to describe the material characteristics and tribological testing for a new bearing surface material, X3 (Stryker Orthopaedics, Mahwah, NJ) designed for knee joint applications.

Materials and Methods

X3 is composed of GUR 1020 polyethylene, which is irradiated and annealed in 3 sequential steps—each consisting of 30 kGy of irradiation followed by annealing for 8 hours at 130°C in air. Following these 3 steps, the part is machined and gas plasma sterilized.

It is crucial that the bearing material properties be fully characterized. Further, the impact of time in the harsh environment of the host on these material properties must be investigated through an accelerated aging regimen. The ultimate tensile, yield strengths, and elongation were determined by following the protocol of American Society for Testing and Materials (ASTM) D638-03 [5]. The free radical concentration of conventional (GUR 1020 with 30 kGy in inert gas) and X3 polyethylene were determined with electronic spin resonance with a Bruker Instruments, Model EMX spectrometer (the authors gratefully acknowledge Dr S Jahan; University of Memphis, Memphis, TN). Six (n = 6) specimens of each polyethylene type were tested. The oxygen bomb, per ASTM F2003-02, was used to simulate aging in the body to determine the resistance of the X3 bearing material to oxidation. Conventional and X3 polyethylene specimens were subjected to 14 days at 70°C at 5 atm of oxygen pressure. After accelerated aging, the mechanical properties (n = 8) and level of oxidation (n = 5) were determined. The level of oxidation was determined using a Nicolet 750 Magna infrared spectrometer on specimens with dimensions of 90 × 20 × 10 mm. The analysis was performed on the full thickness (10 mm) in 250-μm increments per ASTM F2102-01e1 [6].

Tribological testing that simulated level gait and stair climbing (separately) using the Scorpio design knee (Stryker Orthopaedics) was performed [7]. For the gait simulation, the Scorpio Cruciate Retaining (CR) design was used (size 7, nominal 8-mm inserts). Three inserts each of X3 and conventional material were tested. The insert locking mechanisms were disabled to permit easy removal from the corresponding CoCr tibial tray. An MTS motion controlled joint simulator (Eden Prairie, MN) was used with the loading waveforms per ISO 14243-3. The lubricant, Alpha Calf Fraction serum (Hyclone Laboratories, Logan, Utah) was changed every 500,000 cycles, and the inserts weighed per ASTM F2025. Joint fluid absorption correction was accomplished with unloaded soak controls. Testing was conducted for a total of 5 million cycles. The wear debris was collected from the lubricant and pooled for analysis from each polyethylene set. The inserts were visually inspected for wear pattern characteristics. A second iteration of the level gait simulation, X3, and conventional inserts that had been subjected to accelerated aging per ASTM F2003-02 were tested.

The Scorpio Posterior Substituting (PS) design, size 7 using nominal 8-mm inserts, was tested on the MTS joint simulator using a loading waveform to simulate stair climbing [7]. The waveform was chosen to ensure that the cam and post were making contact. Three inserts each of X3 and conventional material were tested. As in the gait study, the inserts were removed every 500,000 cycles and weighed when the Alpha Calf Serum was replaced. Unloaded soak control inserts were used to account for fluid absorption. Testing was conducted for a total of 5 million cycles.

Results

Tensile yield strength and ultimate yield strength were statistically the same (P = .11 and .12, respectively) between the conventional and X3 polyethylene before accelerating aging (Table 1). Elongation for X3 was lower than for conventional polyethylene. However, it is comparable to that of direct compression molded 1900 material that has shown excellent clinical performance [8].

Further, the tensile properties of the X3 were statistically unaffected by the accelerated aging challenge. However, the yield strength, ultimate tensile strength, and elongation of the conventional

Table 1. Tensile Properties of Program Materials

	Conventional (3 mrad in N2)		X3		DCM 1900 (3 mrad in N2)
	Aged	New	Aged	New	New
Yield strength (MPa)	27.9 ± 0.5	23.2 ± 0.4	23.6 ± 0.2	23.5 ± 0.3	23.5
Tensile strength (MPa)	29.9 ± 1.2	54.8 ± 2.5	56.7 ± 2.3	56.7 ± 2.1	51.1
Elongation (%)	143 ± 14	368 ± 10	266 ± 9	267 ± 7	256

polyethylene decreased markedly after accelerated aging. X3 exhibited 99% less free radicals when compared to conventional polyethylene. There were (1550 ± 32) × 1014 spins/g for the conventional polyethylene as opposed to (14 ± 2) × 1014 spins/g for X3 polyethylene. Accelerated aging produced large subsurface oxidation peaks for conventional polyethylene but solicited a minimal response from the X3 material. There were subsurface white bands present in the conventional polyethylene but none in the X3 samples.

The wear characteristics of the conventional and X3 were different for both the gait and stair simulator models. The wear rates for Scorpio CR knee in the gait simulator for conventional and X3 polyethylene were 34.6 ± 1.5 and 7.3 ± 0.7 mm^3/million cycles, respectively. Hence, X3 produced a 79% reduction in the wear rate, which was statistically significant ($P = .0001$).

There was a statistically significant ($P < .001$) decrease in the wear rate when comparing conventional (35.8 ± 1.7 mm^3/million cycles) and X3 (8.2 ± 0.7 mm^3/million cycles) polyethylene wear rates for the stair climbing simulator. This represents a 77% decrease in wear for the X3 relative to conventional polyethylene. The wear scars of all materials from both simulator types exhibited areas of burnishing, deformation, striations, and occasional scratches.

Wear debris results from the 2 types of simulator testing are shown in Table 2. A total of 223 and 221 wear debris particles were identified for conventional and X3 UHMWPE material, respectively, under stair climbing conditions. A total of 145 and 132 particles were also identified for conventional and X3 materials under gait conditions. Results show that conventional polyethylene debris created under stair climbing conditions were statistically significantly larger than X3 debris. X3 debris created under gait conditions showed no difference in length but were wider than the conventional CR debris.

X3 inserts that had gone through the accelerated aging process went through 10 million cycles of knee simulator testing. Results for this test showed no statistical difference ($P = .36$) in wear rate between the accelerated aged samples and the unaged controls. The wear behavior was strongly linear for either aging condition with a correlation coefficient (R^2) of 0.992 or larger for all individual samples. Regions of burnishing or wear polishing along with surface deformation were seen in areas of contact. No gross evidence of delamination, pitting, or cracking was noted anywhere on any insert, either unaged or aged.

Table 2. Wear Debris Length, Width, and ECD

Material	Length (μm)	Width (μm)	ECD (μm)
Control CR	0.39 ± 0.12	0.28 ± 0.07	0.37 ± 0.09
X3 CR	0.43 ± 0.23	0.33 ± 0.17	0.42 ± 0.22
Control PS	0.36 ± 0.12	0.23 ± 0.06	0.32 ± 0.09
X3 PS	0.32 ± 0.13	0.20 ± 0.05	0.28 ± 0.08

PS is the stair climbing test with posterior stabilized knee. CR is the gait test with cruciate retaining knee.

Discussion

Satisfactory wear and mechanical performance of implant bearing surfaces may be dependent upon a number of factors, such as how well the implant is positioned, the demands of the host, the material properties, the locking mechanism, and the geometry of the design [9,10]. Care must be exercised by the surgeon to balance the soft tissues and appropriately align the knee. Technologies such as navigation may aid in accurate and reproducible positioning [11-13]. Patient expectations should be discussed before the operation to help the patient understand the limitations of total knee arthroplasty.

The polyethylene chosen must have sufficient mechanical strength and be resistant to oxidation and wear. The mechanical properties of the bearing material must be optimized not only at the time of implantation, but must also be maintained throughout the service life of the implant. The mechanical properties of X3 exceeded the ASTM requirements for polyethylene both before and after accelerated aging tests. The significant reduction in wear for the X3 polyethylene was also maintained before and after accelerated aging. The aged and unaged X3 material inserts did not show any signs of pitting or delamination after 5 million cycles of simulated gait conditions. The conventional material did not exhibit any signs of pitting or delamination; however, in this study, the material was not exposed to the accelerated aging protocol. Further testing will be necessary to study the effects of accelerated aging in conventional polyethylene.

Wear debris for both materials in either CR or PS testing showed bimodal particle morphology, with small submicron spherical particles and some longer fibers. Size distribution (length, width, and equivalent circle diameter [ECD]) showed similar size ranges for all particles, with a trend toward smaller aspect ratios for X3 material. This indicates slightly more rounded or less elongated thread-like particles. The similarity in wear debris suggests a common wear mechanism for both materials.

Hence, the lower wear rate of X3 should translate to a lower incidence of particle-induced osteolysis than with conventional polyethylene.

The manufacturing processes, in creating highly cross-linked polyethylene, result in the significant reduction of wear that must not compromise the polyethylene's ability to resist the demands placed upon it by the patient. The X3 polyethylene is annealed to reduce the free radicals and enhance cross-linking without compromising mechanical strength. Some manufacturers melt their highly cross-linked material [14]. Melting may be more efficient in reducing detectable free radicals, but melting also reduces the mechanical and fatigue properties of the polyethylene, which may limit its applicability in high stress applications [15,16]. The maintenance of mechanical and wear properties may be critical considerations for treating today's high-demand patients.

There are limitations in the described investigation. Fatigue, fracture toughness, and creep were not directly measured in this study. However, PS knee stair climbing simulation provides an aggressive functional fatigue evaluation due to the high loads that are applied to the post. Under these aggressive conditions, no failures were seen for any of the tested inserts. The effects of edge loading, third body debris, and malalignment on wear and component integrity were not evaluated in this study.

Geometry is an important factor in implant performance. The shape of the articular surfaces through their interaction with the soft tissues and loads determines motion pathways and stresses at the knee. The Scorpio knee used in the wear simulators has a single radius in the coronal plane that has been shown to both enhance conformity and decrease resistance to internal and external rotation in contrast to dual radius condylar knee designs [17]. Retrieval and clinical studies of this device have shown favorable midterm results [18,19]. This design has a single sagittal femoral radius over the flexion arc for activities such as gait and stair climbing [20], and fluoroscopic investigations suggested that this sagittal geometry may lead to more reproducible kinematics [21]. Biomechanical studies of sagittal single-axis and multi-axis knee arthroplasty systems in sit-to-stand and stand-to-sit patient activities demonstrated less hamstring coactivity and less quadriceps electromyography in the single-axis group [22,23]. This observed stability coincides with the fluoroscopic study findings. These kinematic patterns, when coupled with the wear reduction of X3, may be helpful in the survivorship of the arthroplasty. Clinical studies will be needed to document if the potential wear benefits of the X3 bearing material are realized.

References

1. Crowninshield RD, Rosenberg AG, Sporer SM. Changing demographics of patients with total joint replacement. Clin Orthop Relat Res 2006;443:266.
2. Sharkey PF, Hozack WJ, Rothman RH, et al. Insall Award paper. Why are total knee arthroplasties failing today? Clin Orthop Relat Res 2002;404:7.
3. Muratoglu OK, Bragdon CR, O'Connor DO, et al. A novel method of cross-linking ultra-high-molecular-weight polyethylene to improve wear, reduce oxidation, and retain mechanical properties. Recipient of the 1999 HAP Paul Award. J Arthroplasty 2001;16:149.
4. D'Antonio JA, Manley MT, Capello WN, et al. Five-year experience with Crossfire highly cross-linked polyethylene. Clin Orthop Relat Res 2005;441:143.
5. Wang A, Zeng H, Yau S, et al. Wear, oxidation and mechanical properties of a sequentially irradiated and annealed UHMWPE in total joint replacement. J Phys D Appl Phys 2006;39:3213.
6. Yau S, Wang A, Essner A, et al. Sequential irradiation and annealing of highly crosslinked polyethylenes: resist oxidation without sacrificing physical/mechanical properties. Presented at the 51st Annual Meeting. February, Orthopaedic Research Society; Washington, DC, 2005.
7. Essner A, Herrera L, Yau S, et al. Sequentially crosslinked and annealed UHMWPE knee wear debris. Presented at the 51st Annual Meeting. February, Orthopaedic Research Society; Washington, DC, 2005.
8. Keating EM, Meding JB, Faris PM, et al. Long-term followup of nonmodular total knee replacements. Clin Orthop Relat Res 2002;404:34.
9. Naudie DD, Ammeen DJ, Engh GA, et al. Wear and osteolysis around total knee arthroplasty. J Am Acad Orthop Surg 2007;15:53.
10. Engh GA, Lounici S, Rao AR, et al. In vivo deterioration of tibial baseplate locking mechanisms in contemporary modular total knee components. J Bone Joint Surg Am 2001;83-A:1660.
11. Sparmann M, Wolke B, Czupalla H, et al. Positioning of total knee arthroplasty with and without navigation support. A prospective, randomised study. J Bone Joint Surg Br 2003;85:830.
12. Stockl B, Nogler M, Rosiek R, et al. Navigation improves accuracy of rotational alignment in total knee arthroplasty. Clin Orthop Relat Res 2004;426:180.
13. Chin PL, Yang KY, Yeo SJ, et al. Randomized control trial comparing radiographic total knee arthroplasty implant placement using computer navigation versus conventional technique. J Arthroplasty 2005;20:618.
14. Muratoglu OK, Bragdon CR, O'Connor DO, et al. Aggressive wear testing of a cross-linked polyethylene

in total knee arthroplasty. Clin Orthop Relat Res 2002;404:89.
15. Collier JP, Currier BH, Kennedy FE, et al. Comparison of cross-linked polyethylene materials for orthopaedic applications. Clin Orthop Relat Res 2003;414:289.
16. Wang A, Manley MT, Serekian P. Wear and structural fatigue simulation of crosslinked ultra-high molecular weight polyethylene for hip and knee bearing applications. In: Kurtz SM, Gsell R, Martell J, editors. Crosslinked and thermally treated ultra-high molecular weight polyethylene for joint replacements. West Conshohocken: ASTM International; 2003. p. 151.
17. Klein R, Serpe L, Kester MA, et al. Rotational constraint in posterior-stabilized total knee prostheses. Clin Orthop Relat Res 2003;410: 82.
18. Silva M, Kabbash CA, Tiberi III JV, et al. Surface damage on open box posterior-stabilized polyethylene tibial inserts. Clin Orthop Relat Res 2003;416: 135.
19. Kolisek FR, Barnes CL. Scorpio posterior-stabilized knee system: 5-year clinical and functional results. J Arthroplasty 2006;21:1187.
20. Hollister AM, Kester MA, Cook SD, et al, Haddad RJ. Knee axes of rotation: determination and implications. Presented at the 23nd Annual Meeting. February. New Orleans, LA, Orthopaedic Research Society; 1986.
21. Banks SA, Hodge WA. 2003 Hap Paul Award Paper of the International Society for Technology in Arthroplasty. Design and activity dependence of kinematics in fixed and mobile-bearing knee arthroplasties. J Arthroplasty 2004;19:809.
22. Wang H, Simpson KJ, Chamnongkich S, et al. A biomechanical comparison between the single-axis and multi-axis total knee arthroplasty systems for the stand-to-sit movement. Clin Biomech (Bristol , Avon) 2005;20:428.
23. Wang H, Simpson KJ, Ferrara MS, et al. Biomechanical differences exhibited during sit-to-stand between total knee arthroplasty designs of varying radii. J Arthroplasty 2006;21:1193.

The Exeter Universal cemented femoral component at 15 to 17 years

AN UPDATE ON THE FIRST 325 HIPS

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The first 325 Exeter Universal stems (309 patients) implanted at the originating centre were inserted between March 1988 and February 1990 by a group of surgeons with differing experience. In this report we describe the clinical and radiological results at a mean of 15.7 years (14.7 to 17.3) after operation with no loss to follow-up. There were 97 patients (108 hips) with replacements still in situ and 31 (31 hips) who had undergone a further procedure. With an endpoint of revision for aseptic loosening, the survivorship at 17 years was 100% and 90.4% for the femoral and acetabular component, respectively. The mean Merle D'Aubigné and Postel scores at review were 5.4 (SD 0.97) for pain and 4.5 (SD 1.72) for function. The mean Oxford score was 38.4 (SD 9.8) (0 to 48 worst-to-best scale) and the mean combined Harris pain and function score was 73.2 (SD 16.9). Radiological review showed excellent preservation of bone stock in the proximal femur and no failures of the femoral component.

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The Exeter Universal stem (Stryker Orthopaedics, Mahwah, New Jersey) was introduced in 1988 and, apart from a minor change to the neck and spigot, this polished, modular, double-tapered stem has remained unchanged (Fig. 1). In 2002 we described our experience with a consecutive series of the first 325 Exeter Universal stems at eight to 12 years.[1] This highlighted the similarities in behaviour of the Exeter Universal stem and the original Exeter stem,[2,3] with a predictable mean subsidence occurring at the stem-cement interface of 1.32 mm at eight to 12 years. We postulated that this subsidence was crucial to the load transmission and stability of the stem[4-6] and that it was probably protective of the cement-bone interface. The 100% survivorship of the stem with aseptic loosening as the endpoint,[1] and the generally benign radiological appearances seen in a broad spectrum of patients and the Barrack cement grades[7] added credibility to this suggestion.

We now present an update of our series with results at a mean follow-up of 15.7 years (14.7 to 17.3) and with an emphasis on the clinical and radiological performance of the stem.

Patients and Methods

Between March 1988 and February 1990 we undertook 325 primary total hip replacements (THRs) in 309 patients using the Exeter Universal stem. The material properties of the stem were described in our review at eight to 12 years.[1]

Of the 325 THRs, 133 (40.9%) were performed in men. The mean age of the patients at the time of operation was 67.6 years (24 to 87) with 31 patients (9.5%) under 50 years. The numbers of patients in each Charnley category[8] are summarised in Table I. The case mix of diagnoses was presented in our original paper.[1] Most patients had primary osteoarthritis, but three followed previous sepsis, 14 had a previous osteotomy or surgery for a fracture and two were conversions of a previous arthrodesis. A consultant orthopaedic surgeon carried out 48% (156) of the procedures, with a further 50.5% (164) performed by senior registrars, registrars and fellows, and 1.5% (five) by senior house officers. The data capture forms used at the time of surgery did not record details of the assistant surgeon and therefore it was not possible to determine from our database the degree of supervision during operations done by surgeons in training. However, in common with many other units at that time, after a suitable period of training, non-consultant surgeons were allowed to perform operations without direct consultant supervision.

The posterior approach was used in 248 hips and the transgluteal, or direct lateral, approach in 77.[9,10] In all cases cemented polyethylene acetabular components were used; in 306 (94.2%) the acetabular components were