

Metal-Backed and All-Polyethylene Tibial Components in Total Knee Replacement

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One hundred seventy-five patients with 243 consecutive primary Press Fit Condylar® cruciate-substituting total knee replacements were evaluated at a mean of 5.5 years. One hundred thirteen knees had modular metal-backed tibial components and 130 had all-polyethylene tibial components. The mean knee score and functional score for the patients with unrevised components was not significantly different. The incidence of osteolysis and synovitis was higher in patients in the modular metal-backed tibia group (5%; five patients, six knees). No patients in the all-polyethylene tibia group had osteolysis or synovitis. Five revision operations were necessary: four for osteolytic defects and one for synovitis, all in patients in the modular metal-backed tibia group. All of the retrieved polyethylene inserts had evident backside wear. The best case rate of survival of the all-polyethylene tibial components was 96% ± 0.8% at 7 years and for the modular metal-backed components it was 75% ± 10% at 7 years. Metal backing and modularity were added to the Press Fit Condylar® total knee replacement design to improve fixation durability. However, the superiority of the modular metal-backed implants remains in question.

In early condylar total knee replacement designs, the use of an all-polyethylene cemented tibial components was most common.^{7,11,15,19,24} The followup data accrued during the past 20 years have established the significant longevity that these constructs can maintain, with survivorship curves showing 77% to 94% survivorship at 16 to 20 years. Aseptic loosening of the tibial component was one of the causes of failure in these implants.^{7,11,15,19,24,26,29}

Metal-backing of the tibial component was introduced initially in a one-piece, nonmodular design to allow for improved load distribution on the tibial condyles, and protect osteoporotic bone.^{11,21} Apel et al¹ compared 62 all-polyethylene tibial components with 69 metal-backed condylar knee components in patients with 6 years followup, and reported no difference in function between the two groups. They also concluded that the cemented all-polyethylene tibia could produce clinical results equal to those with the metal-back at a lower cost. Rand²⁰ also did a comparative study using the cruciate condylar knee prosthesis. He confirmed that the all-polyethylene and metal-backed tibial components in the cruciate condylar total knee prosthesis provided good results with no significant difference at 10 years followup. Longer-term studies have established that a one-piece nonmodular tibial component maintains excellent durability at 15 years followup.^{4,7}

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Modularity between the polyethylene tibial component and the metal-backed tray was introduced in the mid-1980s to allow greater intraoperative versatility, allowing the surgeon to interchange various polyethylene thicknesses, and to add stems or wedges as needed. A study by Parks et al¹⁶ identified that micromotion occurs between the tibial polyethylene insert and the metal tray in each manufacturer's locking mechanism tested. This process has been shown to create polyethylene wear debris on the nonarticular, or backside of the insert, and contribute to periprosthetic osteolysis.^{2,3,5,6,9,10,12,13,14,17,18,22,23,27,28}

Modular metal-backed tibial components remain the most commonly implanted devices in modern knee replacement designs. Font-Rodriguez et al⁹ had a survivorship of 93.6% with modular metal-backed implants at 10 years, compared with a survivorship of 94.1% with all-polyethylene implants at 16 years. However, there is no study that directly compares modular metal-backed implants with all-polyethylene tibial components of the same geometry, implanted concurrently. The purpose of the current study was to compare the clinical, radiographic, and functional results of the all-polyethylene tibia and the modular metal-backed tibia of the same cruciate-substituting design.

MATERIALS AND METHODS

Two hundred thirteen patients underwent 287 consecutive primary total knee arthroplasties by one surgeon between September 1992 and December 1994. All implants were of a posterior cruciate-substituting

design and were inserted with cement after pulsed lavage, drying, and pressurization of the cement. Of the original 213 patients (287 knees) 15 patients (18 knees) died, 18 patients (20 knees) were lost to followup, and five patients (six knees) were contacted and interviewed by telephone but refused to return for a personal examination and radiograph. The remaining 175 patients (243 knees) were available for clinical and radiographic evaluations at a mean followup of 5.5 ± 0.9 years (range, 5–7 years). One hundred thirteen of the 243 knees had a modular metal-backed tibial component, and the other 130 knees had an all-polyethylene tibial component. Both of these implants had an identical articular geometry, differing only in the nonarticular or back surface (Fig 1).

The technique of alignment and soft tissue balance was done in a uniform manner by one surgeon (CSR) using an identical postoperative protocol. The decision of which implant to use was made intraoperatively at the discretion of the surgeon, with heavy males and patients with bone defects or osteoporosis receiving the modular metal-backed implant preferentially. The patella was resurfaced in all cases with a cemented one peg all-polyethylene component. The average thickness of the polyethylene for the all-polyethylene tibia was 9.1 ± 1.6 mm (range, 8–15 mm) and for the metal-backed tibial components the average polyethylene insert thickness was 7.5 ± 1 mm (range, 6–10.5 mm).

There were 69 men (30 bilateral knee replacements) and 106 women (38 bilateral knee replacements). The mean age of the patients at the time of the operation was 70 years (range, 27–88 years). The average weight of the patients was 79 kg (range, 52–121 kg). The preoperative diagnosis was osteoarthritis in 159 patients (77 patients had modular metal-backed tibias and 82 patients had all-polyethylene tibias) and rheumatoid arthritis in 16 patients (seven had modular metal-backed tibias and nine had all-polyethylene tibias).



Fig 1. An all-polyethylene tibial component and modular polyethylene insert with identical articular geometries are shown.

Clinical Evaluation

All the clinical data were recorded and reviewed by the operating senior surgeon. The clinical rating system of the Knee Society was used to rate the patients' overall function postoperatively and to assign the patients to the three categories A, B, or C.¹² This system assign a maximum of 100 points (50 points for pain, 25 points for range of motion [ROM], and 25 points for stability) for a knee score, and a maximum of 100 points (50 points for walking distance and 50 points for stair climbing ability) for a functional score. Following this scale, an excellent score was 85 to 100 points; a good result was 70 to 84 points; a fair result was 60 to 69 points; and a poor result was less than 60 points. A knee revision represents a poor result and no points are assigned. Statistical comparisons of the clinical scores were done for the all-polyethylene and modular metal-backed tibial components using the chi square analysis.

A complete history and physical examination was done in all the patients, looking for any specific complaints such as unexplained pain, swelling, or effusion, which could represent synovitis caused by polyethylene debris particles.

Radiographic Evaluation

Radiographs were obtained of all knees immediately postoperatively, at 6 weeks, and annually after the operation, and were analyzed by the two surgeons. A research assistant who knew the name of the patients recorded the findings. All preoperative and postoperative radiographs included anteroposterior (AP) radiographs obtained with the patient weightbearing, a lateral view of the knee, and a skyline view of the patella. These radiographs were used to assess the alignment of the limb, the position of the components, and the presence and location of all the radiolucent lines at the bone-cement interface, according to the recommendations of the Knee Society system.⁸

Radiographs also were used to evaluate and describe the incidence of any synovitic reaction, especially in the lateral view of the knee, where the synovitis could be appreciated in the suprapatellar pouch as a large radiolucent swelling. Osteolysis was defined as an area of focal bone resorption identified by the absence of bony trabeculas and a reactive demarcation around the metaphyseal defect, which was not present on the radiograph obtained 1 year postoperative.

The radiolucent lines, alignment, position of the

components, and incidence of synovitis and/or osteolysis were compared between the two groups (all-polyethylene versus modular metal-backed tibia) using a chi square analysis.

Survivorship Analysis

Survivorship analysis was done to determine the cumulative rate of survival of the implant during the study period. The end point for the analysis was a revision operation for any reason or a recommendation for revision. Three outcomes were possible for any particular followup interval: success, failure, or withdrawal. The best case scenario presumes that patients lost to followup all had successful results, whereas the worst case scenario presumes that all patients lost to followup had failed results.⁷

Evaluation of the Polyethylene Implants

All the polyethylene tibial implants were examined for evidence of wear in the articulating and back-side surfaces. A gross description of the wear pattern was done, taking in consideration the articular compartment, symmetric versus asymmetric, and modes of degradation (scratching, pitting, deformation, or delamination) using the criteria of Furman et al.¹⁰ The central tibial peg damage also was assessed and described.

RESULTS

The all-polyethylene tibial components (130 knees, 91 patients) were compared with the metal-backed tibial components (113 knees, 84 patients) in terms of followup, patient age, weight at the time of surgery, preoperative diagnosis, and polyethylene tibial insert thickness. No significant differences were seen in these comparisons between the two groups. The only comparison for which there was a significant difference ($p < 0.001$) between the two groups was in the patients' gender. This difference was notable because in the all-polyethylene tibia group, 70% of the patients were women (Table 1).

Clinical Results

Preoperatively, the overall mean functional score was 48 points (range, 10–75 points) and the mean knee score was 50 points (range,

TABLE 1. Demographics of Patients in the Study Groups

Clinical Factor	Modular Metal-Backed Tibia	All-Polyethylene Tibia	p Value
Weight	176	170	
Osteoarthritis	77	82	
Rheumatoid arthritis	7	9	
Gender (M:F)	40:44	29:62	p <0.001

0–60 points). At the time of the most recent followup, the mean functional score was 93.2 points (range, 70–100 points) and the mean knee score was 93.5 points (range, 61–98 points). Two hundred thirty-nine (98 %) of the functional scores were good or excellent. The four patients who had a poor functional outcome were in Category C.

The mean knee score for patients with the all-polyethylene tibia was 95.1 ± 4 points and for patients with the modular metal-backed tibia it was 92 ± 5 points, which showed no significant difference ($p < 0.87$) between the two groups, taking into consideration pain ($p < 0.67$), ROM ($p < 0.06$), stability, and alignment.

The mean functional score for the all-polyethylene tibia group was 94.2 ± 9 points and for the modular metal-backed tibia group it was 92.2 ± 8 , with no significant difference ($p < 0.36$) between the two groups.

Pain

Seventy patients (105 knees) in the all-polyethylene tibia group did not have pain at the most recent followup. Twenty-one patients (25 knees) complained of discomfort in the knee. Seventeen patients reported mild and occasional pain, whereas the other four reported moderate pain but did not require medications. The pain described mostly was localized in the anterior part of the knee.

Seventy-seven patients (104 knees) in the modular metal-backed tibia group did not have pain and seven patients (nine knees) had mild to moderate pain but did not require medications. Two patients (three knees) had pain mostly localized anterior as in the all-polyethylene tibia group. The other five patients (six knees) complained of knee pain and

swelling but did not have problems with motion, walking, or climbing. All six knees had a discernible effusion on examination. Four of these patients (five knees) had revision surgery: one for synovitis, and four for distal femoral osteolysis and synovitis. When these patients were excluded from the study, the knee and functional scores for the modular metal-backed tibia group increased to 93.5 points and 94 points, respectively.

Patellofemoral Articulation

Lateral release was used for five knees in the all-polyethylene tibia group and two knees in the modular metal-backed tibia group. Two knees in the all-polyethylene tibia group and one knee in the modular metal-backed tibia group had a lateral displaced patellar button, but without any associated symptoms. One of these (modular metal-backed tibia group) had evidence of avascular necrosis. No lateral release was done in these patients. The knee and functional scores remained in the good category for these patients and no patients required revision surgery.

Radiographic Results

One hundred forty-two patients (204 knees) from the 175 patients (243 knees) were available for radiographic evaluation: 71 patients (99 knees) in the modular metal-backed tibia group and 71 patients (105 knees) in the all-polyethylene tibia group. The Knee Society system for evaluation of the radiographs was used. The authors compared the coronal and sagittal plane alignment and the presence of radiolucent lines between the two groups (Table 2).

The overall mean tibiofemoral angle was $4.6^\circ \pm 2.6^\circ$ valgus (range, 1° varus - 12° val-

TABLE 2. Radiographic Alignment of Knees in the Study Groups

Variable	Modular Metal-Backed Tibia (Mean/SD)	All-Polyethylene Tibia (Mean/SD)	Two-Tailed p Value
Alpha	94.8 / 1.3	95.2 / 1.3	<0.37
Beta	89.5 / 2	90 / 2	<0.06
Gamma	80 / 3.5	82 / 2.5	<0.06
Sigma	91 / 1.6	92 / 1.3	<0.35

SD = standard deviation.

gus). Comparing the all-polyethylene tibia group with the modular metal-backed tibia group in terms of the tibiofemoral angle, (all-polyethylene tibia group, $4.8^\circ \pm 2.7^\circ$ and modular metal-backed tibia group, $4.4^\circ \pm 2.5^\circ$) showed no significant difference ($p < 0.31$).

The mean positions for the femoral and tibial components in the AP and lateral radiographs between the two groups also were evaluated and these comparisons showed no significant difference in terms of position and alignment.

Radiolucent Lines

Radiolucent lines were evaluated using the Knee Society system.⁸ Thirty-five knees (14%) had radiolucent lines at the last evaluation. These lines were present in 16% of the all-polyethylene tibial components compared with 21% of the modular metal-backed tibial components, which was not a significant difference. The lines mostly were localized in the medial tibial plateau (Zones 1–2) measuring less than 1.5 mm in width, and without any evidence of progression more than 1 mm in width or length.

Radiolucent lines also were observed adjacent to the patellar components in 41 knees (16%). These lines mostly were localized in Zones 1 and 2, without any evidence of progression at the last followup. There was no significant difference between the two groups in terms of incidence, location, or progression of the lines.

Synovitis and Osteolysis

The incidence of osteolysis, associated with plastic insert wear and deformation, was higher

in the metal-backed group than in the all-polyethylene group ($p < 0.001$). No osteolytic lesion was identified in the all-polyethylene tibial or femoral components. In five patients (six knees) in the modular metal-backed group, there was evidence of anterior suprapatellar pouch synovitis. In the six knees with synovitis, five had associated osteolysis of the distal femoral metaphysis. These osteolytic defects were massive (lesions > 1 cm in diameter) in four knees and minimal (< 1 cm) and nonprogressive (an increase in length or width by 1 mm between the initial postoperative and final radiographs) in one knee. Evidence of polyethylene wear and deformation was not identified in the radiographs by a reduction in space between the femoral and tibial components.

Complications

The complications in the all-polyethylene tibia group of 130 knees consisted of one infection and two patellofemoral problems. The infection was a late infection and the patient was treated with a successful two-stage revision surgery. The two patellofemoral problems consisted of dissociation of the patellar button component from the bone, but the patients were asymptomatic without any significant findings in the physical examination and with a good knee score.

In the modular metal-backed tibia group (113 knees) complications were observed in five knees with synovitis or osteolysis, one with painful synovitis alone, one with patellofemoral problems, and one femoral supracondylar fracture.

The knee with patellofemoral problems had

avascular necrosis of the patella with dissociation of the plastic component. The patient was asymptomatic and did not require revision surgery.

The supracondylar fracture was treated with a retrograde nail. At the last followup, the patient was in rehabilitation, used a cane for walking, and had good ROM of the knee. The last radiographs showed callus around the fracture line.

All six knees with synovitis or osteolysis were revised, with aggressive synovectomy (Fig 2). The mean revision time for the five

knees was 71.6 months. One knee had revision of the femoral and tibial components. Three knees had femoral component revision with bulk allograft, and liner exchange, retaining the tibial component. Two knees with synovitis had a revision to exchange the polyethylene component and synovectomy, and cement filling of small condylar defects, the metal tibial and femoral components were retained.

Survivorship Analysis

Survivorship analysis was done with revision surgery for any reason as the end point (Fig 3).

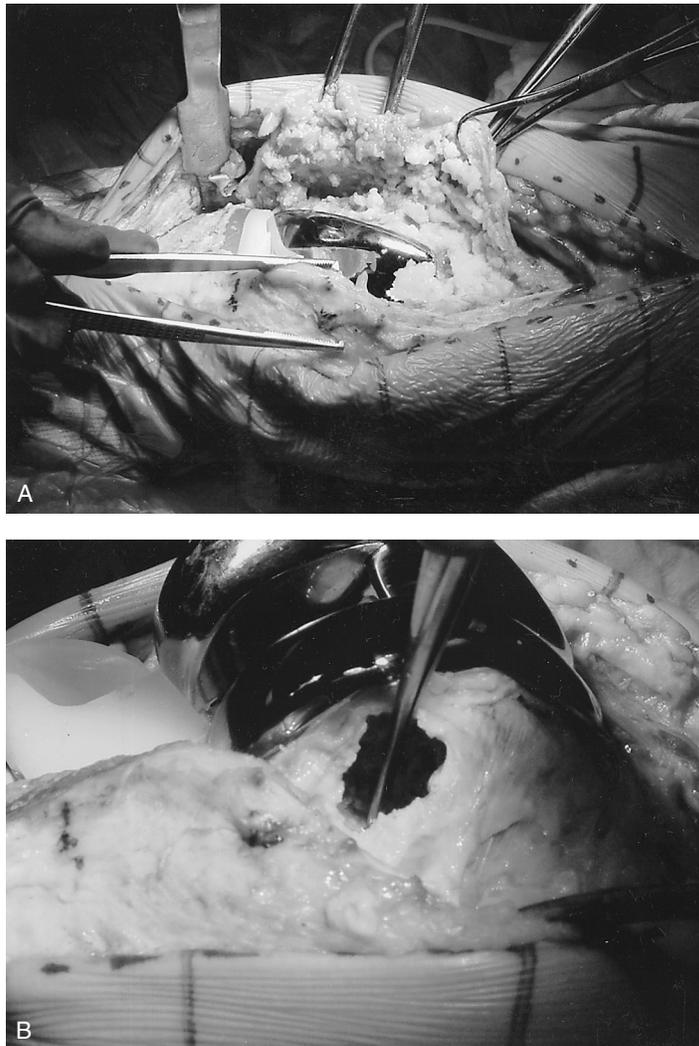
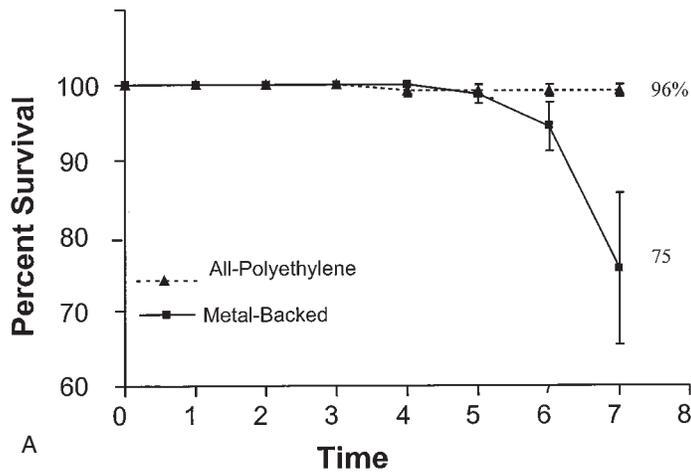
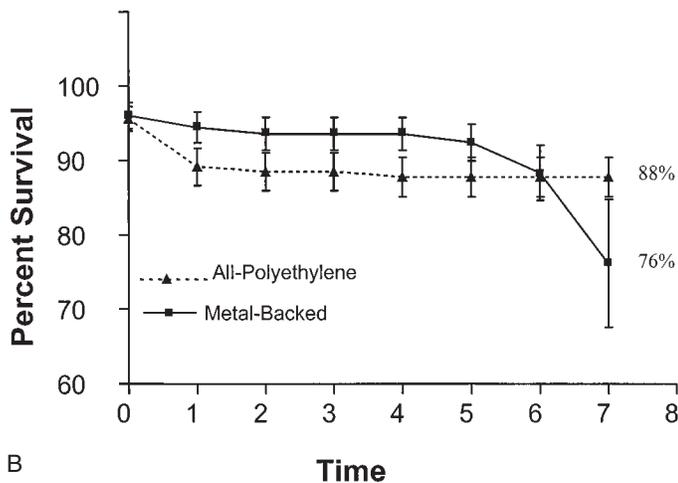


Fig 2A–B. (A) Photographs of the knee of a 65-year-old man 5 years after total knee replacement show extensive synovitis. (B) The synovitic process had invaded the lateral femoral condyle creating an osteolytic lesion encompassing 50% of the condylar bone.



A



B

Fig 3A–B. (A) Survivorship to revision at 7 years was $99\% \pm 0.8\%$ for the all-polyethylene tibia and $75\% \pm 10\%$ for the modular metal-backed tibial components, in which the patients who were lost to followup were considered to have withdrawn from the study (best case scenario). (B) Survivorship to revision at 7 years was $88\% \pm 3\%$ for the all-polyethylene tibia and $76\% \pm 8\%$ for the modular metal-backed tibial components, in which the patients who were lost to followup were considered to have failed results (worst case scenario).

Using a best case scenario, the projected clinical and radiographic rate of survival of the all-polyethylene tibia components was $96\% \pm 0.8\%$ at 7 years and for the modular metal-backed tibial components was $75\% \pm 10\%$ at 7 years ($p < 0.001$). The survivorship to revision at 7 years was $88\% \pm 3\%$ for the all-polyethylene components and $76\% \pm 8\%$ ($p < .001$) for the metal-backed tibial components using a worst case scenario, in which the patients lost to followup were considered as having failed results.

Evaluation of the Polyethylene Insert

All the retrieved components were evaluated for articular and backside surface damage.

The wear pattern was predominantly abrasion and delamination.

The five knees of the metal-backed tibial component group were revised and the tibial inserts were analyzed for wear patterns. Undersurface motion caused polyethylene deformation and wear between the tibial tray and the insert. One of the five was revised for synovitis of the knee. This polyethylene insert showed no deformation or wear in the articular surface, Grade 0, as described by Engh et al⁶ (0 = no recognizable damage, 1 = $< 10\%$, 2 = $10\%–50\%$, 3 = $> 50\%$), but a mild (< 1 mm) symmetric backside wear that showed no evidence of the previous marks and letters from the manufacturer. This pattern of wear



Fig 4. Backside wear and fatigue failure of anterior locking tab on a modular polyethylene insert are shown.

mostly resembled abrasive wear. There also was evidence of abrasive marks in the tibial metal tray and an anterior impression in the central tibial eminence of the polyethylene. Using the criteria of Furman et al,¹⁰ there were two inserts with mild backside wear and creep, and four inserts with severe backside wear and creep. In addition, three inserts had fatigue failure of the anterior locking tab (Fig 4). All six revised inserts had evidence of polyethylene creep and wear on the central tibial peg where the femoral component contacted its anterior surface in extension.

DISCUSSION

Metal-backing initially was introduced to improve the longevity of fixation of tibial components over that of early all-polyethylene implants, particularly in deficient bone. Studies by Apel et al¹ and by Rand²⁰ compared all-polyethylene and nonmodular metal-backed im-

plants at 8 to 10 years followup. They concluded that there were no differences in clinical function, radiographic evaluation, or durability of fixation. Several medium-term studies have been published evaluating modular metal-backed implants.^{9,19,24} Some of these studies report excellent durability, whereas others with longer followup reported an increasing incidence of osteolysis. No study has been done which directly compares modular metal-backed implants with all-polyethylene tibial components of the same articular geometry.

The current study directly compares all-polyethylene and modular metal-backed tibial components of the same articular geometry and cruciate-substituting design, implanted by one surgeon during the same period. The clinical results between the two groups did not show any significant difference in Knee Society clinical or functional scores, in terms of pain, ROM, stability, walking, or climbing ability. There also were no differences in radiographic alignment or the presence of lucent lines. In the current study, the major difference between the two groups was the incidence of synovitis and osteolysis, which was present in six knees in the modular metal-backed tibia group, and absent in all knees in the all-polyethylene group, showing a statistical difference ($p < 0.001$). All six knees were revised, showing a diffuse villous synovitis. No osteolytic lesion or synovitic reaction could be identified in the all-polyethylene tibia group radiographically or clinically. If cases of osteolysis are excluded, there were no cases of fixation failure in either group.

Engh et al^{6,7} showed the increasing incidence of osteolysis in modular metal-backed tibial components. Analysis of the revised liners showed significant damage and wear of the nonarticular or backside of the liners, and this is considered to be the primary source of polyethylene wear debris.^{6,27,28} Moreover, Parks et al¹⁶ showed that micromotion occurs between the polyethylene liners and the metal trays of all of the locking mechanisms tested.¹⁶ This concept also was shown and quantified by Furman et al.¹⁰ In a 20-year followup study of patients with

all-polyethylene tibial components of the total condylar knee replacement, Rodriguez et al²³ showed that there were no cases of osteolysis in the entire series. Similar findings were published by Colliza et al⁵ for a nonmodular metal-backed implant. This corroborates the suggestions by other authors^{6,7,16} that the modular junction is the likely source of the synovitis and osteolysis.

Schai et al²⁴ published a 10-year followup study on the PFC cruciate-retaining modular metal-backed implant, reporting revision for wear related problems in nine polyethylene inserts, or 8 % of knees. However, the implant in their series had a nonconforming articular geometry, and the predominant wear pattern was articular. They did not discuss the issues of backside wear. Ranawat et al¹⁹ published a series of 4-to 6-year results with the PFC modular metal-backed knee replacement in 1997, at which time there had been no cases of osteolysis. That cohort recently was reviewed at an average 9.1 years followup. Of the knee replacements that were manufactured and implanted between 1989 and 1991, there have been two cases of osteolysis (1.5%). The knee replacements in the current series were manufactured and implanted between 1992 and 1994, with six cases of osteolysis (5.3%) at only 5.1 years followup. Between these periods, there has been no change in the polyethylene locking mechanism within the tibial component of the PFC knee replacement, but the primary resin and sterilization techniques used to manufacture the

polyethylene have been modified independently (Table 3). Several authors showed that polyethylene resin choice can directly influence the wear properties in retrieved total knee replacements.^{4,30} The quality of polyethylene also has been shown to directly affect clinical function and longevity.²⁵ This may explain the perceived difference in incidence of osteolysis between these two periods.

The findings of the current study are limited by its retrospective nature, and the demographic differences between the two cohorts. The modular metal-backed group had more men than the all-polyethylene group, and these patients may have a different level of activity, and therefore loaded the joint to a greater degree. However, the similarities in the cohort demographics, and the differences in the outcomes in these groups is sufficiently striking to lead to the suggestion that the all-polyethylene tibial component may be superior to the modular metal-backed component in terms of synovitis and osteolysis.

There is no difference in clinical function between the all-polyethylene group and the modular metal-backed group with this prosthesis. However, the incidence of synovitis and osteolysis is significantly higher in the modular metal-backed group. The superiority of the modular metal-backed tibial component remains in question. Orthopaedic surgeons must be more aware of changes in manufacturing and sterilization of polyethylene implants, because these may affect clinical results and longevity.

TABLE 3. Timeline for PFC Polyethylene Material Supply and Sterilization Method

1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Hyfax 1900 and Hoeschst 412 from Westlake Plastics, Lenni, PA		Hoechst 412 from Westlake Plastics, Lenni, PA				Perplas, GUR 1020 (calcium stearate free)				
Polyethylene Supply and Specification										
Gamma Air at Ethicon Inc (Somerville, NJ) 2.5–3.5 Mrad			Gamma air at Isomedix (Mentor, OH) 3.5–4.5 Mrad			Gamma Vacuum Foil 3.5–5 Mrad				
Sterilization Method and Specification										

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