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Durability of a Cruciate-retaining TKA With Modular Tibial Trays at 20 Years

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Abstract

Background Modular tibial trays have been utilized in TKA for more than 20 years. However, concerns have been raised about modular implants and it is unclear whether these devices are durable in the long term.

Questions/purposes We determined (1) survival, (2) relationship of age and polyethylene thickness with revision, (3) function, and (4) radiographic lucencies and osteolysis in patients having a single TKA implant at 20-year followup.

Methods We prospectively followed 75 patients implanted with 101 Press-Fit Condylar® (Johnson and Johnson Professional, Inc, Raynham, MA, USA) posterior cruciate-retaining TKAs (with modular tibial trays) between 1988 and 1991. At 20 years, 59 patients were deceased. We clinically evaluated the living 16 patients (22 knees) and contacted the relatives of all deceased patients to confirm implant status. We clinically assessed 14 of the 16 patients with the Knee Society score, WOMAC, and UCLA and Tegner activity level scores. Radiographically, we determined lucencies, component migration, and osteolysis. We performed survival analysis including all original patients. Minimum followup was 20 years (mean, 20.6 years; range, 20–21.8 years).

Results Six reoperations were performed in five patients (6% rate of revision) over the 20-year followup. All revisions were related to polyethylene wear and occurred at least 10 years after the primary procedure. Survivorship with revision for any reason as the end point was 91% (95% CI, 0.83–0.97) at 20 years. Average Knee Society clinical and functional scores were 90 (range, 60–100) and 59 (range, 30–87), respectively.

Conclusions Our data demonstrate the durability of this posterior cruciate-retaining TKA design. The data provide a standard for newer designs and newer bearing surface materials at comparable followup.

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

One of the authors (JJC) has or may receive payments or benefits, in any 1 year, an amount in excess of $1,000,000 from DePuy Orthopaedics, Inc (Warsaw, IN, USA) and, in any 1 year, an amount in excess of $1000 from Lippincott Williams & Wilkins (Philadelphia, PA, USA).

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Each author certifies that his institution has approved the reporting of these cases, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation was obtained.

This work was performed at the University of Iowa (Iowa City, IA, USA) and Des Moines Orthopaedic Surgeons (West Des Moines, IA, USA).

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Introduction

Condylar-type TKA has been performed for more than 35 years. Several studies [28, 31, 33] have reported findings at or near a mean of 20 years. These studies show revision rates for aseptic loosening of between 0.8% and 3.3% at a mean 19 to 20 years, with survivorship with revision for any reason as the end point of 83.2% at 20 years, 77% at 21 years, and 91% at 23 years, respectively.

The introduction of modular tibial trays has allowed for greater operative versatility, allowing for cases of polyethylene exchange as an option in revision knee surgery, which allows for a potentially less involved (less destructive) and more cost-effective option. However, modularity has not been without controversy. Backside wear has been one major concern [13, 14, 16, 30]. Some have cautioned against simple liner exchanges, especially in revisions for accelerated polyethylene wear, particularly when there are issues with alignment and instability [2, 15]. Yet, in cases of well-fixed and well-aligned knees, some report polyethylene exchange in the revision knee situation is a reasonable option even in patients with extensive osteolysis [7, 23]. Followup studies of 10 to 17 years of TKA using modular tibial trays [21, 32, 34, 36] have shown survivorship of 87% to 92.8% at 12 to 17 years. We previously reported a 100% survivorship at 10 years [20] and 91% at 15 years [29] in patients with a modular tibial tray (no revisions at 10 years and six revisions at 15 years). Whether these findings are durable at longer followup is unclear.

We therefore determined (1) survival, (2) the relationship of age and polyethylene thickness with revision, (3) function, and (4) radiographic lucencies and osteolysis in patients treated by a single surgeon with a posterior cruciate-retaining device with a modular tibial tray at a minimum 20-year followup.

Patients and Methods

Between November 1988 and January 1991, one of the authors (SSK) performed 101 cemented TKAs with a modular posterior cruciate-retaining Press-Fit Condylar® (PFC®) prosthesis (Johnson and Johnson Professional, Inc, Raynham, MA, USA) in 75 patients. During this interval, the surgeon performed seven additional TKAs: two posterior-stabilized Insall-Burstein II® (Zimmer, Inc, Warsaw, IN, USA), four posterior-stabilized PFC® prostheses when an insufficient PCL was identified intraoperatively, and a hybrid PFC® with an uncemented femoral component in a young patient. Coumadin was routinely used for deep venous thrombosis prophylaxis postoperatively. The average age at the time of surgery was 71.2 years (range, 52.2–88.8 years). Study participants included 44 women (59 knees) and 31 men (42 knees). There were 52 (51%) right knees and 49 (49%) left knees. Twenty-six (35%) patients required bilateral TKAs. Of these, six patients had the bilateral TKAs performed under one surgical procedure. Diagnoses included primary osteoarthritis in 86 (85%) knees, rheumatoid arthritis in 13 (13%), avascular necrosis in one (1%), and posttraumatic osteoarthritis in one (1%). Previous knee procedures had been performed in 11 patients before the index TKA, including six arthroscopies, three meniscectomies, and two patellectomies. At a minimum of 20 years after the primary procedure, 16 patients (22 knees) were living and 59 patients (79 knees) were deceased. No patients were lost to followup. After locating living patients, we obtained consent for study participation as per the protocol previously approved by our institutional review board.

All components were cemented. The modular metal-backed tibial tray was titanium and came in six sizes. The femoral component was a cobalt-chrome alloy. A three-peg, all-polyethylene patella was used in all procedures except two. In these two procedures, the surgeon did not resurface the patella because a prior patellectomy had been performed. A posterior-lipped polyethylene insert with minimally raised anterior and posterior borders and a large radius of curvature was used in all procedures. Gamma-irradiated-in-air polyethylene and all-polyethylene patella components were utilized in all cases. All cases were fixed with cement and prospectively followed at 5-year intervals [20, 29]. During the period of these procedures, a more conforming curved tibial insert did become available but was not used in these patients. The thickness of the polyethylene insert was 8 mm (minimum thickness, 5.3 mm) in 78 (77%) knees, 10 mm (minimum thickness, 8 mm) in 17 (17%), 12.5 mm (minimum thickness, 10 mm) in five (5%), and 15 mm (minimum thickness, 13 mm) in one (1%). Beginning in 1991, the manufacturer increased the minimal thickness of the 8-mm insert from 5.3 to 6 mm, but we exclusively used the thinner implant in this patient cohort. All components were gamma irradiated in air.

Two investigators (MWB, DWH) not involved in the surgical procedures and not receiving compensation from the implant manufacturer contacted all patients. For all deceased patients, we made contact with a surviving relative. In all cases, the survival of the prosthesis at the time of death was confirmed, and no pending revisions or revision indications were identified at the time of death. Of the 16 patients (22 knees) known to be living at the time of followup, all were located, and the survivorship or need for revision of the prosthesis was confirmed. Due to dementia, two patients (three knees) were unable to participate in the full telephone assessment of clinical status as described above. Therefore, 14 patients (19 knees) completed the full

questionnaire evaluation. Clinical measures included the pain and functional components of the Knee Society scoring system [26], WOMAC [4], and UCLA [1] and Tegner [35] activity level scores. We obtained radiographs, including standing AP, lateral, and Merchant views, in the standard fashion. We obtained 20-year radiographic followup for 12 patients (17 knees, 77% of knees in living patients) with an average followup of 20.6 years (range, 20.0–21.8 years). Among the four patients (five knees) living at the time of this study who did not return for radiographic followup, we evaluated radiographs of three patients (four knees) at an average of 15.3 years from the index procedure. The final living patient who chose not to return for followup radiographs had 0 years of radiographic followup but did participate in the questionnaire evaluation via telephone and had not been revised. The average radiographic followup of all living patients was 19.5 years (range, 0–21.8 years). Two authors (DWH, JJC), not directly involved in the surgery or subsequent clinical care of the patients, evaluated all radiographs using the Knee Society protocol [17]. This included the evaluation of radiolucent lines around the components, component position change, and evidence of osteolysis measuring greater than 1.0 cm^2. We have demonstrated good interobserver agreement with this approach [13].

Kaplan-Meier survivorship analysis with 95% CI [27] was performed using SPSS® 13.0 software (SPSS Inc, Chicago, IL, USA) with revision of any component for any reason, revision of any component for aseptic loosening, and component-specific revision as the end points. Additionally, we calculated Kaplan-Meier survivorship, with patient survival as an end point, based on age at the time of index surgery. We utilized the Cox proportional-hazard regression analysis in assessing for correlation of patient age and polyethylene implant thickness with need for revision.

Results

The survivorship (Fig. 1) of any component with revision for any reason as the end point was 90.8% (95% CI, 0.83–0.97) at 20 years. The survivorship of the femoral component with revision for any reason as the end point was 95.3% (95% CI, 0.87–0.99) at 20 years. The survivorship of the tibial component with revision for any reason as the end point was 95.2% (95% CI, 0.87–0.99) at 20 years. The survivorship of the patellar component with revision for any reason as the end point was 95.3% (95% CI, 0.89–0.99) at 20 years. The survivorship of the liner for revision for any reason as the end point was 90.8% (95% CI, 0.83–0.97) at 20 years. The survivorship of any component with revision due to aseptic loosening as the end point was 93.8% (95% CI, 0.87–0.98) at 20 years. The survival rates (Table 1) with revision for any reason as the end point in this cohort of patients were 100% at 10 years, 91% at 15 years, and 91% at 20 years. Six reoperations were performed in five patients (Table 2). One patient had both knees revised. At the time of revision, we assessed the fixation of the tibial, femoral, and patellar components. If the components were well fixed and without obvious malalignment, revision consisted of simple polyethylene exchange. In the presence of additional component loosening or osteolysis, the tibial, femoral, and/or patellar components were revised. Revision for any reason occurred in six of 101 (6%) knees at a minimum of 20 years. All revisions were related to polyethylene wear (four resulting in extensive osteolysis and aseptic component loosening and two related to wear of the polyethylene), and all occurred more than 10 years after the index procedure. There were no new revisions since the previously reported minimum 15-year followup.

We found an association ($p = 0.030$) between need for revision and age at the time of surgery. Among patients requiring revision, the average age at the time of the index procedure was 63.5 years (range, 60.8–68.6 years). The average age of the overall cohort at the time of surgery was 71.6 (range, 52.2–88.8 years). All six revisions occurred in patients with 8-mm polyethylene inserts. Those with 8-mm inserts tended ($p = 0.051$) to need revision. None of the four revised knees in three living patients had clinical or radiographic signs of failure at an average of 7.3 years (range, 5.5–8.9 years) after revision. The other two revised knees in two deceased patients at 20-year followup had not required additional revision surgery at the times of their death, which were 2.8 and 7.5 years after revision.

For living patients, other than the two infirmed patients, the average WOMAC scores (corrected to higher score = higher outcome) were 94 of 100 (range, 75–100) for the pain component, 84 (range, 25–100) for the stiffness component, and 79 (range, 53–100) for the functional component. The average Knee Society pain score was 90 of 100 (range, 60–100), and the average function score was 59 of 100 (range, 30–87). The average patient age at the time of latest clinical followup was 82.0 years. The average UCLA and Tegner activity level scores were 3.9 and 2.9, respectively, which correlated to light labor and mild activities, such as walking, limited housework, and limited shopping. Functional limitations were attributed primarily to other musculoskeletal or systemic morbidities, not the operative knee(s).

Of the 12 nonrevised knees with 20-year followup radiographs (average radiographic followup, 20.4 years; range, 20.0–21.8 years), four had incomplete radiolucent lines on radiographic evaluation. Femoral radiolucencies consisted of two cases in Zone 1, one in Zone 2, and two in Zone 4. Lateral tibial radiolucencies consisted of two cases in Zone 1. On the AP projection of the tibia, there was one

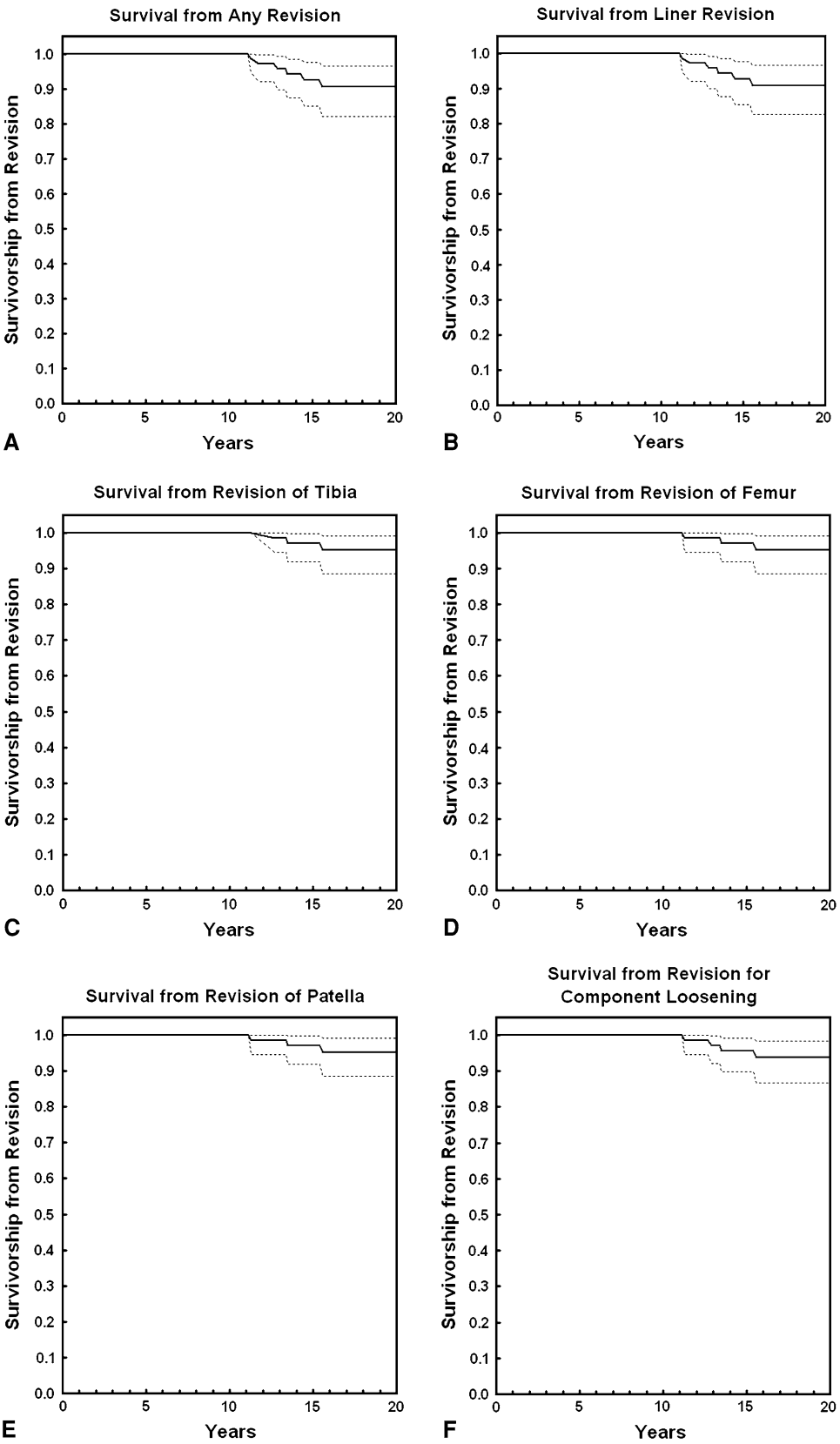

Fig. 1A–F Graphs demonstrate the Kaplan-Meier survivorship curves with accompanying 95% CIs with (**A**) any revision, (**B**) liner revision, (**C**) tibial component revision, (**D**) femoral component revision, (**E**) patellar component revision, and (**F**) revision for component loosening as end points.

Table 1. Comparison of data from previous and current followup times

Patient data	9- to 12-year followup [20]	15- to 18-year followup [29]	Minimum 20-year followup (current study)
Total number of patients (knees) followed	56 (78)	35 (40)	16 (22)
Mean followup (years)	10.5 (9.5–11.8)	16.6 (15.0–18.1)	20.4 (20.0–21.8)
Number of patients who died before minimum followup	19	40	59
Number of patients lost to followup	0	0	0
Number of patients with clinical evaluation	56	35	16
Number of patients (knees) with radiographic evaluation	45 (63) (81%)	28 (38) (81%)	12 (17) (77%)
Number of patients (knees) with reoperations	0	5 (6)	6 (7)
Survivorship	100% at 10 years (revision for any reason)	91% at 15 years (revision for any reason)	91% at 20 years (revision for any reason)
Number of patients (knees) with radiographic evidence of osteolysis in entire cohort	1 (1)	6 (8)	7 (10)
Femoral (number of knees)	0	6	6
Tibial (number of knees)	1	7	9
Number of knees with radiolucencies on latest followup radiographs			
Femoral component (lateral)	43 (5 $\geq$ 1 mm)	11 (1 $\geq$ 1 mm)	5*
Tibial component (AP)	34 (7 $\geq$ 1 mm)	9 (1 $\geq$ 1 mm)	2*
Tibial component (lateral)	25 (2 $\geq$ 1 mm)	3*	2*
Patellar component (Merchant)	6*	0	0

* There were no radiolucent lines greater than 1 mm and no circumferential radiolucencies.

Table 2. Revision operations according to time after index procedure, components revised, and reason for revision

Patient	Age at surgery (years)	Sex	Time to revision (years)	Components revised	Reason for revision
1	62	Male	11.2	Liner, femur, patella	Polyethylene wear (tibia and patella), osteolysis, femoral loosening, pain
2	68	Male	11.8	Liner	Polyethylene wear, pain
3	64	Female	12.9	Liner, tibia	Polyethylene wear, osteolysis, tibial loosening, pain
4*	60	Female	13.5	All components	Polyethylene wear, osteolysis, tibial/femoral loosening, pain
5	67	Female	14.5	Liner	Polyethylene wear, pain
4*	60	Female	15.6	All components	Polyethylene wear, osteolysis, tibial/femoral loosening, pain

* Revision performed by an orthopaedic surgeon from a practice different from the practice of the surgeon performing the primary procedure.

radiolucency each in Zone 1 and Zone 4. There were no radiolucent lines greater than 1 mm identified and no circumferential radiolucencies. We did not see any patellar radiolucencies on followup radiographs. In the same 12 nonrevised knees, osteolysis was evident in three patients (three knees), and in each case, the osteolysis totaled 1 cm^2 or less and was limited to a single tibial zone. Two of these knees had shown no osteolysis at 15-year followup, and the osteolytic lesion in the third knee had not progressed since the 15-year followup radiograph. Of the six revised knees, four had osteolytic lesions (two in both femur and tibia, one in femur only, and one in tibia only) at the time of revision. Hence, for the entire cohort, 10 knees (10%) had osteolysis of at least 1 cm^2 over the course of the 20-year followup.

Other complications in this series were relatively rare. There were no postoperative infections. Three patients required manipulation under anesthesia for poor postoperative

ROM. One patient underwent repair of a quadriceps muscle rupture, related to a fall 4.5 months postoperatively. One patient developed a postoperative deep venous thrombosis, which was treated with anticoagulation. Patellar complications were also rare. Two knees had postoperative patellar instability; however, in both cases, this instability resolved without surgical intervention.

Discussion

Condylar-type TKA has been performed for more than 35 years, with relatively few studies [28, 31, 33] reporting findings at or near a mean of 20 years. Subsequently, the introduction of modular tibial trays and their associated potential benefits of a less destructive and more cost-effective revision have given surgeons an alternative. Although there have been a few studies reporting the results of TKA cohorts out to 20 years or longer [28, 31, 33], none have reported on modular tibial trays at this length of followup. To determine the long-term durability of a modular TKA construct, we prospectively followed a cohort of 75 patients with 101 PFC® cruciate-retaining prostheses at 5-year intervals. We previously reported 100% survivorship in this cohort at 10 years [20] and 91% at 15 years [29]. We therefore determined (1) survival, (2) the relationship of age and polyethylene thickness with revision, (3) function, and (4) radiographic lucencies and osteolysis in patients treated by a single surgeon with a posterior cruciate-retaining device with a modular tibial tray at a minimum 20-year followup.

We note the following limitations of our study. First, only 16 of the original 75 patients were alive. However, we had followup of the entire cohort of patients because of the prospective followup of the patients at 5-year intervals and no patients were lost to followup. We had a minimum 20-year radiographic evaluation in 77% of the living patients. However, the average radiographic followup was 19.5 years for all living patients and 14.7 years for the entire cohort. Our radiographic followup was more complete than most retrospective studies. Second, there was some selectivity of the implant in that seven other TKAs were performed during the time of the study, although this represented less than 10% of the total primary implants

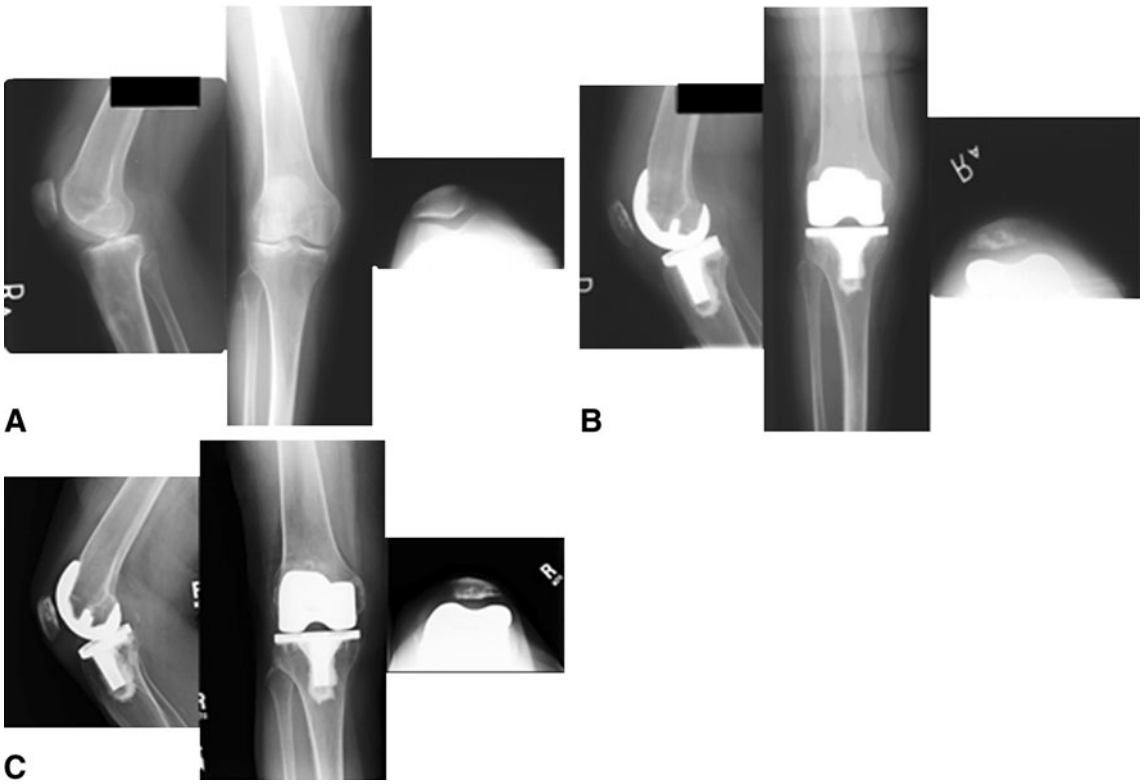

Fig. 2A–C Lateral, AP, and Merchant view radiographs were taken (**A**) preoperatively, (**B**) postoperatively, and (**C**) at the 20-year final followup. This patient was 53 years old at the time of the index surgery and 74 years old at the time of 20-year final followup. Preoperatively, she had 10° valgus deformity with functionally limiting pain. At the time of 20-year followup, she had a Knee Society pain score of 100 of 100 (no pain with activity) and function score of 86 of 100. Her Tegner and UCLA activity level scores were both 5 of 10, which corresponded to moderately heavy labor.

Table 3. Long-term followup of other TKA cohorts

Study	Implant design	Number of knees (patients)	Number of knees (living patients) at followup	Mean age at index surgery (years)	Mean age at followup (years)	Diagnosis of initial cohort	Mean followup (years)	Number of patients (knees) lost to followup	Percentage of living patients with followup radiographs	Number of knees (number for aseptic loosening) with revision surgery	Survivorship (revision for any reason as end point except where noted)
Current study	PFC®	101 (75)	22 (16)	71.2 (52–89)	82 (73–90)	85% OA 13% RA 1% AVN 1% PA	20.4 (20–21.8)	0	77%	6 (4)	90.8% at 20 years
Rodricks et al. [32]	PFC®	160 (134)	64 (52)	70.5 (34.7–94.0)	80 (50–95)	84% OA 13% RA 1% AVN 1% PA	15.8 (14.5–17.3)	1 (1)	53%	11 (3)	92.8% at 17 years
Ma et al. [28]	Total Condylar Knee®	126 (103)	64 (52)	59 (43–82)	78	81% OA 17% RA 1% PA	19 (17–22)	20 (23)	100%	10 (1)	83.2% at 20 years
Gill et al. [22]	Total Condylar Knee®	159 (139)	72 (63)	61.2 (30–80)	78.4	94% OA 4% RA 2% PA	17.2 (15.4–21.6)	0	NR	3 (0)	98.6% at 20 years
Rodriguez et al. [33]	Total Condylar Knee®	220 (164)	45 (30)	65 (31–83)	NR	50% OA 50% RA	20 (18–24)	12 (18)	100%	13 (6)	77% at 21 years
Pavone et al. [31]	Total Condylar Knee®	120 (80)	34 (26)	65 (30–85)	78 (53–94)	43% OA 56% RA 1% JRA	19 (17–22)	13	NR	10 (4)	91% at 23 years
Sextro et al. [34]	Kinematic® Condylar Knee	168 (118)	66 (50)	65 (21–88)	76.5	65% OA 31% RA 3% PA 1% AVN	15.7 (14–20)	3 (5)	NR	13 (7)	88.7% at 15 years (revision for any reason excluding infection)
Gill and Joshi [21]	Kinematic® Condylar Knee	404 (335)	216 (177)	68.4 (30–92)	NR	88% OA 11% RA 1% Other	(10–17)	0	NR	16 (9)	92.6% at 17 years
Weir et al. [36]	Kinematic® Condylar Knee	208 (177)	149 (126)	65 (24–92)	NR	64% RA 35% OA 1% PA	12 (10–14)	7	NR	22 (6)	87% at 12 years (recommend revision for any reason)
Callaghan et al. [8]	LCS® (mobile bearing)	119 (86)	26 (20)	70 (37–88)	83 (63–101)	88% OA 10% RA 2% PA	20.6 (20–21)	1	69%	3 (0)	96.5% at 20 years
Hooper et al. [25]	LCS® (mobile bearing)	414 (400)	244 (238)	66.9 (26–87)	NR	NR	≥ 10	24	79%	25 (4)	92% at 12 years
Buechel [6]	LCS® (mobile bearing, cementless)	169 (140)	NR	63.9 (23–87)	NR	70% OA 23% RA 7% PA	9.8 (4–20)	NR	NR	4 (0)	99.4% at 20 years

PFC® = Press-Fit Condylar®; LCS® = Low-Contact Stress®; NR = not reported; OA = osteoarthritis; RA = rheumatoid arthritis; AVN = avascular necrosis; PA = psoriatic arthritis; JRA = juvenile rheumatoid arthritis.

during the period of the index surgery. Third, this cohort of patients was older (average age at index surgery, 71.6 years). This may have accounted for lower revision and loosening rates than reported in other studies.

We found the PFC® prosthesis had high survivorship (Fig. 2). All revisions occurred greater than 10 years after the index procedure. All six failures were related to polyethylene wear leading to osteolysis and loosening. When comparing these results to the long-term results of this and other devices, survivorship was comparable (Table 3). This study also showed the potential benefit of tibial component modularity in terms of a less extensive revision because, in two of the six revisions, only liner exchange was necessary, and in another with polyethylene wear, the tibial component was retained at the time of femoral component revision. Hence, in 50% of revision cases that occurred over the 20-year followup interval, the modularity allowed for retention of the tibial component. The close-interval followup of this group of patients allowed for modularity to be optimally utilized.

We demonstrated a correlation with younger patient age and revision in this study. The average age at primary surgery of patients requiring revision was 63.5 years as compared to 71.6 years among nonrevised patients. The average age of the overall cohort at the time of the index procedure was 71.2 years, which was older than most contemporary TKA cohorts. Our cohort consisted entirely of polyethylene inserts gamma irradiated in air, a process associated with increased rates of polyethylene wear [10, 12, 37], particularly in combination with increased shelf life of polyethylene before implantation [11, 12, 18]. We were unable to determine the shelf life of the polyethylene utilized in this cohort of patients. The catastrophic early failure observed in PFC® knees of the same design implanted after 1991 [18] was not evident in this cohort, which included only TKAs performed just before that time interval. In 78 of 101 knees, an 8-mm insert was implanted. However, taking into account the tibial baseplate, the actual minimum thickness of an 8-mm insert implanted was 5.3 mm. All failures occurred in patients with 8-mm inserts, but we could not show this related to revision, given the small number of thicker (10-, 12.5-, and 15-mm) inserts implanted. The PFC® implant studied also employed a relatively flat, nonconforming surface, particularly the posterior-lipped insert. In spite of the potentially deleterious effects of thin [3, 9, 24, 38], flat [5, 19] inserts on polyethylene wear, clinically significant wear rates in this study were low and occurred late. However, the low wear rates may have also been a reflection of an elderly, less active cohort. This was further evidenced by the fact that there were no new revisions after 15.6 years, which could be attributed to the aging and less active living cohort.

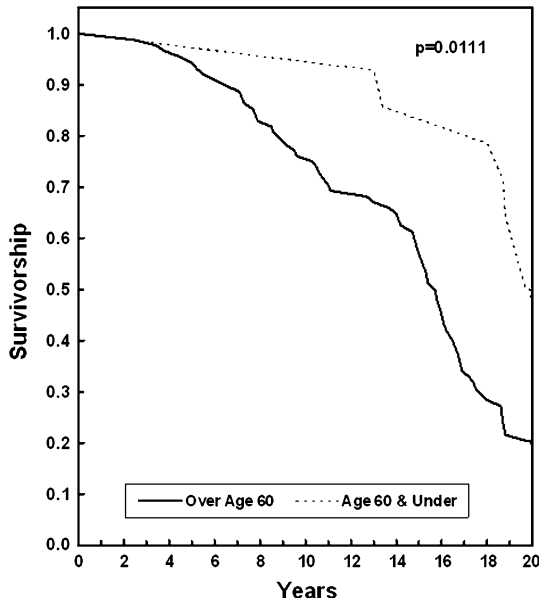

Fig. 3 A graph demonstrates the Kaplan-Meier survivorship curves with the end point of patient survival based on age at the time of surgery of the index procedure.

We found Knee Society clinical and function scores of 90 and 59, respectively. These clinical outcome measures were comparable to the 14- to 17-year followup of PFC® TKA reported by Rodricks et al. [32], as well as other long-term followups of TKA cohorts (Table 3) [6, 8, 21, 22, 25, 28, 31–34, 36].

Our results in terms of loosening are relatively comparable to those of the other series [6, 8, 21, 22, 25, 28, 31–34, 36]. Although the rates of osteolysis are not well defined in other studies, the prevalence of 10% in this study occurred late (after 10 years) and was associated with the knees requiring revision. We attributed the osteolysis to the first-generation modular capturing mechanism and thin gamma-irradiated-in-air polyethylene. Osteolysis has been recognized as the dominant mode of aseptic failure in TKA, particularly with modular designs [12, 18]. Because osteolysis can be asymptomatic for a relatively long period of time, close followup, especially after 10 years, is warranted.

This study should serve as a comparison for other designs utilized during this time, as well as for designs with better capturing mechanisms and better bearing surface materials (ie, polyethylene gamma irradiated in an inert environment and crosslinked polyethylene). In addition, Kaplan-Meier survivorship with patient survival as an end point (calculated by age at the time of surgery) demonstrated the need to follow younger patient cohorts to have a relatively high number of patients available for review at 20 years (Fig. 3).

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