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How Do Knee Implants Perform Past the Second Decade? Nineteen- to 25-year Followup of the Press-fit Condylar Design TKA

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Abstract

Background At 14- to 17-year followup, we reported successful outcomes of the Press-fit Condylar total knee arthroplasty (TKA) system in 160 TKAs performed between 1986 and 1989. However, there are few published reports on TKA survivorship and patient function that include patients evaluated into the third decade after surgery.

Questions/purposes The study purpose was to determine (1) the survivorship of the implant; and (2) knee function in patients with this TKA system at a mean 20-year followup.

Methods We ascertained revision status of all living patients (42 of 160 knees) and all patients (22 knees) who died since the previous study. Among patients alive at the latest followup, Knee Society function scores were obtained and radiographs were evaluated. Kaplan-Meier survivorship analysis with 95% confidence intervals was performed with revision for any reason and aseptic loosening as endpoints. A competing risks analysis with 95% confidence intervals was also performed for revision for any reason as the endpoint.

Results At the mean 20-year (range, 19–25 years) followup, all living patients retained their original implants from the index TKA, exclusive of three polyethylene exchanges. This study demonstrates an 87% Kaplan-Meier survivorship for revision for any reason (95% confidence interval [CI], 80%–92%) and a 98% Kaplan-Meier survivorship for revision for aseptic loosening (95% CI, 93%–99%). Competing risks survivorship was 79% (95% CI, 70%–85%) at 25 years for revision for any reason. Mean Knee Society function score was 46.9. Since the previous study, three revisions have been performed, all for polyethylene wear.

Conclusions The Press-fit Condylar implant system continues to be successful, maintaining longevity up to 25-year followup. This is one of the longest followup studies, reporting continued successes over 20 years, and should serve as a benchmark for current-generation implants.

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

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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.

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Introduction

Very few studies exist that report on patients undergoing arthroplasty into the third decade [3, 4, 7]. It is essential to understand the performance and reliability of a surgical procedure not only for the successful abatement of the disease or disorder, but also on the durability and longevity of such operations.

Our previous 14- to 17-year followup of the Press-fit Condylar knee prosthesis in a series of patients demonstrated an overall survivorship rate of 92.8% with revision

for any reason and of 98% with revision for aseptic loosening, all patella [10].

We report a followup to the previous study with 19- to 25-year (mean, 20.8 years) followup. The study purpose was to determine (1) the survivorship of the implant; and (2) knee function in patients with this TKA system at a mean 20-year followup. Our report is the largest and one of the longest followup studies of the Press-fit Condylar knee implant [3].

Patients and Methods

One hundred sixty Press-fit Condylar (DePuy Orthopaedics, Warsaw, IN, USA) cruciate-retaining primary TKAs in 134 patients (including 26 patients with bilateral arthroplasties) were in the initial group. Seventeen patients had a staged bilateral procedure and nine patients had a simultaneous bilateral procedure. Details of the surgical procedure and implant design are described in the initial report [10]. All prostheses were cemented, all had resurfaced patellae, and all were cruciate-retaining primary arthroplasties performed by a single surgeon (CWC) between November 1986 and September 1989. Data were collected prospectively. During the period in question, this implant was exclusively used for all patients undergoing a primary TKA for any indication.

Institutional review board approval obtained for the previous study extended to the present investigation. We ascertained the revision status of all living patients (34 patients, 42 of 160 knees) as well as all patients (18 patients, 22 knees) who had died since the previous study using telephone interviews with relatives. The patient who could not be found during the previous report was traced and examined in this study (Table 1).

Thirty-four of 134 patients (42 of 160 knees [26%]) were still alive at latest followup and retained their original implants from the index TKA. The mean duration of followup was 20.8 years (range, 18.9–25.3 years). The mean age of the patients at the time of the index procedure was 70.5 years (range, 34.7–94.0 years). The mean age of the 34 surviving patients (42 knees) was 61.7 years at the index procedure and 82.4 years (range, 55.6–96.7 years) at the time of the most recent followup (Table 2). No patients were lost to followup.

Among the patients who were alive and unrevised at latest followup, Knee Society function scores were obtained on 32 knees (26 patients). Thirteen of the 32 knees (11 patients) were examined by a medical professional and radiographs were available on these 13 knees. Weightbearing AP and lateral radiographs of the knee and Merchant-view radiographs of the patella were obtained. The remainder of the patients' information (29 of 42 knees; 23 patients [69%]) was obtained by telephone interviews directly or through caregivers. Although there were no specific general health questions in the questionnaire, each interviewee was asked to comment on any other health issues that they were facing at that time and if it interfered with any activities of daily living. Radiographs were evaluated by one of the authors (SP) for evidence of loosening according to the Knee Society scoring system [5]. These radiographs were compared with available radiographs from the previous study. Means and frequencies were used to summarize patient demographics, Knee Society function scores, and results of itemized questions, radiographic results, and revision rates. The Kaplan-Meier method was used to calculate survivorship with 95% confidence intervals with revision for any reason and revision for aseptic loosening as the endpoints. SPSS Version 12.0 (Chicago, IL, USA) was used for all analyses. To overcome the drawback of using Kaplan-Meier survivorship, which underestimates risk of revision by failing to account for the

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

Variable	Previous report	Present study
Dates of surgery	1986–1989	1986–1989
Mean followup (years)	15.8	20.8
Followup range (years)	14–17	19–25
Total number of patients (knees)	134 (160)	134 (160)
Number of alive patients (knees)	52 (64)	34 (42)
Number of dead patients (knees)	82 (96)	100 (118)
Lost to followup patients (knees)	1 (1)*	0
Number of knees revised (%)	11 of 159 (6.9%)	14 of 160 (8.8%)
Survivorship—revision for aseptic loosening	98%	97.5%
Survivorship—revision for any reason	92.8%	86.9%
Radiographs—number of knees	34	13

* This patient who could not be found during the previous report was traced and examined in this study.

Table 2. Demographics for the unrevised surviving patients (34 patients, 42 knees)

Demographics	Mean	SD	Range
Time to followup (years)	20.8	1.4	18.9–25.3
Age at index procedure (years)	61.7	8.7	34.7–76.1
Age of surviving patients (years)	82.4	8.7	55.6–96.7
Weight (kg)	76.6	16.6	40.8–106.6
Height (cm)	170.4	11.2	150.0–188.0
Body mass index (kg/m^2)	26.2	4.1	16.5–33.1

competing risk of death, competing risk analysis was also carried out to determine the survivorship with 95% confidence intervals with revision for any reason (R version 3.1.0, cmprsk package; R: A Language and Environment for Statistical Computing, Vienna, Austria; www.R-project.org). We have included both measures as a reference because very few long-term reports for TKA have used competing risk analysis.

Results

Our current study demonstrates a 97.5% (95% confidence interval [CI], 93.2%–99.2%) Kaplan-Meier survivorship for revision resulting from aseptic loosening (Fig. 1) and 86.9% (95% CI, 80.4%–91.5%) survivorship for revision for any reason (Fig. 2) at 20.8 years followup. Competing risk survivorship was 75% (95% CI, 67%–81%) at 20 years and 79% (95% CI, 70%–85%) at 25 years for revision as a result of any reason (Fig. 3). A total of 14 revisions have been done to date, of which 11 were reported in the previous study. Six revisions were isolated to the patella, and an additional revision was performed for severe wear of both the tibial and patellar components. Three revisions were performed for polyethylene wear since the last report (Table 3). No other major complications have been reported since the last report.

The mean Knee Society function score was 46.9 (range, 0–100) (Table 4). Sixteen patients (21 knees [66%]) reported no pain, nine (knees/patients, 28%) reported mild pain, and two (6%) reported moderate occasional pain. Nine (28%) were unable to climb stairs. Seventeen (53%) reported using no assistive devices with walking, another 10 (31%) reported using some type of assistive device, whereas five (16%) reported being unable to walk. However, when asked about walking distance, only three patients (10%) reported being unable to walk, five patients (16%) reported being house-bound, 17 patients (53%) reported being able to walk between five blocks and a mile outside the house and seven (22%) were able to walk unlimited distances.

Discussion

Extended long-term reports on a specific implant system are few in number in the arthroplasty literature because of inherent problems such as attrition of subjects in the database, loss to followup for various reasons, frequent change in implant design and materials, and inadequate perseverance on the part of investigators. This study was carried out to address these issues. Long-term studies on TKA frequently report on a design/device, which may no longer be available. However, it is essential to establish a benchmark against which future improvements can be measured.

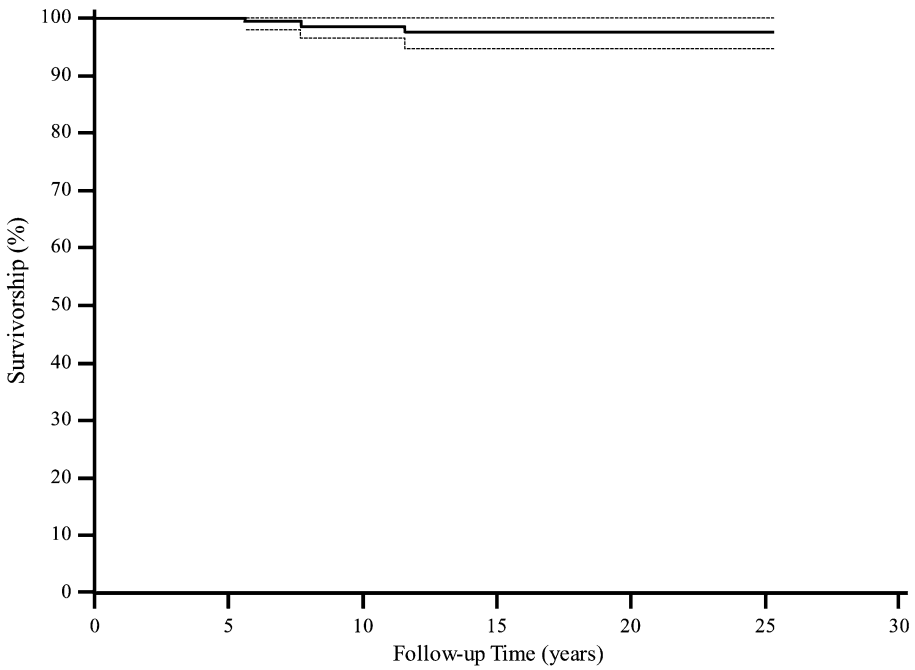

Fig. 1 Kaplan-Meier survivorship curves with 95% CIs are shown: revision for aseptic loosening (97.5% survivorship [95% CI, 93.2%–99.2%] at a mean 20.8 years followup).

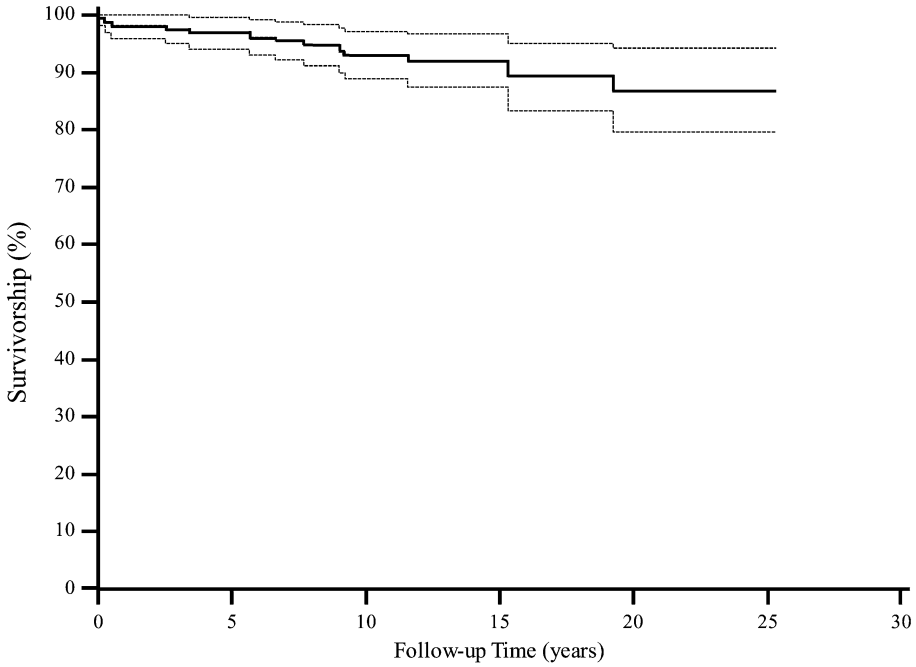

Fig. 2 Kaplan-Meier survivorship curves with 95% CIs are shown: revision for any reason (86.9% survivorship [95% CI, 80.4%–91.5%) at a mean 20.8 years followup).

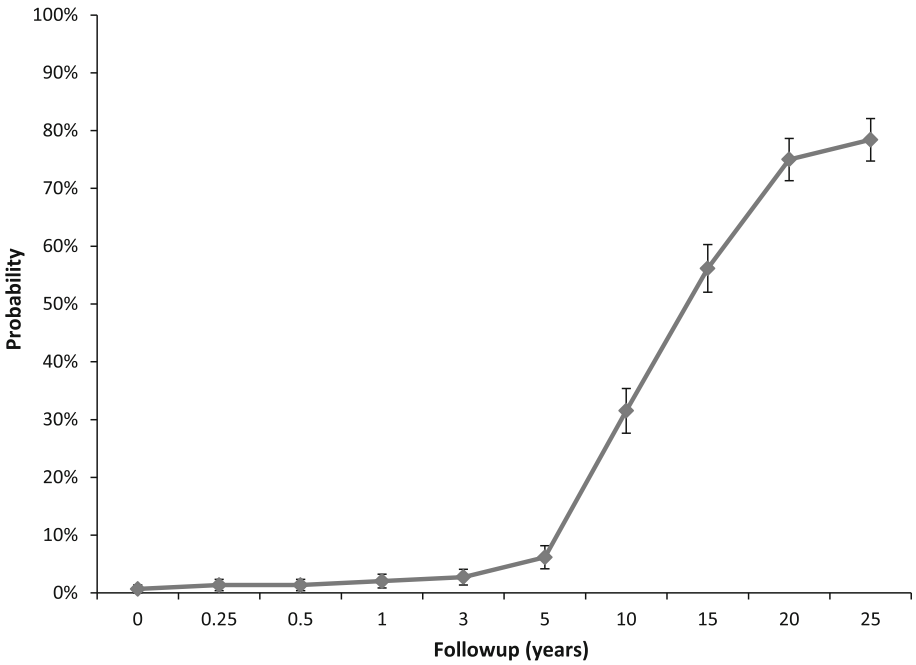

Fig. 3 Cumulative risk probability of revision for any reason with 95% CIs are shown here: 75% at 20 years (95% CI, 67%–81%) and 79% (95% CI, 70%–85%) at 25 years.

One of the major weaknesses in this study and other studies of implant longevity in this age category is the availability of complete radiographic followup in only 13 of 42 knees. This reflects the degree of infirmity of the patient population being studied. However, in those patients who did return for radiographs, no new radiographic lucencies or

Table 3. Details of all revision operations in the cohort*

Diagnosis at index procedure	Age at index procedure (years)	Weight at index procedure (lbs)	Time from index procedure to revision (years)	Indication for revision	Procedure	Notes
RA	63	165	0.1	Early infection	I&D, polyethylene exchange	*Staphylococcus aureus*
OA	74	185	0.33	Patella instability	Patellar revision, lateral release	Subluxation of patellar component
OA	70	190	0.5	Patella instability	Patellar revision, lateral release	Subluxation of patellar component
OA	69	200	3.2	Recurrent hemarthrosis, knee pain	Synovectomy, patellar revision	Wear and loosening of patellar component loose
OA	60	235	3.5	Hyperextension	Tibial polyethylene exchange	Insert changed from 12.5 to 17. 5 mm
OA	73	229	5.8	Aseptic loosening	Tibia tray exchange	Deficiency under medial tibial plateau polyethylene wear
OA	56	195	6.2	Knee pain	Patellar, tibial insert exchange	Severe wear on tibial and patellar polyethylene
OA	55	210	7.6	Aseptic loosening	Patella revision	Aseptic loosening
OA	69	200	9	Patella fracture	ORIF, patellar revision	Trauma
OA	56	145	10.2	Knee pain	Tibial polyethylene exchange	Severe wear posteromedial portion of tibial insert
OA	57	188	12.7	Aseptic loosening	Patella revision	Aseptic loosening
OA	*65*	*176*	*15.3*	*Instability (Rt)*	*Polyethylene exchange*	*Polyethylene wear*
OA	*65*	*176*	*15.3*	*Instability (Lt)*	*Polyethylene exchange*	*Polyethylene wear*
OA	*59*	*122*	*19.2*	*Knee pain*	*Polyethylene exchange*	*Polyethylene wear*

* Patients who had a revision after the last published report are italicized; RA = rheumatoid arthritis; OA = osteoarthritis; I&D = irrigation and débridement; ORIF = open reduction and internal fixation.

Table 4. Knee Society function score and reported pain at latest followup (n = 26 patients, 32 knees)

Measure	Mean (range)
Knee Society function score	46.9 (0–100)
Pain	**Number (%)**
No pain	21 (66)
Mild pain	9 (28)
Moderate or occasional pain	2 (6)

loosening was noted from their most recent followup. The infirmity and limited mobility of most of the surviving patients from our initial cohort were also reflected by the poor Knee Society score. However, most patients were pain-free and had no complaints related to their TKA.

Comparison of the survivorship of this particular implant with other designs is not feasible because to our knowledge only one other published study exists with this duration of followup. Callaghan et al.'s [3] initial cohort was smaller but had similar survivorship of 90.8% at 20 years compared with our patient group survivorship of 86.9% at 20 years. A few other studies have reported on the longevity of differing knee design systems. Buechel et al. [2] and Callaghan et al. [4] have reported on the 20-year followup of the LCS® Mobile Bearing Total Knee System (DePuy Synthes, Warsaw, IN, USA) with survivorship between 96.5% and 99.4% [1]. The Total Condylar Knee design (Johnson & Johnson, New Brunswick, NJ, USA) has also been reported with at least 20 years followup and has survivorship between 77% and 98.6% at 21 years [6, 8, 9, 11]. Only 26% (34 of 134 patients, 42 of 160 knees) of the original cohort of patients has survived with a mean age of 82.4 years compared with the mean age of 80 years at previous followup. We were, however, able to ascertain the status of all implanted prostheses in the patients who died as well as surviving patients.

We use competing risks analysis to account for the overestimation of survivorship in Kaplan-Meier (KM) analysis. In KM survivorship, the subjects who have not experienced the primary outcome (revision in this study) and are lost to followup for any reason are censored. The censored subjects could be "at risk" for revision regardless of why they were censored. Although this works when the outcome of interest is defined, it fails when there are other factors, which can change the risk. In a study population in which the mean age at index procedure is nearly 62 years, death rates are bound to be high when the cohort is followed over two decades. Thus, if a subject were to die during the study period, revision will not occur. This results in an inflated survivorship number and is thus inaccurate. Cumulative incidence competing risk estimate was developed specifically to describe the probability of disease when a competing risk such as death can intervene.

The current knee scoring systems lose their validity when measuring patient cohorts 20 to 25 year after their primary surgery performed at a mean age of 70 years. Most of the patients are either infirm or invalid and cannot travel to a doctor's office for physical and radiographic examination. This is reflected in the small number of radiographs and physical examinations for assessing outcomes.

Despite these drawbacks, long-term longitudinal studies have driven scientific inquiry into the failures of previous implants and have pushed for improvements in processing, sterilization, and design. Although the current implant is no longer used, our study demonstrates excellent survivorship. The long-term outcome of this design should serve as a benchmark for comparison for the current generation of implants, which are essentially minor incremental improvements on the initial design. The current implant designs are also likely to be unavailable for use 2 or 3 decades in the future. Remembering what worked well is advisable before trying to change one or more design features.

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