Follow-up of 11–16 years after modular fixed-bearing TKA

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Abstract To present representative data of long-term survivorship and clinical outcome for the PFC total knee arthroplasty (PFC-TKA). A consecutive series of 141 TKA was followed for a mean of 13 years (range, 11–16 years). Sixty-five knees were evaluated, 30 of these clinically and radiographically. Twenty-eight knees could only be assessed with the use of a questionnaire. Six patients were living in nursing homes. Fifty-four patients (65 knees) had died. Eleven had undergone a revision. One patient was considered lost to follow-up. With re-operation for any reason as the endpoint, the 10-year survival rate was 92% ($n=91$ patients at risk), and the 14-year survival rate was 91% ($n=12$). With aseptic loosening of the implant as the endpoint, the 10- and 14-year survival rates were 97%. The mean Knee Society and function scores were 76 and 48

points, respectively. In this multi-surgeon series modular fixed-bearing TKA had good clinical and radiographic results with excellent long-term survivorship.

Résumé Le but de cette étude est de présenter des données concernant la survie à long terme et le devenir clinique des prothèses totales de genou de type PFC. Une série consécutive de 141 prothèses ont été suivies en moyenne 13 ans (de 11 à 16 ans). 65 genoux ont été évalués, 30 sur le plan clinique et radiographique, 28 uniquement à l'aide d'une questionnaire. 6 patients vivent en institution et ne peuvent se déplacer et 54 patients (65 genoux) sont décédés. 11 patients ont nécessité une réintervention. Un seul patient est considéré comme perdu de vue. Si l'on considère que la réintervention est le critère analysé dans la courbe de survie à 10 ans, celle-ci est de 92% ($n=91$ patients) et à 14 ans le taux de suivi est de 91% ($n=12$). Si l'on considère maintenant comme critère de la courbe de survie le descellement aseptique à 10 et 14 ans, la courbe de survie est à 97%. Le score de la Knee Society et le score fonctionnel sont respectivement à 76 et 48 points. En conclusion, cette étude multi-opérateurs d'une prothèse totale du genou modulaire mais à plateau fixe a montré une bonne évolution clinique et radiologique avec une survie à long terme.

Approval of the ethics committee of the University of Heidelberg was given for this study on May 27, 2004 under the registration no. 097/2004.

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Introduction

Excellent long-term survivorship has been reported for nonmodular and modular TKA [1, 6, 8, 10, 11, 13, 14]. In 2005 Dixon et al. reported excellent survivorship and function at a minimum of 15 years following modular fixed-bearing TKA with retention of the PCL (Pressfit condylar, PFC, DePuy Orthopaedics, Inc.). However, their

study came out of the implant-developing centre and all patients had been operated by one single master knee surgeon. These excellent clinical and radiographic results might not be reproducible in a multisurgeon setting at a teaching hospital.

It is the goal of this study to present our data regarding the same nonmodular fixed-bearing TKA out of a teaching hospital with a mean follow-up of 13 years (range, 11–16 years).

Materials and methods

Between June 1989 and October 1994, a consecutive series of 141 primary posterior cruciate-retaining TKA was performed by ten different surgeons in 122 patients at our institution. The prosthesis was implanted in 76 right and 65 left knees of 106 female and 35 male patients. The preoperative diagnoses were degenerative osteoarthritis in 71% of the cases ($n=101$), rheumatoid arthritis in 27% ($n=38$), and post-traumatic arthritis in two cases.

A modular fixed-bearing posterior cruciate-retaining implant (PFC, DePuy Orthopaedics, Inc.) was used in all patients. All implants were fixed with cement. An all-polyethylene cemented patella with a central peg was used in all cases. The femoral cut was performed with the use of an intramedullary guide system providing 3° of external rotation with the posterior condyles used as a reference. An extramedullary system with 3° of posterior slope was used to cut the proximal tibia plateau.

Fifty-four patients with 65 knees had died with the index TKA in situ at a mean of 8.4 years postoperatively (range, 1.5–14.5 years). Eleven had undergone a re-operation.

Thus, 65 knees were evaluated at a mean of 13 years follow-up (range, 11–16 years). Thirty of these knees were evaluated clinically and radiographically at our institution; 28 knees could only be assessed with the use of a questionnaire and with information given by the primary care physician. Six patients were living in nursing homes with only limited access to clinical details beyond the fact that the knee implant was still in situ and functioning well. One patient could not be located and was considered lost to follow-up.

For the survivorship analysis, the primary care physician or the next of kin of the patients who had died or were unable to come was contacted to confirm that no revision surgery had been performed.

Clinical follow-up was performed with use of the Knee Society clinical rating system (max. 100 points) as well as a functional score for activities (max. 100 points) [7]. In addition, the Oxford Score (12–60 points with 12 representing an excellent result) [3, 4], the FFbH-OA function score (0–100%), as well as an activity score [5] (grades 1–5) were obtained. According to Insall the patients were classified as to whether the operated knee (A), the contralateral side (B), or other comorbidities (C) were the limiting factor in their walking ability [7]. Patient satisfaction was measured using a visual analogue scale from 1 to 5 with 1 representing full satisfaction with the result.

Fig. 1 Survival rate of 141 knees after 10–16 years with any kind of revision surgery as the endpoint

Fig. 2 Survival rate of 141 knees after 10–16 years, not including septic complications or insert exchanges

Radiographic analysis included weight-bearing AP and nonweight-bearing lateral views. Each radiograph was assessed for evidence of loosening, implant positioning, radiolucencies, and osteolysis. Fluoroscopy was not used to obtain orthogonal views of the prostheses.

Statistical analysis was performed using SPSS 15.0. Statistical procedures included survival analysis to estimate survival rates and confidence intervals, t-test statistics for paired and independent samples or nonparametric tests (MWU and Wilcoxon) depending on scaling properties and sample sizes. Significance level was assigned at 5% due to the observational nature of the study.

Results

Survivorship analysis and revisions

With re-operation for any reason (including septic complications as well as insert exchanges) as the endpoint, the 10-year survival rate was 92% (95% confidence intervals: 89–97%) with $n=91$ patients at risk, and the 14-year survival rate was 91% (85–97%; $n=12$) (Fig. 1).

With aseptic loosening of the implant as the endpoint, the 10- and 14-year survival rates were 97% with $n=91$ and $n=12$ patients at risk, respectively. The 95% confidence intervals were 95–99% (Fig. 2).

There were 11 revisions (Tables 1 and 2), including five for septic complications, one early infection at 6 months, and one low-grade infection at 1.9 years postoperatively.

Three late infections required revision surgery at 4.8, 6.2, and 11.8 years. All septic complications were treated with explantation of the implants and two-stage re-implantation. Four patients were revised for aseptic loosening of the tibial component ($n=2$) and both the tibia and femoral component ($n=2$). Two insert exchanges were performed for instability, one at 3 months postoperatively due to an undersizing of the insert at the index procedure and one secondary to wear at 10.3 years.

Clinical and radiographic results

After a mean of 13 years (range, 11–16 years), 65 knees/patients were still alive. In 30 cases we were able to evaluate the patients at our institution clinically and radiographically. In 28 knees we could only evaluate the patients with the help of their primary care physician as well as with our questionnaire. In six cases we only obtained information from next of kin or nursing homes that the implant was still in situ and functioning well. One patient was lost to follow-up.

Table 1 Septic revisions

Date of surgery	Date of revision	Status
February 1993	August 1993	Died March 99
September 1991	August 1993	Alive
September 1992	June 1997	Alive
May 1991	June 1997	Alive
March 1992	November 2003	Alive

Table 2 Aseptic revisions

Date of surgery	Date of revision	Implant(s) revised	Status
August 1993	November 1993	Inlay	Died April 2001
December 1992	August 1995	Tibia, femur	Died Jan 2000
July 1992	January 1998	Tibia	Alive
January 1991	March 1997	Tibia, patella	Alive
March 1990	June 2000	Inlay	Alive
September 1989	April 2004	Tibia, femur	Alive

Therefore clinical scores were available for 58 knees (Table 3). The mean Knee Society and function scores were 76 points (range, 29–99 points) and 48 points (range, 0–100 points), respectively. For 135 of the 141 preoperative knees, Knee Society and function scores were available. Interestingly, at a mean follow-up of 13 years we found a significant improvement for the mean Knee Society scores (preoperative: 26.8 ± 15.5 , $p < 0.01$) but not for the Knee Society function scores (preoperative: 46.7 ± 20.2 , $p = 0.673$). At final follow-up the mean Oxford Score was 30 points (range, 13–56). The mean FFbH-OA function score was 50 (range, 0–100). The activity score according to Devane averaged 2.2 (range, 1–4). Patients' satisfaction as measured by a VAS averaged 2.4 (range, 1–5).

We found a significant difference in the Knee Society function score at a mean of 13 years follow-up between patients who were younger than 65 years of age and those who were older than 65 years at the time of the index arthroplasty ($p = 0.013$). In addition, the younger patients obtained a better improvement of the Knee Society function scores (preoperative vs. postoperative) than the patients who were older than 65 years at the time of the index procedure ($p = 0.015$). No difference was found at final follow-up between the two age groups regarding the Knee Society score ($p = 0.53$), the Oxford score ($p = 0.25$), and the FFbH-OA score ($p = 0.177$).

Patients affected on the contralateral side (Insall index B, $n = 13$) or with functional limitations due to other comorbidities (Insall index C, $n = 36$) had significantly lower

scores in the Knee Society function score ($p = 0.001$), the Oxford score ($p < 0.001$), and the FFbH-OA function score ($p < 0.001$), but not in the Knee Society score ($p = 0.63$) as compared to patients with restrictions due to the operated knee only (Insall index A, $n = 9$).

We were able to evaluate 30 knees radiographically. We found nonprogressive radiolucent lines in three cases (one femoral and two tibial) without therapeutic consequences. In one patient we found tibial osteolysis with potential loosening of the tibia component. Short-term radiographic follow-up was recommended with probable revision surgery in the future. Asymmetric wear of the polyethylene insert was found in one patient who was asymptomatic; therefore, clinical and radiographic follow-up was recommended.

Discussion

Long-term follow-up of patients treated with TKA provides valuable information for surgeons about the survivorship of the implant and the chances that a patient will need revision surgery in his or her lifetime. However, the durability of TKA is affected by many factors such as patient selection, implant design, and surgical technique. Consequently, the literature provides heterogeneous data. In a large multi-surgeon, multi-implant study including 11,600 primary TKA with 2,943 and 595 knees at 10- and 15-years follow-up, respectively, Rand et al. [10] reported overall survivorship of 91% at 10 years and 84% at 15 years. Smaller multisurgeon series evaluating a single implant design reported 100%, 99%, and 97% survivorship at a minimum of 10, 15, and 17 years, respectively, with revision for aseptic loosening as endpoint [1, 13, 14]. However, the definition of failure of TKA has not been consistent in the literature. Dixon et al. [6] presented a 93% survivorship of the PFC system (DePuy) at 15 years with re-operation for any reason as the endpoint in a single surgeon study assuming that all patients lost to follow-up had a failure of the implant (worst case scenario).

Our multisurgeon, one-institution, one-implant (PFC) study reflects a common set-up in which many patients

Table 3 Knee scores dependent on age and activity level

	<65 years Mean ($\pm$ std)	>65 years Mean ($\pm$ std)	<i>p</i>	Insall A Mean ($\pm$ std)	Insall B or C Mean ($\pm$ std)	<i>p</i>	All Mean ($\pm$ std)
AKS-knee score	77.7 (22.7)	74.0 (19.9)	0.527	78.9 (18.2)	75.5 (22.1)	0.629	76.0 (21.4)
AKS-function score	55.6 (31.1)	34.0 (31.6)	0.013*	76.7 (22.2)	40.1 (31.5)	0.001*	46.0 (32.9)
Oxford score	29.8 (12.4)	33.8 (13.2)	0.247	19.2 (6.2)	34.0 (12.4)	0.000*	31.5 (12.8)
FFbH	50.3 (32.7)	39.0 (30.4)	0.177	86.3 (14.8)	37.7 (28.3)	0.000*	45.1 (31.9)

* Significant difference

are currently treated, thus providing representative data in terms of long-term survivorship as well as clinical outcome.

We included all revisions in our survivorship analysis consistent with a previously published paper of the same implant [6], whereas Vessely et al. [14] did not include periprosthetic fracture treatment, irrigation/debridement for infection, and other re-operations without component removal or revision of TKA components. However, we did not include two patients who might become candidates for revisions in the future, since at the time of the latest follow-up only clinical and radiographic controls were recommended.

The absolute survivorship of the same implant type was lower in our study (91% at 14 years) as compared to the survivorship reported by Dixon et al. (93% at 15 years) with very similar cohort sizes; however, in terms of aseptic re-operations the survival rate is quite comparable. The early infection rate of 1.4% (two cases) in our series is consistent with the overall literature data. The paper from Boston [6] reported no early or late infections in their cohort. Whether a single- versus multisurgeon setting might have had an influence on the early infection rate remains unclear.

We do not have a good explanation as to why we had three late infections at 4.8, 6.2, and 11.7 years postoperatively.

We had only one re-intervention addressing the all-polyethylene patella for simultaneous aseptic loosening of the tibia and the patella (<1%). This is consistent with two consecutive series with the same implant demonstrating a higher revision rate for patellar problems with a metal-back patella as compared to an all-polyethylene patella [6, 12].

The overall Knee Society scores in our series were lower than those reported by Dixon et al. [6]. However, in terms of the Knee Society function scores (average of 48 points in our series), a strong correlation between the Insall groups was found in our cohort. Insall A patients had significantly higher scores (77 points) than Insall B and C patients (40 points). In comparison, the average Knee Society function score in the Dixon series was 61 points—no subclassification according to Insall was done. It is possible that our cohort included more patients with concomitant diseases limiting the overall mobility and performance. In general, it has to be considered that long-term results based on clinical scores might be affected by age-related limitations and comorbidities. A sub-analysis of the overall scores, i.e. through the Insall index, is recommended to detect the impact of the index TKA on function and activity of the patient.

We found a low prevalence of radiolucent lines or osteolysis in our patients. They necessitated no surgical intervention at this time, but need to be followed closely. However, the radiographic data are of limited value, since

only about 50% of our living patients agreed to a radiographic follow-up examination.

With long-term follow-up studies survivorship of the patients themselves is of interest—46% of our patients had died at a mean follow-up of 13 years from causes unrelated to the index procedure. This mortality rate of 3.5% per year is consistent with previous studies demonstrating mortality rates between 3% and 3.6% per year [2, 6, 9].

This long-term study showed that in a multisurgeon set-up good clinical and radiographic results with an excellent survivorship of the implant can be achieved with a modular fixed-bearing PCL-retaining TKA.

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