Midterm survival of a contemporary modular total knee replacement

A MULTICENTRE STUDY OF 1970 KNEES

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This retrospective study evaluated the midterm clinical and radiographic outcomes of a second-generation total knee replacement system. In a multicentre consecutive series of 1512 patients, 1970 knees were treated with the PFC Sigma knee system (Depuy, Warsaw, Indiana). The patients were reviewed for functional outcome, and underwent independent radiographic analysis at a mean follow-up of 7.3 years (5 to 10). A total of 40 knees (2%) required revision, 17 (0.9%) for infection. The incidence of osteolysis was 2.2%. The ten-year survival with revision for any cause other than infection as the endpoint was 97.2% (95% CI 95.4 to 99.1).

The PFC Sigma knee system appears to provide excellent results in the medium term.

Various studies using a wide variety of implants have documented the efficacy and durability of total knee replacement (TKR). Factors associated with long-term success include correct alignment and surgical technique. Unsatisfactory results have also been associated with polyethylene irradiated in air, thin polyethylene and poor patello-femoral tracking.

As the demand for TKR increases, particularly in younger and more demanding patients, the design of the implants has been modified. For example in the second-generation PFC Sigma system (Depuy Orthopaedics, Warsaw, Indiana), the updated femoral coronal geometry increases the area of contact with the polyethylene and limits edge loading during lift-off, the deepened trochlear groove improves patellar tracking and the polyethylene is sterilised by gamma-irradiation in a vacuum and packaged in foil.

The purpose of this multicentre study was to report the implant survival and the clinical and radiographic results of this second-generation TKR in a large group of patients with a minimum of five years’ of clinical follow-up.

Patients and Methods

Between June 1996 and December 1997, all patients from eight designated centres who underwent primary TKR with a cemented PFC Sigma TKR were entered prospectively into the study. All surgeons were fellowship-trained or specialised in adult reconstruction surgery. Patients who had a different TKR, and those undergoing revision or partial knee replacement were excluded. Data included age, gender, details of posterior cruciate ligament (PCL) management, functional outcomes according to the Knee Society scoring system, and annual radiographic results.

During the study, 1970 PFC Sigma prostheses were implanted in 1512 consecutive patients with a mean age of 69.7 years (31 to 93). There were 920 women and 592 men. The diagnosis was osteoarthritis in 1894 knees (96.1%), rheumatoid arthritis in 42 knees (2.1%), post-traumatic arthritis in 22 knees (1.1%), avascular necrosis in ten knees (0.5%), Paget’s disease in one, and psoriatic arthritis in one (0.2%). Of the 1512 patients, 1054 (70%) had unilateral procedures and 458 (30%) had bilateral operations. In most cases (1577, 80.1%) the PCL was retained, and of the 1970 cases, 94.5% had the patella resurfaced.

The patients were evaluated clinically and radiographically at six weeks, three months, one year and then annually thereafter. We selected five years as the minimum for midterm analysis. Of the 1970 knees, 654 did not achieve this follow-up; 335 died, 293 were lost to follow-up and 26 underwent revision before the fifth post-operative year. Ultimately there were 1316 knees in 986 patients. The mean follow-up was for 7.3 years (5 to 10), providing a minimum five-year compliance rate of 85.1%.

The clinical data at follow-up were assessed according to the joint and function tools of the American Knee Society (AKS). An independent, experienced radiographer (TAG) assessed the radiographs for osteolysis, as
indicated by an expanding focal radiolucency of at least 1 mm. Of the 1512 patients (1970 knees), post-operative radiographs were available for 1346 (1761 knees, 89.4%) and the most recent anteroposterior, lateral and patellar views were reviewed. If the radiographer identified potential anomalies, earlier radiographs were examined. In these cases, radiographs at a minimum of three different times were usually available: immediately post-operative, intermediate (typically five years after surgery) and latest (typically eight years after surgery). The average post-operative follow-up for these 1761 knees was 5.2 years (0.1 to 10).

Survival was analysed by the Kaplan-Meier method. Cases were censored at their last clinical or radiographic evaluation or date of death, once confirmation was obtained that the prosthesis was doing well at that time. All 1970 knees were included. As previously recommended for orthopaedic studies, survival estimates are reported when at least 20 cases remain. The primary definition of failure was revision for any reason, excluding infected knees, but for easier comparison with other studies, survival estimates were also included where failure was defined as revision for any reason. Survival analysis was also stratified by gender, PCL status and age (< 55 vs ≥ 55 years). The log-rank test was used to assess whether there was a significant (p < 0.05) difference between survival estimates stratified by each of these variables.

Results
Of the 1316 knees with minimum five-year clinical data, the mean AKS score improved from 52.9 (3 to 100) pre-operatively to 87.3 points (13 to 100). The mean AKS function score improved from 47.0 (-20 to 100) pre-operatively to 70.8 points (-20 to 100). There were 293 knees (15%) for which there was not a follow-up for five-years or longer (classified as lost to follow-up). Assuming a worst-case scenario, the ten-year survival estimate was 78.8% (95% confidence intervals (CIs) 74.3 to 82.7). However, we would expect that those 293 knees would have had approximately the same proportion (2%) of failures as the entire study.17

A total of 40 knees (2%) required revision due to infection in 17, osteolysis/polyethylene wear in six, pain in four, instability in four, component loosening in four, fracture in three, component malposition in one, and patellar tendon rupture in one. The ten-year survival estimate was 95.6% (95% CI 93.5 to 97.6), using revision for any reason as the definition of failure. In the four revised cases with loosening, the thickness of the polyethylene insert was 8 mm, 10 mm, 15 mm and 18 mm respectively. In the six revised cases with osteolysis/polyethylene wear, the polyethylene thickness was 8 mm in two cases, 10 mm in two and 12 mm in two.

Of the 1970 knees, the inserts were > 8 mm thick in 1580 (80%) and 8 mm thick in 390 (20%). These required 29 (1.8%) and 11 (2.8%) revisions respectively. There was no significant difference in proportion (Fisher’s exact test, p = 0.23) or Kaplan-Meier survival (log-rank test, p = 0.28) between these groups.

The overall infection rate of 0.86% (17 of 1970 knees) was within reported rates from other large series.10,12,18,19 The diagnosis of infection was confirmed by culture, laboratory data and clinical suspicion. All patients had received a second-generation cephalosporin or vancomycin (if penicillin allergic) as prophylaxis. The predominant infecting organisms were Staphylococcus aureus and Streptococcus. When infection was excluded as the cause of revision, the ten-year survival estimate was 97.2% (95% CI 95.4 to 99.1; Fig. 1).

Some knees, although not revised, remained moderately or severely painful. Using a minimum six-month pain score of moderate or severe pain as an additional definition of failure, the ten-year survival estimate was 91.8%, with 95% CI of 89.3 to 93.7.

When the data were stratified by PCL management, the PCL-substituted knees had a significantly better range of movement than the PCL-retaining knees (1.1° to 115.9° and 1.6° to 114.4°, respectively p = 0.014, Mann-Whitney test), but there was no significant difference between the groups in terms of overall function (p = 0.84, Mann-Whitney test) and survival (p = 0.37, log-rank test) where failure was defined as revision for any reason except infection.

When the data were stratified by gender, women had significantly poorer pre-operative function and pain scores than did men (43.7 vs 51.6 points and 13.3 vs 15.5 points, respectively). However, at final follow-up only the change in overall mean knee scores (an increase of 31.1 points for women vs an increase of 36.0 points for men) was statistically significant (p = 0.003, Mann-Whitney test). Gender-stratified changes in pre-operative versus post-operative function, movement and pain were not significantly different (function p = 0.99, flexion p = 0.99, extension p = 0.14, pain p = 0.45, Mann-Whitney test). The estimated ten-year survival was 97.8% for men and 96.9% for women, but this difference was not statistically significant (p = 0.96, log-rank test).
We found no significant difference in failure rates between patients with or without osteoarthritis (2.0% vs 3.9% failures; Fisher's exact test, p = 0.20; Kaplan-Meier survival log-rank test, p = 0.17).

When the data were stratified by age, we found a significant difference in only one score; patients < 55 years old had significantly better mean function scores at follow-up than did patients ≥ 55 (82.5 and 69.7 points, respectively; p < 0.0001, Mann-Whitney test). The survival was similar.

Analysis of 1761 knees for which radiographs were available showed osteolysis in 39 (2.2%) at a mean of 5.2 years (0.1 to 10)

Discussion

Favourable features of modern knee systems such as the PFC Sigma, include femoral designs that limit edge-loading in flexion, have a forgiving trochlear groove to minimise patellar contact forces and allow improved patellar tracking, and consistent polyethylene manufacture.3,6,10,11,20-23 The polyethylene in the PFC Sigma is sterilised, packed in foil in an oxygen-free environment and gamma-irradiated. This consistent manufacturing method is meant to limit oxidation and improve cross-linking, which is shown to improve wear.10,11 Polyethylene failure is a major risk for long-term survival.10,21 In our group, revisions for osteolysis or polyethylene failures were rare. Six cases (0.3%) required revision for polyethylene wear and osteolysis was found in 39 (2.0%) at final follow-up. We could not identify any common radiographic characteristics in this group. These results are well within the range of reported outcomes of other modern knee systems with similar follow-up.24,25

The main cause for re-operation in this group was infection. The overall infection rate of 0.86% (17 of 1970) was between patients with or without osteoarthritis (2.0% vs 3.9% failures; Fisher’s exact test, p = 0.20; Kaplan-Meier survival log-rank test, p = 0.17).

Although TKR is established for patients over 60 of age, it is controversial in younger patients. Duff, Trousdale and Stuart27, reported 95% survival at 15 years in patients < 55 and in a similar age group, Diduch et al28 found an 87% survival at 18 years using revision as an endpoint. We found a slight but not significant age-related difference (p = 0.077, log-rank test). The ten-year survival was 97.5% for patients < 55 and 98.1% for those ≥ 55. Although young active patients remain at the highest risk for failure after TKR, it is important to note that at midterm follow-up we did not find a statistically significant deterioration in outcome in these patients. Survival was slightly lower in the younger group, but not significantly so. There were no significant differences in outcome with regard to PCL management or gender.

Our review was subject to the usual shortcomings of a retrospective study, and the number of patients lost to follow-up (15%) is larger than the ideal. However, this is a large, multicentre series with good follow-up and evaluation by an independent radiographer, showing excellent functional and radiographic results at midterm review.

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References


