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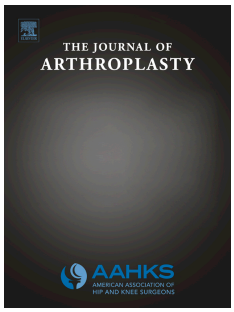

Excellent Survival And Good Outcomes At 15 Years Using The Press Fit Condylar Sigma Total Knee Replacement

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EXCELLENT SURVIVAL AND GOOD OUTCOMES AT 15 YEARS USING THE PRESS FIT CONDYLAR SIGMA TOTAL KNEE REPLACEMENT

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EXCELLENT SURVIVAL AND GOOD OUTCOMES AT 15 YEARS USING THE PRESS FIT CONDYLAR SIGMA TOTAL KNEE REPLACEMENT

Abstract

Background: We report 15-year survival, clinical and radiographic follow-up data for the Press Fit Condylar Sigma total knee replacement (PFC Sigma TKR).

Methods: Between October 1998 and October 1999, 235 consecutive TKRs were performed in 203 patients. Patients were reviewed at a specialist nurse-led clinic prior to surgery, and at five, eight-to-ten and 15 years postoperatively. Clinical outcomes, including Knee Society Score (KSS), were recorded prospectively at each clinic visit, and radiographs were obtained.

Results: Of our initial cohort, 99 patients (118 knees) were alive at 15 years, and 31 patients (34 knees) were lost to follow-up. 13 knees (5.5%) were revised; five (2.1%) for infection, seven (3%) for instability and one (0.4%) for aseptic loosening. Cumulative survival with the end-point of revision for any reason was 92.3% at 15 years, and with revision for aseptic failure as the end-point was 94.4%. The mean KSS knee score was 77.4 (33 to 99) at 15 years, compared with 31.7 (2 to 62) preoperatively. Of 71 surviving knees for which X-rays were available, 12 (16.9%) had radiolucent lines and one (1.4%) demonstrated clear radiographic evidence of loosening.

Conclusion: The PFC Sigma TKR represents a durable, effective option for patients undergoing knee arthroplasty, with excellent survival and good clinical and radiographic outcomes at 15 years.

Keywords

Total knee arthroplasty; implant survival; patient-reported outcome measures

Introduction

The Press Fit Condylar Total Knee Replacement (Johnson & Johnson Professional, Raynham, Massachusetts) has been commercially available since 1984. Despite a reported ten-year survivorship between 93%[1, 2] and 95%,[3] in some series a deterioration in implant survival was observed beyond ten years postoperatively.[4-9]

The Sigma design succeeded the original PFC TKR, arriving on the UK market in 1997. Novel features included an increased radius of medio-lateral femoral condylar curvature, with a corresponding deepening of the polyethylene insert, and modification of the femoral trochlea creating a deeper groove and a more pronounced lateral epicondylar ridge.[10]

We have previously reported results of this device up to ten years post-implantation, demonstrating all-cause survivorship of 95.9% and survivorship for aseptic loosening of 98.7%.[11] Studies extending beyond ten years are scarce,[12] but suggest the decline in implant survival observed in the original design does not extend to the current version. By following our cohort out to 15 years postoperatively, we will evaluate whether the PFC Sigma TKR continues to represent a durable, effective option for patients undergoing total knee arthroplasty.

Patients and Methods

This device was introduced in our unit in October 1998. Between October 1998 and October 1999, all patients undergoing unilateral primary TKR were included in this study. This unselected, consecutive group formed our study cohort, and is the same cohort used in the report of our ten-year results.[11] No other prostheses were used in the department during the study period, with unicompartmental, simultaneous bilateral and revision procedures excluded from the analysis. A summary of baseline demographic details and indication for index TKR is shown in Table I.

In our department, we employ a group of four specialist nurses who review all patients undergoing TKR, and the composition of this group remained constant throughout the study period. They were not part of the study team, and reviewed all patients undergoing TKR during the study period (not just the study cohort). Patients were reviewed by our specialist nurses at a pre-admission clinic prior to surgery, and at five years, eight-to-ten years and 15 years postoperatively. Data including age, gender, weight, height, medical co-morbidities and clinical outcome scores were recorded prospectively using a standardised data collection form, from which data was then entered into the departmental arthroplasty database. Radiographs were also obtained at these appointments.

The operations were performed by six different consultant surgeons, or by trainees under direct supervision. The surgical technique is as described in our previous results.[11] Specifically, the decision to resurface the patella was left to the discretion of the consultant surgeon, and drains were not used routinely. All patients underwent a standard regime of postoperative care, including mechanical and chemical thromboprophylaxis with thromboembolic deterrent stockings and subcutaneous low molecular weight heparin. A standardised transfusion protocol was in place during the study, with a trigger haemoglobin value of 8g/dL.

Using data entered into the departmental arthroplasty database, pre-programmed algorithms were used to calculate the Knee Society Score (KSS)[13] and Oxford Knee Score (OKS)[14] for all study patients. The OKS was categorised as ‘Excellent’, ‘Good’, ‘Fair’ or ‘Poor’, using published thresholds.[15]

Weight-bearing short-leg anteroposterior and lateral X-rays were obtained for all patients who attended their 15-year follow-up appointment. Coronal plane alignment (femorotibial valgus angle) was measured, and femoral and tibial components were assessed for the presence of surrounding radiolucent lines or osteolytic defects.[16] Images were reviewed by three surgeons using Carestream Picture Archiving Communication Software (PACS), all of whom were blinded to the that particular patient’s outcome at the time of X-ray assessment.

A life table was constructed and cumulative survival rates were calculated. End-points were re-operation for any reason, and component revision for aseptic loosening or mechanical failure. A 'worst case' survival analysis was also performed, whereby all knees lost to follow-up were treated as having failed immediately after their last follow-up appointment. Confidence intervals for survival rates were calculated using the Rothman method,[17, 18] which has been validated for this purpose.[19, 20] Where appropriate, a paired t-test was used to assess statistical significance of the relationship between two continuous variables.

Results

From an original cohort of 203 patients (235 knees), at 15 years postoperatively, 104 patients (117 knees) had died, leaving 99 patients (118 knees) alive and theoretically available for follow-up. This equates to a death rate of 3.4% per year. Of the surviving cohort, 60 patients (76 knees) attended clinic, seven patients (seven knees) were contacted by telephone, and one patient (one knee) responded by letter. Responses by telephone and letter provided data for the KSS pain component of the knee score and KSS function score, as well as OKS; however a complete KSS knee score (which includes clinical assessment of alignment, range of motion and stability) was unavailable for these patients. 31 patients (34 knees) did not attend clinic, and were therefore lost to follow-up. A summary of 15-year follow-up is shown in Figure 1.

KSS knee scores were available for 76 knees (64.4%) who attended their final clinic appointment, while pain component scores and function scores were available for a further seven knees who were contacted by telephone (83 knees, 70.3%).

The mean KSS knee score at 15 years postoperatively was 77.4 (33 to 99), showing little deterioration from the five-year (84.3, 35 to 99) and ten-year (78.8, 10 to 99) scores. Similarly, the mean pain component of the knee score was 39.5 (0 to 50) at 15 years, only slightly reduced from the five-year (44.3, 0 to 50) and ten-year (41.3, 10 to 50) scores. Clinically, this corresponds to mild knee pain when climbing stairs. 32 of 83 patients (38.6%) reported no pain.

In contrast to the KSS knee and pain component scores, the mean function score at 15 years was 56.4 (5 to 100), a marked decrease from the five-year (80.5, 30 to 100) and ten-year (68.9, 20 to 100) function scores. Postoperative trends in the KSS are shown in Figure 3.

Oxford Knee Scores were available for 77 knees (65.3%) at 15 years. The mean OKS was 29.0 (3 to 48), representing a ‘Fair’ outcome. Analysis of previous results from this cohort (Table IV) indicates a general decline in OKS from five to 15 years postoperatively, with a marked decrease in the proportion of knees classed as ‘Excellent’ and an associated increase in those classed as ‘Poor’; the proportion of knees in the ‘Good’ and ‘Fair’ category is relatively constant. Distribution of postoperative OKS is shown in Figure 4.

Radiographic data were available for 71 knees (60.2%) at final review. Of these, 12 knees (16.9%) had radiolucent lines. A summary of the distribution of radiolucent lines on AP and lateral radiographs is shown in Table V.

Clinically, five patients with radiolucent lines had occasional mild pain (KSS pain component score = 45), and the remainder reported no pain (KSS pain component score = 50).

One knee (1.4%) had osteolysis on the AP radiograph, which demonstrated a 3mm erosion in zone 1 and 6mm erosion in zone 4 beneath the tibial component.

Of 71 knees, 62 were in valgus, five were in neutral (femorotibial angle = zero degrees) and four were in varus alignment. The mean coronal plane alignment was 4.1 degrees valgus (range 9 degrees valgus to 5 degrees varus). The alignment of 24 knees (33.8%) was found to be outwith the recommended range of 7±3 degrees valgus.[28] Seven of these 24 knees (29.2%) demonstrated radiolucent lines. A summary of radiolucent lines by coronal plane alignment is shown in Table VI.

Overall, 11 patients (13 knees, 5.5%) required a revision procedure. Five knees (2.1%) underwent a two-stage revision for deep prosthetic infection, all within three years of their index procedure. Seven knees (3%) underwent change of polyethylene insert for coronal plane instability secondary to polyethylene wear. In all of these cases the femoral and tibial components were found to be well-fixed at the time of surgery. Two patients, both of whom underwent surgery for deep infection in the third postoperative year, required subsequent revision surgery for reasons other than infection. One patient developed symptomatic aseptic loosening in the tenth year following index TKR, requiring a single-stage revision to a hinged prosthesis; the other patient, who had rheumatoid arthritis, developed instability with synovitis and underwent change of polyethylene insert in the 11th year following index TKR. A summary of patients whom underwent revision surgery is shown in Table II.

At 15 years postoperatively, survival rate with revision for any reason as the end-point was 92.3% (95% CI 84.9 to 96.2). 15-year survival rate with revision for aseptic failure as the end-point was 94.4% (95% CI 87.6 to 97.6). The ‘worst-case’ survival rate, in which all knees lost to follow-up are presumed to have failed immediately following their last follow-up appointment, was 73.2% (95% CI 63.2 to 81.3). The life table and Kaplan-Meier survival curve are shown in Table III and Figure 2.

Discussion

The PFC Sigma TKR represents a durable, effective option for patients undergoing knee arthroplasty, with excellent survival and good clinical and radiographic outcomes at 15 years. Since its introduction it has become a popular prosthesis in the UK, accounting for 34.4% of primary TKRs in 2016.[21] The UK National Joint Registry determines the cumulative risk of revision to be 2.65% at ten years.[21] Previous data from this Unit,[11, 22, 23] and others,[24-26] have shown excellent prosthesis survival, clinical and radiographic outcomes for the fixed-bearing prosthesis up to ten years postoperatively. Our analysis has shown continuing longevity of the PFC Sigma TKR up to 15 years postoperatively, which is the longest reported follow-up for this prosthesis.

In our cohort, 8.1% of patellae were resurfaced at index TKR, and no patient required revision for patellar resurfacing up to 15 years postoperatively. This is consistent with all other long-term reports of the PFC Sigma TKR, and contrasts with series relating to its predecessor in which revisions for patellofemoral pain and instability were described.[1, 3, 6]

The mean 15-year KSS knee score showed very minimal deterioration from 5-year and 10-year scores, and the same was apparent in the pain component score. In the only other series assessing KSS beyond ten years postoperatively, Patil *et al.* report a mean KSS knee score of 84.4 for 39 knees at a mean 11.8 years,[12] and thus the mean 15-year score for our cohort (77.4) compares favourably.

In contrast, we observed a reduction in KSS function score from 80.5 at five years, and 68.9 at ten years, to 56.4 at 15 years. The causes for this functional decline do not appear to be related to either pain within or the objective performance of the prosthesis. As has been postulated, this decline may be an indicator of general activity limitation due to advancing age or co-morbidity.[27] Regardless, previous studies have estimated the minimal clinically-important difference in KSS function score to be 34.5 points,[28] and so this 24.1-point deterioration may not be of relevance to patients.

The mean 15-year OKS was 29, classed as ‘Fair’, indicating a general decline in OKS from five to 15 years postoperatively; this corresponds with the deterioration in KSS function score, and again may simply reflect age-related restrictions in functional ability and activities of daily living. The expected reduction in postoperative OKS over the first 10 years following TKR has been estimated at 4.2 points.[29]

Radiographs of 71 knees attending 15-year follow-up demonstrated non-progressive radiolucent lines in 16.9%, and radiological loosening in 1.4% (one knee). Previous results from this cohort demonstrated radiolucent lines in 43.1%,[11] which suggests a

disproportionate number of those with radiolucent lines at ten years either died or were lost to follow-up by 15 years. Radiolucent lines did not correlate with pain (mean KSS pain component score 47.9).

The mean coronal plane alignment was 4.1 degrees valgus, which is within the recommended range of 7±3 degrees valgus.[30] Interestingly, knees that were 'malaligned' appeared more likely to demonstrate radiolucent lines on 15-year X-rays (29.2%) than those that were not (10.6%). Due to the small sample size, however, this difference was not statistically significant (p=0.55).

We identified 13 revision procedures (5.5%) prior to 15 years post-implantation, which amounts to five additional revisions between ten and 15 years postoperatively. One further TKR from the cohort of 235 knees (0.4%) required revision for aseptic loosening at 15 years postoperatively. This does not appear to represent an excessive deterioration in implant survival, as was observed for the original design.

Two patients required a second revision procedure, both after having undergone two-stage revision for deep prosthetic infection in the third year following index TKR. Both patients had recognised risk factors for infection; both were male[31-33] cigarette-smokers, one had rheumatoid arthritis[31, 34, 35] and the other was morbidly obese[33, 36] (BMI 42kg/m^2). These baseline risk factors, in combination with early revision surgery itself,[37] increase the risk of subsequent revision surgery; however it is reassuring that neither subsequent revision was due to infection (indications = aseptic loosening and instability) and that there was a relatively long time interval between the first and second revision procedures (86 and 99 months, respectively). This suggests their initial revisions for infection had been effective.

Using an end-point of revision for any reason, implant survival in our cohort was 92.3% at 15 years, and using revision for aseptic loosening as an end-point survival was 94.4%. Prior to our study, the longest follow-up for this prosthesis had been a single-surgeon series of 79 TKRs, in which Patil *et al.* reported 14-year survival of 97% using revision for any reason and 100% using loosening as end-points.[12] Accounting for length of follow-up our results are comparable, suggesting ongoing durability for this prosthesis and supporting its continued use.

Previous studies assessing long-term survivorship of the original PFC TKR have quoted survival rates from 84.6%[8] to 92.6%[5] at 15 years; the latter results reported in a single-surgeon series of 139 TKRs in Boston, Massachusetts, where the prosthesis was designed.

As well as comparing our results with other published series of the same design, it is important to consider long-term reports of different designs of condylar knee prosthesis, as

the implant design may confer an advantage in terms of longevity. Schwartz *et al.* reported 10-year survivorship for 179 third-generation cruciate-retaining TKRs of 97.7% and 100%, with end-points of revision for any reason and revision for loosening, respectively.[38] Another report of a mean 11.2 year follow-up for 113 hybrid TKRs demonstrated a survival rate of 93.8% with revision for any reason as the end-point, and 96.5% for revision for loosening as the end-point.[39] A comparative analysis of the Genesis I and II designs (Smith & Nephew, Memphis, Tennessee) described an overall survival of 92.4% at 15 years, which compares well with our results.[40] There are few published TKR series extending into the third decade, although one series of the Anatomic Graduated Component TKR (Biomet, Warsaw, Indiana) at 25-30 years post-implantation reported overall survival of 94.2% at 25 years and 92.4% at 30 years.[41] At these time-points patients were at greater statistical risk of dying than of undergoing revision surgery; however, of revisions carried out by this point the commonest indication was aseptic loosening, with instability the second most common.

The principal limitation of our study is the high rate of loss to follow-up. 34 of 235 knees (14.5%) were lost to follow-up; this is reflected in our 'worst case' survival rate of 73.8% at 15 years. Several other studies assessing long-term outcomes of the original PFC and PFC Sigma TKR have more favourable rates of loss to follow-up,[5-7, 12] and therefore better 'worst case' survival, although all began with cohorts of less than 160 TKRs. Larger cohorts, such as ours, represent a particular challenge when collating 15-year follow-up data.

Moreover, only 60 of 99 surviving patients (74 of 118 surviving knees, 62.7%) were reviewed in the clinic, with a further 8 patients (8 knees) reviewed remotely (by telephone or letter). This not only limits the type of outcome data that can be obtained (in particular the KSS knee score, which requires clinical examination), but potentially introduces bias. Home visits were not considered appropriate or practical, due to patient co-morbidity or institutionalisation, or patients having moved away from the region.

Radiographic follow-up, available for 71 of 76 knees attending clinic, consisted of short-leg weight-bearing radiographs. Although these X-rays are considered suitable for assessing TKR alignment in general clinical practice, full-length (hip-knee-ankle) radiographs are generally preferable in a research setting.[42]

Our cohort of patients was operated upon by a range of surgeons, including consultants without a subspecialty interest in knee arthroplasty and supervised trainees, in a district general hospital. These results, therefore, are highly applicable to general orthopaedic practice. Our results update previous studies from our unit,[11, 22, 23] and continue to confirm excellent survivorship and good clinical and radiographic outcomes for the PFC Sigma TKR at 15 years postoperatively.

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EXCELLENT SURVIVAL AND GOOD OUTCOMES AT 15 YEARS USING THE PRESS FIT CONDYLAR SIGMA TOTAL KNEE REPLACEMENT

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Table I: Baseline patient details and indication for PFC Sigma TKR

Age (years)	66.5 (28 to 91)
Gender (n, *%*)	Male: 100, *49.3%* Female: 103, *50.7%*
Weight (kg)	81.4 (43 to 133)
Height (m)	1.63 (1.39 to 1.88)
Body mass index (kg/m^2)	30.5 (17 to 49)
Indication for TKR (n, *%*)	Osteoarthritis: 209, *88.9%* Rheumatoid arthritis: 20, *8.5%* Post-traumatic arthritis: 6, *2.6%*

Table II: Revision procedures, listed according to indication and time of revision

Indication	Time of revision (months)	Age (years)	Gender	Smoker	BMI (kg/m^2)	Primary diagnosis	Procedure
Infection (mixed)	5	67	Male	Yes	25.6	OA	Two-stage revision
Infection (Staph. aureus)	9	70	Male	Ex	35.2	OA	Two-stage revision
Infection (mixed)	13	77	Male	Ex	27.2	OA	Two-stage revision
Infection (mixed)	26	53	Male	Yes	26.9	RA	Two-stage revision
Infection (Staph. aureus)	27	68	Male	Yes	42.0	OA	Two-stage revision
Instability	59	62	Male	No	25.1	OA	Poly exchange
Aseptic loosening	113	68	Male	Yes	42.0	OA	Hinged TKR
Instability	119	49	Female	Ex	32.3	OA	Poly exchange
Instability	123	62	Male	No	26.4	OA	Poly exchange
Instability, synovitis	125	53	Male	Yes	26.9	RA	Poly exchange
Instability	126	64	Female	Ex	34.5	OA	Poly exchange
Instability	128	50	Female	No	23.4	OA	Poly exchange
Instability	136	74	Male	Ex	28.7	OA	Poly exchange

Table III: Life table for survival of the PFC Sigma TKR

Year	Number at start	Death	LTFU	Failure	Number at risk	Annual failure rate (%)	Annual survival rate (%)	Cumulative survival (%)	Cumulative 'worst case' survival (%)	Survival with revision for aseptic failure (%)
1	235	6	3	2	230.5	0.9	99.1	99.1 (96.9 to 99.8)	97.8 (95.0 to 99.0)	100.0 (98.4 to 100)
2	224	6	0	1	221	0.5	99.5	98.7 (96.2 to 99.6)	97.4 (94.4 to 98.3)	100.0 (98.4 to 100)
3	217	9	2	2	211.5	0.9	99.1	97.8 (94.7 to 99.1)	95.5 (91.8 to 97.6)	100.0 (98.2 to 100)
4	204	10	0	0	199	0.0	100.0	97.8 (94.6 to 99.1)	95.5 (91.7 to 97.6)	100.0 (98.1 to 100)
5	194	10	1	1	188.5	0.5	99.5	97.2 (93.8 to 98.8)	94.5 (90.3 to 96.9)	99.5 (97.1 to 100)
6	182	5	2	0	178.5	0.0	100.0	97.2 (93.7 to 98.8)	93.5 (88.9 to 96.3)	99.5 (97.0 to 100)
7	175	4	3	0	171.5	0.0	100.0	97.2 (93.6 to 98.8)	91.8 (86.7 to 95.0)	99.5 (96.8 to 100)
8	168	5	3	0	164	0.0	100.0	97.2 (93.4 to 98.9)	90.2 (84.7 to 96.6)	99.5 (96.7 to 100)
9	160	5	4	0	155.5	0.0	100.0	97.2 (93.3 to 98.9)	87.8 (81.7 to 92.0)	99.5 (96.7 to 100)
10	151	4	0	2	149	1.3	98.7	95.9 (91.4 to 98.1)	86.7 (80.3 to 91.3)	98.1 (94.4 to 99.4)
11	145	4	16	4	135	3.0	97.0	93.1 (87.5 to 96.3)	73.8 (65.8 to 80.5)	95.2 (90.2 to 97.7)
12	121	6	0	1	118	0.8	99.2	92.3 (86.0 to 95.9)	73.2 (64.6 to 80.4)	94.4 (88.7 to 97.3)
13	114	9	0	0	109.5	0.0	100.0	92.3 (85.7 to 96.0)	73.2 (64.2 to 80.6)	94.4 (88.4 to 97.4)
14	105	9	0	0	100.5	0.0	100.0	92.3 (85.4 to 96.1)	73.2 (63.8 to 80.9)	94.4 (88.1 to 97.5)
15	96	12	0	0	90	0.0	100.0	92.3 (84.9 to 96.2)	73.2 (63.2 to 81.3)	94.4 (87.6 to 97.6)

Table IV: Postoperative Oxford Knee Score classification, following PFC Sigma TKR

OKS classification (n, %)	**5 years (N=216)**	**10 years (N=131)**	**15 years (N=77)**
Excellent (42 to 48)	66, *30.6%*	34, *26.3%*	9, *11.7%*
Good (34 to 41)	59, *27.2%*	46, *34.1%*	24, *31.2%*
Fair (27 to 33)	49, *22.7%*	25, *19.3%*	14, *18.2%*
Poor (<27)	42, *19.3%*	26, *20.1%*	30, *39.0%*

Table V: Distribution of radiolucent lines on AP and lateral radiographs

	1 zone	**2 zones**	**3 zones**	**4 zones**
AP only	2	3	0	0
Lateral only	3	0	1	0
AP and lateral	0	1	1	1

Table VI: Distribution of radiolucent lines by coronal plane alignment

Radiolucent lines (n, %)	**7±3 degrees valgus (N=47)**	**<4 degrees valgus (N=24)**
AP only	1, *2.1%*	4, *16.7%*
Lateral only	2, *4.3%*	2, *8.3%*
AP & lateral	2, *4.3%*	1, *4.2%*
No radiolucent lines	42, *89.4%*	17, *70.8%*

Figure 1: 15-year follow-up of PFC Sigma TKR cohort

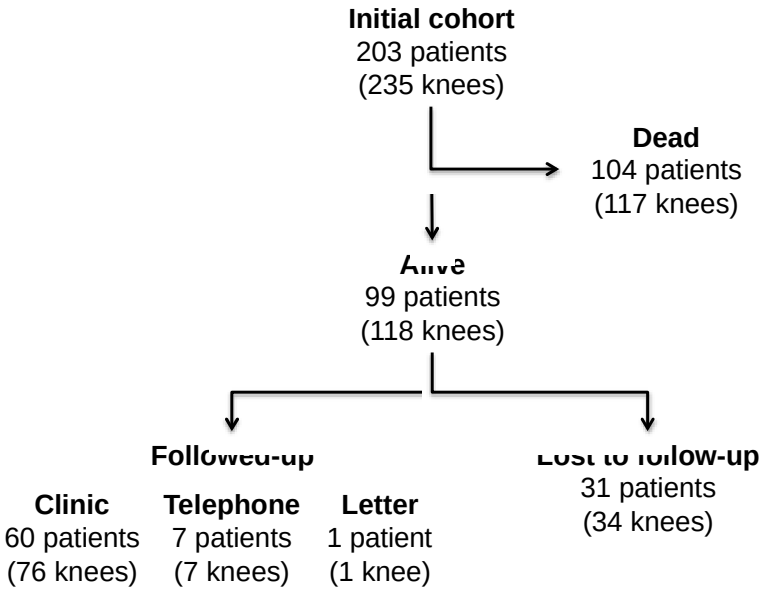

Figure 2: Cumulative 15-year survival rates for the PFC Sigma TKR

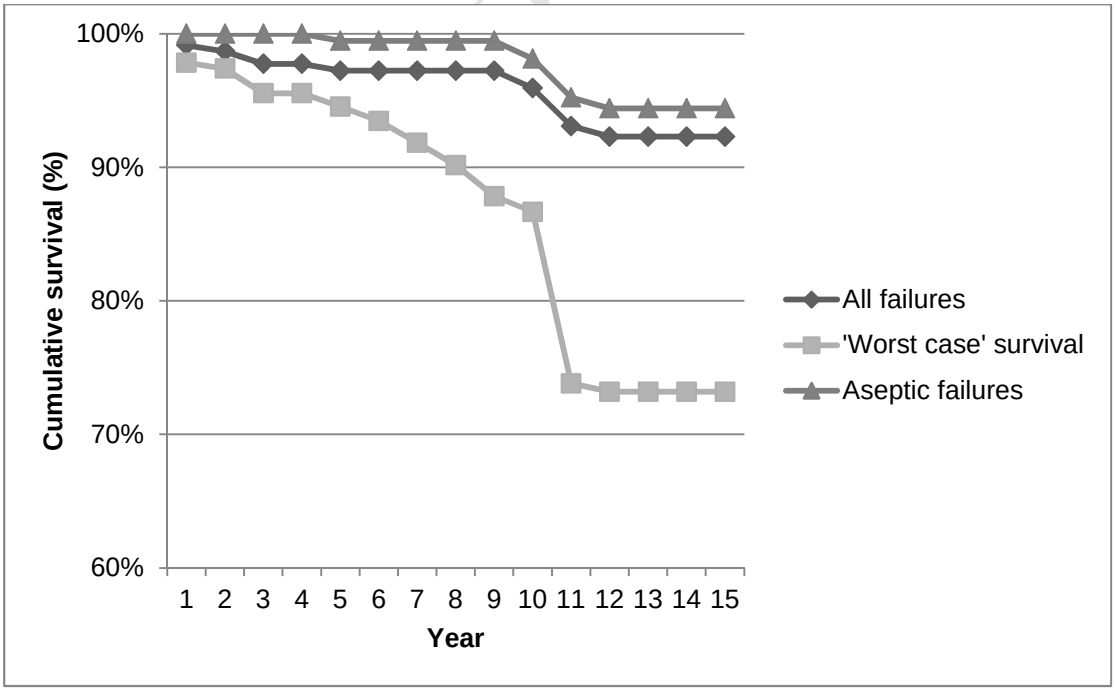

Figure 3: Postoperative Knee Society Score following PFC Sigma TKR

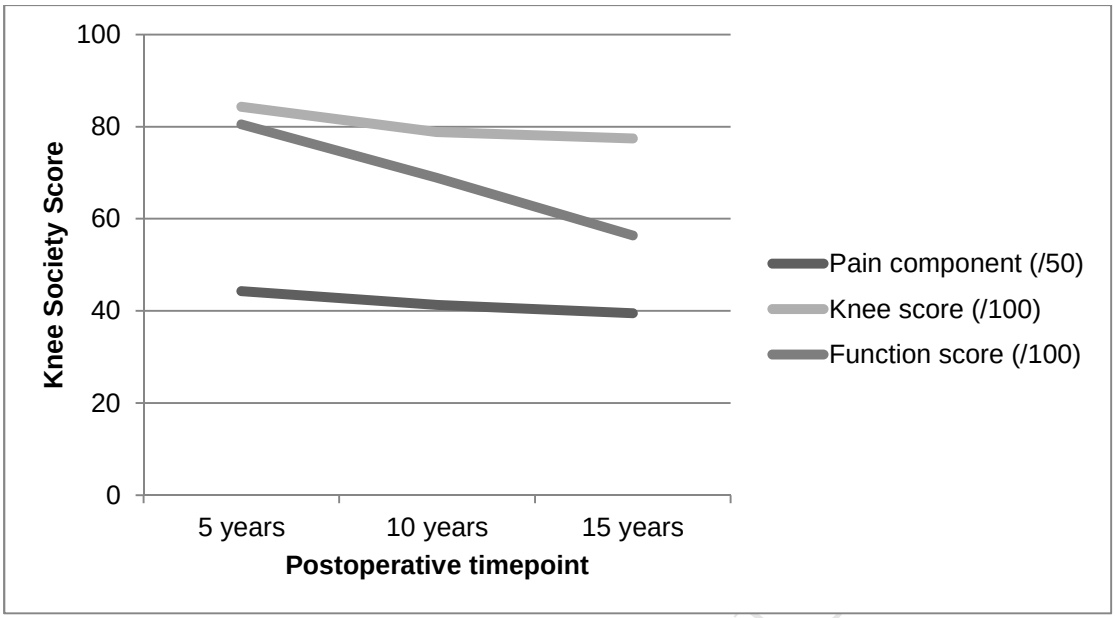

Figure 4: Postoperative Oxford Knee Score classification following PFC Sigma TKR