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Scientific Research

PFC Sigma Cobalt-Chrome Total Knee Replacement: Early Outcomes Demonstrate No Significant Early Failures at the Three-Year Mark

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ABSTRACT

The PFC Sigma Cobalt Chrome Sigma (PFCSCC) was introduced in 2006, and represents further development of the PFC Sigma design aiming at reducing the problem of backside wear. To ensure that there were no significant early failures following the introduction of this knee system to our hospital in 2006, we prospectively identified all patients undergoing TKA with the PFCSCC over a one-year period. Clinical and demographic patient data, American Knee Society scores, Oxford Knee scores, SF-12 scores and radiographic data were recorded pre-operatively and at three-year post surgery. 233 patients underwent 249 primary knee arthroplasties with the PFCSCC. Seven patients (eight TKAs) died before the last review and eight cases were lost to follow up. Mean age was 66.7 (range 34 - 80) with 47.6% male. Mean follow-up days were 1109 (range 741 to 1591). 5 (2.2%) were revised for infection with 1 revised for pain. The 3-year survival rate was 97.6% and 99.6% for aseptic failure. AKS 46.2 (0 - 95) was preoperatively 88.3 (17 - 100) with 3 years $P < 0.001$. OKS 39.0 (22 - 53) was preoperatively 22.6 (12 - 53) with 3 years $P < 0.001$. 17 of the 219 who had x-rays (8%) had radiolucent zones on x-ray. Our results demonstrate a good early aseptic survivorship of the PFCSCC at three years of 99.6%, combined with a good functional and objective improvement in our patients in three years.

KEYWORDS

Arthroplasty; Knee; Outcomes

1. Introduction

Total knee arthroplasty is well established for relieving pain and improving function. The Press Fit Condylar (PFC) Sigma total knee arthroplasty (TKA) (Depuy, Johnson & Johnson) is the most widely implanted knee prosthesis in England and Wales, and accounts for 36% of all the TKAs performed in 2009 [1]. The PFC Sigma Cobalt Chrome (PFCSCC) TKA was introduced in 2006 and represents a design modification based upon the PFC Sigma.

The tibial tray for the PFCSCC TKA is made of a cobalt chrome alloy, whereas in the older PFC Sigma, the tray was made of titanium. The theoretical advantage of this design modification is that microscopically the cobalt chrome alloy is smoother than titanium and therefore less likely to produce backside wear of the polyethylene insert [2]. In addition, the PFCSCC polyethylene insert is exposed to a higher radiation dose than the previous PFC Sigma insert, theoretically resulting in an extended lifetime of the prosthesis. The locking mechanism between the insert and tibia tray has also been improved to minimize backside wear.

Minor changes in arthroplasty can lead to unexpected early catastrophic failure and change the survivorship of implants [3]. Many implants undergo minor changes and it is important to ensure that these changes do not cause early failure [4]. National joint registries [1] may not identify all minor changes and outcomes after a short

period. Therefore, early clinical results in peer-reviewed journals represent an important method of informing surgeons about the initial survivorship and outcomes of newly introduced changes in the implant design and manufacture process [4]. We report the first early clinical, radiological and patient reported results for the PFCSCC TKA in 3 years, in order to allow comparison with published data on its predecessor, the PFC Sigma TKA.

2. Methods

Prospective data have been collected on all primary TKAs performed in our hospital since 1996. The PFCSCC (Depuy, Johnson & Johnson) TKA was introduced in our hospital in February 2006. Between February 2006 and February 2007, 249 primary knee arthroplasties with the PFCSCC TKA were performed on a total patient cohort of 233. Sixteen patients underwent bilateral primary procedures. No other TKA implant designs were used during this time period.

Demographic and clinical data, American Knee Society (AKS), Oxford Knee (OKS) and Short Form-12 Items Survey (SF-12) scores were collected prospectively from all patients on admission and at follow up clinics at six months, 18 months and three years. At final review, the AKS score was calculated using the protocol described by Install *et al*. [5], and standard short leg anterioposterior and lateral radiographs were obtained. Radiographic measurements of varus and valgus angulation, flexion or extension of the tibial and femoral components were taken. Radiolucencies were sought at the bone/cement and cement/prosthesis interfaces of both components.

Eight different operating surgeons, either consultant grade or a trainee under direct supervision, performed the operations. All surgeons used the same instrumentation and patients underwent the same postoperative regimen. The operations were performed in a filtered air operating theatre with laminar flow. Waterproof single use gowns and drapes were used and both the surgeon and assistant were double gloved. A tourniquet was used routinely, and the femoral and tibial cuts were performed using intramedullary and extramedullary alignment, respectively. The patella was not routinely resurfaced, but this was carried out at the discretion of the operating surgeon when patella wear was severe. All patients had antibiotic prophylaxis with 1 g Ceftriaxone shortly before inflation of the tourniquet. Pre- and post-operative thromboembolic prophylaxis was administered in the form of using low molecular weight heparin and full-length graded elastic stockings [6]. Wounds were dressed with gauze, wool and crepe dressings. These dressings were removed on the first post-operative day and continuous passive mobilisation was commenced. Blood transfusion was only performed if the haemoglobin fell below 8.5 g/dl.

Statistical Methods

Continuous data were presented in terms of the mean and range (R). Mean values between groups (AKS scores, OKS, SF-12 scores) were compared using the *t*-test for two groups and the analysis of one-way variance (ANOVA) for three or more groups. A *p*-value of <0.05 determined statistical significance. Life tables were constructed and the cumulative survival rates were calculated. Endpoints chosen were "reoperation for any reason" and "component revision for aseptic loosening or mechanical failure". The Rothman method [7,8] was used to calculate 95% confidence intervals. A "worst case" survival analysis was also performed based on the assumption that all those lost to follow up had failed immediately after the time of their last appointment.

3. Results

Two hundred and forty-nine PFCSCC TKAs were performed on 233 patients, 122 (52.4%) of whom were women. The indication for surgery was osteoarthritis in 226 (97.0%) patients, rheumatoid arthritis in five (2.1%) cases and avascular necrosis in two (0.9%). The mean patient age was 66.7 years (R 34 - 80 yr). The mean patient body weight was 83.2 kilograms (R 49 - 130 kg) and the mean body mass index (BMI) was 30.0 kg/m^2 (R 20.7 - 40.1 kg/m^2).

Two hundred and forty-one TKAs in 226 patients were available for review at three years. The mean follow up was 1109 days (R 741 - 1591 days). The AKS score improved from 46.2 (R 0 - 95) pre-operatively to 88.3 (R 17 - 100) at final review ($p < 0.001$, *t*-test). The OKS (available for 203 patients) improved from 39.0 (R 22 - 53) pre-operatively to 27.6 (R 14 - 53) at three months, and 23.4 (R 12 - 53) at one year ($p < 0.001$, ANOVA).

The patient mean pain score at admission was 11.7 (range 0 - 45) at 3 years: 39.5 (range 0 - 50) ($p < 0.001$). Function score mean at admission 43.5 (range −20 - 85). 59.5 (range −20 - 90) at 3-year follow up ($p < 0.001$).

Table 1 (Top) shows the mean patient reported SF-12 scores for 201 patients. By the three months post-operative time point, there was a statistically significant improvement in all SF-12 domains except the Mental Health score and General Health score. However, between the three months and one-year time points, the only SF-12 domains, which displayed a significant improvement, were the Physical Functioning and Pain scores.

Eight TKAs were lost to follow-up, five underwent revision for infection, and one was revised for persistent pain (**Table 2**). The three-year survival rate was calculated as 97.6% with "reoperation for any reason" (**Figure 1**) and 99.6% with "component revision for aseptic loo-

Table 1. The mean SF-12 scores in each domain at the time of admission, and at three months, one year and three years. *p*-values for comparisons between selected mean values were calculated using *t*-tests. (Physical Functioning score [PF], Role Limitation Physical score [RP], Pain score [BP], General Health score [GH], Vitality score [VT], Social Functioning score [SF], Role Limitation Emotional score [RE] and Mental Health score [MH]).

SF-12 Domains	Admission	3 Months	1 Year	3 Years	Admission versus 3 months	3 months versus 1 year	1 year versus 3 years
PF	6.2	49.3	55.7	51.4	<0.001	0.007	0.09
RP	3.9	44.9	48.6	48.6	<0.001	0.28	0.51
BP	36.4	62.5	74.5	70.8	<0.001	<0.001	0.25
GH	68.4	66.4	65.0	60.3	0.38	0.24	0.020
VT	45.5	52.9	56.2	53.2	<0.001	0.07	0.11
SF	52.4	74.9	77.5	76.1	<0.001	0.30	0.69
RE	96.1	76.1	79.0	75.4	<0.001	0.34	0.51
MH	69.8	72.3	74.9	72.6	0.12	0.10	0.13

Table 2. The life table calculation for survival of the PFC Sigma Cobalt Chrome TKA, with chosen endpoints "reoperation for any reason", "component revision for aseptic loosening or mechanical failure" and "worse case" survival where all the knees lost to follow-up were assumed to have failed. (*Number of knee prosthesis implanted).

Year	No.* at start	Death	Lost to follow up	Failure	No. at risk	Annual failure rate	Annual survival rate	Cumulative survival	Cumulative worst case survival	Survival with reoperation for aseptic failure #
1	249	1	3	6	247	2.4%	97.6%	97.6%	96.4%	99.6%
2	239	2	0	0	238	0.0%	100.0%	97.6%	96.4%	99.6%
3	236	5	5	0	231	0.0%	100.0%	97.6%	94.3%	99.6%

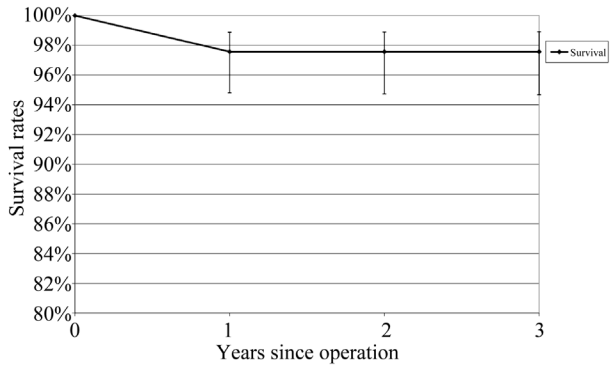

Figure 1. The three-year survival of the PFC Sigma Cobalt Chrome TKA with the endpoint taken as "reoperation for any reason". Error bars indicate 95% Confidence Interval.

sening or mechanical failure" (**Figure 2**). The "worse case" survival was 94.3% at three years where all the knees lost to follow-up were assumed to have failed.

Radiographic data were available for 219 TKAs (88.0%) at final review. Of these 17 radiolucencies were noted in 17 (8%) cases. The mean mediolateral alignment was 5.2 degrees valgus (2 Degrees Varus to 9 Degrees Valgus.) In this series, 22 (10%) knees were out-with the suggested range of 7˚ +/− 3˚ [11]. There was no evidence of increased incidence of radiographic lucency in these knees.

4. Discussion

We present the first early clinical, radiological and patient reported results for the PFCSCC TKA. We have previously reported on the medium- to long-term follow up of the PFC Sigma TKA [9-13]. The design of the PFC Sigma Cobalt Chrome TKA incorporates a number of minor modifications from the PFC Sigma TKA and these initial results show that at three years post-operatively, the prosthesis survival rate stands at 97.6% with revision for any reason and 99.6% with revision for aseptic failure. This is comparable to our experience with the PFC Sigma where there were a small number of failures, mostly in the early period. This would suggest that the design changes have not caused any increase in early failures.

There are few papers which describe the early results of total knee replacements, however when compared to Munziger *et al.* 2010 [14], their 5 year results of the Innex total knee replacement demonstrated a 3% aseptic revision rate and a 4.8% overall revision rate, whereas our results compare favorably at the moment and show no initial early failures. The Munziger *et al.* 2010 [14] paper, showed that all their infective revisions were in the first 4 months and after discussing with the authors, 6 out of 9 aseptic revisions were within the 3 years, and these were due to overstuffing, instability anterior knee pain or arthrofibrosis. This paper does confirm the need

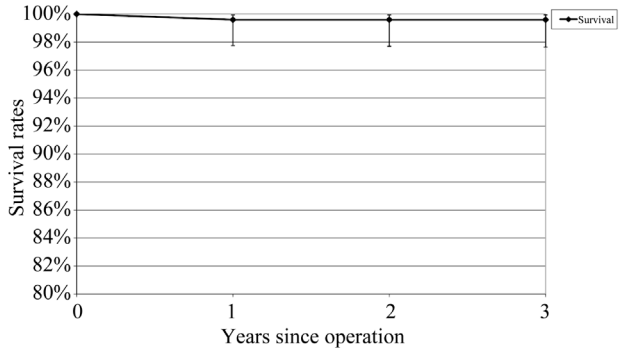

Figure 2. The three-year survival of the PFC sigma cobalt chrome TKA with the endpoint taken as "component revision for aseptic loosening or mechanical failure". Error bars represent 95% confidence interval.

to produce five year results to ensure that there is no mid-term peak in revisions. Apart from our own results, there have been other medium term results published for the predecessor to the PFCSCC, the PFC Sigma, with Dalury *et al*. [15] reporting 99.6% and Zaki *et al*. [16] reporting 99.4% survivorship in the medium term and our revisions for aseptic reasons currently remain on track to be similar to their findings. All of our aseptic failures, required a change of the polyethylene spacer only, with none requiring revision of the tibial or femoral components. This comparison is reassuring, following the design modifications made in changing from PFC Sigma to the PFC Sigma Colbalt Chrome, as there appears to be no drop in survival of the prosthesis during the first 3 years.

There were 8 knees (3%) lost to follow-up during the study period, which highlights the problems with longitudinal studies and represents a weakness in our study. As revision rates are very low, failure to identify a revision from the study group would have a significant effect on the results. If we take a "worst case" scenario, assuming all lost knees were revised, this would give us a survival rate of 94% at three years. This would still represent an acceptable performance at three-year post implantation.

The clinical outcomes were assessed using the American Knee Society scoring system and the results showed pre-operatively the mean AKS Score was 46.2 whilst at 3 years post-operatively, the mean AKS was 88.3. These early results suggest considerably better outcomes than Zaki *et al.* 2007 [16], and Hunter *et al.* 2009 [9], who reported an AKS score at 7 - 9 year review for the PFC Sigma and the result compares well with the Wrightington study [16,17] which had a mean score of 50 and Dalury's results [14] which had a mean score of 50 [15].

The American Knee Society Scoring system is separated into a Knee score and the Function Score to prevent confounding of the Knee Scores by increasing infirmity, and we showed a significant improvement in both Knee Score (mean of 46.2 with a range of 0 - 95 to a mean of 88.3 with a range of 17 - 100 at 3 years) and Function Score (mean of 43.5 with a range of −20 - 85 to a mean of 59.5 with a range of −20 - 90 at 3 years). The mean pain score at admission to 3 year review was significantly increased from 11.7 to 39.5. Our results for the PFC sigma ten year results [10] showed a mean function score of 79.9 at 18 months post surgery which then declined to 68.9 at 10 years. Our initial results for the PFCSCC perform favourably when compared to the PFC Sigma, but Arthur *et al.* 2013 [11] study highlights the importance of continuing to review the AKS for the PFCSCC in order to ensure the scores do not decrease more than expected over time.

The Oxford Knee Score showed a highly significant improvement [16] between the pre-operative score and the scores at 3 months, and the 3-month score and the score at 1 year but there was no significant difference between 1 year and at 3 years, this information is important for patients as it demonstrates that up to one year patients can expect improvements, however these will stabilise out between 1 and 3 years. Our early results were better than the mean Oxford Knee Score for the PFC Sigma at 7 - 9 years [9] and so further research will be required at the ten year mark to ascertain if these early improvements are maintained or diminish.

We used the SF-12 [18] to measure health status and the 3 month review showed significant improvements in all domains except Mental and General Health. After the three month mark the only ongoing significant improvement was an increase in the pain score demonstrating that there was an improvement in pain, which continued up to 1 year whilst these are early results, they are still relevant as early results have been shown to be predictive of overall satisfaction rate by Scott *et al.* 2010 [19].

Radiographs of the study group were also available for review and 219 knees of the 235 surviving knees were analysed. 22 knees (10%) were outside the suggested range (7 +/− 3˚) for mediolateral alignment. This figure compares well to other TKA series using the same definition that reported that only 22% - 34% lie in this range [20-23]. The standard radiographs taken in our unit are short leg films instead of long leg films, which has the limitation of overestimating varus alignment of the knee by approximately 1.6˚. It is likely that our numbers would be lower if long leg films had been used as standard.

5. Conclusion

With escalating healthcare costs combined with multiple minor changes to implants, it is essential that we ensure that small changes to the implants are not going to cause early failures in order to prevent multiple costly revisions

in both monetary and patient morbidity terms. These early results come from the first consecutive cohort of patients using a new implant, with a follow-up rate of 97% that allows a reliable assessment of the initial efficacy of this prosthesis. These early results should be reproduceble in a district general orthopaedic unit. We conclude that the new PFC Sigma Colbalt Chrome knee arthroplasty performs well over the first 3-year post implantation with excellent survival rates and good clinical and radiological outcomes and that ongoing follow-up is required to ensure that it continues to maintain this standard.

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