Journal of Arthroscopy and Joint Surgery 5 (2018) 15–18

Contents lists available at ScienceDirect

Journal of Arthroscopy and Joint Surgery

journal homepage: www.elsevier.com/locate/jajs

Research paper

Press fit condylar cobalt chrome sigma total knee arthroplasty: No difference to original design at five year point

A.M. Wood[a], Kieran M. Heil[b,*], I.J. Brenkel[a], P. Walmsley[a]

[a] Victoria Hospital, Hayfield Rd., Kirkcaldy, KY2 5AH, United Kingdom
[b] Derriford Hospital/INM, Plymouth, PL6 8DH, United Kingdom

ARTICLE INFO

Article history:
Received 14 March 2017
Accepted 22 January 2018
Available online 1 February 2018

Keywords:
Total knee arthroplasty
Outcomes
Press fit condylar
American knee society score
Oxford knee score

ABSTRACT

Background: Total knee arthroplasty (TKA) is an established procedure for relieving pain and improving function. The Press Fit Condylar Cobalt Chrome Sigma (PFCSCC) Total Knee System was introduced by Depuy, Johnson & Johnson in 2006, as an update of their existing PFC Sigma design intended to reduce backside wear.

Methods: To identify any significant early failures following the introduction of this knee system, 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 and five years post-operatively.

Results: 233 patients underwent 249 primary TKA's with the PFCSCC. Seventeen patients (19 TKAs) died before the last review and 29 patients (30 knees) were lost to follow up. The mean age was 66.6 (range 34–80) with 47.6% male. Mean five year follow-up was 1836 days (range 1530–2307). Five knees (2.2%) were revised for infection with three revised for pain. The 5-year survival rate was 96.6% and 98.6% for aseptic failure. American Knee Society Score (AKSS) was 32.6 (0–86.6) preoperatively and 80.7 (29–95) 5 years post-operatively $P < 0.001$. OKS was 20.9 (7–38) preoperatively and 36.4 (10–48) at 5 years $P < 0.001$.

Conclusion: We report the first five year outcome of this design change, which demonstrates a good early survivorship when compared to the previous PFC Sigma design.

1. Introduction

The improvement in mobility and the relief of pain following Total Knee Arthroplasty (TKA) is now clearly established.[1,2] The Press Fit Condylar (PFC) Sigma TKA (Depuy, Johnson & Johnson) is the most widely implanted knee prosthesis in England and Wales, and accounted for 36% of all the TKAs performed in 2009.[3–5] The PFC Sigma Cobalt Chrome (PFCSCC) Total knee system was introduced in 2006 and features a modified design of the original PFC sigma. The PFCSCC incorporates a tibial tray made of a cobalt chrome alloy instead of the titanium featured in the older design. The theoretical advantage of this modification is that microscopically the cobalt chrome alloy is smoother than titanium and therefore less likely to produce backside wear of the polyethylene insert.[5] Theoretically, the PFCSCC also has an extended lifetime due to the polyethylene insert being exposed to a higher radiation dose than the original PFC Sigma insert. Improvements in the design of the locking mechanism between the insert and tibia tray it is believed will also help in reducing backside wear.

Minor changes in arthroplasty can lead to unexpected early catastrophic failure and survivorship of implants.[6] The publication of early clinical results in peer-reviewed journals represent an important method of informing surgeons about early survivorship and outcomes with new implant designs. The aim of this study was to assess the survival, clinical and radiological outcomes of the Press Fit Condylar Sigma Cobalt chrome implant at five years in a district general hospital setting. We provide the first medium term follow-up of the PFCSCC, done by multiple surgeons at a district general hospital, which we believe gives a true reflection of its survivorship outside of specialist centres.

2. Patients and methods

The Press Fit Condylar Sigma Cobalt Chrome Total Knee system by Depuy, Johnson & Johnson was introduced in our hospital in February 2006. Over the next 12 months, 249 primary TKA with the

* Corresponding author.
E-mail address: kieranheil@nhs.net (K.M. Heil).

http://dx.doi.org/10.1016/j.jajs.2018.01.001

PFCSCC were performed on a total patient cohort of 233. All patients were included in the analysis, with no exclusions. Statistical analysis was performed on best and worst case assumptions for patients lost to follow-up.

Eight different operating surgeons, either consultant grade or a trainee under direct supervision, performed the operations in a filtered air operating theatre with laminar flow, waterproof single use gowns and drapes. A tourniquet was used routinely, and the femoral and tibial cuts were performed using intramedullary and extra medullary 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 surgeons used the same instrumentation and patients underwent the same postoperative regime.

Demographic and clinical data was collected prospectively from all patients on admission and at follow up clinics run by arthroplasty nurses at three months, one year, three years and five years. The clinical data included the American Knee Society Score (AKSS)[7] the oxford knee score (OKS)[8] at the five year point along with the Short form-12 health questionnaire (SF-12)[9] at the three year point. Patients who were revised were removed from the outcome score measures at subsequent review points A. At the three year review standard short leg anterioposterior and lateral radiographs were obtained to allow measurements of varus and valgus angulation, flexion or extension of the tibial and femoral components. Radiographs were also reviewed for defects at the bone-implant interfaces and radiolucent lines.

2.1. Statistical analysis

A life table was constructed to demonstrate the cumulative survival rates. The endpoints were “re-operation for any reason” and “revision for pain, aseptic loosening or mechanical failure”. A standard analysis was perfomed along with A “worst case” survival analysis was performed based on the assumption that all those lost to follow up failed immediately after the time of their last appointment. 95% confidence intervals were calculated using the Rothman method.[10,11]

3. Results

Of the 234 patients (249 knees) that were in the study, at the five year review 17 patients (19 knees) have died, leaving 217 patients (230 knees).

Sixteen patients underwent bilateral primary procedures. The mean patient age was 66.6 years (34–80 yrs.) with 47.6% male. The mean patient body weight was 83.2 kg (49–130 kg) and the mean body mass index (BMI) was 30.0 kg/m2 (20.7–40.1 kg/m2). The indications for surgery were primary Osteoarthritis (OA) in 226 (97%) patients, rheumatoid arthritis (RA) in five (2.1%) cases and avascular necrosis in two cases (0.9%). A total of 29 patients (30 knees) have been lost to follow up. In all, there has been eight revisions in total, five of which were revised within the first three months due to deep infection (primarily *S. Aureus*).

Of the three aseptic revisions, one had a patella replacement after 17 months due to patellofemoral articulation. There were two more revisions, one in the third post-operative year due to pain which had cement removed, polyethylene liner changed and manipulation under anaesthesia (MUA). The last revision occurred in the fourth post-operative year due to pain and loosening.

At five years the cumulative implant survival rate from the life table calculation was 96.6% (CI 97.1 to 94.4) with revision for failure for any reason as endpoint. With revision for aseptic failure as the endpoint, the cumulative survival at five years as 98.6% (CI 100.0 to 97.0). The worst-case scenario in which all those lost to follow up are presumed to have failed is 83.8% (CI 58.7 to 80.6) (Table 1, Fig. 1)

The mean American Knee Society Score (AKSS) pre-operative (249 knees) part 1 knee score was 32.6 (0–86.6) with a mean pain score of 11 (0–45). The mean AKSS at the five years post-operatively (190 knees) was 80.7 (29–95) with a mean function score of 71.8 (100-0) and pain component of 41.1 (0–50). At the one year point the best pain score recorded (233 knees) was 45.8 (0–50) and at the three year point a score of 43.0 (0–50). Though at the five year point, 61.4% (129/210) of patients reported no pain at all (pain score of 50) (Fig. 2).

At five years (180 knees) post-operatively the mean Oxford Knee Score (OKS) was 36.4 (10–48) with 67% (120 / 180) being in the excellent (42–48) or good (34–41) range. Pre-operative results (245 knees) included only six results in this range. (Fig. 3).

The mean Medio lateral alignment was 6.6° valgus (4° varus to 11° valgus) at the three month review (244 knees). At five years the mean of the remaining 192 knees was 6.8° valgus (5°–9° valgus) with only 14% (27 of 192) of knees outside of the (−3° to +7°) suggested range.[12] Radiographic data for 219 knees (88.0%) was examined at the three year review point. Of those reviewed 17 radiolucencies were noted in 17 (8%) cases.[3]

4. Discussion

We present the first mid-term clinical, radiological and patient reported results for the PFC Sigma Cobalt Chrome TKA carried out in a district general hospital by multiple surgeons. We have previously reported on the medium- to long-term follow up of the PFC Sigma TKA.[13] The PFC Sigma Cobalt Chrome TKA design incorporates a number of minor modifications over the original PFC Sigma TKA and these initial results show that at five years post-operatively, the prosthesis survival rate stands at 96.6% with revision for any reason and 98.6% with revision for aseptic failure. These results were similar to the PFC sigma which recorded a 97.2% success rate for any revision at five years and a 99.5% rate for aseptic failure.[13] Our results compare favourably with those reported by Munziger et al. 2010,[14] whose 5 year results for the Innex total knee replacement demonstrated a 97% success rate for aseptic revision and a 95.2% success rate for revision for any revision.

The five year aseptic revision results for the PFC sigma by Dalury et al.[15] reported 99.6% and Zaki et al[16] 99.4%, remain very close to these results for the PFC sigma cobalt chrome of 99.5%. However in a systematic review of the PFC sigma, there is a detectable drop off between 5 and 10 years and for this reason we intend to carry this study forward to identify the future trend for the PFCSCC. At up to five years the PFCSCC demonstrates similar results to the PFC and

Table 1
Life table for cumulative survival of the PFC Sigma Cobalt Chrome total knee replacement.

Year since Operation	Number at start	Death	Lost to follow-up	Total Failure	Aseptic Failure	Period Failure Rate	Period Success Rate	Number at Risk	Cumulative survival for all failures	Cumulative worst case	Cumulative survival for aseptic failures
0–1	249	1	4	6	1	2.4	97.6	246.5	97.6	95.9	99.6
1–3	238	8	10	0	0	0	100	229	97.6	91.8	99.6
3–5	220	10	16	2	2	1	99	207	96.6	83.8	98.6