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## The Journal of Arthroplasty

journal homepage: [www.arthroplastyjournal.org](http://www.arthroplastyjournal.org)

## Clinical Outcome of Medial Pivot Compared With Press-Fit Condylar Sigma Cruciate-Retaining Mobile-Bearing Total Knee Arthroplasty

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## ARTICLE INFO

## Article history:

Received 18 December 2016

Received in revised form

19 April 2017

Accepted 10 May 2017

Available online xxx

## Keywords:

Medial-Pivot total knee

PFC Sigma CR mobile-bearing knee

clinical results

radiographic results

range of knee motion

patient satisfaction

## ABSTRACT

**Background:** The purpose of this study was to compare the long-term clinical results, radiographic results, range of knee motion, patient satisfaction, and the survival rate of Medial-Pivot posterior cruciate-substituting, knee prosthesis and a press-fit condylar (PFC) Sigma cruciate-retaining mobile-bearing knee prosthesis in the same patients.

**Methods:** One hundred eighty-two patients received Medial-Pivot knee prosthesis in one knee and a PFC Sigma knee prosthesis in the contralateral knee. The minimum duration of follow-up was 11 years (range, 11–12.6 years).

**Results:** The knees with a Medial-Pivot knee prosthesis had significantly worse results than those with a PFC Sigma knee prosthesis at the final follow-up with regard to the mean postoperative Knee Society knee scores (90 compared with 95 points), Western Ontario and McMaster Universities Osteoarthritis Index score (25 compared with 18 points), and range of knee motion (117° compared with 128°). Patients were more satisfied with PFC Sigma knee prosthesis (93%) than with Medial-Pivot knee prosthesis (75%). Complication rates were significantly higher in the Medial-Pivot knee group (26%) than those in the PFC Sigma knee group (6.5%). Radiographic results and survival rates (99% compared with 99.5%) were similar between the 2 groups.

**Conclusion:** Although the long-term fixation and survival rate of both Medial-Pivot and PFC Sigma prostheses were similar, we observed a worse knee score, worse range of knee motion, and patient satisfaction was less in the Medial-Pivot knee group than in the PFC Sigma knee group. Furthermore, complication rate was also higher in the Medial-Pivot knee group than the other group.

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Mobile-bearing total knee prosthesis was introduced to minimize interface stresses between the implant and cement or bone and cement. Furthermore, it has been claimed that mobile-bearing total knee prosthesis reduces articular and backside wear of the tibial polyethylene bearing [1]. Despite the theoretical advantages, determination of in vivo kinematics suggested that “paradoxical anterior movement” occurred in some mobile-bearing total knee arthroplasties (TKAs) [2]. The Medial-Pivot TKA has been designed with the goal of replicating physiological motion of the native knee joint as much as possible in the hope that it will reduce polyethylene wear

while enhancing stability, range of motion, and patient satisfaction. Its medial articulation is effectively a ball-and-socket joint, with a raised anteroposterior lip preventing “paradoxical anterior movement.” On the lateral side, there is lack of congruence to facilitate rotation [3,4]. High contact surface area is thought to reduce pressure and, therefore, polyethylene wear [5]. Although these salient features have been claimed to support potentially improve the clinical results and a long-term survivorship of this prosthesis, there have been few long-term clinical results in patients undergoing Medial-Pivot TKA [6].

The purpose of the present study was to compare the long-term clinical results, radiographic results, range of knee motion, patient satisfaction, and the survival rate of a Medial-Pivot posterior cruciate-substituting total knee prosthesis (Advance; Wright Medical, Arlington, TN) and a press-fit condylar (PFC) Sigma cruciate-retaining (CR) mobile-bearing prosthesis implanted (DePuy, Warsaw, IN) in the same patients. Furthermore, we investigated complication rates in both knee systems.

No author associated with this paper has disclosed any potential or pertinent conflicts which may be perceived to have impending conflict with this work. For full disclosure statements refer to <http://dx.doi.org/10.1016/j.arth.2017.05.022>.

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<http://dx.doi.org/10.1016/j.arth.2017.05.022>

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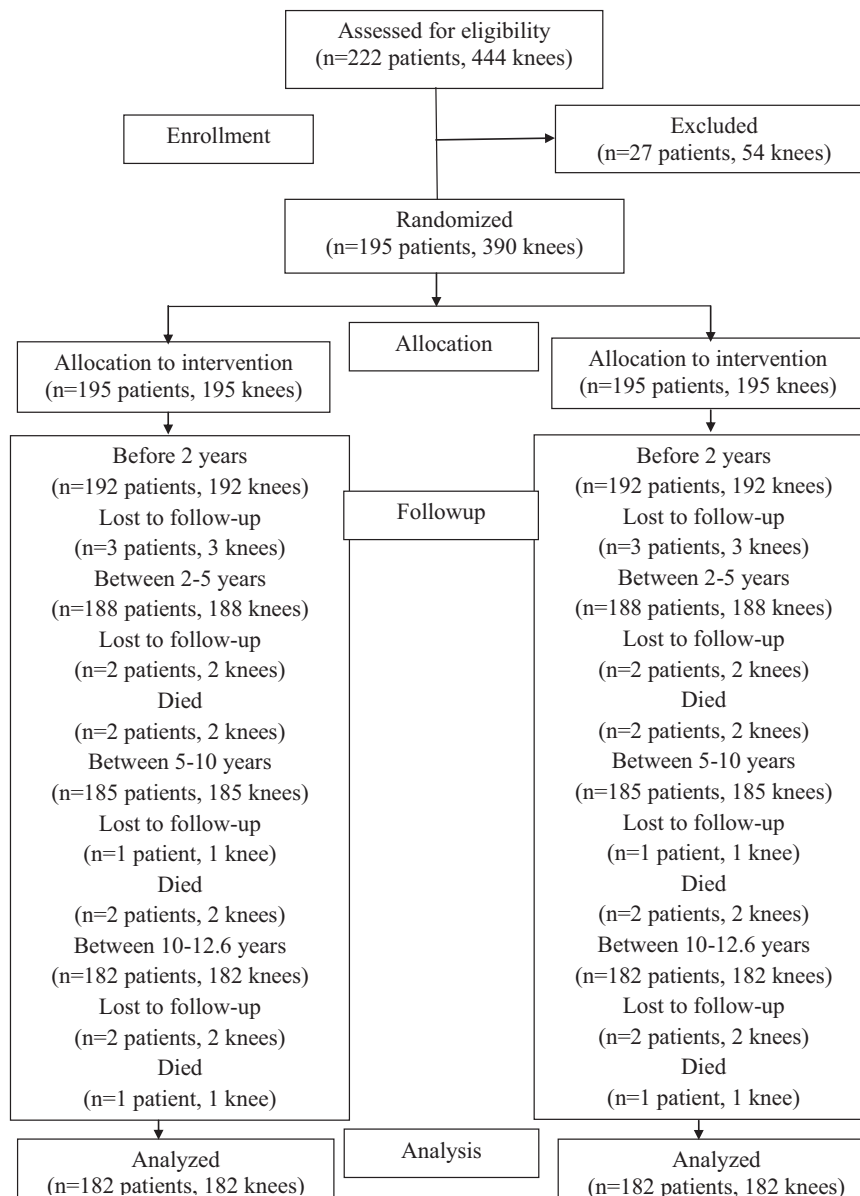


Fig. 1. The CONSORT diagram for our study is shown.

## Materials and Methods

We enrolled 195 consecutive patients (390 knees) from February 2004 to July 2005. Previously reported 96 patients (192 knees) [7] were included in the present series. The requirements for enrollment were the presence of end-stage osteoarthritis of both knees that we considered to be severe enough for bilateral sequential TKAs under the same anesthetic. The study was approved by our institutional review board, and all patients signed and provided informed consent. Patients were excluded if they had inflammatory arthritis, osteoarthritis of the hip causing pain or restricted mobility, a foot or ankle disorder which limited walking, dementia or a neurologic disorder including history of stroke which affects mobility, and were >80 years. Among 195 patients, 5 died, 8 were lost to follow-up, leaving 182 patients (364 knees) available for study with a minimum follow-up of 11 years (range, 11–12.6 years; Fig. 1).

The study group contains 52 men (104 knees) and 130 women (260 knees). Mean age (and standard deviation) was 65.6 years

(6.9; range, 55–79 years). The average height (standard deviation) was 152.5 cm (7.2; range, 135.0–180.0 cm). The average weight (standard deviation) was 64.7 kg (9.2; range, 42–90 kg). The average body mass index (standard deviation) was 29.8 kg/m<sup>2</sup> (3.1; range, 21–36.4 kg/m<sup>2</sup>; Table 1). Three hundred fifty knees had 5°–20° of varus deformity of the knee and 14 knees had 8°–12° of valgus deformity of the knee. There was no difference between the 2 groups with respect to the extent of diseases, pain, functional disability, deformity, range of knee motion, bone loss, and/or prior surgical treatments before the operation.

Randomization to Medial-Pivot posterior cruciate-substituting total knee prosthesis or PFC Sigma CR mobile-bearing total knee prosthesis was accomplished using study numbers in sealed envelope. These sealed envelopes were opened in the operating room before the skin incision was made. All patients were equally assigned, using a computer program, to receive one type of component in one knee and another type in the contralateral knee. The first TKA was performed with a prosthesis indicated in the

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