

Long-Term Clinical Outcomes and Survivorship of Press-Fit Condylar Sigma Fixed-Bearing and Mobile-Bearing Total Knee Prostheses in the Same Patients

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Background: We are aware of no study that has compared press-fit condylar Sigma fixed-bearing and mobile-bearing total knee prostheses in the same patients after more than ten years of follow-up. The purpose of the current study was to compare these two implants with respect to the functional and radiographic results, prevalence of osteolysis, and overall revision rates at a mean of 12.1 years of follow-up.

Methods: The study consisted of a consecutive series of 444 patients (mean age [and standard deviation], 66.5 ± 7.4 years) who underwent simultaneous bilateral total knee arthroplasty, with one side treated immediately after the other. All of the patients received a press-fit condylar Sigma mobile-bearing prosthesis on one side and a press-fit condylar Sigma fixed-bearing prosthesis on the contralateral side. The minimum duration of follow-up was ten years (mean, 12.1 years; range, ten to thirteen years). At the time of each follow-up visit, the patients were assessed clinically and radiographically.

Results: Postoperative total knee scores (95 and 94 points), Western Ontario and McMaster Universities Osteoarthritis Index (19 and 18 points), University of California, Los Angeles activity score (both prostheses, 5 points), range of motion ($129^\circ \pm 6.3^\circ$ and $127^\circ \pm 6.8^\circ$), and radiographic findings did not differ significantly between the press-fit condylar Sigma mobile and fixed-bearing designs at the final follow-up. The prevalence of aseptic loosening (1.4% and 1.8%) did not differ significantly between the mobile and fixed-bearing implant designs. No knee in either group had osteolysis. The estimated survival rate with revision as the end point was 98.2% (95% confidence interval, 91% to 99%) and 97.5% (95% confidence interval, 91% to 99%) at 12.1 years for the mobile and fixed-bearing implant groups, respectively.

Conclusions: The results of the present long-term clinical study suggest that excellent clinical and radiographic results were achieved with both the press-fit condylar Sigma mobile and fixed-bearing cruciate-retaining total knee designs. We found no significant clinical advantage for a mobile-bearing over a fixed-bearing total knee prosthesis.

Level of Evidence: Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

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Mobile-bearing total knee prostheses were designed to provide dual-surface articulation at both the upper and lower surfaces of the polyethylene insert. These designs offer the advantage of conformal geometry with a re-

duction of contact stresses in the polyethylene, which may reduce wear¹⁻³. It has been postulated that a mobile-bearing prosthesis would minimize bone-prosthesis stress at the fixation surface of the tibial component⁴.

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TABLE I Preoperative and Final Follow-up Data for Patients with Press-Fit Condylar Sigma Mobile and Fixed-Bearing Prostheses*

| Parameter | Mobile-Bearing Group (N = 444) | |
|-------------------------|--------------------------------|-----------------------|
| | Preoperative | Final Follow-up |
| Total knee score† | 25.7 ± 8.6 (5 to 45) | 95 ± 5.1 (85 to 100) |
| Knee function score† | 25.1 ± 2.9 (5 to 41) | 81 ± 6.9 (49 to 100) |
| Pain score† | 0.6 ± 0.3 (0 to 4) | 47 ± 4.0 (40 to 50) |
| Pain (%) | | |
| None | — | 333 (75) |
| Mild | — | 104 (23) |
| Moderate | 36 (8) | 7 (2) |
| Severe | 408 (92) | |
| Range of motion† (deg) | 128 ± 5.9 (65 to 150) | 129 ± 6.3 (80 to 150) |
| WOMAC total score† | 68 ± 12.9 (48 to 96) | 19 ± 14.9 (5 to 49) |
| Pain subscore | 19 ± 2.1 (15 to 20) | 1 ± 0.5 (0 to 2) |
| Stiffness subscore | 7 ± 0.9 (5 to 8) | 4 ± 0.9 (3 to 6) |
| Physical function score | 42 ± 3.9 (35 to 68) | 14 ± 1.8 (2 to 41) |
| UCLA activity score | 2 (1 to 3) | 7 (4 to 9) |

*The final follow-up was at a mean of 12.1 years (range, ten to thirteen years). WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index, and UCLA = University of California, Los Angeles. †The values are given as the mean and standard deviation, with the range in parentheses.

To date, there has been no definitive evidence that we are aware of that these theoretical advantages lead to an improvement in clinical outcomes and survivorship of the prosthesis. Various studies have been published that have compared mobile and fixed-bearing knee replacements⁵⁻⁹. However, in many of the studies different types and designs of prostheses were compared. The studies also differed in methodology, patient demographics, operative technique, and outcome measures.

In recent years, authors of several studies have investigated the functional outcomes of the press-fit condylar Sigma fixed-bearing and press-fit condylar Sigma mobile-bearing total knee replacement systems (PFC Sigma; DePuy, Warsaw, Indiana)¹⁰⁻¹³. However, all of the studies had less than ten years of follow-up and only two were randomized controlled trials^{12,13}. To our knowledge, no prospective randomized study with more than ten years of follow-up comparing these two designs in the same patients has been published.

The purpose of the current prospective randomized study in the same patients was to compare the functional scores, radiographic results, prevalence of osteolysis, and overall revision rates between the mobile and fixed-bearing prostheses at a mean of 12.1 years follow-up.

Materials and Methods

From June 2000 to May 2003, 484 consecutive patients (968 knees) with bilateral knee osteoarthritis (Ahlbäck grade III, IV, or V¹⁴) underwent simultaneous total knee arthroplasties, with one side treated immediately after the other. The study protocol and consent forms were approved by the institutional review board. A detailed informed consent form was signed by each patient, and all information was kept confidential. We retrospectively reviewed

the data for prospectively followed patients. Of the 484 patients, fifteen were lost to follow-up before two years, five died, and twenty declined to participate, leaving 444 patients (888 knees). All patients had osteoarthritis. The minimum duration of follow-up was ten years (mean, 12.1 years; range, ten to thirteen years). One hundred and seventy-four of the 444 patients were reported on previously, at a mean of 5.6 years of follow-up¹². The study group included 414 women and thirty men who had a mean age (and standard deviation) of 66.5 ± 7.4 years (range, twenty-seven to eighty-five years) at the time of surgery. The high prevalence of end-stage knee osteoarthritis in the female patients in this ethnic group (Korean) might be attributed to the inherent varus deformity of the knee and daily activity in the squatting position. The mean height of the patients was 153.6 ± 6.5 cm (range, 138.0 to 176 cm), the mean weight was 68.4 ± 9.1 kg (range, 57.0 to 107.0 kg), and the mean body mass index was 29.6 ± 3.7 kg/m² (range, 20 to 34.5 kg/m²). Seventy-nine knees had a valgus alignment of 7° to 13°, and the remaining 809 knees had a varus alignment of 8° to 24°.

All press-fit condylar Sigma mobile and fixed-bearing components were of a posterior-cruciate-retaining design¹⁵, and all of the components were cemented. The tibial polyethylene inserts were 4150 resin and were sterilized with gamma irradiation in a vacuum in both groups. Randomization to treatment with the press-fit condylar Sigma fixed or mobile-bearing total knee prosthesis was accomplished with the use of a sealed study-number envelope. After the envelope was opened in the operating room and before a skin incision was made, the first knee was assigned the prosthesis indicated in the envelope and the contralateral knee was assigned the other prosthesis. There were no cases in which the second procedure was aborted because of intraoperative complications. All procedures were performed by the senior author (Y.-H.K. [Young-Hoo Kim]). An anterior midline skin incision (10 to 12 cm in length) was made, followed by a medial parapatellar capsular incision. For all knees, femoral preparation was performed first. Ten millimeters of tibial bone was resected, referenced from the less-involved tibial plateau, to achieve a surface perpendicular to the axis of the tibia in the coronal plane. A 3° to 5° posterior slope was prepared in the sagittal plane. An anterior cortical reference was used for the anteroposterior cut of the distal part of the femur. Rotation of the femoral component was determined with use of three reference axes: the

TABLE I (continued)

| Fixed-Bearing Group (N = 444) | | P Value (Paired T Test) | |
|-------------------------------|-----------------------|-------------------------|-----------------|
| Preoperative | Final Follow-up | Preoperative | Final Follow-up |
| 26.5 ± 8.9 (3 to 46) | 94 ± 5.9 (88 to 100) | 0.579 | 0.313 |
| 25.1 ± 2.9 (5 to 42) | 81 ± 6.9 (49 to 100) | 1.000 | 1.000 |
| 1.4 ± 6.0 (2 to 4) | 46 ± 4.0 (39 to 50) | 0.629 | 0.621 |
| — | 345 (78) | | |
| — | 93 (21) | | |
| 41 (9) | 6 (1) | | |
| 403 (91) | | | |
| 129 ± 8.3 (65 to 150) | 127 ± 6.8 (95 to 150) | 0.735 | 0.312 |
| 69 ± 12.9 (49 to 96) | 19 ± 14.9 (4 to 49) | 1.000 | 1.000 |
| 17 ± 1.8 (16 to 20) | 2 ± 0.7 (0 to 4) | 0.721 | 0.975 |
| 6 ± 1.1 (5 to 8) | 4 ± 0.9 (3 to 6) | 0.789 | 1.000 |
| 46 ± 4.0 (38 to 68) | 12 ± 1.7 (1 to 39) | 0.671 | 0.965 |
| 2 (1 to 3) | 7 (4 to 9) | 1.000 | 1.000 |

transepicondylar axis, the midtrochlear (Whiteside) line¹⁶, and 3° of external rotation relative to the posterior aspect of the condyles. All patellae were resurfaced with a polyethylene implant. All implants were fixed with cement after pulsed lavage, drying, and pressurization of the cement.

All of the patients were discharged home ten to fourteen days after surgery, with full weight-bearing with crutches or a walker for six weeks and then with a cane when needed thereafter. None of the patients received further outpatient physical therapy because they all had more than 120° of knee flexion and were walking well with a walker or crutches at the time of discharge from the hospital. The patients and their family members were well instructed on how to perform knee-motion and walking exercises at home.

Two of the authors (Y.-H.K. [Young-Hoo Kim] and J.-W.P.) assessed the patients via both physical examination and knee-scoring preoperatively, at three months, at one year after surgery, and annually thereafter with use of the Knee Society system¹⁷ and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaires¹⁸ at each interval. A separate evaluation was performed for each knee. Patients completed reported outcome measures, including the Knee Society and WOMAC questionnaires as well as the UCLA (University of California, Los Angeles) activity scale¹⁹. It was relatively easy for patients to distinguish the degree of pain in each knee. We inquired regarding the degree of stiffness with the WOMAC instrument separately for each knee. Patients were given special instructions to distinguish the degree of functional impairment of each knee. For example, when they had difficulty ascending or descending stairs, they specified which knee bothered them more. At the time of each follow-up, radiographic data were analyzed and recorded by a different author (J.-S.K., who was not part of the operative team). This assessment was not blinded to allocation of the two implants because the radiographic appearances of the implants differ. To ascertain instability of the knee, we asked patients whether they had any feeling of something coming out from the knee. We also carefully examined the stability of the knee in full extension, midrange (60°) flexion, and full flexion to ascertain any instability of the tibial bearing.

The active arc of motion of each knee with the patient in the supine position was measured two times with use of a standard (60-cm) goniometer preoperatively and at each follow-up by two observers (Y.-H.K. [Young-Hoo Kim] and J.-W.P.), both of whom were blinded to the type of prosthesis. The chance-corrected kappa coefficient^{20,21} for intraobserver agreement ranged from 0.81 to 0.91. The level of activity was assessed with the Knee Society

knee score¹⁷ and the UCLA activity score¹⁹. All clinical data were compiled and collected by a separate research associate (S.S.K.).

Standing anteroposterior hip-to-ankle radiographs, supine anteroposterior and lateral radiographs, and skyline patellar radiographs were made preoperatively and at each follow-up. The radiographs were evaluated by one observer (S.S.K.), who was not a member of the operating team, to determine the anatomic axis of the limb, alignment of the components, posterior tibial slope, posterior femoral condylar offset, level of the joint line, presence and location of radiolucent lines at the bone-cement or cement-implant interface, and patellar tilt or dislocation with use of the Knee Society system¹⁷. All radiographs were made under fluoroscopic guidance to control rotation of the knee.

Statistical Analysis

To minimize the chance of a type-II error and increase the power of our study, we adjusted the power to detect a minimum difference in the Knee Society knee score¹⁷ of 5 points with a power of 0.95, which revealed that a total of 398 knees would be needed in each group. We recruited about 10% more patients to account for possible dropouts. The changes in the Knee Society knee scores were evaluated with use of a paired t test, pain scores were assessed with use of the chi-square test, and knee motion was compared between the groups with use of a paired t test. Complication rates and radiographic data were also compared between the groups with use of a paired t test. The level of significance was set at $p < 0.05$.

Source of Funding

There was no external funding for this study.

Results

The Knee Society knee scores did not differ significantly between the groups preoperatively ($p = 0.579$, paired t test) or at the final follow-up ($p = 0.313$, paired t test). In the mobile-bearing group, the mean postoperative Knee Society knee score was 95 points (range, 85 to 100 points); in the fixed-bearing group, it was 94 points (range, 88 to 100 points). The mean postoperative function score was 81 points (range, 49 to 100 points) in both groups. In the mobile-bearing group, 333 knees

TABLE II Radiographic Results for Patients with Press-Fit Condylar Sigma Mobile and Fixed-Bearing Prostheses

| Parameter | Mobile-Bearing Group (N = 444) | Fixed-Bearing Group (N = 444) | P Value (Paired T Test) |
|---|-----------------------------------|----------------------------------|----------------------------|
| Knee alignment* (deg) | | | |
| Preop. | 10.9 ± 3.6 (8 to 25) varus | 11.6 ± 2.9 (6 to 21) varus | 0.731 |
| Postop. | 5.8 ± 3.5 (3 to 7) valgus | 6.2 ± 3.9 (2 to 8) valgus | 0.918 |
| Femoral angle* (deg) | | | |
| Coronal | 97 ± 4.9 (93 to 104) | 98 ± 5.1 (92 to 103) | 0.931 |
| Sagittal | 0.3 ± 0.2 (-7 to 7) | 0.2 ± 0.2 (-10 to 9) | 0.611 |
| Tibial angle* (deg) | | | |
| Coronal | 89 ± 4.1 (83 to 93) | 88 ± 3.1 (84 to 92) | 0.707 |
| Sagittal | 85 ± 3.5 (76 to 86) | 84 ± 2.9 (81 to 95) | 0.817 |
| Joint line* (mm) | | | |
| Preop. | 17 ± 6.9 (11 to 25) | 16 ± 7.1 (8 to 26) | 0.731 |
| Postop. | 16 ± 6.1 (8 to 26) | 16 ± 6.9 (7 to 26) | 0.513 |
| Posterior condylar offset* (mm) | | | |
| Preop. | 24 ± 7.3 (17 to 29) | 23 ± 6.8 (19 to 34) | 0.823 |
| Postop. | 25 ± 6.8 (19 to 33) | 24 ± 6.7 (14 to 30) | 0.871 |
| Radiolucent line ≤1 mm (%) | | | |
| Femoral side | | | |
| Zone 1 (anterior femoral condyle) ¹⁷ | 11 (2) | 13 (3) | |
| Tibial side | | | |
| Zone 1 (medial tibial plateau) ¹⁷ | 45 (10) | 45 (10) | |
| Radiolucent line >1 mm (%) | | | |
| Femoral side | 0 (0) | 0 (0) | |
| Tibial side | 0 (0) | 0 (0) | |
| Osteolysis (%) | 0 (0) | 0 (0) | |

*The values are given as the mean and standard deviation, with the range in parentheses.

(75%) had no pain, 104 (23%) had mild pain, and seven (2%) had moderate pain at the time of the latest follow-up. In the fixed-bearing group, 345 knees (78%) were pain free, ninety-three (21%) had mild pain, and six (1%) had moderate pain at the time of the latest follow-up. The ability of the patients to negotiate stairs was markedly improved after the operation. The mean postoperative range of motion was 129° (range, 80° to 150°) in the mobile-bearing group and 127° (range, 95° to 150°) in the fixed-bearing group. This difference was not significant ($p = 0.312$, paired t test). Sixty-seven knees (15%) in the mobile-bearing group and seventy-five knees (17%) in the fixed-bearing group had <110° of motion at the latest follow-up. The maximum flexion in both groups was 150°. The mean UCLA activity level score for the patients in both groups was 7 points at the time of the latest follow-up, indicating participation in some farm work or household work. The high mean UCLA activity score in this study is related to its relatively healthy patients with low comorbidity. The mean WOMAC score was 19 points (range, 5 to 49 points) in both groups (Table I). Three hundred and eighty-two patients (86%) had no knee preference, thirty-six (8%) preferred the side with the mobile-bearing total knee

prosthesis, and the remaining twenty-six (6%) preferred the side with the fixed-bearing total knee prosthesis.

There were no significant differences between the groups in alignment of the knee (mean, 5.8° of valgus and 6.2° of valgus), the position of the femoral and tibial components in the coronal and sagittal planes, the posterior slope of the tibia (mean, 5.1° and 4.9°), the mean level of the joint line (both groups, 16 mm), prevalence of radiolucent lines, or the posterior condylar offset (mean, 25 and 24 mm) ($p > 0.05$ for all comparisons; paired t test). The prevalence of an incomplete radiolucent line measuring ≤1 mm in the anterior femoral condyle was 2% (eleven knees) in the mobile-bearing group and 3% (thirteen knees) in the fixed-bearing group. The prevalence of incomplete radiolucent lines measuring ≤1 mm in the medial tibial plateau was 10% (forty-five knees) in both groups (Table II). No knee in the mobile-bearing group had subluxation or dislocation of the tibial bearing. The absence of subluxation or dislocation of the tibial bearing appeared to be related to well-balanced extension and flexion gaps. Twenty-seven knees (6%) in the mobile-bearing group and twenty-two knees (5%) in the fixed-bearing group had a patellar tilt. No



Fig. 1-A



Fig. 1-B

Radiographic evaluation of the knees of a forty-six-year-old woman with osteoarthritis following bilateral total knee arthroplasty. **Fig. 1-A** Anteroposterior radiograph of both knees thirteen years after surgery, demonstrating that the press-fit condylar Sigma mobile-bearing (left knee [right side of the figure]) and fixed-bearing (right knee [left side of the figure]) prostheses are fixed in a satisfactory position. There is no evidence of osteolysis. **Fig. 1-B** Lateral radiograph of both knees thirteen years after surgery, demonstrating that the press-fit condylar Sigma mobile-bearing (left knee [right side of the figure]) and fixed-bearing (right knee [left side of the figure]) prostheses are embedded in a satisfactory position. There is no evidence of osteolysis.

knee in either group had subluxation of the patella. One knee (0.2%) in the fixed-bearing group had recurrent dislocation of the patella, but no knee in the mobile-bearing group did.

The prevalence of osteolysis was 0% in both groups (Figs. 1-A and 1-B). Six knees (1.4%) in the mobile-bearing group and eight knees (1.8%) in the fixed-bearing group were revised for aseptic loosening. Two knees (0.5%) in each group were revised for deep infection. One knee (0.2%) in the fixed-bearing group was revised for recurrent patellar dislocation. In the mobile-bearing group, the estimated survival rate according to Kaplan-Meier survival analysis²² was 98.2% (95% confidence interval, 91% to 99%) at 12.1 years, with an overall revision rate of 1.8% (eight of 444 knees). In the fixed-bearing

group, the estimated survival rate was 97.5% (95% confidence interval, 91% to 99%) at 12.1 years, with an overall revision rate of 2.5% (eleven of 444 knees).

Discussion

In this study, we investigated whether the press-fit condylar Sigma mobile-bearing total knee prosthesis provides greater benefit than the press-fit condylar Sigma fixed-bearing prosthesis does. We found that the long-term clinical outcomes for both the mobile and fixed-bearing prostheses were similar in terms of Knee Society knee score, pain score, function score, WOMAC score, range of motion, knee preference, and radiographic results.

Multiple studies^{10-13,23,24} have shown that the press-fit condylar Sigma mobile-bearing prosthesis achieves essentially equal results to the press-fit condylar Sigma fixed-bearing prosthesis. Ranawat et al.¹⁰ reported short-term (forty-six and sixteen-month) results with the press-fit condylar Sigma fixed and mobile-bearing prostheses in twenty-six patients. They found no significant differences between the groups with regard to knee preference, knee pain, knee motion, overall satisfaction, or Knee Society knee scores. Evans et al.¹¹ compared knee flexion after press-fit condylar Sigma mobile or fixed-bearing total knee replacement involving 213 patients and reported no significant difference in knee flexion between the groups. Kim et al.¹² conducted a randomized prospective study involving 174 patients who had simultaneous bilateral knee replacement. They demonstrated that there were no significant differences in knee score, pain score, function score, and knee motion between the groups. Lädermann et al.¹³ concluded that at the seven-year follow-up the press-fit condylar Sigma mobile-bearing total knee prosthesis was not superior to the fixed-bearing one in terms of clinical and radiographic results. Luring et al.²⁴ reported the results of two-year clinical follow-up of patients with press-fit condylar Sigma mobile and fixed-bearing prostheses. They found significantly better values in the press-fit condylar Sigma mobile-bearing group in terms of mediolateral stability in extension and the peak flexion torque. Higuchi et al.²³ demonstrated that the postoperative knee extension was significantly improved after use of the press-fit condylar Sigma mobile-bearing prosthesis compared with the press-fit condylar Sigma fixed-bearing prosthesis.

Dalury et al.²⁵ reported a survival rate of 99.6% for the press-fit condylar Sigma total knee prosthesis at seven years. Arthur et al.²⁶ reported a survival rate of 95.9% for the press-fit condylar Sigma total knee prosthesis at ten years with an end point of revision for any reason and a survival rate of 98.7% with an end point of revision for aseptic failure. Our implant survivorship data agree with those in other reports on these prosthetic designs²⁵⁻²⁷.

Our study documented successful results for total knee arthroplasties with either a press-fit condylar Sigma mobile or fixed-bearing prosthesis. We focused on good cementing technique with pulsed lavage and cement pressurization, correct flexion and extension gaps, and well-balanced ligaments to achieve a high success rate at 12.1 years.

Long-term studies of mobile and fixed-bearing total knee prostheses have shown no real difference in the rate of wear and osteolysis^{5,28-31}. However, Collier et al.³¹ found that fixed-bearing knee prostheses with a grit-blasted tibial baseplate were associated with 2.6 times more osteolysis than were those with a polished-surface baseplate. Some authors have reported bearing mobility is of greater advantage as constraint of the knee prosthesis increases³²⁻³⁴. In vivo kinematic studies³²⁻³⁴ have shown that in fixed-bearing posterior-substituting total knee designs, eccentric angular loading on the post is common if axial rotation occurs; this can place increased stress at the locking mechanism of modular fixed-bearing designs. This increased stress in turn results in increased backside wear in fixed-bearing designs and an increased risk of osteolysis, especially in patients in whom

matte-finished tibial trays have been implanted. In mobile-bearing designs, the tibial bearing tends to self-center with the intercondylar box, lessening angular and rotational stresses on the tibial bearing. Patients with greater body weight who have a posterior-substituting total knee prosthesis will potentially have a higher prevalence of osteolysis. The absence of osteolysis in both groups in the current study may be related to several factors: a high percentage (93%) of the patients were female and had a relatively low body weight (mean, 68 kg), the polyethylene inserts used were sterilized with gamma irradiation in a vacuum, the inserts had a short shelf-life, follow-up was not sufficiently long to reveal osteolysis, and all of the implants were posterior cruciate-retaining. Although the results of the current study revealed neither grossly detectable wear of the polyethylene bearing nor periprosthetic osteolysis in either group at 12.1 years of follow-up, fixed-bearing total knee replacements with a grit-blasted tibial baseplate will potentially have a higher prevalence of osteolysis in the longer term.

The authors of previous studies have emphasized that an exacting surgical technique, especially the balancing of flexion and extension gaps, is mandatory during a mobile-bearing total knee arthroplasty in order to avoid bearing dislocation or instability of the knee³⁵⁻³⁷. Many surgeons believe that the use of an unconstrained mobile-bearing total knee implant is contraindicated in knees with severe varus and valgus deformity³²⁻³⁴. This idea was challenged by Beverland³⁸, who stated that a mobile-bearing total knee implant could be used for virtually every primary total knee replacement, irrespective of knee deformity. In our series, we were able to use a mobile-bearing total knee implant for every primary total knee arthroplasty selected by the process of randomization, irrespective of the range of knee deformity and with no postoperative instability.

The present study has several strengths. We describe one surgeon's experience with a consecutive group of patients in whom simultaneous bilateral total knee arthroplasty was performed. Confounding factors were minimized. Also, apart from the mobility of the tibial polyethylene insert, the two patterns were of very similar designs. This long-term follow-up, with a mean 12.1 years, is similar to one other comparative study²⁶. To our knowledge, our sample size is larger than previously reported ones^{25,26}. Finally, there was no bias involved in the selection of our patients.

Our study has limitations as well. First, it is difficult for patients who have undergone bilateral total knee arthroplasty to distinguish the independent function of each knee. The components of pain, support, and motion were initially differentiated, but the components of distance walked and stair-climbing ability were more difficult to differentiate. In these domains, if the patients had difficulties they could always identify the knee that limited their activities more. Second, the duration of follow-up was 12.1 years; therefore, longer-term variability in outcome, particularly with regard to the prevalence of osteolysis, cannot be predicted. Third, we performed no interobserver-variability testing for the radiographic measurements. Finally, knee motion was not determined under weight-bearing conditions.

The findings of the present, longer-term clinical study suggest that excellent clinical and radiographic results were

achieved with both press-fit condylar Sigma mobile and fixed-bearing cruciate-retaining total knee designs. However, there was no significant clinical advantage for a mobile-bearing over a fixed-bearing total knee prosthesis. ■

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