



Is High-Flexion Total Knee Arthroplasty a Valid Concept? Bilateral Comparison With Standard Total Knee Arthroplasty



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ABSTRACT

Background: The purpose of this study was to determine whether the high-flexion total knee prosthesis significantly improves knee flexion in vivo.

Methods: Forty-four patients undergoing same-day bilateral total knee arthroplasty for primary osteoarthritis of both knees were randomized to receive a standard posterior-stabilized knee prosthesis (P.F.C. Sigma; DePuy Johnson & Johnson, Warsaw, IN) in one knee and a high-flexion concept posterior-stabilized knee prosthesis (LOSPA; Corentec, Inc, Seoul, Korea) in the other knee and were followed up for 2 years postoperatively.

Results: The mean postoperative range of motion was 128.8° (range, 100°–144°) in the LOSPA group and 128.5° (range, 100°–142°) in the P.F.C. Sigma group ($P = .744$). There were no significant differences in the postoperative mean Knee Society score and Western Ontario and McMaster Universities Osteoarthritis Index score between the LOSPA and P.F.C. Sigma groups ($P = .839$ and $P = .972$, respectively).

Conclusion: Despite theoretical range of motion advantages of high-flexion prosthesis, there were no group differences with regard to range of motion, clinical outcomes, and the incidence of radiolucent lines at final follow-up assessment.

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Over the last decade, there have been multiple innovations in total knee arthroplasty (TKA) implant design aimed at improving knee flexion [1–7]. The design modifications have focused on increasing the contact area between the femoral component and the polyethylene insert. The so-called high-flexion femoral component has an extended sagittal curve and a thicker posterior condyle by 2 to 4 mm replacing the additional bone cut to maintain contact area at deep knee flexion. Theoretically, the contact area increment supports the posterior femoral translation and thereby increases range of motion [1–7]. The femoral cam and tibial post designs are also modified to increase the contact surface area and stability at deep knee flexion angles [1,2,4]. In addition, there is an anterior cut out of the polyethylene insert to decrease the potential for impingement of the extensor mechanism [8].

Although published studies comparing the knee range of motion between the standard and high-flexion prostheses have been mixed [6,9–11], recent meta-analyses on this subject do not support the proposition that high-flexion prostheses provide functional advantages over standard prostheses [12–14]. As in various controlled trials, the number of

implants has been limited to certain knee systems that have both high-flexion and standard knee designs, analysis of pure designs may be required.

The LOSPA total knee system (Corentec, Inc, Seoul, Korea) was introduced to enhance deep knee flexion after surgery (approved by the Food and Drug Administration under 510(k)). This system requires removal of additional bone from the posterior femoral condyle to add 10-mm posterior condyle at a large posterior radius of the femoral component. The extension of the posterior condyle increases contact area at deep knee flexion angles, thereby accommodating femoral rollback and increasing range of flexion. In addition, the femoral component has a more rounded contour and a deepened patellar groove to help deep flexion through reducing joint capsule overstuffing. The tibial insert also has a deep flexion favoring design. The posterior surface of the insert is released, and the posterior edge is chamfered to avoid early bone implant impingement (Fig. 1).

In this study, we performed a prospective, randomized study to compare the ranges of motion of the LOSPA posterior-stabilized (PS) total knee system and standard P.F.C. Sigma PS total knee system (DePuy Johnson & Johnson, Warsaw, IN) in patients undergoing same-day bilateral TKAs. P.F.C. Sigma knee, which was introduced in 1984, has had excellent long-term survivorship of 11 to 17 years [15–18]. The posterior condylar thickness of the P.F.C. femoral component is only 8 mm with a short radius. The polyethylene insert does not have the so-called “high-flexion” design (Fig. 1). We examined 3 hypotheses:

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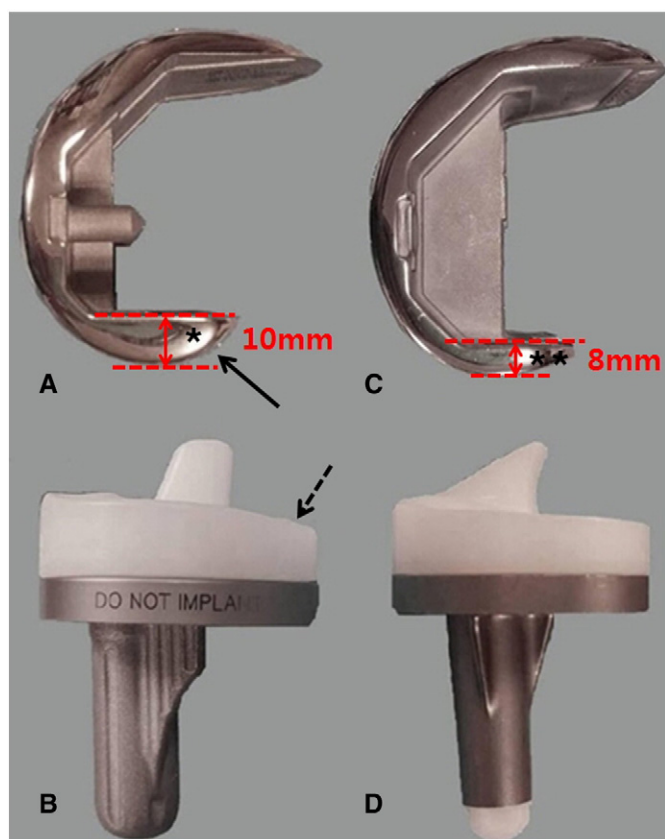


Fig. 1. Comparison of LOSPA PS total knee system (A and B) and P.F.C. Sigma PS total knee system (C and D). The femoral component of LOSPA system has a thicker and elongated posterior condyle (asterisk and arrow) than that of P.F.C. Sigma system (double asterisk). The posterior edge of the tibial insert of the LOSPA system is beveled for high flexion (dotted arrow).

(1) the range of motion of the knee with a LOSPA prosthesis would be better than those with a P.F.C. Sigma prosthesis; (2) clinical outcomes and patient satisfaction would be better in patients having a LOSPA prosthesis than those with a P.F.C. Sigma prosthesis; and (3) radiographic results would be the same in patients having a LOSPA prosthesis as those of patients having a P.F.C. Sigma prosthesis.

Materials and Methods

From February to September 2012, 50 patients (100 knees) were enrolled into a prospective, randomized clinical trial. The study was approved by the Institutional review board of our hospital, and all patients provided informed consent. All the patients underwent same-day bilateral TKAs with a different implant for each knee. Randomization to receive the P.F.C. Sigma prosthesis or the LOSPA prosthesis was accomplished with the use of sealed envelopes that contained the names of 2 prostheses, and these were opened in the operating room before the skin incision for the first of the 2 sequential TKAs. After opening of the randomization envelope, the first knee received the prosthesis indicated by the envelope, and the other knee received the other prosthesis. Each of the 50 patients received P.F.C. Sigma prosthesis on one side and LOSPA prosthesis on the contralateral side.

Inclusion criteria were for patients who agreed to the study with the enrollees having bilateral degenerative osteoarthritis on both knees and requiring TKA. Patients were excluded if they had a diagnosis of inflammatory arthritis, a flexion contracture of greater than 20°, a history of knee surgery on either knee, or those who refused to participate in the study. Six of these 50 patients did not complete the primary end point, at 2 years postoperatively. Five patients were lost to follow-up, and 1 patient had an open reduction and internal fixation due to patellar

fracture, leaving 44 patients (88 knees) who completed a minimum of 2-year follow-up (Fig. 2).

There were 42 women and 2 men with a mean age of 70.7 ± 6.6 years (range, 57–87 years). The mean body mass index was 26.5 ± 3.2 kg/m² (range, 21.2–35.2 kg/m²). All surgeries were performed by the senior author. The operation procedure was identical in LOSPA and P.F.C. Sigma groups. All procedures were performed through a subvastus approach under general anesthesia with tourniquet inflation to 300 mm Hg. Bone cuts were performed using the company's own cutting blocks according to the prosthesis by approximating proper implant size and gap balance. The amount of bone removed from the posterior femoral condyle was 10 mm in the LOSPA prosthesis and 8 mm in the P.F.C. Sigma prosthesis to be replaced by the femoral component. All patellae were resurfaced, and all components were cemented with Refobacin bone cement (Bioment, Warsaw, IN). All patients received the same rehabilitation programs. On the first postoperative day, all patients began full weight-bearing walking with the use of a walker. They started active range motion exercises. The closed suction drain was removed 48 hours after operation. We did not use a continuous passive motion machine, but we encouraged patients to perform active range of motion exercise under our supervision. We used the oral medication, celecoxib 200 mg q day, for all patients for pain control for a period of 6 weeks.

Clinical and radiographic evaluation was done at postoperative 6 weeks, 3 months, 6 months, 1 year, and then yearly thereafter. Each knee was evaluated according to Knee Society score [19] and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score [20] by an independent investigator. At the time of each follow-up, active range of motion of the knee was measured using a standard 60-cm goniometer in supine position by one of the authors who were blinded to the inserted implant. All the complications were recorded. At each follow-up visit, weight-bearing knee anteroposterior, lateral, and skyline radiographs were taken. Each radiograph was assessed for the presence or absence of radiolucent lines. Implant position was radiographically evaluated by anatomical axis of the limb, the alignment of the components, posterior femoral condylar offset, and the presence and location of radiolucent lines by Knee Society TKA roentgenographic evaluation and scoring system [21].

Statistical Analysis

Our primary outcome measurement was maximum flexion at 2 years postoperatively. An a priori sample size analysis was performed based on an overall α of .05 and statistical power of 0.8. We designed the study to detect a difference of 5° of flexion with an SD of 9° [3]. The power analysis estimated that 40 patients needed to be enrolled in both groups. Clinical outcomes (recorded by a Knee Society score and a WOMAC score) and radiologic alignment of LOSPA and PFC prostheses were compared with the independent *t* test. Preoperative and postoperative results were compared with a paired *t* test. The statistical analysis was performed using a statistical software package (SPSS 21; SPSS, Inc, Chicago, IL), and the level of significance for all tests was set at 0.05.

Theory/Calculation

Before the clinical trial, we compared the femoral rollback of P.F.C. Sigma PS prosthesis and LOSPA PS prosthesis with use of 3-dimensional (3D) models to prove the theoretical range of motion advantage of the high-flexion concept prosthesis over the standard prosthesis. A 3D scanner (Surveyor DS-2030; Laser Design, Inc, Minneapolis, MN) collected 3D images of the 2 prostheses. *Femoral rollback* was defined as the distance between the sulcus point which is the deepest point of the polyethylene insert and the contact point between the femoral component and the polyethylene insert at a certain flexion angle of the knee [22]. The measurements were performed at various angles of knee flexion (0°, 45°, 90°, and 135°) using the SolidWorks 3D modeling program (SolidWorks

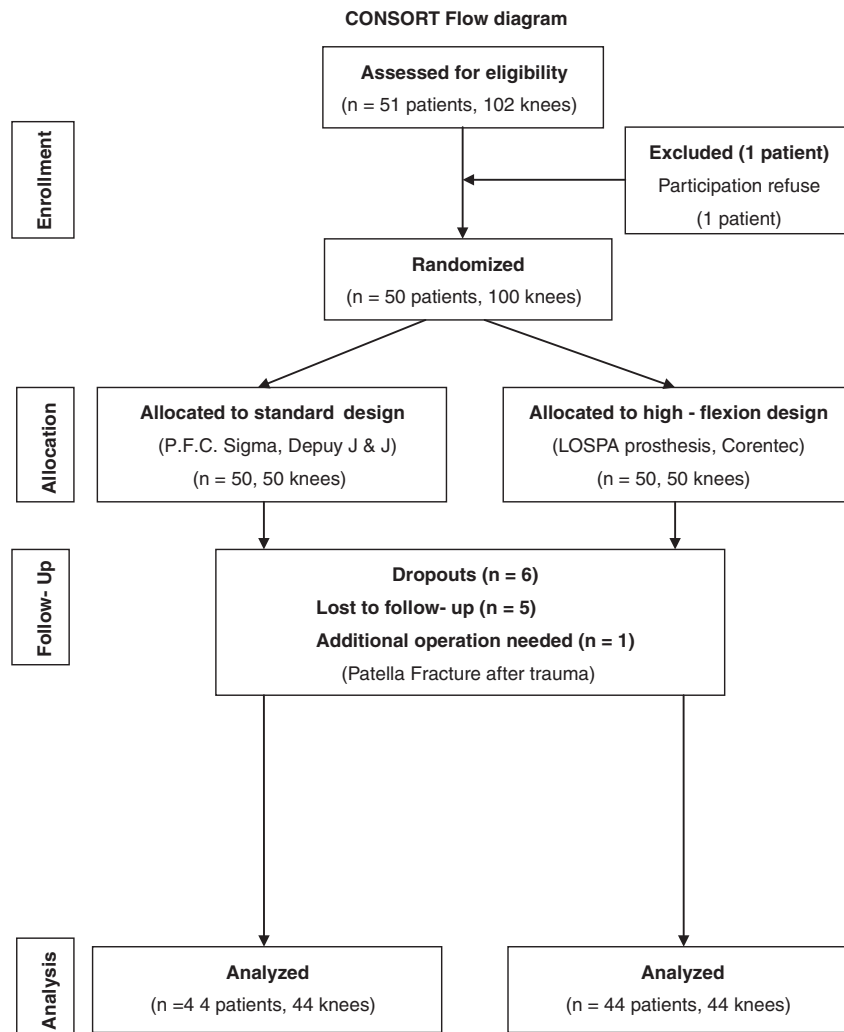


Fig. 2. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

Co, Waltham, MA). At 135° knee flexion position, under the cam post contact condition, the femoral rollback of the LOSPA prosthesis was 11.57 mm and that of P.F.C. Sigma prosthesis was 8.62 mm (Fig. 3). The LOSPA prosthesis had increased contact area between the femoral component and the polyethylene insert. Theoretically, this increment could support the posterior femoral translation and thereby increase range of motion.

Results

The preoperative and postoperative ranges of motion measures for the knee are summarized in Table 1. There were no significant differences in the postoperative mean flexion contracture ($P = .562$), active maximal flexion angle ($P = .745$), and range of motion ($P = .744$) between the LOSPA and P.F.C. Sigma groups.

The preoperative and postoperative clinical scores are summarized in Table 2. The mean postoperative Knee Society score was 158.4 in the LOSPA group and 157.6 in the P.F.C. Sigma group ($P = .839$). The mean postoperative total WOMAC score was 27.6 in the LOSPA group and 27.8 in the P.F.C. Sigma group ($P = .972$).

There were also no significant differences between the LOSPA and P.F.C. Sigma groups with regard to preoperative and postoperative knee alignments using the femorotibial angle ($P = .603$ and $P = .057$, respectively) (Table 3). Furthermore, there were no differences in implant positioning parameters between the 2 groups (Table 3), and there was no significant difference in the postoperative posterior

condylar offset between the groups ($P = .601$). Four knees in each group had a radiolucent line on postoperative radiographs (2 in the zone 1 of the medial tibia and 2 in the zone 4 of the femoral condyle in each group). However, there were no knees showing any sign of osteolysis at the 2-year follow-up. None of the knees had aseptic loosening of the femoral, tibial, or patellar component. No knee had subluxation or dislocation of the tibiofemoral or the patellofemoral joint. In addition, none of the patients required a manipulation after their operation, and there were no major complications needing revision for any reason at this short-term follow-up period.

Discussion

Several updated meta-analyses on the comparison between high-flexion and standard TKA designs have been published recently [12–14]. Among them, Li et al [14] included the largest of the 18 randomized controlled trials on the subject. Although they found no significant differences between high-flexion and standard TKA designs in terms of range of motion, knee scores, patient's satisfaction, and complications, the types of high-flexion and standard implants used in the randomized controlled trial were limited to NexGen knee system (Zimmer, Warsaw, IN) (LPS-flex [4,6,11,23–30] or CR-flex [3,7]) or P.F.C. Sigma knee system (RP-F [1,2,31,32] or CR 150 [33]). Because both NexGen and P.F.C. Sigma high-flexion knee systems were designed from the same original standard version, designs from the same knee family might eliminate the implant difference variable in the randomized

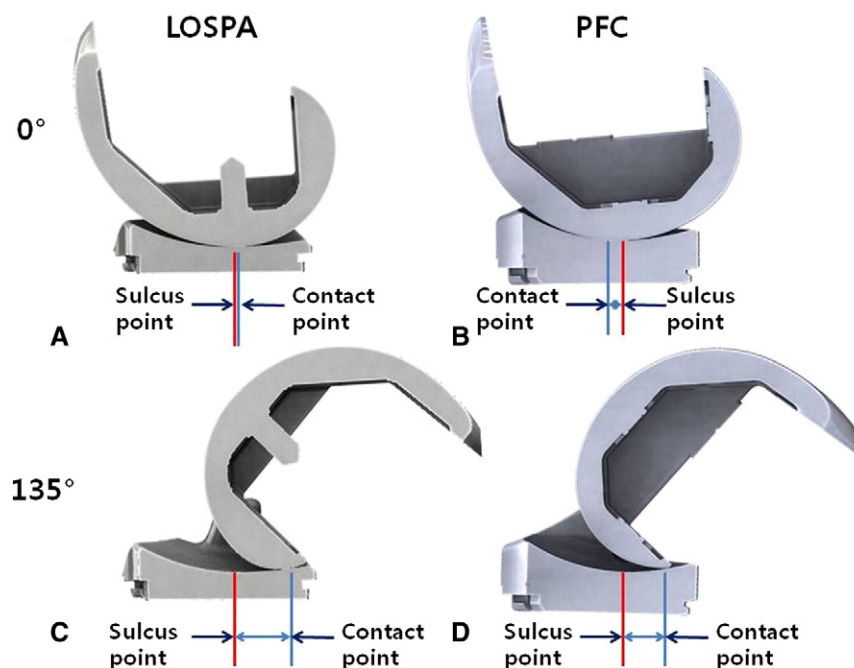


Fig. 3. Three-dimensional images showing contact points of LOSPA and P.F.C. Sigma systems in full extension (A and B) and in 135° flexion position (C and D). The distance from contact point to sulcus point was 0.08 mm in LOSPA prosthesis and -2.52 mm in P.F.C. Sigma prosthesis in full extension and 11.57 mm in LOSPA prosthesis and 8.62 mm in P.F.C. Sigma prosthesis in 135° flexion position.

controlled trials. As most newly introduced knee implants include the high-flexion concept in their femoral component or polyethylene design, the LOSPA knee system is one of the high-flexion concept total knee prostheses specifically developed to enhance knee flexion.

The primary objective of this randomized controlled trial was to determine whether the high-flexion concept knee implant, LOSPA knee system, provided superior knee range of motion compared to a standard knee design which has been used in previous high-flexion comparison studies. Our study revealed no significant differences in the range of motion parameters for the knees receiving either the high-flexion or standard PS total knee prosthesis at 2 years postoperatively.

The strength of this study was the participation of patients undergoing bilateral TKAs, thus minimizing possible confounding variables. However, our study had some limitations. First, we compared 2 total knee prosthesis designs that are not in the same knee system family. Although the LOSPA knee system has elongated femur and an upgraded polyethylene design in accordance with the high-flexion concept, our study could not eliminate the “difference-in-design families” variable between the 2 prostheses. The LOSPA knee system did not have a standard version with thinner posterior femoral condyle. Accordingly, we executed a feasibility testing using 3D models for this study, as there was a significant difference in femoral rollback between the 2 prostheses. Recently, other manufacturers have introduced new total knee implants with a femoral component having 10-mm posterior condyle to enhance knee flexion. We believe that the benefit and safety of thicker

posterior condyle of a femoral component should be verified clinically and not just by theoretical modeling. The second limitation was the relatively short follow-up period of 2 years where we cannot be certain of long-term radiographic results or clinical outcomes. Finally, most of our enrollees were female (95.4%). This may have been hard to control due to prevalence, incidence, and severity of osteoarthritis being higher in women than men [34] including high sex differentials among Asians [35].

Femoral rollback is an important factor to achieve deep flexion of a normal knee [22]. Femoral rollback leads to an increase in the lever arm of the quadriceps muscle, thus reducing the load on patellofemoral joint and increasing the ability to extend the knee without excessive force from the quadriceps muscle [36]. Banks et al [37] analyzed 16 different TKA prostheses which included PS, cruciate-retaining, mobile-bearing implants and reported that 1.4° of knee flexion was gained per 1-mm increment of posterior femoral translation. Internal rotation of tibia is also essential in deep knee flexion, and it is observed during deep flexion in normal knee opposite to “screw-home” movement of full extension [22]. Shi et al [38] evaluated femoral rollback and tibial internal rotation in different bearings of high-flexion PS design knees. They found that femoral rollback and tibial internal rotation correlated with maximum flexion angle. The high-flexion knee prostheses were designed to enhance knee flexion by providing extended femoral condyles which allow posterior femoral rollback with increasing knee flexion [1,3,4].

Table 1
Preoperative and Postoperative Ranges of Motion of the Knees Between Groups.

	Preoperative			Postoperative 2 Years		
	LOSPA (n = 44)	P.F.C. Sigma (n = 44)	P	LOSPA (n = 44)	P.F.C. Sigma (n = 44)	P
ROM (°) ^a	113.0 ± 14.8 (80-137) [108.8-117.4]	111.5 ± 17.5 (70-135) [105.9-116.5]	.651	128.8 ± 7.3 (100-144) [126.9-131.4]	128.4 ± 7.0 (100-142) [126.0-130.5]	.744
Flexion contracture (°)	7.6 ± 7.3 (0-30) [5.6-9.7]	7.0 ± 7.3 (0-25) [5.0-9.4]	.716	0.1 ± 0.7 (0-5) [0.0-0.4]	0.2 ± 1.0 (0-5) [0.0-0.6]	.562
Maximum flexion (°)	120.7 ± 11.9 (100-137) [117.0-124.2]	118.3 ± 14.3 (80-135) [113.9-122.2]	.403	129.0 ± 7.3 (100-144) [126.9-131.4]	128.5 ± 7.1 (100-142) [126.1-130.6]	.745

Abbreviation: ROM, range of motion.

^a The values are presented as mean and SD with the range in parentheses and the 95% confidence interval in brackets.

Table 2
Preoperative and Postoperative Clinical Scores.

	Preoperative			Postoperative (2 Years)		
	LOSPA (n = 44)	P.F.C. Sigma (n = 44)	P	LOSPA (n = 44)	P.F.C. Sigma (n = 44)	P
KSS ^a	102.3 ± 21.2 (42-143) [95.4-108.4]	104.7 ± 23.9 (17-145) [96.6-111.2]	.617	158.4 ± 19.2 (95-192) [152.2-163.9]	157.6 ± 19.6 (9-192) [151.8-163.0]	.839
Pain	24.0 ± 8.5 (0-40) [21.3-26.3]	24.6 ± 8.8 (0-40) [21.8-27.0]	.759	46.1 ± 6.2 (20-50) [44.2-47.8]	45.3 ± 6.2 (20-50) [43.4-47.0]	.549
Function	78.3 ± 18.3 (32-113) [72.3-83.4]	80.1 ± 19.6 (7-125) [73.5-85.9]	.649	112.3 ± 17.4 (50-142) [107.1-117.0]	112.3 ± 17.7 (50-142) [107.0-117.1]	.990
WOMAC ^b	132.7 ± 43.0 (56-217) [120.8-144.7]	126.0 ± 44.9 (20-216) [113.0-139.1]	.473	27.6 ± 19.7 (0-78) [21.7-33.9]	27.8 ± 23.0 (0-112) [21.4-34.6]	.972
Pain	26.3 ± 10.2 (8-50) [23.5-29.3]	24.6 ± 9.8 (5-45) [20.4-27.7]	.407	2.5 ± 3.8 (0-15) [1.3-3.6]	3.0 ± 5.4 (0-23) [1.6-4.6]	.599
Stiffness	9.0 ± 4.8 (0-18) [7.6-10.3]	8.5 ± 4.7 (0-16) [7.2-9.8]	.636	2.4 ± 2.7 (0-8) [1.6-3.2]	2.6 ± 3.2 (0-11) [1.7-3.5]	.771
Function	97.4 ± 31.3 (28-161) [88.3-106.1]	90.6 ± 34.6 (10-161) [80.4-101.0]	.339	22.8 ± 16.6 (0-57) [17.9-28.1]	22.2 ± 17.7 (0-78) [17.3-27.4]	.882

Abbreviation: KSS, Knee Society score.

^a The values are presented as mean and SD with the range in parentheses and the 95% confidence interval in brackets.

^b Modified version of the WOMAC score.

This questionnaire includes 24 questions. The range of score is 0 to 240 points.

We compared the femoral rollback of the LOSPA and P.F.C. Sigma knee systems using 3D models to test the feasibility of the high-flexion concept. By extending the posterior femoral condyle as a result of 2-mm increase in the thickness of the posterior condyle, the LOSPA PS knee system theoretically showed better femoral rollback than the P.F.C. Sigma PS knee system. However, contrary to expectations, this theoretical benefit of LOSPA knee system was not reflected in the clinical outcomes. There were no statistical differences between the 2 implants in terms of knee range of motion, clinical scores, and radiographic results.

Changes in posterior femoral condylar offset can have an influence on knee range of motion after TKA [39,40]. Massin and Gournay [40] reported that a 3-mm decrease of posterior condylar offset could reduce knee flexion by 10° before the occurrence of tibiofemoral impingement. Bellemans et al [39] found that, in 72% of knees, direct impingement of tibial insert posteriorly against the posterior femur was the factor responsible for blocking further flexion. In the present study, the changes in posterior condylar offset did not significantly differ between LOSPA and P.F.C. Sigma knees. The reason may be because the additional 2-mm bone resection was replaced by the 2-mm thicker posterior condyle of the femoral component in the LOSPA knee system. However, the

contact feature at maximum knee flexion was different between the 2 groups. In the LOSPA knee group, the tibial insert contacted to posterior femoral condyle until maximum knee flexion while the tibial insert touches the back of the femur at maximum knee flexion in the P.F.C. Sigma group (Fig. 4). The high-flexion prosthesis provided an increased contact area between femoral and tibial components more than the standard prosthesis. However, there was no difference in range of motion between groups as long as the posterior condylar offset was maintained between groups. The potential clinical implication of an improved contact area in the high-flexion knees may require a longer postsurgery follow-up.

There is concern that high-flexion designs accelerate early aseptic loosening more than a conventional TKA implant [41-43]. In our study, nonsignificant linear radiolucent lines were observed at zone 4 of the femoral component in 2 cases in each group at the minimum 2 years follow-up. For a secure fixation, we applied the bone cement on both implant and bone surfaces including posterior femoral condyles. It was believed that use of a femoral component with 10-mm posterior condyle replacing the same thickness condylar cutting might dispel worries about early loosening. In spite of the relatively short follow-

Table 3
Radiographic Knee Alignment, Implant Positioning, and Prevalence of Radiolucent Lines.

	LOSPA (n = 44)	P.F.C. Sigma (n = 44)	P
Knee alignment			
Preoperative FTA ^a (°)	Varus 3.1 ± 4.8 (varus 12.9 to valgus 10.8) [varus 4.3 to varus 1.8]	Varus 2.5 ± 5.2 (varus 13.7 to valgus 9) [varus 4.1 to varus 0.7]	.603
Postoperative FTA (°)	Valgus 6.1 ± 2.3 (valgus 0.8-11.3) [valgus 5.2-6.8]	Valgus 5.0 ± 2.2 (valgus 1.2-11.6) [valgus 4.4-5.7]	.057
Femoral component position			
Coronal (°)	96.4 ± 1.6 (92.5-98.9) [95.9-96.8]	95.9 ± 1.7 (92.3-100.2) [95.5-96.4]	.157
Sagittal (°)	1.7 ± 1.0 (0-4.2) [1.4-2.0]	1.7 ± 1.3 (0.1-5.9) [1.3-2.2]	.957
Tibial component position			
Coronal (°)	89.2 ± 1.8 (81.3-92.9) [88.7-89.8]	88.8 ± 1.3 (85.2-91.9) [88.4-89.2]	.246
Sagittal (°)	85.3 ± 1.8 (81.8-91.2) [84.8-86.0]	85.6 ± 1.3 (83.3-90.5) [85.2-86.1]	.487
Posterior condylar offset (mm)	29.1 ± 2.8 (22.8-36.7) [28.3-30.0]	29.4 ± 2.8 (24.4-35.5) [28.7-30.2]	.601
Radiolucent lines (n)	4	4	1.0

Abbreviation: FTA, femorotibial angle.

^a The values are presented as mean and SD with the range in parentheses and the 95% confidence interval in brackets.

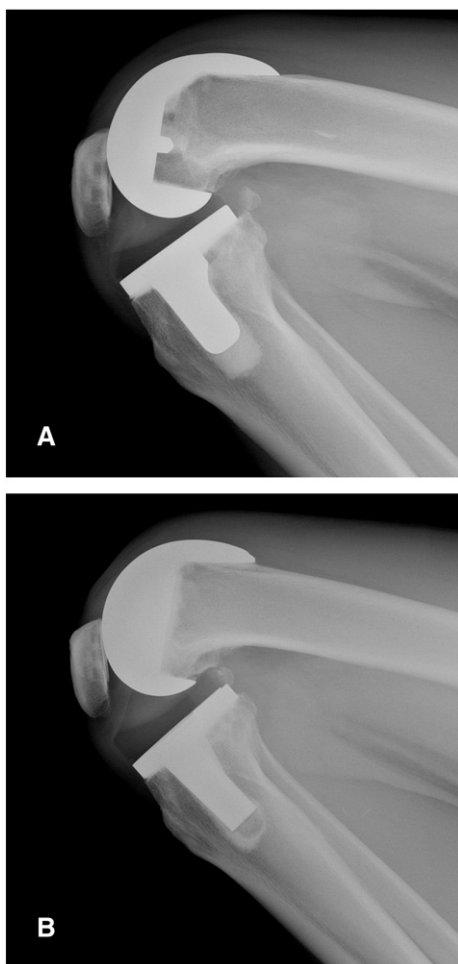


Fig. 4. (A) The femoral component of the LOSPA prosthesis allowed increased contact area with tibial insert in deep knee flexion. (B) The tibial insert of the P.F.C. Sigma prosthesis contacted posterior femoral condylar bone at deep knee flexion angle.

up, no cases of osteolysis were found in either group. This radiographic finding needs further follow-up to confirm its clinical course.

In conclusion, despite theoretical advantages in femoral rollback and improved range of motion in high-flexion design total knee prosthesis, there were no significant differences with regard to range of motion, clinical outcomes, and the incidence of radiolucent lines between high-flexion and standard prostheses.

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