No Better Flexion or Function of High-flexion Designs in Asian Patients With TKA

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Abstract

Background Recently, high-flexion PCL-retaining (CR) and -substituting (PS) knee prostheses were designed to allow greater and safer flexion after TKA. However, the advantages of high-flexion TKA over standard design have been debated in terms of early maximal flexion. A recent study reported a high incidence of early loosening of the femoral component related to the deep flexion provided by high-flexion PS TKA.

Questions/Purposes We determined whether high-flexion fixed bearing CR and PS prostheses would provide (1) a better flexion, (2) a better function, and (3) a higher incidence of radiographic loosening than TKA performed using standard fixed bearing CR prostheses in Asian patients.

Methods From a total of 182 patients with primary unilateral TKA, we retrospectively reviewed 137 TKAs: 47 with high-flexion CR, 42 with high-flexion PS, and 48 with standard CR designs. ROM, Knee Society scores, and WOMAC scores were evaluated and compared among the three groups. Radiographically, we assessed radiolucent zones and component loosening. Minimum followup was 5 years (mean, 6.2 years; range, 5–8 years).

Results We found no differences among the three groups in mean maximal flexion (high-flexion CR: 135°; high-flexion PS: 134°; standard CR: 136°), Knee Society scores, and WOMAC scores at last followup. Also, there were no differences among the three groups in terms of radiolucent lines around the prosthesis. No patient in any group had loosening of the femoral component.

Conclusions The high-flexion CR or PS design had no advantages over the standard CR design with respect to ROM, clinical scores, and radiolucent lines around the femoral or tibial component after 5 years' followup.

Level of Evidence Level III, therapeutic study. See Instructions for Authors for a complete description of levels of evidence.

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All authors certify that their institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Introduction

One of the most important measures of success for a TKA is high ROM after surgery. This is especially true for patients in Asia because high ROM is required for social and religious activities, as well as work [11, 18]. While the majority of modern TKA designs provide pain relief and improved walking ability, patients often do not achieve satisfactory flexion, especially in Asian countries. Even patients who had good preoperative ROM often lose deep flexion (defined as flexion < 120°) after TKA [1–3, 7, 15, 24, 25].

Recently several companies have introduced high-flexion designs for PCL-retaining (CR) and -substituting (PS) TKA to promote greater and safer flexion without increasing the risk of failure compared with standard designs. Although high-flexion designs showed better ROM and larger contact area in in vitro biomechanical studies [10, 26], early clinical studies have shown no advantages of high-flexion TKA over standard designs [5, 17, 19, 20, 28, 30]. Moreover, recent studies found a high incidence of early loosening of the femoral component related to the deep flexion provided by high-flexion PS TKA [8, 16]. These studies raise a question as to whether the theoretical advantages of high-flexion design in terms of safer deep flexion in the laboratory extend to patients.

We therefore asked whether high-flexion fixed bearing CR and PS prostheses would provide (1) a better flexion, (2) a better function, and (3) a higher incidence of radiographic loosening than TKA performed using standard fixed bearing CR prostheses.

Patients and Methods

We followed 182 patients with degenerative arthritis who had 182 primary unilateral TKAs using high-flexion CR (NexGen[®] CR-Flex; Zimmer, Inc, Warsaw, IN, USA), high-flexion PS (NexGen[®] Legacy[®] LPS-Flex; Zimmer), or standard CR (NexGen[®] CR; Zimmer) prostheses between 2004 and 2006. All prostheses were approved by the FDA. During the study period, we operated on a total of 334 patients. For this prospective study, we included patients who had (1) osteoarthritis with varus deformity of 20° or less or valgus deformity of 10° or less and (2) a preoperative ROM of 90° or more. We excluded 152 patients with (1) a history of open knee surgery, (2) a severe deformity (> 20° varus, > 30° flexion contracture, or > 10° valgus), (3) a diagnosis other than primary osteoarthritis, (4) bilateral TKA, and (5) revision TKA. The 182 patients meeting the

criteria were allocated to high-flexion CR or PS or standard CR groups based on the sequential order of surgery. Forty-five of the 182 patients were excluded due to death (10 patients) or loss to followup (35 patients), which left 47 patients with high-flexion CR, 42 patients with high-flexion PS, and 48 patients with standard CR designs. The sex ratio, age at surgery, and followup duration, as well as preoperative nonweightbearing ROM, Knee Society scores [14], and WOMAC scores [4], were similar among the three groups (Table 1). Minimum followup was 5 years (mean, 6.2 years; range, 5–8 years). This study was approved by the institutional review board of our institute and we obtained written informed consent for participation in the study from all patients. This study was conducted according to the recommendations and guidelines of the STROBE initiative [29].

In all three groups, TKAs were performed using the same technique except for the type of implant used. All TKAs were performed by the same surgeon (EKS) under epidural or general anesthesia. We used a standard medial parapatellar arthrotomy with patellar eversion in all patients. Intramedullary instrumentation was used for femoral alignment, and a 4° to 6° valgus cut was selected for all knees. The tibial cut was performed using extramedullary instrumentation with 7° of posterior slope. In the three groups, the patella was not resurfaced and all prostheses were fixed with cement.

Intraoperative and postoperative pain and rehabilitation protocols were identical. We did not use any peri- or intra-articular infiltration of analgesics or nerve block during or after surgery. All patients were provided with an epidural or intravenous patient-controlled anesthesia pump for 2 days after surgery. Then oral cyclooxygenase-2 inhibitor medication was initiated on postoperative day 3 for 2 weeks in all patients. Postoperatively, all patients were encouraged to start active and passive knee motion on the first day after surgery. No special physical therapy except for ice massage was provided. The patients began to walk with partial weightbearing using a walker when tolerated.

Table 1. Comparison of demographics and preoperative knee function among the three groups

Variable	High-flexion CR	High-flexion PS	Standard CR	p value
Number of patients	47	42	48	
Male/female (number of patients)	3/44	1/41	1/47	0.47
Age at surgery (years)	67.6 (65.8–69.7)	66.6 (64.8–68.4)	67.0 (65.0–68.9)	0.76
Followup (months)	74.8 (71.1–78.4)	71.8 (68.1–75.4)	74.6 (71.1–78.4)	0.41
Maximal flexion (°)	132.8 (130.9–134.7)	132.2 (129.2–135.1)	132.1 (129.6–134.5)	0.89
Knee Society score (points)				
Pain	3.6 (1.7–5.5)	4.0 (2.2–5.9)	3.9 (2.1–5.8)	0.94
Function	20.5 (17.7–23.4)	22.1 (18.5–25.8)	20.1 (16.6–23.6)	0.67
WOMAC score (points)	71.6 (67.9–75.3)	73.6 (70.6–78.4)	70.9 (67.8–74.0)	0.32
Femorotibial angle (°, varus)	4.8 (3.2–6.3)	5.6 (3.9–7.2)	5.1 (4.2–7.0)	0.79

Values are expressed as mean, with 95% CI in parentheses; CR = PCL retaining; PS = PCL substituting.

Routine followup evaluation was scheduled at postoperative intervals of 6 months, 1 year, and annually thereafter. At each followup visit, the ROM, Knee Society score, and WOMAC score were obtained and radiographs, including standing knee AP, lateral, and skyline views, were taken. For clinical and radiographic outcomes, we performed statistical analyses to compare differences between preoperative and last followup data.

We evaluated maximal nonweightbearing ROM using a two-arm goniometer with 1° markings in the supine position and the numbers of knees that allowed comfortable kneeling and crosslegged sitting at last followup. One arm of the goniometer was placed parallel to the shaft of the femur (which was estimated from the location of the greater trochanter and the lateral femoral condyle), and the other arm was placed parallel to the shaft of the tibia (which was estimated from the fibular head and the lateral malleolus) [27].

We also evaluated functional outcomes, based on Knee Society and WOMAC scores, in the three groups. All evaluations were made by one of two physical therapists (BSK, IHS) unaware of patient group designations. We also compared the perioperative complications and distinguished them as Grade I, II, III, IV, or V using the classification described in Dindo et al. [12].

Two of us (JHY, HYS) measured the femorotibial angles on standing AP radiographs of the knee taken at last followup. The interobserver reliability for the measurement of femorotibial angle was 0.771. Radiolucencies around femoral and tibial components were examined according to the zones of The Knee Society Roentgenographic

Evaluation System [14] on the last supine AP and lateral radiographs of the knee. Using this system, lucencies are identified in seven zones on the AP view of the tibia, three on the lateral view of the tibia, and seven on the lateral view of the femur. To obtain accurate knee radiographs, the x-ray beam was adjusted under fluoroscopic control.

In a power analysis, we found 40 patients in each group were required to detect an improvement of 7° in ROM among groups (power = 0.8; $p < 0.05$). In a previous study [28], we found the intra- or interobserver errors were less than 6° when using a goniometer to measure motion. We determined the differences among groups in maximal flexion using the ANOVA test and in the numbers of knees that allowed comfortable kneeling and crosslegged sitting using the chi-square test. To compare the functional outcomes regarding Knee Society and WOMAC scores and postoperative femorotibial angle, we used the ANOVA test. We used the chi-square test to determine the differences in perioperative complications and radiolucency of the femoral and tibial component among the three groups. We performed all statistical analyses using SPSS® for Windows® Release 16.0 (SPSS Inc, Chicago, IL, USA).

Results

At last followup, mean maximal nonweightbearing flexion values were similar ($p = 0.41$) among the three groups: high-flexion CR, 135°; high-flexion PS, 134°; and standard CR, 136° (Table 2). Moreover, there were no differences ($p = 0.30$) in the change of maximal flexion at last

Table 2. Comparison of clinical and radiographic outcomes among the three groups at last followup

Variable	High-flexion CR (n = 47)	High-flexion PS (n = 42)	Standard CR (n = 48)	p value
Maximal flexion (°)*	135.3 ± 7.5	133.6 ± 8.7	135.6 ± 7.0	0.41
Change in maximal flexion (°)*	2.2 ± 9.9	1.4 ± 12.1	3.5 ± 11.1	0.30
Kneeling (number of patients)	22 (42%)	20 (48%)	24 (50%)	0.86
Crossleg squatting (number of patients)	35 (74%)	30 (71%)	38 (79%)	0.73
Knee Society score (points)*				
Pain	44.0 ± 6.0	42.0 ± 8.3	44.6 ± 7.2	0.22
Function	89.0 ± 9.8	90.1 ± 8.3	89.7 ± 11.1	0.87
WOMAC score (points)*	20.0 ± 12.5	23.6 ± 11.5	20.5 ± 12.0	0.36
Radiolucent line (number of knees)				
Femoral component				0.82
Zone 1	5	5	5	
Zone 4		1		
Tibial component				0.58
Zone 1	4	4	2	

* Values are expressed as mean ± SD; CR = PCL retaining; PS = PCL substituting.

followup compared with preoperative flexion: high-flexion CR, 2.2°; high-flexion PS, 1.4°; and standard CR, 3.5°. Comfortable kneeling was allowed postoperatively in 22 of 47 (42%) knees in the high-flexion CR group, 20 of 42 (48%) knees in the high-flexion PS group, and 24 of 48 (50%) knees in the standard CR group. Crosslegged sitting was allowed in 35 of 47 (74%) knees in the high-flexion CR group, 30 of 42 (71%) knees in the high-flexion PS group, and 38 of 48 (79%) knees in the standard CR group. However, these numbers were not different among groups ($p = 0.86$ and 0.73 , respectively).

At last followup, mean Knee Society pain scores were similar among groups ($p = 0.22$): high-flexion CR, 44; high-flexion PS, 42; and standard CR, 44 (Table 2). Mean Knee Society function scores were also similar among groups ($p = 0.87$) (89 versus 90 versus 90, respectively). We also did not find any intergroup difference ($p = 0.36$) in mean WOMAC scores (20 versus 24 versus 21, respectively).

We identified no major complications in any group. Seven minor complications in the high-flexion CR group and six minor complications in the high-flexion PS group were observed compared to four minor complications for the standard CR group (Table 3). There was no difference in the complication rates among the three groups and all were successfully treated using nonsurgical treatment without any major sequelae.

Although we observed no evidence of loosening of the femoral component in any group at last followup, there were radiolucent lines around the femoral component on the radiographs of five knees in the high-flexion CR group, six knees in the high-flexion PS group, and five knees in the standard CR group ($p = 0.82$) (Table 2). We observed radiolucent lines around the tibial component in a few patients (four in the high-flexion CR group, four in the high-flexion PS group, and two in the standard CR group) but without intergroup differences ($p = 0.58$) (Table 2). Moreover, the mean maximal flexion values of patients with radiolucent lines around the femoral or tibial component were similar ($p = 0.48$) to those of patients without any radiolucent lines around the femoral or tibial component (133.1 versus 134.4). There was no intergroup difference ($p = 0.75$) in mean femorotibial angle of the knee at last followup: high-flexion CR, 4.9° of valgus; high-flexion PS, 4.7° of valgus; and standard CR, 5.0° of valgus.

Discussion

TKA does not always meet the needs of patients in certain ethnic and religious groups who require greater knee flexion, especially in Asian countries. The majority of total knee systems have been designed to accommodate flexion of up to only 130°, which does not satisfy many patients.

Table 3. Complications found in patients in the high-flexion CR, high-flexion PS, and standard CR TKA groups

Group	Number of complications	Type of complication	Grade*
High-flexion CR	7	2 superficial infection	II
		2 deep vein thrombosis	I
		1 pneumonia treated with antibiotics	II
		1 transient confusion not requiring therapy	I
		1 urinary tract infection	II
High-flexion PS	6	1 plural effusion	II
		1 deep vein thrombosis	I
		1 pneumonia treated with antibiotics	II
		2 urinary tract infection	II
		1 noninfectious diarrhea	I
Standard CR	4	1 superficial infection	I
		1 transient arrhythmia not requiring treatment	I
		1 urinary tract infection	II
		1 constipation requiring medication	II

* Severity classification grade from Dindo et al. [12]; CR = PCL retaining; PS = PCL substituting.

Moreover, many clinical studies have described knee flexion of 120° [3, 7, 24, 25, 30]. Therefore, several implant companies have developed high-flexion knee prostheses. The NexGen[®] LPS-Flex and NexGen[®] CR-Flex high-flexion designs are designed to accommodate a knee flexion of 155° with more contact area. In in vitro experimental studies, the high-flexion design restored intact, native knee kinematics at flexion angles of up to 150° [22, 26]. Although high-flexion knee designs have some advantages over standard designs in contact kinematics [10, 26], their usefulness has been debated in terms of function and survivorship [5, 8, 16, 17, 19, 20, 28, 30]. We therefore asked whether high-flexion fixed bearing CR and PS prostheses would provide a better flexion, a better function, and a higher incidence of radiographic loosening than TKA performed using standard fixed bearing CR prostheses.

We acknowledge several limitations to our study that should be borne in mind. First, the three groups could be biased due to the nonrandomized nature of the study design. However, because the indications, preoperative demographics, and followup durations were identical in the three groups, we believe it reasonable to compare the groups. Second, the clinical outcomes after TKA are not influenced by prosthesis design only. Preoperative, intraoperative, and

postoperative factors, especially preoperative flexion, can affect clinical outcomes, including maximal flexion after TKA. Third, maximal flexion without weightbearing was measured in all patients by one physical assistant using a goniometer rather than radiography. Radiographic measurement of ROM is considered the most accurate technique [27], but in clinical practice most surgeons measure the flexion angle using a goniometer. Several studies have reported on the reproducibility of ROM measurement using a goniometer and have shown high intraobserver and interobserver correlations [6, 23]. Therefore, the flexion data were deemed reliable and suitable for the purpose of this comparative study. Fourth, a minimum 5-year followup may not be long enough to detect radiolucent lines or loosening of the prosthesis. Fifth, we used only types of high-flexion designs from one company and cannot generalize these results to all kinds of high-flexion designs. Finally, the high exclusion rate including both death and loss to followup may have impacted the results and outcomes of the data interpretation.

We found the mean maximal nonweightbearing flexion values of the three groups (about 130°) were similar at minimum 5-year followup. These results are also similar to the results of other studies obtained with a high-flexion PS or CR components in TKA [8, 9, 13, 16, 19–21, 28] (Table 4). These results suggest the most important factor for better flexion is surgeon skill, such as proper component alignment and soft tissue balancing, not implant type. In our study, 42% of high-flexion CR, 48% of high-flexion PS, and 50% of standard CR knees were able to kneel without intergroup differences. Moreover, there were no differences among groups in the percentage of patients who were able to perform crosslegged sitting (74%, 71%, and 79% in the high-flexion CR, high-flexion PS, and standard CR groups, respectively). These results are similar to those of an Asian study of TKA using high-flexion designs,

which obtained about 30% to 40% for kneeling and 70% to 80% for crosslegged sitting [8].

At last followup, Knee Society pain scores were 44, 42, and 45 in high-flexion CR, high-flexion PS, and standard CR, respectively. These results were similar to those reported previously for high-flexion CR (48) or high-flexion PS (43) [19, 20]. The postoperative Knee Society function scores (89 in high-flexion CR, 90 in high-flexion PS, and 90 in standard CR) were comparable to those of other studies [8, 9, 28]. Moreover, we did not find any intergroup differences in WOMAC scores at 5-year followup (20 versus 24 versus 21, respectively).

Even though high-flexion designs have been designed to allow patients to achieve high flexion, some in vivo and in vitro studies reported high rates of early femoral component aseptic loosening. Han et al. [16] reported 36% of early aseptic femoral component loosening and recommended patients not to squat or kneel after TKA using high-flexion PS designs. While Cho et al. [8] found more progressive radiolucent lines in patients with TKA who could squat than in patients who could not squat (67.7% versus 20.2%), we did not observe any difference in ROM between the knees that had radiolucent lines around the femoral or tibial components. However, it is difficult to identify reasons for this difference in early loosening or radiolucent lines because we could not compare the detailed surgical techniques, including cementing technique and soft tissue balancing, between studies.

In conclusion, we investigated the advantages of high-flexion CR and PS TKA over standard CR knees in Asian patients regarding ROM, clinical outcomes, and loosening rate. Our data suggest both high-flexion designs in Asian patients provided high ROM and good clinical outcomes without any revision due to loosening of implant at 5 to 8 years. However, high-flexion designs did not have any advantages over the standard CR design with respect to

Table 4. Literature review of knee flexion and component loosening in high-flexion design knees

Study	Prosthesis	Implant type	Mean followup (years)	Loosening	Mean flexion (°)	Number of knees
Cho et al. [8]	NexGen® LPS-Flex	PS	4.2	30	131	218
Choi et al. [9]	P.F.C.® Sigma® RP-F	Rotating platform	2.3	0	128	85
Endres and Wilke [13]	NexGen® CR-Flex	CR	5	0	122	75
Han et al. [16]	NexGen® LPS-Flex	PS	2.7	27	129	72
Kim et al. [19]	NexGen® CR-Flex NexGen® LPS-Flex	CR PS	2.3/2.3	0/0	133/135	85/85
Lee et al. [21]	NexGen® LPS-Flex	PS	2		131	41
Current study	NexGen® CR-Flex NexGen® LPS-Flex	CR PS	6.2/6/0	0/0	135/134	47/42

PS = PCL substituting; CR = PCL retaining.

clinical outcomes and radiolucent lines around the femoral or tibial components. We believe high-flexion designs may not be useful for Asian patients with TKA who want to perform high-flexion activities.

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