Comparison of Highly Cross-Linked and Conventional Polyethylene in Posterior Cruciate-Substituting Total Knee Arthroplasty in the Same Patients

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Background: We are not aware of any information on in vivo clinical results at a minimum of five years after posterior cruciate-substituting total knee arthroplasties performed with a highly cross-linked polyethylene insert. The purpose of the study was to evaluate whether the clinical and radiographic results of posterior cruciate-substituting total knee prostheses, including the prevalences of fracture of the polyethylene post, failure of the locking mechanism of the tibial polyethylene insert, and osteolysis, would be similar between patients treated with conventional polyethylene and those treated with highly cross-linked polyethylene.

Methods: Three hundred and eight patients with a mean age of 60.3 years (range, twenty-two to sixty-five years) received a posterior cruciate-substituting total knee prosthesis with a conventional polyethylene tibial insert in one knee and the same prosthesis with a highly cross-linked polyethylene tibial insert in the contralateral knee. Twenty patients were men and 288 were women. The mean duration of follow-up was 5.9 years (range, five to 6.8 years). At each follow-up visit, the patients were assessed radiographically and clinically with the rating system of the Knee Society; the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC); and the University of California, Los Angeles (UCLA) activity score.

Results: The two groups did not differ significantly ($p > 0.05$) with regard to the mean postoperative Knee Society total knee scores (93.5 compared with 93.7 points), function scores (82.9 compared with 82.7 points), and pain scores (46.7 compared with 47.1 points); WOMAC scores (16 compared with 15 points); range of motion (129.7° compared with 130.1°); or patient satisfaction assessed with a visual analog scale (7.6 compared with 7.9 points). The mean UCLA activity score was 6.4 points ($p > 0.05$). There were no significant differences between the two groups with regard to radiographic results. No knee in either group had a fracture of the tibial polyethylene post or failure of the locking mechanism of the tibial polyethylene insert. No knee in either group had osteolysis. One knee (0.3%), treated with highly cross-linked polyethylene, was revised because of infection.

Conclusions: The data suggest that clinical and radiographic findings at five years after posterior cruciate-substituting total knee arthroplasty were the same for the patients treated with highly cross-linked polyethylene and those treated with conventional polyethylene.

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

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Although total knee arthroplasty reliably provides pain relief, some total knee implants have been associated with polyethylene wear and osteolysis[1-9]. Numerous contemporary total knee systems were introduced to address these problems. Failure because of polyethylene wear or osteolysis has been infrequent in clinical series of contemporary

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TABLE I Clinical Results

Parameters	Preoperative		Final Follow-up		P Value	
	Prolong Polyethylene	Conventional Polyethylene	Prolong Polyethylene	Conventional Polyethylene	Preoperative	Final Follow-up
Mean Knee Society score* *(points)*						
Total knee	27 (12-45) [24.9-28.2]	27 (13-48) [25.3-28.8]	93.5 (73-100) [91.9-97.9]	93.7 (81-100) [91.9-97.9]	0.571	0.458
Function	54.5 (29-68) [52.2-56.7]	54.5 (29-68) [52.2-56.7]	82.9 (70-100) [81.2-85.1]	82.7 (75-100) [82.0-85.4]	1.000	0.707
Pain	—	—	46.7 (40-50) [46.4-49]	47.1 (40-50) [46.5-48.8]	—	0.618
No. (%) of patients with:						
No pain	—	—	224 (73%)	231 (75%)	—	—
Mild pain	—	—	81 (26%)	75 (24%)	—	—
Moderate pain	—	—	2 (0.6%)	2 (0.6%)	—	—
Severe pain	308 (100%)	308 (100%)	1 (0.3%)	0 (0%)	—	—
WOMAC score* *(points)*	64 (43-96) [61.5-68.2]	61 (43-96) [58.3-67.5]	16 (3-49) [14.1-16.8]	15 (3-48) [14.1-16.8]	0.875	0.996
Range of motion* *(deg)*	126 ± 11.9 (75-150)	125 ± 10.8 (70-140)	129.7 (85-145)	130.1 (75-145)	0.895	0.807

*The values are given as the mean with the range in parentheses and the 95% CI in brackets.

fixed-bearing and mobile-bearing total knee arthroplasties[10-14]. However, Collier et al. suggested that polyethylene wear is a major risk factor affecting long-term survival of total knee prostheses[15].

One potential method of decreasing polyethylene wear in total knee arthroplasty is with highly cross-linked polyethylene, which has had clinical success in total hip arthroplasty. However, the forces and stresses at the site of a total knee arthroplasty differ substantially from those at the site of a total hip arthroplasty. The enhanced resistance of highly cross-linked polyethylene to wear can potentially come at the expense of other mechanical properties[16]. Introduction of highly cross-linked polyethylene to a posterior cruciate-substituting total knee prosthesis might add the risk of fracture of the post of the tibial polyethylene insert and failure of the locking mechanism of the tibial polyethylene insert[17-20].

There is limited information on the in vivo clinical results of total knee arthroplasties[21,22] done with highly cross-linked polyethylene, particularly the mid-term results of posterior cruciate-substituting total knee arthroplasties involving use of highly cross-linked polyethylene. The purpose of this study of posterior cruciate-substituting total knee prostheses was to determine whether (1) the clinical and radiographic results with conventional polyethylene were similar to those associated with highly cross-linked polyethylene; (2) the prevalence of fracture of the tibial polyethylene post and failure of the locking mechanism of the tibial polyethylene insert is higher in knees with highly cross-linked polyethylene than those with conventional polyethylene; and (3) the prevalence of osteolysis is higher in knees with highly cross-linked polyethylene than in those with conventional polyethylene.

Materials and Methods

We prospectively enrolled 319 patients (638 knees) with bilateral end-stage osteoarthritis of the knee who underwent bilateral sequential total knee arthroplasty during the same anesthesia session. No patient was older than sixty-five years of age. 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. Four patients refused to participate and seven others were lost to follow-up at three months, leaving 308 patients (616 knees) available for study at a minimum of five years (mean, 5.9 years; range, five to 6.8 years) (Fig. 1). The study was registered in the ClinicalTrials.gov Protocol Registration System (trial number, NCT02020057).

The study group included 288 women and twenty men with a mean age of 60.3 ± 4.3 years (range, twenty-two to sixty-five years) at the time of surgery. The high percentage of women is presumably due to the preponderance of severe primary osteoarthritis of the knee in Asian women. The mean body mass index (BMI) was 29.1 kg/m^2 (range, 25.5 to 39.8 kg/m^2). Varus/valgus alignment of the knee was determined with use of the anatomical axes of the femur and tibia on standing hip-to-ankle anteroposterior radiographs. Seventy-four knees (12%) had varus alignment of 3° to 5°, and the remaining 542 knees (88%) had valgus alignment of 6° to 25°. Forty-three (14%) of the 308 knees in the highly cross-linked polyethylene group and thirty-six (12%) of the 308 in the conventional polyethylene group had had previous arthroscopic debridement; the remaining knees had had no previous surgery.

Randomization of the NexGen Legacy Posterior Stabilized (LPS)-Flex total knee prosthesis (Zimmer, Warsaw, Indiana) to be used with a highly cross-linked polyethylene (Prolong; Zimmer) bearing or a conventional polyethylene bearing (Zimmer) was accomplished with use of a study number in a sealed envelope. After the envelope was opened in the operating room, before the skin

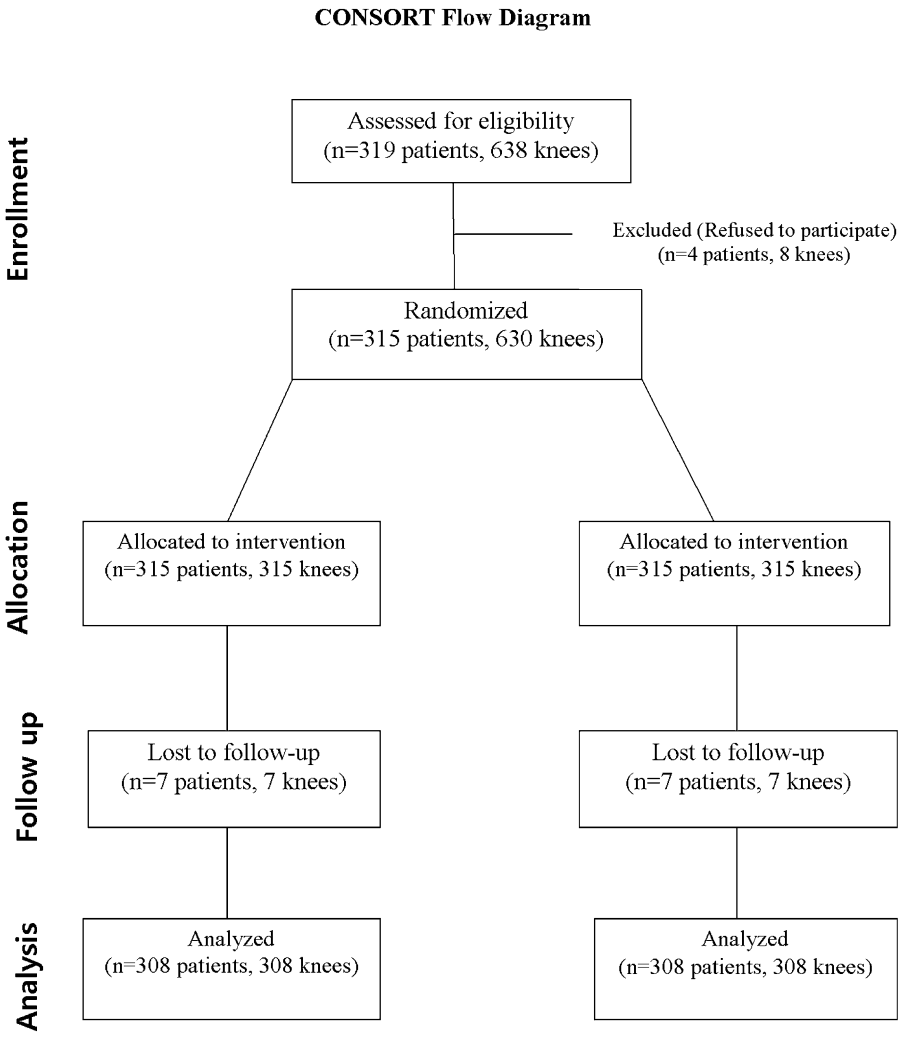

Fig. 1

CONSORT (Consolidated Standards of Reporting Trials) flow diagram. Six hundred and thirty knees in 315 patients treated with bilateral total knee arthroplasty with a NexGen LPS-Flex prosthesis were randomized to receive conventional or highly cross-linked polyethylene. Each patient had one type of polyethylene implanted on one side and the other type implanted on the other side. A minimum of five years of follow-up was completed for both knees of 308 patients.

incision was made, the first knee was assigned to receive the tibial insert indicated by the number in the envelope and the contralateral knee received the other tibial insert. The design and materials of the femoral component (Co-Cr-Mo alloy) and tibial component (Ti-6V-4Al alloy) were the same in the two groups. The design of the polyethylene insert was also the same in both groups, except for the use of highly cross-linked or conventional polyethylene. Both the Prolong and conventional polyethylene were machined from GUR1050 resin bar. Prolong is cross-linked by a 65-kGy electron beam.

All procedures were performed by the senior author (Y.-H.K.) with tourniquet inflation to 250 mm Hg. An anterior midline skin incision (10 to 12 cm in length) was made, followed by a medial parapatellar capsular incision. Ten millimeters of tibial bone was resected with a 7° posterior tibial slope. An anterior cortical reference was used for the anterior-posterior cut of the distal part of the femur. Femoral component rotation was determined with use of three reference axes: (1) the transepicondylar axis, (2) the mid-trochlear (Whiteside) line[23], and (3) 3° of external rotation relative to the posterior aspect of the condyles. Ligamentous balance was established first in knee extension and then in knee flexion with use of a tensor. All patellae were resurfaced with a polyethylene implant. All implants were cemented after pulsed lavage irrigation, drying, and pressurization of vacuum-mixed cement.

On the second postoperative day, patients started active range-of-motion exercises and began to use a continuous passive motion machine. All patients were discharged home from the hospital ten to fourteen days after surgery. They were allowed full weight-bearing and were advised to use crutches or a walker for six weeks.

We (Y.-H.K. and J.-W.P.) assessed the patients with a physical examination and knee scoring preoperatively, at three months after surgery, at one year after surgery, and annually thereafter with use of the systems of the Knee Society[24] and the overall Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score[25], and the level of activity was assessed with use of the University of California, Los Angeles (UCLA) score at the same time points[26]. At each time point, a separate evaluation was performed for each knee. We found that it was relatively easy for patients to distinguish the degree of pain in each knee. We inquired about the degree of stiffness with use of the WOMAC instrument separately for each knee, and it was again relatively easy for patients to distinguish the degree of stiffness in each knee. Patients were given special instructions to distinguish the degree of impairment of the function of each knee. For example, when they had difficulty ascending or descending stairs, they were able to specify which knee bothered them more. At the time of each follow-up visit, radiographic data were analyzed and recorded by a clinical fellow (orthopaedic surgeon) who was not part of the operating team.

TABLE II Radiographic Results

	Mean (95% CI)		
	Prolong Polyethylene	Conventional Polyethylene	P Value (T Test)
Femorotibial angle (standing) *(deg)*			
Preoperative	0.4 (−1.1-1.5)	0.6 (−0.6-1.8)	0.529
Final follow-up	5.8 (5.1-6.8) valgus	6.0 (4.3-7.3) valgus	0.731
Femoral component position *(deg)*			
Anteroposterior	97.3 (96.8-97.8)	97.2 (96.1-98.1)	0.871
Sagittal	2.1 (1.6-2.9)	2.5 (2.1-3.6)	0.413
Tibial component position *(deg)*			
Anteroposterior	88.5 (86.9-89.3)	88.1 (87-88.9)	0.511
Sagittal	84.3 (82.9-84.9)	84.9 (83-85.9)	0.213
Patellar tilt* *(deg)*	2.5 (0.9-3.8)	2.8 (1.1-4.2)	0.591
Joint line level *(mm)*			
Preoperative	14.9 (13.3-15.8)	15.2 (14.5-16.2)	0.336
Final follow-up	14.3 (12.8-15.2)	14.1 (13.0-14.9)	0.243
Posterior condylar offset *(mm)*			
Preoperative	25.1 (24.1-25.9)	24.9 (24.1-25.7)	0.813
Final follow-up	25.8 (24.9-26.8)	26.5 (25.1-27.1)	0.215

*The angle between a line joining the medial and lateral edges of the patella and the horizontal line. The rationale for using a horizontal line is to be independent of the morphology of the trochlea, which is highly variable and may induce underestimation or overestimation of a tilt.

The active motion of each knee with the patient in the supine position was measured twice with use of a standard (60-cm) goniometer preoperatively and at each follow-up visit by two authors (Y.-H.K. and J.-W.P.) who were blinded to the type of implanted prosthesis. Interobserver reliabilities for the range of motion were assessed by calculation of the intraclass correlation coefficient[27]. Interobserver agreement of the range of motion was 0.93 to 0.99. Patient satisfaction was assessed with a visual analog scale (VAS) of 0 to 10. The answers were categorized as ≤2 (fully dissatisfied); 3, 4, or 5 (somewhat dissatisfied); 6, 7, or 8 (satisfied); or 9 or 10 (fully satisfied). The patients were also asked which knee they thought was better. All clinical data were compiled and collected by a research associate.

Anteroposterior standing hip-to-ankle radiographs, supine anteroposterior and lateral radiographs of the knees, and skyline patellar radiographs were made preoperatively and at each follow-up visit. The radiographs were evaluated by one clinical fellow (orthopaedic surgeon), not a member of the operating team, to determine the anatomical axis of the femur and tibia, alignment of the components, posterior 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. All radiographs were made under fluoroscopic guidance to control rotation of the knee. Osteolysis around the components, fracture of the tibial polyethylene post, or failure of the locking mechanism of the tibial polyethylene insert were recorded.

Statistical Analysis

To minimize the chance of a type-II error and increase the power of our study, we aimed to detect a minimum difference in the Knee Society knee score of 3 points with a power of 0.90, and a sample-size analysis revealed that 277 knees were needed in each group[28,29]. We intended to perform a superiority analysis with respect to Knee Society scores. We recruited about 10% more patients to account for possible drop-outs. The differences between the two groups with regard to the Knee Society and WOMAC scores were evaluated with use of the Student paired t test and the Pearson nonparametric chi-square test. The range of motion of the knee was compared between the two groups with use of a two-way repeated-measures analysis of variance. Nonparametric chi-square tests were used to compare complication rates and radiographic data between the two groups. With use of the Bonferroni method[30], the alpha level of each individual test was adjusted downward to ensure that the overall results for the number of tests remained at 0.05. In our study, the alpha level should be <0.0021 after nineteen outcome measures to be a significance level. The level of significance was set at $p < 0.05$.

Source of Funding

There was no external funding source for this study.

Results

Clinical Results

Knee Score

The Knee Society total knee scores did not differ significantly between the two groups either preoperatively ($p = 0.571$) or postoperatively ($p = 0.458$) (Table I). At the time of final follow-up, the mean knee score was 93.5 points (range, 73 to 100 points) in the group treated with the Prolong polyethylene and 93.7 points (range, 81 to 100 points) in the conventional polyethylene group. The ability of the patients to negotiate stairs was markedly improved after the operation.

Pain

The postoperative Knee Society pain scores did not differ significantly between the groups ($p = 0.618$) (Table I). Of the 308 knees treated with the Prolong polyethylene, 224 (73%) were not painful, eighty-one (26%) were mildly painful (no effect on daily activity), two (0.6%) were moderately painful after prolonged walking, and one (0.3%) was severely painful at the time of final follow-up. Of the 308 knees treated with the conventional polyethylene, 231 (75%) were not painful, seventy-five (24%) were

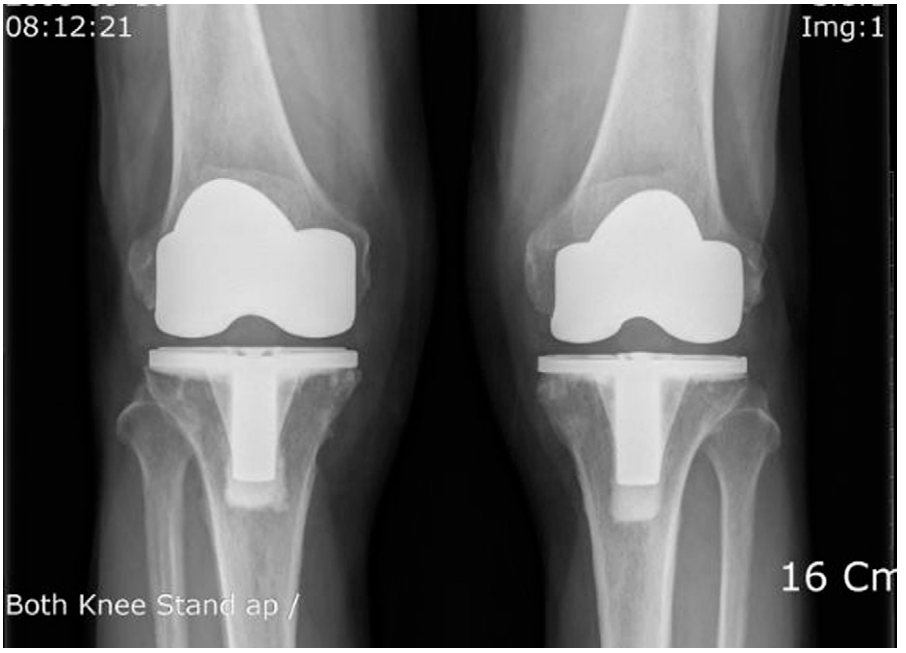

Fig. 2-A

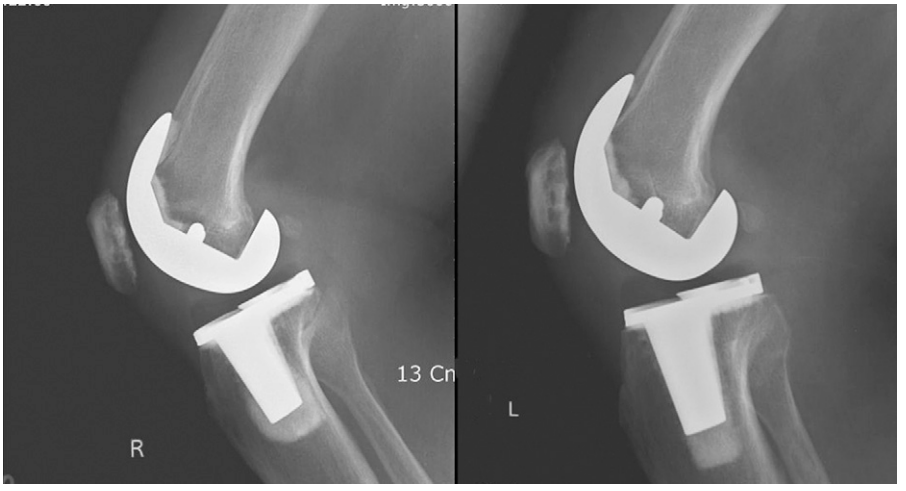

Fig. 2-B

Figs. 2-A and 2-B Radiographs of both knees of a sixty-one-year-old man with end-stage osteoarthritis. **Fig. 2-A** Anteroposterior radiographs of both knees 6.8 years after surgery, revealing that the LPS-Flex prosthesis with conventional polyethylene (right knee, shown in the left image) and the LPS-Flex prosthesis with Prolong polyethylene (left knee, shown in the right image) were embedded rigidly in a satisfactory position. No radiolucent lines or osteolysis were demonstrated adjacent to the tibial component in either knee, and no gross wear of the polyethylene tibial insert was visualized in either knee. **Fig. 2-B** Lateral radiographs of the same knees show the absence of radiolucent lines and osteolysis around the femoral, tibial, and patellar components in both knees. (The radiograph of the left knee has been flipped for the sake of better comparison.)

mildly painful, and two (0.6%) were moderately painful after prolonged walking at the time of final follow-up.

Range of Motion

The ranges of knee motion in the Prolong polyethylene group and the conventional polyethylene group were not significantly different either before ($p = 0.895$) or after ($p = 0.807$) the operation (Table I). Forty-six knees (15%) in the Prolong polyethylene group and forty knees (13%) in the conventional polyethylene group had a range of motion of <110° at the time of final follow-up. Maximum flexion in both groups was 148°.

WOMAC Score

There was a significant improvement in the mean WOMAC score from before the operation to the latest follow-up evaluation ($p < 0.001$). The mean WOMAC scores (16 and 15 points) at the time of final follow-up did not differ significantly between the two groups ($p = 0.996$).

Activity Score

The mean UCLA activity score was 6.4 points (range, 4 to 10 points) at the time of the latest follow-up, indicating participation in moderate/light work activity, occasional house work, swimming, and light bench work. The high UCLA activity score for the patients in this study was related to the fact that they were relatively healthy with little comorbidity.

Satisfaction

Patient satisfaction was similar in the two groups. The mean patient satisfaction score was 7.6 ± 2.4 points in the Prolong polyethylene group and 7.9 ± 2.1 points in the conventional polyethylene group. This difference was not significant ($p = 0.439$). Two hundred and sixty-two patients (85%) with Prolong polyethylene and 268 (87%) with conventional polyethylene were satisfied with the range of flexion while weight-bearing.

Radiographic Results (Table II)

There were no significant differences between the groups with respect to radiographic parameters, including the alignment of the limb (femorotibial angle), positions of the femoral and tibial components, patellar tilt, level of the joint line, and posterior condylar offset. No knee had aseptic loosening of the femoral, tibial, or patellar component, and no knee had subluxation or dislocation of the tibiofemoral or patellofemoral joint. No knee in either group had a fracture of the tibial polyethylene post, failure of the locking mechanism of the tibial polyethylene insert, or osteolysis around the components (Figs. 2-A and 2-B).

Revision

One knee (0.3%) was revised because of infection in the Prolong polyethylene group. No knee was revised in the conventional polyethylene group. The survival rate of the knee prostheses at a mean of 5.9 years after the operation was 99.7% (95% confidence interval [CI], 0.95 to 1.00) in the Prolong polyethylene group and 100% (95% CI, 0.96 to 1.00) in the conventional polyethylene group.

Discussion

The data in our study suggested that, at five years after a posterior cruciate-substituting total knee arthroplasty, the clinical and radiographic findings of patients treated with highly cross-linked polyethylene were the same as those treated with conventional polyethylene.

Hodrick et al.[21] observed fewer radiolucencies and fewer cases of osteolysis and loosening after posterior cruciate-retaining total knee arthroplasty with highly cross-linked polyethylene (Durasul; Zimmer) than after the same procedure done with conventional polyethylene. However, Durasul is irradiated with a higher dose (95 kGy) than that used for Prolong polyethylene (65 kGy), as noted in their study. Minoda et al.[31] found no significant differences in postoperative clinical scores or radiographic results between NexGen cruciate-retaining prostheses with highly cross-linked polyethylene and those with conventional polyethylene. It was difficult to compare the data in our study with those in the existing literature because we found only one in vivo analysis of highly cross-linked polyethylene in posterior cruciate-substituting total knee arthroplasty[22]. Our study of NexGen LPS-Flex prostheses demonstrated no significant differences between highly cross-linked polyethylene and conventional polyethylene with respect to postoperative Knee Society total knee, function, or pain scores; WOMAC scores; knee motion; patient satisfaction; or radiographic results.

Several authors have believed that highly cross-linked polyethylene in total knee arthroplasty potentially reduced fracture toughness. They therefore suggested that surgeons should be cautious about choosing highly cross-linked polyethylene in total knee arthroplasty[32-35]. Although highly cross-linked polyethylene has higher resistance to crack initiation, its resistance to crack propagation is lower; therefore, Ries and Pruitt concluded that highly cross-linked polyethylene should not be used in total knee arthroplasty[35]. On the other hand, Minoda et al.[31] reported no early failures of posterior cruciate-retaining total knee arthroplasty due to highly cross-linked polyethylene. Additionally, Hodrick et al.[21] reported no mechanical failures or osteolysis due to the highly cross-linked polyethylene. Many authors[31,36] believed that the posterior cruciate-substituting tibial post and tibial polyethylene locking mechanism were subject to high stresses and that introduction of highly cross-linked polyethylene to posterior-substituting prostheses might create a risk of fracture of the tibial polyethylene post or failure of the locking mechanism. Long et al.[22] reported that no fractures of the polyethylene post occurred in the early period after posterior stabilized total knee arthroplasty. In our series, there were no fractures of the tibial polyethylene post or failure of the locking mechanism of the tibial polyethylene due to the newly introduced highly cross-linked polyethylene for the tibial insert. The preponderance of female patients with light body weight might have contributed to the absence of tibial polyethylene post fracture and failure of the tibial polyethylene locking mechanism. The duration of follow-up was not long enough to document later problems.

It has been suggested that particles generated by highly cross-linked polyethylene are smaller than those generated by conventional polyethylene[37]. These smaller particles are more biologically active and theoretically could lead to more osteolysis[33,37-41]. Minoda et al.[31] and Hodrick et al.[21] found no osteolysis in their series of posterior cruciate-retaining total knee prostheses. In the current series, no knee in either group had osteolysis, although the follow-up was relatively short.

The strength of our study is that we report on a consecutive group of patients in whom simultaneous bilateral sequential total knee arthroplasty was performed by one surgeon, thereby minimizing confounding factors apart from the type of the tibial polyethylene insert.

Our study had limitations. First, we determined that, to detect a minimum difference in the Knee Society knee score of 3 points with a power of 0.90, 277 knees were needed in each group. However, considering the very low prevalence of fracture of the tibial polyethylene post, a larger number of knees in each group may be required to minimize the chance of type-II error. Therefore, the current study may be underpowered in terms of its ability to demonstrate the prevalence of fracture of the tibial polyethylene

post. Second, while the study of one type of polyethylene in the left knee and the other type in the right knee of the same patient has advantages, it also has disadvantages in that function is generally an integrated concept that is difficult to assign to individual knees. Finally, the mean duration of follow-up was 5.9 years, so longer-term variability in outcomes, particularly with regard to the prevalence of osteolysis, fracture of the tibial polyethylene post, and failure of the locking mechanism of the tibial polyethylene insert, is unpredictable.

The findings of the present mid-term clinical study suggest that excellent clinical and radiographic results were achieved with NexGen LPS-Flex prostheses with either a highly cross-linked polyethylene or a conventional polyethylene tibial insert. The data suggest that clinical and radiographic findings five years after use of highly cross-linked polyethylene in the setting of posterior cruciate-substituting total knee arthroplasty were the same as those after use of conventional polyethylene, and this study provides an impetus for further longer-term investigation. ■

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