Functional Outcome and Range of Motion of High-Flexion Posterior Cruciate-Retaining and High-Flexion Posterior Cruciate-Substituting Total Knee Prostheses

A Prospective, Randomized Study

By Young-Hoo Kim, MD, Yoowang Choi, MD, Oh-Ryong Kwon, MD, and Jun-Shik Kim, MD

Investigation performed at The Joint Replacement Center of Korea, Ewha Womans University School of Medicine, Seoul, South Korea

Background: Although the design features of the high-flexion posterior cruciate-retaining and high-flexion posterior cruciate-substituting total knee prostheses reportedly improve the range of knee motion, a clinical comparison of both systems with regard to range of motion has not been reported, to our knowledge. The purpose of the present study was to compare the range of motion and functional outcome in knees receiving either a high-flexion posterior cruciate-retaining or a high-flexion posterior cruciate-substituting total knee prosthesis.

Methods: Two hundred and fifty patients (mean age, 71.6 years) received a high-flexion posterior cruciate-retaining total knee prosthesis in one knee and a high-flexion posterior cruciate-substituting total knee prosthesis in the contralateral knee. Ten patients were men, and 240 were women. At the time of each follow-up (minimum duration of follow-up, two years; mean, 2.3 years), the patients were assessed clinically and radiographically with use of the knee-rating systems of the Knee Society and the Hospital for Special Surgery. In addition, each patient completed the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) questionnaire. Non-weight-bearing and weight-bearing ranges of knee motion were determined in both groups.

Results: The mean postoperative Knee Society knee score was 94 points for the knees treated with a high-flexion cruciate-retaining prosthesis and 95 points for those treated with a high-flexion posterior cruciate-substituting prosthesis. The mean postoperative Hospital for Special Surgery knee score was 90 points for the knees that had been treated with a high-flexion posterior cruciate-retaining prosthesis and 91 points for those that had been treated with the high-flexion posterior cruciate-substituting prosthesis. At the time of the latest follow-up, the knees that had been treated with a high-flexion posterior cruciate-retaining prosthesis had a mean non-weight-bearing range of motion of 133° and a mean weight-bearing range of motion of 118°. The knees that had been treated with a high-flexion posterior cruciate-substituting prosthesis had a mean non-weight-bearing range of motion of 135° and a mean weight-bearing range of motion of 122°. No knee had aseptic loosening, revision, or osteolysis.

Conclusions: After a minimum duration of follow-up of two years, there was no difference in range of motion or clinical and radiographic results between knees that had received a high-flexion posterior cruciate-retaining total knee prosthesis and those that had received a high-flexion posterior cruciate-substituting total knee prosthesis.

Level of Evidence: Therapeutic Level I. See Instruction to Authors for a complete description of levels of evidence.

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A commentary is available with the electronic versions of this article, on our web site (www.jbjs.org) and on our quarterly CD-ROM/DVD (call our subscription department, at 781-449-9780, to order the CD-ROM or DVD).
The debate over whether to preserve the posterior cruciate ligament in total knee arthroplasty has been ongoing for the past several decades. Several reviews of the literature have found insufficient evidence to recommend either retention or substitution of the posterior cruciate ligament. The NexGen CR-Flex fixed bearing and LPS-Flex fixed bearing total knee systems (Zimmer, Warsaw, Indiana) were introduced to enhance knee flexion after total knee arthroplasty. Compared with the NexGen CR and NexGen LPS prostheses, the NexGen CR-Flex and NexGen LPS-Flex systems include a thicker (2-mm) poste-

Fig. 1-A

Figs. 1-A and 1-B Design features of the NexGen CR-Flex and NexGen LPS-Flex knee prostheses.

Fig. 1-A Frontal views of the NexGen CR-Flex (left) and NexGen LPS-Flex (right) prostheses.

Fig. 1-B

Lateral views of the NexGen CR-Flex (left) and NexGen LPS-Flex (right) prostheses. Extension of the radius and thickness (2 mm) of the posterior condyle in both systems increases the articular contact area at high flexion angles and thereby increases posterior femoral translation and the range of flexion.
rior aspect of the femoral condyles. The intended purpose of a thicker posterior aspect of the femoral condyles in both systems is to extend the surface of the femoral component posteriorly to increase the articular contact area at high flexion angles and thereby increase posterior femoral translation and the range of flexion (Figs. 1-A and 1-B).

As previous studies have not indicated whether posterior cruciate-retaining or posterior cruciate-substituting total knee arthroplasties provide better function, the current study was designed specifically to determine whether high-flexion components were associated with any advantage for either prosthesis (the NexGen CR-Flex or the NexGen LPS-Flex) in terms of the ranges of knee motion and functional outcome.

### Materials and Methods

The present report describes a prospective, randomized clinical trial, initiated in 2004, of a consecutive series of patients who underwent simultaneous bilateral sequential total knee arthroplasty under the same anesthetic. All patients who had the knee arthroplasties at one institution from January 2005 to March 2006 were considered for inclusion in the study. The indication for surgery was osteoarthritis that was severe enough to warrant total knee arthroplasty after an adequate trial of nonoperative therapy and the need for bilateral total knee arthroplasty. Patients were excluded if they had inflammatory arthritis, osteoarthritis of the hip causing pain or restricted

<table>
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<td>Male:female ratio (no. of patients)</td>
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<td>Age* (yr)</td>
<td>71.6 ± 6 (40 to 84)</td>
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<tr>
<td>Height* (cm)</td>
<td>151.8 ± 6.18 (136.5 to 169)</td>
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<tr>
<td>Weight* (kg)</td>
<td>61.8 ± 8.38 (42 to 91)</td>
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<tr>
<td>Body mass index* (kg/m²)</td>
<td>26.8 ± 3.20 (17.9 to 37.9)</td>
</tr>
<tr>
<td>Duration of follow-up† (yr)</td>
<td>2.3 (2 to 3)</td>
</tr>
</tbody>
</table>

*The values are given as the mean and the standard deviation, with the range in parentheses. †The value is given as the mean, with the range in parentheses.
NexGen LPS-Flex total knee arthroplasty was accomplished in both groups who had had no previous surgery. Flex total knee arthroplasty had had previous unilateral or operative treatment. Thirty-one patients with a NexGen CR-flex total knee arthroplasty had had no previous surgery. Eighteen knees had a valgus alignment of between 8° and 20°. We balanced the ligaments in flexion and extension. We attempted to set 3° of external rotation of the femoral component in relation to the posterior aspect of the femoral condyles, perpendicular to the Whiteside line and parallel to the transepicondylar axis. We used all of these rotational guides in every case. None of them were prioritized.

We balanced the ligaments in flexion and extension. We resected approximately 10 mm of tibial bone distally from what was considered to be the least-involved plateau in order to achieve a surface that was perpendicular to the shaft of the tibia in the coronal plane with a 7° posterior slope in the sagittal plane. All patellae in both groups were resurfaced routinely with use of a polyethylene patellar prosthesis. All implants were cemented after pulsed lavage, drying, and pressurization of cement.

Postoperatively, the knee was placed in a continuous-passive-motion machine. Also, active range-of-motion exercises were performed by patients under the supervision of a physical therapist. On the second postoperative day, patients began either standing at the bedside or walking (with use of crutches or a walker) twice daily for thirty minutes each. The patients used a sealed study number envelope, which was opened in the operating room before the skin incision was made. After the envelope was opened, the first knee received the prosthesis indicated by the envelope and the contralateral knee received the other prosthesis. There were no cases in which the second procedure was aborted because of intraoperative problems such as hypotension or heart problems.

All procedures were performed by the senior author (Y.-H.K.). A bloodless field was obtained with use of a pneumatic tourniquet at a pressure of 250 mm Hg after exsanguination with an Esmarch bandage. In all knees, an anterior midline skin incision (10 to 12 cm in length) was used, followed by a medial parapatellar capsular incision. In both groups, femoral preparation was performed first, followed by tibial preparation. We attempted to set 3° of external rotation of the femoral component in relation to the posterior aspect of the femoral condyles, perpendicular to the Whiteside line and parallel to the transepicondylar axis. We used all of these rotational guides in every case. None of them were prioritized.

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crutches or a walker with full weight-bearing for six weeks and used a cane when needed thereafter.

Clinical and radiographic evaluations were done at three months after the operation, at one year, and then yearly thereafter. All clinical data at the time of each follow-up were recorded and compiled by a clinical fellow (Y.W.C.) who was not part of the operative team and was blinded to allocation. We obtained the WOMAC instrument separately for each knee, and it was again averaged and that number was reported. The range of motion was considered to be the arc of motion instead of the flexion angle.

Anteroposterior radiographs with the patient standing (including the hip and the ankle) and with the patient lying supine, lateral radiographs, and skyline patellar radiographs were made preoperatively and postoperatively and were assessed for the alignment of the limb (tibiofemoral angle), the position of the components, the posterior femoral condylar offset, the level of the joint line, and the presence and location of radiolucent lines at the bone-cement interface according to the recommendations of the Knee Society. Anteroposterior standing radiographs were made to determine any sequential change in the alignment of the limb through polyethylene wear and/or loosening of the implant. Supine anteroposterior radiographs were used to determine the presence of a radiolucent line more precisely. Skyline patellar radiographs were examined for patellar tilt, subluxation, or dislocation. All radiographs were made under fluoroscopic guidance to control rotation of the knee.

**Statistical Analysis**

An a priori power calculation was performed with use of a clinically relevant difference in range of motion of 5° and a standard deviation of 9°. For an effect size of 20% in early functional outcome, as measured with a validated instrument such as the linear analog scale assessment, with α = 0.05 and β = 0.80, calculations revealed that 235 patients would be needed in each group. In addition to the required number of subjects, twenty more patients were recruited to allow for possible attrition. The changes in the Knee Society and Hospital for Special Surgery knee scores and WOMAC scores were evaluated with use of the Student t test and the Pearson nonparametric chi-square test. Ranges of motion of the knee were compared between the two groups with use of a two-way repeated-measures analysis of variance. Complication rates and radiographic data were compared between the two groups with nonparametric chi-square tests. All statistical analyses were performed with two-tailed tests. The level of significance was set at p < 0.05.

### TABLE II (Continued)

<table>
<thead>
<tr>
<th>Hospital for Special Surgery Scoring System</th>
<th>Preoperative</th>
<th>Latest Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NexGen CR-Flex</td>
<td>NexGen LPS-Flex</td>
</tr>
<tr>
<td>50 (25 to 57)</td>
<td>51 (27 to 58)</td>
<td>0.511†</td>
</tr>
<tr>
<td>[48.2 to 52.3]</td>
<td>[49 to 53.1]</td>
<td>—</td>
</tr>
<tr>
<td>—</td>
<td>—</td>
<td>28.2 (10 to 30)</td>
</tr>
<tr>
<td>1 (0.4%)</td>
<td>2 (0.8%)</td>
<td>—</td>
</tr>
<tr>
<td>249 (99.6%)</td>
<td>248 (99.2%)</td>
<td>—</td>
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</table>
**Source of Funding**

There was no external funding source for this study.

**Results**

**Clinical Results**

**Knee Score (Table II)**

The preoperative and postoperative knee and pain scores are summarized in Table II. The Knee Society and Hospital for Special Surgery knee scores did not differ significantly between the two groups either preoperatively (p = 0.634 and p = 0.511, respectively; paired t test) or postoperatively (p = 0.850 and p = 0.566, respectively; paired t test). In the NexGen CR-Flex group, the mean postoperative knee score was 94 points (range, 85 to 100 points) according to the system of the Knee Society and 90 points (range, 79 to 100 points) according to the system of the Hospital for Special Surgery. In the NexGen LPS-Flex group, the mean postoperative knee score was 95 points (range, 87 to 100 points) according to the system of the Knee Society and 91 points (range, 77 to 100 points) according to the system of the Hospital for Special Surgery.

**Pain (Table II)**

The postoperative pain scores, according to both the Knee Society and Hospital for Special Surgery knee-scoring systems, did not differ significantly between the groups (p = 0.682 and p = 0.851, respectively; paired t test). Of the 250 knees that had been treated with the NexGen CR-Flex implant, 176 (70.4%) were not painful and seventy-four (29.6%) were mildly painful at the time of the latest follow-up. Of the 250 knees that had been treated with the NexGen LPS-Flex prosthesis, 174 (69.6%) were not painful and seventy-six (30.4%) were mildly painful at the time of the latest follow-up.

**Range of Motion (Table III)**

Preoperatively, the mean knee flexion contracture was 11° (range, 0° to 38°) in the NexGen CR-Flex group and 9° (range, 0° to 33°) in the NexGen LPS-Flex group. At three months, no knee had a measurable flexion contracture. The mean range of flexion during non-weight-bearing and weight-bearing preoperatively, at three months, at one year, and at three years postoperatively did not differ significantly between the two groups (p = 0.183 and p = 0.173, respectively, at three years; paired t test).

**Radiographic Results (see Appendix)**

There were no significant differences between the groups with regard to the position of the femoral and tibial components in the coronal and sagittal planes, the alignment of the knee, the patellar angle (the angle between a line along the patellar cut surface and a line joining the most proximal margins of the femoral condyles of the component on the skyline radiograph), the amount of the tibial surface area covered by the implants (tibial capping), or the mean level of the joint line (p > 0.05 for all; paired t test). The alignment of the knee was a mean of 6.5° of valgus in both groups. There were no radiolucent lines in either group. The prevalence of outliers of limb alignment was not significantly different between the two groups (see Appendix). The mean preoperative posterior femoral condylar offset was essentially the same for the NexGen CR-Flex and NexGen LPS-Flex groups (25.4 and 25.5 mm, respectively). The mean postoperative femoral condylar offset was also similar for both groups (25.8 and 26.5 mm, respectively). No knee had loosening of the femoral, tibial, or patellar component, and no knee had subluxation or dislocation of the tibiofemoral joint or patellar dislocation.

**Complications**

There were two cases of anterior femoral notching in the NexGen CR-Flex group and three cases of anterior femoral notching in the NexGen LPS-Flex group. One knee in each group had a superficial wound infection, and both of these knees were treated with intravenous antibiotics for two weeks without recurrence of a superficial or deep wound infection.

**WOMAC Score (see Appendix)**

Preoperative WOMAC scores were improved significantly in both groups at the time of the latest follow-up.

**Satisfaction**

One hundred and seventy-six patients (70.4%) were fully satisfied with the outcome of the operation with the NexGen CR-Flex prosthesis, and seventy-four patients (29.6%) were satisfied. No differences were identified in terms of patient preference for one knee over the other.

**TABLE III Range of Motion (Total Arc of Motion)**

<table>
<thead>
<tr>
<th>Prosthesis</th>
<th>Preoperative</th>
<th></th>
<th>Three Months</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Non-Weight-Bearing</td>
<td>Weight-Bearing</td>
<td>Non-Weight-Bearing</td>
</tr>
<tr>
<td>NexGen CR-Flex*</td>
<td>125° (80° to 150°)</td>
<td>110° (80° to 135°)</td>
<td>121° (85° to 135°)</td>
<td>101° (65° to 120°)</td>
</tr>
<tr>
<td>NexGen LPS-Flex*</td>
<td>123° (80° to 150°)</td>
<td>108° (80° to 135°)</td>
<td>122° (80° to 130°)</td>
<td>104° (65° to 115°)</td>
</tr>
<tr>
<td>P value (paired t test)</td>
<td>0.145</td>
<td>0.812</td>
<td>0.223</td>
<td>0.256</td>
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*The values are given as the mean, with the range in parentheses.
**TABLE III (Continued)**

<table>
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<th>One Year</th>
<th>Latest Follow-up (Mean, 2.3 Years)</th>
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<tr>
<td>Non-Weight-Bearing</td>
<td>Weight-Bearing</td>
</tr>
<tr>
<td>132° (90° to 145°)</td>
<td>117° (75° to 135°)</td>
</tr>
<tr>
<td>133° (85° to 150°)</td>
<td>119° (70° to 135°)</td>
</tr>
<tr>
<td>0.517</td>
<td>0.261</td>
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</table>

**Discussion**

Clinical studies on the effectiveness of designs intended to provide high flexion following total knee arthroplasty have produced conflicting results. One clinical study demonstrated improvement in the postoperative range of motion in association with the use of a high-flexion rotating-platform-design total knee arthroplasty. Similarly, another study demonstrated significantly greater average knee flexion at one year after the operation in patients who had received a high-flexion design (129° ± 5.2°) than in those who had received a conventional design (124.3° ± 9.2°), particularly among patients with a preoperative range of flexion of <90° (p < 0.05). In contrast, another study did not show significantly greater knee flexion in association with the use of a NexGen LPS-Flex knee replacement (138.6°) as compared with a standard prosthesis (135.8°). In the present study, a high degree of flexion was achieved in association with both types of prostheses. Several factors may have played an important role in the achievement of the high degree of flexion, including the preponderance of women, the low body mass index of the patients, the excellent preoperative range of motion (at least in comparison with Western standards), and the effective restoration of the joint line and posterior femoral condylar offset.

Twenty-six patients (10%) had a preoperative range of motion of <120° in both knees. Postoperatively, all twenty-six of these patients had a range of motion of <120° in both knees. These results indicated that the high-flexion design of the NexGen CR-Flex and NexGen LPS-Flex prostheses will not improve the range of knee motion when it is <120° preoperatively. This finding also suggests that the preoperative range of knee motion appears to be the best guide to the expected range of knee motion after a total knee arthroplasty.

Bellemans et al. showed that, in patients managed with a cruciate-retaining total knee arthroplasty, posterior femoral condylar offset correlated with the range of flexion of the knee. They claimed that restoration of posterior femoral condylar offset is important because it allows a greater degree of flexion before impingement occurs. In the current series, posterior femoral condylar offset was well restored in both groups.

The present study had some limitations. First, there were no interobserver comparisons, and this can lead to substantial bias in interpreting the radiographic results. Second, it is difficult for a patient who has undergone bilateral total knee arthroplasty to distinguish the function of each knee. Comparing the benefits of two different treatments in the same patients has the advantage that patient-dependent prognostic factors are eliminated. However, it introduces the problem involving the difficulty of a patient separating the function of each knee, particularly overall function. Despite this problem, we believe that we were able to obtain fairly accurate information after careful assessment of the performance of each knee.

After a minimum duration of follow-up of two years, we found no significant differences between the two groups with regard to range of motion (p < 0.05 with a power of 80%; 95% confidence interval, 94.6% to 100%) or the clinical and radiographic results. Although the present study does not clearly direct the surgeon toward either arm of treatment, we believe that the extra bone that was removed to allow for the thicker posterior aspect of the femoral condyles and the femoral cam in the NexGen LPS-Flex prosthesis (particularly in patients with small bones) may be a concern should revision be necessary.

**Appendix**

Tables showing the WOMAC score comparisons and the radiographic results are available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on “Supplementary Material”) and on our quarterly CD/DVD (call our subscription department, at 781-449-9780, to order the CD or DVD).

**References**


