

Comparison of a Standard and a Gender-Specific Posterior Cruciate-Substituting High-Flexion Knee Prosthesis

A Prospective, Randomized, Short-Term Outcome Study

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Background: Recently, much debate has focused on the effect of gender-specific total knee arthroplasty. The purpose of the present study was to compare clinical and radiographic results as well as femoral component fit in patients receiving either a standard posterior cruciate-substituting LPS-Flex or gender-specific posterior cruciate-substituting LPS-Flex total knee prosthesis.

Methods: Sequential simultaneous bilateral total knee arthroplasty was performed for eighty-five patients (170 knees). Eighty-five women (mean age, 69.7 years) received a standard LPS-Flex prosthesis in one knee and a gender-specific LPS-Flex prosthesis in the contralateral knee. The mean duration of follow-up was 2.13 years. At each follow-up, the Knee Society score, the Hospital for Special Surgery knee score, the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) score, and radiographs were evaluated. The aspect ratio of the distal part of the femur was compared with those of the standard LPS-Flex prosthesis and the gender-specific LPS-Flex prosthesis.

Results: The mean postoperative Knee Society scores (95.5 points in the standard implant group, compared with 96.5 points in the gender-specific implant group) and Hospital for Special Surgery knee scores (90.7 points in the standard implant group, compared with 91.2 points in the gender-specific implant group) were similar in both groups. The mean postoperative WOMAC score was 36.6 points. Postoperatively, the mean ranges of knee motion in the supine position (125° in the standard implant group, compared with 126° in the gender-specific implant group), patient satisfaction (8.3 points in the standard implant group, compared with 8.1 points in the gender-specific implant group), and radiographic results were similar in both groups. The femoral component in the standard implant group fit significantly better than that in the gender-specific implant group ($p < 0.0001$).

Conclusions: The present study did not show any clinical benefits of a gender-specific LPS-Flex total knee prosthesis at the time of short-term follow-up. Longer follow-up is needed to determine whether there will be an advantage in terms of longer-term function.

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

A gender-specific total knee prosthesis has been introduced to match the three notable anatomic differences in the female population: a less prominent anterior condyle, an increased quadriceps angle (Q angle), and a reduced mediolateral:anteroposterior aspect ratio¹. A NexGen gender-specific femoral component (Zimmer, Warsaw, Indiana) was designed with a narrow mediolateral dimension for a given anteroposterior dimension to more closely match the aspect ratio in the knees of female patients. The anterior flange of the

gender-specific femoral component was modified to include a recessed patellar sulcus and reduced anterior condylar height (to account for a less pronounced anterior condyle in women) and a lateralized patellar sulcus (to accommodate the increased Q angle associated with a wider pelvis).

Although the design characteristics of this gender-specific femoral component are intended to make the implant fit better, there is a paucity of clinical studies evaluating the outcomes of gender-specific total knee arthroplasty in women.

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The purpose of the present prospective, randomized study was to compare functional results, range of motion of the knee, patient satisfaction, radiographic results, femoral component fit, and complication rates in patients who had received either a NexGen standard posterior cruciate substituting-flex (LPS-Flex) or a NexGen gender-specific LPS-Flex total knee prosthesis (Figs. 1-A and 1-B). Several studies have shown that the two-year results of primary and revision total knee arthroplasties are very important because longer-term results can be predicted on the basis of these short-term results¹⁻³.

Materials and Methods

We enrolled eighty-eight women (176 knees) who had sequential simultaneous bilateral total knee arthroplasty from November 2006 to January 2007. The study protocol, including the consent forms, was approved by the institutional review board at our institution. All patients provided informed consent, and all information was kept confidential. The study was registered in the ClinicalTrials.gov Protocol Registration System (Identifier: NCT00917774). We excluded one patient

because she refused to participate, leaving eighty-seven patients available for participation. Two patients were lost to follow-up before three months, leaving eighty-five patients (170 knees) with a minimum duration of follow-up of two years (mean, 2.13 years; range, two to 2.3 years). All patients were women.

The patients had a mean height of 151.2 cm (range, 136 to 164 cm) and a mean weight of 62.1 kg (range, 41.3 to 83.9 kg). The mean body mass index was 27.1 kg/m² (range, 18.2 to 39.2 kg/m²). The mean age of the patients at the time of the index procedure was 69.7 ± 6.8 years (range, fifty-one to eighty-six years). All knees had a varus deformity (range, 6° to 21°). Five knees with a standard LPS-Flex and six knees with a gender-specific LPS-Flex had had previous arthroscopic debridement, and the remaining knees in both groups had had no previous surgery.

Randomization to a standard or gender-specific NexGen LPS-Flex prosthesis was accomplished with use of a sealed study number envelope, which was opened in the operating room before the skin incision was made. Preoperatively, there was no significant difference between the two cohorts in terms of the

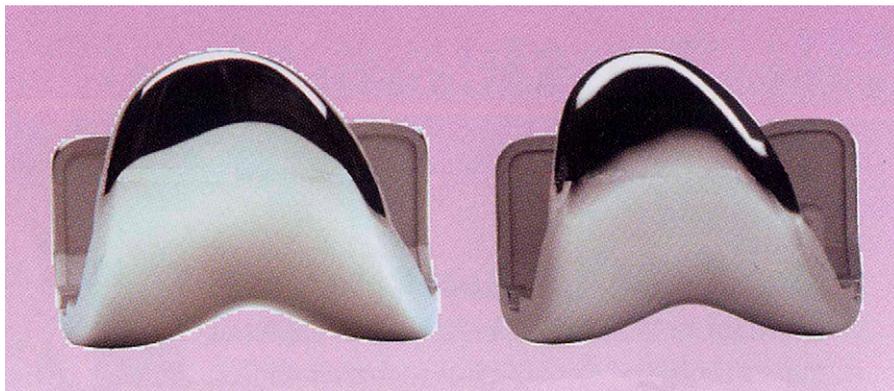


Fig. 1-A



Fig. 1-B

Figs. 1-A and 1-B Photographs showing the design features of standard and gender-specific NexGen LPS-Flex knee prostheses. **Fig. 1-A** Frontal views of the standard (left) and gender-specific (right) NexGen LPS-Flex total knee prostheses. The gender-specific component is narrower in the mediolateral dimension for a given anteroposterior dimension, and the trochlear groove angle is increased (by about 3°) to replicate the Q angle difference. **Fig. 1-B** Lateral views of the standard (left) and gender-specific (right) NexGen LPS-Flex total knee prostheses. In the gender-specific prosthesis, the anterior condylar height is lower and the sulcus is recessed.

extent of the index disease, pain, deformity, range of motion, bone loss, or prior surgical treatment (Table I).

All of the procedures were performed by the senior author (Y.-H.K.). A pneumatic tourniquet was used for all patients. An anterior midline skin incision (10 to 12 cm in length) was made with a medial parapatellar capsular incision. In both groups, femoral preparation was performed first, followed by tibial preparation. All patellae were resurfaced routinely with use of a polyethylene patellar prosthesis. All implants were cemented after pulsed lavage, drying, and pressurization of cement.

On the second postoperative day, patients started passive range-of-motion exercises with use of a continuous passive motion machine. They also started active range-of-motion exercises and began standing at the bedside or walking with crutches or a walker under the supervision of a physical therapist.

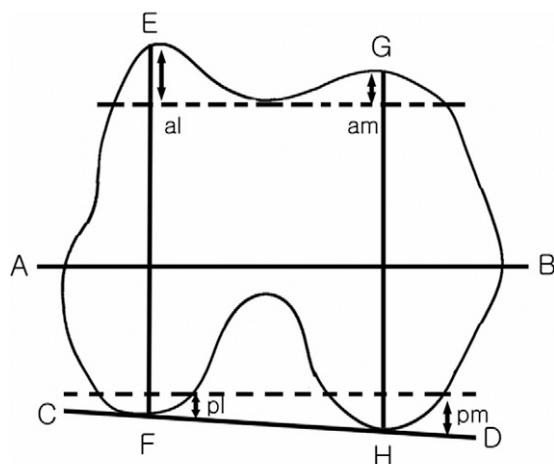
Morphological data from the distal part of the femur were analyzed. The transepicondylar width (the distance from the medial to the lateral epicondyle) of the distal part of the femur was defined as the mediolateral dimension. The average anteroposterior dimension of the lateral and medial condyles (measured as the distance from the most prominent part of anterior aspect of the femoral condyle to the most prominent part of the posterior aspect of the femoral condyle) was defined as the anteroposterior dimension of the distal part of the femur. An aspect ratio (the mediolateral dimension divided by the anteroposterior dimension \times 100) was determined for the distal part of the femur (Fig. 2)⁴. The aspect ratios of the standard and gender-specific NexGen LPS-Flex prosthetic systems were compared with the aspect ratio of the distal part of the femur.

Routine follow-up evaluation was scheduled at postoperative intervals of three months, one year, and yearly there-

TABLE I Preoperative Data

Parameters	Standard NexGen LPS-Flex (N = 85)	Gender-Specific NexGen LPS-Flex (N = 85)	P Value
Total knee score* (points)			
Knee Society	31.2 (0 to 55)	34.4 (7 to 62)	0.145†
Hospital for Special Surgery	59.1 (37 to 68)	59.7 (37 to 58)	0.120†
Function score* (points)			
Knee Society	47.9 (20 to 80)	48.3 (20 to 80)	0.320†
Hospital for Special Surgery	—	—	
Pain score* (points)			
Knee Society	3.1 (0 to 20)	3.1 (0 to 20)	0.838‡
Hospital for Special Surgery	6.5 (0 to 20)	6.7 (0 to 20)	1.000‡
Pain severity (no. of knees)			
None	—	—	
Mild	—	—	
Moderate	23 (27%)	23 (27%)	
Severe	62 (73%)	62 (73%)	
Walking distance (no. of knees)			
Cannot walk	—	—	
<1 block	16 (19%)	16 (19%)	
1 to 5 blocks	69 (81%)	69 (81%)	
Range of motion* (deg)	120 (58 to 150)	123 (85 to 150)	0.139†
Walking support (no. of knees)			
No support	9 (11%)	9 (11%)	
1 cane	72 (85%)	72 (85%)	
1 crutch	1 (1%)	1 (1%)	
2 crutches	3 (4%)	3 (4%)	
Stairs (no. of knees)			
Normal	0 (0%)	0 (0%)	
With support	85 (100%)	85 (100%)	
WOMAC score* (points)	67.9 (31 to 96)	66.8 (29 to 94)	0.148†

*The values are given as the mean, with the range in parentheses. †Paired t test. ‡Chi-square test.



AB: Transepicondylar line
(Medial-lateral dimension)
CD: Posterior condylar line
EF: Anteroposterior dimension of
lateral femoral condyle
GH: Anteroposterior dimension of
medial femoral condyle
al : anterolateral cut
am: anteromedial cut
pl : posterolateral cut
pm: posteromedial cut

Fig. 2

Illustration depicting the measurement of the aspect ratio of the distal part of the femur.

after. Preoperative and postoperative review data were recorded according to the systems of the Knee Society⁵ and the Hospital for Special Surgery⁶ at each follow-up. The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) score⁷ was determined at each follow-up. The active range of motion of the knee in the supine and weight-bearing positions was determined for all patients on two occasions by one of the authors (Y.C.) and as well as by another author (J.-S.K.) with use of a standard (60-cm) clinical goniometer before the operation (in the supine position only) and at the time of the review (in both the supine and weight-bearing positions). The patients were told to bend the knees as much as they could when lying supine and when bearing weight.

Patient satisfaction was assessed with a visual analog scale. The visual analog scale responses were grouped into four categories to determine patient satisfaction: ≤ 2 (fully dissatisfied), 3 to 5 (somewhat dissatisfied), 6 to 8 (satisfied), and 9 or 10 (fully satisfied). This method has been described previously⁸. It is somewhat arbitrary and has not been validated, but nevertheless we believe that it provides a useful impression of the degree of patient satisfaction.

At each follow-up visit, we made anteroposterior radiographs with the patient standing and supine, a lateral radiograph, and a skyline patellar radiograph. One of the authors

(Y.-H.K.) evaluated radiographs three times to perform an intraobserver comparison for the presence and location of all radiolucent lines at the bone-cement interface, following the guidelines of the Knee Society⁵. The chance-corrected kappa coefficient⁹, calculated to determine intraobserver agreement for radiographic measurements for radiolucency at the bone-cement interface, ranged from 0.67 to 0.82.

Statistical Analysis

A sample size estimation showed that twenty knees in each group were required to show a difference in the close-fit parameter of the femoral component, sixty-two knees in each group were required to show a difference in the medial or lateral overhang parameter of the femoral component, and thirteen knees in each group were required to show a difference in the medial or lateral underhang parameter of the femoral component between the two groups with an alpha level of 0.05 and a power level of 80%.

We calculated descriptive statistics (mean, standard deviation, and proportions) for continuous study variables. Knee Society scores, Hospital for Special Surgery knee scores, and WOMAC scores were analyzed with a paired t test. The preoperative Knee Society pain score was compared between the two groups with use of the Fisher exact test. Postoperative Knee Society and Hospital for Special Surgery pain scores were compared between the two groups with use of the Mantel-Haenszel chi-square test. Ranges of motion of the knee were compared between the two groups with use of a paired t test. Radiographic data were compared between the two groups with a paired t test. Complication rates were compared between the two groups with a chi-square test.

Source of Funding

There was no external funding source for this study.

Results

At the time of the latest follow-up, the Knee Society knee, function, and pain scores; Hospital for Special Surgery knee and pain scores; and WOMAC scores were similar in both the standard and gender-specific groups (Table II). The mean preoperative ranges of knee motion in the supine position were 120° and 123° in the standard and gender-specific implant groups, respectively. The mean postoperative ranges of knee motion in the supine position were 125° and 126°, respectively, and the mean postoperative ranges of knee motion in the weight-bearing position were 104° and 105°, respectively. No patient had a postoperative manipulation of the knee to improve the range of motion. All patients but three obtained $>90^\circ$ of flexion. At the time of the latest follow-up, sixty-one (72%) of the eighty-five elderly patients in the series used a banister to avoid falling down or slipping while negotiating stairs. They did not use a banister because of knee pain or knee instability. Knee pain scores and knee stability were similar between the patients who were able to walk stairs independently and those who were able to walk stairs with use of a banister.

TABLE II Clinical Results at Latest Follow-up

Parameters	Standard NexGen LPS-Flex (N = 85)	Gender-Specific NexGen LPS-Flex (N = 85)	P Value
Total knee score* (<i>points</i>)			
Knee Society	95.5 (81 to 100)	96.5 (83 to 100)	0.424†
Hospital for Special Surgery	90.7 (84 to 100)	91.2 (77 to 100)	0.252†
Function score* (<i>points</i>)			
Knee Society	84.8 (60 to 100)	84.8 (60 to 100)	
Hospital for Special Surgery	—	—	
Pain score* (<i>points</i>)			
Knee Society	45.1 (40 to 50)	46.3 (40 to 50)	0.838‡
Hospital for Special Surgery	29.3 (25 to 30)	28.5 (25 to 30)	0.821‡
Pain severity (<i>no. of knees</i>)			
None	65 (76.5%)	66 (78%)	
Mild	19 (22.4%)	17 (20%)	
Moderate	1 (1.2%)	2 (2%)	
Severe	—	—	
Walking distance (<i>no. of knees</i>)			
Cannot walk	—	—	
<1 block	—	—	
1 to <5 blocks	4 (5%)	4 (5%)	
5 to 10 blocks	10 (12%)	10 (12%)	
Unlimited	71 (84%)	71 (84%)	
Range of motion* (<i>deg</i>)			
Supine position	125 (80 to 140)	126 (85 to 140)	0.739†
Weight-bearing position	104 (70 to 130)	105 (70 to 130)	0.756†
Walking support (<i>no. of knees</i>)			
No support	81 (95%)	81 (95%)	
1 cane	4 (5%)	4 (5%)	
1 crutch	—	—	
2 crutches	—	—	
Stairs (<i>no. of knees</i>)			
Normal	24 (28%)	24 (28%)	
With support	61 (72%)	61 (72%)	
WOMAC score* (<i>points</i>)	36.6 (4 to 69)	35.7 (5 to 61)	0.189†

*The values are given as the mean, with the range in parentheses. †Paired t test. ‡Mantel-Haenszel chi-square test.

At the time of the latest follow-up, patient satisfaction was similar in both groups. The mean patient satisfaction score was 8.3 ± 1.7 points for the standard implant group and 8.1 ± 1.9 points for the gender-specific implant group ($p = 0.783$; paired t test). Seventy-one patients (84%) had no preference, eight patients (9%) preferred the standard prosthesis, and six patients (7%) preferred the gender-specific prosthesis.

There were no significant differences between the groups with regard to radiographic parameters, including the alignment of the limb (femorotibial angle), the positions of the femoral and tibial components, tibial surface capping, the

level of the joint line, posterior condylar offset, radiolucent lines, or patellar tilt angle (Table III). We observed no radiolucency at the bone-cement interface in seventy-eight knees (92%) with the standard implant and in seventy-nine knees (93%) with the gender-specific implant (Figs. 3-A and 3-B). Seven knees (8%) with a standard prosthesis and six knees (7%) with a gender-specific prosthesis had an incomplete radiolucent line measuring <1 mm in width at the interface between the tibia and the tibial component. No knee had a complete radiolucent line measuring >1 mm in width around any component in either group. The mean preoperative patellar tilt angle was $12^\circ \pm 6^\circ$ in the standard implant group



Fig. 3-A



Fig. 3-B

Figs. 3-A and 3-B Radiographs of the knees of a seventy-two year-old woman who had osteoarthritis of both knees. **Fig. 3-A** Standing anteroposterior radiograph of both knees, made two years after surgery, showing that the gender-specific (right knee) and standard (left knee) LPS-Flex prostheses are embedded solidly in a satisfactory position. There are no radiolucent lines and there is no osteolysis around the components in either knee. The femoral component of the gender-specific LPS-Flex appears to be undersized. **Fig. 3-B** Lateral radiographs showing that the standard (right knee) and the gender-specific (left knee) LPS-Flex prostheses are fixed satisfactorily. There are no radiolucent lines and there is no osteolysis around the components in either knee.

TABLE III Radiographic Results

Parameter	Standard NexGen LPS-Flex	Gender-Specific NexGen LPS-Flex	P Value*
Alignment† (deg)			
Preoperative	8.6 varus (7 to 14 varus)	8.7 varus (8 to 16 varus)	0.970
Postoperative	5.8 valgus (2 to 7 valgus)	6.4 valgus (1.5 to 8 valgus)	0.901
Femoral component position (femoral angle)† (deg)			
Coronal	97 (93 to 102)	98 (89 to 101)	0.921
Sagittal	1.1 (–3 to 4)	1.2 (–4 to 3)	0.699
Tibial component position (tibial angle)† (deg)			
Coronal	89 (85 to 92)	88 (83 to 93)	0.145
Sagittal	83 (78 to 89)	83 (76 to 92)	0.699
Tibial surface capping† (%)	98 (95 to 104)	98 (92 to 104)	0.897
Joint line† (mm)			
Preoperative	15.8 (9 to 24)	16 (9 to 22)	0.575
Postoperative	14.9 (7 to 24)	15.8 (8 to 21)	0.127
Posterior condylar offset† (mm)			
Preoperative	25.7 (20 to 32)	25.6 (19 to 30)	0.770
Postoperative	25.2 (19 to 30)	25.9 (19 to 31)	0.151
Radiolucent line (overall)‡			
Absent	78 (92%)	79 (93%)	1.000
Radiolucent line (tibial side)‡			
Zone 1 (<1 mm)	7 (8%)	6 (7%)	—
Radiolucent line (femoral side)‡	3 (4%)	4 (5%)	1.000
Patellar tilt angle§ (deg)			
Preoperative	12 ± 6 (n = 79 [93%])	13 ± 7 (n = 77 [91%])	0.792
Postoperative	3.8 ± 1.3 (n = 82 [96%])	3.6 ± 1.6 (n = 81 [95%])	0.873

*Paired t test. †The values are given as the mean, with the range in parentheses. ‡The values are given as the number of knees, with the percentage in parentheses. §The values are given as the mean and the standard deviation, with the number and percentage of knees that were evaluated in parentheses.

and $13^{\circ} \pm 7^{\circ}$ in the gender-specific implant group. The mean postoperative patellar tilt angle was $3.8^{\circ} \pm 1.3^{\circ}$ in the standard implant group and $3.6^{\circ} \pm 1.6^{\circ}$ in the gender-specific implant group. No knee in either group had subluxation or dislocation of the patella or underwent lateral retinacular release.

The gender-specific NexGen LPS-Flex femoral component did not fit better than the standard NexGen LPS-Flex femoral component did (Table IV). There was a significant association between the component type and the amount of overhang or underhang in the standard or gender-specific prosthesis ($p < 0.0001$). In the group with a standard implant, the mediolateral and anteroposterior measurements closely approximated the distal femoral morphologic data for fifty-one knees (60%). Ten knees (12%) had an overhang (mean, 1.4 ± 0.7 mm; range, 1 to 3 mm), and twenty-four knees (28%) had

an underhang (mean, 1.1 ± 0.3 mm; range, 1 to 2 mm). In the group with a gender-specific implant, fourteen knees (16%) had a close fit and seventy-one knees (84%) had an underhang (mean, 2.8 ± 1.3 mm; range, 1 to 7 mm).

The complication rates were low and were similar in both groups. The mean perioperative blood loss (including intraoperative blood loss and blood collected in a Hemovac drain) (ConstaVac BCII; Stryker, Kalamazoo, Michigan) was 1008.6 ± 606.5 mL (range, 200 to 2730 mL) in the standard implant group and 1124.8 ± 265.5 mL (range, 500 to 2340 mL) in the gender-specific implant group. This difference was significant ($p = 0.008$). One knee in each group had a deep infection. Both knees were treated with open debridement followed by intravenous administration of antibiotics for six weeks. There was no recurrence of infection in either knee at the time of the latest follow-up.

TABLE IV Comparison of Fit of Standard and Gender-Specific NexGen LPS-Flex Prostheses

Fit	Standard NexGen LPS-Flex	Gender-Specific NexGen LPS-Flex	P Value*
Close fit†	51 (60%)	14 (16%)	<0.0001
Overhang‡	10 (12%) [1.4 ± 0.699 mm; range, 1 to 3 mm]	—	0.0011
Underhang‡	24 (28%) [1.1 ± 0.316 mm; range, 1 to 2 mm]	71 (84%) [2.8 ± 1.277 mm; range, 1 to 7 mm]	<0.0001

*Chi-square test. †The values are given as the number of knees, with the percentage in parentheses. ‡The values are given as the number of knees, with the percentage in parentheses. The amount of overhang or underhang (presented as the mean, standard deviation, and range) is given in brackets.

Discussion

Recently, much debate and discussion have focused on the effect of gender-specific total knee arthroplasty¹⁰⁻¹³. The concept of a gender-specific total knee implant design is based on the theory that there are clinically important morphologic differences between male and female knees and that standard designs have failed to address these differences, implying that the results of total knee arthroplasty are worse for women than for men. One of the critical questions is whether women derive less benefit, or perhaps less predictable benefit, from total knee arthroplasty that is performed with use of standard conventional devices. Merchant et al.¹⁴ reviewed the literature and reported that, regardless of the criteria that had had been used to measure success or failure in multiple studies about total knee arthroplasty (including implant survival¹⁵⁻¹⁹, pain²⁰, risk of revision²¹, range of motion²², wear-related failures^{23,24}, stiffness²⁵, outcome scores²⁶⁻²⁸, or satisfaction²⁹), women achieved essentially equal or even better results than men when conventional implant designs were used.

In the current study, we found that the early clinical outcomes for the knees with a gender-specific NexGen LPS-Flex prosthesis were similar to those for the knees with a standard NexGen LPS-Flex prosthesis. In both groups, our female patients had improved quality of life in terms of pain, walking distance, deformity, WOMAC scores, and function after total knee arthroplasty.

The searches that the American Academy of Orthopaedic Surgeons conducted and reported in 2008³⁰ did not identify the differences in patient satisfaction and preference between the gender-specific and standard knee replacements. We also found negligible differences in terms of patient satisfaction and preference between the two prostheses.

With the gender-specific NexGen LPS-Flex prosthesis, the anterior condylar height is lowered and the sulcus is recessed to avoid a so-called “overstuffed” patellofemoral joint and to allow increased postoperative knee range of motion. We found that the mean ranges of motion after total knee arthroplasty were indistinguishable between the groups.

Another design feature of the gender-specific prosthesis is the trochlear groove angle of the femoral component, which is increased by approximately 3° in order to replicate the distinct Q angle difference, thereby enhancing patellar tracking and reducing the need for lateral retinacular release. In the

current study, the patellar tilt angle did not differ significantly between the two groups either preoperatively or postoperatively. No knee in either group had subluxation or dislocation of the patella or underwent a retinacular release.

Because the gender-specific femoral component is narrower in the mediolateral dimension for a given anteroposterior dimension, use of this implant would have been expected to reduce the prevalence of medial or lateral overhang in comparison with that noted for the female patients with a standard implant. Clarke and Hentz³¹ found the prevalence of medial or lateral overhang in females to be 5% (two knees) in the gender-specific implant group and 17% (five knees) in the standard implant group, but this difference was not significant. Those authors were unable to confirm that use of the gender-specific femoral component was associated with better radiographic results.

Contrary to the findings of previous studies³¹⁻³⁷ involving Western patients, Urabe et al. observed that the aspect ratio of the distal part of the femur was greater in Japanese patients than in Caucasian patients³⁸. Our data demonstrated that the standard prosthesis fit the distal part of the femur better than the gender-specific prosthesis did. The aspect ratio of the distal part of the femur was closer to that of the standard prosthesis than it was to that of the gender-specific prosthesis. No knee in either group had soft-tissue irritation or soft-tissue imbalance because of a slightly overhanging standard NexGen femoral component. The severe degree of undersizing of the gender-specific prosthesis exposed more cancellous bone, which appeared to be a source of increased bleeding into the knee in the immediate postoperative period. We did not measure either hemoglobin level changes or transfusion rates in these two groups, and hence this slightly higher rate of estimated blood loss (about 100 mL) may not be clinically important. Whether underhanging of the gender-specific knee prosthesis leads to increased osteolysis resulting from wear debris remains to be seen after longer follow-up.

Han et al.³⁹ reported a high rate of aseptic loosening of the standard NexGen LPS-Flex femoral component (38%; twenty-seven of seventy-two knees) after a mean duration of follow-up of thirty-two months. We did not see such early loosening in our previous studies of the standard NexGen Legacy LPS and LPS-Flex and standard NexGen CR and CR-Flex prostheses⁴⁰⁻⁴² or in the current study. Also, we are not

aware of any published studies that have demonstrated such a high failure rate for the NexGen LPS-Flex femoral component, and we are not certain why Han et al. noted such a high failure rate.

The major limitation of the present study is that the follow-up period was too short. However, strong evidence exists that the clinical and radiographic results at two years after primary or revision total knee arthroplasty are similar to those at five to ten years after primary or revision total knee arthroplasty¹⁻³. Kane et al.¹ observed that the functional score after total knee arthroplasty was consistently high. In their study, the mean effect size (defined as the number of standard deviations of change from baseline) for the Hospital for Special Surgery knee score was 3.91 for those with less than two years of follow-up, 3.01 for those with two to five years of follow-up, and 2.97 for those with more than five years of follow-up. For the studies involving the Knee Society knee score, the mean effect size was 2.35 for those with less than two years of follow-up, 2.73 for those with two to five years of follow-up, and 2.67 for those with more than five years of follow-up. In addition, Ryd et al.² found that all of the total knee prostheses that were revised for mechanical loosening could be identified with

roentgen stereophotogrammetric analysis one to two years after the operation, before the onset of symptoms. They concluded that stable fixation of total knee prostheses at two years after the operation was maintained during thirteen years of follow-up.

We can conclude that early clinical and radiographic outcomes, range of knee motion, patient satisfaction, revision rates, and complication rates were similar in both groups. However, the duration of follow-up was short and we can draw no conclusions about the advantage of the gender-specific NexGen LPS-Flex prosthesis with regard to long-term function. ■

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