Comparison of standard and gender-specific posterior-cruciate-retaining high-flexion total knee replacements

A PROSPECTIVE, RANDOMISED STUDY

Y.-H. Kim, Y. Choi, J.-S. Kim

From Ewha Womans University School of Medicine, Seoul, Korea

We undertook a study in which 138 female patients with a mean age of 71.2 years (51 to 82) received a standard NexGen CR-flex prosthesis in one knee and a gender-specific NexGen CR-flex prosthesis in the other. The mean follow-up period was 3.25 years (3.1 to 3.5). The aspect ratios of the standard and gender-specific prostheses were compared with that of the distal femur.

The mean post-operative Knee Society knee scores were 94 (70 to 100) and 93 (70 to 100) points and the function scores were 83 (60 to 100) and 84 (60 to 100) points for the standard implants and the gender-specific designs, respectively. The mean post-operative Western Ontario and McMaster Universities score was 26.4 points (0 to 76). Patient satisfaction, the radiological results and the complication rates were similar in the two groups. In those with a standard prosthesis, the femoral component was closely matched in 80 knees (58.0%), overhung in 14 (10.1%) and undercovered the bone in 44 (31.9%). In those with a gender-specific prosthesis, it was closely matched in 15 knees (10.9%) and undercovered the bone in 123 (89.1%).

Since we found no significant differences between the two groups with regard to the clinical and radiological results, patient satisfaction or complication rate, the goal of the design of the gender-specific CR-flex prosthesis to improve the outcome was not achieved in our patients.

Gender-specific prostheses were introduced for total knee replacement (TKR) to accommodate the anatomical differences between the knees in men and women.1-5 Although their design features are thought to improve the outcome of TKR in women, there is little information to support this view.6,7 We have therefore compared standard and gender-specific posterior-cruciate-retaining high-flexion NexGen (CR-flex) (Zimmer, Warsaw, Indiana) total knee prostheses (Fig. 1) in regard to knee and function scores, radiological findings, fit, rates of complications and patient satisfaction and preference. We hypothesised that all of these parameters would give better results in the gender-specific prosthesis.

Patients and Methods

A consecutive series of 292 bilateral single-stage TKRs in 146 patients which had been performed by the senior surgeon (YHK), at one hospital between May 2006 and October 2006 were included in the study. The study was approved by the Institutional Review Board. A consent form was signed by each patient, and all information was kept confidential. All the patients had grade-III to grade-V bilateral osteoarthritis of the knee according to the criteria of Ahlbäck.8 We excluded three patients post-operatively because of a subsequent diagnosis of rheumatoid arthritis, leaving 143 available for participation. Five patients were lost to follow-up because they returned to their home country after the operation, leaving 138 patients (276 knees) available with a mean follow-up of 3.25 years (3.1 to 3.5). Of the 276 knees, 171 (61.9%) had Ahlbäck grade-III arthritis, 61 (22.1%) grade-IV, and 44 (15.9%) grade-V osteoarthritis. All the patients were women with a mean age of 71.2 years (51.0 to 82.0) at the time of surgery. Their mean height was 150.1 cm (140.8 to 161.4) and their mean weight 61.4 kg (40.0 to 79.0). Their mean body mass index was 27.3 (20.1 to 34.2).

All the knees had a varus deformity of between 1° and 26°. Randomisation to either a NexGen standard CR-flex prosthesis or a NexGen gender-specific CR-flex prosthesis was made using sealed envelopes which were opened in the operating theatre before the skin incision was made. All the patients had single-
There was no significant difference between the two series in terms of their pre-operative condition, including the extent of the osteoarthritis, pain, functional disability, deformity, range of movement, bone loss and previous surgical treatment (Table I).

The surgical technique was the same for both types of knee. We attempted to introduce the femoral component...
tion was undertaken at three months, one year and yearly and after resection. The mediolateral and inferiorsuperior patellar dimensions were determined.

VOL. 92-B, No. 5, MAY 2010

Figs. 2

Diagram showing the measurement of the aspect ratio of the distal femur (AB, transepicondylar line (mediolateral dimension); CD, posterior condylar line; EF, AP dimension of the lateral femoral condyle; GH, AP dimension of the medial femoral condyle; al, anterolateral cut; am, anteromedial cut; pl, posterolateral cut; pm, posteromedial cut).

in $3^\circ$ of external rotation in relation to the posterior femoral condyles or perpendicular to Whiteside’s line or parallel to the transepicondylar axis. All patellae were resurfaced routinely using a polyethylene prosthesis. All the implants were cemented after pulsed lavage, drying, and pressurisation of cement. The patients started active and passive range-of-motion exercises using a continuous passive motion machine on the second post-operative day. Also, they began standing at the bedside or walking with crutches or a walking frame twice daily for 30 minutes under the supervision of a physiotherapist.

Morphological data from the distal femur were analysed. The transepicondylar width (the distance from the medial to the lateral epicondyle) was defined as the mediolateral dimension. The mean anteroposterior (AP) dimension of the lateral and the medial condyles (the distance from the most prominent point anteriorly to the most prominent point posteriorly) was defined as the AP dimension (Fig. 2). An aspect ratio (the mediolateral dimension divided by the AP dimension $\times 100$) was determined for the distal femur. The aspect ratios of the standard and gender-specific prostheses were compared with that of the distal femur. Overhang or under-coverage was measured between the medial or lateral border of the femoral component and the medial or lateral margin of the distal femur. All the measurements were recorded in millimetres using a sterilisable flat ruler, patellar caliper and a femoral sizing template. A microcaliper was used to measure the thickness of the patella before and after resection. The mediolateral and inferiorsuperior patellar dimensions were determined.

Routine post-operative clinical and radiological evaluation was undertaken at three months, one year and yearly thereafter. Pre- and post-operative data were recorded according to the Knee Society system,9 with separate scoring for right and left knees. The Western Ontario McMas ters University Osteoarthritis (WOMAC) score10 was recorded at each visit. Patients, physiotherapists and other evaluators were blinded to the treatment assigned.

Patient satisfaction was assessed using a visual analogue scale (VAS) from 0 to 10 points for each knee. The VAS responses were grouped as follows: ≤ 2, completely dissatisfied; 3 to 5, somewhat dissatisfied; 6 to 8, satisfied; and ≥ 9, fully satisfied.9 This method is somewhat arbitrary and has not been validated, but nevertheless provides a useful indication of satisfaction.

Radiological assessment included AP standing and supine radiographs and a lateral and skyline view. All were taken under fluoroscopic control and were evaluated by one of the authors for the presence and location of radiolucent lines at the cement-bone interface according to the recommendation of the Knee Society.9 The patellar tilt angle11 was measured to assess alignment and identify patellar tracking disorders. It was defined as being abnormal if it exceeded $5^\circ$.12 The chance-corrected kappa coefficient13 was calculated three times at three-day intervals to determine intraobserver agreement for assessment of alignment, radiolucency and patellar tilt angle. Intraobserver agreement ranged from 0.61 to 0.80.

Statistical analysis. When the difference of the patients’ mean satisfaction score was < 3.0 points between the two groups, we hypothesised that satisfaction would be similar between the two groups. In order to accept this hypothesis at alpha = 0.05 and beta = 0.20 (power = 80%), 88 knees were required in each group.

We calculated descriptive statistics (mean, SD and proportions) for continuous study variables. The Knee Society and WOMAC scores were the primary outcome variables. These were analysed using a paired $t$-test. The pre-operative Knee Society pain score was compared between the two groups using a chi-squared test and the post-operative pain score using the Mantel-Haenszel chi-squared test. Ranges of movement of the knee were compared using a paired $t$-test as were radiological data. Complication rates were compared by a chi-squared test. All statistical analyses were performed using SPSS version 14.0 software (SPSS Inc, Chicago, Illinois). A $p$-value ≤ 0.05 was considered to be significant.

Results

The Knee Society knee and function and the WOMAC scores, the range of movement, patient satisfaction and the rate of complications were similar in the two groups at three months, one year and at the final follow-up (Table II). No patient required post-operative manipulation of the knee to improve the range of movement. All except six obtained more than 90° of flexion.

Patient satisfaction was similar in both groups ($p = 0.187$, Student’s $t$-test). The mean satisfaction score for the NexGen standard prosthesis was 8.1 (SD 1.9) points
and for the NexGen gender-specific prosthesis it was 7.9 (sd 2.1) points. Overall, 112 patients (81.1%) had no preference, 12 (8.7%) preferred the standard and 14 (10.1%) the gender-specific prosthesis.

There were no significant differences between the groups with regard to the radiological parameters, including the alignment of the limb (femorotibial angle), the position of the components, cover of the tibial surface, the level of the joint line, posterior condylar offset, radiolucent lines and patellar tilt angle (Table III). No knee had a complete radiolucent line wider than 1 mm around any component. No knee in either group had subluxation of the patella or required a lateral release.

The gender-specific femoral component did not fit better than the standard femoral component. For the knees with a standard prosthesis, the mediolateral and anteroposterior measurements closely approximated the distal femoral morphology in 80 knees (58.0%). In 14 knees (10.1%) there was overhang of a mean 1.7 mm (1.0 to 4.0) and in 44 knees (31.9%) under-coverage by a mean of 1.6 mm (1 to 5). For the knees with a gender-specific prosthesis, 15 (10.9%) were closely matched to the bone margins and in 123 (8.9%) there was under-coverage by a mean of 3.7 mm (1.0 to 11.0; Fig. 3).

Complication rates were low and similar in both groups. Peri-operative blood loss comprising both intra-operative and in the drain in the knees with a standard prosthesis was a mean of 853.5 ml (100.0 to 1980.0) and in those with a gender-specific prosthesis it was a mean of 1032.4 ml (380.0 to 2190.0). This difference was statistically significant (paired t-test, p < 0.001). In those with a standard implant, one had an infection. The implant was removed and an antibiotic-impregnated cement spacer inserted followed by the administration of intravenous antibiotics for...
six weeks. Re-implantation was performed and treatment with intravenous antibiotics continued for two weeks. There was no further recurrence of infection at follow-up at two years. In those with a gender-specific implant, one had an infection and underwent open debridement followed by intravenous antibiotics for six weeks. There was no recurrence of infection at follow-up at two years.

**Discussion**

It has been suggested that proper sizing of a TKR can improve the outcome and reduce the rate of complications.\(^1,2,14,15\) There is little information\(^6,7\) about the outcome of gender-specific prostheses. We found that the early clinical and radiological results, patient satisfaction and complication rates were similar in both of our groups. Contrary to the intended design goal, the femoral component of the NexGen gender-specific prosthesis did not fit better than that of the standard prosthesis.

The concept of a gender-specific TKR is based on the theory that there are clinically important morphological differences between the male and female knee that traditional designs have failed to address, implying that the results of TKR are worse in women than in men. In fact, many studies\(^16-35\) have shown that women achieve essentially equal or better results using traditional designs. In ten studies of primary TKR using traditional designs women had better results than men.\(^17-26\) The remaining nine studies using traditional total knee designs reported no significant difference in the results for men and women.\(^27-35\) The technology overview prepared by the American Academy of Orthopedic Surgeons (AAOS) did not identify any studies which directly addressed whether gender-specific TKR increased the success rate in women.\(^16\) Similarly, in our series, the knee and function scores and the WOMAC score improved significantly and similarly after TKR using either the NexGen standard CR-flex or gender-specific prosthesis. Several factors may have played a role in the achievement of an excellent outcome in both groups. All our patients were women with a low body mass index. They also had a relatively good pre-operative range of movement, with effective restoration of the joint line and the posterior femoral condylar offset, and a short-term follow-up.

The searches which the AAOS\(^16\) carried out did not identify any studies which directly addressed whether gender-specific TKR increased the success rate in women.\(^16\) Similarly, in our series, the knee and function scores and the WOMAC score improved significantly and similarly after TKR using either the NexGen standard CR-flex or gender-specific prosthesis. Several factors may have played a role in the achievement of an excellent outcome in both groups. All our patients were women with a low body mass index. They also had a relatively good pre-operative range of movement, with effective restoration of the joint line and the posterior femoral condylar offset, and a short-term follow-up.

The searches which the AAOS\(^16\) carried out did not identify any difference in satisfaction or preference between the gender-specific and standard TKRs. We also found negligible differences in patient satisfaction and preference.

Several studies have shown that women generally have narrower femora than men when the AP dimension is

---

**Table III. Radiological results (mean, range) in both groups of knee**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Standard</th>
<th>Gender</th>
<th>p-value (paired t-test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alignment (standing on two legs; °)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative (varus)</td>
<td>8.0 (3.0 to 26.0)</td>
<td>6.0 (1.0 to 25.0)</td>
<td>0.448</td>
</tr>
<tr>
<td>Post-operative (valgus)</td>
<td>6.3 (3.0 to 6.0)</td>
<td>6.6 (2.0 to 7.0)</td>
<td>0.970</td>
</tr>
<tr>
<td>Femoral component position (femoral angle; °)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronal</td>
<td>98.0 (93.0 to 102.0)</td>
<td>97.0 (95.0 to 101.0)</td>
<td>0.956</td>
</tr>
<tr>
<td>Sagittal</td>
<td>0.9 (-4.0 to +5.0)</td>
<td>1.2 (-3.0 to +3.0)</td>
<td>0.558</td>
</tr>
<tr>
<td>Tibial component position (tibial angle; °)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronal</td>
<td>88.0 (84 to 93)</td>
<td>88.0 (85 to 92)</td>
<td>0.848</td>
</tr>
<tr>
<td>Sagittal</td>
<td>83.0 (76 to 89)</td>
<td>83.0 (78 to 88)</td>
<td>0.492</td>
</tr>
<tr>
<td>Tibial surface capping (%)</td>
<td>94.0 (92 to 103)</td>
<td>98.0 (92 to 101)</td>
<td>0.683</td>
</tr>
<tr>
<td>Joint line (mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>15.7 (10.0 to 24.6)</td>
<td>16.0 (11.0 to 22.0)</td>
<td>0.498</td>
</tr>
<tr>
<td>Post-operative</td>
<td>13.1 (6.0 to 21.0)</td>
<td>12.7 (7.7 to 19.0)</td>
<td>0.294</td>
</tr>
<tr>
<td>Posterior condylar offset (mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>25.8 (20.0 to 31.0)</td>
<td>25.6 (19.0 to 19.0)</td>
<td>0.806</td>
</tr>
<tr>
<td>Post-operative</td>
<td>25.5 (18.0 to 31.0)</td>
<td>25.9 (19.0 to 37.0)</td>
<td>0.148</td>
</tr>
<tr>
<td>Radiolucent line (overall, number, %)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absence</td>
<td>126 (91.3)</td>
<td>127 (92.0)</td>
<td>1.000</td>
</tr>
<tr>
<td>Radiolucent line (tibial side)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zone 1 (&lt; 1 mm)</td>
<td>12 (8.7)</td>
<td>11 (8.0)</td>
<td>-</td>
</tr>
<tr>
<td>Patella tilt angle (°)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>13 ± 5 (126 knees, 91.3)</td>
<td>12 ± 6 (127 knees, 92.0)</td>
<td>0.898</td>
</tr>
<tr>
<td>Post-operative</td>
<td>3.3 ± 1.7 (12 knees, 4.3)</td>
<td>3.8 ± 1.2 (11 knees, 3.6)</td>
<td>0.919</td>
</tr>
</tbody>
</table>
Adequate evaluation, and used cut bone. Our study evaluated the morphological dimensions of the knee after bony preparation for replacement. These dimensions better reflect the sizing necessary to reproduce the normal anatomy. In contrast to the findings of previous studies, our data showed that a NexGen gender-specific CR-flex prosthesis undercovered the bone in 123 knees (89.1%) and closely matched it in 15 (10.9%). A NexGen standard CR-flex prosthesis closely matched the bone in 80 knees (58.0%), overhung in 14 (10.1%) and under-covered in 44 knees (31.9%). No knee in either group had soft-tissue irritation or soft-tissue imbalancing because of the overhanging femoral component. More undersized gender-specific prostheses exposed more cancellous bone than NexGen standard prostheses which might have been the cause of increased bleeding into the knee in the immediate post-operative period.

In the gender-specific prosthesis, the height of the anterior condyle is lowered and the sulcus is recessed to avoid creating an overstuffed patellofemoral joint and to increase the post-operative range of flexion. We found that the mean range of flexion in knees in the supine position was 127° for the gender-specific prosthesis before surgery and 124° at the final follow-up. For the standard prosthesis, the mean range of movement was 123° before surgery and 126° at the final follow-up. Therefore the range of movement of knees after TKR in both groups is indistinguishable.

Another design feature of the gender-specific prosthesis is that the angle of the trochlear groove of the femoral component is increased by about 3° to replicate the distinct Q-angle difference, which could enhance patellar tracking and reduce the need for lateral retinacular release. In our series, the patellar tilt angle did not differ significantly in the two groups either pre-operatively or post-operatively. No knee in either group had subluxation of the patella or required a lateral release.

There are some limitations of our study. First, we had no interobserver variability which could have led to substantial bias in interpreting the alignment of the knee and radiolucent lines. Secondly, it is difficult for a patient who has undergone bilateral TKR to separate the function of each knee. Although this is a problem when assessing function after bilateral TKR, we believe that we were able to obtain fairly accurate information after careful assessment of the performance of each knee. If patients had a limited walking distance and/or difficulty in negotiating stairs, they were asked to grade which knee contributed most to the functional limitations. Thirdly, the follow-up was relatively short and we can make no conclusions regarding the theoretical advantage of the gender-specific prosthesis regarding function. Finally, our results may have limited applicability to Western patients because there is a considerable anatomical variability in the knee among different ethnic groups.

Since we found no significant differences between the two groups with regard to the clinical and radiological results, patient satisfaction and complication rate, we believe that
the goal of the design of the gender-specific high-flexion knee prosthesis has not been achieved. Furthermore, the femoral component of the gender-specific prosthesis did not fit better than that of the standard implant.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


