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Do High-Flexion Total Knee Designs Increase the Risk of Femoral Component Loosening?

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ABSTRACT

Background: The purpose of our prospective, randomized, long-term investigation is to compare the aseptic loosening rate of the femoral component of the total knee prosthesis and clinical and radiographic results of high-flexion posterior cruciate-substituting knee prosthesis or standard posterior cruciate-substituting knee prosthesis in the same patients.

Methods: There were 960 patients (mean age 71.3 years). The mean follow-up period was 13.2 years (range 10–14). The patients were assessed clinically and radiographically with rating systems of the Knee Society. Furthermore, Western Ontario and McMaster Universities Osteoarthritis questionnaire and ranges of knee motion were determined in both groups.

Results: In the high-flexion knee group, 2 knees (0.2%) had aseptic loosening of both femoral and tibial components. In the standard knee group, 2 knees (0.2%) had aseptic loosening of the femoral component only. The mean postoperative knee scores (97 vs 97 points), Western Ontario and McMaster Universities Osteoarthritis scores (19 vs 19 points), and range of knee motion (128° vs 129°) were not significantly different between the 2 groups. Two knees (0.2%) in the high-flexion knee group underwent a revision of both femoral and tibial components and 2 knees (0.2%) in the standard knee group had a revision of the femoral component only.

Conclusion: After a mean of 13.2 years of follow-up, this study did not show increased incidence of femoral component loosening in the high-flexion knee group. Furthermore, we found no significant differences between the 2 groups with regard to clinical or radiographic parameters or range of knee motion.

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The main goals of total knee arthroplasty (TKA) are pain relief, improvement in ambulatory ability, and restoration of knee motion. Increasing efforts have been made over the past decade to improve the knee range of motion after TKA by refining their design. More than 10 years ago, the so-called NexGen legacy posterior stabilized high-flexion (NexGen LPS-Flex; Zimmer, Warsaw, IN) total knee design was developed in order to restore the full range of knee flexion after TKA. Compared with the standard NexGen LPS prosthesis, the NexGen LPS-Flex system includes an extension of the posterior condyle of the femoral component by 2 mm, a modification of the cam and tibial spine, and a reduction in patellar

impingement. The purpose of the extended posterior condyle of the femoral component 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. The shape of the femoral cam was modified to improve stability of the femoral component on the articular surface and to reduce the bending moment applied to the articular surface of the spine. The femoral cam design increases the subluxation resistance and increases the contact surface between the cam and the tibial spine beyond that of the standard design at flexion angles of >130°. To decrease stress on the quadriceps mechanism and to reduce the potential for patellar impingement during high degree of flexion, the material was removed from the anterior face of the polyethylene tibial bearing.

Several authors have reported that these high-flexion total knee designs improved postoperative knee flexion compared with standard total knee designs [1–3], but others have found no significant differences between these 2 total knee designs with

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respect to the range of knee motion, clinical and radiographic results [4–6]. In addition to an improvement in the range of knee flexion, long-term longevity of TKA is also an important factor in the success of TKA. Because high-flexion total knees were designed to improve the range of knee flexion, there have been reports of early loosening of the femoral component in some high-flexion total knee prostheses. Unacceptably high rate of early aseptic loosening of the femoral component was reported by the NexGen LPS-Flex TKA [7]. Bollars et al [8] reported biomechanical rationales for increased incidence of femoral component loosening of high-flexion knee prostheses compared to that of standard total knee prostheses. Others also were concerned about the increased failure of the femoral component during high-flexion activities [9–11].

The purpose of our prospective, randomized, long-term study is to compare the aseptic loosening and revision rate of the femoral components at 13.2 years between subjects who underwent a high-flexion posterior cruciate-substituting total knee prosthesis or a standard posterior cruciate-substituting total knee prosthesis (these prostheses were produced by a single manufacture). We hypothesized that the incidence of aseptic loosening of the high-flex femoral components would be higher than that of the standard femoral components. Second, we compared the long-term results of high-flexion and standard knee prostheses, with particular emphasis on knee function, range of knee motion, patient satisfaction, complication, and revision rates.

Materials and Methods

We enrolled 1004 consecutive patients (2008 knees) from July 2002 to January 2006. Previously reported 100 patients (200 knees) [12] were included in the current series. The requirement for enrollment was the presence of the end stage of osteoarthritis of both knees. The study was approved by our Institutional Review Board, and all patients signed and provided informed consent. Patients were excluded if they had inflammatory arthritis, osteoarthritis of the hip causing pain or restricted mobility, a foot or ankle disorder which limits walking, dementia or a neurological disorder including history of stroke which affects mobility, and patients older than 80 years old. Among 1004 patients, 10 died, 34 were lost to follow-up, leaving 960 patients (1920 knees) available for study (Fig. 1).

The study group contains 30 male (60 knees) and 930 female patients (1860 knees). Mean age (and standard deviation) was 71.3 years (6.1) (range 40–79). The majority of patients were female in the current series which is attributed to the severe osteoarthritis of the knee in this ethnic group of patients resulting from the inherent bow-leg deformity associated with a habitually squatting and/or yoga position. The bow-leg deformity in the female population was much more severe than male population. Although men also sit or squat, female population do much more than men in their daily activity. The average height (standard deviation) was 151.6 cm (6.0) (range 135.4–168.5). The average weight (standard deviation) was 69.7 (8.3) kg (range 51–105). The average body mass index (standard deviation) was 26.3 ± 3.6 kg/m² (range 24.1–37.5) (Table 1). All patients had 8°–25° of varus deformity of the knees. There was no difference between the 2 groups with respect to the extent of disease, pain, functional disability, deformity, range of knee motion, bone loss, and/or prior surgical treatments before the operation.

Randomization to treatment with high-flexion (NexGen legacy posterior cruciate substituting high-flex: LPS-Flex; Zimmer) or a standard total knee (NexGen legacy posterior cruciate substituting: LPS; Zimmer) prosthesis was accomplished using study numbers in sealed envelope. These sealed envelopes were opened in the operating room before the skin incision was made. All patients were equally assigned, using a computer program, to receive one

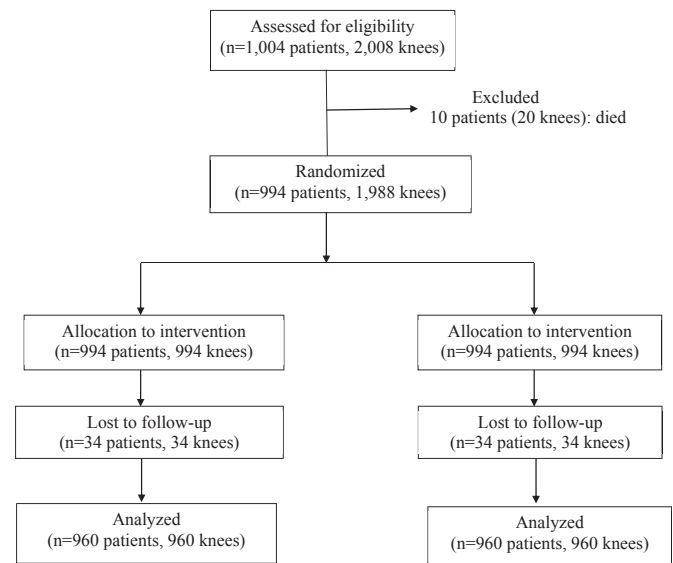


Fig. 1. CONSORT flow diagram. Nine hundred sixty knees (960 patients) in each group were randomized. Nine hundred sixty patients with bilateral TKA had a NexGen LPS-Flex prosthesis on one side and a NexGen LPS prosthesis on the other. CONSORT, Consolidated Standards of Reporting Trials.

type of component in one knee and another type in the contralateral knee. This study was performed by intent-to-treat. The first TKA was performed with a prosthesis indicated in the envelope and the contralateral TKA was performed with the other prosthesis. The second TKA was not aborted in any patient because of intraoperative hypotension or heart problems.

A senior surgeon (YHK) performed all surgeries under the same anesthetic. All surgeries were performed using medial parapatellar approach. In the femoral side, intramedullary femoral instrumentation was used. In the tibial side, extramedullary tibial instrumentation was employed. There was no difference in the surgical technique when performing the high-flex vs standard TKA. The distal and posterior femoral condylar resection was done with an attempt to remove a length of bone that was equal to the thickness of the femoral component to be inserted. The valgus angle of distal femoral resection, made with the use of an anterior referencing system, was the same in the 2 groups. The amount of bone resected from the posterior femoral condyle was 2 mm greater in the knees to be treated with the NexGen LPS-flex prosthesis. Spacer block was used for ligament balancing. We resurfaced patella in all knees, using a polyethylene dome-shaped patellar button. Simplex P cement (Stryker Howmedica Osteonics, Mahwah, NJ) was used to fix all implants using a cement gun after irrigation with a pulsed lavage.

Table 1
Details of the 960 Patients.

Parameters	Value
Number of patients	960 (1920 knees)
Age (y)	71.3 ± 6 (range 40–79)
Male:female ratio (number of patients)	30:930
Height ^a (cm)	151.6 ± 6.0 (135.4–168.5)
Weight ^a (kg)	69.7 ± 8.3 (51–105)
Body mass index ^a (kg/m ²)	26.3 ± 3.6 (24.1–37.5)
Duration of follow-up ^b (y)	13.2 (10–14)

^a The values are given as the mean and the standard deviation, with the range in parenthesis.

^b The value is given as the mean, with the range in parenthesis.

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