Can a High-flexion Total Knee Arthroplasty Relieve Pain and Restore Function Without Premature Failure?

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Abstract

Background High-flexion TKA prostheses are designed to improve flexion and clinical outcomes. Increased knee flexion can increase implant loads and fixation stresses, creating concerns of premature failure. Whether these goals can be achieved without premature failures is unclear.

Questions/purposes We assessed pain relief, knee motion, function, incidence of premature failure, and radiographic appearance in patients with a mobile-bearing high-flexion TKA and determined whether preoperative knee flexion affects postoperative knee flexion.

The senior author (DAD) receives royalties from the manufacturer of the implant analyzed (DePuy Orthopaedics, Inc, Warsaw, IN, USA) although he receives none for the high-flexion femoral component, tibial polyethylene insert, or patellar component evaluated in this report.

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Patients and Methods We prospectively followed all 142 patients implanted with 154 mobile-bearing high-flexion TKAs between 2004 and 2007. We obtained Knee Society scores (KSS) and assessed radiographs for loosening. Minimum followup was 24 months (mean, 46 months; range, 24–79 months).

Results Average knee flexion improved from 123° to 129°. Patients with preoperative flexion of 100° to 120° had a greater postoperative flexion increase (mean, 13°; range, 114°–126°) than patients with preoperative flexion of greater than 120° (mean, 3.0°; range, 128°–131°). The mean KSS improved from 41 to 95 postoperatively. Patients with preoperative flexion of less than 120° had a greater improvement in KSS (62 versus 48). Posterior femoral radiolucent lines were observed in 43% without evidence of prosthetic loosening.

Conclusions Our data were similar to those reported in patients implanted with traditional and other designs of high-flexion TKA. We found no increased incidence of premature failure, although a higher than expected incidence of posterior femoral radiolucent lines merit continued observation. Patients with less preoperative motion were more likely to benefit from a high-flexion TKA.

Level of Evidence Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

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Introduction

Treatment advances in TKA have led to reliable improvements in pain and function. The substantial improvements observed in pain relief, knee function, and survival demonstrated in 10- to 15-year reports of TKA [3, 5, 31] have encouraged many surgeons to perform TKA on younger patients. Typically, these patients have more demanding activity requirements, requiring higher magnitudes of postoperative knee flexion and longevity expectations approaching three decades or more. Increased knee flexion is also required for many daily activities in non-Western cultures. Certain religious and ethnic groups (Indian, Chinese, Japanese, Muslim, etc) perform squatting and sitting cross-legged and typically require 111° to 165° of knee flexion [14, 26].

Several factors affect postoperative flexion after TKA, including preoperative (preoperative flexion, body habitus, presence of previous knee surgery [13, 20, 30, 34]), intraoperative (ligament and gap balance, component size and position, removal of osteophytes, extensor mechanism tension and balance [10, 20, 21, 24]), and postoperative (postoperative rehabilitation [34], postoperative complications) factors. More recently, the effect of prosthesis design on postoperative knee flexion has been of interest, resulting in development of numerous high-flexion TKA (HF-TKA) implants [1, 4, 11, 12, 15, 18, 19, 22, 25, 28, 32]. Early reports of patients implanted with these devices demonstrated differing data, with some reporting enhanced knee flexion and others demonstrating flexion magnitudes similar to traditional “non-high-flexion” TKA implants [1, 15, 18, 19]. Others demonstrated premature failure secondary to femoral component loosening [4, 12]. Many of the reports involved subjects of Asian heritage, analyzed fixed-bearing types of HF-TKA [1, 4, 12, 18, 19], and had short-term followup of 28 months or less [1, 11, 15, 19, 22, 28]. Thus, the literature contains contradictory reports on whether increased motion can be achieved and whether there is an increased risk of premature failures.

We therefore determined (1) the magnitude of pain relief, knee motion, function, incidence of premature failure, and radiographic appearance in a cohort of patients from Western (American, European, etc) cultures implanted with a mobile-bearing HF-TKA; and (2) whether the amount of preoperative flexion affects the magnitude of knee flexion gained postoperatively.

Patients and Materials

From July 2004 to April 2007, we implanted HF-TKAs into 179 knees of 166 patients of Western origin (13 bilateral TKAs). The indications for implanting a HF-TKA

were (1) disabling knee pain and functional loss unresolved with customary nonoperative treatment modalities, (2) radiographic evidence of advanced arthritic change, and (3) presence of a compliant patient willing to participate in the necessary postoperative physiotherapy program. The contraindications for surgery were the presence of active infection or an incompetent extensor mechanism. Based on the senior author’s (DAD) belief at the initiation of the study that HF-TKA designs would most likely benefit individuals with expected higher magnitudes of postoperative knee flexion, we did not consider patients with a preoperative flexion of less than 100° for HF-TKA implantation. Additionally, patients selected by the senior author to receive a mobile-bearing TKA were typically younger than 70 years; therefore, we did not select older patients for analysis. One 80-year-old patient, who was an avid mountain climber and requested a HF-TKA, was included. During the study time, the senior author treated a total of 614 patients with primary TKA. Of the 166 patients, one died before the minimum 2-year followup, 21 (22 knees) had inadequate clinical or radiographic followup, and two refused inclusion in this study, leaving 142 patients (154 knees, 86%) for evaluation. There were 92 women and 50 men with an average age of 64 years (range, 30–80 years) at the time of the surgery. The preoperative diagnoses for patients in this study were degenerative osteoarthritis (136 knees; 88%), traumatic osteoarthritis (14 knees; 9%), rheumatoid arthritis (two knees; 1%), osteonecrosis (one knee; 1%), and conversion from a failed unicompartmental arthroplasty (one knee; 1%). The average body mass index was 25 kg/m² (range, 18–41 kg/m²). Ninety-three of the 154 knees (60%) had previous knee surgery, including open or arthroscopic débridement procedures, fracture fixation, ligamentous repair, extensor mechanism realignment, and a medial unicompartmental knee arthroplasty. Minimum followup was 24 months (mean, 46 months; range, 24–79 months). Patients gave consent for participation in the study and the Institutional Review Board approved the analysis.

The senior author performed all TKA procedures using a gap-balancing surgical technique. For all cases, he implanted the same posterior cruciate-substituting rotating-platform HF-TKA (PFC Sigma[®] RP-F; DePuy Orthopaedics, Inc, Warsaw, IN, USA), cemented all prosthetic components, and resurfaced the patella. Design features incorporated by the implant manufacturer to theoretically enhance postoperative knee flexion include (1) posterior translation (2 mm) of the tibial stabilizing post to enhance posterior femoral translation, (2) material removal from the anterior aspect of the tibial polyethylene insert to lessen tension on the patellar ligament and extensor mechanism, (3) bearing mobility to allow increased magnitudes of axial rotation, and (4) reduced sagittal radius of curvature of the

posterior femoral condyles of the femoral component with the goal of increasing the posterior femoral condylar translation distance. The manufacturer accomplished changing the sagittal radius in the selected design by thickening the posterior femoral condyles, which subsequently necessitated increased resection of the posterior femoral condylar bone when compared with a traditional femoral component (Fig. 1).

When utilizing a gap-balancing surgical technique, the magnitude of posterior femoral condylar bone resection varied based on soft tissue tension of the flexion gap: increased resection was required in knees where the flexion gap was excessively tight and lesser bone resected in cases where the flexion gap was loose. Considering the HF-TKA utilized in this analysis required 2.5 to 5 mm (based on femoral component size) of additional posterior femoral condylar bone resection to accommodate the reduced radius of curvature of the posterior femoral condyles of the femoral component, the surgeon wanted to avoid excessive

osseous resection of the posterior femoral condyles. If the posterior femoral condylar resection exceeded 12 mm, he made an intraoperative decision to switch to implantation of a traditional implant that did not require excessive bone removal, regardless of the selected implant size, resulting in the exclusion of the patient from this analysis.

Postoperatively, all patients began supervised ambulation with bilateral support (walker or two crutches) within 24 hours of surgery, with the goal of hospital discharge by the second or third postoperative day. We initiated outpatient physiotherapy shortly after discharge, 3 days weekly for a period of 4 to 6 weeks. Patients routinely utilized bilateral ambulatory aids for 4 weeks. Pharmacologic prophylaxis of thromboembolic disease consisted of a 3-week duration of warfarin, followed by 3 weeks of aspirin. Patients used antithrombotic foot pumps during the period of hospitalization and compressive stockings for 4 weeks postoperatively.

We requested all patients to return for postoperative evaluation at 6 weeks, 3 months, 1 year, 2 years, and every 2 years thereafter. To maximize patient followup, we attempted to contact by letter or telephone all 21 patients who failed to return before the minimum 2-year followup. We entered all clinical and radiographic data into a research database for later analysis. We assessed preoperative and postoperative functional performance using the Knee Society Scoring System [16]. Patients performed knee motion measurements in an active nonweightbearing mode using a motion goniometer. We recorded and analyzed the presence of postoperative complications and reoperations.

One of two authors (RDB, DRJ) evaluated serial postoperative radiographs to assess component position and alignment, the incidence and location of radiolucent lines using the Knee Society TKA radiographic evaluation system [9], and the presence of prosthetic loosening or osteolysis. A digital imaging system was used to analyze the radiographs. Both radiographic evaluators were orthopaedic surgeons specifically trained to perform precise measurements as recommended by the Knee Society [9]. Prosthetic loosening was defined as the presence of continuous radiolucent lines of 2 mm or less adjacent to the fixation interface of the prosthetic component or the presence of prosthesis migration. Osteolysis was defined as a lytic lesion of greater than 5 mm² that was not present on immediate postoperative radiographs [29]. Due to the authors' initial impression that the incidence of radiolucent lines observed at the posterior femoral condylar fixation interface (Zone 4) was higher than expected, radiographs from a group of 100 consecutive patients implanted with a non-HF-TKA from the same implant system were analyzed for comparison. The senior author also performed those operative procedures during the same time period as the HF-TKA cohort.

Fig. 1A–B (A) Frontal and (B) sagittal photographs show the PFC Sigma® RP-F TKA device. Reprinted with permission from DePuy Orthopaedics, Inc, Warsaw, IN, USA.

To determine whether the amount of preoperative flexion affected the magnitude of postoperative flexion gain, we divided patients into two subgroups based on preoperative knee flexion: 100° to 120° and greater than 120°. After completion of data analysis, we compared our data with other clinical studies of HF-TKA.

For all continuous variables (preoperative and postoperative analysis of KSS, knee extension, knee flexion, and ROM arc), we calculated the mean and SD. To investigate the effect of preoperative motion on postoperative clinical knee function and postoperative improvement in knee flexion, we analyzed the two cohorts (preoperative flexion level of 100° to 120° versus greater than 120°) separately and compared them using a two-tailed t test to determine differences in postoperative flexion, postoperative ROM arc, postoperative KSS, as well as changes in knee flexion, ROM arc, and KSS between the two groups. We performed statistical analysis using Microsoft[®] Excel[®] 2007 (Microsoft Inc, Redmond, WA, USA).

Results

At last followup, pain relief, function, and knee flexion all improved according to the KSS. The mean preoperative KSS improved from 41 to 95 points (range, 65–100 points), while the functional KSS improved from 59 to 90 points (range, 50–100 points). The mean preoperative flexion of 123° (range, 100°–140°) increased to a mean of 129° (range, 90°–150°) postoperatively. We did not observe any premature failures due to implant loosening, instability, or disabling pain. One patient required implant removal due to hematogenous sepsis (discussed below). The average axial alignment was 0.2° varus preoperatively (range, 15° varus to 22° valgus) versus 5.0° valgus postoperatively (range, 2°–9° valgus). We observed no evidence of component loosening or migration and noted the incidence of radiolucent lines about the femoral components (Table 1) and tibial components (Table 2). Radiolucent lines were infrequently noted ($\leq 6\%$) in most radiographic zones with the exception of the posterior aspect of the femoral component (Zone 4), in which there was an incidence of radiolucent lines of 43% (Fig. 2). This compared with a 24% radiolucent line incidence in Zone 4 of a cohort of non-HF-TKA from the same implant design system. We found no radiolucent lines of greater than 2 mm. Radiolucent lines were typically observed within the first postoperative year and were not progressive during the followup period.

Subgroup analysis based on the amount of preoperative flexion revealed patients with preoperative flexion of 100° to 120° demonstrated a greater improvement ($p < 0.001$) in KSS (62 versus 48 points) than those with preoperative

Table 1. Femoral component radiolucent lines

Knee Society femoral zone	Incidence of radiolucent lines (%)
Zone 1	6
Zone 2	1
Zone 3	0
Zone 4	43
Zone 5	0
Zone 6	0
Zone 7	0

Table 2. Tibial component radiolucent lines

Knee Society tibial zone	Incidence of radiolucent lines (%)
AP Zone 1	1
AP Zone 2	2
AP Zone 3	0
AP Zone 4	4
AP Zone 5	0
AP Zone 6	0
AP Zone 7	0
Lateral Zone 1	1
Lateral Zone 2	2
Lateral Zone 3	0

AP Zone = zone on the AP radiograph; Lateral Zone = zone on the lateral radiograph.

Fig. 2 A lateral postoperative radiograph demonstrates a posterior radiolucent line (arrow) in Zone 4.

Table 3. Comparison of patients based on preoperative flexion magnitude

Parameter	Preoperative flexion < 120°	Preoperative flexion > 120°	p value
KSS (points)			
Preoperative	33.1 (−0.4–53.0)	45.8 (15.0–100.0)	< 0.001
Postoperative	95.2 (49.0–100.0)	94.1 (59.0–100.0)	0.57
Improvement	62.1 (19.0–100.0)	48.3 (−1.0–85.0)	< 0.001
KSS (functional) (points)			
Preoperative	57.3 (40.0–90.0)	59.5 (20.0–90.0)	0.29
Postoperative	91.8 (50.0–100.0)	89.5 (50.0–100.0)	0.32
Improvement	34.5 (0.0–60.0)	30.0 (−20.0–80.0)	0.11
Knee flexion (°)			
Preoperative	113.5 (90.0–118.0)	128.3 (120.0–140.0)	< 0.001
Postoperative	126.0 (90.0–145.0)	131.3 (95.0–150.0)	< 0.001
Improvement	12.5 (−25.0–40.0)	3.0 (−37.0–25.0)	< 0.001

Values are expressed as mean, with range in parentheses; KSS = Knee Society score.

Table 4. Complications

Complication	Number
Arthrofibrosis requiring closed manipulation	4
Patellar crepitus requiring arthroscopic knee surgery	3
Distal deep venous thrombosis	1
Superficial cellulitis	1
Nondisplaced intraoperative lateral femoral condylar fracture	1
Traumatic medial epicondyle fracture	1
Traumatic Grade II lateral collateral ligament strain	1
Hematogenous infection requiring component removal	1

flexion of greater than 120°. Patients with preoperative flexion of 100° to 120° also exhibited greater ($p = 0.001$) improvement in mean knee flexion (13°) than patients with preoperative flexion of greater than 120° (3.0°) (Table 3).

There were 13 complications occurring in 13 knees (8%) (Table 4). Four patients developed postoperative arthrofibrosis for which we performed closed manipulation, while three developed postoperative patellofemoral crepitus, successfully treated with arthroscopic débridement. There was one case of distal (calf) deep venous thrombosis managed with warfarin therapy, one case of superficial cellulitis treated with oral antibiotics, and one nondisplaced intraoperative lateral condyle fracture treated with screw fixation, which united without incident. Two patients suffered postoperative traumatic injuries, one from a fall while skiing (medial epicondyle fracture) and the other from a fall down a flight of stairs (Grade II lateral collateral ligament strain); both were successfully managed with 6 weeks of bracing without the need for additional operative intervention. There was one failure secondary to a hematogenous infection in an immune-compromised

patient receiving chemotherapy for lymphoma 5 years after implantation, requiring implant removal and a later two-stage reimplantation of a TKA. His TKA was functioning well without pain before the infection occurred.

Discussion

A myriad of HF-TKA prosthetic designs have recently been introduced with the goal of increasing the magnitude of flexion obtained after TKA [1, 4, 11, 12, 15, 18, 19, 22, 25, 28, 32]. As with introduction of any new medical device, clinical evaluation of its performance and any associated adverse events is critical. We therefore determined (1) the amount of pain relief, knee flexion and function, failure incidence, and radiographic appearance of a cohort of Western patients implanted with a mobile-bearing HF-TKA; and (2) whether the amount of knee flexion preoperatively affected the magnitude of knee flexion gained postoperatively.

Study limitations included the following. First, we had short-term followup with a minimum of 24 months and mean of 46 months, which was inadequate to assess polyethylene wear and long-term fixation. Second, our report considered a single type of HF-TKA design; therefore, the findings may not be applicable to all HF-TKA implants. Third, the study cohort was nonconsecutive in nature and patients with preoperative flexion of less than 100° were not included. The authors believed reporting of these data at the current followup duration was merited based on the fact that other studies reported premature failure with HF-TKA designs at mean followup similar to or shorter than ours [4, 12]. The nonconsecutive nature of the study cohort was based on the authors' belief that HF-TKA designs were not indicated for all patients due to

the increased femoral bone resection required and the increased cost typically charged for a HF-TKA. Based on reports documenting that preoperative flexion was a determinant of postoperative flexion [6, 13, 17, 20, 30], at the initiation of the study, the authors believed HF-TKA designs would most likely benefit those who had a higher magnitude of knee flexion preoperatively. For that reason, only patients with preoperative flexion of greater than 100° were included. Lastly, two different observers assessed and recorded radiographic measurements such as the presence of osteolysis and radiolucent lines adjacent to the prosthetic components. Previous reports have documented potential interobserver measurement error when multiple evaluators have been used [2, 8].

We found improvements in pain and function, with KSS improving from 41 points preoperatively to a mean of 95 points at latest followup. Similar high knee scores and functional improvements were observed in other short-term evaluations of other HF-TKAs [18, 19, 32] (Table 5). The high mean postoperative knee flexion observed in our report (129°) was similarly observed in other reports of various HF-TKA designs [1, 4, 11, 13, 15, 18, 19, 32] (Table 5). Many of these reports involved patients of Asian heritage who often had higher magnitudes of preoperative flexion than customarily observed in Western cultures. The similarity of our results to those of other reports may be related to the high preoperative flexion present in our cohort. Therefore, we believed we needed to critically analyze and compare reports of HF-TKA devices to discern whether knee motion was superior in HF-TKA designs due to cultural or preoperative motion differences present in the cohorts analyzed.

Numerous comparative reports comparing patients implanted with a HF-TKA versus a conventional TKA using the same implant system have been published [1, 4, 11, 15, 18, 22, 28, 32]. Some observed similar degrees of maximal knee flexion [18, 22, 28, 32], while others demonstrated superior flexion was obtained using a HF-TKA [1, 4, 11, 15]. The amount of increase in flexion in studies reporting superior flexion with a HF-TKA design was typically limited (5°–10°). Therefore, it remained unclear whether superior flexion was reproducibly obtained after implantation of HF-TKA designs.

Complication and reoperation rates observed in our analysis were similar to those in clinical reports of conventional TKA. While we noted no prosthetic loosening, we observed a relatively high incidence of radiolucent lines about the posterior femoral condyles (43%), higher than we observed after implantation of a non-HF-TKA from the same TKA implant system (24%). Han et al. [12] reviewed a cohort of 47 patients implanted with 72 fixed-bearing HF-TKAs and observed an alarmingly high incidence of aseptic femoral component loosening of 38% (27 of 72) at

a followup of only 32 months. The postoperative mean maximum flexion was 136° in the group with femoral component loosening versus 125° in the well-fixed group ($p = 0.022$). Cho et al. [4] reviewed a group of 166 patients (218 TKA) implanted with the same fixed-bearing HF-TKA at a mean followup of 51 months. They observed progressive radiolucent lines around 14% (30 of 218) of the femoral components. Seven of these cases (3%) required revision for femoral component loosening at a mean followup of 49 months. A higher mean maximum flexion was similarly observed in those with femoral radiolucent lines (142°) than in the group without radiolucent lines (128°). Additionally, a higher percentage of patients were able to squat in the cohort with progressive radiolucent lines (77%; 23 of 30) than in those without progressive femoral component radiolucent lines (20%; 38 of 188). Both of these reports involved Asian patients, who typically utilize higher knee flexion (squatting, kneeling, praying, etc) more frequently than Western population groups [26].

Numerous factors may play a role in the worrisome incidence of femoral component radiolucent lines and loosening observed in some reports of HF-TKA. High magnitudes of knee flexion result in higher net quadriceps moments and joint reaction forces [27]. Therefore, if HF-TKA implants provide increased flexion, increased stresses are incurred by the implant. Additionally, higher magnitudes of knee flexion may allow patients to perform higher load activities than what they would be able to perform if less knee flexion is present. Lastly, some HF-TKA designs require an increased amount (2.5–5 mm) of osseous resection from the posterior femoral condyles, which may affect femoral component fixation in some way. This information indicates close monitoring of patients implanted with HF-TKA is wise. Hopefully, the implant design changes incorporated into HF-TKA implants lessen the stresses associated with high flexion. Manufacturers suggest changes in HF implant design, such as modifications in femoral and tibial component topography, cam-post mechanics, and bearing mobility, should lessen the increased loads reported with increased flexion.

There is no consensus on the ideal patient to receive a HF-TKA. Since preoperative flexion strongly correlated with the amount of flexion obtained after TKA [6, 17, 23, 33], we initially assumed the ideal patient was an individual with a high amount of preoperative knee flexion. Our data suggest otherwise, as patients with preoperative flexion of less than 120° demonstrated a greater increase in postoperative knee flexion (114°–126°) than those with preoperative flexion of greater than 120° (128°–131°), as well as a greater improvement in KSS. Others also observed greater gains in postoperative knee flexion in patients with lesser magnitudes of preoperative knee flexion when implanted with a HF-TKA [1, 11], while

Table 5. Comparison of results of high-flexion TKA

Study	Study origin	Number of high-flexion TKAs	Mean followup (months)	Implant design*	Mean postoperative flexion (°)	Mean flexion gain (°)	Postoperative KSS (points)	Postoperative KSS (functional)	Postoperative HSS (points)	Failure due to loosening or instability (%)
Bin and Nam [1]	S Korea	90	12	NexGen LPS-Flex [†]	129	6	NA	NA	94	0
Cho et al. [4]	S Korea	218	51	NexGen LPS-Flex [†]	131	14	87	82	NA	4
Gupta et al. [11]	USA	50	12	PFC Sigma RP-F [‡]	125	17	94	96	NA	0
Han et al. [12]	S Korea	72	32	NexGen LPS-Flex [†]	132	11	NA	NA	85–87	38
Huang et al. [15]	Taiwan	25	28	NexGen LPS-Flex [†]	138	28	96	88	NA	0
Kim et al. [19]	S Korea	50	25	NexGen LPS-Flex [†]	139	12	92	NA	89	0
Malik et al. [22]	USA	50	12	Genesis II HF [†]	120	5	93	NA	NA	NA
Nutton et al. [28]	Scotland	28	12	NexGen LPS-Flex [†]	110	2	NA	77	NA	NA
Seon et al. [32]	S Korea	50	26	NexGen LPS-Flex [†]	131	3	NA	NA	94	NA
Current study	USA	154	46	PFC Sigma RP-F [‡]	129	6	95	90	NA	0

* Implants include: NexGen® LPS-Flex (Zimmer, Inc, Warsaw, IN, USA); PFC Sigma® RP-F (DePuy Orthopaedics, Inc, Warsaw, IN, USA); Genesis® II HF (Smith and Nephew, Inc, Memphis, TN, USA); †fixed bearing; ‡mobile bearing; KSS = Knee Society score; HSS = Hospital for Special Surgery knee score; NA = not available.

McCalden et al. [25] reported patients with greater than 120° of preoperative knee flexion were more likely to gain flexion when a HF-TKA was utilized. We are presently reserving use of a HF-TKA for those with stiffer knees preoperatively, since we obtained little benefit in patients with higher magnitudes of preoperative knee flexion.

Improving knee flexion after TKA is a desirable goal. Devers et al. [7] found increased knee flexion correlated with achievement of patient expectations, restoration of a “normal” knee, and improvements in patient function. Implant manufacturers have incorporated numerous implant modifications in an attempt to enhance postoperative knee flexion, such as PCL stabilization and tibial polyethylene insert modifications to enhance posterior femoral translation, material removal from the anterior aspect of the tibial polyethylene insert to lessen tension on the patellar ligament and extensor mechanism, and bearing mobility to allow increased magnitudes of axial rotation. Additionally, many HF designs, including the implant analyzed in this report, have a reduced sagittal radius of curvature of the posterior femoral condyles of the femoral component, with the goal of increasing the posterior femoral condylar translation distance and reducing contact stresses on the polyethylene insert, should high flexion occur. Longer-duration clinical followup studies are needed to determine whether these design modifications are beneficial.

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