High-flexion Prosthesis Improves Function of TKA in Asian Patients Without Decreasing Early Survivorship

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Abstract

Background Two previous studies recently raised the possibility of a high risk of early femoral components loosening with high-flexion (HF) prostheses in Asian populations and suggested that the high failure rate of HF TKAs was associated with HF ability. However, these findings are controversial given other studies reporting a low incidence of aseptic failures in HF prostheses.

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Questions/purposes We therefore determined (1) the rate of achieving postoperative HF after HF TKA; (2) whether the aseptic loosening rate of HF prostheses is high; and (3) whether the survivorship was worsened in patients who achieved postoperative deep knee flexion in our cohort of Korean patients.

Methods We retrospectively reviewed 488 patients who had 698 primary TKAs using the NexGen® Legacy Posterior-Stabilized Flex system implanted from 2003 to 2010. There were 40 men and 448 women with a mean age of 68 years. We obtained Hospital for Special Surgery scores, maximal flexion, and radiographs. The minimum followup for functional and radiographic evaluations was 2 years (median, 4.8 years; range, 2–8.7 years). We performed a survival analysis on all patients for aseptic loosening.

Results Three hundred sixty knees (52%) could achieve $\geq 135^\circ$ maximum flexion. Six of the 698 knees (0.9%) developed aseptic loosening (three femoral and three tibial). The survival at 5 years for aseptic loosening was 99.1%. The overall survival for aseptic failure did not differ between knees that achieved HF and those that did not.

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Conclusions We observed a low incidence of early aseptic loosening of HF designs in this series. Our findings suggest HF TKAs have high survival in Asian patients at 5 years although half of the patients attained maximum flexion more than 135° postoperatively.

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

Introduction

Although TKA has been a predictable solution for advanced osteoarthritis to achieve painless walking, the limited range of flexion that is present after conventional TKA is disadvantageous to an Asian population. Unlike in the Western world, limited flexion less than 130° reportedly impairs patient satisfaction in Asian populations [21, 22] because it precludes performance of common activities of daily living such as squatting, sitting crosslegged, or kneeling [32, 38]. High-flexion (HF) knee prostheses were designed to accommodate flexion up to 155° through modification of posterior condylar geometry and cam design. If postoperative deep flexion can be achieved after HF TKA in Asian patients, these implants may be advantageous to these populations who perform daily HF activities, because they might be associated with less polyethylene wear and subsequent osteolysis by providing more contact area in the deep flexion angle [9, 42, 45].

Despite the expectations of achieving deep flexion, two clinical studies of HF TKA on a Korean population have reported rates of progressive radiolucent lines (RLLs) in the cement-metal interface of the femoral component of 14% at 6 to 76 months [7] and 38% at 30 to 48 months [17]. Both studies suggested this substantial early aseptic loosening was associated with postoperative deep flexion ability. Early aseptic loosening of the femoral component reportedly occurs in 0% to 0.9% of patients at 2 to 10 years [4, 10, 27, 29, 44, 48] in conventional TKA, and concerns have therefore been raised about the high incidence of early aseptic loosening in HF designs [7, 17]. However, a number of clinical studies reporting 25 to 259 knees [3, 8, 20, 24–26] have suggested conflicting findings with only a few instances of prosthesis-related failures after HF TKA at mean followups of 12 to 51 months even in the same ethnic group [5, 20, 24–26, 41]. The risk of early aseptic loosening after HF TKA in large cohort studies is unclear.

We therefore determined (1) the rate of achieving postoperative HF more than 135°; (2) whether the aseptic failure rate is high after HF TKA; and (3) whether the survivorship deteriorated in Korean patients who achieved postoperative deep knee flexion more than 135° after HF TKA.

Patients and Methods

From May 2003 to January 2010, we performed a total of 854 primary TKAs in 610 patients (47 men and 563 women) with a mean age of 68 years (range, 47–84 years). There were 366 unilateral and 244 bilateral procedures performed 1 to 2 weeks apart. The indications for TKA were disabling knee pain on walking despite nonoperative treatment and advanced arthritic change with complete joint space loss on standing radiographs. Osteonecrosis with subchondral collapse of a femoral condyle was also indicated. The contraindications were active infection, poor skin condition, collateral ligamentous insufficiency, which needs a more constrained prosthesis, neurologic deficit making the patient unable to walk, insufficient extensor mechanism, and poor general condition for the operation. During the study period, we used no other design of TKA until May 2007 and, thereafter, we performed TKAs with the HF design in 239 and other designs in 243 without any specific selection. From the 610 patients, we excluded four with a history of surgery on the affected side, including high tibial osteotomy and internal fixation for fracture, or of knee infections from the study; we also excluded two patients (three knees) who died before the 2-year followup and 107 patients (149 knees) who were not followed for at least 2 years after surgery from the analysis of function and radiographic assessments, but all 610 were included in the survival analysis and reporting of complications. Consequently, 488 patients (698 knees [82%]) remained for functional and radiographic evaluations. There were 40 males and 448 females with a mean age of 68 years (range, 47–85 years) at the time of operations. The mean body mass index was 27 kg/m² (range, 16–46 kg/m²). The preoperative diagnoses were 677 osteoarthritis (97%), 11 rheumatoid arthritis (1.6%), and 10 osteonecrosis of medial femoral condyles (1.4%). For patients followed for function, the minimum followup was 2 years (average, 4.7 years; range, 2–8.7 years). Twenty-seven patients (34 knees) died after 2-year followup. One hundred two patients (152 knees) who did not attend the clinic more than 2 years after the latest visit were considered as lost to followup and for these patients, the data at the latest visit were used for the functional and radiographic assessment. No patients were recalled specifically for this study; all data were obtained from medical records and radiographs. The study was approved by our institutional review board.

Preoperative full-length AP films showing hips, knees, and ankles were obtained and used to determine the mechanical axis, the femoral guide axis angle, the angle of the femoral and tibial cuts, the amount of femoral and tibial bone cut, and the desired position of the entry hole for the intramedullary guide. This position would make a perpendicular cut to the mechanical axis without causing

impaction of the guide rod against the intramedullary cortex.

All surgeries were performed by the senior author (SIB) using the NexGen® LPS-Flex system (Zimmer, Inc, Warsaw, IN, USA). We made an anterior midline skin incision with a medial parapatellar incision. Distal femoral bone was first resected using an intramedullary guide, and AP cutting was performed using an anterior referencing system. The femoral component was placed in 3° or 5° of external rotation relative to the posterior condylar axis, which was confirmed by Whiteside's line. We resected the posterior cruciate ligament in all cases. Tibial preparation was then undertaken using an intramedullary tibial guide with a cutting block with 7° of posterior slope as recommended by the manufacturer. We resected 10 mm of tibial bone to obtain a surface that was perpendicular to the shaft of the tibia in the coronal plane. Stability and alignment were assessed using the trial components and ligament balancing was performed. We performed thorough pulsatile lavage to clear the bone cut surface and remove remaining blood clot and debris before cementing. All implants were cemented with Osteobond (Zimmer, Inc) after drying of the cut surface and pressurization of the cement. The tibial component was fully cemented in a doughy state. For femoral fixation, we placed cement on the femoral cut surface for the anterior flange and on the inner aspect of the component before impaction to the femur. Patellar resurfacing was not performed in all knees, except for two that had rheumatoid arthritis.

Immediately after surgery, we instructed patients to perform quadriceps-strengthening exercises and straight leg-raising exercises. On the second postoperative day, the drain was removed and the patients began weightbearing as tolerated with a walker under supervision of a clinical nurse specialist (YHK). Additionally, a continuous passive motion machine was used for passive movement exercises two times a day for 30 minutes each. Patients received no other physiotherapy by a physical therapist. Patients were discharged 10 to 12 days after surgery. Although sitting crosslegged on the floor was allowed, weightbearing deep flexion activities such as squatting and kneeling were discouraged for 1 year. Although weightbearing flexion was allowed as tolerated after that, we did not recommend doing often such activity that may produce excessive load on the prosthesis.

All patients were followed 1 month after discharge (6 weeks postoperatively) with weightbearing AP, lateral, and skyline patellar radiographs and clinical examinations were done to assess joint swelling, extensor strength, and ROM. Passive motion exercise was encouraged until 6 months followup. At the 1-year postoperative visit, a clinical nurse specialist (YHK) obtained the Hospital for Special Surgery (HSS) knee score [19] and one orthopaedic surgeon

(SIB) recorded passive ROM measured to the nearest 5° with a goniometer. Maximum flexion was taken as the angle at which the patient felt slight pain on knee bending. The HSS score and ROM were assessed at every 1- or 2-year postoperative visit with radiographic images, which were taken with the following views: weightbearing AP, lateral, and skyline patellar views. Major complications were recorded that affected the longevity of the prosthesis or may need additional surgical intervention [11] such as deep infection, loosening, osteolysis, instability, wear, patellofemoral problems, and periprosthetic fractures.

Two of us (BSL, JWC) assessed RLLs on standing AP and lateral views based on initial postoperative films according to the Knee Society roentgenographic evaluation system [13]. Signs of component loosening were a RLL more than 2 mm wide that extended under the entire prosthesis and progressive widening of the cement-bone or cement-prosthesis interface when a radiolucent gap exceeded 2 mm wide [15]. Tibial component tilting with subsidence was also considered loosening. Nonprogressive RLLs less than 2 mm that did not progress were not considered loosening. The kappa interobserver reproducibility for radiographic evaluation was 0.72, which indicated fair agreement [2]. The radiolucency and loosening of the component were decided by consensus through discussions by two observers.

Data are presented as mean $\pm$ SD. Student's paired t-tests were used to determine the difference between preoperative and postoperative values of all continuous outcome variables (HSS score, flexion contracture, maximum flexion, and ROM). To analyze the effects of the maximum postoperative flexion and the rate of achieving high flexion more than 135°, we grouped patients according to the maximum preoperative flexion ($\leq 110^\circ$; 105° – 115° ; 120° – 130° ; $\geq 135^\circ$), because this is known as a most predictable factor for postoperative flexion [28, 37] and flexion gain may be different according to preoperative flexion [3, 16, 30]. To determine the knee survival for aseptic loosening, we used the life-table method for all patients [12]. The end point event was a progressive RLL > 2 mm or tibial component migration with subsidence, which was considered as aseptic loosening. Patients who died or were lost to followup were considered to have withdrawn at their latest followup visit. Patients who sustained periprosthetic or patella fracture or infections were also considered to have withdrawn at their latest followup visit. Additionally, with the assumption that the lost patients would have aseptic failures, we performed a survival analysis as a worst-case scenario. We assessed whether the survivorship deteriorated in patients who achieved postoperative HF. This secondary survival analysis was done for patients followed a minimum of 2 years whose maximum flexion was analyzed. A Wilcoxon

Gehan's test was used to compare the overall survival rate between knees that achieved HF (maximum flexion $\geq 135^\circ$) and those did not at the last followup. We performed statistical analysis using SPSS software (SPSS for Windows release 16.0; SPSS, Chicago, IL, USA).

Results

Three hundred sixty knees (52%) could achieve HF ability of 135° or more. All passive knee motions improved from preoperative to last followup: flexion contracture from a mean of 9.3° to 0.9° ($p < 0.001$), mean maximum flexion from 130.3° to 133.1° ($p < 0.001$), and mean ROM from 120.9° to 132.2° ($p < 0.001$). The knees with preoperative flexion $< 135^\circ$ gained flexion ($p < 0.001$) postoperatively. Knees with maximum preoperative flexion $\geq 135^\circ$ showed a decrement ($p < 0.001$) in mean flexion angle from 143.2° preoperatively to 135.6° at last followup despite the rate of achieving high flexion (62%) was the most among the subgroups (Table 1). The HSS score improved ($p = 0.013$) from a mean of 60 preoperatively to 93 at last followup.

The aseptic failure was low. Early aseptic loosening occurred in six knees in five patients (three femoral and three tibial). In three knees (0.4%) from two patients, progressive RLLs more than 2 mm on the lateral radiographs were observed underneath the anterior flange of femoral components (Fig. 1) at a mean of 23 months (range, 19–29 months). However, these two patients with femoral loosening chose not to undergo revision surgery despite our recommendation. Three patients had tibial subsidence with varus collapse without femoral component loosening (found at a mean of 48 months; range, 24–66 months), all of whom underwent revision of the tibial component. All of these six knees with aseptic loosening were considered aseptic failures regardless of revision for survivorship analysis.

There was no deterioration in the survivorship of patients who achieved deep flexion compared with those

who did not. Among six aseptic failures, three knees (one femoral, two tibial) had maximum flexion $< 135^\circ$ and the other three knees (two femoral, one tibial) had maximum flexion $\geq 135^\circ$ at last followup. The overall survival for aseptic failure did not differ ($p = 0.924$) between the two groups (Table 2). Across all 610 patients (854 knees), the survivorship for aseptic loosening at 5 years was 99.1% (95% CI, 98.3–99.9) (Fig. 2). In the worst-case scenario, the cumulative survival at 5 years was 76.8% (95% CI, 73.7–79.8). Nonprogressive femoral RLLs less than 2 mm were observed in 12 knees; there were 10 knees (1.3%) showing femoral RLLs (eight knees in Zone 1, one in Zone 4, one in Zones 1 and 4) on the lateral radiographs. These were first identified at a mean of 19 months postoperatively (range, 5–67 months). There were two knees from a single bilateral case that had tibial RLLs less than 2 mm in Zone 1 at 35 months. None progressed thereafter and these patients did not present with any disabling pain or knee instability.

There were 19 major complications in 19 knees. Thirteen patients had late infections diagnosed between 11 and 76 months postoperatively: six underwent two-stage revision for deep infection; three could not undergo surgical intervention as a result of medical problems; and four were managed in another hospital. Periprosthetic supracondylar fracture of the femur occurred in three cases and was treated successfully with open reduction and internal fixation. Three patella fractures occurred: one was managed conservatively and two required internal fixation. No revision surgery was performed for instability, polyethylene wear, or patellofemoral problems.

Discussion

Although HF prostheses were designed for safe deep flexion, two studies from Korea reported a high incidence of premature radiographic femoral component failure of 38% and 13.8% after HF TKA [7, 17]. They suggested that these implants allowed HF activity such as squatting or kneeling

Table 1. Pre- and postoperative maximum flexion values for knees followed at least 2 years ($n = 698$) and split into groups according to preoperative flexion

Preoperative flexion group boundaries	Number	Preoperative flexion ($^\circ$)	Postoperative flexion ($^\circ$)	p value	Postoperative flexion group membership; number (%)			
					$\leq 100^\circ$	105° – 115°	120° – 130°	$\geq 135^\circ$
$\leq 100^\circ$	69	95.8 ± 6.8	126.7 ± 15.0	< 0.001	6 (8.7)	9 (13.0)	28 (40.6)	26 (37.7)
105° – 115°	53	110.2 ± 2.2	131.7 ± 12.7	< 0.001	2 (3.8)	6 (11.3)	20 (37.7)	25 (47.2)
120° – 130°	228	125.9 ± 4.5	131.7 ± 10.2	< 0.001	2 (0.9)	11 (4.8)	120 (52.6)	95 (41.7)
$\geq 135^\circ$	348	143.3 ± 6.8	135.6 ± 11.0	< 0.001	5 (1.4)	7 (2.0)	122 (35.1)	214 (61.5)
Total	698	130.4 ± 16.5	133.2 ± 11.7	< 0.001	15 (2.1)	33 (4.7)	290 (41.5)	360 (51.6)

Mean $\pm$ SD. Postoperative measurements were taken at final followup.

Fig. 1A–C Lateral radiographs showing femoral component loosening 6 weeks (**A**), 26 months (**B**), and 35 months (**C**) after the operation. Note the radiolucent lines around the anterior and posterior

flanges at 26 months. At 35 months postoperatively, the radiolucent lines were widened more than 2 mm suggesting aseptic loosening.

Table 2. Survival table for aseptic failures split according to maximum postoperative flexion on patients followed a minimum of 2 years (n = 698)

Maximum postoperative flexion	Time interval (years)	Number entering interval	Withdrawal	Number exposed to risk	Failures	Cumulative survival (%)	SE of cumulative survival
< 135°	0–1	338	0	338.0	0	1.00	0.00
	1–2	338	0	338.0	0	1.00	0.00
	2–3	338	76	300.0	2 (1 F, 1 T)	0.99	0.00
	3–4	260	54	233.0	0	0.99	0.00
	4–5	206	53	179.5	0	0.99	0.00
	5–6	153	59	123.5	1 (T)	0.99	0.01
	6–7	93	48	69.0	0	0.99	0.01
	7–8	45	35	27.5	0	0.99	0.01
	> 8	10	10	5.0	0	0.99	0.01
≥ 135°	0–1	360	0	360.0	0	1.00	0.00
	1–2	360	0	360.0	2 (F)	0.99	0.00
	2–3	358	70	323.0	0	0.99	0.00
	3–4	288	55	260.5	0	0.99	0.00
	4–5	233	75	195.5	1 (T)	0.99	0.01
	5–6	157	65	124.5	0	0.99	0.01
	6–7	92	55	64.5	0	0.99	0.01
	7–8	37	33	20.5	0	0.99	0.01
	> 8	4	4	2.0	0	0.99	0.01

F = femoral component failure; T = tibial component failure.

but which might be associated with a marked rate of early loosening of the femoral component. In contrast, other studies involving HF TKA have reported conflicting prevalences of early aseptic loosening even in the same ethnic group [18, 25, 26, 39, 40, 43, 50]. We therefore determined (1) how many patients could achieve HF ability postoperatively; (2) whether the rate of aseptic loosening was high after HF TKA; and (3) whether the survivorship was inferior

in patients who achieved postoperative deep knee flexion more than 135° in our cohort of a Korean population.

Our study had several limitations. First, because we did not compare the outcomes from HF and conventional prostheses, we cannot determine if the observed outcomes are superior to those that would be achieved with conventional prostheses. Second, the uniform use of one HF fixed-bearing prosthesis by a single surgeon suggests our

Fig. 2 Survival curve for aseptic failures as end points in all patients ($n = 854$) with confidence interval (broken lines). The survival at 5 years for aseptic loosening was 99.1%.

findings might not be generalizable to low-volume surgeons or those using other HF prostheses such as cruciate-retaining or mobile-bearing designs. Third, although the high proportion of females in our cohort is typical of Korean patients undergoing TKA [5, 20, 25, 26, 41], this also reduces the extent to which our results can be generalized. Fourth, the followup period of 4.7 years (range, 2–8 years) will not likely reflect the ultimate incidence of prosthesis-related loosening because it will almost certainly increase during further followup of our cohort, although 63% of early aseptic loosening requiring revision occurred within 2 years of followup in another study [36]. Finally, the postoperative radiographs used in our study were not fluoroscopically controlled to assess RLLs and, as such, there may have been unrecognized RLLs.

At the last followup, we observed half of all cases could achieve maximum flexion of at least 135° . Patients with high preoperative flexion ($> 135^\circ$) had more chances of achieving HF showing the highest rate (62%) than those who did not. However, they experienced a decrease in the mean maximum flexion they could achieve. This is similar to previous reports that Western patients with more than 120° of preoperative flexion experienced a decrease in flexion range [30, 46]. There is a tendency for better postoperative flexion after TKA performed in Asian countries [5, 7, 8, 17, 18, 20, 24–26, 34, 40, 41, 43, 45, 50] than after TKA performed in Western countries [1, 35, 39, 47, 49] (Table 3). The higher threshold in the present study (135° versus 120°) may be understood in the same context of higher postoperative flexion in an Asian population. We observed a mean HSS score of 91 and a mean knee flexion of 133° . However, it cannot be determined by the present study and it remains unclear whether HF designs improve

clinical ROM and function more than conventional implants [14, 31, 33].

We also observed a low incidence of early aseptic loosening (six of 698 [0.9%]) that is comparable to conventional implants [4, 10, 29, 44, 48]. The results of this study support several others reporting no or few loosening cases with the same HF prostheses [18, 25, 26, 39, 40, 43, 50] (Table 3). The present study extends these findings to a larger population with the same ethnicity than previous studies involving a small number of cases to address whether early femoral loosening of a HF design is really high. Remarkably, we also observed progressive femoral RLLs as evidence of aseptic loosening in early years, like previous studies [7, 17]. The femoral loosening was observed in only three of 698 cases (0.4%) in the present study. Such low incidence of femoral component loosening was also reported with conventional TKA in 0.35% with an average time to failure of 2 years [48] and in 0.9% (15 of 1600 knees) during 4 to 10 years followup [27], and therefore femoral component loosening cannot be regarded as a specific mode of failure in HF prostheses.

We found no survival difference for aseptic failure between knees that had more than or less than 135° of postoperative flexion. Two previous reports [7, 17] suggest an increased rate of early femoral loosening after HF TKA may be associated with postoperative deep flexion ability. One laboratory study suggested a greater risk for HF femoral component loosening may be attributable to the absence of femoral load-sharing between the prosthetic component and the condylar bone during deep flexion [6]. However, our cohort of Korean patients had conflicting findings in that the patients who could achieve postoperative deep flexion did not have inferior cumulative survival than those who had postoperative flexion less than 135° . Other clinical trials conducted in an Asian population reported a better survivorship with none or just one aseptic failure despite the higher postoperative flexion of 135° to 140° [18, 20, 25, 26, 43, 45] than ours.

Despite designing HF prostheses to accommodate HF activity, concern about premature component loosening after HF TKA has grown among the orthopaedic surgeons since high premature failures were reported by two studies in Asian population [7, 17]. However, we observed a low incidence (0.9%) of early aseptic loosening in a larger cohort of the same ethnicity supporting many other clinical studies reporting rare incidence of aseptic failures in HF prostheses. Moreover, clinical outcomes were good with half of all cases able to achieve deep flexion of 135° or more, which did not worsen the survivorship for aseptic loosening. Our data suggest there is no necessity to have a negative view of the longevity of HF implants up to 5 years although we cannot comment on the long-term durability.

Table 3. Summary of literature on flexion angle and aseptic loosening rate after TKA with LPS- Flex prostheses (sorted in the order of mean followup on Asian and Western population)

Study	Country	Population	Implant type	Number of knees	Mean followup (months)	Mean preoperative flexion (°)	Mean postoperative flexion (°)	Aseptic loosening rate (number [%]) [†]
Bin and Nam [5]	Korea	Asian	Fixed	90	12	123	130	0
Kim et al. [23]	Korea	Asian	Fixed	34	15	118 (ROM)	130 (ROM)	0
Kim et al. [26]	Korea	Asian	Fixed	50	25	127	139	0
Kim et al. [24]	Korea	Asian	Fixed	85	26	120 (ROM)	125 (ROM)	0
Seon et al. [41]	Korea	Asian	Fixed	47	27	129	130	NA
Huang et al. [18]	Taiwan	Asian	Fixed	25	28	110	138	0
Choi et al. [8]	Korea	Asian	Mobile	85	28	126*	128*	0
Kim et al. [25]	Korea	Asian	Fixed	250	28	123	135	0
Han et al. [17]	Korea	Asian	Fixed	72	32	121	132	27 (38%)
Ng et al. [34]	Hong Kong	Asian	Fixed	35	35	104	105	NA
Kim et al. [20]	Korea	Asian	Fixed	259	46	122	135	1 (0.4%)
Cho et al. [7]	Korea	Asian	Fixed	218	51	117	131	30 (13.8%)
Yagishita et al. [50]	Japan	Asian	Fixed	29	60	137	129	0
Seng et al. [40]	Malaysia	Asian	Fixed	41	60	123	128	0
Tarabichi et al. [45]	UAE	Asian	Mobile	218	60	125	140	1 (0.5%)
Tanavalee et al. [43]	Thailand	Asian	Fixed	156	77	138	135	0
Ahmed et al. [1]	UK	Western	Fixed	28	12	108	110	NA
Weeden and Schmidt [47]	US	Western	Fixed	25	12	120	133	0
Nutton et al. [35]	UK	Western	Fixed	28	12	108*	110*	NA
Scuderi et al. [39]	US	Western	Mobile	149	24	115	127	1 (0.7%)
Scuderi et al. [39]	US	Western	Fixed	139	24	115	128	0
Wohlrab et al. [49]	Germany	Western	Mobile	30	66	106	117	1 (3%)
Current study	Korea	Asian	Fixed	698	58	130	133	6 (0.9%)

* Active flexion; [†]progressive radiolucency more than 2 mm is considered aseptic loosening; NA = not available.

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References

- Ahmed I, Gray AC, van der Linden M, Nutton R. Range of flexion after primary TKA: the effect of soft tissue release and implant design. *Orthopedics*. 2009;32:811.
- Bach CM, Biedermann R, Goebel G, Mayer E, Rachbauer F. Reproducible assessment of radiolucent lines in total knee arthroplasty. *Clin Orthop Relat Res*. 2005;434:183–188.
- Bauman RD, Johnson DR, Menge TJ, Kim RH, Dennis DA. Can a high-flexion total knee arthroplasty relieve pain and restore function without premature failure? *Clin Orthop Relat Res*. 2012;470:150–158.
- Bertin KC. Cruciate-retaining total knee arthroplasty at 5 to 7 years followup. *Clin Orthop Relat Res*. 2005;436:177–183.
- Bin SI, Nam TS. Early results of high-flex total knee arthroplasty: comparison study at 1 year after surgery. *Knee Surg Sports Traumatol Arthrosc*. 2007;15:350–355.
- Bollars P, Luyckx JP, Innocenti B, Labey L, Victor J, Bellemans J. Femoral component loosening in high-flexion total knee replacement: an in vitro comparison of high-flexion versus conventional designs. *J Bone Joint Surg Br*. 2011;93:1355–1361.
- Cho SD, Youm YS, Park KB. Three- to six-year follow-up results after high-flexion total knee arthroplasty: can we allow passive deep knee bending? *Knee Surg Sports Traumatol Arthrosc*. 2011;19:899–903.
- Choi WC, Lee S, Seong SC, Jung JH, Lee MC. Comparison between standard and high-flexion posterior-stabilized rotating-platform mobile-bearing total knee arthroplasties: a randomized controlled study. *J Bone Joint Surg Am*. 2010;92:2634–2642.
- D'Lima DD, Steklov N, Fregly BJ, Banks SA, Colwell CW Jr. In vivo contact stresses during activities of daily living after knee arthroplasty. *J Orthop Res*. 2008;26:1549–1555.
- Dalury DF, Gonzales RA, Adams MJ, Gruen TA, Trier K. Midterm results with the PFC Sigma total knee arthroplasty system. *J Arthroplasty*. 2008;23:175–181.
- Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg*. 2004;240:205–213.
- Dobbs HS. Survivorship of total hip replacements. *J Bone Joint Surg Br*. 1980;62:168–173.
- Ewald FC. The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system. *Clin Orthop Relat Res*. 1989;248:9–12.

14. R, Tso P, Davey JR, Mahomed NN. High-flexion implants in primary total knee arthroplasty: a meta-analysis. *Knee*. 2009;16:14–17.
15. Gonzalez MH, Mekhail AO. The failed total knee arthroplasty: evaluation and etiology. *J Am Acad Orthop Surg*. 2004;12:436–446.
16. Gupta SK, Ranawat AS, Shah V, Zikria BA, Zikria JF, Ranawat CS. The PFC Sigma RP-F TKA designed for improved performance: a matched-pair study. *Orthopedics*. 2006;29:S49–52.
17. Han HS, Kang SB, Yoon KS. High incidence of loosening of the femoral component in legacy posterior stabilised-flex total knee replacement. *J Bone Joint Surg Br*. 2007;89:1457–1461.
18. Huang HT, Su JY, Wang GJ. The early results of high-flex total knee arthroplasty: a minimum of 2 years of follow-up. *J Arthroplasty*. 2005;20:674–679.
19. Insall JN, Ranawat CS, Aglietti P, Shine J. A comparison of four models of total knee-replacement prostheses. *J Bone Joint Surg Am*. 1976;58:754–765.
20. Kim TH, Lee DH, Bin SI. The NexGen LPS-flex to the knee prosthesis at a minimum of three years. *J Bone Joint Surg Br*. 2008;90:1304–1310.
21. Kim TK, Chang CB, Kang YG, Kim SJ, Seong SC. Causes and predictors of patient's dissatisfaction after uncomplicated total knee arthroplasty. *J Arthroplasty*. 2009;24:263–271.
22. Kim TK, Kwon SK, Kang YG, Chang CB, Seong SC. Functional disabilities and satisfaction after total knee arthroplasty in female Asian patients. *J Arthroplasty*. 2010;25:458–464.
23. Kim TW, Park SH, Suh JT. Comparison of mobile-bearing and fixed-bearing designs in high flexion total knee arthroplasty: using a navigation system. *Knee Surg Relat Res*. 2012;24:25–33.
24. Kim YH, Choi Y, Kim JS. Comparison of a standard and a gender-specific posterior cruciate-substituting high-flexion knee prosthesis: a prospective, randomized, short-term outcome study. *J Bone Joint Surg Am*. 2010;92:1911–1920.
25. Kim YH, Choi Y, Kwon OR, Kim JS. 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. *J Bone Joint Surg Am*. 2009;91:753–760.
26. Kim YH, Sohn KS, Kim JS. Range of motion of standard and high-flexion posterior stabilized total knee prostheses. A prospective, randomized study. *J Bone Joint Surg Am*. 2005;87:1470–1475.
27. King TV, Scott RD. Femoral component loosening in total knee arthroplasty. *Clin Orthop Relat Res*. 1985;194:285–290.
28. Kotani A, Yonekura A, Bourne RB. Factors influencing range of motion after contemporary total knee arthroplasty. *J Arthroplasty*. 2005;20:850–856.
29. Lee BS, Lee SJ, Kim JM, Lee DH, Cha EJ, Bin SI. No impact of severe varus deformity on clinical outcome after posterior stabilized total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc*. 2011;19:960–966.
30. Massin P, Dupuy FR, Khelifi H, Fornasieri C, De Polignac T, Schiffrine P, Farenq C, Mertil P. Does hyperflex total knee design improve postoperative active flexion? *Orthop Traumatol Surg Res*. 2010;96:376–380.
31. Mehini R, Burnett RS, Brasher PM. Does the new generation of high-flex knee prostheses improve the post-operative range of movement? A meta-analysis. *J Bone Joint Surg Br*. 2010;92:1429–1434.
32. Mulholland SJ, Wyss UP. Activities of daily living in non-Western cultures: range of motion requirements for hip and knee joint implants. *Int J Rehabil Res*. 2001;24:191–198.
33. Murphy M, Journeaux S, Russell T. High-flexion total knee arthroplasty: a systematic review. *Int Orthop*. 2009;33:887–893.
34. Ng FY, Wong HL, Yau WP, Chiu KY, Tang WM. Comparison of range of motion after standard and high-flexion posterior stabilised total knee replacement. *Int Orthop*. 2008;32:795–798.
35. Nutton RW, van der Linden ML, Rowe PJ, Gaston P, Wade FA. A prospective randomised double-blind study of functional outcome and range of flexion following total knee replacement with the NexGen standard and high flexion components. *J Bone Joint Surg Br*. 2008;90:37–42.
36. Piedade SR, Pinaroli A, Servien E, Neyret P. Revision after early aseptic failures in primary total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc*. 2009;17:248–253.
37. Ritter MA, Harty LD, Davis KE, Meding JB, Berend ME. Predicting range of motion after total knee arthroplasty. Clustering, log-linear regression, and regression tree analysis. *J Bone Joint Surg Am*. 2003;85:1278–1285.
38. Rowe PJ, Myles CM, Walker C, Nutton R. Knee joint kinematics in gait and other functional activities measured using flexible electrogoniometry: how much knee motion is sufficient for normal daily life? *Gait Posture*. 2000;12:143–155.
39. Scuderi GR, Hedden DR, Maltry JA, Traina SM, Sheinkop MB, Hartzband MA. Early clinical results of a high-flexion, posterior-stabilized, mobile-bearing total knee arthroplasty: a US investigational device exemption trial. *J Arthroplasty*. 2012;27:421–429.
40. Seng C, Yeo SJ, Wee JL, Subanesh S, Chong HC, Lo NN. Improved clinical outcomes after high-flexion total knee arthroplasty: a 5-year follow-up study. *J Arthroplasty*. 2011;26:1025–1030.
41. Seon JK, Park JK, Shin YJ, Seo HY, Lee KB, Song EK. Comparisons of kinematics and range of motion in high-flexion total knee arthroplasty: cruciate retaining vs substituting designs. *Knee Surg Sports Traumatol Arthrosc*. 2011;19:2016–2022.
42. Sharma A, Komistek RD, Scuderi GR, Cates HE Jr. High-flexion TKA designs: what are their in vivo contact mechanics? *Clin Orthop Relat Res*. 2007;464:117–126.
43. Tanavalee A, Ngarmukos S, Tantavisut S, Limtrakul A. High-flexion TKA in patients with a minimum of 120 degrees of pre-operative knee flexion: outcomes at six years of follow-up. *Int Orthop*. 2011;35:1321–1326.
44. Tanzer M, Smith K, Burnett S. Posterior-stabilized versus cruciate-retaining total knee arthroplasty: balancing the gap. *J Arthroplasty*. 2002;17:813–819.
45. Tarabichi S, Tarabichi Y, Hawari M. Achieving deep flexion after primary total knee arthroplasty. *J Arthroplasty*. 2010;25:219–224.
46. Victor J, Ries M, Bellemans J, Robb WM, Van Hellemond G. High-flexion, motion-guided total knee arthroplasty: who benefits the most? *Orthopedics*. 2007;30:77–79.
47. Weeden SH, Schmidt R. A randomized, prospective study of primary total knee components designed for increased flexion. *J Arthroplasty*. 2007;22:349–352.
48. Windsor RE, Scuderi GR, Moran MC, Insall JN. Mechanisms of failure of the femoral and tibial components in total knee arthroplasty. *Clin Orthop Relat Res*. 1989;248:15–19; discussion 19–20.
49. Wohlrab D, Hube R, Zeh A, Hein W. Clinical and radiological results of high flex total knee arthroplasty: a 5 year follow-up. *Arch Orthop Trauma Surg*. 2009;129:21–24.
50. Yagishita K, Muneta T, Ju YJ, Morito T, Yamazaki J, Sekiya I. High-flex posterior cruciate-retaining vs posterior cruciate-substituting designs in simultaneous bilateral total knee arthroplasty: a prospective, randomized study. *J Arthroplasty*. 2012;27:368–374.