

Comparison of Revision Rates Due to Aseptic Loosening between High-Flex and Conventional Knee Prostheses

Young-Joon Choi, MD, Ki Won Lee, MD, Jung-Ki Ha, MD, Joo-Yul Bae, MD, Suk Kyu Lee, MD, Sang-Bum Kim, MD, and Dong-Kyo Seo, MD

Department of Orthopaedic Surgery, Gangneung Asan Hospital, University of Ulsan College of Medicine, Gangneung, Korea

Purpose: The purpose was to evaluate and compare the revision rate due to aseptic loosening between a high-flex prosthesis and a conventional prosthesis.

Materials and Methods: Two thousand seventy-eight knees (1,377 patients) with at least 2 years of follow-up after total knee arthroplasty were reviewed. Two types of implants were selected (LPS-Flex and LPS, Zimmer) to compare revision and survival rates and sites of loosened prosthesis component.

Results: The revision rate of the LPS-Flex (4.9%) was significantly higher than that of the conventional prosthesis (0.6%) ($p < 0.001$). The 5-, 10-, and 15-year survival rates were 98.9%, 96.2% and 92.0%, respectively, for the LPS-Flex and 99.8%, 98.5% and 93.5%, respectively, for the LPS. The survival rate of the high-flex prosthesis was significantly lower than that of the conventional prosthesis, especially in the mid-term period (range, 5 to 10 years; $p = 0.002$). The loosening rate of the femoral component was significantly higher in the LPS-Flex prosthesis ($p = 0.001$).

Conclusions: The LPS-Flex had a higher revision rate due to aseptic loosening than the LPS prosthesis in the large population series with a long follow-up. The LPS-Flex should be used carefully considering the risk of femoral component aseptic loosening in the mid-term (range, 5 to 10 years) follow-up period after initial operation.

Keywords: Knee, Arthroplasty, Revision, Aseptic loosening, High-Flex prosthesis, Femoral component

Introduction

Total knee arthroplasty (TKA) is an effective method of treating end-stage arthritis of the knee. The main goal of treatment is to relieve pain and achieve functional improvement such as range of motion (ROM). A conventional TKA prosthesis was designed to achieve up to 90°–120° degrees of ROM during daily activity^{1,2}.

Received September 21, 2017; Revised (1st) December 28, 2017;

(2nd) January 24, 2018; Accepted January 29, 2018

Correspondence to: Dong-Kyo Seo, MD

Department of Orthopaedic Surgery, Gangneung Asan Hospital,
University of Ulsan College of Medicine, 38 Bangdong-gil, Sacheon-
myeon, Gangneung 25440, Korea

Tel: +82-33-610-3240, Fax: +82-33-641-8050

E-mail: dongkyoseo@gmail.com

However, further ROM is needed to satisfy functional demand; for example, for kneeling, squatting, and sitting cross-legged, which require greater flexion. Therefore, a high-flex prosthesis (HFP) was developed to increase knee flexion angle up to approximately 150° and to improve quality of life³⁻⁶.

The result of the HFP about aseptic loosening is debatable. Some studies reported that there were no differences between the conventional prosthesis and the HFP⁷⁻¹¹. However, several reports raised concerns regarding the aseptic loosening of the HFP¹²⁻¹⁵. Our hypothesis was that the HFP was more susceptible to revision surgery due to aseptic loosening. The purpose of this study was to evaluate and compare the rate of revision surgery and its causes between two prostheses in a large study population operated by one surgeon.

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/4.0/>) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

Materials and Methods

1. Patient Selection

To compare high-flex and conventional prostheses, two types of total knee implants were selected in this study: LPS-Flex (Zimmer, Warsaw, IN, USA) as a high-flex (case) prosthesis and LPS (Zimmer) as a conventional (control) prosthesis. From February 2000 to November 2013, 3,096 knees (1,769 patients) underwent TKA using either the LPS or LPS-Flex, performed by one surgeon. A retrospective case-control study was designed. An Institutional Review Board approved this study.

2. Operative Methods

The medial parapatellar approach was used in all cases. In most cases, bone cutting was made on the proximal tibia first. For the LPS-Flex, 2 mm more cutting of the posterior femoral condyle was done, and the other aspects of the procedure was the same for both prostheses. The flexion gap was measured, and the size of a femoral component was decided with consideration of not only the actual size of the distal femur but also the flexion gap. Bone cement was used for fixation on both the femur and tibia in all cases. In the femur, cement was applied onto the distal and anterior aspects of the bone and posterior aspect of the prosthesis. Manual pressurization was applied (Fig. 1). Patella resurfacing was done in all cases.

3. Postoperative Rehabilitation

Continuous passive motion exercises were executed on the first day after the initial operation. Straight leg raising exercise was recommended on the bed. Weight bearing walk was initiated on postoperative day 2. All patients were discharged in the postoperative week 2.

After excluding patients who were lost to follow-up (718 knees,

392 patients), postoperative results of 2378 knees (1,377 patients) were reviewed. A plain radiograph was obtained immediately after the primary TKA, and 2 weeks, 3 months, and 1 year after TKA. Sequential plain radiographs (whole lower leg standing view and knee anterior-posterior, lateral, and skyline views) were obtained annually thereafter. Diagnosis of aseptic loosening was made based on follow-up consecutive plain radiographs when a progressive radiolucent line (more than 2 mm wide) was seen in any zone of the component (Fig. 2)^{16,17}. Also, the loosening was confirmed intraoperatively (Fig. 3). Revision surgery for aseptic loosening was performed when the patient consented to the revision operation because of pain interfering with activities of daily living. Demographic characteristics as well as following information were investigated and compared: preoperative and postoperative ROM, Knee Society knee score and functional score, revision and survival rates, and loosening of the prosthesis component.

4. Statistical Analysis

The demographic data, preoperative and postoperative ROM, Knee Society knee score and functional score, and revision rates were evaluated using Student *t*-test. The Kaplan-Meier survival analysis was used to assess the survival rate. Fisher exact test was used for the comparison of loosened prosthesis component. Statistical analysis was performed using the IBM SPSS ver. 21.0 (IBM Corp., Armonk, NY, USA). Statistical significance was set at $p < 0.05$.

Results

There were no significant statistical differences between the two groups regarding the demographic parameters, both preoperative and postoperative total arc of knee motion, and Knee Society

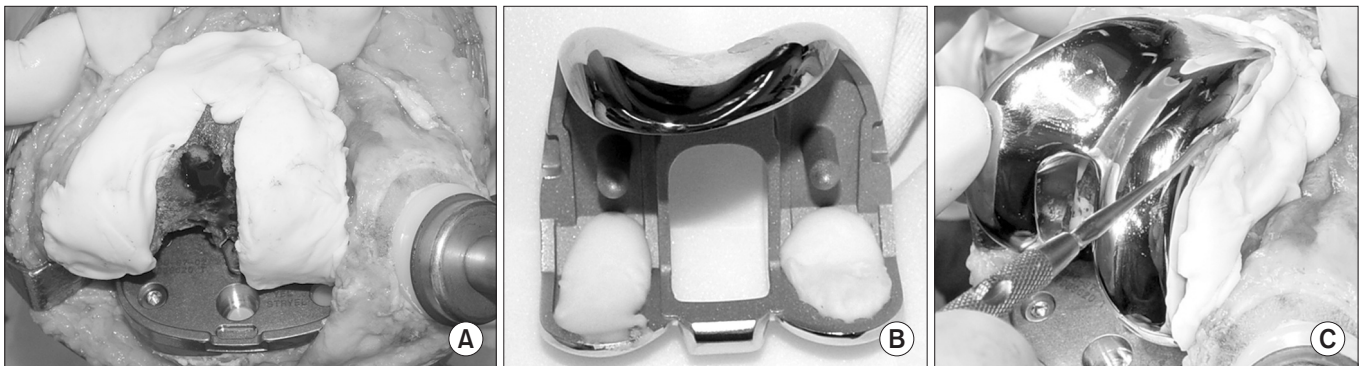


Fig. 1. Cementing technique for the femoral component. Cement was applied onto the distal and anterior aspects of the distal femur (A) and posterior aspect of the femoral implant (B), and manual pressurization was applied (C).

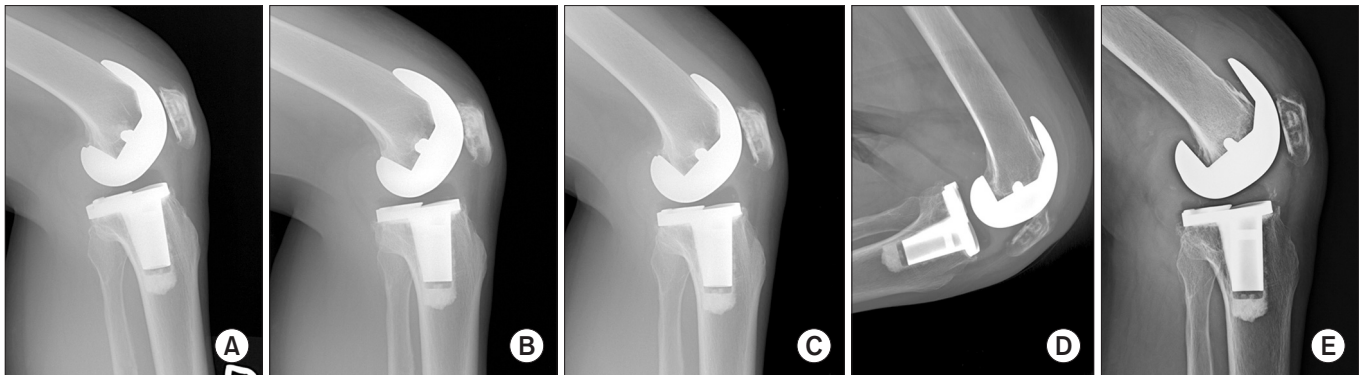


Fig. 2. Sequential plain lateral radiographs of the right knee after the initial total knee arthroplasty. No abnormal findings were seen 1 year postoperatively (A) and until 4 years postoperatively (B). A small radiolucent line was seen on the anterior aspect of the distal femur 7 years postoperatively (C). Ten years postoperatively, the distal anterior gap became wider than before. The anterior gap also became wider, and the posterior gap was seen (D). Osteolysis of the distal femur caused the implant to hang over the bone 11 years postoperatively (E).

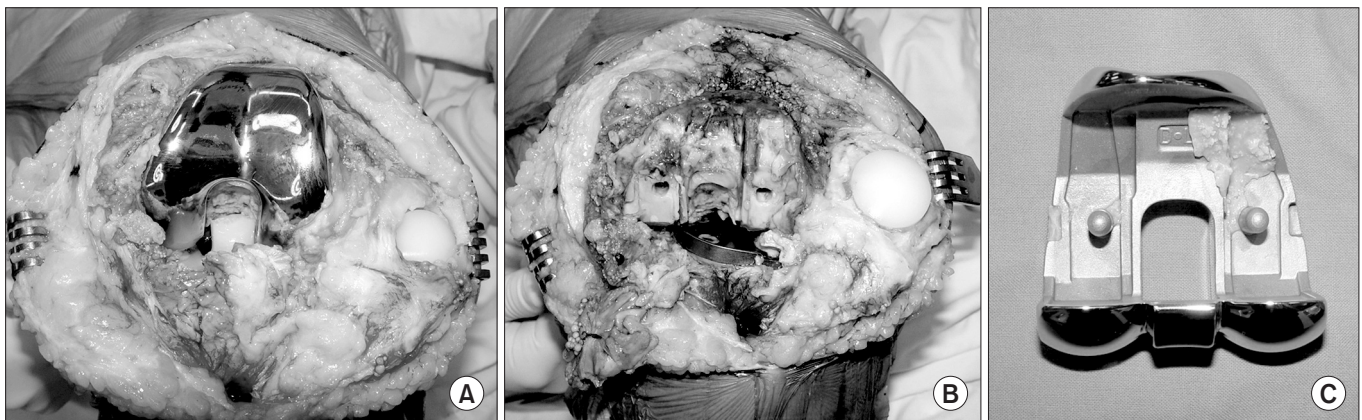


Fig. 3. Intraoperative findings in revision surgery: synovial hypertrophy beyond prosthesis (A) and debonding of cement (B, C) were seen.

knee score and function score. However, the follow-up period was longer in the LPS-Flex group significantly ($p < 0.001$) (Table 1).

Two orthopedic surgeons reviewed the plain radiographs to analyze radiolucent lines. The Kappa coefficient (κ) was used to assess the interobserver reliability and intraobserver reproducibility. Kappa coefficients were interpreted according to Landis and Koch¹⁸⁾: 0.00–0.20, slight agreement; 0.21–0.40, fair; 0.41–0.60, moderate; 0.61–0.80, substantial; and 0.81–1.00, almost perfect). The results showed almost perfect agreement as the Kappa coefficient (κ) of interobserver reliability and intraobserver reproducibility were 0.979 and 0.993, respectively.

Total revision surgeries were performed in 67 knees (2.8%) out of 2,378 knees regardless of implants and causes. The detailed causes of revision surgeries are described in Table 2. Aseptic loosening was diagnosed in 54 knees, which was the most common cause of revision surgery in both prostheses: 52 knees were revised whereas two knees (one knee in each prosthesis) received

conservative treatment because they did not suffer discomfort in daily life. The mean revision rate due to aseptic loosening was 52 (2.1%) of 2,378 knees and all were women. The revision rate of the LPS-Flex group (4.9%) was significantly higher than that of the LPS group (0.6%) ($p < 0.001$). The other causes of revision did not show differences between the two types of prosthesis.

Kaplan-Meier survival analysis was done with revision due to aseptic loosening as the endpoint. The 5-, 10-, and 15-year survival rates with the aseptic loosening as the endpoint were 98.9%, 96.2% and 92.0%, respectively, for the LPS-Flex and 99.8%, 98.5% and 93.5%, respectively, for the LPS, respectively. In the LPS-Flex group, revision was performed in 9, 23, and 10 knees during each 5-year period. More than half (54.7%) of the LPS-Flex knees were revised during the mid-term (5- to 10-year) period. In the LPS group, 2, 4, and 4 knees underwent revision during each 5-year period. The survival rate of the LPS-Flex group with aseptic loosening as the endpoint was significantly lower than that of the LPS

Table 1. Comparison of Mean Demographic Values between the Two Groups

Variable	LPS-Flex group (n=851)	LPS group (n=1,512)	p-value
Sex (female/male)	0.92±0.25	0.93±0.24	0.73
Age (yr)	67.42±6.47	67.83±6.89	0.67
Height (m)	1.51±0.05	1.51±0.06	0.59
Weight (kg)	63.67±8.82	63.89±9.81	0.69
Body mass index (kg/m ²)	27.8±3.56	27.9±3.71	0.85
Follow-up (yr)	11.38±1.37 (2.0–14.5)	5.56±3.14 (2.0–16.1)	p<0.001
Total arc of knee motion (°)			
Preoperative	120 (75–148)	124 (80–150)	0.53
Final follow-up	132 (80–139)	134 (85–140)	0.72
Knee Society knee score			
Preoperative	43 (11–66)	40 (12–63)	0.75
Final follow-up	85 (58–95)	87 (63–98)	0.83
Knee Society functional score			
Preoperative	36 (20–55)	35 (15–60)	0.89
Final follow-up	72 (65–85)	74 (60–80)	0.81

Values are presented as mean±standard deviation (range).

Table 2. Revision Rates and Causes

Causes of revision	LPS-Flex	LPS	p-value
Aseptic loosening	42 (4.9)	10 (0.6)	52 (2.1)
Septic loosening	4 (0.5)	7 (0.4)	11 (0.4)
Polyethylene wear	1 (0.1)	1 (0.2)	2 (0.08)
Periprosthetic fracture	2 (0.2)	0 (0)	2 (0.08)
Total revised knees	49 (5.7)	18 (1.18)	67 (2.8)
Knees without revision	809 (94.3)	1,502 (98.8)	2,311 (97.2)
Total	858 (100)	1,520 (100)	2,378 (100)

Values are presented as number (%).

group (p=0.002) (Fig. 4), especially during the mid-term period. The mean interval from initial operation to revision due to aseptic loosening was 7.5±3.0 years (range, 1.4 to 13.1 years) for the LPS-Flex group and 9.2±4.4 years (range, 3.1 to 14.1 years) for the LPS group. The interval was shorter in the LPS-Flex group but the difference was not statistically significant (p=0.2).

Loosening of the prosthesis was investigated for femoral, tibial, and patellar components. The LPS-Flex group had 39 femoral and 24 tibial loosening in all 42 knees. Eighteen knees (42.8%) had an isolated femoral component loosening. Both femoral and tibial loosening was diagnosed in 21 knees. Three (7%) knees had an isolated tibial loosening. The LPS group had 4 femoral loosening and 8 tibial loosening. Simultaneous loosening of both components was noted in 3 knees. Isolated femoral component

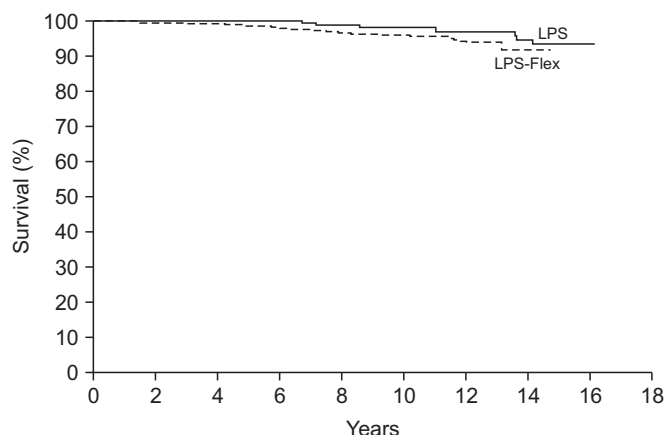


Fig. 4. Kaplan-Meier survival rates of the two groups using revision total knee arthroplasty owing to aseptic loosening as the endpoint.

loosening and tibial component loosening were shown in one and five knees, respectively. The loosening rate of the femoral component was significantly higher in the LPS-Flex group (p=0.01). Tibial component loosening, however, showed no significant difference between groups (p=0.17).

Discussion

In this study, the mean revision rate of LPS-Flex group was higher than the LPS group by about 8 times. The overall survival rate of the LPS-Flex group was significantly lower than the LPS

group. The Kaplan-Meier graph showed a similar survival rate up to 5-years after primary surgery. However, the differences became greater from 5 years to 10 years of the postoperative period. The survival rates of both groups showed a similar tendency thereafter. The 15-year follow-up survival rate showed 1.5% difference between the two groups (92.0% and 93.5% in the LPS-Flex and LPS groups, respectively). In brief, the overall survival rate was lower in the LPS-Flex group than in the LPS group, and this difference was especially prominent between the 5-year and 10-year of the postoperative period.

Han and Kang¹³⁾ reported 27 cases (37.5%) of aseptic loosening in 72 cases. Among the 27 knees with loosening, 15 (21%) required revision surgery. The authors reported that the loosening was associated with squatting. In the follow-up study, the loosening rate was increased to 46% (of 72 knees, 33 underwent revision surgery). Cho et al.¹⁹⁾ retrospectively evaluated 218 knees (166 patients) with LPS-Flex prostheses, and progressive radiolucent lines were observed in 30 knees (13.8%, 27 patients) only around the femoral component.

The rate of aseptic loosening was reported differently in studies. However, most reports are case series, and surgical techniques or activity levels may affect the results. This report is a comparative study involving a large population with the 16 years of maximum follow-up period. The LPS and LPS-Flex prostheses share the same tibial baseplate with different femoral component designs. All operations were done by one surgeon using the same surgical technique. Therefore, the difference of revision rates was presumably associated with the characteristics of femoral prostheses.

In a biomechanical study of 3-dimensional femoral implant-cement interfaces, critical stress was noticed at the femoral fixation site at between 120° and 145°. This raised concern for a higher risk of femoral loosening at high flexion angles²⁰⁾. Some authors have indicated that additional cutting from the femoral posterior condyle might cause implant loosening^{21,22)}. The LPS-Flex showed high peak contact stress, especially at 150° of flexion compared to other implants²³⁾. Relative weak bone support due to additional posterior bone cutting might cause aseptic loosening with repetitive high flexion of the knee.

Sites of the loosened prosthesis were prominent on the femoral side of the LPS-Flex. The incidence of femoral component loosening was 39/42 (92.8%) in the LPS-Flex whereas 4/10 (40%) in the LPS. Although loosening of the tibial side was more frequent in the LPS group, the difference was statistically insignificant.

There are several limitations to this study. First, two types of implants were used in the different periods. The surgeon used the LPS prostheses since February 2000. As usage of the LPS-

Flex became more widespread, he applied it from August 2001 to December 2007. However, as early aseptic loosening related to LPS-Flex was detected, LPS prostheses were selected after 2008. Because of the learning curve of the surgeon, there might have been changes in technical proficiency as the TKAs were done in different periods. However, the use of two prostheses at two different periods could prevent selection bias. Second, specific examinations on pre- and postoperative alignment, implant size, patient factors including labor, and period of high flexion activity after initial surgery were not conducted. These factors could have influenced the revision rates. We will investigate more specific factors related to the aseptic loosening of the LPS-Flex in a future study. Third, the proportion of follow-up loss (714 of 3,096 knees, 23.1%) was relatively high. Therefore, the result could not demonstrate accurate revision rates of the entire patients.

Conclusions

The LPS-Flex had a higher revision rate due to aseptic loosening than LPS prosthesis in this single surgeon, large population series with a long follow-up period. The LPS-Flex prosthesis should be used carefully considering the risk of femoral component aseptic loosening in the mid-term (range, 5 to 10 years) follow-up period after initial operation.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

References

1. Endres S. High-flexion versus conventional total knee arthroplasty: a 5-year study. *J Orthop Surg (Hong Kong)*. 2011; 19:226-9.
2. Miner AL, Lingard EA, Wright EA, Sledge CB, Katz JN; Kinemax Outcomes Group. Knee range of motion after total knee arthroplasty: how important is this as an outcome measure? *J Arthroplasty*. 2003;18:286-94.
3. Bellemans J, Banks S, Victor J, Vandenuecker H, Moemans A. Fluoroscopic analysis of the kinematics of deep flexion in total knee arthroplasty: influence of posterior condylar offset. *J Bone Joint Surg Br*. 2002;84:50-3.
4. Li G, Most E, Sultan PG, Schule S, Zayontz S, Park SE, Rubash HE. Knee kinematics with a high-flexion posterior stabilized total knee prosthesis: an in vitro robotic experi-

- mental investigation. *J Bone Joint Surg Am.* 2004;86:1721-9.
5. Long WJ, Scuderi GR. High-flexion total knee arthroplasty. *J Arthroplasty.* 2008;23(7 Suppl):6-10.
 6. Moro-oka T, Matsuda S, Miura H, Nagamine R, Urabe K, Kawano T, Higaki H, Iwamoto Y. Patellar tracking and patellofemoral geometry in deep knee flexion. *Clin Orthop Relat Res.* 2002;(394):161-8.
 7. Arirachakaran A, Wande T, Pituckhanotai K, Predeeprompan P, Kongtharvonskul J. Clinical outcomes after high-flex versus conventional total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2015;23:1610-21.
 8. Fu H, Wang J, Zhang W, Cheng T, Zhang X. No clinical benefit of high-flex total knee arthroplasty: a meta-analysis of randomized controlled trials. *J Arthroplasty.* 2015;30:573-9.
 9. Li C, Shen B, Yang J, Zhou Z, Kang P, Pei F. Do patients really gain outcome benefits when using the high-flex knee prostheses in total knee arthroplasty? A meta-analysis of randomized controlled trials. *J Arthroplasty.* 2015;30:580-6.
 10. Nieuwenhuijse MJ, van der Voort P, Kaptein BL, van der Linden-van der Zwaag HM, Valstar ER, Nelissen RG. Fixation of high-flexion total knee prostheses: five-year follow-up results of a four-arm randomized controlled clinical and roentgen stereophotogrammetric analysis study. *J Bone Joint Surg Am.* 2013;95:e1411-11.
 11. Radetzki F, Wienke A, Mendel T, Gutteck N, Delank KS, Wohlrab D. High flex total knee arthroplasty: a prospective, randomized study with results after 10 years. *Acta Orthop Belg.* 2013;79:536-40.
 12. Choi YJ, Kang JH, Lee KW, Joo YS, Park JS, Choo HH. Early aseptic loosening after total knee replacement using Legacy Posterior Stabilized-Flex Prosthesis. *J Korean Orthop Assoc.* 2012;47:35-40.
 13. Han HS, Kang SB. Brief followup report: does high-flexion total knee arthroplasty allow deep flexion safely in Asian patients? *Clin Orthop Relat Res.* 2013;471:1492-7.
 14. 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;89:1457-61.
 15. King TV, Scott RD. Femoral component loosening in total knee arthroplasty. *Clin Orthop Relat Res.* 1985;(194):285-90.
 16. Ewald FC. The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system. *Clin Orthop Relat Res.* 1989;(248):9-12.
 17. Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the Knee Society clinical rating system. *Clin Orthop Relat Res.* 1989;(248):13-4.
 18. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics.* 1977;33:159-74.
 19. 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.
 20. Zelle J, Janssen D, Van Eijden J, De Waal Malefijt M, Verdonchot N. Does high-flexion total knee arthroplasty promote early loosening of the femoral component? *J Orthop Res.* 2011;29:976-83.
 21. Ranawat CS. Design may be counterproductive for optimizing flexion after TKR. *Clin Orthop Relat Res.* 2003;(416):174-6.
 22. Ritter MA. High-flexion knee designs: more hype than hope? In the affirmative. *J Arthroplasty.* 2006;21(4 Suppl 1):40-1.
 23. Nakayama K, Matsuda S, Miura H, Iwamoto Y, Higaki H, Otsuka K. Contact stress at the post-cam mechanism in posterior-stabilised total knee arthroplasty. *J Bone Joint Surg Br.* 2005;87:483-8.