



## Do Patients Really Gain Outcome Benefits When Using the High-Flex Knee Prostheses in Total Knee Arthroplasty? A Meta-Analysis of Randomized Controlled Trials



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### ABSTRACT

The purpose of this study was to undertake a meta-analysis to evaluate whether patients really gain outcome benefits when using the high-flex (HF) prostheses in total knee arthroplasty (TKA) compared with standard (STD) implants. Only randomized controlled trials were included in this meta-analysis. After searching PubMed, Embase, Web of Science and Cochrane Library, 1042 papers were identified and 18 trials were finally eligible for meta-analysis including 2069 knees (1906 patients). We found no statistically significant difference between the two designs in terms of ROM, knee scores (KSS, HSS, WOMAC, and SF-36), patients' satisfaction and complications. Hence there is currently no evidence to confirm that the use of high-flex prostheses in short-term is superior to the standard prostheses after total knee arthroplasty.

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A theoretical advantage of high-flexion (HF) prostheses over standard (STD) prostheses designs in total knee arthroplasty (TKA) is improvement in knee flexion and clinical outcomes by modifications in both femoral and tibial insert component for better posterior femoral translation and patellofemoral kinematics [1,2].

In patients doing deep flexion activities, HF prostheses provide both conformity and mobility at the tibiofemoral and patellofemoral surface for attaining more natural knee kinematics after TKA, with larger condylar offset and contact surface, less patellar tendon stress and impingement, and stabilized cam-post mechanism [3–5]. Those changes mentioned above may be associated with good post-operative range of motion (ROM) and, theoretically, have the potential to gain better clinical outcomes compared with STD TKA. Thus, higher flexion, better outcomes and patients' satisfaction might be expected when using HF designs. However, in the academic field, there remains controversy over HF TKAs, with many clinical studies suggesting conflicting results [6–12]. As evidence-based medicine (EBM) has become a tendency in the clinical field, an increasing number of doctors believe that meta-analysis currently provides the most reliable evidence. There have been one systematic review [13] and four meta-analyses [14–17] published from 2009 to 2011 on this subject. Not only did these studies have many limitations, but their conclusions were also conflicting (Table 1). Taking all these issues into consideration, we do not yet

know whether HF TKA offers advantages over STD TKA. Recently, many RCTs on this subject have been published without conclusive results [5,18–27].

Thus, we conducted an updated meta-analysis to investigate whether HF TKA was superior to STD TKA in terms of: 1) post-operative ROM; 2) clinical outcomes; and 3) complications. To perform a thorough and comprehensive assessment of the advantage and potentially risk of HF TKAs, we included 18 RCTs, and added many new statistical indicators that had not been reported before, such as functional KSS, total HSS, functional HSS, WOMAC, physical SF-36 and patients' satisfaction.

### Materials and Methods

#### Inclusion Criteria

We only included randomized controlled trials comparing high-flex (HF) prostheses with standard (STD) prostheses in primary TKA, with adequately reported data on range of motion (ROM), Knee Society score (KSS), Hospital for Special Surgery knee score (HSS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Short Form (SF)-36, and complications. Any prospective studies, retrospective studies, cadaver studies, letters, comments, case reports, guidelines, and review papers were excluded.

#### Search Strategy

We searched electronic databases including PubMed, Embase, Web of Science and Cochrane Library from their inception to March 2014, and our search strategy was conducted with the following search terms: (total knee arthroplasty OR total knee replacement) AND

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(flexion OR range of flexion) AND (high-flexion OR high flexion). We identified all clinical trials about HF prostheses in TKA and manually searched all references of included studies for potentially relevant studies not found in the online search. There was no limitation on research site, year of publication or publication status.

**Study Selection**

After eliminating duplications, one reviewer (LCF) performed an initial screening of all articles based on their titles and abstracts, and discarded those that were obviously ineligible. Then the eligibility of the full text of chosen articles was assessed for inclusion by two reviewers (LCF, SB) independently, and any disagreements were resolved through discussion.

**Assessment of Study Quality**

Two reviewers (YJ, KPD) independently assessed the methodological quality of the inclusive studies on a revised Jadad scale [28] which consists of four questions evaluating random sequence production (2 points), allocation concealment (2 points), appropriateness of blinding (2 points), and description of dropouts and withdrawn (1 point). The total score is 7 points; 0–3 points mean poor quality, and 4–7 points mean high quality. The allocations concealment was ranked as adequate, uncertain, or clearly inadequate and blinding ranked as single blind, double blind, or unclear. Reviewers were blinded to the study’s title, author, and publication journal. Any disagreements were resolved through discussion.

**Data Extraction**

The data were extracted independently by two reviewers (LCF, ZZK) on a predefined data extraction form, including data on patient demographics, surgical technique, implant used, follow-up, methodology, clinical outcomes and complications. The data were checked by a third investigator (SB), and any disagreements were resolved through discussion. The authors of these articles were contacted if necessary to obtain any information. Missing standard deviations were calculated based on the confidence intervals (CIs) or range of values provided in the articles, according to the formula reported by Hozo et al [29]. The outcomes at final follow-up were chosen for analysis because most of the patients were in the early post-operative stages (less than 5 years).

We focus on the question of whether patients really gain clinical outcomes benefits when using the HF prostheses in TKA compared with STD implants. Therefore, our primary outcomes were ROM. The knee scores (KSS, HSS, WOMAC, SF-36) and complications were regarded as secondary outcomes.

**Statistical Analysis**

The statistical analysis was performed by RevMan 5.2 software (The Nordic Cochrane Center, The Cochrane Collaboration) and a *P* value

of < 0.05 was considered statistically significant. We respectively calculated the weighted mean difference (WMD) and the odds of risks (ORs) for continuous variables and dichotomous variables with 95% CIs for each outcome. Statistical heterogeneity was tested using the chi-squared test and *I*<sup>2</sup> statistic. The chi-squared test < 0.1 or the *I*<sup>2</sup> > 50% was indicative of statistical heterogeneity. Depending on the heterogeneity, meta-analysis was performed using fixed effect or random effect models. When there was no statistical evidence of heterogeneity, a fixed effect model was adopted; otherwise, a random effect was used. In addition, publication bias was assessed through a funnel plot of ROM.

**Results**

**Study Characteristics**

Fig. 1 shows the details about the process of study selection. Our search strategy totally generated 1042 articles. 106 articles were considered potentially eligible for further evaluation after removing duplications and scanning titles and abstracts. After reading the full-texts for detailed evaluation, 18 studies were included based on our inclusion criteria, comprising 2069 knees (1906 patients) in this meta-analysis.

Characteristics and quality assessment of the included 18 studies were shown in Table 2. All papers were published in English from 2005 to 2014, and 11 were published after 2010. The mean age of the patients ranged from 61.4 years to 72.2 years, and their BMI ranged from 24.1 to 34.4. Most of the patients had TKAs for advanced osteoarthritis. Of all studies, 14 studies were in short-term follow up (<5 years), 3 studies were in mid-term follow up (5 to 10 years), and only one study in long-term follow (>10 years). Table 3 shows that 14 of the 18 RCTs (85.7%) were high quality (Jadad score > 3), with 12 (66.7%) reporting randomization method, 6 (33.4%) reporting allocation concealment, and 16 (88.9%) reporting masking. No studies’ dropout or withdraw patients rate was more than 20%. Besides, a funnel plot pooled for ROM was broadly symmetrical indicating minimal publication bias. The results of meta-analyses were shown in Table 3.

**Meta-Analysis of ROM**

A total of 15 studies reported pre-operative ROM including 914 HF TKAs and 907 STD TKAs. There was no evidence of statistical heterogeneity between studies (*P* = 0.99, *I*<sup>2</sup> = 0%) and a fixed-effect model was chosen. The pooled mean difference was –0.61 (95% CI –1.83 to 0.61) indicating that there was no difference in pre-operative ROM between the two groups.

A total of 16 RCTs reported the post-operative ROM including 945 HF TKAs and 934 STD TKAs. The pooled result suggested that the ROM of HF group was a little higher than that of STD TKAs (WMD = 2.18, 95% CI 1.36 to 3.0). However, there was statistical heterogeneity between studies (*P* = 0.00001, *I*<sup>2</sup> = 80%), and a random-effect model was chosen. Considering that the surgical technique is a major factor influencing

**Table 1**  
Details of Meta-Analyses and Systematic Review Published on this Subject.

Author	Year	Studies Included	Patients	Knees	Statistical Indicators	Conclusion
Murphy et al	2009	9, only 3 RCTs, 6 case controlled studies	737	799	Flexion, ROM, Flexion contracture, HSS, KSS	There is no established benefit in post-operative knee ROM or physical function when using these implants.
Gandhi et al	2009	6, only 2 RCTs, 4 observational studies	N/S	N/S	ROM, KSS	High flexion designed knee implants improve ROM but no clinical benefits over conventional TKAs.
Mehin et al	2010	Only 5 RCTs	233	183	ROM and maximum ROM	No statistically significant improvement was obtained in flexion with the ‘high-flex’ prostheses.
Sumino et al	2011	18, only 8 RCTs, 6 case controlled studies, and 4 observational studies.	N/S	2104 PS knees, only 518 HF knees	Pre-operative and post-operative flexion	Improvement of flexion after TKA using current HF PS prostheses is similar to that of conventional PS prostheses
Luo et al	2011	11, only 5 RCTs, 1 prospective studies and 5 retrospective studies	N/S	1204	ROM, KSS and complications.	There were no differences between the two designs. In a subgroup analysis there was a small improvement of ROM in Western patients but not in Asian patients

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