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Comparison of High-Flexion and Conventional Implants in Total Knee Arthroplasty: A Meta-Analysis

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Background: The purpose of this study was to evaluate whether high-flexion prostheses are superior to conventional prostheses after total knee arthroplasty (TKA).

Material/Methods: We searched the PubMed and Embase databases for randomized trials and cohort studies comparing high-flexion with conventional knee implants. The heterogeneity across studies was examined by I^2 and Cochran's Q-tests. Then the overall weighted mean differences of range of motion (ROM) and knee functional scores were evaluated.

Results: A total of 16 trials involving 2643 knees met our inclusion criteria. The results revealed that high-flexion implants were superior to conventional implants in the improvement of range of motion (weighted mean difference, 2.92; 95% CI, 1.63–4.22; $p < 0.0001$). The clear advantage of high-flex PS (posterior stabilized) as well as high-flex CR (cruciate retaining) implants was found in ROM when compared to PS implants (2.73; 95% CI, 1.27–4.20; $p = 0.0003$) and CR implants (3.24; 95% CI, 0.28–6.20; $p = 0.003$), respectively. However, there was no difference in Knee Society Scores (0.42; 95% CI, -0.60–1.43; $p = 0.42$), Knee Society function (0.37; 95% CI, -1.48–2.22; $p = 0.70$) and Hospital for Special Surgery scores (0.26; 95% CI, -0.47–1.00; $p = 0.48$) between high-flexion and conventional groups.

Conclusions: The current meta-analysis revealed that high-flexion implants were superior to conventional implants in the improvement of ROM but not in functional outcome scores.

MeSH Keywords: **Arthroplasty, Replacement, Knee • Knee Prosthesis • Meta-Analysis as Topic**

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Background

Total knee arthroplasty (TKA), involving the replacement of both sides of the knee joint, is an effective surgical treatment for patients with end-stage degenerative arthritis of the knee [1,2]. The goal of TKA is to relieve the pain and to improve the knee function and range of motion (ROM) for activities of daily living. A knee flexion angle greater than 90° was required for many daily activities, such that flexion angle of 110° to 130° was essential for cross-legged sitting and squatting and 90° to 120° for stair climbing and sitting on a chair [3,4]. However, the average maximal flexion angle was reported to range from 100° to 110° [5]. A substantial number of patients (approximately 20%) remain uncertain or not satisfied with their TKA, mainly due to the knee pain and poor range of motion [6,7].

The ROM after TKA depends on the individual patient, surgical technique, implants, and many other factors [8–11]. To achieve deep flexion, high-flexion prostheses were designed with the features of improved posterior condylar offset, improved articular contact area, increased patellar tendon recess, and increased posterior femoral translation [8,12,13]. Theoretically, this type of prosthesis would improve the clinical outcomes of TKA. Indeed, several studies have evaluated the effect of high-flexion implants and found they were better than the conventional implants [14,15]. However, several studies did not confirm the differences between these 2 types of prostheses [16–18]. Despite 2 meta-analyses that estimated the outcomes of high-flexion and conventional knee implants, contradictory evidence in favor of the high-flexion design was reported in a 2009 study [19] but not a 2011 study [20]. In addition, 6 new comparative studies [21–26] on those prostheses in TKA have been published in the last 3 years.

Therefore, we performed a meta-analysis comparing the clinical outcomes of high-flexion prostheses and conventional prostheses for primary TKA based on all eligible studies to obtain a comprehensive result.

Material and Methods

Search strategy

We systematically searched PubMed and EmBase databases for articles published up to December 20, 2013. The following key phrases combined with Boolean operators were used: “total knee arthroplasty” OR “total knee replacement” AND “flexion” OR “high-flexion” OR “high flexion”. The reference lists of the relevant reviews and the included articles, as well as the references of paper editions, were also checked manually to obtain more available studies.

Inclusion and exclusion criteria

Studies were included in our meta-analysis if they met the following criteria: (1) prospective or retrospective control study or random control study; (2) compared high-flexion prostheses with conventional prostheses in total knee arthroplasty; (3) indexes including range of motion (ROM), Knee Society Scores (KSS), and hospital for special surgery (HSS) scores were provided; (4) the experimental and control groups were comparable for age, sex, and other preoperative indicators.

Studies were excluded if they met the following criteria: (1) non-English; (2) review, letter or comment; (3) the mean value was available but lacked the standard deviation; (4) duplicate publication; (5) studies applied the same population data except the 1 with the longest follow-up time and the most comprehensive research information.

Data extraction

Two reviewers independently examined and confirmed the eligible studies according to the inclusion and exclusion criteria defined above. Data extracted from the studies included the first author, year of publication, region where the study was conducted, sample size, age and sex of the cases, and follow-up time. Disagreement was resolved by discussion.

Statistical analysis

The ROM, KSS, KS function scores, and HSS scores were selected as the evaluation index in the current study. Heterogeneity between studies was determined using I^2 and Cochran's Q-tests. If there was some evidence for heterogeneity ($p < 0.05$ or $I^2 > 50\%$), a random-effects model was used. If $p \geq 0.05$ and $I^2 \leq 50\%$, we utilized the fixed-effects model. Publication bias was evaluated by funnel plot. The above analysis was performed using RevMan 5.0 statistical software.

Results

Study selection

Initially, the search strategy yielded a total of 3970 studies, comprising 2215 from Embase and 1755 from PubMed. Among them, 2448 were eliminated due to duplication. Subsequently, we excluded another 1499 irrelevant articles after reviewing their titles and abstracts. Full texts of 33 articles were available, which were then retrieved for evaluation. Fifteen studies were excluded through examining their full text because they lacked controls ($n=10$), lacked values of standard deviation ($n=3$), were non-English publications ($n=1$), or reviews ($n=1$). The data of another 2 studies were incomparable between the

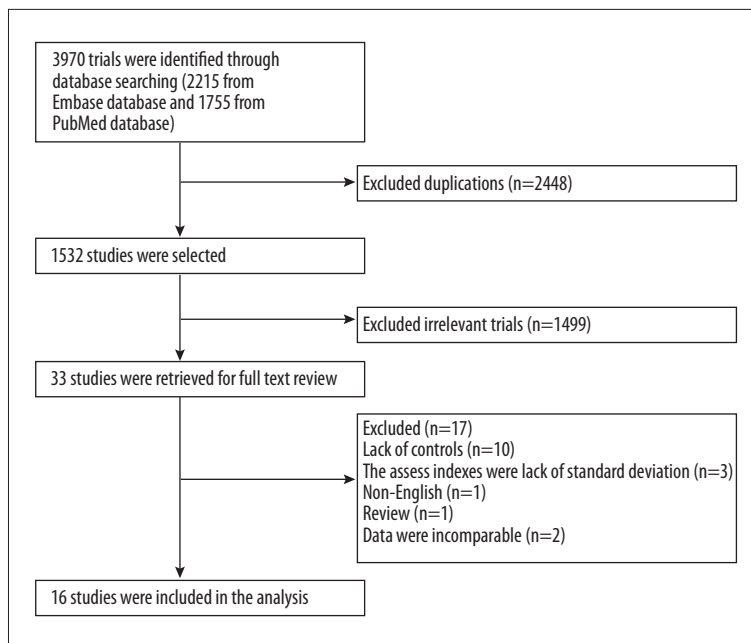


Figure 1. The flow chart of study selection.

2 groups. Manual searching failed to retrieve additional eligible studies. Consequently, only 16 eligible articles [14–18,21–31] were included in the present meta-analysis. Figure 1 is a flow chart of the study selection process.

Characteristics of the included studies

A total of 2848 knees were enrolled in the included papers published from 2007 to 2013. In the study of McCalden et al. [14], TKA with cruciate retaining (CR), posterior stabilized (PS), and high-flex posterior stabilized implants was conducted for 160, 1177, and 197 knees, respectively. We eliminated the data of the 160 knees using cruciate retaining implant on the basis of comparability of data. Similarly, data of 45 knees were eliminated from the study [25]. Finally, we evaluated the outcomes of a total of 2643 knees in the current meta-analysis, among which 747 knees had high-flexion prostheses and 1896 knees had conventional prostheses. The mean age of patients in these studies was more than 60 years (range 62.8–72 years). The follow-up time ranged from 1 to 5.4 years. There were 4 prospective cohort trials [21,26,30,31], 6 retrospective cohort trials [14,15,22,25,27,28], and 6 random control trails [16–18,23,24,29]. Five papers compared PS design implants [14,17,25,27,31], 5 compared CR design implants [16,26,28–30], and the others compared LPS (Legacy Posterior Stabilized) design implants [15,16,21–24]. All papers evaluated the range of motion (ROM) after TAK. The characteristics of the studies are summarized in Table 1.

Knee range of motion

Date of postoperative ROM was available in all 16 trials [14–18,21–31]. There were 1159 and 2067 knees which were

treated with TKA using high-flexion and conventional implants, respectively. There was evidence of statistical heterogeneity across the 16 trials [14–18,21–31] ($I^2=51\%$, $P=0.01$; Figure 2). The random-effects model was applied and the overall weighted mean difference (WMD) in ROM was 2.92 (95% CI, 1.63–4.22; $P<0.0001$; Figure 2). Patients using high-flexion implants achieved more improvement in ROM compared to the ones using conventional implants. Then the 16 trials were divided into 2 subgroups to reduce the heterogeneity based on the type of implants compared. Eleven trials [14–17,21–25,27,31] with high-flexion PS TKA (PS-Flex) vs. standard PS TKA were defined as subgroup 1 and other 5 trials [18,26,28–30] with high-flexion CR TKA (CR-Flex) vs. CR TKA were defined as subgroup 2. In the subgroup 1, a total of 872 knees were treated with PS-Flex TKA and 1780 were treated with PS TKA. Evidence showed heterogeneity across the 11 studies in subgroup 1 ($I^2=49\%$, $P=0.03$), thus the random-effects model was used. The pooled WMD in ROM was 2.73 (95% CI, 1.27–4.20; $P=0.0003$; Figure 2). A clear advantage of high-flex PS implants was found in the improvement of ROM when compared to PS implants. In subgroup 2, heterogeneity was also tested across the 5 trials ($I^2=60\%$, $P=0.04$; Figure 2) and consequently the random-effects model was applied to evaluate the overall effect. The pooled WMD was 3.24 (95% CI, 0.28–6.20; $P=0.003$) and high-flexion CR implants used in TKA were superior to conventional CR implants in the improvement of ROM. The funnel plot displayed graphic symmetry across studies, which indicated no publication bias (Figure 3).

Knee Society Scores

KSS was evaluated on 693 knees in 5 trials [23–25,28,30]. No heterogeneity was detected across these trials ($I^2=0\%$, $P=0.55$;

Table 1. The baseline characteristics of included studies.

Study	Year	Location	Type of trial	Type of control	N (knee) trial	N (knee) control	Age (y)		Sex (F/M)		Follow-up (y)	Outcomes	Type of study
							Trial	Control	Trial	Control			
Crow [26]	2010	US	CR-Flex	CR	85	79	68.3±9.0	68.8±8.6	59/41	78/22	1	ROM	PC
Guild [23]	2013	US	LPS-Flex	LPS	138	140	64.8±8.5	64.0±8.1	71/67	67/73	2	ROM, KSS-knee, KSS-function, HSS	RCT
Singh [21]	2012	India	LPS-Flex	LPS	100	100	64±3	68±6	100/0	100/0	2.1	ROM, KSS-function, HSS	PC
Lee [22]	2011	South Korea	LPS-Flex	LPS	41	39	66.0±6.3	65.1±6.0	100/0	100/0	2	ROM, HSS	RC
Lutzner [24]	2013	Germany	LPS-Flex	LPS	71	51	68.6(9.1)	69.1±8.4	55/45	59/41	1	ROM, KSS-knee, KSS-function	RCT
Lee [25]	2012	South Korea	PS-Flex	PS	94	40	67.5	67.2	87/7	37/3	2	ROM, KSS-knee, KSS-function, HSS	RC
McCalden [14]	2010	Canada	PS-Flex	PS	197	1177	65.9±10.5	67.8±9.7	113/84	682/495	5.4	ROM	RC
Nutton [16]	2008	UK	LPS-Flex	LPS	28	28	71	68	11/17	16/12	1	ROM, KSS-function	RCT
McCalden [17]	2009	Canada	PS-Flex	PS	50	50	70	72	27/23	25/25	2	ROM	RCT
Ng [31]	2008	Hong Kong	PS-Flex	PS	35	35	68	68	28/7	28/7	1	ROM	PC
Bin [15]	2007	South Korea	LPS-Flex	LPS	90	90	66.6±7.3	66.3±6.6	84/6	87/3	1	ROM, HSS	RC
Suggs [28]	2009	US	CR-Flex	CR	11	15	66.6±11.2	69.±10.9	2/9	3/12	1	ROM, KSS-knee, KSS-function	RC
Malik [27]	2010	US	PS-Flex	PS	50	50	66.4±9.6	62.8±10.7	38/12	38/12	1	ROM, KSS-knee	RC
Seon [29]	2009	South Korea	CR-Flex	CR	50	50	69.2±6.7	67.5±6.2	44/6	40/10	2	ROM, HSS	RCT
Minoda [30]	2009	Japan	CR-Flex	CR	87	89	70.7±8.5	70.3±8.9	78/9	70/17	1	ROM, KSS-knee, KSS-function	PC
Kim [18]	2009	South Korea	CR-Flex	CR	54	54	69.7	69.7	49/5	49/5	3	ROM, KSS, KSS-function, HSS	RCT

RCT – randomized controlled trial; PC – prospective cohort; RC – retrospective cohort; PS – posterior stabilized; LPS – legacy posterior stabilized; CR – cruciate retaining; ROM – range of motion; KSS – Knee Society Scores; HSS – Hospital for Special Surgery.

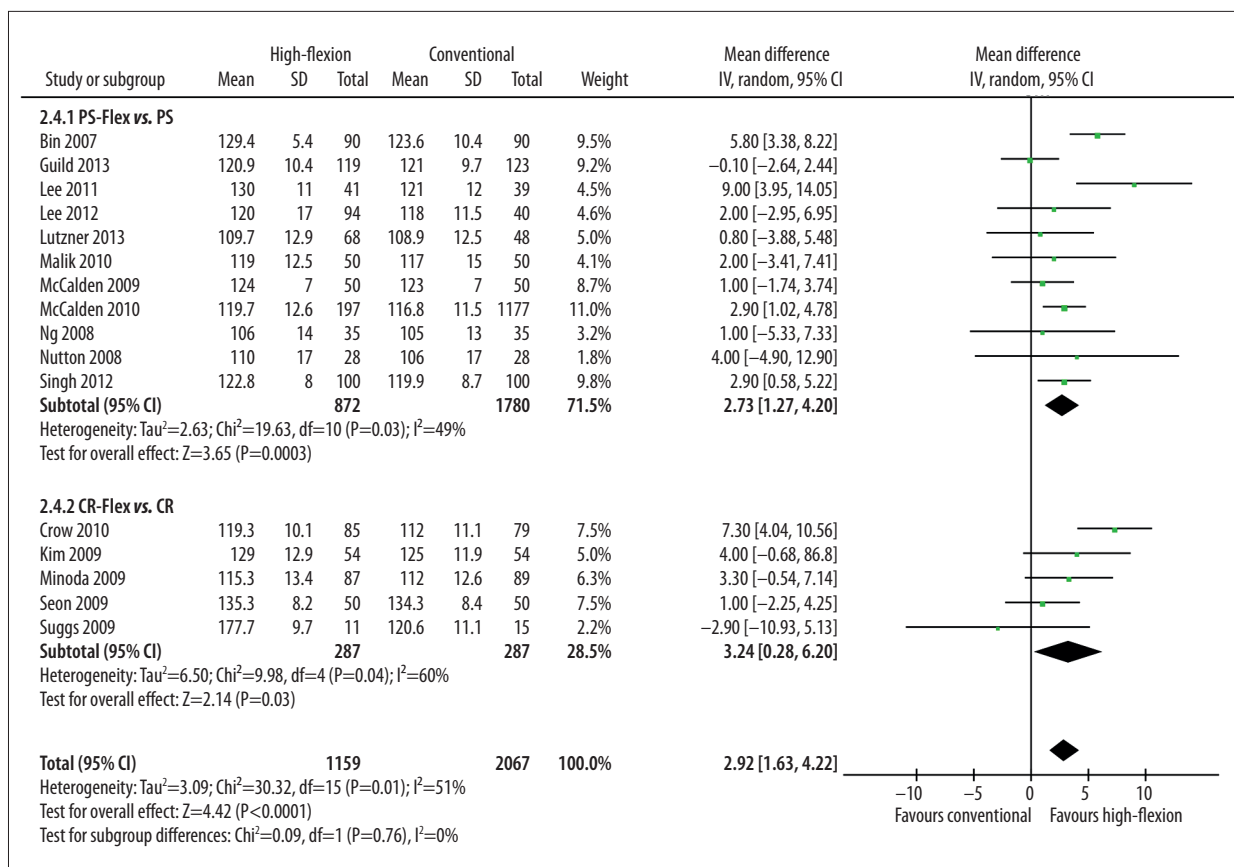


Figure 2. Forest plot of the included trials comparing high-flexion and conventional prostheses on range of motion.

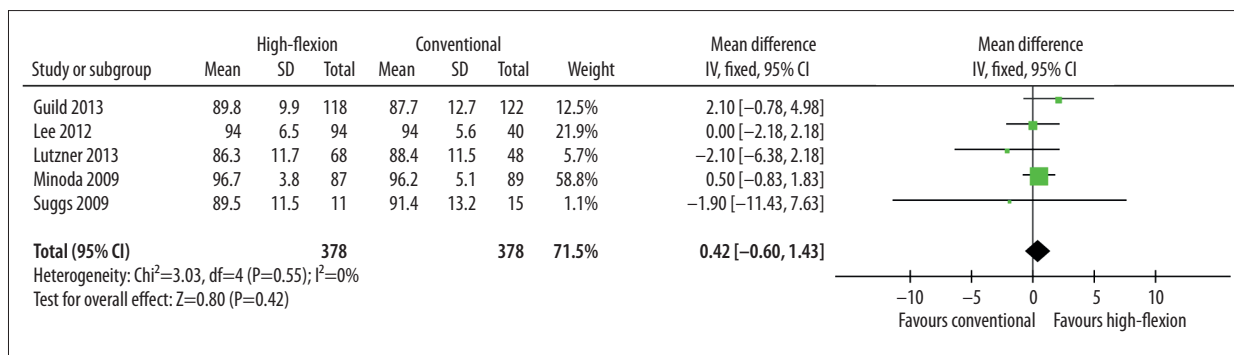


Figure 3. Funnel plot showing no publication bias among the 15 trials comparing high flexion with conventional prostheses on range of motion.

Figure 4) and the pooled WMD was 0.42 (95% CI, -0.60–1.43; $P=0.42$), indicating that there was no statistical significance between the high-flexion and conventional groups in KSS.

Knee Society function

The Knee Society function data were available in 7 trials [16,21,23–25,28,30] (750 knees). The P value of heterogeneity test was 0.34 and I^2 was 12%, indicating that there was no statistical heterogeneity across these studies, so the

fixed-effect model was used. The pooled WMD was 0.37 (95% CI, -1.48–2.22; $P=0.70$), indicating that there was no statistically significant difference between the high-flexion and conventional groups in Knee Society function (Figure 5).

Hospital for Special Surgery (HSS) score

The Hospital for Special Surgery Score was tested in 6 trials [15,21–23,25,29] (933 knees) and no statistical heterogeneity was found across these studies ($I^2=19%$, $P=0.29$; Figure 6).

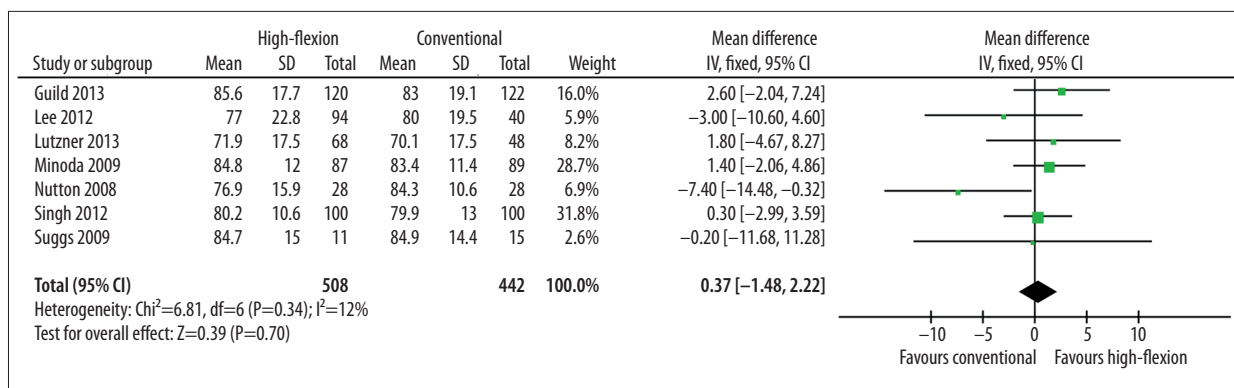


Figure 4. Forest plot of the included trials comparing high-flexion and conventional prostheses on Knee Society scores-knee.

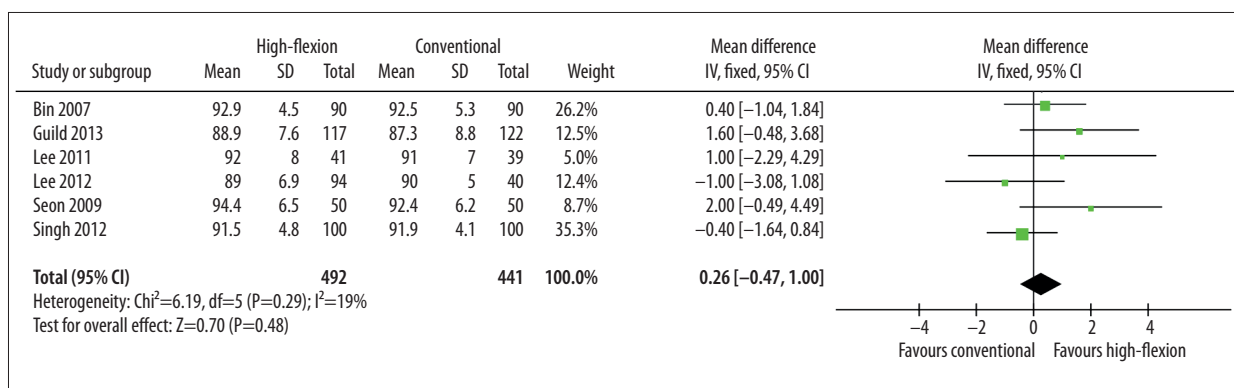


Figure 5. Forest plot of the included trials comparing high-flexion and conventional prostheses on Knee Society scores-function.

The pooled WMD was 0.26 point and no significant difference was detected between these 2 groups (95% CI, -0.47 to 1.00 points; $P=0.48$; Figure 6).

Discussion

In this meta-analysis, we evaluated the results of 16 trials with 747 knees in the high-flexion prostheses group and 1896 knees in the conventional prostheses group. The results revealed that high-flexion implants were superior to conventional implants in the improvement of ROM, but each type of prosthesis achieved an average postoperative ROM of more than 105°. However, no difference was found in Knee Society scores, Knee Society function, and Hospital for Special Surgery scores between these 2 groups.

ROM after TKA is one of the most important indexes in determining clinical outcomes, since many daily activities require a knee with a flexion of greater than 90° and some special activities, such as squatting for certain religious activities (need >120°) and kneeling during prayer (need >135°), require much greater knee joint flexion [3,32,33]. However, patients usually do not achieve satisfactorily high degrees of flexion after TKA, although the clinical outcomes achieved by the majority of modern TKA

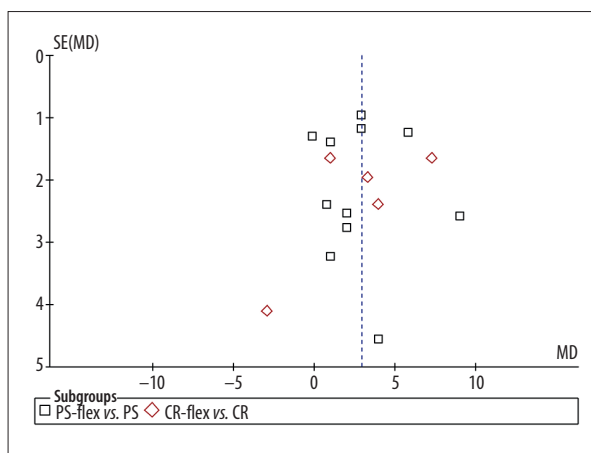


Figure 6. Forest plot of the included trials comparing high-flexion and conventional prostheses on Hospital for Special Surgery scores.

designs are satisfactory for walking ability. Moreover, even patients who had good preoperative ROM often lose deep flexion (defined as flexion >120°) after TKA [34,35]. Therefore, high-flexion implants were designed with the expectation of achieving greater knee flexion [16,36]. The findings in the present meta-analysis indeed demonstrated the greater ROM in the high-flexion group than in the conventional group. The difference was

evident between the 2 groups. Even in the subgroups high-flexion PS vs. standard PS and high-flexion CR vs. standard CR, the advantage of high-flexion implants was still significant. In the meta-analysis conducted by Luo et al. in 2011 [20], evidence did not support that high-flexion prostheses (either PS or CR) were superior to conventional prostheses in ROM after TKA.

Two previous studies [37,38] have demonstrated that no difference in ROM was observed between high-flexion and conventional groups with at least 1-year follow-up. In contrast, our meta-analysis favored the use of high-flexion implants rather than conventional implants in ROM after TKA. Moreover, in the subgroup analysis of high-flexion (CR TKA vs. standard CR TKA), we also confirmed that patients in the high-flexion group achieved more favorable flexion than in the conventional group (112.0° vs. 119.3°, $p < 0.001$).

Although the high-flexion implants were superior to conventional implants in the improvement of ROM, no difference was found in knee functional scores between these 2 groups. It has been reported that knee flexion was not the best predictor for functional outcome after TKA [39]. More importantly, the majority of arthroplasty surgeons and physical therapists suggested that a difference of knee ROM less than 5° was not clinically relevant [40]. In addition to implants, some other factors, including surgical technique and postoperative

care could influence clinical functional outcomes after TKA. Therefore, it is understandable that similar knee functional scores were found between high-flexion and conventional groups even though significantly greater knee flexion was achieved by high-flexion implants.

The current meta-analysis has certain limitations. First, we included cohort trials in our study to obtain comprehensive information when considering the few randomized controlled trials. Therefore, the potential confounding bias of the nonrandomized studies may exaggerate estimates of intervention effects. Second, not all the studies provided every clinical result, so we cannot estimate other indexes associated with the outcomes of postoperative TKA. Third, the follow-up times were varied across the included studies (1–5.4 years), thus different outcomes were generated.

Conclusions

Our meta-analysis indicated the improved ROM using high-flexion implants in TKA over conventional implants. No difference was found in Knee Society scores, Knee Society function, and Hospital for Special Surgery scores between these 2 groups. However, more high-quality studies are needed to confirm these results.

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