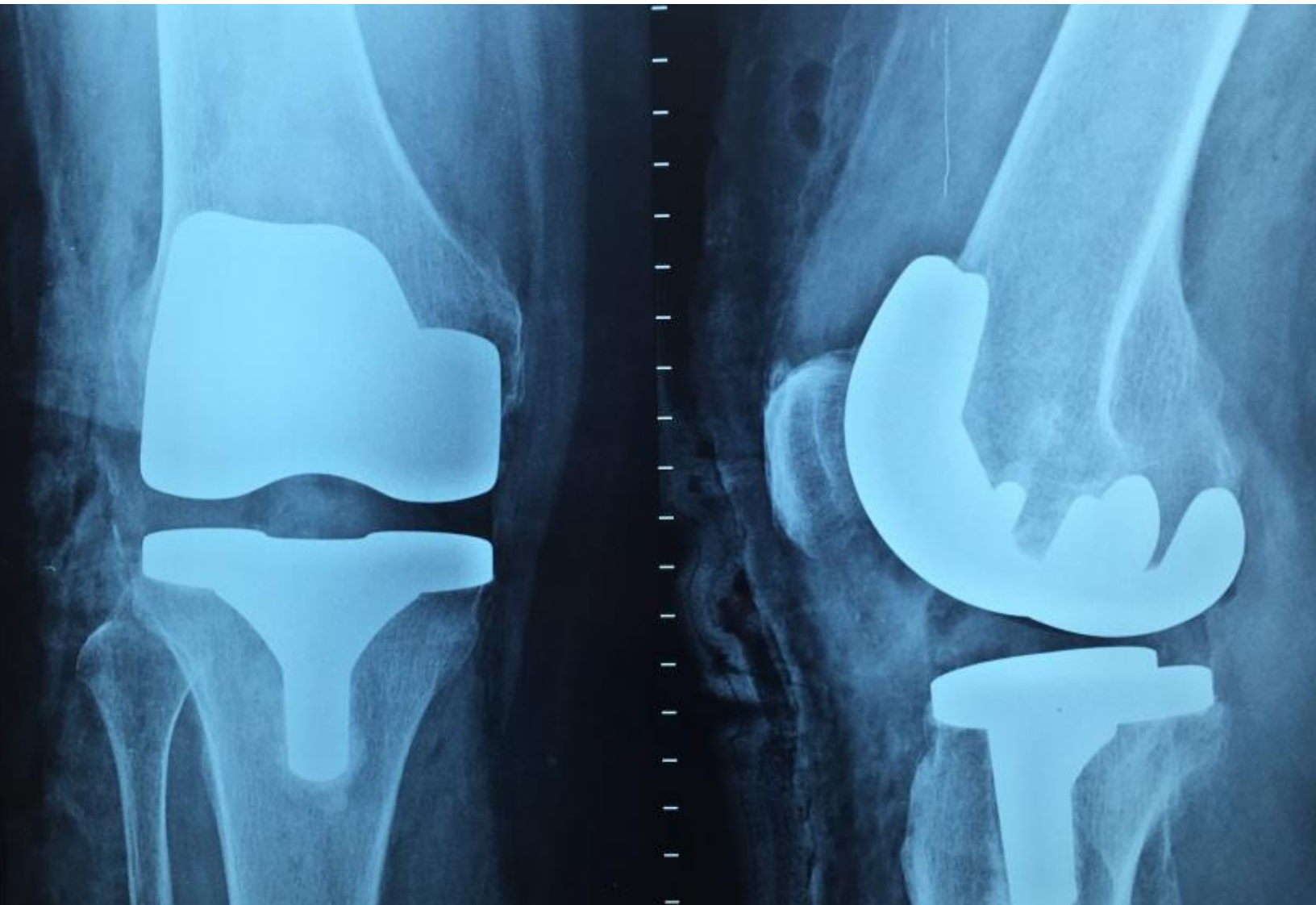
FLEX CEUs

Total Knee Arthroplasty - High Flexion Prosthetic & Exercise



Improved knee flexion following high-flexion total knee arthroplasty

Abstract

Background: The application of new techniques and materials in total knee arthroplasty (TKA) continue to be a primary focus in orthopedic surgery. The primary aim of the present study is to evaluate post TKA total range of motion (ROM) among a group of patients who received a gender specific high-flexion design modification implant compared to a control group of patients who received non-gender specific implants.

Methods and results: The control group was comprised of 39 TKAs that were recruited pre-operatively and received the non-gender specific implant while the study group consisted of 39 TKAs who received gender specific implants. The study group yielded an improvement in mean post-operative ROM of 21° at 12 months, whereas the mean improvement in ROM among the control group was 11°. Thus, the study group had a 10° increased ROM improvement (91%) over the control group ($p = 0.00060$). In addition, 100% of the subjects with gender specific high-flexion implants achieved greater or equal ROM post-operatively compared to 82% for the control cohort. Lastly, women who exhibited greater pre-operative ROM and lower body mass index (BMI) were found to benefit the most with the gender specific prosthesis.

Conclusion: Our study demonstrates that among subjects with a normal BMI, the gender specific high-flexion knee implant is associated with increased ROM as compared to the non-gender specific non-high-flexion implant designs.

Keywords: Osteoarthritis, Gender-specific high-flexion knee prosthesis, Total knee arthroplasty, Body mass index, Range of motion

Background

For the past forty years, advancements in approaches to total knee arthroplasty (TKA) have remained a primary focus in the field of orthopedic surgery. The development of intramedullary and extramedullary cutting instruments and enhanced fixation techniques in the 1970's led to advancements in prosthesis design and surgical expertise in the 1980's that have facilitated long-term implant survival [1-3]. Few changes in this evolution; however, have resulted in proven, lasting improvement of performance despite the plethora of claims in the literature of early recovery, functional excellence, and patient satisfaction. Recently, gender specific prosthetics have been developed to address anatomical differences between male and female knees. The main objective of the prosthesis designers is to provide an implant comparable to the human knee in fit and performance with the aim of improving ROM and enabling patients to perform daily living tasks without difficulty.

In efforts to produce a knee prosthetic with optimal fit, researchers have compared current prosthetic dimensions to morphological knee measurements of large patient populations undergoing TKA. A critical study that analyzed 337 knee surgeries for distal femur size, revealed a wide aspect ratio (medial-lateral (M/L) dimension divided by the anterior-posterior (A/P) dimension) variation between the male and female populations [4]. Results from the study indicated that prosthetic manufacturers were skilled at supplying implant sizes that fit the average patient within the population of those undergoing TKA. Specifically, the Zimmer NexGen implant sizes lie just above the best fit (least squares regression) line for combined male and female morphological data. However, these "unisex" implants

are particularly inadequate at fitting larger-boned women whose femoral A/P measurements exceed 60 mm. For example, a female with a femoral A/P of 65 mm would be fitted for a NexGen unisex implant with a femoral M/L dimension of 77 mm instead of the best fit value of 67 mm, resulting in 5 mm of overhang on each side. A similar mismatch occurs for other manufactures. For example, Duracon (Stryker Howmedica Ostenics) exhibits an average overhang of 4.9 mm for women and only −0.1 mm for men [4]. Such medial or lateral overhang has been conjectured to result in soft tissue irritation complicated balancing efforts.

For a given femoral A/P size, males have a larger or broader femoral M/L dimension; therefore, traditional femoral prosthetics in women tend to be oversized. In addition, women have less prominent anterior condyles. Poilvache and Insall [5] reported an average lateral anterior condyle thickness in men of 13.7 mm as compared to 12.3 mm in women, while the average medial anterior condyle thickness in men was 10.6 mm in contrast to 9.0 mm in women. The contention is that unisex prosthetics may cause overstuffing of the knee capsule in women that may limit post-operative ROM. Moreover, women have a higher Q angle than men due to their broader pelvic dimension. Several authors [6,7] have established an average Q angle of 14° in men and 17° in women, resulting in a 3° gender difference. These authors suggest that Q-angle variations are linked to the etiology of patellar instability and pain post TKA.

The literature is limited regarding the potential benefits of gender specific knee implants for TKA. The primary aim of the study was to evaluate the performance of a newer TKA design that takes into account the noted high-flexion and anatomical differences in male and female knees and evaluate if those modifications truly make a difference in post-operative ROM.

Patients and methods

The study protocol was approved by The Methodist Hospital Research Institute in Houston, Texas. A consecutive series of 77 women with a total of 97 TKAs were recruited pre-operatively in an IRB-approved study from the principal investigator's clinical practice to make up the control group. Each patient underwent primary TKA between November 2005 and October 2006, receiving the Zimmer (Warsaw, Indiana) NexGen CR implant without a high-flexion modification. Of the 77 women, 33 completed their 12-month follow-up visit, yielding 39 total TKAs that were utilized in the analysis. The relatively high rate of attrition can be attributed to loss to follow-up and subjects being excluded if they were unable to comply with the pre-set time points of the post-operative follow-up visits. The study group consisted of 82 women (97 TKAs) who were recruited between October 2006 and February 2008. These subjects received the Zimmer NexGen High-Flex Gender Solutions knee prosthesis. Of the 97 knees, the first 39 TKAs with follow-up data through one year were included in the analysis to yield equal group sizes. A total of 28 of these gender specific implants were NexGen CR-Flex, while the remaining 11 were NexGen LPS-Flex. Additional file 1 provides a sample size calculation for the continuous response variables. All patients of the surgeon for whom TKA was recommended, met all of the inclusion criteria, and met none of the exclusion criteria, were offered participation in the study. Subjects were not exposed to advertising of any specific type of implant at the hand of the investigator. While there were variations in design and cruciate stabilization in the study cohort, we segregated each subset to verify no differences in CR versus LPS exhibited before merging the group into one study group.

All surgeries were performed by the principal investigator utilizing computer-assisted navigation via a minimally invasive (quad sparing) technique with the same gap settings and extension passive ranges in order to normalize surgical technique mismatch. This approach ensured that early patients did not have an advantage due to differences in range under anesthesia or restrictive tightness on ligament tensioning. The control and study cohorts received identical pre- and post-operative care.

Exclusion criteria for participation included: under 20 years of age, cancer, major anatomical compromise, and bone deformity or contradiction. The two cohorts revealed no statistically-significant differences in any demographic feature. The mean age and BMI for the control cohort was 68.3 years and 30.0 kg/m^2 respectively, while the mean age and BMI for the study cohort was 67.9 years and 29.9 kg/m^2. Also, pre-operative extension and flexion did not prove statistically significant, thereby minimizing the possibility of confounding variables in this study.

Patients were evaluated at three designated post-operative time intervals: 2 months, 6 months and 12 months. All patients within the balanced cohorts of 39 TKAs returned for their first and last post-operative visits. At each post-operative visit, the principal investigator determined extension and flexion using a goniometer. Post-operative complications and all occurrences of post-operative manipulation under anesthesia or implant revision were recorded.

Pre- and post-operative extension, flexion, and ROM and net change (improvement) in ROM between pre-operative and each post-operative visit were analyzed using Welch's t-test with $\alpha = 0.05$ (twin-tailed) to accommodate unequal variance and sample size.

The correlation between post-operative ROM and continuous variables (e.g., pre-operative scores, age, BMI, femoral size) was determined using scatter plots and least squares best-fit trend lines. Statistical differences in the occurrences of complications, manipulation under anesthesia, and revisions for each group were determined using Pearson's chi-squared test.

Results

Summary statistics are shown in Table 1 for both control (unisex implant) and study (gender specific implant) subjects. The study group showed no significant difference between CR and LPS design differences when compared to one another. This group of 39 TKA then represented the study cohort of gender high-flexion modification which would serve as the comparison group to the older design NexGen control group. There was no statistically significant difference in mean pre-operative ROM found between the study and control groups; 102.7° and 107.2° respectively. At 2 months, the ROM for the study group improved by reaching an average 10° improvement from baseline, whereas the control group reached an average 2° improvement, which was statistically significant ($p < 0.05$). At 6 months, the control group reached a mean ROM of 115° (10.8) compared to 119.2° (10.2) among the study group, representing equal improvement from the 2-month follow-up visit, but a 16.3° improvement from baseline for the study group and a 6.5° improvement from baseline for the control group. At the final 12-month follow-up visit, the control group averaged a 10.8° improvement over baseline as compared to 20.7° among the study group. When separating the control group where high-flexion without gender was used, there was not a difference.

The progression of ROM improvement from pre-operative values for both cohorts is illustrated in Figure 1. The least square logarithmic trend line was adopted to reveal the asymptotic progression to the noted 10° differential between gender specific high-flexion designs versus the unisex implant group. At the 12-month evaluation, mean ROM improved for both implants-the gender specific prosthesis improved ROM by approximately 21° compared to 11° for the control group representing a 91% improvement (refer Figure 2).

The post-operative (12 months) was analyzed with respect to pre-operative ROM for both cohorts to reveal the class of subjects for which greatest post-operative ROM was achieved. Figure 3 provides further illustration of the resulting post-operative ROM versus pre-operative ROM. As expected, the subjects with greatest pre-operative ROM achieved the greatest post-operative ROM as indicated by the linear least squares trend line. Interestingly, the mean (10° differential) was achieved between the cohorts primarily with the higher pre-operative ROM, often corresponding with lower BMI.

Also, as indicated in Figure 3, the best fit lines (minimum least squared error) further reinforces the consistent improvement arising from the gender specific high-flexion design prosthesis compared to the non-high-flexion whether it is for the unisex or gender-based prosthesis. Although the mean improvement using the gender specific implant over the unisex implant was established to be 10°, the figure depicts the improvement actually varying from approximately 4° for subjects with poor pre-operative ROM (90°) to 10° for subjects with

Table 1 Summary statistics

	Pre-Op		2 Month Post-Op		2 Month Δ		6 Month Post-Op		6 Month Δ		12 Month Post-Op		12 Month Δ	
	mean	std dev	mean	std dev	mean	std dev	mean	std dev	mean	std dev	mean	std dev	mean	std dev
Gender Knee														
N	39.0		39.0		39.0		35.0		35.0		39.0		39.0	
extension	10.8	4.0	4.0	3.4	(6.8)	4.6	1.7	2.1	(9.0)	4.0	0.7	1.4	(10.1)	3.9
flexion	113.5	8.7	117.1	9.3	3.5	11.0	120.9	9.7	7.3	11.1	124.1	9.5	10.5	10.3
ROM	102.7	9.5	113.1	11.0	10.3	12.7	119.2	10.5	16.3	11.9	123.4	9.8	20.7	11.0
Control Knee														
N	39.0		39.0		39.0		30.0		30.0		39.0		39.0	
extension	9.5	4.6	4.6	3.9	(4.9)	5.4	2.6	3.5	(7.0)	5.7	1.3	2.6	(8.2)	4.8
flexion	117.0	9.8	113.8	8.1	(3.2)	11.3	117.6	8.4	(0.5)	10.6	119.6	8.4	2.6	11.2
ROM	107.5	11.5	109.3	10.6	1.7	13.4	115.0	10.8	6.5	13.8	118.3	9.7	10.8	13.2
Difference (G-C)		p-value		p-value		p-value		p-value		p-value		p-value		p-value
extension	1.3	0.18779	(0.5)	0.51676	(1.8)	0.10828	(0.9)	0.25079	(2.0)	0.11190	(0.6)	0.18911	(1.9)	0.05408
flexion	(3.5)	0.09932	3.2	0.10605	6.7	0.00949	3.3	0.14166	7.8	0.00530	4.5	0.03096	7.9	0.001649
ROM	(4.8)	0.04836	3.8	0.12750	8.6	0.00485	4.2	0.11872	9.8	0.00353	5.1	0.02317	9.9	0.000595

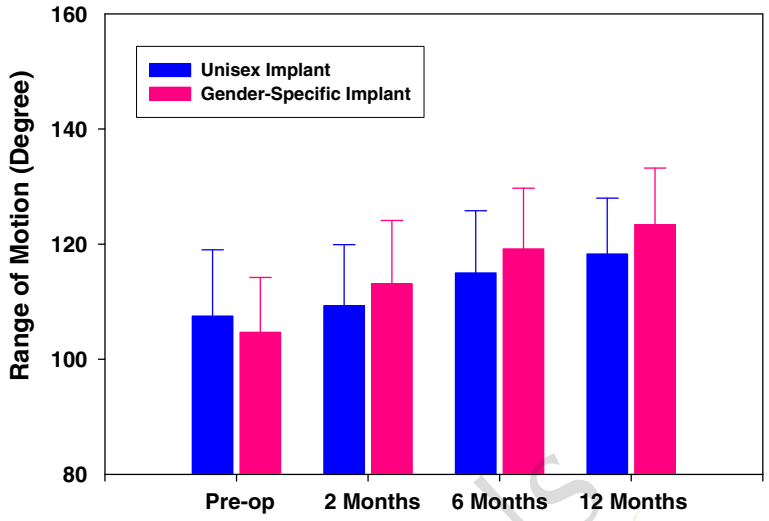


Figure 1 ROM vs. Visit.

high pre-operative ROM (near 120°). Furthermore, all subjects with gender specific implants achieved post-operative ROM at 12 months at least equivalent to their pre-operative ROM. In contrast, 82% of the women with unisex implants realized equal or better ROM at 12 months. Consequently, those women with greater pre-operative ROM benefited most with the gender specific implant relative to the unisex prosthesis, while the more impaired women with low pre-operative ROM experienced, on average, the least ROM improvement irrespective of implant choice.

The ROM improvement was further analyzed with regard to BMI for each cohort as illustrated in Figure 4. Improvement for the unisex implants was sporadic, although the linear regression revealed a near constant improvement of 10°. In contrast, the ROM improvement afforded by the gender specific implant revealed a dependency on BMI; namely the more fit the subject, the better the realized ROM gain. As evidenced by the linear regression, for each unit of BMI decrease in the range of 22 to 39 kg/m^2, ROM improvement increased by 0.8° for the gender specific implant. Based on this analysis, women in the normal range (BMI approximately 20–26) can expect the full gain of the gender specific implant, while obese women (BMI approximately 30–40 kg/m^2) will likely achieve less than 10° improvement over the unisex implant.

The ROM improvement was also analyzed with respect to femoral implant A/P size to assess if physical size could play a role in improving range when using more modern designs in condylar dimensions. Figure 5 depicts the ROM improvement as a function of femoral implant A/P size for both patient cohorts. For the larger aspect ratio-matched gender specific prosthesis, mean ROM improvement was 18° at femoral A/P = 60 mm (was 60.2 mm x 64.7 mm gender specific implant is matched to 60 mm x 65 mm average distal femoral morphological size as opposed to using the nearest 61.5 mm x 72.0 mm unisex implant), whereas in the size-mismatched unisex implant, the ROM improvement was just 11° at femoral A/P = 62. Such trend supports the hypothesis that appropriately matched femoral implants improve ROM outcome. However, the improvement does not progress beyond femoral A/P = 64. Given the low sample number at such femoral A/P extremes, the gains realized by correct aspect ratio matching is not powered to be significant but does represent an interesting trend where body habitus may not be complimentary in larger patients to present implants.

Finally, a total of 184 knee surgeries were retrospectively analyzed with regard to occurrences of post-operative complications and revisions to compare with the same time frame of one year in the study group. With the exception of revisions, no relationship existed between complications (structural, fibrosis, neurological, and manipulation under anesthesia) and type of prosthetic. However, revisions were 5 times more likely ($p = 0.00015$, Pearson's Chi-square test) with the unisex implant than the gender specific implant. The revisions consisted of 4 mechanical failures and one infection.

Discussion

This study provides evidence to support the notion that newer designs of dimensional matching by aspect ratio and high-flexion modifications may yield early recovery advantages over conventional unisex designs of the past. Specifically, upon examining 78 TKAs, the 39 gender-specific high-flexion knee prosthetics improved pre-operative ROM an average 21° at 12 months, while the 39 conventional designed implants improved ROM

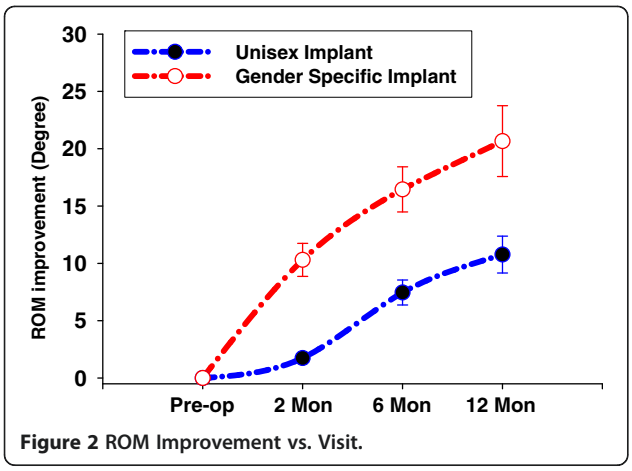


Figure 2 ROM Improvement vs. Visit.

by 11°, resulting in a 10° ROM improvement differential (or equivalently, 91%) attributable to the gender-specific implant ($p = 0.00060$). Computer-assisted surgery was employed in an attempt to hold surgeon related variables constant throughout the study minimizing surgeon bias. Moreover, all subjects with gender-specific high-flexion implants achieved post-operative ROM at least equivalent to their pre-operative value, whereas 82% of subjects with the unisex implant reached or exceeded their pre-operative ROM. Revisions were 5 times more likely ($p = 0.00015$) with the unisex implant.

Regardless of the choice of implant, subjects with greater pre-operative ROM posted the greatest post-operative ROM. However, those women who exhibited greater pre-operative ROM and lower BMI benefited the most with the gender specific prosthesis as compared to the unisex implant. Specifically, women in the normal BMI range (20–26 kg/m^2) achieved the full benefit of the gender specific implant, whereas obese women (30–40 kg/m^2) achieved on average less than the 10° ROM gain possible with respect to unisex implants. As a coarse approximation, for each unit of decreasing BMI, an additional degree of ROM improvement can be expected with the gender specific implant. These BMI-associated results reinforce the notion that non-obese patients fare better in TKA outcome than obese patients as reported by others [8].

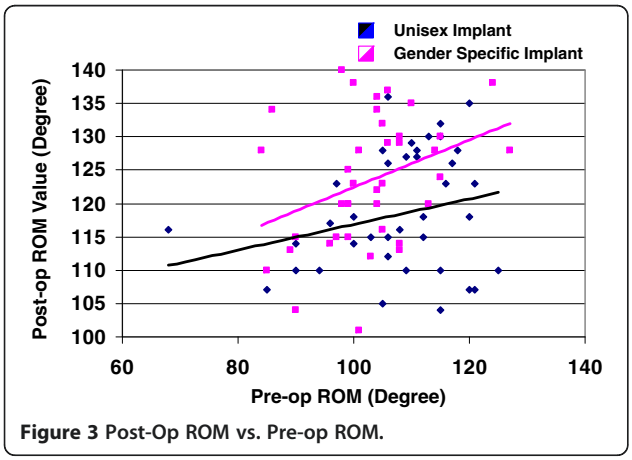


Figure 3 Post-Op ROM vs. Pre-op ROM.

A short-range trend, namely the considerably greater gender specific ROM improvement over unisex implants for femoral A/P sizes 60-64 mm, was discovered to support the hypothesis that appropriately matched femoral implants improve ROM outcome. However, given the low sample size for subjects with femoral A/P sizes greater than 62 mm, additional subjects with larger femurs will need to be examined to yield a definitive conclusion. This exhibits one of two limitations and shortcomings of this study.

First, the trend of larger sized condyles not yielding as much ROM in this small subset does raise questions about body habitus, flexibility, and design matching. While the smaller, thinner individuals represent the more typical athletic group, it may be that their perceived improved performance is one of fitness rather than deficiencies of implant designs. The second limitation is the mix of CR and LPS in the study group. While this may represent a potential of confounding variables, there was no apparent difference in magnitude of ROM in the two subsets. This is supported by the paucity of literature articles showing no differences in ROM on functionality in cruciate sparing and sacrificing designs. As both cohorts yielded a 12-month post-operative ROM of at least 118°, both designs can be considered capable of producing a successful outcome with regard to functionality required for the average American lifestyle. However, the high-flexion design may afford the extra flexion required for more athletic subjects and better accommodates lifestyles involving squatting, leg crossing and deep kneeling. Within this subset of higher demand patients, this subtle improvement in ROM may provide the necessary difference between satisfaction or frustration in certain activities.

There were no significant adverse events attributed to either group. Curiously, the historical group used in review of non-gender revision rates for the same time period of follow-up showed a 5 times higher rate of revision than the study group over the 12-month follow-up period. While this was significant, there did not appear to be a single course effect in the historical group solved by the study group. The 5 patients out of 189 reviewed to compare the authors' historical rate did, however, seem to be improved by the subsequent 39 study patients in the study series. While design may make a difference in failure, this study cannot draw conclusions from such short follow-up or small population.

Collectively, the substantive anatomical differences in male and female knees would be expected to result in

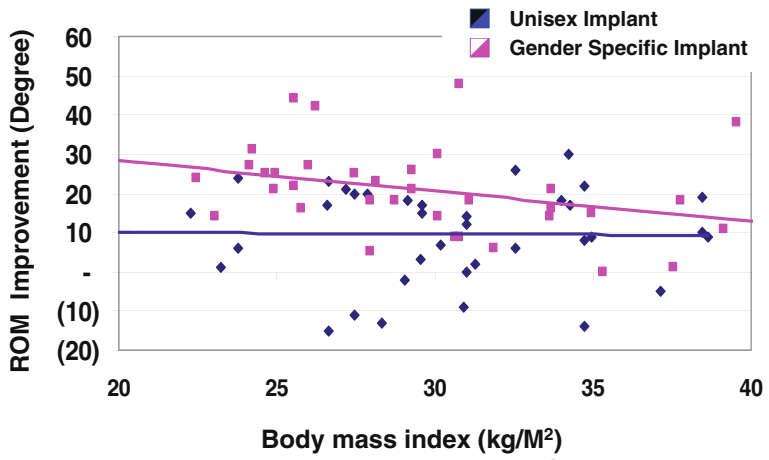


Figure 4 ROM Improvement vs. BMI.

different functional TKA outcomes when employing unisex prostheses as we have found. Most studies, however, do not reveal a significant gender difference or bias in clinical outcomes. To further elaborate, Ritter and Eizember et al. [9] found no significant difference in ROM outcome based on gender, but did show significance based on age. In another study, Ritter and Wing et al. [10] evaluated 7326 knees with respect to Knee Society knee score, flexion, pain relief and walking improvement following TKA. They concluded that with regard to clinical outcome measured by these metrics, women perform just as well as men with the unisex prosthesis system. Finally, MacDonald and Charron et al. [11] also could not identify a gender bias in clinical outcome measured by WOMAC, SF-12, and KSCRS. Although females slightly outperformed males in WOMAC and SF-12 improvement following TKA, men slightly outperformed women in KSCRS improvement. This was also noted in our series (larger implants ≥ 64 mm) by the trend in ROM improvement which also did not translate to better motion.

Absence of gender bias in clinical outcome following the use of unisex knee prosthetics has led some to conclude that high-flexion prosthetics are not warranted. However, uniform outcome across gender with unisex prosthetics may support alternative conclusions. First, the unisex implants may be underperforming in men and women in that the average ROM following TKA reported is only 100°-110° [12-14], while the human knee is capable of 160° [15]. In fact, the American Academy of Orthopaedic Surgeons claims that the normal human knee has a passive ROM of 144° and that TKA "success" should be characterized by post-operative ROM greater than 110°. With a better, more personalized prosthetic fit, the mean post-operative ROM may reach well beyond 100°-110°. Secondly, the perceived

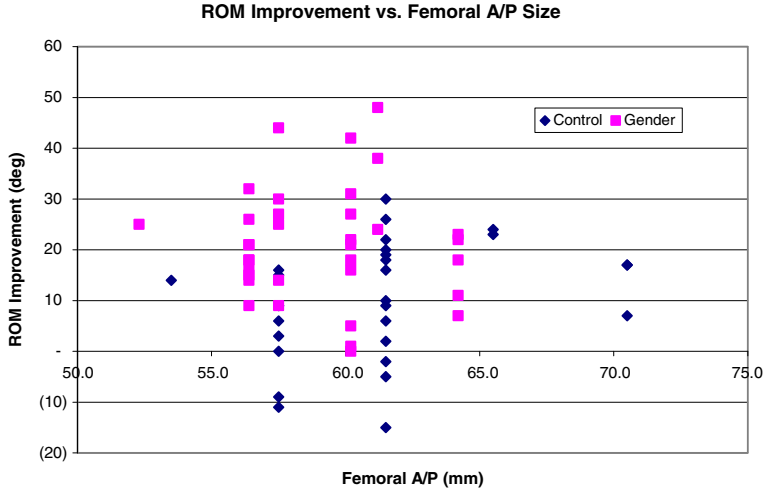


Figure 5 ROM Improvement vs. Femoral A/P Size.

absence of gender bias may be due to the lack of sufficient resolution in commonly used clinical outcome metrics. A gender bias may be present, yet undetectable with conventional metrics such as WOMAC, SF-12, SF-36, and the Knee Society knee score. For example, the Knee Society knee score developed by Insall [16] discounts ROM to 20% of full value (divides ROM by 5) in comprising the overall score. A substantive 10% change in ROM, for example, from 100° to 110°, accounts for a mere 2% change in KS knee score. Together with a reported intraobserver error of 11% and interobserver error of 16% [17], the ability to detect gender bias becomes challenging when using knee score alone. Finally, it is worth pondering whether the 10° differential in ROM improvement between the gender specific high-flexion implant and the unisex implant is due to the high-flexion nature of the gender specific design, the high-flexion, or both. High-flexion knee prostheses have been designed to achieve flexion well beyond the average 100°-110° ROM by removing an additional 2 mm of bone from the posterior femoral condyle, increasing the articulation curvature during high-flexion activities. In many models, the tibial insert is modified with an anterior cut to avoid patellar tendon impingement during high-flexion. Additionally, NexGen LPS Flex exhibits a modified cam/post to avoid dislocation at the high-flexion to provide a theoretical 150° of flexion.

Unfortunately, the literature reporting high-flexion prostheses is inconsistent in their clinical outcome. Both Laskin [18] and Huang and Su et al. [19] investigated 80 and 50 TKAs respectively and found 14° flexion improvement with high flex implants compared to traditional implants. Also, Weeden and Schmidt et al. [20] and Bin and Nam et al. [21] surveyed 50 and 180 TKAs and reported flexion gains of 12° and 6° respectively. However, Suggs and Kwon et al. [22], Kim and Sohn et al. [23], and Seon and Song et al. [24] found no significant difference in clinical outcome between high-flexion and traditional implants.

Consequently, it remains difficult to assert whether the observed 10° gain in ROM improvement is attributable to the gender-specific characteristics, the high-flex modifications, or a combination of both features of this prosthesis design. A future third cohort utilizing a high flex unisex implant may well resolve such question. Clearly, the combination of high-flexion with or without gender specific appears to be consistent with enhanced ROM.

Overall, advances in knee prosthetic design and TKA surgical techniques have yielded implantable knees with ever increasing comparability to the human knee in fit and performance. Our study demonstrated that the short-term (12 months) ROM improvement of a gender-matched high-flexion designknee prosthetic was 10° (or 91%) superior to the conventional unisex prosthesis. Also, women who exhibited greater pre-operative ROM and lower BMI were found to benefit the most with the gender-specific prosthesis. For each decreasing unit of BMI, an additional degree of ROM improvement can be expected with the gender-specific implant. These modest improvements suggest the optimal knee of the future may well be a *personalized* implant designed uniquely, and manufactured rapidly, for each patient. This study also supports the claim that certain design modifications in the newer implants may aid in producing better functional outcomes; therefore, the orthopedic community should strive to embellish these new developments.

Kneeling and standing up from a chair as performance-based tests to evaluate knee function in the high-flexion range: a randomized controlled trial comparing a conventional and a high-flexion TKA design

Abstract

Background: We compared the functional outcome between conventional and high-flexion total knee arthroplasty (TKA) using kneeling and sit-to-stand tests at 1 year post-operative. In addition, the patient's daily functioning, pain and satisfaction were quantified using questionnaires.

Methods: We randomly assigned 56 patients to receive either a conventional or a high-flexion TKA. Primary outcomes were maximum flexion angle and maximum thigh-calf contact measured during kneeling at 1 year post operatively. Secondary outcomes were the angular knee velocity and ground reaction force ratio measured during sit-to-stand performance tests, and questionnaires.

Results: At one year post-operative, maximum knee flexion during kneeling was higher for the high-flexion TKA group (median 128.02° (range 108–146)) compared to the conventional TKA group (119.13° (range 72–135)) ($p = 0.03$). Maximum thigh-calf contact force was higher for the high flexion TKA group (median 17.82 N (range 2.98–114.64)) compared to the conventional TKA group (median 9.37 N (range 0.33–46.58))($p = 0.04$). The sit-to-stand tests showed a significantly higher angular knee velocity in the conventional TKA group (12.12 rad/s (95%CI 0.34–23.91); $p = 0.04$). There were no significant differences between groups in ground reaction force ratios and patient-reported outcome scores.

Conclusion: Although no differences were found in patient-reported outcome scores, differences in performance-based tests were clearly apparent. Standing up from a chair at 90° of knee flexion appeared to be easier for the conventional group. The kneeling test revealed significantly higher weight-bearing knee flexion for the high-flex group. Hence, if kneeling is an important activity for a patient a high-flex design may be recommendable.

Trial registration: The study was retrospectively registered in ClinicalTrials.gov under identifier NCT00899041 (date of registration: May 11, 2009).

Keywords: Total knee arthroplasty, High-flexion, Performance-based tests, Functional outcome, Kneeling, Sit-to-stand

Background

Several types of implant designs have been manufactured in order to optimize the results after total knee arthroplasty (TKA). Range of motion (ROM) is an important outcome parameter of postoperative knee function [1–3]. High-flexion designs are aimed at accommodating larger postoperative ROM necessary for activities of daily living (ADL), such as kneeling, standing up from a low chair, sitting cross-legged, transferring in and out of bath, gardening and stair climbing [4–9].

Design features of a high-flexion TKA are typically a reduced radius and an increased thickness of the posterior femoral condyle resulting in extended condyles. In addition, specific posterior-stabilized high flexion designs have an adapted post-cam mechanism providing increased femoral rollback [9–11]. However, it remains uncertain whether these design changes actually lead to functional benefits for TKA patients.

The results of TKA are mostly assessed using physical examination, X-rays and the evaluation of patient-based questionnaires. Although patient-based questionnaires provide feasible and appropriate methods to address the concerns of patients, they are subjective and assessment is often subject to floor or ceiling effects, which limits the adequate assessment of higher functioning patients [4, 5, 11, 12]. Moreover, most questionnaires were originally not designed for use in high-flexion TKA patients (e.g. no points were scored for extra ROM beyond 125°) [4, 5].

Performance-based testing, specifically targeted at high-flexion activities, has been suggested to help to compensate for the limitations in existing scores [4, 13]. One major advantage of performance-based testing is that pain and pain-related items do not have such a large effect on functional outcome as on patient-based questionnaires [1, 14–17].

Performance-based tests, such as sit-to-stand tests [16], and kneeling [18] have been proposed to evaluate knee function after TKA in the low-flexion (≤90°) and high-flexion range (>120°), respectively. However, during kneeling, thigh-calf contact has been reported to limit flexion and can therefore obscure the potential benefit reached with high-flex TKA designs [18, 19]. In that same study, thigh–calf contact pressures were shown to exponentially increase with increasing knee flexion angles, and to reach maximum values (up to >30%BW) in maximal flexion. Therefore, in order to assess TKA systems at high flexion, flexion angles as well as thigh-calf pressures need to be recorded.

In our clinic we traditionally use a PCL-retaining, fixed bearing device. However, high-flexion TKA systems may provide advantages for patients who perform high-demand activities (such as kneeling and sit-to-stand) on a daily basis. In order to determine whether a high-flexion TKA system would provide clinically relevant benefits for our patients we set up a randomized controlled trial to compare the functional outcome of our patients treated with either a PCL-retaining or a high-flexion TKA device.

Our primary objective was to compare the functional outcome between conventional and high-flexion TKA using kneeling as a performance-based test at one year post-operative. In addition, we compared the functional outcome between conventional and high-flexion TKA using a sit-to-stand test and we quantified patient's daily functioning, pain and satisfaction using questionnaires at one year post-operative.

Methods

We performed a prospective double-blind randomized controlled trial at the department of Orthopedics of the Canisius Wilhelmina Hospital, Nijmegen, the Netherlands. The study protocol was approved by the regional ethical committee (CMO 2008/021; ABR NL21274.091.08) and was carried out in line with the Helsinki Declaration. The study was retrospectively registered in ClinicalTrials.gov under identifier NCT00899041 (date of registration: May 11, 2009).

Patients with primary osteoarthritis or arthritis secondary to rheumatoid arthritis scheduled to undergo primary TKA were considered for inclusion and were enrolled prospectively. Exclusion criteria were: other causes of arthritis, inability to complete the exercises due to contralateral arthritis, contralateral TKA or other co-morbidities, and the inability to complete the questionnaires. Endpoints were defined as death, aseptic loosening, infection, amputation, reoperation or withdrawal on request.

In our protocol we explicitly specified any foreseeable post-randomisation exclusions; 1) death of the patient, 2) aseptic loosening of the prosthesis, 3) infection of the prosthesis, 4) amputation of the leg in which the prosthesis was placed, and 5) withdrawal on own request, as in these circumstances the outcomes of interest could not be measured.

Between November 2008 and November 2012, 75 consecutive patients undergoing unilateral TKA were assessed for eligibility (Fig. 1). Nineteen patients were excluded before randomization; eight patients declined to participate and 11 patients were excluded: mentally incompetent (1 patient), presence of contralateral TKA (2 patients), bilateral osteoarthritis (8 patients).

After written informed consent had been obtained, the patients were randomly allocated to receive either a PFC Sigma FB CR (fixed-bearing, cruciate-retaining; DePuy, Leeds, UK) or a PFC Sigma RP-F PS (rotating platform, posterior stabilized, high-flexion; DePuy, Leeds, UK). Computer-generated randomization with stratification for

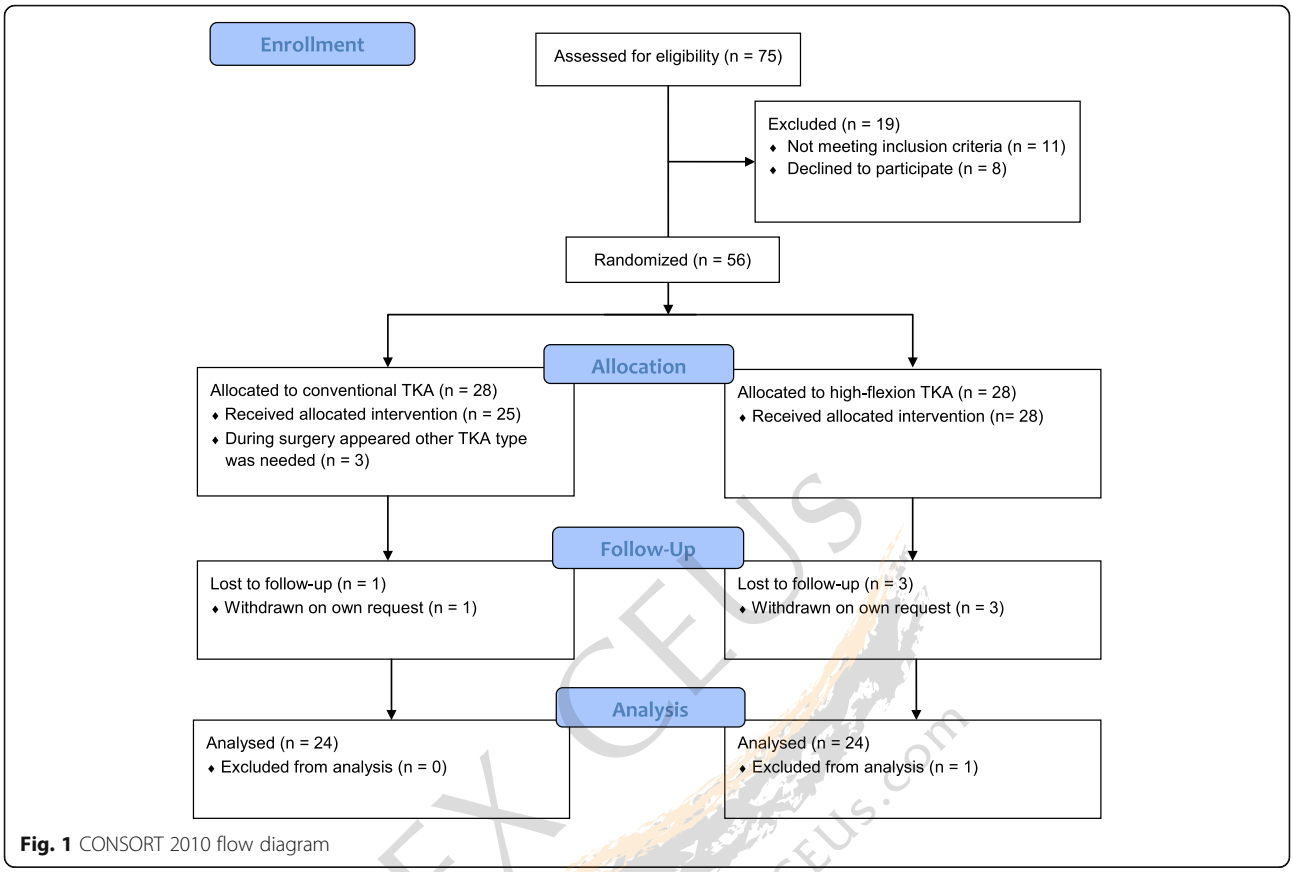


Fig. 1 CONSORT 2010 flow diagram

BMI below or above 30 kg/m^2 was performed by an independent statistician. All patients and investigators were blinded for type of implant. The day before surgery the surgeon received a sealed study number envelope with the allocated TKA.

Identical surgical techniques were used in the groups according to the manuals of the designers. Three experienced knee surgeons were involved in this study. Rehabilitation was done according to the joint-care-protocol used in our hospital, including out of bed mobilization on the first postoperative day.

Primary outcomes

The primary outcome measures were maximum flexion angle and maximum thigh-calf contact force measured during kneeling at one year post operatively. Maximal knee flexion angles during kneeling were measured using wireless accelerometers and gyroscopes (π-node, Philips, Eindhoven, the Netherlands). The accelerometers were positioned on the lateral side of both ankles, on both upper legs (10 cm above the patella) and on the sternum.

The maximal thigh-calf contact force (N) for the affected knee and unaffected knee were measured with a Conformat-pressure mapping sensor (Tekscan, Boston, USA). The pressure map was positioned in the popliteal fossa of both legs. The protocols for both measurements have been described in detail previously [18]. The mean of three consecutive maximum flexion angle and maximal thigh-calf contact force measurements was used in statistical analysis.

Secondary outcomes

Sit-to-stand tests (STS) were used to assess the knee function in the flexion range up to 90° at one year post operatively. During STS we measured the angular knee velocity and ground reaction force ratio of both legs on the floor. The STS is a validated functional tool to assess knee patients which is selective and relatively independent of pain. The protocol has been described in detail previously [16, 20]. Angular velocity of the knee was measured using accelerometers, the ground reaction force (GRF) of each leg by two pressure plates [21]. TKA patients have been shown to produce a lower extension velocity while getting up from a chair as compared to healthy age-matched controls [15]. The ratio of ground reaction force (GRF_{ratio}), which demonstrates the asymmetrical functional usage of the two legs, was expressed as the GRF of the TKA side (F_{TKA}) divided by the GFR of the non TKA side ($F_{no\ TKA}$): $GRF_{ratio} = F_{TKA}/F_{no\ TKA}$.

The patients' daily functioning, pain and satisfaction were assessed using the following questionnaires: Knee Society Score (KSS), Western Ontario and McMaster Universities

(WOMAC) and 0–100 Visual Analogue Scale (VAS) for pain and satisfaction (0 = no pain/extremely dissatisfied and 100 = very painful/very satisfied).

Statistical analyses

Sample size estimation showed that 21 patients per group would be required to detect a clinically relevant difference of 10° of flexion with a standard deviation of 10° in knee flexion angle [10], with an alpha of 0.05 and a power of 90%. A dropout-margin of 7 patients for each group was used, which resulted in 28 patients per group. Descriptive statistics were used to summarize the data. Shapiro-Wilk tests and normality plots were used to assess normality. Differences between conventional and high-flex TKA designs were tested using Student t-tests and Mann-Whitney-U-tests for non-parametric and normal distributed data, respectively. With non-parametric tests, a measure of effect size, *r*, was calculated by dividing Z by the square root of N ($r = Z/\sqrt{N}$; small $r \geq 0.1$, medium $r \geq 0.3$, and large $r \geq 0.5$) [22]. Analyses were performed using SPSS 21.0 (IBM, Chicago, USA). For all data sets, differences were considered statistically significant at p-values <0.05.

Results

After randomization of 56 patients, three patients in the conventional TKA group were excluded: two because of insufficiency of the posterior cruciate ligament and one because an additional patella component was needed to improve patella tracking. During follow-up, one patient in the conventional TKA group was withdrawn on his/her own request without providing any reason. One patient in the high-flexion TKA group was withdrawn on his/her own request because of back problems. Two other patients in the high-flexion TKA group were withdrawn on their own request without providing any reason (Fig. 1). Patient demographics and baseline values are presented in Table 1.

Complications

In the conventional TKA group, one patient had a deep venous thrombosis treated with anti-coagulants 48 days post-operative, one patient had an inadequate knee flexion post-operatively and was treated with manipulation under anesthesia, and one patient had a patellar clunk and was treated using arthroscopic debridement. At 1 year post-operative, one patient in the high-flexion TKA group presented with signs of an infected TKA. Since an infected TKA was explicitly specified as reason for post-randomisation exclusion, and this patient was unable to perform kneeling and STS movements (and therefore no measurements could be obtained) this patient was excluded from the statistical assessment. However, later it appeared that all cultured biopsies were negative.

Table 1 Patient demographics data and baseline clinical status

	Conventional TKA (n = 24)	High-flexion TKA (n = 24)
Sex (F:M)[c]	11:13	12:12
Age (yrs)[a]	64 ± 7	66 ± 8
BMI (kg/m^2)[a]	31 ± 4	32 ± 5
Thigh-calf contact force (N)[b]	15.88 (0–196.83)	9.70 (3.34–178.23)
Maximum flexion angle (°)[b]	127.7 (97–146)	126.6 (97–156)
Angular velocity (rad/s)[a]	80.56 ± 19.74	78.60 ± 18.26
GRF_{ratio} (1)[a]	0.86 ± 0.29	0.84 ± 0.26
KSS[b]	103 (55–132)	104 (78–151)
WOMAC[b]	55.5 (25–94)	49.5 (8–69)
VAS^{b}_{pain}	43.5 (0–90)	40 (0–99)

[a]Values are mean ± SD; [b]Values are median (range); [c]Values represent numbers

Primary outcomes

Kneeling: Maximum knee flexion angle & maximum thigh-calf contact

At 1 year post-operative, maximum knee flexion during kneeling was higher for the high-flexion TKA group (median 128.02° (range 108–146°)) compared to the conventional TKA group (median 119.13° (range 72–135°)) (U = 174, r = 0.32, p = 0.03). Maximum thigh-calf contact force was higher for the high flexion TKA group (median 17.8 N (range 3.0–114.6 N)) than for the conventional TKA group (median 9.4 N (range 0.3–46.6 N)) (U = 177, r = 0.31, p = 0.04).

Secondary outcomes

Sit-to-stand: Angular knee velocity & ground reaction force ratio

At 1 year post-operative, the angular velocity measured during sit-to-stand tests was higher for the conventional TKA group (93.23 rad/s (SD 21.94)) compared to the high-flexion TKA group (81.10 rad/s (SD 17.46)) (difference 12.12 rad/s (95%CI 0.34–23.91 rad/s); p = 0.04). No significant differences in GRF_{ratio} measurements between conventional (0.94 (SD 0.14)) and high-flexion TKA groups (0.87 (SD 0.21)) were found (difference 0.07 (95%CI -0.04 – 0.17); p = 0.21)).

Questionnaires

At one year post-operative, no significant differences between conventional and high-flexion TKA groups in KSS, WOMAC, VAS_{pain}, and $VAS_{satisfaction}$ scores were found (Table 2).

Discussion

In this study we compared the functional outcome between conventional and high-flexion TKA using performance-based tests at one year follow-up. It was found that during

Table 2 Results of primary and secondary outcomes

	Conventional TKA (n = 24)	High-flexion TKA (n = 24)	p-value
Thigh-calf contact force (N)[b]	9.37 (0.33–46.58)	17.82 (2.98–114.64)	0.04[d]
Maximum flexion angle (°)[b]	119.13 (72–135)	128.02 (108–146)	0.03[d]
Angular velocity (rad/s)[a]	93.23 ± 21.94	81.10 ± 17.46	0.04[c]
GRF_{ratio} (1)[a]	0.94 ± 0.14	0.87 ± 0.21	0.21[c]
KSS[b]	179 (90–199)	193 (109–201)	0.10[d]
WOMAC[b]	12.5 (2–62)	7 (0–54)	0.10[d]
VAS^{b}_{pain}	4 (0–54)	5 (0–31)	0.96[d]
$VAS^{b}_{satisfaction}$	89.5 (4–100)	98.5 (8–100)	0.06[d]

[a]Values are mean ± SD; [b]Values are median (range); [c]Student's t-test; [d]Mann–Whitney U test

kneeling both the maximum flexion angle and thigh-calf contact force were significantly higher in the high-flexion TKA group. Sit-to-stand analyses showed no differences in asymmetry between the healthy and affected leg between conventional and high-flexion TKA group, while the patients in the conventional TKA group had a significantly higher angular velocity as compared to the high-flexion TKA group. Questionnaire scores (KSS, WOMAC and VAS scores) were similar in both groups.

Most previous clinical studies failed to show a difference between conventional TKA and high-flex TKA when using traditional outcome scores [4, 12, 13, 23, 24]. In addition, a recent study showed that current outcome measurement tools are not suited for the high flexion range [25].

In this study we found significant differences between conventional TKA and high flex TKA when using weight-bearing functional tests, but not when using traditional outcome scores proposed to evaluate knee function in the normal flexion range. The maximum knee flexion and thigh-calf contact forces during active kneeling were significantly higher in the high-flexion TKA group than in the conventional TKA group. The higher maximum thigh-calf contact in the high-flexion TKA group might be the result of the higher active flexion angle that was reached in that group. Since thigh-calf contact has been reported to limit flexion during kneeling, the flexion potential after high-flexion TKA might have been obscured by thigh-calf contact. In addition, although the surgeons used an identical surgical technique for both designs, it cannot be excluded that there were small differences in terms of treatment of the bone on the posterior region [9]. With the high-flex design more bone has to be removed at the posterior condyles, so it would be logical to also remove more posterior osteophytes and excessive bone that could possibly hamper high flexion. However, judging from the post-operative radiographs this could not be confirmed.

Remarkably, patients with a conventional TKA design produced a higher extension velocity during the sit-to-stand test. A higher angular velocity has been shown to be associated with a better functional performance [15]. Although a higher active flexion angle was obtained in the high-flexion TKA group, it apparently did not lead to a better performance of the extensor mechanism. Conflicting results between different post-operative outcome measures in the evaluation of high-flexion versus conventional TKA designs have also been reported by others [4, 12, 13, 23, 24, 26].

According to several authors performance-based measurements are necessary for an adequate evaluation of high-flexion TKA [4, 12, 13, 23, 24]. Nutton et al. [23] used performance-based measurements to evaluate functional outcome following TKA with NexGen standard and high flexion components. No significant differences in outcomes between patients receiving the conventional and high flexion designs were found. They divided performance-based measurements into 'lower flexion' and 'higher flexion' activities. The lower flexion activities were walking on a flat surface, ascending and descending a slope and a flight of stairs, and sitting and rising from a high chair. The higher flexion activities were sitting and rising from a low chair, getting in and out of a bath and bending the knee to the maximum range of flexion when standing, using a stool as a step. Finally, patients were asked to crouch and rise from a crouching position (squatting), using handrails for support. Patients were not asked to kneel, as most felt anxious about performing this activity. In addition, Palmer et al. [27] reported that some TKA patients were unwilling to kneel or squat because of advice from medical staff or third parties or because of fear of harming the prosthesis, although they state that no published data exists concerning this risk. The kneeling test used in the present study might therefore be a good method to distinguish between different TKA designs as the patient is in control of the movement.

The higher active flexion in the high-flexion TKA group is probably the result of the different design

features and subsequent surgical aspects of the prosthesis. First positioning of the post-cam mechanism more posterior allows the knee to flex more due to a better roll-back of the femoral component. Secondly, due to the thicker posterior condyles, high-flexion TKA surgery results in a better visualization of the posterior aspect of the knee allowing better decompression of posterior osteophytes and capsular tissue [4, 9]. Osteophyte removal could lead to a higher ROM in the high-flex range. Finally, adequate tensioning of the posterior cruciate ligament in the cruciate retaining prosthesis is challenging and the outcome is less predictable than in a posterior stabilized prosthesis and may have therefore jeopardized the ROM required for a kneeling exercise.

We did not find significant differences between conventional and high-flexion TKA when using the KSS, WOMAC and VAS scores. This is in line with previous observations reported by other authors [4, 7, 12, 23]. The self-reported questionnaires have a clear ceiling effect [4, 14, 17], and this makes them less useful for higher functioning TKA patients.

Conclusion

This study showed that although no differences were found in patient-reported outcome scores, differences in performance-based tests were clearly apparent. Standing up from a chair at 90° of knee flexion appeared to be easier for the conventional group. The kneeling test revealed significantly higher weight-bearing knee flexion for the high-flex group. Hence, if kneeling is an important activity for a patient a high-flex design may be recommendable.

Abbreviations

ADL: Activities of daily living; BW: Body weight; FB CR: Fixed-bearing, cruciate-retaining; GRF: Ground reaction force; KSS: Knee Society Score; PCL: Posterior cruciate ligament; ROM: Range of motion; RP-F PS: Rotating platform, posterior stabilized; VAS: Visual Analogue Scale; WOMAC: Western Ontario and McMaster Universities

Performing high flexion activities does not seem to be crucial in developing early femoral component loosening after high-flexion TKA

Abstract

Background: It is still unclear whether high flexion (HF) activities correlated with the early loosening of the femoral component and whether HF activities are possible. We investigated what is the capability for performing various HF activities, and whether high flexion activities increase the chance of aseptic loosening after HF-TKA.

Methods: We retrospectively analysed 260 patients who underwent HF-TKA using the NexGen LPS Flex between 2001 and 2009. The mean follow-up was 6.7 years (range, 5–13). We evaluated range of motion, Knee Society scores, WOMAC, and serial radiographs for aseptic loosening. Responses to questions on individual HF activities were recorded on 5-point Likert scales based on difficulty (0–4). Patients were divided two groups based on their responses to squatting and kneeling, which were important weight-bearing HF activities in Asian population (HF group vs. non-HF group) for comparisons of aseptic loosening and clinical outcomes.

Results: More than 80 % of patients positively responded for various HF activities. The capability of HF activities showed that cross-legged sitting, squatting, and kneeling were 97.7, 51.1 and 52.7 % at the latest follow-up, respectively. Aseptic loosening was identified in two tibial components (0.8 %) but none in femoral components in non-HF group. There was no significant difference of aseptic loosening based on HF activities (0.8% vs. 0%, $p = 0.063$).

Conclusions: The results of this study suggest that HF activities do not seem to be associated with aseptic loosening of femoral component after HF-TKA.

Keywords: Total knee arthroplasty, High flexion activity, Aseptic loosening, Femoral component

Background

The successful pain relief and long-term durability after conventional total knee arthroplasty (TKA) [1] lead patients to expect the feasibility of more demanding activities. With a small modification in surgical technique and implant design, the high-flexion (HF) TKA was introduced to accommodate superior range of motion (ROM) compared to conventional TKA [2]. ROM after TKA is an important determinant of activity level and knee function [3]. Since HF activities are an integral part of many activities of daily living (ADL) in Asian and Middle East population, and owing to increasing patient demands for continuing their HF activities after TKA, HF-TKA is surpassing conventional TKA and is being increasingly preferred by surgeons also as they can safely accommodate knee flexion greater than 135° and can support a knee flexion even up to 155°.

There was still some controversy about clinical result and complication after HF-TKA. Some recent studies performed on Asian population has reported an alarming, increased incidence of aseptic loosening of femoral components in HF-TKA and attributed it to HF activities done by those patients after HF-TKA [4–6]. An in-vitro study has also hypothesised that HF-TKA designs have a greater risk of femoral component loosening [7]. However, in other recent studies, there was no decreased

rate of survivorship after HF-TKA [8,9]. In some studies, HF-TKA showed superior ability to do squatting, kneeling, crossed legged sitting which were the three most important weight bearing HF activities in Asian population requiring a knee ROM between 111 and 165°, compared to conventional TKA [10,11]. Nevertheless, many surgeons are still concerned that some reports of early loosening associated with HF activities after HF-TKA does not exclude a higher risk of loosening in the longer term. Indeed the capability of performing individual HF activities after a HF-TKA is not detailed in any recent literature.

Therefore, we investigated what is the capability for performing various HF activities, and whether HF activities increase the chance of aseptic loosening after HF-TKA.

Methods

We retrospective analyzed prospectively collected data of 294 patients underwent HF-TKA between January 2001 and December 2009. Among 294 patients, 34 patients were excluded (seven patents died and 27 were lost to follow up), leaving 260 patients for this study (88.4 %). Decision for HF-TKA were based on considering their preoperative ROM, life style and activity level, knee alignment, deformities, patient expectation after surgery [12]. We performed HF-TKA for patients with preoperative maximal flexion more than 100° or more. There were 212 women and 48 men with age of 69 years (range, 57–83 years) at the time of surgery. The body mass index was 27.0 kg/m^2 (range, 20.5–34.1 kg/m^2). Minimum follow-up was 5 years (mean, 6.7 years; range, 5–13 years). This study was performed with the approval of the institutional review board of our hospital (Samsung Medical Center 2014-01-065). All participants gave their written informed consent to assessing and using their data.

The senior author (C-WH) of this study performed all the TKAs using standardized technique as described elsewhere [13]. The cement was applied directly on the anterior flanges and distal cut surface of femur and on the posterior facet of the femoral component [14]. Posterior femoral osteophytes were carefully removed with knee in full flexion to aid in increased postoperative flexion. Patella was not resurfaced in this cohort. All surgeries in our study were done using NexGen Legacy Posterior-Stabilized Flex fixed bearing implant (Zimmer, Warsaw, IN, USA). The same postoperative rehabilitation program was used for all patients. Briefly, a closed suction drain was used for 2 days, and ankle pump exercises were commenced immediately after surgery. On the second postoperative day, a continuous passive motion machine was applied at a range of motion tolerated by the patient, and ambulation with a walker was encouraged. Patients were also encouraged to perform active and assisted knee flexion, and quadriceps setting exercises, and straight leg raising exercise against gravity. After the rehabilitation period, HF activities were allowed as tolerated. Even weight-bearing HF activities, such as, squatting and kneeling were not prohibited, if patients needed to perform these activities.

Patients were followed up at 1, 3, 6 months, 1 year after surgery and annually thereafter. Clinical outcomes were evaluated using ROM, American Knee Society knee scores (KSKS) and function scores (KSFS), and Western Ontario and McMaster Universities osteoarthritis index (WOMAC) scores. Non weight bearing passive flexion angles were measured in the supine position by independent examiner and calculated using two reference lines, a femoral line (from the lateral epicondyle of the distal femur to the tip of the greater trochanter) and a line from the tip of the fibula head to the tip of the lateral malleolus. Functional outcomes for HF activities were evaluated using a self-administered questionnaire (in accordance with 5-point Likert scales based on difficulty, 0–4 with zero being no discomfort and four being extreme difficulty), which consisted of seven HF activities that addressed whether the operated knee permitted HF related activities, such as, ascending and descending stairs, sitting or rising from a low chair, sitting or rising from the floor, cross-legged sitting, squatting, and kneeling [13]. Responses to each question were scored according to five grades of difficulty for a particular activity (Grade 0: no difficulty, grade 1: mild difficulty, grade 2: moderate difficulty, grade 3: severe difficulty and grade 4: extreme difficulty (unable to do)). Levels 0, 1, and 2 were considered positive responses and levels 3 and 4 were considered negative responses.

For identifying aseptic loosening, radiographic evaluations were done based on the American Knee Society roentgenographic evaluation and scoring system. Full length and standing anteroposterior, lateral and Merchant's view were acquired at each follow-up visit, and assessed for limb alignment, component positioning, and for any features of loosening. Widths of radiolucent lines were measured along the seven zones on lateral radiographs of the femur, seven zones on anteroposterior radiographs of the tibia, and three zones on lateral radiographs of the tibia. Any radiolucent lines identified were compared with the previous follow-up x-rays to classify them as progressive or non-progressive lines. Aseptic loosening is defined as radiolucency greater than 2 mm width, interval increases in the width of an existing radiolucency, cement fracture, and prosthesis migration [15]. A comparison was also made between two groups (HF group and Non-HF group) divided based on their responses to squatting and kneeling (two of the most important weight bearing HF activities done

in Asian population) for evaluation in loosening rates and functional scores. Both squatting and kneeling activities are known to impose high contact stress at the posterior articular surface in both normal as well as replaced knee [16], hence if at all the concept of HF activities leading to aseptic loosening is valid, the patients doing these activities will be affected first.

Statistical analysis

Paired t-test was used to determine the difference between preoperative and postoperative values of all continuous outcome variables (ROM, KSKS, KSFS, and WOMAC). To evaluate the effect of HF activities on the aseptic loosening, we grouped patients according to feasibility of squatting and kneeling (HF group and non-HF group). A Fisher's exact test was used for finding any statistically significant difference in radiographic loosening rates between HF group and non-HF group. Independent t-test was used for comparison between the two groups. The significance level was set at 0.05. All statistical analyses were performed with SAS 9.3 (SAS Institute, Cary, NC, USA).

Results

The following percentages of patients responded positively (≤Grade 2) to questions regarding their abilities to perform high flexion activities: 96.9 % for ascending stairs, 96.9 % for descending stairs, 96.3 % for sitting or rising from a low chair, 80.8 % for sitting or rising from the floor, 97.7 % for cross-legged sitting, 51.1 % for squatting, and 52.7 % for kneeling (Table 1).

No femoral component loosening was encountered. There was revision of three knees (three patients), two of them for aseptic loosening in zone one of tibial component with tibial subsidence and one for instability in non-HF group and all patients were at follow up of 5 years or above when loosening was identified. All three patients were revised with a varus-valgus constrained prosthesis and all three were negative responders for squatting and kneeling. There was no significant difference in loosening rates between the compared groups ($p = 0.063$). There was a statistically significant difference in ROM and clinical scores between HF group and non-HF group at latest follow-up (Table 2).

The mean flexion improved from 122.5° ± 14.9° preoperatively to 138.4° ± 11.8° at the latest follow-up (Fig. 1). Mean KSKS and KSFS scores improved from 49.1 ± 12.3 and 57.4 ± 12.3 preoperatively to 91.4 ± 3.3 and 94.5 ± 4.8 at the latest follow-up, respectively. Mean WOMAC score improved from 43.4 ± 8.8 to 11.5 ± 4.2.

Discussion

Patient satisfaction after TKA is primarily determined by patient's expectation about surgery and their chances of return to activities similar to the pre-arthritic stage of their life [17]. Since satisfactory pain relief after TKA is proven beyond any doubts, now-a-days many Asian patients are changing their expectations to achieve a superior ROM after TKA so as to safely perform squatting, kneeling and other HF activities that form a part of their ADL. It is for this reason that HF-TKA is gaining popularity among surgeon in Asia, Middle East. Despite these current trends, some recent in vivo and in vitro studies have questioned the long term durability of HF-TKA in those doing HF activities [4–7,18]. Those studies have attributed the increased loosening rates to the HF activities performed after HF-TKA. These alarming reports along with the facts that HF activities causes increase peak stress on articular surfaces of both replaced and nonreplaced knees (evident by increased incidence of osteoarthritis in Asian patients whose ADL involve HF activities), has led many surgeons in to a dilemma of choosing a HF design in Asian population. These study results may also lead surgeons to disallow HF-TKA patients doing HF activities overcoming the fact that the main reason for performing HF-TKA in Asian patients

Table 1 The capability of HF activities at the latest follow-up[a]

	Ascending stairs	Descending stairs	Sitting or rising from a low chair	Sitting or rising from the floor	Cross-legged sitting	Squatting	Kneeling
Grade 0	34 (13.1)	15 (5.8)	71 (27.3)	13 (5.0)	71 (27.3)	21(8.1)	0(0)
Grade 1	169 (65.0)	119 (45.8)	43 (57.7)	90 (34.6)	98 (37.7)	55(21.2)	22(8.5)
Grade 2	98 (18.8)	118 (45.4)	150 (12.3)	107 (41.2)	85 (32.7)	57(21.9)	115(44.2)
Grade 3	8 (3.1)	8 (3.1)	7 (2.7)	50 (19.2)	6 (2.3)	105(40.4)	59(22.7)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	22(8.5)	64(24.6)
Positive[b]	252 (96.9)	252 (96.9)	253 (96.3)	210 (80.8)	254 (97.7)	133 (51.1)	137 (52.7)
Negative[c]	8 (3.1)	8 (3.1)	7 (2.7)	50 (19.2)	6 (2.3)	127 (48.9)	123 (47.3)

HF high flexion

[a]Data are given as number (percentage). HF activities were evaluated using a self-administered questionnaire [13]. Grade means degree of difficulty for a particular activity. Grade 0: no difficulty, grade 1: mild difficulty, grade 2: moderate difficulty, grade 3: severe difficulty and grade 4: extreme difficulty (unable to do)

[b]Grade 0, 1, and 2 were considered positive responses

[c]Grade 3 and 4 are considered negative responses

Table 2 Comparison between groups based on squatting and kneeling of HF activities[a]

	HF group ($n = 122$)	Non-HF group ($n = 123$)	p value
Preoperative			
Age (years)	69.6 ± 6.4	70.2 ± 5.4	0.386
BMI(kg/m^2)	26.8 ± 2.4	27.2 ± 3.1	0.260
Maximum flexion	124.1 ± 14.7	121.5 ± 15.3	0.162
KSKS	50.1 ± 12.1	48.6 ± 11.5	0.316
KSFS	58.3 ± 12.5	56.1 ± 12.2	0.155
WOMAC	42.4 ± 8.3	43.8 ± 11.5	0.203
Postoperative			
Maximum flexion	141.9 ± 7.5	136.1 ± 8.2	<0.001
KSKS	92.4 ± 2.6	90.5 ± 3.7	<0.001
KSFS	96.2 ± 4.6	93.1 ± 4.6	<0.001
WOMAC	8.8 ± 2.7	13.9 ± 3.8	<0.001

HF high flexion, *BMI* body mass index, *KSKS* Knee Society knee score, *KSFS* Knee Society function score, *WOMAC* Western Ontario and McMaster Universities osteoarthritis index
[a]Data are given as mean (SD)

is for them to do HF activities after surgery. Hence we investigated what percentage of patients were capable of doing HF activities, and whether HF activities lead to increased loosening especially of femoral component and after HF-TKA.

More than 80.8 % of patients in this study positively responded for various HF activities excepting weight-bearing HF activities, indicating HF-TKA has allowed these patients to indulge in ADL that require deep knee bending. The capability of patients for performing some routinely used HF activities after HF-TKA is not reported dedicate in any previous studies regarding HF-TKA. As far as we know, our study is the first of its kind to analyse what percentage of patients were doing different HF activities and their responses for questionnaires on routinely used HF activities. Approximately 50 % of patients in this study, low percentage than other HF activities including questionnaire, responded positively to questions regarding the capability of squatting and kneeling. However, Squatting and kneeling are more high demanding activities than other HF activities since they are accompanied by weight bearing. Thus these two HF activities affected not only knee flexion but also hip and ankle motion [19]. Indeed, the kinematics of knee between weight bearing and non-weight bearing is different [20]. Therefore, we believed that HF-TKA was useful for HF activities after TKA.

Our study reveals favorable results for HF-TKA considering femoral component loosening. Some surgeons are still concerned that there might be greater risk of developing early loosening after HF-TKA especially in a longer term follow-up. Han et al. [4] reported a high incidence of early loosening of the LPS-Flex femoral component within 4 years, and noted that there were significantly more patients in the loosening group whose knees allowed squatting, kneeling, or cross-legged sitting postoperatively in the loosened group (85 %) than in the well-fixed group (49 %). They suggested these HF activities were the cause of early loosening of the femoral component. However, others studies with long-term follow-up reported good survival rates of 0–1.3 % for mechanical failure after HF-TKA [8,9]. These results indicated the implant to be a safe choice for Asian patients doing HF activities. Our results of comparison between HF group and non-HF group also revealed that in spite of the former group having better knee scores, we observed no difference in loosening rates between them. The rate of aseptic loosening of tibial component was reported as approximately 1 % after conventional TKA [21]. In the current study, there

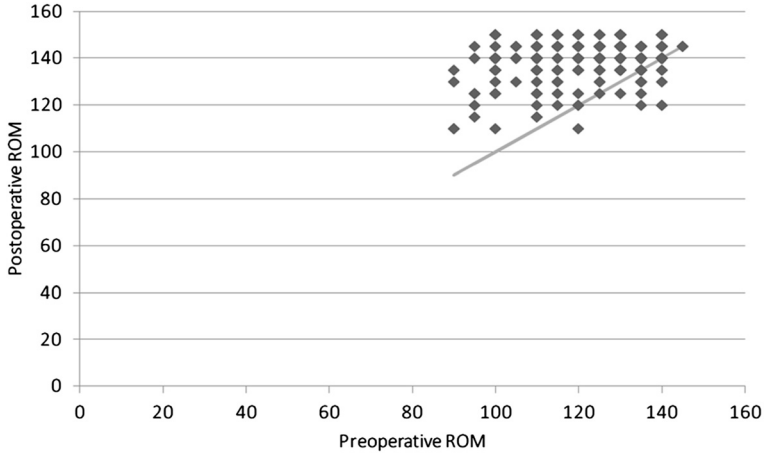


Fig 1 A scatter plot of change of ROM between the preoperative and postoperative state. The portion above linear line means improvement of ROM from preoperative to postoperative state. The plot reveals that postoperative ROM is overall greater than preoperative ROM

was no case of tibial component loosening in the HF group. Two cases of aseptic loosening in tibial component were observed only in the non-HF group (0.8 %). Therefore, HF activities did not seem predispose an early tibial component loosening after HF-TKA. This finding is consistent with the previous reports regarding early loosening after HF TKA [8,22]. Hence, the results of this study reinforce our hypothesis that HF activities are not a predisposing factor for early aseptic loosening after HF-TKA. We consider that the femoral implant bone cementing technique may have been responsible for the early loosening. King and Scott [23] demonstrated the importance of cementing the posterior condyles and noted that an inadequate cementing at this area resulted in premature aseptic loosening. We placed bone cement on the posterior aspect separately, which, we believe, resulted in complete filling and firm fixation of the femoral prosthesis, especially in the posterior condylar region.

Our study had some limitation. First, we did not compare the outcomes from HF-TKA and conventional TKA. But this study provides insight for the capability of HF activities after HF-TKA in Asian population which required HF activities in ADL. Second, the frequency of doing HF activities was not evaluated. A combination of the presence of HF activities and the frequency of doing HF activities would potentially contribute to the component loosening. However, the frequency of activities was difficult to measure quantitatively. Third, the load under ROM was not specifically evaluated along with the ROM itself. High stress is known to be generated by large net quadriceps moment and net posterior force during loading in high flexion angles [16]. However, the quantitative measurement of the load at specific high flexion activities in each patient is very difficult. Thus, we tried to assess the overall effect of performing high flexion activities by using the questionnaire in this study. Fourth, our study included only a specific HF design. Hence our results may be limited to generalize to other HF designs. Fifth, the majority of patients were only in a mid-term follow up; 5–6 years (73.5 %, 191/260). Nevertheless, we believed that the results of this study were meaningful based on the fact that other studies reported premature failure with HF-TKA in short-term follow-up period. Indeed we focused on the association of HF activities and femoral component loosening by group comparison. Sixth, the study cohort was nonconsecutive series. We underwent HF-TKA only to patients with 100° or more of preoperative knee flexion, because preoperative flexion was known as a predominant determinant of postoperative flexion. Seventh, the tibial slope affecting ROM was not separately evaluated in this study. Not only the femoral component geometry but also the tibial slope have significant effect on the ROM after TKA. As we tried to put the tibial component with about 3° of posterior slope in every case of this study cohort, a few degree of differences in the tibial slope does not seem to significantly affect the result of this study. Finally, ascending and descending stairs were included in HF questionnaire. Since these two activities form an important and frequently used ADL in Asian life style and produce very high compressive loads on knee joints, hence can lead to polyethylene wear and loosening [24].

Conclusions

In this study, HF activities after HF TKA were not associated with early components loosening, and a majority of patients can perform different HF activities after HF-TKA. Some studies performed in Asia have reported high incidence of premature aseptic loosening of femoral components in HF-TKA and attributed it to high flexion activities done by those patients after HF-TKA [4–6]. In contrast, other studies have reported low incidence of aseptic loosening even minimum 5 years follow-up (Table 3). These findings suggest that HF activities do not seem to increase incidence of aseptic loosening of femoral component after HF-TKA.

Table 3 Studies with mid-term follow-up after HF-TKA

Study	Number of knees	Minimum follow up (years) (range)	Preoperative flexion (°)	Postoperative flexion (°)	HF activity assessment	Aseptic loosening (number [%])
Kim et al. [8]	100	10 (10 to 10.6)	125	135	No	0
Endres and Wilke [25]	79	5 (All 5)	82	122	No	0
Seng et al. [26]	36	5 (All 5)	123	128	No	0
Tarabichi et al. [27]	152	5 (All 5)	125	140	No	1 (0.5)
Tanavalee et al. [22][a]	178	6 (6 to 7.3)	138	135	No	0
Wohlrab et al. [28]	19	5 (All 5)	106	117	No	1 (3)
Current study	260	5 (5 to 13)	123	138	Yes	2 (0.8)

HF-TKA high flexion total knee arthroplasty, *HF* high-flexion
[a]131 knees had adequate radiographs were included for evaluation

Design modifications of high-flexion TKA do not improve short term clinical and radiographic outcomes

Abstract

Background: The prosthesis of contemporary total knee arthroplasty (TKA) has been modified to provide a more familiar environment for higher flexion angle of the replaced knee. The design modifications continue based on evidence reported in the literature. However, whether these modifications of the prosthesis design lead to improvements in clinical results needs further investigation. We determined whether the prosthesis modifications based on recent evidence improve clinical and radiographic results following high flexion TKA.

Methods: 524 patients who underwent primary TKA using two different high flexion prostheses were divided to Group 1 (HF-1) using a high flexion prosthesis, group 2 (HF-2) using the more recently devised high flexion prosthesis, which claims to be adopted from evidence proposed in the literature. Clinical outcomes included ranges of motion (ROM), the Knee Society knee and function score (KSKS and KSFS), the Western Ontario and McMaster Universities Arthritis Index (WOMAC) score, radiologic evaluation, and complication related to surgery.

Results: No differences in terms of clinical and radiographic results were observed between the groups at the 2 year follow-up. The mean ROM was 123°and 124° in the HF-1 and HF-2 groups, respectively. KSKS were 90 and 89.1, KSFS were 76.6 and 81.8, and total WOMAC scores were 23.1 and 24.9 in the HF-1 and HF- 2 groups. No differences of the incidences of radiolucency on radiographs (1.4% in HF-1, 2.1% in HF-2) and dislocation (1 case in HF-1 only) was observed.

Conclusions: Even if recent modifications in the design of high flexion TKA prosthesis were based on evidence in the literature, they did not provide meaningful improvements in short-term clinical and radiographic outcomes after TKA. Surgeons should consider our findings when choosing a prosthesis for their patients.

Keywords: Total knee arthroplasty, High-flexion knee, Outcome scores, Range of motion

Background

Total knee arthroplasty (TKA) is an effective method to eliminate pain and restore function in a patient with chronic arthritis of the knee joint. Despite excellent surgical outcomes and longevity of contemporary TKA, deep flexion of the knee after TKA may be still requested by patients, particularly Asians, who are accustomed to squatting and sitting on the floor [1-3]. Many investigators suggest a multidisciplinary approach such as improving intraoperative technique and postoperative rehabilitation to achieve a greater range of motion (ROM) after surgery. Furthermore, prosthetic design changes have recently been introduced in an effort to gain higher flexion angles.

High flexion prostheses incorporate several common kinematic modifications compared to traditional designs to improve kinematics at higher flexion angles [4-6]. These devices have an extended sagittal curve and a 2– 3 mm thicker posterior femoral condyle to maintain contact area and reduce stress on the insert at higher flexion angles [7]. The tibial post is located 1–2 mm more posteriorly to guide femoral rollback during high flexion. Furthermore,

the cam is extended to the surface of the femoral component posteriorly to increase the articular contact area at higher flexion angles [8]. The anterior face of the polyethylene tibial bearing has also been cut out to reduce patellar tendon impingement during high degrees of flexion.

However, it has been controversial whether the aforementioned theoretical improvements in design result in clinical improvements. The advantages have been demonstrated in some *in vivo* analyses, and several authors have reported improved postoperative ROM compared with that of the conventional designs [2,9-12]. In contrast, other studies have revealed a high rate of aseptic loosening of the femoral component during high flexion TKA and an increased rate of dislocation during a high-flexion angle at the short-term follow up. Thus, more attention was paid to the cam-post engagement design and the amount of posterior condyle resection after reports of high incidence of early loosening and dislocation [10,13,14]. Thus, implant manufacturers have been striving to assure implant safety and provide improved designs according to evidence reported in the literature. However, it is still controversial whether the modified implants in high flexion designed knee prostheses can actually affect clinical results.

We determined whether these theoretical improvements in implant design improved postoperative ROM, clinical outcome, and reduced complications such as osteolysis and dislocation following contemporary high flexion TKA. We hypothesized that the design modifications would affect postoperative clinical outcomes and complications after TKA.

Methods

We retrospectively investigated 647 patients who underwent primary TKA with two different high flexion prostheses from January 2011 to April 2012 at our institution. All patients were followed up for more than 2 years after surgery.

Two high-flexion designed total knee prostheses (LOSPA, Corentec, Inc. South Korea; Scorpio Non-Restrictive Geometry (NRG), Stryker, NJ, USA) were used. Two prostheses were used bimonthly.

The patients were divided into two groups according to the implant type used. Group 1 (HF-1, Scorpio NRG) consisted of 373 patients who underwent TKA using a high flexion implant, and group 2 (HF-2, LOSPA) was comprised of 274 patients who received a modified prosthesis, which was devised more recently, based on evidence from the literature. Before analysis, we included only those patients who were between 3° of valgus and varus in terms of the mechanical femoro-tibial angle (MFTA) after implantation, which is one of the factors affecting postoperative ROM, early loosening, and outcome [15,16]. Thus, 323 patients in HF-1 (MFTA: mean 1.2°, standard deviation 1.4°) and 249 patients in HF-2 (MFTA: mean 1.5° and standard deviation 2.3°) were registered in this investigation. No significant differences were observed between the groups with regard to the position of the femoral and tibial components in the coronal and sagittal planes or coronal limb alignment on preoperative radiographs (data not shown). Additionally, patients who had postoperative complications that may have had a negative impact on clinical outcome such as patellar fracture or periprosthetic infection (nine patients in the HF-1 group and 11 patients in the HF-2 group) and patients with complex knees and preoperative ROM < 50°, severe varus or valgus deformity > 20° combined with a bone defect requiring bone grafting were excluded. Consequently, 524 patients (291 in the HF-1 and 233 in the HF-2) were included (Figure 1). No demographic differences were observed between the groups (Table 1). The current study obtained Institutional Review Board approval from our institution (Samsung Medical Center, 2013-06-098) and written informed consent was obtained from all participants.

All operations were performed by a single senior surgeon (one of the authors), and all TKAs were performed using an extramedullary femoral and tibial guide system [17]. All the components were cemented with Simplex P (Howmedica, Rutherford, New Jersey) bone cement, and all the patellae were resurfaced with an all polyethylene dome-shaped component, implanted with bone cement. Quadriceps-strengthening exercises were started

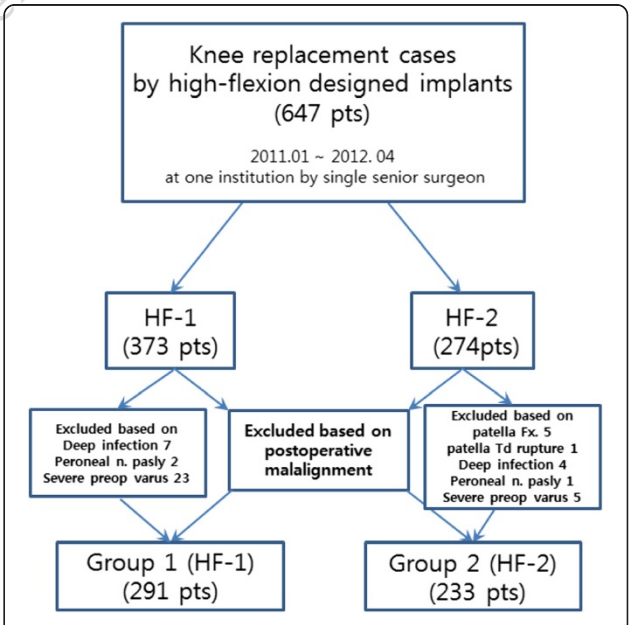


Figure 1 A total of 647 patients were initially eligible for inclusion, and 524 patients were included; the schematic shows subject involvement in the study.

Table 1 Comparison of preoperative demographics and clinical status between the groups

Parameters	HF-1 group (N = 291)	HF-2 group (N = 233)	*P* value
Sex (proportion of female patients)	263 (90%)	213 (91%)	NS (0.141)
Age (year)	68 ± 6.4	69 ± 6.6	NS (0.125)
Preoperative MFTA (°)	9.4 ± 5.4	9.5 ± 4.8	NS (0.816)
Preoperative total WOMAC score	55.9 ± 17.8	55.6 ± 16.5	NS (0.725)

NS: not significant, ROM: range of motion, MFTA: mechanical femoro-tibial angle, WOMAC: Western Ontario and McMaster Universities Index
Values are mean ± standard deviation ($P < 0.05$).

immediately after surgery as basic postoperative rehabilitation, and patients began walking with use of a walker on the first postoperative day. The second postoperative day, they started active and passive range-of-motion exercises under the supervision of a physical therapist. Weight bearing high-flexion activities such as squatting were allowed as tolerated.

All clinical and radiographic evaluations were performed by an independent investigator at each follow up visit, which were scheduled at 2 months, 1 year, and annually thereafter. At 1 year follow-up, the maximum flexion range of knee movement was measured by a physician assistant who was blinded to the study design, using a standard goniometer with the patient in the supine position on a table. The Knee Society Knee and Function score (KSKS and KSFS) [13] and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) index score were obtained [18,19]. Surgical complications that occurred within the follow-up period were also recorded. At 2 year follow-up, the incidence of radiological change such as progressive radiolucency was analyzed for evaluation of early loosening after TKA.

Standing anteroposterior (AP), lateral, and Merchant's view radiographs were obtained at every follow up, and mechanical femorotibial alignment was measured on full limb standing AP radiographs using a picture archiving and communication system (General Electric, Milwaukee, WI, USA). All radiographs were made with standard positioning (directing the patella anteriorly and with a focal film distance of 100 cm), which were analyzed using the Knee Society radiological scoring system to delineate radiolucency around the component [19]. A radiolucent line > 1 mm on the bony contact resurface zone of the femoral component at the 2 year follow up was considered radiolucency to determine how the implant design's modifications affected radiographic results. We compared the incidences between the two groups.

Theoretical differences in design between the two high flexion implants

The two designs of implant incorporated modifications to the geometry of the design intended to improve postoperative ROM and provided safe and adequate flexion by preventing loading on the edge of the posterior tibial articular surface and by increasing the tibiofemoral contact area during high flexion [8,20]. They have common characteristics in their design. That is, the femoral component of the posterior stabilized HF-1 and HF-2 knee prostheses had a single AP femoral radius, a deepened patella-femoral groove, which provided secure guidance of the patella, increased flexion, and reduced peak stress throughout ROM. In contrast, the HF-2 design had some additional modifications in the femoral component. While the posterior radius in the HF-1 femoral component was 8 mm, it was 10 mm in the HF-2 device, leading to increased contact area and higher posterior support length. In contrast, the anterior flanged angle was designed higher by 5° in the HF-2 compare to 3° in the HF-1 device, which was intended to reduce the amount of anterior bone resection. In other words, the HF-2 design preserved more bone anteriorly, and resulted in the same amount of bone loss and a larger posterior radius than those of the HF-1 implant to decrease contact stress (Figure 2). This may reduce loads in the knee during deep flexion and result in less wear or loosening on the insert. Last, both implants were designed to heighten jump distance and prevent exceeding the cam post by rollback at deep flexion. However, the HF-2 design was modified to be extended proximally and moved to the posterior direction to create an inverse slope on the tibial posterior and posterior released articular surface for safety during deep flexion.

The statistical analysis was performed using SAS ver. 9.13 (SAS Institute, Cary, NC, USA). The ROM, clinical outcomes (KSKS, KSFS, and WOMAC subscale scores) and radiographic MFTA of patients are described as means and standard deviations. Differences were compared between the two groups by Student's *t*-test. The incidence of osteolysis was numbered and compared to the statistical significance determined by Pearson's chi-square analysis or Fisher's exact test. The threshold for significance was < 0.05. The statistical analysis in this study had > 80% power to detect a 10° difference in postoperative ROM between the groups (accepting < 5% probability of a type I error). The authors set the score difference according to a previous study [21].

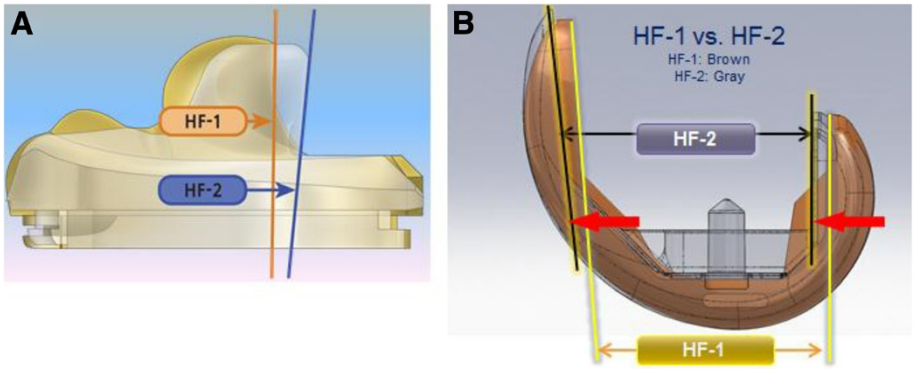


Figure 2 The HF-2 was modified to provide safe and adequate flexion in contrast to the HF-1 device in the cam-post mechanism (A) and femoral component design (B).

Results

The HF-2 group did not show greater postoperative flexion of the knee and improved knee scores than that of the HF-1 group. The mean preoperative angle of flexion of the knee was 123° in the HF-1 group and 124° in the HF-2 group, and the mean postoperative angle of flexion improved to 129° and 127°, respectively ($P = 0.098$) (Table 2). No differences in the postoperative KSKS or total WOMAC scores were observed between the two groups at the 1 year follow-up ($P = 0.448$ and $P = 0.093$, respectively). The mean postoperative KSKS were 90.0 in the HF-1 and 89.1 in the HF-2 group, and total WOMAC scores were 23.1 and 24.9 in the HF-1 and HF-2 groups, respectively (Table 3). However, significant differences were observed in the KSFS and stiffness on the WOMAC subscales, The HF-2 group showed more improved results than those of the HF-1 on the KSFS (HF-1, 76.6 vs. HF-2, 81.8, $P < 0.001$), whereas worse results were observed on the WOMAC stiffness subscale (HF-1, 2.3 vs. HF-2, 2.7, $P = 0.025$).

No significant difference was observed in the postoperative complication rates such as radiographic changes of progressive radiolucency or dislocation at the short term follow-up. The incidence rate of the radiolucency radiographic abnormality of osteolysis in the femoral component did not differ between the two groups on AP and lateral radiographs at the 2 year follow-up ($P = 0.570$). Radiographic changes were observed in four knees in the HF-1 and five knees in the HF-2 group. All osteolytic changes in the bone contact resurface zone of the femoral component were involved in zone 4 area. We found no significant difference in dislocation occurrence between the groups. One revision operation due to a femoro-tibial dislocation was found in HF-1 group, but no dislocations were observed in the HF-2 group.

Discussion

Many implant suppliers are considering biomechanical aspects in their implant designs to provide theoretical advantages of a high flex design and achieve clinical improvements. We hypothesized that the design modifications in the high flexion TKA devices would provide increased ROM and result in better clinical outcomes with fewer complications after TKA. Therefore, we con ducted a retrospective comparative study to identify whether the modifications in implant design affected clinical and radiological follow-up results.

Many researchers have reported that high-flexion type implants result in improved postoperative ROM compared to that of a standard posterior substitution type prosthesis. One important difference was an additional bone cut from the posterior femoral condyle compared to the regular posterior substituted type design. The femoral component has an elongated and widened cam design to increase stability, maintain spine strength, facilitate rollback, and ultimately increase ROM. In fact, Bellemans et al. reported that the posterior condylar offset decreased by 2 mm, and that maximal obtainable flexion was reduced by a mean of 12.2° [22]. It was previously revealed that high-flex designed prostheses for TKA achieve increased flexion angles from 129.4 to 139° [7,9-11]. However our study did not show different

Table 2 Mean range of motion at preoperative and postoperative 1 year

Parameters	HF-1 group (N = 291)	HF-2 group (N = 233)	*P* value
Preoperative ROM (°)	122.9 ± 16.6	123.7 ± 17.3	NS (0.512)
Postoperative ROM at 1 Year (°)	128.9 ± 10.3	126.9 ± 10.3	NS (0.098)

SD standard deviation, NS: no significant.
Values are mean ± standard deviation.

Table 3 Postoperative clinical outcomes at the 1 year follow-up

Parameters	Follow up at one year (Mean ± SD)		
	HF-1 group (N = 291)	HF-2 group (N = 233)	*P* value
KSKS	90.0 ± 10.7	89.1 ± 8.8	NS (0.448)
KSFS	76.6 ± 13.5	81.8 ± 12.7	<0.001
WOMAC	23.1 ± 12.8	24.9 ± 14.4	NS (0.093)
Pain	2.3 ± 3.0	2.5 ± 3.1	NS (0.307)
Function	18.6 ± 9.7	19.7 ± 10.7	NS (0.141)
Stiffness	2.3 ± 1.8	2.7 ± 2.0	0.025

SD standard deviation, NS: no significant, KSKS: Knee Society Score, KSFS: Knee Society function score, WOMAC: Western Ontario and McMaster Universities Index.
Postoperative data were checked at the outpatient department 1 year postoperatively.

result in postoperative ROMs in both groups, which used single radius designed, but different such as posterior radius length, femoral component geometry. We did not fully explain the kinematic differences due to the different geometry of the components but we inferred that a kinematic pattern favoring posterior femoral rollback was not associated with a greater ROM, at least for the high-flexion prosthesis.

Furthermore, our findings did not support the hypothesis that modifying the implant design for the high-flex knee positively affects postoperative clinical outcomes. No significant differences were observed in the KSKS or WOMAC scores, but significant differences were found in the KSFS and the WOMAC subscale stiffness score. Although improved KSFS scores were obtained in the HF-2 group, it may be difficult to acknowledge clinically meaningful results. We put a construction on clinical outcome results in our study to three points. First, clinical outcomes after TKA are affected by several factors such as operative technique, postoperative care and rehabilitation except implanted component's design [23-25]. Second, advances have reached in the aspect of intraoperative skill, prosthetic design, and postoperative care in contemporary TKA. Third, parameters used for assessing clinical outcome are probably too crude to reflect slight modifications. Thus, we did not demonstarte that design modifications of high-flex prosthesis would provides improved clinical outcomes.

The device used in the HF-2 group was designed based on several theoretical improvements for reducing the risk of early loosening. The important modifications in the femoral component design were to manage stress during deep flexion of the knee by using extended and augmented posterior condyles [26] and for maintaining bone support by increasing the anterior flange angle 3–5°. However, we found no difference in the incidence rate of radiographic changes such as progressive radiolucency in either groups. No cases of re-operation due to loosening occurred during the short-term follow-up in either group but differences in the incidence rate of radiolucency in zone 4 were observed three and five cases in HF-1 and 2 groups, respectively. Finally, based on retrospective data, we presumed that the change in polyethylene design to heighten jump distance might reduce the dislocation rate after surgery, but we could not detect a correlation between the implant modification, jump distance, and outcomes (Table 4). Arnout et al. [27] reported that a low jump distance can be associated with dislocation in a posterior stabilized knee prosthesis, and low jump distance is comprised of the relative position of the cam, post height, and a rounded post design. However, we suggest that the modification of the cam and post design be reconsidered as a higher jump distance leads to increased susceptibility to dislocation during knee flexion.

Our study had some inherent limitations because of its retrospective design. The rather short follow up period of 2 year was also a limitation to judge early loosening. The parameters for assessing clinical outcome may be too crude to reflect the slight modifications, and we had a female dominant cohort. Nevertheless, we tried to overcome these limitations by comparing a relative uniform high-volume, matched by tight criteria for classifying radiological change such as progressive radiolucency in zone 4 [28]. Accordingly, a prospective, randomized study is required to determine whether the implant design modification's affect outcomes.

Conclusions

Recent modifications in the design of high flexion TKA prostheses are based on evidence in the literature, but we were unable to detect meaningful improvements in short-term clinical and radiographic outcomes after TKA. Surgeons should consider our findings when choosing a prosthesis for their patients.

Table 4 Incidence of complications such as radiographic change of osteolysis in the femoral component and dislocation at the short-term follow-up (2 yrs)

Parameters (No.)	HF-1 group (N = 291)	HF-2 group (N = 233)	*P* value
Incidence of progressive radiolucency (%)	4 (1.4%)	5 (2.1%)	NS (0.570)
Dislocation	1	0	NA

NS: not significant, NA: not applicable.