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Original Research

# A Five-Year Comparative Functional and Clinical Evaluation of Two Contemporary Cruciate-Retaining Knee Implants

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ABSTRACT

*Background:* The purpose of our study was to compare 2 commonly used highly successful cruciate-retaining knee designs on the basis of patient-reported outcome measures (PROMs), range of motion (ROM), and anterior knee pain (AKP) at a minimum follow-up of 5 years.

*Methods:* A cohort of 65 patients underwent unilateral total knee arthroplasty, from January 2013 to December 2013, using NexGen Cruciate Retaining (Zimmer Biomet, Warsaw, IN), a nonmorphogenic knee (NMK) system. They were subsequently operated upon for the contralateral knee using Persona Cruciate Retaining (Zimmer Biomet, Warsaw, IN), a morphogenic knee (MK) system between January 2014 and June 2014. Of the 65 patients, 63 participated in this study. All the patients were compared preoperatively and postoperatively on the basis of PROMs, ROM, and AKP.

*Results:* On the basis of PROMs, ROM, and AKP, there was a statistically significant difference between the 2 groups favoring the MK group, with an ROM of 126.14° in the MK group as compared with 120.76° in the NMK group and *P* value of <.01.

*Conclusions:* PROMs, ROM, and AKP improved significantly over time after total knee arthroplasty using both MK and NMK implants; however, the outcomes of the former were better than those of the latter, although this difference was not clinically significant.



## Introduction

Total knee arthroplasty (TKA) is an established treatment option in patients with advanced knee arthritis. Advancements in arthroplasty and increased survival rates have led to an increase in the number of TKAs being performed for knee arthritis. All joint registries have witnessed an increase in the number of TKA. It is being speculated that by year 2040, the demand for primary TKA is projected to increase by more than 401% [1].

Functional recovery after TKA is dependent on factors such as range of motion (ROM), muscle strength, joint stability and pain, as well as the patient's general health, sense of well-being, and expectations [2-4]. A pain-free and mobile knee increases patient satisfaction as assessed by various patient-reported outcome measures (PROMs) [5,6]. Despite there being greater emphasis on restoring normal function of the knee, a certain percentage of patients undergoing TKA are dissatisfied with the results [7-9]. In an attempt to reduce the percentage of dissatisfied patients after TKA, newer implants have been designed in the hope that they will address the same. These designs are backed by intensive research based on unmet needs of patients.

The purpose of our study was to compare 2 highly successful knee designs used at our center, on the basis of PROMs, ROM, and anterior knee pain (AKP).

## Material and methods

The study is a retrospective chart review of prospectively collected data of evidence level 4, wherein 65 patients with advanced degenerative knee arthritis were operated by the senior surgeon for unilateral knee replacement using the NexGen Cruciate Retaining (Zimmer Biomet, Warsaw, IN), a nonmorphogenic knee (NMK) system, between January 2013 and December 2013. These patients were subsequently counseled and operated with the Persona Cruciate Retaining (Zimmer Biomet, Warsaw, IN), a morphogenic knee (MK) system for the contralateral knee, between January 2014 and June 2014. Knees with varus, valgus, and flexion

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**Table 1**
Intergroup and intragroup comparison of KSCS and KSFS variables.

| Time point | NMK group (n = 63) | | | MK group (n = 63) | | | Between-group comparison (n = 63) | |
|---|---|---|---|---|---|---|---|---|
| | Mean ± SD | Δ = (preoperative − follow-up) (Mean ± SD) | *P*-value | Mean ± SD | Δ = (Preoperative − follow-up) (Mean ± SD) | *P*-value | Δ =(NMK − MK) (Mean ± SE) | *P*-value |
| KSCS | | | | | | | | |
| Preoperative | 47.60 ± 10.11 | - | - | 47.43 ± 10.75 | - | - | 0.17 ± 1.8 | .932 |
| 6 mo | 82.98 ± 9.56 | −35.38 ± 6.4 | <.0001[a] | 83.13 ± 8.93 | −35.70 ± 5.5 | <.0001[a] | −0.15 ± 1.6 | .924 |
| 12 mo | 88.03 ± 8.95 | −40.43 ± 7.2 | <.0001[a] | 90.10 ± 8.02 | −42.67 ± 5.4 | <.0001[a] | −2.07 ± 1.5 | .152 |
| 24 mo | 90.20 ± 6.98 | −42.60 ± 7 | <.0001[a] | 92.22 ± 6.01 | −44.79 ± 6.2 | <.0001[a] | −2.02 ± 1.1 | .035[a] |
| 60 mo | 91.20 ± 5.70 | −43.60 ± 7 | <.0001[a] | 93.03 ± 5.06 | −45.60 ± 6.9 | <.0001[a] | −1.83 ± 0.9 | .036[a] |
| KSFS | | | | | | | | |
| Preoperative | 52.38 ± 9.04 | - | - | 52.13 ± 8.99 | - | - | 0.25 ± 1.6 | .870 |
| 6 mo | 76.63 ± 7.57 | −24.25 ± 7.5 | <.0001[a] | 77.07 ± 7.16 | −24.94 ± 6.7 | <.0001[a] | −0.44 ± 1.3 | .690 |
| 12 mo | 85.70 ± 7.68 | −33.32 ± 6.6 | <.0001[a] | 88.50 ± 7.76 | −36.37 ± 6.5 | <.0001[a] | −2.80 ± 1.4 | .039[a] |
| 24 mo | 86.40 ± 6.50 | −34.02 ± 6.6 | <.0001[a] | 89.80 ± 6.44 | −37.67 ± 5.6 | <.0001[a] | −3.40 ± 1.1 | .003[a] |
| 60 mo | 87.52 ± 6.16 | −35.14 ± 5.9 | <.0001[a] | 90.25 ± 5.64 | −38.12 ± 5.5 | <.0001[a] | −2.73 ± 1 | .001[a] |

SD, standard deviation.
In the NMK group, there was a significant improvement in patients' KSCS and KSFS scores from preoperative to different stages of follow-up postoperatively, and a similar trend was also observed in the MK group (*P*-value < .05).
While comparing between the NMK and MK groups, no significant difference was observed in improvement of the KSCS score from preoperative to follow-up at 12 months. Better improvement was observed in the MK group than in the NMK group at 24 months (NMK vs MK group: 90.20 ± 6.98 vs 92.22 ± 6.01) and 60 months (NMK vs MK group: 91.20 ± 5.70 vs 93.03 ± 5.06) (*P*-value < .05).
While comparing between the NMK and MK groups, no significant difference was observed in improvement of the KSCS score from preoperatively to follow-up at 6 months. Better improvement was observed in the MK group than in the NMK group at 12 months (NMK vs MK group: 85.70 ± 7.68 vs 88.50 ± 7.76), 24 months (NMK vs MK group: 86.40 ± 6.50 vs 89.80 ± 6.44), and 60 months (NMK vs MK group: 87.52 ± 6.16 vs 90.25 ± 5.64) (*P*-value < .05).
[a] *P*-value < .05, statistically significant.

deformity less than 15° were included in the study. Patients with a history of any other lower limb surgeries, spine surgeries or neurological impairments, ankylosed knee joints, a history of septic arthritis, and deep vein thrombosis before the surgery were excluded. Preoperative evaluation was performed using the Kellgren-Lawrence (KL) grading system for osteoarthritis [10]. Patients exhibiting grade II and III changes as per this system were included. Fifty-four of these patients had KL grade III osteoarthritis, and 11 had grade II. The KL grade II patients had spontaneous osteonecrosis of the medial femoral condyle that did not respond to conservative management. Of the 65 patients, 1 had a myocardial infarction and 1 sustained a periprosthetic fracture after trauma in the postoperative period, and both were excluded from the study. A total of 63 patients were subsequently followed up for a minimum period of 5 years (each side). The mean age of the subject group at the start of the study was 61 years, with 42 females (66.6%) and 21 males (33.4%). The body mass index of the subject group was 24.5.

### *Prosthesis types*

The MK system is characterized by the J curve femoral design with a deeper trochlear groove and a shorter, less-thick anterior flange. It has 12 femoral sizes, of which 9 have standard and narrow options, making a total of 21 different sizes. This system also has 9 tibia sizes, 8 different tibial inserts, and 6 patellar sizes. The NMK system has a traditional trochlear notch with 8 different femoral sizes, 10 tibial sizes, 5 tibial inserts, and 4 patellar sizes.

### *Surgical technique*

The surgery was performed by the senior surgeon on both sides, under tourniquet control. An anterior midline incision was used followed by a medial parapatellar approach. In both the groups, the femur was prepared first followed by the tibia. A distal femoral cut of 5° valgus was used in knees with a varus deformity

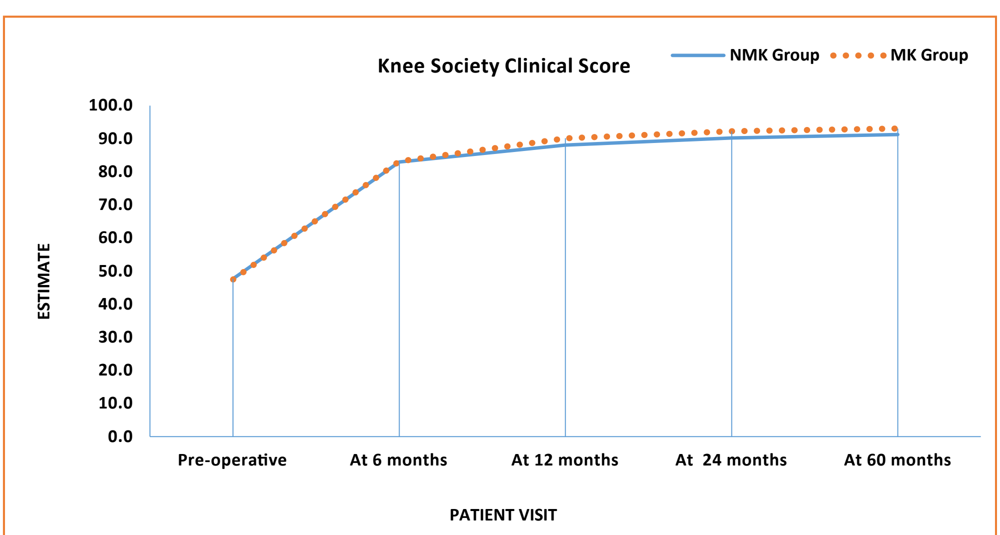


**Figure 1.** KSS (clinical).

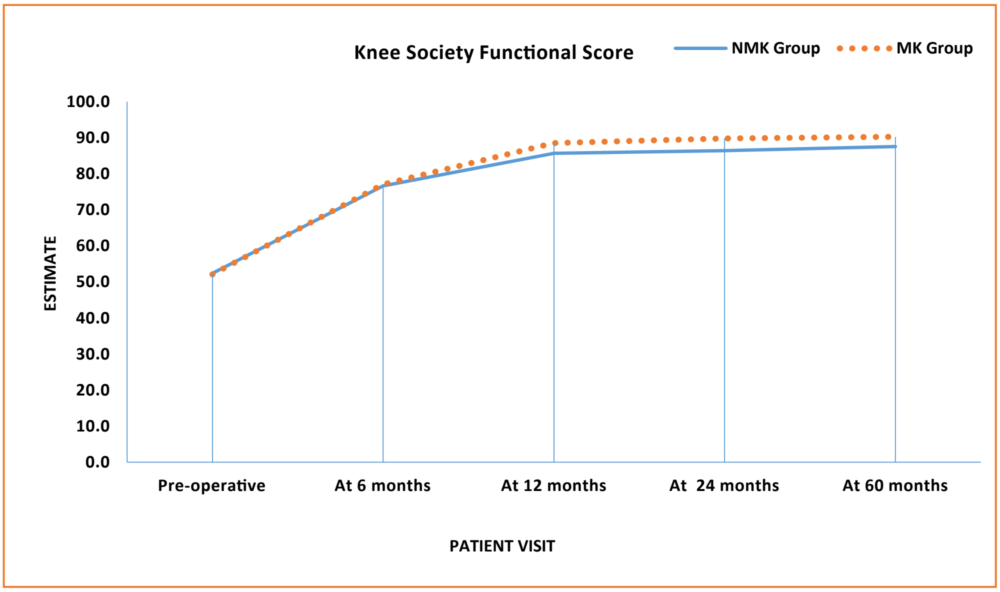


**Figure 2.** KSS (functional).

and 3° in those with valgus deformity. An additional distal femoral cut of 2 mm was taken in patients with fixed flexion deformity. The anterior cruciate ligament was excised, and the posterior cruciate ligament was retained in all the knees. After appropriate sizing of the femur, chamfer cuts were taken, which was followed by tibial preparation. Mechanical alignment was achieved by taking tibial cuts at right angles to the mechanical axis of the tibia, and the posterior tibial slope was approximated to the native slope. The cementing technique followed was first-generation digital pressurization in the tibial surface after lavage and drying. Cement was applied to the posterior aspect of the femoral component, and fixation performed. Patellar resurfacing was not performed in both cohorts, but the osteophytes around the patella were removed.

### *Clinical evaluation*

Each of these patients was followed up for a minimum period of 5 years postoperatively as per our standardized treatment protocol at intervals of 6 months, 1 year, 2 years, and 5 years. Preoperatively and at each follow-up, 3 PROM scores (Knee Society Score [KSS], Oxford Knee Score [OKS], and Forgotten Joint Score [FJS]-12) along with ROM and AKP assessment were evaluated separately for each knee. The data were compiled by an experienced physiotherapist who was blinded with regard to the implant allocation. The FJS-12, being a postoperative score, was measured only postoperatively until the latest follow-up. The ROM was measured with the help of a long-arm goniometer, which is a reliable and accurate means of measuring ROM [11]. The recognized method of measuring angles around the knee is to measure the axis of the femur between the center of the greater trochanter and the lateral epicondyle of the femur and between the axis of the tibia between the lateral femoral epicondyle and the center of the lateral malleolus [12]. AKP was evaluated with the help of the Kujala Knee Score questionnaire with emphasis on the site of pain [13]. The Kujala AKP score is a recognized instrument used within the fields of orthopaedics and sports medicine. It is a 13-item screening instrument designed to assess patellofemoral pain in adolescents, young adults, and in patients who underwent TKA with a variable ordinal response format [14,15]. The questionnaires were handed over to the patients and were completed independently by them preoperatively and at each follow-up.

**Table 2**
Intergroup and intragroup comparison of the Oxford Knee Score.

| Time point | NMK group (n = 63) | | | MK group (n = 63) | | | Between-group comparison (n = 63) | |
|---|---|---|---|---|---|---|---|---|
| | Mean ± SD | Δ = (Preoperative − follow-up) (Mean ± SD) | *P*-value | Mean ± SD | Δ = (Preoperative − follow-up) (Mean ± SD) | *P*-value | Δ = (NMK − MK) (Mean ± SE) | *P*-value |
| Preoperative | 24.51 ± 6.26 | - | - | 23.83 ± 6.48 | - | - | 0.68 ± 1.1 | .550 |
| 6 mo | 33.96 ± 5.24 | −9.45 ± 2.3 | <.0001[a] | 34.08 ± 5.94 | −10.25 ± 3.3 | <.0001[a] | −0.12 ± 0.7 | .452 |
| 12 mo | 38.11 ± 5.05 | −13.60 ± 3.6 | <.0001[a] | 40.08 ± 4.25 | −16.25 ± 4 | <.0001[a] | −1.97 ± 0.8 | .016[a] |
| 24 mo | 39.08 ± 4.58 | −14.57 ± 3.4 | <.0001[a] | 41.40 ± 4.04 | −17.57 ± 4.6 | <.0001[a] | −2.32 ± 0.8 | .001[a] |
| 60 mo | 39.90 ± 4.13 | −15.39 ± 5.2 | <.0001[a] | 41.96 ± 3.58 | −18.13 ± 5 | <.0001[a] | −2.06 ± 0.7 | .001[a] |

In the NMK group, there was a significant improvement in patients' Oxford Knee Score from preoperative to different stages of follow-up postoperatively, and a similar trend was also observed in the MK group (*P*-value < .05).
While comparing between the NMK and MK groups, no significant difference was observed in improvement of the OKS from preoperative to follow-up at 6 months. Better improvement was observed in the MK group than in the NMK group at 12 months (NMK vs MK group: 38.11 ± 5.05 vs 40.08 ± 4.25), 24 months (NMK vs MK group: 39.08 ± 4.58 vs 41.40 ± 4.04), and 60 months (NMK vs MK group: 39.90 ± 4.13 vs 41.96 ± 3.58) (*P*-value < .05).
[a] *P*-value < .05, statistically significant.

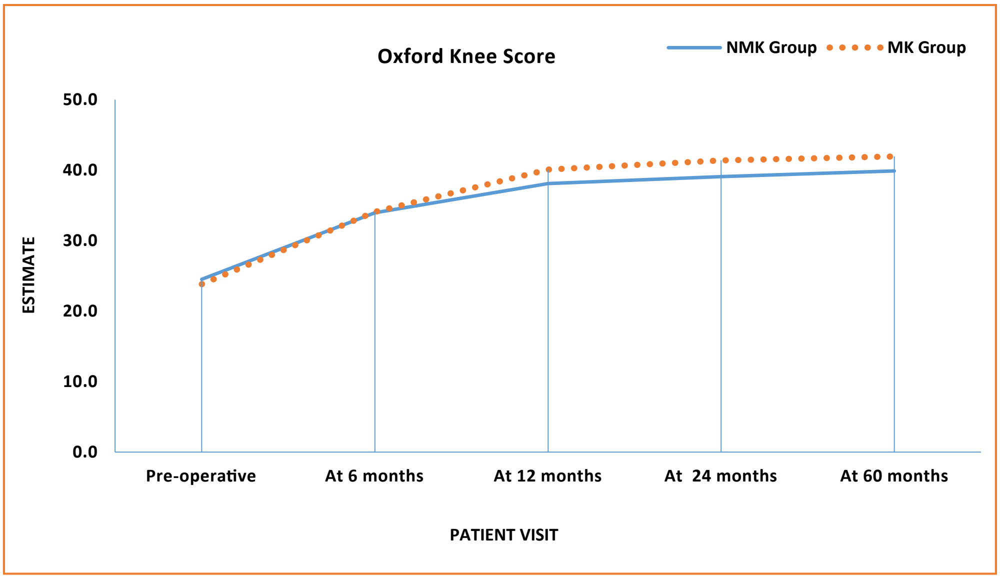


**Figure 3.** Oxford Knee Score (OKS).

*Roentgenographic evaluation*

The patients included in the study were assessed for alignment of the limb (tibiofemoral angle), the position of the components, the level of the joint line, posterior condylar offset, and the presence and location of radiolucent lines at the bone-cement interface as per the recommendations of the Knee Society [16]. Anteroposterior radiographs of the lower limbs including the hip, knee, and ankle along with lateral knee and skyline views were taken preoperatively and postoperatively at each follow-up to assess the aforementioned parameters. The postoperative radiographs were analyzed by the second author who could not be blinded to allocation of the implants because of variations in the radiographic appearance.

*Statistical analysis*

The values of the variables assessed were expressed as mean ± standard deviation. The changes in the Knee Society Clinical Score (KSCS), Knee Society Functional Score (KSFS), OKS, and FJS were assessed using a paired *t*-test. ROM of the knee in both the groups was similarly assessed using the paired *t*-test. All the statistical analyses in the study were carried out using a 2-tailed t test, and the level of statistical significance was kept at <0.05. A Kaplan-Meier survivorship analysis was performed to determine the cumulative survival rate during the period of the study, and the result was reported with 95% confidence intervals.

Power analysis was performed for all 6 parameters, namely KSCS, KSFS, OKS, FJS, ROM, and Kujala Knee Score at 5 years.

In the intrasubject analysis of both NMK and MK cohorts, there was a significant improvement in KSCS, KSFS, OKS, and ROM from preoperative scores to scores obtained at different stages of follow-up postoperatively. The analysis of both the cohorts for different variables revealed that while comparing the NMK and MK groups for KSCS, KSFS, OKS, FJS, ROM, and Kujala Knee Score, there was no significant difference between the 2 groups at the 6-month follow-up. Evaluation at subsequent follow-ups thereafter showed that the MK group performed better than the NMK group with regard to the scores.

## Results

*Functional outcomes*

The KSS (clinical and functional) and OKS did not differ significantly between the 2 groups preoperatively and at 6-month follow-up. In the subsequent follow-ups at 1 year, 2 years, and at 5 years, both the implants showed excellent outcomes; however, the MK group performed better than the NMK group (*P* value < .05). The Knee Society clinical scores at 5-year follow-up was 93.03 in the MK group and 91.20 in the NMK group, while the functional

**Table 3**
Intergroup and intragroup comparison of the FJS.

| Time point | NMK group (n = 63) | | | MK group (n = 63) | | | Between-group comparison (n = 63) | |
|---|---|---|---|---|---|---|---|---|
| | Mean ± SD | Δ = (6 Months − follow-up) (Mean ± SD) | *P*-value | Mean ± SD | Δ = (6 Months − follow-up) (Mean ± SD) | *P*-value | Δ =(NMK − MK) (Mean ± SE) | *P*-value |
| 6 mo | 52.43 ± 6.91 | - | - | 52.45 ± 6.02 | - | - | 0.02 ± 1.1 | .493 |
| 12 mo | 61.06 ± 6.65 | −8.63 ± 3.8 | <.0001[a] | 63.75 ± 6.31 | −11.30 ± 2.8 | <.0001[a] | −2.69 ± 1.1 | .025[a] |
| 24 mo | 80.02 ± 5.75 | −27.59 ± 3.4 | <.0001[a] | 82.13 ± 5.85 | −29.68 ± 2.9 | <.0001[a] | −2.11 ± 1 | .042[a] |
| 60 mo | 81.12 ± 5.17 | −28.69 ± 4.2 | <.0001[a] | 85.67 ± 5.68 | −33.22 ± 3.8 | <.0001[a] | −4.55 ± 0.9 | <.0001[a] |

While comparing between the NMK and MK groups, no significant difference was observed in improvement of the FJS at 6 months.
Better improvement was observed in the MK group than in the NMK group at 12 months (NMK vs MK group: 61.06 ± 6.65 vs 63.75 ± 6.31), 24 months (NMK vs MK group: 80.02 ± 5.75 vs 82.13 ± 5.85), and 60 months (NMK vs MK group: 81.12 ± 5.17 vs 85.67 ± 5.68) (*P*-value < .05).
[a] *P*-value < .05, statistically significant.

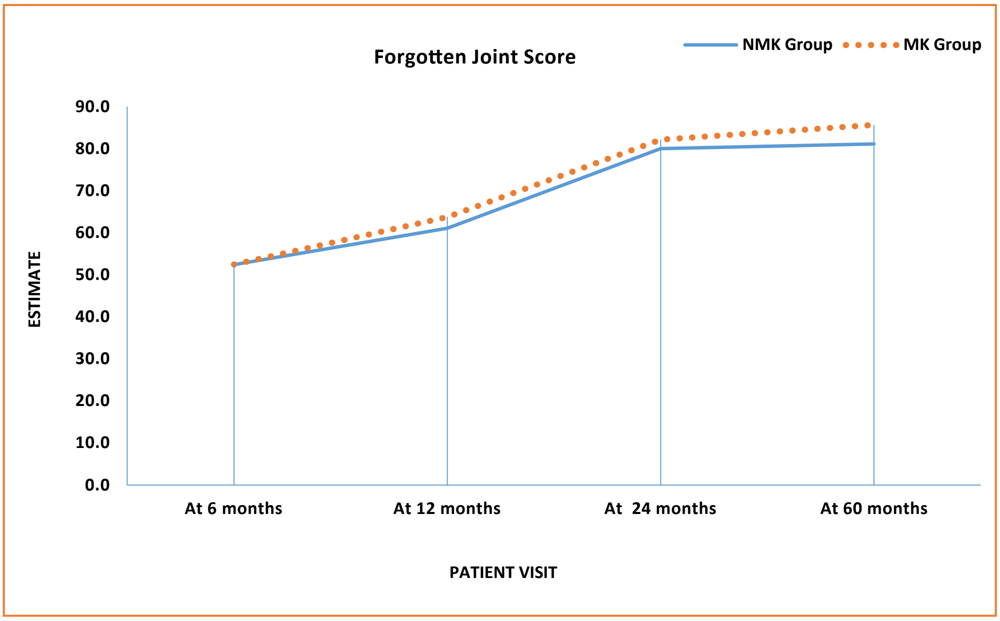


**Figure 4.** Forgotten Joint Score (FJS).

score was 90.25 and 87.52, respectively ($P < .01$) (Table 1, Figs. 1 and 2). The OKS was 41.96 in the MK group and 39.90 in the NMK group ($P < .01$) (Table 2, Fig. 3). The FJS was 85.67 in the MK group and 81.12 in the NMK group ($P < .01$) (Table 3, Fig. 4).

*Range of motion*

The preoperative ROM of both the groups was comparable with a $P$ value of 0.77. The MK group had a mean ROM of 103.30°, and the NMK group had 102.88°. The ROM increased significantly postoperatively in both the groups. The ROM was 122.11°, 124.31°, and 126.14° at 12, 24, and 60 months, respectively, in the MK group and 117.17°, 119.03°, and 120.76° at the same time intervals in the NMK group ($P < .001$, $P < .001$, $P < .001$) (Table 4, Fig. 5).

*Anterior knee pain*

AKP reported in both the groups was assessed by the Kujala Knee Score. The Kujala knee questionnaires were handed over to the patients who filled them independently for each knee preoperatively and at 6 months, 1 year, 2 years, and 5 years of surgery. The preoperative mean score was 38.2. Postoperatively, the mean Kujala score was 68.1 in the MK group and 57.6 in the NMK group at 5-year follow-up; this difference was clinically significant with $P < .0001$ (Table 5, Fig. 6).

*Radiological results*

The tibiofemoral alignment in both the groups was comparable preoperatively and postoperatively. The mean preoperative malalignment was 12.5° and 11.9° in the MK and NMK groups, respectively, while postoperatively it was 5.4° and 5.5° in the MK and NMK groups, respectively. The postoperative femoral and tibial component position in both the groups showed no statistically different values. The posterior condylar offset in both the groups was 33.53 mm and 33.8 mm, respectively, with no statistical difference. The average posterior tibial slope was 4.8 degrees in the NMK group and 4.44 degree in the MK group. Nonprogressive radiolucent lines were seen in 11 MK and 12 NMK groups (Table 6).

The mean with standard deviation of the change from baseline to 5 years of these parameters for MK and NMK were used Table 7. The analysis is underpowered in relation to KSCS, KSFS, and OKS as

**Table 4**
Intergroup and intragroup comparison of the ROM variable.

| Time point | NMK group (n = 63) | | | MK group (n = 63) | | | Between-group comparison (n = 63) | |
|---|---|---|---|---|---|---|---|---|
| | Mean ± SD | Δ = (Preoperative − follow-up) (Mean ± SD) | *P*-value | Mean ± SD | Δ = (Preoperative − follow-up) (Mean ± SD) | *P*-value | Δ = (NMK − MK) (Mean ± SE) | *P*-value |
| Preoperative | 102.88 ± 8.25 | - | - | 103.30 ± 9.03 | - | - | −0.42 ± 1.5 | .771 |
| 6 mo | 115.08 ± 8.95 | −12.20 ± 3.6 | <.0001[a] | 118.76 ± 7.31 | −15.46 ± 2.7 | <.0001[a] | −3.68 ± 1.4 | .031[a] |
| 12 mo | 117.17 ± 7.41 | −14.3 = 29 ± 3.9 | <.0001[a] | 122.11 ± 7.86 | −18.81 ± 2.5 | <.0001[a] | −4.94 ± 1.3 | <.0001[a] |
| 24 mo | 119.03 ± 5.57 | −16.15 ± 4.9 | <.0001[a] | 124.31 ± 5.31 | −21.01 ± 4.1 | <.0001[a] | −5.28 ± 1 | <.0001[a] |
| 60 mo | 120.76 ± 5.01 | −17.88 ± 5.2 | <.0001[a] | 126.14 ± 5.12 | −22.84 ± 4.7 | <.0001[a] | −5.38 ± 0.9 | <.0001[a] |

In the NMK group, there was a significant improvement in patients' ROM score from preoperative to ROM at different stages of follow-up, and a similar trend was also observed in the MK group ($P$-value < .05).
Better improvement was observed in the MK group than in the NMK group at 6 months (NMK vs MK group: 115.08 ± 8.95 vs 118.76 ± 7.31), 12 months (NMK vs MK group: 117.17 ± 7.41 vs 122.11 ± 7.86), 24 months (NMK vs MK group: 119.03 ± 5.57 vs 124.31 ± 5.31), and 60 months (NMK vs MK group: 120.76 ± 5.01 vs 126.14 ± 5.12) ($P$-value < .05).
[a] $P$-value < .05, statistically significant.

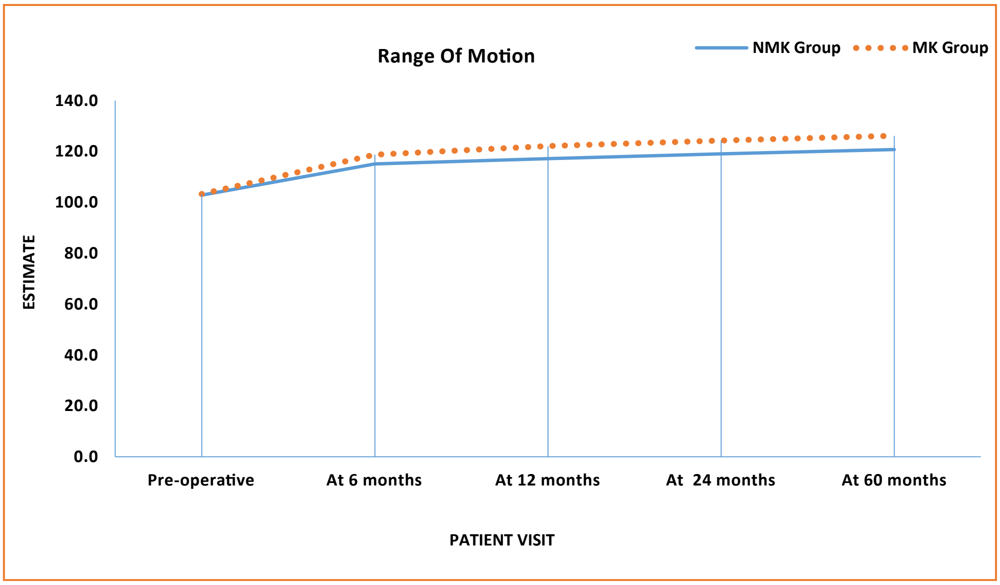


**Figure 5.** Range of motion (ROM).

the sample size was small. Based on these results, the implicit power of the study ranges from 20.5% to 100.0%.

*Survivorship*

The Kaplan-Meier survival analysis when the end point was revision for any cause revealed a survival rate of 99% in the MK group because of one revision surgery for periprosthetic joint infection and 100% in the NMK group. When the end point was revision for aseptic causes, the survival rates were 100% in both the groups.

## Discussion

The purpose of our study was to determine and compare implant survivorship, radiological outcomes, and patient-reported outcomes of the MK and NMK knee implant systems. Our study documented excellent survivorship of both cohorts where either an MK or an NMK implant was used. Although the radiological outcomes of the 2 design groups showed no significant difference, the PROMs along with the ROM were better in the MK group than in the NMK group.

Pain reduction is an important factor in determining reduction of disability and subsequent patient satisfaction after a joint replacement surgery. AKP is one of the common factors leading to dissatisfaction and revision surgeries [17], others being loosening (39.9%), instability (7.5%), periprosthetic fractures (4.7%), and arthrofibrosis (4.5%) [18]. Patients suffering from AKP experience difficulty in standing up from a chair, ascending and descending stairs, and riding a bicycle [3]. The causes of AKP can be functional (muscle imbalance, dynamic valgus) or mechanical (incorrect positioning of components, patellar fractures, aseptic loosening, etc). However, the prosthesis design can also play a role in the development of patellofemoral problems [18]. In our study, at the latest follow-up, 12 patients had complaints of AKP. The MK group had a less number of patients suffering from AKP than the NMK group.

To allow investigators to assess and quantify preoperative to postoperative improvements in the health status of a patient with TKA, many health-related quality-of-life outcomes have been developed [19]. PROMs improved significantly in both the groups postoperatively. The OKS, KSS (clinical and functional), and FJS improvement plateaued after 1 year of follow-up. At the latest follow-up, all the 3 scores were better in the MK group than in the NMK group. An increase by more than the minimal clinically important difference (MCID) owing to its better correlation with clinical improvement is more important than a significant difference. The MCID of KSS is 34.5 points [20]. The mean improvement

**Table 5**
Intergroup and intragroup comparison of the Kujala Knee Score.

| Time point | NMK group (n = 63) | | | MK group (n = 63) | | | Between-group comparison (n = 63) | |
|---|---|---|---|---|---|---|---|---|
| | Mean ± SD | Δ = (6 Months − follow-up) (Mean ± SD) | *P*-value | Mean ± SD | Δ = (6 Months − follow-up) (Mean ± SD) | *P*-value | Δ = (NMK − MK) (Mean ± SE) | *P*-value |
| 6 mo | 44.6 ± 2.6 | - | - | 43.7 ± 2.2 | - | - | 0.90 ± 0.4 | .026[a] |
| 12 mo | 51.7 ± 2.5 | −7.10 ± 1 | <.0001[a] | 55.8 ± 2.7 | −12.10 ± 1 | <.0001[a] | −4.10 ± 0.5 | <.0001[a] |
| 24 mo | 58.4 ± 2.1 | −13.80 ± 2.4 | <.0001[a] | 64.8 ± 2.8 | −21.10 ± 1.4 | <.0001[a] | −6.40 ± 0.4 | <.0001[a] |
| 60 mo | 57.6 ± 2.0 | −13.0 ± 2.5 | <.0001[a] | 68.1 ± 2.2 | −24.40 ± 1.1 | <.0001[a] | −10.50 ± 0.4 | <.0001[a] |

In the NMK group, there was a significant improvement in patients' Kujala score from preoperative to different stages of follow-up, and a similar trend was also observed in the MK group ($P$-value < .05).
While comparing between the NMK and MK groups, no significant difference was observed in improvement of the score at 6 months.
Better improvement was observed in the MK group than in the NMK group at 12 months (NMK vs MK group: 51.7 ± 2.5 vs 55.8 ± 2.7), 24 months (NMK vs MK group: 58.4 ± 2.1 vs 64.8 ± 2.8), and 60 months (NMK vs MK group: 57.6 ± 2.0 vs 68.1 ± 2.2) ($P$-value < .05).
[a] $P$-value < .05, statistically significant.

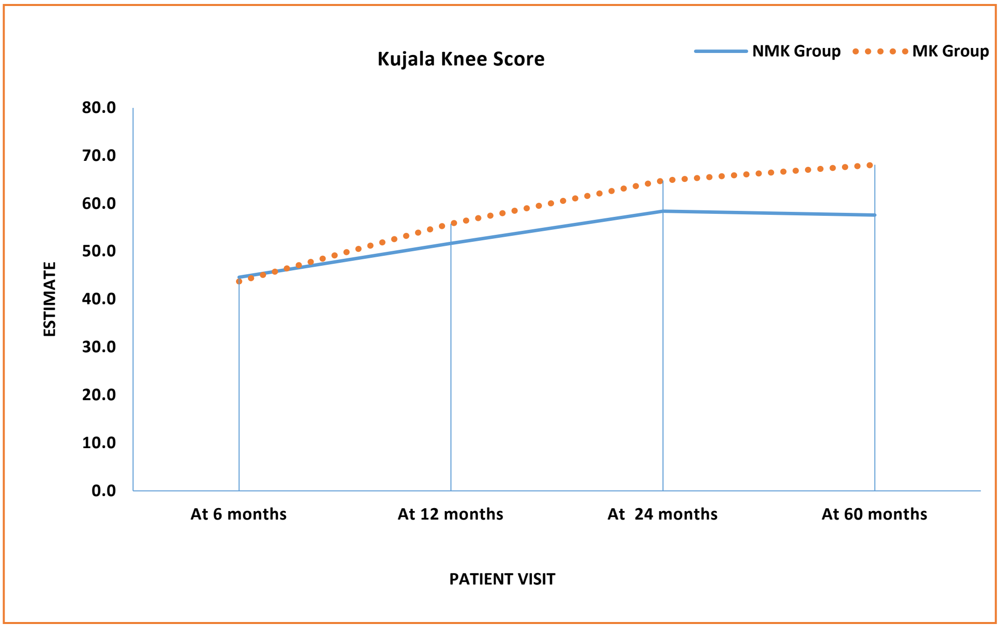


**Figure 6.** Anterior knee pain (AKP).

of the KSS in the MK group was 46, while it was 43 in the NMK group. The OKS before surgery was 23.83 and 24.51, which improved to 41.96 and 39.9 postoperatively at 5 years, in the MK and NMK groups, respectively. The mean improvement in the OKS was 17 and 15 points in the MK and NMK groups, which was more than the MCID of 9 points needed to detect a change over time in a group of patients as postulated by Beard et al. [21]. The OKS similarly to the KSS was better in the MK group than in the NMK group. The FJS-12 is a postoperative PROM that assesses joint awareness during activities of daily living [22] wherein a high value reflects the ability of the patient to forget about the replaced joint during these activities [23]. In our study, the mean improvement in the FJS was more than the MCID with 33 points in the MK group and 29 points in the NMK group. At the latest follow-up, the FJS of the MK group was better than that in the NMK group with a $P$ value of < .001. While there was a statistically significant difference in all the outcomes favoring the MK group, their clinical relevance needs a longer term evaluation.

ROM is an important factor in determining the success of TKA. To complete normal activities of daily living, such as rising from a chair and ascending and descending stairs, a minimum of 110° of flexion is needed [24]. Bellemans et al. reported that in deep squat, the mean maximal flexion angle achieved was 121.7° using a goniometer [25]. Hancort et al have mentioned that 67° of flexion is required for normal gait, 83° for ascending and 90° for descending stairs, 93° to stand from the sitting position, and 105° to tie shoes [26]. In our study, although the ROM shows remarkable improvement in both types of implants, the MK implants show a statistically significant improvement in ROM as compared with NMK implants. The mean ROM was 126.14° at 60 months in the MK group as compared with 120.76° in the NMK group. This difference may, however, not be clinically significant.

Good morphological fit between TKA components and the resected knee anatomy is an important factor for success in TKA [27,28]. Availability of multiple sizing options in the MK system eliminates the problem of overhang and soft-tissue impingement, resulting in decreased postoperative pain, thereby improving overall function and flexion [27]. These factors of less AKP and increased ROM work very well in favor of the Asian community as our culture demands high-flex activities [29]. The lower percentage of patients with residual AKP in the MK group can possibly be attributed to the design modifications of MK implants, namely J curve, deeper femoral groove, and a shorter less-thick anterior flange. These features in the MK knee system result in an increased

**Table 6**
Radiological results.

| Time point | NMK group (n = 63) | | | MK group (n = 63) | | | Between-group comparison (n = 63) | |
|---|---|---|---|---|---|---|---|---|
| | Mean ± SD | Δ = (Preoperative − postoperative) (Mean ± SD) | *P*-value | Mean ± SD | Δ = (Preoperative − postoperative) (Mean ± SD) | *P*-value | Δ = (NMK − MK) (Mean ± SE) | *P*-value |
| Malalignment | | | | | | | | |
| Preoperative | 11.9 ± 5.98 | - | - | 12.5 ± 6.07 | - | - | −0.6 ± 1.1 | .780 |
| Postoperative | 5.5 ± 2.04 | 6.4 ± 4.2 | <.0001[a] | 5.4 ± 2.1 | 6.9 ± 4.3 | <.0001[a] | 0.1 ± 0.3 | .693 |
| Joint line | | | | | | | | |
| Postoperative | 16.1 ± 2.10 | - | - | 16.2 ± 2.4 | - | - | 0.1 ± 0.4 | .881 |
| Posterior condylar offset | | | | | | | | |
| Postoperative | 33.80 ± 2.06 | - | - | 33.53 ± 2.1 | - | - | −0.3 ± 0.4 | .714 |
| Radiolucent lines | 12 | - | - | 11 | - | - | - | - |

[a] $P$-value < .05, statistically significant.

**Table 7**
Power analysis: calculation for power of the study.

| Parameters | N | NMK group (n = 63) | MK group (n = 63) | $m_1 - m_2$ | $(m_1 - m_2)^2$ *n | $(\sigma_1^2 + \sigma_2^2)$ | $(m_1 - m_2)^2$ *n}/ $(\sigma_1^2 + \sigma_2^2)$] | Square root [{$(m_1 - m_2)^2$ *n} /$(\sigma_1^2 + \sigma_2^2)$] | $Z_\beta$ = square root [{$(m_1 - m_2)^2$ *n} /$(\sigma_1^2 + \sigma_2^2)$] − $Z_\alpha$ | Power |
|---|---|---|---|---|---|---|---|---|---|---|
| KSCS | 63 | −43.60 ± 7 | −45.60 ± 6.9 | −2 | 252.00 | 96.61 | 2.61 | 1.62 | −0.34 | 20.5% |
| KSFS | 63 | −35.14 ± 5.9 | −38.12 ± 5.5 | −2.98 | 559.47 | 65.06 | 8.60 | 2.93 | 0.97 | 39.3% |
| OXFORD | 63 | −15.39 ± 5.2 | −18.13 ± 5 | −2.74 | 472.98 | 52.04 | 9.09 | 3.01 | 1.05 | 56.2% |
| FJS | 63 | −28.69 ± 4.2 | −33.22 ± 3.8 | −4.53 | 1292.82 | 32.08 | 40.30 | 6.35 | 4.39 | 99.4% |
| ROM | 63 | −17.88 ± 5.2 | −22.84 ± 4.7 | −4.96 | 1549.90 | 49.13 | 31.55 | 5.62 | 3.66 | 97.6% |
| Kujala score | 63 | −13.0 ± 2.5 | −24.40 ± 1.1 | −11.4 | 8187.48 | 7.46 | 1097.52 | 33.13 | 31.17 | 100.0% |

Sample size = n = $(\sigma_1^2 + \sigma_2^2)(Z_\alpha + Z_\beta)^2/(m_1 - m_2)^2$. $Z_\beta$ = square root [{$(m_1 - m_2)^2$ *n} / $(\sigma_1^2 + \sigma_2^2)$] − $Z_\alpha$.
Power of the study: The power has been calculated for all 6 parameters namely KSCS, KSFS, OXFORD, FJS, ROM, and Kujala score at 5 years. The mean with standard deviation of the change from baseline to 5 years of these parameters for the MK and NMK groups are given in the table. Based on these results, the implicit power of the study ranges from 20.5% to 100.0%. The confidence level is assumed to be 95%.

area of contact in deep flexion, while the curved arcuate bearing pathway on the lateral surface accommodates external femoral rotation in deep flexion. In the MK group, there was no incidence of implant overhang as compared with the NMK group, wherein 7.9% (5 knees) had a 1-2 mm of overhang [28]. The MK implant has an anatomical tibial baseplate as opposed to a symmetrical baseplate in the NMK implant with a separate side specificity [27].The configuration of the tibial baseplate with its anatomical characteristics lends itself to a considerably reduced incidence of tibial malrotation [30]. The differential conformity in articular surfaces in the MK implant has decreasing sagittal radius medially and increasing sagittal radius laterally, whereas the polyethylene liner in the MK knee system has asymmetric condyles based on the “Big Wheel/Little Wheel” principle. The increase in the ROM can possibly be attributed to these factors along with the fact that the posteromedial edge of the tibial baseplate tapers in the MK implant as compared with the NMK implant.

In our study, the 2 implant designs showed excellent survivorship at 5-year follow-up. One knee in the MK group had a periprosthetic joint infection for which debridement and tibial insert exchange were performed. The survival estimate was 0.99 in the MK group and 1 in the NMK group. The survival estimate of revision for aseptic causes was 1.00 in both the groups. Various joint registries have experienced a significant improvement in the survival rates of TKAs because of better implant designs, patient selection, improved surgical techniques, and patient education. The Norwegian arthroplasty registry recorded an improvement of 10-year survival rates to 94% in the period 2005-2015. The Swedish registry recorded an improvement from 89% for TKAs operated during 1985-1994 to 96% for TKAs operated during 2005-2014 [31].

A similar study by Ranawat et al shows that incidence of AKP was less (12.5%) in Attune (which is a subsequent generation to the P.F.C. SIGMA) knee system than in the P.F.C. SIGMA (25.8%) because of an anatomic trochlear groove with a medialized dome patellar component in the Attune design as compared with a single-radius trochlear groove with a dome-shaped patella in P.F.C. SIGMA [32]. Although our study deals with different implant designs, it does show that subsequent generation knee design leads to better results in the patient population.

This study is not without its limitations. One of the limitations of this study is that because of the short-term follow-up and a small sample size, it is underpowered to detect the differences in the KSCS, KSFS, and the OKS. We believe that this is an early review of outcomes, and a longer term study would be desirable. The other limitation may be the method of measuring the ROM using a goniometer. Radiographs may be a more reliable way of measuring ROM but are more time-consuming [33]. The placebo effect influences results after orthopaedic surgery, stating that patients may score better at an earlier stage when they are more enthusiastic about the procedure, whereas at a later stage, the scores are more realistic [34]. Not resurfacing the patella in this study may be another limitation; however, this may possibly be nullified by the fact that in both cohorts the patella was not resurfaced, thereby offering a comparable option.

## Conclusions

While PROMs, ROM, and AKP improved significantly over time after TKA using both MK and NMK implants, our study demonstrated minimal differences in the functional outcomes between the MK and the NMK cohorts. The MK cohort demonstrated a greater reduction in the incidence of AKP than the NMK cohort, although this was not clinically significant. A longer follow-up and a larger sample size may be desirable to evaluate long-term outcomes and function.

## Conflict of interest

A.R. received royalty from Zimmer and serves as a consultant to Zimmer and Smith & Nephew.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2020.05.009.

## References

[1] Singh JA, Yu S, Chen L, Cleveland JD. Rates of total joint replacement in the United States: future projections to 2020−2040 using the National Inpatient Sample. J Rheumatol 2019;46:1134.
[2] Mizner RL, Petterson SC, Stevens JE, Axe MJ, Snyder-Macker L. Preoperative quadriceps strength predicts functional ability one year after total knee arthroplasty. J Rheumatol 2005;32:1533.
[3] Parent E, Moffet H. Preoperative predictors of locomotor ability two months after total knee arthroplasty for severe osteoarthritis. Arthritis Rheum 2003;49:36.
[4] Maohomed NN, Liang MH, Cook EF, et al. The importance of patient expectations in prediction of functional outcomes after total joint arthroplasty. J Rheumatol 2002;29:1273.
[5] Giesingery K, Hamiltonz DF, Josty B, Holznerx B, Giesingerk JM. Comparative responsiveness of outcome measures for total knee arthroplasty. Osteoarthritis Cartilage 2014;22:184.
[6] Weiss JM, Noble PC, Conditt MA, et al. What functional activities are important to patients with knee replacements? Clin Orthop Relat Res 2002;404:172.
[7] Thomsen MG, Husted H, Otte KS, Holm G, Troelsen A. Do patients care about higher flexion in total knee arthroplasty? A randomized, controlled, double-blinded trial. BMC Musculoskelet Disord 2013;14:127.
[8] Dowsey MM, Liew D, Stoney JD, Choong PF. The impact of obesity on weight change and outcomes at 12months in patients undergoing total hip arthroplasty. Med J Aust 2010;193(1):17.
[9] Dowsey MM, Nikpour M, Dieppe P, Choong PF. Associations between preoperative radiographic changes and outcomes after total knee joint replacement for osteoarthritis. Osteoarthritis Cartilage 2012;20(10):1095.
[10] Mark D, Kohn BA, Adam A, Sassoon MD, Navin D, Fernando MD. Classifications in brief Kellgren-Lawrence classification of osteoarthritis. Clin Orthop Relat Res 2016;474:1886.

[11] Gogia PP, Braatz JH, Rose SJ, Norton BJ. Reliability and validity of goniometric measurements at the knee. Phys Ther 1987;67:pp192.
[12] Jones A, Sealey R, Crowe M, Gordon S. Concurrent validity and reliability of the simple goniometer iPhone app compared with the universal goniometer physiother theory practice. Physiother Theor Pract 2014;30(7):512.
[13] Kujala UM, Jaakola LH, Koskinen SK, Taimela S, Hurme M, Nelimarkka O. Scoring of patellofemoral disorders. Arthroscopy 1993;9(2):159.
[14] Ittenbach RF, Huang G, Foss KD, Hewett TE, Myer GD. Reliability and validity of the anterior knee pain scale: applications for use as and epidemiologic screener. PLoS One 2016;11(7):e0159204.
[15] Metsna V, Vorobjov S, Märtson A. Prevalence of anterior knee pain among patients following total knee arthroplasty with nonreplaced patella: a retrospective study of 1778 knees. Medicina 2014;50(2):82.
[16] Ewald FC. The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system. Clin Orthop Relat Res 1989;309:33.
[17] Breugem SJM, Haverkamp D. Anterior knee pain after a total knee arthroplasty: what can cause this pain? World J Orthop 2014;5(3):163.
[18] Sharkey PF, Lichstein PM, Shen C, Tokarski AT, Parvizi J. Why are total knee arthroplasties failing today—has anything changed after 10 years. J Arthroplasty 2014;29(9):1774.
[19] George LK, Ruiz D, Sloan FA. The effects of total knee arthroplasty on physical functioning in the older population. Arthritis Rheum 2008;58:3166.
[20] Mathijssen N, Verburg H, London NJ, Landsiedl M, Dominkus M. Patient reported outcomes and implant survivorship after Total knee arthroplasty with the persona knee implant system: two year follow up. BMC Musculoskelet Disord 2019;20:97.
[21] Beard DJ, Harris K, Dawson J, Murray DW, Carr AJ, Price AJ. Meaningful changes for the Oxford hip and knee scores after joint replacement surgery. J Clin Epidemiol 2015;68(1):73.
[22] Thomsen MG, Latifi R, Kallemose L, Barfod KW, Husted H, Torlsen A. Good validity and reliability of the forgotten joint score in evaluating the outcome of total knee arthroplasty A retrospective cross-sectional survey-based study. Acta Orthop 2016;87(3):280.
[23] Hamilton DF, Loth FL, Giesinger JM, et al. Validation of the English language Forgotten Joint Score-12 as an outcome measure for total hip and knee arthroplasty in a British population. Bone Joint J 2017;99-B:218.
[24] Devers BN, Conditt MA, Jamieson ML, Driscool MD, Noble PC, Parsley BS. Does grater knee flexion increase patient function and satisfaction after total knee arthroplasty. J Arthroplasty 2011;26(2).
[25] Bellemans J, Banks S, Victor J, Vandenneucker H, Moemans A. Fluoroscopic analysis of the kinematics of deep flexion in total knee arthroplasty. J Bone Joint Surg Br 2002;84-B:50.
[26] Dietz MJ, Sprando D, Hanselman AE, Regier MD, Frye BM. Smartphone assessment of knee flexion compared to radiographic standards. Knee 2017;24(2):224. https://doi.org/10.1016/j.knee.2016.11.014.
[27] Clinicaltrials.gov. Persona vs NexGen. 2014. https://clinicaltrials.gov/ct2/show/study/NCT02269254. [Accessed 14 April 2018].
[28] Yifei D, Scuderi GR, Penninger C, Bischoff JE, Rosenberg A. Increased shape and size offerings of femoral components improve fit during total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc 2014;22:2931.
[29] Huang NF, Dowsey MM, Ee E, Stoney JD, Babazadeh S, Choong PF. Coronal alignment correlates with outcome after total knee arthroplasty: five-year follow-up of a randomized controlled trial. J Arthroplasty 2012;27(9):1737.
[30] Dai Y, Scuderi GR, Bischoff JE, Bertin K, Tarabichi S, Rajgopal A. Anatomic tibial component design can increase tibial coverage and rotational alignment accuracy: a comparison of 6 contemporary deisgns. Knee Surg Sports Traumatol Arthrosc 2014;22(12):2911.
[31] Dyrhovden GS, Badawy M, Gøthesen O, Furnes O. Have the causes of revision for total and unicompartmental knee arthroplasties changed during the past two decades? Clin Orthop Relat Res 2017;475(7):1874.
[32] Ranawat SC, White BP, West S, Ranawat SA. Clinical and radiographic results of Attune and PFC sigma knee designs at 2-year follow-up: a prospective matched-pair analysis. J Arthroplasty 2017;32(2):431.
[33] Laverina C, Apuzzo M, Rossi MD, Lee D. Accuracy of knee range of motion assessment after total knee arthroplasty. J Arthroplasty 2008;23(6 Suppl 1):85.
[34] Moseley JB, Malley K, Petersen NJ, et al. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med 2002;347(2):81.