CLINICAL ARTICLE

Knee Scores of Patients with Non-Lateral Compartmental Knee Osteoarthritis Undergoing Mobile, Fixed-Bearing Unicompartmental Knee and Total Knee Arthroplasties: A Randomized Controlled Trial

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Objective: To evaluate knee scores and clinical efficacies of patients with non-lateral unicompartmental knee osteoarthritis (OA) who randomly underwent mobile-bearing (MB) unicompartmental knee arthroplasty (UKA), fixed-bearing (FB) UKA, and total knee arthroplasty (TKA).

Methods: From September 2015 to February 2017, a prospective, randomized, parallel, single-center trial of 180 patients (78 males and 102 females; 63.3 ± 6.9 years) with non-lateral compartmental knee OA was performed in the first author-affiliated hospital. The patients were randomly divided into three groups (each group included 60 patients) and received medial cemented Oxford phase 3 MB UKA, medial cemented Link FB UKA, or cemented DePuy Sigma PFC TKA, respectively. A similar perioperative management and fast-track surgery program was carried out for all patients. The knee scores at 3-year follow-up after operation and clinical efficacies of these three groups of patients were recorded, investigated, and compared.

Results: Primarily, compared to the TKA group, the UKA groups (MB UKA and FB UKA) had shorter operative time (median 63.2 < 67.1 min), less bleeding (8.6 < 30.0 mL), earlier resumption of walking without crutches (3.0 < 8.0 days) and walking up and down the stairs (5.0 < 10.0 days) ($P < 0.001$), higher FJS scores (78.0 > 74.5) ($P = 0.007$), better results in all knee scores (except VAS and KSS function scores) ($P < 0.05$), and a larger maximum flexion angle of the knee at the 3-year follow-up (123.0° > 96.0°) ($P = 0.001$). Secondarily, compared to the TKA group, the MB UKA group showed better results in the Western Ontario and McMaster Universities index (WOMAC) stiffness (83.6 > 79.6), WOMAC total (86.3 > 83.2), Oxford knee score (OKS) (20.0 < 23.0), Forgotten Joint Score (FJS) (78.5 > 74.5), and a larger maximum flexion angle of the knee (123.0 > 96.0) ($P < 0.05$). Moreover, the FB UKA group showed higher Hospital for Special Surgery Knee Score (HSS) (91.0 > 88.5), WOMAC stiffness (84.3 > 79.6), WOMAC function (85.2 > 81.7), WOMAC total scores (87.6 > 83.2), and a larger maximum flexion angle of the knee (119.0° > 96.0°) than the TKA group ($P < 0.05$). Overall, there was no significant difference in all knee scores and maximum flexion angles of the knee for the MB UKA and FB UKA groups ($P > 0.05$). There was one case with original bearing dislocation in MB UKA group. One patient with displacement of the femoral component caused by a fall injury, and another patient, who lost his life in a car accident, were involved in the FB UKA group. There was an infection case and an intermuscular vein thrombosis case in TKA group.

Conclusion: UKA showed more advantages than TKA; however, there was no significant difference between the MB UKA and FB UKA groups for treatment of non-lateral compartmental knee OA.

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Introduction

The optimal procedure of arthroplasty for isolated medial unicompartmental osteoarthritis (OA) of the knee remains a long-term controversy. Some surgeons prefer total knee arthroplasty (TKA), while others recommend unicompartmental knee arthroplasty (UKA)[1]. Even among UKA, there is a dispute on the choice between the mobile-bearing (MB) and fixed-bearing (FB) design[2, 3].

Some reports have shown that UKA has many advantages over TKA, including faster recovery, more physiologic gait, less need for manipulation under anesthesia, shorter hospital stay, earlier discharge to home, less postoperative morbidity, lower perioperative costs, and higher rate of return to sports and sports-related activities[4–9]. However, recent literature has shown that compared to TKA, UKA does not offer as many advantages and is easier to revise. A mid-term follow-up study reported that the benefits of lower perioperative complication rate, improved return to function in UKA did not lead to any differences in satisfaction and PROMs between medial OA patients who underwent TKA or UKA. Both TKA and UKA result in significant improvements postoperatively, with a similar ratio who were clinically improved at 10 years postoperatively but had a similar time dependent decline in quality of life and knee function scores[10]. Another large sample study found that most UKA and TKA are appropriate solutions to treat patients with medial OA or osteonecrosis, but UKA has a higher chance of accepting revision surgery than TKA[11]. Other nationwide population-based cohort research studies came to the similar conclusion that the risk of a complete exchange or failure was higher for patients with UKA than for patients with TKA[12]. Moreover, there are still some problems in UKA itself, for example, aseptic loosening, progression of arthritis, wear of polyethylene insert, and especially the risk of bearing dislocation in MB UKA.

Furthermore, there are two different designs and implants for UKA requiring different surgical techniques, MB UKA and FB UKA, which might lead to different clinical outcomes. Ko reported[2] that MB UKA was more impressionable to revisions compared to FB UKA due to aseptic loosening (0.393 > 0.255), arthritis progression (0.428 > 0.357), inlay dislocation (0.286 > 0), and less polyethylene insert wear rates. However, other observations showed no differences between MB UKA and FB UKA in terms of revision rates, complications, and knee function in patient-related outcomes[3, 13]. A recently meta-analysis discovered no significant differences were presented between the FB and MB prostheses in clinical and radiological outcomes. However, it was evident that there were differences in the modes and timing of the failures, and bearing dislocation resulted in earlier failures in the MB prosthesis, while the FB prosthesis failed later caused by polyethylene wear. There was no evidence of publication bias using the incidence of revisions. There is no significant difference between the FB and MB UKAs; however, there are differences in the modes and timing of failures[14]. Simply, it is not clear which one is more suitable for the treatment of isolated medial OA among TKA, MB UKA, and FB UKA. Facing different operation strategies, selecting the most appropriate knee arthroplasty procedure in accordance with patient's preoperative characteristics has the potential to improve postoperative satisfaction, function, and participation in desired activities.

Patellofemoral chondromalacia (PFCM) and patellofemoral osteoarthritis (PFOA) have been viewed as a contraindication to UKA[15, 16], which prompted surgeons to preferentially perform TKA or combined UKA and patellofemoral arthroplasty. However, recent studies assessing the impact of preoperative PFCM and anterior knee pain on outcomes following UKA with a MB implant have demonstrated that the presence of PFCM and patellofemoral arthritis does not adversely affect the clinical efficacies and patient survival after UKA[17, 18]. Additionally, functional outcomes of medial FB UKA are not adversely affected by PFCM involving the medial patellar facet and/or medial or central trochlea[19].

Goodfellow et al.[20] suggested that these above contraindications[15, 16] can be ignored for mobile-bearing UKA. In anteromedial osteoarthritis, PFOA is not a contraindication to UKA. In 2007, Beard et al.[20–22] proposed that PFOA should not be considered a contraindication to UKA as long as no groove is present in the lateral patella. Some recent studies suggest that the standard proposed by Kozinn and Scott[15] was too strict and that UKA can be applied to more people with moderate patellofemoral joint degeneration[23, 24]. Hence, based on the above research results, the author proposed a new concept of non-lateral compartment knee OA, which was defined as medial compartment knee OA or medial compartment knee OA combined with patellofemoral OA. Moreover, patellofemoral arthritis and lateral knee arthritis have been excluded from the criteria that classifies non-lateral compartment knee OA.

Although there is some research comparing the results of UKA and TKA[4–9], and there are also some articles comparing the clinical efficacy of MB UKA and FB UKA[2, 3], according to our investigation, there are hardly any published studies comparing knee scores and curative outcomes in patients who, due to non-lateral compartment knee OA, underwent MB UKA, FB UKA, and TKA randomly. Therefore, this study aimed to evaluate the knee scores and clinical efficacies of patients with non-lateral compartment knee OA after randomly undergoing MB UKA, FB UKA, and TKA. The different curative outcomes and knee scores between

UKA (including all of MB UKA and FB UKA) and TKA in the 3-year follow-up were the main comparison and first purpose. Additionally, the differences in clinical efficacies and self-report knee scores among MB UKA, FB UKA, and TKA in the 3-year follow-up were the secondary comparison and purpose.

Methods and Materials

Inclusion Criteria

The inclusion criteria were as follows: (i) patients in the range of 50–80 years old at the time of recruitment, with clinical and radiographic evidence (including anteroposterior and lateral X-ray of knee and computed tomography [CT] of knee) of non-lateral compartment knee OA with Kellgren–Lawrence X-ray classification grading level 2–4, who were competent and willing to participate in the trial, had no signs of any severe neurological disorder, and provided informed consent for the treatment and testing program; (ii) this study was conducted from September 2015 to February 2017 at the Department of Orthopedics of Jiangmen Central Hospital, patients receiving randomized medial cemented Oxford phase 3 MB UKA, medial cemented Link FB UKA, or cemented Depuy Sigma PFC TKA; (iii) the operative time, intraoperative bleeding, the time point of walking without crutches for the first time, the walking up and down the stairs independently after the operation for the first time, postoperative complications, and a series of knee scores were recorded, investigated, and compared; (iv) follow-up more than 36 months; and (v) a prospective, randomized, parallel, single-center study and was approved by the ethics committee of the Jiangmen Central Hospital, and patient records and information were anonymized and de-identified prior to analysis.

Exclusion Criteria

The exclusion criteria were as follows: (i) patients with lateral compartment knee OA, contralateral knee replacement, inflammatory arthritis, disseminated malignant disease such as AIDS, syphilis, and hepatitis B; (ii) serious systemic disease such as rheumatoid arthritis, malignancies; (iii) revision arthroplasty and post-infection; (iv) female patients of reproductive age; and (v) patients unable to provide written informed consent.

Randomized and Parallel Blinded

Two hundred and twenty adult participants were included consecutively in the trial who were eligible for the procedures (Fig. 1). The patients were referred to the orthopaedic and joint surgery clinic and screened by a joint surgeon to ascertain eligibility for inclusion in the study. Enrollment of participants occurred in the inpatient department of orthopedic and joint surgery, where a team of joint surgeons finally screened patients using inclusion and exclusion criteria and 40 of the total patients were excluded (Fig. 1).

All the 180 registered patients were provided detailed explanation by the staff regarding the purpose and methods of participation in this trial, random selection of three different surgical procedures, efficacy evaluation, follow-up, etc., and all the registered patients signed the informed and surgical consent. Stratified, permuted block randomization was performed with a 1:1:1 allocation ratio. The random allocation sequence was digitally prepared by the coordinating investigator using a unique database (www.procordo.dk). Prior to surgery, the participant would be randomized online by the surgeon, and the operating room staff were immediately advised which procedure would be performed. The randomization was done as shortly before surgery as possible. Patients were randomly assigned into three groups: Oxford UKA (MB UKA group), Link UKA (FB UKA group), or DePuy Sigma TKA (TKA group); each group included 60 patients. Randomization was blinded to patients, staff, the general practitioner, and physiotherapists, except for the operating theater staff during the 3 years following surgery. Medical staff involved were oriented on the blinding process, and they were blinded to the operation notes, radiographs, and discharge summaries. The early postoperative control radiographs including anteroposterior and lateral X-ray of knee were obtained in the second week of the clinical follow-up or shortly before discharge[25]. The X-ray results were not revealed to the participants.

Surgical Procedure

TKA Group

Anesthesia and Position

All TKA were performed by the same team led by a senior admitting orthopaedic surgeon under general anesthesia. The patients were all placed in a supine position. To facilitate the operation procedure, two pedals were placed at the operation side to achieve the 30° and 90° bending fixed of the knee intraoperatively. A tourniquet was kept in place constantly to obtain a bloodless field. No drainage tube was applied to any patients.

Approach and Exposure

A standard TKA procedure was performed through a midline incision and a medial parapatellar approach. The quadriceps tendon was split longitudinally to expose the patella for subsequent eversion or lateral retraction in an extended knee position.

Pathological Changes, Resection

The meniscus, synovium, and osteophyte were completely resected, and part of the fat pad under the tibia was removed. After the ligaments and the posterior joint capsules were released to achieve a primary balance, osteotomy procedures were performed according to the manual.

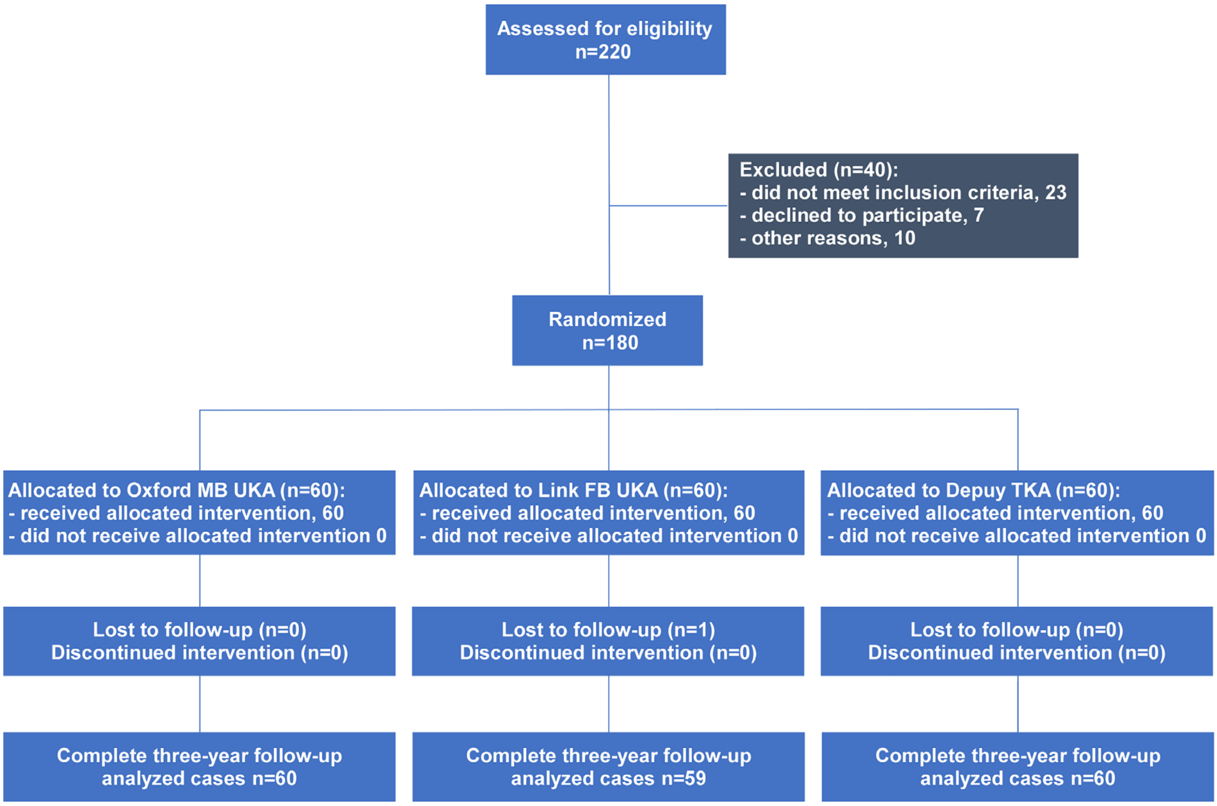

Fig 1 Consort flow diagram for the selection of patients in three groups.

Fixation or Placement of Prosthesis

The prosthesis was fixed in place after the flexion and extension gaps were balanced. The version used with the Sigma PFC cemented TKA had femoral components with rounded coronal geometry, a posterior cruciate ligament (PCL) substituting design and a FB tibial tray (DePuy, Warsaw, IN, USA) was implanted. All TKA operations involved implanting with Palacos bone cement (Heraeus Holding GmbH, Hanau, Germany) and the manufacturer's instructions were followed.

Reconstruction

Patellar tracking was checked every time after the implantation of the test mold and after the implantation of the prosthesis. Patella resurfacing was not performed in all patients. Removing excess peri-patella synovium and osteophytes, trimming the patella with a narrow oscillating saw, and circumferential electrocautery of the patella. After the cement was dry, check the stability of the knee joint and the position of the prosthesis, and then remove the excess cement.

MB UKA Group

Anesthesia and Position

All MB UKA were performed by the same team led by a senior admitting orthopaedic surgeon under general anesthesia. The patients were all placed in a supine position. To facilitate the operation procedure, the thigh root was fixed on a device to maintain stability, and to achieve the 0° to 120° bending of the knee intraoperatively. A tourniquet was kept in place constantly to obtain a bloodless field. No drainage tube was applied to any patients.

Approach and Exposure

A standard MB UKA procedure was performed through a short oblique incision and a medial parapatellar approach was undertaken.

Pathological Changes, Resection

Pathological synovium, fat pads, medial meniscus, and osteophytes in the medial unicompartment were removed. Tibial resection was performed using an extramedullary tibial alignment guide. The femoral condyle was prepared using an intramedullary rod. The distal femoral condyle was milled for balance of the 90° and 20° flexion gaps, that is, the extension and flexion gaps. All osteonecrotic bone was completely removed with a curette.

Fixation or Placement of Prosthesis

The cemented Oxford phase 3 (Zimmer Biomet, Warsaw, IN, USA) was used for the medial MB UKA procedure, which consisted of a two-pegged femoral component with a single radius design with a fully congruous mobile-bearing and a tibial component with a flat articulation surface and a keel at the non-articulating surface. All MB UKA operations involved implanting with Palacos bone cement (Heraeus Holding GmbH, Hanau, Germany). The manufacturer's instructions were followed, and standard surgical procedures were used.

Reconstruction
After moving the knee repeatedly to make sure the joint function was reconstructed, removing the excess cement and suturing were carried out.

FB UKA Group

Anesthesia and Position
All FB UKA were performed by the same team led by a senior admitting orthopaedic surgeon under general anesthesia. The patients were all placed in a supine position. To facilitate the operation procedure, the thigh root was fixed on a device to maintain stability, and to achieve the 0° to 120° bending of the knee intraoperatively. A tourniquet was kept in place constantly to obtain a bloodless field. No drainage tube was applied to any patients.

Approach and Exposure
A standard FB UKA procedure was performed through an oblique incision and a medial parapatellar approach was undertaken.

Pathological Changes, Resection
Pathological synovium, fat pads, medial meniscus, and osteophytes in the medial unicompartment were removed. Standard osteotomy procedures were performed according to the manual. The prosthesis was fixed in place after the flexion and extension gaps were balanced.

Fixation or Placement of Prosthesis
The FB group received cemented Link medial FB UKA (Link, Endo-model Sled, Germany), which consisted of a two-pegged femoral component with a J-curve design, a concave tibial FB component, and a tibial component with a keel and a peg at the non-articulating surface. All FB UKA operations involved implanting with Palacos bone cement (Heraeus Holding GmbH, Hanau, Germany). The manufacturer's instructions were followed, and standard surgical procedures were used.

Reconstruction
After moving the knee repeatedly to make sure the joint function was reconstructed, removing the excess cement and suturing were carried out.

Perioperative Management
All patients received 0.9% isotonic saline (NS) 100 mL with 1 g of tranexamic acid intravenously 30 min preoperatively and again at the time of wound closure. Additionally, 10 mL of isotonic saline with 1 g of tranexamic acid were injected into the knee joint cavity after suture. Further, 0.9% isotonic saline 100 mL with 1.5 g of cefazolin sodium pentahydrate was used intravenously 30 min preoperatively and 24 h postoperatively. Postoperative drain was not used for all patients. The patients were mobilized with crutches on the first postoperative day. They began to walk up and down the stairs when they were able to tolerate the pain postoperatively.

Fast-Track Surgery Program
A similar fast-track surgery program was carried out for all patients. The program included the following elements: a preoperative outpatient information day; confirmed enrollment after hospitalization; a multidisciplinary team of nurses, occupational therapists and physiotherapists; start of mobilization on the day of surgery; and an intensive standardized rehabilitation program that allowed full weight bearing[26–28].

Follow-Up and Data Collection
The demographics and clinical data such as age, gender, weight, body mass index (BMI), varus angle, the Altman classification of patellofemoral joint, the Iwano classification system of patellofemoral arthritis on plain radiographs and the Kellgren-Lawrence X-ray classification of all participants were collected preoperatively.

The Operative Time
The operative time was recorded in this study, which was defined as the time from initiation to closure of the incision. The operative time is one index to assess the complexity of surgery.

Intraoperative Bleeding
The intraoperative bleeding was recorded in this study, which was defined as the bleeding of patient from initiation to closure of the incision. The amount of bleeding is calculated by subtracting the volume of liquid washed from the volume of liquid in the negative pressure suction bottle. The intraoperative bleeding is one index to assess the intraoperative surgery injuries.

The Time Point of Walking Without Crutches for the First Time
All patients first time point of walking without crutches after operation were recorded in this study, which was defined as the day after the operation that the patient could first walk without crutches. The time point of walking without crutches for the first time is one index to assess postoperative recovery.

The Walking Up and Down the Stairs Independently After the Operation for the First Time
All patients first time point of walking up and down the stairs independently after the operation were recorded in this

study, which was defined as the day after the operation that the patient could first walking up and down the stairs with six steps independently. The walking up and down the stairs independently after the operation for the first time is one index to assess postoperative recovery.

Postoperative Complications
Infection, stiffness, deep vein thrombosis, patellar osteonecrosis, and loosening of implants were considered as complications, and the data were collected from medical records. Incidence of overall postoperative complication was calculated as the events of complications/overall events. Incidence of overall postoperative complication was used to evaluate the safety of the operations on knee joint injury in clinic.

Clinical Evaluation

Hospital for Special Surgery Knee Score (HSS)
The HSS[29] was used to evaluate postoperative recovery of knee function in an adult population. The HSS score system mainly includes six aspects: pain, function, muscle force, deformity, stability, and the range of motion. The score standard had a maximum of 100 points (best possible outcome). A total score <60 is considered a poor score, 60–69 is fair, 70–85 is good, and 86–100 is excellent.

The Western Ontario and McMaster Universities Index (WOMAC)
The WOMAC[30] is a validated questionnaire to evaluate lower extremity osteoarthritis and joint replacement. The WOMAC questionnaire produces three subscale scores (pain, stiffness, and physical function) and a total score. Patients are asked to answer each question about the severity of pain, stiffness, or behavioral difficulties experienced in the previous 48 h. There are five response options ranging from "none" to "extreme" to choose. A response of "none" was scored as 0, "mild" as 1, "moderate" as 2, "severe" as 3, and "extreme" as 4. The scores of the questions in each subscale were summed together to get scores for pain, stiffness, and physical function. A lower subscale score indicates less pain, less stiffness, or better physical function. A total score of < 70 is considered a severe score, 21–48 is moderate, <21 is mild.

Knee Society Score (KSS)
The KSS[31] is a condition-specific validated questionnaire widely used to evaluate the functional capabilities of the knee joint before and after total knee arthroplasty. The scoring system consists of two parts. One part is the knee score. The assessment includes pain (maximum 50 points), stability (maximum 25 points), total range of flexion (maximum 25 points), and other items (varus, valgus, extension delay, and flexion contracture). The other part is the function score. The assessment includes walking distance (maximum 50 points), ability to climb stairs (maximum 50 points), and the use of walking aids. The highest score for each part is 100 points, and a higher score means better knee function. The evaluation result score is rated as four levels: 80–100 points, 70–79 points, 60–69 points, <60 points.

Visual Analog Scale (VAS)
The VAS is the most commonly used questionnaire for quantification of pain. It is a continuous scale comprised of a horizontal or vertical line, usually 10 cm in length. For pain intensity, the scale is most commonly anchored by "no pain" (score of 0) and "pain as bad as it could be" (score of 10). A score of 0 is considered as no pain, 1–3 mild pain, 4–6 moderate pain, and 7–10 severe pain.

Oxford Knee Score (OKS)
The OKS[32] is used to assess the function of the knee from the following two domains: pain and physical function. There are five items in the pain domain and seven items in the physical function domain. Higher scores indicate worse pain and physical function.

The Maximum Flexion Angle of the Knee
The maximum flexion angle of the knee is defined as the angle of extreme flexion in knee joint. The maximum flexion angle of the knee was measured by other blinded independent research staff using a standard (30 cm) goniometer. The knee flexion angle with no active effort from the patient (passive movement) was measured by putting the vertex of the goniometer in the middle of the lower edge of the patella, with the two arms, respectively, pointing to the greater trochanter and the lateral malleolus. The maximum flexion angle of the knee was measurement and collected preoperatively and at the 3-year follow-up. Every angle was measured three times, finally, the average was recorded. The maximum flexion angle of the knee is one index to assess postoperative recovery.

The Forgotten Joint Score (FJS)
FJS-12[33] consists of 12 questions and is scored using a 5-point Likert response format with the raw scores transformed onto a 0–100-point scale. Higher scores indicate a more favorable outcome, i.e. a more natural artificial joint. The FJS-12 has been shown to have a low ceiling effect and discriminates well between good, very good, and excellent outcome after joint arthroplasty. All patients in our study completed the FJS-12 questionnaire, and relevant data were obtained for 36-month follow-up patient subgroups.

All patient self-reported outcomes were provided via a questionnaire preoperatively and at the 3-year follow-up except FJS preoperatively, and the research staff were absent during the patients' self-assessment. All trial data were collected by blinded independent research staff. When the patients needed assistance in the evaluation, two research personnel who were not involved in the surgery and were blinded to the type of implanted prosthesis helped them. All patients had undergone anteroposterior and lateral knee radiographs at the 3-year follow-up postoperatively, and these imaging results had been recorded.

Statistical Analyses

Statistical analyses were performed using Prism (version 5, GraphPad Software Inc., San Diego, CA, USA). Continuous variables were expressed as median with interquartile. The postoperative and preoperative statuses were generally compared for all the patients who underwent UKA and for the TKA group using the independent t-test. One-way ANOVA and Tukey tests were used for single or multiple comparisons of continuous variables between the three groups (MB UKA, FB UKA, and TKA). The data count was expressed as frequencies or rates, and the χ^2 test or Fisher's method was performed. Further, gender, median age (>63 and <=63), K-L image level (3 and 4), and maximum flexion angle of knee (>92 and <=92) were analyzed by stratification. $P < 0.05$ indicated statistically significant difference.

Results

Patient Characteristics

Baseline data were collected from all 180 patients, and the baseline data indicated no statistically significant differences among the groups in terms of age, weight, BMI, varus angle, Altman classification of PFJ, Iwano classification system of patellofemoral arthritis on plain radiographs, and Kellgren–Lawrence X-ray classification ($P > 0.05$) (Table 1). Furthermore, there were no significant differences among the groups in terms of preoperative patient knee scores such as HSS, WOMAC pain, WOMAC stiffness, WOMAC function, WOMAC total, OKA, VAS, maximum flexion angle of knee, KSS pain, and KSS function ($P > 0.05$) (Table 1).

Follow-Up

The mean follow-up periods were 38.8 ± 2.2 months (range 36–40) in the MB UKA group with 60 cases, 38.5 ± 2.1 months (range 36–39) in the FB UKA group with 59 cases, and 38.6 ± 2.2 months (range 36–39) in the TKA group with 60 cases ($P = 0.862$).

General Results of Primary Comparison

As a primary comparison, compared to TKA, patients in the UKA groups (MB UKA and FB UKA) had a shorter operative time ($P < 0.001$), less bleeding ($P < 0.001$), and an earlier resumption of walking without crutches and walking up and down the stairs ($P < 0.001$). Moreover, there was no significant difference in the incidence of postoperative complications between the UKA groups (MB UKA and FB UKA) and the TKA group ($P = 1.000$) (Table 2).

TABLE 1 Baseline characteristics and preoperative knee scores of patients in MB UKA, FB UKA, and TKA groups

		MB UKA	FB UKA	TKA	Test statistic	*P* value
N		60	60	60		
Age (years)		63.0 (57.0; 69.0)	63.0 (57.8; 69.3)	64.0 (58.0; 69.3)	0.275	0.760
Weight (Kg)		63.6 (53.8; 74.0)	64.9 (56.0; 76.0)	69.3 (56.3; 77.2)	1.102	0.335
BMI (kg/m^2)		24.0 (21.0; 26.3)	24.0 (20.8; 26.0)	25.0 (21.8; 27.3)	2.241	0.110
Varus Angle(°)		9.0 (7.0;11.0)	9.6 (7.6–11.0)	9.9 (8.4–11.3)	1.995	0.139
Altman classification of PTJ	Medial degeneration	30/60	28/60	29/60	0.756	0.685
	Lateral degeneration	5/60	8/60	7/60		
	No degeneration	25/60	24/60	24/60		
Iwano classification of patellofemoral arthritis	Stage 0	25/60	24/60	24/60	3.480	0.901
	Stage I	12/60	10/60	11/60		
	Stage II	7/60	13/60	12/60		
	Stage III	10/60	8/60	6/60		
	Stage IV	6/60	5/60	7/60		
K-L image classification	Level 2	2/60	2/60	0	2.343	0.673
	Level 3	32/60	34/60	36/60		
	Level 4	26/60	24/60	24/60		
Knee scores of pre-operations	N	60	59	60		
	HSS	38.7 (34.0; 42.3)	40.6 (35.7; 43.2)	39.3 (34.7; 42.8)	1.036	0.357
	WOMAC pain	47.5 (46.0; 48.6)	47.5 (45.2; 48.3)	47.0 (45.5; 48.2)	0.151	0.860
	WOMAC stiffness	42.0 (39.0; 47.0)	43.0 (37.0; 48.0)	45.0 (38.8; 49.0)	1.112	0.331
	WOMAC function	41.0 (38.0; 45.0)	39.0 (32.0; 47.0)	40.5 (32.8; 47.0)	0.978	0.378
	WOMAC total	45.0 (38.0; 49.0)	41.0 (37.0; 47.5)	45.5 (37.0; 49.0)	1.414	0.246
	OKS	39.2 (36.2; 42.3)	37.6 (35.1; 42.7)	40.3 (36.2; 44.6)	2.233	0.111
	VAS	9.0 (8.0; 9.0)	9.0 (8.0; 9.5)	9.0 (8.0; 9.0)	1.742	0.178
	Maximum flexion angle of knee(°)	91.5 (82.0; 96.0)	94.0 (83.5; 98.0)	92.0 (87.8; 98.0)	1.251	0.289
	KSS pain	50.5 (43.8; 56.0)	50.0 (43.5; 56.5)	50.5 (44.8; 58.3)	0.701	0.498
	KSS function	52.0 (46.0; 59.0)	51.0 (43.0; 56.0)	52.0 (46.8; 56.0)	0.508	0.603

BMI, body mass index; FB, fixed-bearing; HSS, hospital for special surgery knee score; KSS, knee society score; MB, mobile-bearing; OKS, oxford knee score; TKA, total knee arthroplasty; UKA, unicompartmental knee arthroplasty; VAS, visual analog scale; WOMAC, The Western Ontario and McMaster Universities index.

TABLE 2 Clinic outcomes of UKA groups (MB UKA and FB UKA) and TKA group

	UKA groups (MB and FB)	TKA	Test statistic	*P* value
N	119	60		
Operation time (min)	63.2 (58.2; 68.2)	67.1 (61.4; 73.3)	3.466	<0.001
Intraoperative bleeding (mL)	8.6 (6.8; 10.3)	30.0 (24.9; 35.1)	30.281	<0.001
First walking time without crutches (d)	3.0 (3.0; 4.0)	8.0 (6.0; 10.3)	18.232	<0.001
First time of walking up and down stairs (d)	5.0 (4.0; 6.0)	10.0 (8.8; 12.0)	21.704	<0.001
Incidence of postoperative complications	3/117	2/58	/	1.000

FB, fixed-bearing; MB, mobile-bearing; TKA, total knee arthroplasty; UKA, unicompartmental knee arthroplasty.

Functional Outcomes of Primary Comparison

All knee scores and maximum flexion angle of the knee were significantly higher in the final follow-up than those preoperatively in the three groups ($P < 0.05$). Moreover, as the primary comparison, compared to the patients in the TKA group, those in the UKA groups (MB UKA and FB UKA) had better results in all knee scores (except VAS and KSS function scores) ($P < 0.05$) and a larger maximum flexion angle of the knee in the 3-year follow-up ($P = 0.001$). Furthermore, the UKA groups (MB UKA and FB UKA) had higher FJS scores than the TKA group at the final follow-up ($P = 0.007$) (Table 3).

General Results of Secondary Comparison

As a secondary comparison, there was no significant difference in the operative times between the MB UKA group and FB UKA group and the FB UKA group and TKA group ($P > 0.05$). However, the MB UKA group had a shorter operative time than the TKA group ($P < 0.01$) (Fig. 2A). Furthermore, the patients in the MB UKA and FB UKA groups had less bleeding and walked without crutches within a shorter time period ($P < 0.001$) compared to those in the TKA group. There was no difference between the MB UKA and FB UKA groups ($P > 0.05$) (Fig. 2B, C). Moreover, there was a significant difference in the first time of walking up and down the stairs among the three groups ($P < 0.01$) (Fig. 2D).

Functional Outcomes of Secondary Comparison

As a secondary comparison, there was no significant difference in all knee scores and maximum flexion angle of the knee between the MB UKA group and FB UKA group ($P > 0.05$) (Fig. 3). Moreover, the MB UKA group had better results in WOMAC stiffness, WOMAC total, OKS, FJS, and a larger maximum flexion angle of the knee in the final follow-up than the TKA group ($P < 0.01$) (Fig. 3C, E, F, H, K). However, there were no significant differences in the HSS, WOMAC pain, WOMAC function, VAS, KSS pain, and KSS function scores between the TKA group and the MB UKA group in the final follow-up ($P > 0.05$) (Fig. 3A, B, D, G, I, J).

Furthermore, the FB UKA groups had higher scores in HSS, WOMAC stiffness, WOMAC function, and WOMAC total scores and a larger maximum flexion angle of the knee than the TKA groups at the final follow-up ($P < 0.05$) (Fig. 3A, C, D, E, H). However, there were no significant differences in WOMAC pain, OKS, VAS, KSS pain, KSS function, and FJS scores at the final 3-year follow-up between the TKA group and FB UKA group ($P < 0.05$) (Fig. 3B, F, I, J, K).

TABLE 3 Knee scores of UKA groups (MB UKA and FB UKA) and TKA group ar final 3-year follow-up

	UKA groups (MB and FB)	TKA	Test statistic	*P* value
N	119	60		
HSS	89.0 (82.8; 95.0)	85.0 (80.0; 91.0)	2.912	0.004
WOMAC pain	91.0 (87.0; 96.0)	89.0 (84.8; 93.0)	2.084	0.039
WOMAC stiffness	84.0 (81.0; 88.0)	78.0 (74.0; 86.0)	4.134	<0.001
WOMAC function	86.0 (78.0; 91.0)	81.0 (75.8; 89.0)	2.596	0.010
WOMAC total	87.0 (82.0; 93.5)	82.0 (78.0; 89.0)	3.412	0.001
OKS	20.0 (19.0; 22.0)	23.0 (20.0; 24.0)	3.720	0.001
VAS	1.0 (1.0; 2.0)	2.0 (1.0; 2.0)	1.006	0.316
Maximum flexion angle of knee (°)	123.0 (111.5; 127.0)	96.0 (89.0; 108.3)	10.612	0.001
KSS pain	92.0 (88.0; 96.0)	89.0 (85.8; 94.0)	1.982	0.049
KSS function	90.0 (85.0; 96.0)	88.0 (83.0; 94.3)	1.675	0.096
FJS	78.0 (74.0; 85.0)	74.5 (72.0; 81.3)	2.708	0.007

FB, fixed-bearing; HSS, hospital for special surgery knee score; KSS, knee society score; MB, mobile-bearing; OKS, oxford knee score; TKA, total knee arthroplasty; UKA, unicompartmental knee arthroplasty; VAS, visual analog scale; WOMAC, The Western Ontario and McMaster Universities index.

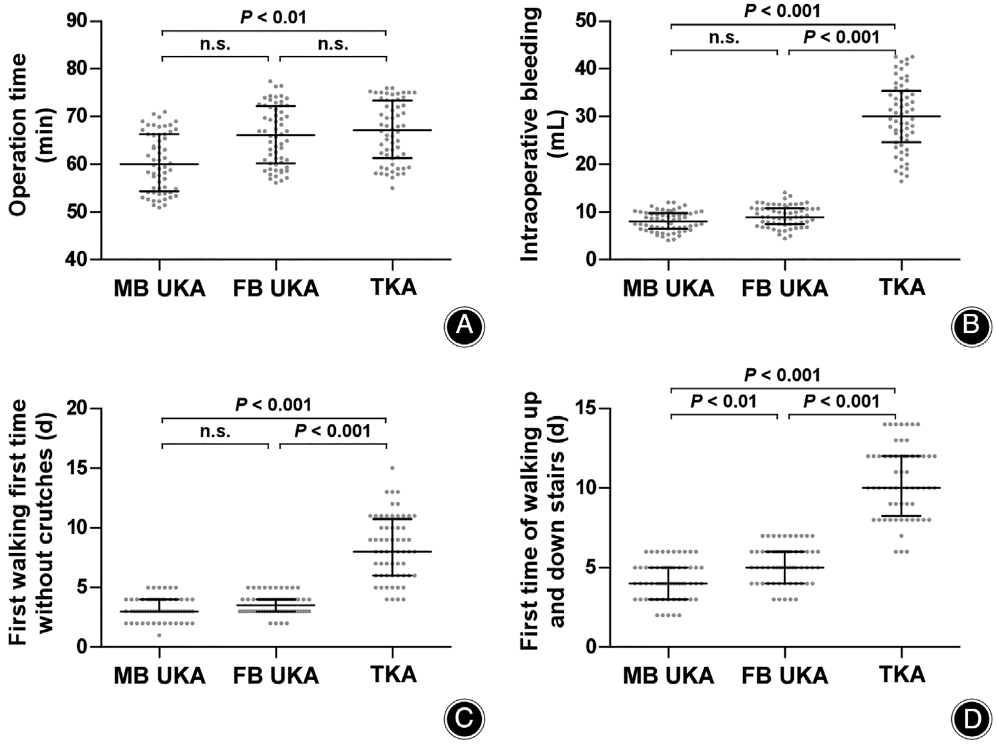

Fig 2 Clinic outcomes of mobile-bearing (MB) unicompartmental knee arthroplasty (UKA), fixed-bearing (FB) UKA, and total knee arthroplasty (TKA) groups. (A) MB UKA group had a shorter operative time than the TKA group. (B) MB UKA and FB UKA groups had less bleeding than TKA group, but there was no difference between MB UKA and FB UKA groups. (C) MB UKA and FB UKA groups had walked without crutches firstly within a shorter time period than the TKA group, but there was no difference between MB UKA and FB UKA groups. (D) MB UKA group had walked up and down the stairs firstly within a shorter time period than FB UKA and TKA groups, and FB UKA group had walked up and down the stairs firstly within a shorter time period than TKA group.

Three typical case studies were provided from TKA group (Fig. 4), MB UKA group (Fig. 5), and FB UKA group (Fig. 6).

Effective Subgroup Analysis

Further, gender, median age (>63 and <=63), K-L image level (3 and 4) and maximum flexion angle of knee (>92° and <=92°) were analyzed by stratification. The analysis found that the scores of TKA group and UKA groups (MB UKA and FB UKA) were significantly different, especially in the maximum flexion angle of knee follow-up, regardless of age, gender, and disease status, TKA group scores were far lower than MB and FB groups, while there was no significant difference between MB and FB groups. It is found that there is little difference in benefits between MB group and FB group among different ages, genders, and disease states. It should be noted that in KSS function follow-up, MB group has a higher score in the middle and lower age groups, while FB group has a higher score in the higher age groups.

Complications

One patient in the MB UKA group underwent the operation 6 months postoperatively, which changed the thicker bearing because of original bearing dislocation by loosening the movement of the knee. However, no original bearing dislocation was observed in both the FB UKA and TKA groups.

In the FB UKA group, one patient was treated by TKA replacement two years postoperatively because of the displacement of the femoral component caused by a fall injury. The FB UKA group lost one case 1 year postoperatively to a car accident.

Furthermore, one patient in the TKA group underwent revision surgery for infection due to pus at 1.5 years postoperatively. This situation may be related to our finding that there were many osteophytes in the knee joint during the operation, and it was very difficult to remove the osteophytes, which leads to more operation time. Another patient in the TKA group had intermuscular vein thrombosis by swelling and pain in the left leg 1 week postoperatively, which was cured after anticoagulation treatment. All patients completed 3 years of follow-up and statistical analysis, except for one case in the FB UKA group who died in a car accident.

Discussion

To our knowledge, this is the first study to compare the clinical outcomes of patients with non-lateral compartment knee OA who have randomly received MB UKA, FB UKA, and TKA and show the results of self-reported knee scores of these patients 3 years postoperatively. The main result in the present trial is that UKA has the advantages of a shorter operative time, less bleeding, earlier independent walking up and down the stairs, a larger knee flexion angle, higher in HSS, WOMAC pain, WOMAC stiffness, WOMAC function, WOMAC total, OKS, KSS pain, and FJS scores than TKA in the treatment of patients with non-lateral compartment knee OA, without significant difference in the

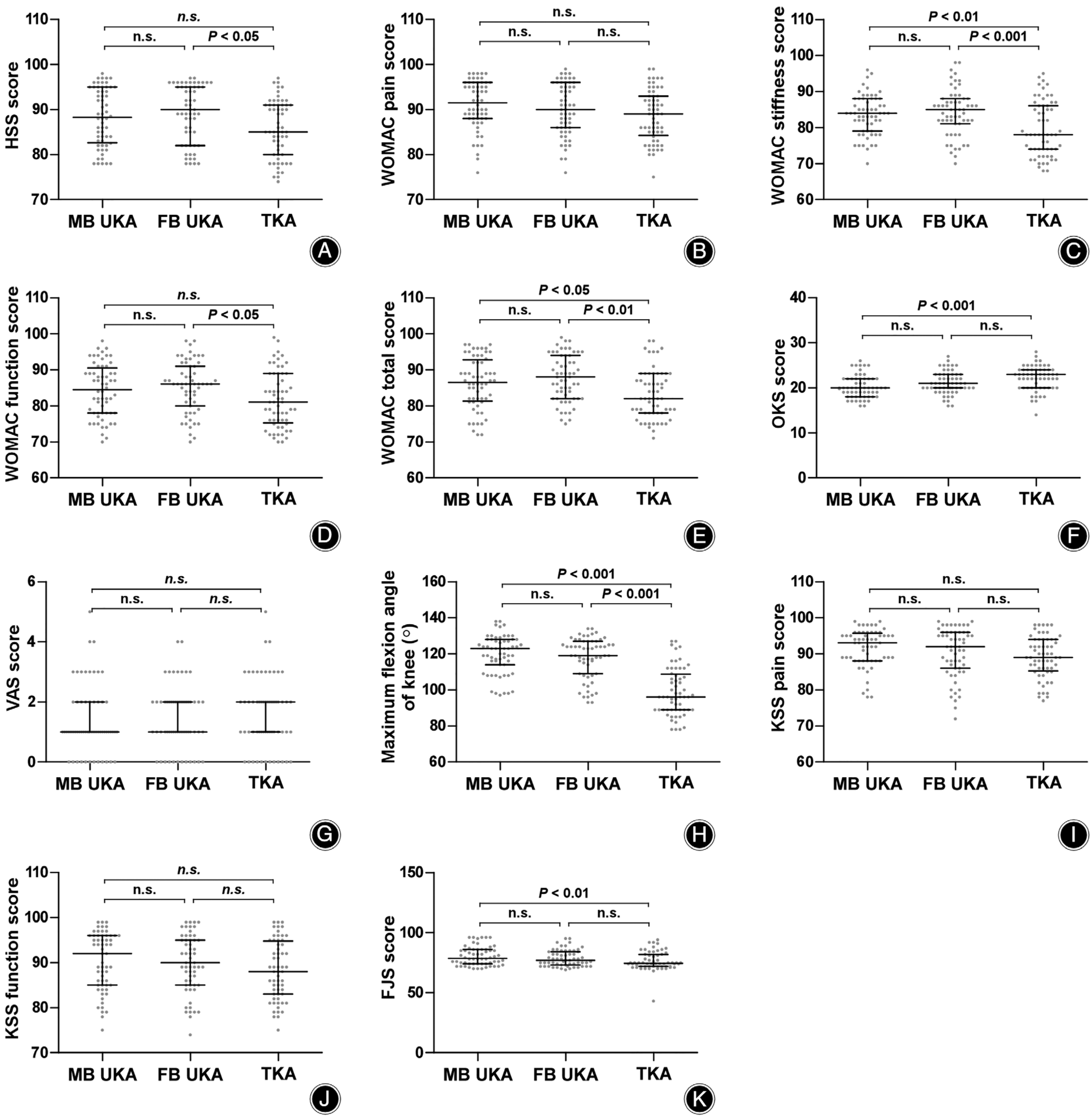

Fig 3 Knee scores of mobile-bearing (MB) unicompartmental knee arthroplasty (UKA), fixed-bearing (FB) UKA, and total knee arthroplasty (TKA) groups at 3-year follow-up. There was no significant difference in all knee scores and maximum flexion angle of knee between MB UKA and FB UKA groups (A, B, C, D, E, F, G, H, I, J, K). Moreover, MB UKA group had better results in the Western Ontario and McMaster Universities index (WOMAC) stiffness, WOMAC total, Oxford knee score (OKS), forgotten joint score (FJS), and a larger maximum flexion angle of knee than TKA group (C, E, F, H, K). However, there were no significant differences in the hospital for special surgery knee score (HSS), WOMAC pain, WOMAC function, visual analog scale (VAS), knee society score (KSS) pain, and KSS function scores between TKA group and MB UKA group (A, B, D, G, I, J). Furthermore, FB UKA group had higher scores in HSS, WOMAC stiffness, WOMAC function, and WOMAC total scores and a larger maximum flexion angle of knee than TKA group (A, C, D, E, H). However, there were no significant differences in WOMAC pain, OKS, VAS, KSS pain, KSS function, and FJS scores between TKA group and FB UKA group (B, F, I, J, K).

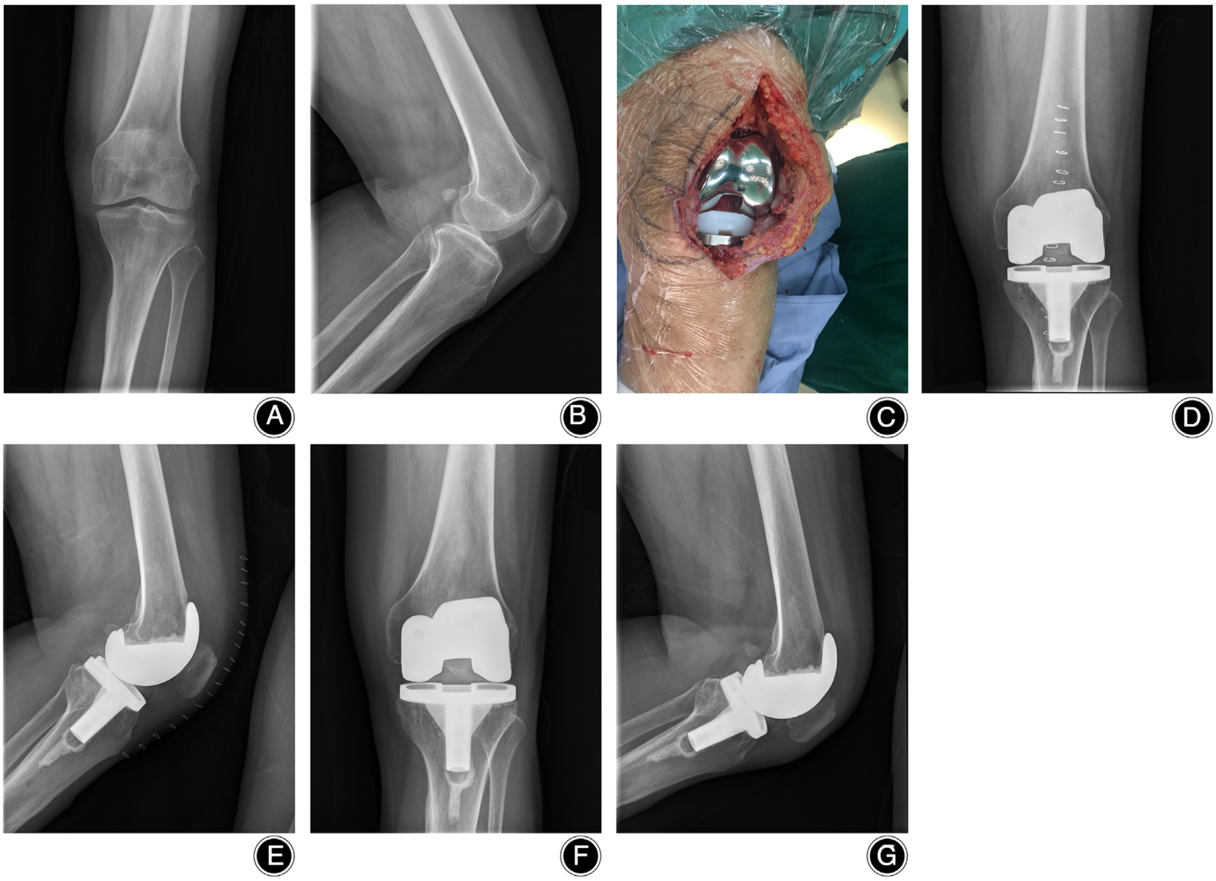

Fig 4 The 68-year-old female patient with non-lateral compartment knee unicompartmental osteoarthritis (OA) was allocated to the total knee arthroplasty (TKA) group randomly. (A) Preoperative anteroposterior X-ray image. (B) Preoperative lateral X-ray image. (C) The TKA prosthesis was fixed intraoperatively. (D) Postoperative anteroposterior X-ray image. (E) Postoperative lateral X-ray image. (F) Anteroposterior X-ray image at 3-year follow-up. (G) lateral X-ray image at 3-year follow-up.

incidence of postoperative complications. Furthermore, there was no significant difference in the clinical outcomes and knee scores between the MB and FB for UKA. These comparisons provide important evidence with the existing literature on the knee scores, curative efficacy, and postoperative complications, which may help in clinical decision-making on the three alternative procedures.

Patellofemoral Diseases Have Little to No Effect in MB UKA and FB UKA

Since Kozinn and Scott proposed the indication of UKA in 1989, pre-existing patellofemoral arthropathy has been widely considered as a contraindication by many surgeons[15]. However, the majority of studies reported that patellofemoral diseases have little to no effect on revision rates and outcomes in MB UKA designs[17, 34–37]. Here, we found that in comparison with TKA, even more than 58.33% cases of the MB UKA group showed shorter operative time, less bleeding, better knee function, similar postoperative complications, and better results in WOMAC stiffness, WOMAC total, OKS, and FJS scores, which included both medial compartmental knee OA and patellofemoral OA. Previous studies on FB UKAs reported that patellofemoral OA has little impact on knee scores, revision rates, and outcomes[18, 23, 38–40]. We also found that, compared to TKA, even more than 60.0% cases of the FB UKA group also showed shorter operative time, less bleeding, better knee function, similar postoperative complications, and higher scores in HSS, WOMAC stiffness, WOMAC function, and WOMAC total scores, which included both medial compartmental knee OA and patellofemoral OA in this research. Therefore, expanding the indications of UKA from anterior medial knee OA to non-lateral compartmental knee OA may be possible, and further research to support the findings is needed.

The Clinical Efficacies and Knee Scores Between UKA (Including MB UKA and FB UKA) and TKA

Here, the patients who underwent UKA had obvious advantages of earlier functional recovery and had a larger maximum flexion angle of the knee than the patients who

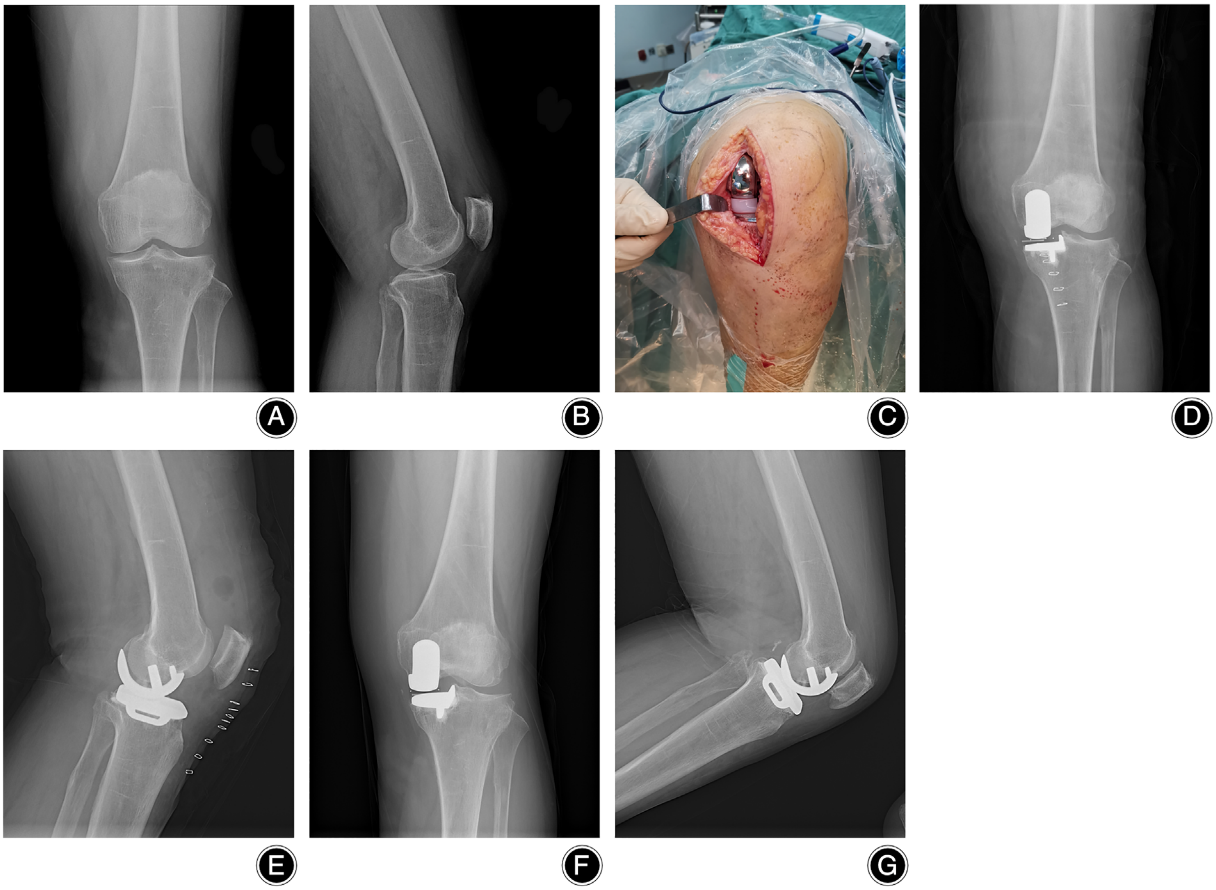

Fig 5 The 65-year-old female patient with non-lateral compartment knee unicompartmental osteoarthritis (OA) was allocated to mobile-bearing (MB) unicompartmental knee arthroplasty (UKA) group randomly. (A) Preoperative anteroposterior X-ray image. (B) Preoperative lateral X-ray image. (C) The MB UKA prosthesis was fixed intraoperatively. (D) Postoperative anteroposterior X-ray image. (E) Postoperative lateral X-ray image. (F) Anteroposterior X-ray image at 3-year follow-up. (G) Lateral X-ray image at 3-year follow-up.

underwent TKA in the 3-year follow-up period. This finding is consistent with Hauer's report[41], which stated that patients who underwent UKA were associated with a higher activity level, higher quality of life, and greater ROM than patients who underwent TKA in a 2.3-year follow-up period. Casper[1] also found that UKA provided significantly greater improvement in the knee functions than TKA. Kievit[42] detected that the patients who underwent UKA returned to work significantly sooner after surgery than patients who underwent TKA. There is a very important reason that anterior cruciate ligament and PCL and lateral meniscus of knee joint could be preserved in UKA procedures, with reduced bleeding. On one hand, these ligaments and meniscus structures could be involved in the joint kinematics and improve the flexion by promoting the rollback[43], and the cruciate ligaments, as mechanoreceptors[44], could detect body kinesthesia and proproception[45, 46]. On the other hand, it could be suggested that patients who underwent TKA were more likely to suffer from quadricep avoidance than patients who underwent UKA during gait, resulting in a reduced knee flexion angle (i.e. "stiff knee") during mid-stance[47, 48] and abnormal knee flexion/extension moment patterns[49].

The Clinical Efficacies and Knee Scores Between MB UKA, FB UKA, and TKA

Moreover, both the MB UKA and FB UKA were significantly associated with higher postoperative WOMAC stiffness and total scores than TKA, and FB UKA also had higher postoperative WOMAC function scores than TKA, without any significant difference in the WOMAC pain score among the three surgical procedures. A prospective study by Noticewala[50], which compared 128 patients who underwent TKA and 70 patients who underwent UKA with a mean follow-up of 3.0 years for UKA and 2.9 years for TKA, found that patients who underwent UKA showed significantly larger improvements in WOMAC pain and function scores than patients who underwent TKA; even though the UKA types in this study were not indicated, this result is consistent with ours on the postoperative WOMAC function scores.

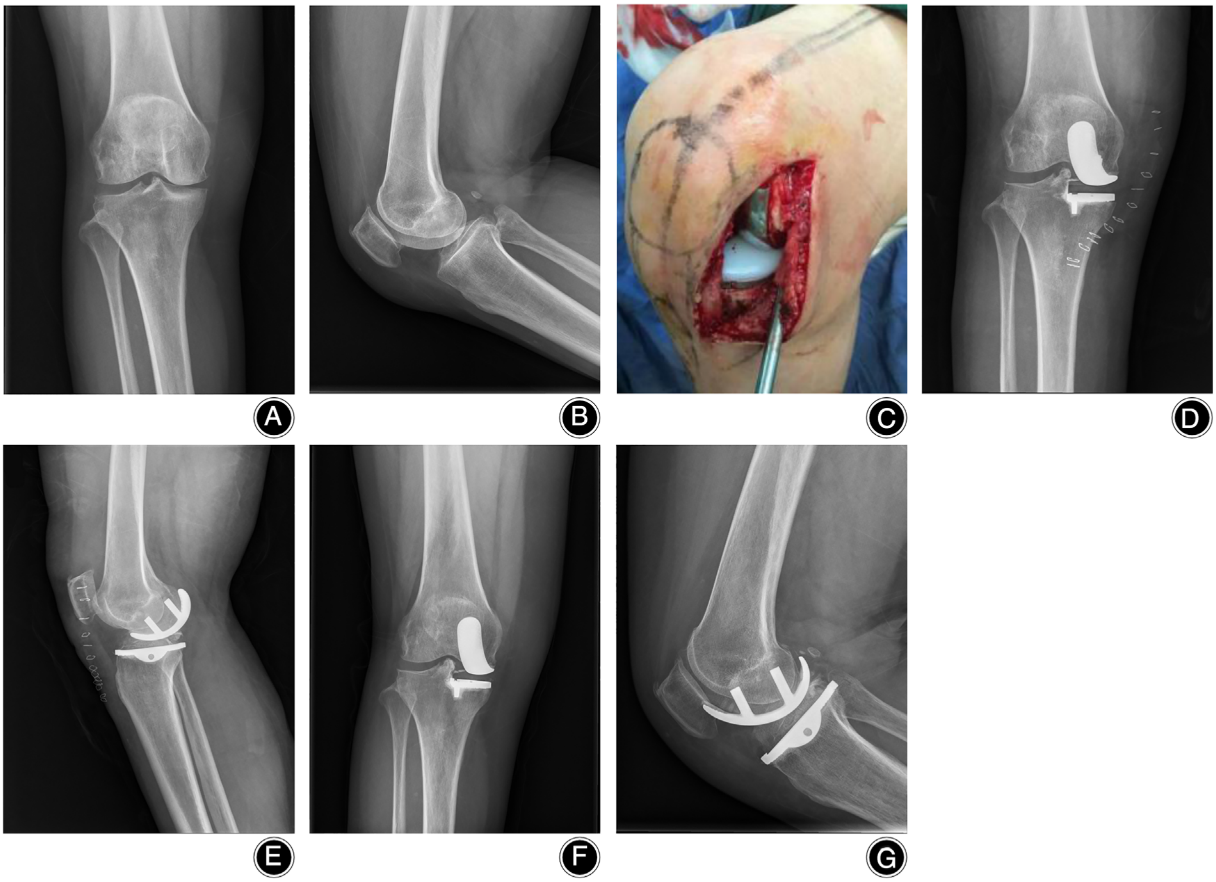

Fig 6 The 63-year-old female patient with non-lateral compartment knee unicompartmental osteoarthritis (OA) was allocated to fixed-bearing (FB) unicompartmental knee arthroplasty (UKA) group randomly. (A) Preoperative anteroposterior X-ray image. (B) Preoperative lateral X-ray image. (C) The FB UKA prosthesis was fixed intraoperatively. (D) Postoperative anteroposterior X-ray image. (E) Postoperative lateral X-ray image. (F) Anteroposterior X-ray image at 3-year follow-up. (G) Lateral X-ray image at 3-year follow-up.

Interestingly, there were no significant differences, not only in the WOMAC pain score among the patients who underwent MB UKA, FB UKA, and TKA in the final follow-up, but also in the VAS and KSS pain scores among the patients who underwent the three surgical procedures. The similar pain scores in this study showed that all the three surgical procedures have a good analgesic effect. Another study[51] also indicated that the UKA group had no statistically significant difference in pain scores (VAS and KSS) compared to the TKA group. Furthermore, all the knee scores were significantly higher in the 3-year follow-up than in the preoperative period among the three groups in this study.

Furthermore, the FJS scores of the UKA groups (MB UKA and FB UKA) are higher than those of the TKA group in the final follow-up, which is consistent with reports by Kim[52] and Zuiderbaan[53] within a 2-year follow-up period. Other prospective studies[5] with a 1-year follow-up period also suggest that patients who underwent UKA are less aware of their joint replacements than patients who underwent TKA for medial knee OA.

There is No Significant Difference in the Clinical Outcomes and Knee Scores of MB UKA and FB UKA

This trial confirmed that there is no significant difference in the clinical outcomes (except for the first time in walking up and down the stairs) and knee scores between patients who underwent MB UKA and FB UKA in the 3-year follow-up period. A randomized controlled radio stereometric analysis[54] within a 2-year follow-up period showed that MB and FB tibial components have similar good fixation and clinical improvement. Both groups experienced a statistically significant and clinically relevant[55] improvement in knee pain and function from being poor preoperatively to good up to 12 months postoperatively. Moreover, some systematic reviews and meta-analyses[2, 13, 56] indicated that no differences exist between the MB and FB modes in revision rates, complications, and knee function. A recent meta-analysis[57] showed that no significant differences were observed between the MB and FB UKA groups in radiolucency, revision rate, and complications, such as arthritis progression, aseptic loosening, and postoperative pain. Therefore, the meta-analysis demonstrated that both prostheses provide excellent clinical outcomes and patient survival rate with unicompartmental knee OA.

Limitations of the Study

There are a number of limitations in this trial. First, it was not multi-centered and did not have a large sample size. Second, the average follow-up time of this study was approximately 3 years, which is relatively short-term and needs to be further extended. Third, there was a relatively large difference in the number of cases between the UKA groups (MB UKA and FB UKA groups) and the TKA group in the primary comparison, which may have led to statistical bias in the results. Fourth, the next step requires a large-sample, multicenter, randomized, double-blind study with longer follow-up time.

Conclusion

This randomized controlled trial suggests that MB UKA, FB UKA, and TKA had significantly higher knee scores in the 3-year follow-up than in the preoperative period for patients with non-lateral compartmental knee OA. Relatively, UKA results in shorter operative time, less bleeding, better knee function, similar complications, better results in HSS, WOMAC pain, WOMAC stiffness, WOMAC function, WOMAC total, OKS, KSS pain and higher FJS score than TKA during the 3-year follow-up period. Meanwhile, there was no significant difference in clinical efficiencies and knee scores between MB UKA and FB UKA.

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