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Mobile- versus fixed-bearing total knee arthroplasty: a prospective randomized controlled trial featuring 6–10-year follow-up

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Objective: The purpose of this study was to compare long-term clinical and radiographic outcomes of mobile- (MB) and fixed-bearing (FB) total knee arthroplasties (TKA).

Methods: A randomized controlled study was conducted to compare the clinical and radiographic outcomes of MB and FB prostheses in 93 consecutive patients who underwent primary TKA for knee osteoarthritis. Mean follow-up of the patients was 100.9 months in the MB group (range: 78–121 months) and 93.7 months (range: 78–120 months) in the FB group. The clinical results were graded according to the Knee Society Knee Score (KSKS) and the Knee Society Functional Score (KSFS). Secondary outcomes included pain, patellofemoral joint function, quality of life (QOL), and radiologic outcomes (Knee Society's roentgenographic evaluation system).

Results: Although there was significant improvement in both groups, there were no significant differences between the groups with respect to mean KSFS and radiologic outcomes. However, mean pain score of the MB group was significantly higher than that of the FB group (48.83±0.62 vs 47.39±0.86, respectively, p=0.011), and mean KSKS was significantly higher than that of the FB group (93.5±6.2 vs 89.7±6.9, respectively, p=0.007).

Conclusion: TKA clinical results were satisfactory in both the MB and FB groups. KSKS and pain scores were significantly better in the MB than in the FB group. However, no differences were found in other assessments. Thus, we conclude that the best design is the one with which the surgeon is most comfortable and most able to implant reproducibly.

Keywords: Fixed-bearing; mobile-bearing; total knee arthroplasty.

Level of Evidence: Level I, Randomised controlled trial.

Total knee arthroplasty (TKA) has become a successful procedure for treating end stage osteoarthritis and rheumatoid arthritis because of its performance in relieving arthritic pain, correcting deformities, and restoring function.[1,2] The continued success of TKA is due to improvements in surgical technique, bearing surfaces, and

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implant design. Two different prosthetic device designs are currently available: fixed weight-bearing and mobile weight-bearing devices, each of which has advantages and disadvantages. The mobile weight-bearing knee prosthesis was designed to provide more conforming surface shapes with reduced polyethylene contact stressors, reduced wear, less tibial loosening, and presumably improved range of motion (ROM), particularly in young, active patients.[3] Despite the potential advantages that exist for mobile vs fixed weight-bearing devices, several comparative studies have indicated no superiority of mobile weight-bearing over fixed weight-bearing devices.[4,5]

This randomized controlled study was conducted to compare the clinical and radiologic results of mobile-bearing and fixed-bearing prostheses in 93 consecutive patients who underwent primary TKA for knee osteoarthritis. The purpose of this study was to compare long-term clinical and radiographic outcomes of mobile- and fixed-bearing TKAs. No follow-up studies are available on the comparative results of the TC PLUS™ SB system for mobile-bearing knees (Plus Orthopedics AG, Luxembourg, Switzerland) or the Maxim system (Biomet, Inc., Warsaw, IN, USA) for fixed-bearing knees.

Patients and methods

The study was approved by the institutional review board and was performed in accordance with the World Medical Association and the Declaration of Helsinki. One hundred sixty-five patients (165 knees) who had severe knee osteoarthritis with tricompartmental involvement requiring TKA were prospectively enrolled. Nine of the 165 patients died during the interim, 27 (27 knees) withdrew from the study for various reasons, and 36 patients did not meet the selection criteria for inclusion. Therefore, 93 patients (93 knees) were included in the study. The patients were assigned by computer-generated randomization the day prior to surgery to receive either the fixed-bearing or mobile-bearing prosthesis. The patients were not informed of the type of implant they would receive and remained blinded throughout the study period.

The patients (n=47) who were randomized into the MB group were treated with mobile-bearing implants and the other group (n=46) with fixed-bearing implants.

The 2 groups were homogeneous and had similar preoperative deformities, knee motion, demographics, and clinical characteristics (Table 1). Exclusion criteria were mediolateral instability, infective arthritis, severe deformity (varus ≥20° and valgus ≥20°), and revision (Table 2). All TKAs were performed by the same surgeon, and all arthroplasties followed the same surgical technique.

All TKAs were performed through a standard medial parapatellar approach under tourniquet control, and all wounds were closed over a negative suction drain. The patella was not resurfaced in any patient. Circumferential denervation of the patella was performed, and osteophytes were excised with a patelloplasty in all patients. All patients received postoperative analgesics and a standard fluid resuscitation protocol (35 cc/kg/24 h intravenous Lactated Ringer's solution). Prophylactic intravenous antibiotic (2 g cefazolin sodium) was administered to all patients 30 min before making the incision, and an additional 1 g was administered every 8 h for 3 days.

The implants used were (Figure 1) the TC PLUS™ SB (MB) and the Maxim (FB) prostheses. Both prostheses were of the posterior cruciate ligament-retaining design and had a similar cemented femoral component design and cemented tibial component.

Table 1. Demographic parameters of both treatment groups.

		Mobile (n=47)		Fixed (n=46)		p	Difference (95% CI)
		Min–Max	Mean±SD	Min–Max	Mean±SD		
[‡]Age (years)		50–78	64.91±6.16	49–78	64.70±8.13	0.884	0.219 (–2.761 to 3.200)
[‡]BMI (kg/m^2)		20.9–46.2	33.25±5.59	25.3–41.6	32.19±3.32	0.272	1.057 (–0.841 to 2.950)
[‡]Follow-up (months)		78–121	100.89±11.21	78–120	93.72±10.68	0.002**	7.176 (2.664 to 11.689)
		n	%	n	%	[b]p	
Gender	Male	6	12.8	5	10.9	0.777	
	Female	41	87.2	41	89.1		
Side	Right	24	851.1	27	58.7	0.460	
	Left	23	48.9	19	41.3		

[‡]Student's t-test (values are reported as minimum–maximum, arithmetic mean±2 SE of mean); mean difference (95% confidence interval);
[b]Pearson's chi-squared test;
**p<0.01. BMI: Body mass index.

Table 2. Inclusion and exclusion criteria.

Inclusion criteria
• Diagnosed with osteoarthritis (also referred to as gonarthrosis)
• Candidate for primary total knee arthroplasty for this reason
• Expected to undergo only one arthroplasty procedure within the next 12 months
• Willing to attend all follow-up examinations
• Expected to make a full recovery
• 50–80 years old
• Live independently
• Preoperative alignment (varus or valgus) <20°
Exclusion criteria
• Missing or having an insufficient posterior cruciate ligament
• Mediolateral instability
• Infective arthritis
• Severe deformity and revision
• Currently enrolled in a clinical investigation with either a drug or an investigational device or has been enrolled in such an investigation during the last 6 months
• Suffer from heart or lung disease

Rehabilitation included use of a knee immobilizer for 2 days, and passive mobilization using a continuous passive-motion machine for passive ROM exercises twice daily for 30 min. Walking with crutches or a walker was permitted twice daily beginning on postoperative Day 2. Quadriceps-femoris-strengthening exercises were initiated immediately after surgery.

Clinical and radiographic evaluations were conducted preoperatively and postoperatively at all follow-up visits. The patients were assessed by a physical examination and knee scoring systems preoperatively and at 3-, 6-, and 12-month follow-up visits, as well as at final follow-up, by an examiner who was not part of the operating team and was blinded to the implant type inserted. The clinical results were graded according to the Knee Society Knee Score (KSKS) and the Knee Society Functional Score (KSFS). Secondary outcomes included pain, patellofemoral joint function, quality of life (QOL), and radiologic outcomes (knee alignment angles, positions of the femoral and tibial components, position of the patella, and radiolucency). Standard anteroposterior and lateral radiographs of the knees were taken preoperatively and postoperatively at all follow-up visits (Figure 2). Radiologic outcomes were assessed by the Knee Society's roentgenographic evaluation system. Radiographs were taken with the patient in the supine position at a tube-to-film distance of 101.6 cm.[6]

The Turkish version of the Short-Form-36 Health Survey (SF-36) questionnaire was used to determine QOL pre- and postoperatively, as its validity and reliability have been established. Postoperative complications discovered at final follow-up examination that were related to the prosthesis–such as superficial or deep infection, instability, bearing breakage, or spinout–were recorded.

All statistical analyses were performed using NCSS 2007 and PASS 2008 statistical software (NCSS, LLC.,

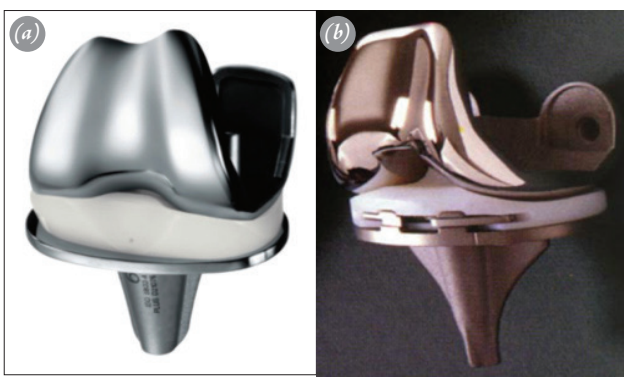


Fig. 1. **(a)** TC PLUS™ SB (MB) prosthesis, **(b)** Biomet Maxim (FB) prosthesis. [Color figures can be viewed in the online issue, which is available at www.aott.org.tr]

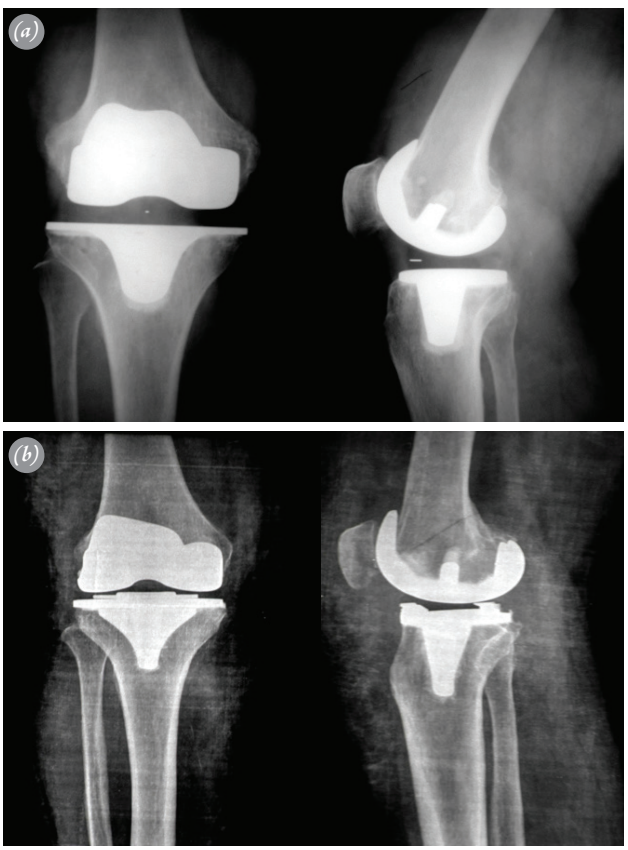


Fig. 2. **(a)** Anteroposterior and lateral radiographs of TC PLUS™ SB (MB) prosthesis, **(b)** anteroposterior and lateral radiographs of Biomet Maxim (FB) prosthesis.

Kaysville, UT, USA). All quantitative variables were estimated using central location (mean and median) and dispersion measures (standard deviation and standard error). Normality of the data distribution was determined with the Shapiro-Wilk test. Means of normally distributed data for the 2 groups were compared using Student's t-test. The Mann-Whitney test was applied for skewed data. Pearson's chi-squared test was used to identify differences in the proportions. A two-tailed p-value <0.05 was considered to indicate significance. A Kaplan-Meier survivorship analysis was performed to determine the cumulative survival rate of implants during the study period[7] and was reported with 95% confidence intervals (CIs). The endpoint for the analysis was aseptic loosening and revision surgery for any reason.

The sample size needed for the study was calculated as follows. According to Cohen,[8] sample size was calculated to be 52 (26/group) to detect a clinically relevant difference in pain score with a power of 0.80 and a significance level of 0.05. Accounting for potential exclusions, 46 cases were included in each group. A two-sided interval was used to establish the superiority design. This sample size was estimated to provide adequate power for the secondary outcome parameters at a cumulative significance level of 0.05.

Results

The flow of participants is shown in the Consolidated Standards of Reporting Trials (CONSORT) diagram in Figure 3. No mortalities occurred during the study, and no patient was lost to follow-up.

The results of each Knee Society Score system parameter during follow-up are shown in Table 3. All patients improved similarly postoperatively. Mean postoperative KSKS score (knee status) at final follow-up was 93.5±6.2 points (range: 0–100 points) in the MB group and 89.7±6.9 points in the FB group (p=0.007). Forty-five (95.7%) excellent, 2 (4.3%) good, and no fair or poor results were detected in the MB group; 35 (76.1%) excellent, 11 (23.1%) good, no fair, and 1 poor result were detected in the FB group (p<0.05). Mean postoperative

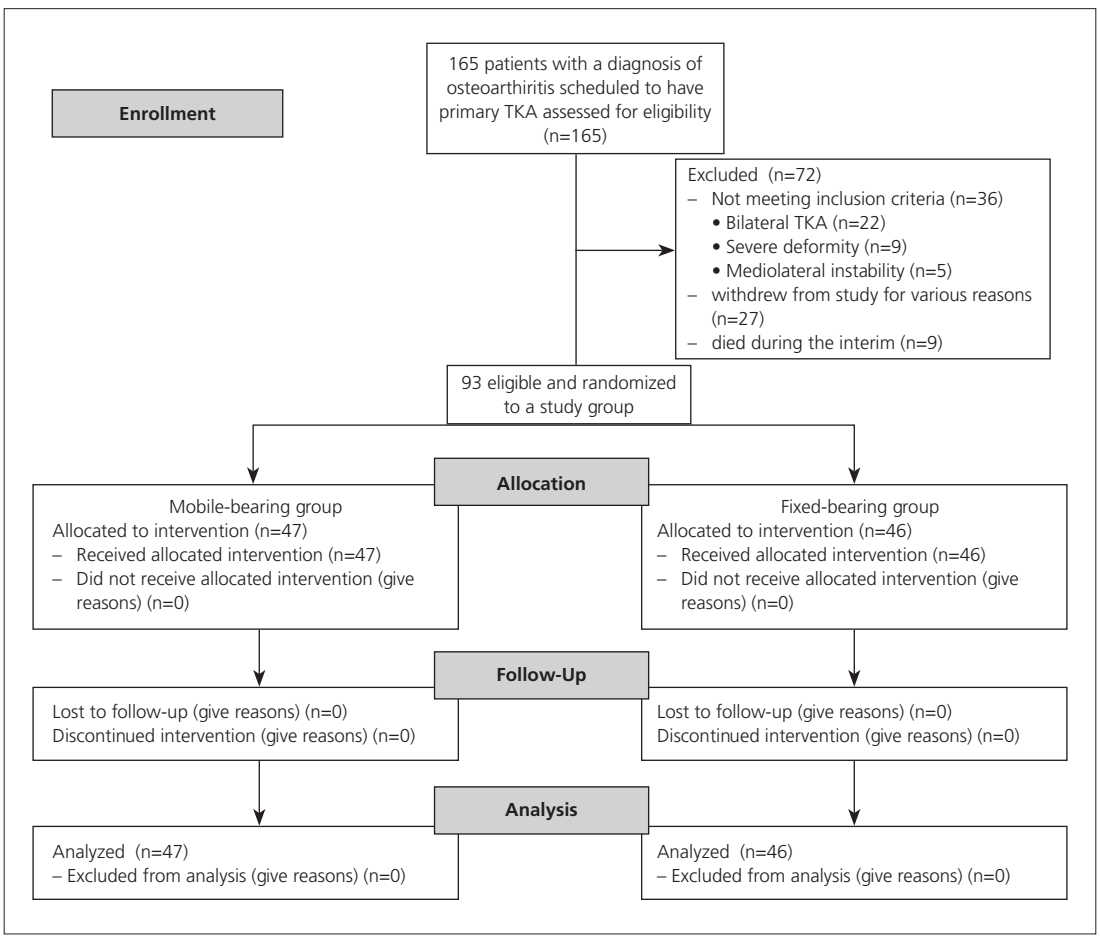


Fig. 3. Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing enrollment, allocation, follow-up, and analysis.

pain score at final follow-up was 48.83±0.62 points in the MB group and 47.39±0.86 points in the FB group (p=0.011). However, no significant differences were found in the functional scores at final follow-up (p>0.05).

The total scores on the SF-36 questionnaire are shown in Table 4. The SF-36 scores increased after TKA in both groups, but no significant difference was observed in QOL between the MB and FB groups at final follow-up (p>0.05) (72.50±5.19 vs 70.97±5.84, respectively; 95% CI –6.212 to 0.277).

Table 3. Comparison of clinical scores in the mobile- and fixed-bearing groups.

	Preoperative				Last follow-up			
	Mobile	**Fixed**	**p**	**†Difference (95% CI)**	**Mobile**	**Fixed**	**p**	**†Difference (95% CI)**
Range of motion	86.28±11.50 (100.00)	89.35±10.49 (100.00)	0.735	0 (–10 to 10)	123.62±2.94 (125.00)	121.96±2.74 (125.00)	0.217	0 (0 to 5)
Pain	1.91±1.16 (0.00)	2.61±1.45 (0.00)	0.546	0 (0 to 0)	48.83±0.62 (50.00)	47.39±0.86 (0.00)	0.011*	0 (0 to 0)
Flexion gap	17.23±2.29 (20.00)	17.89±2.08 (20.00)	0.550	0 (–2 to 2)	24.13±0.45 (25.00)	24.02±0.45 (25.00)	0.402	0 (0 to 0)
Stability	21.06±0.91 (20.00)	21.85±1.09 (22.50)	0.147	0 (0 to 0)	24.47±0.55 (25.00)	24.02±0.67 (25.00)	0.214	0 (0 to 0)
Flexion contracture	–0.96±1.94 (–15.00)	–8.59±2.00 (–12.50)	0.648	0 (0 to 0)	–2.11±1.17 (0.00)	–1.59±0.78 (0.00)	0.525	0 (0 to 0)
Extension gap	–1.70±0.88 (0.00)	–2.07±1.23 (0.00)	0.964	0 (0 to 0)	–0.43±0.41 (0.00)	–0.54±0.46 (0.00)	0.702	0 (0 to 0)
Knee score	16.3±13.6	19±14.7	0.392	0 (0 to 0)	93.5±6.2	89.7±6.9	0.007*	0 (0 to 0)
Functional score	45.3±19.3	38.3±20.8	0.135	0 (0 to 0)	89±13	83.3±17.1	0.129	0 (0 to 0)

Mann-Whitney U test (values are presented as arithmetic mean±2 SE of mean);
†Difference between medians across categories of insert type (95% confidence interval);
*p<0.05.

Table 4. Comparison of clinical scores in the mobile- and fixed-bearing groups.

	Preoperative				Final follow-up			
	MB	**FB**	**p**	**Difference (95% CI)**	**MB**	**FB**	**p**	**Difference (95% CI)**
‡General health	48.29±3.48	50.71±4.31	0.384	–2.421 (–7.914 to 3.071)	72.50±5.19	70.97±5.84	0.695	1.533 (–6.212 to 0.277)
Physical function	43.30±5.11 (50.00)	38.75±6.04 (38.75)	0.278	5 (–5 to 15)	78.72±5.17 (80.00)	71.63±6.85 (80.00)	0.190	5 (0 to 15)
Role physical	47.34±6.84 (50.00)	41.30±7.96 (50.00)	0.318	0 (0 to 25)	90.43±5.80 (100.00)	88.04±6.17 (100.00)	0.479	0 (0 to 0)
Bodily pain	13.62±3.28 (10.00)	10.11±2.87 (10.00)	0.126	0 (0 to 10)	88.35±3.82 (90.00)	87.34±5.20 (100.00)	0.903	0 (0 to 0)
Role emotion	38.97±7.93 (33.30)	32.58±7.60 (33.30)	0.235	0 (0 to 33.3)	92.79±4.02 (100.00)	84.54±6.43 (100.00)	0.049*	0 (0 to 0)
‡Energy/vitality	46.49±3.48	45.54±4.61	0.744	0.946 (–4.799 to 6.691)	74.40±3.81	69.93±4.98	0.158	4.469 (–1.745 to 10.684)
Mental health	64.64±3.62 (68.00)	64.57±3.81 (64.00)	0.984	0 (-4 to 4)	82.91±3.28 (88.00)	80.52±3.20 (84.00)	0.260	0 (0 to 8)
Social function	44.79±5.59 (50.00)	41.03±5.90 (37.50)	0.362	0 (0 to 12.5)	90.53±3.83 (100.00)	83.70±6.16 (93.75)	0.204	0 (0 to 12.5)

Mann-Whitney U test (values are reported as arithmetic mean±2 SE of mean); difference between medians across categories of insert (95% confidence interval).
‡Student's t-test (values are reported as arithmetic mean±2 SE of mean); mean difference (95% confidence interval).
*p<0.05. MB: Mobile-bearing; FB: Fixed-bearing.

Table 5. Radiologic results.

	Mobile-bearing	Fixed-bearing	p	Difference (95% CI)
Femoral valgus (α)	95.32±0.83 (95.00)	91.91±5.76 (96.00)	0.578	0 (–1 to 1)
‡Tibial angle (β)	88.30±0.58	87.43±0.81	0.086	0.863 (–0.119 to 1.845)
Femoral flexion (γ)	2.57±0.60 (3.00)	2.89±0.63 (3.00)	0.812	0 (–1 to 1)
Tibial slope (δ)	89.2±0.8	88±1.4	0.076	0 (0 to 0)
Preop alignment	4.7°varus	5.7° varus	0.113	0 (0 to 0)
Final follow-up	4.3° valgus	3.2° valgus	0.600	0 (0 to 0)
Patellar tilt	5.8° lateral	6.9° lateral	0.370	0 (0 to 0)
Femur-radiolucent line	0.40±0.34 (0.00)	0.72±0.77 (0.00)	0.826	0 (0 to 0)
Tibia-radiolucent line anteroposterior view	0.15±0.21 (0.00)	0.37±0.46 (0.00)	0.616	0 (0 to 0)
Tibia-radiolucent line lateral view	0.11±0.15 (0.00)	0.13±0.19 (0.00)	0.974	0 (0 to 0)

Mann-Whitney U test (values are reported as arithmetic mean±2 SE of mean); difference between medians across categories of insert (95% confidence interval).
‡Student's t test (values are reported as arithmetic mean±2 SE of mean); mean difference (95% confidence interval).

The radiologic results of the MB and FB groups were not significantly different (Table 5). Preoperative and postoperative knee alignment, positions of the femoral and tibial components in the sagittal and coronal planes, and shift in the joint line were not different between the groups. Mean postoperative femorotibial alignment (anatomical axis) at final follow-up was 4.3±2.4° (range: 0–10° valgus) in the MB group and 3.2±2.2° (range: 0–12° valgus) in the FB group (p=0.600). Nonprogressive radiolucent lines (<1 mm in width) in zone 1 were present in 13 knees (7 in the FB group and 6 in the MB group). No osteolytic lesions were detected in either group.

One patient in the MB group who had a body mass index (BMI) of 46.6 kg/m^2 suffered a patellar dislocation and underwent a revision operation including primary repair of the medial parapatellar line. A drop foot deformity developed in another patient in the FB group, but the patient recovered during the follow-up period.

A post hoc power analysis using G*Power (v3.1.7) software was performed. According to the distributions in the MB (n=47) and FB groups (n=46), with α=0.05 and d: 1.921, power was adequate for the postoperative Knee Society Score system, and the calculated power for the pain score was 99.9% (0.999).

Discussion

Favorable TKA results using either the FB or MB prostheses were documented. No follow-up studies are available on the comparative results of the TC PLUS™ SB system for mobile-bearing knees or the Maxim system for fixed-bearing knees.

The most important result was the lack of significant differences in functional, clinical, or radiologic outcomes, as well as complication rates between the FB and MB TKA designs. Only the KSKS and pain scores differed significantly between the 2 designs, and the MB device presented superior results to those of the FB device. In addition, better subjective preference results tended to be observed in the MB group, but the difference was not significant. Our results showed lower levels of pain with the MB implants, and 77% of patients in the MB group were pain-free at final follow-up, which is in agreement with previous reports.[9–11]

Numerous randomized trials and meta-analyses[12–14] have compared the FB and MB designs. Their results demonstrated no differences in clinical or radiologic outcomes between the 2 designs, which are consistent with our findings.[15–19] Overall, only small differences were noted in the clinical outcomes between the FB and MB groups at final follow-up in the present study. Both devices delivered consistent symptomatic and functional improvement in most patients. No differences were found in function scores or other outcome measures assessed at final follow-up. It should be emphasized that the 2 knee designs used here were from different manufacturers. However, as both designs were retained posteriorly, this may not have had any significant effect on ROM. Although one patient with an MB knee experienced early failure (BMI: 46.6 kg/m^2) with a patellar dislocation and underwent revision surgery including primary repair of the medial parapatellar line, no difference related to this late revision was detected between the groups. No other complications were found. Some studies have reported complications requiring revisions in both groups, such as a bearing dislocation, instability, or early component loosening. We believe that surgeon- and patient-specific factors could contribute to these types of complications.

MB knee arthroplasty was introduced to decrease polyethylene wear by increasing implant conformity in

the sagittal and coronal planes and reduce transfer of force to the implant-bone-cement interface compared with that of conventional FB designs, without restricting rotational freedom of this implant type.[20–22] FB TKA suffers from problems of wear and loosening, particularly in more active individuals. However, several studies have shown survival rates of 95–97% after follow-up of 10–15 years.[23] An analysis of several studies that compared FB and MB designs revealed similar clinical results and an annual revision rate of 1% for both implant types.[24,25]

Kim et al. reported on 108 patients younger than 51 years old with osteoarthritis who had received an FB prosthesis in one knee and a rotating platform MB prosthesis in the other. They found no superiority of the MB total knee prosthesis over the FB total knee prosthesis at a mean follow-up of 16.8 years,[26] as they reported previously.[27]

QOL improved significantly for all patients postoperatively, but no significant difference was found between the groups. This finding is in agreement with previous studies.[28,29] Survivorship of the FB and MB designs was similar at final follow-up in the present series. The Kaplan-Meier survivorship analysis revealed 100% survivorship in both groups, using implant revision for any reason as the endpoint.

Stair-climbing ability is the percentage of patients requiring an aid to climb stairs vs those able to climb stairs normally.[30] Our results showed that postoperative stair-climbing ability improved greatly in all patients when compared to the preoperative results. However, no significant difference was detected between the groups. This finding is in agreement with those of previous studies.[31,32] Our radiologic findings were generally in accord with those of Shemshaki et al., who reported no difference in radiologic outcomes between the groups.[28] Consequently, although mobile bearings with free anteroposterior translation may improve knee flexion by allowing femoral rollback, the comparative ROM outcomes between the FB and MB prostheses should be regarded only as a reference to evaluate the superiority of the 2 implants, as few factors affect ROM following total knee replacement. Several authors have presented some determinants of final ROM, including surgically controllable parameters, such as tibial slope, posterior condylar offset, and the level of the joint line leading to a change in the Insall index.[33,34] Factors beyond the surgeon's control include preoperative flexion,[35] sex, and BMI.

The main strengths of our trial included the randomization process (double-blind), the single surgeon's experience with a consecutive group of patients, a homogeneous sample of similarly age-distributed patients with primary osteoarthritis, and no loss to follow-up.

One of the limitations of our study was that we prospectively compared 2 dissimilar prostheses from different manufacturers, although the implants were similar in femoral component geometry. Another limitation was the small sample size and advanced average age of the population in both groups that did not allow evaluation of subtle functional differences.

Our TKA clinical results were satisfactory in both the MB and FB groups. No functional advantage of mobile-bearing TKA over fixed-bearing devices could be detected, although KSKS and pain scores were significantly better in the MB than in the FB group. However, no other differences in other clinical or radiologic results (ROM or maximal flexion angle), or the ability to kneel and sit cross-legged were observed. Thus, we conclude that the best design is the one with which the surgeon is most comfortable and most able to implant reproducibly.

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Conflics of Interest: No conflicts declared.

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