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The John Insall Award

No Functional Advantage of a Mobile Bearing Posterior Stabilized TKA

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Abstract

Background Mobile bearing (MB) total knee design has been advocated as a means to enhance the functional characteristics and decrease the wear rates of condylar total knee arthroplasty (TKA). However, it is unclear if these designs achieve these goals.

Questions/purposes We asked whether function of patients or survivorship would be greater or complications would be lesser in groups of patients with MB compared with fixed bearing (FB) TKA. We also sought to describe retrieval findings.

Methods We randomized 507 primary TKAs in 416 eligible patients to receive MB (n = 252) or FB (n = 255) devices from November 2001 to August 2007 (Investigational Device Exemption G000180, ClinicalTrials.gov registration number NCT00946075). Patients were blinded to treatment allocation. WOMAC Index, SF-12 Health Survey, knee range of motion, and Knee Society scores were collected and compared preoperatively and at 6, 12, and 24 months postoperatively. We recorded device failures and complications until October 2009. Kaplan-Meier survivorship was compared using the log rank test. Twelve retrieved MB devices underwent pathologic analysis. The minimum postoperative time was 2.2 years (mean, 5.9 years; range, 2.2–7.9 years).

Results We found no differences in mean clinical assessment scores or mean score changes from baseline at any postoperative interval through 2 postoperative years. Nineteen of the 252 MB and 13 of the 255 FB knees had undergone revision of any component. Estimated survival at 6 postoperative years was similar for the two devices: 90.1% (95% confidence interval [CI], 84.1–93.9) for MB and 94.2% (95% CI, 90.1–96.6) for FB. Two MB and no FB tibial components were revised for loosening. There was one case of MB insert dislocation. Retrieved MB devices demonstrated no unexpected wear or mechanical device failures.

Conclusion We found no evidence of functional advantage of the MB design. Survivorship was similar, although the study is limited by short duration of followup.

Level of Evidence Level I, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Introduction

Implant designers have long recognized the kinematic conflict between wear-resistant conforming articular surfaces in

TKA prostheses and the need to accommodate complex knee motion patterns [7, 14]. In response to the problems of early delamination and accelerated wear experienced with polyethylene sterilized by gamma irradiation in air during the late 1960s [14, 42], development of high contact area rotating bearing total knees began in the mid- to late 1970s.

Mobile bearing (MB) devices have enjoyed remarkable commercial success [9–11] and are acclaimed for improved functional rotation and stability [16, 21] and low wear rates [2, 23, 32, 33] and when compared with fixed bearing (FB) devices. However, these claims remain controversial and have been largely unsupported by the peer-reviewed literature [20, 22, 36, 39]. Additionally, concerns remain about the risks of bearing dislocation and fine particle debris generation in MB devices [5, 13, 15].

We asked whether function of patients or survivorship would be greater in groups of patients with MB than FB devices of a multicenter randomized trial and whether MB devices were associated with any unusual complications or retrieval findings. Specifically, the purposes of this study are to (1) compare functional scores in patients with MB versus FB devices at 2 years postsurgery; (2) compare survivorship with MB device and FB control device; (3) identify complications; and (4) report retrieval findings.

Patients and Methods

Between November 2001 and July 2007, 423 patients with noninflammatory degenerative joint disease of the knee who had indications for primary TKA and met the inclusion criteria (Table 1) were enrolled from 14 US centers into an Investigational Device Exemption designed to evaluate safety and effectiveness of an investigational MB TKA system (Scorpio® + PS MB prosthesis; Stryker Orthopedics, Mahwah, NJ, USA) in comparison to a commercially available FB system (Scorpio® PS FB prosthesis; Stryker) at 2 years postimplantation. A total of 507 TKAs (255 FB and 252 MB, as randomized) of 416 patients were ultimately included in the trial (Fig. 1). The investigational Scorpio® + PS Mobile Bearing Insert and Osteonics Scorpio® Total Knee PS Tibial Bearing control insert are N_2Vac gamma-sterilized UHMWPE inserts, which differed slightly in their respective tibial topography; the rotating platform design included a reduced posterior profile identical to that of the commercially available Scorpio®Flex bearing insert, whereas the FB device used a more conforming raised posterior lip. The same femoral component (Scorpio® PS) was used for both groups. All components were cemented. The protocol called for replacement of all patellae. Investigative sites underwent a qualification process including evaluation of investigator expertise, research experience and personnel, subject population, and institutional resources. Each enrolled patient was randomized to a treatment arm after collection of all preoperative data. Randomization was centrally administered using randomization lists computer-generated by a statistician, which were blocked by center and whether the patient was scheduled for bilateral or unilateral TKA in block sizes of four in 1:1 allocation ratio. After confirmation of preoperative data and inclusion eligibility, the sponsor assigned a patient identification number and determined the device system assignment by selecting the next system on the list. Patients undergoing bilateral TKA (n = 74) were allocated to receive the same device in both knees. Patients undergoing unilateral TKA who later underwent primary TKA for the contralateral knee were asked to enroll the second knee into the study and allocated to receive the same device (n = 17). Participating patients agreed to forgo knowledge of which

Table 1. Study inclusion and exclusion criteria

Inclusion criteria
Male or nonpregnant female scheduled for unilateral or bilateral TKA procedure
Aged 21–80 years
Diagnosis osteoarthritis, traumatic arthritis, or avascular necrosis
Failed to respond to conservative treatment
Treatment with primary cemented TKA indicated
Collateral ligaments intact
Preoperative Knee Society clinical score < 60 and functional score < 60
Gives valid informed consent
Exclusion criteria
Prior high tibial osteotomy, cruciate ligament reconstruction, or patellectomy
Morbid obesity (> 60% over ideal body weight [17])
Varus or valgus alignment deformity > 45°
Fixed flexion deformity > 45°
Active or suspected infection or malignancy of or about the knee
Immunocompromised or receiving steroids in excess of physiological requirement
Severe osteoporosis, Paget's disease, renal osteodystrophy, or other systemic disease that at the investigator's judgment would affect subject's welfare or overall outcome of the study
Bone stock compromised by disease or infection that cannot provide adequate support/fixation to the prosthesis
Neurologic deficit that interferes with patient's ability to limit weightbearing or places an extreme load on the implant
Female who plans to become pregnant during course of the study
Known sensitivity to device materials
Has an existing TKA on the contralateral side less than 6 months postoperatively
Patient undergoing unilateral TKA and expected to undergo TKA of the contralateral knee within 6 months
Patient is a prisoner

device(s) they had received until completion of the study; however, investigators and assessors were not blinded to treatment group (single-blind, open-label design). Baseline characteristics (Table 2) and preoperative clinical scores (Table 3) were comparable between the groups with the exception of slightly increased average preoperative knee flexion among the MB group (average difference 2.6°, $p = 0.041$). Minimum postoperative time was 2.2 years (mean, 5.9 years; range, 2.2–7.9 years). The Institutional Review Board at each center approved the study and all patients gave informed consent before participation in the trial. The study is registered at ClinicalTrials.gov under registration number NCT00946075.

The Investigational Device Exemption was originally designed and undertaken for the purpose of establishing safety and effectiveness in an active-control design to support a Premarket Approval application to the Food and Drug Administration; as such, the sample size had been designed to support a noninferiority analysis of a binary composite success criteria with a lower confidence bound margin of −10% at 80% power among the subset of unilateral TKA cases. Because the current study constitutes

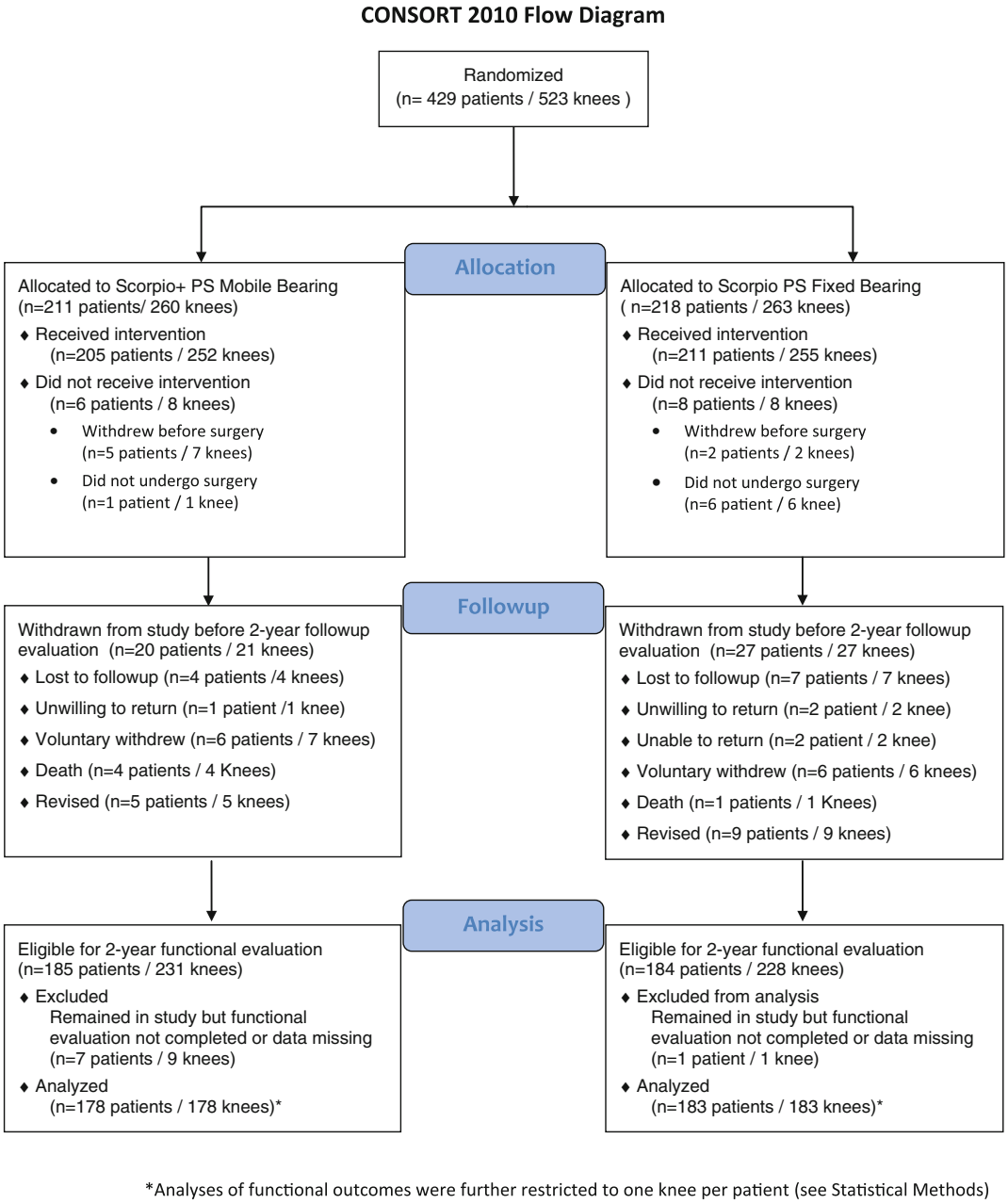

Fig. 1 Treatment allocation and patient followup to the primary analysis end point are shown by flow diagram.

Table 2. Pre- and postrandomization characteristics of study group (n = 507 knees of 416 patients)

Characteristic	Mobile bearing	Fixed bearing	p value
Number of patients/number of knees	205/252	211/255	
Male/female* (number of patients [%])	68 (33%)/137 (67%)	82 (39%)/129 (61%)	0.261
Age (years)*,†	66 ± 9 67 (35, 81)	66 ± 9 68 (40, 83)	0.616
Body mass index (kg/m^2)*,†	31 ± 5 31 (20, 54)	31 ± 5 31 (21, 47)	0.321
Underwent unilateral/bilateral* procedure (number of patients [%])	168 (82%)/37 (18%)	174 (82%)/37 (18%)	0.899
Diagnosis (number of knees [%])‡			
Osteoarthritis	248 (98%)	246 (96%)	0.381
Avascular necrosis	0 (0%)	0 (0%)	
Posttraumatic arthritis	4 (2%)	9 (4%)	
Preoperative knee alignment (degrees, −varus/+ valgus)†,‡,§	−5 ± 7 −6 (−25, 16)	−5 ± 7 −5 (−24, +14)	0.357
Postoperative alignment (degrees, −varus/+ valgus)†,‡	5 ± 2 5 (−5, 9)	5 ± 2 5 (−2, 10)	0.215
Surgical approach (number of knees [%])‡			
Medial parapatellar	140 (68%)	145 (69%)	0.981
Lateral parapatellar	1 (< 1%)	0 (0%)	
Subvastus	58 (28%)	59 (28%)	
Midvastus	6 (3%)	7 (3%)	

* Unit of analysis is n = 416 patients; †results given as mean ± SD, median (range); ‡unit of analysis is n = 507 knees; §tibiofemoral anatomic alignment.

secondary aims/analyses of these data, we conducted power analyses for comparison of functional measures with the sample size available (416 knees of 416 patients included in analyses of clinical outcome measures with ≥ 85% complete data at 2 years); 178 patients in each of two groups would provide > 80% power at two-sided alpha = 0.05 to detect a mean difference with (SD = assumed standard deviation) of 1° knee extension (SD = 2.8) [35], 5° knee flexion (SD = 14.6) [35], 3-point SF-12 component score (SD = 10) [51], 6-point WOMAC domain score (SD = 20) [29], 6-point Knee Society function score (SD = 18.3) [29], and 3-point Knee Society clinical score (SD = 12.8) [29].

Clinical and functional status of patients were assessed preoperatively and at 6 (± 1), 12 (± 2), and 24 (± 2) months postoperatively using the WOMAC visual analog scale version 3.0 [4] (pain, function, and stiffness domains, 100 points each; lower score corresponds to better outcome), the SF-12 Health Survey [49] (mental and physical components, 100 points each; norm-based scores are calibrated to a population mean of 50 and SD of 10; higher score corresponds to better outcome), the Knee Society scoring system [25] (clinical and functional scores, 100 points each; higher score corresponds to better outcome), and knee ROM measurement (degrees active extension and flexion).

Ongoing surveillance for revisions and other operative site-related adverse events was conducted until the time that every patient in the study had completed the 2-year clinical followup interval (October 2009). The severity of each adverse event was classified by the reporting investigator as mild, moderate, or severe according to study guidelines; the definition of severe was similar to the ICH Good Clinical Practice guidelines definition of a serious adverse event [24]. Two adverse events with missing severity classification were classified by the principal investigator by review of the adverse event report form. For the purpose of this analysis we classified severe operative site-related events as major complications and mild or moderate operative site events as minor complications. The protocol specified patients were withdrawn from further followup after any occurrence of revision with the exception that patients with investigational devices continued to be followed for as long as the investigational tibial component remained in situ.

Standard AP, lateral, and merchant view radiographs of the knee were also obtained at all intervals and every 2 years thereafter for the duration of the study. One of two orthopaedic surgeon reviewers who were otherwise unassociated with the study (MB, JA) reviewed each postoperative radiograph for the presence of tibial component subsidence, defined as settling or shifting of the prosthesis in the cavity, and zonal radiolucencies [18], defined as a lucent area ≥ 1 mm in width seen parallel and in close proximity to the device encompassing at least 50% of the zone. Tibiofemoral (TF) angle [18] was measured from the preoperative AP films by the independent

Table 3. Preoperative clinical status of 416 knees* (416 patients) with fixed and mobile bearing devices

Variable	Mobile bearing	Fixed bearing	p value
Number of patients/knees included	205/205	211/211	
Active knee ROM (degrees)			
Extension	6 ± 6	7 ± 7	0.114
	5 (−5, 20)	5 (−2, 40)	
Flexion	112 ± 11	110 ± 14	0.041
	110 (80, 140)	110 (65, 140)	
WOMAC scores (100 points each)			
Pain	60 ± 22	59 ± 23	0.869
	62 (4, 100)	61 (0, 100)	
Functional impairment	61 ± 21	62 ± 21	0.873
	62 (10, 100)	63 (6, 100)	
Stiffness	66 ± 24	65 ± 24	0.594
	71 (8, 100)	68 (4, 100)	
SF-12 scores (100 points each)			
Mental component	49 ± 11	49 ± 12	0.977
	48 (21, 72)	49 (21, 71)	
Physical component	30 ± 7	30 ± 7	0.921
	29 (16, 56)	29 (17, 51)	
Knee Society scores (100 points each)			
Clinical	34 ± 11	33 ± 12	0.611
	35 (0, 59)	34 (0, 59)	
Functional	44 ± 11	44 ± 10	0.605
	50 (0, 60)	50 (0, 70)	

* One randomly selected knee included from patients with bilateral procedures (see Statistical Methods); all results given as mean ± SD, median (range).

reviewers (MB, JA); postoperative TF angle was measured and reported by the local investigator as part of each followup examination. Interobserver correlation of TF angle measurement from standard view radiographs reportedly ranges from r = 0.44 to 0.59 but assessment of radiolucent lines is less reliable (Pearson's r, range, 0.15-0.56) [3]. Interobserver reliability of subsidence measurement has, to the authors' knowledge, not been documented, although it has been suggested that conventional radiographic measurement is likely to overestimate true subsidence of tibial components [45].

Revised investigational devices were retrieved according to the established implant retrieval protocol of the Cleveland Clinic and analyzed there by an independent orthopaedic pathologist (TB).

Baseline characteristics were compared between groups using the independent samples t-test for normally distributed data or the Wilcoxon rank sum test for nonnormally distributed data or Fisher's exact test for discrete data. Average clinical assessment measures (knee extension and flexion; WOMAC, SF-12, and Knee Society scores) were displayed graphically over preoperative, 6-, 12-, and 24-month postoperative intervals and compared between treatment arm groups at each interval using Student's t-test or Wilcoxon rank sum test as appropriate for the distributions. The postoperative change of each clinical assessment measure from baseline to 12 and 24 months postoperatively was calculated for each patient (postoperative minus preoperative value) and summarized as an average and SD for each treatment group. Score changes from baseline were normally distributed within each group for all measures. The differences between the groups of mean score change were tested using the independent samples t-test, and 95% confidence intervals for the estimated difference between the groups were constructed from the t distribution. Borrowing from the principals of bioequivalence testing, we then compared the 95% confidence limits for the difference between groups of mean clinical change from baseline to a minimum clinically important difference (MCID) for each outcome measure [38]. MCID is the smallest difference that represents a clinically meaningful change and/or is perceptible to patients. MCID has been established as 9 to 12 points for the 100-point domains of WOMAC visual analog scale score [17, 47] and approximately 3 points for SF-12 mental and physical components [50] but has not been formally established for Knee Society score or ROM. Thus, as MCID, we chose 9 points for WOMAC scores (each domain), 3 points for SF-12, and, arbitrarily, 2° knee extension and 5° flexion and 9 points for Knee Society clinical and functional scores. The principal of confidence interval equivalence testing is that two randomly allocated treatments can be considered clinically equivalent if the 95% confidence interval for the difference between groups lies wholly inside the limits of –(MCID) and +(MCID) [6].

Survival probability for the FB and MB groups was estimated using the Kaplan-Meier method with revision of any component for any reason as the primary end point. The log rank test with two-sided alpha = 0.05 was used to test for differences of survival curves. Survival estimates were also computed using a more sensitive end point defined as revision of any component for any reason or the earliest occurrence of any of the following radiographic findings: zonal lucency size > 3 mm, which was also present at size > 3 mm at one or more subsequent intervals and/or had been documented as present in smaller size at a previous interval (present for 11 knees); or lucency ≥ 5 mm seen in three or more zones of the same component on any examination (one knee) or tibial component subsidence > 3 mm on any examination (one knee). Knees without the event were censored on the date of the latest clinical evaluation. A peculiarity of our data was that the

latest revision of a MB device occurred at 6.9 years postoperatively with very few (two FB, nine MB) knees left in the analysis (Fig 1); as a result, the final survival estimate for the MB group was spuriously low with wide confidence intervals (survival estimate 81.1% with 95% CI, 56.0%–92.7% for the primary end point) [12]. We handled this by including numbers left on the plot and citing the survival estimates calculated at 6 postoperative years, which were calculated with > 50 left in the analysis [31]; all cases were included in the Kaplan-Meier plot and log-rank test. Rates of major and minor complications were calculated as incidence density and compared between groups as test of incidence density ratio.

To account for statistical nonindependence of two knees of the same patient [8, 37], we included only one knee from any patient in the analyses of patient functional measures. For patients with sequentially implanted bilateral TKAs in the study, the first operated knee was included; for patients with bilateral TKA procedures on the same day, one knee was randomly selected (computer-generated). Survival analyses included data of all 507 knees without account for bilaterality [43]. There were seven unintentional occurrences of randomization error in the study: four knees of four patients that were randomized to the MB system and three knees of two patients that were randomized to the FB system were implanted with the opposite device. Patients who underwent revision, or who had radiographic events used as survivorship end points, had received their allocated device. To assess for possible discrepant results, we repeated all analyses with treatment groups classified as the device received; there were no substantive differences in the results; therefore, groups were analyzed as randomized unless otherwise specified. SAS/STAT software Version 9.2 (SAS Institute, Cary, NC, USA) was used for all data analyses.

Results

No differences of WOMAC (Fig. 2), SF-12 (Fig. 3), or Knee Society scores (Fig. 4) were found between the groups at any postoperative interval. The MB group had slightly greater average knee flexion at 6-month and 1-year intervals (Fig. 5). At 1 postoperative year, 95% confidence intervals for the estimated difference between the groups of mean score change were within ± MCID for all functional measures except SF-12 and WOMAC stiffness scores (MCID defined previously as 2° extension, 5° flexion, 3 points for SF-12 scores, and 9 points for WOMAC and Knee Society scores; Table 4); at 2 postoperative years, they were within ± MCID for all but the WOMAC stiffness score (Table 5).

Survival was similar (p = 0.351) between the groups using revision of any component for any reason as the end point (90.1% [95% CI, 84.1–93.9] for MB and 94.2% [95% CI, 90.1–96.6] for FB; Fig. 6). Survival was also similar (p = 0.952) using revision of any component or a radiographic finding of radiolucency or tibial component subsidence (described previously) as the end point (88.6% [95% CI, 82.2–92.8] for MB and 91.3% [95% CI, 86.6–94.4] for FB). Nineteen MB and 13 FB TKAs underwent revision of at least one component (Table 6). For five FB and six MB knees, the initial revision procedure was an isolated insert revision resulting from pain (three), stiffness (three), infection (two), instability (two), and dislocation of a MB insert (one). Three revised patients of the MB group

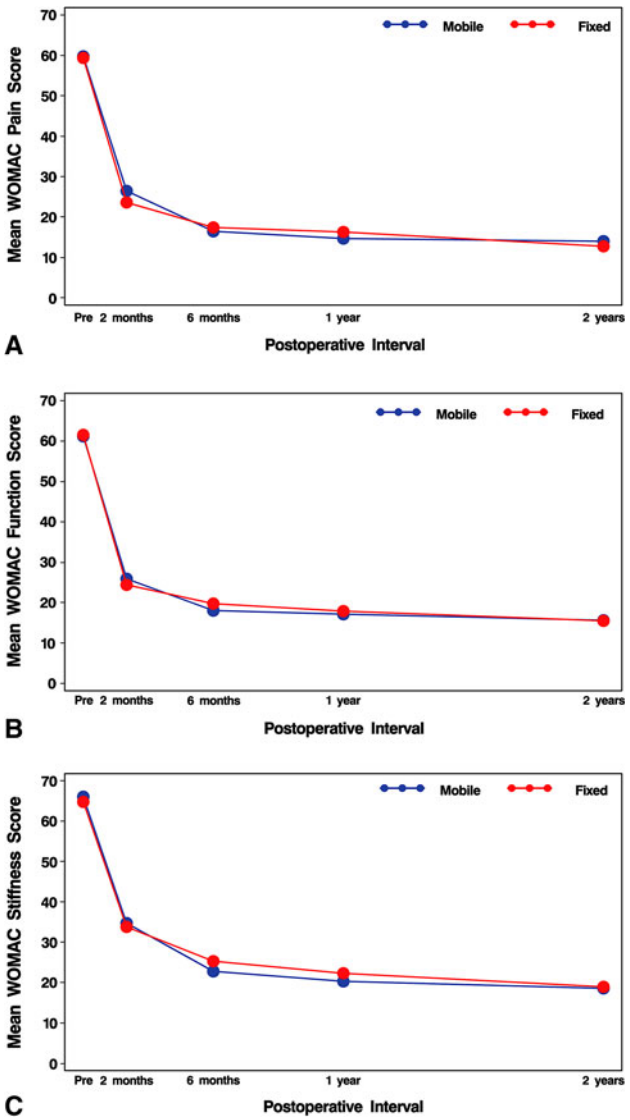

Fig. 2A–C Mean WOMAC pain (**A**), functional impairment (**B**), and stiffness (**C**) domain scores at pre- and postoperative evaluation intervals. Mean scores were similar (p > 0.05) at all intervals.

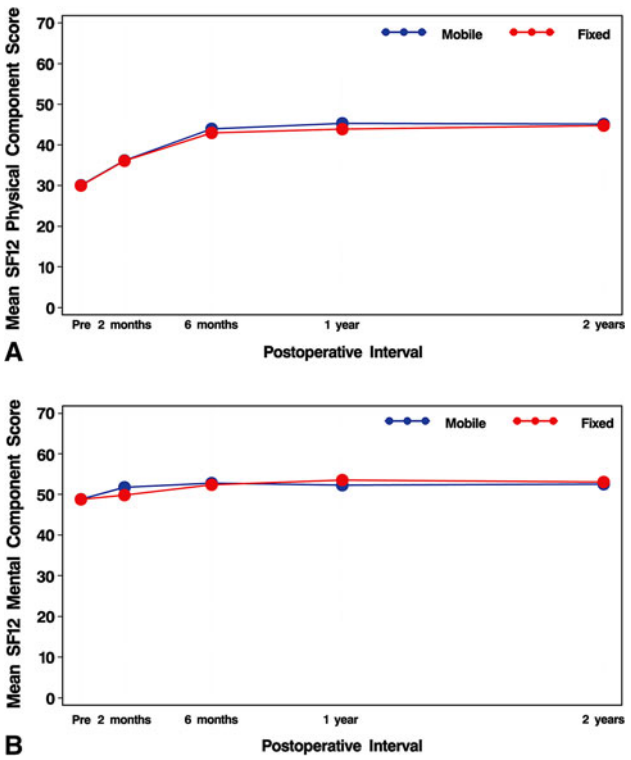

Fig. 3A–B Mean SF-12 physical (**A**) and mental (**B**) component normed scores at pre- and postoperative evaluation intervals. Mean scores were similar ($p > 0.05$) at all intervals.

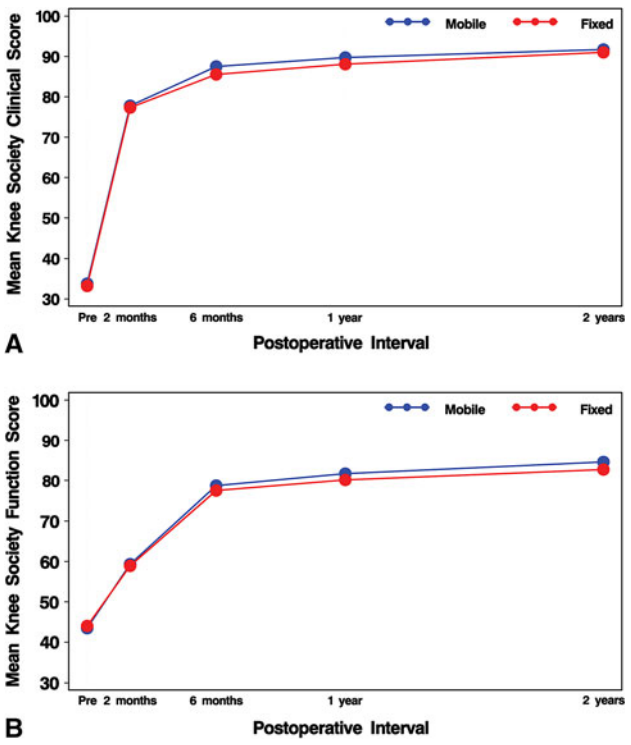

Fig. 4A–B Mean Knee Society clinical (**A**) and functional (**B**) scores at pre- and postoperative evaluation intervals. Mean scores were similar ($p > 0.05$) at all intervals.

later underwent removal of previously unrevised original components during a second revision procedure.

Incidence of complications and nonrevision reoperations was similar between the groups. Rates of operative site adverse events reported for MB and FB groups were 1.6 and 1.1 per 100 person-years ($p = 0.275$) for major complications and 14.5 and 11.9 per 100 person-years ($p = 0.061$) for minor complications, respectively. A total of 37 major and 359 minor operative site adverse events were reported. A total of eight MB and 10 FB knees underwent a reoperation without revision. Four MB and five FB knees underwent closed manipulation; two of these patients subsequently underwent arthroscopy for continued stiffness. Six additional knees (three MB and three FB) also underwent arthroscopic surgery, two for pain and stiffness, three for débridement and/or synovectomy, and one for a lateral release 8 months post-TKA for patellar subluxation. Two knees underwent open wound irrigation and débridement and/or closure secondary to wound healing problems. One underwent open reduction and internal fixation of a periprosthetic femoral fracture.

Retrieved MB devices revealed no failures of the locking rings or unexpected polyethylene wear; abrasive wear was noted on the upper surface of only one insert.

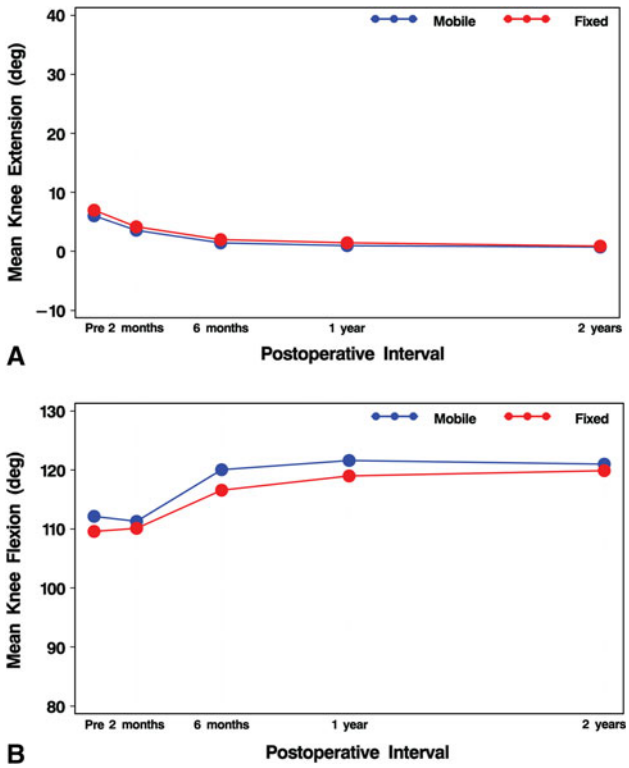

Fig. 5A–B Mean active knee extension (**A**) and flexion (**B**) at pre- and postoperative evaluation intervals. Mean differences of flexion between groups at preoperative, 6-month, 1-year, and 2-year intervals were 2.6° ($p = 0.041$), 3.5° ($p = 0.008$), 2.6° ($p = 0.027$), and 1.1° ($p = 0.303$), respectively.

Table 4. Change of clinical outcome scores from baseline* for 416 knees (416 patients) with fixed and mobile bearing devices at 1 year postoperatively with estimated difference between groups with 95% confidence intervals

Variable	Mobile bearing	Fixed bearing	Difference† (95% CI)
Number evaluated	185	190	
Active knee ROM (degrees)			
Extension	−5 ± 6	−5 ± 6	0.4
	(−20, 17)	(−35, 10)	(−0.8, 1.6)
Flexion	9 ± 15	8 ± 14	1.0
	(−59, 50)	(−35, 55)	(−1.9, 3.8)
WOMAC scores (100 points each)			
Pain	−45 ± 27	−42 ± 28	−2.5
	(−96, 38)	(−92, 51)	(−8.1, 3.0)
Functional impairment	−44 ± 26	−43 ± 26	−0.8
	(−96, 45)	(−92, 31)	(−6.0, 4.5)
Stiffness	−46 ± 29	−42 ± 30	−4.1
	(−98, 50)	(−99, 65)	(−10.2, 1.9)
SF-12 scores (100 points each)			
Mental component	3 ± 12	5 ± 12	−1.8
	(−27, 36)	(−38, 38)	(−4.3, 0.7)
Physical component	16 ± 11	14 ± 12	1.5
	(−16, 36)	(−19, 37)	(−0.9, 3.9)
Knee Society scores (100 points each)			
Clinical	56 ± 18	54 ± 18	1.5 (−2.1, 5.1)
	(−27, 89)	(−14, 91)	
Functional	38 ± 18	36 ± 21	1.5 (−2.5, 5.5)
	(−25, 95)	(−35, 90)	

* Value given represents mean of individual patients' change of score from preoperative (postoperative score minus preoperative score); all results given as mean ± SD (range); †Estimated difference between groups (mobile bearing minus fixed bearing) with 95% confidence interval (CI).

Table 5. Change of clinical outcome scores from baseline* for 416 knees (416 patients) with fixed and mobile bearing devices at 2 years postoperatively with estimated difference between groups with 95% confidence intervals

Variable	Mobile bearing	Fixed bearing	Difference† (95% CI)
Number evaluated	178	183	
Active knee ROM (degrees)			
Extension	−5 ± 6	−6 ± 6	0.5
	(−20, 10)	(−37, 8)	(−0.7, 1.7)
Flexion	9 ± 13	10 ± 13	−0.6
	(−46, 45)	(−30, 45)	(−3.4, 2.2)
WOMAC scores (100 points each)			
Pain	−45 ± 27	−45 ± 27	−0.5
	(−97, 24)	(−94, 34)	(−6.1, 5.1)
Functional impairment	−45 ± 26	−44 ± 25	−0.1
	(−98, 28)	(−94, 35)	(−5.4, 5.2)
Stiffness	−47 ± 31	−45 ± 30	−2.8
	(−96, 36)	(−99, 55)	(−9.1, 3.5)
SF-12 scores (100 points each)			
Mental component	3 ± 13	3 ± 12	−0.2
	(−30, 28)	(−39, 36)	(−2.8, 2.5)
Physical component	15 ± 12	15 ± 12	0.1
	(−17, 38)	(−22, 37)	(−2.5, 2.6)
Knee Society scores (100 points each):			
Clinical	58 ± 16	58 ± 15	0.5
	(0, 89)	(15, 93)	(−2.7, 3.7)
Functional	41 ± 19	39 ± 20	2.3
	(−15, 95)	(−20, 85)	(−1.7, 6.4)

* Value given represents mean of individual patients' change of score from preoperative (postoperative score minus preoperative score); all results given as mean ± SD (range); †Estimated difference between groups (mobile bearing minus fixed bearing) with 95% confidence interval (CI).

The remainder of the inserts demonstrated polishing without any evidence of yellowing, cracking, or delamination. Five inserts demonstrated mild radial scratch markings on the underside; two demonstrated mild impingement markings on the anterior aspects of the tibial posts. Synovial tissue from one demonstrated extensive deposition of calcium pyrophosphate crystals, but there was no associated abrasive wear present on either surface of the insert.

Discussion

Given expectations that the MB TKA design should result in improved functional rotation and stability [16, 21] and low wear rates [2, 23, 32, 33] compared with the FB design, we undertook this study to compare functional measures, survivorship, and complications between groups of patients with MB and FB devices and to report pathologic analysis findings of retrieved MB devices.

Limitations of our study include the following. First, we lacked blinded observers for investigator-assessed evaluations (single-blinded design). Although patient blinding protects the outcomes measured by self-report instruments (WOMAC and SF-12) from rater bias, the single-blind design cannot ensure unbiased measurement of investigator-rated outcomes (ROM or Knee Society scores). Second, we recognize this study period is not sufficient to determine or compare long-term durability of these two implants [2, 23, 32, 33]. The study was designed and conducted for the purpose of gaining Food and Drug Administration approval for marketing of the device in the United States; as such, long-term results were not required. Third, radiographic findings are subject to measurement error, were derived from radiographs that were not fluoroscopically guided [48],

Table 6. Numbers of knees undergoing revision, components revised, and reasons for revision among fixed and mobile bearing groups at 2.2 to 7.8 years followup

Event	Mobile bearing (n = 252)	Fixed bearing (n = 255)
Underwent any revision procedure (number of knees)	19	13
Reasons for revision*		
Loosening	2	0
Stiffness	5	5
Instability	2	3
Pain	6	3
Infection	3	2
Subsidence	1	0
Primary components revised†		
Femoral component	8	5
Tibial component	14	7
Patellar component	3	1
Tibial insert	19	13

* Reason for the first revision procedure to the knee; †numbers of components implanted during primary TKA that were removed during the course of the study.

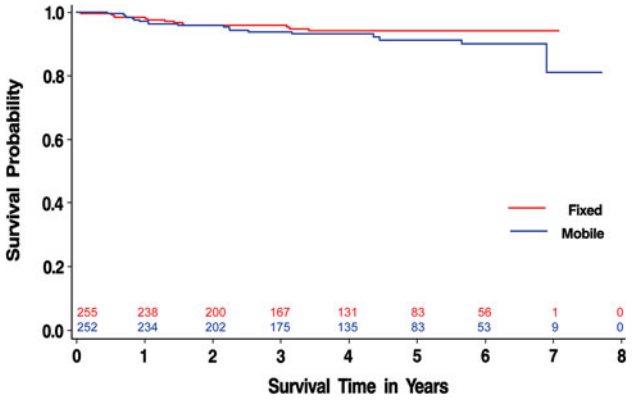

Fig. 6 Kaplan-Meier survival curves are shown for fixed and mobile bearing groups with numbers at risk shown at yearly intervals. End point for the analysis was any component no longer in situ for any reason. Estimated survival probabilities at 6 postoperative years were 94.2% (95% confidence interval [CI], 90.1–96.6) for fixed bearing devices and 90.1% (95% CI, 89.1–93.9) for mobile bearing devices with 56 and 53 at-risk subjects remaining, respectively. Survival curves were similar (p = 0.351).

and were classified according to arbitrary cut points (> 3 mm size lucency or subsidence). Fourth, there was some loss to followup and missing data (Fig 1), although within the commonly accepted limits of < 15% for our primary outcome. Fifth, the confidence interval clinical equivalence approach depends on the correctness of the chosen value for MCID, which is ultimately subjective. An important strength of the confidence limit approach, however, is that one can easily compare any different threshold with the confidence limits that one wishes.

We could identify no statistically or clinically meaningful differences of postoperative WOMAC, SF-12, or Knee Society scores between the MB and FB patient groups of this study. These findings corroborate those of other published randomized comparisons, which include several prosthetic designs as well as both cruciate retaining and substituting versions (Table 7). Average postoperative function scores of our patient groups were similar to those reported in other studies [20, 28, 53]. We evaluated functional measures both by comparing average scores of the groups at each interval and by estimating differences between groups of change from preoperative score. Confidence intervals for score changes were compatible with the hypothesis of clinical equivalence between groups for most outcomes subject to the limitations inherent in choosing the appropriate MCID. We did observe slightly under 4° more mean flexion at 6 and 12 postoperative months in the MB patients, although we do not believe this to be clinically important. This could be explained by the occurrence, despite randomization, of a similar preoperative difference and/or by the differences in the bearing surface topography of the devices. However, the average change of flexion from preoperatively differed by only 1° or less between the groups at every interval (Tables 4, 5), suggesting baseline differences may be implicated.

Midterm survivorship was similar between the MB and FB groups of this study; however, the overall revision rate (32 of 507 knees [6%]) is slightly higher than those reported in other series of MB or FB posterior stabilized devices [1, 26–28, 36, 40]. This could be explained in part by the stringent evaluation process of the Investigational Device Exemption and/or the fact that the study included a large number of participating sites with varying levels of experience with knee arthroplasty. Similar tendencies have been noted in other randomized comparisons [26, 28, 41]. The most common reasons for revision of these patients were pain and stiffness, which accounted for over half (18 of 32).

The overall rates of minor and major complications, some of which required surgical reoperations (nonrevision), were similar to those reported from other randomized evaluations [26, 36] and did not appear to be design-related. A large single-surgeon retrospective series of an FB device similar to the FB device studied here reported lower rates of revisions and complications [30]; however, the surveillance and scrutiny applied to an observational cohort is typically less rigorous than that applied to patients of an Investigational Device Exemption. It is also well recognized that patients who participate in experimental clinical trials differ from general populations of patients in ways that can be associated with general health behavior and outcomes [44].

Table 7. Summary of functional outcomes* reported in published randomized clinical trials comparing mobile to fixed bearing TKA devices

Author, year	Prostheses and numbers treated (MB/FB)	Study characteristics and minimum followup	Outcome time	Flexion (degrees) (MB/FB)	Knee Society Score (MB/FB)	WOMAC (MB/FB)	Short Form (MB/FB)
Aglietti et al., 2005 [1]	103/107 MBK/LPS ZIMMER	Double blinded Single center 30 months	2 years	110/114	92/91 Clinical 85/83 Functional		
Garling et al., 2005 [19]	21/21 Interax MB/ Interax-PS	No blinding Single center 24 months	2 years	116/116	85/85 Clinical 62/62 Functional		
Gioe et al., 2009 [20]	176/136 PFC Sigma RP/PFC Sigma	Double blinded Single center 24 months	Latest followup†	110/112	88/90 Clinical 63/55 Functional	Likert scale‡: 6.7/6.4 Pain 28/26 Function 3.0/2.7 Stiffness	36 Item: PCS, MCS not reported
Henricson et al., 2006 [22]	26/26 MBK/NexGenCR	No blinding Single center 24 months	2 years	110/112	Median reported: 91/89 Clinical 90/100 Functional		
Lädermann et al., 2008 [28]	42/48 PFC Sigma RP/PFC Sigma	No blinding Single center 84 months	Latest followup†	116/119	92/92 Clinical 80/78 Functional		12 Item: 44/44 PCS 54/54 MCS
Pagnano et al., 2004 [36]	80/160 PFC Sigma RP/PFC Sigma	No blinding Single center 12 months	1 year	117/116	92/92 Clinical 89/89 Functional		
Woolson et al., 2004 [52]	57/45 LCS/NexGenPS	No blinding Single center 41 months	Latest followup†	116/118	92/90 Clinical 77/75 Functional		
Wylde et al., 2008 [53]	118/132 Kinemax MB/Kinemax Plus	No blinding 4 centers 24 months	2 years	Not reported		VAS (100 points each)§: 18/20 Pain 26/26 Function Stiffness not reported	
Current study	205/211‖ Scorpio MB/Scorpio PS	Single blinded 14 centers 24 months	2 years	121/120	92/91 Clinical 85/83 Functional	VAS (100 points each) 14/13 Pain 16/16 Function 19/19 Stiffness	12 Item: 45/45 PCS 53/53 MCS

* Average reported unless otherwise noted; †time of outcome assessment unclear and/or not standardized; described as latest available followup; ‡WOMAC Likert scale scores pain on scale of 0-20, function 0-68, and stiffness 0-8 points; §authors of this study reported transformed WOMAC VAS scores (100 minus score); we back-transformed the scores to the original scale; ‖excludes second knee of any patient with bilateral TKA; MB = mobile bearing; FB = fixed bearing; PCS = Physical Component Summary; MCS = Mental Component Summary; VAS = visual analog scale.

Retrieval analysis of explanted MB specimens revealed no unexpected wear patterns or evidence of device failure mechanism. Two specimens showed small anterior impingement marks seen on the anterior aspect of the tibial posts; this finding has been noted previously in this and other posterior stabilized devices [34, 46] and its clinical relevance remains uncertain.

In conclusion, we found no short-term functional advantage to a rotating bearing knee arthroplasty, although questions regarding potential durability advantages remain and require longer observation.

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