

The Chitranjan S. Ranawat Award

No Difference in 2-year Functional Outcomes Using Kinematic versus Mechanical Alignment in TKA: A Randomized Controlled Clinical Trial

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Published online: 25 April 2016

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Abstract

Background Neutral mechanical alignment (MA) in total knee arthroplasty (TKA) aims to position femoral and tibial components perpendicular to the mechanical axis of the limb. In contrast, kinematic alignment (KA) attempts to match implant position to the prearthritic anatomy of the individual patient with the aim of improving functional outcome. However, comparative data between the two techniques are lacking.

The institution of one or more of the authors (SWY, MLW, AB, BF) has received, during the study period, funding from Stryker (Kalamazoo, MI, USA) One or more of the authors (AB, MLW, BF) or a member of his or her immediate family, has or may receive payments or benefits, during the study period, an amount of less than USD 10,000 from Stryker.

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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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Questions/purposes In this randomized trial, we asked: (1) Are 2-year patient-reported outcome scores enhanced in patients with KA compared with an MA technique? (2) How does postoperative component alignment differ between the techniques? (3) Is the proportion of patients undergoing reoperation at 2 years different between the techniques?

Methods Ninety-nine primary TKAs in 95 patients were randomized to either MA (n = 50) or KA (n = 49) groups. A pilot study of 20 TKAs was performed before this trial using the same patient-specific guides positioning in kinematic alignment. In the KA group, patient-specific cutting blocks were manufactured using individual preoperative MRI data. In the MA group, computer navigation was used to ensure neutral mechanical alignment accuracy. Postoperative alignment was assessed with CT scan, and functional scores (including the Oxford Knee Score, WOMAC, and the Forgotten Joint Score) were assessed preoperatively and at 6 weeks, 6 months, and 1 and 2 years postoperatively. No patients were lost to followup. We set sample size at a minimum of 45 patients per treatment arm based on a 5-point improvement in the mean Oxford Knee Score (OKS; the previously reported minimum clinically significant difference for the OKS in TKA), a pooled SD of 8.3, 80% power, and a two-sided significance level of 5%. **Results** We observed no difference in 2-year change scores (postoperative minus preoperative score) in KA versus MA

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patients for the OKS (mean 21, SD 8 versus 20, SD 8, least square means 1.0, 95% confidence interval [CI], -1.4 to 3.4 , $p = 0.4$), WOMAC score (mean 38, SD 18 versus 35, SD 8, least square means 3, 95% CI, -3.2 to 8.9 , $p = 0.3$), or Forgotten Joint score (28 SD 37 versus 28, SD 28, least square means 0.8, 95% CI, -9.1 – 10.7 , $p = 0.8$). Postoperative hip-knee-ankle axis was not different between groups (mean KA 0.4° varus SD 3.5 versus MA 0.7° varus SD 2.0), but in the KA group, the tibial component was a mean 1.9° more varus than the MA group (95% CI, 0.8° – 3.0° , $p = 0.003$) and the femoral component in 1.6° more valgus (95% CI, -2.5° to -0.7° , $p = 0.003$). Complication rates were not different between groups.

Conclusions We found no difference in 2-year patient-reported outcome scores in TKAs implanted using the KA versus an MA technique. The theoretical advantages of improved pain and function that form the basis of the design rationale of KA were not observed in this study. Currently, it is unknown whether the alterations in component alignment seen with KA will compromise long-term survivorship of TKA. In this study, we were unable to demonstrate an advantage to KA in terms of pain or function that would justify this risk.

Level of Evidence Level I, therapeutic study.

Introduction

Mechanical alignment (MA) in TKA aims to position femoral and tibial components perpendicular to the mechanical axis of each bone, aligning the hip-knee-ankle angle of the limb to neutral under static weightbearing conditions. This is a fundamental principle of TKA, aiming to achieve a more balanced load distribution within the medial and lateral compartments and minimize wear and component loosening [1, 3, 8, 18, 27, 30, 32, 39, 41]. Conventional TKA instrumentation is based around this principle, and computer navigation was introduced to aid accuracy in achieving this goal of a neutral mechanical axis [38, 40].

However, this situation differs from the native knee, in which the articular surface of the tibia averages 3° varus and that of the femur 2° to 3° of valgus relative to the mechanical axis [6]. Additionally, there is wide individual variation in limb alignment. A study of 250 young adults without arthritis found only 66% of males and 80% of females had a hip-knee-ankle angle within 3° of neutral with the majority of outliers demonstrating “constitutional varus” [7]. If such patients undergo TKA using MA principles, medial soft tissue releases are likely to be required [5, 6, 25]. In contrast, the kinematic alignment (KA) technique attempts to match implant position to recreate the anatomy of the prearthritic articular surface for the individual patient. Potentially this will improve ligament balancing and minimize the need for releases, because component alignment will more closely

match each individual patient’s anatomy and the soft tissue envelope of the knee. Advocates of KA suggest that this will offer advantages over the MA technique in terms of pain and function. Additionally, recent studies suggest early patient-reported outcomes may be improved with KA [14, 15, 25, 34], but comparative data are lacking.

The aim of this randomized controlled trial was to ask: (1) Are 2-year patient-reported outcome scores enhanced in patients undergoing TKA with KA compared with an MA technique? (2) How does component alignment measured with postoperative CT scan differ between the two techniques? (3) Is the proportion of patients undergoing reoperation at 2 years different between the techniques?

Patients and Methods

Patients undergoing unilateral primary TKA at a single tertiary institution were eligible for enrollment in this prospective, randomized controlled trial. Ethical approval was obtained from the national ethical review board, and the trial and protocol were registered with the ClinicalTrials.gov (Identifier: NCT02527148). Inclusion criteria included a primary diagnosis of osteoarthritis suitable for a cruciate-retaining knee replacement (ie, posterior cruciate ligament intact) and the ability to undergo an MRI. Exclusion criteria were a history of previous osteotomy; gross deformity ($> 15^\circ$ varus/valgus deformity or fixed flexion contracture) that may require the use of stems, wedges, or augments during reconstruction; or instability for which the use of constrained implants was being considered. All procedures were performed by one of six fellowship-trained arthroplasty surgeons (BF, AB, TD-C, RS, DS, MLW), each of whom had performed > 500 TKAs. A pilot study of 20 TKAs was performed before this trial using the same patient-specific guides positioning in KA.

Between August 2011 and April 2013, 114 TKAs in 110 patients were enrolled by a trained research nurse (AJ) in an outpatient setting. Patients were randomized using computer-generated random allocations placed in numbered, opaque, sealed envelopes to either MA ($n = 57$) or KA ($n = 56$) groups. Seven patients in each group did not receive the allocated intervention (Fig. 1), leaving 49 TKAs in the KA group and 50 in the MA group for analysis. Mechanically aligned TKA was performed using an imageless computer navigation system (Stryker, Inc, Mahwah, NJ, USA), whereas kinematically aligned TKA was performed using patient-specific implant guides (OtisMed Inc, Alameda, CA, USA). All TKAs were performed using a cruciate-retaining, cemented, fixed-bearing implant (Triathlon; Stryker, Inc) implanted through a medial parapatellar approach. Patella resurfacing was

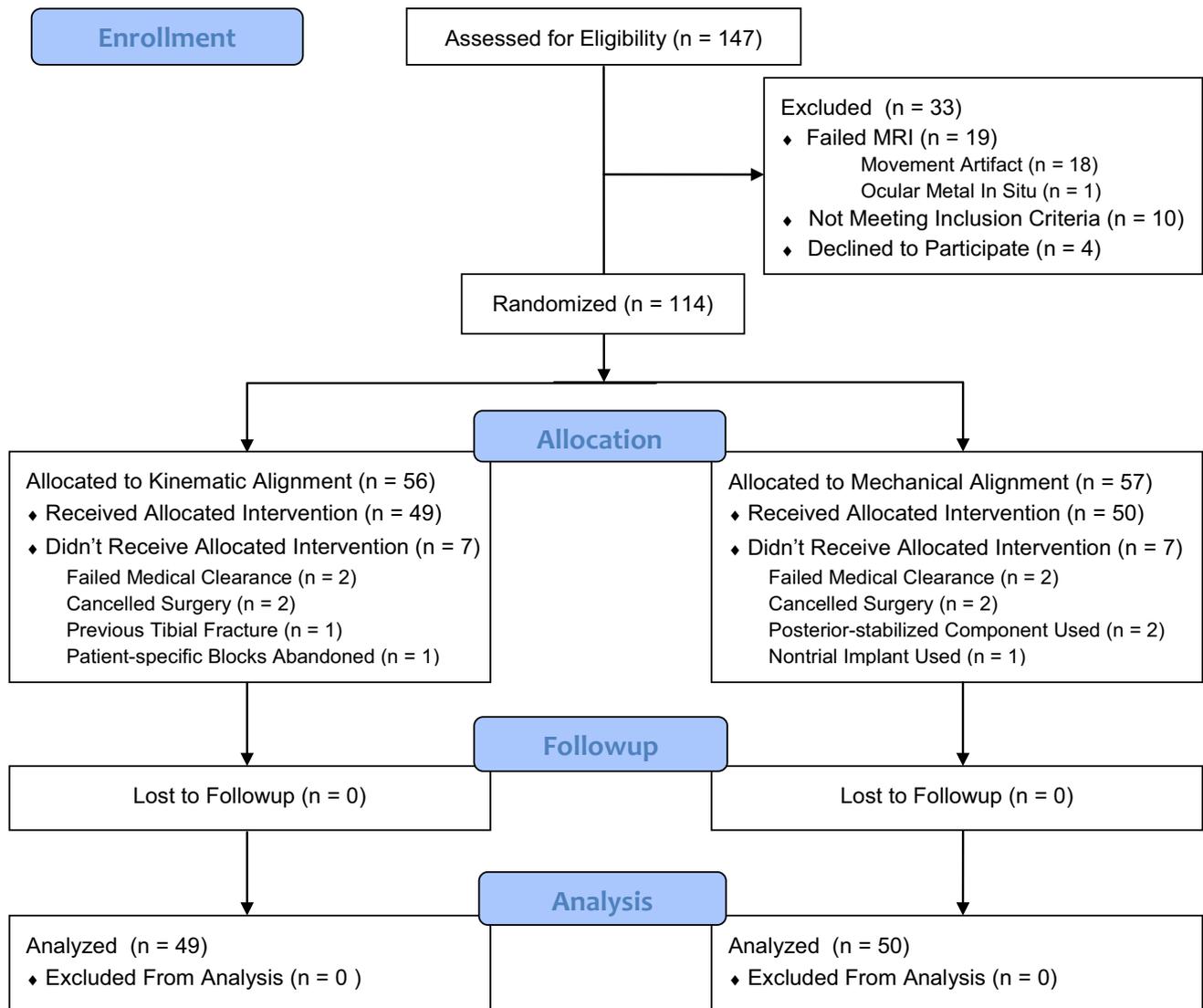


Fig. 1 CONSORT flow diagram showing patient flow through the study.

performed selectively in cases where there was Grade 4 chondral loss on the patella or patellofemoral maltracking. Eleven TKAs in the in the KA group and six patients in the MA group underwent patella resurfacing. Both patients and independent outcome assessors collecting patient-reported outcome measures were blinded to the intervention. To maintain blinding, all patients underwent identical preoperative assessment, including full-length MRI scans of the affected limb. In the KA group, patient-specific cutting blocks were manufactured from individual MRI data using a previously described technique based on KA principles [14, 15, 21–23].

Briefly, the aim of the KA method used in this study is to recreate the prearthritic articular surface of the patient's

native knee using TKA components. In KA theory, three kinematic axes govern motion of the knee. The primary axis is a transverse axis passing through the center of a cylinder fit to the articular surface of the femoral condyles from 10° to 160° of flexion. The tibia flexes about the femur along this axis, and the patella about a second, parallel axes that are proximal and anterior. External and internal rotation of the tibia occurs along a third longitudinal axis perpendicular to the two transverse axes above. A standardized MRI protocol was used with the sagittal component of the MRI scan aligned perpendicular to the “primary flexion axis” of the femur about which the tibia flexes and extends [21]. Proprietary software then creates a three-dimensional knee model, which is transformed into a

“prearthritic” model by removing osteophytes, filling articular defects, and equalizing the gap between the medial and lateral compartments of the knee [23]. A software algorithm selects the best-fitting femoral component to recreate the articular surface of the “prearthritic” knee with a reproducibility of ± 0.5 mm for translations and ± 0.5 for rotations [14] (OtisMed Inc). The coronal and sagittal alignment of the tibial component is positioned in a similar fashion with the rotational axis of the tibial component aligned perpendicular to the primary flexion axis of the femoral component [21]. Patient-specific cutting guides are then manufactured to fit the arthritic knee, which align bony cuts so coronal, sagittal, and rotational positioning of the TKA components matches that planned in the prearthritic knee model.

In the KA group, surgery was carried out according to the manufacturer-supplied surgical protocol. Patient-specific guides were opened within the sterile field and patient identifiers checked. Osteophytes were removed, and the distal femoral cut was made through the slot of the patient-specific guide. The guide was manufactured to match the patient anatomy of the preoperative MRI scan, which determined guide positioning [13]. Two pinholes in the guide were used to position a conventional four-in-one cutting block and set femoral rotation for anterior and posterior cuts. On the tibial side, the patient-specific guide was secured through pinholes on the proximal and anterior surface, and the tibial cut was made through the slot in the guide. Tibial component rotation was set through the pinholes in the proximal surface of the patient-specific guide in accordance with the preoperative plan.

A knee-balancing device (Stryker, Inc) was then inserted to measure the size and varus/valgus tightness of the flexion and extension gaps. In accordance with KA principles, ligamentous release was avoided but was performed if necessary to achieve symmetric ligament balance in both flexion and extension. Trial components were then positioned, and ROM, stability, posterior cruciate ligament tension, ligamentous balance, and patellar tracking were checked before definitive components were cemented in situ.

In the MA group, computer navigation was used according to the manufacturer’s surgical protocol to guide measured resection of bone with the goal of achieving overall neutral coronal limb alignment with tibial and femoral bony cuts perpendicular to the mechanical axis of each bone. Infrared trackers were secured to the tibia and femur and registration of bony landmarks performed. Navigation was used to position the distal femoral cutting guide at 90° to the mechanical axis of the femur. Posterior and anterior femoral cuts were then made with navigation assistance parallel to the surgical epicondylar axis with Whiteside’s line [2] and 3° external rotation relative to the

posterior condylar axis used as additional references. Navigation was then used to position the tibial cutting guide at 90° to the mechanical axis of the tibia with 3° posterior slope. Tibial rotation was aligned to the junction of the medial and middle thirds of the tibial tubercle [29]. Osteophytes were removed, the knee balancer was inserted, and the size and varus/valgus tightness of the flexion and extension gaps checked. Ligament releases were performed where required to achieve symmetric ligament balance in both flexion and extension. Trial components were positioned and final checks of stability performed as described before cementation of the definitive components.

Postoperative management was identical between the two groups with physiotherapists blinded as to the intervention. All patients underwent CT scans of the lower limb according to the standardized Perth protocol [12], and detailed measurement of coronal, sagittal, and rotational alignment was performed by a blinded independent assessor (CG, SH). Patient-reported outcomes were assessed using the Oxford Knee Score (OKS, 0–48 worst to best) [33], the reduced WOMAC (0–100 worst to best) score [42], the pain and function components of the Knee Society Score (KSS, 0–100 worst to best) [26], the Forgotten Joint Score (FJS, 0–100 worst to best) [4, 31], EuroQol EQ-5D [11], and visual analog scales measuring pain at rest and when mobilizing (0–10 none to worst). Scores were measured preoperatively and at 6, 12, and 24 months postoperatively. Frequency and type of reoperations were recorded.

Statistical Analysis

Results were summarized using the mean, SD, range (minimum and maximum) for continuous variables, and frequencies and percentages for categorical variables by navigation (control) and kinematic patient groups. Baseline surgery and alignment data were evaluated using a chi-square test to compare the categorical response rates in each group and a paired t-test for the normally distributed data. The change from preoperative to the 2-year time point for the quality-of-life parameters was analyzed with analysis of covariance (ANCOVA) for repeated measurements. The repeated measurements were the four patients with bilateral knee replacements. The treatment effect was tested against between patient variance as estimated from the ANCOVA. The change from preoperative to the 2-year time point was adjusted for the baseline preoperative score, including the treatment group difference (kinematic—control); the 95% confidence interval (CI) for the treatment group difference was derived from between patient variance.

For each quality-of-life parameter, the absolute scores at 2 years were analyzed with analysis of variance for

Table 1. Baseline data

Baseline characteristic	Kinematic		Mechanical	
	(n = 49)		(n = 50)	
	Mean	SD (range)	Mean	SD (range)
Age (years)	72	6.5 (56–83)	70	7.5 (51–84)
Sex Male	24	(49%)	24	(48%)
Female	25	(51%)	26	(52%)
Height (m)	1.7	10 (1.5–2.0)	1.7	9 (1.5–1.87)
Weight (kg)	86	14 (55–119)	89	17 (55–124)
BMI (kg/m ²)	30	4 (22–38)	31.5	5 (23–42)
ASA score (number, %)				
1	10	20%	4	8%
2	34	69%	43	86%
3	5	10%	3	6%
Preoperative ROM				
Extension (degrees)	3°	4 (0–15)	3°	4 (0–15)
Flexion contracture > 5° (number)	20	41%	16	32%
Flexion (degrees)	118°	11 (100–140)	116°	16 (80–135)
Preoperative scores				
KSS pain/motion	37	15 (3–77)	35	15 (–5 to 79)
KSS function score	54	15.5 (10–100)	55.5	15 (35–100)
VAS pain	4	2 (0.2–9.0)	4	2 (0.1–8.6)
VAS mobilization	6	2 (0.1–9.6)	6	2.5 (0.1–10.0)
Oxford Score	20.3	6 (7.0–34.0)	21	6 (9.0–35.0)
WOMAC score	50	13 (21.4–78.6)	50	15 (23.2–83.9)
Forgotten Joint Score	39	29 (0.0–95.8)	41	29 (2.1–100.0)
EQ-5D index score	0.51	0.17 (0.2–1.0)	0.48	0.21 (0.1–1.0)
EQ-5D VAS score	71	18 (25–100)	76	14 (40–100)

BMI = body mass index; ASA = American Society of Anesthesiologists; KSS = Knee Society Score; VAS = visual analog scale.

repeated measurements (ANOVA). The repeated measurements were the four patients with bilateral knee replacements. The treatment effect was tested against

between patient variance as estimated from the ANOVA. The treatment group difference (kinematic—control) was the least squares mean (LSM) difference with 95% CI.

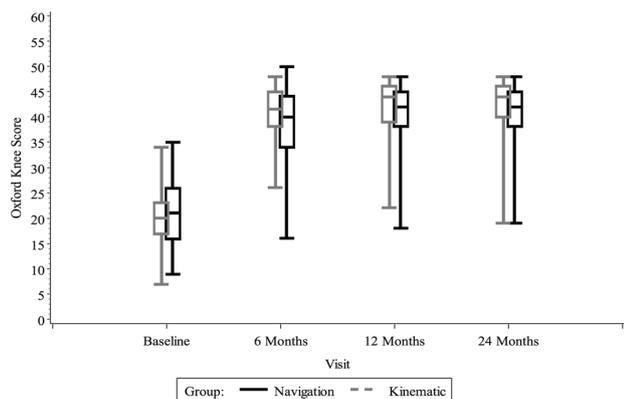


Fig. 2 Comparative box plot of OKS over time showing no significant difference between KA and MA groups. Box plots show median and 25th/75th percentiles.

The significance level was set to 0.05 with no adjustment for multiple comparisons (SAS Version 9.3, Cary, NC, USA).

Power Analysis

The planned sample size for this study was 45 patients per treatment arm. This was based on a 5-point improvement in the mean OKS (the previously reported minimum clinically significant difference for the OKS in TKA [28]) from 37 (mean OKS reported in the New Zealand registry) to 42 (scoring category of excellent) with a pooled SD of 8, 80% power, and a two-sided significance level of 5%. An additional five patients per group (10%) have been included into the target patient number to allow for loss to followup, bringing the target to 50 patients per group.

Baseline characteristics such as age, gender, American Society of Anesthesiologists scores, and body mass index were not different between groups (Table 1).

Results

There was no difference in mean OKS at 2 years between the two groups (KA mean \pm SD 42 ± 6 versus MA 41 ± 6 , difference 1.0; 95% CI, -3.5 to 1.4 ; $p = 0.4$) nor in OKS change scores (2-year score minus preoperative score, KA 21 ± 8 versus MA 20 ± 8 , LSM 1.0, 95% CI, -1.4 to 3.4 , $p = 0.4$; Fig. 2). There was no difference in 2-year absolute or change scores for the KSS pain and function components, visual analog scale pain, WOMAC, or EQ-5D (Table 2). Similarly for the FJS, a score with a reduced ceiling effect specifically designed to differentiate between well-functioning implants, there was no difference in 2-year change scores (mean KA 28 ± 37 versus MA 28 ± 28 ,

LSM 0.8, 95% CI, -9.1 to 11 , $p = 0.8$). Intraoperative parameters did not differ significantly between groups (Table 3).

The mean overall mechanical limb axis (hip-knee-ankle angle) was similar between groups (KA 0.4° varus ± 3 versus MA 0.7° varus ± 2 varus, $p = 0.6$; Table 4), but there was greater variability in the KA group (KA: SD 3, range 11° varus to 6° valgus; MA: SD 2, range, 5° varus to 4° valgus; Fig. 3). In the KA group the tibial component was placed in a mean of 2° more varus than the MA group (95% CI, 1° – 3° ; $p < 0.001$) and the femoral component was placed in a mean of 1.6° more valgus (95% CI, 0.7° – 2.5° ; $p = 0.003$). In the KA group the femoral component was placed in a mean of 2° more internal rotation than the MA group (95% CI, 1° – 3° ; $p < 0.001$). In the KA group, 31% of tibias were in 5° or more of varus alignment compared with 4% in the MA group (Fig. 4).

There was no difference in the proportion of patients undergoing reoperation between groups (Table 5). Three patients in the KA and four patients in the MA group underwent reoperations. In the KA group, one patient sustained a patella dislocation 3 weeks postsurgery, which was treated with a patella realignment procedure. The patient then developed deep infection with *Enterococcus faecalis* successfully managed with débridement and polyethylene exchange with implant retention; OKS at 2 years was 45. Two patients underwent manipulation under anesthesia for stiffness. In one patient this was successful in restoring motion from 0° to 120° ; the second patient continues to have reduced flexion (0° – 80°) despite subsequent open débridement and exchange of the polyethylene liner with a smaller thickness. In the MA group, one patient sustained a distal femoral fracture 3 months after TKA treated with a lateral locking plate. He later developed a wound infection around the plate, which spread to involve the knee and was treated with a two-stage revision. One patient developed *Streptococcus viridans* deep infection 4 months postoperatively treated successfully with débridement and polyethylene exchange with implant retention. One patient developed recurrent hemarthroses with negative cultures, which resolved after open débridement. One patient fell 12 months after TKA and sustained a patella dislocation treated with open repair of the medial retinaculum and secondary patella resurfacing. The patient went on to develop recurrent patella instability, which was managed with a patella realignment procedure.

Discussion

Positioning components to achieve a neutral limb MA is a longstanding principle in TKA, aiming to provide more

Table 2. Two-year outcome data

Parameter	Kinematic		Mechanical		Difference (95% CI) p value
	(n = 49)		(n = 50)		
	Mean	SD (range)	Mean	SD (range)	
ROM					
Flexion contracture > 5° (n)	2	4%	2	4%	0.9
Flexion (degrees)	119°	11 (80–150)	116°	11 (90–140)	0.9
Two-year absolute scores					
KSS pain/motion	89	13 (42–100)	87	16 (34–100)	–2 (–7.8 to 3.9) 0.5
KSS function score	83	18 (35–100)	79.5	24 (5.0–100)	–4 (–12 to 5.0) 0.4
VAS pain	0.7	1.0 (0–4.1)	1.0	1.7 (0–7.2)	0.3 (–0.2 to 0.9) 0.3
VAS mobilization	1.2	1.4 (0–4.2)	1.3	1.8 (0–6.9)	0.1 (–0.5 to 0.8) 0.7
Oxford Score	42	6 (19.0–48.0)	41	6 (19–48)	–1.0 (–3.5 to 1.4) 0.4
WOMAC score	88	14 (50.0–100.0)	85.5	17 (23–100)	–3 (–9.1 to 3.2) 0.6
Forgotten Joint Score	69	26 (2.1–100)	66	26 (0–100)	–3 (–13.3 to 7.5) 0.4
EQ-5D index score	0.9	0.2 (0.2–1.0)	0.8	0.2 (0.5–1.0)	–0.04 (–0.11 to 0.04) 0.3
EQ-5D VAS score	82	19 (30–100)	85	12 (46–100)	3 (–3.4 to 9.2) 0.4
Adjusted* change scores (2-year score—preoperative)					Least square means (95% CI) p value
KSS pain/motion	54	19 (–1 to 85)	50	17 (11–78)	3 (–2.4 to 8.9) 0.6
KSS function score	30	21 (–20 to 80)	23	24 (–45 to 65)	4 (–1.7 to 15.0) 0.3
VAS pain	–4	2 (–8.7 to –0.2)	–3	3 (–7.9 to 3.4)	–0.2 (–0.8 to 0.3) 0.2
VAS mobilization	–5	2 (–9.4 to 0.3)	–5	3 (–10 to 0.7)	–0.05 (–0.7 to 0.6) 0.7
Oxford Score	21	8 (0–39)	20	8 (–3.0 to 34)	1.0 (–1.4 to 3.4) 0.4
WOMAC score	38	18 (–5.4 to 70)	35	19.5 (–13 to 69.6)	3 (–3.2 to 8.9) 0.3
Forgotten Joint Score	28	37 (–85 to 98)	28	28 (–27 to 83)	0.8 (–9.1 to 10.7) 0.8
EQ-5D index score	0.4	0.2 (–0.3 to 0.8)	0.3	0.04 (0–0.8)	0.04 (–0.03 to 0.1) 0.4
EQ-5D VAS score	9	21 (–55 to 64)	11	13 (–30 to 49)	–2 (–8.0 to 3.5) 0.6

* Adjusted for the baseline covariate; CI = confidence interval; KSS = Knee Society Score; VAS = visual analog scale.

Table 3. Surgery data

Parameter	Kinematic		Mechanical		p value
	(n = 49)		(n = 50)		
	Mean	SD (range)	Mean	SD (range)	
Surgical duration (minutes)	83	26 (53–166)	92	SD: 32 (57–191)	0.09*
Average length of stay (days)	5	3 (2–14)	4	4 (3–8)	0.06*
Patella resurfaced (number)	11	22%	6	12%	0.2†
Wound length (mm)	223	SD: 29 (150–280)	233	SD: 24 (180–300)	0.06*
Lateral retinacular release (number)	0	0%	2	4%	0.7†
Knee balancer measurement (degrees, –varus, +valgus)					
Extension	–1°	(–5° to 3°)	–1°	(–6° to 3°)	0.96*
> 3° varus/valgus (number)	4	8%	4	8%	
Flexion	–1°	(–6° to 4°)	–1°	(–6° to 6°)	0.4*
> 3° varus/valgus (number)	10	20%	4	8%	

* t-test; † chi-square test.

Table 4. Alignment data

Parameter	Kinematic		Mechanical		Difference (95% CI) p value
	(n = 49)		(n = 50)		
	Mean	SD (range)	Mean	SD (range)	
Preoperative alignment					
Coronal anatomical axis (femorotibial angle, negative = varus)	1.6°	SD: 6 (–8 to 19)	0.8°	SD: 6 (–10 to –22)	0.5*
Varus	40	82%	43	86%	0.6†
Valgus	8	16%	7	14%	
Patellofemoral	1	2%	0	0%	
Postoperative alignment					
Coronal (negative = varus)					
Mechanical axis: hip-knee-ankle angle	–0.4°	SD: 3 (–11 to 6)	–0.7°	2 (–5.0 to 4.0)	–0.3 (–1.4 to 0.8) 0.6*
Angle between femoral component and mechanical axis femur	2°	SD: 2.5 (–4 to 6)	0.5°	SD: 1.6 (–3 to 4)	–1.6 (–2.5 to –0.7) 0.002*
Angle between tibial component and mechanical axis tibia	–3°	SD: 3 (–10 to 4)	–0.7°	SD: 1.8 (–6 to 2)	1.9 (0.8–3.0) < 0.001 *
Sagittal					
Tibial component slope	4°	SD: 2.5 (–2 to 10)	1.3°	SD: 2 (–3 to 7)	–2.3 (–3.3 to –1.3) < 0.001*
Femoral rotation					
Component rotation relative to surgical epicondylar axis (negative = internal)	–0.5°	SD: 2.5 (–4 to 5)	15°	SD: 2.5 (–5 to 9)	2.0 (1.0–3.0) < 0.001*

* t-test; † chi-square test; CI = confidence interval.

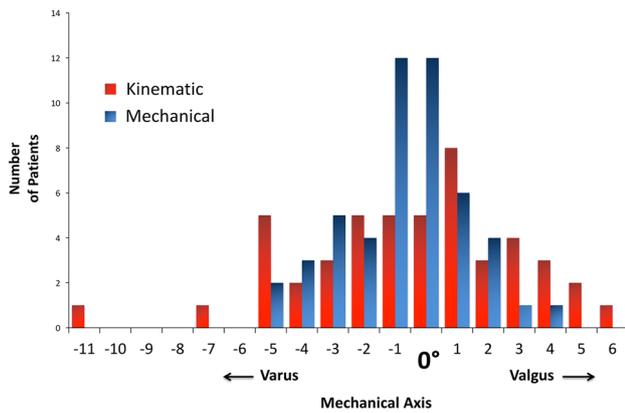


Fig. 3 Postoperative limb alignment showing overall hip-knee-ankle angle. Although the mean is similar, there is more variation within the KA group.

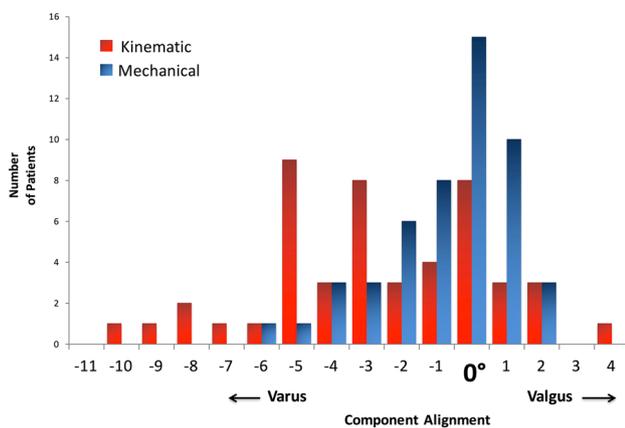


Fig. 4 Postoperative alignment of the tibial component relative to the mechanical axis of the tibia. Thirty percent of KA tibias versus 4% of MA tibias were in 5° or more of varus.

balanced load distribution and improve durability [1, 3, 8, 18, 27, 30, 32, 39, 41]. In contrast, KA aims to position TKA components to recreate the patient’s prearthritic articular surface anatomy, facilitating soft tissue balancing, which may, in turn, improve functional outcome [15, 25, 34]. Prospective data comparing MA with KA are limited to one previous trial [14], and given the excellent long-term results of MA, clear evidence of a functional advantage to KA is required before a change in technique can be recommended. In this prospective, randomized controlled trial, we were unable to demonstrate improved patient-reported outcome scores in KA versus the MA technique at 2-year followup.

This study has a number of limitations. First, the patient-specific instrumentation (PSI) guides used in the KA group were manufactured by a specific company using proprietary software analysis of the preoperative MRI scan. Other variants of KA such as using gap balancing or manual instrumentation to perform KA in TKA are described [25], and our results may not be generalizable to these techniques. However, the PSI guides were identical to those used in previous KA studies [14, 15, 22, 24, 34, 36], and their accuracy has been validated in a clinical study [13]. Currently, these guides are no longer commercially available in the United States nor elsewhere following a commercial decision by the manufacturing company. Second, 2-year followup is inadequate to assess long-term complications such as aseptic loosening, which may be affected by component alignment [18, 37]. Although positive 6-year results of the KA technique have been published [24], the long-term outcome remains unknown. Third, we did not control for patella resurfacing; however, we used set indications for

Table 5. Complications/reoperations

Complication	Kinematic (n = 49)		Mechanical (n = 50)		Odds ratio (95% CI) p value
	Number	Percent	Number	Percent	
Patients with complications/reoperations	3	6	4	8	0.75 (0.16–3.54) 0.72
Patients with one reoperation	2	4	2	4	1.02 (0.14–7.55) 0.98
Patients with multiple reoperations	1	2	2	4	0.49 (0.04–5.58) 0.56
Periprosthetic fracture	–	–	1	2	–
Early deep Infection	1	2	1	2	–
Patella instability	1	2	1	2	–
Stiffness/MUA	2	4	–	–	–
Recurrent hemarthrosis	–	–	1	2	–
Late deep infection	–	–	1	2	–

CI = confidence interval; MUA = manipulation under anesthesia.

patella resurfacing and the proportion resurfaced did not differ significantly between groups (22% KA versus 12% MA, $p = 0.2$). Fourth, although all surgeons involved in this study had considerable experience with the MA technique for TKA, experience with the KA technique was more limited. This did not appear to adversely affect the results of the KA group, because the 2-year change scores were as good or better as those of the KA group in a previous randomized trial [14]. Finally, although the main comparison of this study was KA versus MA component positioning, we used PSI in the KA group and computer navigation in the MA group. We do not believe this distinction compromises the results of the study, because both PSI and computer navigation merely represent techniques to enhance accuracy in achieving defined alignment goals.

Our findings contrast with the single previous randomized trial comparing the KA with the MA technique. Dossett et al. [14] randomized 88 patients undergoing TKA to either the KA technique with PSI or MA technique performed with manual instruments. At 2-year followup, there was a 7-point advantage in OKS to the KA group (mean OKS 40 versus 33, $p = 0.005$). This 2-year mean OKS for KA patients of 40 was comparable to the KA group in our study (mean OKS 42); however, outcomes for the MA group were very different: a mean OKS of 33 in the Dossett et al. trial versus 41 in this study. The reasons behind this are unclear. This previous study was performed on a unique population group of veterans (90% male), which may affect the generalizability of the results. Additionally, manual instrumentation was used for the neutral MA group compared with this study that used computer navigation. Although previous studies report no difference in patient-reported outcomes between TKAs performed with PSI versus manual instrumentation [35, 43], a meta-analysis of Level I studies did report a small functional advantage (mean 7-point increase in KSS score) for mechanically aligned TKAs performed with computer navigation versus manual instruments [38].

We found overall coronal limb alignment (hip-knee-ankle angle) to be similar in both KA and MA groups; however, in the KA group, the tibial component averaged 1.9° more varus and the femoral component 1.6° more valgus. This matches the findings of Dossett et al., who reported the tibial component to be in 2.1° more varus and the femoral component in 2.2° more valgus with the KA technique [14]. These findings are consistent with the stated goal of KA to more closely match the alignment of the native knee [6]. There was also more variation seen in overall limb alignment in the KA group (Fig. 2). The effect of these differences on component survival is currently unknown. Although there is strong biomechanical evidence that varus alignment of the tibial component causes increased load at the implant-bone interface [19, 20], clinical evidence of a negative effect on

long-term survival is mixed [18, 37]. The amount of postoperative component varus or valgus alignment is likely to be important [20], but currently there are limited data with which to define what are “acceptable” postoperative parameters. Additionally, we found the femoral component was positioned in 2° more internal rotation in the KA group. This is to be expected, because a KA principle is to rotationally align the component to the cylindrical axis of the femur, which is distinct from the surgical transepicondylar axis used in the MA technique [16, 17].

We found no difference in the rate of short-term complications between the two groups. In particular we found no increase in the rate of patellofemoral complications in the KA group, similar to previous series using the KA technique [14, 15, 22, 24, 25]. The patellofemoral articulation is relevant because currently there is no implant specifically designed for use with KA; therefore, the relative internal rotation of the femoral component in KA versus the MA technique theoretically may adversely affect patellofemoral tracking [9, 10].

The KA technique used in this study required additional cost for preoperative MRI and PSI, although a KA technique using generic manual instruments has been described [25]. However, the main disadvantage of KA remains the uncertainty regarding the effects of the alignment changes on implant durability. Although 98% survivorship of KA has been reported at 6 years [24], long-term followup is lacking. Over 30% of the KA tibial components in our study were in 5° or more of varus (Fig. 4), and there is a risk that implant durability with KA will be adversely affected compared with MA. In this study, we were unable to demonstrate an advantage to KA in terms of pain or function, which would justify this risk.

In conclusion, we found no difference in 2-year patient-reported outcome scores in TKAs implanted using the KA compared with the MA technique. Currently, it is unknown whether the alterations in component alignment seen with KA will compromise TKA survivorship. Given the lack of a clear functional advantage to KA, until the long-term effect on implant durability is known, we recommend the technique be used with caution.

Acknowledgments We thank research assistants Ani Jardim, Carol Green, and Sherina Holland and surgeons Rob Sharp, Tony Danesh-Clough, and Dean Schluter. We also acknowledge administrative support from Stryker, particularly employees Natascha Millard, Iffat Azeem, Alistair McLean, Matt Carter, and Hugh Guerin.

References

1. Aglietti P, Buzzi R. Posteriorly stabilised total-condylar knee replacement. Three to eight years' follow-up of 85 knees. *J Bone Joint Surg Br.* 1988;70:211–216.

2. Arima J, Whiteside LA, McCarthy DS, White SE. Femoral rotational alignment, based on the anteroposterior axis, in total knee arthroplasty in a valgus knee. A technical note. *J Bone Joint Surg Am.* 1995;77:1331–1334.
3. Bargren JH, Blaha JD, Freeman MA. Alignment in total knee arthroplasty. Correlated biomechanical and clinical observations. *Clin Orthop Relat Res.* 1983;173:178–183.
4. Behrend H, Giesinger K, Giesinger JM, Kuster MS. The ‘forgotten joint’ as the ultimate goal in joint arthroplasty: validation of a new patient-reported outcome measure. *J Arthroplasty.* 2012;27:430–436.e1.
5. Bellemans J. Neutral mechanical alignment: a requirement for successful TKA: opposites. *Orthopedics.* 2011;34:e507–509.
6. Bellemans J, Colyn W, Vandenuecker H, Victor J. The Chitranjan Ranawat Award: Is neutral mechanical alignment normal for all patients? The concept of constitutional varus. *Clin Orthop Relat Res.* 2012;470:45–53.
7. Bellemans J, Vandenuecker H, Van Lauwe J, Victor J. A new surgical technique for medial collateral ligament balancing: multiple needle puncturing. *J Arthroplasty.* 2010;25:1151–1156.
8. Berend ME, Ritter MA, Meding JB, Faris PM, Keating EM, Redelman R, Faris GW, Davis KE. Tibial component failure mechanisms in total knee arthroplasty. *Clin Orthop Relat Res.* 2004;428:26–34.
9. Berger RA, Crossett LS, Jacobs JJ, Rubash HE. Malrotation causing patellofemoral complications after total knee arthroplasty. *Clin Orthop Relat Res.* 1998;356:144–153.
10. Boldt JG, Stiehl JB, Hodler J, Zanetti M, Munzinger U. Femoral component rotation and arthrofibrosis following mobile-bearing total knee arthroplasty. *Int Orthop.* 2006;30:420–425.
11. Brooks R. EuroQol: the current state of play. *Health Policy.* 1996;37:53–72.
12. Chauhan SK, Clark GW, Lloyd S, Scott RG, Bredahl W, Sikorski JM. Computer-assisted total knee replacement. A controlled cadaver study using a multi-parameter quantitative CT assessment of alignment (the Perth CT Protocol). *J Bone Joint Surg Br.* 2004;86:818–823.
13. Clark G, Leong A, McEwen P, Steele R, Tran T, Trivett A. Intraoperative reliability of ShapeMatch cutting guide placement in total knee arthroplasty. *Comput Aided Surg.* 2013;18:159–165.
14. Dossett HG, Estrada NA, Swartz GJ, LeFevre GW, Kwasman BG. A randomised controlled trial of kinematically and mechanically aligned total knee replacements: two-year clinical results. *Bone Joint J.* 2014;96:907–913.
15. Dossett HG, Swartz GJ, Estrada NA, LeFevre GW, Kwasman BG. Kinematically versus mechanically aligned total knee arthroplasty. *Orthopedics.* 2012;35:e160–169.
16. Eckhoff D, Hogan C, DiMatteo L, Robinson M, Bach J. Difference between the epicondylar and cylindrical axis of the knee. *Clin Orthop Relat Res.* 2007;461:238–244.
17. Eckhoff DG, Bach JM, Spitzer VM, Reinig KD, Bagur MM, Baldini TH, Flannery NMP. Three-dimensional mechanics, kinematics, and morphology of the knee viewed in virtual reality. *J Bone Joint Surg Am.* 2005;87(Suppl 2):71–80.
18. Fang DM, Ritter MA, Davis KE. Coronal alignment in total knee arthroplasty: just how important is it? *J Arthroplasty.* 2009;24:39–43.
19. Green GV, Berend KR, Berend ME, Glisson RR, Vail TP. The effects of varus tibial alignment on proximal tibial surface strain in total knee arthroplasty: the posteromedial hot spot. *J Arthroplasty.* 2002;17:1033–1039.
20. Halder A, Kutzner I, Graichen F, Heinlein B, Beier A, Bergmann G. Influence of limb alignment on mediolateral loading in total knee replacement: in vivo measurements in five patients. *J Bone Joint Surg Am.* 2012;94:1023–1029.
21. Howell SM, Howell SJ, Hull ML. Assessment of the radii of the medial and lateral femoral condyles in varus and valgus knees with osteoarthritis. *J Bone Joint Surg Am.* 2010;92:98–104.
22. Howell SM, Howell SJ, Kuznik KT, Cohen J, Hull ML. Does a kinematically aligned total knee arthroplasty restore function without failure regardless of alignment category? *Clin Orthop Relat Res.* 2013;471:1000–1007.
23. Howell SM, Hull ML. Kinematic alignment in total knee arthroplasty. In: Scott WN, ed. *Insall and Scott Surgery of the Knee.* Philadelphia, PA, USA: Elsevier; 2012:1255–1268.
24. Howell SM, Papadopoulos S, Kuznik K, Ghaly LR, Hull ML. Does varus alignment adversely affect implant survival and function six years after kinematically aligned total knee arthroplasty? *Int Orthop.* 2015;39:2117–2124.
25. Howell SM, Papadopoulos S, Kuznik KT, Hull ML. Accurate alignment and high function after kinematically aligned TKA performed with generic instruments. *Knee Surg Sports Traumatol Arthrosc.* 2013;21:2271–2280.
26. Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the Knee Society clinical rating system. *Clin Orthop Relat Res.* 1989;248:13–14.
27. Jeffery RS, Morris RW, Denham RA. Coronal alignment after total knee replacement. *J Bone Joint Surg Br.* 1991;73:709–714.
28. Kamat YD, Aurakzai KM, Adhikari AR, Matthews D, Kalairajah Y, Field RE. Does computer navigation in total knee arthroplasty improve patient outcome at midterm follow-up? *Int Orthop.* 2009;33:1567–1570.
29. Lawrie CM, Noble PC, Ismaily SK, Stal D, Incavo SJ. The flexion-extension axis of the knee and its relationship to the rotational orientation of the tibial plateau. *J Arthroplasty.* 2011;26:53–58.e1.
30. Lotke PA, Ecker ML. Influence of positioning of prosthesis in total knee replacement. *J Bone Joint Surg Am.* 1977;59:77–79.
31. Matsumoto M, Baba T, Homma Y, Kobayashi H, Ochi H, Yuasa T, Behrend H, Kaneko K. Validation study of the Forgotten Joint Score-12 as a universal patient-reported outcome measure. *Eur J Orthop Surg Traumatol.* 2015;25:1141–1145.
32. Moran CG, Pinder IM, Lees TA, Midwinter MJ. Survivorship analysis of the uncemented porous-coated anatomic knee replacement. *J Bone Joint Surg Am.* 1991;73:848–857.
33. Murray DW, Fitzpatrick R, Rogers K, Pandit H, Beard DJ, Carr AJ, Dawson J. The use of the Oxford hip and knee scores. *J Bone Joint Surg Br.* 2007;89:1010–1014.
34. Nam D, Nunley RM, Barrack RL. Patient dissatisfaction following total knee replacement: a growing concern? *Bone Joint J.* 2014;96:96–100.
35. Nam D, Park A, Stambough JB, Johnson SR, Nunley RM, Barrack RL. The Mark Coventry Award: Custom cutting guides do not improve total knee arthroplasty clinical outcomes at 2 years followup. *Clin Orthop Relat Res.* 2016;474:40–46.
36. Nogler M, Hozack W, Collopy D, Mayr E, Deirmengian G, Sekyra K. Alignment for total knee replacement: a comparison of kinematic axis versus mechanical axis techniques. A cadaver study. *Int Orthop.* 2012;36:2249–2253.
37. Parratte S, Pagnano MW, Trousdale RT, Berry DJ. Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. *J Bone Joint Surg Am.* 2010;92:2143–2149.
38. Rebal BA, Babatunde OM, Lee JH, Geller JA, Patrick DA, Macaulay W. Imageless computer navigation in total knee arthroplasty provides superior short term functional outcomes: a meta-analysis. *J Arthroplasty.* 2014;29:938–944.
39. Ritter MA, Faris PM, Keating EM, Meding JB. Postoperative alignment of total knee replacement. Its effect on survival. *Clin Orthop Relat Res.* 1994;299:153–156.
40. Roberts TD, Clatworthy MG, Frampton CM, Young SW. Does computer assisted navigation improve functional outcomes and implant survivability after total knee arthroplasty? *J Arthroplasty.* 2015;30(Suppl):59–63.

41. Tew M, Waugh W. Tibiofemoral alignment and the results of knee replacement. *J Bone Joint Surg Br.* 1985;67:551–556.
42. Whitehouse SL, Lingard EA, Katz JN, Learmonth ID. Development and testing of a reduced WOMAC function scale. *J Bone Joint Surg Br.* 2003;85:706–711.
43. Woolson ST, Harris AHS, Wagner DW, Giori NJ. Component alignment during total knee arthroplasty with use of standard or custom instrumentation: a randomized clinical trial using computed tomography for postoperative alignment measurement. *J Bone Joint Surg Am.* 2014;96:366–372.