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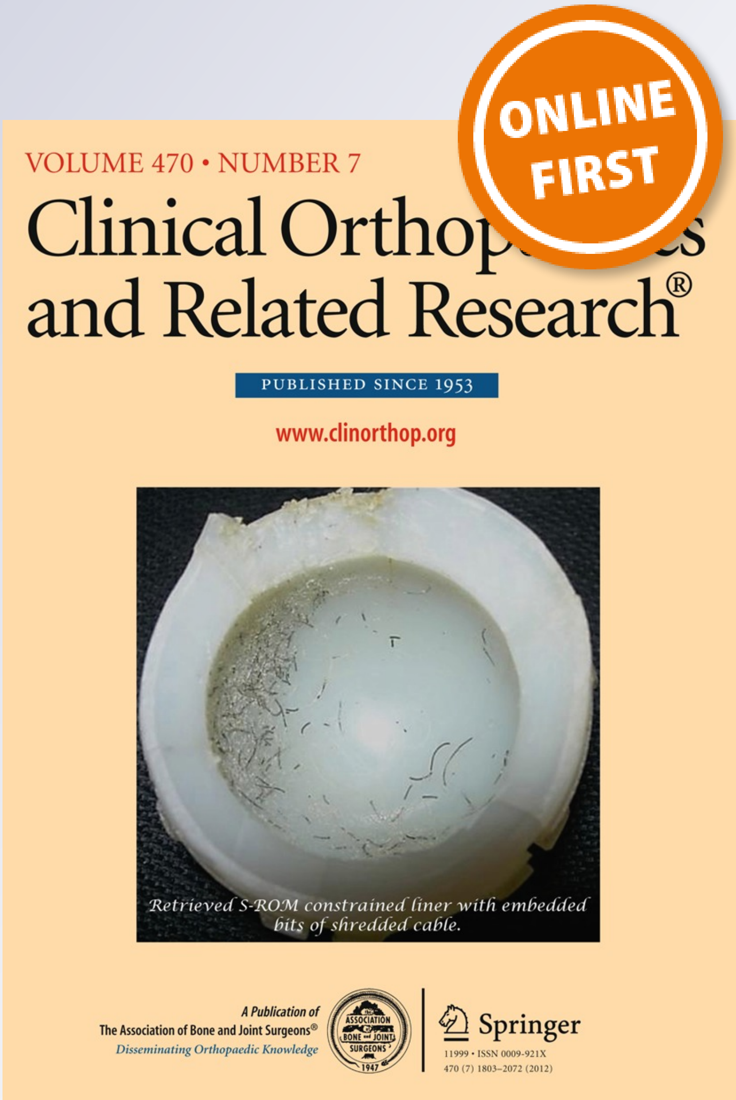

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CLINICAL RESEARCH

Does A Kinematically Aligned Total Knee Arthroplasty Restore Function Without Failure Regardless of Alignment Category?

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Abstract

Background Kinematically aligned TKA restores function by aligning the femoral and tibial components to the normal or prearthritic joint lines of the knee. However, aligning the components to the joint lines of the normal knee also aligns the tibial component in varus, creating concern that varus alignment might result in poor function and early catastrophic failure.

Questions/Purposes We therefore determined whether function and the incidence of catastrophic failure were different when the tibial component, knee, and limb alignment were in a specified normal range, varus outlier, or valgus outlier.

Methods We prospectively followed all 198 patients (214 knees) who underwent TKAs between February and October 2008. We treated each knee in this cohort of patients with a kinematically aligned, cruciate-retaining prosthesis implanted using patient-specific guides. From a long-leg scanogram, we measured and categorized alignment of the tibial component as in range ($\leq 0°$) or a varus outlier ($> 0°$), alignment of the knee as in range (between $-2.5°$ to $-7.4°$ valgus) or a varus ($> -2.5°$) or valgus ($< -7.4°$) outlier, and alignment of the limb as in range ($0° \pm 3°$) or a varus ($> 3°$) or valgus ($< -3°$) outlier. We assessed function using the Oxford Knee Score and WOMAC™ score, and reported catastrophic failure as the incidence of revision attributable to loosening, wear, and instability of the femoral or tibial components. The minimum followup was 31 months (mean, 38 months; range, 31–43 months).

Results The mean Oxford Knee Score of 43 and WOMAC™ score of 92 were similar between the three alignment categories. The incidence of catastrophic failure in each alignment category was zero.

One of the authors certifies that he (KTK) is an employee of Stryker Orthopedics (Mahwah, NJ, USA). One author (SMH) is a consultant for Stryker Orthopedics (Mahwah, NJ, USA). All other authors certify that he or she, or a member of his or her immediate family, has no funding or commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.
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Each author certifies that his or her institution has approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.
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Conclusions Kinematically aligned TKA restores function without catastrophic failure regardless of the alignment category. Because 75% of patients had their tibial component categorized as a varus outlier and also had high function and a zero incidence of catastrophic failure, the concern that kinematic alignment compromises function and places the components at a high risk for catastrophic failure is unfounded and should be of interest to surgeons committed to cutting the tibia perpendicular to the mechanical axis of the tibia.

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

Introduction

A mechanically aligned TKA relies on establishing the hip-knee-ankle angle of the limb in the coronal plane to neutral or a straight line. When neutral alignment is established, the mechanical axis of the leg passes through the center and perpendicular to the joint line of the knee [2, 7]. Although a mechanically aligned TKA improves the patient's function, arthroplasty registries have shown that 20% to 25% of patients remain dissatisfied [1, 4, 26].

The importance of mechanically aligning the tibial component, knee, and limb within accepted in-range categories to the survival of primary TKAs is controversial [2, 3, 6, 7, 24]. One study with a minimum 2-year followup suggested that survival was better when tibial component alignment was categorized as in range ($\leq 0°$) than when a varus outlier ($> 0°$), and when knee alignment was categorized in range (between $-2.5°$ to $-7.4°$ valgus) than when a varus ($> -2.5°$) or valgus ($< -7.4°$) outlier [25]. However, two studies with 14 and 15 years followup showed that when postoperative limb alignment was categorized in range ($0° \pm 3°$) and in varus ($> 3°$) and valgus ($< -3°$) outlier groups, the relationship between alignment category and survival was weaker than previously described [3, 24].

Mechanical alignment may have undesirable kinematic consequences because positioning of the components may change the angle and level of the distal femoral, posterior femoral, and tibial joint lines and limb alignment from normal [2, 6, 7, 9]. Changing joint lines from normal alters knee kinematics because the normal joint lines are either parallel or perpendicular to the three axes that describe tibiofemoral and patellofemoral kinematics [6, 9]. Because function after TKA can be improved, because the usefulness of categorizing alignment as a predictor of component survival is unclear, and because mechanical alignment may have undesirable kinematic consequences, other options for aligning the components should be explored.

The concept of kinematic alignment has gained interest among knee surgeons [2, 7, 10, 14]. A kinematically aligned TKA strives to restore normal knee function by aligning the angle and level of the distal joint line of the femoral component, posterior joint line of the femoral component, and joint line of the tibial component to those of the normal knee [7, 10, 13, 14]. Intraoperatively, alignment of the femoral component with the normal joint lines is confirmed when the calipered thicknesses of the distal and posterior femoral resections after correcting for cartilage and bone wear equal the thicknesses of the distal and posterior condyles of the femoral component [11–13]. However, a limitation of any new alignment method is that the intended position of the components and inconsistency in positioning the components in the intended position can align the tibial component, knee, and limb in outlier categories that might predict compromised function and place the components at a higher risk for catastrophic failure [18, 25].

A randomized controlled trial of patients treated with 41 kinematically aligned TKAs performed using patient-specific guides and 41 mechanically aligned TKAs performed using conventional instruments, found alignment of the tibial component was 2.3° more varus in the kinematically aligned group, whereas alignment of the knee and limb were similar [5]. At 6 months, the 7-point better Oxford Knee score, 16-point better WOMAC™ score, and 5° better flexion indicated higher function in the kinematically aligned group [5]. However, the incidence of catastrophic failure from femoral and tibial component loosening, wear, and instability as a result of varus alignment of the tibial component could not be studied because the followup of 6 months was too short.

We therefore determined at a minimum followup of 31 months, whether function and the incidence of catastrophic failure of the kinematically aligned TKA were different when the tibial component, knee, and limb alignment were categorized as either in range, varus outlier, or valgus outlier.

Patients and Methods

We prospectively followed all 203 patients (219 knees) undergoing a kinematically aligned TKA performed using patient-specific guides from February to October 2008. During the study period no other method for performing a primary TKA was used. The indications for performing TKA were (1) disabling knee pain and functional loss unresolved with customary nonoperative treatment modalities; (2) radiographic evidence of advanced arthritic change; and (3) and all severities of varus, valgus, and flexion contracture deformities. The contraindications for surgery were the presence of active infection and a knee

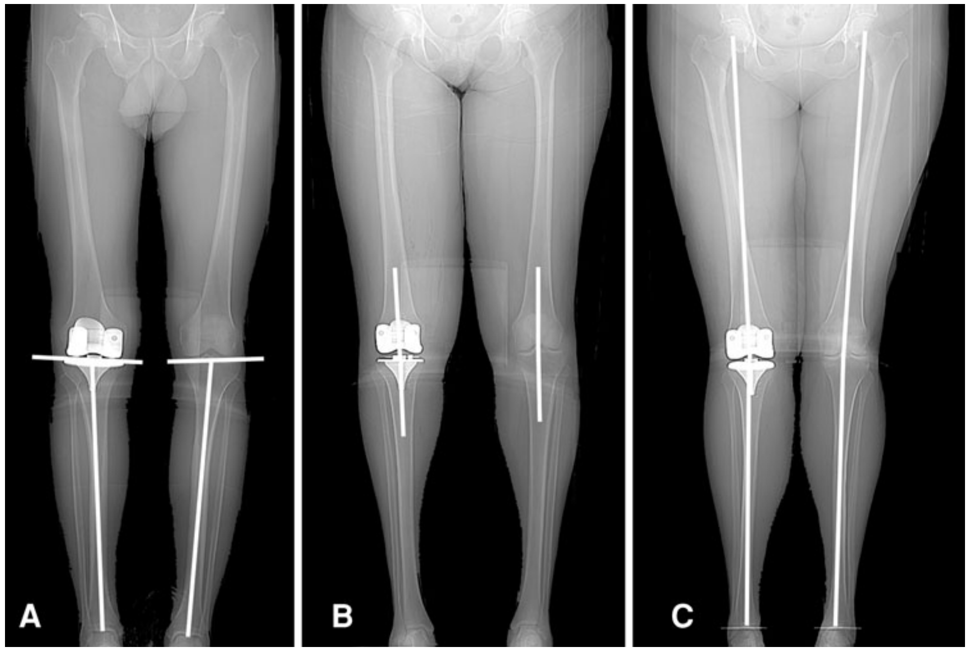

Fig. 1A–C CT scanograms from three patients shows the lines used to measure the alignment of the (**A**) tibial component, (**B**) knee, and (**C**) limb of the kinematically aligned TKA. Because the measurements made on the two extremities in each patient are identical, the femoral and tibial components appear aligned to the normal joint lines. Varus alignment of the tibial components is anatomic and not excessive because it matches the angle of the tibial joint line in the contralateral normal knee. Imaging the extremity when the flange was between the posterior femoral condyles of the femoral component standardized rotation of the knee.

with Charcot changes. We excluded five patients: three with rheumatoid arthritis, one with a chronic patella tendon insufficiency, and one with a deep infection. Of the remaining 198 patients (214 knees), there were 121 women and 79 men with an average age of 68 years (range, 36–95 years) and an average BMI of 30 kg/m^2 (range, 18–45 kg/m^2) at the time of surgery. The preoperative diagnoses for patients in this study were degenerative osteoarthritis (193 knees [89%]), traumatic osteoarthritis (19 knees [9%]), and osteonecrosis (two knees [2%]). For determination of the incidence of catastrophic failure, no patients were lost to followup. The minimum followup was 31 months (mean, 38 months; range, 31–43 months). An institutional review board approved the analysis.

All patients received a general anesthetic. The lead author (SMH) performed all kinematically aligned TKAs using patient-specific femoral and tibial cutting guides (OtisMed Corporation, Alameda, CA, USA) and a cruciate-retaining component (Vanguard; Biomet, Inc, Warsaw, IN, USA) with use of a previously described technique [5, 10, 12–14]. The cutting guides are approved for use in Europe, Canada, Australia, and New Zealand but are not currently approved for use in the United States. Briefly, the femoral patient-specific cutting guide was pinned on the distal femur and the distal cut was made. The conventional 4-in-1 cutting block that matched the planned size of the femoral component was placed into two pinholes used to hold the femoral patient-specific guide and the anterior, posterior, and chamfer femoral cuts were made. The tibial patient-specific cutting guide was pinned to the tibia and the tibial cut was made. The standard guide for positioning the tibial component was pinned to the two holes used to hold the tibial patient-specific cutting guide and internal-external rotation of the tibial component was set. Medial and lateral tibial and femoral osteophytes were removed. The posterior cruciate ligament was left intact. Posterior osteophytes were removed and a posterior capsular release was performed when a flexion contracture required correction. The patella was resurfaced. We qualitatively determined the balance of the knee and patella tracking by manual examination. Kinematic alignment of the components in association with removal of osteophytes and posterior capsular release to correct a flexion contracture balanced the knee without release of the collateral, posterior cruciate, or retinacular ligaments. All components were cemented. A drain was not used. We recorded intraoperatively the fit of the femoral and tibial guides, whether the collateral ligaments, lateral retinacular ligament, or posterior capsule was released, and whether the femur or tibia had to be recut, and the planned size of each component was recorded.

Aspirin, 325 mg twice a day, was started on the day of surgery and used for 4 weeks for prevention of pulmonary embolism. Warfarin was used for patients with atrial fibrillation or a prior thromboembolic event. Postoperatively, patients ambulated on the day of surgery, used a walker or cane until he or she was confident walking independently, and received home physical therapy, which typically lasted 2 to 3 weeks. On the day of discharge each patient had an AP rotationally controlled long-leg, nonweightbearing, CT scanogram using a previously described technique (Fig. 1) [5, 14, 22]. We recorded the incidence of blood transfusion, duration of stay, and disposition at time of discharge (Table 1).

Table 1. Intraoperative findings and details of the hospital stay

Question	Number of TKAs	Response 1	Response 2	Response 3
General anesthesia?	N = 214	Yes - 100%		
Incision to dressing application time in minutes?	N = 214	Mean 36 ± 6	Range 24–60	
Did the femoral guide fit?	N = 213	Yes - 99%	Two unstable	
Did the tibial guide fit?	N = 214	Yes - 100%		
Was the femur recut?	N = 214	No - 100%		
Was the tibia recut?	N = 214	No - 99%	Two recut	
Was a collateral ligament released?	N = 214	No - 100%		
Was the posterior capsule released?	N = 214	Yes - 33%		
Was the planned size femoral component used?	N = 214	Yes - 100%		
Was the planned size tibial component used?	N = 214	Yes - 100%		
Thickness of tibial liner?	N = 214	10 mm - 55%	12 mm - 37%	14 mm - 8%
Did you get a blood transfusion?	N = 214	Yes - 2%		
How many nights in the hospital?	N = 214	1–17%	2–64%	3–11%
Was the discharge directly to home?	N = 214	Yes - 92%		

Table 2. Preoperative demographics and clinical characteristics

Parameter	Number of patients or knees	Mean (SD) or numbers (%)	Range
Demographic			
Age (years)	N = 200	69 (9.8)	36–95
Sex (male)	N = 200	40%	
BMI (kg/m^2)	N = 200	30 (5.2)	18–45
American Society of Anesthesiologists score (1 is best, 4 is worst)	N = 200	1 (2%), 2 (34%), 3 (62%), 4 (2%)	
Preoperative motion and deformity			
Extension (degrees)	N = 214	8 (7.3)	0–30
Flexion (degrees)	N = 214	114 (13.0)	75–140
Varus (+)/valgus (−) deformity (degrees)	N = 214	−2 (7.9)	−20 to 10
Preoperative function scores			
Oxford Knee Score (48 is best, 0 is worst)	N = 214	20 (7.9)	0–36
The Knee Society Score© (100 is best, 0 is worst)	N = 214	40 (14.5)	4–80
The Knee Society Function Score© (100 is best, 0 is worst)	N = 214	45 (19.4)	0–80
Combined Knee Society Score© (200 is best, 0 is worst)	N = 214	85 (27.6)	0–168

Patients were evaluated clinically 4 to 5 weeks postoperatively and as needed thereafter. We prospectively acquired preoperative and intraoperative data and details of the hospital stay and discharge with a handheld data acquisition device [16]. Patient demographics including mean age, sex, BMI, knee motion and deformity, and function scores (Oxford Knee Score, The Knee Society Score© and The Knee Society Function Score©) were collected (Table 2).

All patients were studied in a 4-month period between June 2011 and September 2011. One of two independent observers (SJH, JC) contacted each patient and determined the patient's level of function by asking the patient to complete the Oxford Knee Score (48 best, 0 worst) and WOMAC™ questionnaires (100 best, 0 worst) and whether they had any additional surgery on the knee that might indicate catastrophic failure. Reoperations for any reason including stiffness, instability, wear, loosening of components, fracture, infection, and drainage of hematoma were recorded and the operative note was obtained and analyzed. We determined the

Table 3. Mean Oxford Knee Score and WOMAC™ score for each alignment category

Alignment parameter and function score	In range*	Varus outlier*	Valgus outlier*	Significance
Tibial component alignment (tibial component - mechanical axis of tibia)	≤ 0° 25%, N = 49	> 0° 75%, N = 143		
Oxford Knee Score (48 best, 0 worst)	43 (41 to 44), N = 49	44 (42 to 45), N = 134		p = 0.4491
WOMAC™ score (100 best, 0 worst)	91 (88 to 95), N = 49	93 (90 to 95), N = 132		p = 0.6035
Knee alignment (femoral - tibial angle)	−7.4° to −2.5° 64%, N = 122	> −2.5° 33%, N = 64	< −7.4° 3%, N = 6	
Oxford Knee Score (48 best, 0 worst)	43 (42 to 44), N = 115	45 (43 to 46), N = 63	46 (40 to 52), N = 5	p = 0.1150
WOMAC™ score (100 best, 0 worst)	91 (89 to 93), N = 115	94 (91 to 97), N = 61	98 (88 to 109), N = 5	p = 0.1602
Limb alignment (hip-knee-ankle angle)	0° ± 3° 73%, N = 141	> 3° 6%, N = 11	< −3° 21%, N = 40	
Oxford Knee Score (48 best, 0 worst)	43 (42 to 45), N = 132	47 (43 to 50), N =11	43 (41 to 45), N = 40	p = 0.2316
WOMAC™ score (100 best, 0 worst)	92 (90 to 94), N = 132	99 (91 to 107), N = 9	92 (88 to 95), N = 40	p = 0.2320

* Values are the percent of TKAs, the number of TKAs (N), the mean function score rounded to the nearest integer, and the 95% CI of the function score in parentheses.

incidence of catastrophic failure in 100% of the TKAs (198 patients, 214 knees) and function in 95% of the TKAs (204 of 214 knees) using the following: interviewing patients (166 patients, 175 knees), receiving the completed questionnaire mailed by the patients (23 patients, 28 knees), interviewing relatives (four patients who died [four knees]; two patients with a disabling stroke [two knees]), and interviewing primary care doctors (three patients who refused to fill out the function score questionnaire [three knees]).

One author (KTK), blinded to the function scores and catastrophic failure, measured and categorized coronal alignment of the limb, knee, and tibial component, using a previously described technique [5, 14, 22]. Alignment of the tibial joint line was the angle between the joint line of the tibial component and the mechanical axis of the tibia, knee alignment was the angle between the anatomic axes of the femur and tibia, and limb alignment was the angle between the mechanical axes of the femur and tibia (Fig. 1). The interclass coefficients for independent measurement by two observers of limb and knee alignment were 0.86 and 0.87, respectively [22]. The in-range category of tibial component alignment was (≤ 0°), knee alignment was within −2.5° to −7.4° valgus [25], and limb alignment was within 0° ± 3° [24]. Limb and knee alignment values for patients outside these ranges were categorized as either a varus or valgus outlier. We measured alignment in 91% of the TKAs (194 of 214 knees) and determined whether the category of alignment affects function in 90% of the TKAs (192 of 214 knees) (Table 3).

A single-factor, completely randomized ANOVA determined whether there were differences in the mean Oxford Knee Scores and mean WOMAC™ scores between alignment categories for the tibial component, knee, and limb. We determined whether the incidence of a catastrophic failure, which was revision for loosening of the femoral or tibial component, wear, and instability, was different between alignment categories. We also computed the incidence of reoperation for any reason. The arithmetic mean, SD, and 95% CI of the mean and frequency distribution were computed for each measured quantity when appropriate.

Results

The mean Oxford Knee Score and WOMAC™ score for TKAs grouped in the outlier categories were either the same or slightly higher than those in the in-range categories for tibial component, knee, and limb alignment, although the differences were not significant (Table 3). The overall mean Oxford knee score improved 23 points from a preoperative score of 20 (95% CI, 19–21) to a 31-month followup score of 43 (95% CI, 42–44). The overall mean WOMAC™ score was 92 (95% CI, 90–94). The mean alignment of the tibial component was mild varus (1.8° ± 2.6°), the knee was valgus (−3.4° ± 2.1°), and the limb was mild valgus (−0.9° ± 2.7°). Seventy-five percent of tibial components, 33% of knees, and 6% of limbs were varus outliers (Fig. 2).

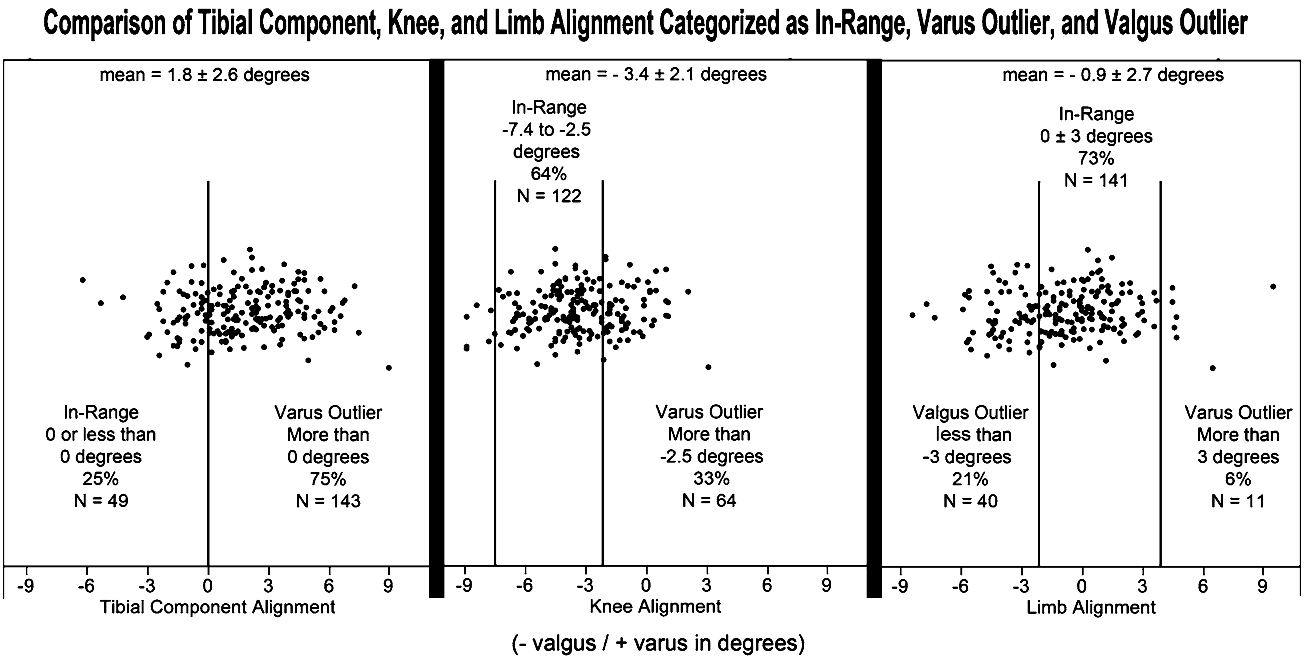

Fig. 2 Scatterplots show distribution of the tibial component, knee, and limb alignment in the in-range, varus outlier, and valgus outlier categories. Few limbs (6%) were in the varus outlier category, whereas most tibial components (75%) were.

No patient reported having revision surgery for premature loosening of the femoral or tibial component, wear, or instability. The incidence of catastrophic failure was zero for the in-range and outlier categories of the tibial component, knee, and limb alignment. However, there were three reoperations (1.4%); one was a manipulation and lateral release for anterior knee pain and lateral patella tracking in a patient with malunions of a supracondylar femur fracture and ankle fracture, one was a removal of a patellar component that had atraumatically dissociated from a patella with avascular necrosis, and one was a recession of the posterior cruciate ligament performed by a surgeon at another institution for pain and flexion limited to 115°. This patient was receiving Workers Compensation.

Discussion

Although establishing neutral mechanical alignment has been considered a cornerstone for a successful and durable TKA, patients report a high incidence of dissatisfaction with this alignment technique [1, 4, 21]. Kinematic alignment, which aligns the articular surfaces of the femoral and tibial components to the normal or prearthritic joint lines of the knee has gained interest because patient-reported function is high [5, 14]. Although a randomized trial showed that kinematically and mechanically aligned TKAs have similar limb and knee alignment, the tibial joint line was in more varus in the kinematically aligned TKA, which is consistent with the average 3° varus tibial joint line of the healthy population [2, 5, 12]. There has been concern that varus alignment of the tibial component might compromise function and place the implants at a higher risk for catastrophic failure [18, 25]. Therefore, we determined, at a minimum followup of 31 months, whether function and the incidence of catastrophic failure were different when alignment of the tibial component, knee, and limb were categorized either as in range, a varus outlier, or a valgus outlier.

Several limitations should be discussed before interpreting the findings of our study. First the rotational position of the knee varies with respect to the hip and the ankle is variable and affects projection of the extremity and measurement of alignment [2]. In our study, we standardized projection of the extremity by positioning the flange between the medial and lateral condyles of the femoral component, which limited malrotation of the knee [5, 14, 15, 22]. Second, we treated three patients who were dissatisfied and who refused to complete the Oxford Knee Score and WOMAC™ questionnaires. We tested the effect of including them on the calculation of the mean Oxford Knee Score by assigning each the lowest possible score of 0. Because their inclusion lowered the mean score less than 1 point, the effect of their nonparticipation on the functional and alignment results of the study was negligible. Third, 20 of 214 knees (9%) did not have a scanogram because the CT scanner either was in use with emergency cases or was inoperable owing to maintenance. Because a random event caused patients to miss the scanogram, the interpretation of the results should not be biased.

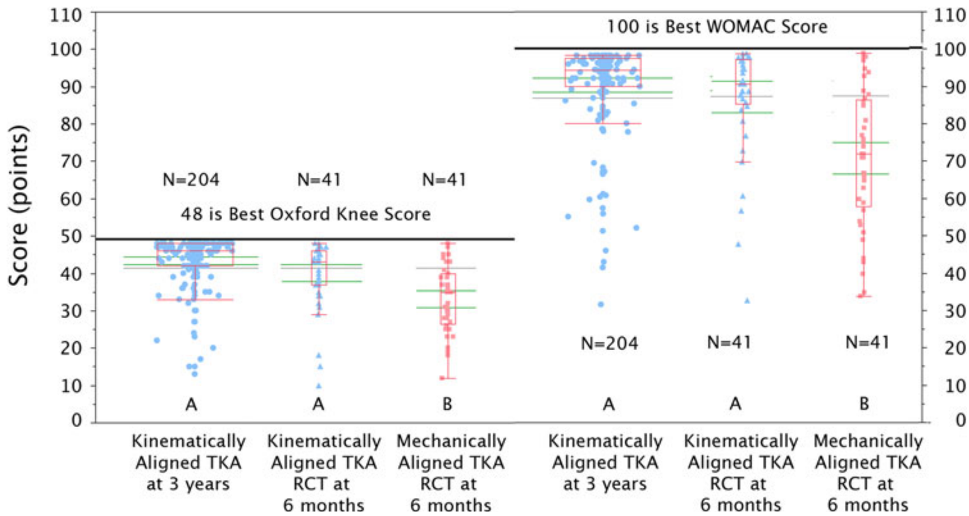

Fig. 3 Box plots compare the Oxford Knee Scores and WOMAC™ scores for the knees in our study (N = 204) at a minimum of 31 months followup with a published randomized control trial (RCT) of kinematically (N = 41) and mechanically (N = 41) aligned TKAs at an average 6-month clinical followup [5]. The gray center line indicates the median; the two green lines indicate the limits of the 95% CI of the mean. The limits of the 95% CI of the mean indicate no difference in the Oxford Knee Scores and WOMAC™ scores between the kinematically aligned TKAs in each study, and differences in the Oxford Knee Scores and WOMAC™ scores between the kinematically aligned TKAs and mechanically aligned TKAs (boxplots with dissimilar letters indicate a difference of $p < 0.05$).

Fourth, a post hoc power analysis was conducted to estimate the minimum sample size needed to observe a significant difference between the in-range and outlier groups. With regard to the first end point (mean Oxford Knee Score) and categorization of tibial component alignment (which was of greatest interest), our study was adequately powered to be able to detect a significant difference ($a < 0.05$) with 80% power with a standard deviation of 6 if the varus outlier group had a 5-point lower score. That degree of power would be achieved with study groups comprising at least 48 in-range TKAs and 48 varus outlier TKAs. Finally, our results require independent confirmation even though the data were obtained independent of the designing surgeon because the function and failure rates published by designing surgeons typically are better than the function and less than the failure rates reported by registries [19]. Our function of the kinematically aligned TKAs is similar and not higher than that reported in a randomized clinical trial whose authors were not designing surgeons [6]. Our 23-point improvement to the mean Oxford Knee Score of 43 at 3 years compares favorably with their TKA 22-point improvement to a mean of 42 at 6 months (Fig. 3) [5].

We found no difference in the mean Oxford Knee Score, and WOMAC™ scores among patients in the three alignment categories for the tibial component, knee, and limb were categorized as either in-range or an outlier. One explanation for this lack of difference in function between alignment categories is that we aligned the femoral and tibial components to the normal, prearthritic joint lines of the knee (Fig. 1). Aligning components to the normal joint lines may be desirable and would be perceived as natural to the patient. Another explanation is that aligning joint lines and not changing alignment of the limb from normal has been predicted to reduce the need for release of collateral, posterior cruciate, and retinacular ligaments [2, 6, 7, 9]. As was predicted, we restored motion without releasing these ligaments, which might be perceived by the patient as less painful and more stable than when ligaments are released as they may be in a mechanically aligned TKA. Finally, the 23-point improvement to a mean Oxford Knee Score of 43 in our study is favorable to if not higher than the 15-point improvement to a mean of 35 for mechanically aligned TKAs reported in a randomized control trial performed with conventional instruments and with computer-assisted instruments at 3 years [17], and the 15-point improvement to a mean of 41 for mobile-bearing unicompartmental knee arthroplasties (UKAs) at 1 and 5 years [23]. Similarly, the mean WOMAC™ score of 92 ± 12 for all our kinematically aligned TKAs is comparable to if not higher than the mean WOMAC™ score of 85 ± 13 for a subset of satisfied patients comprising 76% of mechanically aligned TKAs reported in the Ontario (Canada) province registry [4]. Therefore, the relatively high Oxford Knee Score and WOMAC™ score in each alignment category suggest that a kinematically aligned TKA restores high function regardless of the alignment category of the tibial component, knee, and limb.

No patient experienced catastrophic failure regardless of the alignment category. Our zero incidence of catastrophic failure in any alignment category in 214 TKAs in 198 patients at a minimum followup of 31 months disagrees with a report of four patients, who were treated with kinematic alignment with patient-specific cutting guides without postoperative followup, that stated there was a potential for malalignment with this system and placed the components at high risk of early failure [18]. In contrast, the zero incidence of catastrophic failure in our study agrees with the 96% survivorship at 10 years for mechanically aligned TKAs with a mean varus alignment of the tibial component of 3° ± 3° [20] that is comparable, if not more varus, than the mean varus alignment of the tibial component of 1.8° ± 2.6° in our study. Furthermore, our 1.4% incidence of reoperation for any reason (except deep infection) is comparable to, if not lower than, the 2.8% incidence of reoperation for mechanical alignment of the same component design reported in the Australian registry at 3 years [8]. Our incidence of reoperation also is less than the 7.4% incidence of reoperation reported in a review of the National Joint Registry for England and Wales at 1 year [1]. Collectively, our zero incidence of catastrophic failure and 1.4% incidence of reoperation suggest that kinematically aligned TKAs minimize revision surgery regardless of the alignment category of the tibial component, knee, and limb.

Our findings of high mean Oxford Knee Score and WOMAC™ score and the zero incidence of catastrophic failure at a minimum of 31 months regardless of alignment category should allay the concern that varus alignment of the tibial component will cause poor function and early catastrophic failure in the kinematically aligned TKA. We believe that describing tibial component, knee, and limb alignment as a dichotomous variable (aligned versus outlier) is of little practical value for predicting function and early catastrophic failure of kinematically aligned TKAs.

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