The Effect of Alignment and BMI on Failure of Total Knee Replacement

Merrill A. Ritter, MD, Kenneth E. Davis, MS, John B. Meding, MD, Jeffery L. Pierson, MD, Michael E. Berend, MD, and Robert A. Malinzak, MD

Investigation performed at the Center for Hip and Knee Surgery, St. Francis Hospital—Mooresville, Mooresville, Indiana

Background: The purpose of this study was to determine the effect of tibiofemoral alignment, femoral and tibial component alignment, and body-mass index (BMI) on implant survival following total knee replacement.

Methods: We retrospectively reviewed 6070 knees in 3992 patients with a minimum of two years of follow-up. Each knee was classified on the basis of postoperative alignment (overall tibiofemoral alignment and alignment of the tibial and the femoral component in the coronal plane). Failures (defined as revision for any reason other than infection) were analyzed with use of Cox regression; patient covariates included overall alignment, component alignments, and preoperative BMI.

Results: Failure was most likely to occur if the orientation of the tibial component was <90° relative to the tibial axis and the orientation of the femoral component was ≥8° of valgus (failure rate, 8.7%; p < 0.0001). In contrast, failure was least likely to occur if both the tibial and the femoral component were in a neutral orientation (≥90° and <8° of valgus, respectively) (failure rate, 0.2% [nine of 4633]; p < 0.0001). ''Correction'' of varus or valgus malalignment of the first implanted component by placement of the second component to attain neutral tibiofemoral alignment was associated with a failure rate of 3.2% (p = 0.4922) for varus tibial malalignment and 7.8% (p = 0.0082) for valgus femoral malalignment. A higher BMI was associated with an increased failure rate. Compared with patients with a BMI of 23 to 26 kg/m^2, the failure rate in patients with a BMI of ≥41 kg/m^2 increased from 0.7% to 2.6% (p = 0.0046) in well-aligned knees, from 1.6% to 2.9% (p = 0.0180) in varus knees, and from 1.0% to 7.1% (p = 0.0260) in valgus knees.

Conclusions: Attaining neutrality in all three alignments is important in maximizing total knee implant survival. Substantial ''correction'' of the alignment of one component in order to compensate for malalignment of the other component and thus produce a neutrally aligned total knee replacement can increase the risk of failure (p = 0.0082). The use of conventional guides to align a total knee replacement provides acceptable alignment; however, the surgeon should be aware that the patient's size, as determined by the BMI, is also a major factor in total knee replacement failure.

Level of Evidence: Prognostic Level II. See Instructions to Authors for a complete description of levels of evidence.

The alignment of the knee following total knee replacement, as seen on anteroposterior radiographs, may be the most important factor determining the long-term survival of the prosthesis[1-14]. In addition, we previously reported that a body-mass index (BMI) of >33.7 kg/m^2 was associated with an increased failure rate in total knee replacements with varus malalignment[2]. Proper alignment of implants is strongly associated with greater stability, a lower rate of loosening, and higher clinical scores[1-14]; however, the current literature lacks a precise range of values for the postoperative tibial alignment, femoral alignment, overall anatomic alignment, and BMI necessary to achieve the best possible long-term prosthesis survival.

The present study sought to address four issues: (1) What is the optimal range of postoperative tibial alignment, femoral alignment, and overall anatomic limb alignment in the coronal plane that results in the best prosthesis survival rate? (2) If the component that is implanted first is improperly aligned, would positioning the remaining tibial or femoral component

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to compensate for the malalignment be able to maintain a good prosthesis survival rate? (3) How do tibial alignment, femoral alignment, and overall anatomic alignment relate to the most common failure modes of tibial collapse and ligamentous instability? (4) What range of BMI leads to more frequent failure of a malaligned prosthesis?

Materials and Methods

We retrospectively reviewed 9483 primary knee replacements performed between September 1983 and November 2006. Four hundred and eighty-two knees (5.1%) were completely lost to follow-up, 2204 knees had less than two years of follow-up, and the postoperative alignment for 727 knees that had not failed at the time of our study was not recorded in our database. The remaining 6070 consecutive primary total knee replacements (in 3992 patients) formed our study cohort. The mean duration of follow-up (and standard deviation) was 7.6 ± 3.8 years (range, 2 to 22.5 years), and 1118 (28.0%) of the patients died during the study period.

The mean age at the time of the initial knee replacement was 70.1 ± 8.6 years (range, twenty-one to ninety-three years); 2436 (61.0%) of the patients were women, and 1556 (39.0%) were men. The mean preoperative BMI was 30.2 ± 5.6 kg/m^2 (range, 16.5 to 64.3 kg/m^2). The preoperative diagnosis was osteoarthritis in 5803 knees (95.6%), rheumatoid arthritis in 187 (3.1%), and osteonecrosis in sixty-five knees (1.1%). The diagnosis in the remaining fifteen knees (0.2%) was hemophilia in four, chondrocalcinosis in four, ochronosis in four, Paget disease in one, von Willebrand disease in one, and lupus in one knee. The mean preoperative anatomic tibiofemoral alignment was 0.0° ± 7.7° (range, 25° of varus to 35° of valgus).

Six surgeons (including five of the authors) performed all of the arthroplasties with use of similar instrumentation and techniques. All arthroplasties were performed with use of AGC (Anatomically Graduated Components) implants (Biomet, Warsaw, Indiana); the tibial component was cemented, posterior cruciate-retaining, metal-backed, nonmodular, and composed of cobalt-chromium alloy, and the liner was composed of compression-molded polyethylene (Himont 1900 PE resin)[10]. All patients underwent an identical postoperative rehabilitation regimen; walking was initiated within one day postoperatively, and the distance walked and the range of knee motion were increased on subsequent days.

A standing anteroposterior 14 × 17-in (35.6 × 43.2-cm) radiograph of the knee was made at each follow-up visit (scheduled at six months and at one, three, five, seven, ten, twelve, fifteen, seventeen, twenty, and twenty-two years). The tibial alignment, femoral alignment, and overall anatomic alignment were measured to the nearest 0.1° by the operating surgeons at each follow-up visit with use of a goniometer. However, only the data obtained at the time of the latest follow-up was used in our analysis. The overall anatomic alignment was defined as the angle between the femoral anatomic axis (a line drawn through the center of the femoral shaft) and the tibial anatomic axis (a line drawn through the center of the tibial shaft)[9]. The tibial alignment was defined as the angle between the proximal portion of the tibial component and the previously described tibial anatomic axis. The femoral alignment was defined as the angle between the distal portion of the femoral component and the femoral anatomic axis. The BMI used in the analysis was the preoperative value.

Statistical Analysis

Kaplan-Meier survival analysis of the time to failure was performed with use of three end points: (1) revision for any reason other than infection, (2) revision due to tibial collapse, and (3) revision due to ligamentous instability. Censoring occurred at the date of the last clinical examination, the date of death, or the date on which it was determined that the joint was infected. Cox regression analysis was performed with forward, backward, and stepwise selection in order to determine the variables most strongly predictive of failure, in order of importance. The variables analyzed were postoperative overall anatomic alignment, postoperative tibial alignment, postoperative femoral alignment, age, preoperative BMI, preoperative overall alignment, sex, a diagnosis of rheumatoid arthritis, a diagnosis of osteonecrosis, and polyethylene thickness. The postoperative overall alignment was highly confounded with the tibial alignment and with the femoral alignment; consequently, analysis of covariates was first performed by including overall tibiofemoral alignment and excluding both tibial and femoral alignment, then repeated by including both tibial and femoral alignment and excluding overall alignment.

Possible clustering of failures in both knees of patients with bilateral total knee replacements was examined with use of the robust sandwich covariance matrix method of estimation (SAS Proc PHREG Procedure, Example Analysis of Clustered Data; SAS Institute, Cary, North Carolina), which accounts for the correlation of such a patient's data with itself in the Cox regression. If the ratio between the standard error of the regression model with the sandwich covariance matrix and the standard error of the model without this matrix was consistently <1, then clustering would be shown to exist and the robust sandwich estimator would be used to account for correlations due to clustering of data from bilateral knee replacements.

All covariates were quantified with use of hazard ratios obtained from the Cox regression analysis and p values; a p value of <0.05 was considered significant. Interaction effects were analyzed in order to determine whether the effect of BMI was greater in knees with poor alignment than in knees with acceptable alignment. Each interaction term was added to the full model and examined for significance.

Neutral (optimal) alignment was determined with use of an algorithm that examined the range of angles associated with the lowest failure rate and selected the narrowest range that had the greatest significance in the full model. Neutral alignment was determined separately for the tibial, femoral, and overall anatomic alignment, in the order of decreasing significance indicated by the Cox regression analysis.

Hazard ratios for comparisons between specific combinations of overall, tibial, and femoral alignment were determined with use of the indicated applicable subsets of the 6070 knees (e.g., all knees with valgus overall malalignment and neutral tibial alignment compared with all knees with neutral overall and tibial alignment). For modeling of failure due to collapse and failure due to instability, any alteration of the covariates used is indicated along with the reported result.

Source of Funding

There was no external funding source for this investigation.

Results

Fifty-four (0.89%) of the 6070 knee replacements failed for a reason other than infection. The mean time to failure was 5.2 ± 3.6 years (range, 0.6 to 13.1 years). The mean postoperative overall anatomic alignment in the study cohort was 4.7° ± 2.5° (range, –12° to 20°) of valgus, the mean tibial alignment was 90.4° ± 2.4° (range, 78° to 102°), and the mean femoral alignment was 3.7° ± 3.3° (range, –13° to 22°) of valgus. The mean postoperative overall alignment in the knee replacements that failed was 4.1° ± 3.4° (range, –6° to 13°), the mean tibial alignment was 87.3° ± 3.0° (range, 78° to 94°), and the mean femoral alignment was 6.4° ± 2.6° (range, 2° to 12°).

Failure for Any Reason Other Than Infection

The optimal ranges for overall anatomic alignment, tibial alignment, and femoral alignment are depicted in Figures 1, 2, and 3. The neutral range for overall anatomic alignment was 2.5° to 7.4° of valgus; this optimal alignment was attained in 4310 (71.0%) of the knees, and was associated with a failure rate of 0.65% (twenty-eight of 4310) (Fig. 1). The neutral range for tibial alignment was identified as any angle ≥90°; this optimal

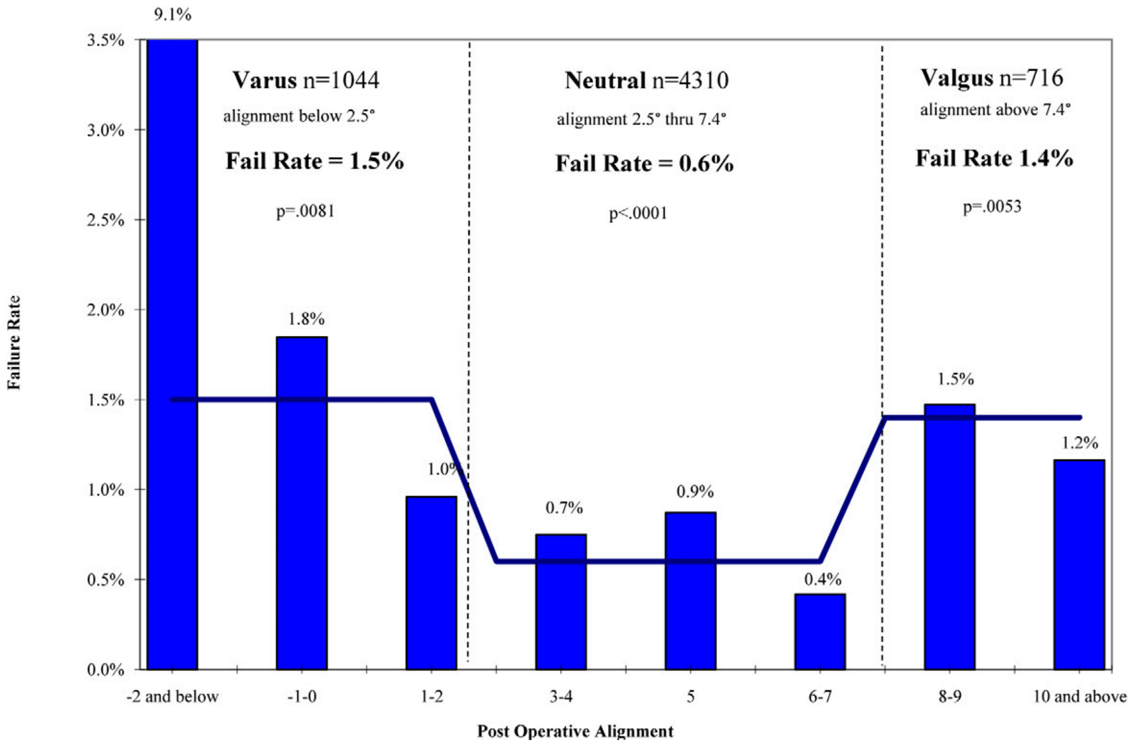

Fig. 1
Failure rate according to overall alignment in degrees.

alignment was attained in 4973 (81.9%) of the knees, and was associated with a failure rate of 0.24% (twelve of 4973) (Fig. 2). The neutral range for femoral alignment was identified as any angle <8.0° of valgus; this optimal alignment was attained in 5562 (91.6%) of the knees, and was associated with a failure rate of 0.65% (thirty-six of 5562) (Fig. 3). The survivorship

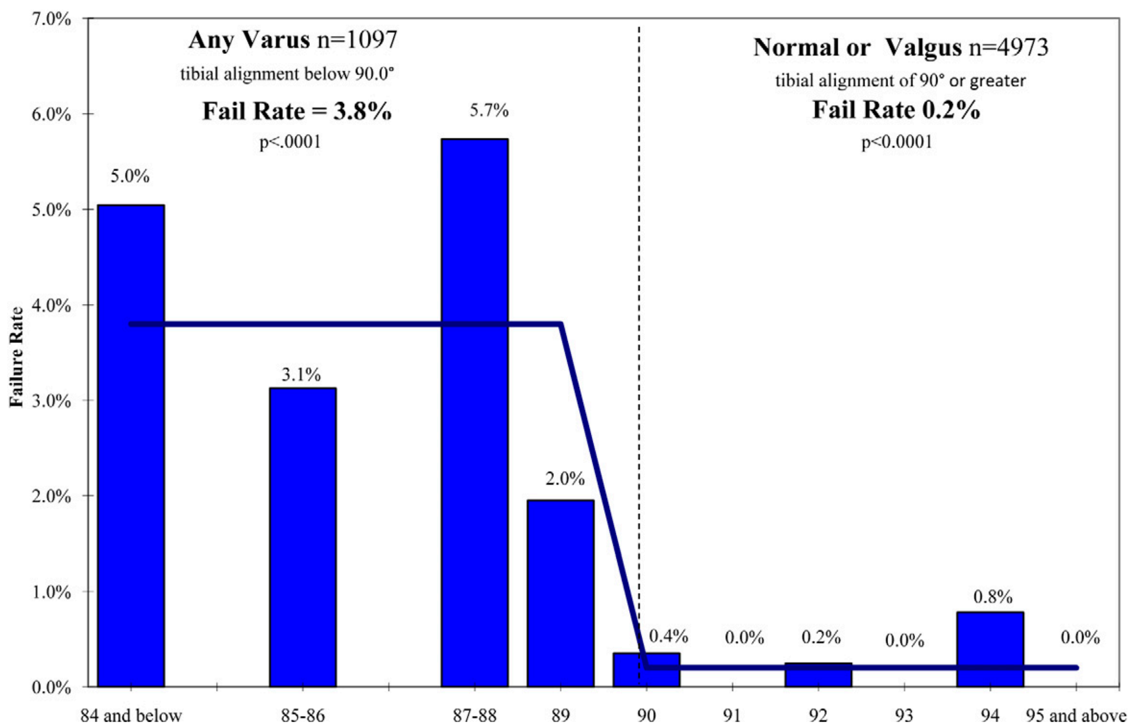

Fig. 2
Failure rate according to tibial alignment in degrees.

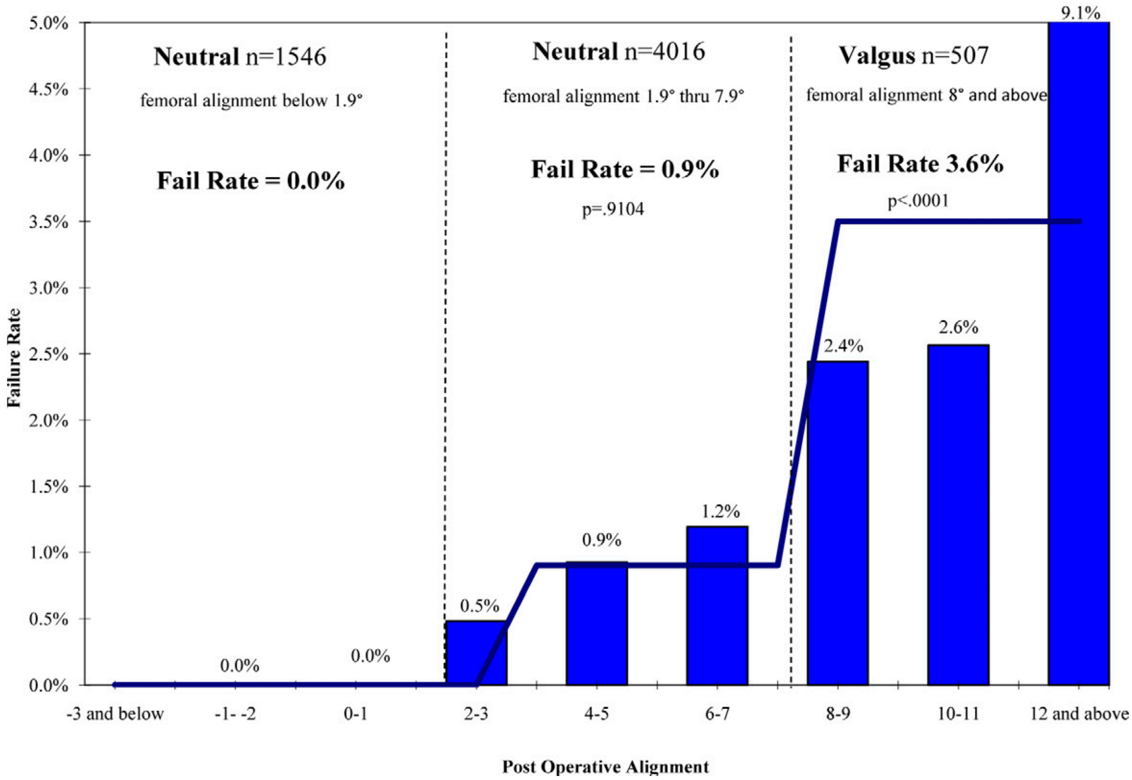

Fig. 3

Failure rate according to femoral alignment in degrees. (One knee that did not fail was not included because the femoral alignment could not be determined at the time of the current study.)

advantage of optimal (neutral) overall anatomic alignment is readily seen in the survivorship curve (Fig. 4).

Cox regression with forward and backward selection identified tibial varus malalignment (<90°) as the most statistically significant predictor of reduced prosthesis survival ($p < 0.0001$), and this variable consistently explained the largest amount of the variance in the failure rate. Varus tibial malalignment (<90°) was associated with a 10.6 times greater risk of failure (hazard ratio, 10.6; 95% confidence interval [CI], 5.4 to 20.6; $p < 0.0001$). The second most important predictor identified by the Cox regression was a valgus femoral malalignment (≥8° of valgus), which was associated with a 5.1 times greater risk of failure (95% CI, 2.8 to 9.5 times; $p < 0.0001$). Other significant covariates were an age of less than seventy years (associated with a greater risk of failure, $p = 0.0003$), a preoperative varus overall malalignment (<–8° of valgus) (associated with a greater risk of failure, $p < 0.0001$), a preoperative valgus malalignment (>11° of valgus) (associated with a greater risk of failure, $p = 0.0187$), and BMI class (discussed below, $p < 0.0001$). Sex ($p = 0.6036$), a diagnosis of rheumatoid arthritis ($p = 0.8713$), and a diagnosis of osteonecrosis ($p = 0.9891$) were not significant predictors of the failure rate. Thus, the covariates included in the final model were an age of <70 or ≥70 years; a preoperative overall alignment of <–8°, –8° to 11°, or >11°; a BMI of <23, 23 to 26, 27 to 40, or ≥41 kg/m^2; and either (1) a postoperative overall alignment of <2.5°, 2.5 to 7.4°, or ≥7.5°, or (2) a postoperative tibial alignment of <90° or ≥90° and a postoperative femoral alignment of <8° or ≥8°.

The possible clustering of failures in patients with bilateral knee replacements was tested by examining the ratio between standard errors calculated with and without the robust estimator; a ratio of <1 indicates the existence of patient clustering. The ratio was 1.11 for varus tibial malalignment, 1.05 for valgus femoral malalignment, 1.14 for a BMI of 17 to 22 kg/m^2, 1.08 for a BMI of 27 to 40 kg/m^2, 1.08 for a BMI of ≥41 kg/m^2, 1.12 for preoperative varus malalignment, 0.95 for preoperative valgus malalignment, and 1.06 for age. Since all but one of these standard error ratios was >1, the nonclustered model was used in the current study. Notably, preoperative valgus malalignment (>11° of valgus) appeared to be susceptible to clustering (since the standard error ratio was 0.95). With the numbers available, no significant interactions between variables were found when the failure rate was analyzed on the basis of the groups (e.g., preoperative alignment of >11° of valgus) used in the final model.

Knees with both neutral tibial alignment (≥90.0° with respect to the tibial axis) and neutral femoral alignment (<8.0° of valgus) had a failure rate of 0.2% (nine failures in 4633 knees), the lowest failure rate of any of the combinations of tibial and femoral alignment. In contrast, knees with varus tibial malalignment (<90°) and valgus femoral malalignment (≥8° of valgus) had the highest failure rate, 8.7% (fifteen of 173, $p < 0.0001$)—i.e., attempting to compensate for a varus tibial

TABLE I Aseptic Failure Rate According to Tibial and Femoral Alignment*

Tibial Alignment	Femoral Alignment	Failure Rate	No. of Failures‡	Hazard Ratio (95% CI)†	P Value†
Neutral (≥90°)	Neutral (<8°)	0.2%	9 of 4624	Reference	
Neutral (≥90°)	Valgus (≥8°)	0.9%	3 of 349	10.7 (2.8, 41.4)	<0.0006
Varus (<90°)	Neutral (<8°)	2.9%	27 of 938	12.1 (5.6, 25.9)	<0.0001
Varus (<90°)	Valgus (≥8°)	9.5%	15 of 158	57.6 (23.3, 141.9)	<0.0001

*Failure of the tibial or femoral component for a reason other than infection occurred in 54 knees. †CI = confidence interval. P values and hazard ratios were calculated by Cox regression of tibial alignment, femoral alignment, BMI class, age, and preoperative alignment class. The hazard ratio for each combination of tibial and femoral alignment (relative to the indicated reference condition of neutral tibial and neutral femoral alignment) was calculated in a separate model (e.g., the hazard ratio of 10.7 for the effect of valgus compared with neutral femoral alignment in knees with neutral tibial alignment was derived from an analysis of a subset of 4624 + 349 knees). An analysis of the full data set showed that the hazard ratios in a more complex model that takes into account the interaction between tibial and femoral malalignment were somewhat lower—10.6 for tibial malalignment and 5.1 for femoral malalignment. ‡One knee that did not fail was not included because the femoral alignment could not be determined at the time of the current study.

cut with a valgus femoral cut was associated with a high failure rate. Failure rates for all combinations of tibial and femoral alignment in the 6070 knees are presented in Table I.

Failure rates for all combinations of tibial and overall anatomic alignment are presented in Table II. Compensating for varus tibial malalignment with a more valgus femoral alignment to yield a neutral overall anatomic alignment was associated with a failure rate of 3.2%, whereas varus tibial malalignment combined with a noncompensating femoral alignment to yield varus overall anatomic malalignment was associated with a failure rate of 4.2%, which was not significantly different (p = 0.4922).

A valgus femoral malalignment (≥8° of valgus) combined with a compensating tibial alignment to yield a neutral overall anatomic alignment was associated with a failure rate of 7.8% compared with a 2.1% failure rate for valgus femoral

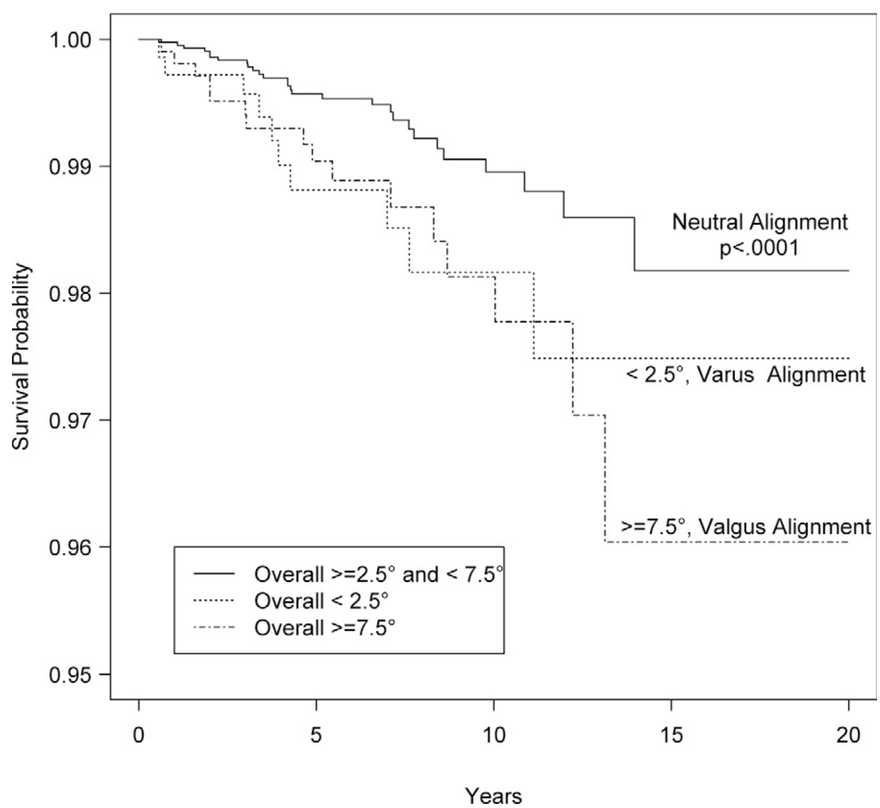

Fig. 4

Kaplan-Meier survivorship for neutral (optimal), varus, and valgus overall tibiofemoral alignment, with failure defined as tibial or femoral revision for a reason other than infection.

TABLE II Aseptic Failure Rate According to Tibial and Overall Alignment*

Tibial Alignment	Overall Alignment	Failure Rate	No. of Failures	Hazard Ratio (95% CI)†	P Value†
Neutral (≥90°)	Varus (<2.5°)	0.0%	0 of 679		0.9934
Neutral (≥90°)	Neutral (2.5° to 7.4°)	0.2%	8 of 4707	Reference	
Neutral (≥90°)	Valgus (≥7.5°)	0.7%	4 of 587	6.5 (1.9, 22.5)	0.0029
Varus (<90°)‡	Neutral (2.5° to 7.4°)	3.3%	20 of 603	13.3 (5.8, 30.4)	<0.0001
Varus (<90°)‡	Varus (<2.5°)	4.4%	16 of 365	15.1 (6.4, 35.5)	<0.0001
Varus (<90°)	Valgus (≥7.5°)	4.7%	6 of 129	24.3 (7.7, 76.1)	<0.0001

*Failure of the tibial or femoral component for a reason other than infection occurred in 54 knees. †CI = confidence interval. P values and hazard ratios were calculated by Cox regression of tibial alignment, overall alignment, BMI class, age, and preoperative alignment class. The hazard ratio for each combination of tibial and overall alignment (relative to the indicated reference condition of neutral tibial and neutral overall alignment) was calculated in a separate model; as described in Table I, a single model including all knees and accounting for the interaction between malalignments would generate slightly different estimates of the magnitude of the effect of tibial or overall malalignment. ‡With the numbers available, Cox regression involving the two indicated subsets (968 knees) and the same covariates as the full model indicated that correcting an excessively varus tibial cut with an excessively valgus femoral cut did not have a significant effect (p = 0.4922).

malalignment and a noncompensating tibial alignment to yield a valgus overall alignment (95% CI, 1.4 to 10.5 times; p = 0.0082) (Table III).

Simultaneous optimal alignment of all three measures (tibial alignment, femoral alignment, and overall anatomic alignment) occurred in 60.5% of the knees (3673 of 6070) and was associated with a failure rate of 0.22% (eight of 3673). The remaining 2397 knees in which at least one of the three measures was not in neutral alignment had a failure rate of 1.9% (forty-six of 2397) (p < 0.0001).

Failure Due to Any Reason, Collapse, and Instability

The failure rate was 1.5% (sixteen of 1044) in the knees with varus overall anatomic malalignment (<2.5° of valgus) and 1.4% (ten of 716) in the knees with valgus overall anatomic malalignment (≥7.5° of valgus). Twelve of the sixteen failures in the knees with varus overall malalignment involved medial collapse. Six of the ten failures in the knees with valgus overall malalignment involved instability (Table IV).

Varus tibial malalignment (<90°) was associated with a 10.6 times greater risk of failure for any reason (95% CI, 5.4 to 20.6 times; p < 0.0001) and a 32.0 times greater risk of failure due to collapse (95% CI, 9.5 to 107.7 times; p < 0.0001) than neutral tibial alignment (≥90°). Likewise, valgus femoral malalignment (≥8° of valgus) was associated with a 5.1 times greater risk of failure for any reason (95% CI, 2.8 to 9.5 times; p < 0.0001) and a 10.6 times greater risk of failure due to instability (95% CI, 3.7 to 29.9 times; p < 0.0001) (Table V) than a neutral femoral alignment (<8° of valgus). The mean time to failure was 3.8 ± 3.0 years (range, 0.6 to 12.2

TABLE III Aseptic Failure Rate According to Femoral and Overall Alignment*

Femoral Alignment	Overall Alignment	Failure Rate	No. of Failures†	Hazard Ratio (95% CI)‡	P Value‡
Neutral (<8.0°)	Neutral (2.5° to 7.4°)	0.5%	19 of 4203	Reference	
Neutral (<8.0°)	Valgus (≥7.5°)	0.9%	3 of 328	—	0.1067
Neutral (<8.0°)	Varus (<2.5°)	1.4%	14 of 1031	2.8 (1.4, 5.7)	0.0043
Valgus (≥8°)§	Valgus (≥7.5°)	1.8%	7 of 388	7.7 (3.2, 19.0)	<0.0001
Valgus (≥8°)§	Neutral (2.5° to 7.4°)	8.5%	9 of 106	27.9 (12.1, 64.6)	<0.0001
Valgus (≥8°)	Varus (<2.5°)	15.4%	2 of 13	35.1 (7.3, 169.6)	<0.0001

*Failure of the tibial or femoral component for a reason other than infection occurred in 54 knees. †One knee that did not fail was not included because the femoral alignment could not be determined at the time of the current study. ‡CI = confidence interval. P values and hazard ratios were calculated by Cox regression of femoral alignment, overall alignment, BMI class, age, and preoperative alignment class. The hazard ratio for each combination of femoral and overall alignment (relative to the indicated reference condition of neutral femoral and neutral overall alignment) was calculated in a separate model; as described in Table I, a single model including all knees and accounting for the interaction between malalignments would generate slightly different estimates of the magnitude of the effect of femoral or overall malalignment. §With the numbers available, Cox regression involving the two indicated subsets (n = 494) with use of the same covariates as the full model indicated that correcting an excessively valgus femoral cut with a more varus tibial cut was associated with a higher risk of failure (hazard ratio, 3.9; 95% CI, 1.4 to 10.5; p = 0.0082).

TABLE IV Hazard Ratio According to Overall Alignment and Failure Mechanism*

			Varus Overall Malalignment, <2.5°		Valgus Overall Malalignment, ≥7.5°	
Cause of Failure	Failure Rate	No. of Failures†	Hazard Ratio (95% CI)	P Value	Hazard Ratio (95% CI)	P Value
All causes other than infection	0.89%	54 of 6070	2.3 (1.2, 4.4)	0.0081	3.1 (1.5, 6.4)	0.0028
Collapse	0.43%	26 of 6070	5.9 (1.4, 6.8)	<0.0001	—	0.7218
Instability	0.26%	16 of 6070	—	0.2002	5.7 (2.0, 16.2)	0.0012

*CI = confidence interval. P values, hazard ratios, and 95% CIs were calculated by Cox regression of overall alignment, BMI class, age, and preoperative alignment class, and are relative to the neutral overall alignment (the reference category, not shown). †Two failures resulted from continuing pain.

years) for collapse compared with 6.5 ± 3.7 years (range, 0.7 to 13.1 years) for instability ($p = 0.0172$, Wilcoxon rank-sum test).

Preoperative valgus malalignment (>11° of valgus) was not significantly associated with failure due to tibial collapse ($p = 0.4208$) and was dropped from the regression model for this type of failure. Likewise, preoperative varus malalignment (<–8° of valgus) and BMI were not significantly associated with failure due to instability ($p = 0.9380$ and 0.7118, respectively) and were dropped from the corresponding regression model.

BMI and Alignment

In general, increasing BMI was associated with an increasing risk of failure of the prosthesis, independent of the effect of tibial alignment, femoral alignment, and overall anatomic alignment ($p < 0.0001$). The lowest failure rate, 0.65% (eight of 1223), occurred in patients with a BMI of 23 to 26 kg/m^2; this group included 20.1% of the knees (1223 of 6070). The risk of failure was 2.5 times greater in patients with a BMI of 27 to 40 kg/m^2 (95% CI, 1.1 to 5.6 times; $p = 0.0335$) and 10.8 times greater in patients with a BMI of ≥41 kg/m^2 (95% CI, 3.6 to 32.4 times; $p < 0.0001$). Surprisingly, patients with a BMI of <23 kg/m^2 (range, 16.5 to 22.5 kg/m^2) also had a higher risk of failure than patients with a BMI of 23 to 26 kg/m^2 (95% CI, 0.6 to 7.4 times; $p = 0.2208$).

Knees with varus overall anatomic malalignment (<2.5° of valgus) had a 5.6 times greater risk of failure in patients with a BMI of 27 to 40 kg/m^2 (95% CI, 1.1 to 28.6 times; $p = 0.0367$) and a 12.9 times greater risk of failure in patients with a BMI of ≥41 kg/m^2 (95% CI, 1.5 to 107.2 times; $p = 0.0180$) than in patients with a BMI of 23 to 26 kg/m^2. Even knees with neutral overall anatomic alignment (2.5° to 7.4° of valgus) had a 7.7 times greater risk of failure in patients with a BMI of ≥41 kg/m^2 (95% CI, 1.9 to 31.8 times; $p = 0.0046$) than in patients with a BMI of 23 to 26 kg/m^2 (Table VI).

The effect of BMI was also evident in knees with varus tibial malalignment (<90°). Knees with varus tibial malalignment had a 2.7 times greater risk of failure in patients with a BMI of 27 to 40 kg/m^2 (95% CI, 1.0 to 7.1 times; $p = 0.0395$) and an 18.0 times greater risk of failure in patients with a BMI of ≥41 kg/m^2 (95% CI, 5.5 to 58.7 times; $p < 0.0001$) than in patients with a BMI of 23 to 26 kg/m^2. Knees with neutral tibial alignment (≥90°) were not affected by increasing BMI ($p = 0.9401$) (Table VII).

Likewise, the effect of BMI was evident in knees with valgus femoral malalignment (≥8° of valgus). Knees with valgus femoral malalignment had an 18.0 times greater risk of failure in patients with a BMI of ≥41 kg/m^2 (95% CI, 3.0 to 129.4 times; $p = 0.0020$) than in patients with a BMI of 23 to 26 kg/m^2.

TABLE V Hazard Ratio According to Tibial or Femoral Alignment and Failure Mechanism*

			Varus Tibial Malalignment, <90°		Valgus Femoral Malalignment, ≥8°	
Cause of Failure	Failure Rate	No. of Failures†	Hazard Ratio (95% CI)	P Value	Hazard Ratio (95% CI)	P Value
All causes other than infection	0.89%	54	10.6 (5.4, 20.6)	<0.0001	5.1 (2.8, 9.5)	<0.0001
Collapse	0.43%	26	32.0 (9.5, 107.7)	<0.0001	3.2 (1.1, 9.0)	0.0271
Instability	0.26%	16	6.8 (2.1, 22.1)	0.0014	10.6 (3.7, 29.9)	<0.0001

*CI = confidence interval. P values and hazard ratios were calculated by Cox regression of tibial alignment, femoral alignment, BMI class, age, and preoperative alignment class, and are relative to the corresponding neutral tibial or neutral femoral alignment (the reference category, not shown). †Two failures resulted from continuing pain.

TABLE VI Aseptic Failure Rate According to Overall Alignment and BMI

	Overall Anatomic Alignment*		
BMI (kg/m^2)	Varus Malalignment, <2.5°	Neutral, 2.5° to 7.4°	Valgus Malalignment, ≥7.5°
≥41	2.9%	2.6%	7.1%
27 to 40	2.1%	0.7%	3.5%
23 to 26	1.6%	0.7%	1.0%
≤22	4.0%	2.0%	0.0%

*Values are given as the rate of failure for any reason other than infection.

TABLE VII Aseptic Failure Rate According to Tibial Alignment and BMI

	Tibial Alignment*	
BMI (kg/m^2)	Varus Malalignment, <90°	Neutral, ≥90°
≥41	21.9%	0.0%
27 to 40	5.2%	0.4%
23 to 26	2.9%	0.3%
≤22	7.3%	0.6%

*Values are given as the rate of failure for any reason other than infection.

Other interactions between alignment and BMI were not significant (p = 0.9809 for interaction of a varus tibial malalignment [<90°] and a BMI of ≥41 kg/m^2; p = 0.1296 for interaction of a valgus femoral malalignment [≥8° of valgus] and a BMI of ≥41 kg/m^2).

Discussion

Proper alignment (tibial alignment, femoral alignment, and overall anatomic alignment) of the prosthesis during total knee replacement is critical in maximizing implant survival. Although the roles that the overall anatomic alignment and/or tibial component alignment in the coronal plane play in total knee replacement failures[1-14] are well documented, little has been reported regarding the effect of the femoral component alignment. The results of our study confirm that attaining neutrality of all three alignments is vital in maximizing implant longevity, and that substantial "correction" of the alignment of the second component in order to produce an overall neutrally aligned total knee replacement when the first component has been malaligned may increase the risk of failure of the total knee replacement.

A previous study conducted at our institution by Fang et al. indicated that poor overall anatomic alignment of a total knee replacement was associated with a 6.9 times greater risk of failure due to tibial collapse and that varus tibial alignment was associated with a 3.2 times greater risk[4]. Likewise, Berend et al.[2] found that twenty of forty-one failures were due to collapse of the medial bone, and that all twenty of these knees were in varus alignment (mean, 3.7° of varus)[2]. To our knowledge, our current study is unique in demonstrating that a femoral alignment of ≥8.0° of valgus was also an important contributor to implant failure (resulting in a 5.1 times greater risk of failure). Although it is important to obtain an overall anatomic alignment that is as close to normal (2° to 7° of valgus) as possible, and it is equally important to obtain a tibial alignment of ≥90° relative to the tibial axis, femoral alignment should also be considered (with the optimal alignment being <8.0° of valgus).

Our study also attempted to address the strategy of overcorrecting the alignment of one of the components in order to offset a malalignment of the previously implanted component. While it is accepted that achieving overall alignment similar to the neutral range in our study (2.5° to 7.4° of valgus) is important for implant survival, our study is one of the first to show that "correction" of one component in order to achieve neutral overall anatomic alignment when the other component is malaligned is not advantageous. Attempting to compensate for a tibial alignment of <90° by performing a valgus femoral cut does not significantly reduce the risk of failure (3.2% for varus tibial malalignment and neutral overall alignment compared with 4.2% for varus tibial malalignment and varus overall malalignment, p = 0.4922). Indeed, although a tibial alignment of <90° contributes to more frequent postoperative problems, compensating by aligning the femoral component in ≥8° of valgus to obtain neutral alignment may actually increase the risk of failure. The failure rate of 8.7% for knees with varus tibial malalignment and valgus femoral malalignment was the highest among the four combinations of femoral and tibial alignment (Table I). Valgus femoral malalignment was associated with a 5.1 times greater risk of failure of the total knee replacement compared with neutral alignment. The goal of total knee replacement should be to restore neutral alignment of both components in order to attain neutrality of the overall anatomic alignment.

Obtaining tibial alignment, femoral alignment, and overall anatomic alignment within the neutral range has often been a subject of discussion in orthopaedics[15-18]. We achieved acceptable neutral alignment in 91.6% of the femoral components and 81.9% of the tibial components, and we achieved neutral overall anatomic alignment in 71.0% of the knees in our study, with the use of conventional extramedullary tibial and intramedullary femoral guide rods. The seven additional years of data from our institution that have become available since the study by Berend et al.[2] show a marked improvement in alignment of the tibial component with use of a conventional alignment system by the surgeons at our institution (21.5% outliers of >3° from the intended angle in the 1990s compared with 5.7% outliers between 2000 and 2006, $p < 0.0001$). We therefore believe that, with proper surgical technique (including careful attention to the femoral and tibial resection angles), the use of conventional alignment systems is reasonable.

We were unable to identify significant interaction effects between tibial or femoral alignment and a high BMI. However, we intuitively believe that poor implant alignment combined with a high BMI represents a much greater risk to implant survival than either risk factor alone.

Berend et al.[2], using the same database as the one used in our study, found that varus tibial malalignment and a BMI of >33.7 kg/m^2 were important contributors to failure of total knee replacements. The present data continue to show that the components should be positioned correctly and that a high patient BMI is detrimental to the survivability of the implant.

Surprisingly, patients with a BMI of <23 kg/m^2 had a higher failure rate than patients with a BMI of 23 to 26 kg/m^2. Although this difference did not reach significance, the fact that patients with a BMI in the lowest range had an elevated failure rate in nearly every alignment group, as seen in Tables VI and VII, is difficult to ignore.

In summary, we believe that a surgeon should aim to place the tibial component at an angle of ≥90° from the tibial axis and the femoral component in <8.0° of valgus in order to yield an overall anatomic alignment (tibiofemoral coronal alignment) between 2.5° and 7.4° of valgus, which should be achievable with conventional instruments. ■

Merrill A. Ritter, MD
Kenneth E. Davis, MS
John B. Meding, MD
Jeffery L. Pierson, MD
Michael E. Berend, MD
Robert A. Malinzak, MD
Center for Hip and Knee Surgery,
St. Francis Hospital—Mooresville,
1199 Hadley Road,
Mooresville, IN 46158.
E-mail address for M.A. Ritter: marittermd@yahoo.com

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