A commentary by Michael A. Mont, MD, and Ormonde M. Mahoney, MD, is available at www.jbjs.org/commentary and as supplemental material to the online version of this article.

Effect of Postoperative Mechanical Axis Alignment on the Fifteen-Year Survival of Modern, Cemented Total Knee Replacements

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Background: One long-held tenet of total knee arthroplasty is that implant durability is maximized when postoperative limb alignment is corrected to 0° ± 3° relative to the mechanical axis. Recently, substantial health-care resources have been devoted to computer navigation systems that allow surgeons to more often achieve that alignment. We hypothesized that a postoperative mechanical axis of 0° ± 3° would result in better long-term survival of total knee arthroplasty implants as compared with that in a group of outliers.

Methods: Clinical and radiographic data were reviewed retrospectively to determine the fifteen-year Kaplan-Meier survival rate following 398 primary total knee arthroplasties performed with cement in 280 patients from 1985 to 1990. Preoperatively, most knees were in varus mechanical alignment (mean and standard deviation, 6° ± 8.8° of varus [range, 30° of varus to 22° of valgus]), whereas postoperatively most knees were corrected to neutral (mean and standard deviation, 0° ± 2.8° [range, 8° of varus to 9° of valgus]). Postoperatively, we defined a mechanically aligned group of 292 knees (with a mechanical axis of 0° ± 3°) and an outlier group of 106 knees (with a mechanical axis of beyond 0° ± 3°).

Results: At the time of the latest follow-up, forty-five (15.4%) of the 292 implants in the mechanically aligned group had been revised for any reason, compared with fourteen (13%) of the 106 implants in the outlier group ($p = 0.88$); twenty-seven (9.2%) of the 292 implants in the mechanically aligned group had been revised because of aseptic loosening, mechanical failure, wear, or patellar problems, compared with eight (7.5%) of the 106 implants in the outlier group ($p = 0.88$); and seventeen (5.8%) of the 292 implants in the mechanically aligned group had been revised because of aseptic loosening, mechanical failure, or wear, compared with four (3.8%) of the 106 implants in the outlier group ($p = 0.49$).

Conclusions: A postoperative mechanical axis of 0° ± 3° did not improve the fifteen-year implant survival rate following these 398 modern total knee arthroplasties. We believe that describing alignment as a dichotomous variable (aligned versus malaligned) on the basis of a mechanical axis goal of 0° ± 3° is of little practical value for predicting the durability of modern total knee arthroplasty implants.

Level of Evidence: Therapeutic Level III. See Instructions to Authors for a complete description of levels of evidence.

One long-held tenet of total knee arthroplasty is that, to promote implant durability, the overall postoperative limb alignment should be corrected to within 0° ± 3° of the mechanical axis (as defined by the center of the femoral head and the center of the talus)[1]. Recently, substantial health-care resources have been devoted to computer navigation systems and advanced imaging-based custom patient instrumentation systems that provide surgeons with the ability to more often achieve a postoperative limb alignment of 0° ± 3° relative to the mechanical axis[2,3]. A fundamental premise of current-generation computer-assisted total knee arthroplasty is that correcting the mechanical axis will promote implant

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durability and that the added costs associated with navigation systems will be subsequently balanced by a decrease in the number of revision total knee arthroplasties[2,3]. A careful review of the available literature, however, suggests that the scientific clinical support for the widely held contention that a postoperative mechanical axis of 0° ± 3° will improve implant survival following total knee arthroplasty is surprisingly weak[1,4-8]. We decided to review, in a large group of patients for whom full-length hip-knee-ankle radiographs were available, the fundamental premise that correction of the mechanical axis predicts the long-term durability of modern total knee replacements. We hypothesized that a postoperative mechanical axis within a range of 0° ± 3° would result in better long-term implant survival as compared with a postoperative mechanical axis beyond that range. Using data on three modern cemented total knee designs, we sought to determine whether a postoperative mechanical axis of 0° ± 3° confers an advantage in terms of implant survival following total knee arthroplasty.

Materials and Methods

After institutional review board approval had been obtained, we performed a clinical and radiographic retrospective study to evaluate the impact of alignment on long-term implant survival following 398 primary total knee arthroplasty procedures that had been performed with cement in 280 patients. All procedures had been performed at our institution, and standardized preoperative and postoperative full-length hip-knee-ankle radiographs were available for all patients. The inclusion criteria were (1) treatment with a primary total knee arthroplasty between 1985 and 1990, (2) performance of the procedure by the same surgeon, (3) the use of one of three types of modern unconstrained implants, (4) the use of cemented fixation of all components, (5) the use of an all-polyethylene patellar component, and (6) the availability of readable preoperative and postoperative full-length hip-knee-ankle radiographs that had been made according to a previously validated protocol[9]. During the study period, only fifteen (5%) of 295 patients, with nineteen knees, were excluded because they lacked available full-length hip-knee-ankle radiographs.

The indications for the procedure were primary osteoarthritis, rheumatoid arthritis, posttraumatic arthritis, or arthritis secondary to a systemic disease. Three types of total knee arthroplasty designs were used in the present series: (1) Kinematic Condylar II (Howmedica, Rutherford, New Jersey) (eighty-three knees), (2) Press-Fit Condylar (DePuy Orthopaedics, Warsaw, Indiana) (114 knees), and (3) GENESIS (Smith & Nephew, Memphis, Tennessee) (201 knees). The same medial parapatellar surgical approach was used for all patients. An intramedullary instrumentation system was used to position the femoral components, and an extramedullary guide was used for the tibia. A goal of the surgeon was to obtain a neutral postoperative mechanical axis as defined by the center of the hip, center of the knee, and center of the ankle. Varus and valgus deformities were corrected first with resection of bone and second with soft-tissue releases when needed. Substantial effort was devoted to obtaining symmetric ligament balance in both flexion and extension independent of limb alignment. Patellar bone was resected to provide a symmetric bone remnant and a bone-implant composite thickness that matched that of the native patella. All three components were cemented. The same postoperative rehabilitation protocol was used for all patients.

All preoperative and postoperative full-length hip-knee-ankle radiographs were made in the same center according to a previously described standardized protocol[9]. The preoperative radiographs were made within two months before surgery, and the postoperative radiographs were made two to three months after surgery. For each knee that was included in the series, lower limb mechanical alignment, tibial and femoral angles, and the distance from the center of the knee to the mechanical axis were measured by an independent observer (S.P.) on the preoperative and postoperative radiographs according the criteria defined by Cooke et al.[10-12]. To confirm the reliability of the radiographic measurements, interobserver and intraobserver comparisons of angle measurements at two different time points were performed with use of the method of Bland and Altman on twenty randomly chosen patients from the series[13]. For these twenty patients, the intraobserver and interobserver measurement errors were <1° for all of the analyzed angles.

Follow-up was performed with use of the comprehensive data available from the total joint registry at our institution[14]. The total joint registry includes patient demographic data, the date of the latest evaluation, whether the implant was in place or removed, and information on reoperations and complications[14]. Patients are scheduled for regular clinical evaluations at one, two, and five years following the arthroplasty and every five years thereafter. Patients who do not return for clinical evaluation are asked to complete a detailed questionnaire regarding the knee and to forward current radiographs. A telephone call is made to individuals who fail to return the questionnaire or to a surviving relative in the event of the patient's death. Furthermore, reasons for reoperations or revisions were identified on the basis of a detailed review of patient records, and radiographs that had been made at the time of the latest follow-up were analyzed by two independent observers (S.P. and M.W.P.) for all of the patients in the series.

Patient demographic data and the preoperative and postoperative radiographic alignment data were expressed as the mean and the standard deviation[15] (Tables I and II) (see Appendix). In order to analyze the influence of alignment on survival, we defined two groups of patients: (1) the mechanically aligned group (mechanical axis, 180° ± 3°) and (2) the outlier group (mechanical axis, <177° or >183°). The prevalence of failure was calculated for each of the two groups. Implant survival was estimated with use of the Kaplan-Meier technique as recommended by Tew and Waugh[16]. Confidence intervals at the 95% level were determined[15]. Three end points were defined: (1) revision for any reason, including revision

TABLE I Demographic Data*

Age† *(yr)*	70 ± 8.5 (range, 22 to 89)
Body-mass index† *(kg/m²)*	28.8 ± 4 (range,17.7 to 42.7)
Sex (n = 280)	
Female	138 (49%)
Male	142 (51%)
Etiology (n = 398)	
Osteoarthritis	337 (85%)
Rheumatoid arthritis	30 (8%)
Other‡	31 (8%)
Involvement (n = 280)	
Unilateral	162 (58%)
Bilateral	118 (42%)
Side (n = 398)	
Right	197 (49%)
Left	201 (51%)
Implant type (n = 398)	
Kinematic Condylar II	83 (21%)
Press-Fit Condylar	114 (29%)
GENESIS	201 (51%)

*The data are based on 398 knees in 280 patients. †The values are given as the mean and the standard deviation. ‡Failed osteotomy, systemic disease, posttraumatic arthritis.

for septic and aseptic complications, (2) revision because of mechanical failure, aseptic loosening, radiographic wear, or patellar complications, and (3) revision because of mechanical failure, aseptic loosening, or radiographic wear, with exclusion of patellar complications. An extended Cox model with use of a generalized estimating equation theory was utilized to compare survival by risk factor and to perform a multivariate analysis of survival of implants[15]. These analyses adjusted for the correlation of patients with two knee replacements and were used in all univariate and multivariate significance tests and for the calculation of all 95% confidence intervals[15]. The analysis was done in two parts: (1) analysis of the risk factors that were selected for evaluation before the study was started and (2) analysis of subsets of patients and risk factors that were found to be both significant and clinically interesting in the primary-hypothesis-driven risk-factor analysis[15]. All statistical tests were two-sided, and p values of <0.05 were considered significant.

With use of the approach of Dupont and Plummer[17], a post hoc power analysis was conducted to estimate the minimum sample size needed to observe a significant difference between the aligned group and the outlier group. With regard to the first end point (revision for any reason), the present study was in fact adequately powered to be able to detect a significant difference ($\alpha < 0.05$) with 80% power if the outlier group had a twofold greater risk of failure (a hazard ratio of 2.0). That degree of power would be achieved with study groups comprising at least 264 aligned knees and ninety-eight outlier knees (total, 362 knees).

Source of Funding
There was no external funding for the study.

Results

In 292 knees the postoperative limb alignment was within the range of 0° ± 3° (mechanically aligned group), and in 106 knees the postoperative alignment deviated from the mechanical axis by >3° (outlier group) (see Appendix). The rates of revision according to the three defined end points are reported in Table III. In the univariate exploratory analysis, age (p = 0.002) and body-mass index (p = 0.0127) were the only two factors associated with survival (see Appendix). Sex, preoperative deformity, tibial component position, and femoral component position did not have a substantial effect on survival. Patients with bilateral total knee arthroplasty were not found to be at greater or lesser risk of failure, enabling us to consider each knee independently in the present study.

A postoperative mechanical axis of 0° ± 3° did not confer an advantage in terms of survival, with revision for any reason as the end point, in the multivariate analysis: forty-five (15.4%) of 292 knees were revised in the mechanically aligned group and fourteen (13%) of 106 knees were revised in the outlier group. After adjusting for age and body-mass index, having an outlier beyond 3° of the me-

TABLE II Limb and Implant Alignment

	Preop.*	Postop.*
Hip-knee-ankle angle	174° ± 8.8° (150° to 202°)	180° ± 2.8° (172° to 189°)
Condylar-hip angle	91° ± 2.9° (77° to 103°)	90° ± 1.9° (80° to 99°)
Tibial plateau-ankle angle	86° ± 5.2° (60° to 105°)	90° ± 2.1° (79° to 96°)
D/T ratio†	0.3 ± 0.4 (–1.0 to 1.3)	–0.02 ± 0.13 (–0.4 to 0.4)

*The values are given as the mean and the standard deviation, with the range in parentheses. †D/T ratio = ratio of the distance (D) between the mechanical axis and the center of the knee defined by the midpoint of the tibial plateau width (T).

TABLE III Revisions

	No. of Revisions*		
	End Point 1	End Point 2	End Point 3
Aligned group† (n = 292)	45 (15.4%)	24 (8.2%)	17 (5.8%)
Outlier group‡ (n = 106)	14 (13.2%)	8 (7.5%)	4 (3.8%)
All knees (n = 398)	59 (14.8%)	32 (8.0%)	21 (5.3%)

*End Point 1 = revision for any reason; End Point 2 = revision because of mechanical failure, aseptic loosening, radiographic wear, or patellar complications; and End Point 3 = revision because of mechanical failure, aseptic loosening, or radiographic wear, with exclusion of patellar complications. †Mechanical axis, 180° ± 3°. ‡Mechanical axis, <177° or >183°.

chanical axis was not associated with a significantly increased risk of revision for any reason in comparison with having alignment along the mechanical axis (hazard ratio = 1.05, p = 0.88) (Fig. 1).

A postoperative mechanical axis of 0° ± 3° did not confer an advantage in terms of survival with revision for aseptic loosening, mechanical failure, wear, or patellar problems as the end point in the multivariate analysis: twenty-seven (9.2%) of 292 knees were revised in the mechanically aligned group, and eight (7.5%) of 106 knees were revised in the outlier group. After adjusting for age and body-mass index, having an outlier beyond 3° of the mechanical axis was not associated with an increased risk of revision because of mechanical failure, aseptic loosening, radiographic wear, instability, or patellar failure as compared with having alignment along the mechanical axis (hazard ratio = 1.05, p = 0.88) (Fig. 2).

A postoperative mechanical axis of 0° ± 3° did not confer an advantage in terms of survival with revision because of mechanical failure, aseptic loosening, or radiographic wear (excluding patellar failure) as the end point in the multivariate analysis: seventeen (5.8%) of 292 knees in the mechanically aligned group were revised, compared with four (3.8%) of 106 knees in the outlier group. After adjusting for age and body-mass index, being properly aligned was associated with a 55% increased risk of revision compared with not being properly aligned (hazard ratio = 1.55, p = 0.49) (Fig. 3).

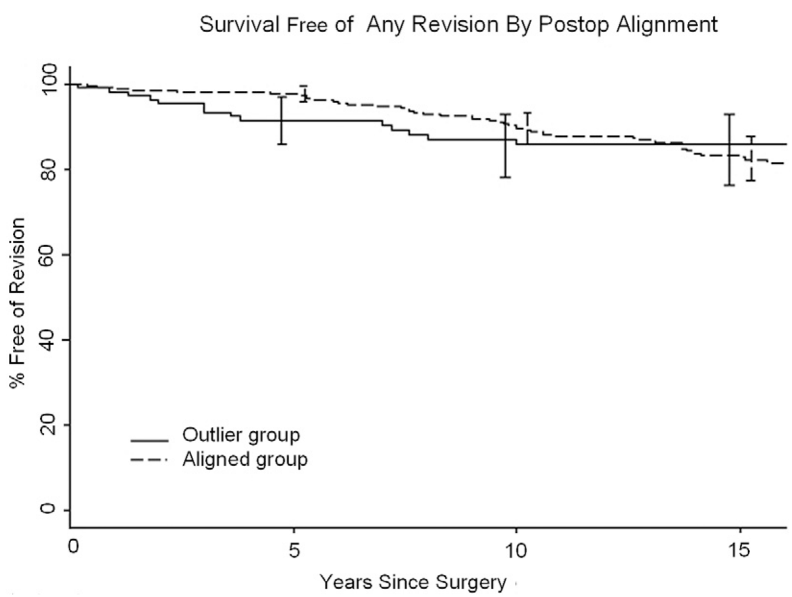

Fig. 1

Kaplan-Meier survival curve with revision for any reason as the end point. At fifteen years, the rate of revision was 15.4% (forty-five of 292) in the aligned group and 13% (fourteen of 106) in the outlier group. After adjusting for age and body-mass index, there was not a significant independent association of alignment with revision (hazard ratio = 1.05, p = 0.88). (With permission of the Mayo Foundation.)

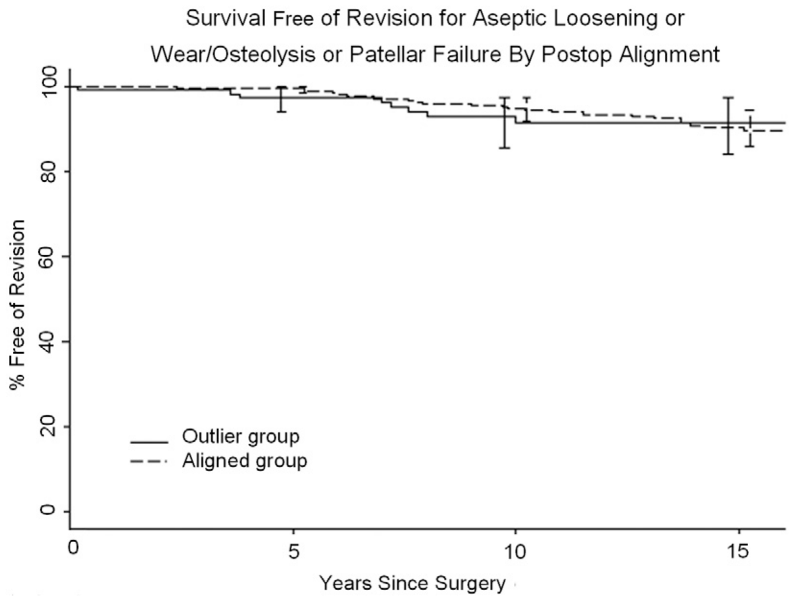

Fig. 2

Kaplan-Meier survival curve with revision because of mechanical failure, aseptic loosening, substantial wear, instability, or patellar failure as the end point. At fifteen years, the rate of revision was 9.2% (twenty-seven of 292) in the aligned group and 7.5% (eight of 106) in the outlier group. After adjusting for age and body-mass index, having an outlier beyond 3° of the mechanical axis was not associated with a significantly increased risk of revision for any reason in comparison with having alignment along the mechanical axis (hazard ratio = 1.05, p = 0.88). (With permission of the Mayo Foundation.)

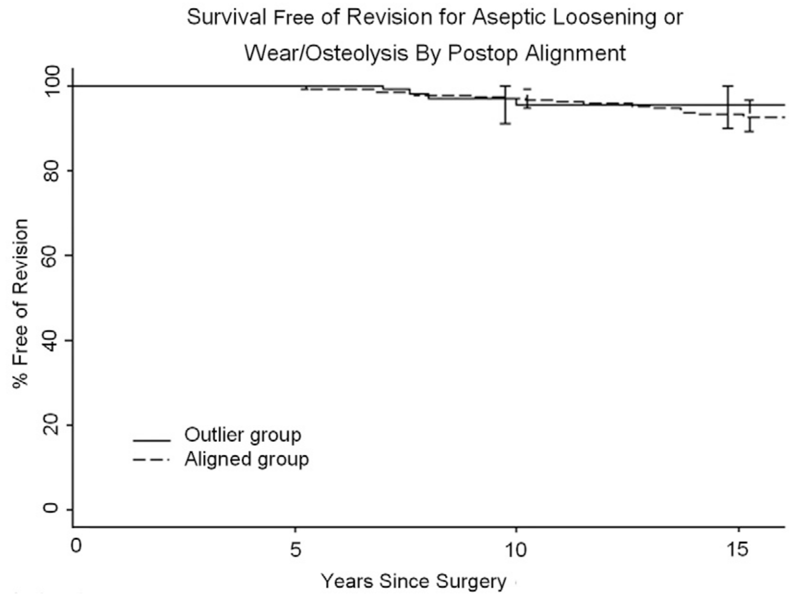

Fig. 3

Kaplan-Meier survival curve with revision because of mechanical failure, aseptic loosening, or substantial wear (excluding patellar failure) as the end point. At fifteen years, the rate of revision was 5.8% (seventeen of 292) in the aligned group and 3.8% (four of 106) in the outlier group. After adjusting for age and body-mass index, proper alignment was associated with a 55% increased risk of revision as compared with improper alignment (hazard ratio = 1.55, p = 0.49. (With permission of the Mayo Foundation.)

Discussion

One long-held goal of total knee arthroplasty has been to achieve a postoperative limb alignment that results in a neutral mechanical axis[1], and the recent clinical introduction of computer navigation has refocused interest on the restoration of lower limb alignment after total knee arthroplasty[2,18]. A basic premise that has been used to justify computer navigation systems has been that restoring limb alignment to a neutral mechanical axis of 0° ± 3° will improve the durability of the implant[2,3,19]. Most studies that have addressed the impact of postoperative coronal alignment on the outcomes of total knee arthroplasty, however, have had substantial limitations, including small numbers of patients, rudimentary implant designs, or radiographs that have included only the knee and thus have not allowed for the assessment of overall limb alignment[1,4-8,18,20]. Despite those clear limitations, most surgeons have accepted the premise that deviation beyond a postoperative mechanical axis of 0° ± 3° is associated with worse implant survival following total knee arthroplasty[2,18,19,21]. While finite model analysis[22], in vitro studies involving a knee simulator[23], and cadaver studies[24,25] have supported the contention that a mechanical axis of 0° ± 3° results in more favorable knee loading, there have been few long-term clinical studies[1,4,7,18,26]. Given that a target of 0° ± 3° is a relatively broad and generic target that does not account for patient-specific differences in gait dynamics, it is reasonable to ask if hitting that broad, generic target provides a clinically meaningful improvement in long-term durability after total knee arthroplasty.

Tew and Waugh previously suggested that while postoperative limb alignment was one factor for determining durability, factors other than alignment might be more important for determining long-term survival following total knee arthroplasty[16]. A recent review by Sikorski[18] concluded that there was a clear need for studies that measured alignment soon after the initial procedure and then provided ten to fifteen years of clinical follow-up to confirm the relationship between alignment and implant longevity following contemporary total knee arthroplasty. In the present study of 398 total knee arthroplasties, we did not find a significant or clinically meaningful difference in the fifteen-year survival of knees that were mechanically aligned (those that had alignment within 0° ± 3° of the mechanical axis postoperatively) and knees that were outliers (those that had alignment outside of 0° ± 3° of the mechanical axis postoperatively). That finding is important in the current clinical environment because it implies that the use of a computer navigation system to more consistently align total knee implants within 0° ± 3° of the mechanical axis would not have improved the fifteen-year durability of the total knee implants in this group of patients.

It is important to underscore the focused findings of the present study. Because alignment in the present study, as in most contemporary studies of alignment, was assessed as a dichotomous variable (the mechanically aligned group versus the outlier group), one cannot and should not infer from or extrapolate from these findings to uniformly state that alignment is not important after total knee arthroplasty. Instead, what the present study demonstrated was that when alignment was defined as a traditional broad target of a neutral mechanical axis ±3°, there was no marginal improvement in terms of survival at fifteen years when that target was hit (mechanically aligned group) as compared with when it was missed (outlier group). It may be that the traditional definition of a well-aligned total knee implant (mechanical axis, 0° ± 3°)[1,7] is simply too broad and imprecise to be clinically meaningful in the setting of contemporary total knee arthroplasty. Current-generation knee instrumentation allows most surgeons to achieve a mechanical axis of 0° ± 3° in the majority of patients, with most of the remaining outliers positioned just 1° or 2° from those boundaries[21,27]. Given the complex, multidimensional, dynamic impact of gait on in vivo knee joint loading[22,23] it seems reasonable to postulate that for any given patient there may be a specific target value for postoperative alignment that will best distribute load across the site of the total knee arthroplasty. For most patients, that specific target value likely falls within the mechanical axis range of 0° ± 3°. However, any individual patient may have a combination of muscular issues (e.g., frank weakness), skeletal issues (e.g., fixed pelvic deformity), or neurologic issues (e.g., balance or proprioception loss) that impact gait and thus alter the dynamic loading of the knee joint[18]. If ideal alignment is influenced by an individual patient's dynamic gait pattern, one can quickly understand the limitations of defining alignment as a dichotomous variable[28].

The present study had some specific limitations, particularly the inability to more precisely define the ideal target values for alignment after total knee arthroplasty, and that should be the focus of future scientific inquiry. Furthermore, like most studies of alignment after total knee arthroplasty, the present study focused on the static, coronal plane alignment and did not specifically evaluate either sagittal plane or rotational alignment or the combined effects of coronal, sagittal, and rotational alignment or the dynamic impact of gait on alignment[18]. Similarly, we did not investigate the dynamic alignment of the limb in either the coronal or sagittal planes or in rotation after total knee arthroplasty[29-31]. Despite these limitations, the present study is, to our knowledge, the largest study to investigate the impact of postoperative mechanical axis alignment on fifteen-year implant survival following modern total knee arthroplasty.

In conclusion, in this large retrospective clinical series, a postoperative mechanical axis of 0° ± 3° did not improve implant survival at the time of the fifteen-year follow-up for these 398 modern, cemented, condylar total knee replacements. Efforts to more consistently achieve mechanical axis alignment of 0° ± 3°, as is currently done with contemporary computer navigation systems, seem unlikely to be rewarded with substantial improvements in implant survival following total knee arthroplasty as compared with that achieved when traditional total knee instruments are employed mindfully. However, until additional data can be generated to more accurately determine the ideal postoperative limb alignment in individual patients, a neutral mechanical axis remains a reasonable target and should be considered as the standard for comparison if other alignment targets are introduced.

Appendix

eA Supporting data tables and a figure depicting the postoperative distribution around the mechanical axis are available with the electronic version of this article on our web site at jbjs.org (go to the article citation and click on "Supporting Data"). ■

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