**A commentary by James Toshio Ninomiya, MD, MS,** is linked to the online version of this article at jbjs.org.

# Effect of Postoperative Mechanical Axis Alignment on Survival and Functional Outcomes of Modern Total Knee Arthroplasties with Cement

## A Concise Follow-up at 20 Years*

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**Abstract:** We previously compared the 15-year survivorship of total knee arthroplasty (TKA) implants that were mechanically aligned (0° ± 3° relative to the mechanical axis) compared with those that were outside that range and considered outliers. The original publication included 398 TKAs (292 in the aligned group and 106 in the outlier group) performed from 1985 to 1990. At the time of follow-up in the previous study, 138 patients (155 TKAs) had died and 59 knees had been revised. Since that publication, 49 additional patients (87 knees) have died. At 20 years, 57 (19.5%) of the 292 knees in the mechanically aligned group had been revised compared with 16 (15.1%) of the 106 knees in the outlier group ($p = 0.97$). Postoperative alignment within 0° ± 3° of the mechanical axis did not provide a functional advantage at 1, 5, 10, 15, and/or 20 years postoperatively as demonstrated by the Knee Society scores being similar between the groups ($p \geq 0.2$ at all intervals). At 20 years, we once again did not find that neutral mechanical alignment provided better implant survivorship than that found in the outlier group.

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

## Background

The effect of coronal plane alignment on durability and function after total knee arthroplasty (TKA) continues to be debated[1-10]. Several studies have indicated that coronal plane alignment deviating more than 0° ± 3° from the mechanical axis is a risk factor for decreased implant survivorship and for functional impairment[1-5]. Much of the literature on TKA alignment and survivorship is several decades old[1-4]. In our previous report of 398 knees, we found no difference in 15-year survivorship between TKA implants that were mechanically aligned (within 0° ± 3° of the mechanical axis) and those that were outside that range[6]. That finding has been cited widely and, subsequent to its publication, there has been renewed interest in alternatives to the mechanical axis as a target for contemporary TKAs. Most notable has been the emergence of so-called kinematic or anatomic alignment targets for TKA[11-15]. Advocates of a kinematic alignment philosophy argue that better patient function can be obtained with no decrement in the durability of the TKA as compared with TKA done with a mechanical axis target[13-15]. Because our previous publication did not report functional outcomes, we thought it appropriate to update our data to reflect the impact of mechanical axis alignment on both durability and function after 20 years of follow-up. We hypothesized that postoperative alignment within 0° ± 3° of the mechanical axis would result in better TKA implant survival and better function than would postoperative alignment outside that range.

**Original Publication:* 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 Sep 15;92(12):2143-9.

**Disclosure:** There was no external funding for this study. On the **Disclosure of Potential Conflicts of Interest** forms, *which are provided with the online version of the article*, one or more of the authors checked "yes" to indicate that the author had a relevant financial relationship in the biomedical arena outside the submitted work and "yes" to indicate that the author had a patent and/or copyright, planned, pending, or issued, broadly relevant to this work (http://links.lww.com/JBJS/E581).

**TABLE I Summary of Results**

| | Univariate* | | Multivariate† | |
|---|---|---|---|---|
| End Point‡/Risk Factor | HR (95% CI) | P Value | HR (95% CI) | P Value |
| End point 1 | | | | |
| Age at surgery (per yr) | 0.95 (0.93, 0.97) | <0.001 | 0.95 (0.93, 0.97) | <0.001 |
| BMI (per kg/m$^2$) | 1.05 (1.02, 1.09) | 0.005 | 1.04 (1.01, 1.08) | 0.026 |
| Male (versus female) | 0.85 (0.53, 1.35) | 0.494 | 0.93 (0.57, 1.49) | 0.753 |
| Outlier (versus aligned)§ | 0.95 (0.55, 1.66) | 0.858 | 0.99 (0.56, 1.75) | 0.979 |
| End point 2 | | | | |
| Age at surgery (per yr) | 0.94 (0.92, 0.96) | <0.001 | 0.94 (0.92, 0.97) | <0.001 |
| BMI (per kg/m$^2$) | 1.07 (1.04, 1.11) | <0.001 | 1.06 (1.03, 1.10) | 0.001 |
| Male (versus female) | 0.87 (0.48, 1.57) | 0.633 | 1.04 (0.56, 1.93) | 0.912 |
| Outlier (versus aligned)§ | 1.07 (0.54, 2.11) | 0.849 | 1.01 (0.49, 2.07) | 0.984 |
| End point 3 | | | | |
| Age at surgery (per yr) | 0.93 (0.91, 0.96) | <0.001 | 0.93 (0.90, 0.96) | <0.001 |
| BMI (per kg/m$^2$) | 1.08 (1.03, 1.13) | 0.001 | 1.07 (1.02, 1.11) | 0.004 |
| Male (versus female) | 0.73 (0.35, 1.51) | 0.397 | 0.89 (0.42, 1.91) | 0.771 |
| Outlier (versus aligned)§ | 0.98 (0.42, 2.27) | 0.955 | 0.81 (0.32, 2.03) | 0.652 |

*The risk factors were analyzed individually in the univariate model. †The risk factors were analyzed simultaneously in the multivariate model. ‡End point 1 = revision for any reason; end point 2 = revision because of mechanical failure, aseptic loosening, radiographic evidence of wear, or patellar complications; and end point 3 = revision because of mechanical failure, aseptic loosening, or radiographic evidence of wear, with exclusion of patellar complications. §The aligned knees had a mechanical axis of 180° ± 3°, and the outlier knees had a mechanical axis of <177° or >183°.

## Methods

After obtaining institutional review board approval, we performed a retrospective review to determine the effect of coronal plane alignment on long-term implant survival and function following 398 primary TKAs done with cement in 280 patients. This was a consecutive series of patients who met the following inclusion criteria: (1) primary TKA done in the period from 1985 to 1990, (2) performance of the TKA by the same surgeon who performed all TKAs in the series, (3) use of 1 of 3 modern unconstrained implant designs, (4) cementing of all components and the use of an all-polyethylene patellar component, and (5) availability of preoperative and postoperative full-length hip-knee-ankle radiographs. During the study period, only 19 knees in 15 patients were excluded because full-length hip-knee-ankle radiographs were not available.

The indications for the procedure, TKA designs, description of the procedure, and outcomes evaluation[16-18] in the initial series were published in 2010[6].

At the last follow-up, the available reasons for reoperations or revisions were identified with specific chart review by 2 independent observers (M.P.A. and M.O.). Preoperative and postoperative functional outcomes were assessed using the Knee Society function and knee scores[19].

In the original series, 138 patients (155 knees; 38%) had died and 59 knees (14%) had been revised at the time of the follow-up, leaving 184 knees for analysis. Since that publication, 49 additional patients (87 knees) have died, leaving 97 knees available for analysis.

### *Statistical Methods*

As described in the initial report[6], we defined 2 groups: (1) the mechanically aligned group (mechanical axis, 0° ± 3°) and (2) the outlier group (mechanical axis, >3° of varus or >3° of valgus) (see Appendix Fig. E-1 in the original publication[6]). The prevalence of failure was calculated for each of the 2 groups. Implant survival was estimated with use of the Kaplan-Meier technique[20]. Confidence intervals (CIs) at the 95% level were determined[20].

**TABLE II Revision Rates 20 Years After TKA**

| | No. of Revisions* | | |
|---|---|---|---|
| | End Point 1 | End Point 2 | End Point 3 |
| Aligned group† (n = 292) | 57 (19.5%) | 34 (11.6%) | 24 (8.2%) |
| Outlier group† (n = 106) | 16 (15.1%) | 11 (10.4%) | 7 (6.6%) |
| All knees (n = 398) | 73 (18.3%) | 45 (11.3%) | 31 (7.7%) |

*End point 1 = revision for any reason; end point 2 = revision because of mechanical failure, aseptic loosening, radiographic evidence of wear, or patellar complications; and end point 3 = revision because of mechanical failure, aseptic loosening, or radiographic evidence of wear, with exclusion of patellar complications. †The aligned knees had a mechanical axis of 180° ± 3°, and the outlier knees had a mechanical axis of <177° or >183°.

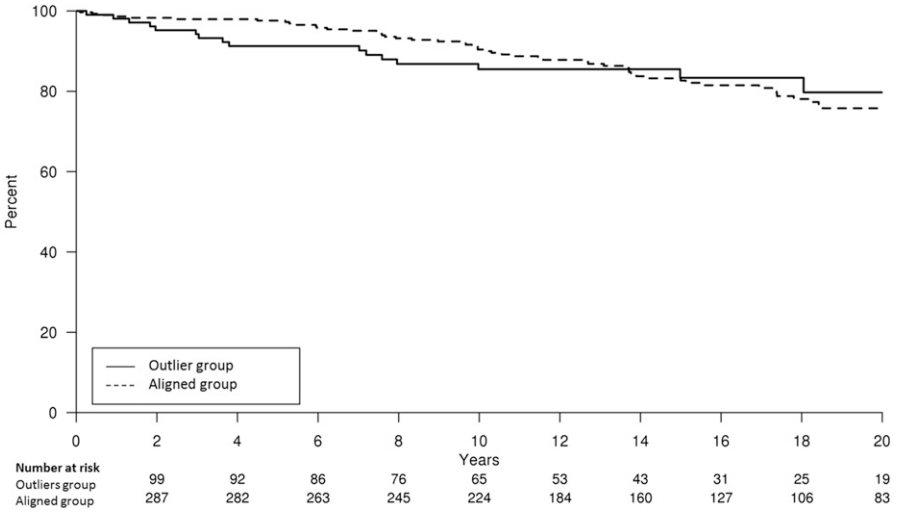


Fig. 1

Kaplan-Meier survival curve with revision for any reason as the end point. At 20 years, the rate of revision was 19.5% (57 of 292) in the aligned group and 15.1% (16 of 106) in the outlier group. After adjustment for age and BMI, there was not a significant independent association of alignment with revision (HR = 0.99; p = 0.97).

End points were selected on the basis of our initial protocol[6]. Two-sample t tests were used to compare the aligned and outlier cohorts with respect to Knee Society scores and other continuous variables. All statistical tests were 2-sided, and p values of <0.05 were considered significant. All analyses were performed using SAS version 9.4 (SAS Institute) and R version 3.1.1 (R Core Team, R Foundation for Statistical Computing).

## Results

The postoperative limb alignment was within the range of 0° ± 3° relative to the mechanical axis in 292 knees (mechanically aligned group) and deviated from the mechanical axis by >3° in 106 knees (outlier group) (see Appendix Fig. E-1 in the original publication[6]). Both age at surgery ($p < 0.001$) and body mass index (BMI) ($p < 0.05$) were inversely related to 20-year implant survivorship at end point 1 (revision or implant removal for any reason), end point 2 (revision due to mechanical failure, aseptic loosening, radiographic evidence of wear, or patellar complications), and end point 3 (revision for mechanical failure, aseptic loosening, or radiographic evidence of wear, with exclusion of patellar complications) (Table I). Patient sex, preoperative deformity, tibial component position, and femoral component position did not have a demonstrable effect on implant survival.

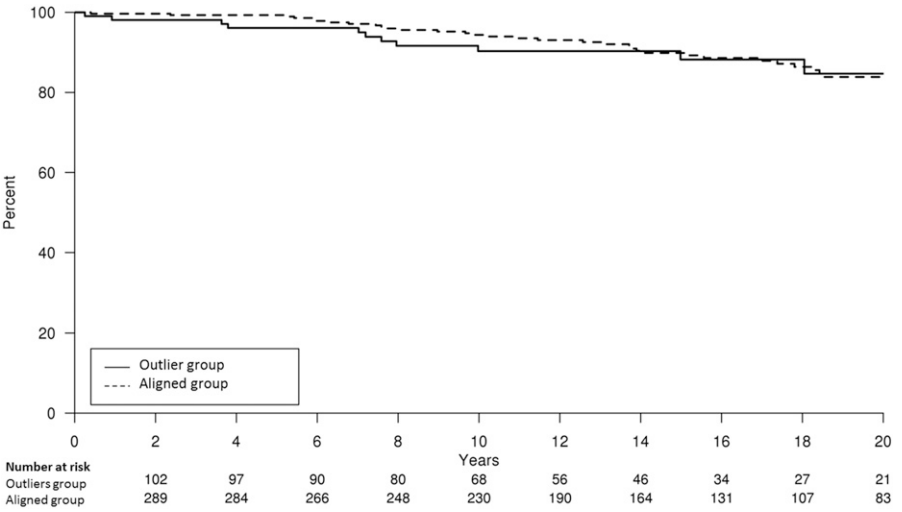


Fig. 2

Kaplan-Meier survival curve with revision due to mechanical failure, aseptic loosening, radiographic evidence of wear, or patellar complications as the end point. At 20 years, the rate of revision was 11.6% (34 of 292) in the aligned group and 10.4% (11 of 106) in the outlier group. After adjustment for age and BMI, there was not a significant independent association of alignment with revision (HR = 1.01; p = 0.98).

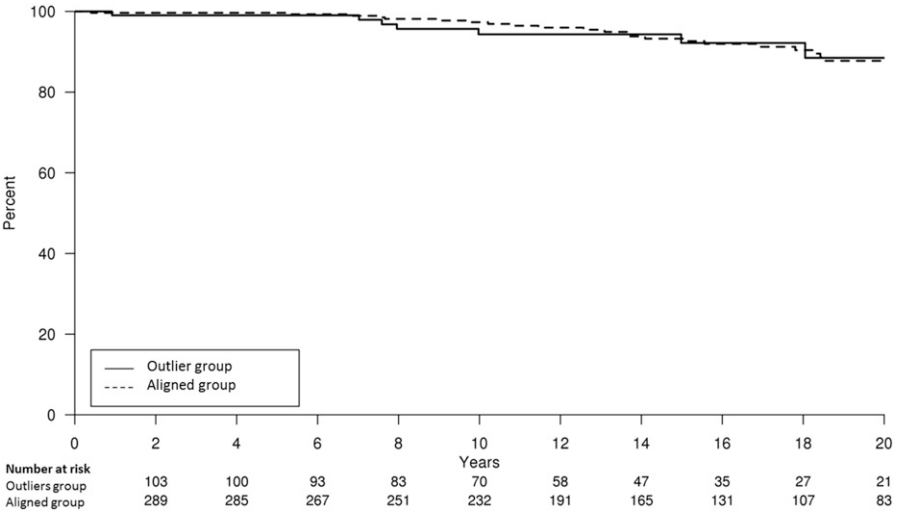


Fig. 3

Kaplan-Meier survival curve with revision due to mechanical failure, aseptic loosening, or radiographic evidence of wear (excluding patellar complications) as the end point. At 20 years, the rate of revision was 8.2% (24 of 292) in the aligned group and 6.6% (7 of 106) in the outlier group. After adjustment for age and BMI, there was not a significant independent association of alignment with revision (HR = 0.81; p = 0.652).

Multivariate analysis showed that a postoperative alignment within 0° ± 3° of the mechanical axis did not improve implant survival at 20 years with use of end point 1 (57 [19.5%] of the 292 knees in the mechanically aligned group were revised compared with 16 [15.1%] of the 106 knees in the outlier group), end point 2 (34 [11.6%] compared with 11 [10.4%]), or end point 3 (24 [8.2%] compared with 7 [6.6%]) (Table II). After adjustment for age and BMI, deviation from the mechanical axis by >3° was still not associated with a significantly increased risk of revision at end point 1 (hazard ratio [HR] = 0.99, 95% CI = 0.56 to 1.75; p = 0.98 [Fig. 1]), end point 2 (HR = 1.01, 95% CI = 0.49 to 2.07; p = 0.98 [Fig. 2]), or end point 3 (HR = 0.81, 95% CI = 0.32 to 2.03; p = 0.652 [Fig. 3]). The 20-year survivorship free of revision for any reason was similar for the aligned (75.8%) and outlier (79.7%) groups (p = 0.97).

The mean Knee Society function and knee scores were similar in the aligned and outlier groups preoperatively (p = 0.5 for both function and knee scores) and at 1 year (p = 0.2 and 0.8, respectively), 5 years (p = 0.6 and 0.8), 10 years (p = 0.9 and 0.7), 15 years (p = 0.4 and 0.3), and 20 years (p = 0.8 and 0.7) after the TKA (Figs. 4 and 5).

## Conclusions

Achieving postoperative lower-limb alignment that results in a neutral mechanical axis has been a long-held tenet that continues to guide the surgical techniques employed in most TKAs. Neutral mechanical lower-limb alignment is close

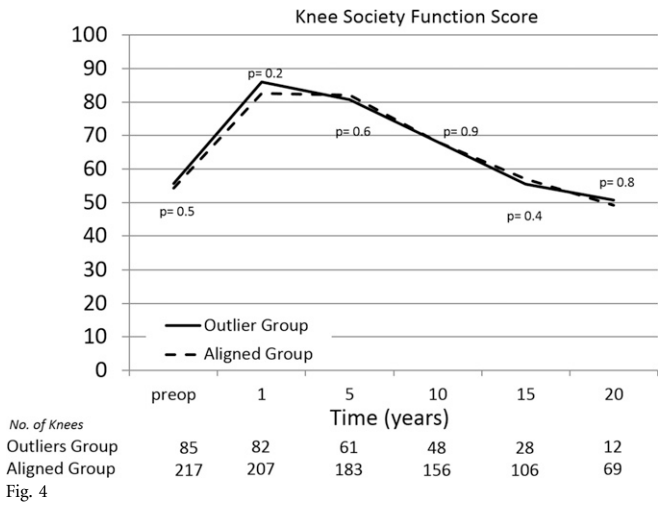


Fig. 4

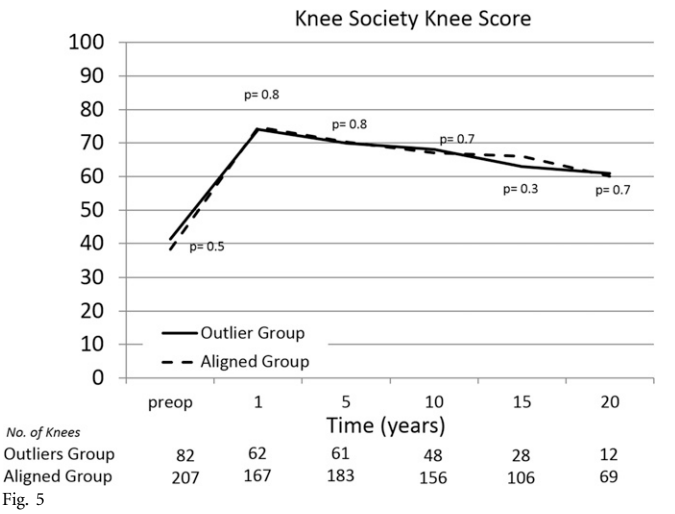


Fig. 5

**Fig. 4** Knee Society function scores were similar between the aligned and outlier groups at all investigated time points, including 20 years. **Fig. 5** Knee Society knee scores were similar between the aligned and outlier groups at all investigated time points, including 20 years.

to the midpoint in the distribution of normal limb alignments observed in nonarthritic patients and typically results in a limb that is also aesthetically pleasing to patients and surgeons alike. Despite clear limitations of the available scientific data, most surgeons believe that a neutral mechanical axis also confers a substantial advantage in terms of TKA implant survivorship. In recent years, some of the focus of intellectual interest in TKA has moved away from questions of durability and toward questions of function. The introduction of alternative TKA alignment philosophies that prioritize better function, such as so-called kinematic alignment, makes it particularly important that the collective orthopaedic community understands the long-term effects of postoperative mechanical axis alignment on both implant survival and functional outcomes.

The present study did not demonstrate a statistically significant or clinically meaningful difference in the 20-year survival between knees that were mechanically aligned and those that were outliers. That information is useful in the current clinical environment in which computer navigation and robotic technologies may be employed in pursuit of disparate goals—i.e., hitting mechanical axis targets more precisely and pursuing alternative alignment targets. While some registry-based data have suggested that use of computer navigation for TKA improves implant survival[21], our current findings suggest that, if it does, the improvement is not explained by higher accuracy in achieving a neutral mechanical axis. We remain influenced by the prior work by Tew and Waugh[22], who suggested that factors other than alignment might be more important in determining long-term survival of TKA implants. That contention is supported by the results reported by Bonner et al.[10], who found no difference in 10-year survivorship free of aseptic loosening between 227 neutrally aligned and 43 outlier TKAs ($p = 0.47$) (Table III). Similarly, in a study of 197 TKAs (153 patients), Morgan et al.[8] found no difference in survivorship free from revision at 10 years among 3 groups based on postoperative tibiofemoral angle: neutral (4° to 9° of valgus), valgus (≥9.1° of valgus), or varus (≤3.9° of valgus). Other data of interest were presented by Berend et al.[23], Ritter et al.[24], and Fang et al.[25], who all reported the results in a similar cohort (6,070 knees) at 3 different time points. However, those authors evaluated anatomic knee joint alignment, not mechanical axis alignment, because full-length standing radiographs were not available. At a mean of 7 years, they did find a higher failure rate in patients with excessive femoral component valgus (≥8° of valgus) and excessive tibial component varus (<90° relative to the estimated tibial mechanical

**TABLE III Summary of Literature Regarding TKA Implant Survivorship and Functional Outcomes Based on Alignment**

| Study | No. of Knees (Aligned/Outlier) | Radiographic Modality | Type of Implants | Mean Follow-up *(yr)* | Rate of Revision for Any Reason (Aligned/Outlier) *(%)* | Last Clinical Outcome Score* (Aligned/Outlier) |
|---|---|---|---|---|---|---|
| Morgan et al.[8] (2008) | 73/124 | Long-leg radiographs | Cruciate-retaining | 9 | 4.1/2.4 | — |
| Parratte et al.[6] (2010) | 292/106 | Long-leg radiographs | Cruciate-retaining | 15 | 15.4/13.2 | — |
| Fang et al.[25] (2009) | 4,029/2,041 | Short-leg radiographs | Cruciate-retaining | 6.6 | 0.5/1.4† | — |
| Choong et al.[26] (2009) | 83/32 | Long-leg radiographs | Cruciate-retaining | 1 | — | 168/135 (IKS)† |
| Longstaff et al.[27] (2009) | 94/41 | CT scan | Cruciate-retaining | 1 | — | 69.5/59.1 (KSS function)† |
| Matziolis et al.[7] (2010) | 154/25 | Long-leg radiographs | Cruciate-retaining | 5 | — | 158/142 (KSS)† |
| Ritter et al.[24] (2011) | 4,310/1,760 | Short-leg radiographs | Cruciate-retaining | 7.6 | 0.65/1.5† | — |
| Magnussen et al.[9] (2011) | 336/181 | Long-leg radiographs | Posterior stabilized | 5.8 | 3.7/1.6 | 168.5/172 (IKS) |
| Bonner et al.[10] (2011) | 227/43 | Long-leg radiographs | Cruciate-retaining | 10 | 5/14, aseptic loosening | — |
| Howell et al.[14] (2015) | 154/57 | CT scan | Cruciate-retaining | 6 | — | 42/43 (OKS) |
| Present study (2018) | 292/106 | Long-leg radiographs | Cruciate-retaining | 20 | 19.5/15 | 50.7/49.2 (KSS function) |

*IKS = International Knee Society score, KSS = Knee Society score, and OKS = Oxford Knee Score. †The difference between the aligned and outlier groups was found to be significant ($p < 0.05$).

axis). Importantly, this resulted in only a 1% difference in implant survivorship between aligned (99%) and outlier (98%) knees at 10 years[24].

Few authors have correlated postoperative function with mechanical axis alignment after TKA, and those who did reported relatively short-term results[8,9,24,26,27]. Choong et al.[26] found better International Knee Society and Short Form-12 physical functioning scores at 6 weeks, 3 months, 6 months, and 12 months postoperatively for 83 knees with a neutral alignment (within 0° ± 3°) than for 32 outlier knees. Longstaff et al.[27] identified trends for better function of 94 knees "with good sagittal and rotational femoral alignment and good sagittal and coronal tibial alignment" on postoperative computed tomography (CT) compared with 41 outlier knees 1 year after surgery. In contrast, Magnussen et al.[9] found no difference in International Knee Society scores between knees with mechanical axis alignment (0° ± 3°; 336 knees) and those with an outlier mechanical axis (outside that range; 181 knees) at a mean of 5.8 years after TKA. Also in contrast, Howell et al.[14] reported that 57 outlier knees (alignment outside the 0° ± 3° range) and 154 knees with neutral mechanical alignment (0° ± 3°) had equivalent Oxford Knee Scores and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores at 6 years postoperatively. In the present study, we found that postoperative alignment within 0° ± 3° of the mechanical axis did not confer an advantage in terms of functional outcome as measured with the Knee Society knee or function score at any time point up to 20 years when compared with outliers (Table III).

The present study has limitations. Of particular note is the inability to determine the ideal coronal plane alignment target from these data. Furthermore, our analysis of alignment, like most studies to date, was confined to a static 2-dimensional assessment on radiographs. More complete information in the future may come from 3-dimensional analysis that includes sagittal and rotational plane measurements as well as dynamic analysis under functional loads. In addition, it is useful to recognize that the outliers in this series had only modest angular deviation from neutral (typically 4°, 5°, or 6° of mechanical varus or valgus), but that reflects the typical real-world scenario as few surgeons would deliberately leave a TKA implant in substantially more angulation. Finally, as with many long-term follow-up studies in an elderly cohort, a number of patients had died prior to the 20-year follow-up. Despite its limitations, we believe that this is the largest study of the impact of mechanical axis alignment on 20-year implant survival and function following modern TKA.

In conclusion, in this large retrospective clinical series, postoperative alignment of 0° ± 3° relative to the mechanical axis did not improve implant survival and was not associated with better function at any time during a 20-year follow-up. Efforts to improve the durability and functional results of TKA by simply focusing on more consistent mechanical axis alignment are unlikely to deliver clinically important benefits. The initiative to use computer and robotic inputs to achieve this goal may not be cost-effective. These data do not suggest that surgeons should be cavalier about alignment in TKA as the goal of each of these procedures was to correct the mechanical axis to neutral. While a failure to achieve that neutral mechanical axis did not adversely affect durability or function, we are unable to comment on whether deliberately aiming for another target would be good, bad, or indifferent. A neutral mechanical axis remains a useful target for contemporary TKAs and should be considered the standard for comparison if and when other alignment targets are studied. ■

NOTE: The authors acknowledge Dirk R. Larson, MS, and Kristin M. Fruth for their statistical expertise.

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