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The effect of post-operative mechanical axis alignment on the survival of primary total knee replacements after a follow-up of 15 years

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Correct positioning and alignment of components during primary total knee replacement (TKR) is widely accepted to be an important predictor of patient satisfaction and implant durability. This retrospective study reports the effect of the post-operative mechanical axis of the lower limb in the coronal plane on implant survival following primary TKR.

A total of 501 TKRs in 396 patients were divided into an aligned group with a neutral mechanical axis ($\pm 3^\circ$) and a malaligned group where the mechanical axis deviated from neutral by $> 3^\circ$. At 15 years' follow-up, 33 of 458 (7.2%) TKRs were revised for aseptic loosening. Kaplan-Meier survival analysis showed a weak tendency towards improved survival with restoration of a neutral mechanical axis, but this did not reach statistical significance ($p = 0.47$).

We found that the relationship between survival of a primary TKR and mechanical axis alignment is weaker than that described in a number of previous reports.

Total knee replacement (TKR) is reported to achieve high patient satisfaction, improved function, pain relief and $> 90\%$ implant survival at 15 years.¹⁻³ Despite this, some patients subsequently undergo revision surgery for a range of causes, including infection, loosening, instability, pain, fracture, stiffness and global dissatisfaction.^{4,5} Recognised reasons for variations in survival include differences in implant design, type of fixation, indication for TKR, surgical technique and patient factors.⁶ There is wide acceptance that one aspect of surgical technique which significantly affects patient satisfaction and implant survival is correct positioning and alignment of the components.⁷ The mechanical axis of the limb in the coronal plane and its effect on function and survival has been reported more than any other alignment parameter.⁸⁻¹⁰ The mechanical axis of the limb has been defined as the angle between one line drawn from the centre of the femoral head to the deepest part of the femoral notch at the knee, with a second line drawn from the midpoint of the tibial plateau to the midpoint of the inner extension of the tibio-talar joint. The apparent benefits of achieving a neutral mechanical axis (angle of 0°) of the lower limb during TKR surgery has encouraged surgeons and manufacturers to invest time and resources into achieving this alignment target.¹¹

Computer-navigated TKR is reported to improve the overall accuracy of positioning of the tibial and femoral components.¹²⁻¹⁴

However, an acceptable target for alignment remains a matter for debate. A mechanical axis within 3° of neutral has been used as the primary outcome measure in many clinical trials comparing computer-navigated and conventional TKR.¹⁵⁻¹⁷ However, the evidence supporting this arbitrary value is unreliable because previous reports are limited by their small sample size, inadequate radiographs, short follow-up and lack of clarity when defining a margin of accuracy.^{8,9,18} The need for further research to establish the effect of the alignment of the components in TKR on the outcome has already been identified, and is especially noteworthy as health-care commissioners begin to evaluate the added cost and resources needed for computer-navigated TKR.^{7,19,20} The cost-benefit analysis of computer-navigated *versus* conventional TKR is dependent upon the assumed impact of malalignment on the probability and timing of revision surgery. The aim of this study was to evaluate whether correction of the mechanical axis of the lower limb to within 3° of neutral is a prognostic marker for later revision surgery due to aseptic loosening. To our knowledge, this is the largest series of prospectively collected data and long-term follow-up pertaining to this important facet of TKR surgery.

Patients and Methods

This was a retrospective comparative review of radiological measurements and clinical data

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©2011 British Editorial Society of Bone and Joint Surgery
doi: 10.1302/0301-620X.93B9.26573 \$2.00

J Bone Joint Surg Br
2011;93-B:1217-22.
Received 21 December 2010;
Accepted after revision 17 May 2011

Table I. Demographic data of the 458 total knee replacements

Demographic details	
Mean age (range) (years)	70 (41 to 88)
Gender (n, %)	
Male	197 (43)
Female	261 (57)
Side (n, %)	
Left	209 (46)
Right	249 (54)
Type of fixation (n, %)	
Cemented	274 (60)
Cementless	184 (40)
Primary pathology (n, %)	
Osteoarthritis	422 (92)
Rheumatoid arthritis	36 (8)

collected prospectively as part of a previously reported randomised controlled trial assessing cemented *versus* cementless primary TKR^{21,22} using the Press Fit Condylar (PFC) cruciate-retaining TKR (Johnson & Johnson Professional Inc., Raynham, Massachusetts). In the original investigation the pre- and post-operative mechanical axis of each lower limb was measured prospectively. In brief, between 1987 and 1997, 599 consecutive knees in 481 patients were considered for inclusion in the trial. In all, 98 knees (85 patients) were excluded because of either gross osteoporosis, insufficiently accurate bone cuts for cementless fixation, bone defects requiring grafting, errors of randomisation, availability of a prosthesis, no consent or bleeding anomalies. The remaining 501 knees (396 patients) entered into the trial with complete survival data available for analysis.

The primary outcome measure was either implant survival or revision due to aseptic loosening. Revision surgery was defined as further surgery to exchange either the polyethylene insert, the femoral component or the tibial tray. Other causes of revision were excluded because they did not fit the hypothesis that malalignment leads to excessive wear, eccentric loading and aseptic loosening. Knees were also excluded if the post-operative mechanical axis had not been recorded prospectively in the original trial. This left 458 TKRs (362 patients) available for analysis. Demographic data and surgical characteristics are summarised in Table I.

Surgical technique and peri-operative care. All procedures were performed either by the senior author (PJG) or under his supervision using a midline longitudinal incision and a medial parapatellar approach. The bone cuts were directed using the manufacturer's intramedullary jig for the distal femur and extramedullary jig for the proximal tibia, with the intention of obtaining a neutral mechanical axis, which was tested using guide rods placed through the cutting blocks or trial components. The posterior cruciate ligament was resected only when there was a marked fixed flexion deformity. A balanced flexion-extension gap was confirmed before components were implanted. The PFC system

consisted of a cobalt-chrome femoral component articulating with a polyethylene insert mounted on a fixed-bearing titanium tibial tray. Both cemented and cementless components had identical surface geometries and were secured according to the manufacturer's recommended technique. Generally an 8 mm polyethylene insert was used, although occasionally a 10 mm insert was necessary to achieve stability. The patella was not resurfaced. Each patient had antibiotic prophylaxis but no chemical thromboprophylaxis. After surgery the knee was immobilised in a Robert Jones bandage²³ for 48 hours, before a standardised rehabilitation programme was started.

Radiological and clinical assessment. All patients had pre-operative and six-month post-operative long leg antero-posterior alignment weight-bearing radiographs according to a standardised protocol. The mechanical axis was measured using a purpose-made protractor with long arms and 1 mm increments, held against each plain radiograph. The angle was made between 2 lines, the first aligned from the centre of the femoral head to the deepest part of the femoral notch at the centre of the knee joint, and the second from the midpoint of the inner extension of the tibio-talar joint to the midpoint of the widest part of the tibial component.¹¹ All measurements were performed and recorded prospectively by a single observer (PJG).

Patients had a clinical assessment pre-operatively, then at six months, one year, and annually until five years. Thereafter, all patients were contacted annually by telephone to establish the status of the TKR. Data related to the survival or revision of the prosthesis for this study was established during a period between November 2003 and December 2004. General practitioners' records, hospital notes and telephone conversations with relatives were used to establish implant survival if the patient had died.

Statistical analysis. A comparative analysis was performed between an 'aligned' group where the mechanical axis was neutral $\pm 3^\circ$ and a 'malaligned' group where the mechanical axis was $> 3^\circ$ from neutral. SPSS version 19 (SPSS Inc., Chicago, Illinois) was used for statistical analysis. Continuous numerical data were expressed as the mean and standard deviation (SD). Parametric data were compared using two-sided Student's *t*-tests. The 15-year survival data of the 458 TKRs in this study were compared using the Kaplan-Meier technique. The log-rank test was used to test the difference in survival between each group. Survival time and revision due to aseptic loosening ten years after the primary TKR were also expressed as categorical data. The chi-squared test and Fisher's exact test were used to compare categorical data. Absolute risk reduction and numbers needed to treat were estimated from the categorical data analysis. Statistical significance was set at $p < 0.05$.

Results

Complete survival data were available for all patients. At the latest review in 2004, 182 patients (232 TKRs) had died. In addition, two TKRs had been lost to above-knee

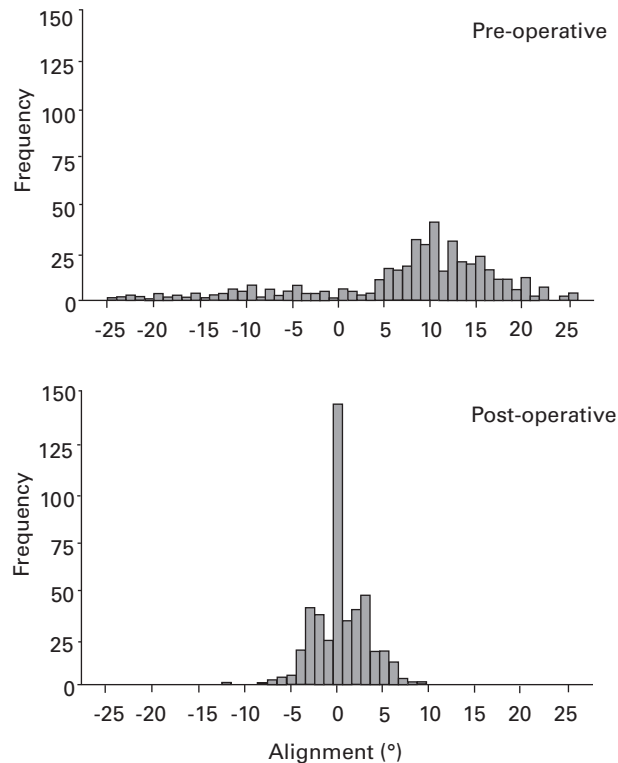


Fig. 1

Histograms of pre- and post-operative mechanical axis alignment of the knees (x-axis limited to $\pm 25^\circ$). Positive values on the x-axis indicate a varus mechanical axis alignment.

amputation, one following a fracture of the femur and one due to infection in a diabetic patient. There was a wide distribution in lower-limb mechanical axis alignment before surgery, with a mild varus deformity as the most common presentation (Fig. 1). The mechanical axis was corrected to a narrow spread about a neutral axis after surgery (Fig. 1). The survival of the implants was assessed at a mean follow-up of 9.8 years (SD 3.0) in the aligned group and 9.7 years (SD 3.5) in the malaligned group. A total of 33 of the 458 TKRs (7.2%) were revised for aseptic loosening, with the Kaplan-Meier survival graphs (Fig. 2) reflecting a weak trend towards improved survival with more accurate alignment of the mechanical axis. However, despite being evident, this trend did not reach statistical significance ($p = 0.47$).

A single time point at 10 years after each TKR is considered to calculate the absolute risk reduction. TKRs were excluded (188 TKRs) from this calculation if it was less than 10 years from the primary surgery or the patient had died before 10 years without needing revision surgery. The incidence of revision due to aseptic loosening ten years after primary surgery was 11 of the 227 TKRs (5%) in the aligned group and 6 of 43 TKRs (14%) in the malaligned group (Fisher's exact test, $p = 0.36$) (Table II). This equates to a 9%

absolute risk reduction for revision surgery due to aseptic loosening between the groups. Therefore, the numbers needed to harm analysis predicts that there would be one additional revision surgery due to aseptic loosening for every 12 TKRs implanted with a malaligned mechanical axis.

The pre-operative alignment, type of fixation and primary pathology did not predict either the accuracy of alignment of the mechanical axis or the survival pattern in either group (Table III). Details of the functional outcome between the groups are very limited, but there was no significant difference between the post-operative ranges of movement in either group at six months (Table III).

Discussion

Interest in the accurate positioning and alignment of arthroplasty components has been the subject of controversy, particularly following the development of computer-navigated surgery.²⁴ Justification for using computer navigation and its cost-effectiveness is based on the implication that accurate alignment improves implant survival, thereby reducing the rate of costly revision, but the evidence supporting this is scarce.²⁰

Our results on the effect of post-operative alignment of the mechanical axis, measured using long-leg radiographs,

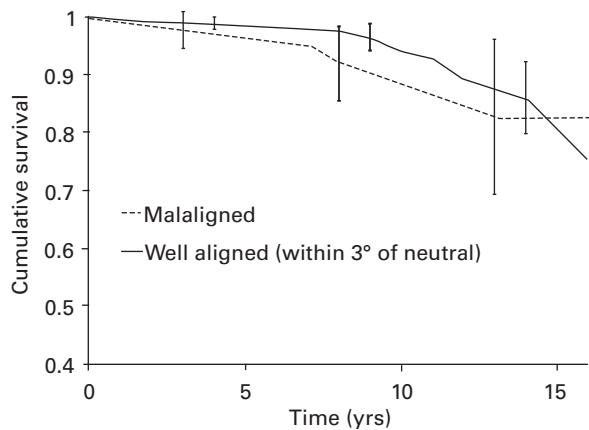


Fig. 2

Kaplan-Meier plot comparing the cumulative survival of the aligned and malaligned groups at 15 years. The endpoint in this analysis is revision surgery due to aseptic loosening. The error bars represent the 95% confidence intervals. The difference in survival is not statistically significant ($p = 0.47$).

Table II. Survival data for both groups at ten years after primary surgery

Outcome	Aligned	Malaligned	p-value*
Survived ten years (n)	216	37	0.36
Revision before ten years (n, %)	11 (5)	6 (14)	0.36
Total	227	43	

* Fisher's exact test

on the long-term risk of revision surgery demonstrate only a weak relationship between alignment and the risk of revision surgery. Survival analysis reveals a tendency towards improved implant survival with accurate alignment, but the validity of this result is limited by the lack of statistical significance. This may be explained by the relatively small number of TKRs in the malaligned group compared with previous reports (Fig. 1).^{10,25} The categorical analysis of TKRs that had reached 10 years since their primary surgery demonstrated a statistically significant improvement in survival for the well-aligned compared with the malaligned group. The 9% difference in implant survival at ten years is consistent with a previous study by Vince et al¹⁰ who report an increased risk of the development of radiolucent lines in a small number of TKRs aligned with a varus mechanical axis. Jeffery et al⁸ also reported a 19% reduction in implant loosening in well-aligned compared to poorly aligned TKRs after ten years. The ability to generalise the findings of Jeffery et al⁸ is limited both by the subjective interpretation of loosening on plain radiographs and the unusual implant design features, such as the very long femoral stem, articulating surfaces made in the shape of matching cylinders and a central hole in the polyethylene component for a tibial alignment rod. However, confidence in the relationship is questioned by a recent paper by Paratte et al²⁶ who demonstrated no improvement in survival if the TKR was positioned within 3° of a neutral mechanical axis using

Table III. Clinical details of the patients in both groups

	Aligned	Malaligned	p-value
Fixation (n, %)			
Cemented	219 (80)	55 (20)	0.39*
Cementless	153 (83)	31 (17)	
Primary pathology (n, %) [†]			
Osteoarthritis	342 (81)	79 (19)	0.89*
Rheumatoid arthritis	29 (81)	7 (19)	
Mean range of movement (°; SD)			
Pre-operative	97.1 (21.8)	98.6 (22.4)	0.78 [‡]
Post-operative	100.1 (16.4)	97.5 (17)	0.54 [‡]
Mean pre-operative alignment (°; SD)	6.4 (10.4)	7.2 (13.8)	0.53 [‡]

* chi-squared test

[†] unknown in one patient

[‡] independent samples Student's *t*-test

conventional jigs compared with an outlier group. The difference between our findings and those of Paratte et al²⁶ might be partly explained by the number of different cemented TKR designs and the smaller sample size in their study. Fang, Ritter and Davis²⁷ reported on the effect of the tibio-femoral angle in the coronal plane in 6070 TKRs (3992 patients). Their analysis found that outliers beyond a single standard deviation of the mean post-operative tibio-femoral angle were at greater risk of revision. At a mean follow-up of 6.6 years (SD 3.5), the revision rate for the neutral alignment group was considerably lower at 0.5%, compared to 1.8% in a varus group and 1.5% for a valgus group.

This study, alongside reports of other modern TKR designs, suggests that the relationship between the post-operative mechanical axis and implant survival is marginal.²⁶ However, the importance of accurate component alignment cannot be dismissed on this clinical evidence alone. Retrieval studies of failed TKRs have found that a mechanical axis > 5° varus/valgus was associated with a significant loss of polyethylene thickness in the medial compartment of the tibial component.²⁸ Laboratory kinematic studies of TKRs have similarly found that malalignment > 3° valgus/varus leads to eccentric loading and significantly increased polyethylene wear.^{29,30} In addition, finite element computer modelling of TKRs also supports the premise that malalignment leads to increase contact stresses and wear.³¹ Although this evidence supports the neutral mechanical axis as a valuable intra-operative target, its achievement does not necessarily confer satisfactory kinematics and implant survival.^{32,33}

Alignment in the coronal plane does not guarantee the accurate position of each component in flexion/extension, valgus/varus or balanced tibio-femoral rotation. The effect on implant survival of accurate positioning of each individual component in six degrees of freedom is not clearly established. There is anecdotal evidence that early mechanical failure is more likely when there is a mismatch of the femoral and tibial components in rotation.⁷ A mismatch in rotation is also recognised to cause problems with patellar tracking and patellofemoral complications, which may

themselves be sufficient for revision surgery.^{34,35} However, reliable evidence of the effect of rotational alignment on implant survival is limited because intra- and post-operative measurement techniques are often inaccurate and the optimal rotational alignment target has not been defined. However, the current evidence does not demonstrate any benefit in rotational alignment with computer navigation versus conventional jigs.^{11,12}

One previous meta-analysis estimated that one in five knees would be better aligned with computer navigation surgery instead of conventional jig methods.¹⁷ The effect of navigational surgery on long-term implant survival, however, remains less certain. Our results estimate that there would be one additional revision operation after 15 years for every 12 TKRs implanted with a mechanical axis in a malaligned group. The product of the findings from the previous meta-analysis and the results of this study provide an estimate of the potential benefit of computer navigation surgery on the long-term risk of revision surgery. This estimate indicates that the benefits of computer-navigated TKR surgery, using 3° as the primary outcome measure alone, may have been exaggerated in some previous reports.²⁰ Some authors have, however, reported clinical benefits apart from accurate implant alignment with the use of computer-navigated TKR surgery, including less blood loss, improved gait and function.^{32,33}

Our study has limitations that might affect generalisation. The study included TKRs with both cemented and cementless methods of fixation, but this further variable did not influence the relationship between alignment and implant survival. Also, we cannot exclude the possibility of bias in grouping by alignment owing to the single-observer unblinded measurements of the long leg mechanical axis. Furthermore, the accuracy of measuring the mechanical axis and component position by plain radiographs has been reported to be inferior to other techniques, such as CT.³⁶ The effect of rotational alignment may be a significant confounding factor in this study because it could reduce the accuracy of the assessment of the mechanical axis on plain radiographs and act as an independent risk factor for implant survival. The external validity of the results must also take account of the exclusion criteria of the original trial, which may underestimate the effect of alignment in patients with gross osteoporosis or bone defects. This study uses revision surgery as an absolute end-point but does not report the effect of accurate alignment on function and patient satisfaction. Despite these limitations, the prospective data collection and sample size are strengths that help reduce bias and support the relationship described above.

In summary, the results of this study are supportive of a relationship between survival after TKR and mechanical axis alignment within 3° of neutral in the coronal plane. However, the link between implant survival and alignment alone is weaker than described in a number of previous reports. A mechanical axis within 3° of neutral in the coronal plane remains a satisfactory target in TKR surgery if the

biomechanical evidence, retrieval evidence, computer predictions and clinical evidence are considered together. However, the reported cost-benefit ratio of computer-navigated TKR surgery using 3° as the primary outcome measure alone may exaggerate its benefit, with the effect of computer-navigated TKR on long-term implant survival remaining unproven.

We would like to acknowledge the financial support of Johnson and Johnson Professional Inc., Raynham, Massachusetts to the randomised controlled trial,²⁰ from which the results of this study have been drawn.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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