Do varus or valgus outliers have higher forces in the medial or lateral compartments than those which are in-range after a kinematically aligned total knee arthroplasty?

**Aims**

The aims of this study were to determine the proportion of patients with outlier varus or valgus alignment in kinematically aligned total knee arthroplasty (TKA), whether those with outlier varus or valgus alignment have higher forces in the medial or lateral compartments of the knee than those with in-range alignment and whether measurements of the alignment of the limb, knee and components predict compartment forces.

**Patients and Methods**

The intra-operative forces in the medial and lateral compartments were measured with an instrumented tibial insert in 67 patients who underwent a kinematically aligned TKA during passive movement. The mean of the forces at full extension, 45° and 90° of flexion determined the force in the medial and lateral compartments. Measurements of the alignment of the limb and the components included the hip-knee-ankle (HKA) angle, proximal medial tibial angle (PMTA), and distal lateral femoral angle (DLFA). Measurements of the alignment of the knee and the components included the tibiofemoral angle (TFA), tibial component angle (TCA) and femoral component angle (FCA). Alignment was measured on post-operative, non-weight-bearing anteroposterior (AP) scanograms and categorised as varus or valgus outlier or in-range in relation to mechanically aligned criteria.

**Results**

The proportion of patients with outlier varus or valgus alignment was 16%/24% for the HKA angle, 55%/0% for the PMTA, 0%/57% for the DLFA, 25%/12% for the TFA, 100%/0% for the TCA, and 0%/64% for the FCA. In general, the forces in the medial and lateral compartments of those with outlier alignment were not different from those with in-range alignment except for the TFA, in which patients with outlier varus alignment had a mean paradoxical force which was 6 lb higher in the lateral compartment than those with in-range alignment.

None of the measurements of alignment of the limb, knee and components predicted the force in the medial or lateral compartment.

**Conclusion**

Although kinematically aligned TKA has a high proportion of varus or valgus outliers using mechanically aligned criteria, the intra-operative forces in the medial and lateral compartments of patients with outlier alignment were comparable with those with in-range alignment, with no evidence of overload of the medial or lateral compartment of the knee.

Cite this article: Bone Joint J 2017;99-B:1319–28.

The principle of mechanically-aligned total knee arthroplasty (TKA) is that durability of the components is achieved by referencing them at the time of implantation to the mechanical axis of the femur and tibia in the coronal plane. Target ranges for varus and valgus have been described by Parratte et al for the limb and components, and by Ritter et al for the knee and components, based on mechanically aligned criteria (Table I). The alignment of the components and the limb may be related using the hip-knee-ankle (HKA) angle, the proximal medial tibial angle (PMTA) and distal lateral femoral angle (DLFA) (Fig. 1). The alignment of the components and the knee may be measured using the tibiofemoral angle (TFA), tibial component angle (TCA) and femoral component angle (FCA).
Computer-assisted navigation, robotics and patient specific instrumentation have been developed in order to achieve mechanical alignment within these ranges in order to improve the durability and function of the components. However, long-term follow-up studies have not shown any differences in the survival of the components or function of the knee between those whose mechanical alignment is within the range or is an outlier.

Kinematic alignment is a surgical technique that closely restores the native alignment of the limb and distal femoral and proximal tibial joint lines. There have been three meta-analyses, three randomised trials and a national
multicentre study which have shown that patients whose components are introduced with kinematic alignment have significantly better relief of pain, function, range of flexion and have a more normal feeling knee joint when compared with those whose components are introduced with mechanical alignment.9,10,15-21 Two randomised trials have shown similar clinical outcomes between the two forms of alignment.22,23

Soft-tissue imbalance accounts for 35% of early revision TKAs in the United States and may present as instability or stiffness as well as high compressive forces in the tibial compartments, leading to local overload, loosening and wear of the insert.24-26 Recently, it has become possible to assess the effect of the bone cuts on ligament balance intraoperatively during passive flexion-extension movement of the components and by measuring the compression force in the medial and lateral compartments with an instrumented tibial insert.27 Kinematic alignment can allow outlier varus and valgus mechanical alignment (Table I).10,12,15-21 It is not known, however, whether patients with outlier varus or valgus kinematic alignment have higher compartment forces than those with in-range alignment.

We conducted a retrospective review of patients treated with a kinematically aligned TKA asking: (1) what proportion of patients have outlier varus or valgus alignment of the limb, knee and components, based on mechanical criteria?; (2) do patients with outlier varus or valgus alignment have higher forces in the medial or lateral compartments than those with in-range alignment? and; (3) do measurements of alignment of the limb, knee and component predict the forces in the medial and lateral compartments?

Patient and Methods
This study is a retrospective review of patients who underwent primary kinematically aligned TKA with intraoperative measurements of the forces in the medial and lateral compartments. A total of 67 patients were identified from 148 consecutive primary kinematically aligned TKAs performed between July 2016 and November 2016 (Table II). A post hoc analysis had compared patients in the present study with those in two representative studies11,12 of kinematically aligned TKAs and showed no clinically significant differences in age, proportion of women, body mass index, pre-operative extension, flexion, varus or valgus deformities and the Oxford Knee Score. The indications for TKA included disabling symptoms from the knee which had not resolved following conservative treatment, radiographic evidence of Kellgren-Lawrence Grade II to IV arthritic changes or osteonecrosis, any severity of varus or valgus deformity as measured when non-weight-bearing with a goniometer and any severity of flexion contracture. Exclusion criteria included those undergoing a revision TKA and those with an inflammatory arthropathy.

All patients were treated with a posterior cruciate ligament (PCL) retaining (CR) primary TKA by a single surgeon (SMH) using a midvastus approach (Vanguard CR; Zimmer Biomet, Warsaw, Indiana). Kinematic alignment was performed using a calibrated technique with manual instruments without a soft-tissue release.10,12 Five intraoperative quality assurance checks aligned the components to the restored joint line of the knee. The first minimised flexion of the femoral component by positioning the starting hole for the intramedullary positioning rod midway between the top of the intercondylar notch and aligning it parallel to the anterior femoral cortex.30 The second set the femoral component relative to the native tibiofemoral articular surface using a caliper and adjusting the thickness of the distal and posterior femoral resections to within standard deviation (SD) 0.5 mm of the thickness of the condyles of the femoral component after compensating for cartilage wear and the bone cut.28 The third set the rotation of the tibial component parallel to the flexion-extension plane of the knee by aligning the anteroposterior axis of the tibial component parallel to the flexion-extension plane of the knee by rotating the component parallel to a line drawn overlying the axis of the elliptical shape of the lateral tibial condyle.31 The fourth set the tibial component relative to the varus-valgus angle of the native tibial joint line using a

Table II. Comparisons of clinical characteristics, pre-operative conditions, function for patients in the present study and two studies of kinematically aligned total knee arthroplasty with three- and six-year follow-up.11,12

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Present study (n = 67)</th>
<th>Three-year study (n = 215)</th>
<th>Six-year study (n = 219)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>69 (SD 7 A)</td>
<td>69 (SD 10 A)</td>
<td>74 (SD 10 B)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Gender (male) (%)</td>
<td>33 (49)</td>
<td>87 (47)</td>
<td>39 (39)</td>
<td>NS (0.2817)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>29 (SD 5 A)</td>
<td>30 (SD 5 B)</td>
<td>31 (SD 6 B)</td>
<td>0.0643</td>
</tr>
<tr>
<td>Pre-operative knee conditions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee extension (°)</td>
<td>11 (SD 7 A)</td>
<td>8 (SD 8 B)</td>
<td>10 (SD 8 B)</td>
<td>0.0031</td>
</tr>
<tr>
<td>Knee flexion (°)</td>
<td>111 (SD 11)</td>
<td>114 (SD 13)</td>
<td>113 (SD 13)</td>
<td>NS (0.232)</td>
</tr>
<tr>
<td>Valgus (-)/Varus (+) Deformity (°)</td>
<td>1 (SD 13 A)</td>
<td>-2 (SD 8 B)</td>
<td>-1 (SD 6 B)</td>
<td>0.0061</td>
</tr>
<tr>
<td>Pre-operative function</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxford knee score</td>
<td>23 (SD 8 A)</td>
<td>20 (SD 8 B)</td>
<td>18 (SD 8 B)</td>
<td>0.0002</td>
</tr>
</tbody>
</table>

For each parameter means annotated with a different letter (A-B) are significantly different from p < 0.05; like letters (either A-A or A-B) indicate no difference between columns whereas different letters (A-B) indicate significant differences

sd, standard deviation; NS, non-significant
caliper to measure the thickness of the medial and lateral tibial condyles at the base of the tibial spines and adjusting the tibial resection until the varus-valgus laxity with trial components was negligible in full extension, which replicates the laxity of the native knee in full extension. Removal of posterior osteophytes without release of the posterior cruciate ligament allowed correction of a flexion contracture to full extension. Contractures of > 30° occasionally required release of the posterior capsule from the femur but did not require additional resection of distal femoral bone. The final quality assurance check set the tibial component relative to the slope of the native tibial joint line by adjusting the flexion-extension of the tibial resection until measurement of the offset of the anterior tibia from the distal medial femoral condyle with trial components matched that of the knee at the time of exposure and the passive rotation of the tibia on the femur had a mean of 14°, which replicates the mean laxity of the native knee in 90° of flexion. Indicators of alignment such as the femoral and tibial mechanical axes, the transepicondylar axis and the border of the tibial tubercle are not used when performing kinematic alignment. All components were cemented. The thickness of the tibial insert was selected and opened but not implanted at this stage.

An instrumented tibial insert that matched the thickness of the selected insert was placed in the tibial baseplate (Verasense, Orthosensor Inc., Dania Beach, Florida). The tablet screen that displayed the forces in the medial and lateral compartments in pounds was rotated away from the view of the surgeon. Towel clips were applied proximal and distal to the patella to close the extensor mechanism provisionally. One hand of the surgeon lifted the posterior thigh to flex the knee while the dorsum of the other hand supported the heel so as not to compress or rotate the limb. The knee was passively cycled from full extension to full flexion three times to precondition the knee. A video camera on a smartphone simultaneously recorded the forces on the tablet screen and the flexion of the knee during three cycles of passive movement.

On the day of discharge, each patient had an anteroposterior rotationally controlled CT scanogram of the limb, with the patient supine and non-weight-bearing to mimic the intra-operative alignment. The HKA angle, PMTA, DLFA, TFA, TCA, and FCA had previously been validated using an open source medical image viewer (Horos; Horos Project) (Fig. 1). The proportion of the selected insert was placed in the tibial baseplate (Verasense, Orthosensor Inc., Dania Beach, Florida). The tablet screen that displayed the forces in the medial and lateral compartments in pounds was rotated away from the view of the surgeon. Towel clips were applied proximal and distal to the patella to close the extensor mechanism provisionally. One hand of the surgeon lifted the posterior thigh to flex the knee while the dorsum of the other hand supported the heel so as not to compress or rotate the limb. The knee was passively cycled from full extension to full flexion three times to precondition the knee. A video camera on a smartphone simultaneously recorded the forces on the tablet screen and the flexion of the knee during three cycles of passive movement.

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The study had institutional ethical approval (993987-1). Statistical analysis. In order to quantify intra-observer repeatability of the measurements of the forces in the medial and lateral compartments, one surgeon (SMH) passively flexed and extended the knee three times on 15 randomly selected patients. A single factor analysis of variance (ANOVA) with repeated measures computed the intraclass correlation coefficient (ICC) for the force in the medial and lateral compartments at full extension, 45° and 90° of flexion. The factor was the cycle of passive flexion-extension cycle with three levels (cycle one, two, three). The ICCs for the force in the medial compartment were 0.95 at full extension, 0.96 at 45° and 0.97 at 90° of flexion, and the force in the lateral compartment was 0.89 at full extension, 0.82 at 45° and 0.96 at 90° of flexion. Of the six analyses, intra-observer repeatability was excellent in four and good in two.

Continuous variables were reported as mean with SD and range. Discrete variables were reported as numbers and proportions (percentage). The force in each compartment was recorded as the mean of the forces at full extension, 45° and 90° of flexion. For each measurement of alignment, a single factor ANOVA determined whether the forces in the medial and lateral compartments were different between patients with outlier varus, outlier valgus and in-range alignment. When there was a significant difference, a post hoc Tukey’s test was used to determine which categories of alignment were different. A linear regression analysis was used to compute the coefficient of determination (r²) to determine whether the measurements of the HKA angle, PMTA, DLFA, TFA, TCA and FCA predicted the force in the medial and lateral compartments. Computations were performed with software (JMP, Cary, North Carolina). Statistical significance was set at p < 0.05.

Results

Many patients treated with a kinematically aligned TKA had outlier varus or valgus mechanical alignment (Figs 2 to 5); the proportion was 16% and 24% for the HKA angle, 55% and 0% for the PMTA, 0% and 57% for the DLFA, 25% and 12% for the TFA, 100% and 0% for the TCA and 0% and 64% for the FCA.

In general, patients with outlier varus or valgus alignment did not have higher forces in the medial or lateral compartments than those aligned in-range (Table III). Those with outlier varus and valgus alignment of the HKA angle, PMTA, and DLFA did not have different mean forces in the medial and lateral compartments from those aligned in-range (p = 0.2642 to 0.9512) (Figs 2 and 3). Patients with outlier varus and valgus alignment of the TFA and FCA did not have different mean forces in the medial compartment from those aligned in-range (p = 0.4596 to 0.8191) (Fig. 4). Those with outlier varus alignment of the TFA had a mean paradoxical force of 11 lbs (SD 11) in the lateral compartment that was 6 lbs greater than the mean of those aligned in-range 5 lbs (SD 5) (p = 0.0314) and not significantly different from the mean of those with outlier valgus alignment 7 lbs (SD 9). (Fig. 5). Patients with outlier varus and valgus alignment of the FCA did not have significantly different mean forces in the lateral compartment from those aligned in-range (p = 0.5225). All patients had outlier varus alignment of the TCA. However, the mean forces in the medial and lateral compartments in these patients were not significantly different from those patients with in-range alignment of the HKA angle, PMTA, DLFA, and FCA (p = 0.4596 to 0.8191).

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Measurements of the HKA angle, PMTA, DLFA, TFA, TCA, and FCA did not predict the force in the medial or the lateral compartment (r² ranged from 0.0017 to 0.0581).

**Discussion**

Kinematically aligned TKA restores the native alignment of the limb rather than a neutral mechanical axis⁴,¹⁰,¹¹,¹²,¹⁸,²⁹,³⁹ and because this alignment uses a different target and different bone cuts than mechanical alignment, there is a possibility that it might have more patients with outlier varus and valgus alignment and be associated with high intraoperative forces in the medial and lateral compartments of the knee, suggesting malalignment.

The main findings of our study were that patients treated with kinematically aligned TKA had a high proportion of outlier varus and valgus alignment of the limb, knee, and components according to mechanically aligned criteria.
Thirdly, measurements of alignment of the limb, knee and components did not predict the forces in the medial or lateral compartments. The study has limitations. First, our results represent the use of one design of PCL retaining (CR) TKA and may not be applicable to other designs such as PCL substituting (posterior stabilised) TKAs, which have higher forces in the lateral compartment. Secondly, the measurements of non-weight-bearing intra-operative forces in the medial and lateral compartments and post-operative alignment might differ from weight-bearing measurements post-operatively. The weight-bearing status should be consistent when making measurements of the forces intra-operatively and the alignment post-operatively. We measured the intra-operative compartment forces during passive movement of the knee and the post-operative alignment on non-weight-bearing CT scanograms with care so as not to apply manual compression across the knee. Even though intra-operative and weight-bearing post-operative forces in the compartments might differ, there is value in measuring these forces intra-operatively as they predict post-operative function.

The proportion of patients treated with a kinematically aligned TKA with outlier varus and valgus alignment of the limb, knee and components as determined by mechanically aligned criteria was generally higher than in those treated with a mechanically aligned TKA (Table IV). For the HKA angle, the proportion of patients with a kinematically aligned TKA who have outlier valgus alignment was three times higher than with a mechanically aligned TKA. The proportion of patients with a kinematically aligned TKA who have outlier varus alignment of 55% and outlier valgus alignment of 57% were both higher than those for a mechanically aligned TKA of 6% and 3% respectively. For the TCA, the proportion of kinematically aligned patients with outlier varus alignment of 100% was higher than in those with a mechanically aligned TKA of 18%. For the FCA, the proportion of patients with a kinematically aligned TKA with outlier valgus alignment of 64% was higher than in those with a mechanically aligned TKA of 8%. As kinematic alignment has a high proportion of outlier varus and valgus alignment and because the patients with outlier alignment had the same low forces in the medial and lateral compartments as those with in-range alignment, the criteria for mechanical alignment of categorising the alignment of the limb, knee and components did not have higher forces in the medial and lateral compartments than those with in-range alignment.
components as a varus and valgus outlier should not be applied to kinematic alignment.

One clinical benefit of a kinematically aligned TKA is that low forces in the medial and lateral compartments were achieved without soft-tissue release, by restoring the native alignment of the limb, knee and joint lines. The forces in the medial and lateral compartments of a kinematically aligned TKA were generally lower than those in a mechanically aligned TKA in whom soft-tissue releases were performed. In our study, the mean force in the medial and lateral compartments were generally lower than those in a mechanically aligned TKA in whom soft-tissue releases were performed. In range (2.5° to 7.4°), varus outlier (< 2.5°) and valgus outlier (> 7.4°). A second benefit is that low intra-operative compartment forces are associated with a low risk of overload, wear of the insert and tibial loosening, and with better outcomes and function, than high intra-operative compartment forces. A third benefit is that low compartment forces explain the high rate of implant survival for kinematically aligned TKAs with an incidence of varus loosening of 0% and of posterior subsidence or wear of the tibial component of 0.2% at two- to nine-year follow-up, and an incidence of catastrophic failure of 0% at three years and 2.5% at six years post-operatively. Finally, the mean intra-operative compartment forces in the present study were lower than the mean in vitro forces predicted by a computer simulation of a kinematically aligned TKA. Positioning components to restore the native alignment of the limb, knee and joint lines, which is the target of kinematic alignment, might explain the poor prediction of the forces in the medial and the lateral compartments by measurements of the post-operative HKA angle, PMTA, DLFA, TFA, TCA, and FCA. An in vitro study showed that the magnitude and the range of the sum of the forces in the medial and lateral compartments were small and narrow, between 1 lb and 26 lbs in extension after kinematically aligned femoral and tibial components were introduced in 13 normal cadaveric knees. Low compartment forces in full extension are notable because full extension is the position with the least laxity and consequently the highest compartment forces. Forces in the compartments that are small and vary little between patients might not be sensitive.
enough to predict alignment of the PMTA, DLFA, and HKA angles. Patients with a post-operative PMTA of 0°, 3° and 6° varus after kinematic alignment that matches the native pre-operative PMTA should have small comparable compartment forces that differ within a narrow range. However, a patient with a decrease in the post-operative PMTA of 0° varus after kinematic alignment, from a native pre-operative PMTA of 3° varus, would have a tibial component set in 3° more valgus from the native tibial joint line. Placement of the tibial component in 1° and 2° more valgus than the native tibial joint line increases the force in the medial compartment in extension by 18 lbs and 54 lbs respectively, when soft tissues are left intact.47,48 Hence, the poor prediction of forces in the medial and the lateral compartments by the measurements of alignment suggests that the intra-operative quality assurance checks of adjusting

Table IV. Comparison of studies of mechanical and kinematic alignment that report the proportion (%) of patients with a varus or valgus outlier alignment for measurements of the limb, knee and components

<table>
<thead>
<tr>
<th>Study</th>
<th>Method of alignment</th>
<th>HKA angle varus outlier</th>
<th>HKA angle valgus outlier</th>
<th>PMTA varus outlier</th>
<th>PMTA valgus outlier</th>
<th>DLFA varus outlier</th>
<th>DLFA valgus outlier</th>
<th>TFA varus outlier</th>
<th>TFA valgus outlier</th>
<th>TCA varus outlier</th>
<th>TCA valgus outlier</th>
<th>FCA varus outlier</th>
<th>FCA valgus outlier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parratte et al6</td>
<td>Mechanical</td>
<td>10</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Luyckx et al37</td>
<td>Mechanical</td>
<td>26</td>
<td>8</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>Magnussen et al42</td>
<td>Mechanical</td>
<td></td>
<td></td>
<td>6</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present Study</td>
<td>Kinematic</td>
<td>16</td>
<td>24</td>
<td>55</td>
<td>0</td>
<td>0</td>
<td>57</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Ritter et al5</td>
<td>Mechanical</td>
<td>17</td>
<td>12</td>
<td>18</td>
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<td>0</td>
<td>64</td>
<td></td>
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</tbody>
</table>

HKA, hip-knee-ankle; PMTA, proximal medial tibial angle; DLFA, distal lateral femoral angle; TFA, tibiofemoral angle; TCA, tibial component angle; FCA, femoral component angle
the thicknesses of the distal femoral and proximal tibial resections set the femoral and tibial components relative to the native joint lines and restored the native alignment of the limb and knee.

In conclusion, categorising the alignment of the limb, knee and components as varus and valgus outlier or in-range, according to criteria of mechanical alignment, cannot predict the intra-operative forces in the medial and lateral compartments after a kinematically aligned TKA. These findings do not support the concept of categorising alignment as an outlier when performing this procedure.11,12

Take home message:
- Kinematic alignment has a high proportion of varus and valgus outliers according to mechanical alignment criteria
- Medial and lateral tibial compartment forces of subjects with varus or valgus outlier alignment were comparable with those with in-range alignment.

Author contributions:
T. J. Shelton: Study design, Data collection, Data analysis, Writing the paper.
A. J. Nedopil: Study design, Data collection, Data analysis, Writing the paper.
S. M. Howell: Study design, Data collection, Data analysis, Writing the paper.
M. L. Hull: Study design, Data collection, Data analysis, Writing the paper.

The study was approved by our ethical committee.

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

This article was primary edited by S. P.F. Hughes and first proof edited by J. Scott.

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