KNEE ARTHROPLASTY

Measuring long radiographs affects the positioning of femoral components in total knee arthroplasty: a randomized controlled trial

Justinas Stucinskas¹ · Otto Robertsson²,³ · Aleksej Lebedev¹ · Hans Wingstrand²,³ · Alfredas Smailys¹ · Sarunas Tarasevicius¹

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Abstract

Introduction The aim of this study was to investigate if preoperative measurements of the femoral valgus angle (FVA) affected the mechanical alignment, individual component positions and clinical outcome in total knee arthroplasty (TKA).

Methods 120 patients were randomized into two groups. In one group (control), a fixed FVA for the intramedullary femoral guide was set at 7°, whereas in the other group (measured) FVA was measured preoperatively on long hip–knee–ankle radiographs, and the angle for the distal femoral cut was set accordingly. Preoperatively and 1 year after TKA, range of motion (ROM) and Knee Society Score (KSS) were assessed. Postoperatively, the coronal alignments of the components and the mechanical alignment were measured comparing the rate of outliers which deviated more than 3° from the neutral mechanical axis.

Results 104 patients remained for the radiological analysis (52 in each group). There were no significant differences either in the mean preoperative or postoperative mechanical alignment, or femoral or tibial component alignment; also, there were no differences in the number of postoperative mechanical axis or tibial component alignment outliers. However, the number of femoral component alignment outliers was significantly higher in the control group. 97 patients were available for clinical outcome analysis. Preoperatively, the groups did not differ significantly with respect to KSS or ROM. The postoperative ROM and KSS functional subscale scores were similar between the groups. However, there was slightly but significantly better postoperative KSS objective subscale score in the measured group.

Conclusions Preoperative FVA measurement and following femoral distal cut adjustments did not affect overall leg alignment postoperatively, while positioning of femoral component was improved together with minor improvements in objective KSS subscale scores.

Keywords Knee · Arthroplasty · Alignment · Mechanical axis

Introduction

The accuracy of postoperative alignment of the lower limb and of the components has been recognized as an important surgeon-related factor in the longevity of implant survival after total knee arthroplasty (TKA) [1–4]. It has been reported that alignment errors >3° in the frontal plane are associated with increased risk of component loosening. Thus, restoring an optimal alignment is important [5]. This can be accomplished by accurate bone cuts perpendicular to the mechanical axis [6, 7]. To perform an accurate distal femoral cut, the appropriate femoral valgus angle (FVA) set on the intramedullary guide should match the angle between the mechanical and anatomical axis of the femur [6].

Kharwadkar et al. reported that in a routine practice for uncomplicated TKA, a fixed 5°–6° FVA on the intramedullary guide for the distal femoral cut has sufficient
anterior–posterior radiographs were obtained at a focal
Burnett’s atlas [12] and graded in stages from 0 to 21. The OA grade was assessed preoperatively according to
excluded knee deformations of more than 15° and no analysis of the femoral or tibial component positioning was performed.

We found only one randomized trial investigating the effect of preoperative FVA measurements on postoperative mechanical alignment of the TKA [10], but that study excluded knee deformations of more than 15° and no analysis of the femoral or tibial component positioning was performed.

The hypothesis of this study was that preoperative FVA measurement and following femoral distal cut adjustment lead to an improved coronal alignment of the femoral component and mechanical alignment as compared to a fixed FVA technique. The aim of our study was to investigate if preoperative measurements of the FVA affected the mechanical alignment, individual component positions and subsequently clinical outcome in TKA.

Materials and methods

120 consecutive OA patients, admitted for elective TKA, were investigated prospectively. All patients were preoperatively (after clinical assessment and radiograph execution) randomized (sealed envelope extraction) and divided into two groups depending on the valgus setting of the intramedullary femoral distal resection guide. In one group (control), the femoral guide was set at 7° valgus, and in the other group (measured) the instrument was set according to the measured angle between the femoral and mechanical axis.

The inclusion criteria and study flowchart are shown in Fig. 1.

One day before surgery, the active range of motion (ROM) in the affected knee was measured with a goniometer. Patient’s age, gender, height and weight were recorded and body mass index (BMI) was calculated. Their Knee Society Score (KSS) was assessed using both objective (pain, leg alignment, stability and joint motion) and functional (walking distance, stair climbing and walking aids) subscales [11]. Mediolateral knee stability (maximum movement in any position) was evaluated according to KSS and graded >15°, 10°–14°, 6°–9°, <5°. The OA grade was assessed preoperatively according to Burnett’s atlas [12] and graded in stages from 0 to 21.

The day before surgery, long-standing lower extremity anterior–posterior radiographs were obtained at a focal distance of 2.5 m with a consistent technique: the patients were standing on both legs with patella facing forward and the medial aspects of both feet parallel [13]. The measurements were performed using a radiology viewer (Cedara I-Reach™ 4.4, Cedara Software corp. Merge OEM). The mechanical alignment (hip–knee–ankle angle centres) of the lower extremity was determined as the medial hip–knee–ankle angle. Hip centre was identified by the Mose circles [14] and the knee centre as the midpoint between the intercondylar femoral sulcus and the eminentia tibiae. The ankle centre was defined as the centre of the superior facet of the talus [15]. The anatomical alignment (femoral shaft-knee-ankle angle) was determined as the medial angle between two lines connecting the femoral shaft–knee–ankle centres. The centre of the femoral shaft was defined as the centre of the intramedullary canal at the isthmus level where the intramedullary guide used for the distal femoral cut was to be positioned. Depending on neutral mechanical alignment, all knees were categorized as “varus” (≤180°) or “valgus” (>180°). Knees in ≥15° varus or valgus against the neutral mechanical alignment were classified as severe deformity. In the measured group, the FVA was measured on preoperative radiographs (Fig. 2) and intraoperatively the intramedullary femoral guide was adjusted accordingly for distal femoral cut. In the control group, the guide was fixed at 7° in all cases and the measurements postponed until after surgery.

All patients were operated by four experienced consultants via a medial parapatellar approach with a spinal–epidural anaesthesia using the same cemented implant [NexGen LPS (Zimmer, Warsaw, Indiana, USA)]. In all patients, the entry point of the intramedullary femoral guide was placed in the centre of the patellar sulcus of the distal femur, 1 cm above the femoral intercondylar notch. An extramedullary tibial guide was used in all cases aiming for a 90° cut perpendicular to the mechanical axis.

At 1 year follow-up, ROM and KSS were assessed in a blinded fashion for both investigator (JS) and patients. As accurate radiological assessment would have been difficult to achieve immediately postoperatively, long-standing radiographs were taken after 6–12 months. The coronal alignment of the femoral and tibial components as well as the mechanical/anatomical alignment was measured by one investigator (JS), blinded to randomisation (Fig. 3). The femoral component angle was defined as the angle medially between the distal surfaces of the femoral component and the femoral mechanical axis, and the tibial component angle as the medial angle between the tibial component plateau and the tibial mechanical axis [16].

Outliers were defined as cases in which the position of components or the measured mechanical axis deviated more than 3° from the neutral mechanical axis. The
Informed consent was obtained from all individual participants included in the study. The study was approved by the Institutional Review Board (No.: BE-2-5) and was performed in accordance with the ethical standards outlined in the 1964 Declaration of Helsinki and its later amendments.

Fig. 1 Study flowchart

proportion of outliers, mean alignment angles, as well as ROM and KSS results between the groups were compared.
Statistical analysis

The primary effect variable, used for power calculation analysis, was the mechanical axis malalignment. With an assumption of a difference in means of 3°, and a standard deviation of 4° for both groups, and aiming at a power of 0.95 and a risk of 0.05 for type-1 error, 47 patients were required in each group. For possible dropouts, 60 patients in each group were included in the study.

Data are presented as means ± standard deviations (SD). To determine whether the data were normally distributed, a Shapiro–Wilk normality test was performed. As most of the data were normally distributed, parametric t test for independent samples was used. Fisher’s exact test was used when comparing proportions between the groups. Pearson’s rank correlation coefficient was used to investigate the relation between the mean FVA, height and BMI.

A p value of <0.05 was considered to be significant. SPSS software (SPSS, Chicago, Ill) was used for the calculations.

Results

Both TKA patients groups did not differ significantly with respect to age, gender, BMI, preoperative KSS, ROM or knee deformity (Tables 1, 2).

Fig. 2 Mechanical (MA) and anatomical (AA) alignment and femoral valgus angle (FVA) were measured on the preoperative long-standing hip–knee–ankle radiograph

Fig. 3 Mechanical and anatomical alignment, and femoral (FCA) and tibial (TCA) component angles were measured on the postoperative long-standing hip–knee–ankle radiograph
The mean preoperative FVA for all patients was 6.7° ± 1.3°, ranging from 4° to 10°. It was 6.7° ± 1.3° in varus knees and 6.5° ± 1.2° in valgus knees (p = 0.507). Females had a mean preoperative FVA of 6.6° ± 1.3° and males 7° ± 1.5° (p = 0.383), and there was no significant difference between the measured (6.9° ± 1.3°) and control (6.6° ± 1.3°) groups (p = 0.238). The preoperative distribution of the FVA (Fig. 4) and mean mechanical and anatomical alignment did not differ significantly between the groups (Table 1).

A significantly greater number of femoral component alignment outliers was found in the control group compared to the measured group (15 vs 5, p = 0.023). The distribution of femoral component outliers is presented in Fig. 5. The number of tibial component alignment outliers was the same (nine in each group) (Table 3). On comparing the mean tibial and femoral component angles, no significant differences between the groups were observed (Table 4).

On comparing the mean postoperative mechanical alignment, there were no significant differences between the groups. There were 15 mechanical alignment outliers among the measured group and 18 among the controls (p = 0.674).

The mean postoperative ROM and KSS functional subscale scores were not significantly different between the measured and control groups, but the mean postoperative KSS objective subscale score in the measured group was 77 ± 12 versus 70 ± 14 in the control group (Table 2). Postoperative knee stability according to KSS was similar in the groups. There were no patients with mediolateral knee instability with ≥15°. 10°–14° instability was observed in 1 patient in the measured group versus 2 in the control group (p = 0.617), 6°–9° in 7 patients versus 6 (p = 1) and <5° in 41 patients versus 40 (p = 1) respectively.

23 knees had severe preoperative knee deformity (≥15°), 15 in the measured group and 8 in the control group (p = 0.155). Of these, two and three had femoral component malalignment (>3°), respectively (p = 0.297).

There was no correlation between the mean preoperative FVA and height or BMI.

### Discussion

The optimal alignment of TKA is still being debated in the literature. Parratte et al. analysed long-standing radiographs of 398 modern TKA and found that a postoperative mechanical axis within 3° deviation from the neutral did not improve the 15-year implant survival rate [17]. Furthermore, the debate continues on how alignment should be corrected as restoration of mechanical alignment to neutral in patients with so-called “constitutional varus” knees may be abnormal and undesirable [18]. However, the majority of the literature supports the restoration of the neutral mechanical axis and still remains the gold standard when performing TKA [19]. The restoration of a straight mechanical axis in TKA is dependent on the surgeon’s technique in positioning the components. Tibial component positioning is usually aimed perpendicular to the

### Table 1 Comparison of patient data between the control and measured groups

<table>
<thead>
<tr>
<th>Data</th>
<th>Control n=52</th>
<th>Measured n=52</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>70 ± 7</td>
<td>72 ± 8</td>
<td>0.069</td>
</tr>
<tr>
<td>Gender (female/male)</td>
<td>43/9</td>
<td>42/10</td>
<td>1</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>166 ± 8</td>
<td>165 ± 9</td>
<td>0.331</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>92 ± 17</td>
<td>88 ± 17</td>
<td>0.318</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>33 ± 6</td>
<td>33 ± 6</td>
<td>0.607</td>
</tr>
<tr>
<td>Preoperative knee deformity (varus/valgus)</td>
<td>47/5</td>
<td>44/8</td>
<td>0.555</td>
</tr>
<tr>
<td>Severe knee deformity &gt;15°</td>
<td>8</td>
<td>15</td>
<td>0.155</td>
</tr>
<tr>
<td>Preoperative mechanical alignment (°)</td>
<td>172 ± 9</td>
<td>172 ± 11</td>
<td>0.930</td>
</tr>
<tr>
<td>Preoperative anatomical alignment (°)</td>
<td>179 ± 9</td>
<td>179 ± 11</td>
<td>0.951</td>
</tr>
<tr>
<td>Insert thicknesses (9/10/11/12/14/17/20 mm)</td>
<td>8/23/0/12/6/3/0</td>
<td>4/14/1/21/8/3/1</td>
<td>0.219</td>
</tr>
</tbody>
</table>

* Statistically significant
mechanical axis, whereas to perform an accurate femoral distal cut we should know the preoperative FVA, which is measured on long-standing radiographs [20–22]. However, many TKA surgeons use a fixed angle for distal femoral cuts, not taking into account the anatomical variations of FVA. Our study shows that such a standardized technique results in a threefold increase in the number of outliers on the femoral side. It was reported that even an isolated malposition of the femoral component increases revision rates in the long term [2, 23]. Thus, preoperative measurements of FVA, and subsequently better precision in femoral component positioning, should affect long-term implant survival.

Concerning the mechanical alignment, 18 (35 %) TKA in the control group and 15 (29 %) in the measured group deviated from the neutral mechanical axis in our study, but the difference between the groups in mechanical axis outliers was not significant despite the observed significant difference in the number of femoral component outliers.

![Fig. 4](image4.png)

**Fig. 4** The distribution of femoral valgus angles between the control and measured groups

![Fig. 5](image5.png)

**Fig. 5** The distribution of femoral component outlier angles between the control and measured groups

<table>
<thead>
<tr>
<th>Component alignment outliers (&gt;3°)</th>
<th>Control</th>
<th>Measured</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral</td>
<td>15 (29%)</td>
<td>5 (10%)</td>
<td>0.023*</td>
</tr>
<tr>
<td>Tibial</td>
<td>9 (17%)</td>
<td>9 (17%)</td>
<td>1</td>
</tr>
<tr>
<td>Mechanical</td>
<td>18 (35%)</td>
<td>15 (29%)</td>
<td>0.674</td>
</tr>
</tbody>
</table>

* Statistically significant

<table>
<thead>
<tr>
<th>Alignment/angle</th>
<th>All (range) n-104</th>
<th>Control n-52</th>
<th>Measured n-52</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical postop</td>
<td>(169–187)</td>
<td>178 ± 3</td>
<td>179 ± 3</td>
<td>0.623</td>
</tr>
<tr>
<td>Anatomical postop</td>
<td>(175–193)</td>
<td>185 ± 3</td>
<td>186 ± 3</td>
<td>0.413</td>
</tr>
<tr>
<td>Femoral component angle</td>
<td>(85–94)</td>
<td>89 ± 2</td>
<td>90 ± 2</td>
<td>0.098</td>
</tr>
<tr>
<td>Tibial component angle</td>
<td>(84–94)</td>
<td>90 ± 2</td>
<td>89 ± 2</td>
<td>0.738</td>
</tr>
</tbody>
</table>

Table 3 The incidence (rate, percentage) comparison of femoral and tibial components and mechanical alignment outliers between the control and measured groups

Table 4 Comparison of postoperative mechanical, anatomical and component alignment (mean ± SD, *) between the control and measured groups
Thus, our hypothesis that FVA measurement and following femoral distal cut adjustments will improve overall leg alignment and femoral component positioning postoperatively was only partially proven. The explanation is likely that a combination of deviation on the tibial side and outlier on the femoral side in opposite directions will result in a mechanical axis within normal range. One can wonder if it is a problem to have a femoral outlier of more than 3° if it is compensated for on the tibial side so that the mechanical axis is straight. However, such a compensation mode may affect the long-term survival, as it has been reported that correcting varus or valgus malalignment of the first component by placing the second component to attain neutral alignment is associated with an increased failure rate [2]. In our study, the isolated tibial component outlier rate was the same in both groups. This is what one could expect, as the preoperative measurement of the FVA only affects the positioning of the femoral component. Thus, according to our study, it seems reasonable to evaluate preoperatively long-standing radiographs and adjust the FVA cut accordingly to reduce the number of femoral component outliers. However, we have to admit that no significant changes were observed in overall leg alignment between the groups. Having in mind that in many hospitals it might be difficult to obtain long-standing radiographs and/or relevant software, which is related to additional expenses, we suggest that further, more detailed research is needed to prove the long-term clinical advantage of this concept.

In our OA patients scheduled for TKA, the FVA was 6.7° ± 1.3°, ranging from 4° to 10°. Kharwadkar et al. found a mean FVA of 5.4° ± 0.9°, ranging from 3.1° to 8° in a British TKA population [8]. In adults of Chinese descent, Tang et al. found the FVA to be 5.1° ± 0.9° with a range from 2.6° to 7.4° [24].

With a mean FVA of 7° in our patients, the decision to use a 7° fixed FVA as a standard for primary TKA seems appropriate. However, 23 % of our patients deviated ≥2° (4°, 5°, 9° and 10°) from the mean. This is in concordance with the finding reported by Mullaji et al. [25], who investigated OA patients before TKA and found that 79 % of patients had FVA of 7° ± 2°, and on choosing a routine FVA of 5°, 6°, or 7° in his study, the planning error in FVA would be ≥2° in 45.1, 28.2 or 21.1 % of limbs, respectively. Such a high implantation error possibility suggests that it is reasonable to adjust the setting of the intramedullary guide accordingly to the preoperative measurements, as the femoral component alignment will affect the mechanical axis. This is important because the alignment of the knee following total knee replacement affects long-term survival [1–5] of the prosthesis as well as of good clinical scores [26–28].

The effect of accurate postoperative alignment on TKA function is controversial [26–34]. Choong et al. [26] and Huang et al. [28] reported better KSS in TKA patients with a mechanical axis within 3° as compared to malaligned knees, consistent from 6 weeks to 5 year follow-up. However, other studies comparing computer-assisted surgery with conventional TKA surgery have not been able to correlate mechanical axis malalignment with inferior functional or patient-reported outcome measures [30–34]. In our study, the outlier rate of the mechanical axis alignment was similar in the groups, suggesting that the greater number of femoral component outliers in the control group did not affect the overall mechanical axis. However, patients in the measured group with smaller proportion of femoral component outliers had small, but significantly better KSS objective scores. Thus, our results indicate that individual component positioning may affect clinical outcome at the 1 year follow-up after TKA.

The drawback of our study is that the radiological FVA measurements included patients operated for severe OA, knee deformity and flexion contracture. It might be that severe knee deformity could affect limb rotation and thus affect the accuracy of angle measurements for about 0.036° to 0.014° with every degree of limb rotation [35, 36]. However, all our patients had a standardized positioning during radiological examination, and preoperative and postoperative FVA was not different, which represents reliable accuracy. Another drawback of our study is that the rotation of the components or their alignment in the sagittal plane were not investigated and thus we do not know about the posterior offset and tilting of the femoral component or the slope of the tibial component. These parameters might affect ROM and clinical outcome. However, there is no reason to believe that the use of long radiographs for adjusting the intramedullary femoral guide should affect femoral rotation or tilting of the components.

Preoperative FVA measurement and following femoral distal cut adjustments did not affect the overall leg alignment postoperatively, while positioning of the femoral component was improved together with minor improvements in objective KSS subscale scores.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

References


