

Influence of intentional femoral component flexion in navigated TKA on gap balance and sagittal anatomy

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Abstract

Purpose Navigation has proven its ability to accurately restore coronal leg axis; however, for a good clinical outcome, other factors such as sagittal anatomy and balanced gaps are at least as important. In a gap-balanced technique, the size of the flexion gap is equalled to that of the extension gap. Flexion of the femoral component has been described as a theoretical possibility to balance flexion and extension gap. Aim of this study was to assess whether intentional femoral component flexion is helpful in balancing TKA gaps and in restoring sagittal anatomy.

Methods One hundred and thirty-one patients with TKA were included in this study. Implantation was performed in a navigated, gap-balanced, tibia-first technique. The femoral component flexion needed to equal flexion to extension gap was calculated based upon the navigation data. The sagittal diameter, the anterior and posterior offset were measured pre- and postoperatively based on the lateral radiographs. Medial and lateral gaps in extension and flexion as well as flexion/extension gap differences pre- and postoperatively were analysed. Additionally range of motion (ROM) and patient satisfaction (SF 12) were obtained.

Results To achieve equal flexion and extension gap, the femoral component was flexed in 120 out of 131 patients showing mean flexion of 2.9° (SD 2.2°; navigation data) and 3.1° (SD 2.0°; radiological analysis), respectively. Based on this technique, it was possible to balance the extension gap (<2 mm difference) in 130 out of 131 patients (99 %) and the flexion gap in 119 out of 131 (91 %). The difference between extension and flexion gap was reduced from 39 to 24 out of 131 patients (81 %) on the medial side and from 69 to 28 on the lateral side (79 %). The sagittal diameter was restored in 114 out of 131 cases (87 %); however, anterior offset was significantly reduced by 1.3 mm (SD 3.9°), and posterior offset was significantly increased by 1.6 mm (SD 3.3°). No correlation between any navigation and radiological parameter was found with ROM and SF 12.

Conclusions The navigation-based, gap-balanced technique allows intentional flexion of the femoral component in order to balance gaps in more than 90 % of primary TKA cases. Simultaneously, the sagittal diameter is restored in 87 % of patients. However, to achieve equal gaps, the posterior offset is significantly increased by 1.6 mm and the femoral component is flexed by 3°. To evaluate the effect of this technique on the clinical outcome, future studies are needed.

Level of evidence II.

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Posterior offset · Flexion gap · Gap balance

Introduction

Instability is known as one of the main reasons for early TKA revision [21]. Different reasons for and different

types of instability exist [10]. One common cause is a mismatch between extension and flexion gap. Increased sagittal femoral diameter due to an oversized femoral component can lead to a tight flexion gap, leading to a minor ROM and inferior clinical outcome. This has been reported in up to 30 % of cruciate-retaining knees [14, 19], potentially leading to tightness in flexion [2] and finally to anterior knee pain, limited flexion, secondary patella baja and stiff knee [12, 23]. Another type of flexion/extension gap mismatch can be caused by over-resection of the posterior condyles. This can lead to a reduction in the posterior femoral offset and a loose flexion gap, thus resulting in flexion instability and/or limited flexion [1, 3]. In both scenarios, the resulting joint line in extension does not equal the joint line in flexion. This demonstrates the relevance of restoration of the sagittal anatomy [11].

Another parameter of femoral implant positioning in the sagittal plane is its flexion/extension, relatively to the sagittal femoral axis. Different authors [15, 27] have shown in simulations that around 2° of flexion of the femoral component leads to a decrease in flexion gap by 1 mm. The amount of flexion of the femoral component, however, has limits. In PS designs, a severely flexed position can cause increased polyethylene wear [25]. On the other hand, highly extended positions can cause anterior notching and, due to that, fracture risk is increased [16]. Different studies have shown a large variability of the flexion/extension position of the femoral component postoperatively, regardless whether surgery was performed conventionally or with navigation [24]. With the use of a standard intramedullary device, definition of femoral flexion in the sagittal plane can strongly be influenced by the bowing of the distal femur and the entry point of the intramedullary rod [26, 29]. In navigation systems, on the other hand, different sagittal femoral mechanical axes are used to determine the femoral flexion and, therefore again, the results are not comparable [6]. Until now, it has not been shown in a clinical study, whether intentional flexion of the femoral component is a sufficient way to restore the sagittal anatomy and to simultaneously equalize flexion and extension gaps.

Purpose of this study was therefore to analyse (1) whether flexion of the femoral component is helpful in adjusting the flexion gap to the size of the extension gap and (2) whether it is helpful in restoring the sagittal anatomy by applying a navigated, gap-balanced technique.

Materials and methods

Out of 810 patients who underwent TKA surgery in our hospital between October 2008 and January 2011, 131

patients were selected for this study. The patients were chosen randomly, independent of their clinical result. They were selected out of the Hospital Arthroplasty Register, based on the completeness of navigation protocols and all clinical and Register data. The patients were included in this study on condition that they received a fixed-bearing, CR implant; complete CAS protocol was available; and sufficient pre- and postoperative radiographs were available. All patients included were operated by the same two surgeons (M.S; H.G.), and all surgeries were performed with the use of computer-assisted surgery (Vector vision sky; knee unlimited 2.1, BrainLAB Feldkirchen Germany). A tibia-first, gap-balanced technique was applied. General indications and contraindications for TKA were respected.

The group consisted of 74 female and 57 male patients, aged between 44 and 89 (average 67 years). In 61 cases, left-side and, in 70 cases, right-side primary TKA were performed. Sixty-four of these knees were classified as varus ($>3^\circ$ of varus alignment), 42 as neutral ($\pm 3^\circ$ from 0° alignment) and 25 as valgus knees ($>3^\circ$ of valgus alignment). The mean follow-up time was 1 year after surgery. The mean ability of flexion preoperatively was 113° (SD = 15.6). The mean BMI of all the patients was 30.4 kg/m^2 (SD = 4.6).

Surgical technique

In all cases, a cruciate-retaining, fixed-bearing, cemented prosthesis was implanted (PFC sigma CR, DePuy Orthopaedics Inc., Warsaw, USA). The patella was resurfaced in all patients. A navigated, gap-balanced technique was applied. In this setting, data of the initial and final leg alignment (varus/valgus angle) as well as the intraoperative range of motion (extension and flexion angle) were obtained at the beginning and at the end of surgery. After the tibial cut, a spreader was applied in order to measure the extension gap medially and laterally. If an imbalance in extension was detected, a soft tissue release was performed until medial and lateral gaps were equal. After that, the sizes of the medial and lateral flexion gaps were measured. Based on both gap information, a suggestion for the femoral component size and position was offered by the navigation system. The surgeon then performed the individual, intraoperative planning, checking for femoral component size, femoral rotation and joint line shift in distal and in anterior/posterior direction. Extension and flexion gap size as well as the amount of posterior condyle resection were taken into account (Fig. 1). The aim was first to equalize the flexion and extension gaps. Further, the surgeon aimed to restore the sagittal femoral diameter based on the individual femoral model of each patient. As a second option for adjusting the flexion gap to the extension gap, the

Fig. 1 Navigation image of the femoral component planning. The size of the component matches the individual model of this patient knee well. Femoral component is placed in 0° of flexion. Please notice that the flexion gap is 14.5 mm, being 5 mm larger than the flexion gap

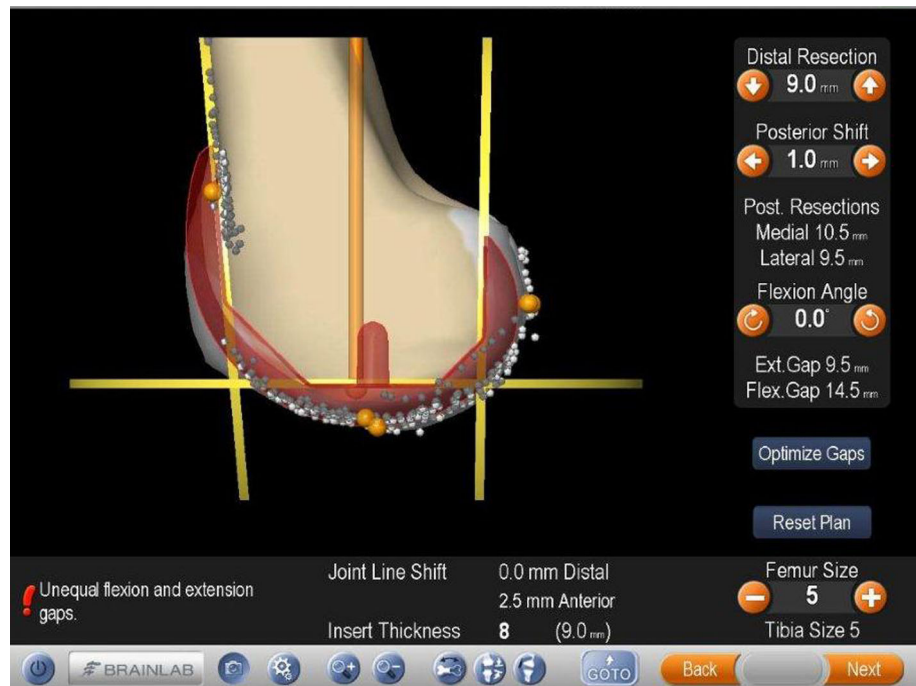
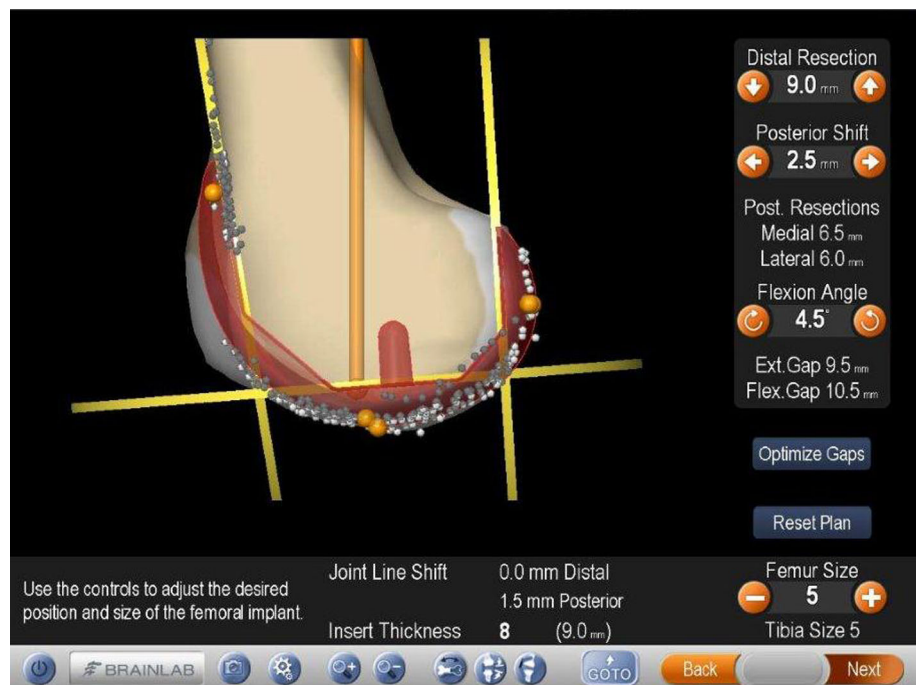


Fig. 2 Same picture but after flexing the femoral component by 4.5°; with that the difference between gaps is reduced to 1 mm. Based on that, the joint line is shifted 1.5 mm posteriorly and the amount of posterior bone resection is reduced



surgeon flexed the femoral component, with a maximum of up to 7°. Based on the algorithm of the navigation system, flexion of the component is performed around the anterior cortical contact point of the femur and not around the epicondylar axis. The effect of component flexion on the flexion gap was immediately calculated and presented on-screen (Fig. 2).

Navigation data analysis

The following parameters were analysed at the beginning of surgery and with the final implant in place: the difference between the medial and lateral gap in extension and in 90° of flexion, leg axis and range of motion. The differences between extension and flexion gaps were calculated

separately for the medial and lateral gap. All measurements were taken at the beginning and at the end of surgery, and differences between both time points were calculated.

The amount of femoral component flexion in the sagittal plane was recorded as well as the joint line shift in distal/proximal direction and in anterior/posterior direction according to the CAS software data.

Clinical analysis

Clinical outcome was assessed using the SF-12 score. Out of the clinical examination in particular range of motion (ROM), pre- and postsurgery was analysed.

Radiological analysis

In each case, standardized radiographs (long-leg-ap including hip and ankle joint, a lateral knee and patella skyline) were obtained before and at least 3 times after surgery (10 days; 6 months and 1 year, postoperatively). To include the radiographs, the projection of the lateral view had to be strictly lateral, meaning that the outlines of the posterior femoral condyles were less than 3 mm. The knee was flexed in a standard position of 45°. Two of the three radiographs needed to show identical results regarding size and offset before the patient was included in this evaluation. The radiological analysis was performed by two different surgeons, not being the operating surgeons. Measurement was taken with the GEMED tool by Agfa Germany allowing 0.1 mm and 0.1° of accuracy.

Based on the lateral radiographs, the sagittal flexion of the femoral component as well as the tibial slope was identified. Additionally, we measured the overall sagittal diameter of the femur preoperatively. For postoperative measurement of the sagittal diameter, we used the defined sizes of the different femoral implants. Further, the anterior and posterior femoral offset was calculated. To assess the anterior and posterior femoral offset, we measured the distances according to Bellemans et al. [3].

The long-leg-ap radiograph was taken on the standing, fully load-bearing patient, pointing the patella to the front.

The HKA (hip–knee–ankle angle) was measured pre- and postoperatively to additionally validate the coronal axis outcome.

IRB approval was obtained by local ethics committee (Bayerische Landesärztekammer Ethik-Kommission Nr. 12018).

Statistical analysis

Data were analysed using IBM SPSS 20 and R 2.15.1 (R Foundation for Statistical Computing, Vienna, Austria). Categorical data are presented as frequencies and

percentages, continuous data as means (standard deviations). Differences are reported with 95 % confidence intervals (95 % CI).

Outcome measures were assessed in two different ways. First, all alterations between the pre- and postoperative data (ROM, anatomical axis, anterior and posterior femoral offset, patellofemoral alignment, gaps, joint line shift) were compared using paired t tests. A comparison of differences more or less than 2 mm pre- and postoperatively was made using the McNemar test. To test the probability of success (deviation less than 2 mm), we used an exact binomial test. Second, the differences of all the single collected data were correlated with the outcome (SF 12 score) and ROM in a nonparametric way using Spearman's Rho correlation coefficients. All analyses were done using a two-sided 0.05 level of significance and have not been adjusted for multiple testing.

Results

The mean flexion of the femoral component in the sagittal plane measured by navigation intra-operatively varied between 0° and 7° (mean 2.9°, SD 1.8°). In 92 % of patients (121 out of 131), the femoral component was flexed in order to equal the gaps. In average, a femoral component flexion of 5° resulted in a flexion gap reduction of 4 mm, meaning that 1.2° changes the gap by 1 mm. Comparing navigation data with radiographic measurements showed no significant difference between methods. The mean was 3.1° (SD = 2.2°) ranging from 0° to 10° of femoral component flexion in the radiological analysis.

A discrepancy between the extension and flexion gap on the medial side of more than 2 mm was found in 43 % (56 out of 131 patients) of knees preoperatively. Postoperatively, this could be significantly reduced to 19 % (25 out of 131 patients) ($p < 0.001$) on the medial side. On the lateral side, it could be significantly reduced from 53 % (69 out of 131 patients) preoperatively to 21 % (27 out of 131) postoperatively ($p < 0.001$).

The mean sagittal femoral diameter was preoperatively 64.7 mm (SD = 4.6) and postoperatively 64.8 mm (SD = 4.5) [mean difference -0.09, 95 % CI (-0.52; 0.34) $p = \text{n.s.}$] (Table 1). In 87 % (114 out of 131 patients), the alteration in the sagittal femoral diameter was less than 2 mm. In the remaining cases, 10 patients showed an increase of more than 2 mm, whereas in 7 of the cases, the sagittal diameter was decreased by more than 2 mm.

The mean anterior femoral offset was significantly reduced from 40.0 mm (SD = 4.6) preoperatively to 38.7 mm (SD = 4.6) postoperatively, the mean difference being 1.3 mm [95 % CI (0.64; 2.05) $p < 0.001$]. Posterior femoral offset was significantly increased from 26.9 mm (SD = 3.8) preoperatively to 28.5 mm (SD = 3.8)

Table 1 Radiological parameters

	Mean value \pm SD preoperatively	Mean value \pm SD preoperatively	Difference preoperatively–postoperatively	<i>p</i> value
Femoral diameter lateral	64.7 mm \pm 4.6	64.8 mm \pm 4.5	–0.09 mm \pm 2.48	n.s.
Anterior femoral offset	40.0 mm \pm 4.6	38.7 mm \pm 4.6	1.3 mm \pm 3.9	<0.001
Posterior femoral offset	26.9 mm \pm 3.8	28.5 mm \pm 3.8	–1.6 mm \pm 3.3	<0.001
Anatomical valgus axis	3.7° \pm 7.4	6.0° \pm 2.3	–2.5° \pm 7.8	<0.001
HKA	178.8 \pm 8.27	178.4 \pm 1.83	0.1 \pm 7.8	<0.001

postoperatively. The mean increase in the posterior femoral offset was 1.6 mm [95 % CI (1.05; 2.20) p < 0.001] (Table 1).

The navigation data showed that the distal femoral joint line was restored within the 2-mm deviance in 92 % (119 of 131 patients) of cases. In anterior–posterior direction, a small but significant posterior shift of 0.6 mm was measured, however, still showing in 72 % (94 out of 131 patients) a joint line shift of less than 2 mm (p < 0.001) (Table 2).

The amount of external femoral rotation showed an average value of 2.7° (SD = 3.32°) referring to the posterior condylar plane.

The postoperative alignment showed a HKA of 178.4° (SD = 1.83°). A total of 97 % were within the 3° corridor.

The mean knee flexion was slightly increased from 113.1° preoperatively (SD = 15.6) to 116.3° (SD = 15.3) postoperatively. The difference being not significant [mean difference –2.8° 95 % CI (–7.0; 1.4) p = n.s.]. Both knee flexion and SF 12 showed no significant correlation with any of the radiographic or navigation parameters.

Discussion

The most important findings of this study were (1) that flexion of the femoral component is a helpful option in

order to establish flexion–extension balance and (2) to restore the sagittal anatomy in TKA.

This study could show that navigated, gap-balanced technique is able to balance the extension gap of a primary TKA in more than 90 % of cases within a 2-mm margin. In 80 %, it was possible to equalize flexion and extension gap. To achieve this, flexion of the femoral component was intentionally performed in more than 90 % of cases (mean of 3°), in order to adjust the flexion gap to the extension gap. An average 5° of flexion lead to 4-mm reduction in the flexion gap. With this technique in 87 % of knees, the sagittal anatomy could be restored within 2 mm.

Navigation has proven to increase accuracy regarding restoration of the leg axis [4] as well as providing rectangular gaps in extension and flexion [20]. This could be confirmed in this study, too, showing more than 97 % within the critical 3° interval. Restoration of the sagittal anatomy has been shown to be important, too [12, 15]. Measured resection techniques imitate natural sagittal anatomy, and gap balancing is done after bone resection by different releasing techniques [18, 28]. In a ligament-balanced technique, on the other hand, flexion gap size is adjusted to the size of the extension gap and an individual femoral rotation provides a symmetrical flexion gap [5]. To solve the problem of an imbalance between gaps, oversizing of the femoral implant in the sagittal plane has been

Table 2 Navigation parameters

	Mean value \pm SD preoperatively	Mean value \pm SD postoperatively	Diff. preoperatively–postoperatively	<i>p</i> value
Extension gap difference mediolateral	–1.1 mm \pm 2.5	–0.2 mm \pm 0.96	–0.92 mm \pm 2.79	<0.001
Flexion gap difference mediolateral	–2.1 mm \pm 2.9	0.3 mm \pm 1.3	–2.5 mm \pm 3.32	<0.001
Extension/flexion gap difference medial	–0.8 mm \pm 2.99	0.01 mm \pm 1.94	–0.92 mm \pm 3.21	<0.002
Extension/flexion gap difference lateral	–1.9 mm \pm 3.14	0.5 mm \pm 1.75	–2.46 mm \pm 3.66	<0.000
Joint line shift distal/proximal	0.0 mm	0.2 mm \pm 1.27	0.2 mm \pm 1.27	n.s.
Joint line shift posterior/anterior	0.0 mm	0.6 mm \pm 1.92	0.6 mm \pm 1.92	<0.000

described as one solution in a gap-balanced technique. This oversizing has been observed in up to 30 % of cases, which can in PCL-retaining knees lead to an increased stress of the PCL [2]. This might finally lead to an overstuffing of the joint and possibly to anterior knee pain, reduced ROM and stiffness. To avoid this problem, restoration of the individual anatomy regarding the femoral diameter has been advocated [12, 15]. With this presented technique, we were able to restore the sagittal anatomy in almost 90 % of patients.

Another way to reduce flexion gap size is flexion of the femoral component. Different authors [15, 27] have described in their models that a component flexion of around 2° is leading to a reduction in the flexion gap of around 1 mm. In this study, the femoral component was intentionally flexed in more than 90 % of patients in order to reduce the flexion gap. Flexion ranged between 0° and 7°, showing a mean flexion of the component of 3°. In this study, a flexion of 1.2° lead to a flexion gap decrease of 1 mm, which is almost in the range of the above-mentioned studies.

The navigation technique has proven its technical precision [8, 17]. The maximum difference is 0.5° and 0.5 mm for axis or distances. By that, not only bony resections can be accurately performed and verified, also gap balancing can be assessed with high precision. Different authors could prove the benefit of a navigation-based technique for gap balancing [9, 13]. In this study, it was possible to confirm this advantage by reaching a balanced extension gap in 99 % of knees and a balanced flexion gap in 91 % of knees.

Different studies have described that the correlation between the radiological parameters and the clinical and subjective patient outcome is low [22]. In the presented work, the correlation between the radiological parameters (mechanical axis, posterior offset and sagittal diameter), navigation data and patient outcome was again low.

One limitation of this study is the accuracy of the radiological analysis. Although defined positions were chosen and meticulously controlled, the reproducibility is described to be low [7]. To overcome this problem, radiographs were obtained at different time points and reproducibility was tested. Patients were only included in this study if at least two radiographs gave identical results for both investigators. Further different parameters were compared with navigation data in order to prove the accuracy of radiographs. Femoral flexion of the component in the sagittal plane, leg axis and tibial slope showed no significant differences between navigation and radiological analysis. Quality of radiographs was the main reason for patient exclusion in this study.

Conclusions

Based on the presented results, it was possible to demonstrate that in a navigated, ligament-balanced technique, flexion of the femoral component is helpful to equal and balance the gaps and to restore the sagittal anatomy in TKA. However, to achieve equal flexion and extension gaps, the posterior offset was significantly increased by 1.6 mm. Although the radiological and navigation data showed a good anatomical reconstruction and a well-balanced knee in the vast majority of patients, the clinical benefit regarding knee flexion was only minor and not significant. At this moment, intentional flexion of the femoral component is only possible in a navigated technique; however, in a conventional technique, an optional instrument should also be available in order to alter femoral component flexion.

Future studies are needed to assess the long-term clinical result of this navigation-based technique.

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