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Accuracy of a patient-specific instrumentation for coronal plane alignment of an anatomic alignment total knee arthroplasty system: A radiographic study

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Abstract.
BACKGROUND: Patient-individualised anatomic alignment in total knee arthroplasty (TKA) requires exact positioning of the tibial and femoral components. Patient-specific instrumentation (PSI) may be advantageous for implantation. However, the role of PSI in the instrumentation of such knee designs has not been investigated.
OBJECTIVE: The aim of this study was to investigate the accuracy of a PSI system designed for patient-individualised anatomic alignment.
METHODS: Fifty-four patients from a single centre were consecutively enrolled in this study. Patient-specific femoral and tibial cutting guides were manufactured using 3D models from computed tomography (CT) scans. All patients received an anatomic TKA implant design through an extension gap first technique. Postoperative radiography was taken, and implant component alignment and leg alignment were compared to the preoperative planning.
RESULTS: Thirty-four patients were evaluable. Mean differences between planned angles values obtained from CT scans and the measured radiographic values were small and not significantly different from zero.
CONCLUSIONS: Implantation of an anatomic knee design that allows individual component alignment using PSI is feasible. The percentage of component misalignment in the coronal plane was remarkably low. Whether this leads to clinical benefits requires further verification.

Keywords: Total knee arthroplasty, patient-specific instrumentation, anatomic alignment, surgical technique

1. Introduction

Obtaining alignment and soft-tissue balance are key to a successful total knee arthroplasty (TKA). Accurate implant coronal plane alignment along with equal flexion and extension gaps are essential to achieve this objective [1].

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Conventional measured resection TKA performed with patient-specific instrumentation (PSI) aims to achieve a neutral axis alignment and is solely oriented in relation to bone landmarks [2]. A neutrally aligned leg axis is still considered the gold standard in knee arthroplasty [3]. However, other alignment philosophies that are based on the reconstruction of native anatomy have emerged. In some cases, an undercorrection of mechanical alignment has been recommended [2,4,5]. Among these, philosophies such as kinematic and anatomic alignment are becoming increasingly common [6]. Anatomical, personalised alignment tolerates deviations from the neutral mechanical axis while minimising the need for performing ligament releases [5].

The restoration of a patient's native anatomy during TKA can be challenging. The surgeon must decide to what extent the patient's tibial and femoral bone morphology, which is typically affected by osteoarthritis, can be followed. A coronal plane joint line orientation of the knee is not perpendicular to the mechanical axis but is in 3° of varus [7]. When TKA is performed following the philosophy of anatomical alignment, the components are implanted according to these physiological and individual angles.

Although PSI in measured resection TKA has not been proven to be superior to conventional instrumentation in terms of alignment [8], it has been demonstrated to be advantageous when applying surgical techniques that are based on patient-specific alignment [5,9].

The present study assesses the first TKA implant system (4-motion, ARTIQO GmbH, Lüdinghausen, Germany) which is intended for up to 3° of varus positioning of the tibial component. The reconstruction of this anatomical specification produces several changes in the prosthesis design and potential advantages in the context of prosthesis implantation. An anatomic reconstruction of the native joint line renders positioning of the femoral component in external rotation to achieve a rectangular flexion gap obsolete. On the femoral side, this technique allows the native posterior condylar offset to therefore be reconstructed. In addition, the need for iatrogenic soft-tissue releases is considerably reduced.

The aim of this study was to investigate the accuracy of the planning of the 4-motion PSI system designed for patient-individualised anatomic alignment.

2. Methods and patients

From January to July 2019, 54 patients from a single centre were consecutively enrolled in this study. The patients' informed consent was obtained prior to study commencement, and the local ethics review committee approved this study (Ethics Committee no. BO/44/2018). In all the patients, TKA with a fully cemented cruciate retaining 4-motion implant system was performed using PSI with patient-specific cutting guides (Medivation AG, Brugg, Switzerland). All procedures were carried out by a single senior surgeon specialised in TKA (KM). A preoperative computed tomography (CT) scan of the affected leg was obtained for each patient. A defined CT acquisition protocol was used (proximal femur and distal tibia: slice distance of 2.0 mm; distal femur and proximal tibia: slice distance of 0.5 mm). A three-dimensional (3D) model of the leg anatomy was retrieved from each CT dataset. Dedicated software was used to perform the semi-automatic segmentation step. Patient-specific cutting femoral and tibial guides were then planned and designed using the resulting 3D models. The 3D models were coupled to osteophytes and bone structures at the border of the joint surface in order to provide a stable fit to the patient's anatomy. A planning website (Webplanning, Medivation) was used to present the resultant plan together with the designed patient-specific cutting guides to the surgeon. The website had a 3D visualisation of all bones and cutting planes so that the surgeon could adjust the planning, including the size and position of the implants (Fig. 1). The planned leg axis (between 0° and 3° residual varus)

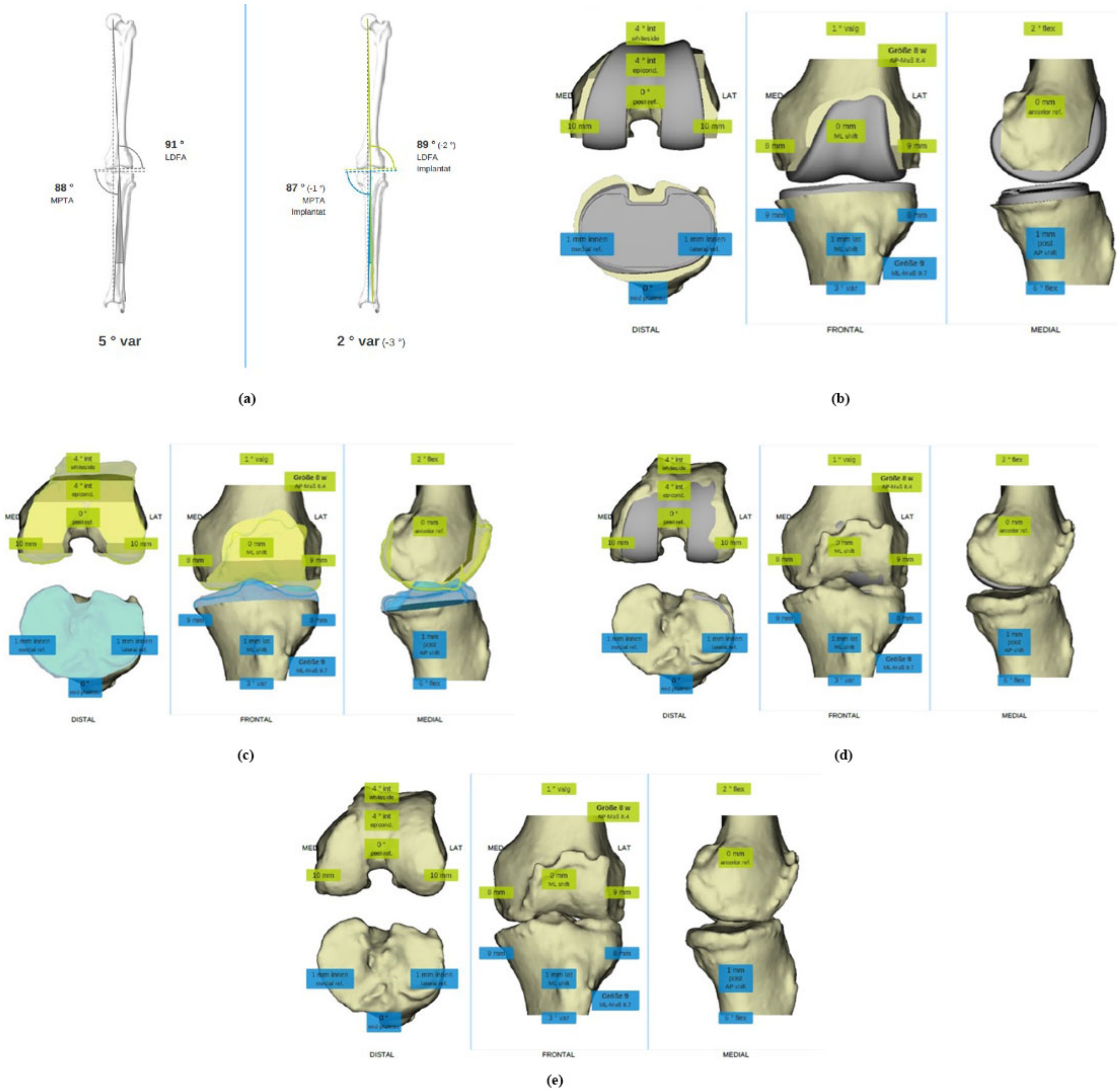

Fig. 1. Visualisation of the preoperative (left) and the planned hip-knee-ankle (HKA) with the relevant pre- and postoperative angles (a). Three-dimensional simulation of the planned implant position with relevant angles, implant sizes and bone cuts (b). The knee with resected bone (c), the projection of the implant on the unresected bone (d) and the preoperative knee with the relevant angles and implant sizes are also visualised.

depended on the preoperative varus – valgus status and flexion – extension angle of the specific patient. Upon confirmation by the surgeon, the cutting guides were produced by an additive manufacturing technique (3D Systems, Duraform PA, USA) (Fig. 2). TKA was then conducted according to the standard clinical routine and using the PSI. A medial parapatellar approach was used in all surgeries. All contact surfaces for the PSI were visualised during initial preparation, leaving the osteophytes intact. Once the PSI was securely positioned, the proximal tibia and distal femur were resected according to the surgical

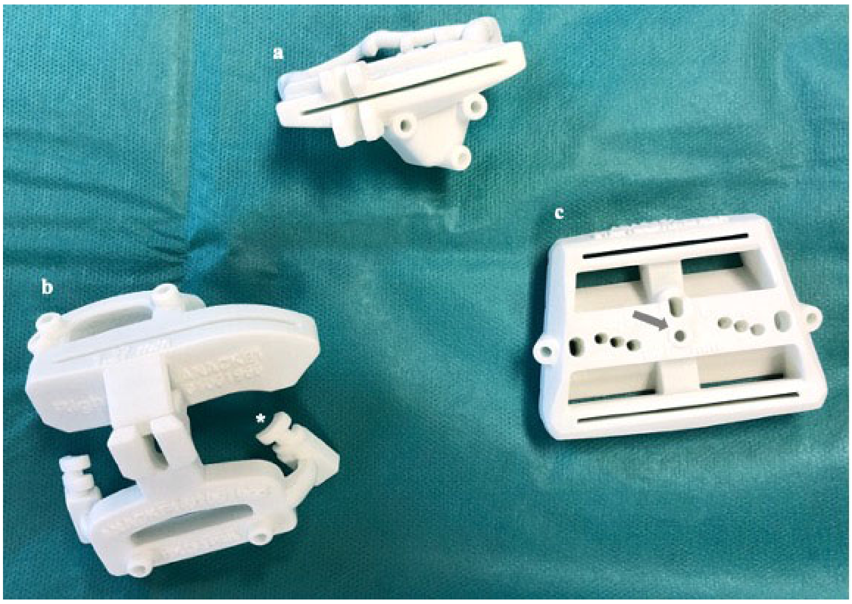

Fig. 2. Patient-specific cutting guides for tibial (a), distal femoral (b) and ventral/dorsal femoral resection. The white * marks the flange coupling to the osteophyte. The grey arrow marks the pinholes for the tensioner device.

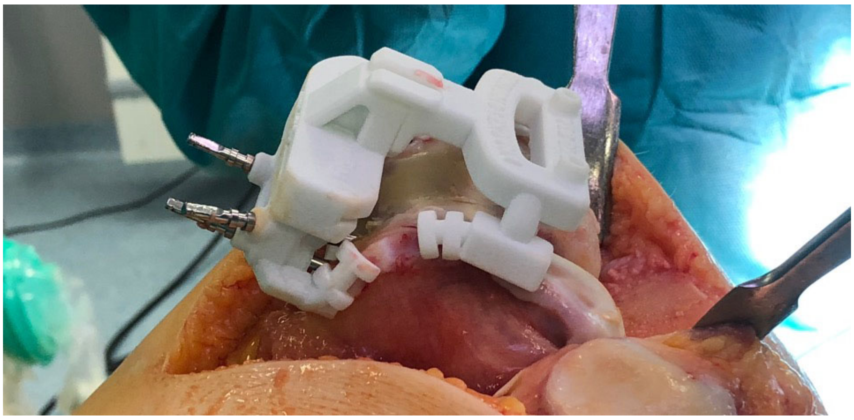

Fig. 3. Patient-specific cutting guides securely positioned and fixed to the intact osteophytes on femoral site before the femoral resection.

plan (Fig. 3). Pinholes indicated the planned femoral rotation, which was not yet determined by the distal femoral resection. The lateral, medial and accessible posterior femoral osteophytes were removed after these two resections because they were no longer needed as references for the PSI. This step avoids further influence on ligament tension and is therefore a crucial element of the new functional alignment technique presented [10]. Next, to assess the resulting extension gap, a laminar tensioner device (ARTIQO GmbH) was inserted and spread by hand (Fig. 4). Gap mismatch was avoided by performing this step with care and reproducible force [5]. In the case of gap asymmetry, angular deviations could be corrected either by a corrective recut of the tibia or the femur or by ligament release. The values that were established for the extension gap tension were then applied to the flexion gap. A rectangular flexion gap was achieved

Fig. 4. A laminar tensioner device (ARTIQO GmbH) is inserted, fixed to the femoral cut guide and spread by hand to assess the extension gap.

by adjusting the femur rotation based on the soft tissue tension. Drilling of the pinholes for the 4-in-1 block was performed over the balancer device. Final bone cuts were then made, and the implant was placed according to the manufacturer's instructions. In this patient series, no recuts for joint balancing or ligament releases were required.

In accordance with our clinic's standard practice, full leg weight-bearing AP radiographs of all legs were taken 3 weeks prior to surgery and at the 8-week postoperative visit (Fig. 5). All radiographs were analysed using the open-source software Ginkgo-CADx (www.ginkgo-cadx.com) by a single assessor (KM). The following angles were defined: hip-knee-ankle (HKA), which is a measure of lower limb alignment and defined as the angle between the mechanical axes of the femur and the tibia [11]; the lateral distal femoral angle (LDFA), which is the angle between the mechanical axis of the femur and the knee joint line of the femur [12]; the medial proximal tibial angle (MPTA), which is the angle between the tibial mechanical axis (drawn from the centre of the knee to the centre of the talus) and the knee joint line of the tibia [11]; physiological LDFA, which is between 85° and 90°, and physiological MPTA, which is between 85° and 90° [12].

For the purpose of this study, only radiographs with a flawless quality were accepted. All of the following features had to be achieved in each radiograph: clearly visible ankle joint, clearly visible hip rotation centre, clearly visible tibia plateau (no tilting), clearly visible femoral condyles and implant (no tilting), absent twisted shooting direction and absence of artefacts [7,13].

Two of the 54 images could not be evaluated because of slightly low image quality. In nine cases, the relevant points (especially the femoral head centre) were not exactly recognisable. In nine cases, artefacts or slight malpositioning of the leg in the X-ray images, such as slight knee flexion (more than estimated 0°) or slight internal/external rotation, did not allow an accurate determination of the required angles. Therefore, 34 patients (males, 15; females, 19) could be included in the study. The mean age of the study population was 62.9 ± 25.9 years. The right knee joint was operated on in 14 cases, and the left knee joint in 20 cases.

Fig. 5. The pre- and postoperative full leg weight-bearing AP radiographs show the resulting correction of the hip-knee-ankle and the anatomically aligned implants.

The postoperative measurements of the HKA, LDFA and MPTA were subsequently compared with the preoperative planning. Malalignment was defined as a measurement that was $> 3^\circ$ from the intended value [14]. Implant sizes and surgery times were recorded from the patients' surgery protocols.

2.1. Statistics

The reliability of the measurements was confirmed by calculating intraclass correlations to determine absolute agreement of the measurements by means of two-way mixed-effects models for individual measurements. After violation of the normality assumption was verified, descriptive statistics (mean, standard deviation, and range) were calculated. A one-sample t-test was used to assess for the presence of any deviation from the planned alignment. The proportion of differences within $\pm 2^\circ$ and $\pm 3^\circ$ were calculated for the alignment values. Statistical significance was set at $p < 0.05$. All statistics were performed using Stata 15.1/SE (StataCorp, College Station, TX, USA).

3. Results

Thirty-one patients had a preoperative varus leg axis, whereas the three remaining patients had preoperative neutral alignment. No difficulties using the cutting blocks were reported by the surgeon. For three

Table 1
Difference between the planned angles obtained from preoperative and postoperative radiography

Angle	Signed deviation					Unsigned (absolute) deviation	
	Mean ± SD	Range	p-value	Outside ± 3°	Outside ± 2°	Mean ± SD	Range
Global – HKA	0.4 ± 2.1	−4.0, 3.5	0.246	5 (14.7%)	16 (47.1%)	1.8° ± 1.0°	0.0, 4.0
Femur – LDFA	−0.3° ± 1.8	−5.1, 3.6	0.317	5 (14.7%)	6 (17.6%)	1.4 ± 1.3	0.1, 5.1
Tibia – MPTA	0.1° ± 1.6°	−4.0, 2.7	0.851	1 (2.9%)	8 (23.5%)	1.3 ± 1.0	0.0, 4.0

Abbreviations: SD, standard deviation.

cases, a downsizing of the femoral component was required, and a recut was performed for the smaller size. The downsizing was required because the implant was too wide in the mediolateral dimension or in order to maintain size compatibility to a smaller tibial implant. In seven cases, the tibia implant was smaller than planned; recutting was not required in any of these patients. No additional soft tissue releases were necessary in any of the patients. The mean duration of surgery was 40.4 ± 5.6 min.

The mean preoperative HKA was −3.5° ± 1.9° (range, −8°–0°), which was corrected to −1.0° ± 2.6° (range, −4.6°–4.0°). The mean LDFAs were 87.6° ± 2.4° (range, 83.0°–93.0°) preoperatively and 87.9° ± 2.0° (range, 83.4°–92.1°) postoperatively.

The mean preoperative and postoperative MPTAs were 85.9° ± 1.7° (range, 82.0°–88.0°) and 87.0° ± 1.7° (range, 84.3°–91.0°), respectively.

For all 34 knees, except the unsigned outcome variables, no major violation of the normality assumptions was observed for the differences between the target angles and measured angles. All mean differences between planned angles values obtained from preoperative and postoperative radiography were small and not significantly different from zero (Table 1). A total of 11 patients (32.4%) had TKAs that resulted in a postoperative valgus HKA (i.e., HKA $>$ 0°). Of five knees that were all targeted at neutral alignment and had more than a 3° difference between the targeted angle and the angle measured with postoperative radiography, three were placed into valgus (HKA, 183.0°, 183.6° and 184.0°) and two into varus (176.5° and 176.7°).

4. Discussion

Anatomic alignment, initially introduced in the 1980s by Hungerford and Krackow [15], is a technique that aims to obtain an oblique joint line (3° valgus) relative to the limb's mechanical axis. This technique is believed to promote an improved load distribution on the tibial component [6]. Furthermore, it promotes better patella biomechanics, because it leads to a reduction in the risk of lateral retinacular ligament stretching when the knee flexes [16]. In the 1970s, the widespread use of this technique was not possible because of the technical challenge of precisely achieving bone cuts and the risk of having a supposedly deleterious excessive ($>$ 3°) varus of the limb or tibial implant positioning [6,17,18]. This lack of surgical accuracy can now be overcome by two means: precision tools, such as PSI, or implants that have been developed and approved for varus positioning of the tibial component, such as the 4-motion TKA system that has been subject to this study.

The primary goal of the present study was to investigate the accuracy of the planning of a PSI system designed for the alignment of the femoral and tibial implant components of a TKA that allows patient-individualised anatomic alignment.

Table 2
Proportion of malaligned knees, comparison of measured resection PSI, standard instrumentation and anatomic alignment PSI

Angle	Measured resection PSI [8]	Standard instrumentation [8]	This study
HKA	20.2% (15.6–25.1%)	25.7% (21.6–30.0%)	14.7% (5.0%–31.0%)
Tibia Coronal Plane	10.5% (5.9–16.1%)	7.9% (4.9–11.5%)	2.9% (0.1–15.3%)
Femur Coronal Plane	10.3% (6.2–15.3%)	11.0% (6.5–16.3%)	14.7% (5.0%–31.0%)

Abbreviations: HKA: hip-knee-ankle; PSI: patient-specific instrumentation.

Comparing the risk of malalignment (employing a 3° threshold) of this PSI system with measured resection PSI and conventional instrumentation [8] revealed a lower proportion of outliers for tibial coronal plane alignment. Femoral component coronal plane alignment and HKA appeared to be in line with the values previously reported for PSI [8] (Table 2).

Preliminary evidence shows that tibial component malalignment, in both varus and valgus directions, results in increases in contact stress and pressure [17] and a higher failure rate than in a malalignment of the femoral component. Moreover, a significant increase in the failure rate results from compensation for a varus or valgus orientation of the tibial component via an alteration of the femoral component alignment [18]. Furthermore, a key criticism of the gap-balancing technique is that the alignment of the components is based on the proximal tibial cut; hence, the risk of an initial error in the alignment being carried through to all subsequent cuts occurs [19,20]. In the present study, the rate of malpositioning of the tibial component appears to be particularly low compared with that presented in the literature, from which we infer that the instruments are particularly suited to this surgical approach.

Besides the alignment accuracy of the cut blocks in the operation, intraoperative factors, such as pin/resection accuracy and final positioning/cementing of the implant components, may also affect the final alignment and postoperative results. However, the named intraoperative factor also affects implant positioning in conventional TKA.

The limitations of the present study are its retrospective study design and the relatively small number of patients that were included. Due to the very high quality standard we applied to the radiographs, 20 patients had to be excluded. Nonetheless, we feel that this reduced the confounder of inaccurate data from the radiographs. Another major limitation of the present study is the fact that postoperative alignment measurements were based on standard radiographs rather than on CTs. However, standard radiography has a satisfactory precision (coefficient of repeatability, 0.8°) for long leg full weight-bearing X-rays [21], with the obvious advantage of having a lower radiation exposure compared with CT. Furthermore, potential confounding factors for HKA measurements are the rotation of the limb and extension or flexion limits of the knee in long leg radiography [22]. For ethical reasons, additional CTs were not authorised by the local ethic committee. Thus, we were not able to measure the difference between the planned rotation and the final rotation of the femoral component in cases of femoral rotation adjustment. However, in cases of ligament balancing we adjusted the rotation be around 4°, but we did not record the intraoperative deviation from the anatomic landmarks. This should be subject to future investigations. Another limitation of this study was that the exclusion of patients may have been related to factors associated with the outcome, which may have introduced selection bias. Sagittal and axial component alignment was also not evaluated. Finally, no clinical data of the study were analysed. Hence, no inferences can be made with regard to clinical safety and whether anatomical alignment eventually contributes to the ultimate goal of TKA, the 'forgotten joint'. However, this was not the aim of the present study. Further studies are warranted to assess the clinical benefits of anatomic knee alignment design.

5. Conclusion

The implantation of an anatomical knee design that allows individualised component alignment with the use of PSI is feasible. The accuracy of component alignment and overall alignment appears to be consistent with meta-analysed values from the literature, although the percentage of tibial component malalignment in the coronal plane was notably low.

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Conflict of interest

None to report.

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