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ORIGINAL ARTICLE

Influence of the femoral entry point for intramedullary alignment in total knee arthroplasty: A computer-aided design approach

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The determinants for a good clinical performance following primary total knee arthroplasty (TKA) are not fully understood.[1] Regardless of the alignment method (mechanical/kinematic/anatomical), femoral instrumentation using an intramedullary (IM) device is still the most commonly used technique in TKA thanks to high accuracy.[2,3] The femoral entry point for the insertion of the alignment rod is crucial for the IM instrumentation and following surgical steps. In cases of post-traumatic deformities or abnormal axis deviations, when IM instrumentation is not feasible, alternatives include patient-specific instruments and computer-assisted surgical navigation.

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ABSTRACT

Objectives: The aim of this study was to simulate different entry points and investigate potential angulation errors of the intramedullary device and resulting changes in the distal femoral cut using a computer-aided design (CAD) approach.

Materials and methods: We used a CAD approach to simulate various distal femoral entry points for intramedullary instrumentation. Simulations were performed on *(i)* a commercially available three-dimensional (3D) CAD model of a human femur (DigitalFemur) and *(ii)* a digital 3D model of an analogue large femur model produced using a coordinate measuring machine (FaroFemur). Divergent insertion points medial, lateral, anterior and posterior to the ideal position were simulated. Angulation deviations of the resulting positions of the intramedullary rod were measured and changes in the anatomical-mechanical axis angle were calculated. Differences between the two simulation models were quantified.

Results: The ideal entry point in the FaroFemur was 9.9 mm anterior and 4.3 mm medial to the apex of the intercondylar notch, and 9.2 mm anterior and 3.6 mm medial in the DigitalFemur. A medial entry point increased the angle between the anatomical femoral axis and the alignment rod in the FaroFemur and DigitalFemur (with 5 mm displacement 2.510° and 2.363°, respectively; with 10 mm displacement 3.239° and 3.283°, respectively). In contrast, a lateral entry point decreased the angle between the anatomical femoral axis and the alignment rod (with 5 mm displacement 2.267° and 2.262°, respectively; with 10 mm displacement 3.158° and 3.731°, respectively). An anterior entry point changed the angle between the anatomical femoral axis and the alignment rod towards extension (1.802° in the FaroFemur; 2.142° in the DigitalFemur), while a posterior entry point generated a deviation toward flexion (2.045° in the FaroFemur; 2.055° in the DigitalFemur). The mean difference between the two models was 0.108±0.121° with the highest difference for anterior displacement.

Conclusion: Minor deviations of the entry point for intramedullary instrumentation during total knee arthroplasty can result in malalignment of several degrees.

Keywords: Computed-aided design, entry point, intramedullary instrumentation, total knee arthroplasty.

Deviation of the IM device may influence the valgus cut,[4] particularly when a standard distal femoral cut (e.g. 6° or 7°) is used.[5] Resulting axis deviations are likely to impair clinical performance[6] and malalignment of implants contributes to the probability of failure after TKA.

The femoral entry point is located at the distal femoral surface in the midaxial line of the femoral canal in the coronal and sagittal plane. There is a general agreement that it is located medial and anterior to the posterior intercondylar notch.[7,8] Opening of the femoral canal should be performed 3 to 5 mm medial to the apex of the posterior intercondylar notch and 7 to 10 mm anterior to the origin of the posterior cruciate ligament. However, different locations have been described in the literature and intraoperatively, without the use of navigation, the determination remains highly subjective and shows high variation.[9]

To further investigate the influence of the entry point for IM instrumentation during TKA, we used computer simulation. In a computer-aided design (CAD) approach, we simulated various entry points and quantified potential deviations of the IM alignment rod. First, we hypothesized that varying femoral entry points could influence the orientation of the IM device and result in changes of the distal femoral resection in the coronal and sagittal plane. Second, we hypothesized that findings between two different three-dimensional (3D) simulation approaches (commercially available digital femur, and 3D model generated using Faro® arm) could produce similar results. Therefore, we aimed to simulate different entry points and investigate potential angulation errors of the IM device and resulting changes in the distal femoral cut using a CAD approach.

MATERIALS AND METHODS

This experimental study was conducted at the Danube University Krems, between February 2020 and August 2020. Two approaches to simulate distal femoral entry point for IM instrumentation were carried out. First, simulations were performed on a commercially available 3D CAD model of a human femur ("Digital femur"; Femur, Scan of 4th Generation #3406, Fa. Sawbones, Figure 1). The CAD file contains the digital external and internal anatomy of an averaged left large-size adult (age less than 80 years) human femur. Simulations were performed using a multi-platform software for CAD (CATIA V5-6R2019 SP3, Dassault Systèmes, Vélizy-Villacoublay, France).

Additionally, a digital 3D model of an analogue large femur model (#3406, Fa. Sawbones) was produced using a coordinate measuring machine (FaroArm®, Inition Digital Limited, Wembley, United Kingdom). For this purpose, the bone model was positioned freely suspended on thin threads and scanned with the FaroArm® (Figure 2). The FaroArm® scans the surface of an object with a laser beam and creates a point dataset and digital

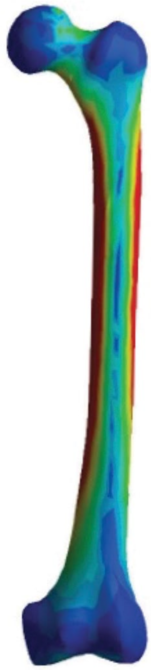

FIGURE 1. 3D model of a left human femur (Femur, Scan of 4th Generation #3406, Fa. Sawbones).

FIGURE 2. Scanning of the analogue large femur model using FaroArm®

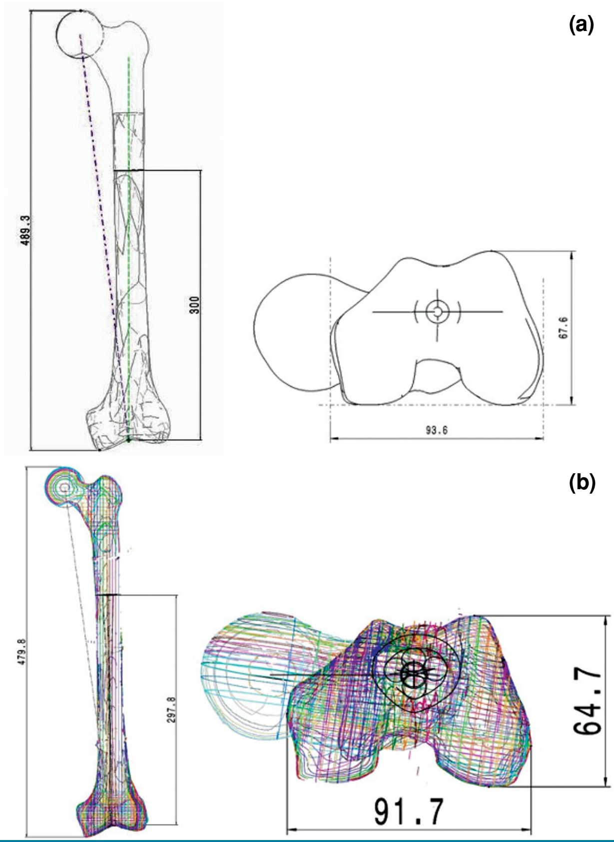

FIGURE 3. Dimensions of the **(a)** digital femur (Fa. Sawbones) and **(b)** the 3D model produced using the FaroArm®.

3D model. The resulting point cloud of the femur model surface contained approximately five million points. The data were, then, transferred to a CAD program (CATIA V5-R19 SP3, Dassault Systèmes, Vélizy-Villacoublay, France) where simulations could be performed ("FaroFemur").

The dimensions of both digital femora differed slightly (Figure 3). These models were, then, used for digital simulations of different entry points and resulting orientation of the IM alignment rod. The simulations were carried out in the same manner on both models.

The proper entry point of the IM rod in the distal femur was determined at the intersection of the midaxial line of the distal femur on the articular surface. The midpoints of the femoral canal 10 and 30 cm proximal to the distal end of the femur were connected and the point of the intersection on the articular surface was defined as the ideal entry point. The opening drill hole for the medullary canal was set with a diameter of 9 mm and an IM guide rod (length 30 cm, diameter 9 mm) was digitally placed into the femoral canal. For the reference entry point, the IM rod was placed centered in the femoral canal. Then, deviating entry points were presumed 5 mm and 10 mm medially and laterally and 5 mm anterior and posterior to the reference entry point (Figure 4). The thickness of the cortical bone was defined to be 5 mm in the diaphyseal area.[10] Since the diameter of the medullary canal is larger than that the inserted rod, the rod could be placed in different positions in the medullary canal. The maximum deviation of the axis of the rod compared with the centered position of the rod (anatomical axis) using the ideal entry point was measured for each presumed entry point by projecting the IM rod on the coronal and

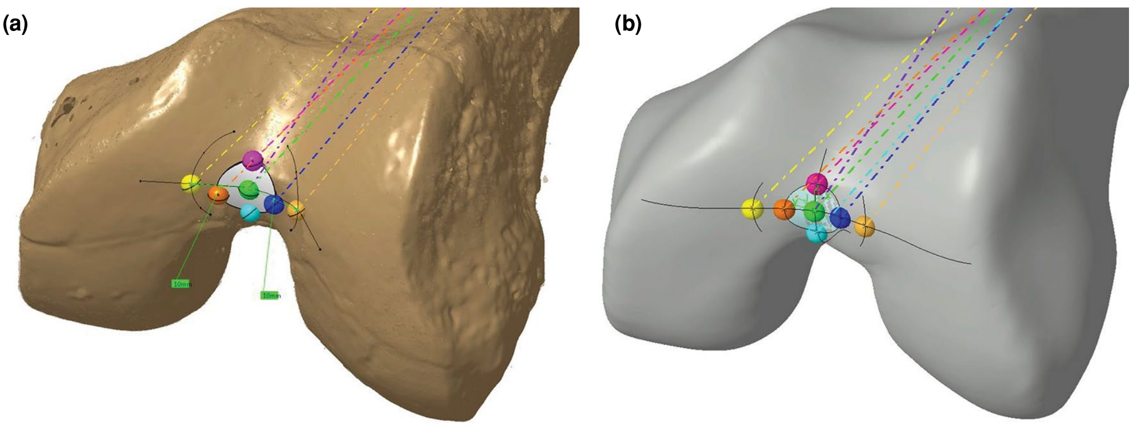

FIGURE 4. Entry points for the intramedullary alignment rod for **(a)** the FaroFemur and **(b)** digital femur model; the reference entry point at the intersection of the anatomical axis on the articular surface is illustrated in green, the deviating entry points are marked orange (5 mm medial), yellow (10 mm medial), blue (5 mm lateral), light orange (10 mm lateral), pink (5 mm anterior) and turquoise (5 mm posterior).

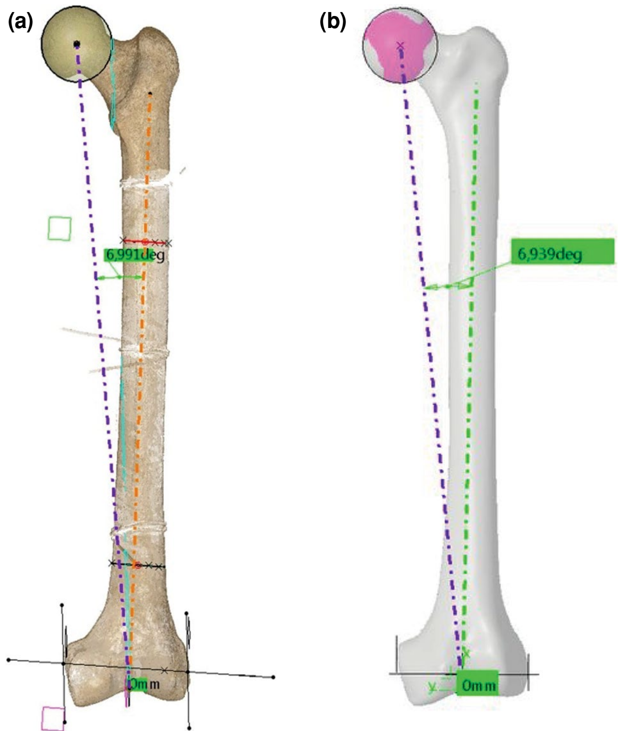

FIGURE 5. Anatomical-mechanical axis angle for **(a)** the FaroFemur and **(b)** DigitalFemur

sagittal plane. Additionally, resulting changes of the mechanical valgus angle were calculated.

Statistical analysis

For both models, the anatomical-mechanical angle (AMA) for the central and for all deviating entry points was determined. The differences between the FaroFemur and DigitalFemur and deviations for all entry points are displayed as absolute values.

RESULTS

The mechanical valgus angle was 6.991° for the FaroFemur and 6.939° for the DigitalFemur (Figure 5). The difference between the two simulation models was 0.052°.

Ideal entry point

The ideal entry point (in extension of the anatomical axis at the intersection with the articular surface) was 9.9 mm anterior to the apex of the intercondylar notch (AIN) and 4.3 mm medial to the AIN in the FaroFemur model. In the DigitalFemur, the entry point was 9.2 mm anterior and 3.6 mm medial to the AIN.

Potential angulation error

Coronal plane

Maximum deviations of the axis of the rod in the coronal plane for all entry points are displayed in Table I.

Medial deviation

A medial entry point increased the angle between the anatomical femoral axis and the alignment rod (Figure 6). With greater medial displacement, the angulation error increased to a maximum of 3.284° in the DigitalFemur model and 3.239° in the FaroFemur. The difference of the rod-mechanical-axis between the two models was 0.199° for 5 mm displacement and 0.008° for 10 mm displacement.

Lateral deviation

A lateral entry point decreased the angle between the anatomical femoral axis and the alignment rod (Figure 7). With greater lateral displacement, the deviation error increased to a maximum of 3.208° in the DigitalFemur model and 3.158° in the FaroFemur model. The difference of the rod-mechanical-axis between the two models was 0.047° for 5 mm lateral displacement and 0.102° for 10 mm lateral displacement.

TABLE I
Maximum deviations of the axis of the rod in the coronal plane for all entry points

Entry point	FaroFemur Deviation (°)	FaroFemur AMA (≙rod-mechanical-axis) (°)	DigitalFemur Deviation (°)	DigitalFemur AMA (≙rod-mechanical-axis) (°)	Difference (°)
Central		6.991		6.939	0.052
5 mm medial	+2.510	9.501	+2.363	9.302	0.199
10 mm medial	+3.239	10.230	+3.283	10.222	0.008
5 mm lateral	-2.267	4.724	-2.262	4.677	0.047
10 mm lateral	-3.158	3.833	-3.208	3.731	0.102

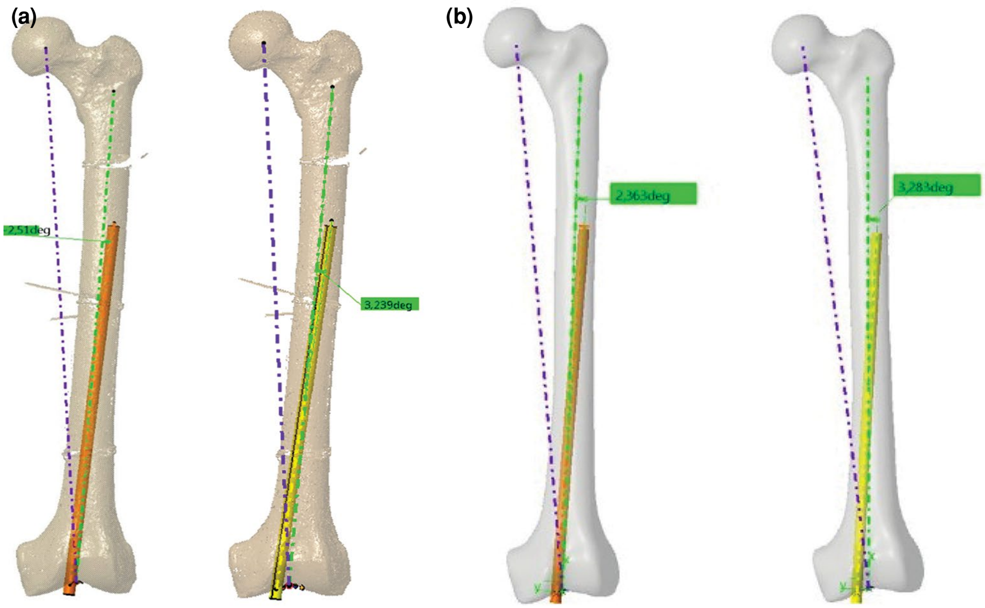

FIGURE 6. Maximal angulation errors for 5 mm (orange) and 10 mm (yellow) medial displacement for **(a)** FaroFemur and **(b)** DigitalFemur in the coronal plane.

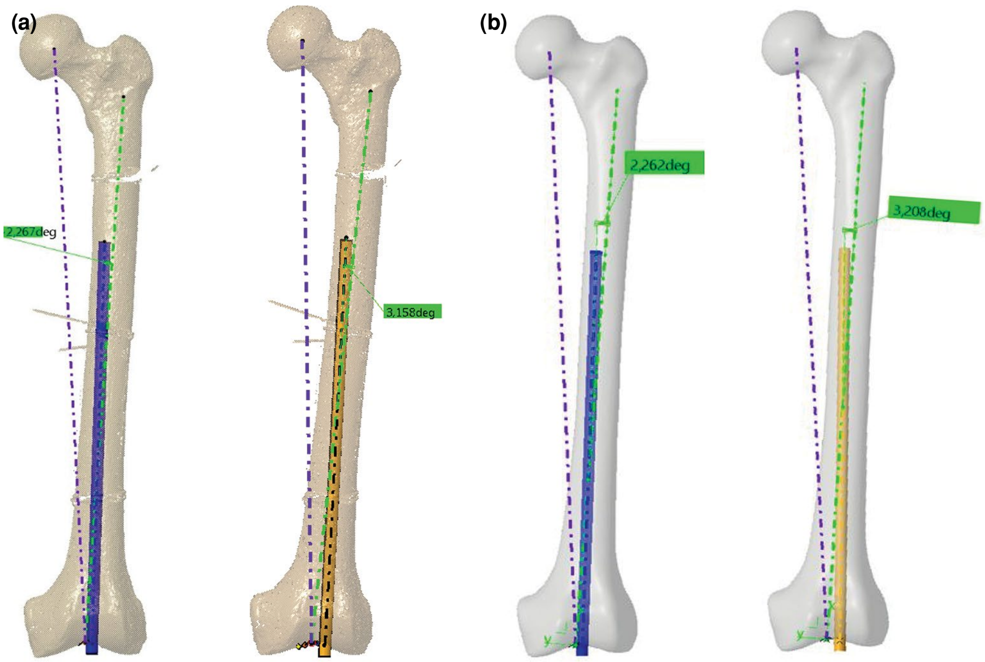

FIGURE 7. Maximal angulation errors for 5 mm (blue) and 10 mm (light orange) lateral displacement for **(a)** FaroFemur and **(b)** DigitalFemur in the coronal plane

Sagittal plane

Maximum deviations of the axis of the rod in the sagittal plane for all entry points are displayed in Table II.

Anterior-posterior deviation

An entry point 5-mm anterior changed the angle between the anatomical femoral axis and the alignment rod towards extension by 1.802°

TABLE II
Maximum deviations of the axis of the rod in the sagittal plane for all entry points

Entry point	FaroFemur	DigitalFemur	Difference (°)
	Deviation (°)		
5 mm anterior	+1.802	+2.142	0.340
5 mm posterior	-2.045	-2.055	0.010

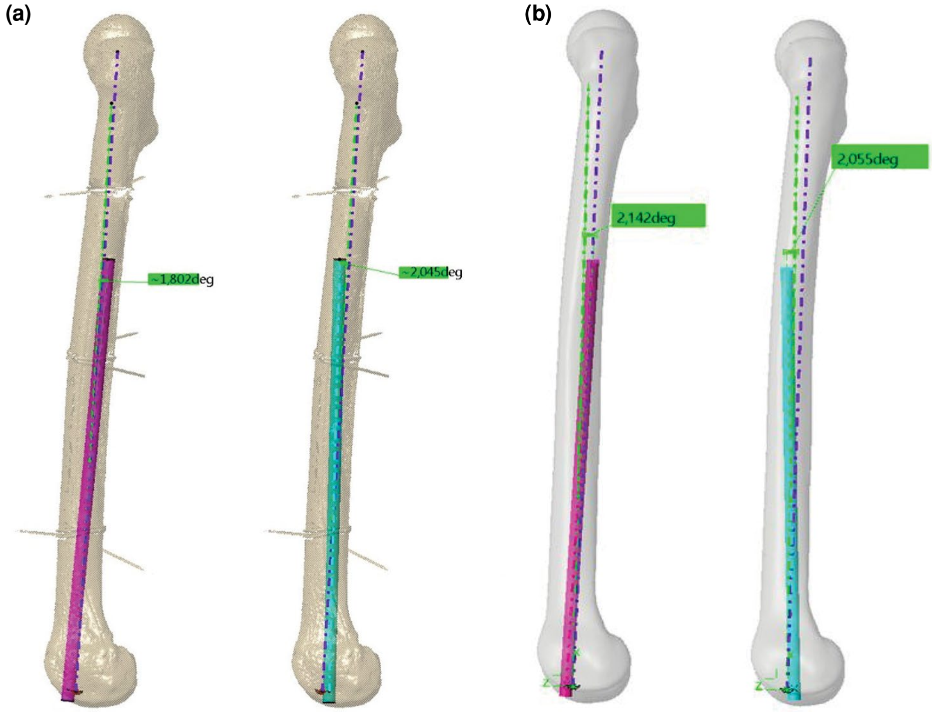

FIGURE 8. Maximal angulation errors for 5 mm anterior (purple) and 5 mm posterior (turquoise) displacement for **(a)** FaroFemur and **(b)** DigitalFemur in the sagittal plane.

in the FaroFemur and 2.142° in the DigitalFemur (Figure 8). A posterior entry point generated a deviation towards flexion by 2.045° (FaroFemur) and 2.055° (DigitalFemur). The difference between the two models was higher for anterior displacement (0.340° *vs.* 0.010°).

DISCUSSION

Our results demonstrate that minor deviations of the insertion point of the IM instrumentation during TKA can result in malalignment of several degrees.

In the sagittal plane, an anterior deviation results in increased femoral extension, while a posterior deviation leads to increased femoral flexion. In the coronal plane, medial deviation increases the valgus angle, more precisely, the angle between the axis of the rod and the mechanical axis of the femur. Thus, a medial entry point may result in increased medial resection and varus malalignment, particularly with a fixed femoral valgus correction angle. Likewise, a lateral entry point favors increases lateral resection and valgus malalignment.

We used a two-fold CAD approach to simulate various femoral insertion points and rod positions. The use of a CAD software allowed for precise determination of the anatomical axis. Consistent with the literature, the proper entry point was set where the anatomical axis intersected the articular surface. The reference rod was, then, placed in ideal position centered in the femoral canal. For each entry point, the maximum potential angulation error was calculated. High agreement between the two models with a maximum difference of 0.34° provided proof of concept for our CAD approach.

Our findings appear to be well supported by previous studies. A similar approach using preoperative computed tomography (CT) scans and computer simulation in 30 patients showed a possible deviation of the IM rod of 0.8° in the coronal and 1.1° in the sagittal plane.[11] Ma et al.[8] calculated potential angle errors below 2° in the coronal plane and below 3° in the sagittal plane, while inserting the IM rod from the recommended point. Even with an optimal entry point, following mathematical models, errors can occur and increase with short rod length and large femoral canal diameter.[12]

Cadaveric studies showed that entry points displaced anteriorly and posteriorly resulted in significant changes in the sagittal, but not in the coronal plane.[9] Harding et al.[13] demonstrated that the femoral IM entry point directly influenced the valgus angle, independently of valgus angulation of the distal femur, body habitus and leg length. An entry point 10-mm anterior and 8-mm medial to the intercondylar notch gave a valgus angle of 10.2°, while entry points 10-mm anterior to the intercondylar notch showed a valgus angle of 8°. Their findings differed from previous radiographic studies. Errors can be minimized by giving careful attention to the entry point of the IM instrumentation or by increasing the rod diameter and length used during primary TKA.[4]

In general, there is an agreement that the optimal entry point is located anterior and medial to the AIN.[2,8] The anatomic axis was found to exit the distal femur at an average of 6.6 mm medial to the center of the femoral notch.[14] Wangroongsub and Cherdtaweesup[2] defined the mean entry point 1.5±2 mm medial and 12±3 mm anterior to the highest point of the femoral notch.[2] The proper femoral IM access point showed sex-specific differences and was located more medial and anterior to the AIN in females compared to males (1.77 mm medial and 15.29 mm anterior *vs.* 1.49 mm medial and 13.39 mm anterior).[8]

Novotny et al.[12] defined the optimal entry point for the IM rod as a ratio of the mediolateral and anteroposterior dimensions of the distal femur. They found an average mediolateral ratio of 0.53 offset medially and 0.33 anterior offset from the anterior cortex in the sagittal plane.

Different techniques to identify the correct femoral entry point have been proposed. Preoperative X-rays, including a full-weightbearing long-leg view, are crucial for planning the surgery and to determine the ideal insertion point, located at the intersection of the anatomic axis of the femur with the articular surface. In lateral projection, the entry point has been defined at the point at which a line parallel to the anterior cortex of the distal femur placed posteriorly from the anterior cortex by one half the isthmus diameter intersects the articular surface.[12]

Furthermore, preoperative CT scans can be used to identify the intended location of the insertion for the IM rod. The anatomical axis can be marked as a line connecting the midpoints of the distal femur at 10 cm and 20 cm above the intercondylar notch. By three-dimensional simulation, precise planning of the point where the anatomical axis intersects the articular surface of the distal femur is possible.[8,11]

Intraoperatively, marking of the anteroposterior axis (Whiteside's line) that runs from the center of the intercondylar notch anteriorly to the deepest point of the trochlear groove may be used for orientation. However, it has been shown to be highly inaccurate and difficult to reproduce.[15] Therefore, the entry point is often described in relation to the intercondylar notch, or in relation to the anterior border of the origin of the posterior cruciate ligament.[16] Computer-assisted surgical navigation has been introduced to improve accuracy and precision in TKA. Numerous studies have confirmed that navigation is more reliable in accomplishing neutral alignment (±3°) compared to IM alignment techniques. Despite improved accuracy and decreased numbers of outliers in alignment, no significant influence on clinical outcome measures has been demonstrated.[17]

Such caution in identifying the entry point in IM instrumentation is exercised, as it has been recognized that the entry site of the rod into the distal femur has a significant effect on the valgus angle[18] and that malposition of the starting hole can cause divergence of the IM rod from the anatomic axis.[14] Due to the varying angles between the mechanical and the anatomical femoral axis, different valgus pre-sets have been recommended for the distal femoral cut using IM alignment rods. In a study by Maderbacher et al.,[19] a valgus pre-set of 7° resulted in best positioning of the cutting block and measuring the femoral AMA preoperatively could not improve accuracy. However, these findings are also dependent on the femoral entry point of the IM device. During the preoperative planning and by measuring the AMA and hip-knee-ankle angle the most suitable valgus cut for each patient can be estimated.

Regardless of the alignment technique (classic/ kinematic), the distal femur cut determines the extension gap, femoral component positioning and ligamentous balancing and consequently affects clinical outcome. Accurate coronal alignment within 3° of neutral correlates with better function and quality of life.[20] However, it needs to emphasized that the ideal alignment depends on the native hip-knee-ankle angle and that over-correction in both, valgus and varus knee, should be avoided. Furthermore, coronal alignment of the femoral component influences failure rates. Both, varus and valgus malalignment, showed significantly higher failure rates compared to neutrally aligned (2 to 8° valgus) implants.[21]

Flexing the femoral implant provides increased knee flexion compared to a neutral position, but was not associated with a benefit in patient reported outcome measures or clinical performance at one year.[22] However, high flexion reduces the implant contact area ventrally and causes overstuffing of the trochlea.[23] Accordingly, sagittal femoral component alignment affects early component failure. While neutral sagittal positioning showed no failures, a flexion greater than 3° was associated with a significantly higher failure rate.[21]

With navigation, the proportion of neutrally aligned (within 3° of neutral) implants increases significantly (91% *vs.* 61%)[20] and outliers regarding mechanical axis and component alignment can be avoided.[21] The accuracy of component alignment improves significantly in coronal and sagittal plane. Although navigation provides aforementioned benefits, it has not been implemented, as there is no evidence for better clinical performance and as it has certain drawbacks, such as higher costs, longer duration and higher invasiveness.[17]

A systematic review of 1,167 patients from six studies showed that an individualized valgus correction angle for the distal femoral resection could increase the accuracy of postoperative limb and femoral component alignment in the coronal plane.[24] However, correct placement of the IM device is a prerequisite for surgical execution. For increasing the accuracy with IM instrumentation, meticulous identification of the insertion point seems crucial. Furthermore, intraoperative control of the axis of the rod, using an extramedullary alignment rod or fluoroscopy, might disclose potential errors. Briefly, our CAD simulations demonstrated that the femoral entry point influenced the orientation of IM device and might results in divergent distal femoral cuts.

Nonetheless, there are several limitations to this study. First, a CAD approach was used to simulate varying entry points. Both, the commercially available digital femur and the digitized femur model constitute an averaged adult human femur. Thus, individual conclusions need to be drawn carefully. Second, we considered only one rod size (length 30 cm, diameter 9 mm). However, based on previous studies, we aimed to avoid the influence of rod characteristics by using large dimensions. For reference, we chose the entry point at the intersection of the anatomical axis with the distal articular surface and placed the IM rod centered into the femoral canal. However, due to the differences in diameter between rod and femoral canal, deviations might occur even with an ideal entry point. Furthermore, the influence of the entry point on rotational positioning has not been investigated. However, a dependence is self-evident, as the center of rotation changes.

In conclusion, our study results show that minor deviations of the femoral entry point result in malalignment of the IM alignment rod. The distal femoral resection during TKA may be altered several degrees in both the coronal and sagittal planes.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Conceptualized the study developed the study design: C.S., E.R. and W.S.; Performed the simulations: P.R., S.N. and T.K.; Discussed the results: C.S.; Wrote the manuscript: P.R., S.N. and T.K.; Provided valuable comments on the manuscript. All authors agreed to the final version of the manuscript for submission and have given approval for this version to be published. All authors contributed extensively to the work presented in this manuscript.

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