Orthopaedic Surgery

CLINICAL ARTICLE

Optimal Sagittal Insertion Depth and Direction of Femoral Intramedullary Rod in Total Knee Arthroplasty in Chinese Osteoarthritis Patients

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Objective: To identify the optimal femoral intramedullary rod insertion depth and direction on the sagittal plane in total knee arthroplasty (TKA) of Chinese osteoarthritis (OA) patients.

Methods: From January to December 2019, CT data were collected for 85 consecutive entire lower extremity Chinese OA patients. A three-dimensional method was used to simulate intramedullary rod penetration. The intramedullary rods were inserted toward the anterior (TA), center (TC), and posterior (TP) of the femoral canal, respectively. Four penetration depths of 150, 200, 250, and 300 mm from the joint line were set. The intersection angle was measured between the simulated intramedullary rod and the mechanical axis of the femur (FMA) on the sagittal plane.

Results: Our study included 85 Chinese OA patients: 46 women, with a mean age of 65.7 ± 8.4 years (range, 51–85 years) and 39 men, with a mean age of 65.6 ± 8.1 years (range, 46–86 years). The intersection angle between the FMA and the femoral anatomical axis was smaller in men, 2.4° ± 1.6° (range, 0°–4.8°), than in women, 3.5° ± 2.3° (range, 0.7°–8.2°), with a significant statistical difference ($P < 0.01$). In the comparison of the intersection angle between the simulated intramedullary rod and the FMA, there was no statistical difference between TA200 and TC200 in women ($P > 0.05$). The proportions were up to 91% and 96% of TA200 at 0°–3° and 0°–5° intervals, respectively, but just 63% and 78% in TC200. In TA150, 76% of intersection angles were greater than 5°. Only approximately 60% in TA250 and TA300 were within the 0°–5° interval and 40% were less than 0°. Only 57% of intersection angles in TC150 were in the 0°–3° interval. TC250, TC300, and TP150 were mostly below 0°. In men, there were statistical differences between all groups. All intersection angles were greater than 5° in TA150. TA200 and TA250 were mostly greater than 5° (87% and 59%, respectively) and 72% of intersection angles were within 0°–5° interval in TA300. TC150 had 92% of intersection angles within the 0°–5° interval but only 62% between the 0° and 3° interval. In the TC200, up to 90% and 97% were within 0°–3° and 0°–5° intervals, respectively. TC300, TP150, and TP200 were mostly below 0°.

Conclusion: We described an innovative method for rapidly, simply, and accurately identifying the sagittal insertion depth and direction of the femoral intramedullary rod in TKA, which can optimize the position of the femoral prosthetic component on the sagittal plane in TKA.

Key words: Arthroplasty; Intramedullary rod; Sagittal; Knee

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Introduction

Total knee arthroplasty (TKA) is one of the most successful surgical procedures for eradicating advanced knee pain, restoring knee function, and improving the quality of life of patients[1]. Limb alignment, prostheses selection, precise surgical techniques, and perioperative management are all critical to the success of the procedure[2]. Restoration of the mechanical axis of the lower extremity is a crucial factor to improve the postoperative function, reduce liner wear, and prolong the survival of the prosthesis in TKA[3]. The concept of the mechanical axis was introduced by Insall *et al.*[1] in 1985, which required that both femoral and tibial cuts were perpendicular to the mechanical axis of the femur and tibia to facilitate equal load distribution on the new joint line.

In traditional TKA, the alignment of the femoral component is more complex than that of the tibial component, including the alignment of the coronal, rotational, and sagittal positions. Based on the weight-bearing, full-length hip to ankle preoperative radiograph, the intersection angle between the mechanical axis of the femur (FMA) and the distal anatomic axis of the femur (FAA) on the coronal plane can be measured to determine the valgus angle at which the distal femur needs to be cut on the coronal plane to align the femoral component perpendicular to the mechanical axis of the femur during the operation. The distal femoral valgus correction angle is commonly believed to be between 5° and 7°[4]. There is a consensus that the best flexion gap and patella track can be obtained by 3° external rotation placement of the femoral prosthesis[4].

Relative to the coronal and rotational localization of the femoral prosthesis, the optimal localization of the femoral component on the sagittal plane has not yet been defined. This topic has come into focus only in the past decade. Specifically, increasing the flexion placement of the femoral component on the sagittal plane will reduce the contact area between the prosthesis and the femoral anterior cortex, decrease the flexion gap, and increase the posterior condylar offset, while placement in extension will increase the risk of supracondylar fracture resulting from anterior notching of the distal femur[5]. Research showed that 25% (73/297) of patients had anterior knee pain at 10 years following a single-radius cruciate-retaining TKA without routine patellar resurfacing. Sagittal plane positioning and alignment of the femoral component are associated with long-term anterior knee pain, with femoral component extension being a major risk factor[6]. Therefore, placement of the femoral component in slight flexion on the sagittal plane has been recommended to avoid notching[7]. However, excessive flexion may cause patellofemoral overstuffing or anterior impingement between the tibial post and the intercondylar box of the femoral component in posterior-stabilized TKA, resulting in polyethylene wear and cam-post engagement[8]. Some authors consider 0°–5° of flexion of the femoral component to be a reasonable range, while others consider 0°–3° of flexion to be a better range because the incidence of implant failure and postoperative flexion contracture can be significantly reduced[6, 9, 10]. When the femoral prosthesis is 0° flexion in relation to the FMA, there is increased risk of anterior femoral notching. Because of the femoral bowing, a combination of external rotation and flexion can cause anterior femoral notching[11].

In clinical practice, intramedullary alignment devices are used as they show satisfactory accuracy and are easy to apply. Some authors have reported that intramedullary alignment could produce more accurate and reproducible placement and could reach 85%–96% in the normal range[2]. However, some studies have shown a very high variation of the femoral flexion position between 2.5° of extension and 14° of flexion related to the FMA on the sagittal plane when using a standard intramedullary alignment technique for the femur[10].

The insertion of a short thin intramedullary rod according to the manufacturer's specifications on the sagittal plane may not provide adequate alignment accuracy, which can compromise the consequent alignment of the femoral component[12]. Moreover, there are ethnic and gender differences in femoral bowing. Femoral bowing has a significant influence on the direction and depth of the intramedullary rod, as well as on the sagittal alignment of the distal femoral cuts[13].

The question has arisen of how we can obtain accurate alignment using a femoral intramedullary rod in TKA for Chinese osteoarthritis (OA) patients and thereby increase the ratio of the ideal sagittal alignment of the femoral component. Therefore, the present study describes an innovative method to measure the intersection angle of FMA and the simulated intramedullary rod within a three-dimensional computed tomography (CT) model, and to explore: (i) the optimal femoral intramedullary rod insertion depth on the sagittal plane in TKA in Chinese OA patients; (ii) the optimal sagittal femoral intramedullary rod insertion direction on the sagittal plane in TKA in Chinese OA patients; and (iii) the location of intramedullary rods on the sagittal plane in Chinese OA patients for both genders.

Patients and Methods

Inclusion and Exclusion Criteria

Inclusion Criteria

The inclusion criteria were as follows: (i) patients had been diagnosed with knee osteoarthritis through medical history, symptoms, physical examination, and standing knee joint anteroposterior and lateral radiography; (ii) patients had undergone CT scan of the entire lower extremity and three-dimensional (3D) reconstruction; (iii) regarding the staging of knee osteoarthritis, patients were Kellgren–Lawrence stage III and IV; (iv) the main evaluation indicators included the intersection angle between the simulated intramedullary rod and the FMA, and the intersection angle between the FMA and the FAA; (v) and this study was an exploratory design study.

Exclusion Criteria

The exclusion criteria were as follows: (i) previous lower extremity surgery; (ii) obvious varus or valgus deformity; (iii) any disease of the femur; (iv) severe osteoporosis; and (v) osteofusion of the knee joint.

General Information of Participants

Each patient provided informed consent to participate in the study. This study was conducted in accordance with the Declaration of Helsinki (Ethical Principles for Medical Research Involving Human Subjects) and was approved by our institutional review board.

From January to December 2019, we collected CT data (Siemens SOMATOM 16, Germany) with a thickness of 0.625 mm of the entire lower extremity of Chinese OA patients who were consecutively admitted to our hospital. Finally, nine patients were excluded and 85 patients (46 women and 39 men) were included in the study. Patients' age, gender, height, weight, and body mass index (BMI) were also recorded.

Measuring Methods

Establishment of Femoral Digital Model

The Digital Imaging and Communications in Medicine data were imported into Mimics 19.0 (Materialize, Leuven, Belgium). In the software, we selected femoral cortical bone as the seed points, and did not choose to fill the long bone. The 3D model with only cortical bone was obtained through automatic calculation by computer. Rhinoceros 5.0 (Robert McNeel & Assoc, USA) software was used to simulate intramedullary rod penetration.

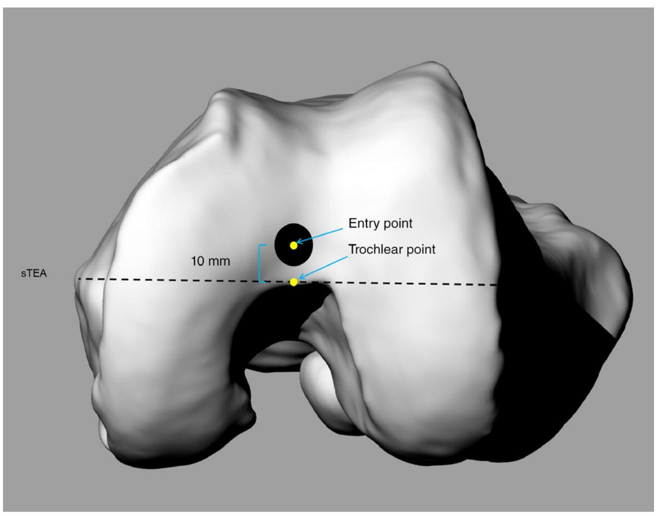

Fig. 1 Schematic diagram: the point 10 mm anterior to the origin of the posterior cruciate ligament as the entry point.

Select the Entry Point

We chose the point 10 mm anterior to the origin of the posterior cruciate ligament (PCL) as the entry point. The trochlear point was used as the anatomical landmark to identify the point 10 mm anterior to the origin of the PCL. The diameter of the entrance was 10 mm and the diameter of the intramedullary rod was 8 mm (Fig. 1).

Establishment of Femoral Intramedullary Rod

The diameter of the simulated intramedullary rod was set to 8 mm. On the standard sagittal plane of the 3D CT model, intramedullary rods were inserted toward the anterior (TA), center (TC) and posterior (TP) of the medullary cavity, respectively; four penetration depths of 150, 200, 250, and 300 mm from the joint line were set. We measured the intersection angle between the simulated intramedullary rods which were inserted at different directions and depths, and the FMA (Fig. 2).

We marked the length of the femoral model on the sagittal plane and selected points in the femoral cortex 15, 20, 25, and 30 mm away from the joint line. One point was 4 mm above the lowest edge of the entrance, the other point was 4 mm vertical to the inner layer of the bone cortex in front of the femur, and the line connecting the two points was the axis of the simulated intramedullary rod entering the medullary cavity in the forward direction. In the same way, the line connecting the point 4 mm below the uppermost edge of the entrance and 4 mm perpendicular to the inner

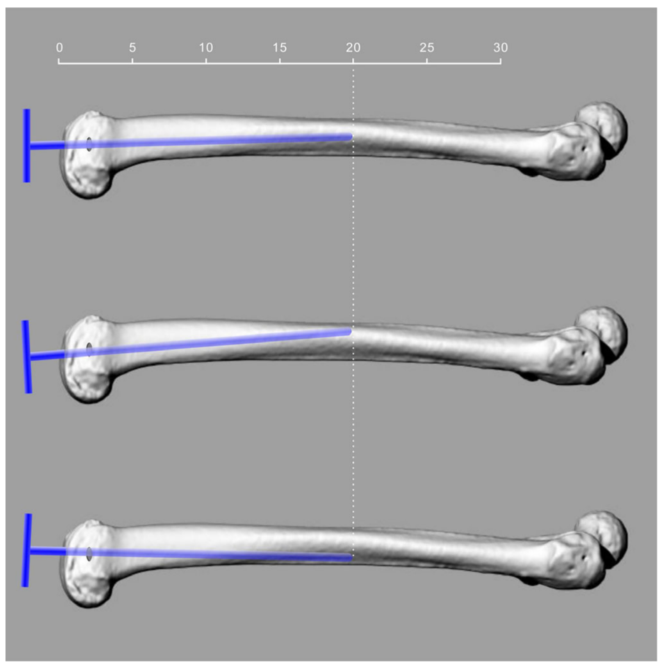

Fig. 2 Schematic diagram: the simulated intramedullary rod inserted at different directions with 200 mm depth from the joint line on a standard sagittal plane.

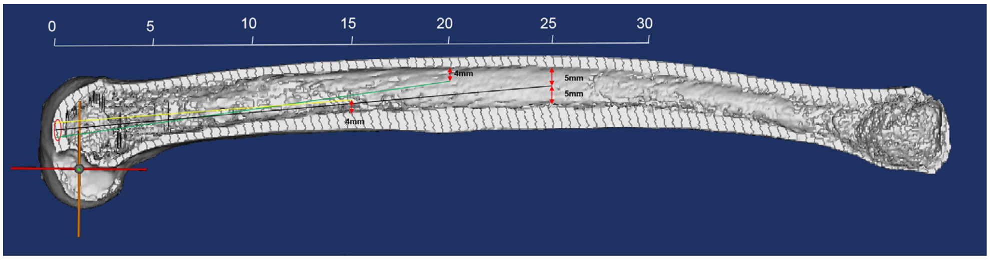

Fig. 3 How to place the axes of the simulated intramedullary rods in a three-dimensional CT model.

layer of the bone cortex of the posterior femur was the axis of the simulated intramedullary rod entering the medullary cavity in the backward direction. The line connecting the midpoint of the bisector of the medullary cavity and the midpoint of the entrance was the axis of the simulated intramedullary rod entering the medullary cavity in the central direction (Fig. 3). The intersection angle was not recorded when the axis of the simulated intramedullary rod was out of the femoral canal.

Observation Indicators

Intersection Angle between Simulated Intramedullary Rod and Mechanical Axis of the Femur

The surgical transepicondylar axis (sTEA) was identified by two points, one on the medial epicondyle (sulcus) and one on the lateral epicondyle (prominence). The FMA is defined as the line from the center of the femoral head to the midpoint of the sTEA. We simulated the insertion of the intramedullary rod with different depths and directions using 3D methods and projected the axis of the rod and the FMA to the sagittal plane to measure the intersection angle between them. This angle will directly affect the sagittal placement and alignment of the femoral prosthesis during TKA. We measured the angle between two lines on the sagittal plane. The range between 0° and 3° of flexion is marked as the optimal interval; the range between 0° and 5° of flexion is marked as a reasonable interval.

Intersection Angle between the Mechanical Axis of the Femur and the Femoral Anatomical Axis

The FAA is defined as the line best fitting the centroid of the femoral canal 10 to 20 cm from the joint line[14]. We projected FMA and FAA to the sagittal plane to measure the intersection angle between them. This angle shows the effect of the anterior bowing of the femur on the sagittal alignment of the femoral component. We measured the angle between two lines on the sagittal plane. An angle within 3° was considered reasonable (Fig. 4).

Statistical Analysis

All data were statistically analyzed using the statistical software IBM SPSS 24.0 (International Business Machines, Armonk, New York, USA). Data were presented as mean and standard deviation. Differences between groups were tested using paired *t*-tests. A *P*-value <0.05 was considered statistically significant. All measurements were performed twice by two senior authors (P.Y.L. and H.X.). We assessed the intraobserver and interobserver reliabilities. The measurements were considered reliable if the interclass correlation coefficient was calculated as more than 0.80. Due to the

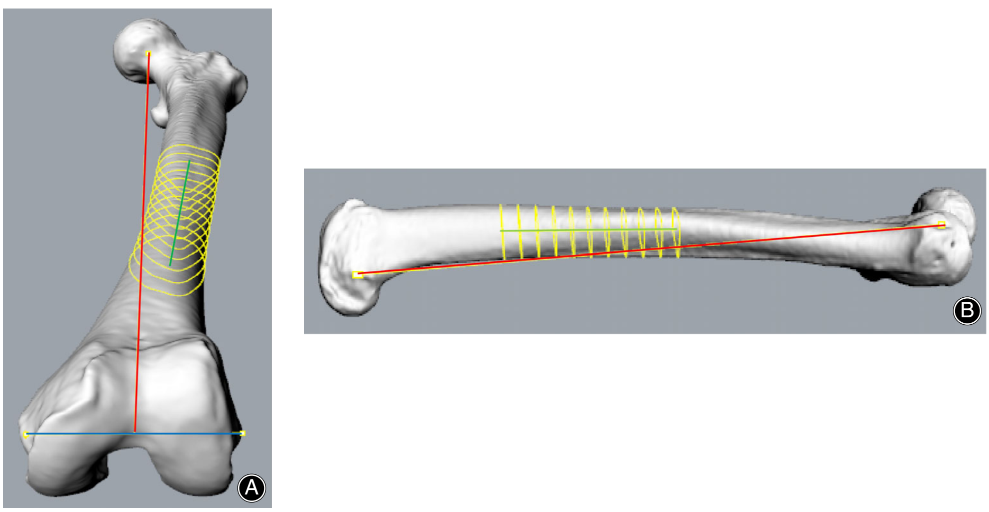

Fig. 4 Schematic diagram: the blue line connects the medial epicondyle (sulcus) and the lateral epicondyle (prominence) is the surgical transepicondylar axis (sTEA); the red line from the center of the femoral head to the midpoint of the sTEA is the mechanical axis of the femur (FMA); the green line which best fits the centroid of the femoral canal 10 to 20 cm from the joint line is the femoral anatomical axis (FAA) (A, B); we measure the intersection angle between FMA and FAA on a standard sagittal plane (B).

TABLE 1 Basic information of patients (mean ± SD [range])

Gender	Number	Age (years)	Weight (kg)	Height (cm)	BMI (kg/m^2)	Angle between FMA and FAA (°)
Male	39	65.6 ± 8.1 (46–86)	72.4 ± 8.3	168.8 ± 5.7	25.4 ± 2.6	2.4 ± 1.6
Female	46	65.7 ± 8.4 (51–85)	61.5 ± 9.9	154.6 ± 4.4	25.7 ± 3.8	3.5 ± 2.3
t-value		0.546	−12.495	−5.672	0.428	2.768
P-value		0.589	0.001	0.001	0.671	0.009

BMI, body mass index; FAA, femoral anatomical axis; FMA, femoral mechanical axis.

exploratory design of our study, the sample size calculation was conducted *post hoc*.

Results

Demographic Data

Our study collected the entire lower extremity CT data of 85 OA patients, including 46 women, with a mean age of 65.7 ± 8.4 years (range, 51–85 years), and 39 men, with a mean age of 65.6 ± 8.1 years (range, 46–86 years). In the height and weight comparisons, men were taller and heavier than women, with statistical differences between the sexes ($t = -12.495$, $P = 0.001$; $t = -5.672$, $P = 0.001$). However, there was no significant difference in BMI between the sexes ($t = 0.428$, $P = 0.671$). In the comparison of the intersection angle between the FMA and the FAA, men 2.4° ± 1.6° (range, 0°–4.8°) were smaller than women 3.5° ± 2.3° (range, 0.7°–8.2°), with a significant statistical difference ($t = 2.768$, $P = 0.009$; Table 1).

Intersection Angle on the Sagittal Plane

Intersection Angle between Simulated Intramedullary Rod and Mechanical Axis of the Femur

The angles between the FMA and the simulative intramedullary rod, which was inserted at different directions and depths, were measured and recorded. Negative values show extension, and positive values flexion in relation to the FMA. The range between 0° and 3° of flexion is marked as the optimal interval and the range between 0° and 5°of flexion is marked as a reasonable interval. TA150 represented the simulative intramedullary rod inserted toward the anterior of the femoral canal, and the depth was 150 mm.

Similarly, TC and TP represented the simulative intramedullary rod being inserted toward the center and posterior of the femoral canal, respectively. Measurement reliability was excellent, with a value of 0.925 for intra-rater and 0.962 for inter-rater reliability.

Intersection Angle between Mechanical Axis of the Femur and the Femoral Anatomical Axis

In women, except for TA200 and TC200 ($t = 1.753$, $P = 0.086$), as well as TC300 and TP150 ($t = 1.471$, $P = 0.171$), there were statistical differences between different groups. The proportions were up to 91% and 96% of TA200 in 0°–3° and 0°–5° intervals, respectively, but just 63% and 78% in TC200. In TA150, 76% of intersection angles were greater than 5°. Only approximately 60% in TA250 and TA300 were within the reasonable interval and 40% were less than 0°. Only 57% in TC150 was in the optimal interval. TC250, TC300, and TP150 were mostly below 0°. In men, there were statistical differences between all groups.

All intersection angles were greater than 5° in TA150. TA200 and TA250 were mostly greater than 5° (87% and 59%, respectively); 72% of intersection angles were within the reasonable interval in TA300. TC150 had 92% within the reasonable interval but only 62% in the optimal interval. In TC200, up to 90% and 97% were within the reasonable and optimal intervals, respectively. TC300, TP150, and TP200 were mostly below 0° (Fig. 5).

Discussion

The most important finding of the present study was that the intramedullary rod inserted toward the anterior of the femoral canal with the depth of 200 mm from the joint line could obtain the optimal alignment on the sagittal plane of the femur in Chinese female OA patients, and the intramedullary rod inserted toward the center with a depth of 200 mm could obtain the optimal alignment on the sagittal plane of the femur in Chinese male OA patients.

Alignment of the Femoral Prosthesis on the Sagittal Plane

Accurate positioning of the femoral component is essential to ensure the longevity of the prosthesis and successful outcomes of TKA[15, 16]. As described in previous studies, placement of the femoral component extension in the sagittal plane would increase the risk of anterior notching of the distal femur, while placement in flexion would decrease the flexion gap, increase the posterior condylar offset, cause overstuffing of the trochlea, and reduce the contact surface between prosthesis and bone ventrally[4].

Currently, there is no clear consensus about the exact degree of flexion of the femoral component in TKA as it is also dependent on component design[4]. Paola's study confirmed that the femoral flexion position was a very high variation between 2.5° of extension and 14° of flexion (mean 5.5°) related to the sagittal FMA when using a standard

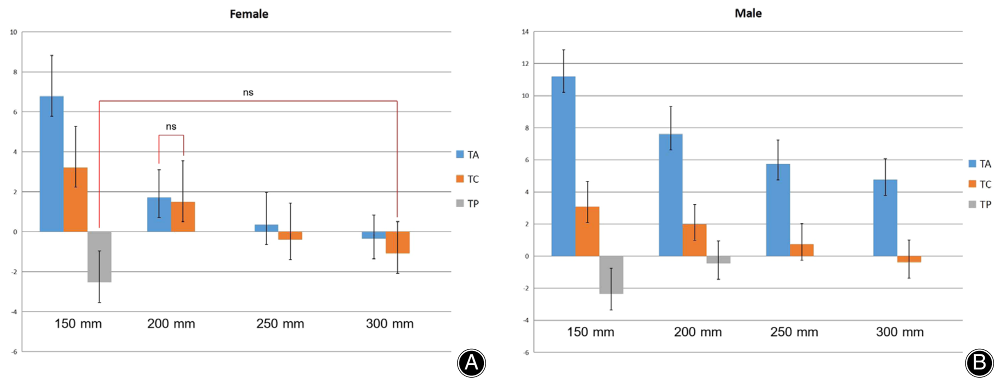

Fig. 5 Intersection angle of mechanical axis of the femur (FMA) and the simulated intramedullary rods with different insertion depth and direction. ns, no statistical difference.

intramedullary alignment technique for the femur[10]. Similarly, Ma's research showed that in a computerized model of a cadaveric femur, an average flexion of 3.2° (3.2° extension to 9.7° flexion) in relation to the FMA was found when a 200 mm × 5 mm rod was used[12]. It has been shown that only 70%–80% cases would obtain the ideal positioning of the prosthesis when using the intramedullary rod[17]. However, the optimal location of the femoral prosthesis on the sagittal plane has not been determined[18, 19]. Kim *et al.* demonstrated an influence of femoral component alignment in the sagittal plane on early component failure of 3048 knees investigated; 1735 were neutrally aligned between 0° and 3° of flexion, 748 were flexed more than 3°, and 565 were extended. After 15.8 years, no neutrally aligned femoral implants required revision, while 25 out of 748 (3.3%) of the flexed and 5 out of the 565 (0.9%) extended femoral implants needed to be revised[4]. Therefore, in our study, we consider that the flexion between 0° and 5° is the reasonable interval and 0°–3° is the optimal interval.

Sagittal placement of the femoral component is influenced by patient-related factors, like the individual anatomy of the distal femur (e.g. race, gender, height, weight, BMI, and degree of antecurvation), as well as the surgical technique (e.g. entry point, depth, and direction of penetration). In our study, all subjects were Chinese OA patients and gender, height, weight, and BMI were recorded. The tools commonly used in clinical practice by different manufacturers are not uniform: the diameter of drills is between 9 and 12 mm, while the diameter of intramedullary rods is between 7 and 9 mm, and the difference between the two tools is between 1 and 3 mm. To be as close as possible to clinical application, we set the diameter of entry hole as 10 mm and the diameter of the intramedullary rod as 8 mm in our study.

Entry Point of the Femoral Intramedullary Rod

According to Yongsak's research, the proper entry point at the distal femur should be 1.5 ± 2.0 mm medial and 12.0 ± 2.7 mm superior to the top of the femoral intercondylar notch[19]. In Ma's study, the average ideal entry point was 1.49 mm medial and 13.39 mm anterior to the apex of the intercondylar notch (AIN) in men, and 1.77 mm medial and 15.29 mm anterior to the AIN in women[3]. However, the number of specimens in these two studies was relatively small and bowing of the distal femur was not considered in the study. To reduce the bias of the results, we chose the point 10 mm anterior to the origin of the PCL as the entry point, which was in agreement with most surgeons and anatomical studies.

Sagittal Insertion Depth and Direction of the Femoral Intramedullary Rod

Neither the surgeons nor the implant manufacturers had a clear consensus on the direction and depth in using the intramedullary rod in TKA. The operation was often decided by the surgeon, based on the preoperative image data and intraoperative experience, so the accuracy of the sagittal position of the femoral component could not be ensured[20]. Earlier studies had demonstrated that using the conventional alignment technique a femoral flexion within the range from 0° to 5° flexion was achieved in only 25% and 48% of TKA, respectively.[20, 21] However, that study did not explore how to improve the accurate placement of the component. Up to now, no clinical or anatomical studies have explored this. Tsukeoka's study confirmed that the preoperative planned insertion depth of the rod could increase the accuracy of the femoral component positioning in the modified conventional TKA compared with the accelerometer-based navigation. However, the author only considered the depth of the rod, not the direction of the insertion. In addition, in his study, 88% of the subjects were women. In this research, we simulated the placement of the intramedullary rod in a 3D CT model, and obtained the optimal insertion depth and direction, which can provide a reference for the sagittal alignment of femoral prostheses for the conventional TKA of Chinese OA patients.

In addition, according to the results, there was no statistical difference in BMI between the sexes, but there were statistically significant differences in height and weight, and there was also a statistical difference in the intersection angle between FMA and FAA. In the comparison of the angle between the FMA and the simulated intramedullary rod which was inserted to the same depth and direction in the two groups, all of the flexion angles in the male group were greater than those of the female group. This proved that the femur of Chinese women is shorter than that of men, but the bowing of the distal femur is larger than in men. This is similar to the results of many previous anatomical and morphological studies.

Limitations

There are some limitations to our study. First, the number of participants in the study was relatively small. Second, the size, type, and design of the prosthesis have not been taken into account. Third, reasonable placement of the femoral prosthetic component needs to comprehensively consider the coronal and rotational alignment.

Conclusion

We described an innovative method for rapidly, simply, and accurately identifying the sagittal insertion depth and direction of the femoral intramedullary rod in TKA, which can optimize the position of a femoral prosthetic component on the sagittal plane in TKA.

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