


CLINICAL ARTICLE

A Novel Method for Preoperative Positioning of Total Ankle Replacement Using 3D Digital Model

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Abstract

Objective: To establish a digital model of the ankle joint through 3D imaging technology and explore the preoperative placement of ankle replacement prostheses.

Methods: Computed tomography images of intact ankle joints from 54 cases in the outpatient and inpatient departments of our hospital were collected; according to the INBONE[®] total ankle system surgery process, the surgery model and surgical osteotomy were finished using MIMICS based on computer simulation method. The shortest distance was measured between the center point and the anterior, posterior, medial, and lateral, respectively, to ensure the precise position of the ankle replacement prosthesis by digital simulation surgery. The relationship between the two variables was analyzed by bivariate correlation analysis.

Results: The dataset of this study included 48 cases of the sub-data set (26 males and 22 females) and included 27 cases of left ankle and 21 cases of right ankle. The average medial malleolar angle was $18.67^\circ \pm 2.87^\circ$, the average amount of bone resection was $12.13 \pm 1.86 \text{ cm}^3$, the mid-anterior distance was $1.72 \pm 0.19 \text{ cm}$, the mid-posterior distance was $2.00 \pm 0.19 \text{ cm}$, the ratio of mid-anterior to mid-posterior was 0.87, the mid-medial distance was $1.26 \pm 0.17 \text{ cm}$, the mid-lateral distance was $1.19 \pm 0.16 \text{ cm}$, and the ratio of mid-medial to mid-lateral was 1.06. After osteotomy, the anteroposterior diameter was $3.73 \pm 0.32 \text{ cm}$, the transverse diameter was $2.46 \pm 0.27 \text{ cm}$, and the ratio of anteroposterior diameter to transverse diameter was 1.53. In the bottom view, the shape after osteotomy is rectangular. The mid-anterior distance was strongly negatively correlated with age, the mid-anterior distance and the amount of bone resection, the mid-medial distance and the amount of bone resection, the mid-lateral distance and the amount of bone resection, the mid-lateral distance and the anteroposterior diameter, the anteroposterior diameter and the transverse diameter were all strongly positively correlated.

Conclusion: The projection point of the lower tibia centerline on the tibial horizontal osteotomy surface is located at a position slightly anterior to the midpoint of the transverse diameter after ankle arthroplasty. The rational positioning of the total ankle replacement is located at both a position slightly anterior to the midpoint of the transverse diameter and midpoint of the anteroposterior diameter, which can be used as a reference method before total ankle arthroplasty surgery.

Key words: ankle arthritis; preoperative planning; ankle joint replacement; osteotomy; anatomical parameters

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Introduction

There are 29,000 cases of symptomatic ankle osteoarthritis (AOA) in the UK every year, and approximately 10% of patients with end-stage ankle disease who receive arthrodesis or arthroplasty treatment.¹ The analysis results of the discharge database of California Hospital show that the proportion of ankle fusion surgery is gradually decreasing in clinical practice, while the total ankle replacement (TAR) surgery is increasing year by year, its complications are gradually decreasing.² A systematic meta-analysis of gait biomechanics after TAR showed that patio-temporal, kinematic and kinetic gait patterns were improved when compared to pre-operation, yet gait biomechanics after ankle arthrodesis were not improved due to walking speed and ankle movement.³ Independent risk factors related to readmission were related to deficiency anemia, coagulopathy, renal failure, other insurance relative to private, and tibiotalar fusion.⁴

However, the revision rate of ankle arthroplasty is much higher than that of ankle fusion.⁵ It has also been reported that the failure rate of ankle joint replacement is relatively high, which is related to 45% of poor alignment after operation.⁶ Compared with anterior approach, TAR through the lateral transfibular approach can relieve pain and also improve ankle function for patients who suffer from ankle osteoarthritis.⁷

Mobile bearing total ankle replacement has a risk of motion in polyethylene and prostheses, and the perfect position of the prosthesis and technical realignment procedure are very important for preventing overload of ligaments after TAR. Moreover, tibiofibular fusion is an effective revision method for improving ankle function.⁸ A meta-analysis of comparative studies between TAR and ankle arthrodesis was performed to explore the difference in clinical scores and patient satisfaction, reoperations, and complications. The clinical results of TAR and ankle arthrodesis were similar; the rate of reoperation in TAR was increased, while marked loss of ankle motion and diminished gait efficiency in ankle arthrodesis was observed.⁹

Computer navigation technology was mainly used to improve the accuracy of ankle joint implantation,^{10,11} but due to the expensive equipment, many medical institutions cannot carry out this procedure effectively. Moreover, during ankle replacement surgery, the placement of the tibial prosthesis is mainly based on fluoroscopy during operation,¹² while a small controllable range due to a small diameter of the lower tibia, and intraoperative fluoroscopy is not satisfactory because of large perspective errors. The method of preoperative planning can be used to determine the accurate placement of tibial components, so it can be used as a relatively accurate estimation method. Moreover, studies have reported that there are morphological differences between Chinese and Caucasian individuals through three-dimensional analysis, and TAR prostheses designed for Caucasian may not be suitable for Chinese people.¹³ Patients suffering from post-traumatic end-stage arthrosis after TAR have high revision rates, which are related to symptomatic

periprosthetic bone cysts. These worse outcomes will not be improved through tibiotalar arthrodesis (TTA).¹⁴ Therefore, precise implantation of ankle joint prostheses is very important.

Preoperative measurement combined with intraoperative fluoroscopy can further improve the accuracy of prosthesis placement. In recent years, three-dimensional CT imaging technology has been widely used in orthopaedic imaging diagnosis, and the accuracy of CT diagnosis is much higher than that of X-ray examination. At present, there is no research on CT three-dimensional imaging combined with simulated surgical osteotomy and ankle joint anatomy measurement. This manuscript shows the availability of this evaluation method and the precise placement of the tibial prosthesis.

The aims of our research are as follows: (i) to establish the rational positioning of tibial prosthesis during total ankle replacement surgery; and (ii) to explore a new method of preoperative planning for TAR.

Methods and materials

Data collection and storage

CT data of the ankle joint from 48 subjects were collected in the outpatient and inpatient departments of our hospital. The inclusion criteria were as follows: (i) patients with a history of trauma but without fracture or dislocation from the lower tibia. The exclusion criteria were as follows: (i) the patient suffered from fracture of the ankle joint, (ii) the patient had congenital or acquired skeletal deformity; and (iii) the patient suffered from inflammation, tumor, and tuberculosis.

In this study, a SOMATOM Definition Flash dual-source CT machine (Siemens Healthineers, Forchheim, Germany) was used to scan the ankle joints of observers, including 8 cm above the joint space and the entire ankle. The scanning parameters were set as: 120 KV, 205.50 mAs, and the layer thickness was 1 mm. All DICOM images (521 px × 512 px) in 336 layers for each ankle were imported into Materialise's Interactive Medical Image Control System (MIMICS) 17.0 software (Materialise, Leuven, Belgium). The region of interest was calculated using both the "Thresholding" module and the "region growing" module. All three-dimensional models of the ankle joint were reconstructed by the "calculate 3D from mask" function, and then imported into 3matic software (Materialise, Leuven, Belgium) for measurement (see Figure 1). The computer configuration of this study is as follows: Windows 7-64 bit operating system, processor Intel (R) Core (TM) i7-4600, running memory 8 GB, 256 SSD hard disk.

Simulating the Surgical Osteotomy Process

According to the INBONE[®] total ankle system (Wright Medical Technology) surgery process,^{12,15} osteotomy of the ankle was simulated using the Materialise Mimics software by computer, as follows: in front view mode, align the origin point of the world coordinate system (WCS) with the lowest point of the ankle mortise, establish plane 0 with reference

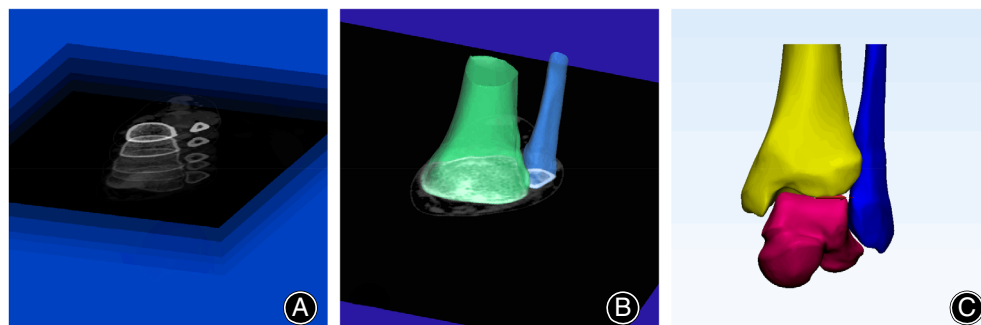


Fig. 1 From CT image to digital 3D model construction. (A) CT cross-sectional scan was finished by a SOMATOM Definition Flash dual-source CT machine. (B) The skeleton Model was generated using the function of the “Calculate 3D from mask” in Mimics software. (C) Measurement of the 3D model was executed in 3-matic software

to the x axis and y axis of the WCS, simulate osteotomy at 12 mm in the z-axis direction (osteotomy plane 1), refer to the y and z axes of the coordinate system to establish plane 2 and plane 3, respectively, move and rotate at the medial malleolus and lateral malleolus (osteotomy plane 2 and osteotomy plane 3 respectively), and simulate osteotomy with three osteotomy planes. After removing the non-interesting bone, the remaining bones were merged (shown in Figure 2A,B,E).

Plane 4 and plane 5 were established with reference to the y axes and z axes of the WCS, moved so that they were tangent to the innermost and outermost points of the tibial cortex, and established midplane 1 of plane 4 and plane 5 (shown in Figure 2C). In the same way, plane 6 and plane 7

were established referring to the x and z-axes of the WCS and were moved to ensure that they were tangent to the most anterior point and the most posterior point of the tibial cortex (shown in Figure 2D). Then, midplane 2 of these two planes was established, and finally the centerline (line 1) of midplane 1 and midplane 2 was calculated (shown in Figure 2B). The mapping point (center point) of line 1 on plane 1 was obtained (shown in Figure 2F).

Measuring Distance for Determining the Center Point of Tibial Prosthesis

In the bottom view mode, the midmedial distance was defined as the shortest distance from the center point on osteotomy plane 1 to the medial; midlateral distance was

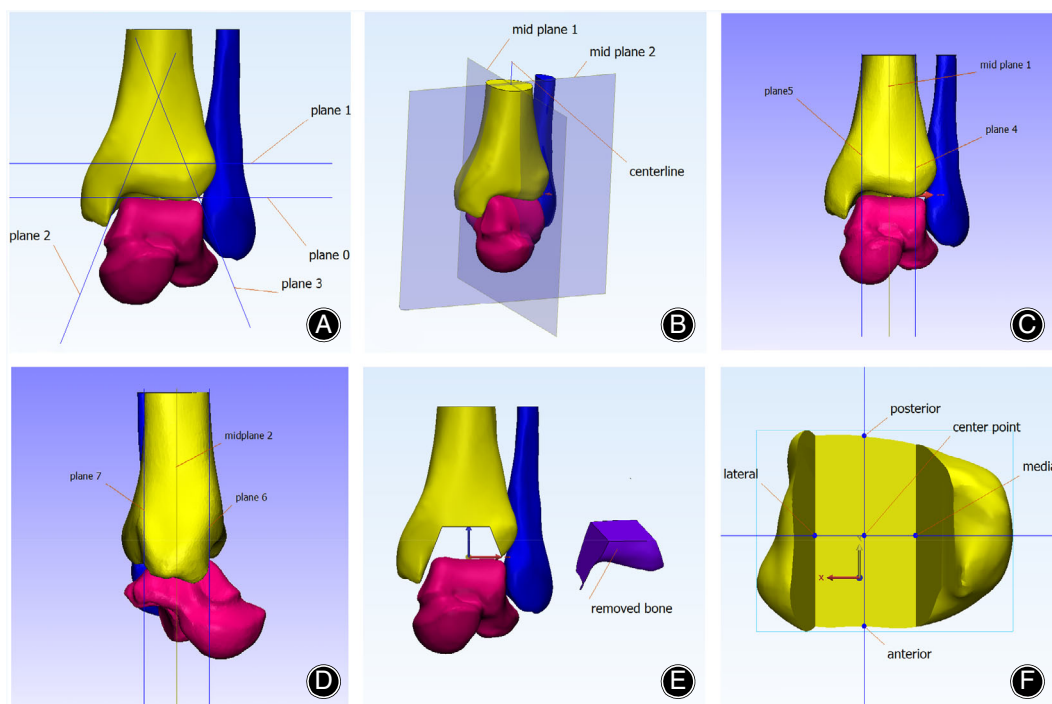


Fig. 2 Simulation of the ankle osteotomy process. (A) Plan for osteotomy. (B) Centerline was calculated based on midplane 1 and midplane 2. (C) established midplane 1 of plane 4 and plane 5. (D) established midplane 2 of plane 6 and plane 7. (E) Simulated tibial osteotomy. (F) Point of measuring distance in the bottom view.

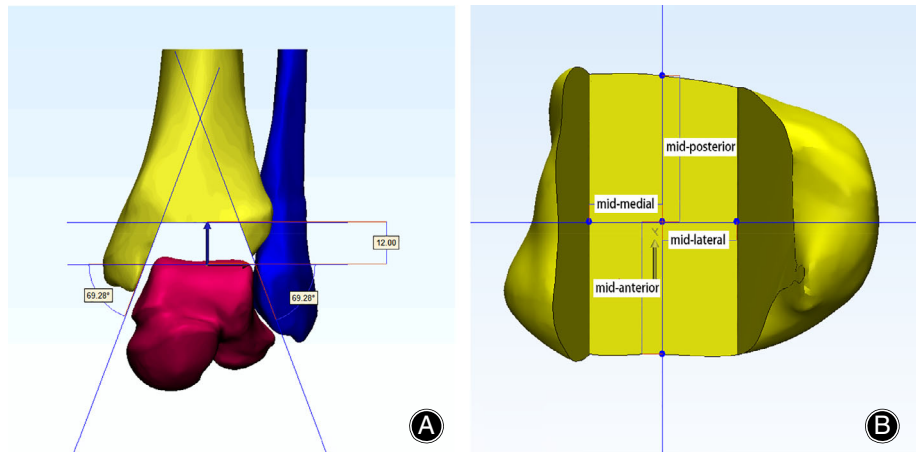


Fig. 3 Diagram of the measurement method for angle and distance after osteotomy. (A) Medial malleolus angle, (B) Schematic diagram of measuring distance in the bottom view.

defined as the shortest distance from the center point on osteotomy plane 1 to the lateral bone; a vertical line was produced perpendicular to midplane 1 through the center point, the midanterior distance was defined as the mapping point between the vertical line and the front edge of the tibia to the center point; and the midposterior distance was defined as the mapping point between the vertical line and the posterior edge of the tibia to the center point. All shortest distances were measured by 3 matic software (see Figure 3B).

Measurement of the Medial Malleolar Angle

In the standardized front view, make a plane along the medial malleolus (plane 2), make a plane parallel to the ground along the lowest point of the ankle mortise (plane 0), measure the angle between plane 0 and plane 2, and calculate the remaining angle, which we call the medial malleolus angle (see Figure 3A).

Statistical Analysis

All data were collected and entered into Microsoft Excel 2016 in this study, and SPSS17.0 statistical software package (SPSS Statistics for Windows, Version 17.0. Chicago: SPSS Inc.) was employed to calculate the means and standard deviations. Measurement data are expressed as the mean \pm standard deviation, and the relationship between the two variables was analyzed by bivariate correlation analysis. The Pearson correlation coefficient was set as follows: $|r| < 0.3$ is a weak correlation, $0.3 \leq |r| \leq 0.5$ is a medium correlation, $|r| > 0.5$ is a strong correlation. Scatter plots for distance values were produced using GraphPad Prism 8 software (Graphpad Software, Inc.), and fit to a line with simple linear regression. All statistical tests were two-sided tests, and $p < 0.05$ was considered statistically significant.

Results

Basic Information of Subjects

The data consisted of 48 CT sub-data sets, including 26 males and 22 females with an average age of 49.13 years (range,

22–70 years), 27 cases in the left ankle, and 21 cases in the right ankle. All subject bones had no congenital malformations and no traumatic or pathological diseases. The study was approved by the Ethics Committee of Shaanxi Provincial People's Hospital.

Measurement of the Angle Between the Medial Malleolus and Ankle Mortise

The medial malleolar angle was defined as the angle between the medial malleolus and ankle mortise, and the result in our study was $18.67^\circ \pm 2.87^\circ$.

After the osteotomy was completed, the amount of bone resection was measured using the software (see Figure 2C). The average amount of bone resection was $12.13 \pm 1.86 \text{ cm}^3$.

Determination of the Center Point of the Tibial Prosthesis During Total Ankle Replacement

After the simulated osteotomy is completed, during the bottom view, the center point is the intersection between the centerline and plane 1 (see Figure 2D). The mid-anterior distance is $1.72 \pm 0.19 \text{ cm}$, the mid-posterior distance is $2.00 \pm 0.19 \text{ cm}$, the antero-posterior ratio is 0.87. These results indicate that the projection of centerline for the lower tibia to plane 1 is anterior, and the tibial prosthesis should be placed anteriorly during TAR.

The mid-medial distance was $1.26 \pm 0.17 \text{ cm}$, the mid-lateral distance was $1.19 \pm 0.16 \text{ cm}$, and the medial-lateral ratio was 1.06, indicating that the centerline of the lower tibia almost projected on the midpoint of the osteotomy surface. The center point of the prosthesis was the midpoint of the transverse diameter for osteotomy plane 1.

The measurement results show that the anteroposterior diameter after osteotomy is $3.73 \pm 0.32 \text{ cm}$, the transverse diameter is $2.46 \pm 0.27 \text{ cm}$, and the ratio is 1.53, indicating that the shape on the bottom view after osteotomy is rectangular.

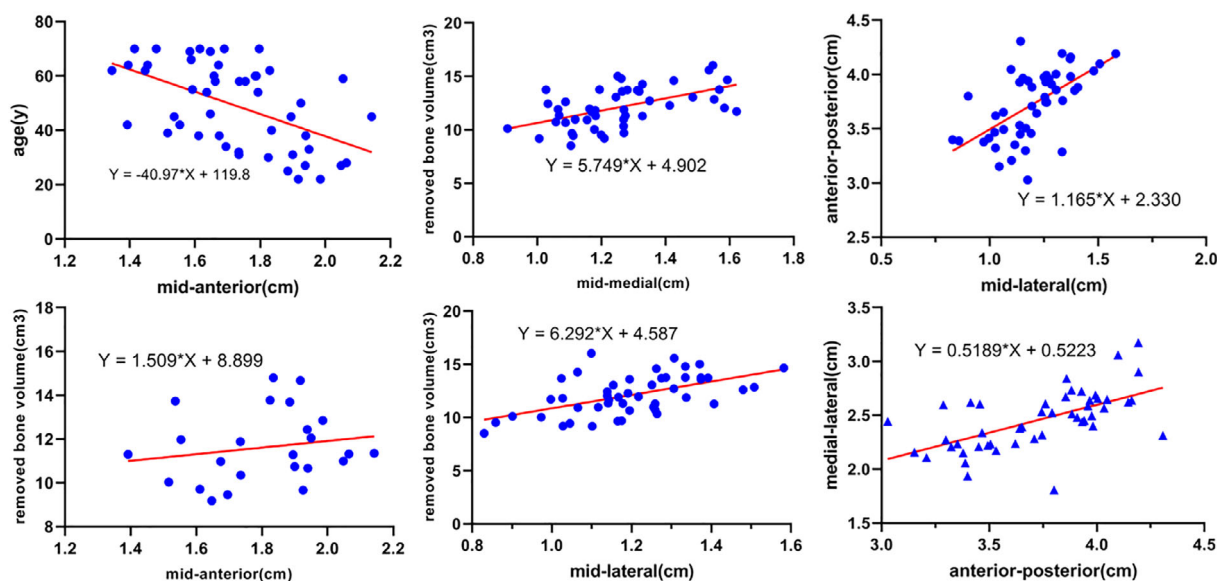


Fig. 4 Correlation diagram of various variables (strong correlation). A positive correlation was found between age and mid-anterior, yet a negative correlation was found for other variables that showed a strong correlation.

Correlation Analysis of Measured Parameters

The results of the two-sided Pearson correlation analysis showed that the mid-anterior distance was positively correlated with the mid-lateral distance (correlation coefficient $r = 0.389$, $P = 0.006$), and strongly negatively correlated with age (correlation coefficient $r = -0.523$, $P = 0.000$). There was a strong positive correlation with the amount of bone resection (correlation coefficient $r = 0.635$, $P = 0.000$); the anteroposterior distance ratio was moderately negatively correlated with age (correlation coefficient $r = -0.341$, $P = 0.018$), and moderately positively correlated with the amount of bone resection (correlation coefficient $r = 0.381$, $P = 0.008$); age and medial malleolus angle were moderately negatively correlated (correlation coefficient $r = -0.485$, $P = 0.000$); both mid-medial and mid-lateral distances were positively correlated with the amount of bone resection and anteroposterior diameter (the correlation coefficients were $r = 0.541$, $r = 0.386$, $r = 0.549$, $r = 0.597$, respectively); and the anteroposterior diameter was significantly positively correlated with the transverse diameter (correlation coefficients $r = 0.603$, $P = 0.000$) (Figure 4).

Discussion

Osteotomy can not only correct the biomechanical abnormalities of the ankle joint but also reduce the load on the articular cartilage of ankle, and even extend the longevity of the ankle joint.¹⁶ For patients with good structural stability of ankle mortise and no deformity, TAR is better for the treatment of traumatic ankle arthritis, and ankle function is improved significantly.^{17,18} Ankle replacement surgery is only suitable for patients over 50 years old with low physical needs. However, a recent study¹⁹ found that patients under

50 years have better clinical effects and higher satisfaction, and complications are comparable with survival rates. TAR has higher failure rates and will require revisions within 10 years.²⁰ So, the effectiveness of TAR surgery seems still controversial owing to unknown reasons.

Reasonable Positioning of the Tibia Component

Internal rotation of the ankle in the transverse after TAA is increased, which is related to the medial-lateral position of the tibial component.²¹ Improper implant positioning and realignment caused overload of soft tissue structures that was correlated with impaired clinical and radiographic outcomes.⁸ In a finite element model simulation study, mal-positioning of the tibia/talus component during TAR may result in an increase in micromotion and bone strains.²² To the best of our knowledge, there is no evidence about precision positioning related to the tibial component of the TAR surgical operation. Our outcomes based on the INBONE prosthesis procedure demonstrate that the shape after osteotomy is rectangular from the bottom view. The centerline of the tibial component passes through both a position slightly anterior to the midpoint of the transverse diameter and the midpoint of the anteroposterior diameter after ankle arthroplasty. This may be helpful for foot and ankle surgeons to decide the precise position of tibial prostheses.

Significance of Measuring Distance and Removed Bone Volume

It was reported that Scandinavian total ankle replacement (STAR) was used for treating end-stage ankle arthritis, which achieved better long-term clinical effects and higher patient satisfaction.²³ There is strong evidence that the survival rate

of implants with a coronal varus deformity before surgery is not different from that of implants without a varus deformity. Preoperative valgus deformity has a greater negative impact on implant survival.²⁴ Studies on anatomical measurements have been performed on the three-dimensional model of the ankle joint. For example, the asymmetric shape of the medial talus trochlea is related to the fixed or changing axis of rotation at the ankle joint. It is recommended to consider the characteristic rotation axis of ankle joint²⁵ when treating patients suffering from ankle joint injuries. Other studies have also shown that the design of total ankle prostheses needs to take into account gender differences, and it is recommended that ankle bone morphology evaluation by CT scans before TAR surgery can improve the surgical accuracy of prosthesis placement.²⁶

Our study shows that the removed bone volume was positively correlated with the mid-medial/mid-anterior/mid-lateral distance, which means that the removed bone volume depends on the volume of lower tibia; thus, preoperative simulated osteotomy is suggested to be individualized in clinical practice as follows: (i) bone model could be reconstructed from ankle CT of the patients; (ii) simulated osteotomy could be implemented using the method in this study. It will be helpful for the surgeon to decide the position and size of the tibia prosthesis during the TAR operation. Moreover, there was a positive association between anteroposterior diameter and medial-lateral diameter, which also existed in the mid-lateral distance and anteroposterior diameter. These findings were dependent on the consistent anatomical features of the lower tibia.

Limitations

Our research does have some limitations that should be improved. First, placement in this study may not be the exact

same situation during the operation since the surgical osteotomy process in our study was simulated using a computer and it was not a real TAR. Therefore, we should verify the reliability of our results by a number of clinical practices as the next phase of this study. Second, the biomechanical mechanism of prostheses placement should be explored in order to further improve the appropriateness of positioning by Finite-Element Analysis (FEA) in the upcoming research. Third, the sample size in this research was relatively small, so a larger sample size study is needed for further clarification.

Conclusion

The procedure of the INBONE® Total Ankle System requires accurate positioning of the centerline of the lower tibia, and the final position of the prosthesis in the coronal and sagittal planes is determined according to the position of the centerline. In our manuscript, a three-dimensional imaging model was used to simulate surgical osteotomy to detect the exact position of the centerline in the lower tibia. The tibia shape after ankle arthroplasty was characterized by an anteroposterior diameter greater than the transverse diameter. The projection point of the tibia centerline on the tibial horizontal osteotomy surface was located at the anterior position in the anteroposterior diameter and the midpoint of the transverse diameter, which can be used as a reference method for measurement before TAR.

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None.

CONFLICT OF INTEREST

The authors have no conflicts of interest with regard to this work.

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