The Knee 26 (2019) 1102–1110

Contents lists available at ScienceDirect

The Knee

Intra- and interobserver reliability and agreement in three-dimensional computed tomography measurements of component positions after total knee arthroplasty

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ARTICLE INFO

Article history:
Received 14 January 2019
Received in revised form 17 June 2019
Accepted 1 July 2019

Keywords:
Total knee arthroplasty
Intra- and interobserver reliability
Agreement
Component position
Three-dimensional measurement
3D-CT

ABSTRACT

Background: Accurate evaluation of the postoperative position of total knee arthroplasty (TKA) components is crucial in the analysis of the association of alignments with clinical outcomes. The aim of this study was to investigate the reliability of measurements of component positions after TKA using three-dimensional computed tomography (3D-CT) reconstruction.

Methods: Two independent orthopedic surgeons (an attending surgeon and a fellow) examined 30 knees after primary TKA. The coronal, sagittal, and rotational positions of the femoral and tibial components were measured twice at an interval of six weeks on 3D-CT images reconstructed using ZedKnee software. Mean intra- and interobserver differences of measured angles were calculated, and the intra- and interobserver reliability was determined using intraclass correlation coefficients (ICCs), with agreement assessed by Bland–Altman analysis.

Results: The mean intraobserver difference between alignment measurements for femoral and tibial components was <2° (range 0.23–1.17°) and the mean interobserver difference was <1° (range 0.22–0.97°). The intra- and interobserver ICCs were >0.8 for all component positions. The only systematic bias found in the intra- and interobserver agreements occurred for the sagittal position of the femoral component.

Conclusion: Three-dimensional-CT measurements of component positions after TKA showed good intra- and interobserver reliability for the femoral and tibial components in coronal, sagittal and rotational positions. The intra- and interobserver agreements were favorable for all but the sagittal position of the femur. These results suggest that 3D-CT can be used to evaluate the alignment of all TKA components except for the sagittal position of the femur.

1. Introduction

In total knee arthroplasty (TKA), appropriate implant placement is necessary for stable fixation and favorable long-term survival, sufficient postoperative range of motion, and patient satisfaction [1–3]. Plain radiographs are generally used to assess the varus–valgus and flexion–extension alignment of components after TKA. Rotation can be assessed using two-dimensional computed tomography (2D-CT), and several methods are used to evaluate the femoral and tibial components [4,5]. Measurements

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https://doi.org/10.1016/j.knee.2019.07.001
0968-0160/

by these methods using 2D slices are convenient, but may be inaccurate because the leg position during scanning may influence the location of anatomical landmarks [6].

Three-dimensional CT (3D-CT) reconstruction can avoid the influence of the leg position, and has been used to measure the position of components after TKA [7–10]. The ZedKnee system (LEXI, Tokyo, Japan) is 3D-CT preoperative planning software for TKA that has a function for matching pre- and postoperative CT images, which permits 3D comparison of planned positions with those of implanted components. Intra- and interobserver reliability of this 3D planning software for total hip or knee arthroplasty has been reported [11,12], but the reliability of 3D-CT measurements of the position of TKA components has not been widely investigated. Notably, to our knowledge, there is no literature on intra- and interobserver agreement of 3D-CT measurements using the Bland–Altman method [13], despite the importance of validation of the method for evaluation of the position of TKA components in analysis of alignments and postoperative outcomes. Therefore, the purpose of the study was to examine 3D-CT measurements of component positions after TKA to test the hypothesis that 3D-CT data are highly reliable and will show good intra- and interobserver agreement.

2. Materials and methods

2.1. Participants

A total of 24 consecutive patients (30 knees) who underwent primary TKA and had no previous knee surgery were included in the study. A sample size of 30 was chosen according to the reported estimates for reliability studies using intraclass correlation coefficients (ICCs) described by Walter et al. [14]. The cohort consisted of 18 women and six men, and had an average age of 71.6 (range 50–85) years. The mean weight, height, and body mass index (BMI) were 68.5 (42.8–83.0) kg, 155.2 (137–171) cm, and 28.4 (20.1–35.9 kg/m^2), respectively. The diagnosis was osteoarthritis with varus deformity classified as Kellgren–Lawrence grade 3 or 4 in all knees, with a mean femorotibial angle (FTA) of 187.9° (range 181–203°) and hip–knee–ankle angle of −11.8° (range − 30° to −2°). The study was approved by our hospital institutional review board and all patients gave written informed consent before any study-related procedures were performed.

2.2. Measurement of component positions

All patients underwent preoperative high-resolution CT of the lower limbs from the pelvis to the ankle (16-row detector, Toshiba Medical, Japan) in helical mode with a 512 × 512 matrix and a slice thickness at one millimeter. CT data were reconstructed into 3D models using ZedKnee software and used for preoperative planning of TKA by the attending surgeon (T.T.). All surgeries were performed by T.T. using a Persona Cruciate Retaining knee system (Zimmer, Warsaw, IN, USA) with a measured

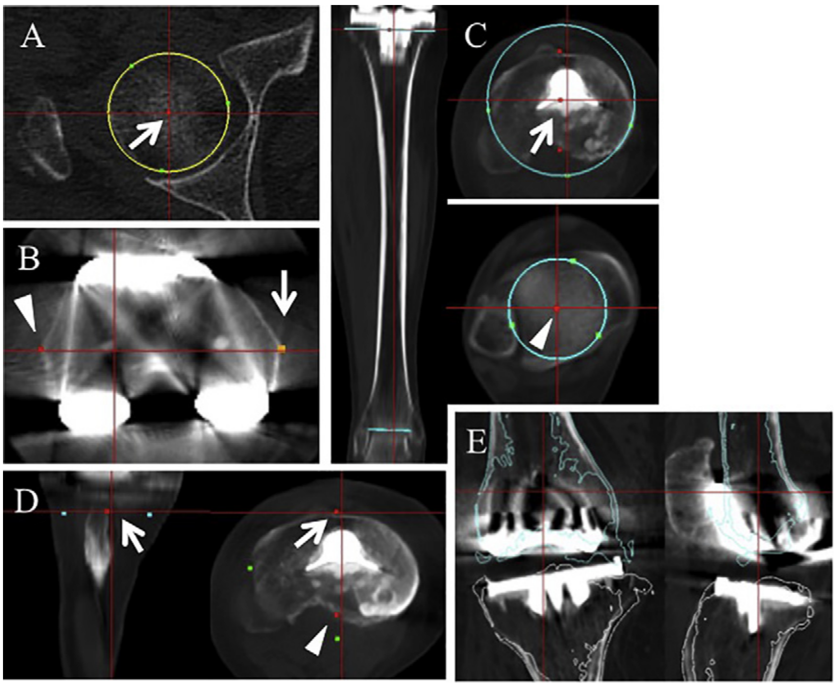

Figure 1. Reference points for the right femur and tibia. (a) Center of the femoral head (arrow). (b) Medial (arrow) and lateral (arrowhead) epicondyles. (c) Center of the tibial proximal cut surface (arrow), center of the distal tibial plafond (arrowhead), and the two ends of the tibial shaft axis. (d) Medial edge of the tibial tubercle (arrow) and posterior proximal cut surface (arrowhead). (e) Postoperative computed tomography images fused to preoperative images.

resection technique, conventional manual instruments, and cement fixation. Postoperative surgical drains were not used in any case. One week postoperatively, a similar CT scan was performed and 3D measurements of component positions were made using the ZedKnee image-matching function (as described below). Component positions were measured twice postoperatively at an interval of six weeks by two independent board-certified orthopedic surgeons (A and B: attending surgeon and fellow) who had no knowledge of previous measurements or those of each other at the time of observation.

2.3. Image matching process

Reference points were defined on CT images to overlap pre- and postoperative femur–tibia axis coordinates. The center of the femoral head (Figure 1(a)), and medial and lateral epicondyles (Figure 1(b)) were used as reference points for the femur; and the shaft axis (Figure 1(c)), medial edge of the tubercle, and posterior proximal cut surfaces (Figure 1(d)) were used for the tibia. Using these points, preoperative CT images were fused to postoperative images automatically by matching bone surfaces (Figure 1(e)). After matching, the femoral–tibial component template from a computer-aided design (CAD) model was superimposed on the implant image manually to match their contours (Figure 2). At this time, femoral component rotational and coronal positioning was determined with reference to the two pegs. Digitally reconstructed radiographs were used for sagittal component positioning to reduce the influence of halation of the implant. In tibial component positioning, the keel wings, hole, or grooves of the tibial tray were referred similarly to the femoral component. Based on the positioning of the templates, the coronal, sagittal, and axial alignments of both components were measured using ZedKnee software with reference to the coordinate systems (Figure 3). The postoperative FTA was also measured as the leg-axis angle between the anatomical axis of the femur and tibia in the coronal plane defined by the coordinate systems.

The respective coordinate systems were determined using the femoral and tibial mechanical axes. The mechanical axis of the femur was defined as a line connecting the center of the femoral head and the midpoint of the tips of the bilateral epicondyles. The coronal plane was defined by the center of the femoral head and the two epicondyles. The sagittal plane was set vertical to the coronal plane through the femoral mechanical axis, and the axial plane was defined as perpendicular to these two planes. The mechanical axis of the tibia was defined as the line connecting the center of the proper-sized tibial component without the posterior slope, and the center of the distal tibial plafond [15]. The anteroposterior axis of the tibia was determined using the ‘Akagi line’, a straight line from the midposterior cruciate ligament enthesis to the medial edge of the tibial tubercle [16]. The sagittal plane was set parallel to the Akagi line through the tibial mechanical axis, and the coronal plane was set vertical to the Akagi line. The axial plane was determined in a manner similar to that for the femoral coordinate system. Femoral and tibial varus alignments are expressed as positive and valgus as negative. Femoral flexion is expressed as positive, extension as negative, and the tibial posterior slope as positive. In rotational alignment, internal rotation is expressed as positive and external rotation as negative for both components.

2.4. Statistical analysis

Mean intra- and interobserver differences in measurements of femoral and tibial components and FTA were calculated for all alignments. Intra- and interobserver reliability was determined by calculating the ICC with a confidence interval (CI) of 95%. An ICC value of one indicates perfect reliability, 0.81 to one very good, 0.61–0.80 good, 0.41–0.60 moderate, and <0.40 poor [14]. Intra- and interobserver agreement between two measurements was assessed using the Bland–Altman method and the limits

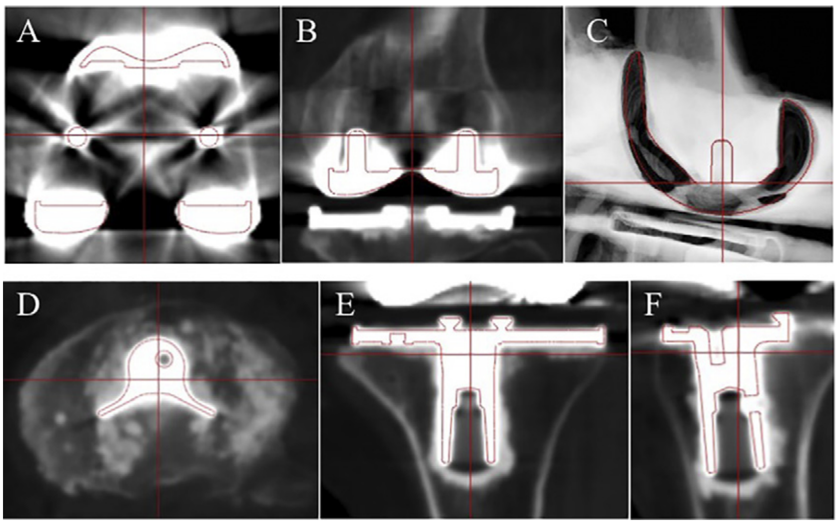

Figure 2. Component templates superimposed on images of implants. (a) Femoral axial, (b) femoral coronal, (c) femoral sagittal, (d) tibial axial, (e) tibial coronal, (f) tibial sagittal. The femoral sagittal image was digitally reconstructed to reduce the influence of implant halation.

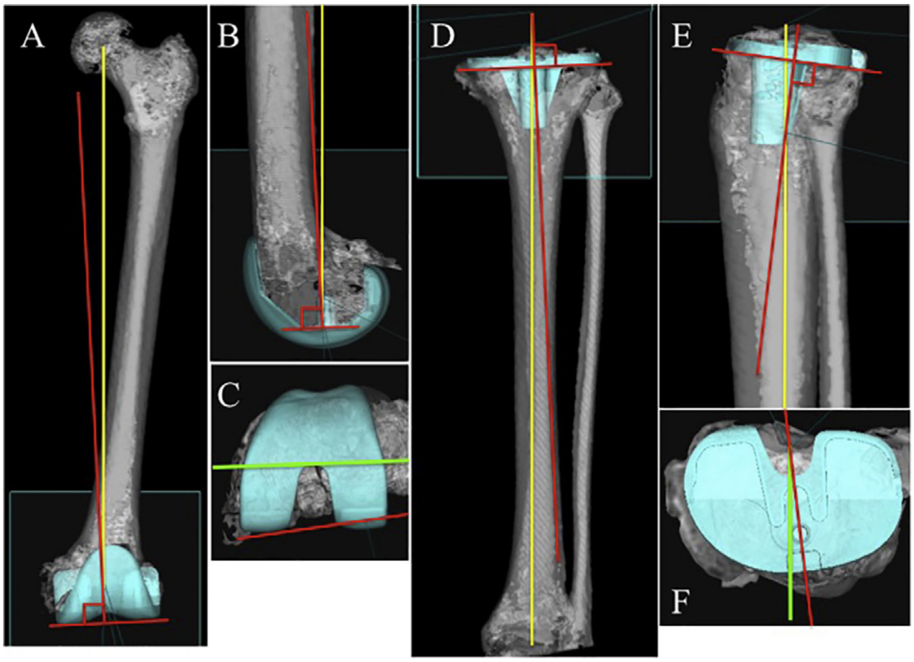

Figure 3. Three-dimensional measurements of component positions. (a) Femoral varus–valgus alignment: angle between a perpendicular line to the femoral distal surface (red line) and the femoral mechanical axis (yellow line). (b) Femoral flexion–extension alignment: angle between a perpendicular line to the distal cutting surface of the femoral component (red line) and the femoral mechanical axis (yellow line). (c) Femoral rotational alignment: angle between a line connecting the bilateral epicondyles (green line) and posterior condylar prosthesis axis (red line). (d) Tibial varus–valgus alignment: angle between a perpendicular line to the inferior surface of the tibial component (red line) and the tibial mechanical axis (yellow line). (e) Tibial slope alignment: angle between a perpendicular line to the inferior surface of the tibial component (red line) and the tibial mechanical axis (yellow line). (f) Tibial rotational alignment: angle between the Akagi line (green line) and the anteroposterior prosthesis axis (red line).

of agreement (LOAs) were calculated [13]. The LOA was defined as the 95% CI of the mean differences between measurements of the angles. No systematic bias was considered to be present if the range of the LOA included zero. All analyses were performed using International Business Machines Corporation (IBM), Statistical Package for Social Science (SPSS) for Windows (v.22.0; IBM Corp., Armonk, NY).

3. Results

3.1. Intraobserver reliability

The mean intraobserver differences for alignment measurements for femoral and tibial components were all <2° (Table 1). For observer A, all differences were <1° except for the rotational position of the tibial component (1.17°) and for observer B, all were within one degree. ICCs for all measurements were very good (Table 1). Bland–Altman plots showed systematic bias in only one alignment: the sagittal position of the femoral component for observer B (Figure 4(a–f)). For the FTA, the mean differences were within 0.2°, ICCs were very good to perfect (Table 1), and no systemic bias was present (Figure 4(g), (h)).

Table 1
Intraobserver reliability of ZedKnee alignment measurements for femoral and tibial components and the femorotibial angle.

Component		Observer A			Observer B		
		Mean difference (range)	ICC (95% CI)	LOA	Mean difference (range)	ICC (95% CI)	LOA
Femur	Coronal	0.23 (0.00–0.88)	0.98 (0.95–0.99)	−0.22 to 0.02	0.29 (0.00–1.44)	0.96 (0.91–0.98)	−0.12 to 0.21
	Sagittal	0.72 (0.00–2.50)	0.95 (0.91–0.98)	−0.25 to 0.51	0.93 (0.00–5.00)	0.93 (0.86–0.97)	0.14 to 1.12
	Axial	0.62 (0.00–3.44)	0.90 (0.80–0.95)	−0.24 to 0.51	0.44 (0.00–1.50)	0.97 (0.94–0.99)	−0.01 to 0.43
Tibia	Coronal	0.35 (0.00–1.06)	0.93 (0.85–0.96)	−0.22 to 0.11	0.27 (0.00–1.63)	0.93 (0.86–0.97)	−0.16 to 0.18
	Sagittal	0.50 (0.00–2.62)	0.82 (0.67–0.91)	−0.18 to 0.41	0.58 (0.00–1.89)	0.87 (0.75–0.94)	−0.15 to 0.44
	Axial	1.17 (0.00–6.47)	0.93 (0.87–0.97)	−0.58 to 0.90	0.65 (0.00–4.43)	0.98 (0.96–0.99)	−0.48 to 0.31
Femorotibial angle		0.11 (0.00–1.17)	0.99 (0.98–1.00)	−0.14 to 0.06	0.02 (0.00–0.09)	1.00	−0.001 to 0.02

CI, confidence interval; ICC, intra-class correlation coefficient; LOA, limits of agreement.

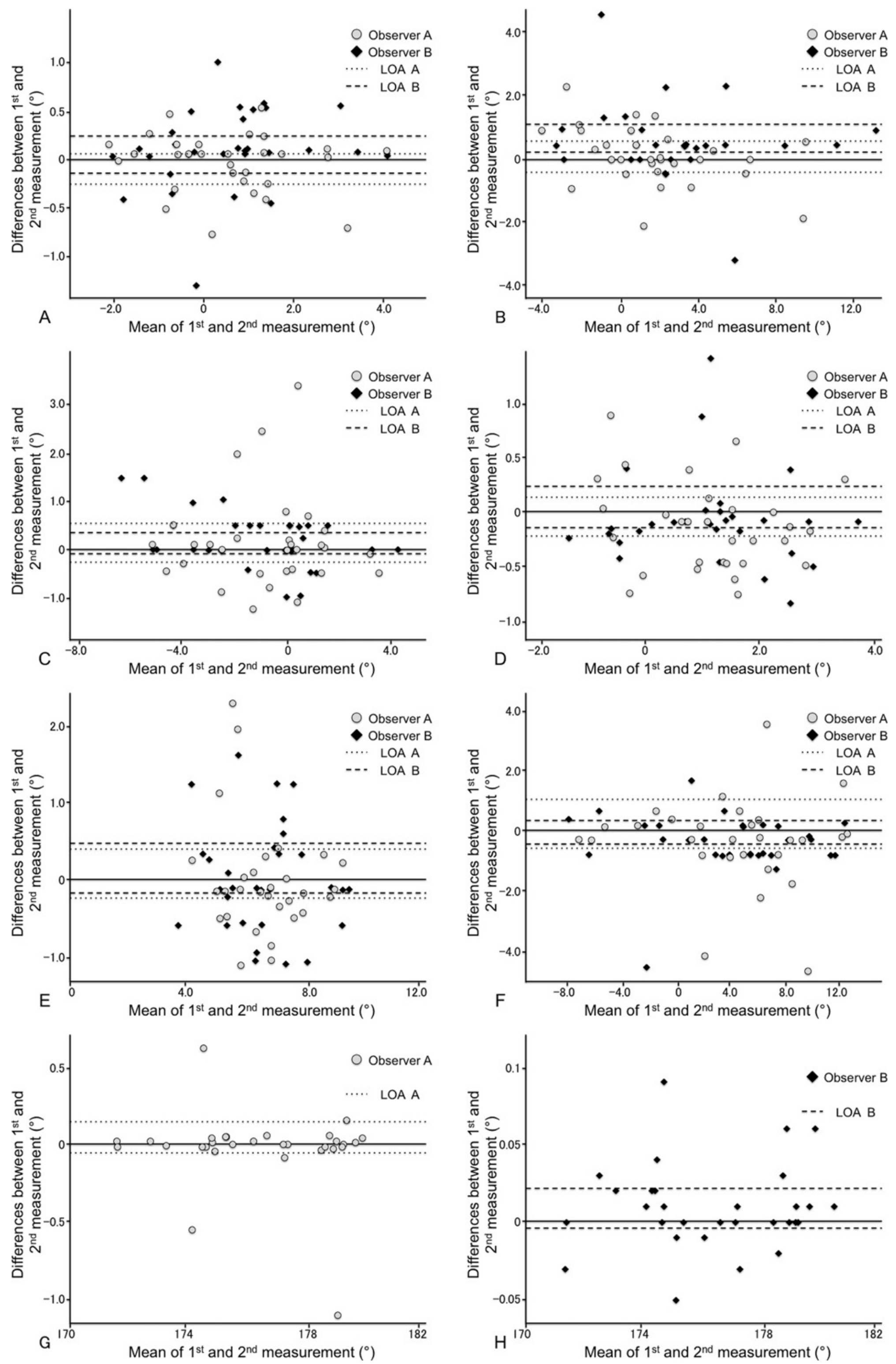

Figure 4. Bland–Altman plots for the first and second alignment measurements to examine intraobserver agreement: (a) femoral coronal, (b) femoral sagittal, (c) femoral axial, (d) tibial coronal, (e) tibial sagittal, (f) tibial axial, (g), (h) femorotibial angle. The limits of agreement (LOAs) are represented by the dotted line for observer A and the short dashed line for observer B. The upper and lower LOAs for the femoral sagittal position for observer B were 1.12 and 0.14, respectively; that is, the LOA range did not include zero.

3.2. Interobserver reliability

The mean interobserver differences were <1° for measurements for the femoral and tibial components, and ICCs for all measurements were very good (Table 2). Bland–Altman plots showed systematic bias only for the sagittal position of the femoral component (Figure 5(a–f)). For the FTA, the mean differences were within 0.1°, ICCs were very good (Table 2), and no systemic bias was present (Figure 5(g)).

4. Discussion

There were three main findings from the study. First, intra- and interobserver measurements for coronal, sagittal, and rotational positions of TKA components and the FTA using 3D-CT reconstruction were sufficiently reliable with regard to ICCs, which were >0.8 for all alignments. Second, the mean intra- and interobserver differences between 3D-CT measurements were all <2° in the coronal, sagittal, and rotational positions for both femoral and tibial components. Third, the intra- and interobserver agreements for measurements of positions of the components were favorable, with systematic bias only in the alignment of the femoral sagittal position.

Several previous studies have shown the intra- and interobserver reliability of measurements of TKA components on radiographs and 2D- and 3D-CT images. Boonen et al. [17] reported good ICCs for interobserver measurements of femoral and tibial coronal alignment using long leg radiographs (ICC 0.70–0.80). In contrast, Hirschmann et al. [18] reported moderate or poor intraobserver reliability of measurements of femoral varus–valgus, femoral flexion–extension, and tibial varus–valgus values on radiographs (ICC 0.33–0.40). Konigsberg et al. [19] reported contrasting results for intra- and interobserver ICCs for 2D-CT measurements of femoral and tibial rotation, with good ICCs for the tibial component (0.670–0.896), but poor values for the femoral component (0.386–0.606). In contrast, the reliabilities of 3D-CT measurements have been equal or higher for all alignments of femoral and tibial components in past reports. Hirschmann et al. [18,20] used customized software to reconstruct 3D images from CT data and obtained excellent intra- and interobserver ICCs (0.73–0.99) and mean differences in measurements for all alignments for both components (0.6–1.1°).

We found ICCs >0.8 and mean differences in measurements within two degrees, similar to previous 3D-CT findings. These results can be largely attributed to the advantages of reconstructed 3D-CT images. One advantage is that 3D reconstruction can reduce the influence of the leg position and joint contracture during scanning or radiography; that is, the visualization and identification of anatomical landmarks can improve reliability regardless of the orientation of the patient's legs or the direction of the X-ray beam. Another advantage is that the coordinate systems can be set according to the mechanical axes. Using coordinate systems, alignment measurements in accurate coronal, sagittal, and axial planes for femoral and tibial mechanical axes can be accomplished. Detailed contour matching using femoral pegs or tibial keel wings with the aid of 3D-CT reconstruction can also lead to high reliability and low variability of measurements.

This study showed very good intra- and interobserver agreements for femoral–tibial varus–valgus, tibial slope, and femoral–tibial rotation measurements in 3D-CT reconstruction images, with systematic bias only in assessment of femoral flexion–extension. This may be due to blurring associated with the femoral component contour in the sagittal position in 3D-CT images. In the sagittal plane, the femoral component generates considerable halation that makes contour matching difficult, even in digital image processing. In contrast, the tibial component did not generate much halation at any position, which might be due to differences in the component shapes. The metal artifact level is also highly dependent on the material of the prosthesis [21], and ceramic or titanium TKA prostheses can reduce CT artifacts [22]. Additionally, several artifact reduction methods are available in modern CT systems [23], and these may provide a solution to the propensity for artifacts.

There are some differences between our study and the reports by Hirschmann et al. [18,20] that also examined the reliability of 3D-CT measurements. A strength of our study is the assessment of intra- and interobserver agreement, which was unclear in the previous reports. Another strength includes examination of the FTA as the leg-axis angle. Correct positioning of the TKA components with axial alignment of the limb and restoration of the mechanical axis are associated with a better outcome [24]; therefore, this is as important as the positions of individual components. Our results showed excellent intra- and interobserver ICCs (0.99–1.00) and mean differences (0.02–0.11°), and good agreement in measurements for FTA. This indicates that 3D-CT measurement of the FTA is sufficiently reliable to evaluate the leg-axis angle, as well as the positions of the femoral and tibial components.

Table 2
Interobserver reliability of ZedKnee alignment measurements for femoral and tibial components and the femorotibial angle.

Component		Mean difference (range)	ICC (95% CI)	LOA
Femur	Coronal	0.22 (0.01–0.78)	0.98 (0.96–0.99)	−0.09 to 0.12
	Sagittal	0.97 (0.00–3.67)	0.94 (0.81–0.97)	−1.06 to −0.30
	Axial	0.57 (0.01–4.58)	0.87 (0.73–0.93)	−0.07 to 0.80
Tibia	Coronal	0.25 (0.00–0.72)	0.97 (0.93–0.98)	−0.12 to 0.11
	Sagittal	0.41 (0.02–1.98)	0.92 (0.84–0.96)	−0.14 to 0.28
	Axial	0.84 (0.03–4.38)	0.97 (0.94–0.99)	−0.38 to 0.58
Femorotibial angle		0.08 (0.00–1.35)	0.99 (0.98–1.00)	−0.14 to 0.05

CI, confidence interval; ICC, intra-class correlation coefficient; LOA, limits of agreement.

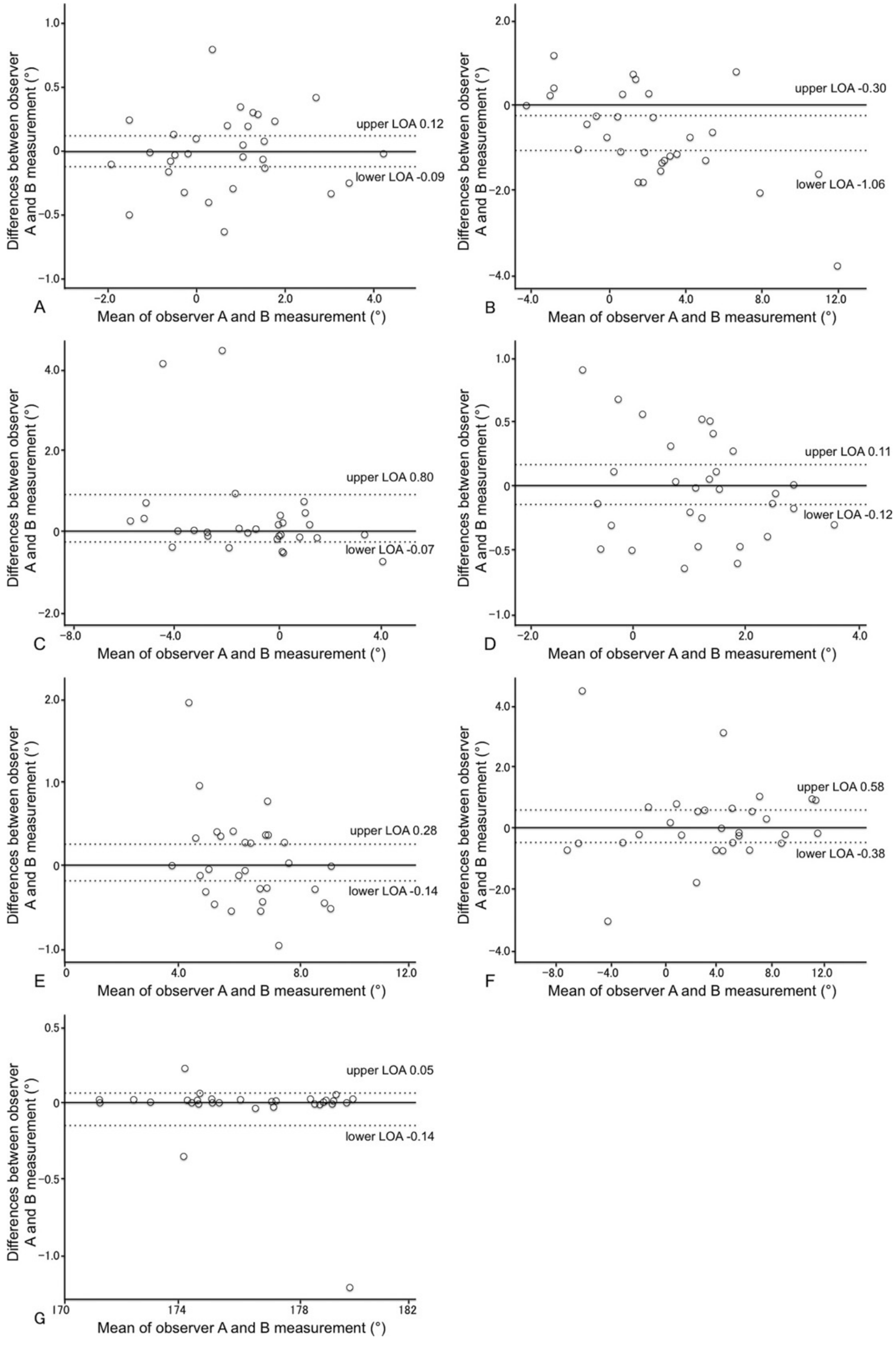

Figure 5. Bland–Altman plots for alignment measurements made by observers A and B to examine interobserver agreement: (a) femoral coronal, (b) femoral sagittal, (c) femoral axial, (d) tibial coronal, (e) tibial sagittal, (f) tibial axial, (g) femorotibial angle. The limits of agreement (LOAs) are represented by the dotted line. The upper and lower LOAs for the femoral sagittal position were −0.30 and −1.06, respectively; that is, the LOA range did not include zero.

Studies of the association of the alignment of TKA components with clinical outcomes such as longevity and patient satisfaction require accuracy of the position evaluation method because this could influence the reliability of the results. Ueyama et al. [25] found poor agreement between plain or fluoroscopically guided radiographs and 3D-CT measurements in identification of outliers of >3° in the femoral sagittal and tibial coronal and sagittal planes. Thus, previous reports using radiographic measurements may have misidentified alignment outliers and resulted in erroneous conclusions, suggesting that 3D measurements for prosthetic alignment are desirable [25]. Our study showed that 3D-CT measurements had high accuracy (within two degrees for all alignments, 0.2° for FTA), high validity (ICC >0.8), and no systemic bias, except for the femoral sagittal position. These findings suggest that 3D-CT measurements of the position of TKA components can be used to evaluate the alignment of TKA components and the leg-axis angle, with caution regarding the sagittal position of the femur. Therefore, we recommend use of 3D-CT measurements in analysis of alignments and postoperative outcomes to reduce measurement errors.

This study had several limitations. First, we evaluated the reliability of only one type of TKA implant and did not investigate others. Contour differences of components may influence the accuracy and reproducibility of manual superimposition of component templates. Second, we did not investigate differences among three or more observers because the number of observers was set to two to assess intra- and interobserver agreements using the Bland–Altman method. Third, there was some inequality of gender and limited diseases in the cohort. Fourth, we did not have a comparison group in which radiographs or 2D-CT evaluations were used. Thus, we cannot state that 3D-CT measurements are superior in reliability to these 2D measurements. However, a previous study showed higher reliabilities of 3D-CT compared with these methods [18]. In addition, TKA using ZedKnee software was used for preoperative 3D planning in all cases, and evaluation after TKA was performed routinely using a special function of this software; therefore, evaluations using plain radiographs or 2D CT were not conducted.

5. Conclusion

Three-dimensional-CT measurements of component positions after TKA showed sufficient intra- and interobserver reliability. Agreements for measurements of component positions were favorable in all alignments except for the femoral sagittal position. These results show that 3D-CT images can be used to investigate the association of alignment of TKA components with clinical outcomes such as longevity and patient satisfaction, with the possible exception of the sagittal position of the femur.

Author contributions

K.Y. collected and analyzed data, and drafted the manuscript. S.H. and J.N. helped to draft and proofread the manuscript. T.T. conceived the study, collected data, confirmed the data analysis, and proofed the manuscript. Y.T. assisted in drafting and proofing of the manuscript. S.O. revised and approved the final version of the manuscript.

Declaration of Competing Interest

None. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Acknowledgments

We are grateful to Dr. Yohei Kawasaki, Associate Professor of Biostatistics, Clinical Research Center, Chiba University Hospital, Chiba, Japan, for advice on statistical analysis. He is one of the statistists of our hospital, and advised us for free in this study.

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