

Interobserver and Intraobserver Repeatability and Reliability of Three-Dimensional Postoperative Evaluation Software in Total Hip Arthroplasty

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Research article

Keywords: Total hip arthroplasty, CT-based templating, Postoperative analysis, intra-class correlation coefficients, postoperative evaluation software

Posted Date: July 20th, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-42569/v1>

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Abstract

Background: We investigated the reliability of measurement of the alignment and position of the prosthetic components after total hip arthroplasty (THA) using three-dimensional computed tomography (CT)-based postoperative evaluation software.

Methods: We evaluated the postoperative CT data from 20 hips in 20 patients, using postoperative evaluation software. The alignment and three-dimensional positioning of the cup and stem were assessed by eight orthopedic surgeons for repeatability (intraobserver reliability) and reproducibility (interobserver reliability) of postoperative evaluation software using intra-class correlation coefficients (ICC). The radiographic inclination (RI) and radiographic anteversion (RA) of the cup, and anteversion, varus-valgus angle and flexion-extension angles of the stem were measured for alignment. The implant positioning was measured along three axes, X-axis (transverse), Y-axis (sagittal), and Z-axis (longitudinal).

Results: The intra- and inter-observer ICC of alignment measurement were very good for both cup and stem (0.86–1.00). The intra-observer and inter-observer ICC of cup positioning were very good in X-axis and Y-axis (0.91–0.94) and good in Z-axis (0.68–0.80). The intra-observer and inter-observer ICC of implant positioning were very good for the stem (0.98–0.99) for all axes.

Conclusion: CT-based postoperative evaluation software was able to evaluate the position of total hip implants with high reproducibility.

Background

In primary and revision total hip arthroplasty (THA), appropriate implant size and placement is important to prevent complications such as dislocation [1][2][3], wear of the polyethylene liner, and loosening of the components [4][5][6]. Lewinnek et al. proposed a “safe zone” of cup alignment, and Widmer et al. proposed an optimal combination of cup alignment and stem anteversion to minimize the risk of impingement [7]. To achieve precise implant placement, the use of a navigation system and a fluoroscopy-guided technique have been reported [8][9]. Currently, the gold standard for postoperative assessment of component orientation, inclination, anteversion of the acetabular component, and varus-valgus angle of the femoral component is conventional plain radiography [10][11][12]. While these measurement methods can evaluate implant alignment accurately, they are less reliable in assessing the components' exact size and position in the acetabulum and femur, [13] because it is difficult to assess three-dimensional (3D) implant alignment using a 2-dimensional (2D) plain radiograph or intraoperative measurement [1][4]. In the case of revision total hip arthroplasty with unknown implant size because of undergoing primary total hip arthroplasty at other hospitals, case urgency, patient migration, clerical error, or destruction of records, it would be very helpful to predict the implant size and alignment accurately[14]. A computed tomography (CT)-based method using low-dose digital stereo-radiography, commercialized as the EOS imaging system, has been reported to have good reliability [15][16][17].

Recently, a CT-based 3D preoperative planning and postoperative evaluation software, which can measure the alignment and 3D position of the implant has become available and has shown good reliability for preoperative planning [18][19]. In total knee arthroplasty good reliability has been reported regarding the femoral and tibial component positions and alignment [20]. The aim of this study was to evaluate the accuracy, intraobserver, and interobserver reliability of the CT-based postoperative evaluation software in THA.

Material And Methods

Study design

We performed a retrospective study using CT-based 3D preoperative planning and postoperative analysis software for THA. The study was approved by our hospital institutional review board and all patients gave written informed consent before any study-related procedures were performed.

Subjects

We selected perioperative CT data from 20 hips in 20 patients who underwent primary THA for osteoarthritis (OA) of the hip and osteonecrosis of the femoral head (ONFH). The operations were all carried out by the same senior surgeon (N.J.). All patients underwent a unilateral THA between March 2016 and December 2017. Fifteen right and five left hips in eight male and 12 female patients were included in this study. R3 cementless acetabular cup (Smith & Nephew, Memphis, TN), and Profemur Z cementless stem (Microport Orthopedics, Arlington, TN) were implanted in all cases. Exclusion criteria for this study were previous hip surgery including THA, osteotomy, and osteosynthesis, subluxation of Crowe type 2 or greater, and ankylosis. There were 15 hips with OA and 5 hips with ONFH each in stage 3B and stage 4 of the Japanese Ministry of Health, Labor and Welfare stage classification [21]. The mean age at postoperative CT scan, mean height, body weight, and body mass index are shown in Table 1. The shape of the femoral canal [22] was classified as champagne-flute (canal flare index [CFI] > 4.7) in 3 hips, normal ($3.0 \leq \text{CFI} \leq 4.7$) in 14 hips, and stovepipe ($\text{CFI} < 3.0$) in 3 hips.

Table 1
Demographics of all patients for postoperative analysis.

Characteristic (n = 20)	Mean (SD)
Age at CT [years]	64.8 (11.5)
Sex (Male), n	8
Weight [kg]	59.2 (12.6)
Height [m]	1.53 (11.5)
Body mass index [kg/m ²]	25.1 (4.2)
Diagnosis	Number (Rate)
Osteoarthritis	15 (75%)
Osteonecrosis	5 (25%)
Shape of the femoral canal	Number (Rate)
Champagne-flute (CFI ≥ 4.7)	3 (15%)
Normal (3.0 ≤ CFI ≤ 4.7)	14 (70%)
Stovepipe (CFI < 3.0)	3 (15%)
CFI, Canal Flare Index.	

Planning and analysis

Both preoperative and postoperative CT scans from the bilateral iliac wing to the tibial plateau were performed with a slice thickness of 1 mm using a helical CT scanner (Aquilion ONE; TOSHIBA Medical Systems Corporation, Tokyo, Japan). The CT data were transferred to ZedHip (Lexi Corporation, Tokyo, Japan). This preoperative planning software enables the surgeon to simulate placing the prosthetic components into their proper positions in the 3D space of the CT data using a computer-aided design model [18]. It is also possible to compare the postoperative component size and position with the position planned preoperatively. It determines the coordinates of the acetabular and femoral sides using skeletal reference points. Each coordinate was also adapted for postoperative implant positioning and alignment evaluation. The cup positioning and alignment were evaluated by a functional pelvic plane coordinate system (Fig. 1) and the stem was evaluated by the coordinate system recommended by the International Society of Biomechanics (ISB) (Fig. 2) [23][24]. Preoperative and postoperative coordinates were unified by an “image matching” system mounted on postoperative evaluation software. The “Image matching” system can automatically superimpose the preoperative and postoperative CT images (Fig. 3).

The following parameters regarding implant alignment and positioning were calculated automatically and component size was manually by postoperative evaluation software [1].

Component size accuracy

We investigated the concordance rates of each component (head, cup, and stem) between 3D CT-based postoperative templating and the actual implant used.

Alignment measurement

Radiographic inclination (RI) and radiographic anteversion (RA) were evaluated for the acetabular component alignment. RI is the angle between the acetabular axis and the Z-axis projected onto the XZ plane and RA is the angle between the acetabular axis and the Y-axis projected onto the XZ plane (Fig. 4).

Anteversion, varus-valgus angle, and flexion-extension angles were evaluated for the femoral component alignment. Anteversion is the angle between the posterior condylar line and the line from the center of the stem head to the stem axis. The varus-valgus angle is the angle between the proximal bone axis and the femoral component on the coronal plane. The flexion-extension angle is the angle between the proximal bone axis and the femoral component on the sagittal plane (Fig. 4).

Implant positioning

For the positioning of the acetabular and femoral components, the distance between the postoperative implant position and preoperative planned position was measured. 3D distance axes were defined according to each acetabular and femoral component coordinate systems; X-axis (transverse), Y-axis (sagittal) and Z-axis (longitudinal) (Figs. 1, 2).

Statistics

The statistical analysis was performed with JMP® 14 (SAS Institute Inc., Cary, NC, USA). To evaluate the component size accuracy, eight observers performed 3D CT-based postoperative templating without knowing the clinical information. The accuracy was measured with concordance rates of postoperative templating and the actual implant size within a range of ± 1 size. The repeatability (intraobserver reliability) and reproducibility (interobserver reliability) of postoperative evaluation software were calculated using intraclass correlation coefficients (ICC). The measurements were performed by three independent observers (A, B, and C) and two successive measurements were performed at 2-week intervals by the same observer (A) for the 20 patients. The intra- and interobserver differences of alignment measurements and implant position for acetabular and femoral components were calculated.

An ICC value of 1 was considered perfect reliability, 0.81–1 was very good, 0.61–0.80 was good, 0.41–0.60 was moderate, and < 0.40 indicated poor reliability[25] [26].

Results

Component size accuracy

Table 2 shows the concordance rates of each parts. The exact concordance rate of head, cup, and stem was 96.6% (309/320), 94.7% (303/320), and 97.8% (313/320), respectively. The concordance rates of postoperative templating within a range of ± 1 size was 100% in all component.

Table 2
Component size accuracy of templating

	-1 size	0 size	+1 size
Head	2 (0.6%)	309 (96.6)	9 (2.8)
Cup	0 (0%)	303 (94.7%)	17 (5.3%)
Stem	5 (1.6%)	313 (97.8%)	2 (0.6%)

Alignment measurement

Table 3 shows the intra- and interobserver ICC for alignment measurement. The intra-observer and inter-observer ICC were 0.972 and 0.970-0.982 in RA, respectively, and 0.955 and 0.892-0.965 in RI respectively, for the acetabular component. The intra-observer and inter-observer ICC were 0.993 and 0.999, respectively, in anteversion, 0.956 and 0.987-0.995, respectively, in varus-valgus angle, and 0.991 and 0.994-0.997, respectively, in flexion-extension angle for the femoral component.

Table 3
interobserver reproducibility for alignment measurement

		Average (SD)	Intra-observer Reliability (CI)	Inter-observer Reliability (CI)		
				A1-B	A1-C	B-C
Cup	RA	17.6 (4.3)	0.972 (0.933-0.989)	0.978 (0.943-0.991)	0.970 (0.915-0.989)	0.982 (0.955-0.993)
	RI	36.6 (3.8)	0.955 (0.893-0.982)	0.898 (0.765-0.958)	0.965 (0.913-0.986)	0.892 (0.753-0.956)
Stem	Anteversion	27.6 (13.1)	0.993 (0.984-0.997)	0.999 (0.998-0.999)	0.999 (0.997-1.000)	0.999(0.997-0.999)
	Varus-Valgus angle	1.2 (1.7)	0.956 (0.894-0.982)	0.987 (0.877-0.995)	0.991 (0.977-0.996)	0.995 (0.988-0.998)
	Flexion-Extension angle	1.8 (2.3)	0.991 (0.980-0.997)	0.994 (0.985-0.998)	0.995 (0.986-0.998)	0.997 (0.992-0.999)
SD, Standard deviation						
CI, 95% confidence intervals						
RA, Radiographic anteversion; RI, Radiographic inclination						

Implant positioning

Table 4 shows the intra- observer and inter-observer ICC for implant positioning. They were 0.992 and 0.948–0.989 in the X-axis (transverse), 0.992 and 0.853–0.987 in the Y-axis (sagittal), and 0.966 and 0.834–0.947 in the Z-axis (longitudinal), respectively, for the acetabular component. The intra-observer and inter-observer ICC were 0.976 and 0.977–0.987 in the X-axis (transverse), 0.993 and 0.992–0.995 in the Y-axis (sagittal), and 0.996 and 0.996–0.997 in the Z-axis (longitudinal), respectively, for the femoral component.

Table 4
Intra- and interobserver reproducibility for implant positioning

		Average (SD)	Intra-observer reliability (CI)	Inter-observer reliability (CI)		
				A1-B	A1-C	B-C
Cup	x (transverse)	0.8 (2.8)	0.992 (0.981- 0.997)	0.987 (0.965- 0.998)	0.989 (0.974- 0.996)	0.948 (0.875- 0.979)
	y (sagittal)	0.2 (2.5)	0.992 (0.979- 0.997)	0.987 (0.968- 0.995)	0.982 (0.952- 0.993)	0.853 (0.665- 0.939)
	z (longitudinal)	1.2 (2.0)	0.966 (0.917- 0.986)	0.947 (0.865- 0.979)	0.960 (0.900- 0.984)	0.834 (0.626- 0.931)
Stem	x (transverse)	0.9 (2.0)	0.976 (0.943- 0.991)	0.977 (0.938- 0.991)	0.978 (0.946- 0.991)	0.987 (0.965- 0.995)
	y (sagittal)	1.0 (2.8)	0.993 (0.983- 0.997)	0.993 (0.983- 0.997)	0.992 (0.981- 0.997)	0.995 (0.988- 0.998)
	z (longitudinal)	0.2 (5.1)	0.996 (0.990- 0.998)	0.996 (0.990- 0.998)	0.996 (0.990- 0.998)	0.997 (0.992- 0.999)
SD, Standard deviation						
CI, 95% confidence intervals						

Discussion

This study investigated the component size accuracy, and the intra- and inter-observer reliability of CT-based postoperative evaluation software in THA. The results showed that postoperative evaluation software can evaluate postoperative implant size and orientation with perfect to very good reliability.

The use of two-dimensional plain radiography has been standard for the evaluation of the acetabular component. Radiographic inclination is measured between the long axis of the implant and the tear-drop line. The ratio of the short axis and long axis of the implant is widely used for assessing the anteversion [12]. Some reports have suggested that the reliability of the acetabular component measurement on plain radiographs using a normal PACS system is high [26][27][28]. The EOS system is a novel imaging method using biplanar low-dose X-rays, which can evaluate implant alignment semiautomatically [16]. Lazennec et al. reported that the reliability of conventional acetabular component measurement on plain radiographs was lower than the performance of the EOS system [13]. However, the measurement of radiographic anteversion is a problem that is yet to be solved. In our study, we demonstrated very good reproducibility for radiographic anteversion. Since the pelvic coordinate axis is set after CT imaging and

is available as a reference, it is not affected by posture and limb position. We found a slight decrease in the reliability of inclination. With this system, the reference point for the distal implant edge can affect the inclination and positioning on the Z-axis. The relatively lower reliability of the inclination and Z-axis indicates that the reference point may vary.

Although many reports on the reliability of evaluation methods after THA have concerned acetabular components, there are a few reports on the femoral component [16][17][27]. Some studies focused on the stability of the component and the bone reaction of the femur [29], however, there have been no studies exploring the reliability of the femoral component varus-valgus and flexion-extension angles. The alignment of the femoral component is, however, thought to be important in preventing impingement and dislocation of the femoral head [30]. Lee YK et al. reported that the reliability of identifying stem anteversion by plain radiographs is high; intraobserver reliability was 0.944 and interobserver reliability 0.934 [31]. Another study using the EOS system reported intraobserver reliability of 0.998 and interobserver reliability of 0.997[17]. The reliability of femoral component anteversion in this study is equal to or better than other methods. In addition, with this method, the proximal bone axis and 3D coordinate system of the femur can be placed automatically from the CT image, so it is not affected by the orientation of the lower limbs.

The 3D position of each implant is thought to affect the biomechanics of the joint [32], the impingement of components, and leg length [33]. Therefore, the 3D position of each implant is also measured and installed by navigation [34]. Nonetheless, there are few reports on its positional evaluation method [35]. Leg length is measured from the transverse line and femoral offset is measured from the hip center on the X-ray. However, the sagittal positional shift (Y-axis, in this study) cannot be evaluated without a 3D approach. This method, therefore, can be useful in evaluating the leg length discrepancy or postoperative biomechanics of the hip joint.

This system allows us to simulate the range of motion and evaluate impingement after surgery. Precise evaluation of the implant position and alignment with residual osteophytes after surgery, identified by postoperative CT, can enable the assessment of the risk of dislocation due to impingement. It can also provide information that is useful for patient guidance. Another potential clinical advantage of this system is the long-term evaluation of implant stability since this method can evaluate implant alignment and position three-dimensionally; it would be possible to detect even slight loosening. In revision THA, knowledge of the diameter of the existing cup is very important. Knowledge of the correct size of acetabular cup can save time and decrease intraoperative complications by having the correct explant equipment size selected and available to the surgeon without delay.[36]

Our method has several limitations. First, our evaluation involved only one type of implant, and we do not know what the results of evaluation with other implants would show. Most acetabular components are spherical, therefore our results might be generalizable to other acetabular components. Second, the implant size was blinded. Knowing the size, however, might improve reliability because we could calibrate

for the implant size making it easier to determine the location of the implant edge. However, we believe that we performed this study under stricter conditions than most.

Conclusion

The CT-based postoperative evaluation software was able to evaluate the position of the implant with high reproducibility. It can, therefore, be a useful tool for evaluating the accuracy of implant size and placement after primary THA and before revision THA.

Abbreviations

THA: total hip arthroplasty; CT: computed tomography; ICC: intra-class correlation coefficients; RA: radiographic inclination; RA: radiographic anteversion; 3D:three-dimensional; 2D:2-dimensional (2D); OA: osteoarthritis; ONFH: osteonecrosis of the femoral head; CFI: Canal Flare Index; SD: Standard deviation; CI: 95% confidence intervals

Declarations

Acknowledgements

Not applicable.

Authors' contribution

Conception and design: All authors

Analysis and interpretation of the data: All authors

Drafting of the article: All authors

Critical revision of the article for important intellectual content: SH, AY, and HY

Final approval of the article: All authors

Provision of study materials or patients: AY, MS, and HY

Administrative, technical, or logistic support: SH, ST, YK, TN, and HY

Collection and assembly of data: SH, AY, and MYFunding

Funding

Junichi Nakamura, M.D. has been supported by JSPS KAKENHI grant number 17K10954, Takeda Science Foundation, the Japan Osteoporosis Foundation, the Futaba Foundation, and Novartis research grant.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on request.

Ethics approval and consent to participate

The research protocol of this prospective cohort study was in compliance with the Helsinki Declaration, approved by the Institutional Review Boards of Chiba University (reference number 2986), and written informed consent was obtained from all study participants

Consent for publication

Not applicable.

Competing interests

The authors have no conflict of interest to disclose.

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Figures

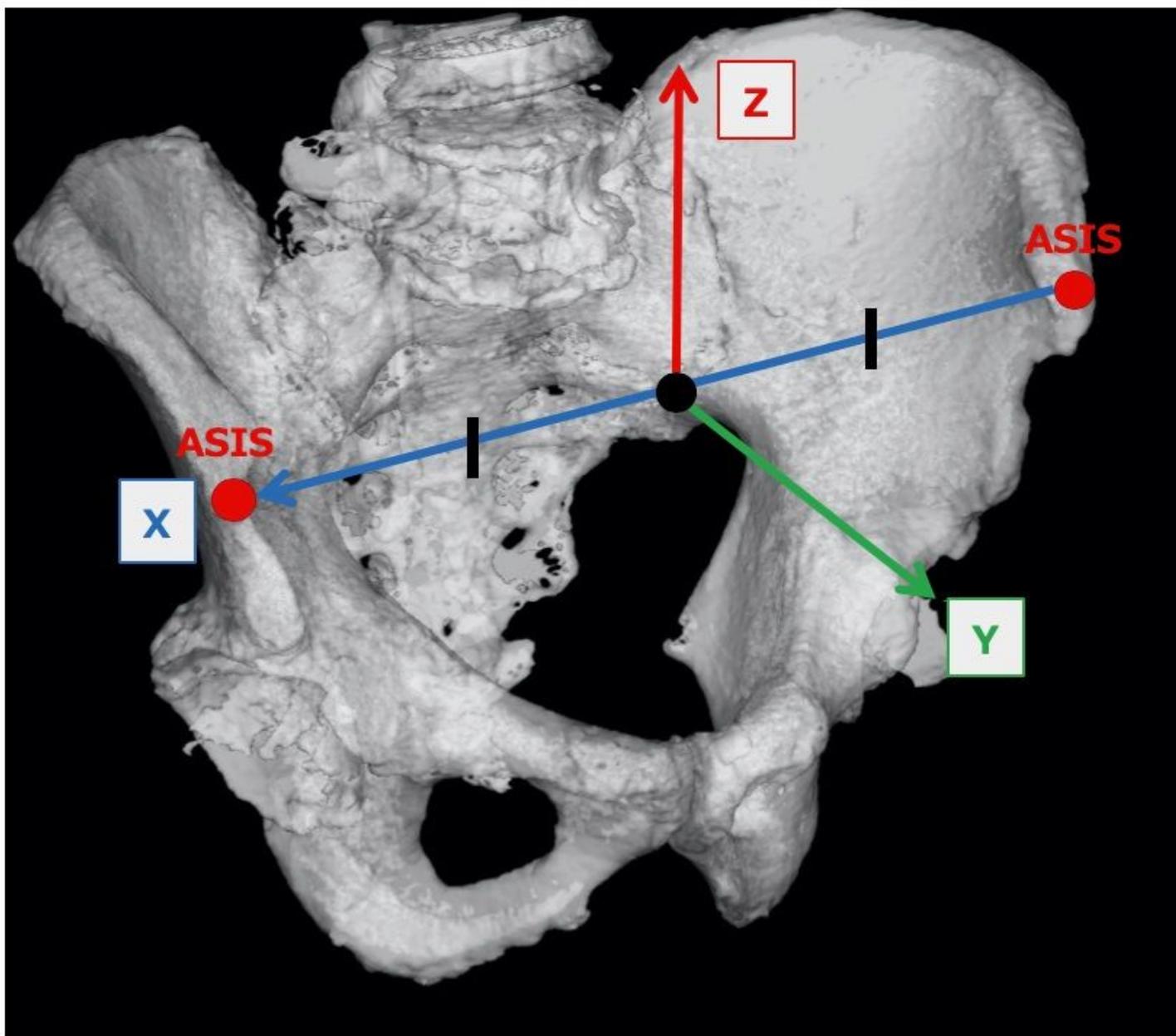


Figure 1

Functional pelvic plane coordinate system. The origin (white point) coincident with the middle point of the left and right anterior superior iliac spine (ASIS). X-axis: The line passing through the left and right ASIS. Positive direction from left to right of the pelvis. Y-axis: The line perpendicular to the X-axis and the CT coordinate system Z-axis and passing through the origin. Positive direction is from the posterior to the

anterior of the pelvis. Z-axis: A straight line perpendicular to the X and Y axes. Positive direction is from the inferior to the superior aspect of the pelvis.

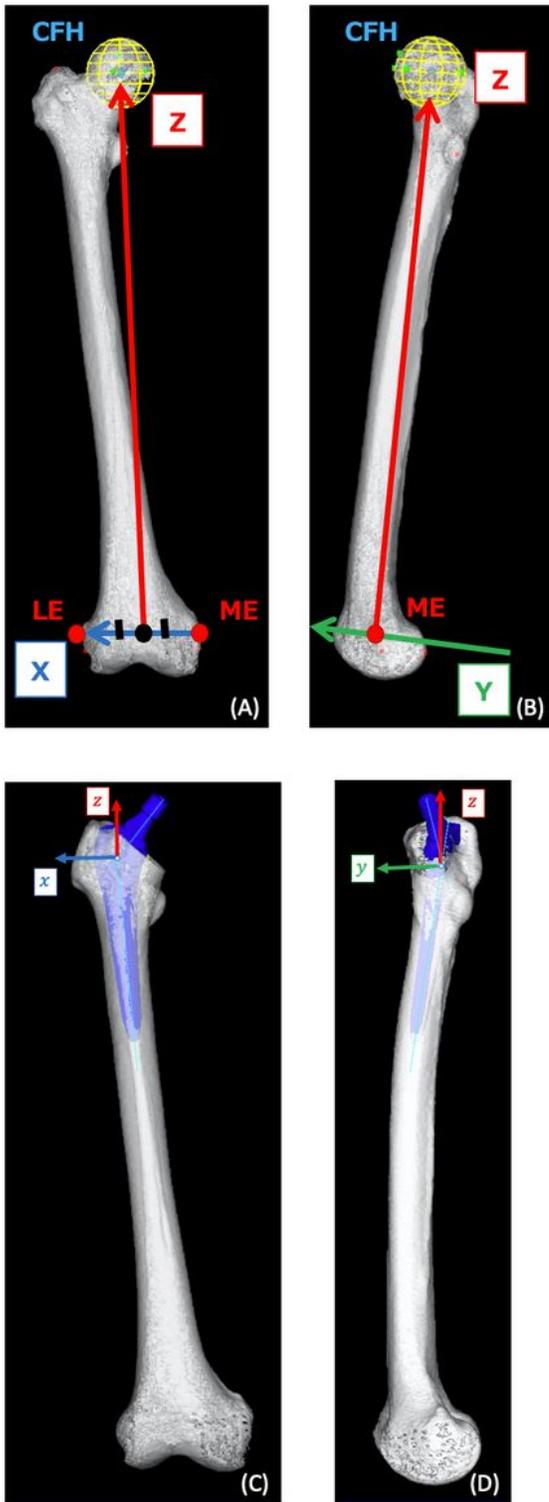


Figure 2

The coordinate system recommended by the International Society of Biomechanics (ISB): The origin (black point) coincident with the middle point of the medial femoral epicondyle (ME) and lateral femoral epicondyle (LE). Z-axis: The line connecting the center of the femoral head (CFH) and the origin. Positive

direction is from distal to proximal femur. X-axis: The line perpendicular to the Z-axis and passing through the origin on the plane created by the three points of CFH, ME and LE. Positive direction is from left to right of the body. Y-axis: The line perpendicular to the Z and X axes and passing through the origin. Positive direction is from the posterior to the anterior of the body.

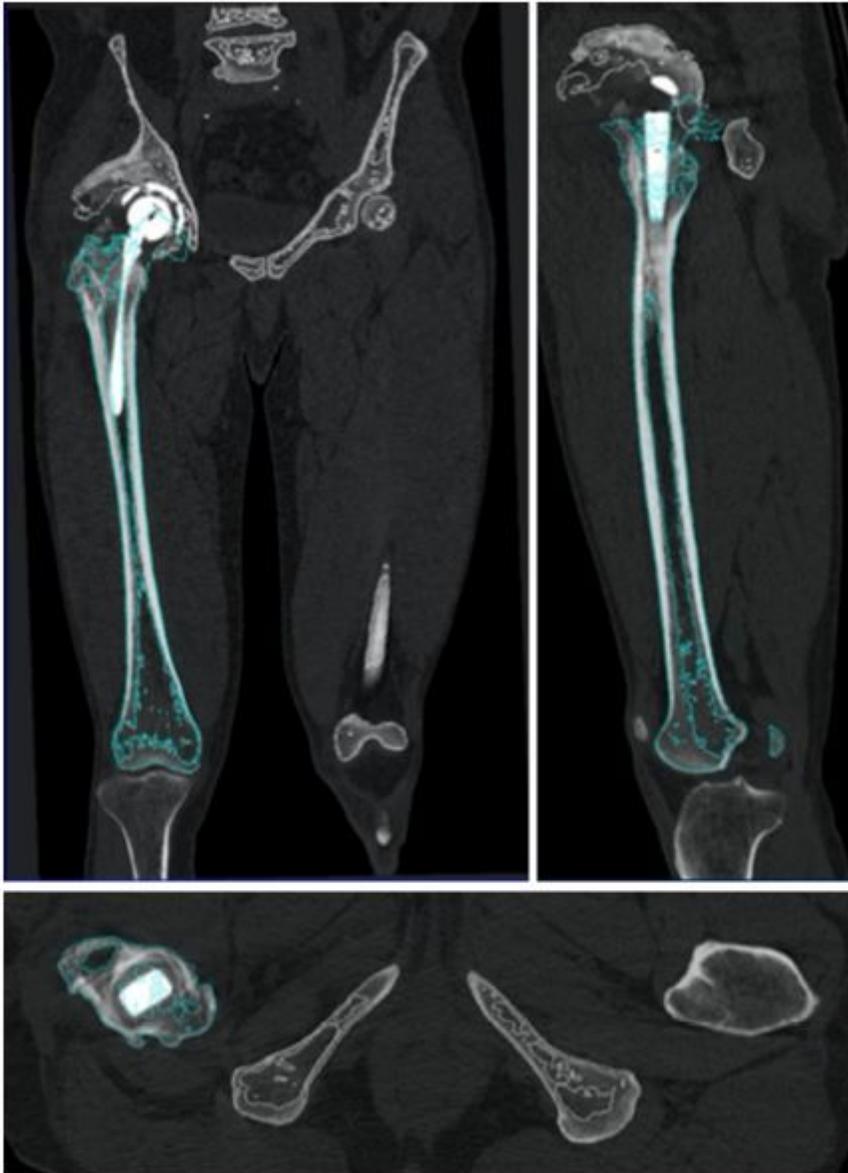


Figure 3

Image matching of the pre- and postoperative CT images. Preoperative CT images were fused to the postoperative images automatically as bone surfaces matched. Blueline presents the bone 3D image of the preoperative femur and the white line presents the bone 3D image of the preoperative pelvis.

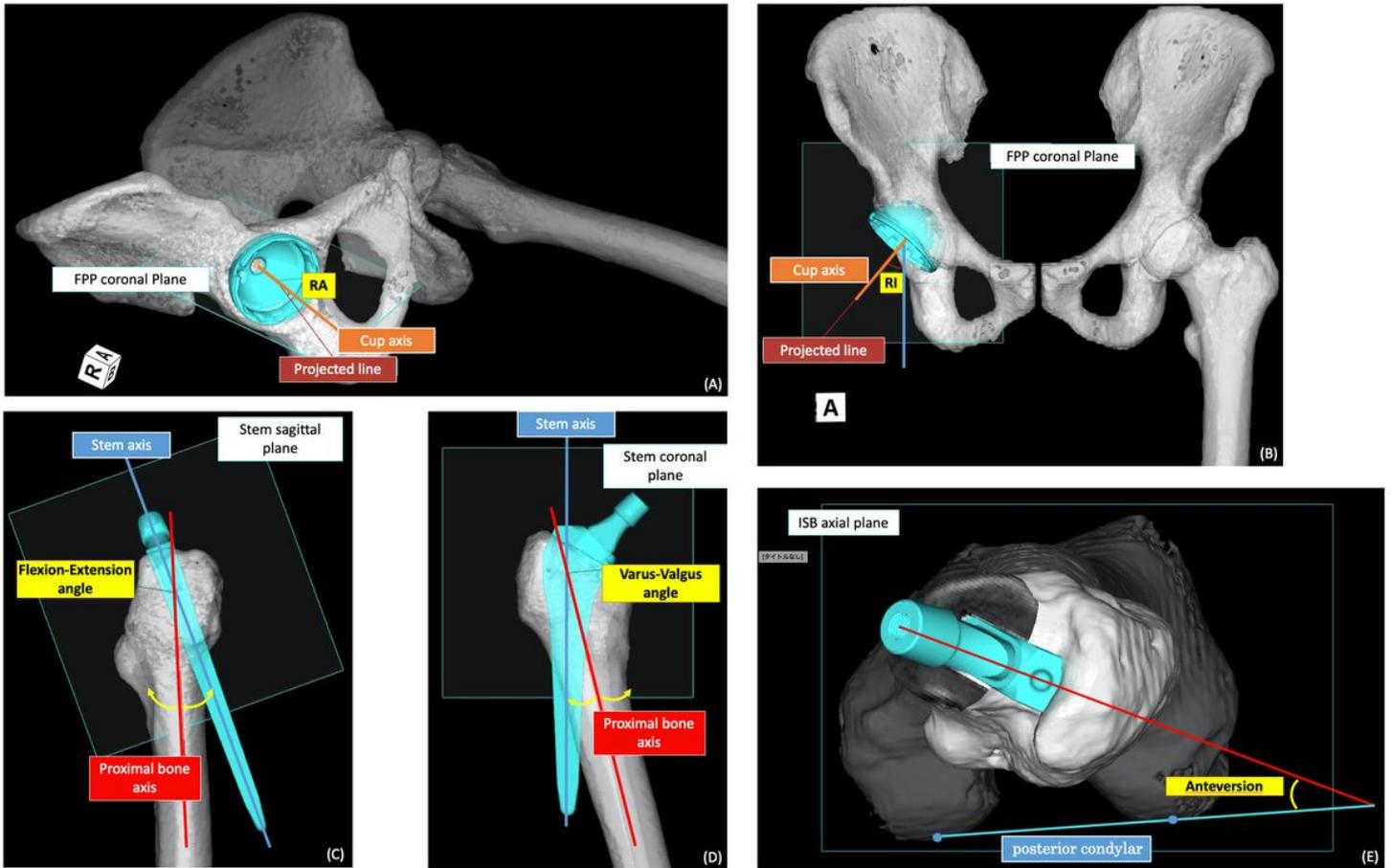


Figure 4

Alignment of components. The radiographic inclination (RI) is the angle between the acetabular axis and the Z-axis projected on the XZ plane (A) and radiographic anteversion (RA) is the angle between the acetabular axis and the Y-axis projected onto the XZ plane (B). The flexion-extension angle is the angle between the stem axis and proximal bone axis on the stem sagittal plane (C). The varus-valgus angle is the angle between the stem axis and proximal bone axis on the stem coronal plane (D). Anteversion is the angle between the posterior condylar line and a line from the center of the stem head to the stem axis on the International Society of Biomechanics (ISB) axial plane (E).