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A simple method for accurate rotational positioning of the femoral component in total knee arthroplasty

A prospective study on 80 knees with 3 years' follow-up with CT scans and functional outcome

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Background and purpose — There are many techniques for placing the femoral component in correct rotational alignment in total knee arthroplasty (TKA), but only a few have been tested against the supposed gold standard, rotation determined by postoperative computed tomography (CT). We evaluated the accuracy and variability of a new method, the clinical rotational axis (CRA) method, and assessed the association between the CRA and knee function.

Patients and methods — The CRA is a line derived from clinical judgement of information from the surgical transepicondylar axis, the anteroposterior axis, and the posterior condylar line. The CRA was used to guide the rotational positioning of the femoral component in 80 knees (46 female). At 3 years follow-up, the rotation of the femoral component was compared with the CT-derived surgical transepicondylar axis (CTsTEA) by 3 observers. Functional outcome was assessed with the Knee Injury and Osteoarthritis Outcome Score (KOOS), the Oxford Knee Score (OKS) and patient satisfaction (VAS).

Results — The mean (95% CI) rotational deviation of the femoral component from the CTsTEA was 0.2° (–0.15°–0.55°). The standard deviation (95% CI) was 1.58° (1.36°–1.85°) and the range was from 3.7° internal rotation to 3.7° external rotation. No statistically significant association was found between femoral component rotation and KOOS, OKS, or VAS.

Interpretation — The CRA method was found to be accurate with a low grade of variability.

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Rotational alignment of the femoral component in the axial plane affects knee kinematics, function and prosthetic survival after total knee arthroplasty (TKA) (Berger et al. 1998, Olcott et al. 1999, Barrack et al. 2001, Hanada et al. 2007, Romero et al. 2007, Victor 2009, Kim et al. 2014). Excessive internal rotation may lead to pain (Barrack et al. 2001, Bell et al. 2014), patella-femoral instability (Berger et al. 1998), failure of the patellar component (Berger et al. 1998), tibio-femoral instability in flexion (Romero et al. 2007) and valgus malalignment in flexion (Hanada et al. 2007). Excessive external rotation may cause laxity in flexion (Olcott et al. 1999) and varus malalignment in flexion (Hanada et al. 2007).

2 principles for placing the femoral component in correct rotation exist, the gap-balancing technique and the measured resection technique (Vail et al. 2012). In the pure gap-balancing technique, femoral rotation is determined by the soft tissue tension in the flexed knee. If the soft tissues are contracted malrotation can occur (Lee et al. 2011). In the measured resection technique, femoral component rotation is based on anatomical bony landmarks. These landmarks may be difficult to localize during surgery. Current surgical techniques are often hybrids taking advances from both principles, thus both principles depend more or less on bony landmarks (Vail et al. 2012).

The CT derived surgical transepicondylar axis (CTsTEA) is considered the gold standard for rotational alignment (Asano et al. 2005, Victor et al. 2009, Seo et al. 2012, Talbot et al. 2015). This axis can be drawn on axial CT scans, but is not visible intraoperatively. Therefore, several surrogate axis or anatomical lines have been suggested to help navigate the femoral component into correct rotational alignment during surgery. However, these axes depend on anatomical landmarks that might be hard to define precisely intraoperatively.

The most widely used surrogate axes (secondary reference axes) are the posterior condylar line (PCL) (Laskin 1995), the surgical transepicondylar axis (sTEA) (Berger et al. 1993) and the antero-posterior axis (APA) (Whiteside's line) (Whiteside

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Table 1. Patient characteristics and preoperative coronal plane alignment (n = 80)

	Group 1 (n = 29)	Group 2 (n = 51)	p-value	Group 3 (n = 39)	Group 4 (n = 41)	p-value
Mean age (range)	69 (48–79)	69 (42–81)	0.9 [a]	70 (42–81)	69 (49–81)	0.6 [a]
Number of women	18	28	0.6 [b]	23	23	0.8 [b]
Mean BMI (range)	28 (20–36)	29 (23–43)	0.3 [a]	30 (20–43)	28 (22–34)	0.2 [a]
Preoperative coronal alignment						
Varus, number of knees	21	44	0.1 [b]	32	33	1.0 [b]
mean deformity (range)	9° (4°–22°)	10° (1°–21°)	0.8 [a]	10° (3°–22°)	9° (1°–21°)	0.3 [a]
Valgus, number of knees	8	6	0.1 [b]	7	7	1.0 [b]
mean deformity (range)	6° (2°–13°)	7° (2°–13°)	0.4 [a]	7° (3°–13°)	5° (2°–11°)	0.2 [a]
Neutral, number of knees	0	1		0	1	
mean deformity (range)	–	0		–	0	
Number of knees with patella resurfacing	17	23	0.4 [b]	22	18	0.4 [b]

First, knees were split into 2 groups: Group 1, internally rotated femoral components and Group 2, neutral and externally rotated femoral components. Thereafter, knees were split into two new groups: Group 3, knees with ≥ 1° malrotation of the femoral component in any direction and Group 4, knees with < 1° malrotation of the femoral component in any direction.
[a] Independent samples t-test. [b] Fisher's exact test.

and Arima 1995). The PCL is easy to define and normally it is internally rotated 3–4 degrees relative to the sTEA, but in in knees with deformity due to osteoarthritis or condylar dysplasia there might be substantial variations. The sTEA is considered a good reference for femoral component rotation, but it may be difficult to define in the surgical field. Kinzel et al. (2005) reported that the epicondyles were correctly identified in only 75% of the knees, with a wide range of malrotation from 6 degrees of external rotation to 11 degrees of internal rotation. The APA is also a widely used landmark to determine rotation, but this line too can be hard to draw correctly. Yau et al. (2007) found a wide range of error from 15 degrees of external rotation to 17 degrees of internal rotation.

More recently new and more reliable surrogate axes have been described (Victor et al. 2009, Talbot et al. 2015), and some studies combine information from 2 or more axes (Siston et al. 2008, Inui et al. 2013, Paternostre et al. 2014). Additionally, some techniques add information from preoperative CT scans or conventional radiographs (Luyckx et al. 2012, Seo et al. 2012, Inui et al. 2013), and some require special alignment jigs, computer navigation or patient-specific instruments (Seo et al. 2012, Inui et al. 2013, Parratte et al. 2013).

Postoperative CT scan is the only widely accepted method to determine both the ideal and the actual rotational alignment of the femoral component (Berger et al. 1998, Olcott et al. 1999, Asano et al. 2005, Oussedik et al. 2012, Talbot et al. 2015).

In this prospective cohort study, the rotation of the femoral component was determined intraoperatively with the clinical rotational axis (CRA) method. The CRA is established by clinical judgement of information from three surrogate axes: the sTEA, the APA and the PCL. Our aim was twofold: first, to evaluate the accuracy of the CRA method; second, to investigate the association between femoral component rotation and functional outcome 3 years after the operation.

Patients and method

All patients were consecutively recruited from another ongoing prospective, randomized and double-blind study comparing TKA with and without patellar resurfacing (Aunan et al. 2016). The patients were operated between January 2009 and June 2011. Inclusion criteria were patients less than 85 years old scheduled for TKA because of osteoarthritis. Exclusion criteria were knees with severe deformity not suitable for standard cruciate-retaining prosthesis, rheumatoid arthritis, and severe medical disability limiting the ability to walk or to fill out the patient-recorded outcome documents.

80 consecutive knees (46 female) were investigated at 3 years' follow-up. Mean age was 69 (42–81) years. Mean BMI was 29 (20–43). 65 knees had varus deformity ranging from 1° to 22°, 14 knees had valgus deformity from 2° to 13° and 1 knee was without deformity (Table 1).

Surgical technique

All knees were operated through a standard midline incision and a medial parapatellar arthrotomy, using a posterior cruciate-retaining prosthesis (NexGen, Zimmer, Warsaw, IN). We used the measured resection technique, which involves resecting the amount of bone from the distal femur and the proximal tibia that will be replaced by the prosthetic components. The valgus angle of the femoral component was set at 5–8 degrees, depending on the hip–knee–femoral shaft angle (HKFS) as measured on preoperative standing hip–knee–ankle (HKA) radiographs. To assure conformity in surgical technique the first author (EA) was either operating or assisting in every operation.

Description of the CRA method

Rotation of the femoral component was established by combining information from the PCL, the sTEA and the

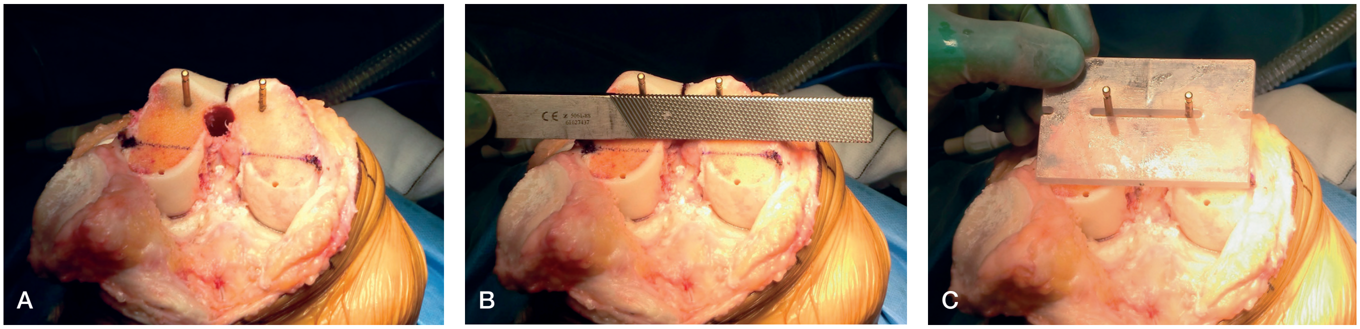

Figure 1. A. Before the distal resection of the femur the sTEA was established by marking the most prominent point of the lateral epicondyle and the sulcus on the medial epicondyle with cautery. Thereafter, the APA was marked from the highest point in the intercondylar notch to the deepest point of the trochlea. Then, after distal femoral resection, a line 3° externally rotated compared with the PCL was marked with two pins on the distal femoral cut.
B. The parallelism between the sTEA and the PCL+3° was judged with a ruler.
C. The orthogonality between the sTEA and the APA and between the PCL+3° and the APA was judged with a transparent angle-measuring device.

APA. First, the sTEA was established by marking the most prominent point of the lateral epicondyle and the sulcus on the medial epicondyle with cautery. Second, the APA was marked from the highest point in the intercondylar notch to the deepest point of the trochlea. Third, after distal femoral resection, a line 3° externally rotated compared with the PCL was marked with 2 pins on the distal femoral cut. Theoretically, the sTEA and the PCL+3° should now be parallel, and these 2 lines should be at a 90° angle to the APA. The parallelism between the sTEA and the PCL+3° was judged with a ruler, and the orthogonality between these 2 lines and the APA was judged with a transparent angle-measuring device (Figure 1). In the cases where perfect correlation between the lines was achieved (parallelism between the PCL+3° and the sTEA, and orthogonality (90° angle) between these 2 lines and the APA) the rotation was accepted. If there was agreement between 2 of the lines, these were accepted. If disagreement between all three lines occurred, the in-between line was selected. In the case of visible bony attrition (International Cartilage and Repair Society (ICRS) grade 4) on 1 or both posterior condyles, the PCL was excluded from the work-up. The PCL was also excluded in cases with posterior lateral condylar dysplasia. Dysplasia was suspected in knees with distal femoral valgus deformity on HKA radiographs and no noticeable valgus deformity on the tibial side. If, during the operation, a visible valgus deformity in 90° of flexion was present, the posterior lateral condyle was considered dysplastic. In the cases were 2 lines remained and were not parallel, the average angle between these 2 lines was preferred.

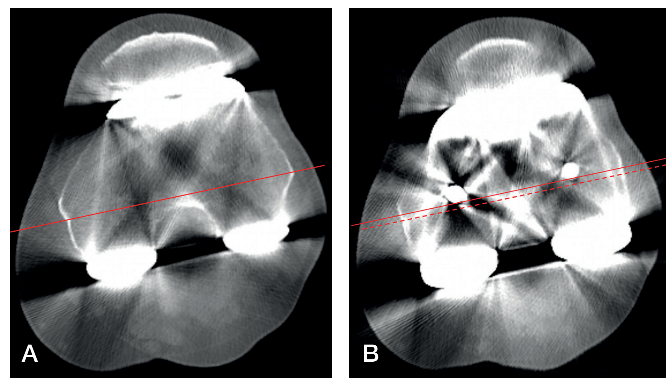

Figure 2. A. The CT-derived surgical transepicondylar axis (CTsTEA) is the line drawn from the most prominent part of the lateral epicondyle to the sulcus in the medial epicondyle.
B. Femoral component rotation is defined by the femoral component rotational axis (FCRA), the common tangent of the 2 pegs on the inside of the femoral component (continuous red line). Then the CTsTEA (stippled red line) from Figure 2A was superimposed, and the femoral component rotational angle (FCR angle) was measured. In this case the angle was 0°.

Outcome measures

At 3 years' follow-up 80 knees were examined with CT for rotational alignment of the femoral prosthetic components. Scans were performed using the Philips Ingenuity 128-row multidetector scanner (Philips Healthcare, Andover, MA) with our standard knee protocol (140 kV, 150 mAs; rotation time 0.5 s, pitch 0.485/0.391; slice thickness 0.9 mm, interval 0.45 mm). The imaging material was evaluated using the Philips Intellispace system (Philips Healthcare, Andover, MA) and measurements were done as described by Berger et al. (1998). Standard radiographic evaluation with antero-posterior, hip–knee–ankle (HKA), sagittal and patella-axial radiographs was also performed. All patients were clinically evaluated with the Knee Injury and Osteoarthritis Outcome Score (KOOS) (Roos et al. 1998, 2003), the Oxford Knee Score (OKS) (Dawson et al. 1998) and patient satisfaction (visual analogue scale (VAS)) at the 3-year follow-up.

The CT scans were evaluated independently by 3 observers: 1 radiologist (DØ) and 2 experienced orthopedic surgeons (EA and AM). First the CTsTEA was defined by drawing a line from the lateral epicondyle to the sulcus in the medial epicondyle. Second, the femoral component rotational axis (FCRA) was defined by drawing the common tangent of the

2 pegs on the inside of the femoral component (Figure 2). Finally, the angle between these two lines, called the femoral component rotational angle (FCR angle), was measured. No corrections or eliminations of outliers were performed. Inter-rater reliability for the measurements performed by the 3 observers was estimated and accuracy and precision of the CRA method was calculated.

The effect of femoral component rotation on functional outcome was assessed in 2 ways: initially by comparing KOOS, OKS, and patient satisfaction 3 years after the operation between internally rotated knees (group 1), and neutral and externally rotated knees (group 2). Thereafter, the knees were split into 2 new groups: knees with any degree of malrotation of the femoral component (group 3) and knees with perfectly rotated (< 1°) femoral components (group 4).

Statistics

Inter-rater reliability for the measurements was estimated with intra-class correlation coefficient (ICC), 2-way mixed models, and absolute agreement. ICC (95% CI) for inter-rater reliability was 0.62 (0.51–0.72) for single measurements and 0.83 (0.76–0.89) for average measurements. Accuracy of the CRA method was expressed as the mean FCR angle and its 95% confidence interval (CI). The variability was expressed as the standard deviation (SD) and range of the FCR angle. Finally, the 95% CI of the SD was calculated. Negative values were given for internal rotation of the femoral component and positive values for external rotation.

The effect of femoral component rotation on functional outcome between groups 1 and 2 and between groups 3 and 4 was tested with the independent samples t-test or Fisher's exact test. The length of the 95% CI of the FCR angle was used as an indicator of sample size adequacy (Machin et al. 2009). Statistical significance was defined as p-values below 0,05. Statistical analyses were performed with IBM SPSS® 22 software (IBM, Chicago, IL, USA).

Ethics, funding, and potential conflicts of interest

The protocol was approved by the regional committee of research ethics (2010/ 1678 D 33-07172b 1.2007.952 with changes 05.03.2012) and before enrolment all patients signed an informed-consent form. The study was funded by the Sykehuset Innlandet Hospital trust and the authors have no competing interests to declare.

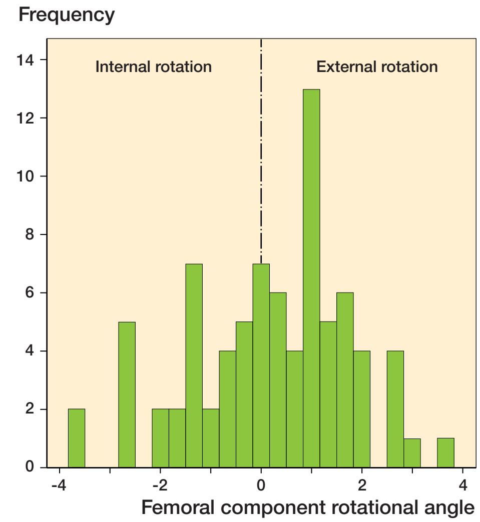

Figure 3. The femoral component rotational angle (FCR angle) relative to the CT-derived surgical transepicondylar axis (CTsTEA) in 80 knees.

Results

Patient characteristics and preoperative coronal plane alignment are given in Table 1. The mean (95% CI) FCR angle was 0.2° (–0.15°–0.55°). The standard deviation was 1.58° and the 95% CI of the SD was 1.36°–1.85°. Maximum and minimum values were 3.7° external rotation and 3.7° internal rotation. The distribution of the FCR angles for all knees is presented in Figure 3.

No statistically significant difference was found between group 1 and group 2, or between group 3 and group 4 in KOOS, OKS, or patient satisfaction (VAS) at follow-up 3 years after the operation (Table 2).

Table 2. Comparison of functional outcome measures at 3 years' follow-up between groups

	Group 1 (n = 29)	Group 2 (n = 51)	p-value [a]	Group 3 (n = 39)	Group 4 (n = 41)	p-value [a]
KOOS						
Pain	89 (58–100)	94 (33–100)	0.3	94 (33–100)	94 (39–100)	0.8
Symptoms	89 (64–100)	93 (32–100)	0.9	93 (54–100)	89 (32–100)	0.2
ADL	97 (53–100)	93 (31–100)	0.5	97 (53–100)	91 (31–100)	0.1
Sport/recreation	70 (0–100)	70 (5–100)	1.0	70 (5–100)	65 (0–100)	0.4
QOL	88 (31–100)	94 (19–100)	0.05	88 (31–100)	94 (19–100)	1.0
OKS	16 (12–37)	15 (12–43)	0.2	16 (12–37)	15 (12–43)	0.9
Patient satisfaction [b]	96 (70–100)	99 (10–100)	0.3	99 (41–100)	98 (10–100)	0.7

For Groups, see Table 1
KOOS: Knee Injury and Osteoarthritis Outcome Score (0–100); the best score is 100. ADL activities of daily living. QOL knee-related quality of life.
OKS: Oxford Knee Score (48–12); the best score is12.
[a] Mann–Whitney U test. [b] VAS scale (0–100); the best score is 100.

Table 3. Data from the present and previous studies that compare the rotational alignment of the femoral component with the gold standard (CTsTEA)

Author	Method	Number of knees	Rotational alignment [a] mean	SD (range)	Number of measurements [b]	Comments
The present study	The clinical rotational axes method (CRA method)	80	0.2°	1.6° (–3.7°–3.7°)	3	
Talbot et al. 2015	Sulcus line	181	0.6°	2.9° (–7.2°–6.7°)	2	28 knees excluded due to poor CT scans, and 19 excluded due to unidentified sulcus line.
Inui et al. 2013	Transepicondylar axis, Whiteside axis and the condylar twist angle	26	0.3°	1.7° (–3°– 3°)	2	Preoperative radiographs in 90° knee flexion. Computer navigation
Luyckx et al. 2012	Gap technique	48	2.4	2.5° (–2.8°–6.9°)	6 [c]	Gap technique
Luyckx et al. 2012	PCL adapted to preop. CT	48	1.7°	2.1° (–2.5°–6.5°)	6 [c]	Preoperative CT of the knee
Seo et al. 2012	Mechanical axis-derived rotational axis	120	1.6°	2.2° (–4.8°–7.9°)	3	Preoperative radiographs of both hips. Customized graduated ruler and extramedullary alignment jig

[a] Positive values represent external rotation and negative values represent internal rotation.
[b] The number of measurements and observers may influence the values for rotational alignment. See text for further information.
[c] 3 observers, 2 measurements each
PCL = posterior condylar line.

Discussion

The CRA method generated results very close to the gold standard with a low grade of scatter. The fact that no statistically significant association was found between the degree of malrotation and functional outcome indicate that the CRA method is a safe method for intraoperative estimation of femoral component rotation. However, because only 3 knees were malrotated more than 3° and only 13 knees more than 2°, the effect of more than 2° malrotation cannot be judged in this study.

The length of the 95% CI of the FCR angle was only 0.7°, indicating that the sample size of our study is adequate (Machin et al. 2009).

The CTsTEA is widely accepted as the gold standard for rotational alignment of the femoral component. Many studies have investigated different anatomical rotational axes, but as long as they do not refer to postoperative CT scans and the CTsTEA the results are hard to interpret. Table 3 presents data from the present and earlier studies that compared femoral component rotation with the CTsTEA. Talbot et al. (2015) described a new surrogate axis called the sulcus line by marking the deepest part of the trochlear groove with multiple diathermy points from the anterior edge of the intercondylar notch to the proximal trochlear groove. In another study, Inui et al. (2013) determined the rotational alignment of the femoral component by combining information from the computer navigation system and preoperative radiographs in 90° of knee flexion. This method has much in common with our method: both methods combine information from the sTEA, the APA and the PCL, and both methods accept that the PCL differs, to some degree predictably, with varus and valgus deformities. The main difference between the methods is that in our method the determination of the PCL is done by clinical judgement intraoperatively and does not depend on computer navigation and preoperative radiographs at 90° knee flexion. Luyckx et al. (2012) compared the classical gap technique and the so-called adapted measured resection technique in which the native rotation of the distal femur measured on preoperative CT scans was taken into account. They did not find a statistical significant difference between the 2 methods. Seo et al. (2012) defined the "the mechanical axes derived rotational axis" with a combination of preoperative radiographs of the pelvis to determine surface landmarks and an extramedullary alignment jig. They found that "the mechanical axes derived rotational axis" was on average 1.6° externally rotated compared with the sTEA. They also concluded that the method was relatively time-consuming and complicated.

When comparing data in Table 3 it is important to bear in mind that the number of measurements performed at each CT scan may affect the level of accuracy and precision. Averaging data from 2 or more measurements may result in mean values closer to the truth, but the ranges and the standard deviations (SD) will tend to decrease. In our study we used 3 observers, so for completeness and in order to make the data of our study easier to interpret we also calculated mean values, ranges, and SDs for all 3 combinations of 2 observers: Mean values: 0.1°, 0.5°, and 0.2°. Ranges: –4°–3°, –4°–4°, and –4°–4°. Standard deviations: 1.7°, 1.7°, and 1.6°. Therefore, in our study the effect of 3 versus 2 observers did not seem to affect the results to an important degree.

In a recent review article, Valkering et al. (2015) performed a correlation analysis based on 490 patients. They found a large positive correlation between femoral component external rotation and better functional outcome. In contrast, we did not find any statistically significant effect of femoral component malrotation on the outcome measures. The reason for this may be the very few and small deviations in rotation found in our study (maximum ± 3.7°).

Our study has some limitations. First, the reliability of Berger's method for measuring femoral component rotation on postoperative CT scans is not perfect (Luyckx et al. 2012, Inui et al. 2013). The ICC values vary considerably between studies depending on whether data are given for single measurements or average measurements, and on which statistical model was chosen. This information is missing in many studies, making comparison between studies difficult. In our study, we have specified ICC values for the most conservative options. Second, due to the low number of malrotated femoral components we cannot estimate the effect of malrotation above 2° on functional outcome. Third, half of the knees had the patella resurfaced. Therefore, patella resurfacing is a potential effect modifier (interaction). Stratifying the material on patellar resurfacing revealed a trend in disfavor of internally rotated femoral components in the group without patellar resurfacing. However, multiple testing without correction were performed and the numbers were small; 12 femoral components were internally rotated and 28 were neutral or externally rotated. Finally, we used a tibial platform with fixed bearing and minimal constraint. Our results on functional outcome may not be valid for prostheses with mobile platforms and/or more constraint.

The validity of our study is strengthened by the fact that no knees were excluded and no corrections or exclusions were done because of outliers or disagreement between observers.

A major advance of the CRA method is its simplicity. There is no need for additional preoperative radiographs or CT imaging and no need for computer navigation. Likewise, customized equipment or alignment jigs are not required.

In summary, the CRA method for rotational alignment of the femoral component in TKA appears to be simple, safe, accurate, and precise.

EA: Conception, design, data collection, statistical analysis, interpretation and writing of the manuscript. DØ, AM and KD: Data collection. LS: Statistical analysis. All the authors took part in revision of the manuscript.

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