Rotational component alignment in patient-specific total knee arthroplasty compared with conventional cutting instrument

Nuttawut Chanalithichai[1] · Nattapol Tammachote[1] · Chane Jitapunkul[1] · Supakit Kanitnate[1]

Abstract

Background Although many studies investigated the accuracy of customized cutting block (CCB), the data on rotational alignment are still lacking. The study aimed to assess whether CCB improved the component rotational position compared with conventional cutting instrument (CCI) using computed tomography scanning.

Methods Eighty-six of 102 total knee arthroplasties from the previous randomized study were analyzed. The outcomes were rotational position of the femoral and tibial components, frequency of outliers and intra-class correlation coefficient.

Results The mean femoral component rotation was not different between CCB versus CCI: $0.9° \pm 0.8°$ versus $1.1° \pm 1.1°$ ($P = 0.29$). Both groups had similar outlier frequencies: 2% (CCB) versus 2% (CCI) ($P = 0.74$). CCB had nearly 1° less mean tibial component deviation compared with CCI ($P < 0.001$): (1) dorsal tangent reference (DTR): $0.7° \pm 0.8°$ versus $1.5° \pm 1.0°$, and (2) tibial trans-epicondylar reference (TTR): $0.5° \pm 0.9°$ versus $1.4° \pm 1.1°$. Outlier frequencies were similar: (1) DTR: 0% CCB versus 5% CCI ($P = 0.24$), and (2) TTR: 5% in CCB versus 12% CCI ($P = 0.20$). Measurements based on tibial tubercle showed that CCB had ~$1.4°$ less mean tibial component deviation compared with CCI: $0.3° \pm 1.4°$ versus $1.7° \pm 1.6°$ ($P < 0.001$) with a corresponding, less frequency of outliers: 0% versus 19% ($P = 0.002$). However, there was poor intra-observer reproducibility (0.61).

Conclusions CCB did not improve femoral component rotational alignment compared with CCI nor affect outlier frequency, but it marginally improved the accuracy of tibial rotational alignment. The tibial tubercle reference point had poor intra-observer reproducibility.

Keywords Customized cutting block · Conventional cutting instrument · Total knee arthroplasty · Rotational alignment

Investigation performed at Thammasat University Hospital, Faculty of Medicine, Thammasat University, Pathumthani, Thailand.

✉ Nattapol Tammachote
 tammachotemd@gmail.com

 Nuttawut Chanalithichai
 nuttawut.cha@pccms.ac.th

 Chane Jitapunkul
 jitach49@gmail.com

 Supakit Kanitnate
 naypeng@hotmail.com

[1] Department of Orthopaedics, Thammasat University, 99 Moo 18, Khlong Nueng, Khlong Luang, Pathumthani 12120, Thailand

Introduction

An important goal of total knee arthroplasty is to properly align the prosthetic components with the natural anatomical alignment of the knee to achieve a successful result [1]. Malposition of the prosthesis may result in increasing 'wear and tear,' unsatisfactory outcomes and, sometimes, a revision [2, 3]. Coronal and sagittal mal-alignment predicts an increased risk of prosthetic loosening, pain and instability [4, 5]. Rotational mal-alignment impairs patellar tracking, joint stability and biomechanics, which often leads to pain [6, 7]. By contrast, accurate alignment correlates with favorable functional scores and faster rehabilitation [8].

The customized cutting block (CCB), designed for patient-specific instrumentation (PSI), was developed to improve positioning of the three-dimensional component; it may reduce operation times, improve outcomes and be more cost-efficient [9–11]. Manufacturers produce cutting blocks

specific to each patient's anatomy, using either magnetic resonance (MRI) or computed tomography (CT) images. In this way, the optimal component size and alignment can be mapped onto a virtual knee, which can then be reviewed and modified by the surgeons. Several recent meta-analyses describe similar coronal component positions (mechanical axis), when comparing CCB with conventional cutting instruments (CCI), but the assessment of rotational component positions was inconclusive due to limited data [12–17].

To date, a limited number of studies that have reported on rotational outcomes have either been small cohort, retrospective studies or non-randomized trials, which have involved many surgeons and multiple types of CCB [18–22]. Moreover, each study used a unique technical protocol for obtaining preoperative imaging data and different CCBs from several manufacturers, which makes comparing and contrasting outcomes challenging.

The purpose of this study was to assess whether total knee arthroplasty (TKA) performed by using CCB improves the accuracy of the alignment of the rotational component compared with conventional instrumentation measured by computer tomography in participants from a previously published, randomized control trial (RCT) [23].

Materials and methods

This study was investigated upon data from a randomized control trial study assessing the clinical and radiographic outcomes of TKA between CCB and CCI that was conducted between December 2014 and 2015. [23]. This study was approved by the institutional ethics review board (MTU-EC-OT-6-115/56).

The primary study objectives were to compare component rotational alignment between CCB and CCI measured by CT scan and determine rotational outliers. The secondary objective was to assess intra-observer reproducibility and inter-observer reliability in each rotational alignment measurement method. The null hypothesis was that there was no difference in mean deviations of the femoral and tibial component rotational alignments between CCB and CCI.

All patients from the previous RCT study were expected to be recruited in this study ($n = 102$), but 16 were excluded: (1) seven in CCB group (six patients declined to participate and one patient had since died) and (2) nine in the CCI group (four deaths, five declined to participate). So, we had 44 patients in the CCB group and 42 patients in the CCI group. Based on the number of analyzable patients ($n = 86$), the study has 80% power to detect a minimal difference in deviation of component rotation of $0.5°$ between the two groups.

All patients underwent TKA (Genesis II posterior stabilized total knee prostheses; Smith and Nephew, Memphis, TN). The femoral component had $3°$ of external rotation

built in with asymmetrical tibial tray. The patients were followed up to 2 years for clinical assessments, and a knee CT scan was performed at least 2 years after surgery.

CCB pre and operative procedures

Aside from the cutting instrumentation, all other aspects of perioperative management were the same between the two groups and followed a standardized protocol.

The Visionaire™ system (Smith and Nephew, Memphis, TN) was used to cut the bone using a customized cutting guide. Patients underwent a preoperative knee MRI and a 3-feet standing knee radiograph that included the hip and ankle joints, as per the Visionaire™ protocol. These data were sent to Smith and Nephew, which digitally constructed the three-dimensional models of the tibial and femoral cutting blocks. The digital models and prosthetic templates were uploaded to the software planner and were reviewed, including component alignments in multiple planes, by the surgeon. (The models were modified, as needed, before final approval.) Lastly, the manufacturer produced customized cutting blocks and sent them back to our institution in a sterile package within 4 weeks. The CCB was used in accordance with the manufacturer's instructions.

CCI pre and operative procedures

Preoperative templating was carefully performed using the long-leg radiograph to determine the position and size of the prosthesis. The final decision on the component size was done intra-operatively using standard anteroposterior sizing guides. TKAs were performed with conventional TKA instruments, including a long (40 cm) intramedullary alignment guide for the femur that was set at $5°–7°$ of valgus aiming for a distal cut perpendicular to the mechanical axis of the patient's femur. After the distal femoral bone was cut, the anterior–posterior femoral size was determined using the posterior referencing device. The posterior femoral condylar, Whiteside line and trans-epicondylar axis were used to determine the femoral component rotation. The extramedullary alignment guides were used for the tibial cut perpendicular to the mechanical axis with a $3°$ posterior slope, and the rotational tibial alignment was set from a line parallel to posterior cruciate ligament insertion on the tibia to the medial one-third of the tibial tubercle.

Outcome assessment

A 256-slice multi-detector CT scanner (Brilliance iCT; Philips Medical Systems, Amsterdam, the Netherlands) was used to perform 0.67-mm cuts in the fully extended knee and the images loaded using IntelliSpace™ Portal (Philips Medical Systems, Best, the Netherlands). The

outcomes were (1) femoral rotational alignment, (2) tibial rotational alignment and (3) the frequency of component rotational outliers; the latter was defined as a deviation of > 3° external or internal rotation from the expected reference. Femoral component rotation was determined by measuring the angle between the line connecting the lateral femoral epicondyle to the medial epicondylar sulcus (surgical trans-epicondylar axis) and a line through the posterior condylar surface of the femoral component (Fig. 1), according to the method of Berger et al. [7, 24, 25]. The femoral component rotational alignment was considered neutral when the two lines were parallel.

The tibial component rotation was determined using three different reference lines and compared with a line tangent to the tibial keel. The first method (Fig. 2) used a tangent line to the dorsal tibial condyle, described by Heyse et al. [26], and the second method (Fig. 3) used the tibial trans-epicondylar axis as reference, described by Bonnin et al. [27]. For both techniques, tibial component rotational alignment was considered neutral when either the tangent line or tibial trans-epicondylar line was parallel to the line connecting the posterior tibial keel. The third method (Fig. 4) used the tibial tubercle as the reference with the line perpendicular to a tangent line linking the posterior tibial keel. The neutral rotation of the tibial component was defined at 18° of internal rotation from the center of the tip of the tibial tubercle, as described by Berger et al. [7].
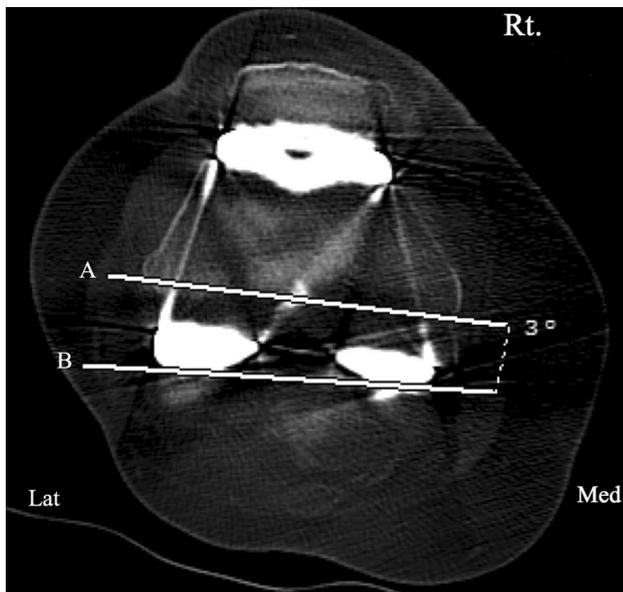

Fig. 2 Method 1: Tibial component rotation is the angle between a tangent line to the dorsal tibial condyles reference (A) and a line connecting the posterior tibial keel (B). The tibial component in this right knee was 3° of external rotation

Methods and assessment

All rotational alignments of the prostheses were measured using the measurement tool in the picture archiving and communication system (PACS), SYNAPSE program (FUJIFILM Medical Systems Inc., Hanover Park, Illinois). Measurements of component rotation were performed

Fig. 1 Femoral component rotation is the angle between the line connecting the lateral femoral epicondyle to the medial epicondylar sulcus (surgical trans-epicondylar axis) as reference (A) and a line through the posterior edge of the femoral condyles (B). The femoral component in this right knee has 3° of external rotation
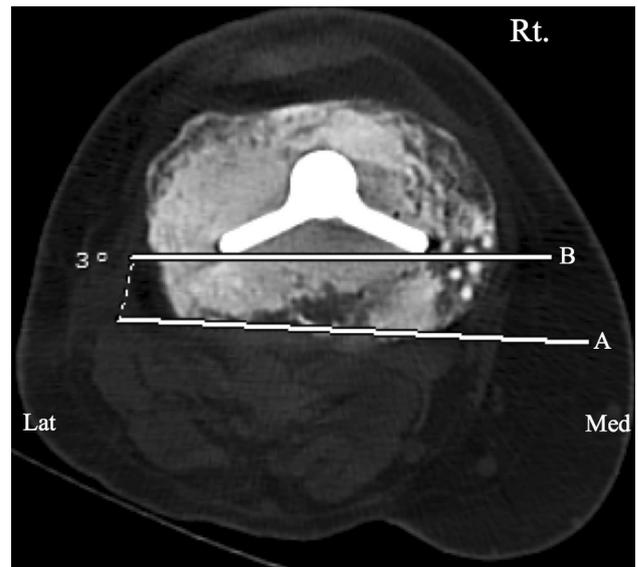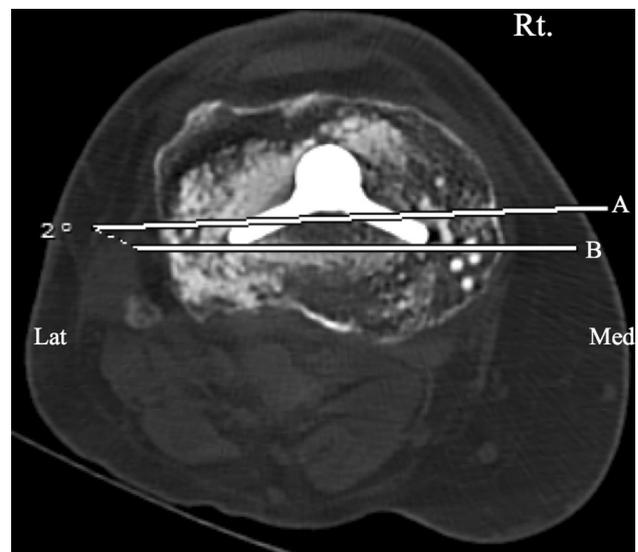

Fig. 3 Method 2: Tibial component rotation is the angle between tibial trans-epicondylar axis as reference (A) and a line connecting the posterior tibial keel (B). The tibial component in this right knee was 2° of internal rotation
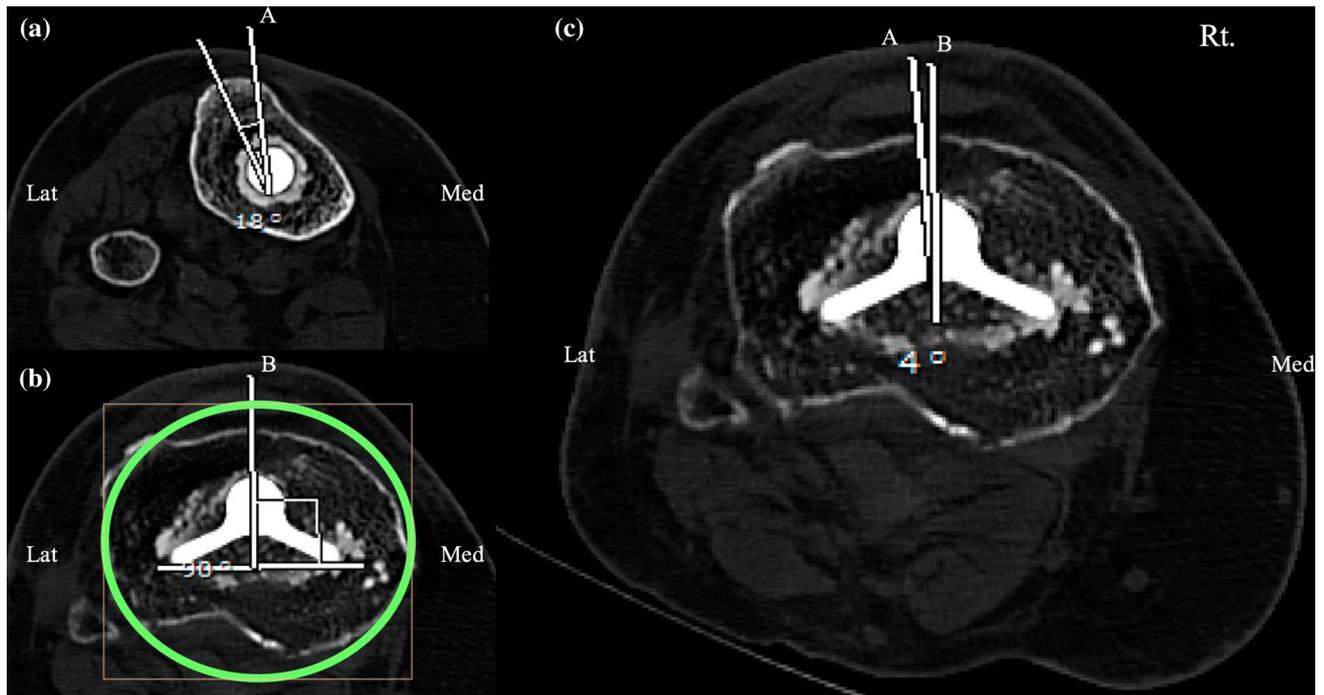
Fig. 4 Method 3: Analysis of tibial component rotation using the tip of the tibial tuberosity as reference (picture a) in a right knee: The neutral rotation (A) of the tibial component was defined as 18° of internal rotation from a line from the tip of the tibial tubercle to the geometric center of the tibial plateau, as determined by the center of the overlying circle (picture b), and the tibial component axis is defined as a line perpendicular to a line connecting the posterior tibial keel (B). The component is 4° of internal rotation from this reference (picture c)

independently by two hip and knee fellowship-trained orthopedic surgeons who were blinded to the patient allocation; two measurements were taken at least 2 weeks apart.

Statistical analysis

The Student's *t* test was used to analyze differences in mean rotation of femoral and tibial components that deviated from the reference lines between the two groups. Fisher's exact test was performed to analyze differences in frequency of outliers between the two groups. A two-sided $P < 0.05$ was considered statistically significant. We assessed intra-observer reproducibility and inter-observer reliability by intra-class correlation coefficients (ICC); values > 0.75 were considered significant.

Results

Eighty-six osteoarthritic knee patients were included in this analysis: 44 and 42 in the CCB and CCI groups, respectively. Baseline characteristics of study subjects were similar and are presented in Table 1.

Table 1 Baseline characteristics

Factor	CCB ($n = 44$)	CCI ($n = 42$)	P value
Age[a] (years)	71 (7.0)	71 (7.6)	0.94
BMI[a] (kg/m^2)	26 (4.2)	26 (3.2)	0.81
Sex[b] (%)			
Female	35 (80%)	31 (74%)	0.61
Male	9 (20%)	11 (26%)	
Side[b] (%)			
Left	25 (57%)	20 (48%)	0.52
Right	19 (43%)	22 (52%)	
Preoperative alignment (°)			
Varus/valgus[b] (n)	42/2	39/3	
HKA angle in varus knee[a]	169 ± 5	167 ± 7	0.31
HKA angle in valgus knee[a]	182 ± 1	185 ± 7	0.55

CCB customized cutting block, *CCI* conventional cutting instrument, *BMI* body mass index, *HKA* hip–knee–ankle angle

[a]The values are given as the mean and the standard deviation or numbers

[b]The values are given as the number of the patients

Femoral component rotation measurement

The mean femoral component rotation deviated from the trans-epicondylar axis was not significantly different between the two groups: $\Delta = 0.2°$ (95% confidence interval [CI]: -0.2–0.6; $P = 0.293$). Both groups had similar rates of outliers ($P = 0.74$) (Table 2). The inter- and intra-observer reliability for determining the femoral rotation using the posterior condylar line and trans-epicondylar axis was good (Table 3).

Tibial component rotation measurement

Using the dorsal tangent as reference, the mean tibial component had nearly 1° less external rotation ($\Delta = 0.7°$, [0.4–1.1]; $P < 0.001$) in the CCB group compared with the CCI group. The CCB group had a similar outlier rate compared with the CCI group ($P = 0.236$) (Table 2). The inter- and intra-observer reliability to determine the tibial rotation using the tangent line to the dorsal condyles as reference was good (Table 3).

Using the tibial trans-epicondyles as reference, the mean tibial component had approximately 1° less external rotation ($\Delta = 1.0°$ [0.6–1.4]; $P < 0.001$) in the CCB group compared with the CCI group. Excessive external rotation was identified in two (5%) and five (12%) patients in the CCB and CCI groups, respectively, but the difference was not statistically significant ($P = 0.198$) (Table 2). The inter- and intra-observer reliability to determine the tibial rotation using the tibial trans-epicondylar line as reference was good (Table 3).

Using the tibial tubercle as reference, the mean tibial component had approximately 1.5° less external rotation ($\Delta = 1.3°$ [0.7–2.0]; $P < 0.001$) in the CCB group compared with the CCI group. The CCB group had a significant lower outlier rate compared with the CCI group ($P = 0.002$) (Table 2). However, the intra-observer reproducibility to determine the tibial rotation using this technique was poor (Table 3).

Table 3 Inter- and intra-observer reliability values for each measurement method

Measurement methods	Intra-observer reproducibility	Inter-observer reliability
Femoral rotation	0.79	0.83
Tibial rotation		
Method 1 posterior tibial condyle	0.78	0.81
Method 2 trans-epicondylar	0.77	0.86
Method 3 tibial tuberosity	0.61*	0.77

The values are given as the intra-class correlation coefficients (ICC)

*Values < 0.75 were not statistically significant and indicate poor intra-observer reliability

Discussion

In our study, we have shown that the use of CCB did not improve the femoral rotational alignment when compared with CCI but it marginally improved the accuracy of the tibial rotational alignment. Moreover, there were similar rates of rotational outliers for both components.

Poor femoral or tibial component rotation after TKA can adversely affect patellar tracking [28] and knee kinematics [29]. Isolated internal rotation of the femoral component was associated with anterior knee pain, knee instability and stiffness [6, 7, 30]. Incavo et al. [31] reported that mal-rotation of the tibial and femoral components was a recognized cause of early onset and persistent pain after TKA, and Pietsch et al. [32] demonstrated that a painful TKA with a single component internal rotation $\geq 4°$ needed early revision. Unsatisfactory excessively internal rotation prosthesis placement had led to severe stiffness of the knee and impending patellar dislocation. The internally rotated femoral components tightened the medial side of the flexion gap, whereas the internally rotated tibial components restricted lateral femoral condylar rollback on the tibia during flexion [33]. Berger et al. [7] reported that excessive combined internal rotation of prostheses was directly related to the severity

Table 2 Rotational alignment of components

Parameter	Mean rotation deviated			Rotational outliers		
	CCB ($n = 44$)	CCI ($n = 42$)	P value	CCB ($n = 44$)	CCI ($n = 42$)	P value
Femoral rotation	$0.9° \pm 0.8°$	$1.1° \pm 1.1°$	0.293	1 (2%)	1 (2%)	0.741
Tibial rotation						
Method 1 posterior tibial condyle	$0.7° \pm 0.8°$	$1.5° \pm 1.0°$	< 0.001	0 (0%)	2 (5%)	0.236
Method 2 trans-epicondylar	$0.5° \pm 0.9°$	$1.4° \pm 1.1°$	< 0.001	2 (5%)	5 (12%)	0.198
Method 3 tibial tuberosity	$0.3° \pm 1.4°$	$1.7° \pm 1.6°$	< 0.001	0 (0%)	8 (19%)	0.002

Rotational alignment: positive values stand for external rotation; negative values stand for internal rotation

CCB customized cutting block, *CCI* conventional cutting instrument

of patellofemoral complications. They found that lateral tracking and patellar tilting correlated with small degrees of combined internal rotation (1°–4°), while patellar subluxation correlated with moderate degrees (3°–8°) and early patellar dislocation or late failure of the patellar prosthesis correlated with large degrees (7°–17°).

Regarding femoral rotational alignment, Parratte et al. [34] reported a study of 40 TKA patients randomized to either CCI or CCB. Femoral component rotation was measured with CT scans using the trans-epicondylar axis as reference. They found no significant difference of femoral rotation between the two groups with a mean of 0.4° and 0.2° external rotation, respectively, and no outliers in both groups. They concluded that CCB did not improve femoral component rotation. Similar conclusions were drawn by Victor et al. [35] who reported on 125 TKA patients randomized to CCI or CCB (multiple designs). The femoral component rotation was not different between the two groups: −1.9° ± 1.7° versus −1.7° ± 2.1°, respectively. Chotanaphuti et al. [36] reported a non-randomized study of 80 TKAs by CCI and CCB (TRUMATCH™). They analyzed only the femoral rotational alignment and found that CCB was 0.6° closer to the trans-epicondylar axis compared with CCI. Heyse et al. [22] reported a retrospective MRI study of 94 patients following TKA using CCI and CCB (Visionaire™). The femoral component rotation was similar in both groups (2.6° ± 2.6° vs. 2.6° ± 1.5°, respectively), but there were significantly higher outliers in the CCI group (23% vs. 2%). They concluded that CCB was effective in reducing outliers.

Our study showed similar femoral rotational alignment between the two methods with a trend for fewer outliers in the CCB group. The similarity of the rotational alignment may be explained by the surgeon meticulously estimating the rotational position using the three reference lines (Whiteside's line, trans-epicondylar axis and posterior condylar axis). We speculate that CCB may help less experienced surgeons in achieving similar outcomes as more experienced surgeons who use CCI. One limitation of previous studies was the use of different CCB systems and surgical protocols, so comparison results across studies were inaccurate.

Regarding tibial rotational alignment, Parratte et al. [34] did not find any difference in the mean tibial rotation between the two groups in their small and probably underpowered study. Inter- and intra-observer reliability of rotational measurements was not investigated. Heyse et al. [37] reported a retrospective study of 58 patients who had CCI or CCB (Visionaire™) TKAs. They used MRI to measure tibial component rotation by three different methods. Using the tangent line of the dorsal condyles and the tibial trans-epicondylar line as reference, they had excellent inter- and intra-observer reliability and narrow standard deviations for the determination of tibial component rotation. However, measurements based on the tibial tubercle showed poor intra-observer reproducibility and inter-observer reliability. Using the dorsal tangent line as reference, they found higher outliers (deviation > 9° external rotation or > 1° internal rotation) in the CCI group (34%) versus CCB (7%) group; using the tibial trans-epicondylar line as reference, the corresponding outlier proportions were 26% versus 7%. They concluded that CCB reduced outliers of the tibial component. In our study, CCB marginally improved the accuracy of the mean tibial rotational alignment by 1° compared with CCI and our outlier rate was not significantly different, even though our cutoff point was more narrow; moreover, both groups had similar outcomes measured by modified WOMAC and range of motion at 2 years [23].

The accuracy of measuring the component rotational position is surgeon dependent and has been assessed using multiple techniques. We investigated the inter- and intra-observer reliability and good intra-observer reproducibility and inter-observer reliability (mean differences < 0.5° with standard deviations < 1°) except for the tibial tubercle reference technique which had poor intra-observer reproducibility. (Mean differences were 1° with standard deviations of 0.9°.) This finding was similar to the study reported by Heyse et al. [22, 37].

Our study had some limitations. Firstly, it was relatively small and we were not able to include all of the 102 patients from the original RCT. However, the sample size of over 40 patients per arm had sufficient power to detect a small difference of 0.5° in femoral or tibial component rotation between the two groups. Secondly, deviation > 3° external rotation or > 3° internal rotation was used to define outliers, although there is no widely accepted gold-standard cutoff. Thirdly, there was performance bias because the surgeon had done > 1500 CCI TKAs but only 10 cases of CCB TKAs before this study. Finally, the dorsal tangent to the tibial epicondyles and the tibial trans-epicondylar line has never been used to correlate clinical symptoms with rotational component alignment.

In conclusion, we found that customized cutting blocks did not improve femoral component rotational alignment compared with conventional instrumentation, only marginally improved the accuracy of tibial rotational alignment and did not decrease the number of rotational outliers. The tibial tubercle reference point had the least inter- and intra-observer reliability. The cost-effectiveness of the CCB should be further investigated.

Compliance with ethical standards

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