### **KNEE**

# Differences in component and limb alignment between computer-assisted and conventional surgery total knee arthroplasty

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### Abstract

*Purpose* Marked coronal femoral bowing may bear a risk for mal-alignment of femoral component and reconstructed mechanical axis (MA) by using conventional instrumentations. The aim of this study was to investigate the usefulness of computer-assisted surgery-total knee arthroplasty (CAS-TKA) under this circumstance.

*Methods* We retrospectively analyzed patients with osteoarthritic knee and marked coronal femoral bowing who underwent TKA at our institution. The CAS-TKA and the conventional techniques were compared by radiographic parameters in coronal and sagittal planes, and rotational alignment of femoral component was assessed by computed tomography (CT) scans. The Hospital for Special Surgery (HSS) and International Knee Society (IKS) scores were obtained for all patients preoperatively and at the last follow-up.

*Results* A total of 65 knees were enrolled in this study. Twenty-eight TKAs implanted using a CT-free navigation system, and the remaining 37 TKAs implanted using the

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Division of Orthopaedic Traumatology, Department of Orthopaedic Surgery, Chang Gung Memorial Hospital, Chiayi, No 6, West Section, Chia-Pu Road, Putz 613, Chia-Yi, Taiwan conventional technique. CAS-TKAs were more consistent than conventional TKAs in aiding proper postoperative MA and ideal alignments of femoral component in the coronal and sagittal planes. However, CAS-TKA group was not obtained at significantly higher rates of femoral component in axial plane. At a mean follow-up of 43 months, there was no significant difference in HSS and IKS scores between the groups.

*Conclusions* Although CAS-TKA did not have superior functional outcomes in the short-term follow-up, proper coronal and sagittal alignment of femoral component and postoperative MA were obtained in patients with marked coronal femoral bowing. The long-term follow-up will be needed to clarify the eventual benefits.

*Level of evidence* Retrospective comparative study, Level III.

**Keywords** Total knee arthroplasty  $\cdot$  Extra-articular deformity of the femur  $\cdot$  Coronal femoral bowing deformity  $\cdot$  Computer-assisted surgery  $\cdot$  Computed tomography

## Introduction

The aim of total knee arthroplasty (TKA) is to restore the function and neutral mechanical axis of the limb and offers acceptable longevity [2, 9–11, 24, 32, 44]. Finite element models and long-term survival studies confirm that bone-cut errors should be within 3° from the ideal position to prevent abnormal wear, premature mechanical loosening of the components, and patellofemoral problems [6, 32, 39, 42].

Mechanical alignment guides are designed to compensate for variations in the valgus correction angle of the distal femur; however, several studies have reported that an ideal position of the components is achieved in only 70–80 % of patients when using an intra- or extra-medullary alignment system [12, 25]. Coronal femoral bowing deformity is particularly relevant in Asian patients, and a higher prevalence of coronal femoral bowing has been reported in China, India, Japan, Korean, and Taiwan [11, 12, 21, 28–31, 48]. This deformity of the femur is likely to alter the relationship between the mechanical and anatomical axes of the lower extremity and further decrease the accuracy of the position of the femoral component and postoperative mechanical axis [11, 12, 21, 28–31, 48].

Computer-assisted surgery-total knee arthroplasty (CAS-TKA) has been shown to improve limb axis correction and result in less gap symmetry and component alignment in patients with arthritic knees complicated by intraand extra-articular deformities [2, 3, 7, 15, 37, 39, 46]. However, limited relevant information is available to evaluate the accuracy of CAS-TKA in patients with marked coronal femoral bowing [19, 28, 29]. An intra-articular bone resection technique has been reported to be effective but technically difficult for extra-articular deformity [44, 45]. The purpose of this study was to investigate the impact of marked coronal femoral bowing on radiographic and clinical outcomes. We tested the hypothesis whether CAS-TKA is useful for this circumstance compared with conventional TKA by using an intra-articular bone resection technique.

## Materials and methods

Between 2005 and 2010, patients with osteoarthritic knee with marked coronal femoral bowing who underwent primary TKA at our institution were enrolled in this study. All patients were evaluated by radiographic analysis using anteroposterior and lateral radiographs of the knees and long-leg weight-bearing split scanograms taken preoperatively and postoperatively [9]. All limbs underwent computed tomography (CT) to evaluate the rotational alignment of the femoral component using the Perth CT Protocol [27].

For radiographic analysis, the valgus correction angle of the distal femur was measured using the method of Yau et al. [48], and the magnitude of coronal femoral bowing was measured using the method of Mullaji et al. [28]. According to the criteria established by Mullaji and Shetty [29], a coronal femoral bowing magnitude of  $>5^{\circ}$  was identified as a marked coronal femoral bowing deformity. Patellofemoral tracking was performed by analyzing the preoperative congruent angle and the postoperative patellar tilting angle (using the method described by Kawahara et al. [16]). Radiographic parameters including mechanical axis, magnitude of coronal femoral bowing, valgus correction angle of the distal femur, preoperative congruent angle and the postoperative patellar tilting angle, and the alignment of components including femoral valgus angles, tibial valgus angles, femoral flexion angles, and tibial flexion angles were measured [5]. The desired femoral valgus angle was based on the valgus correction angle of the distal femur, which was measured on long-leg weight-bearing split scanograms. The planned position for the femoral component was a femoral flexion angle of  $0^{\circ}$  in the sagittal plane, for the tibial component a tibial valgus angle of  $90^{\circ}$  in the coronal plane, and for the tibial component a tibial flexion angle of  $87^{\circ}$  in the sagittal plane. The goal was to reconstruct the mechanical axis and component alignment to within  $3^{\circ}$  of the ideal position.

CT scans were taken and then evaluated using the Perth CT Protocol [27]. The femoral component rotational angle was defined as the angle between the surgical epicondylar axis and the tangent to the posterior femoral condyles of the femoral component. The differences in absolute value from the target angle were recorded and analyzed [27]. The ideal femoral component rotational angles were defined as within  $3^{\circ}$  of the target angle ( $0^{\circ}$ ) [17, 18, 26]. All measurements were made by a blinded observer using digital radiographs on a computer.

Preoperative and postoperative functional scores were obtained for all patients using the Hospital for Special Surgery (HSS) [13] and International Knee Society (IKS) [14] scoring systems. Patients with a deformity and sclerosis of the diaphyseal femoral canal or tibia because of trauma or previous surgery, with retained hardware, or with incomplete records of radiographic analysis and functional evaluations were excluded from this investigation.

## Surgical technique

All TKAs were done using an anterior midline longitudinal skin incision and a medial parapatellar arthrotomy. Cruciate-retaining total knee prostheses (P.F.C. Sigma Knee System: DePuy Orthopaedics, Warsaw, IN) were used in all patients. In the conventional group, the whole knee prosthesis was implanted using an intramedullary alignment guidance system for femoral preparation and an extramedullary guide for tibial preparation. The angle of the cutting block was adjusted according to the valgus correction angle of the distal femur, which was measured using a long-leg weight-bearing split scanogram. If the intramedullary femoral guide could not provide the planned valgus correction angle, the intra-articular bone resection technique described by Wang et al. [44, 45] was used. Using the intramedullary guidance system, modification of the starting hole in the lateral femoral condyle for a varus deformity and in the medial femoral condyle for a valgus deformity was made. The rotation of the femoral component was guided by the epicondylar line and the line parallel to the tibial cutting plane. The rotation of the tibial component was adjusted to be parallel to the axis between the medial third of the tibial tuberosity and the center of the tibial plateau. In the CAS-TKA group, the prostheses were implanted using a CT-free navigation system. The femoral preparation was done first, followed by the tibial preparation under the guidance of the CT-free navigation system. The femoral component was referenced parallel to the transepicondylar line, which was previously registered in the navigation system. The rotation of the tibial component was adjusted to match the femoral component and made parallel to the axis between the medial third of the tibial tuberosity and the center of the tibial plateau. The soft tissue balance was assessed at the trial reduction and achieved by sequential release of the tight structures in both flexion and extension. The posterior cruciate ligament was assessed using the "pull-out lift-off" (POLO) test [36] and released as needed from its insertion site in the tibia to obtain the desired tension. The femoral and tibial reference arrays were retained until the cement had fully set and then subsequently removed after their alignment had been verified using the navigation system. The tourniquet was then deflated, and assessments of the hemostasis and patellar tracking were done. All TKAs were performed by the senior surgeon (R.W.-W.H.), who has extensive experience with conventional TKA and CAS-TKA.

All patients enrolled in this investigation were treated with the same protocol. One hour before surgery and every 8 h postoperatively for 48 h, each patient was given a prophylactic intravenous injection (1.0 g) of a first-generation cephalosporin. Wound suction drains were used for 48 h. All patients were allowed to walk with full weight-bearing after the surgery. A continuous passive-motion machine was used from the day of surgery throughout the hospital stay.

The patients were divided into two groups: Those with marked coronal femoral bowing (>5° measured using Mullaji's method [28] and defined using Mullaji's criteria [29]) who underwent CAS-TKA were assigned to group A, and those with marked coronal femoral bowing who underwent conventional TKA were assigned to group B. Medical records, functional outcomes, radiographic parameters, and the percentage of TKAs placed within 3° of the ideal mechanical axis and component alignment angles were retrospectively reviewed and compared. The intraobserver reliability was assessed, and the intraclass correlation coefficients (ICCs) were measured according to the method described by Konigsberg et al. [20]. The ICCs of the intraobserver reliabilities of all measurements were  $\geq 0.61$  (range 0.612-0.975). Because the measurements were judged reliable, measurements made by this blinded observer were used in the analyses. The study protocol was approved by the Institutional Review Board of Chang-Gung Memorial Hospital (101-3699C), and all patients provided signed informed consent.

Statistical analysis

All data were collected and independently entered into a Microsoft Excel spreadsheet by two independent surgeons who were blinded to the surgical techniques and allocation. After the spreadsheets had been rechecked for missing and illogical data, the data were copied into SPSS version 13.0 for Windows (SPSS Inc., Chicago, IL) and analyzed. A Mann–Whitney U test was used to determine statistically significant differences in absolute value from the target angles between the two groups using these parameters. Fisher's exact test was used to compare the quality of implantation, measured against the ideal position, between the two groups with these parameters. A Student's t test was used to compare the variables of age, body weight, hospital stay, tourniquet time, blood loss, follow-up time, functional results, and radiographic parameters. With regards to sample size calculation, an a priori power analysis using the two-sided hypothesis test with a power of 80 % and a significance of 0.05 was done. It was calculated that 33 knees were required to detect a difference of five points in the Knee Society score (estimated SD of >8). The cutoff value was selected because a difference of five points has been suggested as the minimal clinically important difference for the Knee Society score. All data were analyzed by an independent statistician who was blinded to the surgical outcomes. Significance was set at p < 0.05.

# Results

A total of 42 patients (65 knees) were enrolled in this retrospective study. There were 28 knees in group A and 37 knees in group B. There were no statistically significant differences in demographic data including age at time of surgery, body height, body weight, body mass index, and length of hospital stay. Patients in group A had significantly less total blood loss and longer tourniquet time (Table 1).

Comparing the alignment data between groups A and B, the preoperative mechanical axis, valgus correction angle, magnitude of coronal femoral bowing, preoperative congruent angle, and postoperative patellar tilting angle were very similar. Differences in the postoperative mechanical axes were found (p = 0.036). With regard to component alignment angles in the coronal and sagittal planes, there were significant differences in the alignment of femoral components including femoral valgus and femoral flexion angle (p = 0.044 and p = 0.001, respectively). However, there were no differences in tibial valgus angle or tibial flexion angle between the two groups. In the axial plane, a similar femoral rotational angle was noted by CT between groups A and B (Table 1).

Table 1 Demographic and   radiographic data of the patients	Parameters	Group A ( $N = 28$ )	Group B ( $N = 37$ )	P value			
in both groups	Demographic data						
	Age at time of operation (years)	$70 \pm 4$	$70 \pm 4$	n.s.			
	Body height (cm)	$150 \pm 6$	$150 \pm 6$	n.s.			
	Body weight (kg)	$68 \pm 8$	$69 \pm 9$	n.s.			
	Body mass index (kg/m <sup>2</sup> )	$30 \pm 4$	$30 \pm 4$	n.s.			
	Follow-up (months)	$43 \pm 18$	$43 \pm 16$	n.s.			
	Perioperative data						
	Total blood loss (ml)	$497\pm201$	$621\pm291$	0.048*			
	Tourniquet time (min)	$77 \pm 15$	$66 \pm 10$	0.034*			
	Hospital stay (days)	$6 \pm 1$	$7 \pm 1$	n.s.			
	Radiographic data of leg axis						
	Valgus correction angle of the distal femur (°)	$9 \pm 1$	$9\pm1$	n.s.			
Group A: osteoarthritis underwent computer-assisted surgery-total knee arthroplasty	Coronal femoral bowing angle (°)	$11 \pm 3$	$10 \pm 2$	n.s.			
	Preoperative coronal MA (°)	$165 \pm 4$	$167 \pm 5$	n.s.			
	Postoperative coronal MA (°)	$179 \pm 1$	$177 \pm 3$	0.036*			
Group B: osteoarthritis underwent conventional total knee arthroplasty	Patellofemoral tracking						
	Preoperative congruent angle (°)	$12.4\pm16$	$14.1 \pm 18$	n.s.			
	Postoperative patellar tilting angle (°)	$2.4 \pm 1.7$	$2.1 \pm 1.8$	n.s.			
Values are shown as mean $\pm$ SD. <i>P</i> values for between-groups comparison were determined by Mann– Whitney <i>U</i> test	Component alignments						
	Femoral valgus angle (°)	$99 \pm 2$	$98 \pm 3$	0.044*			
	Femoral flexion angle (°)	$1 \pm 1$	$3\pm3$	0.001*			
	Femoral rotation angle (°)	$1\pm 0$	$1 \pm 1$	n.s.			
MA mechanical axis	Tibial valgus angle (°)	$90 \pm 1$	$90 \pm 1$	n.s.			
* Statistically significant ( <i>p</i> value <0.05)	Tibial flexion angle (°)	$88 \pm 1$	$88 \pm 2$	n.s.			

The results of CAS-TKA were better than conventional TKA with regards to the percentage of TKAs achieving the ideal femoral valgus and femoral flexion angle between the two groups (p = 0.039 and p < 0.001, respectively) (Table 2). Similar differences were noted when comparing the percentage of knees achieving the ideal postoperative coronal mechanical axis between the two groups (92.9 vs. 72.9 %, p = 0.039) (Table 2). The chief difference in the coronal plane was with the femoral valgus angle, which resulted in the postoperative coronal mechanical axis becoming significantly different.

The mean preoperative IKS and HSS knee scores were similar in both groups, and the HSS score improved postoperatively in both groups. According to the IKS scoring system, improvements in postoperative outcomes with regard to the pain score, clinical knee score, and functional knee score were also found (Table 3). The difference in all scores did not achieve statistical significance between the two groups (p > 0.05).

# Discussion

The most important finding in this investigation was that CAS-TKA was more consistent than conventional TKA for

aiding proper femoral component placement when marked coronal femoral bowing deformities were present. However, with regard to clinical function, we were not able to show a statistically significant difference between CAS-TKA and conventional TKA.

Surgeons may wonder whether there is a need to completely correct the mechanical axis, because most patients present with a natural varus alignment [21, 26, 32]. Reducing the need to release soft tissue may cause less pain and be more stable than when ligaments are released, as they may be in a completely corrected coronal alignment. However, there has been concern that a mal-aligned knee may compromise function and place the implants at a higher risk for catastrophic failure [6, 32, 42]. Moreover, finite element models and long-term survival studies have confirmed that achieving a distal femoral bone cut perpendicular to the mechanical axis of the femur is critical for the long-term outcome and longevity of the TKA [39]. Good component alignment and a reconstructed mechanical axis within 3° of neutral has been reported to reduce abnormal wear, prevent premature mechanical loosening of the components, and prevent patellofemoral problems [6, 33, 39, 42].

The prevalence of marked coronal femoral bowing has been reported to be as high as 18.8 % in Asian patients with end-stage osteoarthritis of the knee. Evidence of this

Deviation	No. of postoperative component alignments within 3°				
	$\overline{\text{Group A}(N=28)}$	Group B ( $N = 37$ )	P value <sup>‡</sup>		
Coronal mechanical axis within $\pm 3^{\circ}$	26 (92.9 %)	27 (72.9 %)	0.039*		
Component alignments within $\pm 3^{\circ}$					
Femoral valgus angle	26 (92.9 %)	27 (72.9 %)	0.039*		
Femoral flexion angle	28 (100 %)	21 (56.8 %)	< 0.001*		
Femoral rotation angle	25 (89.3 %)	33 (89.1 %)	n.s.		
Tibial valgus angle	28 (100 %)	36 (97.3 %)	n.s.		
Tibial flexion angle	28 (100 %)	37 (100 %)	n.s.		

Table 2 Comparison of postoperative leg axis and component alignment within 3° deviation between the two groups

Group A: osteoarthritis underwent computer-assisted surgery-total knee arthroplasty

Group B: osteoarthritis underwent conventional total knee arthroplasty

The values are given as n (%)

\* Statistically significant (p value <0.05)

<sup>‡</sup> P values for between-groups comparison were determined by Fisher's exact probability test

Table 3	Comparison	of prec	perative a	nd poste	operative	knee	scores i	in both	groups
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Parameters	Group A ( $N = 28$ )	Group B ( $N = 37$ )	P value	
Postoperative knee scores				
Hospital for Special Surgery knee score	$59.7 \pm 11.1$	$60.9 \pm 5.2$	n.s.	
International Knee Society knee score	$60.4 \pm 14.6$	$58.3 \pm 7.8$	n.s.	
International Knee Society pain score	$21.4 \pm 10.1$	$22.2 \pm 7.1$	n.s.	
International Knee Society function score	$40.9 \pm 12.6$	$38.1 \pm 8.5$	n.s.	
Preoperative range of motion (°)	$103 \pm 14$	$101 \pm 13$	n.s.	
Postoperative knee scores				
Hospital for Special Surgery knee score	$88.5 \pm 4.0$	$87.8 \pm 5.4$	n.s.	
International Knee Society knee score	$94.4 \pm 2.9$	$94.4 \pm 3.2$	n.s.	
International Knee Society pain score	$48.0 \pm 2.5$	$47.4 \pm 2.5$	n.s.	
International Knee Society function score	$90.7 \pm 6.0$	$91.4 \pm 5.3$	n.s.	
Postoperative range of motion (°)	$121 \pm 11$	$120 \pm 10$	n.s.	

Group A: osteoarthritis underwent computer-assisted surgery-total knee arthroplasty

Group B: osteoarthritis underwent conventional total knee arthroplasty

Values are shown as mean  $\pm$  SD

P values for between-groups comparison were determined by Mann-Whitney U test

\* Statistically significant (p value <0.05)

deformity cannot be seen in short-film radiographs of the knee, and it does not present with a clinical or intraoperative appearance [11, 12, 22, 28–31, 48]. According to longleg weight-bearing split scanograms, the angular relationship between the mechanical and anatomical axes of the femur is influenced by a coronal femoral bowing deformity [10, 11, 20, 26–29, 46]. To obtain accurate alignment is theoretically difficult with the use of intramedullary guides when femoral diaphyseal deformity, distortion of the osseous canal of the femur, and variations in femoral anatomy exist. In conventional TKA, intra-articular bone resection using modification of the starting hole of the intra-medullary guide system in knees is used; however, it is technically difficult to perform this in patients with a femoral extra-articular deformity in conjunction with ipsilateral osteoarthritis of the knee [44, 45]. The incomplete insertion of intramedullary rods may contribute to the subsequent erroneous distal femur resection and further provide an improper postoperative mechanical axis [22, 38].

Patient-specific instrumentation (PSI) is a modern technique that has been used to obtain proper mechanical alignment and component placement for over 5 years. The theoretical benefits of PSI may be useful for end-stage arthritis of the knee joint in conjunction with extra-articular deformities [34]. However, the role of PSI in TKA has yet to be clearly defined. Some authors have reported that PSI requires less surgical time, improves the efficiency of the operating room, does not result in an increase in perioperative morbidity, and has a similar cost to conventional TKA [4, 22]. Conversely, other studies have reported that PSI does not appear to be superior to conventional instrumentation in terms of the postoperative mechanical axis of the limb or femoral component placement, and perhaps a worsening of tibial component alignment [1, 8, 35, 38, 40, 41, 43, 47].

CAS-TKA provides more accurate bone cuts, more precise component placement in the coronal, sagittal, and rotational planes, better restoration of coronal limb alignment, and lower gap asymmetry [3, 7, 15, 17, 18, 46]. Our results are consistent with those of Mullaji and Shetty [29]. We also showed significant postoperative improvements in all measured clinical outcome scores, in radiographic benefits for the ideal percentage of the postoperative mechanical axes, and in a higher level of proper placement of the femoral components at the last follow-up visit.

At a mean follow-up period of 43 months, there were no significant differences in functional scores between the two groups. With regards to the radiographic parameters, significant differences were only noted in the alignment of femoral components including femoral valgus and femoral flexion angle (p = 0.044 and p = 0.001, respectively) and postoperative mechanical axis (p = 0.036). In the sagittal plane, CAS did result in a significant improvement in femoral component alignment; however, difficulty in achieving good sagittal alignment has been reported [18]. In addition, studies on the true impact of sagittal mal-alignment are relatively rare and the results have not clearly been established. The chief difference in the coronal plane was in the femoral valgus angle, which resulted in the postoperative coronal mechanical axis becoming significantly different.

With the use of modern prostheses, the short- to midterm functional outcomes of aligned knees and outliers in the coronal plane are not consistent. Lasam et al. [21] studied 367 knees with coronal femoral bowing and 60 knees without bowed femurs and concluded that well-aligned knees had better clinical outcomes in terms of American Knee Society, WOMAC, and SF-36 scores. Conversely, Matziolis et al. [26] found no differences between the two techniques when assessing the same functional scores. Our results are consistent with Matziolis et al. [26], and the improvement in radiographic results did not translate into superior clinical outcomes. This inconsistency on the effect of complete correction of the coronal mechanical axis suggests that a mal-aligned knee may influence patient function only to a limited extent. For example, this difference may only be significant by chance [22]. In addition, only a few relevant studies regarding coronal femoral bowing

have been reported. Whether the improvements in radiographic results translate into better long-term clinical outcomes and survival with the use of modern prostheses is a matter of speculation. Long-term and large-scale follow-up investigations are warranted to clarify this issue, which has potentially important surgical implications.

The present study has several limitations. This was a radiographic and short-term clinical follow-up study; thus, we were unable to assess the correlations between proper alignment and long-term functional outcomes. To the best of our knowledge, only one prospective randomized trial [19] has compared CAS-TKA with a conventional technique during long-term radiographic and clinical followup. The authors reported no significant differences between the long-term radiographic and clinical assessments of CAS-TKA and conventional TKA. However, with regards to marked coronal femoral bowing, the CAS-TKA group had higher percentages of ideal postoperative mechanical axes and alignment of components than the conventional TKA group. However, it is possible that complete correction of a natural varus alignment occurred in these patients. Additional long-term results of CAS-TKA are needed to determine whether radiographic benefits result in better long-term clinical outcomes. Second, the present study is also limited by its retrospective design. However, the same experienced surgeon performed the TKAs using the same protocol for all of the patients in this study, which may diminish the bias. Finally, there were only 65 knees in this study. According to Lizaur-Utrilla et al. [23], using the IKS scoring systems to calculate the sample size with a power of 80 % and a significance of 0.05 and to detect a difference of five points in Knee Society score (estimated SD of 8) and a difference of five points in the Knee Society score (estimated SD of >8), 33 knees were required per group. There were only 65 knees (28 knees in CAS group and 37 in conventional group) in this study. Because of the relative rarity of marked coronal femoral bowing deformities (>5° measured using the method of Mullaji et al. based on longleg weight-bearing split scanograms) in patients undergoing TKA, this study was too underpowered to show a true difference with conventional TKA. A randomized controlled trial with a large sample size comparing computerassisted surgery to conventional instrumentation under these circumstances is worthwhile; however, it would be still difficult to obtain adequate power.

The presence of marked coronal femoral bowing results in loss of accuracy in femoral component and postoperative mechanical axis when an intra-articular resection technique is used. Using staged or simultaneous femoral osteotomy combined with TKA or PSI are all viable options. Our data suggest that CAS-TKA can be an effective alternative for proper position of the femoral component and postoperative mechanical axis. However, with regards to clinical function, we were not able to show a statistically significant difference between two techniques. Long-term follow-up will be needed to determine if the improvement in radiographic results actually translates to better clinical outcomes.

# Conclusions

CAS-TKA appears to be an effective method to properly restore the mechanical axes as well as femoral component placement in coronal and sagittal planes. However, CAS did not provide better clinical outcomes in this short-term investigation. The long-term follow-up studies are needed to elucidate this issue.

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**Conflict of interest** The authors declare that they have no competing interests.

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