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Abnormal rate of intraoperative and postoperative implant positioning outliers using "MRI-based patient-specific" compared to "computer assisted" instrumentation in total knee replacement

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Abstract

Purpose The aim of this study was to analyze first intra-operative alignment and reason to abandon the use of patient-specific instrumentation using intraoperative CAS measurement, secondly assess by postoperative CT analysis if CI, based on preoperative 3D-MRI data, improved postoperative component positioning (including femoral rotation) and lower limb alignment as compared with results obtained with CAS.

Methods In this randomized controlled trial, 80 consecutive patients scheduled to undergo TKA were enrolled. Eligible knees were randomized to the group of PSI-TKAs ($n = 40$) or to the group of CAS-TKAs ($n = 40$). In the CAS group, CAS determined and controlled cutting block positioning in each plane. In the PSI group, CAS allowed to measure adequacy of intraoperative alignment including femoral component rotation. At 3 months after surgery, implants position were measured and analyzed with full-weight bearing plain radiographs and CT scan.

Results Intraoperatively, there was a significant difference concerning Sagittal Femoral mechanical, Frontal tibial mechanical angle and tibial slope between the two groups (respectively $p = 0.01$, $p = 0.02$, $p = 0.046$). Custom instrumentation was abandoned intraoperatively in seven knees (17.5 %). Abnormal tibial cuts were responsible of the abandon in three out of seven cases, femoral cut in 1/7 and dual abnormalities in 3/7. Postoperatively, tibial slope outliers percentage was higher in the patient specific instrumentation group with six patients (18.18 %) versus one patient (2.5 %) in the CAS group ($p = 0.041$).

Conclusion Patient specific instrumentation was associated with an important number of hazardous cut and a higher rate of outliers in our series and thus should be used with caution as related to. This study is the first to our acknowledgement to compare intra-operative ancillary and implant positioning of PSI-TKA and CAS-TKA. High rate of malposition are sustained by our findings, as such PSI-TKA should be used with caution, by surgeons capable to switch to conventional instrumentation intra-operatively.

Level of evidence Randomized control trial, Level I.

Keywords Total knee arthroplasty · Custom instrumentation · Computer assisted instrumentation · Implant positioning

Introduction

Coronal, sagittal, and rotational plane outliers have been shown to be associated with inferior function after total knee arthroplasty (TKA) [1, 2, 4, 7, 8, 22, 26, 31]. Computer-assisted surgery (CAS) TKA was introduced to minimize these outliers in component positioning and alignment [21]. However, navigated TKAs usually take a longer time than conventional methods, and potentially increase the risk of infection and pin site complications [6, 9, 24]. Patient-specific "custom" instrumentation (PSI) has been introduced to minimize potential drawbacks of CAS-TKA and to improve the accuracy of component placement compared to the standard technique. Although several studies have reported improved accuracy of implant positioning

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with PSI compared with conventional instruments [18, 23, 32], the results of those PSI tools remain controversial, as recent randomized controlled trials have found equal accuracy between standard instrumentation and PSI [27, 35, 36]. In these trials, computed-tomography (CT) was used to compare limb alignment and implant positioning in a standard and custom instrumentation group. If PSI did not decrease outlier numbers in the coronal, sagittal, and rotational planes, the authors of these two studies [35, 36] described a high rate of intraoperative instrumentation's conversion due to hazardous cuts in the PSI group when cross-checked with a conventional cutting guide. Thus, to the best of our knowledge, no study has assessed intraoperative implant positioning of PSI and CAS-TKA instrumentations.

The aim of this study was firstly to analyze intraoperative alignment and the reason to abandon the use of PSI using intraoperative CAS measurement, and secondly to assess by postoperative CT analysis if PSI, based on preoperative 3D-MRI data, improved postoperative component positioning (including femoral rotation) and lower limb alignment as compared with results obtained with CAS.

It was our hypothesis that there is no difference in the accuracy of femoral and tibial component placement between the two surgical instrumentations.

Materials and methods

In this randomized controlled trial, 80 consecutive patients scheduled to undergo TKA were enrolled. Inclusion criteria were: patients aged 18–85 years old the day of surgery who had varus deformity and were undergoing TKA for primary osteoarthritis. Patients with valgus knee or any history of previous surgery (arthroscopy excepted) or trauma to the affected knee were excluded, as were patients who declined to participate in the trial. Knees were allocated according to a permuted block randomization program. The patients and surgeons were notified a few days before the surgery. Eligible knees were assigned to the group PSI-TKAs ($n = 40$) or to the group CAS-TKAs ($n = 40$). There were no differences between the groups in preoperative demographics and clinical and radiographic data (Table 1). An MRI examination was planned preoperatively in both groups. Posterior condylar angle was defined as the angle between the anatomical transepicondylar axis and posterior condylar axis. In the PSI group, an MRI-based VisionaireTM Personalized Patient Care System (Smith and Nephew®, Andover, MA, USA) was planned; raw images were sent to Smith and Nephew for validation and uploaded to the 3D surgical planning software. The surgeon checked and edited the sizing and positioning of the components in every step of the preliminary planning. Patient-specific guides were produced to fit on the distal femur and proximal tibia of the patient based on the calculated resection levels and proper positioning and size of the prosthesis components in the three planes. The initial target position of the implants was set to restore the mechanical alignment of the lower extremity in the coronal plane at 0° flexion from the mechanical axis of the femur and at 3° posterior slope to the mechanical axis of the tibia in the sagittal plane. Femoral component rotation was set at 2° relative to the anatomical transepicondylar axis [21]. All cutting block models were made from Nylon-12 and delivered in a sterile pack.

The same type of implant was used: Legion Primary™ Total Knee System Posterior-Stabilized (Smith and Nephew®, Andover, USA). In both groups, a standard medial para-patellar approach was performed without tourniquet. For every patient, a CAS Navitrack™ Orthosoft System® (Zimmer®, Warsaw, USA) was prepared. In the CAS group, CAS determined and controlled the cutting block positioning in each plane. In the PSI group, CAS allowed to measure the adequacy of intraoperative alignment obtained with PSI. The reported accuracy of the CAS system was 0.2 ± 0.1 mm and 0.3 ± 0.3° [37]. Our criteria for intraoperatively abandoning PSI for standard CAS were global limb alignment and/or femoral mechanical angle

Table 1 Demographic data and preoperative radiological parameters

	Global series	Computer assisted instrumentation	Custom instrumentation	*p* value
Gender ratio (female:male)	56:24	28:12	28:12	
Age (years)	73.7 ± 14.2 (33.6–87.1)	72.2 ± 17.4 (33.6–85.9)	76 ± 7.1 (61.4–87.1)	n.s.
BMI (kg m$^{-2)}$	26.9 ± 6.5 (17–41)	27 ± 6.1 (17–41)	26.3 ± 6.9 (18–39)	n.s.
Lower limb mechanical angle HKA (°)	173 ± 5.7 (158–179)	172 ± 5.2 (158–178)	173.3 ± 6.2 (164–179)	n.s.
Frontal femoral mechanical angle (°)	89.9 ± 3.4 (80–97)	89.6 ± 3.6 (80–96)	90.1 ± 3.1 (82–97)	n.s.
Frontal tibial mechanical angle (°)	83.6 ± 5.1 (70–82)	83.2 ± 4.5 (70–82)	84.2 ± 5.7 (72–81)	n.s.
Femoral rotation (°)	5.2 ± 1.7 (0.9–9.7)	5.4 ± 1.6 (1.5–9.7)	5 ± 1.9 (0.9–8.0)	n.s.
Tibial slope (°)	4.4 ± 2.2 (1–8)	5.1 ± 2.3 (1–8)	3.6 ± 1.7 (1–6)	n.s.

Values are represented as mean ± SD (range) (frontal femoral mechanical angle; FFMA) and sagittal femoral mechanical angle (SFMA), and/or tibial mechanical axis (frontal tibial mechanical angle; FTMA), differing from the initial target position by more than 3°. Anterior tibial slope and femoral rotation distant from the preoperative planning by more than 5° were also "PSI abandon" criteria. The rate of intraoperative conversion to CAS instruments in the PSI group and the specific causes for this conversion were recorded.

Three months after surgery, hip-knee-ankle angle (HKA), frontal (FFMA, FTMA), and sagittal (SFMA, STMA) alignments were measured with full weight-bearing radiographs. Rotation of the femoral component was assessed with axial CT images by comparing the posterior condylar axis of the implants and the anatomical transepicondylar axis [21].

Postoperative "outlier" status was defined as an implant position differing by more than 3° from the mechanical axis in the frontal plane and greater than 3° from the initial target angles in the frontal and sagittal planes, femoral rotation, or tibial slope.

The regional Committee for Patients' Protection (CPP) (May 14, 2012—Protocol CHV 12/05 no. 12014) approved the study protocol.

Statistical analysis

An a priori sample size analysis for this study suggested that at least 25 TKAs were required in each group on an assumption that a 2.5° difference in femoral implant rotation is clinically significant between groups ($\alpha = 0.05$; $\beta = 0.8$). Forty patients per group were included, allowing 15 dropouts for each instrumentation type. This calculation was based on a previously published method of femoral rotation measurement showing a mean value of 1.6 ± 2.7° [21].

An intent-to-treat (ITT) analysis was conducted for the intraoperative parameters of interest and a per-protocol analysis for the postoperative radiological parameters. In the per-protocol analysis, the patients were divided according to whether the patient-specific cutting blocks were used to make both the femoral and tibial cuts in all planes. Two groups were defined accordingly for the statistical analysis a PSI ($n = 33$) and a CAS ($n = 40$) groups. The dropout patients were described as a subgroup, their numbers ($n = 7$) did not allow statistical calculation. The differences between the groups were examined using a Student's t test for continuous variables and Pearson's Chi square test for categorical variables. Outlier rates were compared using Fisher's exact test. Statistical analyses of the outcomes were performed with SPSS 18.0 statistical software (SPSS Inc., Chicago, IL, USA).

Table 3 Rate of intraoperative outliers

Outliers	FFMA	SFMA	Femoral rotation	FTMA	Tibial slope
CAS(%)	0	2.5	0	0	0
CI (%)	2.5	10	5	10	7.5
Fisher exact	n.s.	n.s.	n.s.	0.01*	0.02*

FFMA frontal femoral mechanical angle, *SFMA* sagittal femoral mechanical angle, *FTMA* frontal tibial mechanical angle, *CAS* computer assisted surgery, *CI* custom instrumentation

Results

Intraoperative parameters

The intraoperative parameters assessed by a CAS method were evaluated in ITT (Tables 2, 3). HKA angle, FFMA, and rotational positioning of the femoral implant were similar between the groups. There was a significant difference concerning SFMA ($p = 0.01$), FTMA ($p = 0.02$), and tibial slope ($p = 0.046$).

The use of the custom instrumentation was abandoned intraoperatively in seven knees (17.5 %). Table 4 presents the demographic data and the preoperative, intraoperative (reason for abandoning PSI), and postoperative parameters of interest of each case. Abnormal tibial cuts were responsible for the abandonment of 3/7 of the cases, femoral cuts for 1/7 of the cases, and dual abnormalities in three cases.

Table 2 Intraoperative parameters assessed by computer assisted measurements

	Computer assisted instrumentation	Custom instrumentation	p value
Sagittal femoral mechanical angle (°)	91.2 ± 1.8 (87.5 to 95)	93.3 ± 3.4 (76 to 101)	0.01*
Frontal femoral mechanical angle (°)	89.8 ± 1.70 (88 to 93)	89.3 ± 1.7 (85 to 93)	n.s.
Frontal tibial mechanical angle (°)	89.7 ± 0.83 (88.5 to 91.5)	87.5 ± 1.85 (76 to 95)	0.02*
Femoral rotation (°)	5.4 ± 1.6 (1.5 to 9.7)	5 ± 1.9 (0.9 to 8.0)	n.s.
Tibial slope (°)	3.5 ± 0.8 (−6 to 2)	2.3 ± 3.9 (−9 to 8.5)	0.046*

Values are represented as mean ± SD (range)

* Statistically significant findings

Table 4 Demographic data, preoperative, intraoperative (reason for abandoning PSI) and postoperative parameters of all the dropout (from PSI group) patients

Patients anthropometric parameters				Preoperative radiological parameters						Reason for conversion	Intraoperative parameters assessed by CAS						Postoperative parameters assessed by CT-scan				
No.	Gender	Age	BMI	Alhback grade	HKA	FFMA	FTMA	Fem rot	Tib slope		HKA	FFMA	SFMA	FTMA	Tib slope	Fem rot	HKA	FFMA	FTMA	Tib slope	Fem rot
1	M	73.2	27.0	3	165.0	91.0	74.0	5.0	4.0	Dual	163.5	71	94.5	79	6.5	3	178.4	90	82.9	1.2	3.9
6	M	84.5	31.0	3	172.0	89.0	83.0	5.0	6.0	Tibial	178.5	87	96.5	86	4	4	179.1	92.7	88.3	3.3	1
5	M	68.3	25.0	3	175.0	91.0	88.0	8.0	2.0	Dual	171.5	83	90.5	86	3	4	174.1	84.9	87.6	2.1	2
4	M	75.1	18.0	4	178.0	91.0	78.0	8.0	5.0	Femoral	177	87	101	89.5	3.5	13	179	88.4	91	3.6	2.6
7	F	67.7	34.0	3	174.0	90.0	84.0	6.0	4.0	Tibial	173	89.5	93	76	2	−1	179.2	87.5	91.3	3	3.9
2	F	78.6	25.0	3	169.0	86.0	83.0	4.0	3.0	Dual	190	91	96	94	−5	8.5	177.5	88.9	87.5	3	0.7
3	F	72.5	24.0	3	169.0	92.0	77.0	8.0	1.0	Tibial	171	89	89.5	85	−9	0	181.7	90.1	91.8	1.6	4.7
		72.5	24.0	3	169.0	92.0	77.0	8.0	1.0	Tibial	171	89	89.5	85	−9	0	181.7	90.1	91.8	1.6	4.7

Postoperative assessment

No difference was found between the PSI (33 cases) and CAS (40 cases) groups in terms of hip-knee angle or frontal, sagittal, or rotational implant positioning values (Table 5).

The tibial slope outlier percentage was higher in the PSI group with six patients (18.18 %) versus one patient (2.5 %) in the CAS group ($p = 0.041$) (Table 6).

Discussion

The most important finding of the present study was that intraoperative PSI positioning results in an important rate of outliers. Moreover, the use of PSI was abandoned intraoperatively for seven knees (17.5 %).

Our study first aimed to compare intraoperative cutting guide positioning as evaluated by CAS. Significant differences in component positioning were found, as the PSI cutting blocks were positioned for a higher "femoral flexion cut," "neutral tibial slope cut," and "tibial varus cut" than in the CAS group.

Although postoperative results of PSI-TKA have been thoroughly described in the literature, little data on the ability of PSI to achieve the intraoperative component alignment are available. Two studies have investigated the agreement between Visionaire® PSI-TKA and computer navigation in the sagittal plane [20, 30], and their results are contradictory. Scholes et al. [30] found variations for femoral and tibial components positioning exceeding 3° (compared to preoperative planning) for 17 % of their sample.

Lustig et al. [20] reported that a Visionaire® cutting block would have placed 79.3 % of the sample within ±3° of the preoperative plan in the coronal plane, while the rotational and sagittal alignment results within ±3° would have been 77.2 and 54.5 %, respectively. Theyconcluded that PSI can compare favorably with the accuracy of traditional jigs [11] but does not approach the accuracy achieved with computer navigation [13].

The main issue concerning PSI in the current literature is the rate of intraoperative abandon, and, to the best of our knowledge, this study is the first to describe individually intraoperative component 3D positioning. A PSI cutting block was abandoned in seven cases (17 %) in this series. These results are consistent with those of Conteduca et al. [10] concerning a small series of patients undergoing PSI-TKA controlled by CAS. Scholes et al. [30] reported 27 % of outliers for coronal alignment in their series of 25 CAS-controlled PSI® (Zimmer Inc., Warsaw, IN, USA) TKA. Roh et al. [29] analyzed a series of 50 Signature® (Biomet Inc., Warsaw, IN, USA), PSI guides were abandoned in

Table 5 Postoperative parameters assessed by CT-scan evaluation

	Computer assisted instrumentation	Custom instrumentation	*p* value
Sagittal femoral mechanical angle (°)	91.6 ± 1.4 (88.5 to 93)	92.1 ± 2.4 (86 to 96)	n.s.
Frontal femoral mechanical angle (°)	89.8 ± 1.8 (85.6 to 94.6)	90.2 ± 1.6 (87.3 to 94.7)	n.s.
Frontal tibial mechanical angle (°)	89 ± 2 (83.8 to 93.4)	89 ± 1.8 (84.5 to 92.8)	n.s.
Tibial slope (°)	2.4 ± 1.4 (0 to 6)	2.4 ± 2 (0 to 8)	n.s.
Femoral rotation (°)	2.7 ± 2.5 (−3.3 to 0.2)	3.4 ± 2.3 (−1.6 to 8)	n.s.
Hip-knee angle (°)	179.2 ± 3 (173.2 to 184.1)	179.4 ± 2.5 (175 to 183)	n.s.

Table 6 Rate of postoperative outliers

Outliers	FFMA	SFMA	Femoral rotation	FTMA	Tibial slope
CAS (%)	2.5	5	7.5	5	2.5
CI (%)	0	9	9	6	18.1
Fisher exact	n.s.	n.s.	n.s.	n.s.	0.04*

FFMA frontal femoral mechanical angle, *SFMA* sagittal femoral mechanical angle, *FTMA* frontal tibial mechanical angle, *CAS* computer assisted surgery, *CI* custom instrumentation

eight knees (16 %) during surgery because of malrotation of the femoral components and inverted tibial slope.

Moreover, in a recent study, Victor et al. [35] described a 22 % rate of intraoperative PSI abandonment using four different PSI systems: Signature® (Biomet Inc., Warsaw, IN, USA), PSI® (Zimmer, Warsaw, IN, USA), Visionaire® (Smith and Nephew Inc., Andover, USA), and TruMatch® (DePuy Inc., Warsaw, IN, USA). In their randomized controlled study, the authors used surgical navigation measurement of an intraoperative PSI cutting block position. They concluded that PSI did not improve the accuracy of TKA, and that in the hands of inexperienced surgeons, PSI could cause misalignment, especially in the sagittal plane, necessitating early revision. Our results confirm that PSI will lead to hazardous cutting guide positioning. However, in their control group, Victor et al. [35] did not assess intraoperative implant positioning with CAS, and thus the intraoperative result of their PSI groups cannot be compared to the conventional technique.

Abnormal tibial cuts were responsible for the abandonment of PSI in 3/7 of cases, femoral cuts in 1/7 of cases, and dual abnormalities in 3/7 of patients. We aimed to describe our dropout group (7/40: 17 %) based for each individual on the CAS parameters assessed intraoperatively: abnormal coronal alignment for five patients, abnormal sagittal component positioning for four patient (three abnormal tibial slope), and femoral rotation for three patients were found. An instrumentation switch permitted us to obtain optimal component positioning postoperatively in all but one patient, who was considered as an outlier for coronal alignment (HKA: 174.1°).

Our second aim was to analyze in a per-protocol analysis the postoperative results of the PSI and CAS-TKA groups in terms of component positioning and outliers. Our results showed that even after a 17 % dropout with intraoperative instrumentation changes, the PSI groups had more outliers concerning the tibial slope than the CAS group (18.8 vs 2.5 %).

An excessive or insufficient tibial slope seemed to cause detrimental effects such as limited range of motion [12]. Although some short-term radiographic or CT studies have favored PSI with an acceptable rate of outliers [14, 16, 23], a growing number of controlled studies have reported opposite results. In a retrospective study of 57 Visionaire® TKA, Nunley et al. [25] reported no improvement in the accuracy of the final coronal alignment of the implants when compared to a standard procedure. Victor et al. [35] described in their global series more outliers in the PSI group (64 patients) concerning tibial slope and tibial component coronal positioning than in a conventional TKA group. Tibial slope issues was also pointed out in Woolson et al.'s [36] randomized controlled study as the rate of outlier was 32 % in the PSI/Tru-match TKA group (30 patients) and 8 % in the conventional TKA group.

Potential sources of error in Visionaire® have been studied before [20, 33]. For the authors, [36] a cutting block design may include image acquisition and interpretation of the 3D image using MRIs of the knee joint limited to a 22 cm field of view explaining the variation between the planned sagittal alignment and the operative measurements of the femoral and tibial parameters. Another potential reason for inaccuracy could be the error by the surgeon during the application of the PSI on the bone, even if the fitting was reportedly good in every case for the 40 patients in our study. Adaptation, such as the recently described CT-based and potentially more precise custom instrumentation [3, 17], should be performed before proposing this new tool to inexperienced surgeons.

Our study has limits, as it assumes that CAS provides accurate information on intraoperative parameters. The accuracy of navigation has been previously described within 1° or 1 mm [19, 28], superior to radiographs [15] or CT [34]. Thus, in a previously reported comparison of CAS versuss standard instrumentation, CAS achieved alignment within ±3° of neutral mechanical axis in 75 % of TKAs [5].

Despite these limits, previously described unsatisfactory intraoperative and postoperative results of MRI-based PSI are confirmed by our study. To the best of our knowledge, our series is the first to describe the intraoperative reason for PSI abandonment compared to CAS-instrumented TKA, which is our standard technique and the postoperative consequences of conversions. As the rate of tibial slope intraoperative and postoperative outliers is substential in our study, ancillary modifications should be performed before proposing PSI to inexperienced surgeons.

Conclusion

An important number of hazardous cuts and intraoperative and postoperative outliers were associated with PSI in the present study. For more than 15 % of our PSI-TKA patients, a conversion to conventional CAS instrumentation was necessary. This argument outlines the further need of evaluation and modification of PSI ancillaries.

Conflict of interest P. Beaufils is educational consultant for Zimmer and Smith & Nephew. N. Pujol is educational consultant for Zimmer. M. Ollivier, Q. Tribot-Laspiere, J. Amzallag and P. Boisrenoult declare that they have no conflict of interest.

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