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ORIGINAL PAPER

Patient-specific computed tomography based instrumentation in total knee arthroplasty: a prospective randomized controlled study

Andrzej Kotela · Ireneusz Kotela

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Abstract
Purpose The aim of this study was to compare radiological results of total knee arthroplasties (TKAs) performed with patient-specific computed tomography (CT)-based instrumentation and conventional technique. The main study hypothesis was that CT-based patient-specific instrumentation (PSI) increases the accuracy of TKA.
Methods A prospective, randomized controlled trial was carried out between January and December 2011. A group of 112 patients who met the inclusion and exclusion criteria were enrolled in this study and randomly assigned to an experimental or control group. The experimental group comprised 52 patients operated on with the aid of the Signature™ CT-based implant positioning system. The control group consisted of 60 patients operated on using conventional instrumentation. The radiographic evaluation of implant positioning and overall coronal alignment was performed 12 months after the surgery by using standing anteroposterior radiographs of the entire lower limb and standard lateral radiographs.
Results Of the 112 patients initially enrolled for the study, 95 were included in the subsequent analyses. There were no statistically significant differences between groups in respect to coronal and sagittal component positioning and overall coronal alignment, except for frontal tibial component positioning. For this parameter, better results were obtained in the control group, with borderline statistical significance.
Conclusions Our study did not reveal superiority of the CT-based PSI system over conventional instrumentation. Further high-quality investigations of patient-specific systems are absolutely indispensable to assess their utility for TKA. In our opinion, the surgeon applying PSI technology is required to have advanced knowledge and considerable experience with the conventional method.

Keywords Knee · Arthroplasty · Malalignment · Patient-specific instrumentation

A. Kotela (✉) · I. Kotela
Department of Orthopedic Surgery and Traumatology, Central Research Hospital of Ministry of Interior, Wołoska 137, 02-507 Warszawa, Poland
e-mail: andrzejkotela@op.pl

A. Kotela
Department of Orthopaedics and Rehabilitation, 2nd Faculty of Medicine, Medical University of Warsaw, Warsaw, Poland

A. Kotela · I. Kotela
Department of Physiotherapy, Jan Kochanowski University of Humanities and Sciences Kielce, Kielce, Poland

Introduction

Total knee arthroplasty (TKA) is a method of proven efficacy in the treatment of advanced osteoarthritis of the knee joint. It can eliminate the progressive pain and improve the quality of patient's life and therefore remains one of the most frequently performed orthopaedic procedures [1]. The demand for primary TKA is projected to grow by 673 % to 3.48 million procedures by 2030 in USA alone [2]. The prerequisites for stable positioning of an implant are restoring neutral limb alignment and establishing adequate soft tissue balance [3, 4]. Malalignment may be related to pain, stiffness, instability, wear, osteolysis and increased risk of loosening [5–8]. It has been demonstrated that a varus or valgus malalignment of the mechanical axis of the operated limb > 3° is associated with up to 20 % higher incidence of implant loosening [9, 10]. With currently available conventional instrumentation, malalignment > 3° is seen in ~30 % of primary knee arthroplasty procedures [11, 12].

The number of different types of endoprostheses on the market keeps growing, with increasingly newer tool sets designed to facilitate correct implantation. One particular

modern solution for knee arthroplasty involves systems in which intraoperative navigation is based on single-use guides fashioned for the specific patient. The main idea behind patient-specific instrumentation (PSI) is that knee-joint arthroplasty procedures can be individualised, with benefits including precise realignment of the normal mechanical axis of the operated lower limb, minimised resection of the patient's bony tissue, reduced surgical times, simplified instrumentation, reduced peri- and postoperative blood loss, no need of femoral medullary cavity reaming and a reduced rate of thromboembolic complications [3, 13–16]. A recently published survey showed a considerable interest in PSI among surgeons, confirmed by the massively increasing numbers of PSI-aided procedures performed in Europe and worldwide; PSI use for TKA increased globally by an average of 1.5 times between 2011 and 2012 [17].

The efficacy of all new solutions introduced into clinical practice needs to be confirmed in clinical studies, especially in the presence of such massive interest in a new method. In the case of CT-based PSI instrumentation, this need is particularly evident, as there is very limited experience with these devices in the world literature. To our knowledge, this is the fifth study to assess radiographic outcomes of TKA performed with CT-based PSI [14, 18–20]. The aim of this study was to compare radiological results of TKAs performed with CT-based PSI and conventional technique. The main hypothesis formulated in this study was that CT-based PSI increases the accuracy in TKA.

Materials and methods

The study was performed in the Department of Orthopedic Surgery and Traumatology of Central Research Hospital of the Ministry of the Interior in Warsaw. One hundred and twelve consecutive patients scheduled to undergo TKA were enrolled in this prospective randomised controlled trial between January and December 2011. The study was performed in accordance with its protocol, which was approved by the ethical review board. All patients fulfilled inclusion and exclusion criteria specified in Table 1. Informed consent was provided by all patients.

Participants were divided into two groups using a simple randomisation procedure. Group 1 consisted of 52 patients who underwent TKA performed with the use of CT-based PSI (Signature™ Personalized Patient Care System; Biomet Inc, Warsaw, IN, USA). Group 2 consisted of 60 patients operated with conventional instrumentation. There were no significant differences between groups in preoperative demographics, clinical and radiographic data (Table 2). All operations were performed by a single senior surgeon.

No bilateral TKA procedures were performed in this study. In all cases, the same type of uncemented cruciate-retaining prostheses were implanted (Vanguard™ Complete Knee System; Biomet Inc. Warsaw, IN, USA), without resurfacing the patella. The process by which Signature™ instrumentation is produced and used has been described precisely in previous studies [3, 13, 14, 21–23]. Briefly, each patient in group 1 obtained a preoperative CT scan of the knee joint, along with

Table 1 Inclusion/exclusion criteria

Inclusion criteria
• primary end-stage knee osteoarthritis
• primary uncemented TKA
• implant: Vanguard™ (Biomet), cruciate retaining
• age >18 years
• provision of written informed consent
Exclusion criteria
• nonosteoarthritic conditions as reason for operation (e.g. rheumatoid arthritis)
• comorbidities that might affect bone quality (e.g. osteoporosis)
• a history of previous surgery or trauma to the affected knee within 12 months preceding the study
• advanced osteoarthritis and other conditions of large joints precluding reliable assessment of the operated knee joint
• cognitive disorders resulting in suboptimal co-operation of the patient
• a different operator than the person determined by the protocol
• failure of the patient to present for a follow-up examination
• incomplete medical recordso

Table 2 Patient demographics, baseline clinical status, preoperative limb deformities: a between-group comparison

Patient characteristics	Group 1 (PSI)	Group 2 (Control)	*P* value
Gender: male/female	16/33	13/33	n.s.
Operated side: left/right	21/28	20/26	n.s.
Age [years][a]	66.1±8.4	68.6±9.9	n.s.
Weight [kg][a]	82.0±14.5	80.0±15.1	n.s.
Height [m][a]	1.7±0.1	1.6±0.1	n.s.
BMI [kg/m²][a]	30.0±4.6	29.6±5.6	n.s.
KSS knee[a]	28.5±13.6	33.7±16.8	n.s.
KSS Function[a]	39.4±18.8	42.8±18.4	n.s.
WOMAC[a]	59.5±11.5	58.3±14.5	n.s.
HKA [*n*][a, b]	188.2±7.0	188.9±7.1	n.s.
HKA outlier±3° [%]	96.6	86.7	n.s.
ZMA outliers [%]	96.7	89.3	n.s.

PSI patient-specific instrumentation, *CI* conventional instrumentation, *SD* standard deviation, *BMI* body mass index, *KSS* Knee Society Score, *WOMAC* Western Ontario and McMaster Universities Arthritis Index, *HKA* hip–knee–ankle angle, *ZMA* zone of mechanical axis, *n.s.* not significant

[a] Data presented as mean±SD

[b] Positive values indicate varus alignment.

several slices through the hip and ankle (using the Signature™ system manufacturing protocol). Based on CT data and surgeon preferences, virtual 3D models of the femur and tibia were created, and pre-operative software planning was developed and sent to the surgeon for review and approval. Subsequently, rapid prototyping technology was used to fabricate disposable custom guides for intra-operative navigation. Patient-specific guides, carefully positioned over previously cleaned articular surfaces, determined accurate pin placement for the standard resection blocks during the operation [3]. For all patients from group 1 the following TKA preferences were predetermined: femur varus/valgus 0° (perpendicular to mechanical axis), flexion/extension 3° of flexion, rotation 0° (parallel to transepicondylar axis); tibia varus/valgus 0° (perpendicular to mechanical axis), posterior slope 3°, rotation 0° [from anteroposterior (A/P) axis].

In group 2 all patients were operated on with traditional jig-based instrumentation; extramedullary instruments were used for the tibial component, with an alignment goal of 0° varus/valgus, and and intramedullary rod using a 5°- to 7°-valgus resection cut for the femoral side. The target was 3° of flexion for the femoral and tibial components in the sagittal plane, 0° of tibial component rotation from the A/P axis, and a femoral component rotation parallel to the surgical transepicondylar axis.

All procedures in both groups were performed through the standard approach with medial parapatellar arthrotomy, the use of tourniquet until prostheses were implanted and administration of antibiotics and prophylaxis against venous thrombosis. Postoperative management was identical for both groups. Rehabilitation was commenced on the first postoperative day. At discharge, patients were able to perform at least 90° flexion of the knee joint and moved about efficiently using elbow crutches. Full-length standing AP radiographs and non-weight-bearing lateral radiographs were carried out 12 months after the surgery to determine the alignment of prosthesis components. The long-plate radiographs used in the study were obtained with an Axiom Aristos digital radiographic capture device from Siemens, using the Ortho system. Patients were placed 300 cm away from the X-ray tube, in a standing position, with the lower limbs fully extended at the knee. It was emphasised that the patellae were directly facing the source of radiation. Exposure parameters were automatically selected by the radiography system depending on the physical properties of the patient. The radiographs were computer processed to obtain uniform and real images of the lower limbs in all patients. If a radiograph did not ensure that measurements could be performed correctly (e.g. when the lower limb of interest was externally rotated), another image was obtained. All measurements of radiographic details were performed using the graphic package AutoCad® 2010. The evaluation of coronal and sagittal implant positioning was performed by assessing relevant angles and determining the zone of the mechanical axis (ZMA), as shown in Figs. 1 and 2.

Radiographs were assessed by an independent orthopaedic surgeon for two angle measurements. The observer was blinded to surgical technique. The second set of measurements was carried out two weeks after the first. To evaluate observer reliability, the interclass correlation coefficient (ICC) was calculated and grated using previously described semiquantitative criteria: excellent $0.9\leq (p\leq 1.0)$, good $0.7\leq (p\leq 0.89)$, fair $0.5\leq (p\leq 0.69)$, low $0.25\leq (p\leq 0.49)$ and poor $0.0\leq (p\leq 0.24)$ [13] . The ICC is proven to be excellent for all measured angles. Statistical analysis (group comparisons) was performed using Fisher's exact test for qualitative variables and Mann–Whitney U test for quantitative variables (SAS, Inc., Chicago, Ill). $P<0.05$ was considered statistically significant.

Results

Of the 112 patients initially enrolled for the study, 12 did not report for a follow-up examination, and another five had incomplete medical records. As a result, 95 patients were included in the subsequent analyses. Mean hip–knee–ankle angle (HKA) was 183.6±4.2° (176–195°) in group 1 and 182.6±3.0° (175–189°) in group 2. A varus or valgus malalignment of the operated limb's mechanical axis > 3° was seen in 48.98 % of patients in group 1 and 30.43 % of patients in group 2 (Table 2). There were no statistically significant differences between groups in respect of HKA angle.

The ZMA intersected with the central zone of the tibial base plate in 57.1 % of group 1 and 76.1 % of group 2. Varus malalignment of the knee joints was greater in the group 1, with the postoperative mechanical axis intersecting with zones II and IV in 40.8 % of patients vs. 23.9 % in the group 2. Notably, in group 2, postoperative mechanical axis passed through zones I and II in all patients. Patients in group 1 were those with greater postoperative varus and valgus malalignment of the limbs, in whom the mechanical axis intersected with zones III and IV of the implant. In this regard, the differences between groups were not statistically significant (Fig. 3).

There were no other statistically significant differences between groups in terms of implant alignment, except from the frontal tibial component (FTC) angle. Mean FTC angle was 91.8±3.1° (83–99°) in group 1 and 91.0±2.3° (83–95°) in group 2. These values fell within the normal range (90±3°) for 61.22 % of cases in group 1 and 80.43 % of cases in group 2. Group 1 displayed a more marked tendency towards varus positioning of the tibial component than did group 2, with percentages of patients in whom the FTC angle > 93°

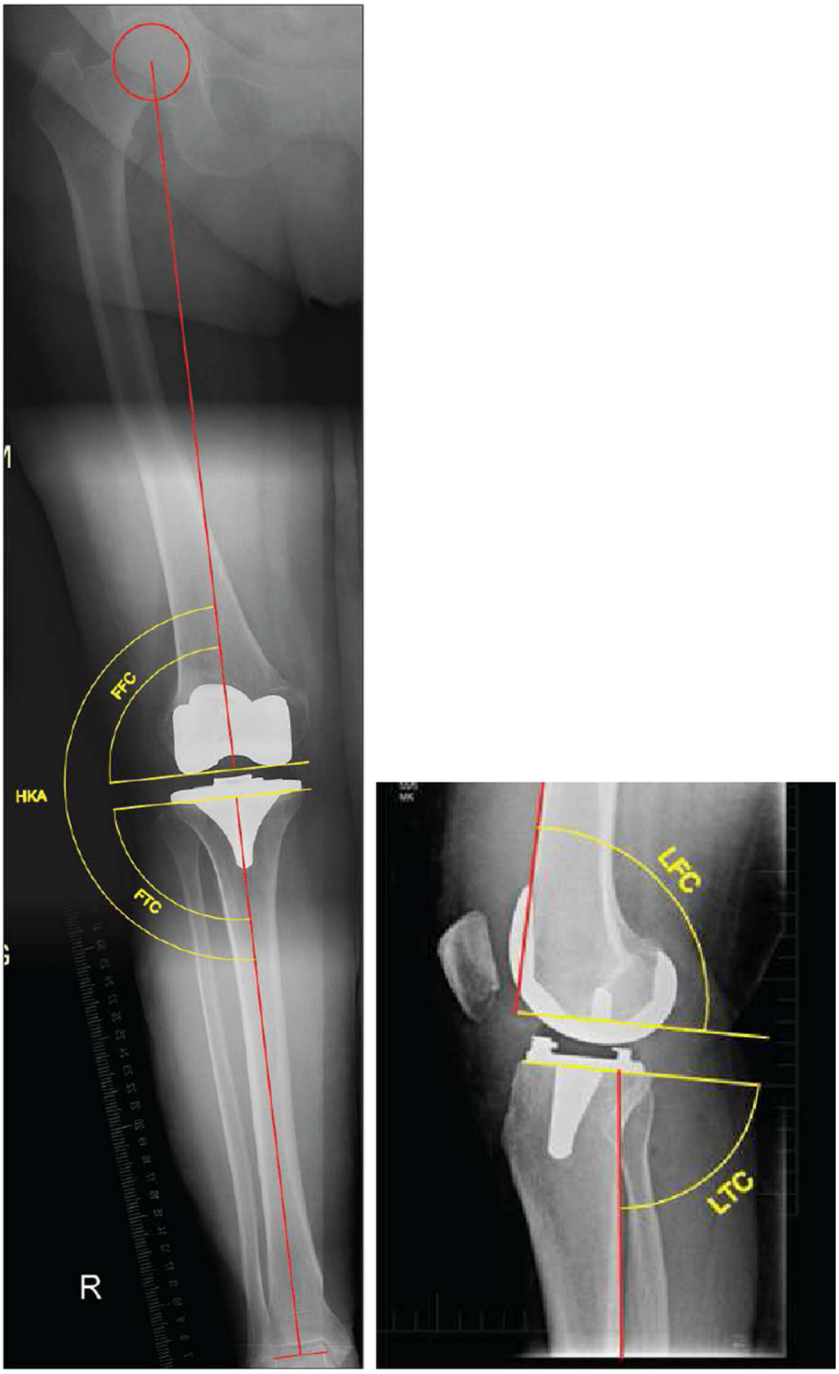

Fig. 1 To assess coronal and sagittal implant positioning, the following angles were determined: hip–knee ankle (*HKA*), frontal femoral component angle (*FFC*), frontal tibial component angle (*FTC*), lateral femoral component angle (*LFC*) and lateral tibial component angle (*LTC*). The target values for these angles were defined as 180°, 90°, 90°, 87° and 87°, respectively. A deviation of > 3° was considered an outlier

amounting to 32.65 % in group 1 and 17.39 % in group 2. These results differed significantly between groups, but statistical significance was borderline ($p<0.0458$). The findings described above are summarised and complemented in Table 3.

No conversion to traditional instrumentation was reported in group 1. Nevertheless, in 26.5 % of patients, the position of the tibial guide had to be changed at least once after the pins had been placed; the figure for the femoral guide was 4 %.

Discussion

Although there is a significant interest in PSI for TKA, the number of papers on this issue is still very limited, with only a few randomised trials available [17]. As a result, the necessity of performing further high-quality investigations has been previously emphasised by other authors [14, 17]. Our study was designed to verify the utility of CT-based Signature™ PSI for precise implant positioning.

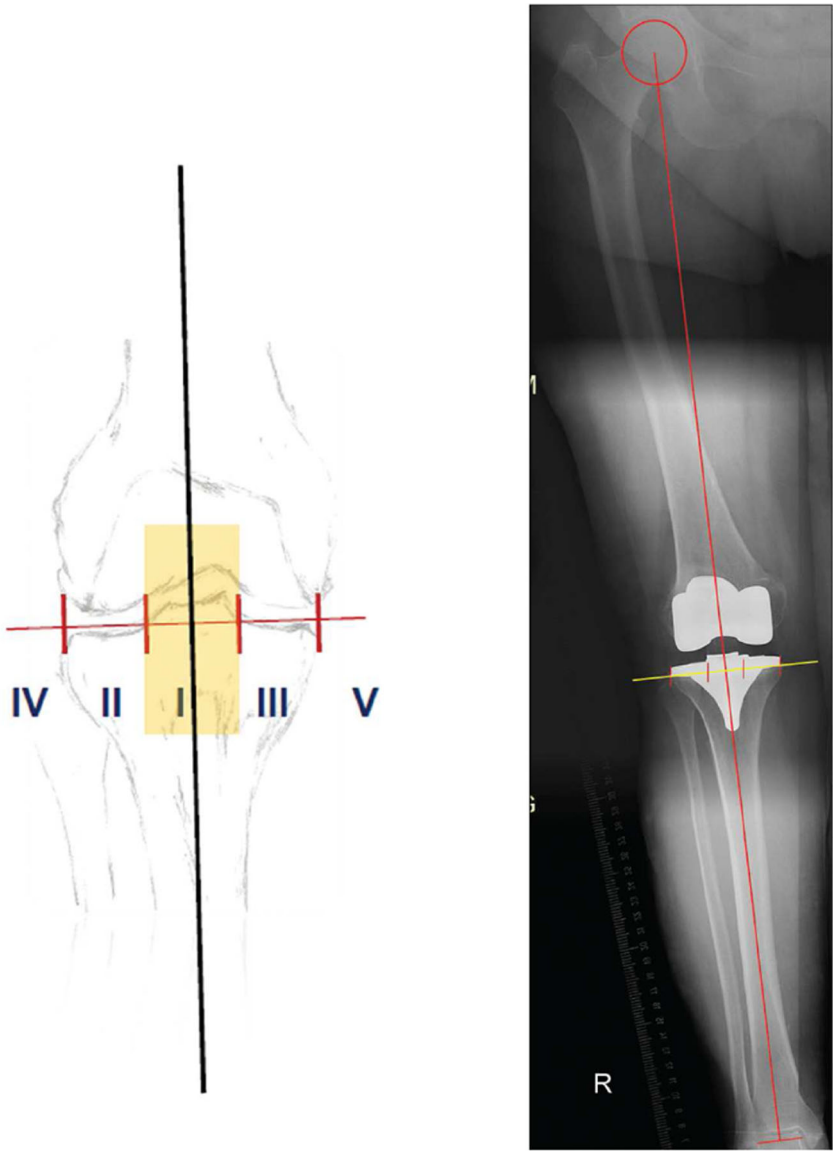

Fig. 2 Determination of the zone of mechanical axis (*ZMA*), i.e. the zone of the tibial base plate (divided into three equal regions) that intersect with the mechanical axis of the limb [24]; intersection with zones II–V was considered an outlier

In general, results of studies on PSI are equivocal [8, 15, 25–28]. We believe that results obtained with one particular PSI system are not automatically applicable to other systems and should not be generalised [14, 23]. At the moment, several companies offer various PSI systems for TKA. Custom-made guides may be designed to align components along the mechanical axis or in relation to a natural transcylindrical axis [8, 29, 30]. There are pinning systems that determine accurate pin placement for the standard resection instrumentation, and cutting guides with immediately integrated resection blocks [3, 17, 29]. Particular systems differ in terms of shape and contact areas between the guide and bone. Finally, there are magnetic resonance imaging (MRI)- and CT-based custom guides available[17], and in some systems, pre-operative standing AP X-ray of the entire leg is required to fabricate PSI [26]. In the Signature™ system, which was the subject of this paper, pinning guides are used to restore mechanical axis, and both MRI and CT scans may be used. In our study, only CT-based guides were used.

The leading objective of this study was to verify whether CT-based PSI increases TKA accuracy, especially in terms of mechanical axis restoration. We found 48.98 % outliers for HKA in the PSI group and 30.43 % in the control group. Despite this gap, there was no statistically significant difference between groups for this parameter. Boonen et al. [22] compared 38 radiographs of patients operated using MRI-based Signature™ PSI to 35 radiographs of patients operated with the conventional method and found 28.95 % and 45.71 % outliers for HKA, respectively. Admittedly, they obtained better results in their PSI group, but in comparison with a control group with malalignment in almost every other patient.

These preliminary findings were confirmed in a multicentre, randomised control trial performed by Boonen

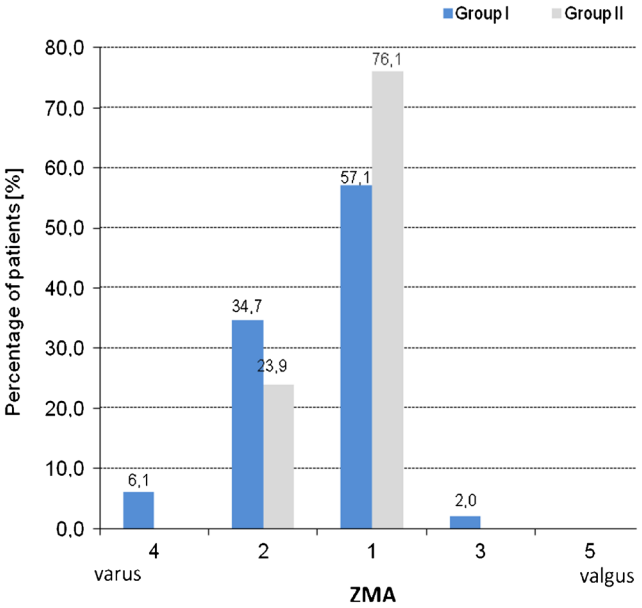

Fig. 3 The zone of mechanical axis (ZMA): postoperative histogram

et al. [31], who found no statistically significant differences between MRI-based Signature PSI and traditional instrumentation in terms of obtaining a neutral mechanical axis and individual component alignment in the frontal plane. Nunley et al. [8] compared coronal alignment measurements after TKA performed using traditional instrumentation and two different types of custom-made guides: Signature™ MRI-based PSI, and OtisMed™ MRI-based PSI (manufactured to restore kinematic alignment). They found no differences in HKA angle or ZMA between TKAs performed using Signature™ PSI and conventional instrumentation, and there was a significantly greater number of outliers in the OtisMed™ PSI group (HKA 18 % vs. 16 % vs. 44 %; ZMA 32 % vs. 40 % vs. 64, respectively). Contrary results were obtained by Ng et al. [32], who revealed statistically significant superiority of PSI over traditional instrumentation. They compared 105 TKAs performed with MRI-based Signature™ PSI to 55 TKAs performed with manual instrumentation and obtained 9 % vs. 22 % of outliers in respect to HKA angle, respectively. Nam et al. [13] performed a nonrandomised, retrospective study to compare the alignment accuracy of MRI-based Signature™ PSI to an imageless computer-assisted-surgery (CAS) system. They found that 70.7 % of patients operated on with PSI had an alignment within 3° of neutral mechanical axis vs. 92.7 % in the CAS group ($p<0.02$). In their study, PSI was not able to obtain the same degree of accuracy as the CAS system with respect to both the tibial component and overall lower-extremity axis. Of note, the results obtained in the PSI group were comparable with most reports of TKA performed using conventional instrumentation.

To our knowledge, there are only four reports assessing CT-based PSI in the literature, and one of them pertains to Signature™. In the study by Roh et al. [14], radiographic outcomes of the CT-based Signature™ PSI group were not statistically different from those of the conventional instrument group across all parameters measured, with 12 % vs. 10 % of outliers in respect to HKA, respectively. Koch et al. [18] assessed the radiological results of 301 TKAs performed with CT-based McKnee© PSI and found significant accuracy of implant position in all planes, with 14.4 % of outliers for HKA angle. Barrett et al. [20] compared postoperative mechanical alignment achieved using CT-based TruMatch™ PSI with conventional and CAS instruments; postoperative mechanical alignment was comparable across groups. Lastly, Ensini et al. [19] analysed and compared the accuracy of CT-based MyKnee® PSI and MRI/X-ray-based Visionaire® PSI. They found 37 % and 18 % of outliers for postoperative mechanical axis, respectively, with no statistically significant differences between groups.

The second method for assessing overall coronal alignment involved identifying the ZMA. In a study by Jeffery et al. [10], the percentage of loosened implants at eight years of follow-up

Table 3 Comparison of postoperative radiographic results

Variable	Mean±SD (range)		Outliers		*P* value
	PSI *n*=49	CI *n*=46	PSI *n*=49	CI *n*=46	
HKA	183.6±4.2° (176–195°)	182.6±3.0° (175–189°)	48.98	30.43	n.s.
FFC	91.2±2.4° (85–97°)	91.5±2.4° (86–97°)	16.33	26.09	n.s.
FTC	91.8±3.1° (83–99°)	91.0±2.3° (83–95°)	38.78	19.57	0.0458
LFC	84.0±4.2° (77–96°)	83.3±3.9° (67–90°)	42.87	47.82	n.s.
LTC	85.9±3.8° (73–91°)	87.9±2.6° (83–93°)	28.57	19.56	n.s.
ZMA			42.9	23.9	n.s.

PSI patient-specific instrumentation, *CI* conventional instrumentation, *SD* standard deviation, *HKA* hip–knee–ankle angle, *FFC* frontal femoral component angle, *FTC* frontal tibial component angle, *LFC* lateral femoral component angle, *LTC* lateral tibial component angle, *ZMA* zone of mechanical axis, *n.s.* not significant

in patients in whom the mechanical axis passed through the central part of the tibial base plate was 3 %, compared with as much as 24 % in the remaining patients, who demonstrated a more severe malalignment of the mechanical axis. To our knowledge, our study is the first report on ZMA in patients operated on with CT-based PSI.

In our study, more good results (zone I) were obtained in the control group (76.1 % vs. 57.1 %). Although the difference did not reach statistical significance, the experimental group included patients with greater postoperative varus and valgus deviation of the limb, and the difference in the percentage of acceptable ZMA outcomes between groups was nearly 20 %. Ng et al. [32], in a study of 569 patients operated on using MRI-based Signature PSI and 155 patients who underwent a conventional procedure, reported 88 % vs. 78 % of good outcomes, respectively ($p<0.0001$). It is clear that both studies showed strikingly different outcomes in patients operated with the Signature™ system, whereas outcomes in patients who underwent traditional TKA were nearly the same. In our opinion, these findings may raise the question of superiority of MRI-based PSI over CT-based PSI. The correct use of guides designed using CT data requires the removal of soft tissues and cartilage from the future guide-bone contact areas. This is necessary because of the limitations of CT, which does not sufficiently visualise all articular structures, whereas MRI data allow inclusion of soft tissue in the design of patient-specific guides. Inaccurate removal of all soft tissues in the area of guide supports may hinder its correct placement. As a result, MRI-based Signature™ guides may match the profile of patient anatomy much more closely; they are also much easier to position. Obviously, a definite answer to this question requires a separate randomised trial. It should be also noted that, unlike CT, MRI does not involve the use of potentially harmful X-radiation, but MRI is more expensive and access is still limited in many countries.

In a correctly seated implant, the plane of the implanted knee joint is perpendicular to the mechanical axis of the lower limb, and the loading force on the tibial component is evenly distributed. Varus or valgus positioning of any of the implant's components produces an abaxial load on the tibial component, which causes a biomechanical problem similar to that seen in deformed osteoarthritic joints. This leads to premature wear of the polyethylene insert of the implant and implant loosening. In turn, posterior slope of the tibial plate affects postoperative range of motion in the joint but also impairs anteroposterior stability of the implant and tension of the posterior cruciate ligament. In our material, the use of the Signature™ system resulted in more precise positioning of femoral components (in a nonsignificant manner) and less precise positioning of the tibial components (with a borderline significance). Patients operated on using Signature™ guides demonstrated a more marked tendency towards varus positioning of the tibial component with excessive posterior slope. By contrast, Boonen et al. [22] found a statistically significant difference in the percentage of outliers for the frontal femoral component (FFC), lateral femoral component (LFC) and lateral tibial component (LTC) angles. In their study, designed to compare MRI-based Signature™ PSI with standard instrumentation, better results were obtained with PSI for all of the above angles. Less optimistic results were observed in a multicentre, randomised control trial performed by Boonen et al. [31], who found a statistically significant difference in outliers for the LFC angle, with a higher percentage of outliers in the MRI-based Signature™ PSI group than in the conventional group (65 % vs. 49 %, respectively). Stronach et al. [23] reported inadequate fit of MRI-based Signature™ PSI. In their study, the femoral guide did not fit the bone structures precisely in 12 % and tibial guide in 5 % of PSI patients,. The authors expressed concern that the guides may not be an accurate reflection of patient anatomy and about the presence of limitation in any of the multiple steps involved in the PSI production. In our series, some intra-operative observations were also made. The Signature™ femoral guide fitted the distal femoral end completely in most cases, and its placement was not difficult. At the same time, determining correct placement for the tibial guide was subjective and ambiguous in many cases; in 26.5 % of patients, the position of the tibial guide was changed at least once after the pins had been put in place. On the basis of these intra-operative observations, it may be supposed that misplacement of the Signature™ guides (and especially the tibial component) might have affected the precision of prosthesis seating and final outcomes.

At present, the gold standard for assessing the mechanical axis is by using standing radiographs of the entire lower limb (long plate) [33]. The correct acquisition of such images may be difficult, especially in patients qualified for knee arthroplasty, as pain and limitation of motion of the affected joint both before and after surgery may make it difficult to assume an appropriate position for the study.

The effect of body position on results of radiographic details has been discussed in a large number of studies. Hunt et al.[34] investigated the correlation between rotational positioning of the foot and marking of the mechanical axis of the lower limb in a radiograph. They found that when measured at different foot positions (15° external and internal rotation), the mechanical axis deviated by as much as 3.59°. Specogna et al. [35] noted divergent measurement results when the lower limbs did not bear weight uniformly, finding a mean varus deviation of 7.1° in a group of patients with uniform loading of the lower limbs compared with 8.7° in patients who stood on both lower limbs but only one bore the body weight. Langenbach et al. [36] found that standing radiographs were superior to recumbent images, and Lonner et al. [37] stressed a significant influence on results of even slight flexion at the knee.

In our study, all patients assumed a predefined body position for radiographic examination, according to a previously developed protocol for acquiring long-plate radiographs, to allow later comparisons of radiographs. If a radiograph did not guarantee correct measurements, the acquisition was repeated. All images were acquired with a digital capture device, and measurements were obtained using graphic software. The validity of computer-aided assessment of radiographs has been confirmed by, among others, Hankemeier et al. [38].

Another issue that merits a comment is the matter of surgeon experience with patient-specific guides. Before starting the study, the operator attended several courses and had the opportunity to assist in operations performed by surgeons with considerable experience with Signature PSI; in more than ten operations, he was responsible for positioning the pinning guides. In our trial, the accuracy of implant positioning did not improve throughout the study period, and all initial cases were therefore intentionally included in the analyses.

This study has several strengths and limitations. Strengths are, above all, it's randomised and controlled design. All measurements were performed twice by one observer blinded to surgical technique used, and observer reliability was proved to be high for all measured angles. As it was the first series of CT-based PSI TKAs in Poland and CT-related costs hindered execution of our study, population size of both groups should be viewed as relatively high, especially in comparison with most other studies. Although all procedures were performed by one surgeon experienced in TKA with previous training in PSI Signature™ method, we acknowledge the potential influence of the learning curve on our findings. Results of this paper are limited to the coronal and sagittal plane and do not take into account rotational alignment and clinical outcomes. Finally, only one CT-based PSI system was used, and the results may not apply to other CT- or MRI-based positioning guides.

With 30.43 % of knees within the ± 3° range in the conventional group, our results are just in line with the average rate of outliers obtained in the HKA angle by other authors [11, 12]. In our opinion, this confirms that the study followed a correct procedure and adds credibility to our findings. Although there was no statistically significant difference between cohorts, our findings, with 48.98 % of outliers in HKA angle and 42.9 % of malalignments in ZMA in the PSI group are puzzling. Similarly to Boonen et al. [31], we have no firm explanation as to why the alignment in our series in the PSI group was not superior to the conventional method, and why literature data are so discrepant. Nevertheless, against such a backdrop, we believe our article is a compelling contribution to the discussion on the utility of PSI systems.

Our study did not reveal the superiority of CT-based PSI over conventional instrumentation. Further high-quality investigations of various patient-specific systems are absolutely indispensable to assess their utility for TKA. The patient-specific approach simplifies instrumentation and surgical technique, and the possibility of analysing interactive, 3D software data enables more accurate preparation for surgery. We suppose that the idea of improving the precision of implant positioning with the use of disposable, patient-specific positioning guides, is a step in the right direction. However, this new direction needs further refining. In our opinion, the surgeon using PSI is required to have advanced knowledge and considerable experience with the conventional method.

Conflicts of interest None.

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