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Comparison between navigated reported position and postoperative computed tomography to evaluate accuracy in a robotic navigation system in total knee arthroplasty

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ABSTRACT

Background: Computer navigation increases reproducibility compared to non-navigated total knee arthroplasty (TKA). Robotics navigation is a branch of computer navigation technology that might further improve accuracy of implant placement. The aim of this study is to assess the accuracy achieved in TKA with a robotic navigation system.
Methods: One hundred seventy three knees. System studied: Omni navigation System (OMNI, Raynham, MA). Navigated femoral and tibial cuts were compared to postoperative computed tomography (CT). Measurements reviewed: femoral coronal alignment (FCA), femoral sagittal alignment (FSA), femoral rotational alignment (FRA), tibial coronal alignment (TCA), tibial sagittal alignment (TSA) and hip–knee–ankle (HKA) angle. Statistical analysis was made using R.
Results: The mean differences between the navigated reported and the CT positions were: FCA: $0.1 \pm 1.2°$ more varus ($P = 0.58$), FSA: $1.5 \pm 0.3°$ more flexed ($P < 0.001$), FRA: $0.0 \pm 1.7°$ ($P = 0.93$), TCA: $0.7 \pm 1.1°$ more varus ($P < 0.001$), TSA: -1.3 ± 1.5 more negative slope ($P < 0.001$), HKA angle: 0.4 ± 2.4 more varus ($P < 0.049$).
The percentages of concordance inside a three degree difference were: FCA: 98% (169 knees), FSA: 100% (173 knees), FRA: 94% (162 knees), TCA: 99% (171 knees), TSA: 93% (161 knees) and HKA angle: 83% (144 knees).
Conclusions: The current study showed that the robotic navigation system studied is highly accurate regarding final implant positioning for FCA, FRA and TCA. It has less accuracy in FSA, TSA and the HKA angle.

1. Introduction

For patients with disabling knee osteoarthritis, total knee arthroplasty (TKA) is widely considered a successful management option [1]. Following TKA, most patients can expect long-term reduction in pain and improvements in quality of life [2,3], and between 72% and 86% of patients report that they are satisfied with their postoperative outcome [4–6].

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The stepwise improvements in implant technology and surgical techniques have contributed to broad success with TKA, though a significant portion still fail to experience their desired outcome. This is a particular problem among the most active, younger, and higher-demand patients [7].

In a recent study from more than 60,000 revision TKAs in the USA, infection was identified as the leading cause of revision (25.2%), with mechanical loosening (16.1%), and implant failure/breakage (9.7%) following [8]. The most important determinants of failure secondary to prosthesis loosening are poor positioning of the prosthesis and subsequent malalignment of the postoperative lower limb [9]. A recent meta-analysis found that postoperative varus (more than three degrees of deviation from neutral alignment in the coronal plane) significantly increased the risk of TKA failure [10]. Greater bone stress on the medial side of the knee in failed arthroplasties suggests that lower-limb malalignment alters the distribution of forces across the knee and that this, in turn, accelerates prosthesis failure [11]. This belief has been challenged by other studies showing that 'outliers' have no more risk of revision surgery compared to 'aligned' TKAs [12,13]. Recently, a trend of a more 'kinematic' TKA has been proposed by some authors, showing that an 'outlier' TKA has no clinical differences compared to a 'mechanical' TKA at short term follow-up [14]. However, there is a paucity of data regarding long-term follow-up of these patients, in particular regarding survival of the TKA [15].

Whatever the goal that the surgeon is looking for, one of the most important goals in TKA surgery is the optimal implant positioning. Strategies that increase the accuracy of prosthesis positioning may improve long-term prosthesis survival rates for patients, as well as increase the chances of a satisfied patient.

Computer-assisted navigation was introduced as an adjunct to TKA surgery with the potential to improve positioning and alignment of the TKA prosthesis [1]. The first computer-assisted knee replacement was performed almost 20 years ago [16–18].

Computer-assisted navigation can assist the surgeon in aligning the cutting instruments to make the appropriate bone cuts for implant positioning, as well as checking the cuts that have been made and the resulting alignment of these components and the limb. This can take additional time, and errors can still occur with the positioning of the jigs and delivery of these cuts, resulting in mal-position of the final components. These limitations have led to the development of different robotic systems (with different degrees of autonomy) to facilitate the preparation of bone surfaces. The term 'robot' here refers to any mechanical device that is accurately controlled by a computer with use of intelligent software [19].

The OMNIbotics system (OMNIlife Science, Raynham, MA, USA) is an imageless passive robotic TKA system that incorporates the iBlock robotic cutting guide and the NanoBlock cutting guide. The OMNIbotics computer station is an imageless closed software that uses bone morphing technology to generate a unique three dimensional (3D) digital model of the patient's knee following intraoperative registration of the anatomical landmarks by the surgeon. The system allows for planning of implant position and size intraoperatively as well as to visualize the planned bone cuts before they are made. The iBlock robotic cutting guide is a motorized, bone-mounted cutting guide that positions a saw guide for all femoral resections according to the surgeon's plan, allowing the surgeon to then complete the resections with a standard oscillating saw. The system is complemented with the NanoBlock, a separate, adjustable, resection block used for tibial resection.

There are, however, few publications investigating the accuracy of this robotic system in the literature, such that it is difficult to determine its efficacy.

The aim of this study was to assess the in vivo accuracy achieved with the iBlock and NanoBlock cutting systems using postoperative computed tomography (CT) scans as the final reference. Our hypothesis was that the system produces highly accurate bone cuts.

2. Material and methods

The study was a retrospective review of 173 consecutive knees in which a TKA was performed by a single surgeon between April 2015 and April 2018. The robotic navigation system utilized was the iBlock (Figure 1) for the femoral cuts and the NanoBlock for the tibial cuts. Each femoral and tibial cut performed during the intraoperative process was measured with the navigation system and recorded. These measurements were then compared to postoperative CT scans for each case (Figure 2).

2.1. Surgical technique

Patients were in supine position in an operating-theatre table. A tourniquet was used in all cases. A midline skin incision was made and a medial parapatellar arthrotomy was performed to expose the articular surfaces, without patellar eversion. The infrapatellar fat pad, meniscus and anterior cruciate ligament were resected to obtain better exposure. Percutaneous pins were placed distal to the incision in the anteromedial tibia for the tibial navigation array, and the femoral array was attached to the medial side of the femur through the surgical incision via two five-mm-diameter cancellous bone screws. This array provided the platform for attachment of the iBlock robotic device when required.

After registering the necessary anatomical landmarks, a 3D model of the individual anatomy of the distal femur and proximal tibia was created, along with the limb alignment. The surgeon could then position the femoral and tibial components in the desired positions on this model as they saw fit. Adjustments could be made to this positioning before any cuts were made. Desired alignment was defined based on surgeon discretion or case-to-case basis. Once the desired position of the implant had been finalized on the virtual knee, the iBlock device was mounted for delivery of the cuts needed to achieve the plan. The iBlock was attached to the femoral array and manually aligned in the frontal and axial planes under navigated control using two adjustment screws. The motorized unit then moved a single cutting guide around the femur in the sagittal plane, moving

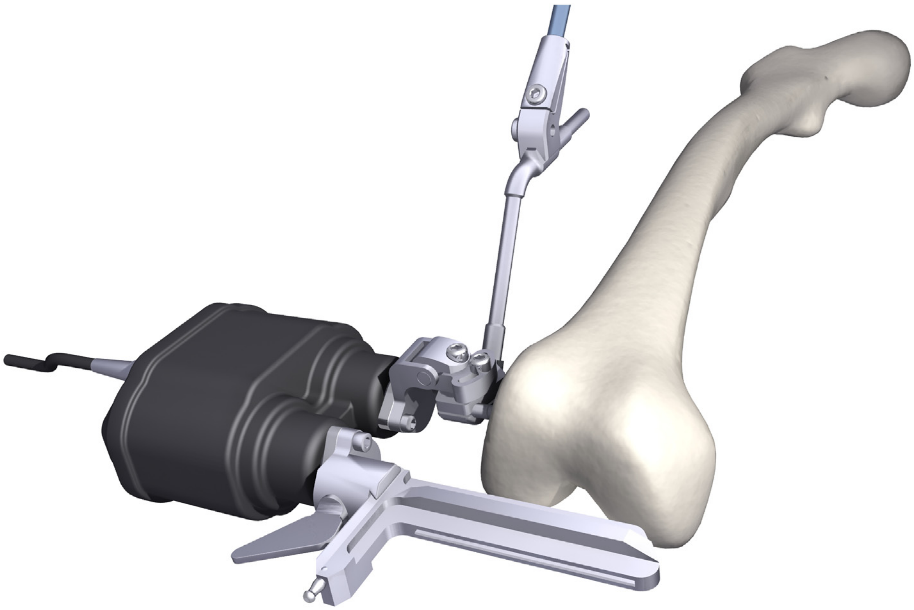

Figure 1. iBlock System (OMNIlife Science, Raynham, MA, USA).

the guide to the position required for each of the five femoral cuts. These cuts were made by the surgeon with a standard oscillating saw; the distal and anterior cuts could be verified with a navigated check-guide to confirm the desired resections had been performed accurately. If needed, the cutting guide could be repositioned in as little as 0.25-mm increments to ensure the desired cuts are made.

For the tibial resection, the NanoBlock was fixed to the anterior tibia using a navigation reference array against the planned position. The design of the NanoBlock allowed for rapid attachment of the block to the tibia in a zone of acceptable positions. Three adjustment screws on the top of the block then allowed the cutting slot to be manually adjusted under the guidance of the navigation system for precise fine-tuning of the final position. The tibial cut was then made with a standard oscillating saw, and verified with a navigated check-guide.

Trial components were inserted, and resultant alignment and soft tissue balance were measured with the navigation system. Provided the range of motion, stability and alignment were satisfactory, the definitive APEX TKR (OMNIlife Science, Raynham, MA, USA) was inserted. If not, soft tissue releases or recuts were made until the desired balance and alignment were achieved. Re-cuts were required in the distal femur in three patients (1.7%) and in the tibia in seven patients (four percent). In the majority of cases, hybrid fixation was used (cemented tibial plate and uncemented femoral component), though a selected portion had cemented femoral component where patient bone quality was insufficient.

2.2. CT protocol

Independent to the OMNI implant system, preoperative planning of total knee replacement surgery was performed. As stated by a study of our group, the preoperative state of the patient is a critical source of missing data from most analyses, which prevents accurate reporting of component position [20]. Such planning required a preoperative CT scan of the hip, knee and

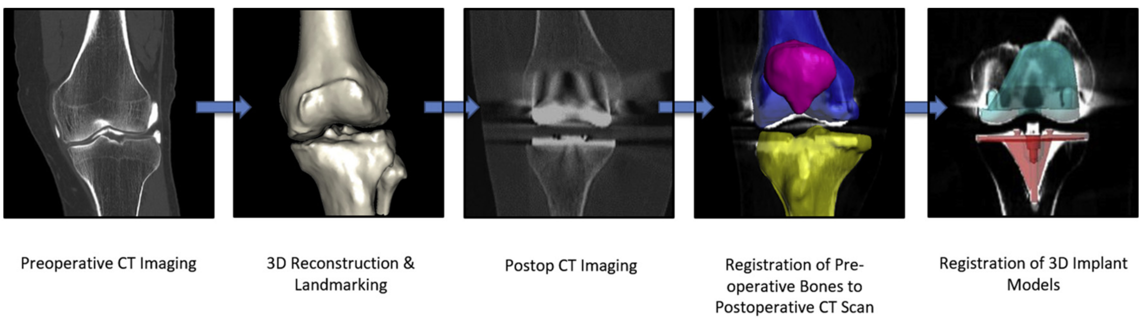

Figure 2. The process used to accurately determine the placement of the components. CT, computed tomography; 3D, three-dimensional.

ankle less than six months before the patient's operation. Each scan was segmented using ScanIP software (Simpleware, Exeter, UK). Segmentations of the femur, tibia and patella bone were filled and smoothed in order to create a 3D model representing the patient's arthritic knee joint. CT scans were taken at 1.25-mm slice thickness.

Anatomical landmarks were registered by two engineers blinded to each other's selections. The differences between registered points were algorithmically compared and a mean result found. If a large difference (four mm or more) between the selected landmarks points was found, the land-marking was then triple checked and a new point in relation to the other two points was determined.

2.3. Femoral definitions

The mechanical axis of the femur was defined during CT analysis as the line joining the centre of the femoral head to the centre of the intercondylar notch as landmarked by engineers. The lateral epicondyle was defined by the centre of the prominence on the lateral side of the distal femur, while the medial sulcus was defined as the depression posterior to the medial epicondyle on the medial side of the femur. The surgical trans-epicondylar axis (TEA) was defined by the lateral epicondylar point and the sulcus of the medial epicondyle.

2.4. Tibial definitions

The tibial coronal plane is defined as the cross product of the mechanical and antero-posterior axes of the tibia. The mechanical axis of the tibia was defined as the line joining the midpoint of the lateral and medial malleoli of the tibia, and the midpoint of the line joining the posterior cruciate ligament (PCL) insertion and medial one-third of the tubercle as landmarked by engineers. These landmarks were chosen to allow the native bone axis to be identified in both pre- and postoperative CT scans. The PCL and tubercle points where then projected onto the axial plane defined from the mechanical axis in order to determine the antero-posterior axis of the tibia. A sagittal plane was then defined as perpendicular to the defined coronal and axis planes.

2.5. Measurement comparison and postoperative registration

Navigated and validated femoral and tibial cuts obtained during the intraoperative process were extracted from the navigation system's log files, which reported angles rounded to the nearest 0.5°. Postoperative CT scans were obtained to accurately assess the 3D alignment and position of each component (AURORA Protocol, IRB approval, number: 2012-03-710) [20]. The CT scans were taken at an average of 14 days after surgery, up to two years postoperatively. To obtain the CT scan, the patient was required to have enough pain control to be able to reach full extension during the examination. Rotation was controlled by taking into account the full 3D position of the knee, as explained in the AURORA Protocol [20]. The preoperative bone models of each patient were registered to the postoperative CT scans by matching the topology of the non-implanted regions in each scan. In addition, computer-aided design models of the implants were also registered to the postoperative CT scan and the resulting final position of each component relative to its bony axes was determined. The points on the implants used to define the component position in the OMNiNav system were replicated in the postoperative analysis, thereby reducing errors due to differences in measurement definitions. The component positions determined from the CT were then compared with the intraoperatively navigated and validated cuts.

Measurements for accuracy of placement of each implant were compared in several planes; femoral coronal alignment (FCA), femoral sagittal alignment (FSA), femoral rotational alignment related to the TEA (FRA), tibial coronal alignment (TCA), and tibial sagittal alignment (TSA). In addition, the hip–knee–ankle angle (HKA) was determined by comparing the coronal angle achieved at maximum extension on the operating table with that found in the postoperative CT scan. These comparisons provide an assessment of the correlation between what the surgeon had planned to achieve intraoperatively, and what had actually been achieved based on postoperative CT scan measurements.

Table 1
Results summary.

	Mean value (Nav)	Mean value (CT)	Mean difference (Nav − CT)	Mean difference P-value (from 0)	Inside of 3° (%)	Inside of 2° (%)
FCA	1.3 ± 1.9	1.2 ± 2.1	0.1 ± 1.2	$P = 0.58$	98% (169)	90% (155)
FSA	2.4 ± 1.9	3.9 ± 2.1	-1.5 ± 0.3	$P < 0.001$	100% (173)	97% (167)
FRA	-1.3 ± 1.8	-1.3 ± 2.2	0.0 ± 1.7	$P = 0.93$	94% (162)	84% (146)
TCA	1.2 ± 1.6	1.9 ± 1.5	-0.7 ± 1.1	$P < 0.001$	99% (171)	92% (159)
TSA	-3.2 ± 1.4	4.5 ± 1.7	-1.3 ± 1.5	$P < 0.001$	93% (161)	75% (130)
HKA	0.8 ± 2.1	1.3 ± 2.1	-0.4 ± 2.4	$P = 0.049$	83% (144)	64% (111)

CT, computed tomography; FCA, femoral coronal alignment; FRA, femoral rotational alignment related to the trans-epicondylar axis; FSA, femoral sagittal alignment; HKA, hip–knee–ankle angle; Nav, navigation; TCA, tibial coronal alignment; TSA, tibial sagittal alignment.

2.6. Statistical methodology

All statistical analysis was performed using R. The mean difference of each patient's achieved alignment from the planned alignment was determined, and the percentage with less than three degrees of deviation was determined. Furthermore, the difference in the means between navigated and CT alignment was determined and the existence of any systemic difference was calculated by *t*-testing the differences for statistically significant difference from 0.

3. Results

A total of 173 patients were identified from the 360 Knee Systems database in which patients received a preoperative CT for surgical planning, and postoperative CT for alignment analysis and received an OMNI APEX CR knee using the technique described in the methods.

The results are summarized in Table 1. The mean value for the FCA in Navigation (Nav) was 1.3° valgus ±1.9 and 1.2° valgus ±2.1 in CT. The FSA was 2.4 ± 1.9° in Nav and 3.9 ± 2.1° in CT. The FRA in Nav was 1.3 ± 1.8° internally rotated to the TEA and 1.3 ± 2.2° internally rotated to the TEA in CT. The TCA was 1.2 ± 1.6° varus in Nav and 1.9 ± 1.5° varus in CT. The TSA was 3.2 ± 1.4° of negative slope in Nav and 4.5 ± 1.7° of negative slope in CT. The overall HKA angle was 0.8 ± 2.1° varus in Nav and 1.3 ± 2.1° varus in CT.

The mean differences between the navigated reported and the CT positions were: FCA: 0.1 ± 1.2° more varus ($P = 0.58$), FSA: 1.5 ± 0.3° more flexed ($P < 0.001$), FRA: 0.0 ± 1.7° ($P = 0.93$), TCA: 0.7 ± 1.1° more varus ($P < 0.001$), TSA: 1.3 ± 1.5° more negative slope ($P < 0.001$), and HKA angle: 0.4 ± 2.4° more varus ($P < 0.049$) (Figure 3).

The percentages of concordance inside a three degree difference were: FCA, 98% (169 knees); FSA, 100% (173 knees); FRA, 94% (162 knees); TCA, 99% (171 knees); TSA, 93% (161 knees); and HKA angle, 83% (144 knees) (Figure 4).

When the data was compressed into a two degree concordance margin, the differences were: FCA: 90% (155 knees), FSA: 97% (167 knees), FRA: 84% (146 knees), TCA: 92% (159 knees), TSA: 75% (130 knees) and HKA angle: 64% (111 knees).

4. Discussion

The purpose of any surgical delivery system is to aid the surgeon in accurately achieving the desired surgical plan. In knee arthroplasty, this is defined as how successfully the final implant position matches the position in which the surgeon had intended to place the components during surgery. The current study showed that the OMNIbotics navigation system is accurate in the coronal, sagittal and axial planes. There was very high agreement between the intraoperatively navigated position of the implant for FCA, FSA, FRA and TCA compared with the postoperative position measured on CT. It had less accuracy in the tibial sagittal plane though the TSA angles were still within a three degree difference between navigated and CT-measured positions in over 90% of cases and three-quarters of them were within a two degree difference. The least accurate measurement was the overall HKA angle. While the mean difference between navigated and CT-measured positions was only 0.4°, 17% of cases had a difference greater than three degrees and 36% a difference of more than two degrees. This indicates there was small bias for one direction over another, but a high variation in the results recorded. An explanation for this could be that the HKA angle is very different between surgery and non-functional supine, meaning that the CT overall alignment could be wrongly measured because of the flexion position of the knee at the moment of the examination.

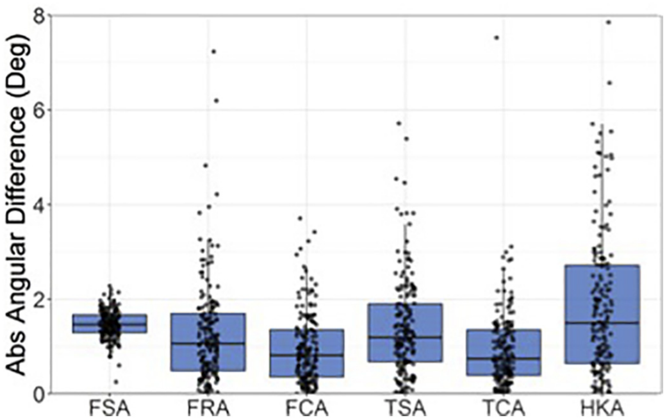

Figure 3. Mean differences graphics between measurements. FCA, femoral coronal alignment; FRA, femoral rotational alignment related to the trans-epicondylar axis; FSA, femoral sagittal alignment; HKA, hip–knee–ankle angle; TCA, tibial coronal alignment; TSA, tibial sagittal alignment.

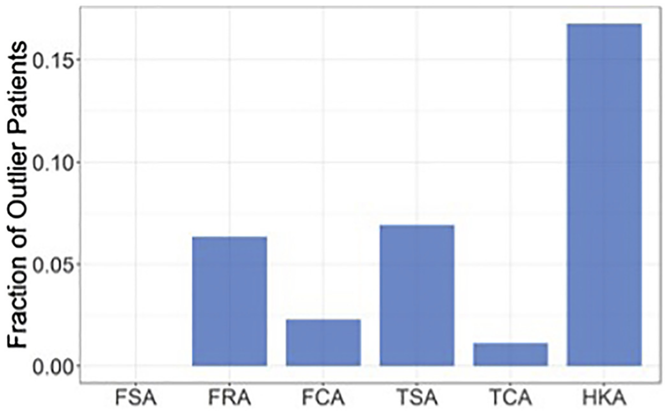

Figure 4. Fraction of outliers between measurements. FCA, femoral coronal alignment; FSA, femoral sagittal alignment; FRA, femoral rotational alignment related to the trans-epicondylar axis; HKA, hip–knee–ankle angle; TCA, tibial coronal alignment; TSA, tibial sagittal alignment.

The CT protocol utilized in this study (1.25-mm slice thickness with 1.25-mm spacing across the whole limb) balanced the need for accurate imaging and radiation exposure. Segmentation of the scans into 3D computational models allowed full reconstruction of the knee, and for measurements to be made without parallax error. This method was preferred to a two dimensional (2D) method of evaluating a CT scan in which parallax errors from combined component rotation and patient position within the CT scanner may propagate [20–22]. A preoperative CT allows registration of the preoperative bones to the postoperative CT frame of reference. Landmarks obtained preoperatively may then be used to define postoperative anatomic axes and angles without introducing inaccuracies due to metal component flare. Using this protocol combined with an engineer double-checking the positions of all bones and components during registration, accurate and reliable postoperative measurements are ensured.

There are few publications regarding this robotic system in the literature. Koulalis et al. [23] in 2011 published a cadaveric study comparing the iBlock femoral system with conventional navigation. They found that the bone cuts performed with the iBlock were significantly more precise than those performed with the freehand conventional guides in all three directions studied (frontal/rotational plane, sagittal plane and cut height). The mean duration for femoral preparation was also significantly shorter using the iBlock. They concluded that the variability in the final implant position using the iBlock was smaller than using conventional navigation with free-hand guides. In a subsequent study from the same group in 2012, Suero et al. [24] evaluated the NanoBlock comparing it to conventional navigation in vivo. They found that postoperative neutral mechanical alignment variability was significantly less in the NanoBlock group (standard deviation (SD) = 1.7°) than in the conventional navigation group (SD = 2.7°). Tourniquet time was significantly reduced by 14.8 min in the NanoBlock group compared to the conventional navigation group. Differences in component alignment, however, were not significant.

Clark and Schmidt [25] compared the efficiency and accuracy of iBlock compared to conventional navigation in primary TKA in vivo. They concluded iBlock navigation times were, on average, 9.0 min shorter compared to conventional navigation. The average absolute intraoperative malalignment was 0.5° less in the iBlock group compared to the conventional navigation group and patients in the iBlock group tended to be discharged 0.6 days earlier compared to patients in the conventional navigation group.

A potential drawback of this robotic system, compared to semi-autonomous haptic systems is that cuts are made completely by the surgeon, which is a potential source of error. Several studies have demonstrated that cutting errors are frequent during TKA [26–28] but at the same time registration and testing using the navigation system contained in the robot can help to limit this potential drawback.

This is the first study to evaluate final positioning of implants in patients operated with the iBlock and NanoBlock using a CT scan as reference. Recently, several studies had evaluated navigation results with CT scans [29–32], but this is the first to do so in evaluating a robotic-assisted knee replacement system.

The limitation of this study is the absence of any clinical evaluation of the patients. More research is needed to assess whether the improvement of accuracy correlates with better results in patient satisfaction and overall survival rates of total knee replacements. Another possible drawback of the study is that the reference standard (in this case CT) is not entirely free of measurement error. Individual angular and resection measurements reported here have an error of ±1°/mm. Measurement errors are minimized due to patient/leg position in the examination tube through the fully 3D registration; however, differences may arise due to the impossibility of measuring ligament balance in static examinations, and human errors (e.g., engineer's registration). In order to avoid such errors, we standardized that the patients needed to have full knee extension before the CT and two different engineers performed the registration with a third engineer in case of large differences between measurements to improve reliability. Inaccuracy arising from the imaging modality was considered acceptable as 3D-CT is the current gold standard for determining TKA alignment postoperatively [33].

5. Conclusions

The current study showed that the robotic navigation system studied is highly accurate regarding final implant positioning for FCA, FSA, FRA and TCA. It has less accuracy in TSA and the HKA angle.

Conflict of interest

The authors have no conflicts of interest to declare.

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