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Radiographic accuracy in TKA with a CT-based patient-specific cutting block technique

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Abstract
Purpose Patient-specific instrumentation (PSI) technology for the implantation of total knee arthroplasty (TKA) has a rising interest in the orthopaedic community. Data of PSI are controversially discussed. The hypothesis of this paper is that the radiological accuracy of CT-based PSI is similar to the one of navigated TKA published in the literature.
Methods Since 2010, all 301 consecutively performed PSI TKAs (GMK MyKnee©) were included in this study. The radiological assessment consisted in a preoperative and postoperative standard X-ray and long-standing X-ray. Changes from the planned to the definitively implanted component size were documented. Postoperative analysis included limb alignment and position of femoral and tibial components (for varus/valgus and flexion or tibial slope).
Results The postoperative average hip–knee–ankle angle was 180.1° ± 2.0°. In the frontal plane a total of 12.4 % of outliers >3°, for the tibial components 4.1 % of outliers >3° and for the femoral components 4.8 % of outliers >3° were measured. A total of 12.3 % of outliers for posterior tibial slope and 9 % of outliers >3° for the femoral flexion were noted. 10.8 % of the 602 planned size components were adapted intraoperatively.
Conclusion Although it is still unknown which limb axis is the correct one for the best clinical result, a technology providing the aimed axis in a most precise way should be chosen. Comparing the outcome of the current study with the data from the literature, there does not seem to be any difference compared to computer-assisted surgery.
Level of evidence IV.

Keywords Patient-specific · Patient-matched · Instrumentation · PSI · Total knee arthroplasty · Alignment

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Introduction

Total knee arthroplasty (TKA) is a frequent, but delicate, operation in orthopaedic surgery. Although efforts were made to improve accuracy for a correct axis since the beginning, opposed opinions regarding the higher failure rate of a malaligned TKA exist [6–9, 16, 21]. It remains a matter of debate whether the mechanical or the constitutional axis is the correct for the individual patient [4]. However, goal of surgery must be to achieve the planned axis. Nowadays, the most accepted definition for limb malalignment is >3° of varus or valgus (=outliers) [5, 10, 11].

The introduction of computer-navigated TKA led to a more precise implant positioning. In today's meta-analysis, most of the papers show significantly better results in terms of positioning and limb axis compared to manual instrumentation [5, 13, 15]. While the number of outliers is up to 32 % for the manual technique, navigation accomplishes values of 9–13 % [13, 15].

The use of individualized cutting jigs designed from 3D images from the patient's anatomy (based on CT scan or MRI) is called patient-specific instrumentation (PSI) [1]. This technology has the potential to decrease operating time by far less surgical steps, improved alignment accuracy and decreased blood loss by less invasive surgery without intramedullary canal violation [19, 20]. Furthermore, a preoperative 3D planning helps to find the best component size and position. To date in the literature, different data exist concerning the possible gain in precision, most of them obtained with MRI-based systems [2, 12, 17]. The CT examination is faster, cheaper and has less dropouts (i.e. metal hardware artefacts, pacemaker) compared to MRI. Furthermore, we believe that for cutting block adaption, bony landmarks (from CT scan analysis) are better references than cartilage surfaces (from MRI analysis). Finally, the theoretical possibility of rotational error between slices through hip, knee or ankle seems to be more at risk during longer lasting MRI than the fast CT scan. In contrast, CT scan has the disadvantage of exposure to radiation compared to MRI.

The hypothesis of this study is that the radiological accuracy of CT-based PSI regarding the alignment and component positioning is similar to the one of navigated TKA published in the literature.

Materials and methods

In two orthopaedic institutions between 2010 and 2012, six different surgeons performed 301 TKA using a CT-based patient-specific cutting block technique (MyKnee©, Medacta International S.A., Castel San Pietro, Switzerland) with the same type of prosthesis (GMK©, Medacta International S.A., Castel San Pietro, Switzerland). Three were senior surgeons (more than 5 years of experience in knee surgery with at least 50 TKA/year), and three were less-experienced junior surgeons who did not fulfil those criteria. All patients undergoing primary TKA with the stemless GMK MyKnee© PSI system were included in the study. The prospectively collected radiographic data according to our routine follow-up protocol were retrospectively analysed. Therefore, no ethical approval was necessary. All patients gave their informed consent.

Workflow

The data of the preoperatively assessed standardized CT scan are sent to the company (Medacta International S.A., Castel San Pietro, Switzerland). Their engineers plan the position and size of the TKA according to the surgeon's preferences and return the protocol back to the surgeon. In all cases, a neutral mechanical axis [0°; or hip–knee–ankle angle (=HKA) = 180°], a posterior slope of the tibia component between 2° and 4°, a flexion of the femoral component between 0° and 4° aiming best component position without notching or overhang and an external rotation of the femoral component of 3° or 4° were intended. After assessment and eventual correction, the surgeon confirms the protocol and the patient-specific cutting blocks were manufactured. In this first generation of the company's website, a 3D online planning was not possible.

Surgical technique

All TKA are performed in the tibia-first technique and with a standard anteromedial approach (mini quadriceps split). The cutting block is fixed onto the tibial plateau after cleaning the contact points from cartilage and soft tissue. After controlling the position of the cutting block with help of a reconstructed 3D-model of the patient's knee and double checking visually with an extramedullary rod (Fig. 1), the tibial cut is performed. On the femoral side, the contact points are cleaned and the cutting block is fixed and checked with the plastic model. The two pin wholes for the 4-in-1 cutting block are prepared through the cutting block in the preoperatively planned external rotation. Then, the distal femoral cut is performed. After balancing the knee in extension, the balancing in 90° of flexion is

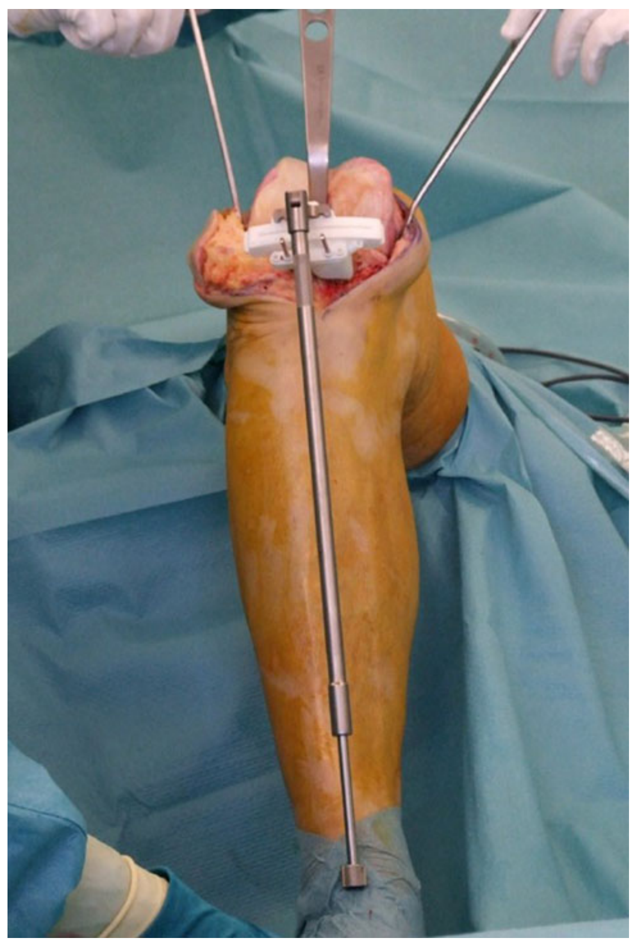

Fig. 1 An extramedullary alignment rod can be fixed onto the tibial MyKnee© cutting block as an additional checking tool

controlled and the rotation of the femoral 4-in-1 cutting block is changed if necessary before performing the remaining femoral cuts. In all cases, a fully cemented or tibial cemented and femoral cementless GMK TKA with a posterior, stabilized, fixed bearing design was implanted. All changes from the planned component size to the definitive implanted were noted.

Radiological assessment

The radiological assessment consisted of preoperative standard X-rays of the knee (ap and lateral, patella axial) and a CT scan according to a special protocol including integration of hip and ankle defining the mechanical axis. At the beginning of that PSI procedure, an additional long-standing X-ray was performed, but with rising confidence into the technology, it was not used on a regular basis anymore. Between 6 weeks and 3 months postoperatively, standard radiographs with long-standing X-ray were repeated according to our routine.

The achieved mechanical axis of the lower extremity as well as the independent mechanical axis of the tibial and femoral components in the frontal plane was measured in the postoperative long-standing X-ray. A neutral mechanical alignment was defined within ±3°. For the tibial and femoral components, a perpendicular position to the mechanical axis was planned and a deviation of >3° was defined as an outlier. The tibial posterior slope and the femoral flexion of both components were analysed in the lateral X-rays. For the posterior tibial slope and the femoral flexion of the correspondent components, the planned value was compared with the achieved one. A difference of >3° was defined as an outlier.

Statistical analysis

The χ^2 test (Fisher's exact test) was used to compare the number of outliers between the senior and the junior surgeons as well as within the senior surgeons group.

All statistical analyses were performed using SPSS 13.0 for MacIntosh OS X. The significance level was set at $p < 0.05$.

Results

In all of the 301 TKAs, a standard radiograph (ap/lateral view) was present and used for sagittal analysis. Ten cases out of these 301 missed the postoperative long-standing X-ray, resulting in 291 cases available for entire assessment including frontal analysis.

The postoperative average hip–knee–ankle angle (HKA) was 180.1° ± 2.0° (Table 1). In the frontal plane, a total of 36 cases (12.4 %) were outliers with more than 3° deviation from the neutral axis. Comparing the 227 cases of senior surgeons (25 outliers, 11.0 %) with the 64 cases of junior surgeons (11 outliers, 17.1 %), the percentage of outliers >3° in the junior's group was higher but without any significance. The two outliers >5° (one case with varus 6.3° and one with valgus 6.1°) were performed by a junior surgeon. Senior surgeons did not improve their accuracy, comparing the first 115 cases (12 outliers, 10.4 %) with the second 116 cases (13 outliers; 11.2 %) without any significance. The detailed results of tibial and femoral frontal positioning can be seen in Table 1.

For the tibial slope out of 301 cases, a total of 37 cases (12.3 %) of outliers >3° were found. Comparing the 231

Table 1 Outliers of our patient-specific implantation (PSI) results regarding the mechanical axis, the positioning of tibial and femoral component each and the tibial slope and the femoral flexion

	Outliers				
	PSI (>3°–5°)	PSI (>5°)	PSI total	Meta-analysis (>3°)	
				Navigation (CAS) (%)	Conventional instrumentation (%)
Mechanical axis (varus/valgus; totally)	11.7 % (14/20; 34)	0.7 % (1/1; 2)	12.4 % (15/21; 36)	9.0–12.8	30.1–31.8
Tibia component (varus/valgus; totally)	3.8 % (6/5; 11)	0.34 % (0/1; 1)	4.1 % (6/6; 12)	4.0–5.8	11.1–12.4
Femur component (varus/valgus; totally)	4.5 % (5/8; 13)	0.34 % (1/0; 1)	4.8 % (6/8; 14)	4.9–7	16.0–16.4
Slope tibial component (more+/less−; totally)	10.6 % (+9/−23; 32)	1.7 % (+5/−0; 5)	12.3 % (+14/−23; 37)	11.8–15.8	17.8–25.4
Flexion femoral component (more+/less−; totally)	7.3 % (+20/−2; 22)	1.7 % (+5/−0; 5)	9.0 % (+25/−2; 27)	17.3–18.1	26.1–34.4

The PSI results can be compared to the published values for navigated and conventional surgery, listed in the right side [11, 13] cases of senior surgeons (34 outliers, 14.7 %) with the 70 cases of junior surgeons (3 outliers, 4.3 %), the percentage of outliers >3° in the senior's group was significantly higher ($p < 0.02$). Senior surgeons seemed to improve their accuracy, comparing the first 115 cases (21 outliers, 18.2 %) with the second part of 116 cases (13 outliers; 11.2 %), but this improvement was statistically not significant. Despite the improved second part of the senior group, still a significant higher number of outliers were found compared to the junior group ($p < 0.02$).

For the femoral flexion, out of 301 cases, a total of 27 cases (9 %) of outliers >3° were found. Comparing the 231 cases of senior surgeons (22 outliers, 9.5 %) with the 70 cases of junior surgeons (5 outliers, 7.1 %), the percentage of outliers >3° in the senior's group was higher but statistically not significantly.

The planned size of components was changed intraoperatively in a total of 10.8 % of all 602 implanted components. The tibial component was changed in 53 cases (8.8 %). In 26 cases an upsizing and in 27 cases a downsizing were performed. 9.3 % (43 out of 462 components) senior surgeons and 7.1 % junior surgeons (10 out of 140 components) did not implant the tibial component according to the preoperative planning. This difference was statistically not significant.

The femoral component was changed in 12 cases (2 %). In seven cases an upsizing and in five a downsizing were needed. 1.7 % (6 out of 462 components) senior surgeons and 2.8 % junior surgeons (4 out of 140 components) did not implant the femoral component according to the preoperative planning. This difference was statistically not significant.

No PSI specific complications occurred during surgery.

Discussion

The most important finding of this study was the fact that CT-based patient-specific cutting blocks provides accurate and constant radiological data with a number of outliers >3° for the frontal mechanical axis (12.4 % in our cohort) comparable to the results achieved and published with computer-assisted TKA (CAS TKA) and clearly better than with conventional instrumentation [8, 15]. Secondly, no significant difference of accuracy between senior and junior group in the frontal plane was found, but in the sagittal plane (tibial slope), the junior group was significantly better.

Our data are supported by several other studies, indicating a better limb alignment compared to PSI with manual instrumentation [12, 14, 17, 18]. HKA outliers >3° of 9 % for PSI (Signature™, Biomet Inc., Warsaw, IN, USA) and 22 % for manual instrumentation were indicated by Ng et al. [17]. By Daniilidis and Tibesku [12, 14], 11 % of outliers >3° and 3 % of more than 5° for PSI (Visionaire™, Smit&Nephew, Memphis, TN, USA) were reported, with a significantly better rotational control of the femoral component compared to the manual instrumentation [14].

Comparing the results of component positioning between CAS TKA and our data achieved with PSI, an identical precision for frontal tibial and femoral plane as well as for posterior tibial slope was achieved [13, 15]. In contrast, femoral component flexion had even better accuracy (17.3–18.1 % for CAS vs. 9 % for our PSI group). It can be supposed that this difference in precision may be due to a more accurate definition of the sagittal mechanical axis in the CT scan compared to the protocol during navigation.

In contrast, PSI TKA system is also criticized for not providing a better limb alignment compared to a manual instrumentation [3, 19, 20]. No statistical significant differences have been reported; nevertheless, the amount of outliers, using the same definition with >3° varus or valgus, was surprisingly high with MRI-based patient-specific system: in one study, the outlier data were 16 % for the manual instrumentation and 18 % for the PSI instrumentation [20]; in a second study, the same author group outliers were even as much as 17.5 % (10 out of 57 cases) for the manual group and 26 % (15 out of 57 cases) for the PSI group [19]. These results were even topped by the third study, reporting 23 % outliers in the manual group and 31 % in the PSI group [3]. Measuring the HKA angle in CT scout image may play a minor role compared to a charged long-standing X-ray. Nevertheless, the studies are showing a realistic accuracy for the manual instrumentation technique but an unacceptable one for that of PSI system.

Analysis of outliers >3° between the junior and senior group and between the early and late cases in the senior group revealed no statistically significant difference for the frontal mechanical axis, even if in the senior group, the percentage of outliers was clearly less (seniors 25 outliers, 11.0 %; juniors 11 outliers, 17.1 %). The outliers in the senior group were similar between early and late cases without any significance and though without a learning curve. For the posterior tibial slope, the junior group showed significantly less outliers than the senior group (juniors 3 outliers, 4.3 %, seniors 34 outliers, 14.7 %). In contrast, the senior group showed a trend regarding the reduction in outliers (21 outliers, 18.2 %; versus 13 outliers, 11.2 %). Analysing the data continuously and realizing the high number of slope outliers, the operation technique was improved by cleaning the contact points for the cutting blocks. This may explain the evolution. Even as the second part of the seniors group showed still a significant difference compared with the juniors results, we believe that the learning curve for the posterior tibial slope in the seniors group led to a better instruction and starting point for the juniors. Why the seniors even for the late cases were not as precise as the juniors remains unclear as no case selection existed, and senior surgeons did not have the impression of overruling the accuracy of the PSI system. The CT-based PSI technology seems to provide a safe implantation technique not only for experienced but also for non-experienced surgeons with fewer numbers of TKA implantation. We could not find a statistically significant improvement in time without a relevant learning curve.

The preoperative information of the size component reduces the number of instruments. Intraoperative size exchange rate around 53 % for the tibial component and 77 % for the femoral component as published by Stronach et al. [22] waste the above-mentioned advantage. Our study revealed a rate of 8.8 % for the tibial and 2 % for the femoral component. Therefore, we cannot confirm those data with our CT-based PSI system. Although our rates of component changing are lower, we think that they still are too high. A reason therefore may be that in this first series, no interactive 3D-web-planning tool was available. With the newly introduced 3D-planning tool, the number of intraoperative mismatch compared to the preoperative planning should become smaller.

Even in the more PSI-critical papers, most of them accord that the new technology is more efficient with significant lesser time of OR use [3, 19]. A cost comparison study analysed the entire procedure related to cost for TKA [23]. The cost for conventional instrumentation was the lowest, followed by PSI and then navigated TKA. Interestingly, the conclusion was that with the time sparing PSI technique, more operation capacity is provided, and an additional case can be performed decreasing the costs per case and making PSI the most cost-effective. However, this needs to be proven. A precise cost analysis is required including the MRI and CT scan prior surgery, and the cost for the production of the patient-specific instruments.

There are limitations in this study: while component positioning and mechanical axis preoperatively are planned with the help of a CT scan, the postoperative assessment consisted in long-standing X-rays and standard X-rays. A CT scan only is performed for examination of the component rotation or bony integration. It would be interesting to analyse all cases with a postoperative CT scan, but it is almost impossible to realize it for a routine setting, because of the high irradiation exposure. Although there is some lack of precision while measuring axis and component position on conventional X-rays, almost all studies measure the precision of TKA placement in this way, which makes the values comparable. A further limitation is the missing of a control group either conventional or CAS TKA. However, we compared our PSI data with data from relevant literature. We believe that this is a correct procedure as it does not illustrate a well-performed single-surgeon series, but a heterogeneous series of different surgeons at several levels of formation—a somehow more realistic situation with even inferior results regarding the two outliers more than 5° were operated by junior surgeons. Last but not least, we do not have any clinical data of those patients. Being focused on the reliability and accuracy of that novel instrumentation technology, we do not attend better clinical date in a short- or mid-term follow-up. Therefore, we strongly believe that for the analysis of the component positioning, clinical data will not add more or important information.

Respecting the basics of TKA implantation and respecting the pathway and checkpoints of the CT-based PSI technology, a constant and precise implant positioning can be achieved. This does not mean that PSI technology does substitute a good training in total knee replacement with ligament balancing and bone resection. Although we still do not know which limb axis is the correct one, we should choose the implantation technology that provides us the aimed axis most accurate [4].

Conclusion

Comparing the outcome of the current study with the data from the literature, there does not seem to be any difference compared to computer-assisted surgery. The system shows similar accuracy without relevant learning curve between junior and senior surgeons.

Conflict of interest Two authors (P.P.K., M.P.) are paid consultants for Medacta International S.A. (Castel San Pietro, Switzerland); none of the other authors have any conflict of interest to declare. No benefits or funds were received in support of the study.

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