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Rotation in total knee arthroplasty: no difference between patient-specific and conventional instrumentation

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Abstract

Purpose It was our hypothesis that patient-specific instrumentation (PSI) can improve the accuracy of the rotational alignment in TKA based on the concept of the system and on the potential to clearly identify pre-operatively during planning the classical anatomical landmarks that serve as references to set-up the rotation both for the femur and tibia.

Materials and methods In this prospective comparative randomized study, 40 patients (20 in each group) operated in our institution between September 2012 and January 2013 by the 2 senior authors were included. Randomization of patients into one of the two groups was done by the Hospital Informatics Department with the use of a systematic sampling method. All patients received the same cemented high-flex mobile bearing TKA. In the PSI group, implant position was compared to the planed position using previously validated dedicated software. The position of the implants (frontal and sagittal) was compared in the 2 groups on standard X-rays, and the rotational position was analysed on post-operative CT-scan.

Results 90 % of the patients add <2° or mm of difference between the planned position of the implants and the obtained position, except for the tibial rotation where the variations were much higher. Mean HKA was 179° (171–185) in the PSI group with 4 outliers (2 varus: 171° and 172°:184° and 185°) and 178.3° with 2 outliers (171° and 176°) in the control group. No difference was observed between the two groups concerning the frontal and sagittal position of the implants on the ML and AP X-rays. No significant difference of femoral rotation was observed between the two groups with a mean of 0.4° in the PSI group and 0.2° in the control group (*p*: n.s). Mean tibial rotation was 8° of internal rotation in the PSI group and 15° of internal rotation in the standard group (*p*: n.s).

Conclusion Based on our results, we were unable to confirm our hypothesis as PSI cannot improve rotation in TKA. More work needs to be done to more clearly define the place of PSI in TKA, to keep on improving the accuracy of the system and to better define the individual targets in TKA in terms of frontal, sagittal and rotational positioning of the implant for each patient.

Level of evidence Prospective comparative randomized study, Level II.

Keywords Total knee arthroplasty · Patient-specific instrumentation · Rotation · Frontal alignment

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Introduction

With conventional instrumentation in total knee arthroplasty, the rate of implant malposition can be as high as 20–40 % even in major arthroplasty centres as reported in the literature [8, 14, 20, 22]. To limit implant malposition, smart tools such as navigation or patient-specific instrumentation have been developed in TKA [7, 12, 14, 17, 30]. Navigation in TKA has demonstrated a good accuracy for

the frontal and sagittal placement of the implants, but limited efficacy concerning the rotational alignment of the implants [7, 12, 14, 17, 32]. Navigation also required a longer surgical time and fractures at the location of the pins insertion have been reported [25]. Furthermore, recent papers demonstrated that the restoration of a straight mechanical axis for every patient is not enough to improve implant survivorship at 15 years [13, 29]. Following this observations, patient-specific instrumentation (PSI) has been introduced with the aim to improve implant positioning in the three dimensions of the space while reducing the overall costs of the implants, minimizing the size and numbers of instruments required, and also reducing surgery time [7, 26, 28, 34, 35]. Initial studies have compared the frontal and sagittal alignment of the implants with or without the PSI and have shown the interest for the technique to restore the mechanical axis but limited data exist concerning the role of PSI concerning the rotation of the tibial and femoral implants [7, 18, 21, 26, 34, 35]. Based on the fact that classical anatomical landmarks that are used to set-up the rotation may theoretically be properly identified on the pre-operative tridimensional reconstruction of the knee and be integrated in the pre-operative planning, it was our hypothesis that PSI can improve the accuracy of the rotational alignment in TKA. We therefore compared in this prospective comparative randomized study: (1) in the PSI group, the matching between the pre-operative planning and the post-operative position of the implants analyse on CT-scan and (2) the position and particularly the femoral rotation of the implants with or without PSI.

Materials and methods

In this prospective comparative randomized study, 40 patients (20 in each group) operated in our institution between September 2012 and January 2013 by the 2 senior authors (JNA-SP) were included. The patient inclusion criteria were as follows: patient disabling knee arthritis [2], age between 50- and 85-year old, at an acceptable medical risk, and failed nonoperative management, the willingness to wait 4–6 weeks before surgery, and the acceptance of the relatively new technology. The patient exclusion criteria were as follows: metallic hardware within 10 cm of the knee or prior THA, previous surgery of the knee that could lead to artifacts. The study protocol (including the use of PSI and post-operative computed tomography evaluation) and consent forms were approved by the local ethical committee. Randomization of patients into one of the two groups was done by the Hospital Informatics Department with the use of a systematic sampling method.

The first patient was randomly chosen and assigned to the PSI or the control group; then, one patient was selected out of every six patients on a list of all patients meeting the inclusion criteria who were candidates for a total knee arthroplasty performed by the 2 senior authors. All of the patients provided informed consent to participate in the study. The randomization protocol was not revealed to the authors, who received the information regarding the group to which the patient was assigned in numbered, sealed envelopes. The patients assigned to the control group were matched for gender, age within 5 years, pathological condition, operatively treated side, and body mass index within 3 points. All patients received the same cemented high-flex mobile bearing TKA (NexGen® LPS-Flex mobile, Zimmer®, Warsaw) [4, 5].

For the patients allocated to the PSI group after randomization, an MRI (Philips® 1.5 Tesla Intera) was performed 6–8 weeks before the surgery in the department of radiology of the hospital according to a standardized protocol validated by the manufacturer (Materialise®, Belgium) For every patients, the protocol included images acquisition on the hip, on the knee (between 80 and 120 cuts) and on the ankle. After anonymization, the images were uploaded on the dedicated online management software. After segmentation, the engineers performed a planning of the TKA and submitted it to the surgeon. Based on the clinical exam and on the standing full-length X-rays (flexion contracture), an edition of the planning was systematically performed by the surgeon concerning the depth of the distal femoral cut and the tibial cut. The flexion of the femoral implant and the slope of the tibial plateau were also systematically controlled. The rotation of the femoral implant was based on the transepicondylar axis and never changed in our study. The tibial rotation was controlled and set-up according to the anterior tibial tuberosity and according to best fitting with the anterior cortex [1, 3, 19, 23]. At the end of the edition, the flexion and extension spaces were finally checked and the planning was approved. Following this approval, rapid-prototyping computer-assisted design/computer-assisted manufacturing technology created PSI jigs. After exposure of the knee, we carefully positioned PSI guide over previously cleaned and dried articular surfaces, ensuring an accurate fit. Then, guided by the PSI jig, drill holes and pins were placed in the cartilage surface, which then determined the orientation of standard cutting guides. We then carried out the remainder of the TKA procedure as usual [6]. We did not have to convert from a PSI technique to a conventional technique. For 5 patients, we had to made intra-operative changes, three times to increase the distal femoral resection (2 mm increment) and twice to increase the depth of the tibial cut (2 mm). The patients of

the control group were operated according to a previously described technique using an extra-medullar guide for the tibia and an intra-medullar guide for the femur. The patella was systematically resurfaced in both groups. In both groups, patients were operated without any tourniquet and using identical pain and blood management protocols [11, 33]. The same post-operative protocol was used for all the patients.

In each group, the radiographic analysis included pre- and post-operative full-length standing X-rays, an ML view of the knee and a skyline view at 30° of flexion. The radiological evaluation was performed according to a previously described method by two independent observers (one orthopaedic fellow and one staff radiologist) blind to the type of technique used intra-operatively on a dedicated software (Centricity Web®) and included an analysis of the following angles: HKA, frontal femoral component angle (FFC), frontal tibial component angle (FTC), lateral femoral component angle (LFC) and lateral tibial component angle (LTC) as well as the tibial slope [15, 29]. A notch on the anterior cortex was searched on the ML view. A post-operative CT-scan (General Electrics® Lightspeed VCT 16, including between 88 and 100 cuts) was performed at 3 days post-operatively in the same center than pre-operatively. The post-operative CT-scan included images on the hip and on the foot according to the same protocol than for the pre-operative MRI. For the patients of the PSI group, a copy of the post-operative CT-scan was sent to engineers for segmentation and analysis. Three-dimensional angle calculations were made post-operatively according to the same protocol than pre-operatively and directly compared to the pre-operative planning. (Figs. 1, 2). In another hand, the two previously mentioned observer blind to the type of technique used intra-operatively analysed the rotational positioning of femoral and tibial components using a previously described technique [1, 18, 37].

Statistical analysis

We first analysed the accuracy of the PSI system through a two-group pair comparison of the perioperative and post-operative angles previously described for the patients in the PSI group. Means and variances of the different angles including frontal, sagittal and rotation of the tibial and femoral implants achieved with the PSI technique were compared with those achieved with conventional instrumentation. The number of outliers according to the previously given definition was compared in each group [25]. Statistical analysis was performed, with SPSS software (version 12; SPSS, Chicago, Illinois), as a two-group pair comparison with use of the t test for the means comparisons and a variance comparison test for linked groups.
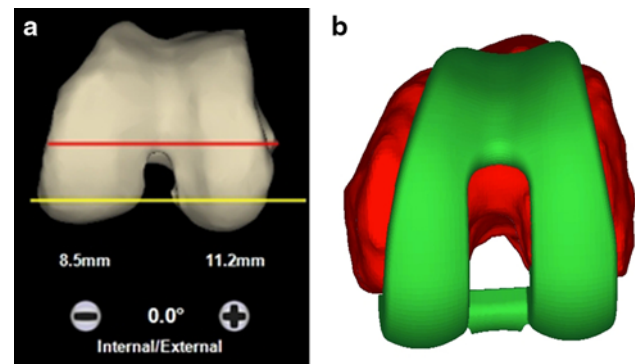
Fig. 1 The planning was performed by the surgeon concerning all the parameter including the femoral rotation (**a**). Post-operatively according to the same protocol than pre-operatively, the segmentation was performed on the CT-scan and directly compared to the pre-operative planning (**b**) for all the values of positioning including the femoral rotation
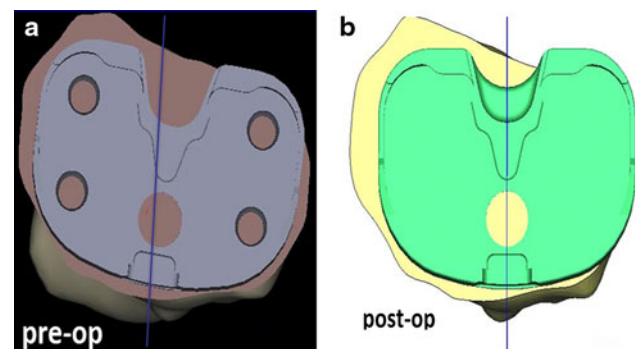
Fig. 2 Three-dimensional angle calculations were made on the pre-operative MRI after extraction of the 3D images of the femur, and then, the planning was performed by the surgeon concerning all the parameter including the tibial rotation (**a**). Post-operatively according to the same protocol than pre-operatively, the segmentation was performed on the CT-scan and directly compared to the pre-operative planning (**b**) for all the values of positioning including the tibial rotation

Results

The results of the comparison between the planned position and the obtained position controlled on the CT-scan in the PSI group are presented in the Table 1. A total of 90 % of the patients add <2° or mm of difference between the planned position of the implants and the obtained position, except for the tibial rotation where the variations were much higher.

On the weight-bearing full-length X-rays at 3 months, no difference was observed between the two groups. Mean HKA was 179° (171–185) in the PSI group with 4 outliers (2 varus: 171° and 172°:184° and 185°) and 178.3° with 2 outliers (171° and 176°) in the control group. No difference

Table 1 Results of the comparison between the position planned pre-operatively and the position obtained post-operatively in the PSI group as measured on the CT-scan

Difference pre/post-op	Mean	Max	Mini	SD	95 % CI
Femur					
Distal cut varus angle (°)	1.4	−2.9	4.1	1.1	0.5
Distal cut flexion angle (°)	2.6	−0.8	6.8	1.8	0.9
Distal cut (mm)	1.1	−2.6	2.6	0.9	0.4
Posterior cut (mm)	1.1	−2.0	2.8	0.7	0.4
Femoral rotation (°)	0.9	−3.4	2.2	0.9	0.5
Tibia					
Tibial slope angle (°)	2.2	−2.5	5.6	1.5	0.8
Tibial proximal cut (°)	1.2	−2.9	3.6	1.0	0.5
Tibial rotation (°)	6.8	−4.1	12.6	4.1	2.1

Differences are expressed in degrees for the angles and in mm for the measure of resection

Pre pre-operatively, *Post-op* post-operatively

Table 2 Results of the frontal and sagittal alignment of the tibial and femoral implants in the two groups

	Group PSI	Control group	*p*
Mean HKA (°)	179 (171–185)	178.3 (171–180)	n.s
Number of outliers	4	2	n.s
FFC angle (°)	90.1 (84–83)	89.8 (83–93)	n.s
FTC angle (°)	89.1 (85–96)	88.6 (85–91)	n.s
LFC angle (°)	8.15 (2–14)	9.1 (7–11)	n.s
Notching	2	2	n.s
LTC angle (°)	84.1 (81–87)	84.15 (82–86)	n.s
Tibial slope (°)	5.9 (3–9)	5.85 (4–8)	n.s

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

Table 3 Results of the femoral rotation in both groups

Femoral rotation (°)		PSI group		Control group	
		nTKA	%	nTKA	%
External rotation	3	3	15	2	10
	2	1	5	2	10
	1	5	25	5	25
Neutral rotation	0	7	35	4	20
Internal rotation	1	3	15	4	20
	2	0	0	2	10
	3	1	5	1	5

Table 4 Result of the tibial rotation in both groups

Tibial rotation (°)		PSI group		Control group	
		nTKA	%	nTKA	%
External rotation	10–15	3	15	1	5
	5–9	1	5	0	0
	0–4	1	5	0	0
Internal rotation	0–4	0	0	1	5
	5–9	3	15	1	5
	10–14	4	20	4	20
	15–20	8	40	13	65

was observed between the two groups concerning the frontal and sagittal position of the implants on the ML and AP X-rays (Table 2). According to these results and with the use of a 0.80 test power, a minimal difference of 3.5° of frontal alignment and 5.5° in the sagittal alignment would have been detected.

No significant difference of femoral rotation was observed between the two groups with a mean of 0.4° in the PSI group and 0.2° in the control group (*p* = n.s). The exact values for the femoral rotations in the two groups are summarized in the Table 3. Mean tibial rotation was 8° of internal rotation in the PSI group and 15° of internal rotation in the standard group (*p* = n.s). The exact values are summarized in the Table 4. According to these results and with the use of a 0.80 test power, a minimal difference of 3° of femoral rotation and 10° of tibial rotation would have been detected.

Discussion

The main finding of our study was that PSI did not improve femoral or tibial rotation in TKA. We therefore were unable to confirm our hypothesis. In fact, when comparing the PSI group with the control group, no significant difference between the two groups was observed in terms of frontal or sagittal positioning of the femoral or tibial implant. No difference was observed for the femoral rotation between the 2 groups. Despite a higher number of patients with internal rotation of the tibial plateau in the control group, no significant difference was observed. The results of our study have also shown that for 10 % of the patients in the PSI group, the PSI is not accurate enough with potential variations >5°. The femoral rotation was one of the most accurate positioning obtained by the PSI, and the tibial rotation was the less predictable one.

Several limitations should be outlined in this paper. Firstly, the number of patient is limited, with 20 patients in each group. This number was limited to 40 patients, as for the rotation analysis, this study was considered as a pilot study with no data available when the protocol was submitted to the IRB [18]. Furthermore, the design of the study compensates the potential lack of power related to the smaller number of patients. Another limit of this study is the lack of clinical comparison between the two groups.

The goal of this analysis was, however, strictly limited to the positioning analysis including the comparison between the planned and the obtained position. This type of comparison is to our knowledge original and has never been reported before. Furthermore, the comparison of rotational positioning between two groups has only be reported once based on the MRI, but never on the CT-scan which can be considered as the methods of reference to analyse the rotation of the implants [18, 36].

The planning was edited in all the cases in our study based on our early experience with PSI. We considered this step with lot of caution because it has been shown that the planning is a key to optimize the success of the PSI procedure. In fact, in a previous study, the authors outlined the need for a mean of 2.4 changes per case intra-operatively, concerning the sizing and the alignment [28]. As we were very cautious with the planning, we did not have had this problem in our study with only limited changes intra-operatively. Questions remain, however, concerning the 10 % of patients with high discrepancies between the pre-operative planning and the obtained position of the implant. In fact, the agreement between the planning and the result was good in our study for most of the patients, but not all showing that PSI can be considered as a reliable tool to achieve a desired position in 90 % of the cases. We have to keep on working with the engineers to understand why discrepancies were observed for some of the patients in our study. We were not able a posteriori to identify reasons for such differences. Furthermore, to our knowledge, this study is the first that directly prospectively compare the planned position and the real position of the implant.

In our series, we were able to restore the mechanical axis of the knee in both groups with comparable results except for two "outliers" in the PSI group that were in a post-operative valgus [8, 29]. These results were comparable with the results reported in previous series with more outliers in the PSI group than in the conventional group, as reported by Spencer et al. [35] with 15 outliers in the PSI group versus 10 in the conventional group out of a series of 57 knees (p = n.s.). Other studies reported comparable results than in our series with a good reliability of PSI to achieve the actual standard target of alignment [12, 28]. Once again, the planning is the key, and in our experience, it seems important to use the long-leg standing X-rays when performing the planning to complete the values obtained from the MRI, as these X-rays analyse the full weight-bearing alignment of the patient pre-operatively. The sagittal alignment in our study was comparable in the two groups for the tibia and femur. The restoration of the tibial slope was satisfying with a tibial slope of 6° in both groups for a pre-operative tibial slope of 5.3° in the PSI group and 5.8° in the control group. We did not observe any anterior slope as reported in the previous series [21, 23, 31]. These good results for the slope may be

explained by the fact that we respected the technique and performed all the femoral cuts first to optimize the placement of the tibial PSI guide, particularly the posteromedial leg of the jig. We also cleaned and dried the cartilage surfaces to optimize the placement. We did not observe in our study the extremely bad results reported in recent series comparing the PSI and the navigation with only 79.3 % of acceptable positioning in the frontal plane and only 54.5 % on the sagittal plane [24]. The technique used in this series was not the same than in our paper, and all the PSI systems are not exactly the same, with different planning principle, different intra-operative techniques and of course different way to analyse the results [24]. Once again, after a strict respect of the planning principles that should be done by the surgeon and not only by the engineers, it is crucial to respect the surgical technique, to dry and clean the surfaces before applying the guide, to perform all the femoral cuts before using the tibial PSI jig and to carefully check the good positioning of the jig.

There is to our knowledge only one series in the literature reporting the results of PSI for the rotational position of the implants [18]. In this series, 46 operations were performed using PSI and 48 using conventional instrumentation. The rotation of the femoral components was determined in the MRI, and deviations >3° were considered as outliers [18]. There were significantly more outliers in the conventional (22.9 %) group than in the PSI group (2.2 %, p = 0.003) [18]. The authors of this series concluded that PSI could be a good alternative to navigation particularly concerning the control of the implant rotation as the navigation has limited control on the axial positioning of the implant [18, 25]. In our study, the results for the patients of the PSI group were comparable to their results. The results for the control group were, however, different and that may explain why our results were not significant. This may be related to the technique that they were using in the conventional group. In fact, they used the Genesis prosthesis that come with an intrinsic 3° of rotation as mentioned in the "Materials and methods" section of the paper. That means that they did not perform any adaptation intra-operatively for the control group. In our control group, we were able to choose between 0, 3, 5 and 7° of rotation in our ancillaries based on our intra-operative landmarks. That may explain why we have less outliers in our control group. In our series, the target during the planning of the PSI patients was to align the femoral component parallel to the transepicondylar axis of the femur, and the degree of agreement for this target in the PSI group was 2° [1, 10]. In the control group, the target was 3° of external rotation relative to the posterior condyles axis with the possibility to adapt this target in the valgus knee with lateral condyle hypoplasia [1, 10, 27]. This target is a classical target based on the assumption that the mean angulation between the posterior condyle and the transepicondylar axis

is comprised between 3° and 6° [1, 10, 27]. This target is probably not adapted for every patient, and today, there is still a debate on the exact target concerning the rotation of the femoral component [1, 10, 27, 36]. Anatomical studies are still required to understand a little bit better the variations of the femoral rotation [1, 10, 27, 36]. Once we will have these data, PSI seems to be a great tool to achieve the proper rotation target. In our series, the mean tibial rotation was 8° of internal rotation in the PSI group and 15° of internal rotation in the control group. In the literature, the results of tibial rotation obtained with a PSI technique have never been reported. The results of the tibial rotation with a conventional instrumentation are very variables [9, 19]. In fact, many anatomical landmarks have been used to analyse the tibial rotation, and this wide range of analysis methods makes the comparison limited [1, 3, 9, 10, 19]. Furthermore, due to the asymmetry of the tibial plateau, properly measure the rotation of a symmetric tibial implant is difficult and providing "normal" values is even more difficult [16, 23]. Previous authors have defined that the tibial rotation can be considered as normal when lower than 8° of internal rotation based on the top of the anterior tibial tuberosity [10, 16, 23]. According to these criteria, the position of the tibial implants in our series was still considered as in a normal position particularly in the PSI group [16, 23]. Furthermore, we did not observe any post-operative stiffness in the series, even in the control group with higher values of internal rotation [9]. As for the femoral rotation, there is a need for more anatomical studies to understand better the ideal target of tibial rotation, and the databank obtained by the PSI scanning could be considered as a great resource to do this evaluation on a large number of patients.

In our series, we were able to observe a good agreement between the planning and the obtained position for 90 % of the patients, with no significant difference between the two groups. No difference was observed in terms of femoral rotation between the two groups. The results, for the tibial rotation showed a high number of patients in internal rotation and more work needs to be done to optimize the control of the tibial rotation, with the PSI technique, but also with conventional techniques. More work needs to be done also to more clearly define the place of PSI in TKA, to keep on improving the accuracy of the system and to better define the individual targets in TKA in terms of frontal, sagittal and rotational positioning of the implant for each patient.

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