

Evaluation of the accuracy of a patient-specific instrumentation by navigation

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Abstract

Purpose The aim of this study is to evaluate the accuracy of a patient-specific instrumentation (PSI) as assessed by the intraoperative use of knee navigation software during the surgical procedure.

Methods Fifteen patients with primary gonarthrosis were selected for unilateral total knee arthroplasty. The first three patients were excluded from this study, as they were considered to be a warm up to set-up the procedure. All patients were operated on with a cemented posterior-stabilised prosthesis cruciate ligament-sacrificing by the same surgeon using the patient matched cutting jigs. The size of the implant, level of resection, and alignment in the coronal and sagittal planes were evaluated. An unsatisfactory result was considered an error $\geq 2^\circ$ in both planes for each component as a possible error of 4° could result in aggravation.

Results On the coronal plane the mean deviation of the tibial guide from the ideal alignment was 1.2 ± 1.5 (range $0\text{--}5^\circ$) and in the sagittal plane was 3.8 ± 2.4 (range $0\text{--}7.5^\circ$). On the coronal plane the mean deviation of the femoral guide from the ideal alignment was 1.2 ± 0.6 and in the sagittal was 3.7 ± 2 .

Conclusion On the basis of this preliminary experience the PSI system based only on data acquisition with A-P radiograms and RMN cannot be defined as accurate. In cases of the use of the custom made cutting jigs it is

recommended to perform an accurate control of the alignment before making the cuts, for any step of the procedure.

Level of evidence II.

Keywords TKA · Navigation system · Patient-specific instruments · Custom-made technology

Introduction

The correct alignment of the components and the balancing of soft-tissue have been cited as the most important aspects of a successful knee arthroplasty [7, 8, 11]. Misalignment of the components in any anatomical plane can lead to early loosening, increased polyethylene wear and poor function [1, 4, 14]. While varus or valgus misalignment has been described as the commonest cause of early loosening, restoring the mechanical axis has been correlated with improved implant survival. A number of studies [10, 13] have suggested that alignment errors of $>3^\circ$ are associated with more rapid failure and less satisfactory functional resource. Moreover a malposition on the sagittal plane may play a significant role in the maximal post-operative flexion, as fact knees with a greater tibial slope have the tendency to flex better than knees with little or no tibial slope [3].

The use of computer-based surgery (CAS) during TKA has become more common during recent years [2, 6, 7, 17] due to the inability of the standard instrumentation to accurately determine the correct location of crucial alignment landmarks, such as the centre of the femoral head and the centre of the ankle.

One of the issues regarding CAS is the complexity of the instrumentation [18]. Although the new trend is to

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downsize instruments, the instrumentation is still fairly large and complex, resulting in an increased cost and surgery time [16, 19].

In recent years, patient-specific instrumentation (PSI) has been introduced with the aim to reduce the overall costs of the implants, minimising the size and number of instruments required, and also reducing surgery time. However these systems should also be precise enough to eventually result in a good alignment. The VISIONAIRE Patient Match Technology (Smith & Nephew, Inc, Memphis, Tenn) is a system designed to reduce the overall instrumentation complexity and to reduce the overall time and costs of the TKA surgery with the use of custom cutting blocks for every patient.

The aim of this study is to investigate the accuracy and reliability of this PSI by analysing the jig data as detected by the intra-operative use of VectorVision knee navigation software (BrainLAB, Redwood City, Calif). The null hypothesis is that PSI is not fully accurate in positioning prosthetic components.

Materials and methods

Patient selection

Between February 2011 and May 2011, 15 consecutive patients with primary gonarthrosis were selected for unilateral TKR. There were no real exclusion criteria. All patients were operated on using cemented posterior-stabilised cruciate ligament-sacrificing prosthesis (Journey BCS, Smith & Nephew, Inc, Memphis, Tenn) by the same surgeon using the patient matched cutting jigs. None of the patients had the patella resurfaced.

The first three patients were excluded from this study, as they were considered to be a warm up to set-up the procedure. Therefore 12 patients entered the study, and their demographics data are shown in Table 1.

No patient had a bleeding diathesis. Anti-inflammatory drugs were suspended 7 days before surgery. Before surgery, an autologous blood transfusion program was done following a pre-ordained schedule: All patients pre-donated two units of autologous blood.

All patients gave written informed consent prior to participation in the study, which was approved by the

institutional Ethics Committee (Comitato Etico “La Sapienza” ID 213554121).

Rationale for the pre-operative imaging used for alignment

All patients underwent a full-length weight-bearing radiograph and an MRI of the knee following the protocol approved by the manufacturer.

The imaging protocol is compatible with MRI machines with a magnet strength of at least a 1.5 T (Tesla) using a standard knee coil as the imaging device, which are readily available in MR facilities and are widely used on a routine basis. On average, each individual scan takes approximately 8–10 min, while complete knee scans can range anywhere from 30 min to an hour.

The pre-operative study was sent to the manufacturer laboratory to produce the tibial and femoral resection guides.

Operative technique and prosthesis

All patients were operated on by the same surgeon in the same hospital. The operations were carried on in a bloodless field using a pneumatic tourniquet at a pressure of 350 mmHg after exsanguination.

A medial parapatellar approach and medial parapatellar arthrotomy was performed on all but one of the patients.

According to the surgical technique no osteophytes were removed from the tibial and femoral surfaces.

Before starting with complete exposure of the knee, the procedure set up was accomplished as for a navigated TKA, including positioning of the tracker and the identification of anatomic landmarks. After complete and accurate exposure of the proximal tibia, a tibial guide was positioned and fixed. The position was verified for accuracy by placing the dedicated navigation instrument into the slot of the guide, and any deviation from the planned resection that was detected by the navigator was recorded (0° on the coronal plane, 3° of the posterior slope on the tibia and 4° of flexion on the femur in the sagittal plane). The same procedure was repeated for the femoral cutting jigs (Figs. 1a, b, c, 2a, b, c).

The following data were recorded: the coronal plane of the tibia and femur, the posterior slope of the tibia and the flexion of the femur. An unsatisfactory result was considered an error $\geq 2^\circ$ in both planes for each component. A tighter tolerance for the individual component alignment was to reduce the potential additive effect of individual component alignment. In case of a greater deviation from the planned resection a recut was performed.

Table 1 Demographics data

Age (mean, SD, range)	72 ± 4.7 (66–81)
Sex	3 men and 9 women
Side	6 right and 6 left
Pre-operative full leg deformity (mean, SD, range)	8.9 ± 3.3 (4.2–14.2)

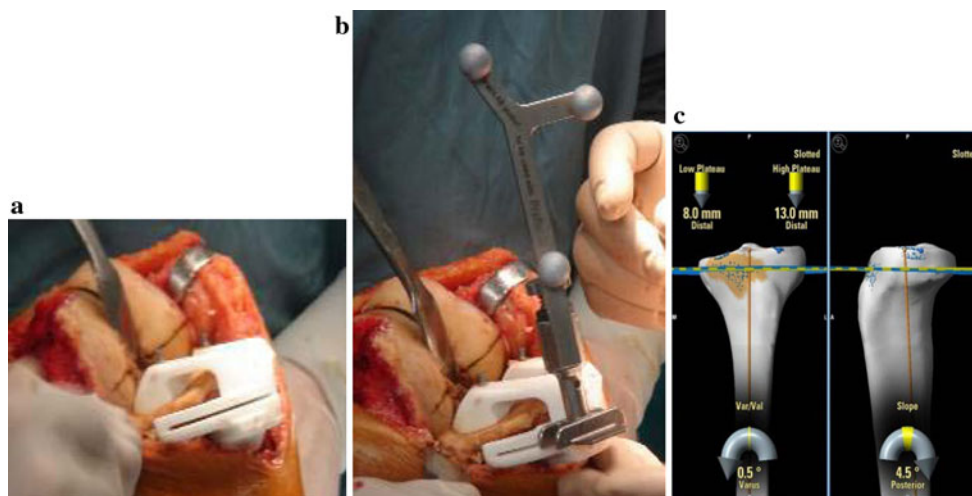


Fig. 1 a Positioning of the tibial cutting jigs. b Evaluation with the navigation system. c The system showed data

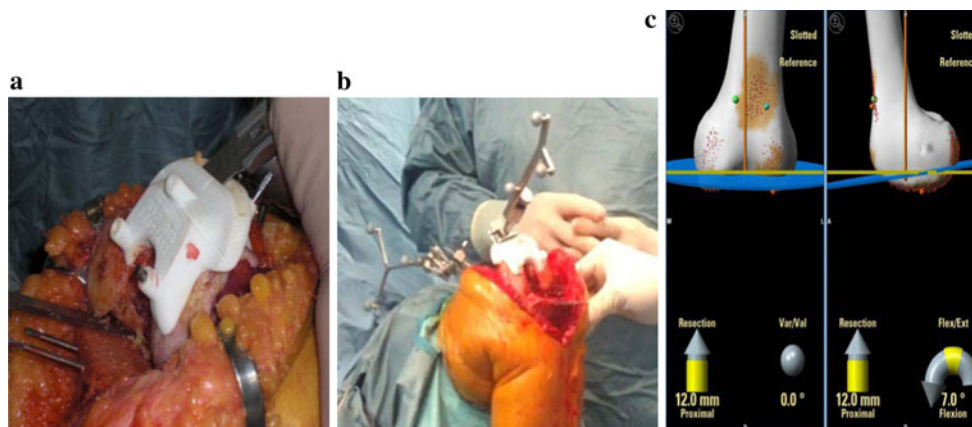


Fig. 2 a Positioning and fixation of the femoral cutting jigs. b Evaluation with the navigation system. c The system showed the data in both planes

All measurements were completed twice using the navigator, and by a single surgeon to eliminate inter-observer variability. No differences were identified. All measurements were recorded to an accuracy of one decimal place. No *p* values or statistical analysis are present in this paper, because the data showed only the accuracy of the patient-specific instruments.

Results

10 satisfactory alignments (83.3 %) were obtained on the tibial coronal plane (Fig. 3). A correct alignment was achieved on the tibial sagittal plane in 5 patients only (41.6 %) (Fig. 4).

On the femur, a correct alignment was obtained for 11 measurements (92.6 %) in the coronal plane (Fig. 5) and in 9 (71 %) in the sagittal plane (Fig. 6).

Overall the cutting jigs showed a correct alignment in 35 out of 48 measurements (72.9 %).

Complete data are shown in Table 2.

Discussion

The most important finding of this paper is that PSIs are not fully able to achieve satisfactory alignment in both planes.

To our knowledge there are still very few published studies regarding the use of custom-fit cutting blocks. In a preliminary laboratory study, Hafez et al. [9] analysed the

Fig. 3 The alignment on the coronal tibial plane

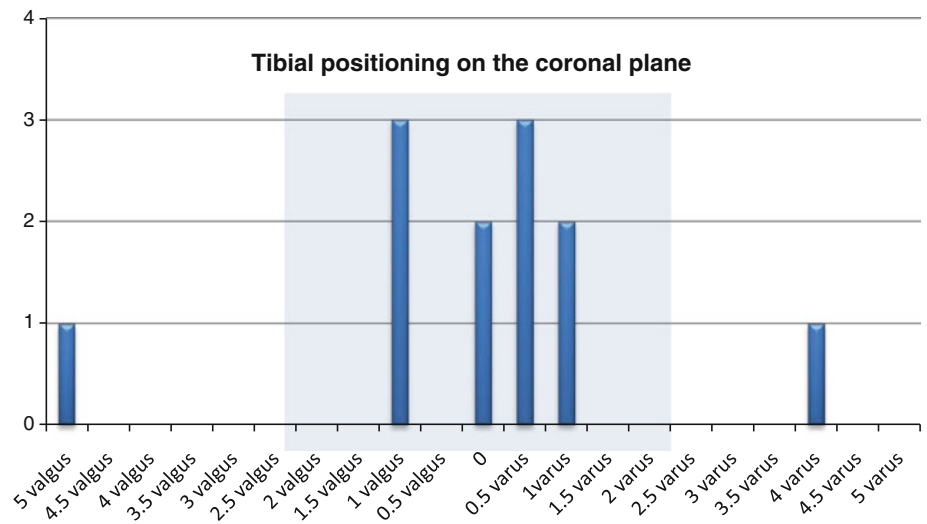


Fig. 4 The alignment on the sagittal tibial plane

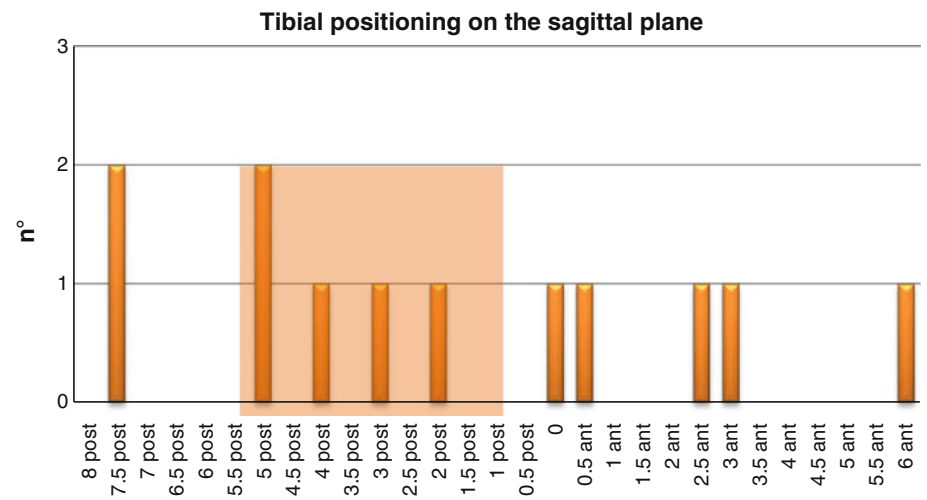


Fig. 5 The alignment on the coronal femoral plane

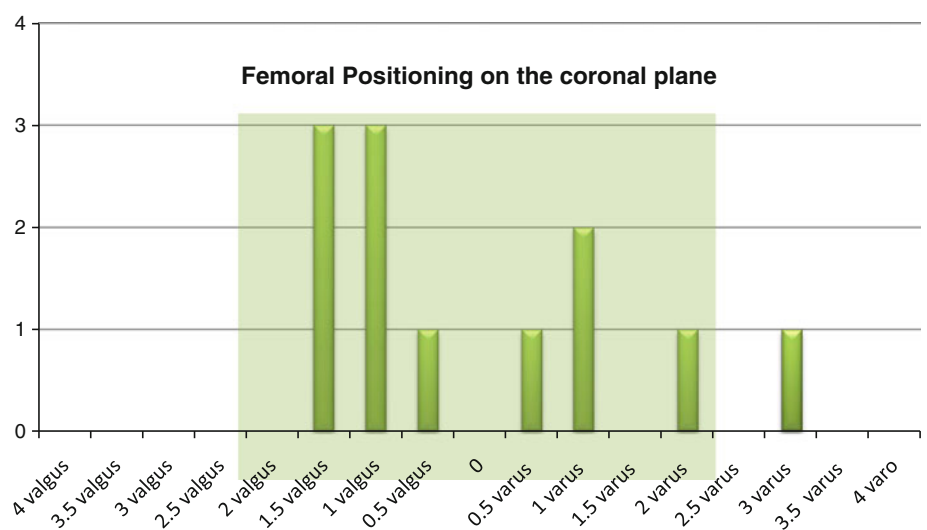
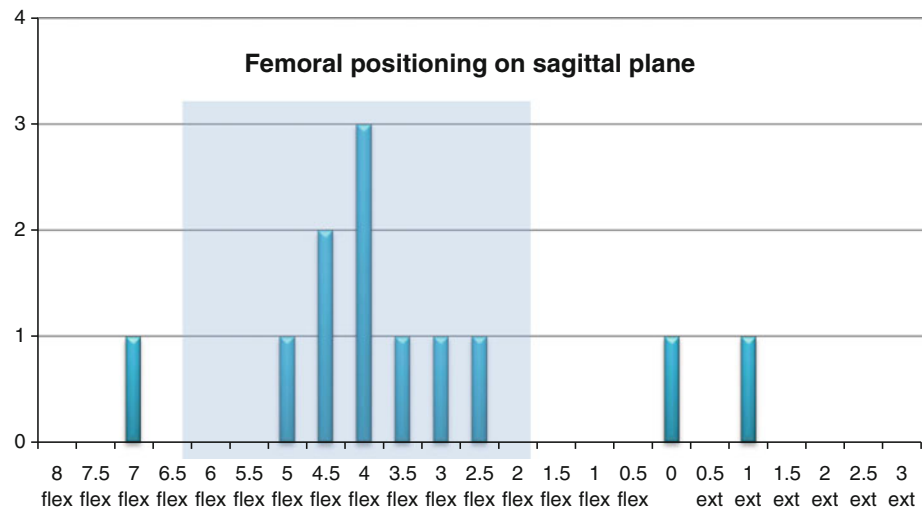


Fig. 6 The alignment on the sagittal femoral plane**Table 2** Complete datas

Tibia	Coronal plane	$1.2 \pm 1.5^\circ$
	Sagittal plane	$3.8 \pm 2.4^\circ$
Femur	Coronal plane	$1.2 \pm 0.6^\circ$
	Sagittal plane	$3.7 \pm 2.0^\circ$

The mean deviation and SD from the ideal alignment

use of this technology on cadaver knees and plastic bones. Although there were limitations of their study, they found that they were able to achieve good alignment and that they were able to reduce overall surgical time. However, they only evaluated the final alignment by CT scans without referring to the position of each component.

In a recent small cases series study, Klatt et al. [12] suggested that the custom-fit technique resulted in misalignment, with component positioning, as measured by a navigation system and referenced to the mechanical axes, ranged from 5° valgus to 7.5° varus. In another recent clinical study, Spencer et al. [18] studied the use of custom-fit technology on 21 patients with the use of post-operative CT scans. They obtained good clinical results and an acceptable alignment. In their opinion, aligning components to the mechanical axis is not the main goal of the custom-fit knee, as they believed that the system was designed to align components to the natural flexion/extension axis, thus recreating the natural pre-arthritis alignment of the patient's knee with the goal of increasing function. However, they pointed out that a gross deviation from the mechanical axis would be a concern. Their post-operative coronal alignment was close, but not ideal, to the mechanical axis, and could possibly lead to early wear

rates. Noble et al. [18] found that custom-made cutting jigs are mostly reliable, but their study was based on the post-operative x-ray. All previous authors [9, 12, 15, 18] agreed that the custom-made cutting blocks were able to reduce surgery time, sterilisation costs and surgical complications, such as bleeding, infections and embolism.

The final alignment of a prosthetic implant may be the result of several factors besides the correct positioning of the cutting jigs, as an error can occur even while cutting the bone or when the final impaction is made [5, 19]. In the present study it was decided to verify the accuracy of the PSI system by checking the actual positioning of each cutting jig.

The choice to consider an error $\geq 2^\circ$ as an unsatisfactory result was due to the risk of obtaining an unacceptable overall error $\geq 3^\circ$ if the error occurred in the same direction both in the tibial and femoral resection.

According to the above criteria, the custom cutting jigs were reliable in 34 out of 48 measurements (75 %), and for 20 in the coronal and 14 in the sagittal plane. Although there are no rigorous studies which analyse the effect of poor positioning of the components on the sagittal plane on the outcome of the implant, it is this group's belief that the error that was found, especially in the sagittal plane, should be considered unacceptable.

The data collected suggested that the error on the sagittal plane is partially due to the lack of a complete pre-operative radiological examination, as the shape of the cutting jigs on the sagittal plane is determined only by an MRI of the knee without considering an image of the whole limb in a lateral projection. When considering the alignment on the coronal plane, the system appeared to be more reliable, even if an acceptable error was found in 36 of the total 48 measurements. However, the technique cannot be considered reliable without adopting further intra-operative measures.

A limitation of this study is the relatively low number of patients included. This is a very specific protocol used to assess the accuracy of the custom cutting jigs, and it was therefore not possible to involve more patients due to the particular surgical protocol chosen.

An important drawback is the inability to evaluate the clinical impact of this paper. There has not been a previous follow-up that can be used to compare the conventional technique to the PSI technique.

Another limitation is the fact that surgery time, costs, blood-loss and other factors were not calculated. The suggestion that PSIs are able to reduce the cost of surgery is questionable, especially when considering the costs of a pre-operative MRI and the processing of the individual instrumentation. However, in the early series it was not possible to calculate factors such as cost reduction or surgery time due to the extra-time needed to place trackers on the landmarks for the CAS. We believe that the effect of PSI on those factors should be calculated only after the development of the surgical technique and the assessment of reliability.

Conclusion

On the basis of this preliminary experience, the PSI system based only on data acquisition with A-P radiograms and RMN cannot be defined as accurate. In cases using custom-made cutting jigs, we recommend performing an accurate control of the alignment before making the cuts in any step of the procedure.

Conflict of interest The authors disclose any possible conflict of interests.

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