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Original article

Posterior tibial slope accuracy with patient-specific cutting guides during total knee arthroplasty: A preliminary study of 50 cases

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ABSTRACT

Background: Patient-specific cutting guides were recently introduced to facilitate total knee arthroplasty (TKA). Their accuracy in achieving optimal implant alignment remains controversial. The objective of this study was to evaluate postoperative radiographic outcomes of 50 TKA procedures with special attention to posterior tibial slope (PTS), which is difficult to control intraoperatively. We hypothesized that patient-specific cutting guides failed to consistently produce the planned PTS.
Material and methods: The Signature™ patient-specific cutting guides (Biomet) developed from magnetic resonance imaging data were used in a prospective case-series of 50 TKAs. The target PTS was 2°. Standardised digitised radiographs were obtained postoperatively and evaluated by an independent reader. Reproducibility of the radiographic measurements was assessed on 20 cases. The posterior cortical line of the proximal tibia was chosen as the reference for PTS measurement. Inaccuracy was defined as an at least 2° difference in either direction compared to the target.
Results: The implant PTS was within 2° of the target in 72% of knees. In the remaining 28%, PTS was either excessive ($n = 10$; maximum, 9°) or reversed ($n = 4$; maximum, –6°). The postoperative hip-knee-ankle angle was $0° \pm 3°$ in 88% of knees, and the greatest deviation was 9° of varus.
Conclusion: These findings support our hypothesis that patient-specific instrumentation decreases PTS accuracy. They are consistent with recently published data. In contrast, patient-specific instrumentation provided accurate alignment in the coronal plane.
Level of evidence: IV, cohort study.

1. Introduction

Over 5 years ago, patient-specific instrumentation for total knee arthroplasty (TKA) was introduced as an alternative to conventional instrumentation and computer assisted surgery, to improve the reproducibility and ease of the procedure, while decreasing its invasiveness [1–7]. By obviating the need for intramedullary femoral referencing, patient-specific cutting guides should also minimise blood loss [8] and shorten the operative time [2–4]. The costs associated with creating patient-specific guides [9,10] are offset to a variable extent by the elimination of the conventional aiming devices and the decrease in operating-room turnover time. The 3D data set provided by the software allows planning in all three planes, thereby optimising implant size selection [11,12] and positioning [13]. In several studies [14–17], compared to conventional instrumentation, patient-specific guides were associated with a significant decrease in the difference between the hip-knee-ankle (HKA) angle and neutral alignment. Patient-specific guides and computer navigation produced similar mechanical alignment of the femoral and tibial components in one study [18]. However, recent meta-analyses failed to demonstrate a convincing advantage of patient-specific guides in terms of implant alignment in the coronal plane [19–22]. Furthermore, two studies [23,24] showed significantly lower accuracy of patient-specific instrumentation in achieving the PTS, with respectively 23% and 24% fewer patients within 2° or 3° of the target value, compared to the group

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managed using conventional instrumentation. Thus, a major concern is the limited ability to control tibial alignment in the sagittal plane during the TKA procedure.

The objective of this study was to evaluate the postoperative radiographic outcomes of 50 TKAs with special attention to PTS, which is difficult to control intraoperatively. We hypothesised that patient-specific tibial cutting guides lacked accuracy in the sagittal plane, while ensuring good control of alignment in the coronal plane.

2. Material and methods

2.1. Patients and procedure

This prospective single-centre study included consecutive patients who underwent TKA performed by a senior orthopaedic surgeon between September 2012 and February 2013 because of tricompartmental knee osteoarthritis grade 2 or 3 in the Ahlbäck classification system [25]. Of the 63 eligible patients, the first 10 were excluded to allow for the learning curve. In addition, 2 patients were excluded because of metal artefacts on magnetic resonance imaging (MRI) and 1 because of a history of valgus tibial osteotomy with major epiphyseal deformity.

The remaining 50 patients (27 males and 23 females) had a mean age of 69.5 years (range, 52–85) and a mean body mass index (BMI) of 26.2 kg/m^2 (range, 21–44). The cementless, mobile bearing, polyethylene Vanguard-ROCC (Biomet Inc., Warsaw, IN, USA) prosthesis with a built-in PTS of 7° was implanted via the medial para-patellar approach in all 50 patients.

The knee-anatomy data set was created according to the MRI Signature™ protocol (Materialise, Leuven, Belgium). MRI was performed 6 weeks before the surgical procedure, using a 1.5-Tesla machine (Intera, Philips Healthcare, Eindhoven, The Netherlands). Three acquisitions were recorded: low-resolution T1-weighted axial images through the ankle and hip and high-resolution 1-mm sagittal images through the knee. After image segmentation and conversion to the DICOM format, the anatomic reference points were identified to allow construction of the skeletal landmarks (Table 1).

The height of the cut was determined by taking into account the thickness of the residual cartilage to identify the most proximal point on the healthy tibial plateau and the most distal point on the least damaged femoral condyle, along the mechanical axis of the limb. The surgeon determined the 3D angle values for implant position using the Signature Online Management System® (Materialise) with a pre-specified PTS of 2°. The patient-specific cutting guides rested on the epiphysis, at three sites: a cartilaginous site at the anterior portion of each tibial plateau and a bony antero-medial metaphyseal site located well above the anterior tibial tubercle. Two aiming devices supported by a metallic connector to the guide were used to position two guide pins. These pins served to orient the final cutting guide, whose resection height was adjustable (Fig. 1a and b).

PTS was evaluated using a simple extramedullary alignment guide, using the anterior tibial cortex as a visual landmark.

2.2. Postoperative evaluation

Digitised radiographs were obtained 3 months after the TKA procedure, using fluoroscopy to superimpose the femoral condyles. The posterior cortical line was drawn as the line tangent to the posterior edge of the posterior tibial cortex, 4 cm under the plane of the plateau, through two points located 5 cm apart, on a short film measuring 14 by 17 inches. The PTS of the implant was measured as the angle subtended by the line perpendicular to the posterior cortical line and the line through the plane of the tibial tray.

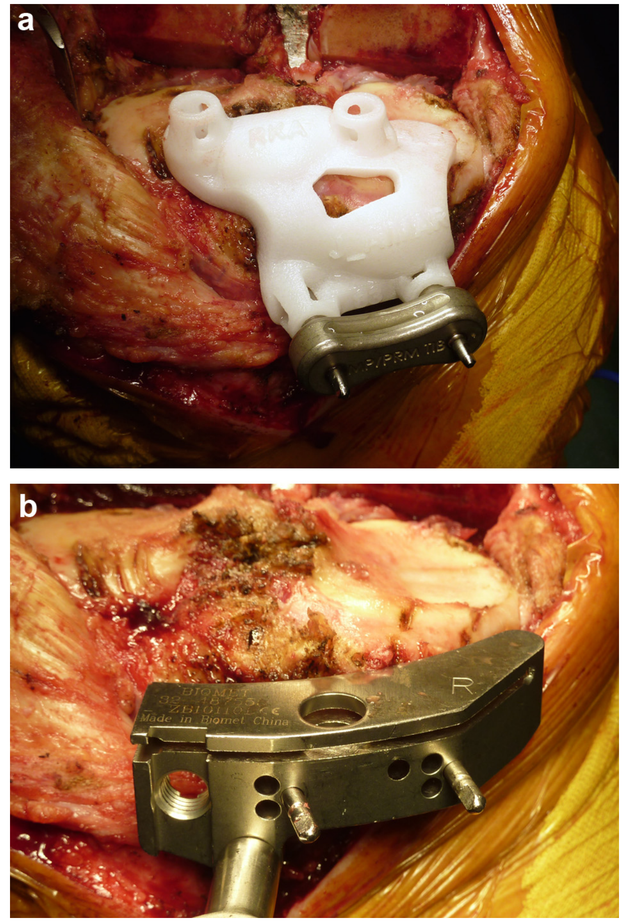

Fig. 1. a and b: Signature™ system used for the tibial epiphysis after implantation of the two positioning pins. Guide for the final tibial cut, with adjustable resection height.

Radiographic angle measurements were performed by an independent observer, who used Global Imaging software (Global Imaging On Line, Montreuil, France). The mechanical tibio-femoral implant angle in the coronal plane (HKA angle) was obtained using standardised telemetry in the standing position.

2.3. Statistical analysis

Descriptive statistics were computed using StatView software version 5.0 (SAS Institute, Cary, NC, USA) on a PC. The observer measured the HKA angle and PTS twice for the same 20 knees. Comparison of the two sets of values using Wilcoxon's test indicated excellent intra-observer reproducibility. The Shapiro–Wilk test established that the HKA angle and PTS values were normally distributed. The target ranges were 180° ± 3° for the HKA angle and 2° ± 2° for PTS.

3. Results

The implant PTS values produced an asymmetric box-and-whisker plot with a median at 1° and values representing posterior tibial slopes in more than 2/3 of the cases (Fig. 2). The target range of 2° ± 2° was achieved in 35 (70%) knees and the mean overall PTS was 2.06° ± 2.79°. In 15 (30%) knees, PTS was either excessive (n = 10; maximum value 9°) or reversed (n = 4; greatest anterior

Table 1
Sequence for acquiring the anatomic points used to build skeletal landmarks after segmentation and orientation of the MRI slices, and bone cut simulation.

Anatomical reference points	Method for point acquisition after segmentation	Skeletal orientation for placing the points	Skeletal landmarks used to orient the bone cuts	Rotation of the implants and level of the bone cuts
Centre of the hip	Sphere shaped after the contours of the femoral head	Defined in 3D based on the native-knee MRI slices	([a]) The femoral mechanical axis was defined in several steps: the first step consisted in defining the femoral axis connecting the middle of the epicondylar line and the centre of the hip A distal plane was defined as the plane perpendicular to the above-described femoral axis and running through the middle of the epicondylar line An antero-posterior plane was defined as the plane perpendicular to the distal plane and running through the antero-posterior axis This antero-posterior plane intersected the epicondylar line at a point The femoral mechanical axis was defined as the line connecting this point to the centre of the hip	A distal femoral plane was defined as the plane perpendicular to the femoral mechanical axis and located 9 mm above the distal-most point of the medial condyle Valgus-varus (0°) relative to an axis projected onto the plane and parallel to the antero-posterior axis of rotation, through the distal-most point of the medial distal femoral condyle that determines the height of the cut
Centre of the distal femoral epiphysis	([a])	([a])		
Whiteside line	2 points at the trochlear groove	3D reconstruction first then confirmation using the axial slices	Antero-posterior axis	
Lateral and medial epicondyles	Medial sulcus (point at the centre of the medial sulcus at the medial epicondyle) and tip of the lateral tuberosity (most lateral point on the lateral epicondyle) The medial sulcus and lateral tip are defined by evaluating the distance between the bony epicondylar surface and the antero-posterior plane		Surgical transepicondylar axis projected onto the plane of the distal femoral bone cut	Posterior cutting line within the plane of the distal femoral bone cut and parallel to the projection of the transepicondylar axis onto this same plane The flexion axis (flexion set at 3°) ran through the point at which the mechanical axis projected onto the plane of the distal femoral cut and was parallel to the posterior bone cut The plane of the posterior femoral cut was defined as the plane perpendicular to the plane of the distal femoral bone cut and parallel to the transepicondylar axis projected onto this same plane The axial rotation line was expressed in the plane of the posterior femoral cut running through the projection of the most posterior point of the medial condyle in the posterior plane and perpendicular to the plane of the distal bone cut

Table 1 (*Continued*)

Anatomical reference points	Method for point acquisition after segmentation	Skeletal orientation for placing the points	Skeletal landmarks used to orient the bone cuts	Rotation of the implants and level of the bone cuts
Centre of the proximal tibial epiphysis	The middle of the plane of the plateaux is determined based on a virtual bony slice through the tibial plateaux, immediately distal to the osteophytes and proximal to the anterior tibial tubercle	Defined in 3D based on the native-knee MRI slices	Tibial mechanical axis	The antero-posterior axis matched the axis of rotation for varus/valgus, which was set at 0° The axis of rotation in flexion/extension used to obtain a posterior tibial slope of 2° was the projection onto the tibial plane of the axis perpendicular to the antero-posterior axis and running through the most proximal tibial point
Centre of the ankle	Sphere shaped after the contours of the talar dome at the level of the malleoli			
Anterior tibial tubercle	A tibial plane was defined 10 mm distal to the highest lateral or medial tibial point. The height of these points was defined perpendicularly to the tibial mechanical axis. The anterior tibial point was the projection on this plane of the medial third of the anterior tibial tubercle	Tibia oriented longitudinally along its mechanical axis	The antero-posterior axis was defined as the line connecting the posterior sulcus and the anterior tibial point	
Posterior sulcus	The intersection of the tibial plane with the mechanical axis defined a point The posterior sulcus was obtained by positioning the perpendicular to the line through this point and the anterior tibial point at the level of the most anterior point of the posterior edge of the tibial plateau plane	The tibia was subjected to a final rotational movement relative to its mechanical axis to align it in the sagittal plane according to its antero-posterior axis		

[a] The information is implemented in the second row of the fourth column.

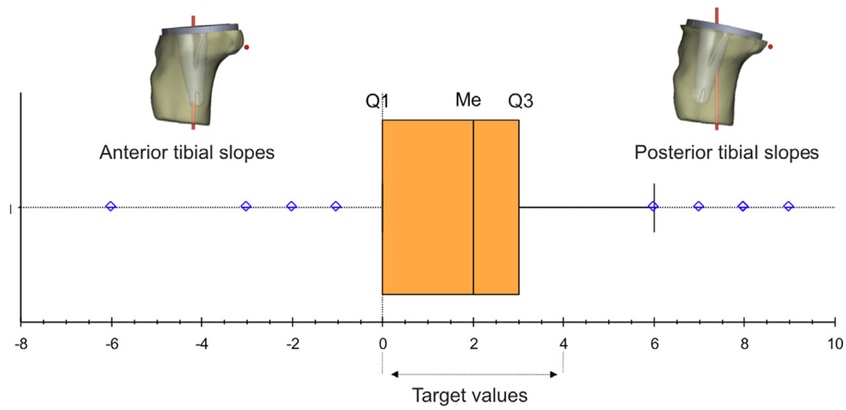

Fig. 2. Radiographic measurements of the posterior slope of the tibial component, shown as box-and-whisker plots.

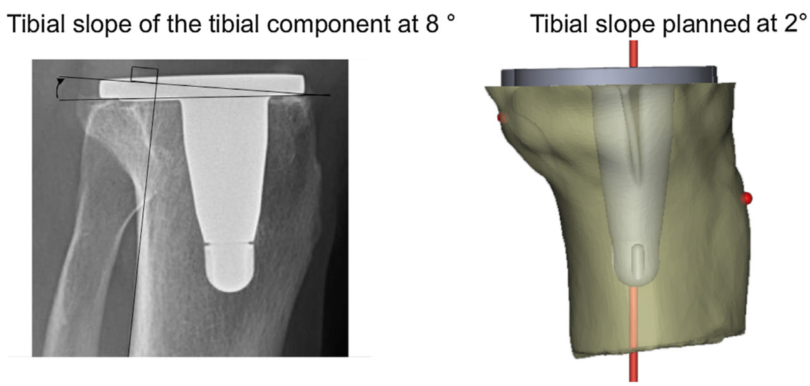

Fig. 3. Posterior slope of the tibial component measured on radiographs. In this patient, the difference between the planned and actual slope was 6°.

slope −6°). The mean difference with the target value of 2° was 2.1°; in 95% of cases, the difference ranged from 7.1° to −3° (Fig. 3).

The mean postoperative HKA angle was 178° ± 2.81°. In 88% of knees, the value was within the target range (180° ± 3°). The greatest HKA angle values were 9° of varus and 4° of valgus (Fig. 4).

4. Discussion

4.1. Main findings and limitations

Our sample size was limited to 50 knees, after exclusion of the first 10 cases to allow for the learning curve. We used no functional measures, instead confining our study to radiographic data. Coronal lower-limb alignment in the standing position was fairly reliable, with a postoperative HKA within 3° of the target in 88% of knees. Patient-specific instrumentation was far less accurate for determining the PTS, whose highest and lowest values differed by 15°. Some authors define the PTS target range as a ± 3° difference with the target value. With this criterion, however, reversal of the normal configuration producing an anterior tibial slope of up to −3° is acceptable if the target is set at 0° as recommended by the manufacturer of the implant. In our study, an anterior tibial slope of −1° or more was classified as failure to achieve the target range of 2° ± 2°, with 2° being the target value determined from a 3D imaging data set. Our findings agree with previously reported results (Table 2) showing that patient-specific guides perform less well than conventional instrumentation for achieving the desired PTS. In particular, a randomised controlled trial showed a 4-fold increase in PTS errors with patient-specific guides than with conventional instrumentation [24].

4.2. Skeletal references: selection and 3D-2D matching

Selection of the anatomical axis to be used for measuring PTS deserves discussion. The American Knee Society has recommended a short proximal anatomical axis for assessing the implant PTS [39]. In contrast, navigation and patient-specific instruments developed from preoperative 3D data rely on a longer mechanical tibial axis. Using the mechanical axis of the entire tibia may avoid errors related to focal bowing or deformity of the bone. However, even with a long mechanical axis on a 2D radiograph, measurement bias may be induced by rotation of the leg skeleton, which should

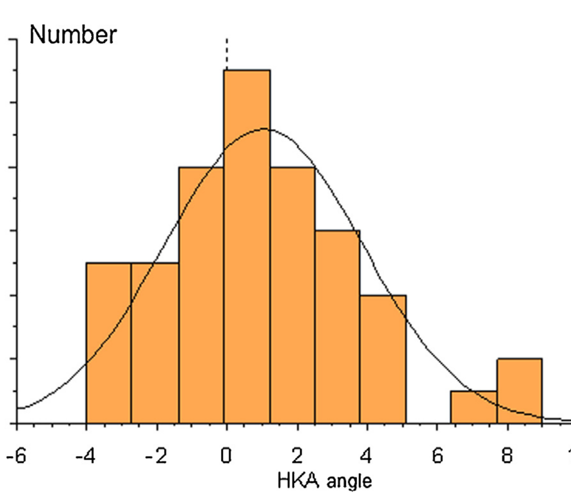

Fig. 4. Histogram of differences between postoperative hip-knee-ankle (HKA) angles and the planned angle of 180° in the coronal plane.

Table 2
Recent reporting posterior tibial slope values achieved using various types of patient-specific cutting guides.

	Study	System used	Case-series T/PSI/CAS	Evaluation	Outliers as the % relative to the target range (±2° or ±3°)
Stronach et al. [23]	P	Signature® MRI, Biomet	62 CI/54 PSI	X-ray	61CI/38 PSI[a]
Kotela et al. [26]	RCT		60/52	X-ray	19.56 CI/38.78 PSI
Boonen et al. [27]	M-RCT		90 CI/90 PSI	X-ray	28 CI/33 PSI
Notre série	P		50 PSI	X-ray	28 PSI
Koch et al. [28]	P	MyKnee® CT	301 PSI	X-ray	12.3 PSI
Albane et al. [29]	M-RCT	Visionnaire® MRI Smith&Nephew	67 T/59 PSI	X-ray	22 CI/30 PSI[a]
Lustig et al. [30]			60 PSI	CAS	19 PSI
Conteduca et al. [31]	P		15 CAS	CAS	60 PSI
Pfitzener et al. [16]	RCT	Truematch® Visionnaire®	30 T/30 PSI/30 CAS	X-ray	37 CI/10 PSI[a]/13 CAS
Hamilton et al. [32]	RCT	Truematch® CT Depuy	26 T/26 PSI	X-ray	50 CI/35 PSI[a]
Woolson et al. [24]	RCT		26 T/22 PSI	CT	8 CI/32 PSI[a]
Franceschi et al. [33]	P	Knee-Plan® CT Symbios	107 PSI	CT	30 PSI
Portier et al. [34]	RCT	PSI® MRI Zimmer	10 T/9 PSI	X-ray	4.20° vs 7.33°[a]
Ng et al. [35]	RCT		27 T/51 PSI	CT	37 CI/38 PSI
Chen et al. [36]	P		30/29	X-ray	20/24
Yan et al. [37]	RCT		10 T/10 PSI/10 CAS	X-ray	36.6 CI/20 PSI/10 CAS
Victor et al. [38]	RCT	4 different systems	64 T/64 PSI	X-ray	3 CI/21 PSI[a]

P: prospective; RCT: randomised controlled trial; M-RCT: multicentre randomised controlled trial; MRI: magnetic resonance imaging; CT: computed tomography; CI: conventional instrumentation; PSI: patient-specific instrumentation; CAS: computer assisted surgery; X-rays: lateral X-ray.
[a] Significant difference

ideally be aligned based on the anterior tibial tubercle, as performed in our study (antero-posterior axis). In addition, the results are influenced by the definition of the proximal end of the tibial mechanical axis [40,41]. When evaluating postoperative outcomes based on 2D radiographs in patients whose preoperative planning relied on 3D data, the correspondence must be determined between preoperative 3D and postoperative 2D skeletal landmarks [42]. In one study [43], the mean differences on long-leg 2D radiographs between the tibial mechanical axis used as the reference and the posterior cortical line of the proximal tibia or the proximal anatomical axis were 2.9° and 0.2°, respectively, and the corresponding PTS ranges were –0.2 to 19.3° and –2.5° to 1.8°. The posterior cortical line of the proximal tibia is not yet among the parameters available for 3D modelling. Nevertheless, it was selected in our study for the postoperative evaluation, as it can be readily and reproducibly drawn on radiographs that are easily obtained. On a long lateral radiograph of the tibia, when the middle of the medial tibial plateau is chosen as the proximal point for defining the tibial mechanical axis in order to replicate the 3D construction parameters as closely as possible, then the tibial mechanical axis tends towards the posterior cortical line of the proximal tibia [44].

4.3. Value of MRI for anatomic landmark selection and accuracy

Patient-specific guides are created based on skeletal landmarks identified on MRI slices. This technique is therefore dependent on the reproducibility and accuracy of DICOM images for positioning the anatomical landmarks used to define the rotational axes for the bone cuts. The superior contrast provided by MRI compared to computed tomography (CT) ensures better identification of the various soft tissues, most notably the cartilage [45]. However, CT may be more accurate than MRI for delineating bone contours. In our study, the most proximal point on the proximal tibia was located at a cartilaginous site to allow adjustment of the height of the cut. The other two points, in contrast, were at sites composed only of bone. Tibial guides developed from CT data are more bulky, do not take the cartilage into account, and require stabilisation at four contact sites, two at each tibial plateau. As a result, in most cases, the part of the cartilage in contact with the guide must be painstakingly removed using an electrocautery pen or a currette. In a prospective study of 107 patients who underwent TKA with patient-specific guides developed from CT images using the Knee-Plan® system, only 70% of knees had PTS values within 2° of the target of 4° [33]. Independently from issues pertaining to the quality of digitised images, the anatomical definition of the ideal rotational axis of the tibia remains controversial [46]. In our study, PTS was computed based on a rotational axis perpendicular to the antero-posterior axis of the tibia, defined as the line through the anterior tibial tubercle and the posterior sulcus separating the two tibial plateaux. The use of this short and imperfectly reproducible axis results in lack of accuracy. The effect of ±0.5-cm variability in the acquisition of one of these two anatomical points located about 6 cm apart modifies the measured angle by ±5.77°. With a tibial mechanical axis defined by two points located 36 cm apart, the same 0.5-cm error would modify the measured angle by less than 1°. This fact may explain the decreased accuracy of navigated bone cuts performed using short rotational axes.

4.4. Geometric design and stability of the patient-specific tibial guide

Patient-specific cutting guides are composed of a rigid material which is resistant to deformation even when subjected to heat during sterilisation. In addition, the two aiming devices for the tibia in the Signature™ system used in our patients are equipped with a removable metal guide that ensures optimal placement of the two pins used to position the tibial cutting guide (Fig. 5). There might be an ideal tibial-guide geometry that immediately ensures optimal positioning. The bone model (model of the patient's epiphysis obtained from the 3D data set) allows intraoperative simulation of the optimal patient-specific guide position but is not always available and entails additional costs. Importantly, the guide has two stabilising extension tabs, one resting on each tibial plateau, which are designed to provide good PTS control. In a randomised

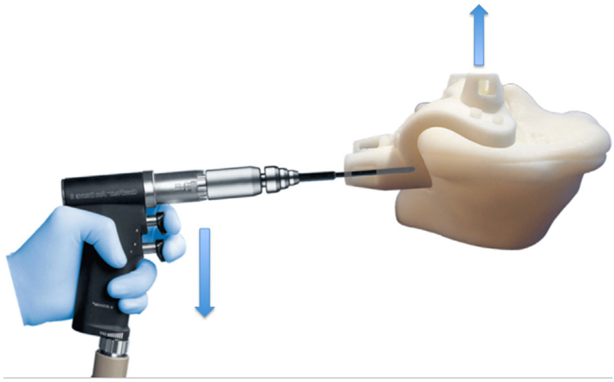

Fig. 5. The weight of the motor on the guide pins acts as a lever that can alter the orientation of the guide.

controlled trial versus conventional instrumentation, PTS accuracy was greater with Zimmer patient-specific instrumentation, whose tibial guide has a long extension tab that rests firmly on the entire medial tibial plateau [34]. An advantage of MRI-based guides over CT-based guides is that they can rest not only on the marginal osteophytes but also on the cartilage surface of the healthy plateau.

Large PTS errors occurred in some of our patients. One possible explanation is that the weight of the motor connected to the guide pins produces a lever effect on the aiming devices. If the guide is unstable, it can be tilted by this lever effect (Fig. 5). Therefore, the proximal extension tabs of the guide must be firmly applied onto the tibial plateau to prevent tilting in flexion or extension. The bony surface of the anterior tibial metaphysis in contact with the guide also acts as a stabiliser and should be fully exposed by removing all capsular and periosteal attachments [47]. PTS errors are difficult to correct intraoperatively: with the anterior edge of the tibia taken as the reference, the extramedullary alignment rods (also used with conventional instrumentation) are not sufficient when used alone to check the PTS of the two plateaux.

5. Conclusion

Despite promising developments, in our study the tibial patient-specific cutting guide resulted in marked flexion-extension variability of the tibial component. Uncertainty regarding the position of the 3D landmarks derived from the MRI data set adversely affects development of the guide. A very stable guide that rests on both tibial plateaux is essential to control PTS. Improvements in the geometry of patient-specific guides can be expected to limit operator-dependent errors.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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