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REVIEW

Evaluation of the accuracy of a patient-specific instrumentation

Daniele MAZZA *, Raffaele IORIO, Matteo GUZZINI, Andrea REDLER, Fabio CONTEDUCA, Andrea FERRETTI

Orthopedic Unit and "Kirk Kilgour" Sports Injury Centre, S. Andrea Hospital, University of Rome "Sapienza", Rome, Italy

*Corresponding author: Daniele Mazza, Via Grottarossa, 00054 Rome, Italy. E-mail: daniele.mazza@hotmail.it

ABSTRACT

Patient-specific instruments (PSI) has been introduced with the aim to reduce the overall costs of the implants, minimizing the size and number of instruments required, and also reducing surgery time. The aim of this study was to perform a review of the current literature, as well as to report about our personal experience, to assess reliability and accuracy of patient specific instrument system in total knee arthroplasty (TKA). A literature review was conducted of PSI system reviewing articles related to coronal alignment, clinical knee and function scores, cost, patient satisfaction and complications. Studies have reported incidences of coronal alignment ≥3° from neutral in TKAs performed with patient-specific cutting guides ranging from 6% to 31%. PSI seem not to be able to result in the same degree of accuracy as for the CAS system, while comparing well with standard manual technique with respect to component positioning and overall lower axis, in particular in the sagittal plane. In cases in which custom-made cutting jigs were used, we recommend performing an accurate control of the alignment before and after any cuts and in any further step of the procedure, in order to avoid possible outliers.

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Total knee arthroplasty (TKA) is one of the most successful orthopedic procedures restoring a significant degree of function in arthritic knees in most cases. However, errors in surgical technique and component placement can compromise the long-term performance.[1] It has been proven that one of the most important factors influencing the longevity of implants in TKA is the restoration of mechanical axis, as deviations of greater than 3° of varus/valgus in the mechanical axis lead to poor survivorship because of the accelerated wear as a result of abnormal stresses at the bearing surfaces.[2]

The use of computer-assisted surgery (CAS) in TKA results in better coronal alignment of the leg and the implants compared to TKA performed using the standard technique.[3]

However, the majority of published studies have not found statistically significant differences between CAS and conventional TKA based on the Knee Society Score (KSS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) or University of California Los Angeles activity score (UCLA). Only one prospective study [4] reported better 5-year KSS results in the CAS TKA group.

Moreover, the duration of surgery performed with computer navigation was significantly longer. This is due in part to the surgical technique which requires the placement of the

reference arrays, digitization of the knee, and waiting for the computer to work out the algorithms.[5]

In recent years, patient-specific instruments (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. PSI uses anatomical data, as detected by pre-operative axial computed tomography (CT) or magnetic resonance imaging (MRI), to create disposable cutting jigs individualized to the patient's unique anatomy. However previous studies [6, 7] documented an only fair accuracy of the method with a consistent risk of error of more than 2°, especially in the sagittal plane.

PSI system

PSI were recently introduced as a new technology, to pursue the same goal of navigation in increasing the accuracy of the surgical technique, avoiding the practical issues related to the complexity of the CAS, such as the costs, surgical time and the learning curve related to the procedure.

The pre-operative planning of the TKA procedure is outsourced to engineers who identify the anatomical landmarks needed for components alignment on CT/MRI based 3D models, therefore transferring the informations to patient-specific instruments that can be used during surgery. These instruments, created by laser sintering, can be produced in the most complex forms and are thus patient specific.[8] This technology gained widespread acceptance in dental surgery and was gradually introduced in TKA. Using a preoperative CT or MRI scan, disposable cutting blocks are produced.

Thienpont *et al.*[9] showed that the total volume of PSI in Europe for 2012 was 17,515 total knee arthroplasty and 82,556 TKA worldwide. The seven companies which provided PSI are by alphabetical order: Biomet (Warsaw, IN, USA), DuPuy-Synthes (Warsaw, IN, USA), Medacta (Castel San Pietro, Switzerland), Smith & Nephew (Memphis, TN, USA), Stryker (Mahwah, NJ, USA), Wright Medical (Memphis, TN, USA) and Zimmer (Warsaw, IN, USA). Biomet was the number one in volume, both in Europe as worldwide with their Signature system. Biomet represented 27 % of the market share in PSI worldwide.

Preoperative data

Bone models generated from CT data have been shown to be more accurate and smooth in their external surface boundaries than MRI-generated models.[10] By contrast, the segmentation process of the images can be performed on the surface of the articular cartilage using MRI data, whereas the articular cartilage surface cannot be estimated using CT data. A study of cadaveric knees demonstrated that the patient-matched cutting block based on CT imaging shows good rotational alignment accuracy except for one specimen with badly damaged cartilage.[11] Because the patient-specific guide based on CT images was created using a bone model without the cartilage, the guide did not make contact the local area of the articular surface where the cartilage was worn away. In varus deformity osteoarthritis, the articular cartilage has already been worn away at the distal part of medial femoral condyle and the proximal part of medial tibial plateau. Therefore, the residual cartilage evaluation seemed to influence the alignment particularly on the coronal plane.

Because the purpose of undergoing MRI was to construct three-dimensional bone models, the patient had to be immobilized from the start to the end of the procedure to avoid motion artifacts. Conversely, there was considerable concern regarding the radiation dose from CT to create the patient-specific guide. Although it is still unknown whether the cancer risk for TKA patients after CT scan exposure increases, and, CT scans should be limited to definite situations in order to avoid unnecessary radiation exposure.[12] If the results obtained using the patient-specific guide based on CT images were the same as those based on MRI, the radiation dose from modern CT scanners might be of little concern for cases that could not receive MRI because of metallic hardware or motion artifacts.

Cost analysis

DeHaan et al. analyzed costs of PSI.[13] Of the variables assessed for patient-specific TKAs, the two that added cost were the price of the pre-operative advanced imaging ($430-$1360) and the cost of the custom cutting blocks ($500). The other variables measured all served to save money and increase efficiency for the patient-specific instrumentation group: shorter operating room time, fewer instrument trays requiring sterilization, and a shorter operating room turnover time.

The 20.4 min shorter operating room time for the patient-specific TKA group provided an average cost savings of $1326 (20.4 min × $65/min) per case when compared to conventional TKA. Similarly, arthroplasty done with patient-specific instrumentation used 4 fewer instrument trays than with conventional instrumentation, and would thus provide an additional cost savings of $240 (4 trays × $60/tray) per case. Unfortunately, the financial impact of a 42% shorter operating room turnover time could not be quantified; however, this increased efficiency would provide additional cost savings to the hospital through money saved in fewer nursing and surgical staff hours, along with the potential of having additional time for more surgical cases.

Thus, they found that the routine use of patient-specific instrumentation in TKA added between $830 and $1860 per case based on the cost of the advanced imaging and the prefabricated cutting blocks. However, shorter operating room time and the use of less surgical trays per case saved $1566 per case, along with the additional variable of increased turnover time efficiency. Thus, routine use of patient-specific instrumentation does not appear to add to the overall cost to primary TKA, but can actually result in significant cost savings dependent upon which imaging center is used.

Blood loss

Spencer *et al.*[14] analyzed the results of 30 TKA's performed with the OtisMed custom-fit technique and compared them to a matched cohort operated on using conventional alignment guides. There were no differences in blood loss, and there was a mean decrease in tourniquet time of 14 % compared to a cohort of patients with conventional knee replacements (80±17 *vs.* 93±12 min).

Chareancholvanich *et al.*[15] randomized 80 patients to undergo TKR with PSG or conventional instrumentation and found that the operating time was reduced by a mean 5.1 minutes (P=0.019), without tangible differences in postoperative blood loss (P=NS) or need for blood transfusion (P=NS).

Noble et al. carried out prospective randomized study comparing Visionnaire (15 patients) to standard instrumentation (14 patients). They found a small although significant reduction in the length of hospital stay (59.2 *vs.* 66.9 h, NS) and operative time (121.4 *vs.* 128.1 min, P<0.048). They found no significant difference in blood loss (71 *vs.* 62.5 mL, NS).

Boonen *et al.*[16] reported significantly lower blood loss and shorter operation time with the PSG system than with the conventional system. Blood loss being 100 mL less and operation time being 5-minutes shorter.

Final alignment

The peer-reviewed literature on PSI is still limited with only a few high-quality studies available. The initial papers by early adopters of the technology were globally showing a mean mechanical axis comparable to conventional surgery with a lower rate of outliers in the coronal plane, but without significant difference.[8, 17] Subsequently, a few retrospective studies about a MRI-based system,[6, 7] and a recent randomized controlled trial, where different PSI systems were controlled with navigation during surgery, did not show convincing evidence for three-plane alignment superiority for PSI in comparison with standard technique.[8]

Previous studies have reported incidences of coronal alignment ≥3° from neutral in TKAs performed with patient-specific cutting guides ranging from 6% [18] to 31% [19] (Table I). Moreover, the PSI system did not demon-

TABLE I.—*Comparative studies for PSI assessments.*

Study	Patient	System	Implant
Lee *et al.*[36] 2016		Vega system (CT)	Vega (B Braun)
Nam *et al.*[22] 2013	41	Signature Biomet (MRI)	Vanguard Complete Knee System (Biomet)
Chen *et al.*[19] 2013	29	Zimmer PSI system (MRI)	Zimmer Nexgen LPS system
Boonen *et al.*[16] 2013	45	Signature Biomet (MRI)	Vanguard Complete Knee System (Biomet)
Parratte *et al.*[32] 2013	20	Zimmer PSI system (MRI)	Zimmer Nexgen LPS system
Pietsch *et al.*[18] 2013	50	Zimmer PSI system (MRI)	Zimmer Nexgen LPS system
Daniilidis *et al.*[23] 2013	150	Visionaire PSI Smith&Nephew (MRI)	Genesis II (Smith and Nephew)
Vundelinckx *et al.*[33] 2013	31	Visionaire PSI Smith&Nephew (MRI)	Genesis II (Smith and Nephew)
Koch *et al.*[25] 2013	301	MyKnee Medacta (CT)	GMK (Medacta)
Scholes *et al.*[26] 2013	30	Zimmer PSI system (MRI)w	Zimmer Nexgen LPS system
Lustig *et al.*[27] 2013	60	Visionaire Smith&Nephew (MRI)	Genesis II (S&N)
Daniilidis *et al.*[34] 2012	124	Visionaire Smith&Nephew (MRI)	Genesis II (Smith and Nephew)
Bali *et al.*[17] 2012	32	Visionaire Smith&Nephew (MRI)	Genesis II (Smith and Nephew)
Ng *et al.*[24] 2012	569	Signature Biomet (MRI)	Vanguard Complete Knee System (Biomet)
Conteduca *et al.*[7] 2012	12	Visionaire Smith&Nephew (MRI)	Journey BCS (S&N)
Noble *et al.*[21] 2012	15	Visionaire Smith&Nephew (MRI)	Legion Total Knee System (Smith & Nephew)
Nunley *et al.*[35] 2012	57	Vanguard total knee system (Biomet) (MRI)	Signature system (Biomet)

HKA: hip-knee-ankle angle; CTA: coronal tibial angle; CFA: coronal femoral angle; STA: sagittal tibial angle; SFA: sagittal femoral angle.

strate a marked improvement in the incidence of outliers in final coronal alignment, comparing poorly with computer-assisted navigation (9%), with rates of outliers to technique (31.8%).[20]

Bali *et al.*[17] shared their initial experience with use of PSI in 32 TKAs. At 6 weeks, long-leg radiographs were obtained to evaluate the coronal alignment and twenty-nine of the 32 knees (90.6%) had a mechanical axis restored to within 3° of neutral. The authors concluded that custom-fit system in TKA was found to be as accurate in restoring the postoperative alignment as the standard TKA.

Noble *et al.*[21] compared the value of the new mechanically aligned patient-matched instrument system for total knee arthroplasty to that of standard TKA surgical instrumentation. Mechanical alignment was significantly closer to neutral zero in the PSI group (1.7° range 0-6° *vs.* 2.8° range 0-5°). The results of the this randomized study support the value of patient-matched cutting blocks. However this study is only representative of one surgeon's experience.

Nam *et al.*[22] compared the alignment accuracy of PSI to an imageless CAS system in TKA. In the PSI cohort, 70.7% of patients had an overall alignment within 3° of a neutral mechanical axis (*vs.* 92.7% with CAS), 87.8% had a tibial component alignment within 2° of perpendicular to the tibial mechanical axis (*vs.* 100% with CAS), and 90.2% had a femoral component alignment within 2° of perpendicular to the femoral mechanical axis (*vs.* 100% with CAS). The author concluded that, while

Method	HKA	CTA	CFA	STA	SFA
X-rays	0.4±2.5° 3.1% outliers	90.1±1.9° 3.1% outliers	90±1.7° 9.4% outliers	83.8±1.1 6.3% outliers	NA
X-rays	0.8±2.9° 29.3% outliers	0.4±1.6° 12.8% outliers	0.1°±1.5° 9.8% outliers	NA	NA
X-rays	179.2±3.4 9 outliers (31%)	89.8±1.9 3outliers (10%)	89.9±2.1 2 outliers (7%)	84.2±3.4 7 outliers (24%)	87.7±2.6 7 outliers (24%)
X-rays	179±2.8 30% outliers	90±2.0 9% outliers	89°±2.1 13% outliers	92°±3.2 33% outliers	96°±5 49% outliers
X-rays	179° (171-185) 4 outliers (20%)	89.1 (85-96)	90.1 (84-83)	5.9 (3-9)	8.15 (2-14)
X-rays	3 outliers (6%)	4 outliers (8%)	5 outliers (10%)	3 outliers (6%)	3 outliers (6%)
X-rays	178.4±1.5 14 outliers (9.3%)	NA	NA	NA	NA
X-rays	183±2.59	NA	NA	NA	NA
X-rays	180.1±2.0 34 outliers (11.7%)	11 outliers (3.8%)	13 outliers (4.5%)	37 outliers (12.3%)	27 outliers (9%)
Nav	179.5° 8 outliers (27%)	NA	NA	NA	NA
Nav	179.8 20.9% ouliers	NA	NA	NA	NA
X-rays	178.5±1.7 11 outliers (11%)	NA	NA	NA	NA
X-rays	179.9 3 outliers (9.4%)	NA	NA	NA	NA
X-rays	180.6° 9% outliers	89.9° 10% outliers	90.7° 22% outliers	NA	NA
Nav	NA	1.2±1.5 2 outliers (16%)	1.2±0.6 2 outliers (16%)	3.8±2.4 9 outliers (75%)	+0.5±2.15 3 outliers (25%)
X-rays	181.7	NA	NA	NA	NA
CT-scan	26% outliers	NA	NA	NA	NA

PSI techniques appear sound in principle, this system did not obtain the same degree of overall mechanical and tibial component alignment accuracy as a CAS technique.

Daniilidis *et al.*[23] determined whether PSI would lead to a hip-knee-ankle (HKA) angle within ±3° of the ideal alignment of 180°. The average HKA changed from 173.7°±3.9 preoperatively to 178.4±1.5° postoperatively. The rate of ±3° and ±5° HKA outliers was 11% and 3%, respectively. On the basis of their data, authors showed that these results also reconfirm the conclusion that this specific technology is effective in addressing the issue of malalignment.

Ng *et al.*[24] compared the effectiveness of MRI-based patient-specific positioning guides to manual instrumentation with intramedullary femoral and extra-medullary tibial guides in restoring the mechanical axis of the extremity and achieving neutral coronal alignment of the femoral and tibial components. The overall mean HKA angle for patient-specific positioning guides (180.6°) was similar to manual instrumentation (181.1°), but there were a statistically fewer ± 3° HKA angle outliers with patient-specific positioning guides (9%) than with manual instrumentation (22%).

By our knowledge only one study analyzed CT-based system. Koch *et al.*[25] showed that the postoperative average HKA angle of a CT-based system 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. Comparing the outcome of

this study with the data from the literature,[20] there does not seem to be any difference compared to computer-assisted surgery.

Based on these studies we could speculate that the MRI-based PSI system was not able to obtain the same degree of accuracy as the CAS system, with respect to both the tibial component and overall lower extremity axis in particular in sagittal plane. While the mean values are comparable to most reports of TKAs performed using conventional intramedullary and extramedullary alignment methods, it falls far below the accuracy reported with CAS techniques.[20] However in most cases the authors failed to report about recut performed during surgery to correct possible misalignment related to inaccuracy of the guided cut.

Moreover these studies only evaluated the alignment in the coronal plane, not considering possible malposition in the sagittal plane that may play a significant role in the maximal post-operative flexion and in the polyethylene wears.

Another limitation of previous studies is that the accuracy of the PSI was evaluated using post-operative x-rays, whose data can be influenced by several factor other than accuracy of the cutting guide (sawing errors, cut adjustment, final impaction technique). Computer navigation provides the only real-time method for assessing alignment of system and to our knowledge only few studies [6, 7, 26-28] used this to evaluate the PSI.

Lustig *et al.*[27] used intraoperative computer navigation to evaluate the accuracy of the cutting blocks in the coronal and sagittal planes. The PSI would have placed 79.3% of the sample within ±3° of the preoperative plan in the coronal plane, while the sagittal alignment results within ±3° were 54.5%. Their results are very similar to the data previously reported by us.[6, 7]

Even more disappointing were the results of Klatt *et al.*[28] who used an image-free computer navigation system to evaluate the alignment of the components that was more than 3° off of mechanical axis in all cases. On the basis of their data, author showed that the custom cutting jigs have the potential to place the components outside of the accepted range of alignment and even place the components out of the accepted alignment range.

In a similar study Scholes *et al.*[26] assessed reliability of PSI in TKA using imageless computer navigation. The error between in-theatre measurements and pre-operative plan for the femoral and tibial components exceeded 3° for 3% and 17% of the sample respectively, while the error for total coronal alignment exceeded 3° for 27% of the sample. The authors concluded that alignment with PSI patient-specific cutting guides, assessed by computer navigation, is not accurate. To prevent unnecessary increases in the incidence of malalignment in TKA, it is recommended that these devices should not be used without verification of alignment.

Our experience

We started using PSI in 2011 after a consistent experience with navigation in TKA.[6, 7, 29-31] In a recent study [7] we evaluated the accuracy of a patient-specific instrumentation as assessed by the intraoperative use of knee navigation software during the surgical procedure. Ten satisfactory alignments (83.3%) were obtained on the tibial coronal plane. A correct alignment was achieved on the tibial sagittal plane in 5 patients only (41.6%). On the femur, a correct alignment was obtained for 11 measurements (92.6%) in the coronal plane and in 9 (71%) in the sagittal plane.

We also evaluate the accuracy of VISIONAIRE (Smith & Nephew Inc., Memphis, TN, USA) in comparison with extra-medullary (EM) tibial instrumentation by analyzing data as detected by intra-operative use of knee navigation software. In the coronal plane the mean deviation of the EM tibial guides from the ideal alignment (0°) was 0.7±0.39 and of the VISIONAIRE was 1.2°±1.5 (P=0.22). In the sagittal plane the mean deviation of the EM tibial guides from 3° of posterior slope was -1.6±1.7° and of the VISIONAIRE was +1.1±4.2 (P<0.05). Negative values indicate a more posterior slope from the ideal and positive values an anterior slope.[6]

All data were showed in Figures 1A, B, 2A, B.

These studies documented only a fair accuracy of the method with a consistent risk of error of more of 3° especially in the sagittal plane. We could speculate that the problem in the sagittal plane was due to the fact that the pre-operative protocol does not include a lateral X-ray projection of the knee and only includes an AP standing X-ray of the straight leg and MRI.

Conclusions

PSI have been introduced to reduce the surgical time, the overall costs of the implants, minimising the size and number of instruments required. However current PSI seem not to be able to result in the same degree of accuracy as for the CAS system, while comparing well with standard manual technique with respect to component positioning and

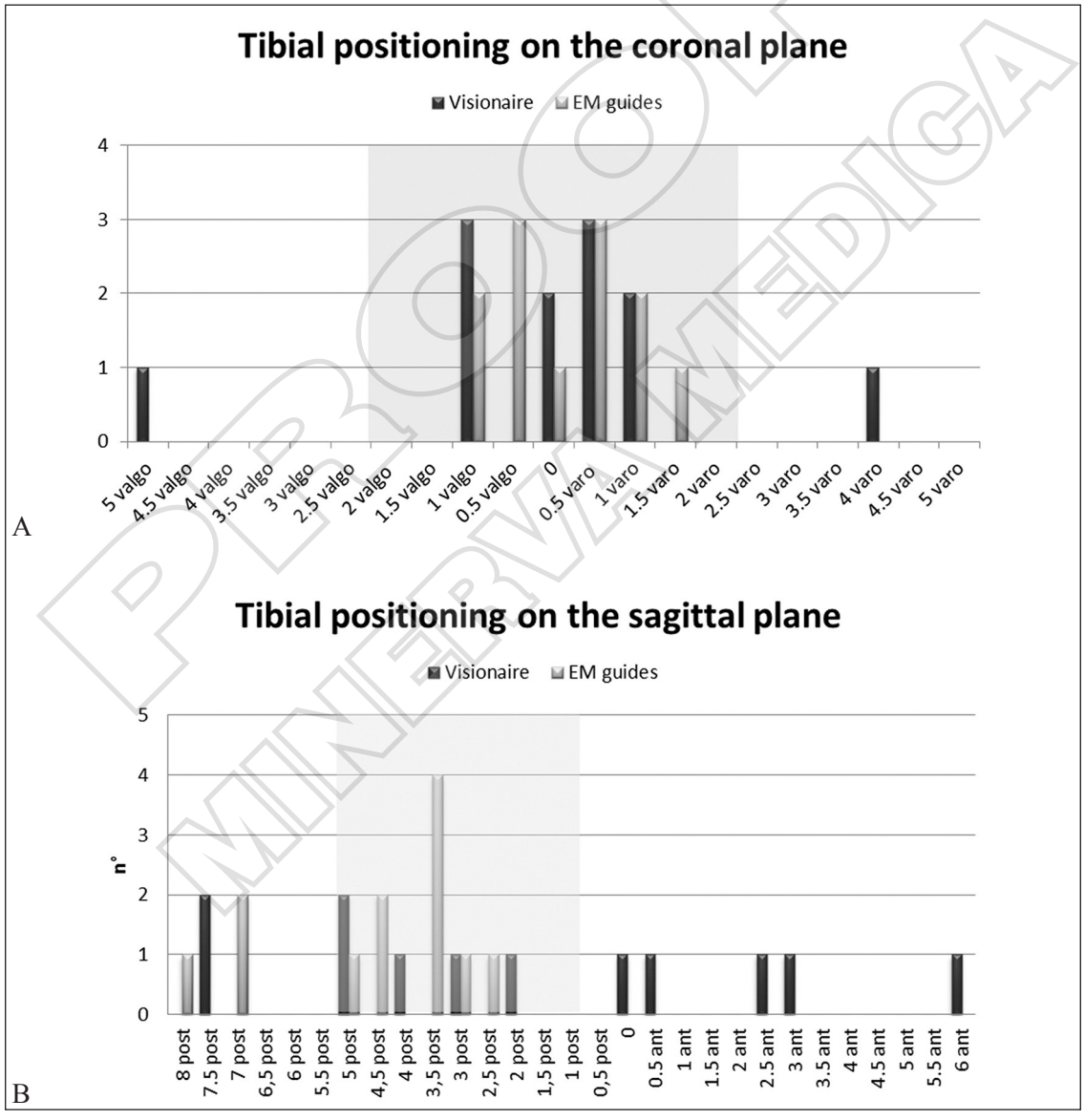

Figure 1.—A) EM guide *vs.* VISIONAIRE on the coronal plane; B) EM guide *vs.* VISIONAIRE on the sagittal plane.

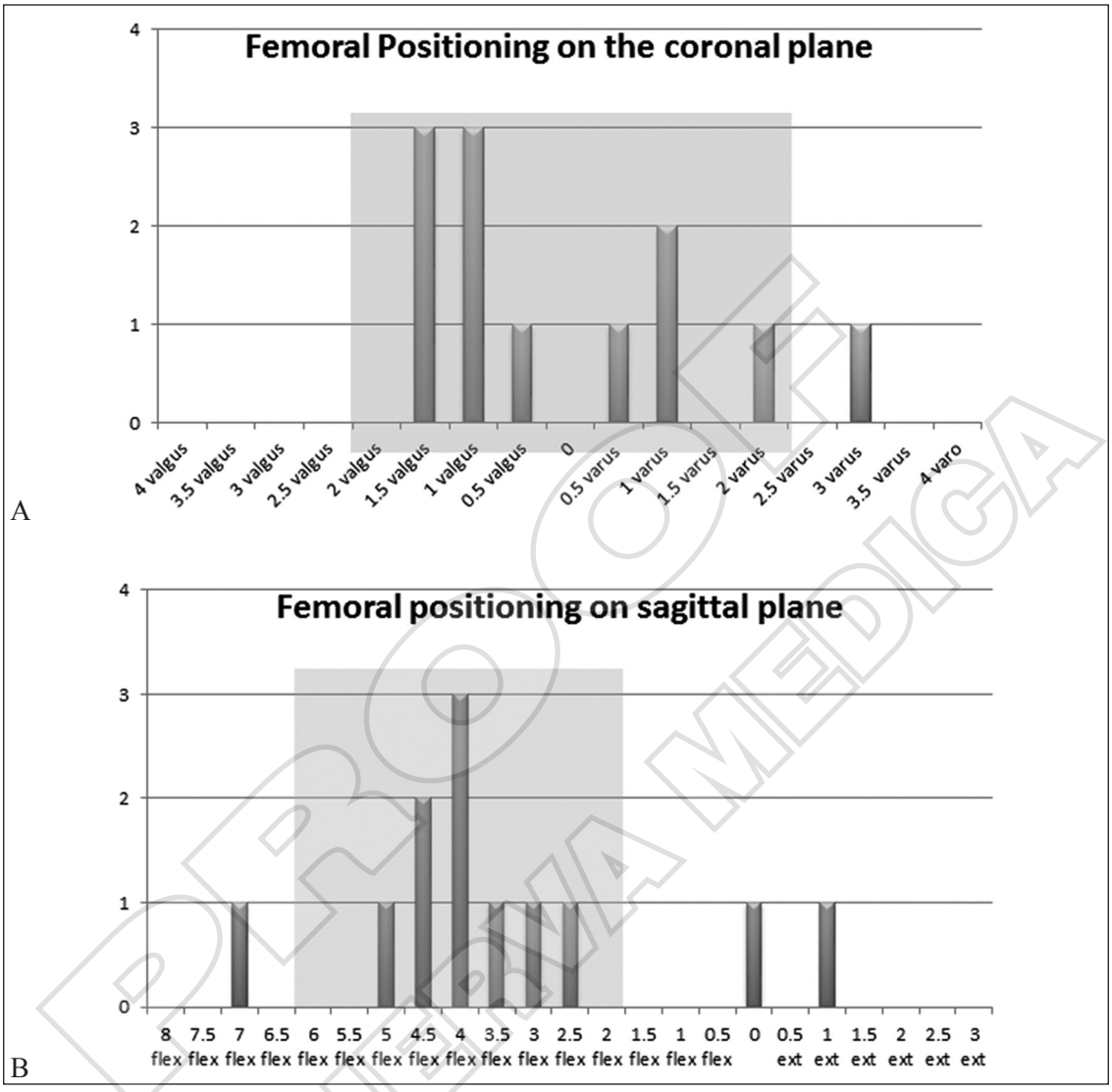

Figure 2.—A) The alignment on the coronal femoral plane; B) The alignment on the sagittal femoral plane.

overall lower axis, in particular in the sagittal plane.

Nowadays, in cases in which custom-made cutting jigs were used, we recommend performing an accurate control of the alignment before and after any cuts and in any further step of the procedure, in order to avoid possible outliers.

Therefore even if PSI appears as a promise technology, their accuracy could be still improved, possibly leading to greater reliability.

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