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ORIGINAL PAPER

Computed tomography evaluation of total knee arthroplasty implants position after two different surgical methods of implantation

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Abstract

Purpose The objectives of this study were to determine the reliability of a novel method of measuring the rotational alignment of an anatomical tibial tray, the difference in the rotational alignment of the femoral and tibial component according to pure measured resection or blended technique with tensor, and, finally, the difference in terms of clinical results according to the two different methods.

Patients and methods We performed a total of 60 consecutive TKAs: 30 according to pure measured resection and 30 according to blended technique with tensor (FuZion®). Clinical scores and CT scan were done at six months to measure patient's outcome and prosthetic components rotation.

Results The method of measurement of tibial tray had high agreement between different radiological observers. Mean external rotation alignment of the femur was 2.7° in standard group and 0.5° in the FuZion® group. For all clinical indices, we observed a large and significant improvement at follow-up, better in blended technique group, but without a clear superiority, and no statistically significant difference was evident between the two groups. At follow-up, HSS was to 89.7 in the FuZion® group and 89.0 in the standard group, KSS (clinical) was 92.6 in and 91.3 respectively, and KSS (Functional) was 91.0 in the FuZion® group and 87.6 in the standard group.

Conclusions Our CT measurement method is reliable and reproducible. All patients operated with this personalized knee system design obtained excellent results; the customization of femoral rotation with a blended technique is, probably, the key to optimize the outcomes and achieve the state of forgotten knee.

Keywords CT measurement TKA rotation · Personalized TKA design · Measured resection and gap balancing · Blended technique with tensor

Introduction

Total knee arthroplasty (TKA) is an effective and worldwide-accepted treatment modality for severe knee osteoarthritis. Despite the increase in the number of operations performed over the last decade, the improvement of the surgical technique as well as of the design, many patients cannot feel the knee as "normal" after surgery and the satisfaction rate remains between 75% and 89% [1, 2]. Often causes are the mismatch between the prosthetic components and the anatomy and the consequent malpositioning of the prosthetic components for the surgical compromises necessary to fit the metal onto the bone. The surgical goal of a TKA is to create symmetric and balanced flexion and extension gaps, with proper rotational alignment. Axial malrotation of components is often related with anterior knee pain [1], patellofemoral complications such as pain, tilting, subluxation and dislocation [3], tibiofemoral instability, and arthrofibrosis [4].

CT scan and Berger's protocol are globally accepted to determine component rotation after TKA [3]. In the series used to popularize the method, the tibial plate had a symmetric design; for asymmetrical tibial design, the rotational

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measurement can be more demanding although some methods have been proposed [5].

Prosthesis alignment and components rotation can be determined by two techniques: measured resection technique (MR) and gap balancing (GB) technique. In literature, there is no consensus regarding which technique results in better outcomes [6], and traditionally, they are considered two completely different philosophies. Femoral component rotation is more influenced than tibial baseplate by the different techniques.

In MR, bone resections for the implant thickness follow anatomic landmarks and the ligaments are adjusted with releases after the bone cuts. The rotation of the femur is fixed and independent from ligaments tension; the surgeon can use transepicondylar axis, Whiteside's line and posterior condylar line with an average of 3° of external rotation of the component [7].

In GB technique, soft tissue tension in flexion and extension guides the bone cuts and it is independent from bony landmarks. Removing the osteophytes and performing the releases before referencing on ligaments tension are prominent for the effectiveness of the technique.

Persona knee system (Zimmer Biomet, Warsaw, IN) can be implanted with a pure measured resection technique, either anterior or posterior referenced, as well as with a blended technique with a tensor (FuZion®).

The aims of the present study are the following:

1) To assess the reliability of the novel method of measuring the rotational alignment of the tibial tray, (in consideration of its unique anatomical design with the progressive medialization of the keel, according to the size), coupling the data with the measurement of the rotational alignment of the femoral component
2) To assess the difference, if any, in the rotational alignment of the femoral component, according to the two different methods (pure MR, with anterior referencing, and FuZion® tensor, with posterior referencing), as well as of the tibial component
3) To assess any difference in terms of clinical results according to the two different methods and specifically to ascertain if the use of FuZion® can bring results at least as good as those obtained with the standard techniques [8, 9].

Patients and methods

Ethical committee approval was obtained for this study (protocol number 20150003437).

It was a prospective study done at a tertiary care referral institute in which we enrolled 60 consecutive patients for elective TKAs using Persona knee system (posterior-stabilized design). Inclusion criteria were three-compartmental degenerative arthritis with a clear indication for joint replacement; exclusion criteria were secondary osteoarthritis (post-traumatic, rheumatic disease, hemophilia), previous osteotomy, and the knee necessitating a higher level of constraint for ligaments incompetence. From every patient, we obtained an informed consensus statement to take part in the study. Demographics and pre-operative evaluation are shown in Table 1.

All surgery was performed via standard para-patellar approach with a mini trivector [10]. The standard measured resection technique was adopted in 30 patients with the following steps: distal femoral cut, proximal tibial cut, anterior referencing for femoral component sizing, and rotational alignment according to the transepicondylar axis and Whiteside line. In other 30 patients, we have adopted a blended technique with the tensor FuZion® (Zimmer-Biomet, Warsaw, IN). This tensor is a sort of mechanical navigation, allowing, after the distal femoral and the proximal tibial cuts have been made, to balance the knee in extension first with the tension required for the amount of space to be filled with the thickness of the metal component and plastic and to report the same space in flexion at 90°, sizing the femur with posterior referencing, and deciding the rotation blending the ligament tension and the usual bony landmarks. The rotational alignment can be corrected or decided by the surgeon within the AP sizer (up to 4° of correction, both directions) or with the additional shift block (up to 2°). The first evaluation of the rotational alignment is made with the paddles flush against the posterior condyles; they are influenced by the ligament tension and by the posterior condylar line (Fig. 1). The second evaluation is independent from the PCL and solely determined by the position of the cutting jig 4-in-1 to verify the true rotational alignment and equality of the flexion and extension spaces (Fig. 2).

CT scan was performed by a skilled musculoskeletal radiologist at a follow-up of six months with a Siemens Somatom Sensation 64 spiral detectors. Spiral scan with axial reconstruction with slices of 1 mm thick and recon increment of 0.7 mm with dedicated algorithm and window (kernel B80S Ultrasharp Window Osteo).

Table 1 Description of patients characteristics at the time of surgery (data are reported as mean (SD) for continuous variables and as *N* (%) for categorical variables)

Characteristic	Description
Age (years)	70 (9)
Male	23 (38%)
Female	37 (62%)
HSS	56.6 (7.5)
KSS (clinical)	53.9 (5.9)
FF	48.7 (9.1)
SF-36-PCS	36.4 (6.1)
SF-36-MCS	48.2 (8.8)
VAS	7.5 (1.6)

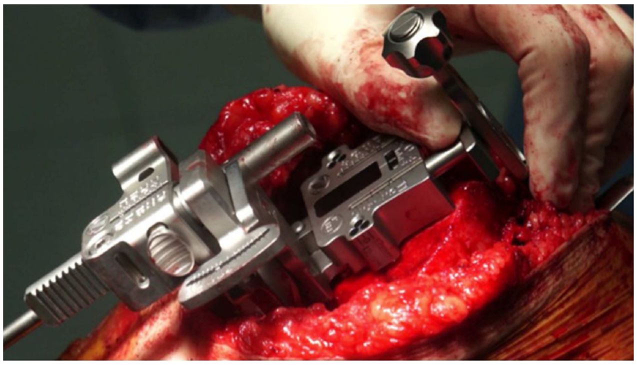

Fig. 1 The first evaluation of the rotational alignment is made with the paddles flush against the posterior condyles; they are influenced by the ligament tension and by the posterior condylar line. The rotational alignment can be corrected/decided by the surgeon with the AP sizer (up to 4° of correction, both directions) or with the shift block (2°)

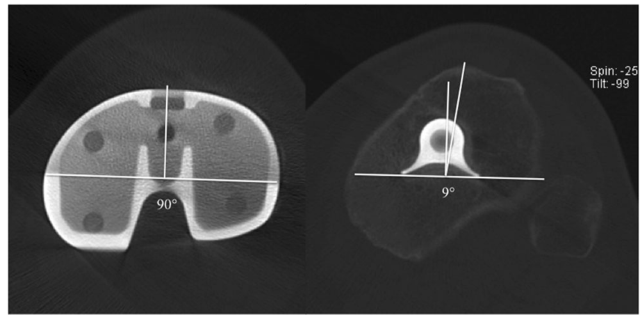

Fig. 3 The central body of the prosthesis was bisected by a line passing through the centre of the hole, which intersects at 90° the tangent line to the two posterior wings. The angle formed with the straight line passing through the TTA corresponds to the angle of rotation of the tibial component

For the measurement of the femoral component rotation, we used the method proposed by Berger [3]: the line between surgical TEA (line connecting lateral epicondyle and medial sulcus of the medial epicondyle) and the line connecting medial and lateral prosthetic posterior condylar surface (posterior condylar line) subtend the angle of component rotation [3].

For the measurement of the tibial rotation, the central body of the prosthesis was bisected by a line passing through the center of the hole, which intersects at 90° the tangent line to the two posterior wings. The angle formed with the straight line passing through the TTA corresponds to the angle of rotation of the tibial component (Fig. 3).

The measurements were done independently by the radiologist and by two orthopaedic surgeons (GD, SP). The analysis of the images was done using Carestream Pacs system (Rochester, NY, USA).

Clinical evaluation was performed by an independent orthopaedic surgeon, not belonging to our institution and outside the team of authors and blinded to the aims of the study, at a follow-up of six months after the index surgery.

We have adopted four scores to measure patient's satisfaction and clinical results:

- Hospital for Special Surgery Score (HSS)
- Knee Society Score (KSS), Clinical and Functional (FF)
- Short Form (36) Health Survey (SF-36): Physical (PCS) and Mental (MCS) Component Summary scores
- Visual Analogic Scale (VAS)

Statistics

Analyses were undertaken using Stata, version 15.1 (Stata Corp, College Station, TX, USA). A two-side $p < 0.05$ was considered statistically significant. Continuous data were reported as mean and standard deviation (SD) and categorical variables as counts and percent. The inter-observer agreement of rotation angles between two independent observers was assessed with Lin's concordance correlation coefficient and 95% confidence interval (95% CI) for continuous measures. The Kappa statistic was used for agreement, after dichotomizing the femur and rotation angle according to their accepted ranges (in-range for femur: 2 to 5°; in-range for tibia: 0–18°). The paired Student t test was used to compare pre-operative with six months clinical indices (HSS, KSS, and FF) and the unpaired t test to compare in- and out-of-range groups; the mean differences and 95% CI were computed. The Pearson R (95% CI) was used to measure the strength of the association of rotation angle and clinical indices. To verify whether the use of the Fuzion technique modified these associations, linear regression models with an interaction term were fitted. For longitudinal changes, Huber-White robust standard errors were computed to account for intra-subject correlation of measures.

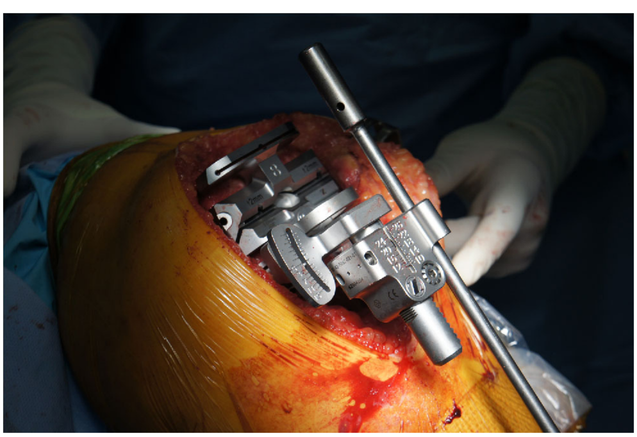

Fig. 2 The second evaluation is independent from the PCL and solely determined by the position of the cutting jig 4-in-1 to verify the true rotational alignment and equality of the flexion and extension space (zero on the mark)

Results

Enrolled population

We enrolled 60 consecutive patients, candidates to knee replacement at our hospital and we followed them for six months. Their clinical and radiologic characteristics are summarized in Table 1. In half of them, we used the blended technique with FuZion®. The measured functional indices were expression of impaired function, with half of patients with HSS < 60, KSS < 55, and FF < 51.

Agreement of measurements between independent observers

The agreement between the two radiological observers is shown in Table 2 and Fig. 4.

Lin's coefficient was always above 0.90 and the K statistic above 0.80.

Difference in rotational alignment of the femur according to use of the standard or the FuZion® technique

In the standard group, the mean external rotation of the femur was 2.7° with a range of − 1 to 6°; the femoral component was externally rotated in 26 patients, neutral (0°) in three patients, and internally rotated in one patient.

In the FuZion® group, the mean external rotation of the femur was 0.5° with a range of −6° to 6°; the femoral component was external rotated in 13 patients, neutral in seven patients, and internally rotated in ten patients (Table 3).

Changes over time of clinical indices

The changes over time of HSS, KSS clinical and functional, SF-36 (PCS and MCS), and VAS are summarized in Table 4, overall and according to use of the FuZion® technique. For all indices, we observed a large and significant improvement during follow-up (Fig. 5).

HSS increased from a pre-operative mean value of 58 to 89.7 in the FuZion® group and from 59.3 to 89.0 in the standard group. KSS (clinical) increased from a pre-operative mean value of 53.5 to 92.6 in the FuZion® group and from 54.2 to 91.3 in the standard group. KSS (Functional) increased from a pre-operative mean value of 49.1 to 91.0 in the FuZion® group and from 48.2 to 87.6 in the standard group.

As shown also by the non-significant interaction terms, the size of these changes was not modified by the use of the FuZion® technique.

Association of femur rotation angles and clinical outcome at 6 months

The correlation of femur rotation angle and HSS at six months was poor ($R = -1\%$, 95% CI −35 to 15, $p = 0.398$) and so were the correlations with KSS ($R = -8\%$, 95% CI −32 to 18, $p = 0.557$) and with FF ($R = -15\%$, 95% CI −38 to 11, $p = 0.270$). These correlations were not modified by the use of the Fuzion technique, as shown by the non-significant tests for interaction (respectively $p = 0.448$, 0.688, and 0.600) and illustrated in Fig. 6 (upper panel), though the strength of the association with HSS appeared marginally better, though not significant, in the absence of FuZion® ($R = -20\%$, $p = 0.286$) than in its presence ($R = -4\%$, $p = 0.817$). Similarly, the strength of the association with KSS and FF were marginally better, though not significant, in the absence of FuZion® (KSS: $R = -11\%$, $p = 0.571$; FF: $R = -14\%$, $p = 0.474$) than in its presence (KSS: $R = -2\%$, $p = 0.919$; FF $R = -9\%$, $p = 0.617$). In particular, in patients in whom the FuZion® technique was not used, the six months HSS and FF were lower for larger external rotation, while almost no relationship was evident in the FuZion® group (Fig. 6, upper panel).

The difference in HSS between values in- vs. out- of the reference range was very small, both as a whole ($D = 0.20$, 95% CI −4.0 to 4.4, $p = 0.923$) and in the presence or absence of the FuZion® technique (Fig. 6). Similar finding was observed for KSS ($D = -1.8$, 95% CI −6.8 to 3.1, $p = 0.461$) and FF ($D = -3.1$, 95% CI −10.9 to 4.6, $p = 0.421$). In no case, the use of FuZion® significantly modified the size of the difference (p for interaction 0.377, 0.574, and 0.729, respectively).

Discussion

The surgical goals in TKA are normal leg alignment, secure implant fixation, adequate soft tissue balancing, and satisfied patients and surgeons. Due to lack of full satisfaction after TKA in all the patients [1, 2], there has been an ongoing search to establish which is the ideal surgical technique to hit the target of the forgotten knee joint.

Table 2 Agreement in rotation angles of tibia and femur between independent observers for rotation angle measured on a continuous scale (Lin's concordance correlation coefficient) and after dichotomizing at within-range/out of range values (Kappa Statistic)

Rotation angle	Observer 1 Mean (SD)	Observer 2 Mean (SD)	Lin's concordance correlation coefficient (95%CI)	Observer 1 *N* (%) in-range	Observer 2 *N* (%) in-range	Kappa statistic (SE)
Tibia	11.9 (4.8)	11.9 (4.6)	0.97 (0.95–0.98)	55 (97%)	55 (97)	1.00 (0.13)
Femur	1.6 (2.5)	1.6 (2.5)	0.97 (0.95–0.98)	33 (55%)	35 (58%)	0.93 (0.13)
Standard						
Tibia	13.2 (5.5)	13.2 (5.3)	0.99 (0.99–1.00)	25 (83%)	25 (83%)	1.00 (0.18)
Femur	2.7 (1.7)	2.7 (1.9)	0.91 (0.85–0.97)	21 (70%)	23 (77%)	0.83 (0.18)
FuZion®						
Tibia	10.5 (3.6)	10.7 (3.5)	0.97 (0.95–0.99)	30 (100%)	30 (100%)	1.00 (−)
Femur	0.5 (2.6)	0.5 (2.5)	0.98 (0.97–1.00)	12 (40%)	12 (40%)	1.00 (0.18)

In-range for femur: 2 to 5°; in-range for tibia: 0–18°

The agreement between the two radiological observers was excellent, both on a continuous scale and when dichotomizing according to the in-range/out-of-range categories, as shown by Lin's coefficient and the Kappa statistic, respectively overall and for both the techniques. This evidence demonstrates that our method is reliable and reproducible especially in presence of anatomical tibial baseplate. We decided to setup the method on the centre of the prosthesis and not on the periphery because in our opinion the centre is more reliable, due to the anatomical shape of the tray. Identifying precisely the central point of the tibial baseplate is more difficult in this type of design than in symmetric design, so we recommend to calculate the measurement using the central portion of the prosthesis and not the peripheral edges of the plateau. In our opinion, CT scan is the ideal method to measure components rotation both for tibial and for femoral side. Sarmah et al. [11] confirmed that CT is now the procedure

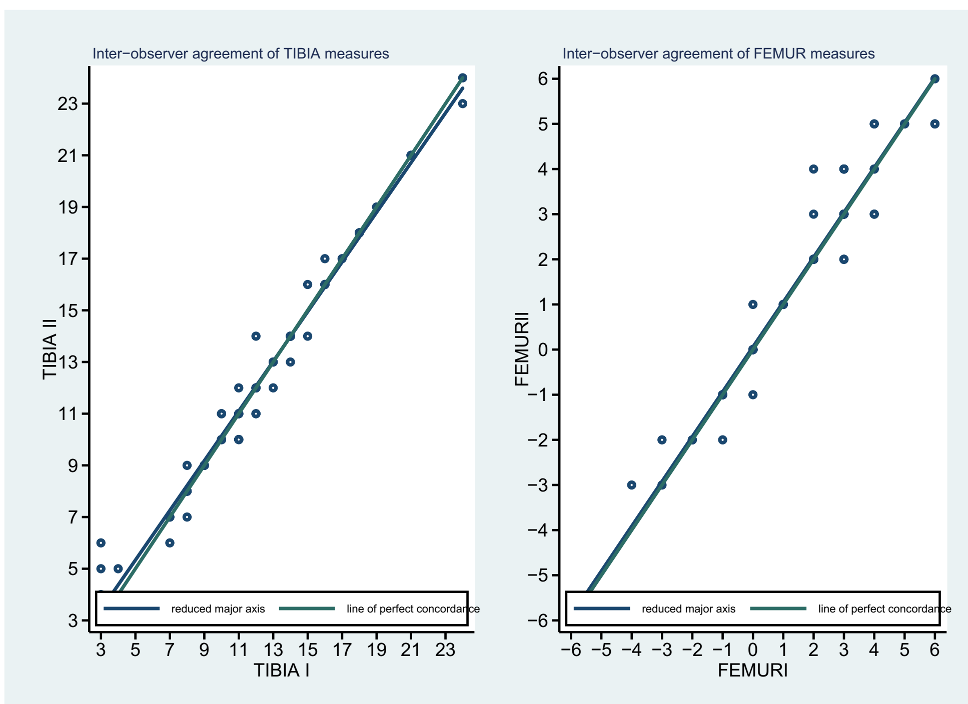

Fig. 4 Scatterplot showing the line of perfect agreement between the two independent observers and the corresponding observed correlation line for tibia (left panel) and femur (right panel)

Table 3 Difference in rotation alignment according to standard and the FuZion® technique

	Mean	Minimum	Maximum	External-rotated	Neutral	Internal-rotated
Standard	2.7°	− 1°	6°	26 patients	3 patients	1 patient
FuZion®	0.5°	− 6°	6°	13 patients	7 patients	10 patients

of choice in determining the rotational alignment of the components. Figueroa et al. [12] demonstrated that component rotational assessment by CT scan has good inter- and intra-observer reliability, but they observed that there is a difference between true and CT rotation measurement, so they recommend caution to interpret values obtained from CT scan.

The changes over time of all scores showed a large and significant improvement at a short midterm follow-up. First of all, these data demonstrate that Persona knee system is a reliable design and the surgical technique is reproducible allowing the prosthesis to be implanted easily and with high precision both for measured resection and for ligament balancing technique (Figs. 7 and 8). Our study confirmed that the implant design provides excellent clinical and functional results and improved patient reported outcome measures as demonstrated in our previous data collection [8, 9]. Giesinger et al. [13] proposed a threshold for treatment success for the KSS, knee score, and function, respectively 85.5 and 72.5 points at 12 months, to determine treatment success after TKA and facilitate interpretation of data; in our study values of KSS, clinical and functional part are always over the cutoff both for overall patients and for the two independent groups.

Results at follow-up are better for the FuZion® group but not a clear superiority can be demonstrated and no statistically significant difference is evident between the two groups. However, at follow-up, FuZion® group showed a more marked improvement of the clinical score between pre-operative and follow-up. This evidence seems to confirm the disagreement in literature

Table 4 Changes over time of the clinical indices

	Before surgery Mean (SD)	At 6 months Mean (SD)	Change at 6 months (95%CI)	*p* value
Overall				
HSS	58.6 (7.5)	89.3 (7.9)	30.7 (28.2–33.2)	< 0.001
KSS (clinical)	53.8 (5.9)	91.9 (9.5)	38.1 (35.7–40.4)	< 0.001
FF	48.7 (9.0)	89.3 (14.8)	40.6 (37.9–43.3)	< 0.001
SF-36 PCS	36.4 (6.1)	44.7 (8.3)	8.3 (6.2–10.4)	< 0.001
SF-36 MCS	48.1 (8.8)	49.4 (6.8)	1.2 (− 0.6–3.2)	0.198
VAS	7.4 (1.6)	1.1 (1.6)	− 6.3 (− 6.9 to − 5.7)	< 0.001
FuZion®*				
HSS	58.0 (8.0)	89.7 (8.1)	31.7 (28.0–35.3)	< 0.001
KSS (clinical)	53.5 (6.47)	92.6 (9.9)	39.1 (35.0–43.1)	< 0.001
FF	49.1 (9.3)	91.0 (11.0)	41.8 (38.9–44.7)	< 0.001
SF-36 PCS	36.4 (5.1)	44.9 (8.0)	8.5 (5.7–11.3)	< 0.001
SF-36 MCS	48.9 (9.0)	50.2 (5.7)	1.3 (− 1.7–4.3)	0.386
VAS	7.4 (1.5)	1.1 (1.3)	− 6.2 (− 7.0 to − 5.4)	< 0.001
Standard				
HSS	59.3 (7.0)	89.0 (8.0)	29.7 (26.2–33.2)	< 0.001
KSS (clinical)	54.2 (5.3)	91.3 (9.2)	37.1 (34.5–39.7)	< 0.001
FF	48.2 (8.9)	87.6 (17.9)	39.4 (34.7–44.0)	< 0.001
SF-36 PCS	36.4 (7.1)	44.5 (8.8)	8.1 (4.8–11.4)	< 0.001
SF-36 MCS	47.4 (8.7)	48.7 (7.7)	1.2 (− 1.4–3.8)	0.349
VAS	7.5 (1.7)	1.1 (1.8)	− 6.3 (− 7.3 to − 5.4)	< 0.001

*p for interaction of time and FuZion®: HSS $p = 0.440$; KSS $p = 0.407$; FF $p = 0.367$; SF-36 PCS = 0.852; SF-36 MCS = 0.973; VAS $p = 0.869$

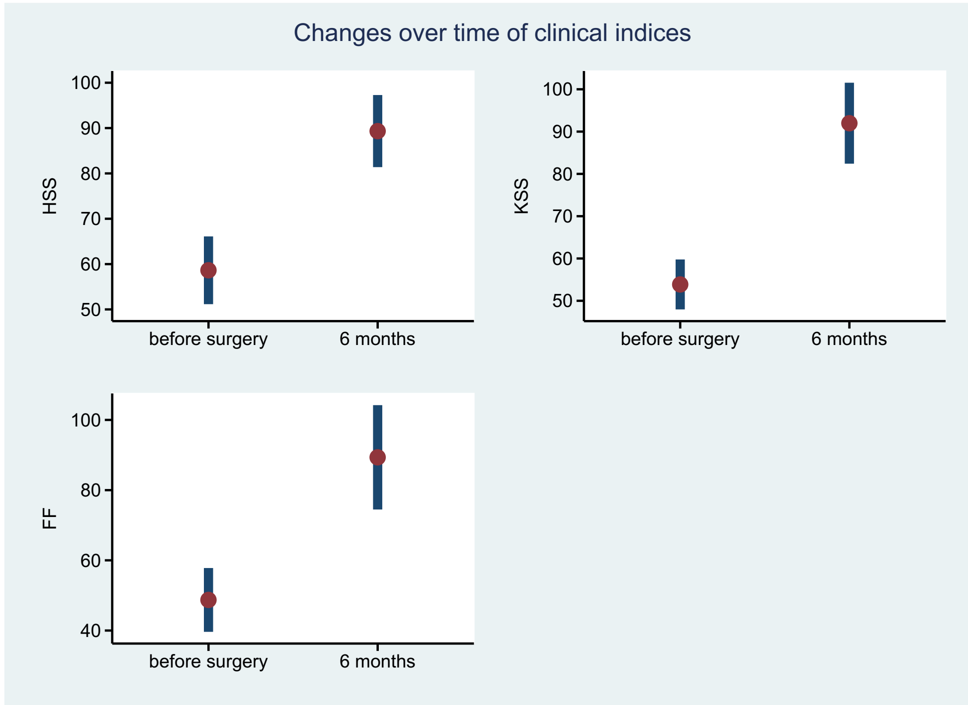

Fig. 5 Changes over time of the clinical indices; mean (dot) and SD (whisker) are shown

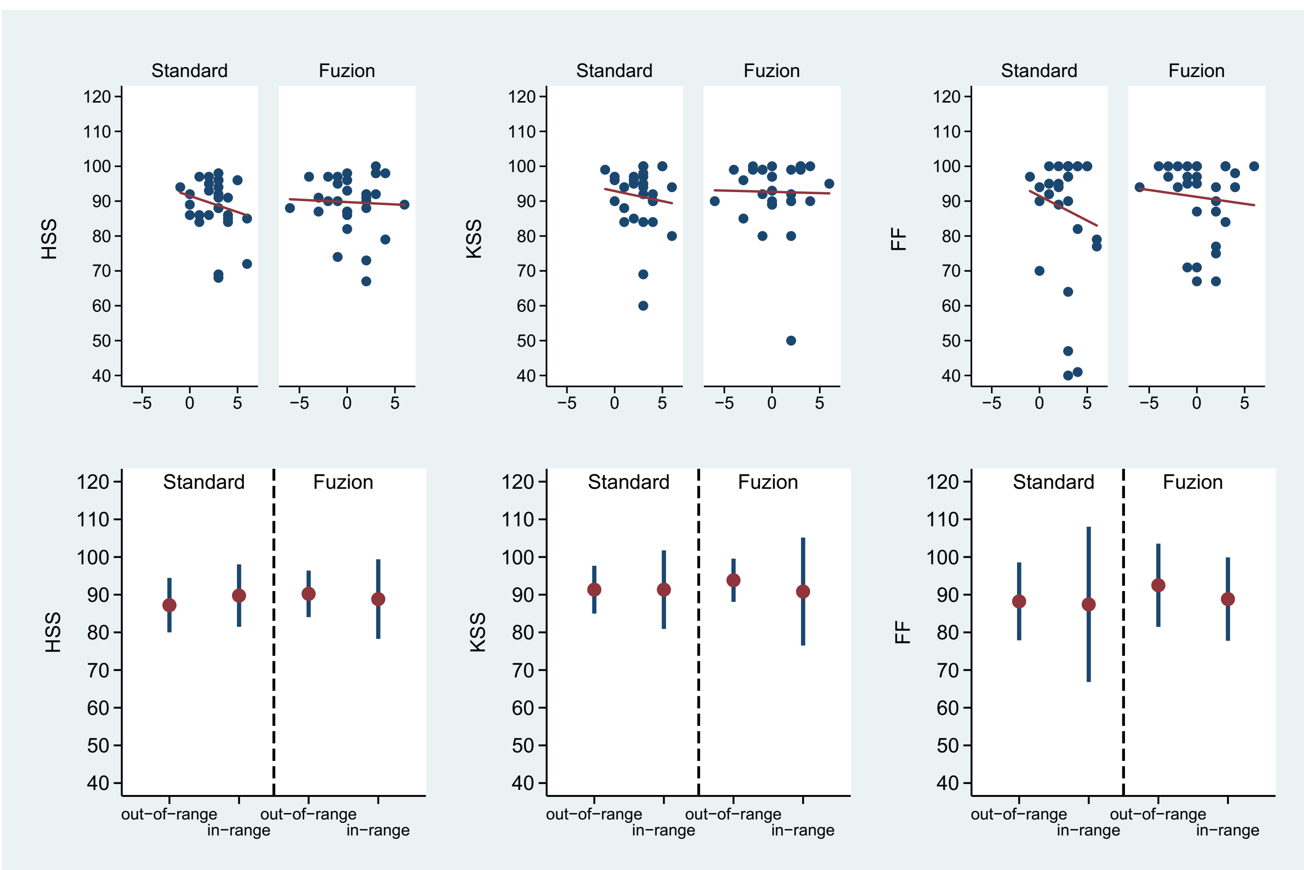

Fig. 6 Association of femur rotation angle and clinical indices at 6 months, on a continuous scale (upper panel) and by dichotomizing according to the in-range/out-of-range values (lower panel; mean (dot) and SD (whisker))

regarding which technique results in a better outcome [5].

Daines and Dennis [7] illustrated in a precise review advantages and disadvantages of both techniques. The surgeon has to place femoral component parallel to TEA to obtain a rectangular flexion gap, because this axis most consistently recreated a balanced flexion space [14], but unfortunately, there is a high inter- and intra-observer variability between the surgeons [15]. Locating the medial and lateral epicondyles precisely is often difficult to reproduce intra-operatively. Posterior condylar line is not reliable and Whiteside's line is also variable, because there is a great inter-individual variability [15]. So, in measured resection, technique is important to utilize all bone landmarks available to determine femoral component rotation [7].

Moon et al. [16] performed a meta-analysis to compare soft tissue balancing, femoral component rotation, and joint-line change between the two techniques; they included eight studies in literature and they concluded that measured resection and gap balancing yielded similar gap symmetries, except for the medial/lateral extension gaps difference which is greater in patients undergoing the measured resection (0.58 mm). The authors demonstrated also that femoral component was more externally rotated (0.77°) in cases of gap balancing technique and that the joint line was more elevated (1.17 mm) in patients underwent gap balancing technique. The authors concluded that the differences were minimal, and therefore, they may have little effects on knee biomechanics and that the two techniques are not mutually exclusive. In our study, in the FuZion® group, femoral component rotations values are in a wide range; they are meanly more internally rotated than in measured resection group and there is a greater distribution of the values between external, neutral, and internal rotation. Traditionally, we can define in-range values of rotations between 2° and 5° of ER, however we think that it is a "good" range only for measured resection technique; in fact, our clinical score demonstrated that in case of MR technique, better results are included in this range of degrees. On the opposite, the FuZion® group demonstrated a wide range of rotation values (external, internal, and neutral rotation) and results are very good for any angle of rotation. The direction and the inclination of the red line in Fig. 6 (upper graphics) showed that in the FuZion® technique, the results are more standardized and similar for different value of femoral component rotation. Heesterbeek et al. [6] affirm that the knee will be balanced when using balancing gap technique, but some patients will have an internal rotation of the femoral component as a cost of a balanced flexion gap and there is no conclusive evidence how this fact affects patellofemoral tracking, so an internally rotated component can be tolerated but more research should be needed. In their study, femoral component rotation can vary freely within the restrictions produced by soft tissue structures and this high variability cannot be explained by ligament releases alone; however, knees with major medial releases (superficial medial collateral ligament, semimembranosus) had less external femoral component rotation than knees with minor lateral releases.

Savin et al. [17] suggest that pre-operative measurement of distal femoral torsion supports the surgeon to give correct rotation of femoral component to each patient because literature contains controversies regarding the ideal value of external rotation of the femur. They proposed to add an anteroposterior radiography of the knee in 90° flexion (seated view) during the pre-operative planning. In our study, in the standard group, we observed external rotation of component almost in all patients of standard technique group; conversely, there is greater values dispersion in the FuZion® group between external, neutral, and internal rotation; however, in both groups, clinical scores are excellent, and in the FuZion® group, there is a better change of the clinical score at six months. Scott [18] underlines the consequence of femoral component rotation on trochlear groove location; for every 4° of femoral component rotation, the trochlear groove is displaced by about 2 mm. This relatively small amount can be compensated by undersizing the patellar component by one size and shifting it medially, bevelling the uncapped patellar surface to prevent impingement. Ferlic et al. [19] demonstrate that tibial tuberosity-trochlear groove distance correlates with several parameters of knee joint size and leg length in patients with patellofemoral instability. In our series, we do not have complications related to patellar pain, tilt, or instability.

As a matter of fact, other studies investigate if navigation can improve patient's satisfaction, Saragaglia et al. [20] concluded that navigation is useful to evaluate intra-operatively axis and sagittal ligament balance, although a few isolated studies found it did not improve precision in arthroplasty implantation [20].

There are limitations to our study: the number of patients is small; a larger number of patients could achieve statistically significant difference to our results. CT scan is a static evaluation and its measurements could not really represent the kinematic of prosthetic knee and the differences between two techniques.

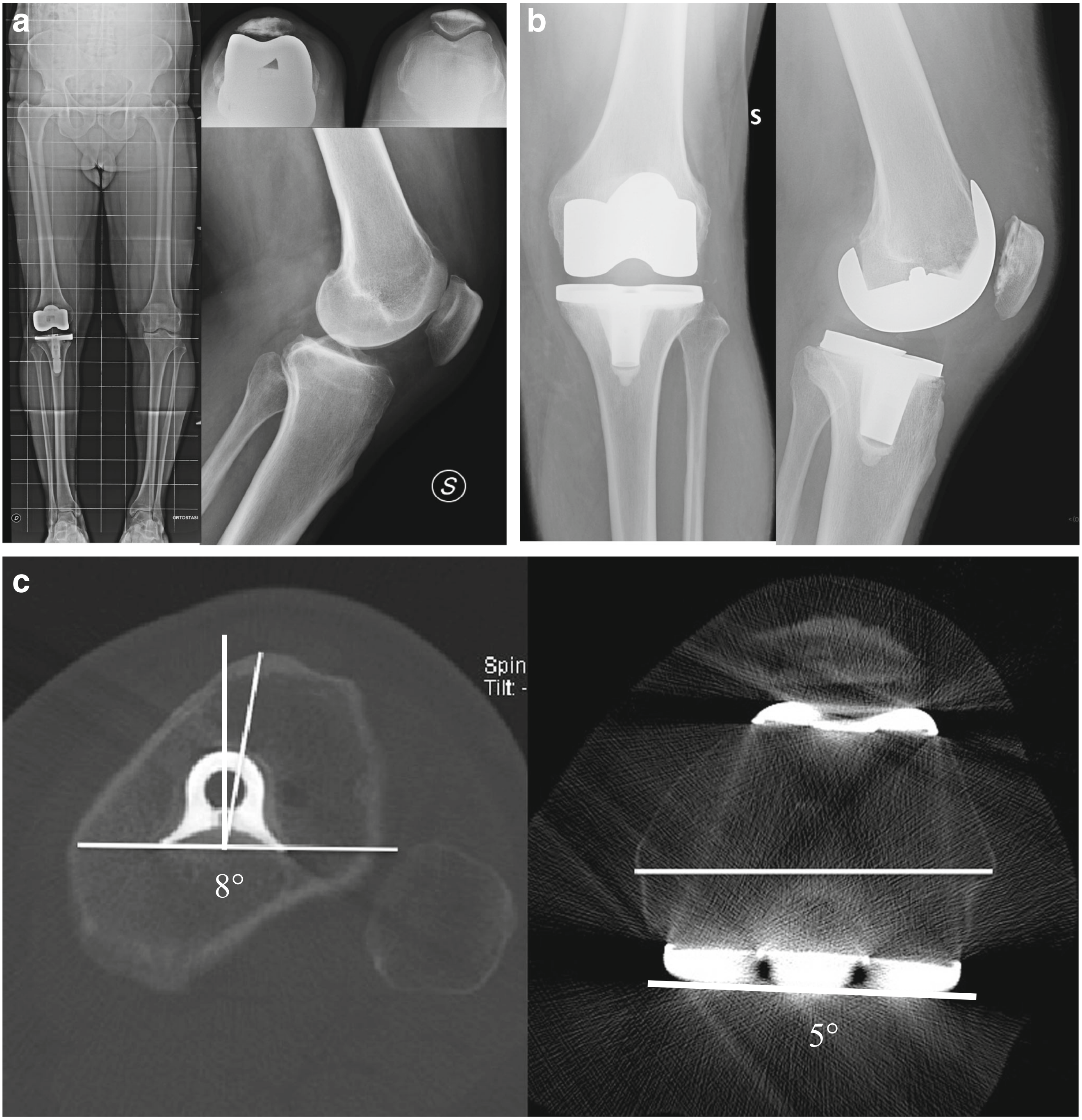

Fig. 7 Male patient, 56 years old, left knee arthritis, pre-operative X-rays (**a**), post-operative (**b**), and CT measurement (**c**) after total knee arthroplasty by measured resection technique. Post-operative X-rays demonstrate a good axis of the knee in a–p and lateral view; CT scan shows a tibial baseplate internally rotated of 8° and a femoral component externally rotated of 5° according to instrumentation of measured resection technique

The strength of our study is that the patient series is consecutive, the surgical steps of the two different techniques are standardized and reliable, the radiological measurements performed by different observers with good agreement, and, finally, the clinical evaluation was performed by an independent and blinded observer not belonging to our institution.

In our investigation, we have demonstrated that with a sound MR technique and with the proper design of the

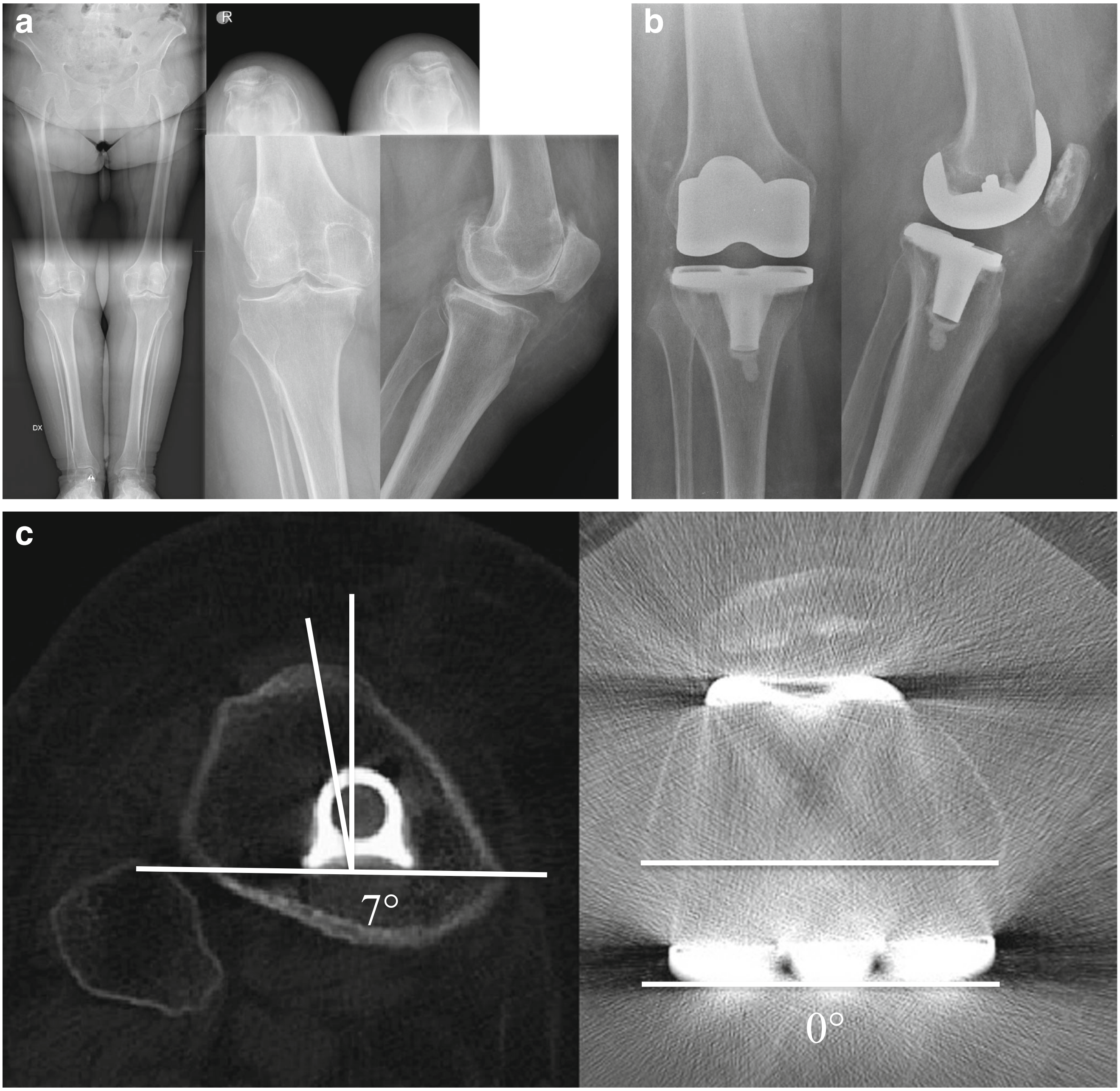

Fig. 8 Female patient, 73 years old, right knee arthritis, pre-operative X-rays (**a**), post-operative (**b**), and CT measurement (**c**) after total knee arthroplasty by blended technique with tensor. Post-operative X-rays demonstrate a correct axis of the knee in a–p and lateral view; CT scan shows a tibial baseplate internally rotated of 7° and a neutral rotation of femoral component (0°) according to intra-operative ligament tension balancing established by tensor FuZion®

component in terms of sizing and coverage, we can achieve good clinical results with standardized implantation of the component in terms of rotation. However, it is our opinion that the optimal solution concerning the rotational alignment can be found intra-operatively with the harmonization of the two techniques, with FuZion® instrumentation, rather than base the decision on a pre-operative imaging technique, difficult to be translated in surgical decision, or on standardized good-for-all technique. The wide range of rotational alignment obtained in our study with the tensor device, related with the good clinical results as above showed, support the fact that every knee deserves a unique self-alignment, and FuZion® can provide the surgeons with the proper tool to hit that target.

Conclusions

Our CT method measurement is reliable so it can be used routinely. Persona knee system is a personalized prosthetic design which allows to obtain excellent outcome after TKA, but no clear superiority between MR and GB technique is evident. The harmonization of the two techniques allows also to customize femoral rotation and probably it is the key for improving outcome and achieving the state of forgotten knee.

Compliance with ethical standards

Ethical committee approval was obtained for this study (protocol number 20150003437).

Conflict of interest The first Author (FB) is part of the design team of the implant. The other authors (MG, GD, CK, SMPR, and SP) declare that they have no conflict of interest. The study is a spontaneous observational investigation carried out by the Authors.

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