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ORIGINAL PAPER

Clinical and radiological analysis of a personalized total knee arthroplasty system design

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Abstract

Purpose The objectives of this study were to determine the radiological outcome of a new personalized total knee arthroplasty (TKA) design and also to analyze the radiological reproducibility of the surgical technique.

Patients and methods A total of 100 consecutive TKAs performed in 99 patients using Persona knee system were recruited. Weight-bearing standing anteroposterior and lateral radiographs were done in all the patients, both pre-operatively as well as post-operatively, and various radiological parameters were analyzed and compared.

Results The full correction of the limb mechanical axis was achieved in 97% of patients, and the radiological parameters of coronal and sagittal alignment of femoral and tibial components showed good results. There were no substantial differences between the mean pre-operative and post-operative patellar height indices, and data were in the normal range. Posterior condylar offset (PCO) and posterior condylar offset ratio (PCOR) had increased as expected after TKA. The coverage of tibia was optimal with data in the normal range.

Conclusions Radiological assessment of the new personalized knee system design showed excellent results with various parameters restored to the normal values. Therefore, the prosthesis can be considered anatomic, and the surgical technique is reproducible allowing the prosthesis to be implanted easily and with high precision.

Keywords Total knee arthroplasty · Radiological assessment · New design

Introduction

Total knee arthroplasty (TKA) has been globally accepted as an effective treatment modality for terminal-stage knee osteoarthritis. Over the last decade, there has been a rapid surge worldwide in the number of TKAs performed. Despite the increase in the number of surgeries and the improvement in design of knee prosthesis as well as the surgical technique, the satisfaction rate remains between 75 and 89% and has not reached 100% [1]. In 28% of TKA cases, the patient do not feel the knee as "normal" after surgery; the reason being stiffness in majority of such patients followed by pain, weakness, knee instability, and foreign sensation. Often the cause is the anatomical mismatch between the prosthetic components and the different people anatomies. It is well known that there are anatomy difference between genders and among ethnicities, because female anatomy is smaller than male and Caucasian anatomy is generally larger than Asian. The main morphology difference at the level of total knee arthroplasty resection across genders and multiple ethnicities is related to variations in overall proximal tibial size [2]. In order to improve patient satisfaction after TKA and to mitigate such complaints, a need was felt to develop an anatomical knee design so that optimal clinical outcome can be obtained with an easily reproducible surgical technique. A recent study [3] compares six tibial contemporary designs (anatomical, asymmetric, and symmetric), and the authors concluded that anatomic tibial component increases tibial coverage and rotational alignment accuracy. This design is the closest morphological match to the tibial size and shape resulting in the least compromise across the

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multi-ethnic dataset studied. The main objectives of our study are to exclude anatomical mismatch of a new anatomical prosthetic design (based on wide range anatomical study) and to evaluate the fitting of this new design related to different knee anatomies.

Persona knee system (Zimmer-Biomet, Warsaw, IN) is distinguished by its anatomical design, asymmetrical and side-specific components, large number of available sizes of all the components, and the ergonomic and precise instrumentation that has improved the reproducibility of the surgical technique. The development of this new knee design has helped to fit the needs of different ethnic groups and complexity of morphotypes and to restore the kinematics of the knee. The implant design has been reported to provide excellent clinical and functional results and improved patient-reported outcome measures [4, 5]. However, there is paucity of information about the radiological outcomes with this knee prosthesis.

It is possible to determine whether the pre-operative radiologic relationships are maintained, upgraded, or downgraded using different radiographic parameters, while other parameters are used to evaluate the placement of the prosthetic components and possible related clinical consequences. We therefore aimed to determine the radiological outcome of a new personalized total knee arthroplasty (TKA) design and also to analyze the radiological reproducibility of the surgical technique.

Patients and methods

Ethical Committee approval was obtained for this study.

It was a retrospective cohort study done at a tertiary care referral institute in Italy in which we enrolled 100 consecutive elective TKAs in 99 patients between 2012 and 2013 using Persona knee system. We included 100 cases because it is a pilot study with many different radiographic parameters as endpoint; some of them are well known in literature and some others were proposed from ourselves, so the sample size was different for each specific parameters. We evaluated all the pre-operative and post-operative radiographs of the above patients available in the database of the institute. The radiographic measurements can be performed in an accurate manner because the true lateral view radiographs of the knees have a good quality with overlapping femoral condyles.

Inclusion criterion is that the patients were diagnosed of three-compartmental primary arthritis suitable for primary standard total knee arthroplasty; exclusion criteria are secondary arthritis (rheumatoid arthritis, haemophilia), previous osteotomy, bone loss, collateral ligament incompetence, and revision surgery.

All the surgeries were performed by the same surgeon using the mini-trivector [6] surgical approach and the standard measured resection technique by the following steps: distal femoral cut, proximal tibial cut, anterior referencing for femoral component sizing, and rotational alignment according to transepicondylar axis and Whiteside line. A posterior-stabilized knee prosthesis was used in all the cases. The sample consisted of 70 women and 29 men, 60 right knees and 40 left knees. The average age was 68.78 years (range 26–93 years).

We analyzed the pre-operative and post-operative knee radiographs of all the patients consisting of weight-bearing anteroposterior views, true lateral views (with overlapping images of condyles), and standing scanograms of both the lower limbs. The post-operative radiographic examinations were performed after a minimum follow-up of three months. The analysis of the radiographic images was done by CARESTREAM PACS system (Rochester, NY, USA). The parameters which were evaluated in the pre-operative radiographs included mechanical axis of the limb, angle of valgus/varus deformity of the distal femur (α angle), angle of valgus/varus tibial plateau (β angle), patellar height using Insall-Salvati ratio and Caton-Deschamps ratio, posterior condylar offset (PCO), and posterior condylar offset ratio (PCOR). In the post-operative radiographs, we analyzed the mechanical axis of the limb, coronal and sagittal alignment and position of the components (α angle and γ angle for the femoral component, β angle and σ angle for the tibial component), patellar height using Insall-Salvati ratio and Caton-Deschamps ratio, PCO and PCOR, tibial overhanging lines (TOL), femoral overhanging lines (FOL), anterior coverage line (ACL), posterior coverage line (PCL) (Fig. 1), and notching of the femur, if present. Radiographic parameters to be measured were decided by the first author, and they were measured independently by other two observers involved in the study; in presence of different measurements, the observers recalculated it accordingly together.

We have adopted the Forgotten Joint Score (FJS-12) to evaluate patient's satisfaction at a midterm follow-up; it is a 12-item score that assesses joint awareness during activity of daily living following joint replacement.

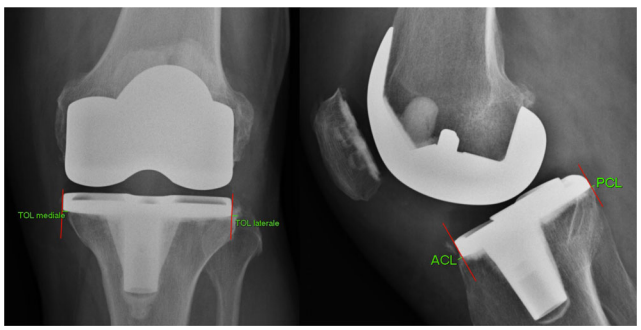

Fig. 1 The tibial overhanging lines were drawn in order to determine the correct tibial plateau coverage and the overhang of the tibial component

Measurements

The α and β angles, which describe the valgus/varus of the distal femur and proximal tibia, respectively, as well as alignment in the frontal plane of the prosthetic femoral and tibial components, were assessed using the angles proposed by the American Knee Society [7]. The α angle was drawn between the anatomical axis of the femur and the tangent line to the femoral condyles, while the angle β was drawn between the anatomical axis of the tibia and the tangent line to the plate of the tibial component or tibial articular surface [8]. The γ and σ angles were calculated according to the guidelines of the American Knee Society evaluating the true lateral knee radiographs. The γ angle was drawn between the lateral projection axis of the femoral shaft and the neutral line of the femoral component; it measures the flexion-extension of the femoral component. The σ angle was drawn between the lateral projection of the tibial shaft axis and the tangent to the tibial tray; it measures the tibial slope which is calculated as 90° − σ angle.

The Insall-Salvati ratio [9] was described as the ratio between the length of the patellar tendon and the length of the patella. The Caton-Deschamps ratio [10] was the ratio between the distance of the lower pole of the patella from the anterosuperior edge of the tibia and the length of the articular surface of the patella. PCO was defined as the maximum thickness of the posterior femoral condyles, calculated on the true lateral view measuring the distance between the radius corresponding to the margin of the posterior cortex and its tangent parallel to the condyles posteriorly [11]. PCOR was defined as the ratio between PCO and the distance between the radius corresponding to the anterior femoral cortex and its tangent parallel to the posterior condyles [12]. In order to find out notching, a line was drawn through the posterior margin of the femoral flange on the true lateral view knee radiograph and its relationship with the anterior cortex of the femur was studied. The medial and lateral TOL were drawn as tangent lines to medial and lateral edges of the tibial component, respectively, and ACL and PCL were drawn as tangent lines to anterior and posterior edges of the tibial component, respectively, in order to determine the correct tibial plateau coverage and any excess bone or excess prosthetic plate (overhang of the tibial component). The FOL were defined as the distances between the medial and lateral margin of the flange of the femoral component and the medial and lateral femoral epicondyles, respectively.

Statistical analysis

Statistical analysis was done using the software Stata, version 11.1 (TX, USA). Descriptive analysis was performed to determine means, medians, and percentages. Continuous variables were expressed as means/medians ± standard deviation (SD), along with range. We did a basic numeric qualitative analysis in this pilot study demanding a prospective methodological statistical analysis for a further study.

Results

In the pre-operative radiographs, the assessment of mechanical axis showed that 69 knees had varus deformity, 13 had valgus deformity, and 18 were orthomorphic; in the post-operative radiographs, 97 knees were orthomorphic (Fig. 2), and only in 3 cases (1 varus and 2 valgus), the full correction of the mechanical axis was not achieved. In all the three cases however, α angle and β angle of the prosthetic components were in the normal range.

The mean pre-operative α angle was 83.85° ± 2.6° (range 78.98 to 90.96°), while the mean post-operative α angle was 85.30° ± 1.42° (range 81.87 to 88.63°) (Fig. 3). The deviation from normal anatomical axis of the tibia was calculated as 90° − β. In the pre-operative radiographs, the mean tibial axis

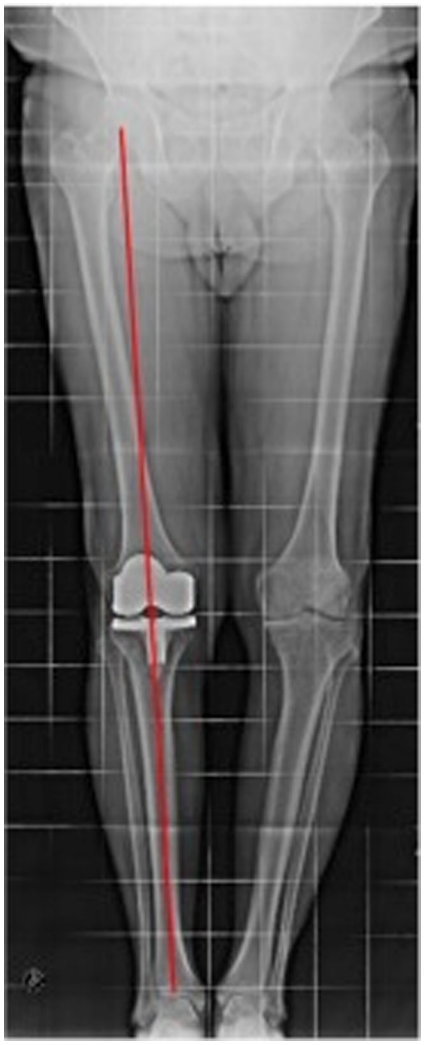

Fig. 2 Post-operative weight-bearing full-length x-ray with orthomorphic alignment of the limb

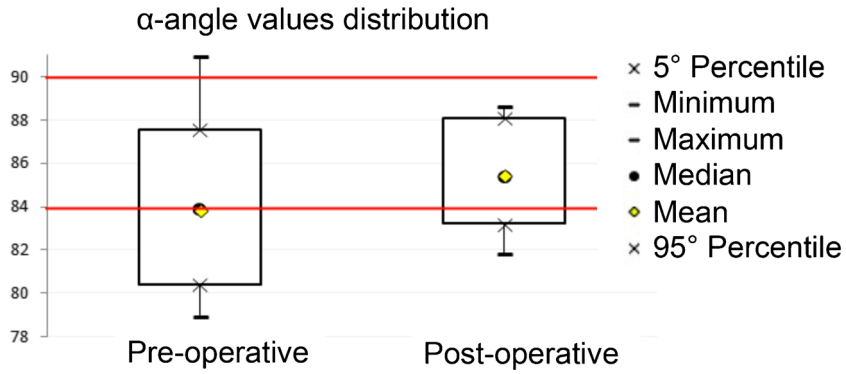

Fig. 3 Comparison of the pre-operative and post-operative α angle values

deviation was 4.75° ± 2.67° (range 0.29 to 13.49°), while the mean post-operative tibial axis deviation was 0.79° ± 1.22° (range 0 to 4.3°). With the formula α + (180° − β), we calculated the post-operative valgus angle at the knee joint. The mean post-operative knee joint valgus angle was 176.10° ± 2.16° (range 171.54 to 181.68°). The mean post-operative γ angle was 0.49° ± 2.62° (range − 7.04 to 6.88°). The mean tibial slope angle (calculated as 90° − σ) was 3.54° ± 2.74° (range – 3.38 to 8.22).

The PCO was found to be increased after the surgery; the mean difference between pre-operative and post-operative PCO was 7.74 mm ± 7.85 (range − 8.27 to 28.66 mm) (Fig. 4). The mean pre-operative PCOR was 0.47 ± 0.04 (range 0.42 to 0.60) (normal value 0.44 ± 0.02) while the mean post-operative PCOR was 0.50 ± 0.04 (range 0.42 to 0.60) (normal value 0.47 ± 0.02). The difference between the normal values of the pre- and post-operative PCOR (0.47–0.44 = 0.03) was found to be retained.

The mean pre-operative Caton-Deschamps ratio was 0.80 ± 0.19 (range 0.30 to 1.57), while the mean post-operative value was found to be maintained at 0.80 ± 0.19 (range 0.46 to 1.45). So there had been no substantial changes in the patellar height according to this index, and the values were within the normal range (0.60–1.20). The Insall-Salvati ratio showed the same correlation: the mean pre-operative value was 1.02 ± 0.18 (range 0.56 to 1.57), while the mean post-operative value was 1.10 ± 0.20 (range 0.66 to 1.66).

The mean value of the medial TOL was − 0.30 ± 1.33 mm, mean lateral TOL was − 1.30 ± 2.36 mm, mean ACL was − 1.20 ± 1.94 mm, and mean PCL was − 0.83 ± 2.18 mm (Fig. 5). The medial TOL was within the normal range (0–2 mm) in 95% of the cases, 4% values were between 3 and 5 mm (oversizing 1, undersizing 3), and one case had medial tibial undersizing of 6 mm. Laterally, the TOL was within the normal range (0–2 mm) in 78% cases and slight undersizing (between 3 and 5 mm) was found in 13% cases, while in 7% cases, the value was between 5 and 9 mm and two cases had slight overhang (3.58 mm and 3.89 mm). Anteriorly, 90% of the cases had normal values of TOL, 9% had slight undersizing (3–5 mm), and one case had greater undersizing (7.51 mm). Posteriorly, 80% of the cases had normal values of TOL, 13% had slight undersizing (3–5 mm), and 3% were between 5 and 6 mm, while the overhang was mild (< 5 mm) in 2% cases and greater than 5 mm in two cases. The mean medial FOL was 8.94 ± 9.30 mm and the mean lateral FOL was 8.06 ± 3.09 mm. So these results showed that the prosthesis covered 82.19% of the femoral condyles anteriorly. We did not find femoral notching in any of the cases (Figs. 6 and 7).

The mean FJS in this series of patients, at a mean follow-up of 48 months (range 36–56), is 81.2 with a range of 35.4–100. Two patients had a revision surgery without prosthetic component substitution: patellar osteofitectomy (1 case) and saphenous nerve neurotomy (1 case).

Discussion

Due to lack of full satisfaction after TKA in all the patients, there has been an ongoing search for factors which need to be improved to achieve the same. Achieving perfect radiologic alignment of the lower limb after surgery is one of the many such fields which are being focused upon in order to achieve the target of universal patient satisfaction post TKA. Although

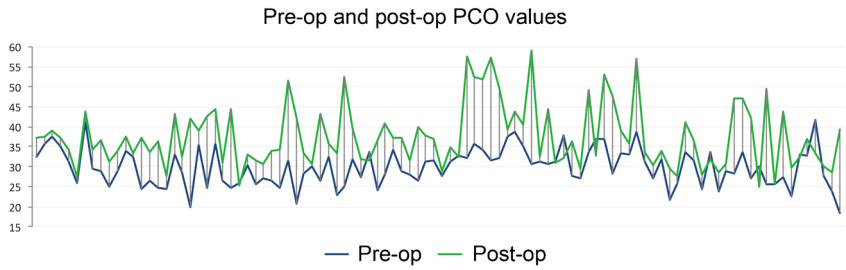

Fig. 4 Comparison of the pre-operative and post-operative PCO values

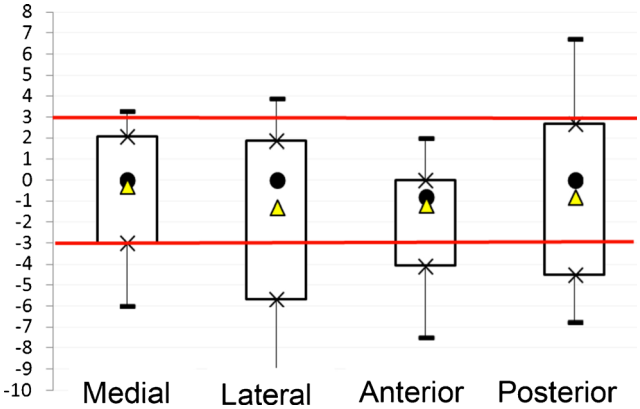

Fig. 5 Value distribution of tibial overhanging and coverage lines

the correlation between perfect alignment and good functional outcome has been controversial, an acceptable alignment is defined as one in which the components do not deviate more than 3° from the mechanical axis [13, 14]. Persona knee system was designed taking care about the different ethnic groups and providing improved reproducibility of the surgical technique. As there are not many reports about the radiological outcomes of this knee implant, we therefore tried to find out whether this novel knee design can provide improved radiological outcomes and also tried to analyze the radiological reproducibility of the surgical technique.

We found that the mechanical axis of the lower limb was re-established in 97% of the cases, and only 3% of the cases failed to do so. In a prospective study, it was reported that although 21 patients out of 91 patients were mal-aligned (> 3° deviation) after TKA at one year follow-up, the muscle strength and functional outcome were similar to the normally aligned knees [13].

In our study, the alignment of the individual prosthetic components was found in the optimal range for both femoral and the tibial components. The average value of femoral angle α was found to be 85.30°, ranging from 81 to 88°, and 75% of the cases were between 84 and 86°; these data are comparable with the other similar studies [15, 16] which have shown good medium-term results. The mean tibial β angle increased from 85.25° pre-operatively (mean deviation from the anatomical axis 4.75°) to 89.06° post-operatively (mean deviation from the anatomical axis 0.94°).

The mean post-operative knee joint valgus angle was found to be 176.24° whereas the angle of physiological valgus at knee is accepted as 175°, so we found that the alignment in frontal plane was achieved. The sagittal alignment of the femoral component (γ angle) was 0.49° and the angle of tibial slope was 3.54°. Only two cases had a negative tibial slope post-operatively (− 3.38° and − 2°); both the above knees had history of chronic post-traumatic deformities. The surgical technique requires the tibial cut at 3° posterior slope, so this data demonstrates the effectiveness of the instruments.

The evaluation of PCO showed a mean increment of 7.74 mm after the surgery. Bellemans et al. [11] have shown that a decrease in PCO by 2 mm corresponded to a decrease of 12.2° of flexion post-operatively. Thus, the increase in PCO observed in our series provided improved knee flexion. We also measured PCOR in our series, as its relationship is less susceptible to variability in measurements [12]. In our series, we resected the posterior cruciate ligament and consequently the flexion gap was higher by 1–2 mm, so the preservation and increment of PCO allowed not only to improve the range of motion but also to avoid the development of flexion instability. The PCOR assessment in our series (mean pre-operative and post-operative 0.47 and 0.50, respectively) did not correlate with the normal values reported in a previous study [14] (mean pre-operative and post-operative 0.44 and 0.47, respectively); however, the difference between the pre- and post-operative PCOR was maintained.

The evaluation of the patellar index showed no substantial differences between pre- and post-operative measurements, and all the results were in the normal range. Thus, we respected the anatomical patellar height avoiding the risk of low or high patella and the consequent negative effect on the extensor mechanism (pain, mal-tracking, subluxation, dislocation, stiffness). Femoral notching was not detected in any case thereby demonstrating the precision and reliability of the instrumentation and the surgical technique.

In our series, the limit to define an overhang or undersizing was placed at ± 3 mm. The mean width of the TOL was found to be 1.04 mm on the medial side and 2.64 mm on the lateral side; in the sagittal plane, the mean value was 1.72 mm anteriorly and 2.23 mm posteriorly. The proper sizing of the tibial component is important for optimal bone coverage and correct baseplate orientation. Its assessment is more complicated when the component is symmetric, unlike the normal anatomy of the tibial plateau where the medial portion is wider and longer than the lateral side. In this process, there is a risk of underestimating/overestimating the tibial size when analyzing for the different portions of the tibial plateau. If we take into account the lateral tibial plateau as reference, there is the risk of subsidence and varus alignment of the component; conversely, if we measure the edge of the medial plate, wider than the lateral one, there is the risk of overhang and a conflict between soft tissue and the component. An additional problem for the symmetric tibial component is the risk of internal rotation if we align the component referring to the posterior edge of the tibial plateau, and the development of patellofemoral complications (subluxation, dislocation, wear). Based on our results, it can be concluded that the anatomical design of the tibial component in this knee system allows an excellent coverage of the tibial plateau, reducing the risk of sinking, loosening, mal-alignment, and overhang. The values for FOL were found as 8.96 mm medially and 8.06 mm laterally, but these data are difficult to analyze because such measurements

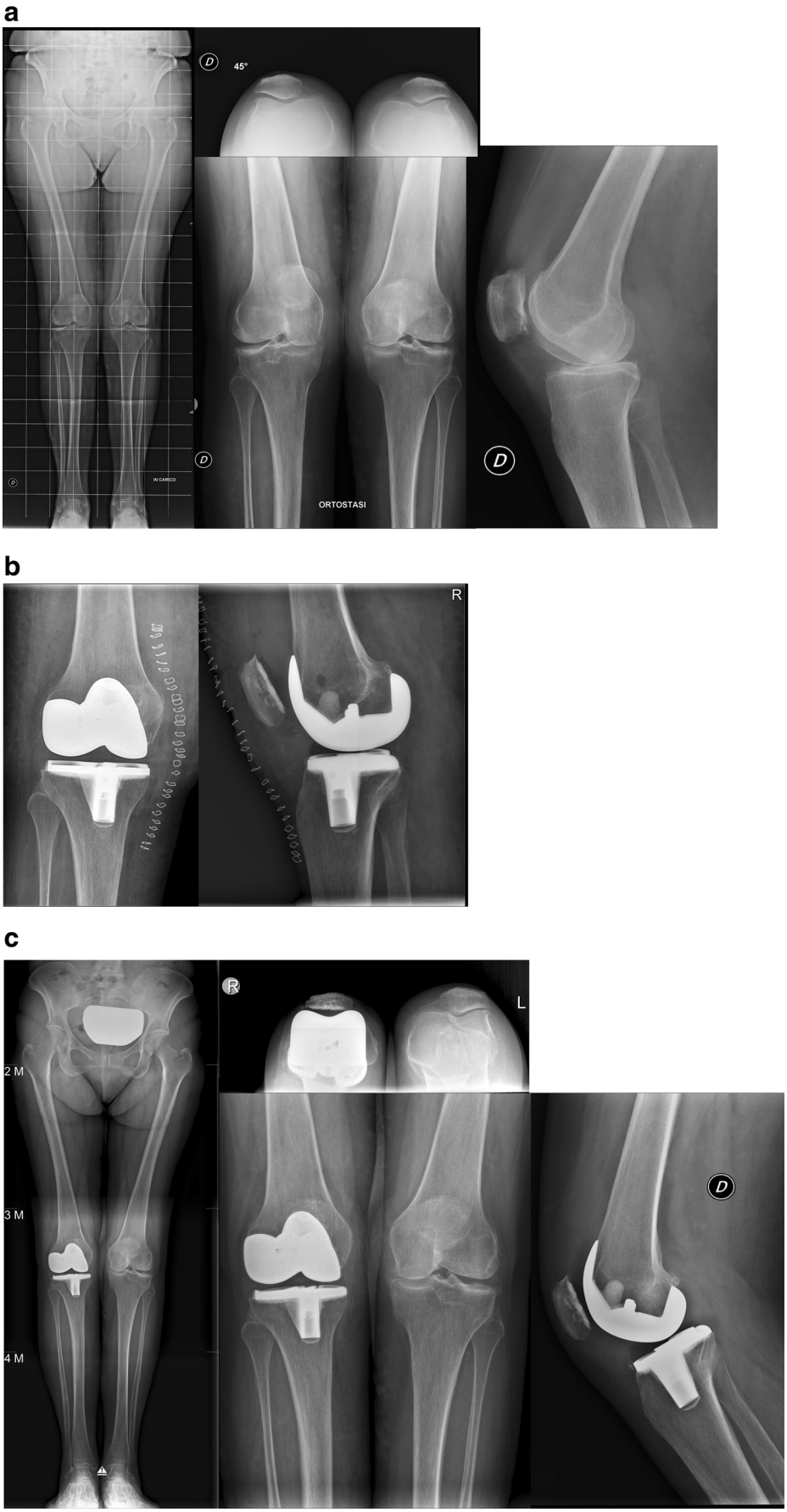

Fig. 6 Female, 71 years old. Pre-operative X-rays (**a**), post-operative (**b**), and follow-up at 3 years (**c**)

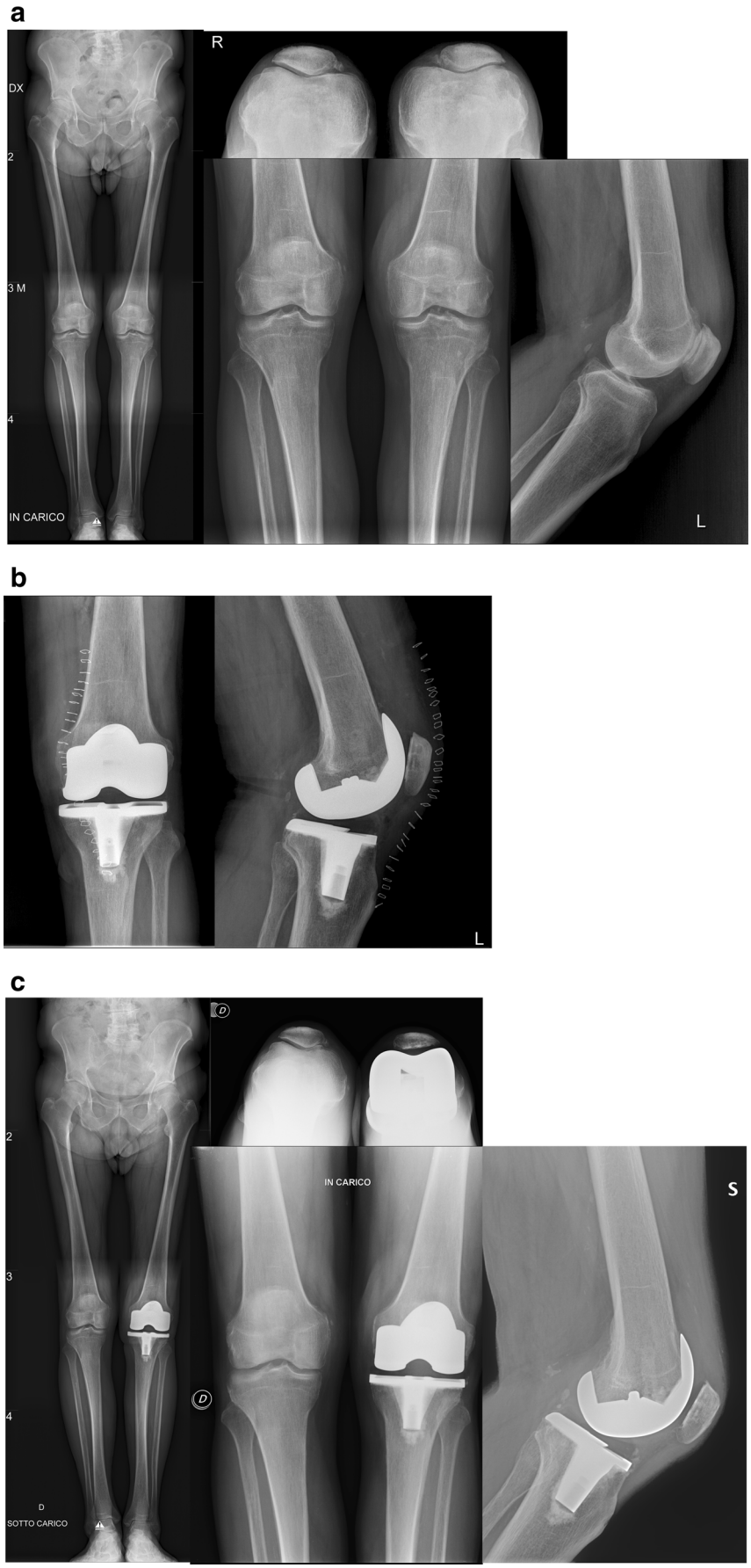

Fig. 7 Male, 78 years old. Pre-operative X-rays (**a**), post-operative (**b**), and follow-up at 3 years (**c**)

should ideally be taken by computed tomography to have an exact and reliable value of femoral bone coverage and the real overhang of the femoral component.

As a matter of fact, CT scan is widely used to assess component rotation after TKA; Figueroa et al. [17] 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 of 2.5° for femoral component and 3.2° for tibial component, so they recommend caution to interpret values obtained from CT scan. Savin et al. [18] suggest that pre-operative measurement of distal femoral torsion supports the surgeon to give correct external rotation of femoral component to each patient. It is the angle between the tangent to posterior femoral condyle and the transepicondylar axis, and it is measured on an anteroposterior radiography of the knee in 90° flexion ("seated view"). Pedraza et al. [19] proposed a new partially loaded plain radiographic projection to measure component rotation and to get an impression of the femoro-tibial flexion behavior. The patient is in a supine position with 60–70° of knee flexion and he puts load exclusively on the operated limb. They have demonstrated that this new radiographic technique shows the most relevant anatomic landmarks in order to assess rotational alignment, and the results obtained by this new projection are comparable to that of CT.

Thus, the analysis of the various radiologic parameters showed only a limited variation of the values; this limited interpersonal variability is indicative of good reproducibility of the total knee system design and the accuracy and reliability of instrumentation. The ideal design reproduces the anatomy to cover the complexity of the anthropometric variants and respect them without surgical compromise. Furthermore, an accurate and efficient instrumentation increases the reproducibility and the standardization of the surgical technique in different patients. Our results showing limited variation of the measurements seem to respect these concepts. The different anatomies and the similar results are not related to number of surgeons but solely due to prosthesis design.

Thus, the study has a predominant radiological purpose; the FJS results showed that the patients are very satisfied and they reach an awareness of the artificial joint in most cases. We compared our results with other studies in literature, and we observed that our series obtained a high degree of awareness in relationship to other literature's studies. Thienpont et al. [20] presented a paper on 100 TKAs (50 fixed-bearing e and 50 mobile-bearing) and they observed a mean FJS of 71 in the fixed-bearing group and 56.5 in mobile-bearing group. Olivier et al. [21] reported a study on 80 patients (40 treated by computer-assisted surgery and 40 by conventional technique), and they showed similar FJS in both groups (83 points for computer-assisted group and 82 for conventional group). Carlson et al. [22] evaluated 566 patients at different follow-ups and at two years the mean FJS was 76.4, the highest level of awareness because after this period, there is a progressive decline (64.4 at 5 years). Our results can be defined very satisfactory and we can find a positive relationship between radiological parameters and clinical outcome. Other studies are ongoing with CT measurements regarding the bone coverage and the rotational alignment of the components, with the purpose to correlate them with patient-reported outcome measures and different clinical scores.

Conclusions

Radiological assessment of the new personalized knee system design showed excellent results with various parameters restored to the normal values. Therefore, the prosthesis can be considered anatomic, and the surgical technique is reproducible allowing the prosthesis to be implanted easily and with high precision.

Compliance with ethical standards

Ethical Committee approval was obtained for this study.

Conflict of interest The first author (FB) is part of the design team of the implant. The other authors (MG, SMPR, EP, VT, 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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