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VALUTAZIONE CINEMATICA INTRAOPERATORIA CON UTILIZZO DEL NAVIGATORE E POSTOPERATORIA CON RSA DINAMICA NELLE PROTESI TOTALI DI GINOCCHIO

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SUMMARY

Intraoperative evaluation of total knee replacement: kinematic assessment with a navigation system

Introduction

The reduction of perceived pain with a satisfactory recovery of knee mobility and function, are the main goals of total knee arthroplasty (TKA). TKA is an effective technique to treat osteoarthritic knees (OA). However, some postoperative evaluations by fluoroscopy studies have shown abnormal tibial rotation and abnormal anterior translation of the femur on TKA knees [2, 5, 6, 24, 25]. Interest in kinematics of reconstructed knees has increased, since it was shown that the alteration of knee motion patterns could lead to abnormal wear in prosthesis components, as well as damage to soft tissue [4, 9, 19, 21]. According to some authors, TKA should influence knee kinematics [7, 18, 22, 23]; however different outcomes might be related to the specific prosthetic design [8] and the expected kinematics of the reconstructed knee might be influenced by preoperative pathologic conditions of severe OA knees [14, 23]. Navigation systems, which were introduced to allow a higher precision of implantation than that of conventional instruments, use bony landmarks to collect accurate, instantaneous information regarding joint position and motion during surgery that are useful to guide the surgeon during the implant. Such systems mainly offer a step-bystep guide for correct alignment of the implant based on joint alignment and component rotation [17], but they do not allow extensive analysis of knee kinematic behaviour throughout the whole range of flexion. Using a navigation system and following a customised acquisition protocol, we performed intraoperative kinematic measurements to study the effect of posterior substituting rotating platform TKA on knee kinematics. In particular, we verified (1) if varus/valgus (VV) laxity and anterior/posterior (AP) laxity were restored after TKA; (2) if TKA induced abnormal femoral rollback; and (3) how tibial axial rotation was influenced by TKA throughout the whole range of flexion.

Materials and methods

Ten patients (8 F, 2 M, average age 69 years, range 67– 79 years) undergoing posterior substituting rotating platform TKA (PFC Sigma RP-F; DePuy Orthopaedics Inc., Warsaw, IN, USA) at our institute from September 2006 to February 2007 gave their informed consent to participate in this study. All patients had intact cruciate ligaments before the implantation, which were sacrificed as required by the operation. Only patients with primary osteoarthritis (OA), Ahlba¨ck grade III [1], and no patello-femoral-associated pathology were included in this study. Patients with posttraumatic or rheumatoid arthritis, valgus knees, and those overweight (BMI[25 kg/m2) and over 80 years of age were excluded. Intraoperative passive kinematics was measured with a surgical navigation system (KIN-Nav navigation system) [15, 16, 27]. The KIN-Nav navigation system has an optoelectronic localizer (Polaris, Northern Digital Inc., Waterloo, ON, Canada), two removable reference arrays (fixed by the standard surgical approach onto the femur and tibia using 3-mm Schanz screws), and a stylus equipped with optical markers. The navigation system is controlled by a commercial laptop with dedicated elaboration software. The software was designed to allow flexible anatomical and kinematic acquisitions and respond to any additional demands of the surgeon during the standard surgical protocol. After exposing the knee, the surgeon attached passive removable optical reference frames distally to the femur and proximally to the tibia, without performing additional cuts. By a femoral circumduction movement, the surgeon first located the hip centre and then used the stylus tracked by the optoelectronic localizer to establish the standard anatomical landmarks, to compute the reference system in the femur and tibia (femoral epicondyles, tibial malleoli and tibial plateau extremities) (Fig. 1). Then, the surgeon tested the laxity of the knee with VV rotation at 0_ and at 30_ and the Anterior-posterior (AP) translations at 90_ of flexion (Drawer's test) at maximum load [3, 10, 11, 15, 27]. Next, he performed passive range of motion (PROM) from maximum extension to maximum knee flexion.

Fig. 1 Landmark acquisition during total knee arthroplasty

The surgical reconstruction was then performed by following the standard indications for implanted prostheses. Kin-Nav was used to evaluate the alignment of the implant and obtain further kinematic data, and the operation was performed manually. The tibial cut was performed first, with a 0_ plane cut and a 0_ posterior slope. The plane of the tibial cut was centred on the AP transtibial axis. The femoral cut was 5_–7_ valgus with respect to the anatomical axis, or 0_ to the mechanical axis. The AP femoral cuts were made using spacer blocks to balance flexion/extension space. Release was then performed to achieve joint balance both in extension and flexion. When the prosthesis was in place, kinematics tests were again recorded. We evaluated knee kinematics from data acquired during laxity tests and passive motion, by comparing data obtained before and after the implantation. Instantaneous rotations and translations were computed from the relative motion of the tibial frame with respect to the femoral frame using the Grood and Suntay algorithm [12]. We calculated VV laxity as the difference between maximum and minimum instantaneous rotations achieved during VV tests at 0_ and 30_ around the antero-posterior axis, and the AP laxity as the difference between maximum and minimum instantaneous translations achieved during Drawer's tests along the antero-posterior axis [16]. Student's t test for paired samples was used to compare laxity values obtained before and after surgery (VV at 0_, VV at 30_, AP at 90_). The PROM analysis included all six degrees of freedom of the joint. VV rotation was measured to verify knee alignment in extension both before and after TKR. Tibial axial rotation, [internal/external (IE) rotation around the proximo-distal axis] and AP displacement were plotted as a function of flexion throughout PROM. For statistical comparison, continuous data obtained from passive motions were re-sampled each 2_, from 10_ to 110_ (to include the PROM of all the patients). To assess repeatability of passive motions, intraclass correlation coefficients (ICC) were used to compare repeated PROMs on each patient. ICCs were also used to compare the curves before and after implantation. The total amount of IE rotation during flexion was calculated as the difference between minimum and maximum IE rotation achieved during the PROM test. Significant changes in amount of tibial axial rotation due to component implantation were evaluated by comparing values before and after TKA using Student's t test for paired samples. For data elaboration we used customised software (Report Generator, IOR_) and SPSS (Version 13.0, SPSS Inc., Chicago, IL) for statistical analysis. For all statistical analyses, the level of significance was set at $P = 0.05$.

Results

Preoperative alignment was neutral (between -2_ and 2_ varus) in three cases, and varus (between 2_ and 10_ varus) in seven cases. TKA improved alignment in preoperative varus knees, which became neutral after surgery. In preoperative neutral knees the alignment was maintained neutral after TKA. The VV laxity at 0_ was significantly reduced by 2_ ± 2_ ($P = 0.006$), whereas at 30_ of flexion the VV laxity of the replaced knee remained similar to that of the OA knee ($P = 0.363$) (Fig. 2). Drawer's test at 90_ significantly increased after TKA from 6 ± 2 to 9 ± 1 mm ($P = 0.004$). The PROM test was highly repeatable: the ICCs between repeated motions were 0.97 when performed by the same surgeon and 0.87 when performed by different surgeons. Analysing the AP displacement during PROM showed significantly different pattern and total amount of displacement between knees before reconstruction and knees following TKA ($P = 0.01$). Before reconstruction the femoral rollback increased linearly during flexion with a total posterior displacement of 23 ± 8 mm. Following TKA, the femur had an abnormal anterior translation up to 60_ of flexion, followed by a rollback of 12 ± 5 mm (Fig. 3). Individual patterns of translations were similar to mean patterns despite the predictable variability of values. Analysing the tibial axial rotation during PROM, we found that TKA influenced the pattern of tibia rotation during flexion (ICC between the curves before and after the TKA = 0.484), but not the total amount of IE rotation during whole range of flexion which did not change before (8_ ± 4_) or after TKA (6_ ± 5_) ($P = 0.094$) (Fig. 4). Analysis of individual cases showed that while all neutral knees had initial scarce values of rotation (4_ ± 1_), all varus knees presented more normal values of tibial axial rotation (10_ ± 2_).

Discussion

The purpose of this study was to describe the effect of rotating platform TKA on knee kinematics using a navigation system. We measured alignment and laxities, as defined in conventional surgical evaluations; in addition we calculated the complete 3D motions of the individual knee during the whole ROM, which can be useful to evaluate the prosthesis performance intraoperatively. Rotating platform posterior substituting TKA improved alignment in preoperative varus knee and preserved the neutral alignment in neutral knees, which should assure a good joint kinematic and reduction of wear [4, 19]. VV laxity in extension after TKA was reduced in all cases compared to values before TKA, and approached values found for ACL-deficient knees [27]. VV laxity at 30_ in TKA knee did not significantly change compared to that of knees before TKA. Drawer's test at 90_ showed increased AP laxity in TKA knees compared to knees before TKA (Fig. 2). AP laxity at 90_ was larger compared to intact [10] and ACL-deficient knees [27], as expected from a posterior substituting design.

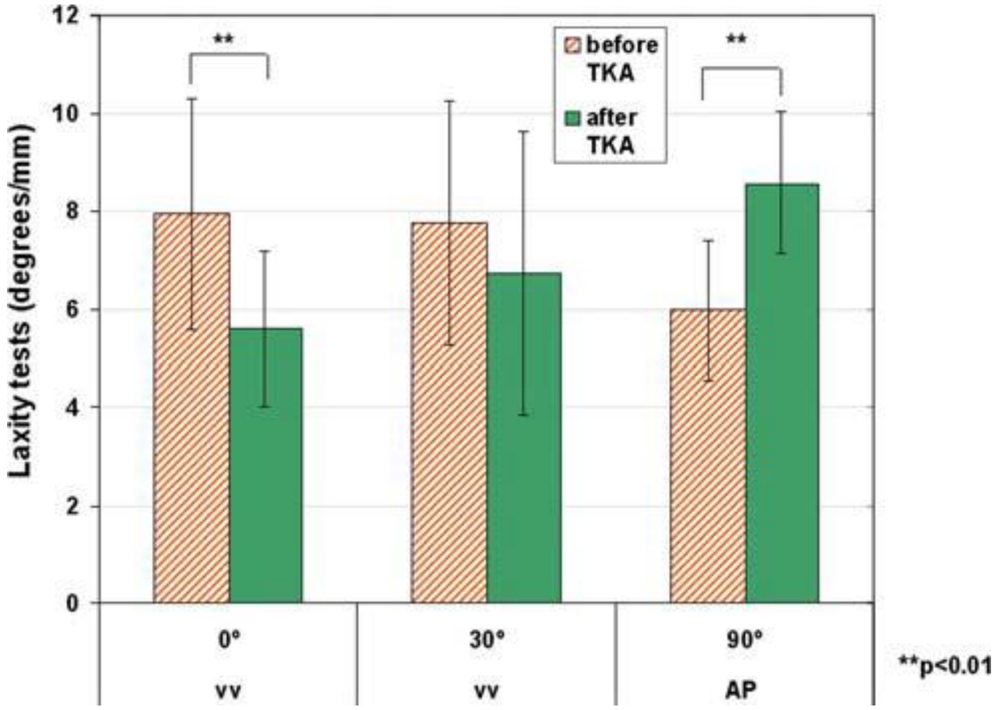

Fig. 2 Varus/valgus laxity (degrees) at 0_ and 30_ of flexion, anterior/posterior laxity (mm) at 90_ of flexion. Values are expressed as mean ± SD in OA knees before TKA and in TKA knees

The trend of AP femoral translations during flexion was very similar in all cases analysed (Fig. 3). Furthermore, in OA knees before TKA we noticed a femoral rollback that increased with flexion similarly to what has been reported for intact knees in both in vitro and in vivo studies [20, 26]. Conversely, after TKA, we observed an abnormal anterior translation of the femur up to 60_ of flexion followed by a small femoral rollback of 12 ± 5 mm. A similar trend has been described in previous studies on posterior stabilized TKA knees and can be explained by the action of the posterior cam after 60_ [5, 13, 23]. In conclusion, femoral rollback was homogeneous in all subjects analysed and it was also comparable with other postoperative evaluations. The influence of TKA on tibial axial rotation (IE rotation) is a controversial point in the literature. In a postoperative study on different TKA designs some authors found that rotation magnitudes and the number of cases with normal axial rotation patterns decreased in all TKA groups during a deep knee bend [7]. When studying a cruciate substituting fixed bearing implant intraoperatively, Siston et al. [23] found less screw-home motion in knees following TKA (2_ ± 4_) compared to that of OA knees (5_ ± 4_) and concluded that posterior stabilized fixed bearing does not preserve screw-home motion. We found that rotating platform cruciate substituting TKA influenced the pattern of rotation during flexion (Fig. 4), but the amount of rotation during whole motion remained similar before (8_ ± 4_) and after TKA (6_ ± 5_). Therefore, the amount of tibial axial rotation was preserved by this mobile bearing implant. The axial rotation values observed in our intraoperative study are comparable with the amount of rotation found by Ranawat et al. [22] in a postoperative video videofluoroscopic study on the same TKA implant that was assessed in our study. They compared a mobile bearing with a fixed bearing implant and found that the total amount of axial rotation was of 7_ and 4_, respectively [22]. Unlike AP translations, when observing tibial axial rotation, we observed that although this TKA implant preserved the preoperative amount of tibial axial rotation, all knees with different preoperative alignment behaved differently also after TKA. In preoperative neutral knees the amount of tibial axial rotation was scarce and was not improved by the implant. In varus knees IE rotation was normal before and after TKA. Therefore, while varus knees had an improvement in alignment and did not lose IE rotation, neutral knees were already aligned before surgery and after TKA rotation were not increased.

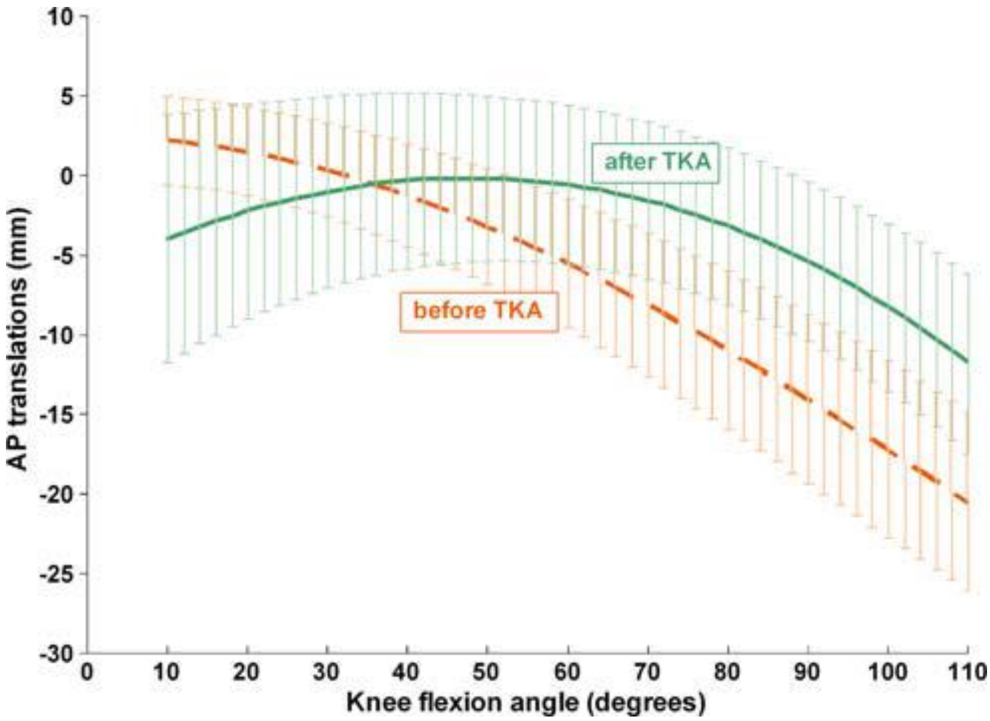

Fig. 3 Anterior (?)/posterior (-) translation in function of flexion during the PROM test. Values are expressed as mean ± SD in OA knees before TKA and in TKA knees

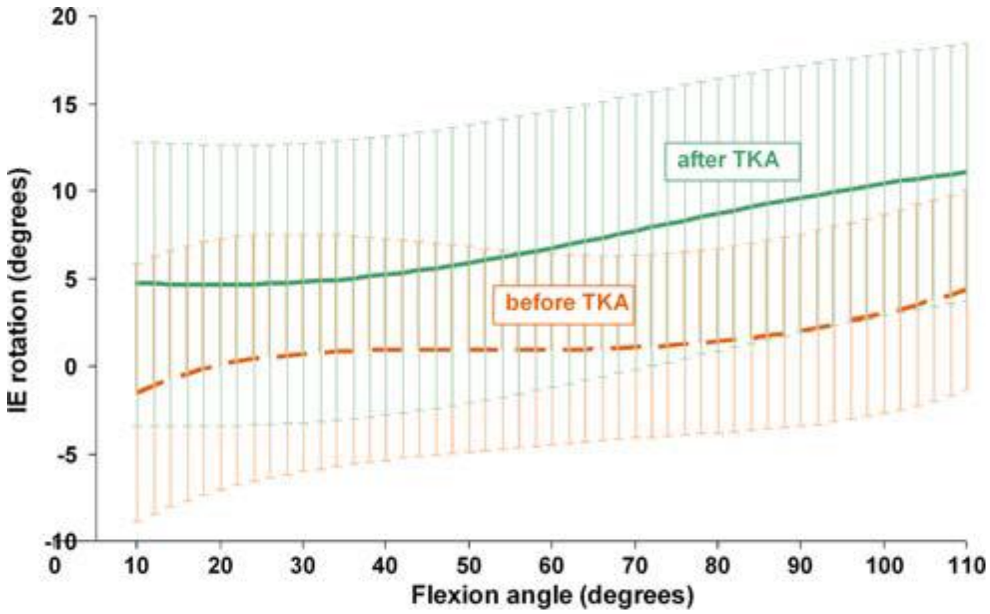

Fig. 4 Internal (?)/external (-) rotation in function of flexion during the PROM test. Values are expressed as mean ± SD in OA knees before TKA and in TKA knees

These findings, supported by more data, might help to explain the influence of preoperative conditions of the OA knee on kinematics after TKA [14, 23] and perhaps suggest new patient selection criteria if this implant design could be more suitable for some patients. A limit of our study was certainly the small number of cases. However, the inclusion criteria were strict to guarantee the homogeneity of the sample and kinematics in TKA knees was compared with kinematics in the same OA knees before TKA to study the effect of the implant on individual cases. Moreover, this was a preliminary study performed to verify the usefulness of the protocol more than the clinical outcome of a specific implant. In conclusion, this study shows that navigation system might be used to analyse kinematic patterns throughout the range of motion of TKA at time zero. The use of navigation systems to evaluate knee kinematics intraoperatively provided quantitative and extensive information on reconstructed and arthritic knee behaviour and data comparable to postoperative studies. That means that they could be used as a first time evaluation of prosthetic function during surgery. However, further studies including intraoperative evaluations on different prosthetic designs supported by postoperative assessments could be useful for understanding the improvements related to TKA on individual OA knee kinematics.

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Three different cruciate sacrificing TKA designs: no intraoperative kinematic differences and no clinical differences at 2 years follow up

Introduction

In vitro studies on TKR showed that a restored physiological posterior translation of the femur component over tibia during flexion, is associated to a better function of flexor extensor mechanism [8, 10]. In addition axial rotation, more commonly referred to screw-home mechanism, permits a more posterior translation of the lateral condyle and may also lead to a greater knee flexion.

Implant designs have been developed to restore physiological rollback and screw-home. It is well known that femoral rollback and internal rotation of the tibia are reduced after TKA when compared with the normal knee condition [1, 20]. In general, PS designs display more rollback than CR designs and have better ranges of knee motion [4, 14, 15]. Evidence is emerging that better kinematic patterns after TKA may help patients in their functional performance [16, 33, 47, 50].

When the posterior cruciate ligament (PCL) is not functional (slackened, released or cut), options to prevent antero-posterior (AP) instability include the use of: (1) a PS design with post- cam mechanism, or (2) an anterior stabilized (AS) design with a dished polyethylene insert with a raised anterior lip. PS-TKA with a cam and post mechanism provides good range of knee motion, maintains femoral rollback during flexion, prevents posterior subluxation, provides more conforming knee kinematics, increases the efficiency of the quadriceps muscle, and facilitate balancing the soft tissues. Whereas, disadvantages of PS-TKA includes: distal femoral fracture, patellar clunk, and cam post impingement and the potential wear sequelae of that mechanism [31, 37, 48]. Advantages of AS TKAs include bone preservation, decreased wear rate [21, 37]. Whereas critics of AS bearings report their inability to restore normal knee kinematics, and decreased condylar rollback [11, 30, 37, 42].

Rotating-platform MB TKAs have been designed to increase tibiofemoral articular conformity without restricting tibio femoral axial rotation [13, 25].

However, the ability of contemporary TKAs to restore kinematics towards normal is still not fully understood [40, 43]. Most in vivo studies assessed the kinematics of either osteoarthiric (OA) knees or TKA knees and only few intraoperative compared passive knee flexion kinematics before and after TKA using surgical navigation systems [3, 9, 43].

The purpose of this prospective study was to examine whether three types of mobile-bearing PCL sacrificing TKA could restore the native knee translation and rotation. The primary hypothesis was that there are differences in knee kinematics and laxity between three different cruciate-substituting TKA designs: 1 with post-cam mechanism, 2 post-cam mechanism based on an inter-condylar ‘third condyle’ concept, 3 anterior stabilized with deep-dished highly congruent tibial insert; specifically, showing different femoral external rotation with flexion, different femoral translation with flexion and different laxity under stress test. The secondary hypothesis was that there is different clinical outcome between the three TKA designs at 2 years follow-up.

Materials and Methods

We recruited 104 patients with primary osteoarthritis of the knee designated for total knee arthroplasty within a 12 months period. Patients older than 85 years of age, patients with secondary osteoarthritis of the knee, extra-articular deformities, severe varus or valgus deformity (>15 degrees) requiring a hinged implant, or patients not willing to participate were excluded from the study. 14 patients out of the total had to be excluded due to the reasons mentioned above. Patients provided informed consent to this study, which was approved by the ethical committee of our Institute. Inter-operative data from consecutive TKA operations randomly assigned to 3 different TKA implants: First Symbios, HLS Noetos Tornier and Gemini Link. The three cohorts of 30 patients each were performed by two authors (SZ MM).

Patient's demographic study showed no differences in the three groups (Table 1).

Implant	**Type of constrain**	**Age** mean±st.dev (range)	**Sex**	**Preop limb alignment** mean±st.dev (range)
HLS Noetos	3rd condyle	71 ± 7 (56 to 82) y	12m 18f	4.2±4.4° (12 to -7) varus
Gemini	deep dished poly	69 ± 7 (57 to 83) y	1m 29f	4.6±4.1° (10 to -4) varus
FIRST	Post cam	68 ± 6 (56 to 77) y	5m 25f	4.0±2.5° (11 to -9) varus

Table 1.Patients demographic of the three cohorts.

Implant design

First cohort received a PS TKA (FIRST, Symbios SA, Switzerland). This prosthesis design is characterized by being semi-constrained; by the ultra-congruence between the articular surfaces throughout the flexion process, from 0° to 90°; by the post and cam mechanism that acts starting from 90° of flexion.

Second cohort received a PS TKA (HLS Noetos, Tornier SA, Montbonnot, France). The femoral component is designed with symmetrical 'multi-radius' femoral condyles, coupled with a congruent mobile tibial insert. The prosthesis provides flexion stability and femoral roll-back through a small rounded inter-condylar 'third condyle' that engages with the tibial insert beyond 35º of flexion.

Third cohort received a PC sacrificing TKA (Gemini, Waldemar Link GmbH & Co, Hamburg, Germany). This implant has a deeply dished sagittal profile and an increased AP lip to improve the tibiofemoral contact area, conformity and the antero-posterior stability [21].

Surgical technique

All patients received a cemented TKA with patellar resurfacing. The femoral component of all implants is designed with symmetrical ‘multi-radius’ femoral condyles, coupled with mobile tibial insert. Rotating platform mobile bearing tibial insert was used in all patients.

All operations were guided by a navigation system (BLU-IGS, Orthokey LLC, Delaware, USA). The navigation system does not alter the original surgical technique nor affect knee kinematics, and its protocol and accuracy have been reported [9, 29]. All operations were performed under general anaesthesia and a tourniquet was used for all patients. After subcutaneous dissection, the capsule was opened to register patient anatomy, while maintaining cruciate ligaments, menisci and osteophytes for pre-operative kinematic acquisitions. Post-operative kinematic acquisitions were performed after implant fixation and before capsule closure. Kinematic tests specifically included:

1. PROM: passive range of motion, that is flexion-extension movement from 0º to 120º of knee flexion under anaesthesia;

2. AP90: anterior drawer test at 90° of knee flexion, applying maximum manual force;

For each patient, the tests were repeated three times, and average values were recorded.

Data analysis

Femoral and tibial anatomic reference systems were calculated and the relative tibio-femoral movement was decomposed using Grood & Suntay (G&S) algorithm [19]. The femoral coordinate system was established using Whiteside’s line for the antero-posterior (AP) axis, the mechanical femoral axis (femoral head centre to distal inter-condylar notch) for the proximal-distal (PD) axis, the and the cross-product of these two for the medio-lateral (ML) axis. The tibial reference system was calculated using the line connecting the tibial spine to the medial third of the tibial tuberosity for the AP axis, the mechanical tibial axis (tibial spine to midpoint of malleoli) for the PD axis, and the cross product of these two for the ML axis.

The raw data was processed using a smooth curve-fitting function that enabled direct comparison of patient data at 5º intervals. The internal-external (IE) rotation, recorded during PROM, was plotted against knee flexion. The AP translation was computed for both the medial and lateral epicondyles, evaluating their displacement projected in the axial plane on the tibial reference system [23]. In the AP90 test, the tibial translation on AP tibial axis was evaluated.

Clinical Score

Preoperative and postoperative at 2 years follow-up clinical scores have been acquired. Three scores were used: Womac to monitor arthritis and treatment outcome [39], KSS to monitor patient functionality [22] and SF36 to survey health status of the patients [49].

Statistical analysis

Differences between pre-operative and post-operative clinical and kinematic results with paired Student t test. Differences between post-operative results of the 3 different cohorts of patients were analysed with ANOVA. Level of significance was set at p=0.05. Based on previous data acquisition data distribution was expected to be 4.5°/mm, power of the data to detect differences between cohorts greater than 3°/mm was 0.8.

Results

Tibial rotation during flexion

Preoperative rotation pattern were superimposable for all three cohorts of patients (Fig.1). All patients showed an average external rotation of 12±5° in extension. In the first part of flexion (0°-30°) screw-home mechanism was present with an internal tibial rotation of about 8°. After this the rotation of the tibia remained stable within 1° up to 120°.

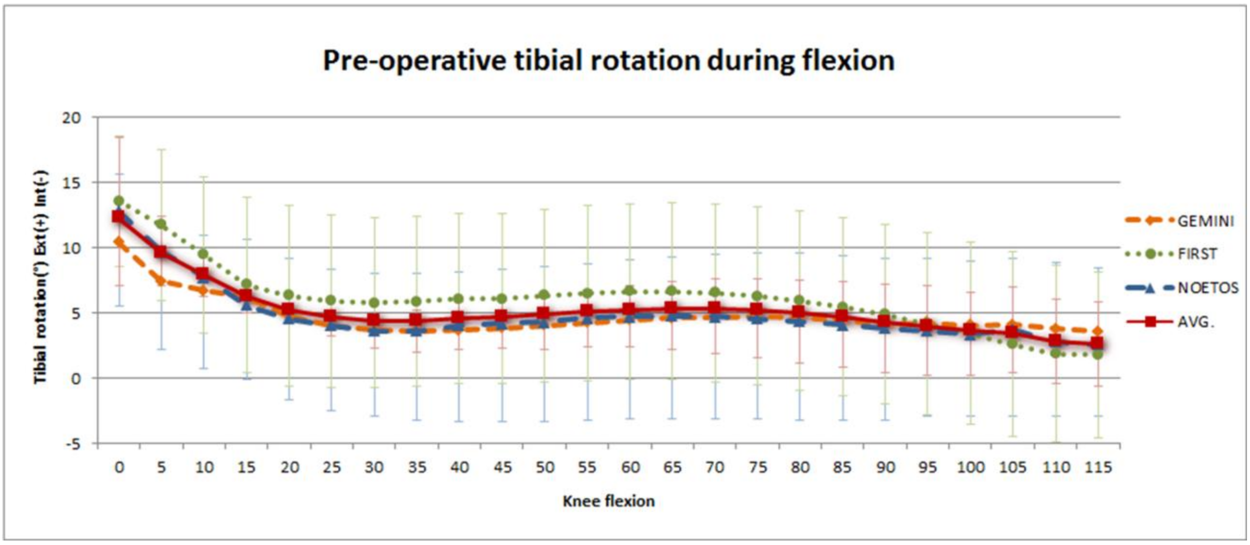

Figure 1. Pre-operative tibial rotation pattern during flexion of all 3 cohorts of patients. Average of all patients is show in red.

After implant, compared to preoperative status, all patients had less external rotation in extension, (6.5±7.1° for First ; 4.6±5.3° for Gemini; 5.6±7.2° for Noetos), even if this reduced external rotation did not change significanlty with respect to preoperative conditions (Fig.2).

Screw home mechanism was distributed in a larger flexion range (0-90° for HLS Noetos, 0-100° for FIRST, 0-110° for Gemini) with respect to native knee.

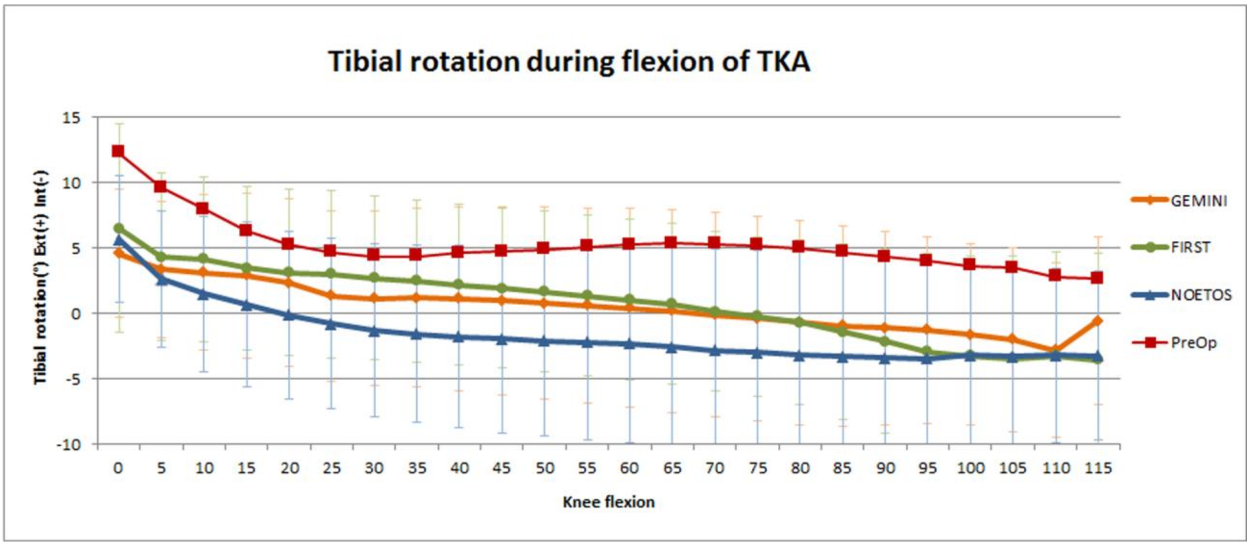

Figure 2. Post-opeative tibial rotation pattern during knee flexion for all implant models. Average preoperative rotation is shown in red for comparison.

Femoral translation during flexion

Pre-operative translation of medial and lateral compartments of femur had similar pattern in all three cohorts (fig 3). Lateral compartment had greater translation: 41mm for First; 40mm for HLS Noetos; 35mm for Gemini, while medial compartment had a smaller translation: 9mm for First; 17mm for HLS Noetos; 16mm for Gemini. For all patients the translation occurred in the first 80°-90° of flexion range.

After implant, knee was in a more anterior position in extension, especially in the medial compartment. During flexion lateral compartment had a translation range similar to pre-operative conditions: 41mm for FIRST; 41mm for HLS Noetos; 41mm for Gemini, while the medial compartment presented a greater translation with respect to preoperative condition ($p<0.05$): 25mm for First; 33mm for HLS Noetos; 25mm for Gemini.

For all implants femoral position in flexion (range 90-120°) was similar to native knee.

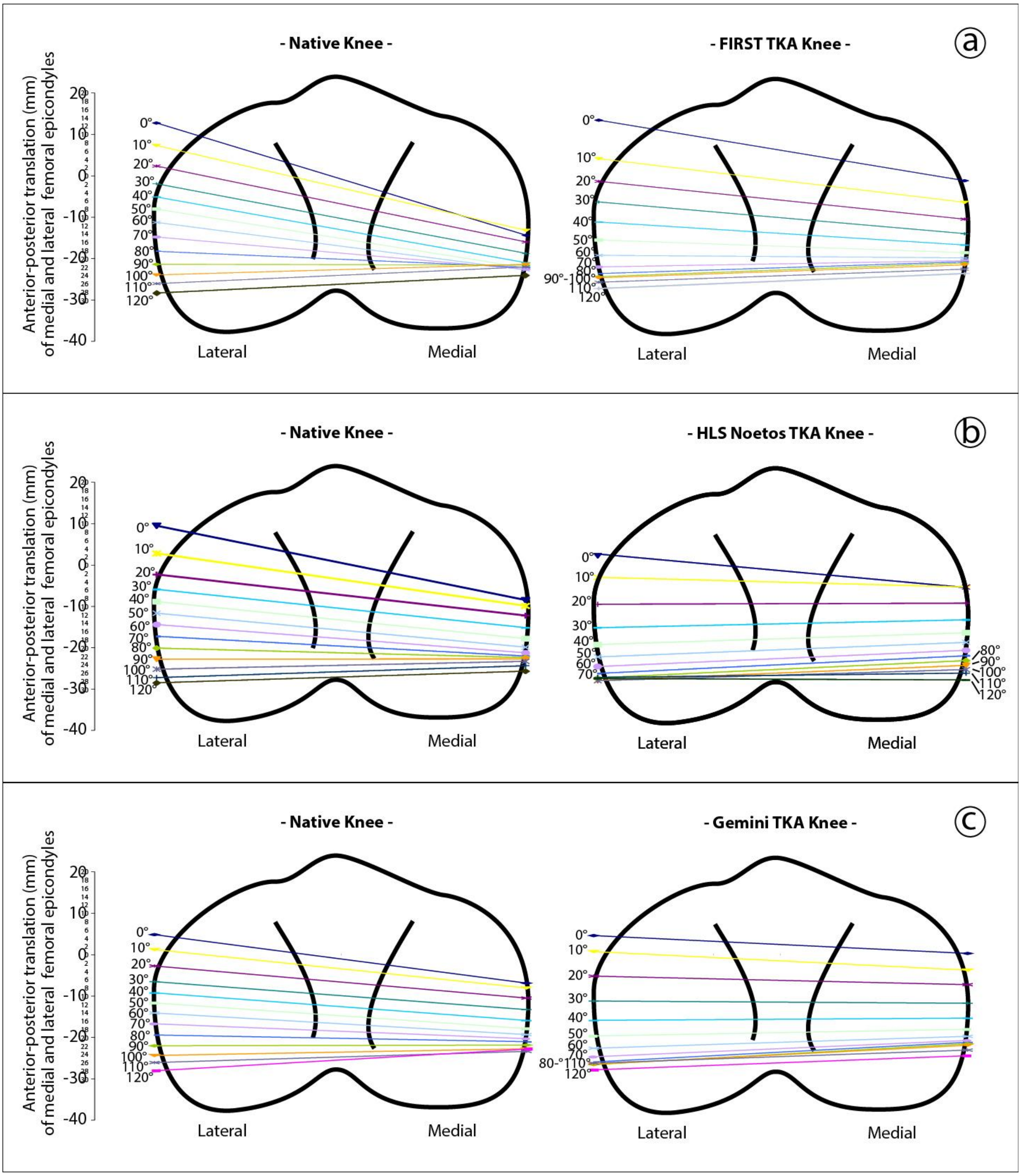

Figure 3. Translation pattern of transepicondylar line during knee flexion over. Preoperative (left) and postopeative (right). Results are divided for First (a), HLS Noetos (b) and Gemini (c) cohorts.

Tibial laxity under antero-posterior stress test.

All patients had similar preoperative AP translation during stress test at 90° of knee flexion, which was on average 8.7±4.1mm. Postoperative translation was higher for Gemini (13.2±5.2mm) and First (13.3±5.8) implants, with respect to preoperative condition ($p<0.001$)and also with respect to HLS Noetos (8.0±3.1mm) ($p<0.001$). AP laxity of HLS Noetos implant was not different from preoperative condition ($p=0.532$) (Fig.4)

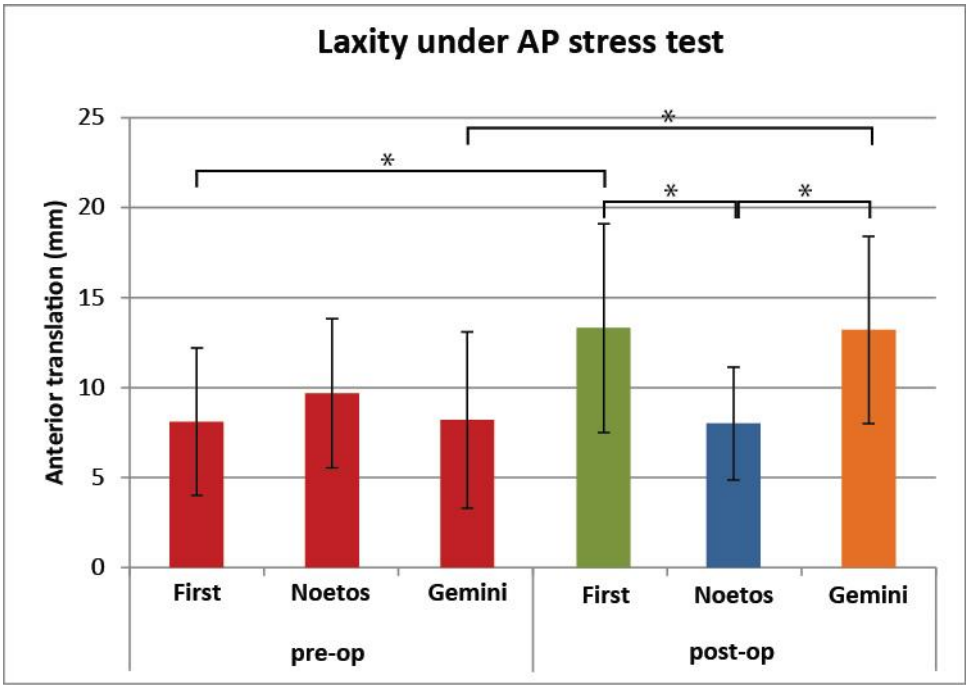

Figure 4. Antero posterior tibial translation during drawer test with limb at 90° of flexion.

Clinical scores

After implant all clinical scores were significantly improved (p<0.001). No differences were found between the three cohorts both in the pre-operative and post-operative values.

Score		*time*	**NOETOS Mean (SD)**	**GEMINI Mean (SD)**	**FIRST Mean (SD)**	**P**
WOMAC		pre-op	51,6 (17.3)	48,1 (17,0)	44,7 (15,4)	0,716
		2y FU	84,9 (6,1)*	80,5 (10,2)*	84,9 (8,967)*	0,209
KSS (function score)		pre-op	44,9 (14,4)	40,6 (12,1)	38,6 (10,2)	0,890
		2y FU	85,6 (16,6)*	77,1 (15,9)*	87,9 (18,3)*	0,121
SF36	**ISF**	pre-op	20,0 (9,5)	22,1 (11,7)	18,6 (10,2)	0.912
		2y FU	42,1 (9,1)*	37,4 (10,2)*	38,1 (10,7)*	0,331
	ISM	pre-op	26,3 (9.2)	24,9 (14,4)	21,4 (10,2)	0,890
		2y FU	50,2 (8,6)*	44,7 (12,5)*	48,3 (9,3)*	0,259

*Table 2. Results of the pre-operative and post-operative clinical scores for all three cohorts of patients. p value indicates the significance of the ANOVA test between cohorts, * statistical difference (p<0.05) with respect to preoperative result*

<u>Discussion</u>

The purpose of our study was to compare kinematic and clinical differences of three different PCL sacrificing TKA designs. The most important finding is that there is no differences in the three implants except for AP translation during stress test in flexion: the HLS Noetos TKA was the only that had comparable laxity values between pre-op and post-op tests.

Preoperative tibial rotation during flexion was comparable to passive kinematic data of OA knees reported in literature (range 4.9° - 12.1°) [9, 41, 43, 44] where magnitudes of tibial axial rotation, in the OA are reduced compared to normal knees [35, 38, 40, 43] and after TKA, is further reduced compared to normal and OA knees [43, 45]. After implant we found no significative reduction of tibial axial rotation. This result is in contrast with literature were a reduction of rotation was observed in TKA except for the works of Stiehl et al. [44] and casino et al [9]were no significant reduction was found. Moreover in Baier et al rotation increased after TKA [3].

In the normal knee, the femoral posterior translation is greater on the lateral side (range 15-22 mm) than on the medial side (range 1-10 mm) [2, 17, 24, 27, 45] which lead to a medial pivot type of axial rotation pattern in which the tibia internally rotates relative to the femur as flexion progresses and externally rotates as the knee extends [17, 40].

In our study all three mobile bearing implants had a lateral compartment translation range similar to pre-operative conditions, while the medial compartment presented a greater translation with respect to preoperative condition and in extension it was in a more anterior position. This results is in contrast with literature [30, 43, 46] and found confirmation only in the work of belvedere et al, which used the same technology to perform the study [5]. The femoral posterior asymmetrical rollback of the two condyles was preserved, this phenomenon was observed also in [12, 27, 32] after PS-TKA.

The pre and post-operative anterior translations during stress test in flexion of all three TKA implants were higher compared to normal knees [18, 28]. AP laxity of HLS Noetos implant was not different from preoperative condition which could be due to the efficacy of the third condyle, that engages the tibial post at 35°, in preventing AP translation of the tibia, while the anterior translations of Gemini and First was higher with respect to preoperative conditions. This result is in agreement with a previously published study with another cohort of patients and PS TKA implant [9]. While Nabeyama et al [34] found reported a mean lower AP translation of the knee under stress test (4.6mm) with respect to preoperative conditions (8.2mm).

All clinical scores, of the three cohorts of patients, were significantly improved postoperatively compared to the preoperative values. Moreover, although, no statistical differences of the clinical outcome between the three designs were found, a higher rate of excellent Knee Society Score in the Symbios First group (64,7 %) compared with the HLS Tornier group (58,8%) and the Gemini Link group (33,3 %) was observed. Our results are in agreement with literature: many studies did not found differences between different types of TKA [7, 21, 26, 36, 37].

Limitations to this study: only passive intraoperative knee kinematics were assessed. Siston et al. [43] stated that the active, weight bearing, kinematics following TKA are likely different than the passive kinematics recorded intraoperative. While Belvedere et al. [6] demonstrated that the Intra-operative kinematic measurements, accessible by a surgical navigation system, are predictive of the following motion performance of the replaced knees as experienced in typical activities of daily living. Finally, the short term clinical outcome were reported, future studies should investigate the long-term outcome. Second, the soft-tissue balancing was not controlled dynamically throughout the range of motion, and no information was available about condylar lift-off, posterior offset, or changes to joint line and posterior tibial slope. Third, kinematic behaviour was measured with the joint capsule open, which increases overall laxity, and with the muscles inactive due to anaesthesia, which altered the constraint patterns, though the comparisons between native knees and implanted knee are direct and valid because they were performed on the same patient and under identical conditions. The magnitude of translation of our cohorts is not directly comparable to other studies since we did no evaluated the femoro-tibial contact points but the position of the medial and lateral epicondyles.

Conclusion

Rotating platform MB TKA reproduced femoral translation and tibial rotation postoperatively compared to preoperative knees, despite design variations. Moreover, no superiority of one design over another in clinical function was observed.

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Deep-dished highly congruent tibial insert in CR-TKA does not prevent patellar tendon angle increase and patellar anterior translation.

Introduction

Posterior cruciate ligament (PCL) retention allows the femoral rollback, increases range of motion (ROM), decreases shear forces between implant and bone and preserves proprioception [12, 45]. Many studies reported that patients having a cruciate-retaining total knee arthroplasty (CR-TKA) showed a paradoxical anterior femoral translation with knee flexion [7, 14, 35]. Bertin et al. [9] found that CR-TKA with asymmetrical femoral condyles leads to posterior femoral rollback, although its amount was less than that of normal knees. Some authors [22, 31] suggested to use a deep-dished highly congruent polyethylene insert to reproduce the femoral posterior rollback and to increase knee flexion. This design is characterized by the anterior lip of the polyethylene insert that prevents the anterior translation of the femoral condyles during flexion [22, 31] thus stabilizing the knee joint, even in cases of PCL deficiency [21, 22, 27]. Nevertheless, a 6 mm anterior translation has been observed on stress radiographs, indicating that a residual laxity can induce the condyles to roll up on the anterior lip of the insert [29]. The main function of the patella is to increase the effective lever arm of the quadriceps. To perform this task in an optimal way, the patella requires a correct tracking in the femoral trochlea during the movements of flexion and extension of the knee joint [18]. Anterior knee pain, component wear and loosening can be generated by patellar altracking [8, 36]. In normal knees, patellar maltracking can be caused by numerous factors: a vastus medialis oblique insufficiency, shortening of the lateral structures of the knee joint, a patella alta and an increase in the Q angle [39]. Moreover, the factors affecting the patellar tracking after TKA are manifold, including the correction of the limb alignment, the position of the femoral and tibial components, the design of the implant, the restoration of the joint line, the cut angle of the patella and the patellar thickness [3, 4, 33]. Several studies analysed the patello-femoral (PF) kinematics, both in vitro [8, 25, 33, 35] and in vivo [5, 28, 37], but in the literature, analyses focused on the effect of the patella kinematics on clinical outcomes are still lacking. Therefore, to our knowledge, this is the first study that assessed whether a correlation exists between the in vivo patellar kinematics and the clinical scores, and moreover, it has a clinical relevance because it evaluates whether surgeons, when using a deep-dished highly congruent tibial insert in a CR-TKA, should optimize soft tissue balance to prevent the anterior femoral translation, the abnormal patellar kinematics and, accordingly, to avoid poor clinical outcomes. Starting from the hypothesis that the use of a deep-dished highly congruent tibial insert in a CR-TKA would prevent the increase in the patellar tendon angle and of the anterior translation of the patella, reducing the paradoxical anterior femoral translation, the first purpose of the present study was to demonstrate that this prosthetic design did not affect the patellar position, thus permitting to restore a correct knee kinematics. The second purpose was to investigate whether a correlation existed between an increased patellar tendon angle and anterior patellar translation, and a reduction in clinical scores according to SF-36 and Knee injury and Osteoarthritis Outcome Scores, in order to demonstrate the improvement of clinical outcomes by using this surgery approach.

Materials and methods

Twenty patients with primary knee osteoarthritis and a Kellgren and Lawrence (K/L) [26] score of at least four points, treated with a unilateral, CR mobile-bearing (MB) TKA (Gemini-Light, Waldemar Link, Hamburg, Germany), with a deep-dished highly congruent tibial insert, using a computer-assisted surgical technique between 2009 and 2010 were included in the present study and prospectively followed up at 6 months. Relevant demographics are resumed on Table 1.

Table 1 Demographic data	
No. of patients	**20**
Age at surgery (a)	**71 ± 20 years (57–83)**
BMI (kg/m2) (b)	**30 ± 10 (23–36)**
Gender	**12 F, 8 M**
Side	**12 L, 8 R**

BMI body mass index, F female, M male, L left, R right
a) Values are reported as median ± standard deviation with range in parentheses
b) Values are reported as mean ± standard deviation with range in parentheses

Clinical and functional evaluation

All the patients were assessed with the SF-36 score [42] and the KOOS [15] both in pre-operative and in postoperative conditions at 6-month follow-up.

Surgical technique

All the surgeries were performed by using a non-imagebased navigation system (BLU-IGS Orthokey, Lewes, Delaware) equipped with the specific software able to provide a protocol to both guide the implant positioning, to verify the accuracy of bone resections and to acquirepassive joint kinematics. This system was reported by the producer to have a 3D RMS volumetric accuracy of 0.350 mm and a 3D RMS volumetric repeatability of 0.200 mm [44]. The standard surgical approach and the passive knee kinematics were not altered by the use of the navigation system. The reliability of the provided method was reported by the literature [10, 30]. Two bicortical pins were inserted to fix the navigation trackers to the femur and tibial shafts. After subcutaneous dissection, the capsule was opened to register patients' anatomy, while maintaining intact cruciate ligaments, menisci and osteophytes. Cemented TKA was performed by using the navigation system based on a measured bone resection technique; then, the flexion and extension gaps were equalized, and soft tissues were balanced. A tourniquet was used in all patients, and the patella was resurfaced.

Acquisition protocol

Anatomical and kinematic data were intra-operatively collected in both pre-operative conditions—after medial parapatellar arthrotomy and before anterior cruciate ligament and meniscal removal—and in post-operative conditions— after cementing final implant. Data were analysed offline (Matlab, The Mathworks, Natick, MA, USA). Femoral and tibial joint coordinate reference systems (JCS) were calculated as proposed by Cole et al. [13], and the relative tibiofemoral (TF) movement was decomposed using Grood and Suntay (G&S) [19] algorithm. Several anatomical landmarks were specifically acquired in order to define the JCS. The landmarks were also used to intraoperatively plan the surgery and perform the TKA navigation protocol. On the femur, the surgeon identified the following: the femoral head (by leg pivoting), the most distal part of the femur in the inter-condylar notch (over to the lateral margin of the PCL), the anterior shaft, the medial and lateral epicondyles and the most posterior and distal part of the condyles. The medial and the lateral malleoli, the tibial spine, the tibial tuberosity and the lateral and medial plateaux were acquired on the tibia. The femoral anatomical reference system was established using the femoral mechanical axis (femoral head centre to distal intercondylar notch) for the proximal-distal (PD) axis, the anterior–posterior (AP) axis was determined as the cross product between the PD-axis and the surgical transepicondylar line, and the cross product between APaxis and PD-axis for the medial–lateral (ML) axis, thus achieving an anatomical orthogonal reference system. The tibial reference system was calculated using the line connecting the tibial spine to the medial third of the tibial tuberosity for the AP-axis, the mechanical tibial axis (tibialspine to midpoint of malleoli) for the PD-axis and the cross product of these two for the ML-axis. A further cross product between PD-axis and ML-axis was done to obtain an orthogonal reference system also for the tibia. In order to evaluate the position of the patella before and after TKA, the superior pole and the inferior pole of the patella were acquired with the limb at 90_ of flexion and with the patella in situ, reduced with a clamp on medial retinaculum. The following parameters were determined before and after TKA (Fig. 1): • the AP patellar translation: the projection on the sagittal plane of the position of the inferior pole with respect to tibial tuberosity, computed in the tibial reference system. This represented the translation in AP direction of the patella. • the patellar tendon angle: the projection on the sagittal plane of the angle subtended between the mechanical axis of the tibia and the patellar tendon (identified as the line between the inferior pole and the tibial tuberosity). It was computed as defined by Hollinghurst et al. [23] with the knee at 90_ of flexion. • the patellar ML translation with respect to femur: the projection on the axial plane of inferior and superior poles position with respect to femur reference system. This represented the translation in ML direction of the patella. • the patellar height: the projection, on the sagittal plane, of the distance between the superior pole and the femoral mechanical axis. The computation was done according to Laurin method [2] using the femoral mechanical axis instead of the line tangent to the femur anterior cortical line; this line was easier to estimate and more accurate, and this choice did not affect the measure. Pre-operative and post-operative ROM at 6-month follow- up was acquired. Patellar thickness was determined manually using a calliper before and after patellar replacement. It was measured at the most prominent point of the patellar dome. The study was approved by the Institutional Review Board of the Istituto Ortopedico Rizzoli (Bologna, Italy, protocol number 11551/CE/US/ml, May 5th 2006), and all patients provided their informed consent to the operating surgeon before the surgery.

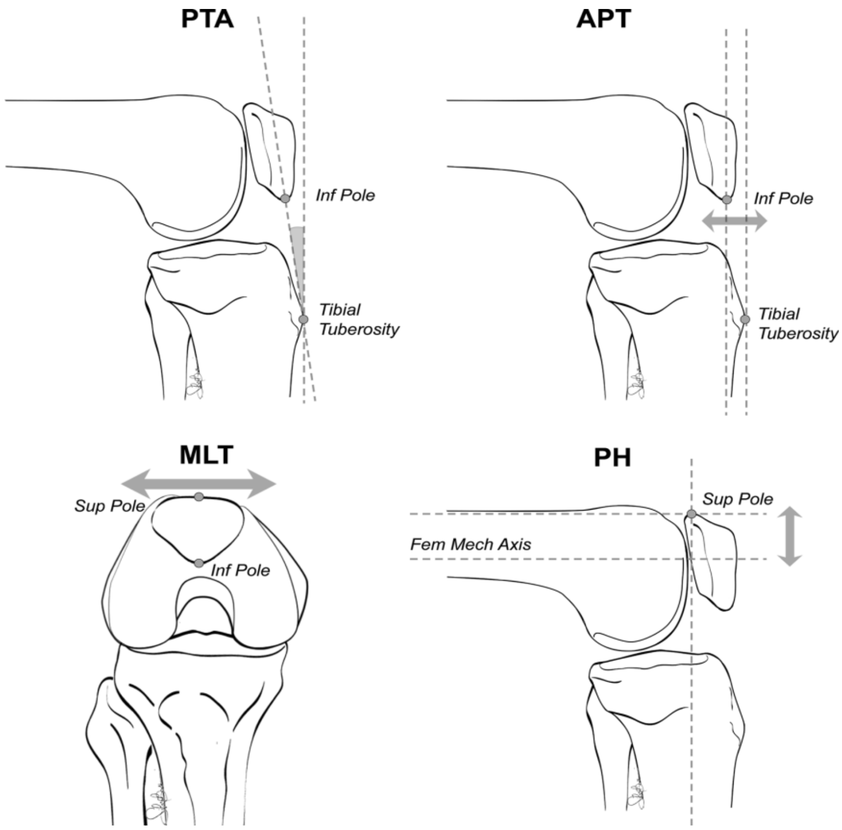
Statistical analysis

The comparison between pre-operative and post-operative data was performed for each parameter under analysis and for the ROM, with a paired Student's t test. A Pearson correlation analysis was performed to evaluate the correlation between clinical scores at 6-month follow-up and post-operative values of patellar tendon angle and anterior patellar translation. In particular, theSF-36 Physical Functioning (SF-36 PF) subscale and the KOOS Function in Daily Living (KOOS ADL) subscale were analysed. Statistical significance was set to 95 % ($p = 0.05$) for all the tests. Analyse-it software (Analyse-it Software, Ltd., The Tannery 91 Kirkstall Road, Leeds, LS3 1HS, United Kingdom) was used to perform the reported statistical analysis. A priori power analysis, assuming a difference between pre- and post-operative condition of 1 mm/1_ ± 1.5 as clinically significant (paired Student's t test, power[0.8, alpha = 0.05) obtaining a minimum sample size of 20 patients, was performed.

Results

As showed in Fig. 2a, the patellar tendon angle significantly increased in post-operative conditions (from -2.5_ ± 7.5_ to 1.7_ ± 6.9_; p\0.0001). According to patellar tendon angle results, the anterior patellar translation showed (Fig. 2b) a statistically significant anterior translation of the inferior pole after implant positioning, moving just beyond the tuberosity (from -2.5 ± 7.0 to 1.5 ± 6.6 mm; p\0.0001). The medio-lateral translation, computed with respect to femoral reference system, showed a statistically significant medial translation both for the inferior (from 9.4 ± 7.3 to 6.7 ± 7.2 mm; p = 0.0080) and superior (from 11.4 ± 7.8 to 8.4 ± 6.6 mm; p = 0.0053) poles after the implant positioning (Fig. 2c). The patellar height did not show any difference (Fig. 2d) between pre-operative and post-operative conditions (from 28.2 ± 15.0 to 27.0 ± 13.9 mm; n.s). Clinical score results and ROM are reported in Table 2. Pearson correlation showed a significant correlation between the patellar tendon angle and SF-36 PF (r = -0.57; p = 0.0254), the anterior patellar angle and the SF- 36 PF (r = -0.53; p = 0.0417), the patellar tendon angle and the KOOS ADL (r = -0.71; p = 0.0092) and the anterior patellar translation and the KOOS ADL (r = -0.65; p = 0.0225) Fig. 3). Paired Student's t test showed a significant decrease (p\0.0033) in post-operative ROM compared to the pre-operative values. No statistically significant difference was found in patellar thickness (n.s) before (20.5 ± 1.2 mm, range 16–18 mm) and after patellar replacement (19.8 ± 0.3 mm, range 15–17 mm).

Fig. 1 Schematic representation of the anatomical parameters analysed to evaluate patella position: patellar tendon angle (PTA), anterior–posterior patellar translation (APT), patellar medial–lateral translation (MLT), patellar height (PH). All measures were performed at 90_ of knee flexion



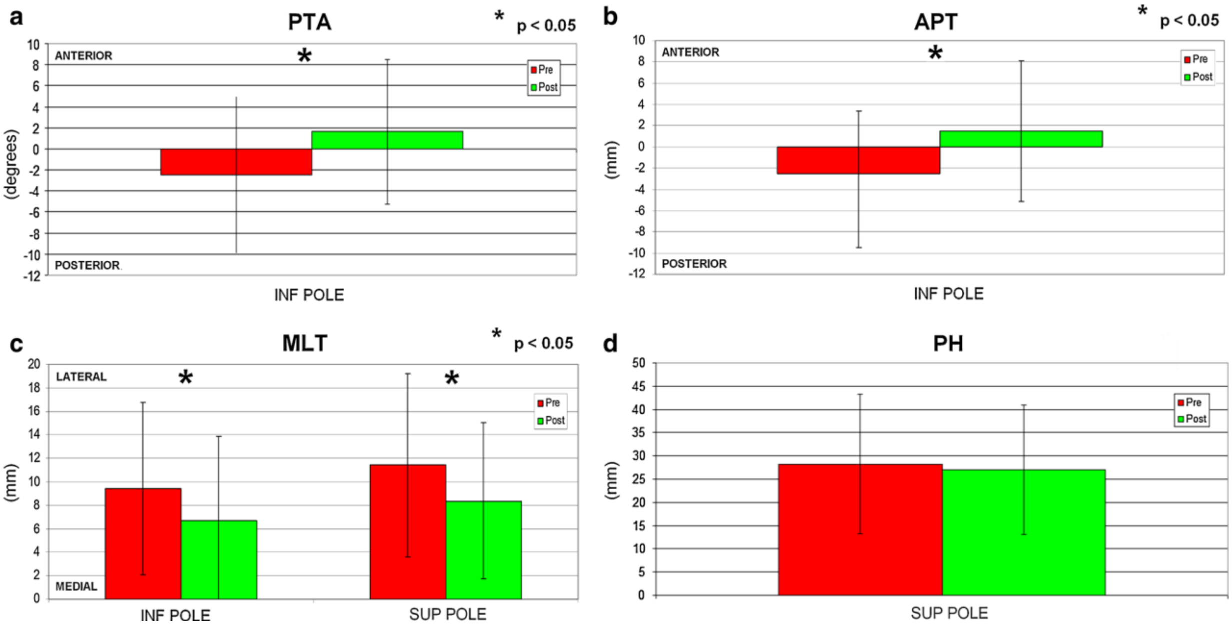


Fig. 2 Pre-operative and post-operative values of PTA (a), APT (b), MLT (c) and PH (d)

Table 2 Clinical scores and ROM

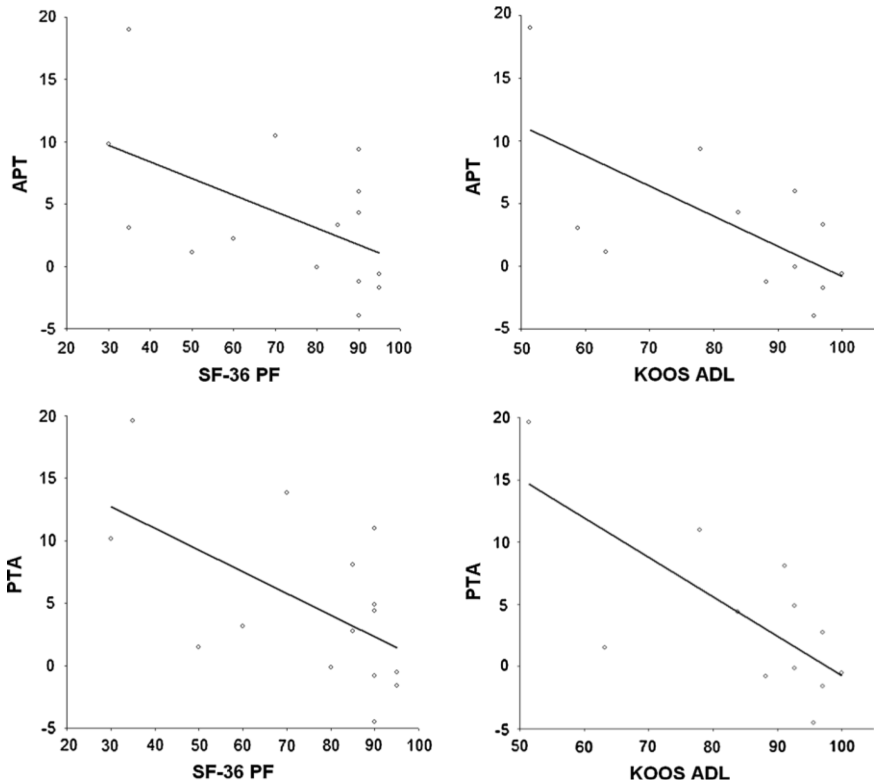
	SF-36 PF (a)	KOOS-ADL (a)	ROM (a)
Pre-operative	35 ± 19 (16–58)	56 ± 22 (36–79)	110 ± 22 (80–120)
6-month follow-up	63* ± 20 (45–80)	79* ± 13 (68–88)	97* ± 22 (70–120)

SD standard deviation
* p\0.05
a) Values are reported as mean ± standard deviation with range in parentheses

Discussion

The main finding of the present study was that the use of a deep-dished highly congruent polyethylene insert in CRTKA does not prevent an increased patellar tendon angle and anterior patellar translation with respect to pre-operative condition. Moreover, a significant correlation was found between higher post-operative patellar tendon angle and anterior patellar translation and reduced clinical results according to KOOS ADL and SF-36 PF scores. The influence of the patella on clinical outcomes in TKA was assessed by considering the position of the patella with respect to femur and tibia at 90_ of knee flexion. The comparison between pre- and post-operative position of the patella on AP, ML and PD directions was analysed. One of the problems in AP direction that might occur after TKA is the PF joint overstuffing. This mechanism might be a potential cause of limited post-operative flexion [1], PF maltracking [33], patellar component wear and increased PF force (PFF) [24]. To better understand the mechanism of the onset of this problem, the PF tracking, particularly in AP direction, has to be considered. In the present study, the patellar tendon angle and anterior patellar translation analyses were performed.

Fig. 3 Pearson correlation of post-operative values of PTA and APT versus SF-36 PF and KOOS-ADL clinical scores.



The patellar tendon angle is strongly correlated with both PF and tibio-femoral joint kinematics and can be considered an indicator of the AP translation of the femur with respect to the tibia [40]. Patellar tendon angle is approximately 20_ in the extended position while, in flexion, it reduces, in a linear fashion, becoming zero at approximately 80_ of knee flexion, and -10_ at 120_. This is due to the net posterior translation of the femur on the tibia in the sagittal plane as flexion occurs [38]. In the literature, some authors assessed that after a CRTKA, the tibia subluxes posteriorly as a result of the ineffectiveness of the PCL [35], with a reduced posterior movement of the femur on the tibia during flexion and a paradoxical anterior translation [38], thus increasing the patellar tendon angle. In the present in vivo study, a significant increase in post-operative value of patellar tendon angle compared to the pre-operative native knee at 90_ of knee flexion was observed, which is consistent with in vitro results previously reported in the literature [35, 38, 41]. Anterior patellar translation was analysed to assess the effect of the implant on patellar tracking. A more anterior position of the patella after TKA and a statistically significant difference between pre- and post-operative anterior patellar translation were found. These results could be theoretically due to the increase in patellar thickness or to the increased thickness of the anterior flange of femoral component with respect to the distal femoral resection, as observed by some authors [24, 33]. Merican et al. [33] analysed the effect of patellar thickness on PF kinematics in TKA in three different conditions, -2, ?2 and 4 mm. They found that after TKA, the differences in the anterior position of the patella compared to the TKA group were on average -2.2, ?1.7 and ?3.6 mm, respectively. They also found that even when the pre-cut thickness of the patella was restored to equal that of the native knee, the patella was displaced anteriorly in the extended knee, and they attributed it to the increased thickness of the anterior flange of the prosthesis. In the present study, patellar thickness measurement showed no significant modification with respect to preoperative value; therefore, the increase in post-operative patellar tendon angle and anterior patellar translation cannot be produced by an increased post-operative thickness of the resurfaced patella. Moreover, the accuracy of bone resections was evaluated with the navigation system. For these reasons, it is the authors' opinion that the increased patellar tendon angle and anterior patellar translation, which in turn caused the inferior clinical outcome observed in this study, were produced by a paradoxical anterior femoral translation through flexion, which was not prevented even by using a deep-dished, highly congruent polyethylene insert CR-TKA. The deep-dished highly congruent insert was designed with a higher anterior lip to prevent both the paradoxical anterior femoral translation and the posterior tibial translation even when the PCL is sacrificed (Hofmann). According to the results of this study, other authors previously demonstrated, in vivo and in vitro, that femoral anterior translation may be caused by the ineffectiveness of the deep-dished highly congruent tibial insert [29, 31]. Among these, Massin et al. [31] assessed, by means of a navigation system, the passive kinematics of ten knees replaced with deep-dished highly congruent tibial insert in posterior-sacrificing TKA. They found that deep-dished design significantly reduced posterior displacements of medial and lateral femoro-tibial contact points, and the magnitude of tibio-femoral axial rotation, and that it inconstantly controlled paradoxical displacements, which persisted in four patients. Louisia et al. [29] observed a 6 mm anterior translation on stress radiographs of deep-dished mobile-bearing posterior-stabilized TKA. Regarding the medio-lateral patellar position, a significant medial translation after TKA was found, confirming that the prosthesis produces kinematic changes in TF and PF joint. In normal knees, the patella is lateral to the knee centre at 0_, and it shifts slightly medially when the knee is flexed to 30_; then, it shifts laterally as flexion increases, as found by Li et al. [28]. Our results are consistent with some studies in the literature [6, 34]. Armstrong et al. [6] analysed the influence of femoral component malposition in seven cadaveric knees. The experimental protocol was conducted in different conditions: intact knee, knee after TKA with a femoral component external rotation of 3_ (standard TKA group) and knee after TKA with three different femoral component malpositions (5 mm of medialization, 5 mm of lateralization and 10_ of external rotation). The results showed that each malposition affected the patellar shift in its own direction, while the standard TKA group showed a medial patellar shift, confirming the results of the present study. The PD position of the patella was evaluated analysing the patellar height, computed with the Laurin method [2]. One of the complications regarding the height of the patella and resulting from TKA is the patella baja [32, 43]. The patella baja may occur secondary to distal positioning of the patella relative to the femoral trochlea or shortening the patellar tendon, as a result of the trauma or surgery [11]. Patella baja reduces knee function and increase knee pain following TKA [17]. In the present study, the PD patellar position showed no statistical differences between pre- and post-operative conditions, demonstrating that the prosthesis design did not affect the height of the patella. In the present study, the analysis of the correlation among patellar tendon angle and anterior patellar translation and the clinical scores was performed. The increased patellar tendon angle and anterior patellar translation were correlated with inferior clinical outcomes, and to the best of our knowledge, no previous papers demonstrated that the increased patellar tendon angle and anterior patellar translation produce inferior clinical outcome in CR-TKA. These results were in agreement with the literature about TF kinematics. Some authors [16, 20] reported that alterations of post-operative knee kinematics were correlated with reduced clinical outcome. Fantozzi et al. [16] showed in patients who underwent CR-TKA that more posterior locations of the condyles were correlated with higher clinical scores and higher passive ROM, and vice versa. Hartford et al. [20] found that knees, replaced with a lowcontact stress meniscal-bearing CR-TKA, with anterior sliding of the condyles, had a significantly smaller average range of flexion and a lower average Knee Society Score than did knees demonstrating femoral rollback. Finally, a significant decrease in ROM after TKA at 6 months follow-up was found. This result is probably due to a posterior direct impingement of the tibial insert against the back of the femur, maybe caused by the anterior translation of the femur during knee flexion in CR-TKA, as showed also by Bellemans et al. [7]. The present study has some limitations. The number of patients was small, and only intra-operative passive patellar condition was investigated. Patellar kinematics during weight-bearing activities with active muscle contraction, i.e. walking or climbing stairs, should be investigated. Patellar position was analysed only at 90_ of flexion; therefore, further studies should evaluate the patellar kinematics at different angles of knee flexion. Finally, the present study focused on a single CR-mobile-bearing design, without comparing different implants, i.e. posterior stabilized and/or fixed bearing. From the clinical point of view, the present study provided useful information about the biomechanical role of the patella in TKA, focusing the attention on the importance of the PF kinematics on the final clinical outcomes. Moreover, this study demonstrated that the surgical navigation system could help surgeons to optimize soft tissue balance intra-operatively in order to prevent the paradoxical anterior translation of the femur. Finally, the results reported in this study suggested that the deep-dished highly congruent CR-TKA does not ensure the prevention of the paradoxical anterior femoral translations; therefore, whether the PCL is found to be functional intra-operatively, it should be properly balanced and a deep-dished highly congruent tibial insert in CR-TKA could be used, whereas, whether it is found to be deficient, the surgeon should switch to another implant design. This information will be fundamental in choosing the most appropriate surgical approach to restore the correct joint kinematics and will allow to prevent alterations of the joint stability under loading condition, thus achieving a relevant improvement of the clinical results.

Conclusions

The present study failed to demonstrate that deep-dished highly congruent tibial insert prevents increased patellar tendon angle and anterior patellar translation in patients treated with a CR-

TKA. Furthermore, an increased patellar tendon angle and anterior patellar translation were correlated with inferior clinical scores.

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Analysis of knee functional flexion axis in navigated TKA: identification and repeatability before and after implant positioning

Introduction

A critical aspect in total knee arthroplasty (TKA) is to obtain a correct rotational alignment of the femoral component in order to achieve good joint kinematics, correct ligament balance and optimal patellar tracking, thus providing patients with the best chance for satisfactory functional outcome. Several methods, mainly classified as functional or anatomical references, have been studied to achieve this goal. However, at present, there is still a debate about which method is the most precise and accurate in TKA. Anatomical techniques are based on the acquisition of several landmarks, such as the transepicondylar line (TEA) [6, 37, 38], the line tangent to the posterior condyles (PCL) [17, 24, 31] and the Whiteside line (WSL) [2, 19, 40, 43]. These references have been widely used in surgery to estimate the femoral component rotation, despite the fact that their localisation is quite variable. This can lead to miscalculation. For this reason, literature extensively reported the analyses of the influence of their identification on component positioning [1, 2, 14, 19, 22, 25, 34, 35]. Conversely, functional techniques—i.e. estimation techniques based on the kinematic behaviour of the joint— identify functional references (i.e. centre or axis of rotation) using relative motions between bones. These references are subject- and joint-specific and depend only on the performed movement and not on the identification of specific anatomical landmarks [16, 26]. One of the methodologies already used in navigated TKA and based on a functional technique is the ''functional flexion axis (FFA)'' method [27, 28, 45, 46]. The identification of FFA is based on the estimation of the mean helical axis (MHA), which consists of applying a least square approach to a set of instantaneous helical axes (IHA). As stated by Woltring et al. [46], this method aims to describe the motion of a rigid body as a rotation around and a translation along an instantaneous axis of rotation. Several biomechanical studies defined FFA as a specific parameter to characterise flexion–extension movement, recommending this technique as a useful method to describe the tibiofemoral kinematics [7, 8, 13, 33, 36, 46]; furthermore, FFA is not influenced by the typical variability related to the identification of anatomical references [14, 15, 34, 42]. Colle et al. [12] performed an intraoperative study comparing two groups of patients, one undergoing TKA and one anterior cruciate ligament (ACL) reconstruction, respectively. They reported no statistical differences in preoperative FFA estimation between the two groups, suggesting FFA is a reliable reference during surgery, but they did not provide any results about the differences in FFA estimation introduced by surgery, especially in TKA patients. The hypothesis of this study is that the positioning of the prosthesis—following standard surgical procedure—aiming to ensure correct knee joint kinematics does not change the pre-operative estimation of FFA since it is a functionally defined reference, and therefore, it is related only to the joint movement. Accordingly, the objective of this study was to analyse the FFA estimation in pre- and post-implant conditions, thus reporting the influence of TKA on FFA in both the axial and frontal planes. Moreover, in order to support this analysis, the reliability in estimating FFA during navigated TKA was also investigated by analysing the agreement [5] of the proposed method and comparing the obtained results with the anatomical approaches, as reported by the literature. In fact, only a few studies have dealt with the repeatability of functional techniques [14, 16, 26, 32], and the analysis of reliability for surgical navigation purposes is particularly lacking, in terms of actual literature reports.

Materials and methods

A cohort including 87 patients with osteoarthritis (OA), undergoing TKA with rotating-platform prostheses (Gemini- Light, Waldemar Link, Hamburg, Germany), from 2008 to 2010, was selected for this study. The average age of the patients was 71 ± 7 years (range 55–84 years). Primary OA with a Kellgren\Lawrence score up to 4 and a BMI \40 kg/m2 was the inclusion criteria used in the study. Patients with post-traumatic or rheumatoid arthritis were excluded. The mean value of pre-operative limb alignment was -5.1_ ± 4.8_ (varus), showing a range between -12.5_ (varus) and 6.0_ (valgus), while the post-operative mean value was -0.6_ ± 2.0_ (varus) ranging between -5.5_ (varus) and 6.0_ (valgus).

Acquisition protocol

Passive joint kinematics was acquired by means of a commercial navigation system (BLU-IGS Orthokey, Lewes, Delaware) equipped with a software specifically focused on kinematic analysis (KLEE, Orthokey, Lewes, Delaware) [29]. This system was reported by the producer to have a 3D RMS volumetric accuracy of 0.350 mm and a 3D RMS volumetric repeatability of 0.200 mm [44]. All the kinematic data were off-line processed by applying proprietary routines developed in Matlab (Mathworks, Natick, MA, USA). Several anatomical landmarks were specifically acquired on the femur and tibia in order to define the joint coordinate reference system, as proposed by Cole et al. [11] and Grood and Suntay [18] and to perform TKA navigation protocol. The surgeon identified on the femur: the femoral head (by leg pivoting), the most distal part of the femur in the intercondylar notch (over to the lateral margin of the posterior cruciate ligament), the anterior shaft, the medial and lateral epicondyles, the most posterior and distal part of the condyles and the WSL. The medial and lateral malleoli, the tibial spine, the tibial tuberosity and the lateral and medial plateaus were acquired on the tibia. Due to these acquisitions, the navigation system was able to automatically identify the standard anatomical references for femoral and tibial implant positioning, specifically femoral mechanical axis, surgical TEA, WSL, PCL for femur and tibial mechanical axes and the line connecting medial and lateral tibial plateau for tibia (Fig. 1).

The femoral anatomical reference system was defined using the femoral mechanical axis as the proximal–distal (PD) axis, the anterioposterior (AP) axis was determined as the cross-product between the PD-axis and the surgical transepicondylar line, and the cross-product between AP axis and PD-axis as the medial–lateral (ML) axis, thus achieving an anatomical orthogonal reference system. In order to define an anatomical orthogonal reference system also for the tibia, the PD-axis was set as the tibial mechanical axis, the ML-axis as the cross-product between the line connecting tibial spine and tibial tuberosity and the PD-axis, and the AP-axis as the cross-product between PD axis and ML-axis. The kinematics of tibiofemoral joint was manually acquired performing a passive flexion–extension movement (0_–120_–0_ of knee flexion), three times for each subject, both before and after implant positioning, maintaining the foot in neutral position (i.e. not introducing any additional stress/torque at foot level during the flexion– extension movement). Intraoperative anatomical and kinematic acquisitions were collected both in pre- and post-implant conditions. Pre-implant data were specifically acquired after skin incision—allowing the fixation of the tibial and femoral trackers—before meniscal and ACL removal, reducing the patella; post-implant data were collected after definitive prosthesis implantation. Surgery followed the conventional navigated technique [9], and in this specific case, the surgeon used the WSL to orient the femoral component; the implant positioning was verified and approved according to the planning by using the navigation system. The study was approved by the Institutional Review Board of the Istituto Ortopedico Rizzoli (Bologna, Italy), and all patients provided their informed consent to the operating surgeon.

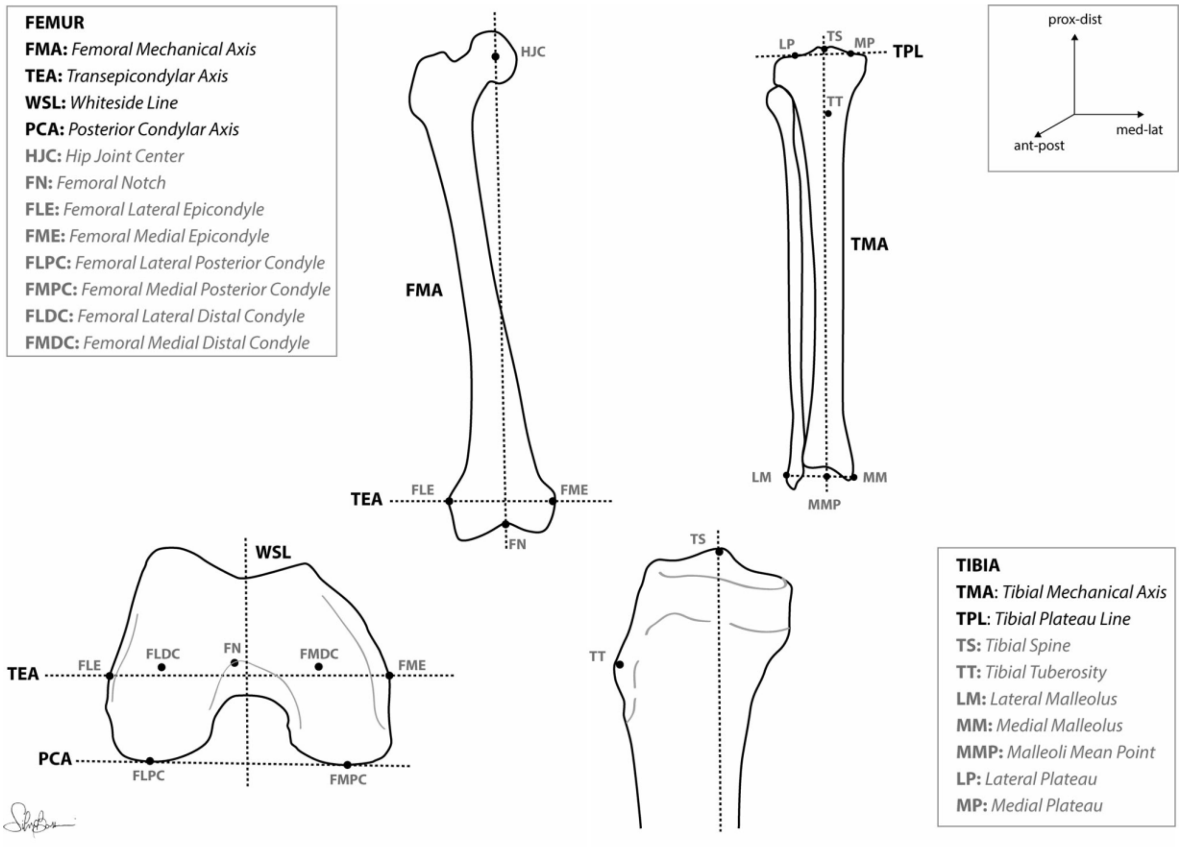

Fig. 1 Anatomical landmarks and axes acquired on femur and tibia during navigation

Statistical analysis

As previously reported, the proposed approach used to estimate the FFA relied on the use of the MHA computational method [46]. The IHA were elaborated for each flexion– extension movement between 0 and 120_ with a least square approach, and the average value of the three repetitions was computed, both in pre- and post-implant conditions. The angle between the surgical TEA (intraoperatively identified and used as a gold standard) and the FFA was analysed projecting the axes in both frontal and axial planes. These angles were chosen to describe any variation in FFA estimation, both before and after prosthesis implantation. According to these parameters, the minimum sample size was prospectively estimated for a two-tailed paired Student's t test with a power of 95 %, starting from the hypothesis of a mean of difference of 2.3_ ± 5.4_ between pre- and post-operative angles in the frontal plane and of -0.7_ ± 1.0_ in the axial plane (referring to Colle et al. [12]). Considering a minimum 15 % dropout rate in a possible long run follow-up (given the intention to perform further additional long-term biomechanical analyses on this group), we decided to enrol at least 85 patients. A descriptive statistical analysis was performed to evaluate data distribution both on pre- and post-implant values. The presence of outliers from data parameters was checked with the Thompson Tau method [39]. Statistical differences between pre- and post-implant conditions in TEA-FFA angles in both axial and frontal plane were analysed by paired Student's t test. The repeatability coefficient [5] and the intraclass correlation coefficient (ICC) [30] were used for the analysis of FFA reliability and agreement [5], evaluated from within-subject replicated measurements obtained with the same method. Confidence intervals (CI) for every analysed parameter were evaluated at 95 % level. Analyse-it software (Analyse-it Software, Ltd., The Tannery 91 Kirkstall Road, Leeds, LS3 1HS, United Kingdom) was used to perform the reported statistical analysis.

Results

Data distribution was analysed both in pre- and postimplant conditions; all data showed normal distribution (n.s.) both in frontal and axial view (Fig. 2).

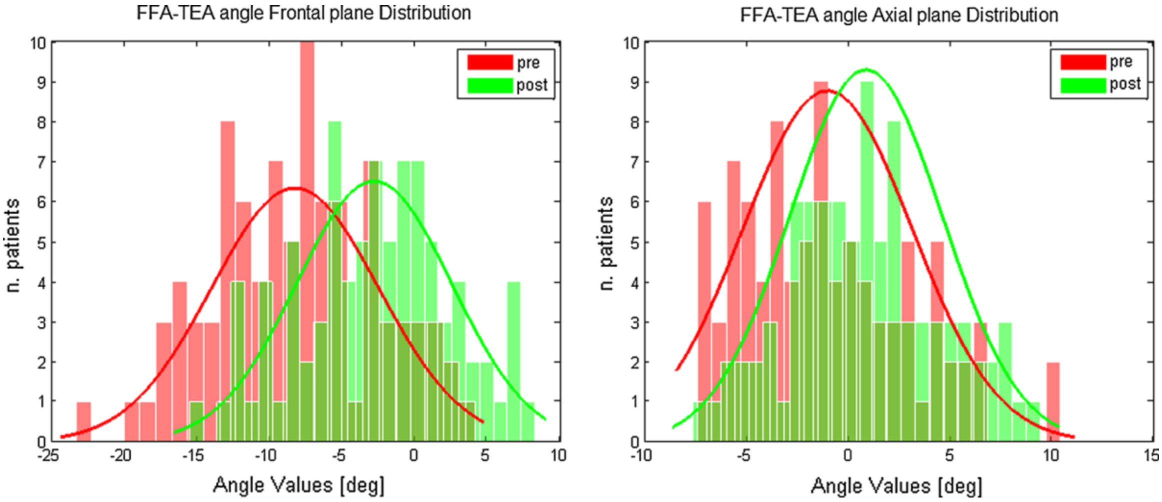

Fig. 2 Distribution of pre-operative and post-operative values of FFA-TEA angle in frontal and axial plane

As reported in Fig. 3, the pre-operative mean value of TEA-FFA angle in the frontal plane was -8.3_ ± 5.5_ and in the axial plane was -0.1_ ± 4.0_. Post-operative mean value of TEA-FFA angle in the frontal plane was -2.8_ ± 5.3_ and in the axial plane was -0.9_ ± 3.7_ (Fig. 4). Comparison between pre- and post-operative data showed a statistically significant difference in the frontal plane (p\0.0001) but not in axial plane (n.s.). Concerning TEA-FFA angle, intraobserver agreement (i.e. repeatability coefficient [5]) and reliability (i.e. ICC values), considered both in frontal and axial views and in pre- and post-implant conditions, are reported in Tables 1 and 2, respectively.

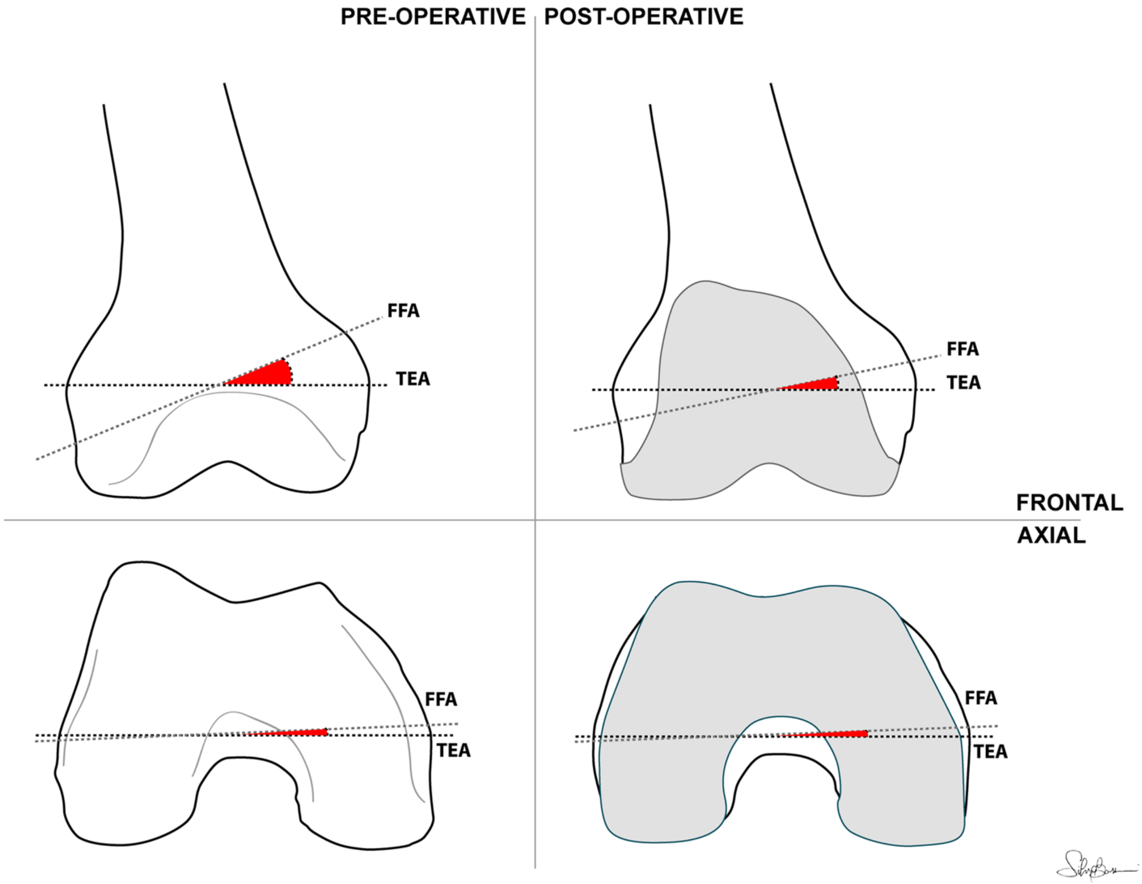

Fig. 3 Schematic representation of pre-operative and post-operative FFA-TEA angle in frontal and axial plane

Discussion

The main finding of this study was that FFA changed significantly after TKA in the frontal plane, while in the axial plane, there was no difference between pre- and postoperative conditions. Moreover, good intraobserver agreement and reliability were identified in both before and after implant conditions. As suggested by the literature and the obtained postoperative results, prosthesis implantation changed knee kinematics. The angle between TEA and FFA in the frontal plane significantly decreased after TKA and showed similar results to the angle in the axial plane. Different pre-implant FFA orientations in the frontal plane could be related to the condition of the posterior condyles, whose surface could be affected by osteoarthritis, while in the axial plane orientations are probably less influenced by pathology. No previous work has analysed the behaviour of FFA in pre- and post-operative conditions, specifically in frontal plane. Many authors have compared traditional anatomical references to kinematic methods, but the analysis was conducted primarily in axial plane and without considering the pathologic condition of the knee. Siston et al. [34] performed, on nine cadavers, an interesting comparison among different functional and anatomical alignment axes, estimating FFA as the most precise technique. Asano et al. [4] analysed the movement of the functional axis with respect to TEA both in frontal and axial planes in nine volunteers, thus only in healthy subjects. Colle et al. [12] evaluated the behaviour of FFA in pre-operative conditions in frontal and axial planes on 111 osteoarthritic patients, highlighting the difference in TEAFFA angle between axial and frontal planes and comparing the results with a control group including ACL patients. Kessler et al. [23] studied specifically the post-operative condition of FFA, comparing two different prosthesis designs, but not analysing pre-implant conditions. Their outcomes showed that different TKA designs, in particular different femoral component designs, resulted in different knee kinematics. Moreover, they confirmed the potential clinical application of FFA thanks to the advantage of being an observer independent reference. Concerning the second purpose of this study, the repeatability analysis of FFA estimation, this study

reported good intraobserver agreement and reliability, in both before and after implant conditions. The repeatability coefficient specifically ranged between 4.4_ (3.7–4.9_) and 3.4_ (2.9–3.8_), the ICC between 0.87 (0.83–0.91) and 0.93 (0.90 - 0.95) and the standard deviation ranged between 5.5_ and 3.7_. These results were comparable with the literature regarding both functional and anatomical methods. In particular, only a few authors have studied FFA repeatability for femoral component positioning in TKA. Doro et al. [14] performed a cadaver study on twelve specimens analysing FFA reproducibility and reliability in the axial plane at different limb loading conditions. They showed standard deviations and intrasurgeon ICC in normal loading conditions (2.03_ and 0.84, respectively) similar to those reported in this study. Moreover, they affirmed that FFA was more reproducible than anatomical landmarks for the TEA and WSL. Oussedik et al. [32] assessed FFA reliability in thirty-seven patients undergoing TKA. The FFA detected in the pre-incision condition, and the surgical TEA was compared to a gold standard, the TEA identified from pre-operative CT scans. Results showed that the reliability of pre-incision FFA and surgical TEA was similar but with a greater value of intrasubject variability with FFA (standard deviation greater than 3_). Despite this result, the authors accepted the FFA as a reliable reference for clinical purpose.
As opposed to functional techniques, the repeatability of anatomical methods for femoral component positioning in TKA has been widely analysed in the literature [2, 3, 10, 20, 22, 40]. Studies on WSL repeatability [2, 40] have shown different results. Vanin et al. [40] reported high values of intra- and interobserver variability on thirty patients treated with computer-assisted TKA. In a cadaver study, Arima et al. [2] maintained that the WSL was a more reliable and easier method for femoral component positioning than the TEA. The literature has reported different outcomes regarding both anatomical and surgical TEA [1, 6, 20, 21, 41]. Several authors have reported the low intraoperative reproducibility of this landmark due to the difficulty in reliably identifying the epicondyles [14, 22, 25]. Regardless, this problem especially occurs when surgeons performing acquisitions are not expert, and the variability decreases when skilled surgeons are involved, thus increasing the reliability of this reference in TKA [20, 34, 35]. A survey on variability of anatomical techniques in femoral rotational alignment was performed by Siston et al. [35] to understand which anatomical axis is more accurately and easily identified during surgery. All techniques had highly variable results but reliability increased according to own surgeon preferences and experience.
In summary, all anatomical landmarks are reported to be extremely variable and highly surgeon dependent (including skills and experience); although they are widely used as supposed gold standards, the degree of accuracy needed for femoral component positioning in TKA still remains open.

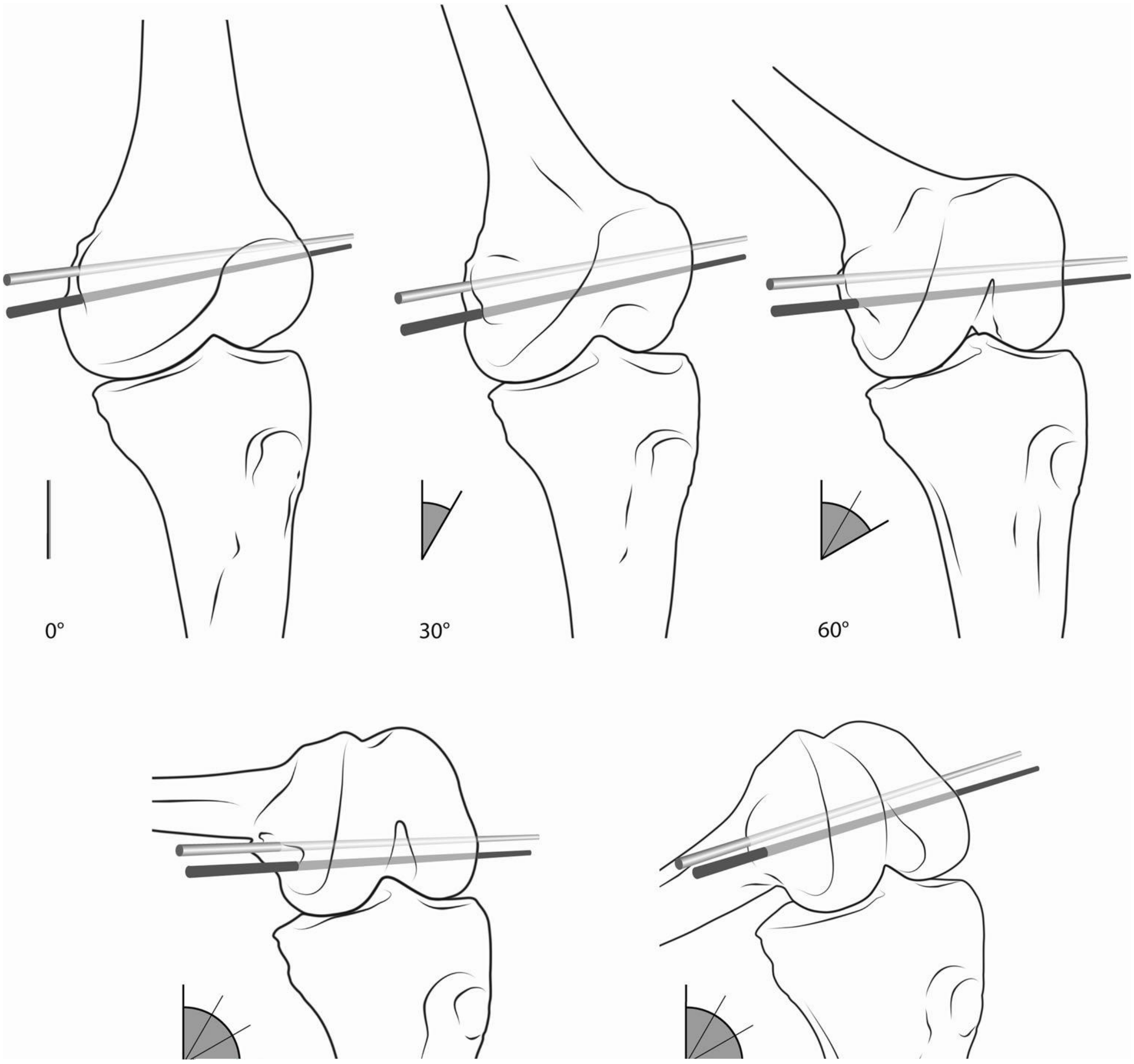

Fig. 4 Schematic representation of FFA position with respect to TEA during flexion–extension movement

Table 1 Agreement of TEA-FFA angle computed with repeatability coefficient in frontal and axial view, in pre- and post-implant conditions,with the corresponding confidence intervals at 95 %

Agreement repeatability coefficient	TEA-FFA (frontal plane)	TEA-FFA (axial plane
PRE-OP	4.4 (3.7–4.9)	4.3 (3.3–5.0)
POST-OP	4.4 (3.6–5.0)	3.4 (2.9–3.8)

Table 2 Reliability of TEA-FFA angle computed with ICC in frontal and axial view, in pre- and post-implant conditions with the corresponding confidence intervals at 95 %

Reliability ICC	TEA-FFA (frontal plane)	TEA-FFA (axial plane)

PRE-OP	0.93 (0.90–0.95)	0.87 (0.83–0.91)
POST-OP	0.92 (0.88–0.94)	0.90 (0.86–0.93)

This study has some limitations. Although this did not affect the repeatability analysis, the registration of anatomical landmarks was intraoperatively performed by manual digitisation, involving possible bias and misleading effects on computed rotations [20]. Yet this procedure is the gold standard for imageless navigation systems, which generally allow for intraoperative planning performed by directly acquiring a series of defined landmarks. Moreover, since the study was designed to analyse the variability in estimating FFA, only skilled surgeons were involved in the acquisition, in order to minimise errors, as reported in literature [20, 34, 35]. This approach indeed also reduced the variability due to the identification of TEA, which could therefore be used as a gold standard in the comparison to FFA. Intraoperative acquisitions of flexion–extension movements were performed without control on applied torques, but with the visual feedback of the navigation system, thus permitting to surgeon to verify the movement reproducibility. The passive joint kinematics was conducted with the capsule open, possibly affecting the kinematic stability of the joint, even if results suggested that this did not influence the accuracy in FFA estimation. Only the intraobserver reliability was considered in this study, because one of the goals of the work was to determine the reliability in estimating FFA during TKA. Further analyses are required to evaluate also the interobserver reliability, thus to fully estimate the reliability of FFA in femoral component positioning as alternative choice for anatomical landmarks. Finally, literature has reported that the estimation of FFA in post-implant conditions could be mainly correlated to the femoral component positioning and corresponding prosthesis design [23]. In this study, the reported values are specifically representative of the positioning defined through the standard navigated surgical procedure. However, the performed FFA method was reported to be reliable in this condition as well. Now, after established FFA reliability, further studies will be performed using the FFA as reference for femoral component positioning. From the clinical point of view, the present study demonstrated that TKA surgery significantly changed knee kinematics and consequently the estimation of FFA. However, this occurred only in frontal plane, mainly due to the influence of osteoarthritis on the posterior condyles. In comparison, the axial plane showed no difference between pre- and post-operative conditions probably because the osteoarthritis did not affect the estimation of the axis in that plane. These results suggested that FFA could be used as a functional reference for femoral component positioning; however, more analyses are required on frontal plane to better understand the relationship between FFA behaviour and pre-operative degree of deformity. Secondly, the current study showed good results for the repeatability in estimating FFA in both pre- and postimplant conditions, highlighting better reliability and agreement compared to the literature relative to both anatomical and functional techniques. Moreover, to our knowledge, this is the first study on FFA repeatability performed in vivo on such a large group of patients, thus giving a stronger statistical basis to our analysis.

Conclusions

Correct rotational alignment of the femoral component is critical to achieve successful outcomes in TKA. Literature has shown that anatomical landmarks are variable and extremely surgeon dependent. The present study demonstrated that TKA significantly changed knee kinematics, and consequently the estimation of FFA, although only in the frontal plane. Moreover, the findings also reveal satisfactory results for ICC and repeatability coefficient and low values of standard deviation, thus suggesting that FFA method is a reliable technique for clinical purposes, particularly to evaluate rotational positioning of the femoral component in the axial plane. The FFA, which is defined by individual knee motion, avoids the bias inherent in the variability of identifying anatomical landmarks and provides a good alternative choice in navigated TKA.

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Comparing flexion and extension movements in estimating knee functional axis

Introduction

The rotational alignment of the femoral component has been reported to influence the tibio-femoral

and patellofemoral kinematics in total knee arthroplasty (TKA) [31, 36]. The femoral component malpositioning is indeed a critical aspect in TKA because it may cause several problems such as joint instability, excessive wear of the polyethylene component and joint stiffness, which may lead to the early failure of the implant [1, 29].

Literature reported several standard methods used to identify the optimal femoral component placement and which are based on the acquisition of anatomical landmarks – i.e. the transepicondylar line (TEA) [5, 33, 34], the line tangent to the posterior condyles (PCL) [18, 23, 28], the Whiteside line (WSL) [3, 20, 35, 39].

Recently, a novel method called Functional Flexion Axis (FFA) has been introduced to overcome the issues related to the use of the anatomical landmarks. This method is inherently joint- and patient-specific and it is based on the identification of a functional landmark estimated through the knee joint Mean Helical Axis (MHA) [40]. Several studies reported the benefits of using the FFA to describe the tibio-femoral flexion-extension movement [6, 7, 13, 30, 40] and also to assess the rotational alignment of the femoral component [12, 14, 15, 29, 31, 38].

On the other hand, the literature highlighted that further analyses are required to better verify the FFA applicability to the general clinical practice [12, 29]. In particular, several works focused on assessing the reliability of the FFA compared to the anatomical landmarks [12, 14, 29, 31] as first step

to prove its applicability. Doro et al. [14] used a navigation system on twelve cadavers to compare the reproducibility of the FFA with respect to the TEA and the WSL concluding that FFA is more reliable than anatomical landmarks but that more studies are needed before introducing this technique in the clinical practice.

This study started from the hypothesis that the FFA can thoroughly describe knee kinematics but that the joint kinematics itself can be different from flexion to extension movements, as already highlighted by Amis et al. for the patellofemoral joint [2]. These differences in kinematics can influence both the FFA estimation and its variability, even 54 compromising its reliability. The first purpose of the present study was therefore to analyse which factors could affect the axis estimation by separately focusing on flexion and extension movements, thus to verify whether the FFA was affected by the different paths of motion.

Patients and Methods

Demographics

A cohort of consecutive subjects presenting osteoarthritic knees was prospectively enrolled for the evaluation of FFA study between September 2008 and September 2010. Inclusion criteria consisted

in primary osteoarthritis (OA), Kellgren\Lawrence score up to 4 and BMI < 40 kg/m². Exclusion criteria included all with post-traumatic and rheumatoid arthritis. Seventy-nine patients were thus included in the analysis, presenting an average age of 72 ± 5 years (range 56 - 82 years). All the patients involved underwent cemented TKA with rotating-platform prosthesis (F.I.R.S.T, Symbios, Yverdons-les-Bains, Switzerland and Gemini-Light, Waldemar Link, Hamburg, Germany). Design of the study was approved by the Institutional Review Board.

Surgical procedure

All patients received a cemented TKA with patellar resurfacing. All the surgeries were guided by a commercial navigation system (BLU-IGS, Orthokey LLC, Delaware, USA) that neither did alter the original surgical technique nor affect knee kinematics. The navigated protocol and the accuracy of the method have been already widely reported in literature [8, 25]. All the surgeries were performed under local anaesthesia and using a tourniquet. After subcutaneous dissection, the capsule was opened to register patients' anatomy, while maintaining intact cruciate ligaments, menisci and osteophytes. Cemented TKA was then performed by using the navigation system applying the measured bone resection technique, equalizing 79 the flexion and extension gaps and balancing the soft tissues.

Navigation setup

The navigation system was used to both guide the surgery and to intraoperatively acquire the anatomical data and the passive joint kinematics. A software specifically designed for kinematic analysis (KLEE, Orthokey LLC, Lewes, Delaware, USA) [25] allowed to acquire kinematic data in both pre-implant and post-implant condition.

After skin incision and before meniscal and Anterior Cruciate Ligament (ACL) removal, femoral and tibial trackers were fixed, with patella reduction, and anatomical and pre-implant kinematic data were acquired. Post-implant kinematic data were collected after definitive prosthesis implantation.

The joint coordinate reference system (JCS) was specifically defined by means of anatomical landmarks acquisitions, performed on femur and tibia, as proposed by Cole et al. [10] and Grood and Suntay [19].

Kinematic acquisition protocol

Passive flexion and extension movements, from 0° to 120°, were separately acquired three times for each subject, both before and after implant positioning. The movements were performed by the expert operating surgeon maintaining the foot in neutral position, i.e. without introducing additional stress/torque at foot level thus to not constrain the knee joint.

Data Analysis

All the information acquired by the navigation system were off-line processed with proprietary routines (Matlab, Mathworks, Natick, MA, USA). The relative motion of tibia with respect to femur was analysed 104 with Grood and Suntay algorithm [19]. Rotations during the passive range of motion (PROM) were computed and described in terms of instantaneous flexion–extension (FE) and internal-external (IE) rotations. For statistical comparison of kinematic behaviour, continuous data obtained from passive movements were resampled each 5° of knee flexion, extrapolating the values from 0° to 120° of knee flexion. Internal external rotation values of flexion and extension were then averaged on the three repetitions, at every re-sampled angle, for both pre- and post-operative conditions for each patient. The mean values obtained for each patient were then averaged for the whole set of subjects, thus obtaining one mean curve for the two different paths before and after the implant positioning. The MHA computational method was used to estimate the FFA. In particular the instantaneous helical axes (IHA) were evaluated for each movement and then, with a least square approach, the corresponding FFA was estimated [40, 41]. An average FFA obtained from the three performed repetitions was computed separately for flexion (0°-120°) and extension (120°-0°) movements in both pre- and post-implant conditions. The angle between FFA and TEA was studied in two different anatomical planes (specifically axial and frontal) in order to more easily compare the obtained results from a clinical point of view (Figure 1). *Statistical analysis* Starting from the available literature [12], the minimum sample size was prospectively estimated for

a two-tailed independent Student's t test with a power of 95%, hypothesising for the estimated FFA-TEA angle a mean of difference of 1.5° ± 1.5° between flexion and extension movement in both the frontal plane and the axial plane. Considering the most restrictive factor, at least 27 patients should have been enrolled. According to the objective of the study, the statistical analysis was performed considering flexion (0°-120°) and extension (120°-0°) movements, separately. Difference in internal-external rotations during 129 flexion and extension paths in pre- and postoperative conditions were tested with independent and two-tailed paired Student t-test respectively, thus to evaluate any statistical difference between flexion and extension movements at each frame of PROM. A descriptive statistical analysis was performed on the FFA-TEA angles in both axial and frontal planes, on both pre- and post-implant values. A Shapiro-Wilk test of normality was performed in order to evaluate the null-hypothesis of the population is normally distributed. .Independent Student t-test was performed on the angles identified by FFA with respect to TEA in both the planes, to evaluate any statistical difference in the estimation of FFA between flexion and extension movements. These inferential statistics was also individually performed on both pre- and post implant data.

Moreover paired Student t-test was executed between pre-operative and post-operative estimation of FFA analysing the corresponding angles between FFA and TEA, in order to identify the differences introduced by the implant in the FFA estimation.

Statistical significance was set to 95% ($p = 0.05$) for all the tests. Analyse-it software (Analyse-it Software, Ltd., The Tannery 91 Kirkstall Road, Leeds, LS3 1HS, United Kingdom) was used to perform the reported statistical analysis.

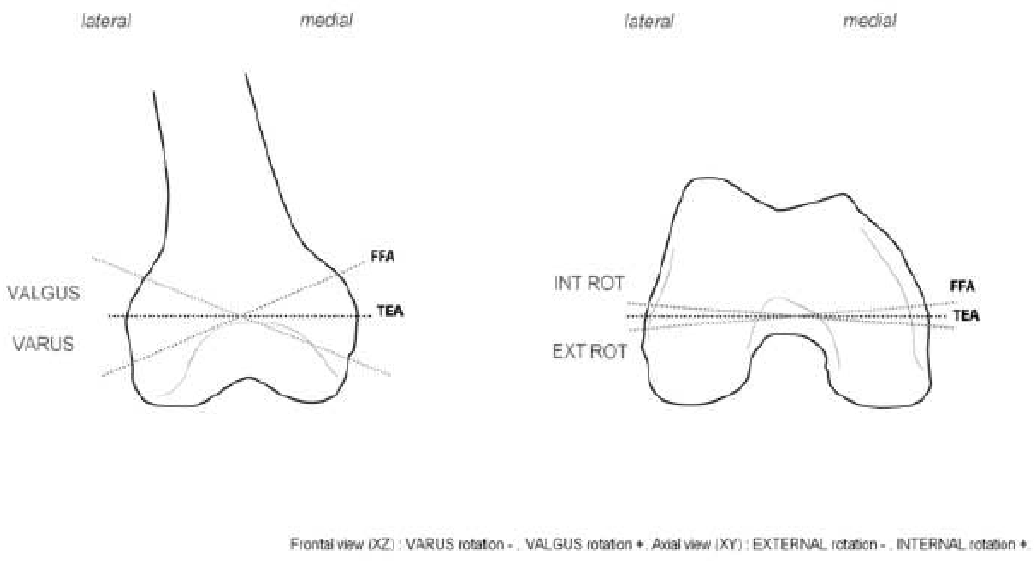


Figure 1. **The angle between the FFA and the TEA in frontal (left) and axial (right) plane.**

Results

The analysis of IE rotation during flexion and extension both in pre- and post-implant condition was

reported in Figure 2. A statistically significant difference between the two paths was found in pre implant condition, between 25°and 35° of flexion ($p < 0.05$).

The descriptive statistical analysis concerning the angles between FFA and TEA estimated for flexion and extension movements separately and for pre- and post-operative condition is showed in Figure 3. The normality test reported that all the data presented normal distribution (Shapiro-Wilk test, n.s.). The specific corresponding mean va 155 lues of FFA-TEA angles are reported in Table 1. Summarizing the statistical analysis in figure 2 and figure 4, we found that the independent Student t-test, showed significant statistical differences between flexion and extension movements in both pre- and post-implant conditions and in both frontal and axial plane (Figure 4). Analogously, pre- and post-operative conditions presented statistically significant difference as showed in Figure 5.

Table 1. Pre-operative and post-operative FFA-TEA angle in frontal (XZ) and axial (XY) plane for flexion and extension movements.

TIME	MOVEMENT	TEA-FFA XZ	TEA-FFA XY
PRE	ext	-1.7° ± 5.1°	-4.0° ± 4.7°
	flex	-8.5° ± 7.0°	-0.9° ± 4.4°
POST	ext	0.7° ± 5.2°	-0.6° ± 4.5°
	flex	-3.2° ± 5.4°	1.3° ± 3.8°

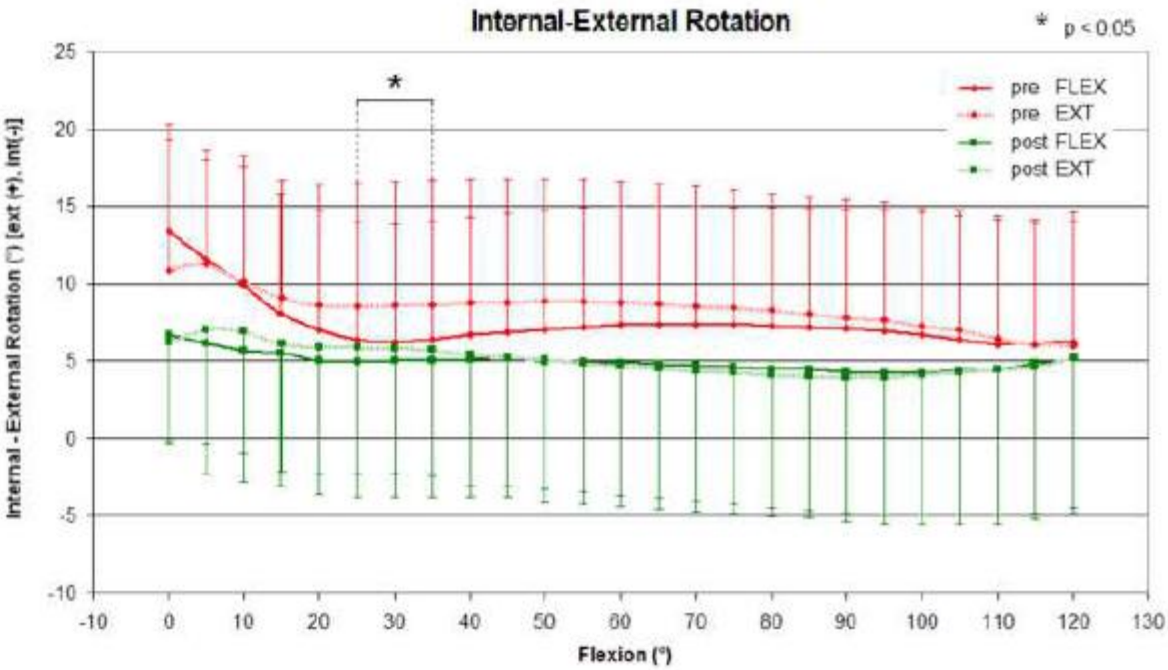


Figure 2. Internal-External (IE) rotation during PROM in pre- and post-implant conditions for flexion and extension paths.

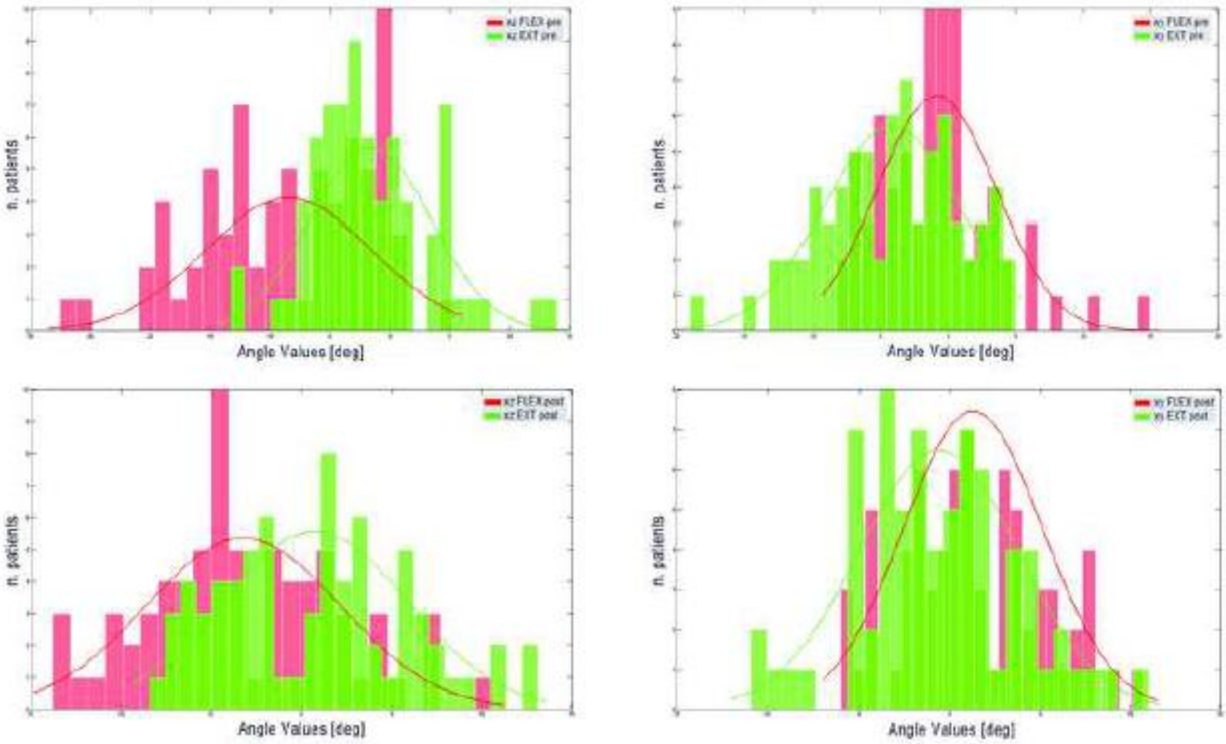


Figure 3. Distribution of pre-operative and post-operative values of FFA-TEA angle in frontal (XZ) and axial (XY) planes.

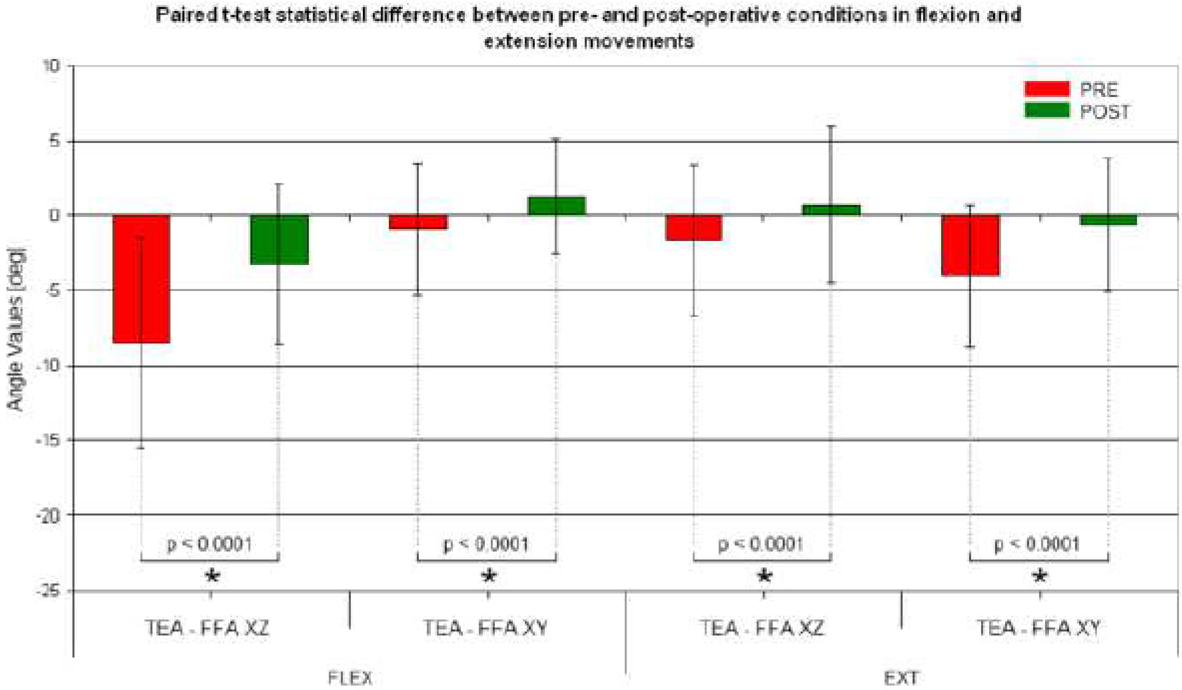
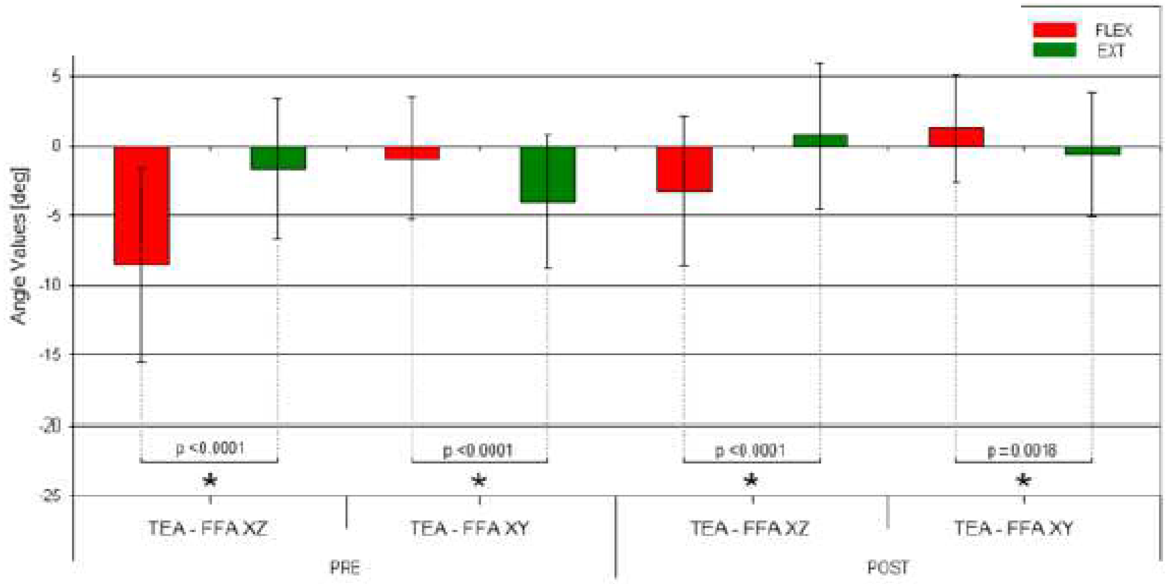


Figure 4. Student t-test statistical difference between flexion and extension movements in pre- and post-operative conditions (XZ (frontal plane): varus -, valgus +; XY (axial plane): internal +, external -).

Figure 5. Paired t-test statistical difference between pre- and post-operative conditions in flexion and extension movements (XZ (frontal plane): varus -, valgus +; XY (axial plane): internal +, external -).



Discussion

The most important finding of the present study was that the estimation of FFA, identified through the FFA-TEA angle, changed in the frontal plane in relation to flexion and extension movements, above all considering pre-operative conditions. Specifically pre-implant FFA, computed during flexion movements, significantly differed from TEA, whereas the FFA-TEA angle resulting from extension movements was closer to zero. Moreover, the orientation of FFA changed significantly after TKA both in flexion and extension, mostly in frontal plane, while the correspondence between

FFA and TEA was generally maintained in axial plane. In this study, the kinematics of the tibio-femoral joint was analysed by means of a navigation system, assessing the functional method used to estimate the FFA in different kinematic conditions (flexion and extension movements) and knee condition (pre- and post-implant). The differences in identifying the FFA compared to an arbitrary anatomical reference (i.e. the TEA) were specifically analysed in both the axial and the frontal plane and also in relation to the osteoarthritic condition and after TKA. The role of the FFA in TKA component positioning has been widely analysed in literature [4, 12, 14, 15, 29, 31], due to its inherently subject- and joint-specific characteristic, which pretends to make the FFA less influenced by the typical variability related to the identification of anatomical landmarks [17, 24]. Several authors assessed FFA usefulness in the rotational alignment of the femoral component, analysing both the axis reliability with respect to defined 181 anatomical landmarks [12, 14,29, 31] and its distance from the TEA, which still remains one of the most studied references for the femoral component positioning in TKA [1, 5, 21, 22, 37]. Furthermore, several authors reported also the correspondence between the FFA and TEA, thus supporting a functional-anatomical relationship [1, 4, 9, 11, 26]. While literature agreed on the fact that the FFA requires further analyses in order to achieve the possibility of being used in the daily clinical practice [12, 15, 16, 29], at present no studies have been focused on analysing the reliability of the procedure related to the performed movements. Most of the reported studies were in fact based on the hypothesis that passive flexion and extension movement were exactly symmetrical, thus giving no importance to the influence of the specific path on the FFA estimation. In particular, some authors decided to analyse only flexion movements [4, 13, 16, 29] defining different ranges of motion. Asano et al. [4], analysed the knee motion from 0° to 90° of flexion and investigated the so-called functional “flexion-extension” axis reaching a correspondence with TEA in axial plane, similar to results of the present study (2.7° ± 2.1°). Eckhoff et al. [16] assessed the FFA by passively flexing the joint from 15° to 115° with a knee simulator for motion analysis, concluding analogously that the FFA and TEA differed approximately of 2.0° in the traditional 2-dimensional planes (axial and frontal). Oussedik et al. [29] estimated the FFA in axial plane, performing a movement from 20° to 80° of flexion and comparing it to the TEA. They specifically reported a difference of 1.6° approximately, thence in agreement with the results obtained in the present work. Other authors estimated the FFA by performing complete flexion-extension cycles (from 0° to 120° and back to 0°), but without analysing the contribution of the two separate kinematic paths. Doro et al. [14] started from the acquisition of flexion-extension movements and assessed the FFA reproducibility and reliability in the axial plane. Siston et al. [31] compared different functional and anatomical alignment axes, including FFA. The angle in axial plane between FFA and the surgical TEA resulted to be 10.5° ± 5.7°. Also Colle et al. [11, 12] 207 performed two different in-vivo studies on the FFA during TKA, analysing the kinematics of tibiofemoral joint acquired with a passive flexion-extension movement (0°-120°-0° knee flexion). Their results were in agreement with those reported in this study, above all for what concerned the frontal plane. The only work which underlined the differences between flexion and extension movement, although focused on the patello-femoral joint, was authored by Amis et al. [2]. The current paper, following that hypothesis, aimed to understand the influence of the path followed by the tibio femoral joint during flexion and extension movements separately. Given more details, in pre-operative conditions the FFA computed in the frontal plane by flexion movements, showed a greater distance from TEA and an higher variability (-8.5° ± 7.0°), while in the axial plane a grater distance derived from the analysis of the extension movements (-4.0° ± 4.7°). These values reduced in post-operative conditions mainly due to the influence of the prosthesis: the FFA-TEA angle was specifically -3.2° ± 5.4° in the frontal plane for flexion movements, and -0.6° ± 4.5° in the axial plane for extension movements. Both pre-operative and post-operative results were in agreement with those reported by Colle et al. [12], but the present study better highlighted the differences during flexion and extension movements that could be due to different factors. First of all, the presence of the screw-home mechanism, that occurs in the first 30° of PROM, as highlighted in Figure 1. In particular, the effects of the first 30° was more evident in the frontal plane during flexion movement, whereas the FFA estimation resulted less stable in the axial plane during extension.

These results could be also due to the differences involuntarily introduced by the surgeon in passively performing flexion or extension movements. In particular, during flexion the articular surfaces were supposed to be in contact, while, it is possible that an abnormal external rotation was

maintained during extension, especially during the first 30° of flexion, due to a temporary loss ofcontact of the articular surfaces and therefore causing the absence of the screw home mechanism in frontal plane and the FFA unusual variation in axial plane. Furthermore, the IE rotation during flexion and extension movements showed a statistically significant difference between 25° and 35° of PROM, thus confirming the importance of this range in the FFA estimation. From the clinical point of view, this study demonstrated that the FFA requires further analyses in order to allow its application to the daily clinical practice. In particular, its estimation in the frontal plane remains crucial. The pre- implant FFA-TEA angle showed in fact a greater value in the frontal plane with respect to axial plane for both flexion and extension movements. This was probably due to the influence of osteoarthritis on altering the proper condyles shape that did not occur in axial plane. In fact, the osteoarthritis mainly affects the distal condyles and less the posterior condyles and the effect of the pathology is biomechanically more evident on the frontal plane, due to the alteration of the physiological limb alignment (varus/valgus. Moreover the osteoarthritis influences the limb deformity not constantly through the flexion arc [27], but it is more evident in the first 30° of flexion, during the screw-home mechanism [11]. Therefore further analyses are required to better understand the relationship of FFA with the osteoarthritis. Moreover, the present work demontrated that the FFA computation was significantly influenced by the different paths of motion, i.e. flexion and extension, suggesting the importance of considering the only flexion movements for FFA estimation during navigated TKA. It is worth to mention that no previous works considered this aspect in passive knee kinematics.

This study presented some limitations. In spite of involving only skilled surgeons in order to minimize the error during the acquisition [21, 31, 32], the registration of anatomical landmarks (used 255 as reference) was intraoperatively performed by manual digitisation thus introducing possible bias.

However at present this procedure could be considered the gold standard for imageless navigation systems [21]. As previously discussed, the flexion and extension movements were performed without control on applied torques, but with the only 258 visual feedback. Finally, the passive joint kinematics was conducted in both pre- and post-implant condition with the capsule maintained vented, thus possibly affecting the kinematics of the joint and letting the control of stability only to the surgeon.

The malpositioning of the femoral component is a critical aspect in TKA that affects both the tibio femoral and the patello-femoral kinematics and that may cause several problems including the early failure of the implant. Several methods, based on both anatomical and kinematic features, have been used to guide the surgeon during the implant placement. Navigation systems in fact have been demonstrated to provide added value giving the possibility of identify functional references. Out of these proposed methodologies, the literature reported that the FFA method is reliable in femoral component positioning, but also that further analyses are required in order to use this functional method during the daily clinical practice. This paper tried to add some knowledge to the current state of the art, aiming to understand the influence of the motion path followed by the knee on the FFA estimation, analysing flexion and extension movements separately. Eventually this work demonstrated the influence of these different movements on the FFA estimation, above all in the frontal plane. This findings are particular important when considering FFA as a possible functional landmark during navigated TKA.

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Roentgen Stereophotogrammetric Analysis: an effective tool to predict implant survival after an all-poly unicompartmental knee replacement. A 10 years follow-up study.

Introduction:

Unicompartmental knee arthroplasty (UKA) is a surgical procedure that has gained an increasing interest over the last 25 years [23]. Suggested advantages of UKA over TKA are faster recovery [17], better range of motion (ROM), kinematics closer to a normal knee [26], reduced blood loss and decreased postoperative pain [7], lower risk of infection, more normal gait and decreased morbidity [3,8,9].Several studies have demonstrated that implant fixation is a key feature for both TKA and UKA and that it strongly affects implant survival [15,18,27]. Loss of implant fixation reduces the clinical and functional results [2,3,4,5,6,13] finally leading to failure for aseptic loosening. New prosthetic designs and new materials are produced to improve fixation quality over time, in order to increase the implant's lifespan, to delay aseptic loosening, and to improve long-term clinical and functional outcome.

Roentgen Stereophotogrammetric Analysis (RSA) represents nowadays an excellent solution for high-accuracy fixation measurement of UKAs, with a degree of accuracy significantly higher than other techniques [20,24]. Several RSA studies [10,18,19,20] demonstrated the efficacy of this technique to describe, in vivo, fixation of the implant over time. Different Authors [15,18] also concluded that early micromotion between prosthesis and bone predicts aseptic loosening [10,18] with a power of approximately 85% [15].

Despite this, to date, to the best of our knowledge, no previous study has investigated long-term micromotions of a UKA using RSA. For this reason, the main purpose of the present study is to determine long-term implant fixation of 37 UKAs with all-poly tibial component using RSA at more than 10-years follow-up. The secondary purpose was to investigate whether the progressive loss of implant's fixation correlates with a reduction of KSS score [22].

Materials and Methods:

Thirty-seven non-consecutive patients (12 males and 25 females) with primary knee osteoarthritis received a UKA with an all-poly tibial component (Howmedica Duracon UNI prosthesis, Limerick,
Ireland) between January 1995 and April 2003 in the Authors' institution. Ethical Committee approval was obtained and all patients gave their informed consent prior to their inclusion in the present study.

Indications for UKA were: age over 60 years, pain and joint space narrowing limited to the involved compartment, mild joint deformity (up to stage III according to the Ahlbäck classification[1]) and normal anterior cruciate ligament. Mean age at surgery was 71 (range 70-76 dev.st 6.63). Relevant demographics are resumed on Table 1. Pre-operative KSS score was recorded for all patients. Post-operative KSS score was also recorded at 3, 6, and 12 months and yearly thereafter.

RSA evaluation was performed on day 2 after surgery and it was repeated at 3, 6, and 12 months and yearly thereafter.

Twenty-two patients were lost at last follow-up: 5 patients died; 6 patients were unable to participate to follow-up because of severe comorbidities and 11 patients were not available. The remaining 15 patients (5 males and 10 females) with a mean age of 81 (range 74-87 dev.st 4.70) were evaluated using RSA with a mean follow-up of 10 years (range 4-15 dev.st 3.38); 4 of them were revised (respectively at 4,4,7,10 years) with a TKA because of persisting residual pain respectively at 4, 4, 7 and 10 years of follow-up.
RSA results were not known to the surgeon who performed revisions and they did not influence the indications for surgery.

Tab. 1 Patient's Demographics	
Total number of patients	37
Patients lost at FU	22
Patients examinated	15
Males and Females	5 males , 10 females
Number of revisions	4
Age at surgery (years)	71 (range 70-76 dev.st. 6.63)
Age at last observation point (years)	81 (range 74-87 dev.st. 4.70)
Follow up duration (years)	10 (range 4-15 dev.st. 3.38)

RSA technique

RSA, as described by Selvik [25], was used to study implant micro-motion and stability. The insertion of radiopaque markers in each object of interest provides easily identifiable landmarks on the radiographs. Two x-ray tubes were placed perpendicularly to each other at a focus-to-film distance of 100 cm, and frontal and lateral projections of the patient's knee, inside a marker-equipped Plexiglas calibration cage, were taken simultaneously. The 2-dimensional film coordinates of all the markers were measured by digitizing the 2 radiographs. The 2-dimensional–to–3-dimensional transformation of the marker coordinates was performed using a specific computer program (Model Based RSA, Medis Special, Leiden, The Netherlands). The markers implanted in the tibia and those implanted in the polyethylene were modeled as distinct rigid bodies, and their relative motion was calculated according to rigid body kinematics. A parameter called mean error of rigid body fitting (ME) measuring changes in marker configuration geometry over time was calculated for each rigid body. Examinations showing unstable tibial rigid bodies (ie, with >200 µm ME) were not considered in this investigation.
The program provide RSA results expressed as segment motion (ie, translation and rotation of 1segment in relation to the reference segment) and point motion (ie, translation of each individual marker). The results are presented as rotations and translations around and along the 3 cardinal axes, which coincides with the main anatomic axes of the body, whereas the total motion of the marker that undergoes the greatest displacement is called maximum total point motion (MTPM).
Soon after surgery, before the patient was allowed to put any weight on the operated leg, a reference RSA examination was performed (post-operative reference (POr)). Implant displacement was studied using MTPM of the polyethylene tibial insert with respect to the tibial

rigid body at *each* follow-up examination and comparing this value with the corresponding data at the POr examination.

Statistical analysis and data

Three types of data were used:
1) clinical KSS score;
2) functional KSS score;
3) MTPM (mm).
Comparisons between clinical scores' values and radiographic data (MTPM) at the different time intervals were performed using Pearson correlation test. Level of significance was set at 95% ($p = 0.05$).

Results:

A moderate increase of MTPM values in the period from 6 months to 1 year post-operatively was found respect to POr. In all patients , displacement was less than 2 mm during the first 6 months; after this period we have noticed two different trends:

1. in 11 of 15 patients, values of displacement became stable under 2mm (Fig1, non-revised implants) (mean 0.99 mm st.dev.0.47) and remained under this cut-off value until the last observation point; implant subsidence between two consecutive observation points was always <0.37 mm; maximum subsidence between two consecutive evaluations was always observed between the two last observation points and it was higher in patients with more than 8 years of follow-up . KSS scores of these patients were always Good or Excellent at all postoperative observation points (Fig. 4,5).
2. A marked and continuous increasing of MPTM values over 2mm was found after 6 months in 2 cases, after 1year in 1 case and after 4 years in 1 case (Fig1, revised implants). Thi trend towards increasing MTPM went on until the end of follow-up. Implants subsidence between two consecutive observation points was >0.49 mm in all cases. The same patients showed fair or poor KSS outcomes at all postoperative observation points (Fig. 4,5). All these patients were revised for persisting residual pain respectively at 4, 4, 7, 10 years.

   At the end of the first year of follow up, only 1 of these 4 patients showed displacement values under 2mm until year 4 of follow up, however showing MPTM values >2mm from year 4 to the end of FU (Fig 1, revised implants).

   A linear and inverse significant correlation was found between clinical KSS scores and MPTM values (R^2= 0.5959, $p<0.001$) (Fig2). A linear and inverse correlation was also found between functional KSS scores and MTPM values (R^2= 0.5743, $p<0.001$) (Fig3).

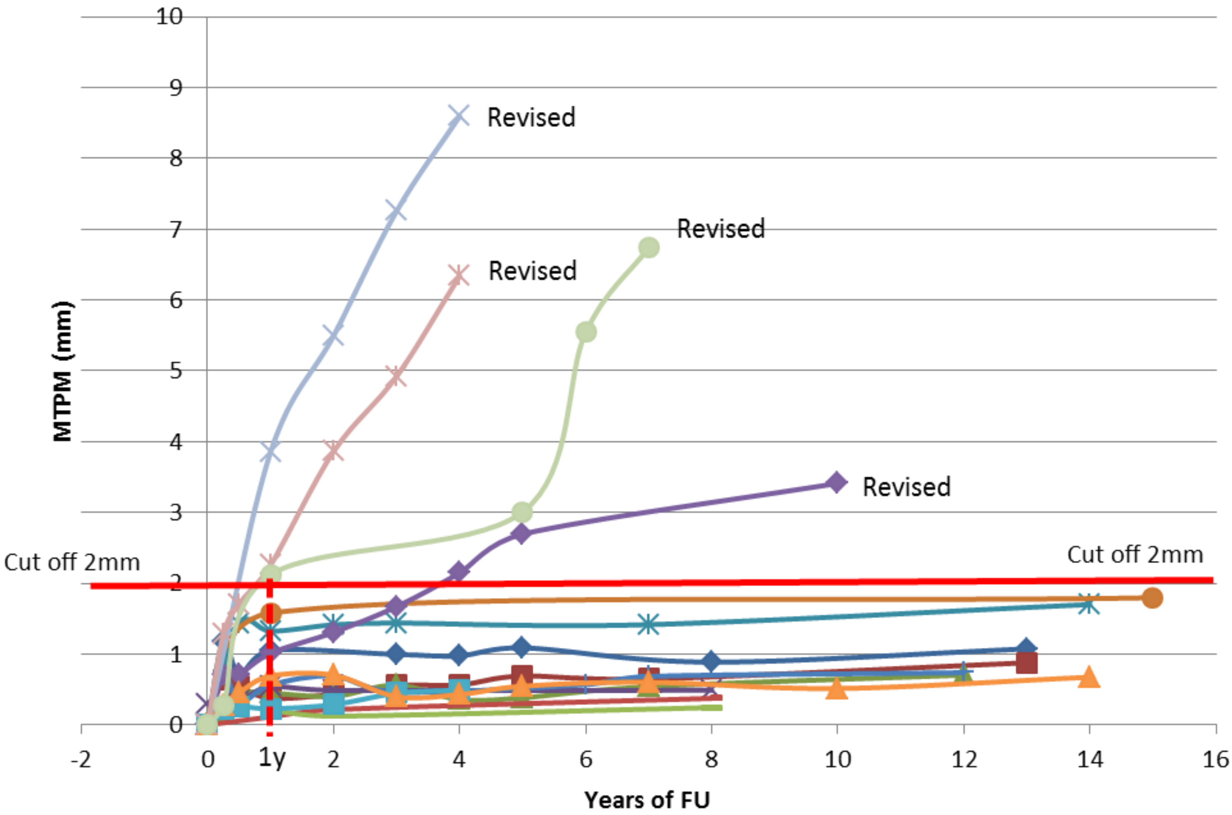

Fig.1: MTPM (mm) trend over time

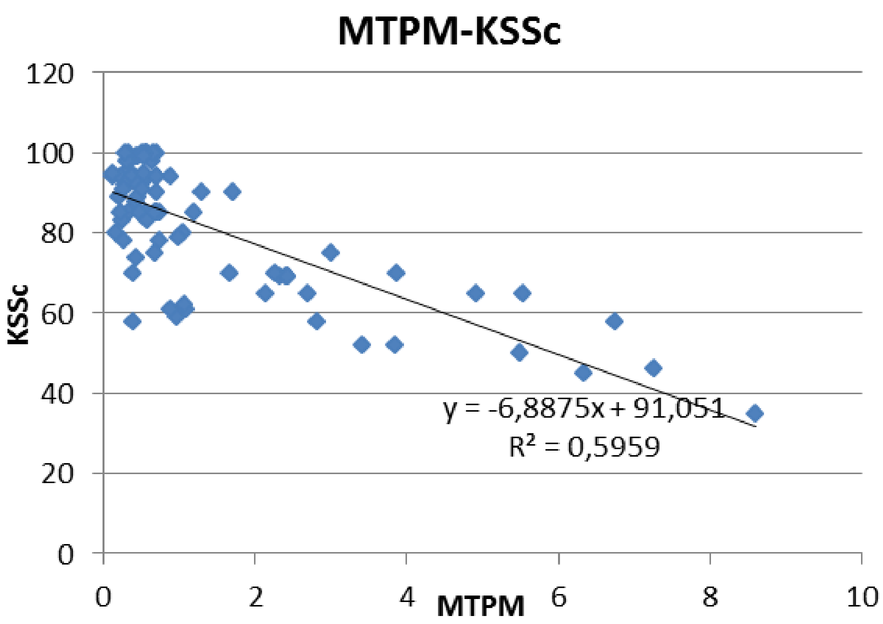

Fig.2: Correlation between MTPM(mm) and clinical KSS scores.

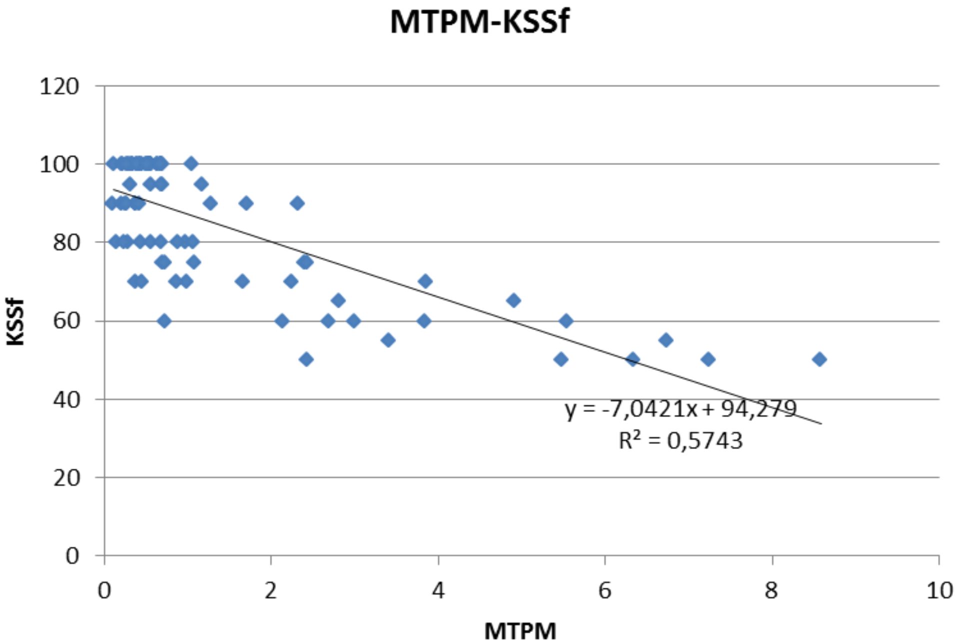

Fig.3: Correlation between MTPM(mm) and functional KSS scores.

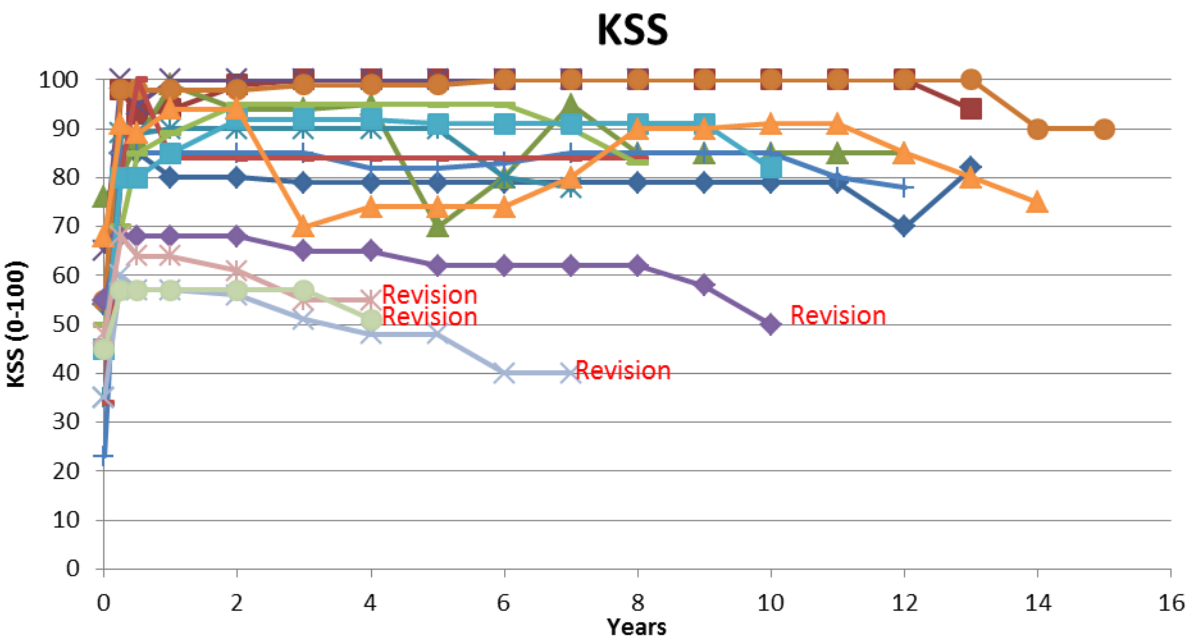

Fig.4: KSS results over time.

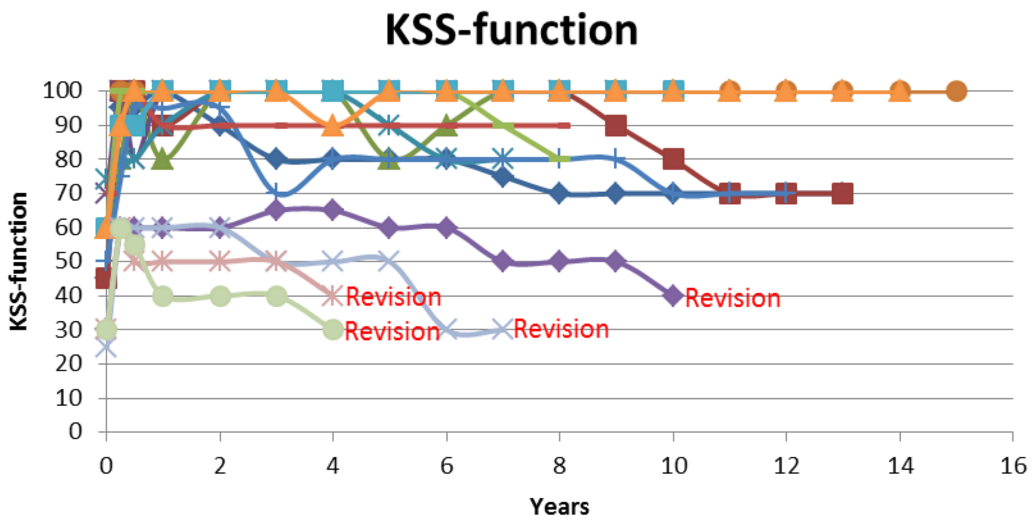

Fig.5: KSS-function results over time.

Discussion:

The main purpose of this study was to determine long-term implant fixation of 37 UKAs with all-poly tibial component using RSA at more than 10-years follow-up. The secondary purpose was to investigate whether the progressive loss of implant's fixation correlates with a reduction of KSS score. To the best of our knowledge, very few RSA fixation studies concern with UKA and all of them investigate implant fixation with short or mid-term follow-up [11,12]; conversely, different studies dealing with total knee replacement and with short, mid and long term follow-up are available from literature [13,15,18,19,20].

As demonstrated by short- and mid-term RSA studies [11,12,13,15], the natural history of an implant's micromotion begins immediately after surgical treatment, with a temporary increase of MTPM values with a duration of about 6months-1year [15,18]. This process affects all implants and is probably due to bone remodeling [18]. In our study implant displacement values were always less than 2mm for the first 6months or at most 1 year of follow-up. Similar results are described in literature by Linstrand et al. on UKA [12] and by Ryd et al. on TKA [18,19,20]. Revised patient have shown in this early phase of the study a greater tendency toward mobilization, reaching displacement values >2mm before year 1 of follow up in 2/4 cases. After this period it is possible to observe two different displacement patterns:

1.the implant reaches and maintain a state of stability;

2.the implant continues to migrate;

Mid and long-term studies on TKA confirmed these data [18] demonstrating also that the majority of the prosthesis that continue to migrate, have a high tendency to evolve towards revision for aseptic loosening [15,18].

On the basis of these considerations, has been calculated a predictive power of RSA technique for implant's fixation , of approximately 85% [15].

In the present study, 11 of 15 implants showed a displacement curve similar to the first displacement pattern, with a state of stability maintained until last observation point, at a mean 10 year of follow-up; these patients all showed good or excellent KSS score results at all observation points, while they didn't show signs of aseptic loosening of the implant on radiographs.

Similar data were found by Ryd et al. [18] for total knee replacement, while to the best of our knowledge, no paper has ever investigated UKA fixation status in a long term FU.
In the present study, all patients with a stable implant and with stable clinical conditions showed a progressive and slow increase of MTPM values, especially for those patients with more than 8 years of follow up. It is the Authors' opinion that this condition is due to an initial process of late loss of fixation of the implants, associated to a late aseptic loosening that will markedly affect the implants in 5 years or more. Future studies with longer follow-up will confirm or deny this trend.
Four of 15 implants showed a displacement curve similar to the second displacement pattern, with MTPM>>2mm after 6months in 2 cases, after 1 year in 1 case and after 4 years of follow up in 1 case. Moreover, in the same patients, it was noticed an important worsening of KSS scores after 6 months post-treatment in all cases. All these implant were revised after a period between 4 and 10 years confirming RSA prediction.
As described previously, in 1 implant of the 4 revised, we have observed a MTPM pattern with displacement values under 2mm until year 4 of follow up; this late cut-off exceeding could be explained considering the late date of revision of the implant: the revision was performed after year 10 of follow up (late revision), while other implants were revised 3 or more years before (mid-term or early revisions).
In the present study, considering by hypothesis a cut off of 2mm, (chosen according to literature results [11,12,15,18]), RSA prediction at 1year was respected in 14 of 15 cases (1 implant of the 4 revised showed MTPM values <2mm at 1 year) confirming therefore a predictive power at 1 year of 93.3%.
The second purpose of this study was to find a correlation between clinical/functional outcomes of the patients and radiographic findings obtained with RSA technique. A linear and inverse correlation with statistical significance was found between clinical KSS scores and MPTM values (R^2= 0.5959, p<0.001) and between functional KSS scores and MTPM values (R^2= 0.5743, p<0.001) confirming therefore our hypothesis.
The present study has several limitations. First, the small numbers of the patients could have reduced the statistical power of data analysis. Secondly, the high drop-out rate of the present study (mainly due to the high average age of the patients) coud have altered the survival rate of the implants, however the analysis of the survival rate is not the subject of the present paper. Third, non-consecutive patients were treated by two different surgeons over a long time interval. Fourth, no comparison between different prosthetic designs was performed. Fifth, BMI, physical activity level of revised and non-revised patients and other causes of revision were not investigated; however the study of the failure mechanisms was not a purpose of the present paper.

Conclusions:

Considering the previously described MTPM trends and considering the relation existing between MTPM values and both clinical and functional KSS scores, we can conclude that also in a long term follow up evaluation, RSA is an effective tool to predict functional results after an all-poly UKA. Moreover no adverse effect has been reported with use of tantalum markers. Further investigation will demonstrate if the increasing of MTPM values at more than 8 years of follow up can be used to predict late failures of the implants for aseptic loosening and to determine the lifespan of the prosthesis.

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