International Journal of Orthopaedics Sciences 2022; 8(2): 124-131

International Journal of Orthopaedics Sciences

E-ISSN: 2395-1958
P-ISSN: 2706-6630
IJOS 2022; 8(2): 124-131

www.orthopaper.com
Received: 25-02-2022
Accepted: 27-03-2022

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Effect of rotational malalignment of components on functional outcome of total knee arthroplasty: A prospective observational study

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DOI: https://doi.org/10.22271/ortho.2022.v8.i2b.3125

Abstract
Background: Correction of coronal alignment alone may not translate into optimum functional outcome after total knee arthroplasty. Painful knees and patellofemoral complications are quite common after total knee arthroplasty, and rotational malalignment of the prosthetic components may be responsible.
Objectives: We conducted a prospective observational study to compare functional outcomes following total knee arthroplasty among subjects with and without rotational malalignment.
Methods: We studied 396 patients (contributing 709 knees with Kellgren-Lawrence grade 4 osteoarthritis) undergoing total knee arthroplasty in a tertiary care hospital setting, with 2-3 years of follow-up. Postoperative axial CT scans were obtained to estimate the rotational alignment of femoral and tibial components. External and internal rotation of components was measured with software to estimate combined external rotation, combined internal rotation, or component mismatch, based on which knees were grouped into two cohorts: having rotational malalignment or with normal alignment. Functional outcome was assessed by Knee Society Score, Oxford Knee Score, Knee Society Pain Score, Lower Extremity Functional Scale, and Public Health Questionnaire-9.
Results: Normal alignment (combined external rotation < 10 degrees) was observed in 475 knees, while the rest of 234 knees had rotational malalignment in the form of combined external rotation of 10 degree or above, combined internal rotation or component mismatch. A significant difference in outcome scores was found between these two cohorts at the first follow-up itself. Knee Society Pain Score clearly indicated painful knees in the rotational malalignment cohort. Poorer improvement in outcome scores occurred in this cohort, throughout the duration of follow-up.
Conclusions: Rotational malalignment of components is almost invariably associated with the poorer outcome of total knee arthroplasty; manifested by anterior knee pain or incomplete functional recovery, compared to the knees with normal alignment.

Keywords: Osteoarthritis, total knee arthroplasty, rotational malalignment, knee pain, knee society score, lower extremity functional scale

Introduction

Osteoarthritis and of the knee can be a severely crippling joint disease with pain, stiffness, deformities and disability. Total knee arthroplasty (TKA) can provide a stable painless knee in such patients restoring quality of life. However, only coronal alignment (Hip-Knee-Angle [HKA]) correction may not always provide desired functional outcome following TKA. The longevity of the knee prosthesis in TKA depends on the correct alignment (frontal, sagittal and axial alignments) of the prosthetic components, soft tissue/ligament balancing and restoration of the mechanical axis of the lower limb [1].

Restoration of a neutral mechanical axis is necessary for the successful outcome of TKA as coronal malalignment, specially enhanced varus, is associated with increased strain, higher failure rates, and in most cases poorer outcome of TKA [2]. A common hypothesis is that a postoperative mechanical axis / HKA angle of 0 ± 3° would result in a better long-term outcome of TKA.

Incidence of knee pain with patello-femoral symptoms like patellar pain and tilting with wide Q angle, due to inadequate extensor mechanism functioning after TKA, even after coronal alignment correction, has been observed.

Positioning of implants in the axial plane during TKA is called rotational alignment [3] and internal rotational malalignment of components has been implicated as a cause of knee pain after TKA [4, 5, 6]. Malrotation of components after TKA may cause patello-femoral complications, as femoral and tibial component positioning have effects on patellar tracking following TKA [7, 8]. This prospective observational study was conducted to assess the effect of rotational malalignment (RM) of prosthetic components after TKA for the assessment of long-term functional outcomes.

Materials and Methods

The study was a collaborative effort of three centers although patient recruitment, operative intervention and follow-up were carried out at a single tertiary care hospital from October 2015 to July 2021. Patient recruitment continued for the first 4 years [October, 2019], followed by follow-up of 3 years & 2 years respectively; thus extending the total study period to 5&1/2 years. The respective institutional ethics committees approved the study protocol. All patients included in the study provided written informed consent after being appraised of the study purpose, methodology, potential risks and benefits, in a language which they could comprehend. They were also apprised of their right to opt out of the study without penalties or loss of privileges. All radiological investigations were done in the same hospital with due consent.

Patients recruited were of either sex, age 45-85 years, with severe osteoarthritic varus or valgus knees (Kellgren-Lawrence Grade 4 osteoarthritic changes), with or without fixed flexion deformity. Those with rheumatoid arthritis, Charcot's joints, severe kyphoscoliosis, or critical comorbidities likely to interfere with scheduled follow-up were excluded. All patients included in the study attended the Orthopaedics OPD, with knee pain, joint deformities, antalgic waddling gait and often with walking aids.

TKA was done under spinal anesthesia with a femoral nerve block. All operations were carried out by the same surgical team, using a midline medial para-patellar approach and ligament balancing technique with measured resection. Medial release for varus knees (682 in number), lateral release for valgus knees (27 in number), posterior capsular release for fixed flexion deformity were done, together with patellar resurfacing. Surgery was performed using a standard implant (DePuy, PFC Sigma, Johnson & Johnson), which was posterior stabilized, cemented, cruciate sacrificing and fixed bearing type. Patients were usually discharged after 5 days for unilateral TKA, and 10 days for bilateral TKA and axial CT Scans of components were done just before discharge. For study purpose, they were followed up post-operatively at 6 months, 1 year, 2 years and 3 years, but 3-year follow-up was not completed for all subjects.

The rotational alignment of the femoral and tibial components after TKA was measured on axial CT scans (SIEMENS Somatom SENSATION 64 Slice scanner) using angle tools software, with the patient lying supine and knee fully extended. The gold standard for such measurements is Berger's CT Protocol l [9] which was followed. The process of measurement of rotational alignment of femoral condyles was as follows: [Figures 1A, 1B] a) The surgical trans-epicondylar axis (STEA) was drawn by joining the lateral epicondylar prominence with the midpoint of the medial sulcus of the medial epicondyle. The anatomical TEA was not considered here due to errors of measurement; b) the line joining the posterior part of the prosthetic condyles of the femur represents the posterior condylar line (PCL); c) the angle formed by these two lines is called the posterior condylar angle. The STEA is generally taken as the flexion-extension axis of the knee. The process of measurement of the tibial condyles by angle tools was as follows: [Figures 1C, 1D] a) The alar line (AL) is a transverse axis drawn joining the midpoints of the ala of the polytibia; b) the PCL of the tibia is drawn joining the posterior part of the condyles of the prosthetic tibia; c) The angle between these two lines is called the posterior condylar angle of the tibia. All measurements were taken uniformly as per protocol on the 10th post-operative day for bilateral TKA knees and on the 5th post-operative day for unilateral TKA knees. Patients were not sedated for such CT scans, except for substantially apprehensive patients with very painful TKA knees, who were given mild midazolam sedation intramuscularly. The axial CT scans used to measure the rotational alignment of the prosthetic knee after TKA, were done using minimal dose radiation [6-8 mGray/m^2]; the scan time being 12-14 seconds.

The combined component rotation for each patient was obtained by adding the femoral component rotational angle with that of the tibial component; in these cases, external rotation of each component was taken as positive (+), and internal rotation of components was taken as negative (–).[9] The combined external and internal rotation of components[CER & CIR], has been calculated according to this principle, whereas component mismatch (CM) was calculated by subtracting the femoral component rotation from the tibial component rotation [9]. Figure 2 provides examples of combined component rotation and CM.

Functional and quality of life outcomes were assessed through Knee Society Score (KSS), Knee Society Pain Score (KSS-P), Oxford Knee Score (OKS), Lower Extremity Functional Scale (LEFS), and Public Health Questionnaire-9 (PHQ-9). The scoring assessments were done at baseline and at all scheduled follow-up visits by a single rater with the use of assistants when required.

The KSS is a 200-point scoring system, involving 100 points for a function score [KS-FS] and 100 points for a knee score [KS-KS] [10]. The original version of OKS has been used here [11], comprising 12 questions, with scoring from 1 to 5, making a total score of 60; here 12 was taken as the best outcome and 60 as the worst. The pain was assessed by KSS-P, with 50 points; here, 0 indicating severe / constant pain, while 50 indicated a painless joint. LEFS is a 20-item scale related to knee function [12] with 4 points each; a painful knee needing TKA would score 9-10, whereas a painless TKA knee would score close to 80. Most patients needing TKA suffer latent depression due to chronic knee pain, fixed flexion deformities and walking disabilities, which are detrimental to a normal lifestyle. PHQ-9 is a multipurpose instrument for screening, diagnosing and monitoring the severity of depression, that incorporates American Psychiatric Association Diagnostic and Statistical Manual 4th edition (DSM-IV) depression diagnostic criteria with other major depressive symptoms into a brief self-reported tool reflecting overall satisfaction with life [13]. Quality of life before and after TKA was assessed by the PHQ-9 Score, which also reflects patients' compliance to physiotherapy for recovery after TKA.

Sampling in the present study was purposive in nature. All patients attending the TKA clinic in the orthopedic outpatient were recruited if they consented to be in the study. The recruitment period extended over 3 years, while the postoperative follow-up was for 2-3 years. The sample size for the study was calculated based on the proportion of operated knees likely to achieve a satisfactory outcome with respect to all anatomical and functional parameters evaluated. Conservatively assuming this to be 50% and an indefinitely large target population, the sample size was estimated to be 600 knees, keeping a 4% margin of error and 95% confidence level. Allowing a 15% margin for dropouts, the recruitment target was 706 knees. Raosoft sample size calculator (http://www.raosoft.com/samplesize.html) was used for sample size estimation.

Statistical analysis was by Statistica version 8 [Tulsa, Oklahoma: StatSoft Inc., 2007] and MedCalc version 15.8 [Mariakerke, Belgium: MedCalc Software bvba; 2015] software. Variables have been summarized as mean and standard deviation (SD), when normally distributed, or as median and interquartile range (IQR), when skewed; 95% confidence interval (CI) values have been presented where relevant. Normality of data was assessed by Kolmogorov-Smirnov goodness-of-fit test. Numerical variables were compared between groups by Student's independent samples t test. Rotational alignment parameters and functional outcome variables were skewed, and hence non-parametric tests were used with median & inter-quartile ranges. Comparison between non- RM and RM cohorts was done by Mann-Whitney-U test; within group, comparison was done by Wilcoxon matched pairs signed rank test. Comparison over time within a group was done by Friedman's analysis of variance (ANOVA). Cut-off for statistical significance was taken as $p<0.05$.

Results

The present study included 420 patients contributing to 737 operated knees. However, 16 patients were lost to follow-up; thereby allowing evaluation of 709 TKA knees from 396 patients, of which 83 were unilateral TKA and 626 knees were bilateral TKA (from 313 patients) cases. Follow-up data were available for 3 years from 404 knees and for 2 years for the rest.

Axial CT scans done post-operatively to estimate the rotational alignment of prosthetic components of TKA showed femoral component external rotation (ER) for 539 knees [76.02%], femoral component internal rotation (IR) for 170 knees [23.98%], tibial component ER for 514 knees [72.50%], and tibial component IR for 195 knees [27.50%]. Of the 709 knees, rotational malalignment (RM) of components was found in 234 cases (33.00%; 95% CI 29.64 to 36.54%)-158 cases were followed up for 3 years and the rest 76 knees for 2 years. The RM cohort comprised combined external rotation (CER) of 10 degrees or more in 17 out of 709 knees (2.40%), combined internal rotation (CIR) of any degree in 147 out of 709 knees (20.73%), component mismatch (CM) in 70 out of 709 knees (9.87%). Among the 70 CM cases, 23 knees showed femoral component IR with tibial component ER; whereas 47 knees showed tibial component IR with femoral component ER; which indicates a higher frequency of IR of a tibial component than the femoral component in the rotational malalignment cohort. No rotational malalignment was found in 475 (67%) cases, of which 246 cases were followed up for 3 years, and the rest 229 knees for 2 years-these represented the non-RM cohort.

Comparisons between age, weight, height, and BMI between RM and Non-RM cohorts are depicted in Table 1. There was a modest but significant difference in BMI between the two groups ($p<0.05$), which indicates that more obese and overweight patients had knees with rotational malalignment post-operatively.

A comparison of functional outcome scores (KSS, KSS-P, OKS, LEFS, PHQ-9) over time in the two cohorts is depicted in Table 2. The KSS, which is a composite score reflecting pain, alignment, mobility and stability, was comparable between the groups at baseline and showed a steady improvement over time in the non-RM cohort. Improvement also occurred in the RM cohort, but at a slower pace, as reflected in the statistically significant differences in median score in favor of the non-RM cohort at all postoperative time points ($p<0.001$). The differences between the RM and Non-RM cohorts were observed throughout the duration of follow-up.

The KSS-pain score reached the optimal level in the non-RM cohort with 2-3 years follow-up; but not in the RM cohort, which indicates that painful TKA (anterior knee pain with patellofemoral dysfunction) is found in the knees with rotational mal-alignment (CM, CIR, CER of 10 degrees or above).

OKS, which is a patient-reported outcome measure specifically intended to assess function and pain after total knee replacement surgery, also showed a steady decline (improvement) in both cohorts, but at a faster pace in the non-RM knees, leading to statistically significant differences with the RM cohort ($p<0.001$) over time.

The LEFS is also a patient-reported outcome measure for the assessment of lower extremity function in adults. Though it is not specific for knee osteoarthritis or TKA, it was used in these situations to provide a summary assessment integrating a range of day-to-day activity involving lower extremity mobility. Consistent with the other functional outcome measures used in this study, it also showed faster improvement in the non-RM cohort, compared to the RM cohort, with statistically significant differences between the 2 cohorts ($p<0.001$) at various time points.

Finally, the improvements in PHQ-9 score was also better in the non-RM cohort and improved sharply after surgery, reflecting significant improvement in quality of life, in contrast to subjects in the RM cohort. The essence is thus functional outcome scores were better achieved in the non-RM cohort compared to the RM cohort.

Table 3 compares the proportions in the non-RM and RM cohorts that achieved an optimum functional outcome in terms of the various scores, as indicated, at successive follow-up visits. Chi-square for trend analysis for proportion clearly indicated that functional recovery was better in the non-RM cohort. However, it may be noted that quality of life improved for more than 97% of subjects in both the groups and there was no difference in proportion between the groups in this regard. For KSS-P, $p<0.05$ was achieved in the non-RM cohort, which indicates painless knees after TKA. But this was not so in knees with rotational mal-alignment after TKA, as anterior knee pain was observed on long-term follow-up.

Overall, the results clearly indicate that CER of less than < 10 degrees of femoro-tibial components was associated with painless TKA and desired functional outcomes. Any kind of rotational malalignment in the form of CER of 10 degrees or above, CIR or CM is associated with painful TKA and less satisfactory functional recovery over time.

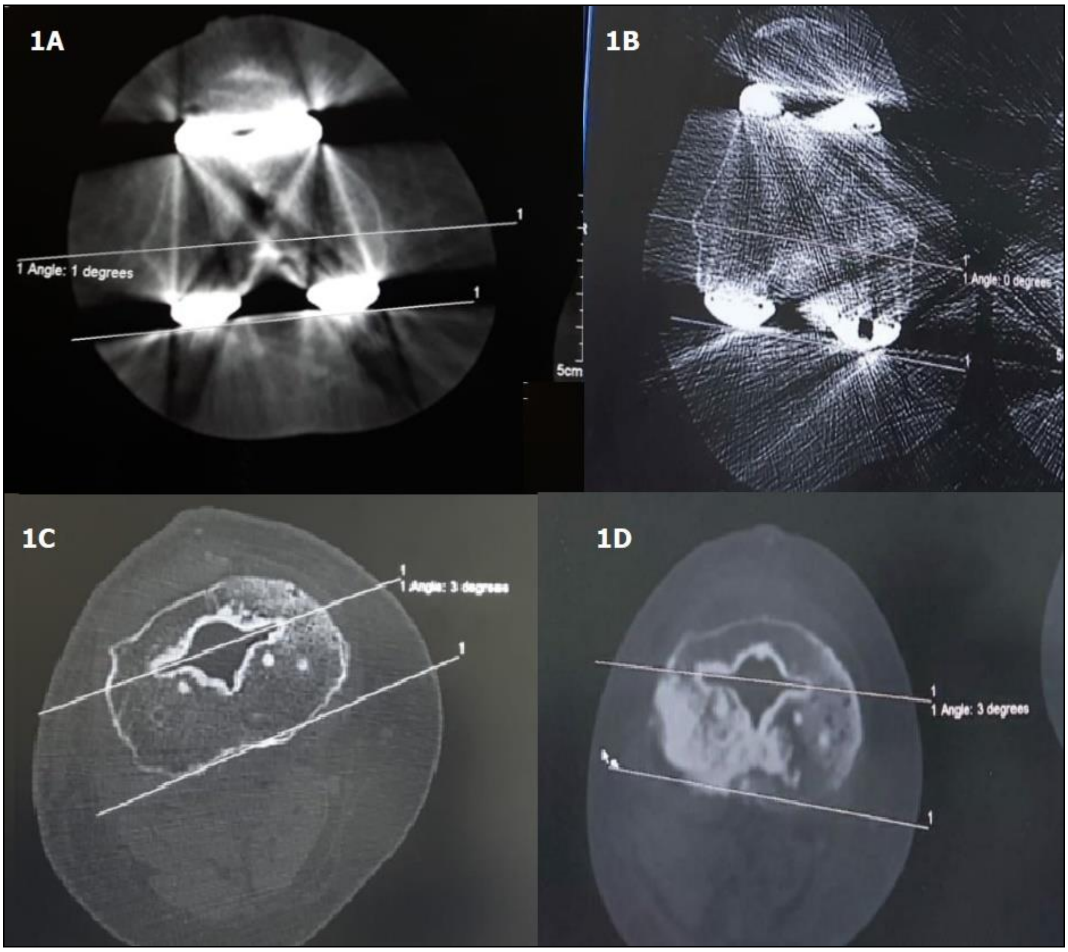

Fig 1: Measurement of rotational alignment of the femoral and tibial components by axial computed tomography following total knee arthroplasty: A. Femoral condylar external rotation (ER), Right; B. Femoral condylar internal rotation (IR), Left; C. Tibial condylar ER, Right; and D. Tibial condylar IR, Right. The lines are explained in the text.

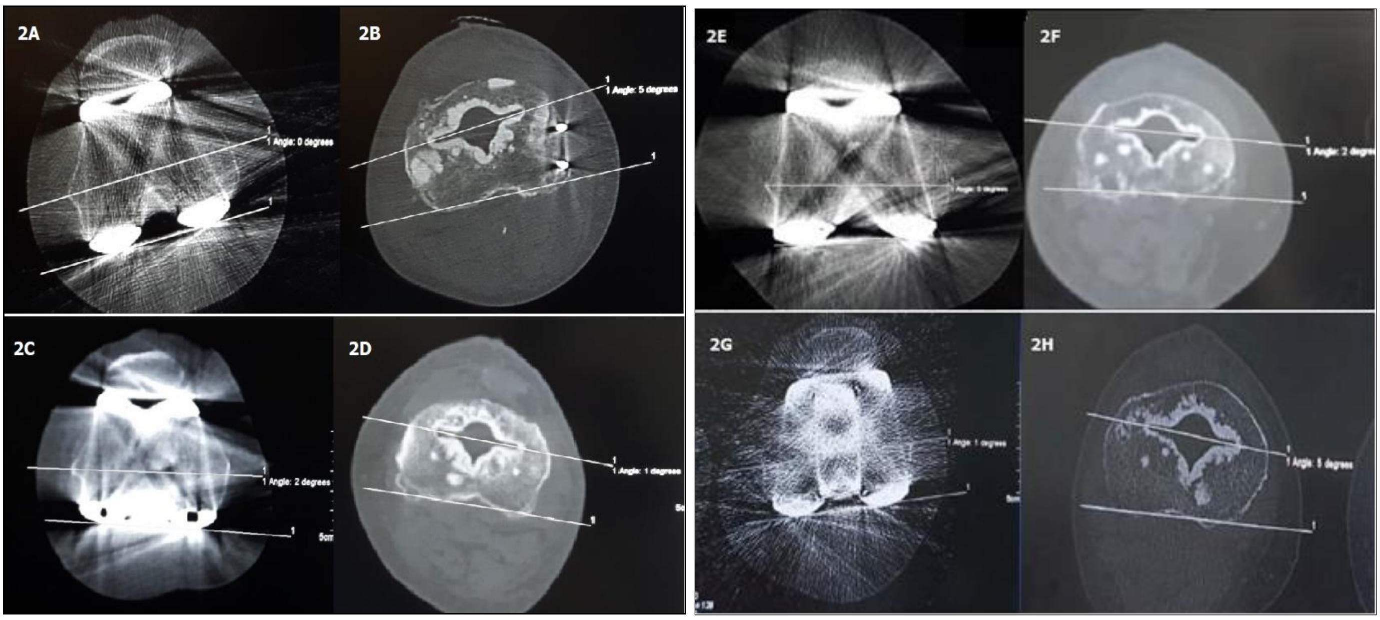

Fig 2: Axial computerized tomography scans depicting rotational malalignment and component mismatch after total knee arthroplasty: A. Combined external rotation (CER) of the femur, right; B. CER of the tibia, right; C. Combined internal rotation (CIR) of the femur, right; D. CIR of the tibia, right; E. Component mismatch: Femoral condylar external rotation (ER) with tibial condylar internal rotation (IR), right; F. Component mismatch with femoral condylar ER, right; G. Component mismatch: Femoral condylar IR with tibial condylar ER, left; and H. Component mismatch, with femoral condylar IR, left.

Table 1: Age and baseline anthropometry comparison between rotational malalignment (RM) and no rotational malalignment (non-RM) cohorts

Parameter	Non-RM cohort (n = 475 knees)	RM cohort (n = 234 knees)	*p* value
Age (years)			
Range	46-83	47-80	0.092
Mean (SD)	65.6 (6.79)	64.7 (6.55)	
Weight (kg)			
Range	41.3-114.1	41.3-106.0	0.026
Mean (SD)	68.5 (11.65)	70.6 (11.39)	
Height (m)			
Range	1.35-1.80	1.35-1.70	0.346
Mean (SD)	1.53 (0.08)	1.54 (0.08)	
Body mass index (kg/m^2)			
Range	16.1-44.4	16.1-44.0	0.022
Mean (SD)	29.06 (4.83)	29.93 (4.65)	

- Abbreviations: RM = rotational malalignment; SD = standard deviation; kg = kilogram; m = meter
- p value in the last column is from intergroup comparison by Student's independent samples t test.

Table 2: Changes in functional outcome scores over the 3-year study period compared between non-RM and RM cohorts, in knees after total knee arthroplasty [TKA]

Functional outcome	Non-RM cohort	RM cohort	*p* value
Knee Society Score			
Baseline	70.00 (60.00 to 80.00)	68.00 (57.00 to 79.00)	0.286
6 months	110.00 (100.00 to 120.00)	100.00 (90.00 to 100.00)	< 0.001
1 year	130.00 (120.00 to 150.00)	110.00 (110.00 to 120.00)	< 0.001
2 years	150.00 (130.00 to 170.00)	120.00 (120.00 to 130.00)	< 0.001
Study end (3 years)	160.00 (130.00 to 180.00)	130.00 (120.00 to 130.00)	< 0.001
Within group *p* value	< 0.001	< 0.001	
Change at 6 months	42.00 (31.00 to 55.00)	28.00 (22.00 to 40.00)	< 0.001
Change at 1 year	62.00 (48.00 to 76.00)	42.00 (34.00 to 54.00)	< 0.001
Change at 2 years	80.00 (62.00 to 95.00)	54.00 (45.00 to 68.00)	< 0.001
Change at study end	94.00 (73.00 to 107.00)	60.00 (52.00 to 72.50)	< 0.001
Knee Society Pain Score			
Baseline	10.00 (10.00 to 10.00)	10.00 (10.00 to 10.00)	0.927
6 months	45.00 (45.00 to 50.00)	30.00 (30.00 to 30.00)	< 0.001
1 year	45.00 (45.00 to 50.00)	30.00 (30.00 to 50.00)	< 0.001
2 years	45.00 (45.00 to 50.00)	30.00 (30.00 to 50.00)	< 0.001
Study end (3 years)	45.00 (45.00 to 50.00)	30.00 (30.00 to 50.00)	< 0.001
Within group *p* value	< 0.001	< 0.001	
Change at 6 months	35.00 (35.00 to 40.00)	20.00 (20.00 to 20.00)	< 0.001
Change at 1 year	35.00 (35.00 to 40.00)	20.00 (20.00 to 20.00)	< 0.001
Change at 2 years	35.00 (35.00 to 40.00)	20.00 (20.00 to 20.00)	< 0.001
Change at study end	35.00 (35.00 to 40.00)	20.00 (20.00 to 20.00)	< 0.001
Oxford Knee Score			
Baseline	55.00 (53.00 to 56.00)	54.00 (53.00 to 56.00)	0.284
6 months	26.00 (24.00 to 28.00)	28.00 (26.00 to 28.00)	< 0.001
1 year	22.00 (22.00 to 24.00)	24.00 (24.00 to 26.00)	< 0.001
2 years	20.00 (18.00 to 20.00)	22.00 (20.00 to 22.00)	< 0.001
Study end (3 years)	18.00 (16.00 to 20.00)	20.00 (20.00 to 22.00)	< 0.001
Within group *p* value	< 0.001	< 0.001	
Change at 6 months	-29.00 (-30.00 to -27.00)	-27.00 (-28.00 to -25.00)	< 0.001
Change at 1 year	-32.00 (-34.00 to -30.00)	-29.00 (-31.00 to -28.00)	< 0.001
Change at 2 years	-35.00 (-37.00 to -34.00)	-33.00 (-35.00 to -31.00)	< 0.001
Change at study end	-36.00 (-38.00 to -35.00)	-33.00 (-35.00 to -32.00)	< 0.001
Lefs			
Baseline	16.00 (14.00 to 21.00)	16.00 (14.00 to 20.00)	0.439
6 months	50.00 (46.00 to 52.00)	46.00 (44.00 to 48.00)	<0.001
1 year	52.00 (50.00 to 56.00)	50.00 (48.00 to 50.00)	< 0.001
2 years	56.00 (54.00 to 60.00)	52.00 (50.00 to 54.00)	< 0.001
Study end (3 years)	60.00 (56.00 to 62.00)	54.00 (52.00 to 54.00)	< 0.001
Within group *p* value	< 0.001	< 0.001	
Change at 6 months	33.00 (30.00 to 36.00)	29.00 (26.00 to 32.00)	< 0.001
Change at 1 year	36.00 (33.00 to 39.00)	32.00 (29.00 to 36.00)	< 0.001
Change at 2 years	40.00 (37.00 to 42.00)	35.00 (32.00 to 38.00)	< 0.001
Change at study end	42.00 (39.00 to 45.00)	36.50 (34.00 to 40.00)	< 0.001
PHQ-9			
Baseline	5.00 (5.00 to 6.00)	6.00 (5.00 to 6.00)	0.059
Study end (3 years)	0.00 (0.00 to 2.00)	2.00 (2.00 to 3.00)	< 0.001
Within group *p* value	< 0.001	< 0.001	
Change at study end	5.00 (4.00 to 5.00)	3.00 (2.00 to 4.00)	< 0.001

- Abbreviations: RM = rotational malalignment; LEFS = Lower Extremity Functional Scale; PHQ-9 = Public Health Questionnaire-9
- In non-RM and RM Cohorts, n = 475 and 234 respectively up to 2 years and 246 and 158, respectively at 3 years.
- Values denote Median (Interquartile range).
- *p* value in the last column is for intergroup comparison by the Mann-Whitney U test.
- The *p* value for within-group comparison is from Wilcoxon's matched pairs signed rank test for PHQ-9 and Friedman's analysis of variance [ANOVA] for other parameters.

Table 3: Chi-square for trend analysis for proportion for achieving optimum functional scores with time in the Non-RM and RM cohorts

Optimum functional scores	Proportion achieving in non-RM cohort	Proportion achieving in RM cohort
Knee Society Score [170 - 180]		
At 1 year	2 (0.42%)	0
At 2 years	129 (27.16%)	1 (0.43%)
At 3 years	108 (43.90%)	0
Change over time	p<0.001	p = 0.877
Chi square for trend	212.711, p<0.001	0.338; p=0.561
Knee Society Pain Score [45 - 50]		
At 1 year	434 (91.37)%	3 (1.28%)
At 2 years	435 (91.58%)	3 (1.28%)
At 3 years	212 (86.18%)	2 (1.27%)
Change over time	p<0.050	p = 0.990
Chi square for trend	3.383; p<0.05	0.017; p=0.896
Oxford Knee Score [18 - 16]		
At 1 year	35 (7.37)%	0
At 2 years	219 (46.10)%	1 (0.43%)
At 3 years	153 (62.20)%	3 (1.90)%
Change over time	p<0.001	p = 0.025
Chi square for trend	204.859; p<0.001	4.99; p=0.025
LEFS [60 - 62]		
At 1 year	0.84%	0%
At 2 years	39.15%	0.86%
At 3 years	86.18%	1.89%
Change over time	p<0.001	0.038
Chi square for trend	537.443; p<0.001	4.289; p=0.038
PHQ-9 [0 - 4]		
At 1 year	97.05%	97.00%

- Abbreviations: RM = rotational malalignment; LEFS = Lower Extremity Functional Scale; PHQ-9 = Public Health Questionnaire-9
- In non-RM and RM Cohorts, n = 475 and 234 respectively up to 2 years and 246 and 158, respectively at 3 years.

Discussion

In this study, rotational alignment of prosthetic femoral and tibial components was assessed by axial CT scans to designate the presence of external or internal rotation of components; depending on which the CER, CIR or CM was calculated. The optimum outcome was seen in those patients with CER < 10 degrees (67% of the operated knees) following surgery. The geometry of the proximal tibia and distal femur is intimately linked with the biomechanics of the tibio-femoral and patello-femoral joints; and hence rotational malalignment of tibio-femoral components accounts for a number of unacceptable features after TKA [3].

In the non-RM cohort, comprising 475 knees, 246 knees were followed up for 3 years, and all the functional outcome scores-KSS, OKS, and LEFS-showed significant improvement with time; KSS-Pain Score improved considerably by 1 year, with steady consistent improvement at 2 years, indicating painless TKA knees, as a successful outcome of TKA. This has been substantiated by other authors too [14], according to whom malrotation of fixed bearing posterior stabilized total knee prosthesis causes a postoperative rotational mismatch between the femur and tibia; correct rotational alignment of components after TKA is essential for desired functional outcomes in terms of a painless functional knee allowing a near normal lifestyle The optimum outcome was not observed in 234 out of 709 TKA knees [33%], where CER of 10 degrees or more, CIR of any degree or CM was present. In this RM cohort, 158 knees were followed up for 3 years, and significantly inferior outcome scores were observed even at 3 years. The KSS-Pain score showed poor improvement at 1 year, indicating persistence of patello-femoral pain or anterior knee pain. In these 234 knees, CER of 10 degrees or more, CIR, and CM were found in 17 (2.4%), 147 (20.73%), and 70 knees (9.87%) respectively; clearly indicating the high incidence of internal rotation of tibial component in rotational malalignment. According to Nicoll and Rowley [6], internal rotation of more than 6 degrees of the femoral component is associated with pain, but the degree of internal rotation of the tibia to produce anterior knee pain was not identified. The present study indicates that all categories of rotational malalignment can lead to anterior knee pain following TKA and not just the internal rotation of the tibial component. The latter results in excessive external rotation of the tibia, causing a resultant increase in Q angle and abnormal stress on extensor muscles, leading to a painful knee [4]. This may happen particularly in obese patients with fixed flexion deformities, where a tibial cutting jig can be inadvertently deflected into internal rotation, causing excessive internal rotation of tibial components. The postero-lateral overhang of tibial component may impinge on popliteus tendon, causing a painful TKA knee, as the popliteus initiates flexion; to avoid this, inadvertent internal rotation of the tibial component may happen, further causing patello-femoral pain after TKA [15]. According to Lee *et al*. [16] extent of medial release is a definite factor associated with the internal rotation of components and should therefore be taken into account during TKA.

Berger *et al*. [7] have attributed patello-femoral dysa function to the fact that small amount of CIR (1-4 degrees) correlates with lateral tracking and patellar tilting, moderate CIR (3-8 degrees) with patellar subluxation, and large amounts of CIR (7-17 degrees) with early patellar dislocation or late patellar prosthesis failure; the control group being in CER of 0-10 degrees. We also found that mild to moderate degrees of CIR may similarly be a cause of patellar subluxation on long term follow-up, together with excessive wear and tear of the polyethylene insert, which may account for implant failure and poor outcome. However, in contrast to this study, which implicates CIR to be the main cause of patello-femoral complications, our findings indicate that CM and CER of 10 degrees or above can also be responsible for anterior knee pain and related patello-femoral complications. Internal femoral and tibial component malrotation in TKA significantly alters tibio-femoral kinematics, much more than neutrally and externally rotated components, as seen in this study and also suggested by Heyse *et al*. [17].

In patients presenting with patellofemoral pain in otherwise well-aligned, well fixed and sterile total knee prosthesis, rotational malalignment should be suspected, which can be detected by axial CT scans. Ranawat *et al*. [18] have also concluded that patellar dislocation, subluxation, tilt and excessive patellar wear result from malrotation of the tibial and femoral components. According to Victor *et al*. [3], any misplacement of components will affect the loads on the interface and tension in the ligaments, which in turn will cause aberrant kinematic behavior, inducing stiffness, instability and early loosening of prosthetic knee components combined with anterior knee pain, as also found in this study. Romero *et al*. [19] found that increased lateral flexion laxity is associated with increased internal rotation of femoral component and poorer clinical outcome of TKA. Similarly, Bell *et al*. [20] and Bedard *et al*. [21] have concluded that appropriate component rotation in TKA is important for normal patellar tracking, symmetrical patello-femoral joint contraction, neutral varus-valgus positioning in flexion, correct rotational alignment of the tibia in extension and for avoiding anterior femoral notching. Our study findings are in broad conformity to this wide-ranging experience from various groups around the world.

Our study had some limitations. Assessment of rotational alignment of femoral and tibial components after TKA remains a challenge as visualizing these prosthetic components on simple axial CT scans can be difficult without scatter reduction software and proper understanding of the reference axes of both components [3]. We had access to appropriate hardware and software, but it was not feasible to repeat scans for cross-checking. For logistical reasons, we had to wind up the study without completing third year follow-up for all the knees, though a substantial proportion [404 TKA knees] could be followed up for three years. Finally, as we observed, patents' anxiety level could influence their response to the functional outcome questionnaires and we had no means of controlling for this.

Conclusions

We can conclude that rotational malalignment of components in TKA is almost inevitably associated with pooreroutcomese in the form of anterior knee pain, or other patellofemoral complications like patellar tilting, subluxation, or peri-prosthetic fractures requiring revision arthroplasty. Therefore, total knee arthroplasty should avoid component mismatch or other kinds of rotational malalignment of the tibial and femoral components, in addition to restoring the coronal alignment.

Declarations

Ethics Approval: Ethics approval was obtained from all the hospitals from where patients were included in the study; prior to beginning the study. Ethics approval document was obtained first from Fortis Hospital, Anandapur, Kolkata on 30.9 2015, followed by the same from IPGMER, Kolkata, on 28.10.15 & R. G. KAR Medical College & Hospital on 5.12. 2018. The patients were recruited from Fortis Hospital for the first 4 years [October 2015-2019], followed by follow-up for 3 years [404 knees] and the rest for 2 years till July 2021, until the completion of the study [5&1/2 years].

Consent to Participate: Patients gave written consent to participate in the study through informed consent document forms as per ICMR [Indian Council of Medical Research] Guidelines.

Availability of data and materials: Available. Patient data has been recorded in Excel sheets for statistical analysis after obtaining proper consent. The data sets generated during and / or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: All contributing authors, declare that they have NO competing interests/ conflicts of interests.

FUNDING: The study received NO financial grant/ support from any sponsor. The hospitals concerned provided free access to patients and imaging facilities for academic purpose.

Authors contributions

Author 1: contributed to the concepts and study design, patient data acquisition, literature search, data analysis, manuscript preparation, final drafting and editing of the manuscript.

Author 2: contributed to study design, data analysis, statistical analysis, manuscript preparation, and final editing.

Author 3: contributed to study design, literature search and manuscript preparation.

All authors have contributed to the study and have finally reviewed the manuscript, and each author believes that the manuscript represents honest research work.

Informed consent

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). Informed consent was obtained from all patients for being included in the study.

Acknowledgements

We wish to acknowledge the contributions of the following individuals in Fortis Hospital, Anandapur, Kolkata: Dr. Ronen Roy, Senior Consultant Orthopedic Surgeon, with team members, namely Dr. Mistun Banerjee and Dr. Shirazul Kamal, whose TKA patients provided the patient pool for our study and who facilitated access to these patients.; the entire team in the Surgical Intensive Care Unit (SICU) who provided immediate postoperative care to these patients and the physiotherapists (Aditya and Ravi) who helped in mobilizing the TKA patients from the second postoperative day itself, with utmost care and concern; the Chief Radiologist Dr. Salim Parvez, and his technical team for providing access to long leg films (Debashis, Tuhin) and to axial CT Scans of TKA implants (Mukul, Sandip, Abhijeet, Tarun Chatterjee) and helping in their interpretation. Lastly, we extend our heartfelt thanks to all our TKA patients who participated in the study, for being with us for up to 3 long years, patiently submitting to all our scoring assessments and making the project a success.

References

1. Hartinian EG, Pimpalnerkar AL. Computer assisted total knee arthroplasty: Does it make a difference? Maedica. J Clin Med. 2013;8:176-81.
2. Colebatch AN, Hart DJ, Zhai G, Williams FM, Spector TD, Arden NK. Effective measurement of knee alignment using AP knee radiographs. Knee. 2009;16:42-5.
3. Victor J. Rotational alignment of the distal femur: A literature review. Orthop Traumatol Surg Res 2009;95:365-72.
4. Barrack RL, Schrader T, Bertot AJ, Wolfe MW, Myers L. Component rotation and anterior knee pain after total knee arthroplasty. Clin Orthop. 2001;392:46-55.
5. Hoffmann S, Romero J, Roth- Schiffl E, Albrecht T. Rotational malalignment of the components may cause chronic pain or early failure in total knee arthroplasty. Orthopade. 2003;32:469-76.
6. Nicoll D, Rowley DI. The internal rotational error of the tibial component is a major cause of pain after total knee arthroplasty. J Bone Joint Surg Br. 2010;92:1238-44.
7. Berger RA, Crossett LS, Jacobs JJ, Rubash HE. Malrotation causing patello-femoral complications after total knee arthroplasty. Clin Orthop Relat Res. 1998;356:144-53.
8. Matsuda S, Miura H, Nagamine R, Urabe K, Hirata G, Iwamoto Y. Effect of femoral and tibial component position on patellar tracking following total knee arthroplasty: 10-year follow-up of Miller-Galante I knees. Am J Knee Surg Summer. 2001;14:152-6.
9. Berger RA, Crossett LS. Determining the rotation of the femoral and tibial components in total knee arthroplasty: A computer tomography technique. Operative Techniques Orthop. 1998;8:128-33.
10. Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the knee society clinical rating systems. Clin Orthop. 1989;248:13-4.
11. Dawson J, Fitzpatrick R, Murray D, Carr A. A response to issues raised in a recent paper concerning the Oxford Knee Score. Knee. 2006;13:66-8.
12. Dingemans SA, Kleipool SC, Mulders M, Winkelhagen J, Schep NWL, Goslings JC, *et al*. Normative data for the lower extremity functional scale (LEFS). Acta Orthopaedica. 2017;88:422-6.
13. Lowe B, Unutzer J, Callahan CM, Perkins AJ, Kroenke K. Monitoring depression treatment outcomes with Patient Health Questainnaire-9. Med Care. 2004;42:1194-201.
14. Ueyama H, Minoda Y, Sugama R, Ohta Y, Yamamura K, Nakamura S, *et al*. Malrotation of the fixed-bearing posterior stabilized total knee prosthesis causes a postoperative rotational mismatch between the femur and tibia. Knee Surg Sports Traumatol Arthrosc 2020;28:3810-20.
15. Dennis DA, Komistek RD, Mahfouz MR, Walker SA, Tucker A. A multi-center analysis of axial femorotibial rotation after total knee arthroplasty. Clin Orthop Relat Res. 2004;428:180-9.
16. Lee SY, Lim HC, Jang KM, Bae JH. What factors are associated with femoral component internal rotation in TKA using the gap balancing technique? Clin Orthop Relat Res. 2017;475:1999-2010.
17. Heyse TJ, El-Zayat BF, De Corte R, Chevalier Y, Fuchs-Winkelmann S, Labey L. Internal femoral component malrotation in TKA significantly alters tibiofemoral kinematics. Knee Surg Sports Traumatol Arthrosc. 2018;26:1767-75.
18. Ranawat C. The patello-femoral joint in total condylar arthroplasty: Pros and cons based on five to ten year follow-up observations. Clin Orthop Relat Res. 1986;205:93-9.
19. Romero SJ, Stahelin T, Binkert C. The clinical consequences of flexion gap asymmetry in total knee arthroplasty. J Arthroplasty. 2007;22:235-40.
20. Bell SW, Young P, Drury C, Smith J, Anthony I, Jones B, *et al*. Component rotational alignment in unexplained painful primary total knee arthroplasty. Knee. 2014;21:272-7.
21. Bedard M, Vince KG, Redfern J, Collen SR. Internal rotation of tibial component is frequent in stiff total knee arthroplasty. Clin Orthop Relat Res. 2011;469:2346-55.