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Assessment of average femoral component rotation for balancing functionally aligned total knee replacement in varus deformity: Robotic image guidance study

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A R T I C L E I N F O

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A B S T R A C T

Introduction and purpose: Ensuring proper femoral component alignment post-Total Knee Arthroplasty (TKA) is crucial for normal patellofemoral (PF) kinematics. However, the customary 3° external rotation relative to the Posterior Condylar Axis (PC Axis) may not universally apply, and the expected final femoral component rotation remains unclear in functionally aligned knees. This study examines the relation between the Transepicondylar Axis (TEA) and PC axis, known as Posterior Condylar Angle (PCA) in Indian patients along with factors influencing PCA, and the feasibility of reproducing patient-specific PCA using image-guided Cuvis joint robot.

Methods: Forty patients (52 Knees) with primary osteoarthritis and varus deformity were prospectively evaluated. Native PCA was determined using CT-based J planner. Pre-operative patellar shape, PF tilt, PF shift, final femoral component rotation (representing post-operative PCA), final patellar tracking, and post-operative functional and radiological assessment at 3 months were recorded.

Results: Study participants averaged 64.3 years of age, with a female-to-male ratio of 23 to 17. Varus deformities varied, with IA2 being most prevalent, and sagittal plane deformities included fixed flexion (34.6 %) and hyperextension (44.2 %). The average PCA was 1.9° (range: 0°–7.3°), with most knees (41 out of 52) below 3°. The majority had Wiberg type 1 patellae, with pre-operative patellar tilt averaging 5.63°, reducing post-operatively to 4.43°. Most patients (37 out of 40) achieved excellent Knee Society functional scores at the 3-month mark. Complications included one case of delayed wound healing and one femoral array pin breakage. Notably, our study revealed a significant deviation in PCA from the commonly reported 3° in Western literature, underscoring the need for region-specific considerations in TKA planning.

Conclusion: PCA of our population is statistically different from customary 3° followed with jig system. Image guided Robotics helps to identify patients specific PCA and reproducing the same was more commonly possible in patients with reducible Varus deformity.

1. Introduction

Rotational alignment of femoral component is important for a good functional outcome while performing a Total Knee Arthroplasty (TKA).[1,2] The Patellofemoral Joint (PFJ) can be called upon as the third joint space.[3] Abnormal internal or external rotation of femoral component leads to improper PFJ balancing and can result in anterior knee pain, instability, poor function and in certain instances, early revision.[4]

Of the various references for femoral component rotation, placing the component parallel to *Trans*-Epicondylar Axis (TEA) is the most reliable for practical purposes.[5–7] To reproduce the same, while performing TKA with conventional jig system, the femoral component is guided to be placed 3° externally rotated in relation to the Posterior condylar axis (PC axis).[8,9] This corresponds to an implant parallel to the TEA.[9]

The relation between TEA and PC axis, is called as the Posterior Condylar Angle (PCA).[10] The value of 3° for PCA is based on the morphological study of the Caucasian population.[11] Studies on knees of Japanese, Chinese, and Indian populations have demonstrated increased

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Abbreviations

Computed Tomography CT
Flexion-extension FE
Hip-Knee-Ankle axis HKA axis
Kinematic alignment KA
Mechanical axis alignment MA
Posterior condylar axis PCA
Posterior femoral axis PC axis
Patellofemoral Joint PFJ
Robotic assisted total knee arthroplasty RA-TKA
Total knee arthroplasty TKA
Transepicondylar axis TEA

PCA, as high as 9°.[12–14] Therefore, adhering to a standard 3° external rotation for all patients, as recommended by conventional jig systems, may not be suitable in the context of the current era of Kinematic and robotic-assisted TKA.

Despite the demonstrated superior outcomes of Kinematic TKA in terms of patellofemoral (PF) kinematics[15] the concept of kinematic alignment (KA) revolves around replicating the natural femoral and tibial morphology, which inherently addresses PF alignment concerns. However, there remains ambiguity regarding the optimal final rotation of the femoral component in Kinematic TKA. Functional alignment essentially entails TKA performed with robotic assistance, aiming to achieve KA.[16] During surgery, the surgeon adjusts overall limb and component alignment, conducts bone resections, and fine-tunes component positioning, with or without necessary soft tissue releases.[16]

Given the significant impact of femoral component rotation on the success of TKA procedures, it is imperative to conduct comprehensive studies aimed at optimizing patient outcomes. Understanding the nuances of femoral component alignment, particularly in relation to the PCA, is essential for achieving optimal PF joint balance and overall functionality post-surgery. Furthermore, as demographic variations exist in PCA values, especially among populations like the Indian demographic, tailoring surgical approaches to individual patient needs becomes increasingly crucial. Therefore, this study aims to address these critical gaps in knowledge to enhance the precision and effectiveness of TKA procedures for patients in the Indian population.

The Primary purpose of the study is.

1. To study the average PCA in Indian population,
2. If reproducing patient's native PCA is possible?
3. To ascertain the average femoral component rotation required for balancing the PFJ and flexion space in a functionally aligned TKA done for varus deformity.

And the Secondary purpose is.

1. To assess the factors influencing the final femoral component rotation when a knee is balanced functionally.
2. The role of robotics in patient specific axial orientation of femoral components.

2. Population and methods

This study is designed as a prospective longitudinal investigation to assess the outcomes of patients undergoing TKA using fully automated Cuvis Joint Robot system (Curexo, South Korea, supported by Meril Healthcare Pvt. Ltd. India) at a single center in India. The study duration spans 7 months, starting from March 2023 until September 2023.

Inclusion criteria included patients diagnosed with primary Osteoarthritis (OA) of the knee. Additionally, patients suffering from Thienpont IA and M type varus deformity, along with the presence of Fixed Flexion Deformity (FFD) or hyperextension of the knee joint. Moreover, only patients who underwent robotic TKA with functional alignment were included. Exclusion Criteria: Patients with Thienpont D type varus deformity or valgus deformity were excluded from participation; individuals with post-traumatic OA, rheumatoid arthritis, or neuromuscular disorders, patients who underwent robotic TKA with mechanical alignment were excluded from the study.

Local Ethical committee of the site approved the study. All patients had given consent for participation in scientific research at the time of initial treatment at our institute.

Upon clinical evaluation, the study population underwent weight-bearing radiographs. The severity of varus deformity was classified according to the Thienpont & Parvizi classification for varus knees.

Theinpont & Parvizi Classification[17]:

Intra-articular (Type IA).

1. Reducible Antero-medial OA with intact ACL
2. Reducible Antero-medial + Posteromedial OA with deficient ACL
3. Fixed Varus without lateral laxity
4. Fixed Varus with lateral laxity

Metaphyseal (Type M) (Femoral/Tibial).

1. With wear (bone loss)
2. With Joint line obliquity

Diaphyseal (Type D) (Femoral/Tibial).

Associated clinical sagittal plane deformity was recorded. In the axial view, native patellar morphology was recorded based on Wiberg's classification,[18] native PF orientation was recorded using patellar tilt and patellar shift.

Patellar tilt[19,20] was defined as the angle between a line from the anterior limits of the femoral condyles and the equatorial line of the patella (Fig. 1**a**) (0–5°-normal, 5 to 10°-borderline, angle >10°–abnormal).

Patellar shift[19,20] is measured between the deepest point on femoral sulcus and median ridge of the patella (Fig. 1b). A value of 0.3 mm ± 2.5 mm is considered normal.

All patients were subjected to Lower limb Computed Tomography (CT) as a part of pre-operative planning done using J Planner software. Once the bony landmarks were marked in J Planner 3D images, the orientation of TEA in relation to PC Axis, i.e., PCA specific to each knee was recorded.

The femoral component size and the spatial orientation was planned such that the removed articular surface was replaced by the component thickness. The femoral component was flexed as required to prevent notching. Component was positioned mediolaterally to seat the patella in trochlear groove with focus to avoid lateral overhang, and peg holes centered on the corresponding condyles, as visualized in axial 3D views in J planner. Tibial component was spatially placed to restore the resected bone thickness and to begin with, a standard 3° posterior tibial slope was given. The tibial tray was aligned in accordance with the Akagi line and sized to accommodate maximal coverage on the tibial cut surface without overhangs.

All patients underwent robotic assisted TKA under Combined Spinal Epidural anesthesia under torniquet control via Medial parapatellar approach. All the procedures were done by a single surgeon using Posterior Stabilized Freedom Total Knee System (Maxx Orthopaedics Inc. Plymouth Meeting, Pennsylvania, USA). Soft tissue release was done just enough to expose the knee with no target for deformity correction at this stage.

Once the tibial and femoral sensors were fixed and bone mapping was done, a gap-check was performed. During this process, the extension space was first balanced followed by flexion space. Varus alignment of component up to 3° is accepted on tibial side and up to 4° on the femoral

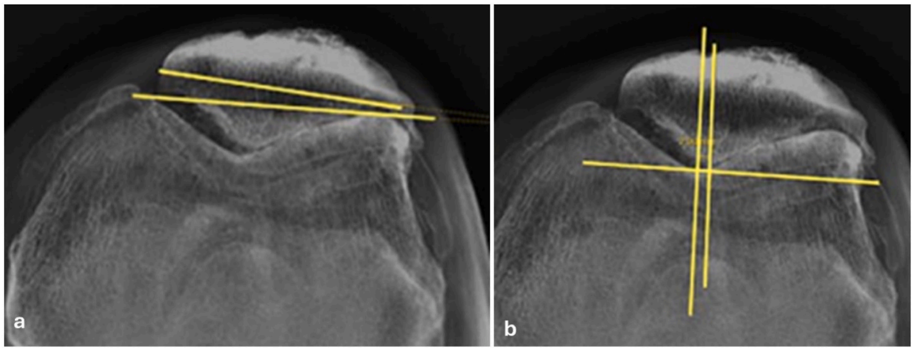

Fig. 1. Pre-operative Patellar tilt (a) and Patellar shift (b).

side, as required to balance the knee with an overall target of Hip Knee Ankle angle (HKA) within ±3° of neutral.

For balancing the flexion gap, the femoral component was externally rotated to open the medial joint space. The extent to which it can be externally rotated is limited by the thickness of the posteromedial bone resection, which should not be beyond the posterior condylar thickness of the prosthesis. The center of rotation for each step is adjusted to position the component as required for medio-lateral (ML) gap discrepancy. The posterior tibial slope was altered as required for flexion-extension mismatch. The final target of gap check was to have an equal medial gap in both 90° flexion and 0° extension, no ML laxity in extension, 1–2 mm ML laxity (lateral side being lax) with the knee in 90° flexion. Soft tissue release was done if HKA is 3° beyond neutral alignment. The final thickness of distal and posterior femoral cut, along with component flexion, final proximal tibial resection thickness and slope are recorded. The HKA at the end of the procedure was also recorded.

Once gap balancing was optimized, bone cuts are executed by fully automated Cuvis Joint Robot. During trial implantation the precision of execution of the planned gap check was confirmed, with special attention to patellar tracking using "No thumb" technique.[21]

A lateral retinacular release was done if the patella off-tracks after the final component cementation. Post-operatively, patients were assessed at the end of 3 months both clinically and radiologically. Clinical assessment was done using functional component of knee score. The patellar tilt and shift were recorded in axial views.

3. Statistical analysis

The recorded data were statistically subjected to Linear regression analysis in R-language using Wilcoxon Rank sum test, Wilcoxon signed rank test, Krukal-Wallis Test and Spearman's rank correlation.

4. Results

A total of 40 patients were operated on, of which 12 were single staged bilateral TKA's, accounting for a total of 52 knees which were functionally aligned during the study period. The mean age of the study population was 64.3 years. Our study was female dominant with 23 (64 %) females and 17 (36 %) males. Of the 52 knees, 30 (57.7 %) were left and 22 (42.3 %) were right.

The order of Varus deformity in descending frequency was IA2 (40.4 %, n = 21), IA3 (12 %, n = 23.1), MT1 (17.3 %, n = 9), MT2 (9.6 %, n = 5), IA4 (5.8 %, n = 3) followed by IA1 (3.8 %, n = 2). Twenty-three knees exhibited hyperextension (44.2 %, n = 23), while fixed flexion deformity (FFD) was observed in 18 knees (34.6 %). Neutral knees were seen in 21.2 % of the study population (n = 11).

The average PCA among our study participants was 1.9°, demonstrating a considerable variation ranging from 0 to 7°. Among the 52 knees assessed, 41 exhibited a PCA below 3° (Table 1).

Twenty-six knees showed Wiberg type 1 patellae while Wiberg type 2 patellae was observed in 24 knees. Only 2 knees were of type 3 patella. The mean pre-operative Patellar tilt was 5.63 ± 1.83° and the average pre-operative Patellar shift was 1.36 ± 1.11 mm.

Table 1
Shows the average Posterior condylar angle and range observed among the study population. Difference between mean PCA of study population and hypothesized PCA.

Posterior condylar angle (Degrees)	Values	
Mean (SD)	2.12° ± 1.34°	
Median [Min, Max]	1.9° (0°–7.3°)	
Posterior Condylar Angle (PCA)	**Hypothesized mean**	**P value**
1.90° (1.38°, 2.6°)	3°	<0.001

At the end of gap check, a varus alignment of 1° was seen in 9 knees (17.3 %) on the tibial component and 7 knees (13.5 %) on the femoral component. Furthermore, a 2° varus alignment was observed in 6 (11.5 %) knees on the tibial side and 7 (13.5 %) knees on the femoral side. The mean HKA angle at the end of the procedure was 2.12° ± 1.52°, with a median of 2° (range: 0°–5°). A neutral alignment, with neither varus or valgus component alignment was duly observed in 37 (71.2 %) and 38 (73.2 %) knees on the tibial and femoral side, post-operatively, respectively.

The mean final femoral component rotation at the end of balancing the knee was 3.3°, with a wide range of 0.8–7.9°. We were able to balance close to 50 % of the knees (23 knees) with a final component rotation <3° (Fig. 2).

The mean post-operative patellar tilt was 4.43° ± 1.62° and post-operative patellar shift was less than 1 mm. The patellofemoral orientation had a significant improvement in the post-operative X-rays, as the borderline patellar tilt became normal (Table 2).

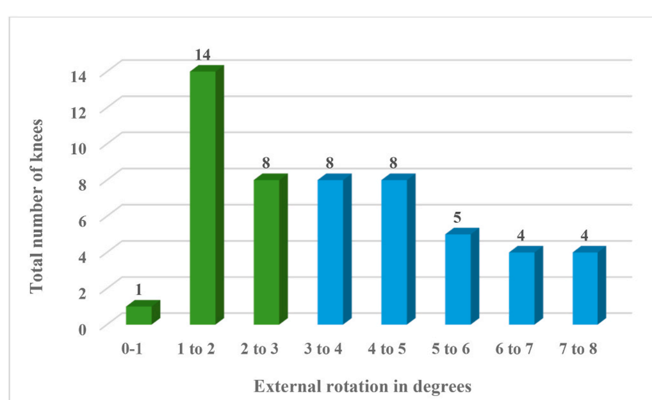

Fig. 2. Shows the final component rotation where a rotation of less than 3° is achieved with 23 knees and 29 knees achieving the rotation of more than 3° (3°–8°).

Table 2
Pre-operative and post-operative Patellar tilt and shift observed in the study population.

Patellar tilt (degrees)	Preoperative values	Postoperative values	P value
Mean (SD)	5.63° ± 1.83°	4.43° ± 1.62°	
Median [Min, Max]	6° (0°–10°)	4.35° (0°–10°)	<0.001
Patellar shift (mm)			
Mean (SD)	1.36 ± 1.11	0.619 (0.761)	
Median [Min, Max]	1.5 (0–4)	0 [0, 3.00]	<0.001

All 40 patients had an excellent Knee society functional score, with the mean score of 88.5 ± 10.6. Intraoperatively, all patients exhibited satisfactory patellar tracking, with none necessitating lateral retinacular release.

Complications: One patient who was on prolonged anti-platelet therapy for her cardiac condition had delayed wound healing resulting in delayed initiation of knee bending and suture removal. However, at the end of 3 months follow-up despite these challenges, patient had a Knee society functional score of 90. Another patient had a femoral array pin breakage with the retained remnant pin in situ.

4.1. Factors influencing PCA and final component rotation

On statistical analysis of factors affecting PCA, a negative correlation (−0.005) was noted by Spearman's rank correlation test between age and PCA i.e., as age increases, PCA decreases. The median age of the study population was 64 (range 57 years–71 years) p = 0.9703. Patient's gender or knee deformity had no influence on PCA. Female showed the median PCA of 1.90° (IQR: 1.45°, 2.95°), and in male patients, PCA was 1.80° (IQR: 1.33°, 1.98°), p = 0.2314. In patients with sagittal plane deformity, PCA achieved was as follows: FFD patients — 1.90° (1.63°, 2.80°); Hyperextension patients — 1.70° (0.95°, 2.35°) and in neutral patients — 1.90° (1.70°, 2.65°), p = 0.2812.

Posterior Condylar Angle and final component rotation was found to have a linear relationship i.e., as the patient's native PCA increased, the final component rotation required to functionally balance the knee also increased. Reproducing patient's native PCA was more commonly possible in patients with a correctable Varus deformity. An excessive external rotation beyond native PCA was required in patients with a fixed varus deformity (Fig. 3).

The median PCA of our study population differed significantly from the commonly reported PCA value of 3° found in literature with Western population.

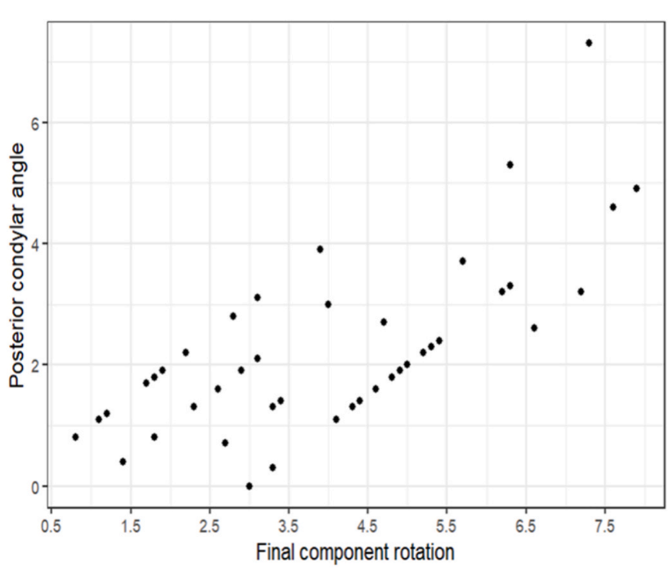

Fig. 3. Linear graph showing the relationship between Posterior Condylar Angle (PCA) and final component rotation.

5. Discussion

The long-established practice of utilizing a 3° external rotation of the femoral component as a universal standard[22] is commonly accepted, largely due to the prevalence of jig systems providing guidance for this angle and beyond. However, it is imperative to re-evaluate this assumption, particularly as we strive to provide our patients with a more nuanced approach to TKA.

The pioneering work by Dr. Stephen Howell on KA[23] and other corroborating studies[15,22,24] advocate for precise bony cuts to replace the knee articular surface while preserving the patient's joint line obliquity. This approach anticipates that PF kinematics will naturally align once this is achieved. However, the optimal final rotation of the femoral component remains uncertain. Exact reproduction of patient's native anatomy can be effective and safe when TKA is done in early stages of the disease.[25] With our population, presenting most commonly in advanced stages of the pathology for TKA, reproducing patient's native morphology can lead to mechanical outliers, where long-term survival of TKA is questionable.[25] Hence, we chose to go with a propensity to follow the functional alignment principle, described by Chang et al.[16] where the surgeon choses to go with the target to provide a TKA without much soft tissue release, altering the component alignment for balancing the knee under robotic guidance. The limit to play between component alignment and soft tissue release is tailored to each patient as opted by the Surgeon. A level III retrospective study by Clark G et al.[26] compared the balance achieved through mechanical axis alignment (MA) and KA alignment plans in TKA. Among 300 knees, 130 were initially planned with MA and 170 with KA. Results indicated that functional alignment yielded greater balance (in 97 %) in extension, medial aspects, and overall compared to both MA (55 %) and KA (73 %) alignment without soft tissue release.

In our study population, the PCA ranged from 0° to 7.3° with a median of 1.9°. A negative correlation was noted between age and patient's native PCA i.e., an increment in age caused a decline is PCA. This can be due to the fact, as the age progresses, the pathology progresses[27] and posterior condylar bone stock might decline due to wear from the disease. The way to reproduce patient's native PCA is to have the same amount of femoral component rotation during TKA.

It is evident that femoral component rotation cannot always be kept as constant value, as externally rotating the femoral component helps in opening the tight medial flexion gap in a varus knee. In our study we found that a correctable varus deformity can help to prevent excessive external rotation beyond patient's native PCA. This is very well understandable as the medial joint space can be opened out in a correctable deformity, whereas in a fixed deformity this medial joint space tightness can be managed to some extent, without much soft tissue release, by externally rotating the femoral component, ultimately ending up in a final component rotation beyond patient's native PCA.

Are we going to be misguided by knowing the pathological PCA in a varus knee? The study by Matsuda et al. makes it clear that no major difference was noted in PCA values between a normal knee and an arthritic knee with varus deformity, even though it varied significantly in a valgus knee. The authors compared the 30 normal knees, 30 osteoarthritic knees with varus deformity, and 30 osteoarthritic knees with valgus deformity using radiographs and MRI and showed no significant difference between normal and varus knees, while substantial variation in posterior condylar rotation was observed among valgus knees.[28]

Even though a minimum of 3° external rotation of the component with reference to PC Axis is considered safe for a satisfactory patellar tracking, it is evident in our study that there was a statistically significant improvement in the pre and post-operative patellar tilt and shift, even though in 50 % of our knees, we were able to balance the knee with a femoral component rotation less than 3°. Even in these knees, we found that none of the patients required an internal rotation of femoral component beyond patient's native PCA/Surgical TEA, in other words, the component is never internally rotated when an individual patient's native PCA is considered.

Initially, a study by R.A. Berger emphasized the importance of understanding rotational alignment using the PCA, suggesting precision in rotational alignment checks during surgeries. The researchers assessed seventy-five embalmed anatomic specimen femurs to quantify the posterior condylar angle. The results showed that males exhibited a mean angle of 3.5°, while females displayed a mean angle of 0.3°, suggesting precise rotational alignment. The authors concluded that the visual rotational alignment checks can be performed at this angle during primary arthroplasty and revisional surgeries.[5] Griffin FM further elaborated on this, highlighting the challenge posed by higher PCAs in valgus knees, questioning the reliability of posterior condyles as references for femoral component rotation.[11]

In a contrasting study, the focus shifted to healthy Indian patients, revealing notable differences in femoral condyle geometry compared to Caucasian and Japanese knees. This divergence, particularly evident in PCA values, underscores the necessity for precise rotational alignment strategies tailored to individual demographics. A study on healthy Indian patients ($n = 100$) revealed differences in distal femoral rotational axes compared to Caucasian and Japanese knees, particularly in the Whiteside-epicondylar and Whiteside-posterior condylar angles.[14] Specifically, Indian knees exhibited a smaller mean Condylar twist angle (relation between PC Axis and Clinical TEA) compared to Japanese knees (5° vs. 5.8° and 6.3°). The deviation was more pronounced in Indian knees compared to Caucasian and Japanese knees, with the Wiberg's Posterior Condylar angle approximately 3° more externally rotated. Additionally, the Wiberg's Epicondylar angle exceeded 90° in Indian knees but was less than 90° in Caucasian and Japanese knees.

Furthermore, a CT-based study proposed a novel approach for knee arthroplasty, aligning with the femoral flexion-extension (FE) axis for improved implant positioning and size selection. This underscores the potential benefits of innovative alignment techniques in enhancing surgical precision and functional outcomes. By comparing this approach with conventional anterior-referenced planning, the study demonstrates its potential validity in achieving more accurate implant positioning and size selection, particularly for single-radius components. This could lead to improved surgical outcomes and better functional results for patients undergoing knee arthroplasty.[29]

Considering the findings it becomes evident that the conventional approaches to TKA may not adequately address the diverse anatomical variations and pathologies encountered in patients. The studies highlight the importance of re-evaluating standard practices, such as the 3° external rotation of the femoral component, and adopting more personalized and precise techniques, such as functional alignment and CT-based planning. By embracing these advancements, surgeons can optimize implant positioning, improve surgical outcomes, and enhance patient satisfaction, ultimately advancing the field of TKA towards more tailored and effective interventions.

While the study offers valuable insights, it also faces several limitations. Notably, both CT planning and intraoperative assessments were conducted in the supine position, potentially diverging from the knee's functional position. Furthermore, preoperative patellofemoral planning was executed solely in full extension, aligning with the position during CT scanning and possibly restricting its applicability across different degrees of knee flexion. However, the study's notable strengths include its pioneering use of the functional alignment technique and image-based robotics, along with the employment of the surgical *trans*-epicondylar axis and standardized radiological measurements by a singular experienced surgeon. These strengths underscore the study's significance despite its limitations.

6. Conclusion

The statistical variance in the posterior condylar angle among the Indian population averages 1.9° which contrasts sharply with the conventional 3° benchmark outlined in Western literature. The majority of the knees had final component rotation less than 3°, with an excellent functional outcome. Given the insights obtained from image-guided robotics, in none of the knees, an internal rotation of femoral component was warranted in relation to surgical TEA.

Conflict-of-interest statement

None.

Declaration of interest

None.

Submission declaration

The work described here has not been published previously, it is not under consideration for publication elsewhere, and its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out. If accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder.

Ethical statement

The study received approval from the local ethical committee review board. Prior to their participation, all individuals submitted the written informed consent.

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Statement of informed consent

Written informed consent was obtained from all enrolled patients and the Institutional Ethics Committee approved the study.

CRediT authorship contribution statement

Harish Kumar Murugesan: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation. **S. Amudhaganesh:** Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization. **Rex Chandrabose:** Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization. **Ravi Teja Rudraraju:** Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization. **S. Vijayanand:** Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The authors declare that the research was conducted in the absence of any commercial or financial ties that could be construed as a potential conflict of interest. Hence, there are no conflicts of interest to disclose.

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