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Original article

Novel technique for achieving the under-correction of native tibial varus in calipered restricted kinematically aligned total knee arthroplasty - A validation study

Arghya Kundu Choudhury [a], Shivam Bansal [b], Souvik Paul [c], S. Raja Balgovind [d], Sajid Ansari [e], Roop Bhushan Kalia [b,*]

[a] Intitute of Joint Replacement and Orthopaedics, Indus My Hospitals, Mohali, India
[b] Department of Orthopaedics, All India Institute of Medical Sciences, Rishikesh, India
[c] Department of Orthopaedics, AMRI Mukundapur, Kolkata, India
[d] Department of Orthopaedics, All India Institute of Medical Sciences, Patna, India
[e] Department of Orthopedics, All India Inisititute of Medical Sciences, Kalyani, India

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ABSTRACT

Purpose: Restricted kinematic alignment (rKA) TKA is relatively newer technique for achieving an overall under-corrected limb alignment. The present study aims to provide an easy and reproducible technique for achieving calipered rKA-TKA (crKA-TKA) using routine instrumentation.
Method: A prospective study was conducted including 30 patients (30 knees). All patients underwent crKA-TKA by the same surgeon. Pre-operatively all patients underwent long film standing radiographs, and coronal angles were measured to plan tibial bony cuts and the femoral axis angle (FAA) to restore tibial varus under correction and native distal femoral anatomy, respectively. Intra-operatively while taking tibial cuts, the alignment rod was noted to be always pointing towards the "third metatarsal" of the ipsilateral foot.
Results: 30 patients underwent total knee replacement with crKA technique. Angular corrections were satisfactory with all patients reaching the target MPTA of 87.48 $\pm$ 0.78 and LDFA of 90.301 $\pm$ 2.66 as planned, with an overall under-corrected limb alignment. HKA was achieved within a target of $< \pm 3$ degrees of the native knee (3.56 $\pm$ 1.29). Post-operative radiological parameters were checked by two separate observers with excellent intra-class correlation coefficients.
Conclusion: The present study validates a novel intra-operative technique of confirming an under-corrected native tibial varus while performing crKA-TKA. The radiological outcomes of the study confirm that with careful pre-operative planning, coronal angular targets were easily achievable with very less outliers. Study further establishes that this method of calipered technique in rKA-TKA using routine digital templating software and standard instrumentations is an alternative method of executing rKA.
Level of evidence: IV, Prospective case series.

1. Introduction

Osteoarthritis (OA) of the knee is one of the most commonly encountered debilitating orthopaedic conditions among the elderly.[1] Surgical management like total knee arthroplasty (TKA) is considered safe and a successful procedure for end-stage OA knees usually when the patient complains of extremely unbearable pain limiting their activities of daily living. TKA is aimed at improving the quality of life post-operatively with alleviation of pain, however, the literature suggests 20 % of patients dissatisfaction after the procedure.[2,3] One of the causes for this dissatisfaction has been considered to be the lack of restoration of the pre-arthritic limb alignment with conventional mechanically aligned TKA (MA-TKA), which aims at complete correction of varus, minimizing the load on either joint compartment.[4]

Various alignment philosophies for the patient undergoing TKA have been very recently introduced. Kinematically aligned TKA (KA-TKA),

* Corresponding author. Uttarakhand, 249203, India.
E-mail addresses: arghyakunduchoudhury@gmail.com (A.K. Choudhury), Shivam.ban19@gmail.com (S. Bansal), 1990.souvik@gmail.com (S. Paul), balgovindsraja@gmail.com (S.R. Balgovind), sajidans89@gmail.com (S. Ansari), roopkalia2003@yahoo.com (R.B. Kalia).

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being the most studied principle has been regarded as a true bony procedure without any ligamentous or soft tissue releases[5] and with component positioning in overall under corrected limb alignment to restore the pre-operative varus state.[6,7] However, it has also been considered that restoring the full varus, in patients with severe native varus-aligned knees may lead to more stress on the medial tibial insert increasing the chances of early failure.[8,9] Restricted KA TKA (rKA) has been introduced to be “the ideal compromise” acting as a middle path between KA and MA-TKAs.[10–13] It is hypothesized that restoration of native knee varus alignment will also improve the post-operative PROMs and better sense of joint position with rKA TKA. Obtaining these alignments often requires the use of expensive equipment like computer navigation or robotic technologies.

The present study aims to highlight a novel technique for achieving target tibial varus alignment for calipered-rKA-TKA (crKA-TKA) with pre-operative planning and intra-operative guidance without using any sophisticated tools and instrumentation in a resource-limited scenario and compare the accuracy to the target post-operative radiological alignment parameters.

2. Methodology

A prospective observational validation trial was conducted at a university-level teaching tertiary care between, November 2020 to July 2021, and thirty consecutive patients (thirty knees) scheduled for total knee replacement procedure for end-stage primary knee osteoarthritis (OA) were included. All patients took an informed decision to take part in this present trial. Clearance from the institutional ethics committee was obtained before conducting this study. Only patients with the varus alignment within the true boundaries for restricted kinematic alignment TKA, with a Hip-knee-ankle (HKA) angle between 5 and 10 degrees of varus, were enrolled. Patients with a confirmed diagnosis of secondary inflammatory or post-traumatic knee arthritis, or any pre-operative knee ligamentous laxity, or with prior knee surgery, varus thrust gait, or with the joint line congruence angle (JLCA) more than 5° or revision knee arthroplasty were excluded from this study. Also, patients with any knee

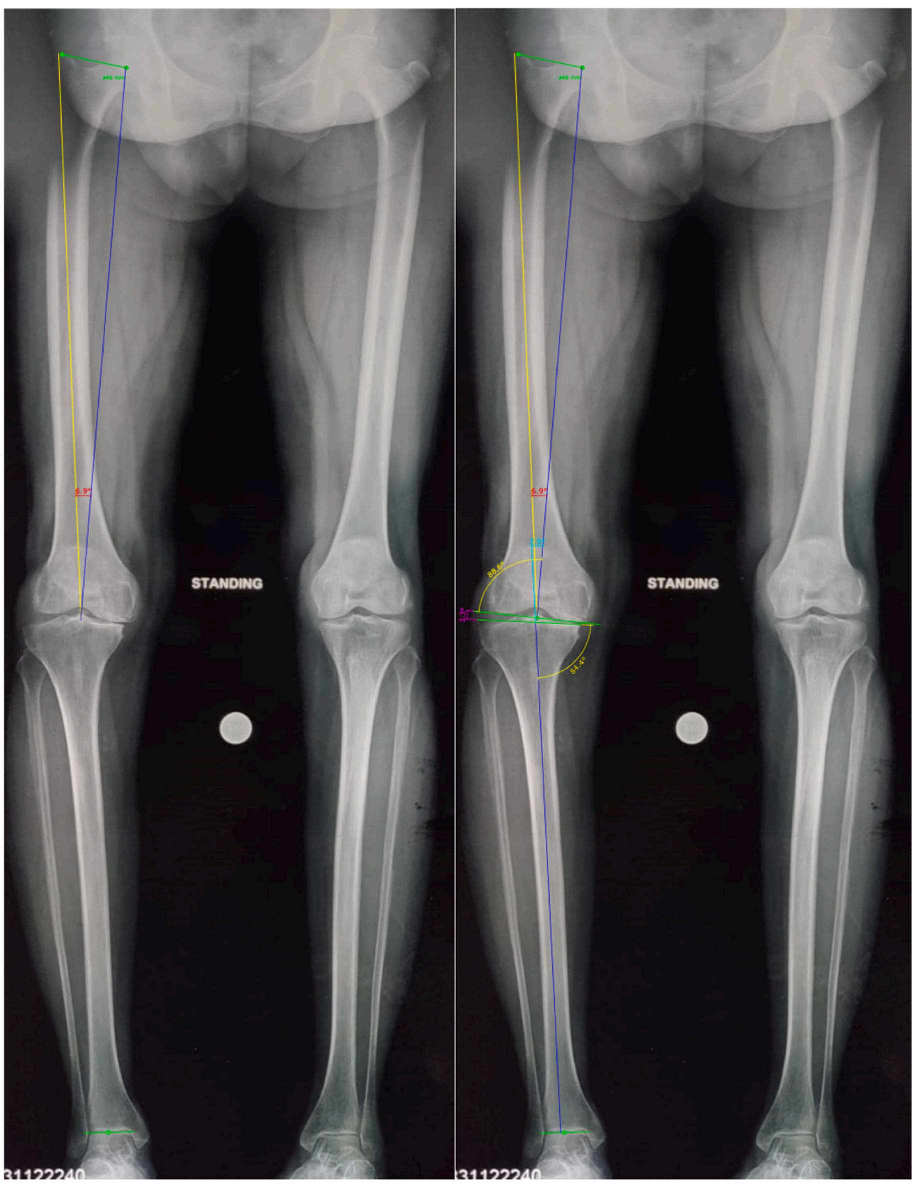


Fig. 1. a – Long film weight-bearing antero-posterior view radiograph showing the Femoral Axis angle (FAA), the angle subtended between the femoral anatomical axis and the mechanical axis Fig. 1b – Long film weight-bearing antero-posterior view radiograph showing the MPTA, mLDFA and JLCA Fig. 1c – Long film weight-bearing antero-posterior view radiograph showing the target MPTA set at 87° ± 1 Fig. 1d – Long film weight-bearing antero-posterior view radiograph showing the target tibial bony resection to achieve the under-corrected tibial varus.

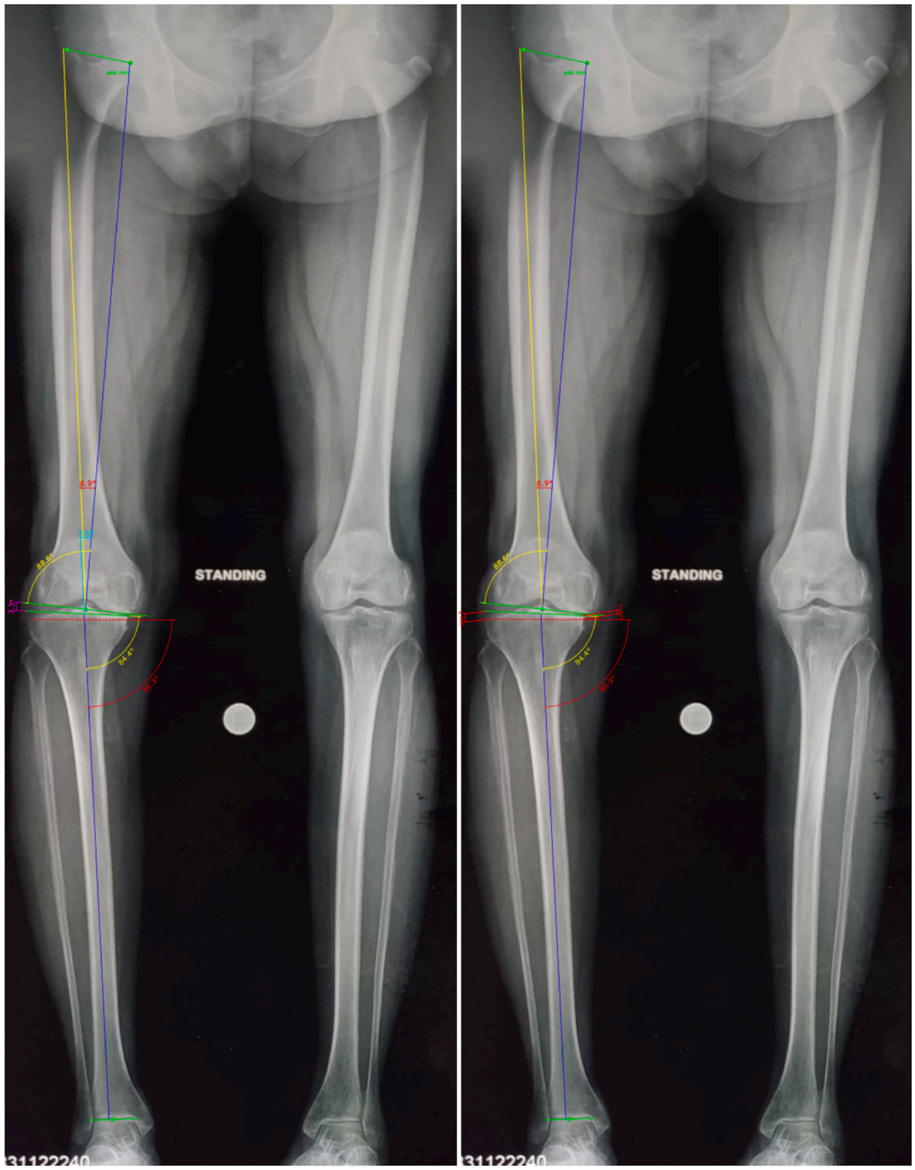


Fig. 1. (*continued*).

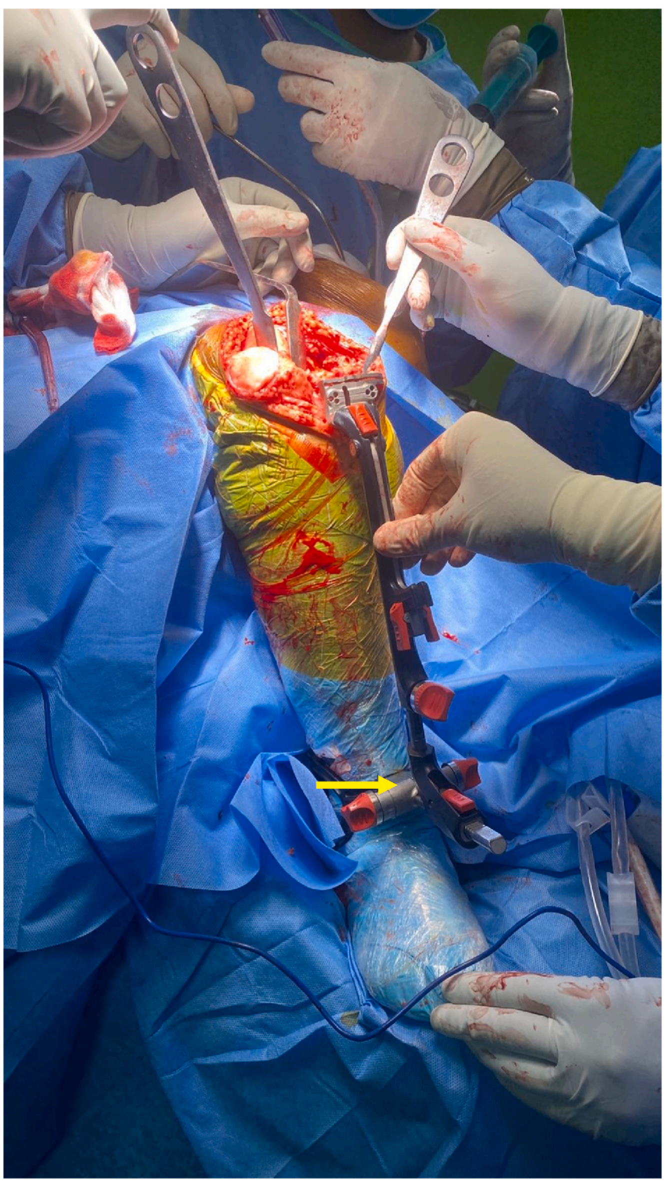
fixed flexion deformity (FFD) of more than 15° or uncorrectable varus deformity of more than 15° or with any extra-articular knee deformity were excluded from this study. All cases were performed by the senior-most arthroplasty surgeon, trained in the conventional technique of TKA. The surgeon introduced using rKA-TKA in his clinical practice for these specific subsets of varus OA knees and the first 5 cases performed were not included in this study analysis.

2.1. Pre-operative planning

All patients were planned for rKA-TKA with the help of weight-bearing scaled long film digital radiographs in an anteroposterior (A/P) view, including their bilateral lower limbs, using a standard and valid digital pre-operative templating software (mediCAD Hectec GmbH, Germany).[14] The hip centre, and the femoral anatomical and mechanical axis with the tibial mechanical axis were drawn. Following this, the proximal tibial joint line, distal femoral joint line, and ankle joint lines were marked. The angle subtended between the femoral anatomical axis and the mechanical axis was noted to be the femoral axis angle (FAA) (Fig - 1a). The medial proximal tibial angles (MPTA), mechanical lateral distal femoral angle (mLDFA), and the JLCA were also templated (Fig. 1b). The HKA angle was then calculated (Fig. 1b). The study was conducted to keep the tibial MPTA target at 87° ± 1 (Fig. 1c), with complete restoration of the distal femoral native anatomy (restoring the native mLDFA target angle ± 1°), with under-correction of the overall limb alignment, so that the HKA falls within its restricted boundaries. The HKA was targeted and restricted to ≤ ± 3°, or in other words the arithmetic combination of LDFA and MPTA was limited to ±3°. FAA is of utmost importance as we cannot restore the mechanical axis intra-operatively with the help of intramedullary distal femoral zig. We assumed the FAA to be the next higher absolute whole number or a lower absolute whole if it was more than or less than 0.5, respectively. For example, if the FAA was 5.6, it was assumed to be 6° and the distal femur valgus cut angle was set in the intramedullary zig at 6°. However, if the FAA was 7.1°, the distal femoral valgus cut angle was set at 7°. To create the tibial varus the medial tibial and lateral tibial bony resection values were pre-operatively planned. In varus knees subjected to TKA the medial tibia is usually completely denuded off its articular cartilage and the lateral tibia is either partially eroded (1 mm of articular cartilage is present) or completely preserved (2 mm of articular cartilage is present). This was taken into consideration while pre-operative tibial resection values were planned (Fig -1d). Component sizes were also templated pre-operatively using the same digital software (mediCAD Hectec GmbH, Germany).[14]

2.2. Surgical technique

All surgeries were performed with the patient in a supine position, with limited tourniquet use only during cementation using a standard medial parapatellar approach. Femoral resection was planned after adequate arthrotomy and visualizing the medial cartilage erosion status, with the planned valgus cut angle as templated pre-operatively with the resection value usually set at 9 mm. The distal femoral resection depth was adjusted if the patient had a pre-operative FFD, but it was never more than 2 mm over the usual 9 mm. The intramedullary rod of the zig was pivoted laterally before pinning the distal femoral cutting block to compensate for the medial cartilage erosion. This was followed by the proximal tibial cut to under-correct the tibial varus, with the extra-medullary zig at 3 degrees of posterior slope and with the distal end of tibial zig fixed at the centre using the varus/valgus adjustment knob so that a varus tibial cut can be executed (Fig - 2a). An adjustable tibial stylus is used according to the pre-operative resection value using the slotted feature over the tibial cutting block. If the lateral tibial cartilage is pristine then 1 mm is added over the pre-operative lateral tibial resection to compensate for the articular cartilage, and the block is fixed using pins. This was followed by tibial resection and confirmation of the medial and lateral tibial cut values using a calliper (Fig. 2b). Balancing of the knee was confirmed using the standard extension first gap balancing followed by flexion balancing. Anterior, posterior, and chamfer cuts were taken following the anterior referencing principle at 0 degrees of rotation on the cutting guide. The flexion gap stability was noted before taking the cuts using the same spacer block placed under the A/P chamfer cutting block. Box cut was taken using standard technique. Soft-tissue releases were planned only if adequate rectangular flexion or extension gap was not achievable using the spacer block. Balance was checked using standard trial components in extension, mid-flexion, and full flexion. Patellar tracking was confirmed by the routine “no thumb technique” throughout the knee range of motion.[15] This was followed by tourniquet inflation, through lavage, cementation, and final component placement. All cases were done using the same posterior stabilized (PS) cemented components with patelloplasty and peripheral denervation of the patella (Attune PS Knee system, Depuy, Johnson, and



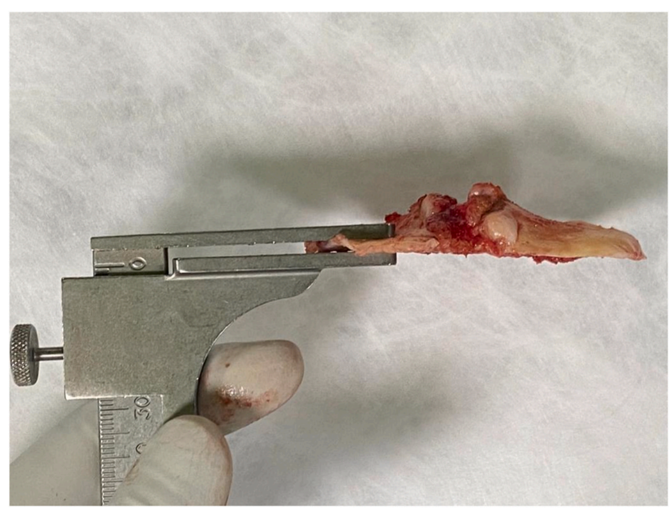


Fig. 2. a – intra-operative image suggesting the position of tibial zig, with the distal end of tibial zig fixed at the centre using the varus/valgus adjustment knob to achieve the varus tibial cut Fig. 2b – intra-operative image to note the resected lateral tibial cuts using a caliper.

Johnson).[16]

2.3. Intra-operative method for checking tibial varus

Following the tibial resection, the tibial varus alignment was rechecked using a long alignment rod over the adjustment handle fixed to the tibial trial base, and it was noted to be always pointing at the "third meta-tarsal" of the ipsilateral foot, in all cases undergoing rKA-TKA at 90 degrees of knee flexion and full extension (Fig. 3a and b). The ankle and the foot were always kept in neutral position with carefully avoiding any rotation at these joints. Any adjustment for the accurate varus tibial cut was done using a free-hand oscillating bone saw, at this stage if the pointer was aligned towards or at the second meta-tarsal, considering as minimum bony resection as possible.

2.4. Post-operative protocol

Rehabilitation protocol was the same for all the patients with a range of motion exercises, rigorous quadriceps strengthening, and supported full weight-bearing mobilization with a knee brace, from postoperative day 1. Patients were discharged to their houses with written and explained post-surgery rehabilitation protocol, when they could ambulate independently out of the bed with walking frames and their pain was in control with oral analgesics, usually by postoperative day 3.

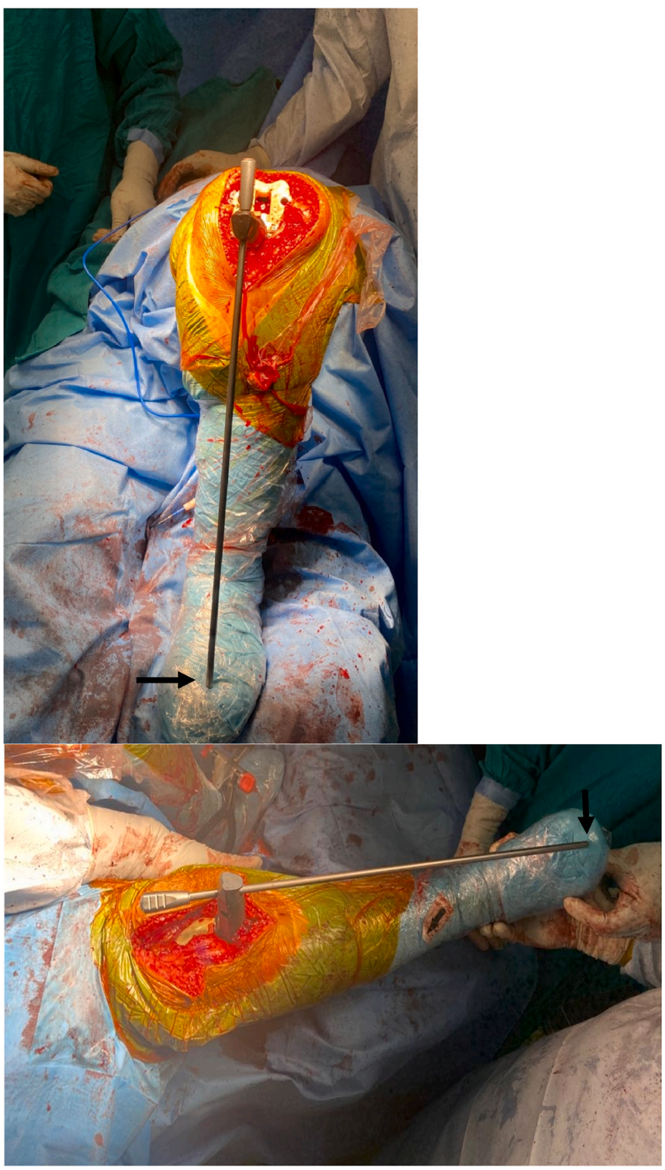


Fig. 3. a and b - Intraoperative technique of confirming the under-corrected native tibial varus, long alignment rod placed over the adjustment handle fixed to the tibial trial base, and it was noted to be pointing at the "third meta-tarsal" of the ipsilateral foot.

2.5. Outcomes measures and their assessment

Intra-operative data for any soft-tissue releases during balancing and the tibial, distal femoral, and posterior femoral resections were noted by a single assistant surgeon in all cases.

All patients followed up with post-operative long film weight-bearing full-length radiographs after their suture removal. Post-operative angular data of the proximal tibia, distal femur, and overall limb alignment were noted by measuring the MPTA, mLDFA, JLCA, HKA, and OLA (Fig - 4). Two independent observers (resident orthopaedic trainees) calculated all radiological outcomes two weeks apart.

2.6. Statistical analysis

All collected data was noted initially on a Microsoft Excel spreadsheet and tabulated after performing the statistical tests after surgery. All continuous variables were expressed as means and standard deviations and categorical variables in terms of absolute numbers. Data on the target and the achieved values of MPTA and mLDFA are plotted using scatter plots showing the accuracy of the technique. The correlation of the pre-operative target cuts values and intra-operative cuts values for tibial cuts were compared using the Pearson correlation test. Intra-observer and inter-observer reliability were tested by repeated measurements of all the radiological parameters. The result was expressed as intraclass correlation coefficients (ICC) with a 95 % confidence interval (CI). All statistical analyses were conducted using SPSS software version 25.0 (SPSS Inc., Chicago, IL, USA).

3. Results

Thirty patients (30 knees) were included in this study and they underwent crKA-TKA. All the patients were followed up after their suture removal on POD 14, at the end of their third or fourth post-operative week. The baseline demographic characteristics of the study participants are laid out in table-1. Pre-operative and post-operative angular corrections were satisfactory, with almost all cases within the MTPA target of $87 \pm 1^{\circ}$, and mLDFA reconstructed as per the native anatomy (Table 2, Fig. 5a and b). The HKA axis was noted to be within its set restricted boundary of $\pm 3^{\circ}$ (Table 2). There was a moderately fair to good correlation between pre-operative tibial resection values and those seen intra-operatively (Table 3). The medial distal femur cuts were 2 mm less than the lateral distal femoral cuts which ensures the cartilage compensation to restore the native distal femoral anatomy. Posterior condylar cuts were similar medially and laterally, which indicates neutral femoral component rotation (Table 4). Radiological parameters were assessed by two independent observers and with excellent inter-observer and intra-observer reliability (Table 5).

4. Discussion

The present study finding highlights that with careful individualized pre-operative planning using standard digital templating software, execution of crKA-TKA is a feasible option, even without the use of sophisticated tools like a computer-assisted navigation system or robotics. The selected cohort of consecutive patients receiving crKA-TKA further validates our novel intra-operative technique of under-correcting the native tibial varus, with the help of a long alignment rod mounted on the adjustable handle fixed to the trial tibial base, pointing towards the "third meta-tarsal" of the ipsilateral foot.

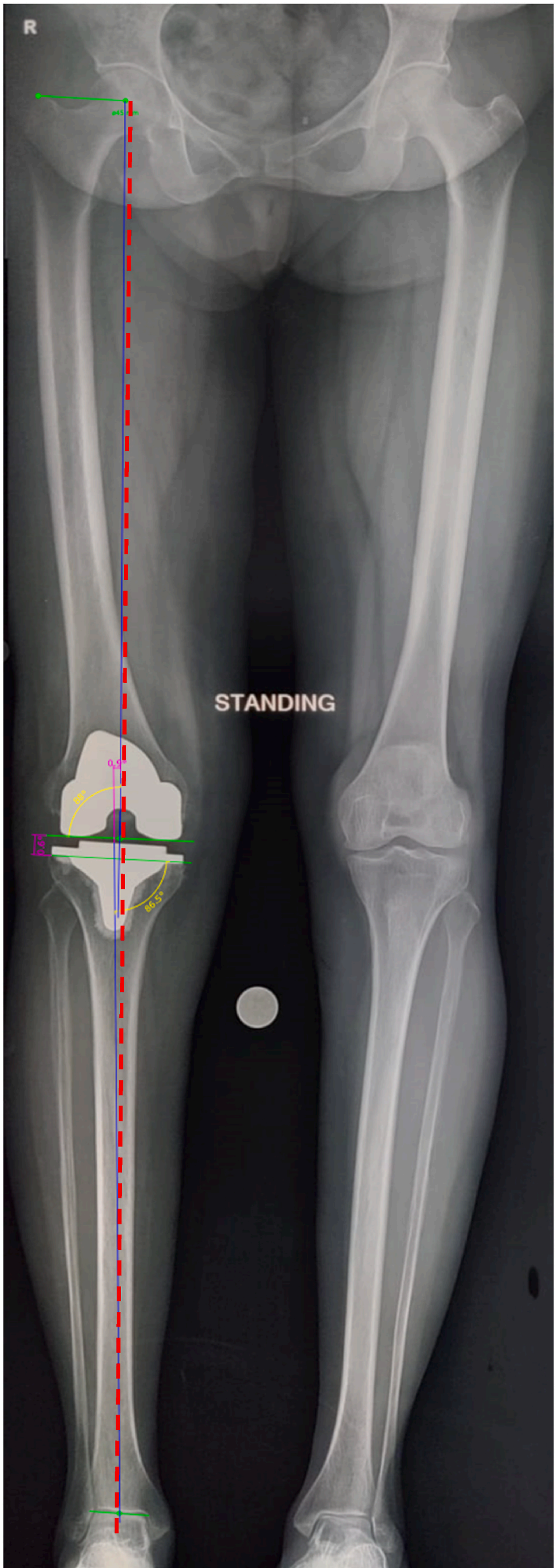


Fig. 4. Post-operative coronal measurements for crKA-TKA, the red dotted line represents the OLA.

Table 1
Baseline demographic criteria patients included in either groups.

Variables	Patients Demographics
Age (mean ± SD, 95 % CI)	63.42 ± 2.43, 61.29–67.23
Sex (M: F)	9:21
BMI (mean ± SD, 95 % CI)	30.02 ± 2.69, 29.65–32.34
Pre-op OKS (mean ± SD, 95 % CI)	16.23 ± 4.33, 14.46–17.86
Pre-op HKA (mean ± SD, 95 % CI)	10.04 ± 4.08, 9.86–10.78

Footnote – SD- Standard deviation.

Table 2
– Pre-operative and post-operative coronal alignment parameters.

Variables	crKA -TKA (mean ± SD, 95 % CI)	
	Pre-op	Post-op
Medial proximal tibial angle (MPTA) [in degrees]	82.41 ± 2.05, 81.72–83.09	87.48 ± 0.75, 87.194–87.759
Lateral distal femoral angle (LDFA) [in degrees]	90.53 ± 2.74, 89.51–91.56	90.301 ± 2.66, 90.23–91.63
Hip knee ankle (HKA) [in degrees]	10.04 ± 4.08, 9.83–10.781	3.56 ± 1.24, 3.19–4.12

Footnote – SD- Standard deviation.

Medical sciences have been constantly evolving, and a recent paradigm shift has also been noted in knee arthroplasties with the introduction of various alignment philosophies. An upcoming and trendy hybrid alignment philosophy considering the best of both kinematic and conventional mechanical alignment is the restricted kinematic alignment for TKA. Kinematic alignment (KA) remains a true bony procedure, with complete restoration of the native tibial varus, and distal femoral anatomy with overall limb alignment in the pre-operative same degree of varus.[17] For a large group of patients where the MPTA falls between 5 and 10 degrees of varus, aligning the knee according to the KA principles will lead to the tibial component in a large degree of varus. The increased medial stress because of the significant component varus can lead to aseptic loosening and early component failure.[8,9] Young et al. at their mid-term follow-up, at 5 years suggested no difference between KA and MA-TKA and advocated not to use KA-TKA except for research settings as the long-term survivorship of KA is still unknown.[18] On the other hand, conventional techniques in TKA were described as mechanically aligning the knees during TKA. However, this traditional mechanical alignment (MA) markedly alters the native anatomy and overall, completely corrects the lower limb alignment. This has been suggested to be disturbing the native anatomical joint lines,[19,20] and thus patients often do not perceive the native feel of their joints after surgery.[18,21,22] The concept of rKA has been recently introduced where the distal femoral native anatomy is restored, the native tibial varus and overall limb alignment are under-corrected. In other words, an under-corrected to neutral HKA alignment within the safe boundaries of $\leq \pm 3°$, with an anatomical joint line, is recreated with rKA.[23] Thus, rKA acts as a middle path, utilizing the benefits of both KA and the traditional MA. It is hypothesized to be targeting better patient-reported satisfaction after surgery with its restored natural limb alignment and kinematics.

The calipered method of performing KA has been widely studied already and has been projected to have a short overall learning curve. The present study highlights a calipered technique of conducting rKA-TKA, and a novel intra-operative method of checking the under-correction of native tibial varus. PROMs have also been studied between KA and MA already and some of the studies have shown improved outcomes of KA over MA, while others have denoted it to be non-inferior when compared to MA.[24–26] One of the recent meta-analyses by Liu et al.[27] has highlighted better functional outcomes of KA over MA-TKA. However, the most recent meta-analyses by Essen et al.[28] suggests although the functional outcomes of KA are better compared to

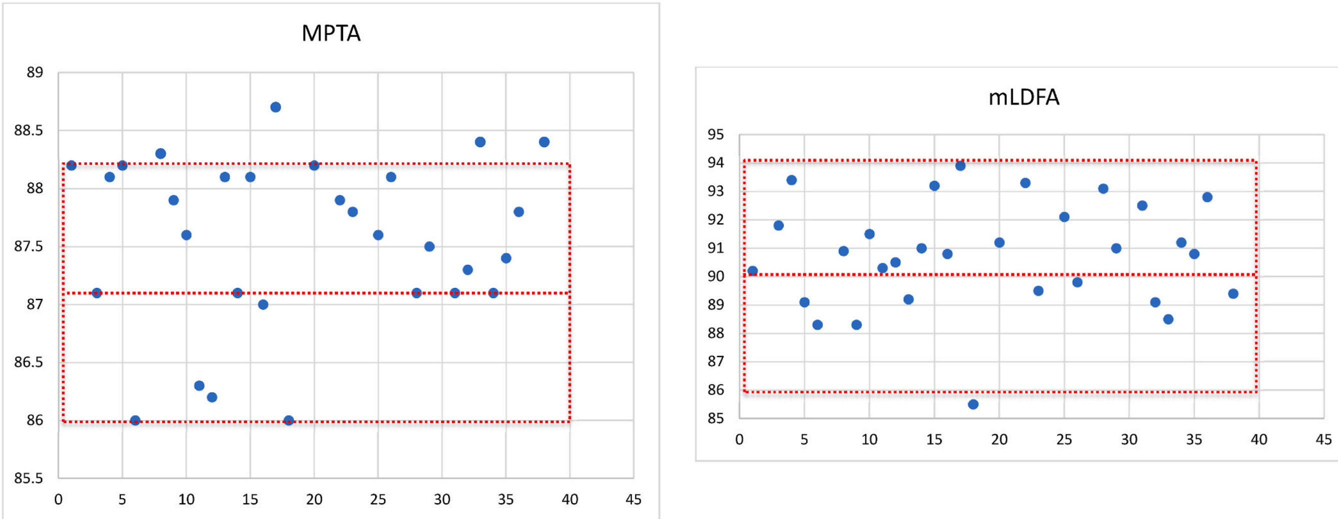


Fig. 5. a – Scatter plot MPTA of all patients withing the target range Fig. 5b – Scatter plot mLDFA of all patients withing the target range.

Table 3
– Correlation between pre-operative resection values planned and intra-operative executed

	Variables	Pre-operative planned (mean ± SD, 95 % CI)	Intraoperative values (mean ± SD, 95 % CI)	Correlation coefficient (r, P value)
crKA-TKA	***Medial Tibial Cuts (MTC) [mm]***	2.78 ± 0.7, 2.46–2.97	2.64 ± 0.82, 2.42–2.95	**0.424*, 0.01**
	Lateral Tibial Cuts (LTC) [mm]	8.23 ± 1.82, 8.12–9.24	7.89 ± 1.53, 7.44–8.45	**0.678*, 0.01**

Footnote – SD- Standard deviation; Statistically significant P values mentioned in Bold, * - Fair to good correlation.

Table 4
– Intra-operative resection values in patients undergoing crKA-TKA.

Variables	crKA-TKA (mean ± SD, 95 % CI)
Medial tibial Cuts (mm)	2.66 ± 0.682, 2.42–2.95
Lateral Tibial Cuts (mm)	7.89 ± 1.53, 7.44–8.45
Medial distal femoral cuts (mm)	6.47 ± 0.82, 6.21–6.77
Lateral distal femoral cuts (mm)	8.17 ± 1.32, 7.70–8.59
Medial Posterior femoral cuts (mm)	8.31 ± 1.18, 7.9–8.7
Distal posterior femoral cuts (mm)	8.18 ± 1.06, 7.81–8.52

Footnote – SD- Standard deviation.

Table 5
– Observer Reliability analysis of radiological parameters for crKA-TKA.

Variables	crKA-TKA	
	Intra-observer reliability (ICC, 95 % CI)	Inter-observer reliability (ICC, 95 % CI)
Medial proximal tibial angle (MPTA) [in degrees]	0.969[a] (0.952–0.991) 0.945[b] (0.880–0.975)	0.948 (0.885–0.977)
Lateral distal femoral angle (LDFA) [in degrees]	0.924[a] (0.845–0.968) 0.964[b] (0.920–0.984)	0.926 (0.916–0.983)
Hip knee ankle (HKA) [in degrees]	0.904[a] (0.794–0.956) 0.921[b] (0.808–0.960)	0.957 (0.905–0.981)

Intra-observer reliability ICC[a] – Between observer 1 at two separate occasions 2 weeks apart.
Intra-observer reliability ICC[b] – Between observer 2 at two separate occasions 2 weeks apart.

MA-TKA, they are not clinically significant. TKA according to the rKA protocol remains a less studied aspect according to the available literature. Recent literature highlights only one meta-analysis by Risitano et al.[29] included only 6 heterogeneous studies.[21,25,30–33] They concluded that rKA performs comparable or slightly better to MA-TKA considering the PROMs without increasing the risks of implant failure at short-middle-term follow-up. All these reported studies on rKA, have used robotic or computer-navigation assistance for conducting their surgeries. The present study on the contrary describes a conventional technique of reporting similar radiologically replicative results of rKA, with meticulous pre-operative planning.

This study highlights a technical note of performing the calipered rKA-TKA in a standard operating room set-up with routine surgical tools, which is economical and easily reproducible. The study further also describes a novel intra-operative technique for confirming the under-correction of native tibial varus bony cut, which gives scope for on-table adjustments if at all required. Despite this, the study has some limitations as well, like the replication of native tibial slope could not be verified using this standard technique. Although individually each case was carefully pre-operatively planned by a single assisting orthopaedic surgeon, this method of manual planning is observer-dependent and can lead to inadvertent biases included in this trial. We could only plan the cases for coronal angular alignment; however, we do agree that the latest technological guidance with robotics or computer navigation systems does help in achieving more accurate outcomes with intra-operative real time assistance of the precise resection values and asymmetric flexion-extension gaps. Post-operatively all radiological outcomes were evaluated independently by two different observers on separate occasions, which can be regarded as an important strength of this study. This novel technique of confirmation of the under-correction of native tibial varus, helps in refining the overall surgical accuracy and precision of crKA-TKA, making it more repeatable and reproducible. This technique will be utilized in future while conducting TKA following the caliper verified rKA principle, using standard routine instrumentation without any sophisticated tools. Further, we plan to study the patient reported outcome measures (PROMs) in crKA-TKA and compare it against the age old, conventional MA-TKA in future.

5. Conclusion

The present study validates a novel intra-operative technique of confirming an under-corrected native tibial varus while performing crKA-TKA. The radiological outcomes of the study confirm that with careful pre-operative planning coronal angular targets were easily achievable with very less outliers. The study further establishes that this method of calliper-verified technique in rKA-TKA using routine digital templating software and standard instrumentations is an alternative method of executing rKA in an era of sophisticated technologies like computer-aided navigation systems or robotics.

Learning points of the study

1. The study validates a novel technique where the tibial alignment rod was seen to be pointing towards the "third metatarsal of the foot" - to confirm the under-correction of tibial varus while performing total knee arthroplasty following the principle of caliper verified restricted kinematic alignment (rKA-TKA).
2. Careful pre-operative planning helps in execution of individual cases with minimum errors in achieving adequate angular correction and restoration while performing rKA-TKA.
3. This method of calliper-verified technique in rKA-TKA using routine digital templating software and standard instrumentations is an alternative method of executing rKA in an era of sophisticated technologies like computer-aided navigation systems or robotics.

Informed consent

Informed consent was taken from all individual participants included in the study.

Consent to participation

Not applicable.

Ethics approval

Ethics approval for the study had been taken from the institutional ethics committee before starting the study.

Ethical review committee statement

Not applicable.

Authors credit statement

A.K.C - Planning of study, literature search, writing the manuscript, outcome assessment.

S.B – Data management, manuscript preparation, revising the manuscript.

S.P. - Literature search, writing the manuscript.

B.S.R - Data management, outcome assessment, manuscript preparation.

S.A. - Literature search, writing the manuscript.

R.B.K - Planning of study, writing and revising the manuscript

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Nil.

Conflict of interest statement

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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