

Evaluation of tibial tray coronal plane alignment in total knee replacement using intramedullary JIG-a prospective study

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Abstract

Introduction: Long term survivorship in total knee replacement [TKR] is significantly dependant on prosthesis alignment. In a standard total knee replacement, tibial component alignment is a key factor for the long-term success of the surgery. **Materials and Methods:** A prospective observational study on 176 subjects who underwent TKR with intramedullary jig for tibial alignment with a minimum follow up period of 6 months was conducted in the Department of orthopaedics, KIMS Al Shifasuper-specialty hospital, Kerala. The Tibial component alignment was measured by the Tibial Component Angle [TCA] and Error in Tibial tray alignment. The other outcome variables were knee score, functional score, and Tourniquet time. **Results:** The mean TCA in the study population was $90.56 \pm 1.194^\circ$ ranging from 86.45° to 94.05° . The mean error observed in tibial tray alignment was -0.56 ± 1.199 degrees, ranging from -0.45 to $+ 3.55$ degrees. Accuracy of TCA within 90 ± 2 degrees was achieved in 91.48% of subjects. The mean knee score at 6 months was 89.45 ± 3.83 . The mean functional score at 6 months was 87.55 ± 4.93 . The mean tourniquet time was 59.08 ± 5.88 minutes. **Conclusions:** Intramedullary tibial referencing guide can be used in TKR with great accuracy (91.48%) to achieve desired coronal plane tibial component alignment (90 ± 2). When TCA was accurate, knee score and functional score were better than non-accurate TCA cases

Keywords: Tibial Component Angle [TCA], Total Knee Replacement [TKR], Total Knee Arthroplasty [TKA], intramedullary jig, Tibial tray alignment.

Introduction

Total knee replacement [TKR] surgery, or Total knee arthroplasty [TKA], is a highly effective procedure for end stage knee arthritis giving highly gratifying functional results. With increasing indications for TKR, younger patients are also undergoing TKR because of longer survival of the prosthesis [1,2]. Long term survivorship in TKR is significantly dependant on prosthesis alignment and balancing. In a standard TKR, tibial component alignment [TCA] is a key factor for the long term success of the surgery [3-5].

This becomes more so important when we are using gap balancing technique. Out of the 6 bone cuts in TKA, probably the most important one is the tibial cut. The restoration of neutral mechanical alignment in femur and tibia, achieved in coronal and sagittal plane with the

transverse axis of knee made parallel to the ground results in best alignment of TKR [6,7]. Malposition of the components is the main cause of early failure [7]. Of the three planes, coronal plane mal-alignment is a major cause of wear, loosening, instability, failure and revision surgeries [8] and hence restoring it is one of the most important goals. Although the gold standard guide for achieving coronal plane alignment for the femoral cut is intramedullary jig [9,10], a few popular choices exist for tibial cuts such as conventional intramedullary jig, conventional extra medullary jig or computer assisted navigation.

Conventional intramedullary and extra medullary techniques are used most commonly depending on the surgeon preferences and institutional protocols. It is less reliable to use an extra medullary guide in obese patients [4,11] but on using intra medullary guide the positioning and orientation of the tibial cut is carried out

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more accurately besides reduced surgical and tourniquet time [3,9]. The neutral mechanical alignment in tibia in the coronal plane means the tibial base plate of the tibial component of TKR should be perpendicular to the mechanical axis of tibia which is measured by the Tibial Component Angle [TCA] and error in tibial tray alignment [12]. In developing countries, the cheaper, easier, conventional alignment guides are used and studies on results of intramedullary guide regarding coronal plane alignment in Indian population is very limited.

Our hospital is using primarily intramedullary guide for tibial tray alignment. Hence, we carried out our study with the primary objective of measuring the TCA and the error in tibial tray alignment and our secondary objective was to compare the impact of accuracy in tibial tray alignment within $90^{\circ} \pm 2^{\circ}$ on knee score and functional score, and also measure tourniquet time, knee score and functional score in the study population.

Materials and Methods

Place of study: Department of orthopedics, Kims Al Shifa super-speciality hospital, Perinthalmanna Kerala, from October 2015 to July 2016

Type of study: Prospective observational study

Sampling methods: Convenient sampling, Sample size was calculated as 108 by assuming the expected TCA angle to be 90 with a standard deviation of 3.2 as per study by Da Rocha Moreira Rezende B et al [13] and a null value of 89 degrees with 90% power and 5% alpha error using the formula proposed by Kirkwood B et al [14]. Our primary outcome variables were TCA and error in tibial tray alignment. The Secondary outcome variables were Tourniquet time, knee score, functional score.

Sample size and collection: 176 subjects who underwent TKR with intramedullary jig for tibial alignment with a minimum follow up period of 6 months were the subjects. TCA, error in tibial tray alignment, Tourniquet time, knee score and functional score were obtained from all the samples (subjects). TCA is the medial angle formed between mechanical axis and the tibial base plate line [12,13]. It was measured using a previously published and validated method [14]. The error in tibial tray alignment was calculated by subtracting 90° from TCA. If the TCA is less than 90° then the tibial component is in varus and if it is more than 90° then the tibial component is in valgus.

Inclusion criteria: We included subjects who had undergone primary TKR [cruciate retaining/Posterior stabilized].

Exclusion criteria: Subjects with extra articular deformities of tibia in sagittal or coronal plane or with implants that may impede the passage of intramedullary jig were excluded. We also excluded subjects who underwent revision TKR, and those who were lost to follow up and who developed periprosthetic fractures.

Statistical Methods: Data was entered in Microsoft excel. IBM SPSS version 22 was used for statistical analysis. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables.

Independent sample t-test/ ANOVA/ Paired t- test was used to assess statistical significance for Quantitative outcome while Chi square test was used for Categorical outcome. P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

Any specific score: Modified knee society score

Surgical process: Along with detailed history, Pre-operative Clinical, Radiological assessment and basic laboratory investigations were done with measurement of knee society score.

All cases were operated with Smith and Nephew Genesis II total knee prosthesis under spinal or combined epidural and spinal anesthesia by the same surgeon. The tibial intramedullary jig entry point was marked at intersection of lines drawn from lateral tibial spine and medial 1/3rd of tuberosity and another line crossing the 1st line at anterior 1/3rd and posterior 2/3rd junction using a marker pen.

Stem less tibial tray trial of appropriate size was used to further confirm the entry point. Total knee prosthesis cruciate retaining or posterior stabilized [depending on status of PCL and degree of deformity] was fixed.

TCA and error in tibial tray alignment were also measured. Post-operative radiological assessment and measurements were then done.

The subject was discharged from hospital to home on day 5 and was reviewed after 2 weeks for suture removal and was reviewed again at 6 weeks, 3 months and at 6 months.

Results

A total of 176 subjects were included in the analysis.

Table-1: Summary of base line characteristics (N=176)

Base line characteristics	Summary
Age in years (Mean \pm S.D)	64.42 \pm 7.182
Gender	
Male	62 (35.23%)
Female	114 (64.77%)
BMI category	
Normal	6 (3.41%)
Over weight	136 (77.27%)
Obese	34 (19.32%)
Side	
Right	91 (51.70%)
Left	85 (48.30%)
Pre-op coronal plane deformity	
Genu varum	158 (89.77%)
Genu valgum	18 (10.23%)
Diagnosis	
Osteoarthritis (OA)	166 (94.3%)
Rheumatoid arthritis (RA)	7 (4.0%)
Post traumatic arthritis (PA)	2 (1.1%)
Osteonecrosis (ON)	1 (0.6%)
Tibial component angle [TCA] in degrees (Mean \pm SD)	90.56 \pm 1.194
Error in tibial tray alignment in degrees (Mean \pm SD)	-0.56 \pm 1.199
Accuracy	
Yes	161 (91.48%)
No	15 (8.52%)

Among the study population, the mean age was 64.42 \pm 7.182 years. Among the study population male participants were 62 (35.23%) remaining 114 (64.77%) were female participants. Among the study population, 6 (3.41%) were normal, 136 (77.27%) were overweight and 34 (19.32%) were obese.

Among the study population, side was right in 91 (51.70%) subjects and the remaining 85(48.30%) had left. Among the study population, pre-op coronal plane deformity was genu varum in 158 (89.77%) subjects and the remaining 18 (10.23%) had genu valgum.

Among the study population, diagnosis was Osteoarthritis (OA) in 166 (94.3%), Rheumatoid arthritis (RA) in 7(4.0%), Post traumatic arthritis (PA) in 2(1.1), and Osteonecrosis (ON) in 1 (0.6%) respectively.

Among the study population, the mean tibial component angle (TCA) was 90.56 \pm 1.194 $^\circ$ in degrees. Among the study population, the mean error observed was -0.56 \pm 1.199 in degrees. Among the study population accuracy was achieved in 161 (91.48%) and accuracy was not achieved in 15 (8.52%) of subjects (Table 1).

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Table-2: Descriptive analysis of post-operative deformity and complications in the study population (N=176)

Post-operative deformity and complications	Summary
Post-op coronal plane deformity	
Valgus	6 (3.41%)
Varus	9 (5.11%)
No deformity	161 (91.48%)
Complications detected if became symptomatic	
Yes	2 (1.14%)
No	174 (98.86%)

Among the study population, post-op coronal plane deformity was valgus in 6 (3.41%) subjects and the remaining 9(5.11%) had varus deformity. Among the study population, post-operative complications were detected in 2 (1.14%) of study population (Table 2).

Table-3: Descriptive analysis for other post-operative parameters in study population (N=176)

Parameter	Mean \pm SD
Tourniquet time in minutes	59.08 \pm 5.879
Knee score at 6 months	89.45 \pm 3.831
Functional score at 6 months	87.55 \pm 4.927

Among the study population, the mean tourniquet time was 59.08 \pm 5.879 minutes. Among the study population, the mean knee score at 6th month was 89.45 \pm 3.831. Among the study population, the mean functional score at 6th month was 87.55 \pm 4.927.

Table-4: Comparison of mean tibial component angle in degrees across study groups (N=176)

BMI category	Mean \pm SD	Mean difference	95% confidence interval for mean		P value
			lower bound	upper bound	
Normal	90.33 \pm 0.554				
Over weight	90.61 \pm 0.846	0.278	-0.708	1.265	0.578
Obese	90.43 \pm 2.132	0.10	-0.943	1.152	0.844

The mean tibial component angle in degrees among normal group was 90.33 \pm 0.554, 90.61 \pm 0.846 among over weight group and 90.43 \pm 2.132 among obese group. Considering normal group as base line, the mean difference of tibial component angle in degrees (0.278) in over weight group was statistically not significant (P value 0.578) and obese group (0.10) was also statistically not significant (P value 0.844). (Table 4)

Table-5: Comparison of mean knee score at 6 months across study groups (n=176)

Accuracy	Knee score at 6 months Mean \pm SD	Meandifference	95% CI		p value
			lower	upper	
Yes	90 \pm 3.372	6.40	4.59016	8.20984	<0.001
No	83.6 \pm 3.660				

The mean of knee score at 6 months was 90 \pm 3.372 in subjects with accuracy and without accuracy 83.6 \pm 3.660. The mean difference (6.40) between two group was statistically significant (P value <0.001).

Table-6: Comparison of mean functional score at 6months across study groups (N=176)

Accuracy	Functional score at6months Mean \pm SD	Mean difference	95% CI		P value
			lower	upper	
Yes	88.32 \pm 3.910	8.99	6.72602	11.25327	<0.001
No	79.33 \pm 7.037				

The mean of functional score at 6 months was 88.32 ± 3.910 in subjects with accuracy and without accuracy 79.33 ± 7.037 . The mean difference (8.99) between two group was statistically significant (P value <0.001) difference across the group is (8.99). It is statistically significant (p value<0.001).

Discussion

One of the most common major surgeries performed to alleviate pain caused by moderate to severe *knee arthritis is TKR*. In our study, from October 2015 to July 2016, 176 patients underwent TKR using intra medullary jig at Kims Al Shifasuper-specialty hospital, Perinthalmanna, Kerala. If a patient had undergone bilateral TKR both knees were considered separately. About 8 patients had simultaneous bilateral TKR in a single sitting. The idealtibial component angle should be $90^\circ \pm 2^\circ$ [13]. If the Error intibial tray alignment was more than $+2^\circ$, it was considered as varus deformity [tibial component angle $<88^\circ$] less than -2° was considered as valgus deformity [tibial component angle $>92^\circ$].

The mean age group of the subjects in our study was 64.42 ± 7.182 years almost similar to that observed by Reed MR et al [4] with 69 years and, Cashman JP et al [15] with 68.9 years. In our study group, majority were females constituting to about 64.74% of the study group higher than that reported by Reed MR et al[4] with 48.15% but lower than reported by Cashman JP et al[15] (79%). In our study, 51.7% of surgeries were done on right knee higher than that reported by karade V et al [13] with 44.44%. In our study, 89.77% of them had genu varum as pre-op coronal plane deformity as reported by other authors[4, 13] while 94.3% of subjects had osteoarthritis as pre-op diagnosis in our study similar to that reported by Reed MR et al[4] with 94.44%.

In our study, the mean TCA was $90.56^\circ \pm 1.94^\circ$ which was similar to that reported by Reed MR et al [4] with a Mean TCA of 90.8 degrees. da Rocha Moreira Rezende B et al[16] in their study reported a mean of 90.3 degrees. In our study, the mean error observed in TCA was $-0.56^\circ \pm 1.99^\circ$ and similarly Karade V et al [13] also observed a mean error in TCA of $-0.34^\circ \pm 2.3^\circ$. In our study, the Mean error was less compared to the Studies by Blakeney WG et al [17] and Chin PL et al [18].

Proper alignment of TKA prosthesis requires that the tibial component stem be parallel to mechanical axis of tibia[19]. As the tibial component base plate aligns itself along the cut plane, an accurate alignment of the cut plane with respect to the anatomical axis of the bone becomes very important. The cut should be perpendicular to the anatomical axis of the tibia. In our study, the accuracy within $90^\circ \pm 2^\circ$ was achieved in 91.48% of cases, which was higher than that observed by Reed MR et al [4] with 85% of the cases while Karade V et al [13] observed a very lower percentage with only 67% in the optimal range.

The accuracy obtained by intramedullary jig in our study was higher than the accuracy of most of the studies published in the literature using either intramedullary or extra medullary jig. But in the study by Cashman JP et al [15] all subjects were within two standard deviations of the mean alignment. In our study, the most severe post-op varus angle was 86.45° while valgus angle was 94.05° .

In our study, when TCA was accurate, then knee score and functional score was better on comparison with non-accurate TCA. In our study, the difference in TCA between various categories of BMI didn't have any influence on TCA while using intramedullary jig. It establishes that intramedullary jig can be used in obese persons to get good accuracy in situation where extra-medullary jig produces difficulty to find anatomical landmarks to align.

However, Lozano et al [11] examined obese patients and found no difference in the alignment of the tibial component between intra and extramedullary guides but he observed a reduced tourniquet time associated with the intramedullary guide. This is justified by the fact that the positioning and orientation of the tibial cut with intramedullary referencing is carried out more rapidly as anatomical references are not needed and the correct orientation is guided by the anatomical axis of the tibia.

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One of the limitations of our study was that only coronal plane alignment was considered as it is known to be associated with a poor outcome. Our study had only short follow up of 6 months duration. Patients were not evaluated with devices to know the effect of opening the tibial marrow canal.

Conclusion

We conclude that intramedullary tibial referencing guide can be used in TKR with great accuracy (91.48%) to achieve desired coronal plane tibial component alignment ($90^{\circ} \pm 2^{\circ}$). When TCA was accurate, knee score and functional score were better than non-accurate TCA cases emphasizing the results from various studies that accurate placement of the implant may have a role in long term survival of the implant. High BMI did not affect the accuracy of tibial component angle in our cases using intramedullary jig. The accuracy of TCA using intramedullary jig in our study was better compared to accuracy using extramedullary jig in most of the published studies.

The First author of this article conducted the study after getting ethical clearance under the guidance of second author. Discussion was written by the second author. Sample selection, recruitment, Data collection and analysis were done by the first author. This study was done entirely by using instruments and implants of a particular manufacturer and hence the results may not be generalized, which emphasizes the need for large studies involving commonly used implants across India.

In developing countries like India, the cheaper and conventional alignment guides are still used but data regarding accuracy of intramedullary tibial referencing guide in TKR was very limited. Our study adds further knowledge that intramedullary tibial referencing guide can be used in TKR with great accuracy to achieve desired coronal plane tibial component alignment.

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