RESEARCH ARTICLE

The Effect of Intramedullary vs Extramedullary Tibial Guides on the Alignment of Lower Extremity and Functional Outcomes Following Total Knee Arthroplasty: A Randomized Clinical Trial

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Abstract

Objectives: Total knee arthroplasty (TKA) has been known as a definitive treatment for advanced knee osteoarthritis. Both intramedullary (IM) and extramedullary (EM) tibial guides have been used to restore the desired extremity alignment. However, controversy exists regarding the superiority of either technique We aimed to compare the functional outcomes and accuracy of IM and EM tibial guides in providing neutral alignment after TKA.

Methods: In a randomized, double-blinded clinical trial, we studied 98 patients undergoing primary TKA in two groups of IM and EM. We measured the medial proximal tibial angle (MPTA), varus angle (VA), and joint-line convergence angle with normal ranges of 90°±3°, 0-2°, and 0±3°, respectively, on a three-joint alignment view after three months. We also assessed the functional outcomes at the last follow-up. Finally, we compared these outcomes between the two groups.

Results: Eighty-four patients (IM=42, EM=42) were included in the final analysis (16 males, 68 females, mean age: 63.9±8.6 years, mean follow-up: 13±2.9 months). The mean postoperative (post-op) alignment angles showed no significant difference, although MPTA outliers were significantly more frequent in the EM group (26.2% vs. 9.5% in IM, P=0.04). None of the functional outcomes showed a significant difference between the two groups. However, the mean increase in knee range of motion (ROM) was significantly higher in the knees with VAs within ±3° of neutral than those outside this range (30.8 vs. 27.4, respectively, P=0.039).

Conclusion: We conclude that both techniques were not different regarding the mean alignment angles and functional outcomes. However, fewer MPTA outliers can be seen with the IM technique. A post-op mechanical axis within ±3° of neutral can result in a more ROM increase after one year.

Level of evidence: I

Keywords: Extramedullary guide, Functional outcome, Intramedullary guide, Total knee arthroplasty

Introduction

Total knee arthroplasty (TKA) has been known as an end to analgesics in patients with knee osteoarthritis and as a means of restoring physical activity and function.[1] Several factors are influential in the long-term outcome of a TKA, including patient selection, the prosthesis of use, and surgical technique.[2] The surgical technique is of great importance among knee surgeons as it should implement proper lower extremity alignment for a good long-term prognosis.[1-3] several studies have reported poor outcomes of lower extremity malalignment, as prosthesis mispositioning can lead to loosening, recurrence of pain, and compromised physical performance.[4-8]

Among surgical techniques, both intramedullary (IM) and

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extramedullary (EM) tibial guides have been used to provide the desired lower extremity alignment. However, there are still controversies over the outcome of TKA using either technique to provide a neutral alignment.[1, 9] some studies have preferred one for providing a more accurate tibial alignment, [9-11] while others found no significant difference between the two techniques.[1, 12-14] many studies have demonstrated that most knees are suitable for both techniques; however, this is not always the case. The EM guides are unreliable in soft tissue or ankle abnormality, whereas the IM technique is not preferred in patients with excessive tibial bowing, previous fracture, or retained metalwork.[9] Moreover, the functional outcomes following both techniques were compared only by a few studies.[10, 15] In the present study, we decided to compare the accuracy of IM and EM techniques in providing neutral lower extremity alignment in patients undergoing TKA. We also compared the functional outcomes following TKA between both techniques.

Materials and Methods

This randomized clinical trial was designed and reported based on the CONSORT principles. The Ethics Committee Board of our institute declared no ethical concern in the current study. This study was registered in the clinical trial registry of our country with the identification number of IRCT20160809029286N5.

Study design and participants

This study was a randomized controlled clinical trial. A total of 98 consecutive patients who met the inclusion criteria of the study were enrolled through the orthopedic clinic of our institute. The inclusion criteria were patients with primary knee osteoarthritis indicated for TKA who had a varus or neutral knee alignment. On the other hand, the exclusion criteria were: 1) hemophilia, 2) inflammatory knee arthritis, such as rheumatoid arthritis, 3) previous tibial fracture, 4) genu valgum, and 5) inadequate radiographs.

Study protocol and interventions

The enrolled patients were admitted and underwent pre-operative imaging and TKA according to the study protocol. The patients participated voluntarily and signed the informed consent. An assistant researcher did the data collection and clinical assessment of the functional outcomes following the surgery, and a single experienced knee surgeon performed all the TKAs.

Imaging protocol

A full standing three-joint alignment view (3-JV) of the lower limb, as well as the anteroposterior (AP) and lateral knee projections, was performed for each patient before and three months after the surgery. For the 3-JV, the patient must stand with the knees in full extension and no aid. The patella should face forward in the direction of the x-ray beam. The collimator is set superiorly on the iliac crest and inferiorly on the sole. The radiograph is composed automatically after three projections done by the CARESTREAM DRX-Evolution device (Carestream Health Inc., US). The alignment angles of the lower limb were measured on 3-JV using the MediCAD software (version 3.50) by a single experienced knee surgeon. The acceptable (inlier) range for medial proximal tibial angle (MPTA), joint-line convergence angle (JLCA), and varus angle (VA) was considered 90°±3°, 0-2°, and 0±3°, respectively.

Surgical technique

After spinal anesthesia and standard prepping and draping, TKA was performed using a standard anterior midline incision with the anteromedial approach. A pneumatic tourniquet had been applied above the knee prior to the operation. After releasing the medial soft tissue of the knee, we subluxated the patella and, subsequently, exposed the proximal tibia. For femoral cuts, we used an IM jig, and to perform the tibial cut, we used an IM or EM jig in each group accordingly. According to the preoperative planning, the entry point for the IM jig was the center of the tibial axis, on the tibial plateau, anterior to the insertion of the anterior cruciate ligament. The EM jig was mounted on the leg, parallel to the tibial axis, and leveled proximally with the tibial crest in the coronal plane and distally with the talus center in the axial plane (3mm medial to ankle center). The posterior slope of the tibial cut was performed according to the prosthesis design that is 7° for Zimmer NexGen © LPS-Flex (Zimmer Biomet ®, Warsaw, Indiana, US). The external rotation cut was made perpendicular to the whiteside and parallel to the transepicondylar axes. We used a cemented posterior stabilized NexGen© LPS-Flex Knee prosthesis (Zimmer Biomet ®, Warsaw, Indiana, US) in all patients. Finally, standard wound closure and care were done.

Outcomes

The primary outcome measures were the radiologic and functional outcomes assessed pre- and postoperatively. The radiologic outcomes included the MPTA, mechanical femoral mechanical tibial (MFMTA) or VA, and JLCA. The functional outcomes included the knee society score (KSS), functional knee society score (fKSS), pain visual analog scale (VAS), and the measurement of knee range of motion (ROM). The postoperative (post-op) assessment of the radiologic and functional outcomes was performed three months post-op and in the last follow-up visit, respectively.

Sample size

The sample size was calculated based on the study of Chin et al.[16] which compared the three techniques of IM tibial guides, EM tibial guides, and computer-navigated surgery in patients undergoing TKA. We used the risk ratio of post-op MPTA angle outliers (p_1=43.34% IM vs. p_2=13.34% EM) as a reference value for power analysis and assumed a β-value of 20% and an α-value of 5%. We found that 35 patients per group (70 patients in total) were required to achieve statistical significance. The calculations are presented below. We considered a sample size of at least 90 to compensate for possible losses during the follow-up.

$$n_1 = \frac{\left\{ z_{1-\frac{\alpha}{2}} * \sqrt{\overline{p} * \overline{q} * \left(1 + \frac{1}{k}\right)} + z_{1-\beta} * \sqrt{p_1 * q_1 + \left(\frac{p_2 + q_2}{k}\right)} \right\}^2}{\Delta^2}$$

$$q_1 = 1 - p_1,\ q_2 = 1 - p_2\ ,\ \overline{p} = \frac{p_1 + kp_2}{1+k}\ ,\ \overline{q} = 1 - \overline{p}\ , \Delta = |p_1 - p_2|, k = \frac{n_2}{n_1} = 1$$

Randomization and blinding

The patients were randomly assigned to two groups of IM (n=48) and EM (n=48), based on the tibial guide used during the surgery. The patients had an equal chance of being randomly assigned to each of the two study groups. The randomization of patients was conducted using the permuted balanced block method. Six blocks of four were assumed, and the patients were divided into 21 sequentially numbered groups. The groups were randomized using a list of random numbers generated by Microsoft Excel 365, and the patients of each group were allocated to each intervention arm accordingly. The randomization sequence was concealed before the enrollment until the patient was transferred to the operation room. An independent researcher who was not involved in the data collection and outcome assessment performed the randomization. This study was triple-blinded, as neither the patient, the assistant researcher, nor the analyzer researcher was aware of the technique used during the surgery.

Data analysis

Data were analyzed by the SPSS software (version 25.0, SPSS Inc., Chicago, Illinois, US). The normality of the variables was tested by the skewness-kurtosis and Spearman tests. The Student's independent t-test was used to compare continuous outcome variables, such as the alignment angles in both groups. On the other hand, the Chi-squared and Fischer's exact tests were used to compare the nominal outcome variables. The significance level was set at 0.05.

Results

A total of 98 patients who underwent TKA using either EM or IM tibial guide were included in the study from September 2018 to May 2019. Two patients were excluded as they declined to participate in the study. The patients were randomized into two groups of IM (n= 48) and EM (n=48) tibial guides. All of them received the allocated intervention, and there was no loss of follow-up. Twelve patients were excluded from the final analysis due to inadequate post-op radiographs. The CONSORT flow chart is shown in [Figure 1].

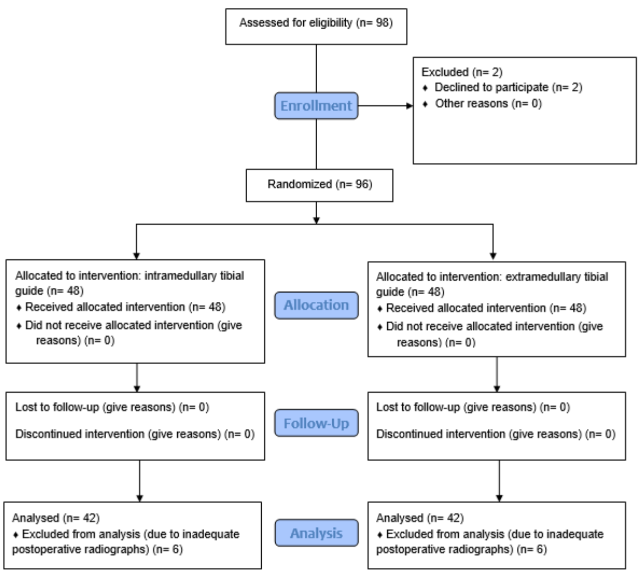

Figure 1. CONSORT flowchart of the study

The mean age and body mass index (BMI) of patients were 63.9±8.6 and 29.6±4.8, respectively. There were 16 (19%) males and 68 (81%) females. The mean follow-up duration was 26±5.8 months. As seen in [Table 1], both groups had the same and matched demographics (P>0.05) [Table 1].

As seen in [Table 2], the mean of the lower limb alignment angles, including MPTA, JLCA, and VA, was compared between both groups preoperatively and three months postoperatively. The findings showed no significant difference between the two groups regarding the lower limb alignment angles (P>0.05) [Table 2].

Table 1. Demographic data of the patients

		IM (N = 42)	EM (N = 42)	*p* Value	Total (N = 84)
Age (years)		66.0 ± 9.8	62.4 ± 7.4	0.56*	63.9 ± 8.6
Sex	*Male*	10	6	0.71**	16
	Female	32	36		68
BMI (Kg/m²)		29.5 ± 5.1	29.6 ± 4.7	0.92*	29.6 ± 4.8
Follow-up (months)		25.6 ± 3.8	26.4 ± 7.4	0.93*	26 ± 5.8

The mean ± standard deviation is reported for age, BMI, and follow-up (* independent *t* test).
The frequency is reported for sex (** chi-square test).

Table 2.The preoperative vs. postoperative alignment angles of lower extremity (MPTA, JLCA, and VA) in both groups of the study

		Intramedullary Mean (SD)	Extramedullary Mean (SD)	*p* Value*	Total Mean (SD)
MPTA	*Preop*	84.3 (±2.9)	84.8 (±4.1)	0.48	84.6 (±3.7)
	Postop	88.9 (±2.1)	88.4 (±2.9)	0.42	88.6 (±2.6)
JLCA	*Preop*	9.0 (±5.0)	9.2 (±8.2)	0.88	9.1 (±7)
	Postop	0.5 (±1.2)	0.2 (±0.5)	0.12	0.3 (±0.9)
VA	*Preop*	15.7 (±7.9)	14.3 (±7.5)	0.38	14.9 (±7.7)
	Postop	3.5 (±2.7)	3.4 (±2.2)	0.86	3.4 (±2.4)

* independent t test

As mentioned earlier, we considered the normal range (inliers) for MPTA, JLCA, and VA as 90° ±3°, 0-2°, and 0±3°, respectively. The outlier cases of MPTA, JLCA, and VA are presented in [Table 3]. The post-op MPTA outliers were significantly more frequent in the EM than in the IM group (26.2% vs. 9.5%, P=0.04). However, no significant difference was found between the JLCA and VA outliers of the two groups (P>0.05) [Table 3]. As shown in [Table 4], our data showed that body weight was significantly lower in the outliers of the EM group than the inliers (71.5±10.2

vs. 80.2±10.6, P=0.02). The same result was found in all patients (71.7±8.5 vs. 79.1±12.1, P=0.04). However, no significant difference was detected between the outliers and inliers of the IM group (72.5±2.0 vs. 78.2±14.5, P=0.43) [Table 4].

Table 3. The MPTA, JLCA, and VA outliers following TKA in both groups of the study

	Intramedullary Frequency (*ratio %*)	Extramedullary Frequency (*ratio %*)	*p* Value*
MPTA¹ Postop	4 (*9.5%*)	11 (*26.2 %*)	0.04
JLCA² Postop	3 (*7.1%*)	1 (*2.4%*)	0.306
VA³ Postop	16 (*38.1%*)	19 (*45.2%*)	0.507

¹ 90°± 3° range was considered as normal.
² 0-2° range was considered as normal.
³ 0± 3° range was considered as normal.
* chi-square test

Table 4. The mean patients' weight (Kg) of the outliers vs. inliers based on the postoperative MPTA angle following TKA

	Outliers Mean (SD)	Inliers Mean (SD)	*p* value* Mean (SD)
Intramedullary	72.5 (±2.0)	78.2 (±14.5)	0.43
Extramedullary	71.5 (±10.2)	80.2 (±10.6)	0.02
Total	71.7 (±8.5)	79.1 (±12.1)	0.04

¹ 90°± 3° range was considered as normal.
* independent t test

The risk ratio of MPTA outliers was 5/32 and 5/10 in patients of the EM group with weights of >70 and ≤70 Kg, respectively, the difference of which was significant (Chi-squared test, P=0.03). However, it was 3/27 (weight>70 Kg) and 1/15 (weight≤70 Kg) in patients of the IM group, showing no significant difference (Fischer's Exact test, P=1.0). The mean BMI was also compared but showed no significant difference between the MPTA outliers and inliers of IM (29.7 vs. 28.3, respectively, P=0.62) and EM (30.1 vs. 28.6 Kg/m^2, respectively, P=0.37) groups. Moreover, the risk ratio of MPTA outliers was 1/8 and 9/34 in patients of the EM group with BMIs of ≥35 and <35 Kg/m^2, respectively, with no significant difference (Fischer's Exact test, P=0.66). On the other hand, it was 0/8 (BMI≥35 Kg/m^2) and 4/34 (BMI<35 Kg/m^2) in patients of the IM group, respectively, with no significant difference as well (Fischer's Exact test, P=0.58).

The patients were followed for an average of 13±2.9 months. The functional outcome measures, including KSS, fKSS, VAS, and knee ROM, were measured for all patients preoperatively and in the last follow-up visit, as seen in [Table 5]. However, no significant difference was found between the EM and IM groups regarding these outcome measures at a mean follow-up of 26 months (P>0.05). The preoperative and post-op VAS pain scores showed no significant difference as well (1.09±1 vs. 1.2±1, P=0.45).

Table 5. The preoperative vs. postoperative of KSS, FKSS, VAS score, and the increase in ROM in both groups of the study

		Intramedullary Mean (SD)	Extramedullary Mean (SD)	*p* Value*	Total Mean (SD)
KSS	*Preop*	34.2 (±12.3)	32.0 (±8.7)	0.3	32.9 (±10.4)
	postop	91.1 (±5)	90.4 (±4.8)	0.45	90.7 (±4.9)
FKSS	*Preop*	30.1 (±7.2)	29.7 (±3.9)	0.76	29.9 (±5.5)
	postop	91.1 (±4.2)	90.7 (±4.5)	0.67	90.9 (±4.4)
VAS Pain	*Preop*	8.07 (±1.2)	8.1 (±1.2)	0.89	8.09 (±1.2)
	postop	1.09 (±1.0)	1.2 (±1.0)	0.45	1.19 (±1.07)
Increase in ROM (postop)		30.1 (±9.3)	27.6 (±5)	0.95	28.7 (±7.2)

* independent t test

The functional outcomes were also compared between the inlier and outlier ranges of post-op VA, demonstrating no significant difference except for the increase in ROM. In those patients with a VA within ±3° of neutral, the mean increase in ROM following TKA was significantly higher than that of those with a VA outside ±3° of neutral (30.8 vs. 27.4, respectively, P=0.039) [Figure 2].

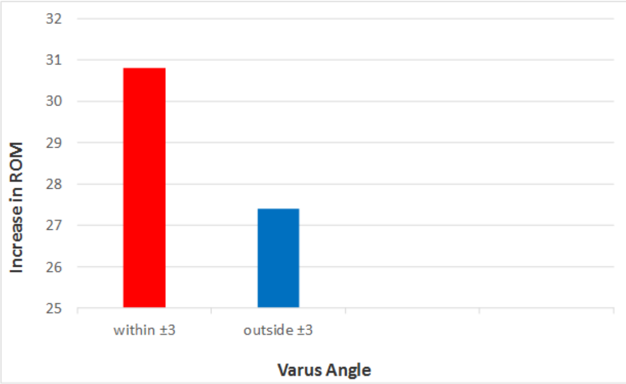

Figure 2. Increase in knee ROM in patients with a postoperative VA within ±3° of neutral versus those outside this range at the mean follow-up of 26 months

Discussion

The controversy over IM and EM tibial guides has existed in the literature since the very introduction of both techniques.[1,9,17] Based on a systematic review, the published literature includes nearly 20 original articles on this issue over the last three decades. Of these, 52.6% indicated the two techniques had comparable accuracy, 36.8% preferred IM guides, and 10.5% found EM guides more accurate.[1] However, not all these studies had a sufficient sample size and proper methodology or reported all the important radiologic or functional outcomes. Accordingly, only six were eligible for the meta-analysis by

Zeng et al.[1] The results of our trial showed no significant difference between the accuracy of the two techniques in terms of the mean post-op MPTA, JLCA, and VA values. However, the number of MPTA outliers was significantly lower in the IM group. The number of outliers for JLCA and VA showed no significant difference. Therefore, both groups demonstrated good functional outcomes with no significant difference.

Three radiologic measures have been discussed in the literature to compare the accuracy of tibial alignment following IM and EM techniques. These include the MPTA, VA, and tibial slope angles. The mean values of these measures were not significantly different between both techniques in many studies. However, it should be noted that the mean value overlooks the presence of outliers, which might be significant when comparing both techniques, noted only by a few studies.

The MPTA is the angle between the tibial mechanical axis and the articular surface of the tibial component in AP knee projection. Different studies have used various terms for it, such as the frontal tibial component angle,[1] coronal tibiofemoral angle,[15] and tibial component angle.[9] Although the mean MPTA reported by Chin et al. and Reed et al. was insignificant between both techniques, the two studies were contradictory regarding the relative risk of outliers. The EM-to-IM risk ratio of outliers was 0.31 versus 2.35 in the studies of Chin et al. and Reed et al., respectively.[9,16] However, the meta-analysis of the pooled data of both studies (20/76 EM vs. 21/84 IM) showed no significant difference.[1] Our study also showed no significant difference between the mean post-op MPTAs of both techniques. However, the difference between the outliers was significant (11/42 EM vs. 4/42 IM, EM-to-IM risk ratio=2.75), consistent with the results of the study by Reed et al.

The VA or MFMTA is the angle between the mechanical axis of the femur and tibia in the AP radiograph, which has also been designated as the mechanical axis angle.[1,16,18] Neither the mean value nor the outlier relative risk of VA was significantly different between the two techniques in the studies of Chin *et al*., Blakeney *et al*., and Kroon *et al*.[16,18,19] The meta-analysis of pooled data (31/83 EM vs. 30/89 IM) also demonstrated the same result.[1] Our result (19/42 EM vs. 16/42 IM) is also consistent with the results of these studies. The tibial slope is another angle that showed no significant difference in the meta-analysis study of Zeng *et al*.[1] We did not report this measure. However, we compared post-op JLCA between the two techniques (not reported before), which also showed no significant difference.

In the ancillary analysis of the outlier data, we found that the patients' mean weight was significantly lower in the MPTA outliers than the inliers in the EM group. However, no such difference was seen in the IM group. On the other hand, BMI showed no significant difference between the outliers and inliers of each group. We found no relevant data in the previous studies comparing both techniques. Nevertheless, a recent study by Compton et al. showed that BMI did not influence the post-op MPTA following TKA using EM guides. They found no difference between the MPTA outlier (defined as outside ±5°) ratio of patients with a BMI of <35 (2/100) and ≥35 (2/62). [20] It was also not significantly different between those with a BMI of <35 (9/34) and ≥35 (1/8) in the EM group of our study, which is consistent with the findings of Compton et al. However, the significantly lower weights of the patients, who underwent TKA using an EM guide and have a final MPTA outside the normal range, might indicate that thinner legs are associated with a higher chance of error in the appropriate mounting of an EM jig and doing tibial cuts. It might be due to the underestimation of a thinner leg by the surgeon, as he usually expects obese legs to be a challenge. We think further comparative studies between both techniques are needed, which focus particularly on the length and girth of the leg to determine the effect of these parameters on the final lower extremity alignment.

The functional outcomes following TKA using either IM or EM techniques have been compared only by a few studies. Cashman et al. reported the SF-36 and Western Ontario and McMaster Universities Osteoarthritis Index scores in 103 Triathlon TKAs (36 IM vs. 67 EM), which were not significantly different between both techniques at six months.[10] Blakeney et al., in their second study in 2014, compared the physical and mental component scores of SF-12 and the Oxford Knee Score (OKS) between 107 patients undergoing TKA using IM, EM, and computer-assisted techniques at a median follow-up of 46 months. None of these measures differed significantly between IM and EM techniques, although OKS, adjusted for gender and age, showed a difference, close to the significance level, between computer-assisted and conventional techniques.[15] In our study, the post-op values of KSS, fKSS, pain VAS, and increased ROM were not significantly different between IM and EM groups at a mean follow-up of 26±5.8 months. However, a post-op mechanical axis within ±3° of neutral was associated with more knee ROM increase than that outside this range [Figure 2].

Conclusions

In this randomized clinical trial, no significant difference was observed between IM and EM techniques for TKA in terms of the mean post-op lower extremity alignment angles, including MPTA, JLCA, and VA. However, the IM technique was associated with fewer post-op MPTA outliers. Moreover, both techniques were found equal regarding the good functional outcomes seen with both. A post-op mechanical axis within ±3° of neutral was generally associated with increased ROM at the mean 26-month follow-up.

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