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

Mohammadreza Razzaghof, MD; SM Javad Mortazavi, MD; Alireza Moharrami, MD; Abbas Noori, MD; Pouya Tabatabaei Irani, MD

Research performed at Tehran University of Medical Sciences, Tehran, Iran

Received: 17 February 2022 Accepted: 17 November 2022

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. Several factors are influential in the long-term outcome of a TKA, including patient selection, the prosthesis of use, and surgical technique. The surgical technique is of great importance among knee surgeons as it should implement proper lower extremity alignment for a good long-term prognosis. Several studies have reported poor outcomes of lower extremity malalignment, as prosthesis mispositioning can lead to loosening, recurrence of pain, and compromised physical performance.

Among surgical techniques, both intramedullary (IM) and...
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. Some studies have preferred one for providing a more accurate tibial alignment, while others found no significant difference between the two techniques. 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. Moreover, the functional outcomes following both techniques were compared only by a few studies. 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 soft tissue of the knee. 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. 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.

\[
N_3 = \left\{ \frac{x_1 - q_1 + p_1 + \frac{z_{1-\alpha}}{2} + \frac{z_{1-\beta}}{2} + q_1}{\Delta^2} \right\}
\]

\[
q_3 = 1 - p_1, \quad q_3 = 1 - p_2, \quad \beta = \frac{\alpha}{1 - \alpha} \quad q_1 = 1 - p_1, \quad \Delta = |q_1 - p_2|, \quad k = 30 \quad N_3 = 90
\]
**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 enrolment 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 (MPTA, JLCA, and VA) in both groups of the study. 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 IM or EM tibial guides 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 flowchart is shown in Figure 1.

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].

As mentioned earlier, we considered the normal range (inliers) for MPTA, JLCA, and VA as 90°±3°, 0±3°, 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 kg vs. 89.9±16.3 kg, P=0.001).

---

**Table 1. Demographic data of the patients**

<table>
<thead>
<tr>
<th></th>
<th>IM (N=48)</th>
<th>EM (N=48)</th>
<th>P Value</th>
<th>Total (N=96)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>66.0 ± 9.8</td>
<td>62.4 ± 7.4</td>
<td>0.56*</td>
<td>63.9 ± 8.6</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>10</td>
<td>6</td>
<td>0.71**</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>38</td>
<td>36</td>
<td>0.93*</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>29.5 ± 5.1</td>
<td>29.6 ± 4.7</td>
<td>0.92*</td>
<td>29.6 ± 4.8</td>
</tr>
<tr>
<td>Follow-up (months)</td>
<td>25.6 ± 3.8</td>
<td>26.4 ± 7.4</td>
<td>0.93*</td>
<td>26 ± 5.8</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th></th>
<th>Intramedullary</th>
<th>Extramedullary</th>
<th>P Value*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPTA  Preop</td>
<td>84.3 ± 2.9</td>
<td>84.8 ± 2.1</td>
<td>0.48</td>
<td>84.6 ± 2.7</td>
</tr>
<tr>
<td>Postop</td>
<td>88.9 ± 0.2</td>
<td>88.4 ± 1.8</td>
<td>0.88</td>
<td>89.2 ± 0.7</td>
</tr>
<tr>
<td>JLCA Preop</td>
<td>9.0 ± 0.0</td>
<td>9.2 ± 0.2</td>
<td>0.12</td>
<td>9.1 ± 0.1</td>
</tr>
<tr>
<td>Postop</td>
<td>0.5 ± 0.5</td>
<td>0.2 ± 0.9</td>
<td>0.38</td>
<td>0.4 ± 0.8</td>
</tr>
<tr>
<td>VA Preop</td>
<td>15.7 ± 7.9</td>
<td>14.3 ± 7.5</td>
<td>0.86</td>
<td>14.9 ± 7.7</td>
</tr>
<tr>
<td>Postop</td>
<td>3.5 ± 2.7</td>
<td>3.4 ± 2.2</td>
<td>0.86</td>
<td>3.4 ± 2.4</td>
</tr>
</tbody>
</table>

* independent t test

---

**Figure 1. CONSORT flowchart of the study**
of neutral versus those outside this range at the 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).

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].

**Discussion**

The controversy over IM and EM tibial guides has existed in the literature since the very introduction of both techniques. 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. 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
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.

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 outpatients 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 might be significant when comparing both techniques, noted only by a few studies.

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.

Acknowledgement
Not applicable

Conflict of interest: Not applicable

Funding: Not applicable

References