

Comparative Study of Outcomes of Patient Specific Instruments and Conventional Jigs in Primary Total Knee Arthroplasty

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Abstract

Background: Total knee arthroplasty is now a commonly performed surgery with successful outcomes. Larger number of patients expected to undergo this procedure in future. Shortcomings with conventional jigs have led to development of patient specific instruments, with the aim to improve mechanical alignment after total knee arthroplasty. This study compared the outcomes of surgery with use of patient specific instruments and conventional jigs.

Material and Method: Total 80 knees were included in the study, 40 in each group. We compared mechanical alignment achieved, blood loss, surgical time, postoperative pain, and length of hospital stay.

Results: There was significant improvement in postoperative mechanical alignment (p value - 0.001), surgical time (p value - 0.004) and postoperative pain (p value - 0.001) in patient specific instruments group. Lesser blood loss and shorter hospital stay was also noticed in patient specific instruments group but this difference was not statistically significant.

Conclusions: Patient specific instruments improve mechanical alignment after total knee arthroplasty, compared to conventional jigs. It also decreases surgical time and blood loss. Postoperative pain is also less with patient specific instrument. With lesser complications and faster rehabilitation it also shortens length of hospital stay.

Keywords: Total knee arthroplasty, Patient specific instruments, conventional jigs.

THESIS SUMMARY

Introduction

Total Knee Arthroplasty (TKA) is now a very commonly done procedure for end stage arthritis of knee. Although TKA, a highly successful orthopaedic procedure that gives long lasting good results, but short term failure have also been reported in some cases, which are worrisome for arthroplasty surgeons. It has been recognized that accurate limb alignment is one of the important factor responsible for successful outcome in TKA. Thus a surgeon aims to achieve neutral mechanical alignment (180°) of lower limb postoperatively through properly oriented bone cuts. Currently, the commonly used instruments for TKA are extramedullary (EM) alignment guide for the tibial resection and intramedullary (IM) alignment guide for the distal femoral resection. However, these have demonstrated some fallacies

and limited degree of accuracy. Inaccuracies with conventional instruments could be due to several factors like a) relying on assumption about the difference between the femoral mechanical and anatomical axis, b) the accuracy of guide is dependent on a rigid fit of the IM rod in the femoral canal and on the position of the entrance hole. The invasion of the IM canal has been implicated to cause increased pulmonary pressures, fat embolism and increased blood loss in TKA.

Patient Specific Instruments (PSI) was introduced as an alternative to conventional ones, with the aim of improving postoperative alignment and implant positioning. It uses anatomical data obtained from preoperative computed tomography (CT) images to create disposable cutting jigs individualized to the unique anatomy of the patient. It seem to offer added advantages of preoperative planning, accurate

mechanical alignment, decreased surgical time, lesser trays of instruments, less blood loss, and shorter hospital stay. These advantages come with caveats of increased cost (imaging and PSI block fabrication), exposure to radiation and waiting period for the manufacturing of blocks. We studied a comparative group of patients to identify whether the use of PSI has any advantages over conventional technique in primary TKA.

Aims and Objectives

A) Primary -

- To assess and compare the mechanical alignment of the operated limb with Patient specific instruments (PSI) and Conventional jigs for TKA.

B) Secondary -

- To assess and compare
 - Operative Time
 - Post-op Pain
 - Blood loss
 - Length of stay.

Materials and Methodology

Study type: Prospective comparative cohort study.

Sample size: Total 80 knees with 40 in each group (PSI and conventional jigs).

Study population: Patients with advanced arthritis of knee joint requiring TKA. All the patients were operated by the same surgeon, with same approach and in the same hospital set up. Patients who fulfilled the inclusion criteria for PSI were operated with PSI (group 1) and remaining patients were operated with conventional jigs (group 2).

Inclusion criteria (PSI):

1. Patient having severe arthritis of knee joint (Ahlback's Grade 3, 4 or 5)
2. Patient willing to undergo CT scan.
3. Patient who were willing to bear the extra cost of manufacturing these jigs and CT scan (approx. Rs 25000 per knee).
4. Patient who could wait for 1 week to undergo TKA (manufacturing time for PSI jigs).
5. Patient who consented to undergo TKA with PSI.

Exclusion criteria (PSI):

1. Mild arthritis (Ahlback's Grade 1 and 2).
2. Patient not willing for CT scan.
3. Patient who couldn't wait for 1 week.
4. Patient who couldn't bear extra cost.

All patients were thoroughly clinically evaluated and necessary blood investigations were done as per general protocol.

Special planning for patients of Group 1 (PSI):

1. Preoperative CT scannogram of lower limb was done and the data was sent in CD to jigs manufacturing unit.
2. Virtual 3-D anatomical bone model was constructed from the data obtained through CT scannogram.
3. Cuts made were checked virtually and then jig design was changed according to the bone cuts desired.
4. After approval from surgeon, manufacturing unit prepared the final

block specific to the patient's knee.

5. Patient specific cutting blocks were prepared in a manufacturing unit and were transferred to the hospital before the day of surgery.

6. These blocks were autoclaved and then used intra-operatively for taking the bone cuts for TKA surgery, after appropriate exposure.

Method of assessment:

1. Mechanical alignment – Mechanical axis (MA) is a load bearing axis of the lower limb. Normally it is a straight line passing from the center of femoral head to the center of ankle and through center of the knee. It is measured in the form of mechanical femoral tibial angle (MFT angle). Thus with neutral MA, MFT angle is 180°. We measured and analyzed MA postoperatively by measuring MFT angle on long leg radiograph, done on one of the follow up visit, using picture archiving and communication system (PACS).

2. Operative time – We measured tourniquet time (in minutes) to assess and represent operative time required for TKA.

3. Postoperative pain – Postoperative pain after TKA was recorded on 1st and 2nd POD using Visual analogue score (VAS).

4. Blood loss – To assess the total blood loss in TKA we recorded fall in hemoglobin (Hb) after TKA on 1st POD and collection in drain on 1st and 2nd POD. It is a general presumption that larger the blood loss more is the chance of requirement of blood. Thus we also measured frequency of patient requiring blood transfusion postoperatively. We only transfused blood (Packed red cells) to patients with Hb level less 8 gm/dl.

5. Length of hospital stay – All patients were admitted in hospital a day before the surgery and were discharged after TKA when patients were stable and mobilized with support comfortably.

Follow up visit:

Minimum two follow up visit were done. First on 10th day of surgery and second after 3 weeks of surgery. Further follow up visits were done as per convenience and need of patients.

Result

1. There was no statistically significant difference in both groups with respect to age, sex and side wise distribution and so both the groups were matched.

2. Mean postoperative MFT angle in group 1 (PSI) was 178.23° compared to 175.73° in group 2 (conventional jigs). This improvement in MFT angle in group 1 was found statistically significant (p value - 0.001).

3. In unilateral TKA mean drop in Hb in group 1 was 1.90 gm/dl while in group 2 it was 2.07 gm/dl. Whereas in bilateral TKA mean drop in Hb in group 1 was 2.76 gm/dl while in group 2 it was 3.31 gm/dl. Though there was no statistically significant difference in fall of Hb in both the groups but results showed lesser fall in Hb level in group 1 compared to group 2 in both unilateral and bilateral TKA.

4. On assessing collection in drain we found mean collection on 1st and 2nd postop day (POD) in group 1 was 232.5 ml and 110 ml while in

group 2 it was 290 ml and 100 ml respectively. Thus mean total collection in drain postoperatively was less in group 1 compared to group 2 but the difference was not statistically significant.

5. From the assessment of fall in Hb level and collection in drain we expected less blood loss and lesser requirement of blood transfusion in group 1. This was confirmed by our observation that fewer patient in group 1 required blood transfusion postoperatively compared to group 2. No unilateral TKA patient required blood transfusion in either group while in group 1 only 3 out of 13 (18.7%) bilateral TKA patient required blood transfusion compared to 6 out of 17 (35.3%) total bilateral TKA patient in group 2. Although difference was not found statistically significant.

6. Mean tourniquet time in group 1 was 43.3 minutes while in group 2 it was 48.82 minutes. This difference in tourniquet time was found to be statistically significant (p value- 0.004).

7. We also observed significantly lesser pain postoperatively in group 1 compared to group 2 (p value < 0.001). Mean VAS score on 1st and 2nd POD in group was 1.87 and 1.17 compared to group 2 where it was as high as 2.52 and 2 respectively.

8. Mean length of hospital stay in unilateral TKA patient was found to be 5.38 days in group 1 and 6 days in group 2 while in bilateral TKA patient it was 7.25 days in group 1 and 7.47 days in group 2. However this decrease in length of hospital stay in group 1 was not found statistically significant.

Conclusion

In this study we found that PSI significantly improved mechanical alignment of the lower limb after TKA compared to conventional jigs. There was significant decrease in operative time required for surgery with lesser postoperative pain with the use of PSI. A decreased blood loss and blood transfusion requirement was found in PSI group. Shorter surgery time (thus lesser anesthesia) and lesser invasive nature of PSI resulted in faster rehabilitation and thus decreasing the hospital stay.

Clinical Importance

PSI is an innovative technique in the field of TKA promising added advantages not only to patients but also to the surgeons and to the hospitals.

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