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Our Initial Experience of First 50 Cases of Robotic-Arm Assisted Total Knee Arthroplasty

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Abstract

Purpose: Robotic-arm-assisted total knee arthroplasty (RA-TKA) has been criticized for an increased operative time, longer incision, the extra incision for insertion of pins and various other potential complications. We want to describe our initial experience of the first 50 cases of RA-TKA (of fully automatic robot) regarding the learning curve for operative time, accuracy of implant positioning, and the accuracy of achieving a well-balanced knee through the assessment of gaps.

Materials and Methods: Retrospective analysis of the first 50 patients was done who underwent RA-TKA, all of which were performed by a senior surgeon experienced in conventional manual jig-based TKA. Operative time, accuracy of implant positing, restoration of limb alignment, and intraoperative gap balancing were assessed. Linear regression analysis and cumulative sum (CUSUM) sequential analysis were used to assess the learning curve for the operative time.

Results: In our experience, the learning curve for operative time in RA-TKA is around 25 cases as per CUSUM sequential analysis. The linear regression analysis showed a gradual decrease in the operative time as the number of RA-TKA performed cases increased (cases 1–10 = 76.8 ± 16 min, cases 11–20 = 72.5 ± 13 min, cases 21–30 = 63.6 ± 7 min, cases 31–40 = 61.3 ± 6 min, and cases 41–50 = 57.3 ± 10 min) – statically significant ($P < 0.05$) after 20 cases. There is no learning curve for the accuracy of achieving the planned implant position (P = n.s.) and limb alignment (P = n.s.). Only three cases were outliers, HKA angle <174° for varus phenotype, and HKA >183° for valgus phenotype. Forty-six cases (out of 50) had all the gaps within 3 mm of each other (sensitivity of the robot is <1 mm).

Conclusion: Implementation of RA-TKA into the surgical workflow is associated with a learning curve for the operative times, which eventually decreases but this does not lead to any compromise in the accuracy of implant positioning or overall limb alignment. The RA-TKA has shown improved accuracy in implant positioning, improved limb alignment, thereby reducing outliers, and improved gap balancing. All this translates to better clinical outcomes and patient satisfaction.

Keywords: Robotic arm assisted Total Knee Arthroplasty, Learning Curve, Operative time, Implant Positioning, Gap Balancing

Introduction

Total knee arthroplasty (TKA) has revolutionized the care of patients with end-stage knee arthritis. Despite significant advancements in the design of implants, operative techniques, and alignment principles, a sizeable portion of the patients are not satisfied with their primary total knee replacement. Approximately 1 in 5 (19%) primary TKA patients are not satisfied with the outcome. This indicates that the TKA is not achieving its primary goal that is alleviating pain of arthritis and restoring the function [1].

Robotic-arm-assisted TKA (RA-TKA) has gained increased attention and popularity as a means of improving patient satisfaction. RA-TKA provides the surgeon with a tool that accurately executes bone cuts according to pre-surgical planning, as well as provides the surgeon with intraoperative feedback including appropriate implant positioning helpful for restoring native knee kinematics and soft-tissue balance, thereby improving the satisfaction rates among the TKA patients [2, 3]. RA-TKA also helps in achieving implant positioning more accurately and consistently [4, 5, 6].

Despite the potential advantages, RA-TKA has been criticized for an increased operative time when compared to the manual conventional jig-based TKR. While initially the operative times are increased due to the extra number of intraoperative steps, there appears to be a shorter learning curve with the

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decrease in the operative times as the familiarity of the surgeon with the robotic system improves. Therefore, a reduction in the operative times while achieving the potential benefits of the RA-TKA in terms of accurate implant positioning, a decrease in the number of outliers, well-balanced knee is possible.

Here, we describe our initial experience with the RA-TKA in terms of a learning curve for operative times, the learning curve for the accuracy of implant positioning, and the accuracy of robotic system in achieving a well-balanced knee through the assessment of different gaps.

Materials and Methods

This prospective cohort study includes 50 patients with symptomatic knee osteoarthritis who underwent RA-TKA. Inclusion criteria for the patients were as follows: Patients with symptomatic knee osteoarthritis undergoing primary TKA. All operative procedures were performed by the senior author who is experienced in performing conventional jig-based TKA and had undergone cadaveric training on RA-TKA. The robotic group was the first cohort of patients undergoing RA-TKA under the operating surgeon. All the surgeries were carried out with help of Cuvis Joint® robot system (fully automatic robot) by Meril healthcare. All the patients underwent a standard medial parapatellar approach with implantation of cemented Meril freedom cruciate-retaining knee prosthesis. All the patients underwent routine pre-operative anteroposterior and lateral weight-bearing knee radiographs and full-length lower limb hip-to-ankle radiographs. In addition, pre-operative computed tomography (CT) scan was done to create a patient-specific computer-aided design (CAD) model of the patient's unique anatomy. This helps to plan peroperatively the optimal implant positioning and implant sizes for achieving the desirable limb alignment.

Surgical technique

In patients undergoing RA-TKA, first, the pre-operative planning is done with help of CT scan on J-Planner (software provided for CAD model based on CT scan by the Cuvis Joint® robot system). The initial planning is done following the philosophy of either mechanical or kinematic alignment and changes are made in the implant position intraoperatively after an assessment of the ligament status is made, thereby following the concept of functional alignment or patient-specific alignment [7, 8].

The knee is exposed with a standard medial parapatellar approach, followed by insertion of femoral and tibial bicortical pins onto which the arrays are mounted. Bone registration is done as per the sequence of points to be marked displayed on the screen to verify the anatomy and bone geometry. Once the bone registration is complete, an assessment of the ligaments is done with corrective forces assessed kinematics at 0 and 90° flexion. This enables fine-tuning of the implant positioning based on the laxity of soft-tissue envelope. Once the implant positions are finalized, the fully automated robot is set up to execute the pre-operative plant to within 1 mm of planned resection. Optical motion capture technology is used to assess limb alignment, range of motion, flexion and extension gaps, and range of motion with trial implants before final implantation of components.

Outcome measures

1. Operative time

Operative time was defined as time from skin incision to final wound closure. The cumulative sum (CUSUM) sequential analysis tool was used to assess learning curves in RA-TKA for operative time.

2. Implant positioning and limb alignment

Accuracy of implant positioning and limb alignment was assessed by comparing the values achieved in the post-operative radiographs to the planned values in the corresponding pre-operative plan. The femoral coronal implant alignment was measured as the medial angle subtended by the femoral mechanical axis and the line connecting the distal points of the medial and lateral condyles of the femoral component. The femoral sagittal implant alignment was calculated as the angle subtended between the perpendicular line running proximally from the distal femoral surface in contact with the femoral component and the femoral mechanical axis. The tibial coronal implant alignment was measured as the medial angle subtended by the tibial mechanical axis and the medial-to-lateral axis of the tibial implant. The tibial sagittal alignment was calculated as the angle between the tibial mechanical axis and the anterior to posterior axis of the tibial implant.

The limb alignment was assessed as HKA angle within 174–180° for varus morphotype and 180–183° for valgus morphotype. HKA values falling outside this range were considered as outliers following the functional alignment philosophy [7, 8].

3. Gap assessment

Gap check is done through the optical motion capture technology which is done after the final cemented implantation of the tibial and the femoral components and the data recorded in four variables:

a. Medial-lateral gap difference in extension
b. Medial-lateral gap difference in flexion
c. Flexion-extension gap difference on lateral side
d. Flexion-extension gap difference on medial side.

Statistical analysis

The data were collected in a sequential manner as the cases were operated and stored in an Excel document. For operative time, a univariate linear regression was performed with the operative

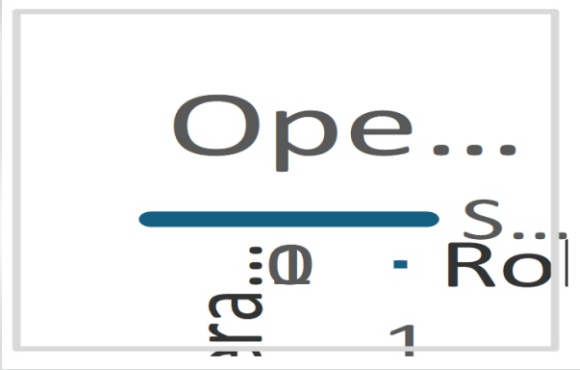

Figure 1: Linear regression analysis of the operative time data – a gradual decrease in the operative time.

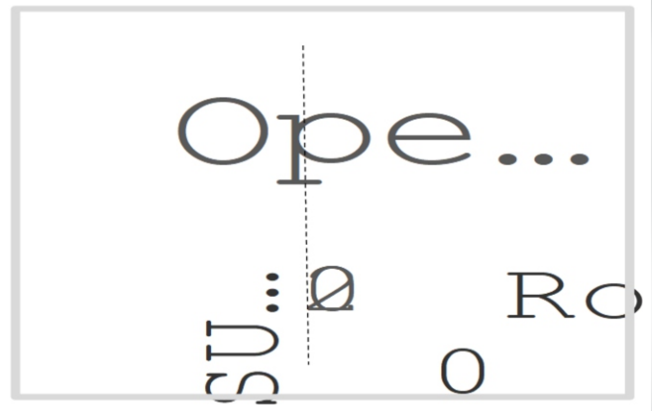

Figure 2: Cumulative sum chart for operative times in consecutive robotic-arm-assisted total knee arthroplasty cases. Dashed vertical line represents the inflexion point at which the learning curve transitions from the learning phase to the proficiency phase.

time as a dependent variable and the consecutive case number of each surgeon as independent variable. The patients were divided into five groups of ten patients each as per the linear sequence. A group mean and an overall mean was calculated with statistical significance set at 0.05. The CUSUM sequential analysis tool was used to assess learning curves in RA-TKA for operative time. An inflexion point in the visualized trend is defined as the transition from a learning phase to a proficiency phase. The target used for the operative time used for robot-assisted TKA was the mean average of operative time.

Learning curves for the accuracy of implant position and limb alignment in RA-TKA were assessed by calculating mean values for the deviation between the planned position and the final position of the implant and the progression was assessed in groups of ten patients. Statically significance was at $P < 0.05$.

The accuracy of achieving a well-balanced knee was assessed as a measurement of all the gaps, that is,

a. Medial-lateral gap difference in extension
b. Medial-lateral gap difference in flexion
c. Flexion-extension gap difference on the lateral side
d. Flexion-extension gap difference on the medial side.

Table 1: Operative time data in patients undergoing robotic-arm-assisted total knee arthroplasty

	Cases 1–10	Cases 11–20	Cases 21–30	Cases 31–40	Cases 41–50
Operative time (min)	76.8±16.089	72.5±13.962	63.6±7.763	61.3±6.893	57.3±10.285

Summary statistics are: Mean value and SD,*P* value for trend – statistically significant fall after 20 cases. SD: Standard deviation

Table 2: Accuracy of implant positioning and limb alignment in patients undergoing robotic-arm-assisted total knee arthroplasty

Outcome (°)	Cases 1–10	Cases 11–20	Cases 21–30	Cases 31–40	Cases 41–50	*P*
Limb alignment	1.45±3.3457	2.28±2.0858	1.53±1.201	1.53±1.201	2.1±1.792	NS
Femoral coronal alignment	0±0	0.4±0.699	0±0	0.4±0.699	0.4±0.843	NS
Femoral sagittal alignment	0±0	0.4±0.843	0.1±0.316	0.1±0.316	0.5±0.85	NS
Tibial coronal alignment	0.4±0.966	0.9±0.994	0.3±0.675	0.4±0.843	0.7±0.823	NS
Tibial sagittal alignment	0.2±1.476	0.2±0.422	0±0	0.1±0.316	0.3±0.675	NS

Data expressed as mean±1 SD. SD: Standard deviation, NS: Not significant

Results

Operative time

The overall mean operative time of 50 patients was 66.1 min. The linear regression analysis showed a gradual decline in operative time as the number of RATKA performed cases increased due to increased experience the technology (Fig. 1). The mean operative time for the five cohorts is mentioned in Table 1. The mean operative time values for Group 1 (cases 1–10) and Group 2 (Cases 11–20) were 76.8 min and 72.5 min, respectively. These were statistically significant ($P < 0.05$) when compared with Group 3 (Cases 21–30), Group 4 (Cases 31–40), and Group 5 (Cases 41–50) which were 63.6 min, 61.3 min, and 57.3 min, respectively.

The CUSUM sequential analysis showed a sharp inflexion point around Case no 25, which helped to identify two distinct phases – the initial learning phase and the proficiency phase (after Case No. 25) (Fig. 2).

Implant positioning and limb alignment

There was no learning curve for RA-TKA on the accuracy of achieving the planned implant position and limb alignment. Table 2 shows the average deviations of the implant position

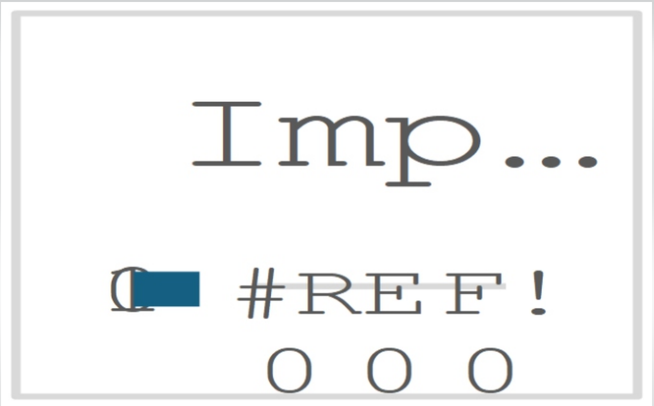

Figure 3: Bar chart showing changes in mean for accuracy in femoral and tibial implant positioning (degrees) in consecutive patient groups undergoing robotic-arm-assisted total knee arthroplasty.

Table 3: Assessment of gap difference in consecutive patients undergoing robotic-arm-assisted total knee arthroplasty

	Case 1–10	Case 11–20	Case 21–30	Case 31–40	Case 41–50
Medial-lateral gap difference in extension	0.2±2.2 (range=−4–±4)	0.9±0.99 (range=−1–±2)	0.18±0.87 (range=−2–±1)	0.4±0.51 (range=0–±1)	0.2±0.63 (range=−1–±1)
Medial-lateral gap difference in flexion	1.5±2.27 (range=−1–±5)	0.88±1.69 (range=−3–±3)	1±0.81 (range=0–±2)	0.4±1.5 (range=−2–±3)	0±1.05 (range=−1–−2)
Flexion-extension gap difference in medial comp	−1.9±2.51 (range=−5–±2)	−0.7±1.33 (range=−2–±2)	−1.4±1.42 (range=−3–±1)	−0.7±1.33 (range=−4–±1)	−1.3±1.56 (range=−3–±1)
Flexion-extension gap difference in lateral comp	−0.6±1.57 (range=−3–±2)	−0.6±1.64 (range=−3–±2)	−0.5±0.84 (range=−2–−1)	−0.7±1.88 (range=−4–±3)	−1.5±1.17 (range=−3–0)

Data expressed as mean±1 SD. SD: Standard deviation

from the planned position (Fig. 3). About 94% of cases (47 cases) had their mechanical alignment within the acceptable alignment criteria of the functional alignment philosophy, that is, HKA <174° for the varus morphotype and HKA angle >183° for the valgus morphotype. Only three cases were outliers.

Gap assessment

The gap assessment was done after the cement implantation of the final components. The precision and accuracy of the robot is <1 mm. About 40% of the cases (20) had all the gaps within 1 mm of each other. About 30% of the cases (15) had gaps within 2 mm of each other. About 22% of the cases had (11) had gaps within 3 mm of each other. The gap assessment is shown in Table 3.

Discussion

The important findings of this study were as follows:- (1) a learning curve of around 25 cases is associated with operative times in RA-TKA, (2) there is no learning curve for the precision of implant positioning, and (3) with the advent of RA-TKA, it was possible to achieve a well-balanced knee with all the gaps well balanced within 3 mm of each other in 92% of the cases (46).

The learning curve for operative time in our experience is around 25 cases, there was a sharp inflexion point after 25 cases in CUSUM sequential analysis. The linear regression analysis showed a gradual decrease in the operative time as the number of RA-TKA performed cases increased. Most marked improvement in the operative time stemmed from improvement in the time taken in the bone registration phase. Since the intraoperative landmarks for bone registration are similar in all the patients, as the number of RA-TKA performed cases increased, the operating surgeon was able to pre-emptively place the probe tip over the oncoming registration point. The fallacies during the registration phase, from our experience, are as follows:- (a) re-registration of all the marking points had to done (50 registration points for femur and 49 points for tibia) if the root mean square error calculated at the end the bone registration phase exceeds the set standard value of 1.5 – this should be shown simultaneously, as the points are marked and (b) sometimes the points to be marked are below the overhanging osteophytes – these osteophytes are not captured by the pre-operative CT scan; hence, an amateur surgeon may end up marking the points onto the osteophytes. The second area of improvement was the gap balancing phase where the operating surgeon was able to finely tune the position of the components to have an adequate gap balancing, and this improved with an increased number of cases performed. The results are comparable to the similar studies in literature, by Sodhi et al. [9], Jung et al. [10], Vermue et al. [11], and Marchand et al [12]. However, one of the studies by Kayani et al. [13] mentioned the learning curve for operative times to be as low as seven cases, the probable reason for that may be – they were exposed to the usage of navigation systems before the introduction of robotic systems.

One major finding was that there was no learning curve for the accuracy of achieving implant positioning, that is, right from the first case the final position of the implants did not alter significantly when compared to the pre-operative plan. The results are similar to studies by Kayani et al. [13] and Vermue et al. [11]. RA-TKA uses bone registration to confirm intraoperative spatial orientation of the limb and fixed arrays accurately track the femoral and tibial bone resection windows throughout the procedure. Stereotactic boundaries also confine bone resection to the limits of the haptic windows, which helps to reduce manual errors in bone resection and iatrogenic soft-tissue injury [14, 15]. The robotic arm helps to limit the bone resection to the pre-operative plan and hence minimizes surgeon-induced errors in implant positioning. The improved accuracy in implant positioning and restoration of limb alignment is importantly as these parameters influence the outcomes, clinical recovery, long-term survivorship of the implant, and ultimately the patient satisfaction [16, 17].

Another finding is that the number of mechanical alignment outliers (HKA <174° for the varus morphotype and HKA angle >183° for the valgus morphotype) is significantly decreased with help of RA-TKA which, in our study, was only observed in three cases, this is consistent with the studies by Song et al. [16] and Kayani et al. [13].

The accuracy of achieving a well-balanced knee is also greatly improved in RA-TKA. About 92% of cases (46 cases) had gaps within 3 mm of each other. The robot has precision and accuracy to <1 mm in measuring the gaps; hence, even a knee which appears to be well balanced to the human eye, may show a gap difference of say up to 2 mm or 3 mm which is not possible to be picked up by the human eye. A well-balanced knee corresponds to decreased instability, decreased number of outliers, better clinical outcomes, early rehabilitation and improved ROMs, improved survival of implants, and an overall improvement in patient satisfaction rates.

Conclusion

Implementation of RA-TKA into the surgical workflow is associated with a learning curve for the operative times, which eventually decreases but this does not lead to any compromise in the accuracy of implant positioning or overall limb alignment. The RA-TKA has shown improved accuracy in implant positioning, improved limb alignment thereby reducing outliers and improved gap balancing. All this translates to better clinical outcomes and patient satisfaction.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

Conflict of Interest: NIL; **Source of Support:** NIL

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