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Achieving accuracy and gap balancing with fully autonomous Cuvis Joint Robot assisted total knee arthroplasty: A single-center, non-randomized retrospective study

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ABSTRACT

Background: Achieving accuracy and precision during total knee arthroplasty (TKA) is challenging due to complex knee anatomy, patient demographic and expectations of younger patients opting for the surgery. Real-time input and personalization help surgeons achieve their aim with robotic surgery.
Method: This single-center, non-randomized, retrospective study included male and female patients over 18 years with primary OA knee with Varus and Valgus deformity, and able to provide written informed consent. Patients with infected TKR requiring revisional surgery and those reluctant to engage in the trial were excluded. The accuracy and efficiency of the fully automated Joint Robot was measured by the difference between planned and measured resection thickness and angle.
Results: The study enrolled 100 patients of whom 53 % underwent RA-TKA of right knee and 47 % had left knee RA-TKA. Women patients dominated the study (69 %), and overall average age of the patients enrolled was 65.55 ± 9.15 years. The difference in mean resection thickness was well within the desired limit, with root mean square of 0.78 mm and 0.96 mm in medial distal and lateral distal planes; 0.94 mm and 1.13 mm in posterior femoral planes. Medial tibial as well as lateral tibial planes were 0.83 and 0.95 mm. The differences in mean resection angle were 0.77° (varus/valgus [V/V]), 0.98° (flexion/extension [F/E]) at distal femoral plane and 0.59° (V/V) and 1.5° (F/E) at posterior femoral plane. At tibial plane V/V was 0.76° and 0.85 °F/E.
Conclusion: The study's results support the efficacy and precision of RA-TKA, showcasing its ability to maintain resection thickness and angles in line with anticipated values. These findings solidify the reliability and safety of robotic assisted total knee arthroplasty, characterized by minimal variations in resection parameters.

1. Introduction

Recent technological advancements in the surgical orthopedics sphere have led to innovative and cutting-edge tools which is designed to address the unmet clinical needs of patients.[1] The number of total knee arthroplasty (TKA) procedures performed in the field of orthopedics has significantly increased but there has been a decreasing trend in the satisfaction of patient oriented clinical and functional outcomes.[2] As a "gold standard", TKA for patients needing surgical interventions, the Surgeons look for achieving the well-balanced and accurate implant positioning.[3] Common causes of failed TKA and patients dissatisfaction include instability, persistent pain, aseptic loosening which remains true to date.[4] Intraoperative soft tissue balance and prosthesis alignment can lead to success of TKA.[5] With the TKA global burden increasing with an estimation of 673 % by 2030, and with increasing demand in younger population for the need for arthroplasties there needs to be a constant advancement in surgical innovation and Surgeons continuously look for more innovative technologies to improve the patient related outcome measures[6] which may be achieved by robotic-assisted (RA)-TKA.

Numerous robotic devices have been developed to improve bone resection accuracy and decrease misalignments during TKA.[7] The advanced fully automatic Cuvis Joint robotic system (Curexo, Korea, supported by Meril Life Sciences, Pvt. Ltd, India) explored in this investigation has greater flexibility, allows intraoperative modifications by analyzing the patient's soft tissue condition which are lacking in the existing active robotic systems.[8] Protection of soft tissues during milling is one of the critical features of Cuvis Joint robot.[9]

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List of abbreviation:

3-D:	3-dimensional images
ACL:	anterior cruciate ligament
CT:	computed tomography scans
E:	extension
F:	flexion
HKA:	hip/knee/ankle axis
OA:	osteoarthritis
PCL:	posterior cruciate ligament
PS:	posterior stabilized
RA:	robotic assisted
RMS:	root mean square value
TKA:	total knee arthroplasty

This study aimed to assess accuracy of the resection thickness and angle in post-operative patients undergoing TKA using a state-of-the-art fully automated Cuvis Joint Robot system.

2. Method

2.1. Study design

This is a non-randomized, retrospective assessment of safety, accuracy and efficacy of novel Cuvis Joint Robot in Indian patients undergoing RA-TKA for primary knee osteoarthritis (OA).

2.2. Study device

Cuvis Joint robotic system is completely automatic, cutting-edge surgical robot, providing support to surgeons with precise bone cutting using tailored preplanned patient's anatomy for predictable and reliable outcomes.[8] It uses patient's pre-operative 3D computed tomography (CT) images, which helps in customized individualized treatment approach while minimizing the complications often associated with conventional TKA such as difference of limb length, pulmonary embolism, fracture, and risk of infection due to the need of fewer instruments than the conventional surgery.[10]

2.2.1. The precision of Cuvis Joint Robot system surgery allows for.[11,12]

- More accurate implant placement, increasing patient's satisfaction,
- Minimizing injury of adjacent tissues results in improved safety and reduced risk of infection,
- Lower blood loss and smaller incisions, help in quicker recovery and less pain,
- Early rehabilitation, decreased admission time and early discharge from hospital,
- The potential for better long-term function, better implant survivorship and longevity and improved quality of life.

2.3. Population and surgical technique

The study was authorized by the ethical committee of the institutional review board, and signed informed consent was obtained from each patient in advance. Baseline and pre-operative medical history were noted for all patients. The inclusion criteria comprised: patients identified with primary knee OA with varus and valgus deformity; patients aged 18 years opting for RA-TKA. Exclusion criteria included pregnant women, individuals with a life expectancy under 5 years, patients who underwent manual TKA and had additional deformities, as well as those with revision or infected TKA.

A 3D-CT scan was performed before the surgery to examine the hip, knee, ankle (HKA) axis. Instead of manually calculating the mechanical femorotibial angle (mFTA), the CT scan provided measurements of the femur's and tibial varus/valgus and flexion/extension angles.

The scan was subsequently segmented to facilitate the generation of a 3-D model using the software of Cuvis Joint J-Planner and the locations of the femoral and tibial registration sites were recorded and visualized using software. The original placement of the implant was selected based on principles of mechanical alignment, and afterwards, the balance was evaluated and adjusted to achieve functional alignment. The resection depth was determined to be 7 mm to ensure that the final depth, accounting for the 2 mm cartilage, would be 9 mm, which aligns with the thickness of the femoral component. An incision of 7 mm was made on the tibial side, which exposed an average depth of 2 mm of cartilage on the unaffected area including a 9 mm poly on the lateral side of varus knees. The angle of the HKA was determined, ranging from 6° varus to 3° valgus. The range of femoral flexion seen was between 0° and 7°, with a combined flexion limitation of 10°. The procedure employed posterior stabilized (PS) TKA implant design. During the day of the surgical procedure, the preoperative planning was uploaded onto the robotic equipment using a pen drive. The calibration of the system was performed on each occasion. While intraarticular pins were pinned on the medial plane of the femoral side, extraarticular pins were attached to the tibia. A surgical procedure known as a subvastus arthrotomy was conducted. During the surgical procedure, one senior surgeon with 4K/5K JT replacement experience performed all the procedures and was assisted by two assistant surgeons with 3K/4K JR experience. All the procedures were performed as per the manufacturing guidelines and technical assistance was provided by the manufacturers. Following the completion of the registration process, the osteophyte was excised, and the anterior and posterior cruciate ligaments (ACL and PCL) were resected during the surgical procedure. A probe with sensor was placed on distal and posterior femur and tibial plane after cuts were taken by robot. The yellow line i.e., planned resection thickness and angle was matched with green line i.e., actual/verified resection thickness and angle (Fig. 1). A total of four gap values were collected and employed manually to stress on the joint (maximum medial flexion and extension gap as well as maximum lateral extension and flexion gap)

The functional alignment principle in Cuvis software was utilized to alter the position of components until the knee achieved equilibrium, following the acquisition of maximal gaps. The robotic arm was then positioned so that eight bone cuts on the femoral side and three bone cuts on the tibial side could be executed. The bone pieces, meniscus, and posterior osteophyte were later removed. The posterior condylar, distal femoral, and tibial cut surfaces are consistently examined by the surgeon, auxiliary surgeon, and company representative on each occasion. Subsequently, a trial implant of 9 mm was inserted, and the subsequent assessment of balance and ligament tension was conducted utilizing the Cuvis software. Upon completion, the final components were implanted. Three independent observers noted the actual measurements at the end of the procedures.

2.4. Statistical analysis

The results are displayed as the average, standard deviation (SD), and root mean square (RMS) for continuous variables, while categorical variables are shown as frequencies and percentages (%).

3. Results

One-hundred patients were enrolled with an average age of 65.55 ± 9.15 years, with 69 % of the group being female dominated. A total of 53 patients received right knee and 47 got left knee implant (Table 1). The average operative time was 60 minutes and average hospital stay 3 days.

For the resection thickness at femoral medial plane, the distal and proximal root mean square (RMS) values were 0.78 mm and 0.94 mm respectively and for femoral lateral plane (distal and proximal) 0.96 mm

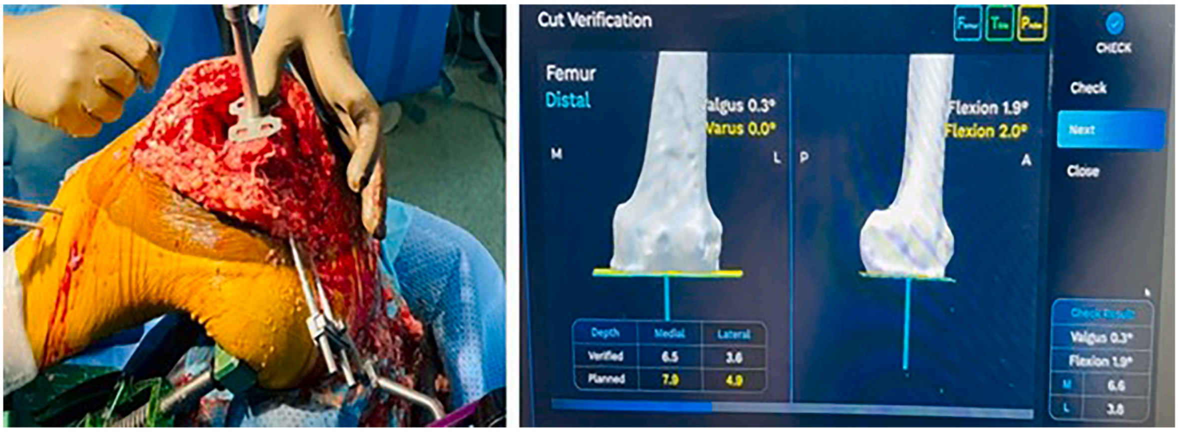

Fig. 1. Shows the distal femur cut verification.

Table 1
Baseline demographic of enrolled patients.

Variables	n = 100 Patients
Age, Years, mean ± SD	65.55 ± 9.15
Gender, n (%)	
Male	31 (31)
Female	69 (69)
Side, n (%)	
Right	53 (53)
Left	47 (47)

and 1.13 mm. The values for the tibial lateral and medial sides were 0.83 mm and 0.95 mm, respectively (Table 2, Fig. 2).

The planned resection angle (RMS values) for distal femoral plane, [varus (V)/valgus(V)] was 0.77°, flexion (F)/extension (E) was 0.98° and for posterior femoral plane internal rotation/external rotation was 0.59° and F/E was 1.5°; whereas, for tibial plane (V/V) was 0.76° and F/E was 0.85° (Table 3, Fig. 3). Table 4 shows the difference between planned and actual verified values obtained post resection.

Fig. 4 shows the gap balance check in full extensionand 90° flexionand Fig. 5 the radiograph of the implanted knee.

Two incidences of periprosthetic fracture were observed and were treated with intramedullary femoral nailing and ORIF with plate and screw and one incidence of pin tract infection on day 7th was noted which was addressed with local dressing and oral antibiotic.

The disparity in alignment accuracy between post-operative and anticipated outcomes when utilizing the Cuvis Joint robot was found to be equal to or less than 1mm or 1°.

4. Discussion

The current study highlights the utilization and accuracy of pre-operative planning in achieving optimal outcomes in RA-TKA, specifically in terms of bone resection thickness and angle in both the femoral and tibial planes. This study presents a single-center experience of fully automated Cuvis Joint Robot, emphasizing importance and efficacy of RA-TKA in patients with primary knee OA. Our findings correspond with prior research that has demonstrated the successful attainment of high-levels of precision, accurate alignment, while preserving the soft tissues, resulting in favorable clinical and functional outcomes when utilizing RA-TKA.[13–15] The disparity in alignment accuracy between post-operative and anticipated outcomes when utilizing the Cuvis Joint robot was found to be equal to or less than 1mm or 1°. To the best of our understanding, this study represents the first large-scale investigation documenting the precision, accuracy, and resection characteristics pertaining to the Cuvis Joint Robot in patients with primary knee OA who have undergone RA-TKA at our institution.

The preliminary report on precision and accuracy of this robot was studied and presented by Han-Jun Lee et al., in cadavers.[9] The study reported the accuracy in terms of cutting depth as well as resection thickness and angle and found to have significant precision with no deviation more than 1° mean RMS. The authors did not achieve any significant difference between planned and assessed values. They concluded that a high degree of resection thickness and angle accuracy could be achieved with this new Joint robot (Cuvis) in patients suffering from end-stage OA.

Successful achievement of knee alignment, preservation of soft tissue, and implant stability can be attained by the utilization of RA-TKA. This approach, facilitated by the Cuvis Joint robotic system, allows for intra-operative adjustments to optimize implant location, alignment, and bone resection. The surgeons can manipulate and regulate the several bone incisions to attain gap balance during both flexion and extension, while also overseeing the release of soft tissues.[7] In a study conducted by Song et al. in 2013,[12] and previously in 2011,[16] a prospective and randomized design was employed to compare the outcomes of 50 manual TKA procedures with 50 procedures utilizing a RA-TKA approach. The findings of this investigation revealed that the utilization of RA-TKA in enhanced precision in establishing alignment and a decrease in the occurrence of outliers above 3°, as compared to the manual TKA technique.[12,16] Our findings correlate closely with the observations made by Song et al. wherein we noticed a high level of precision in the alignment by the Cuvis Joint robotic system. We also saw a significant reduction in outliers and a no deviation from the predetermined method exceeding 1.5 mm or 2°.

The outcomes of sixty patients who were randomized to one of two groups were investigated in a study by Liow MHL et al.: RA-TKA (31 patients) and manual TKA (29 patients). Researchers found no deviations from the mechanical axis in either group, but a p-value of 0.049 indicated a substantially higher rate of joint-line outliers (>5mm) in the manual TKA group (20.6 %) compared to the RA-TKA group (3.23 %).[17] In a different study led by the same group, it was demonstrated that the

Table 2
Difference in resection thickness and root mean square values in femoral and tibial planes.

	Difference in Resection thickness with plan (mm)					
	Distal Femoral Plane		Posterior Femoral Plane		Tibial Plane	
	Medial	Lateral	Medial	Lateral	Medial	Lateral
Mean	0.34	0.49	0.10	0.27	0.20	0.32
SD	0.71	0.83	0.94	1.11	0.81	0.90
RMS	0.78	0.96	0.94	1.13	0.83	0.95

Abbreviations: RMS, root mean square; SD, standard deviation.
Note: The fact that every value is positive indicates undercutting.

Fig. 2. Represents the posterior femoral cut verification.

Table 3
Difference in resection angle and root mean square values in femoral and tibial planes.

	Difference in Resection Angle with plan (degrees)					
	Distal Femoral Plane		Posterior Femoral Plane		Tibial Plane	
	V/V	F/E	I/E	F/E	V/V	F/E
Mean	0.41	0.48	−0.01	0.53	0.10	0.15
SD	0.66	0.86	0.59	1.41	0.76	0.84
RMS	0.77	0.98	0.59	1.50	0.76	0.85

Abbreviations: V/V: varus or valgus F/E: flexion or extension; I/E: internal rotation or external rotation; RMS: root mean square; SD: standard deviation. A positive value indicates alignment of the varus, flexion, or internal rotation, while a negative value indicates alignment of the valgus, extension, or external rotation.

rate of accuracy in implant sizing reached 100 %. Post-operative mechanical alignment in the coronal plane consistently remained within a narrow margin of 2°, with an average alignment of $-0.4 \pm 1.7°$.[18] These findings provide evidence supporting the precision of preoperative planning and bone cutting. In our research, we have observed consistent findings that indicate the absence of mechanical-axis outliers in RA-TKA cohort of 100 patients. Additionally, we observed a significant level of precision in aligning the resection angle, with deviations not exceeding 2° in the posterior femoral plane. These findings confirm the remarkable accuracy attained through the implementation of the totally automatic Cuvis Joint Robot system.

The major findings regarding the fully automated Cuvis Joints Robot system include its ability to achieve greater precision in executing predetermined angles and bone resection techniques. Furthermore, this system allows for real-time modifications during the surgical procedure while still achieving optimal implant alignment. These advantages lead to better patient satisfaction, increased stability, and mobility.

5. Conclusion

According to our initial observations of RA-TKA utilizing the fully automated Cuvis Joint Robot system, we have noted a significant level of precision across multiple parameters, encompassing resection thickness, angle, cutting depth, and alignment. It allows for real-time modifications during the surgical procedure while still achieving optimal implant alignment. This work presents, for the first time, a comprehensive analysis of the precision achieved by a novel robotic system in Indian patients from our center, thereby emphasizing its significance. The results of this study provide evidence to support the practical application of the Joint robotic system for the treatment of individuals with advanced knee OA. Additional prospective investigations with a control group are necessary of the cutting-edge technology on patient-reported outcomes and explore other associated benefits, such as increased surgical efficiency and optimized implant location.

Fig. 3. Represents the post-tibial (proximal) cut verification.

Table 4
Difference in femur and tibial resection thickness and angle between the planned and verified values.

Variables	Resection Thickness (mm)						Resection Angle (degrees)					
	Femur				Tibia		Femur				Tibia	
	DFC		PFC		PTC		DFC		PFC		PTC	
	Medial	Lateral	Medial	Lateral	Medial	Lateral	V/V	F/E	I/E	F/E	V/V	F/E
Planned	10.3	6.5	8.7	7.4	0.8	7	0.0	0.3	0.9	2	0.0	3.0
Verified	10.3	6.3	8.8	7.2	1.1	7.2	0.3	0.5	1	2	0.0	3.5
Difference	0	−0.2	+0.1	−0.2	+0.3	+0.2	−0.3	+0.2	+0.1	0	0	+0.5

Abbreviations: DFC-Distal femoral cut; PFC- Proximal femoral cut; PTC: Proximal tibial cut; V/V-varus/valgus; F/E: Flexion or Extension; I/E: Internal Rotation or External Rotation.
Note: The positive value means varus, flexion or internal rotation alignment and negative value means valgus, extension, or external rotation alignment.

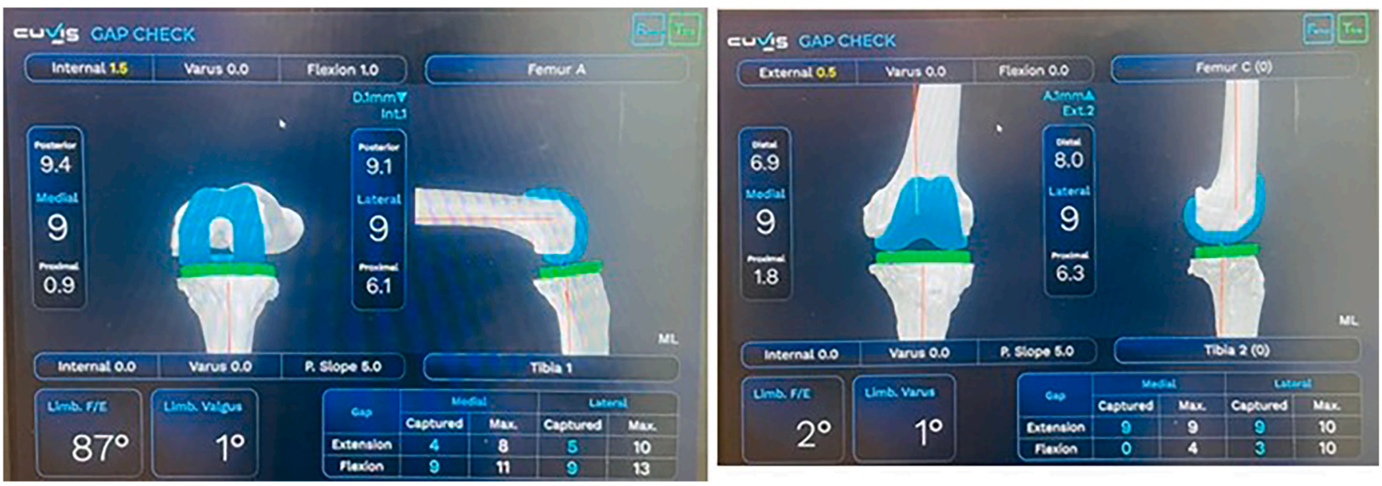

Fig. 4. Represents the gap balance check in full extension and 90° flexion.

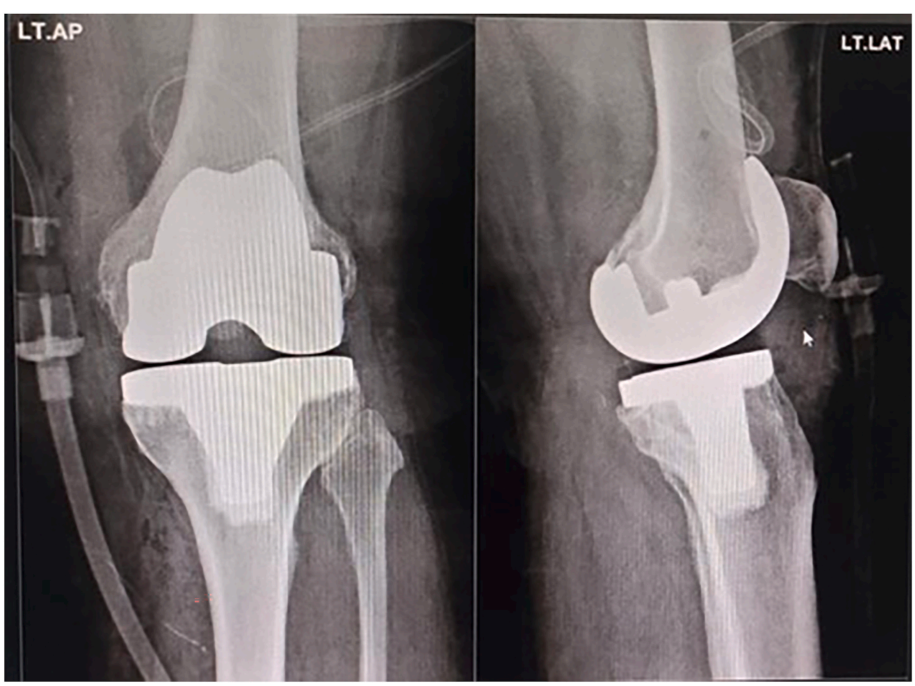

Fig. 5. Shows the radiograph of implanted knee.

Ethical statement

The study received approval from the local ethical committee review board. Prior to their participation, all individuals submitted the written informed consent.

Funding sources

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Patient's consent statement

Written informed consent was obtained from all enrolled patients and the Local ethics committee approved the study.

CRediT authorship contribution statement

Shailendra Patil: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Chetan Wankhede:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The author declare that the research was conducted in the absence of any commercial or financial ties that could be construed as a potential conflict of interest. Hence, there are no conflicts of interest to disclose.

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