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Original article

Evaluating the accuracy of Cuvis™ robot assisted total knee arthroplasty using offset type tensor system in ligament gap balancing

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ABSTRACT

Background: Conventional total knee arthroplasty (TKA) is a widely accepted and cost effective procedure for treating symptomatic knee osteoarthritis. Despite its success, patient satisfaction rates range from 82 % to 89 %, primarily due to suboptimal functional outcomes, reduced implant longevity, and the need for revision surgeries stemming from component malalignment or soft tissue instability. Robot-assisted total knee arthroplasty (RA-TKA) offers a promising approach to address these challenges.This study aims to evaluate the accuracy of robot-assisted total knee arthroplasty in achieving optimal ligament gap balancing, based on 159 cases performed in 2023.

Method: A total of 159 RA-TKA procedures using the Cuvis™ robot were conducted in 2023, with 9 valgus knees and 150 varus knees. Ligament gaps were measured twice by the robotic system: initially before bone cuts and subsequently after bone cuts. During surgery, an off-set type tensor was used to reassess ligament gaps. Cases exhibiting a discrepancy greater than 3 mm between extension and flexion gaps, as measured by both the tensor and robot, were included for further analysis. Discrepancies between surgeon-measured values and robot-predicted values were also evaluated.

Result: Of the 159 cases, 35 demonstrated a ligament gap discrepancy of more than 3 mm, as measured by the tensor. Among these, 24 cases (15 %) exhibited discrepancies between robotic measurements and tensor assessments. All 9 valgus knee cases showed discrepancies, while 15 varus knee cases also displayed discrepancies. The robot recorded 20 errors in ligament gap measurement, 2 errors in balancing, and 2 cases with both errors.

Conclusion: While robot-assisted TKA excels in bone cutting accuracy, errors in predicting ligament balancing and gaps remain in some cases. Therefore, caution is advised when adapting surgical strategies intra-operatively, relying solely on the Cuvis™ robotic system's measurements.

1. Introduction

The incidence of total knee arthroplasties (TKAs) has markedly increased over the past decade, with projections reaching 3.5 million procedures annually in the USA by 2030.[1] In South Korea, 90,000 TKA procedures were performed in 2020.[2] Despite its efficacy, approximately 19 %–25 % of patients remain dissatisfied with conventional TKA, primarily due to component malalignment and instability, where deviations as small as 3° can result in pain and instability.[3] Achieving a mechanical axis within 3° of neutral is critical for favorable long-term outcomes. Manual instrumentation in knee arthroplasty is associated with higher rates of alignment outliers compared to advanced technologies like computer navigation, robot assisted and patient-specific instrumentation.[4]

Robotics was first used for TKAs in 1980s to improve precision in managing flexion and extension gap balancing, optimizing implant positioning, and ensuring accurate prosthesis alignment, thereby mitigating complication rates associated with traditional technique.[5] Haptically controlled systems provide real-time intraoperative feedback, facilitating precise bone resctions in the coronal, sagittal, and axial planes while safeguarding surrounding soft tissues and ligaments.[6] Robotic TKA (RA-TKA) has demonstrated more consistent postoperative prosthesis alignment through individualized distal femoral resection angles, precise femoral component rotational alignment, and accurate bone cutting, while maintaining moderate bone temperatures to prevent injury.[7,8] Early outcomes of RA-TKA indicate enhanced patient

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satisfaction, and improved early functional recovery compared to manual TKA.

However, the adoption of RA-TKA faces limitations such as high initial capital costs, disposable component expenses, and an associated learning curve that may prolong operation times, reduce patient throughput, and increase infection rates. The placement of percutaneous pins for optical tracking arrays carries the risk of fractures, neurovascular injuries, and pin track infections, albeit these complications are infrequent.[9] Additionally, some systems require preoperative computed tomography (CT) scans for surgical planning, introducing extra radiation exposure and costs not typically necessary in conventional TKA.

The literature on robotic TKA, till date, showed consistently good results with improved post-operative results in terms of multiple objective and subjective parameters. There is paucity of literature which compares the offset tensor and the robotic method of gap measurement. Thus, this study aims to (1) evaluate the accuracy of robotic gap assessment and ligament balancing compared to the offset tensor system, and (2) analyze the correlation between joint laxity and robotic assessment of gap and ligament balance. It is hypothesized that the Cuvis™ robot excels in accurately assessing gap and ligament balance.

2. Materials and methods

This was a prospective study done on 159 knees which underwent RA-TKA, by a single primary surgeon, in our institute, in the year 2023, after taking ethical approval from institutional ethical committee (MH/2023/IEC/010). The inclusion criterion was the patients of OA knee with KL grade 3 or more (undergoing robotic total knee arthroplasty for various reasons). Exclusion criteria for the study were patients with local/remote infection and severe morbid conditions rendering patient unfit for the surgery. Out of these 159 cases, 9 knees were valgus and 150 knees were varus. Patients with outliers based on offset tensor measurement were further analyzed. There were 35 outliers. Out of these 35 outlier knees, robot had similar readings as measured by tensor in 11 cases. Therefore, these 11 knees were further excluded and remaining 24 knees were further scrutinized for difference in readings between offset tensor measurement and robotic measurement.

Laxity was measured radiologically with knee at full extension and varus/valgus force of 10 kg/10 kDa was given while taking radiograph in which medial laxity is considered as more than 4.1° difference and lateral laxity more than 5.4° difference.[10] (Fig. 1).

During the surgery extension and flexion gap was checked with offset tensor, block test and by robot itself. Outliers were identified on the basis of mismatch more than 3 mm between flexion and extension gap on offset tensor test.

Pre-operative evaluation: All the patients underwent through X-rays (AP, lateral and bilateral full limb length weight bearing, medial and lateral stress views), CT scan and MRI of the knee joint. Then, knees were evaluated for medial and lateral laxity.

CT scan and X-rays, both, were used for templating and pre-op measurement of the implant size (Fig. 2). Condylar plateau line (CPL) and trans-epicondylar axis (TEA) was measured in 3D CT and 2D coronal cuts of CT scan (Fig. 3). CPL was measured pre-operatively to predict mechanical axis perpendicular cut as measured for extra-medullary guide conventional TKA. It was measured because this same concept of planning was employed by the robotic software for measurement of cuts. MRI was used to recheck TEA (Fig. 4) and to assess the soft tissue condition of the joint which could explain the cause of laxity, if any. Additionally, Beighton scoring was used to assess any hyper-laxity condition (Fig. 5). And then, the knee (of the same patient who underwent intense pre-operative evaluation by templating and other sophisticated methods) was also checked by robotic installed software in the computer to predict the cuts and size of the final implant which could be used during the surgery (Fig. 6).

Surgical technique: The surgical procedure commenced with the preparation of the robotic system, including the setup of the camera and handpiece. Prior to making the skin incision, the procedure selection, handpiece calibration, and burr verification were conducted. A standard medial parapatellar approach was utilized for exposing all knees, and a posterior-cruciate substituting (PS) type implant was employed in every case. Soft tissue dissection was done and patella was everted. Following this, anterior and posterior cruciate ligaments were excised, then, removal of lateral and medial meniscus was done. Thereafter, pins were placed on tibial shaft and distal femur for placement of tracker/sensor. To construct a three-dimensional (3D) bone model of the knee joint, the femoral and tibial anatomies must be registered using a pointer probe. Following this, the preoperative gap measurement was checked by the robotic system (Fig. 6). Subsequently, the prosthesis positioning was meticulously planned in relation to the extension and flexion gaps throughout the entire range of motion. The robotic system's autonomous burr is then employed to execute the preselected virtual plan for prosthesis positioning during the surgery. Femur cuts were taken first followed by the tibial cut. With the help of trial components, post bone cuts gap measurement was taken by robot (Fig. 6) and compared with blocks and offset type tensor system (Stryker Howmedica Osteonics, Allendale, NJ (176.4 N, 18 Kg)), the surgeon was able to check the gaps

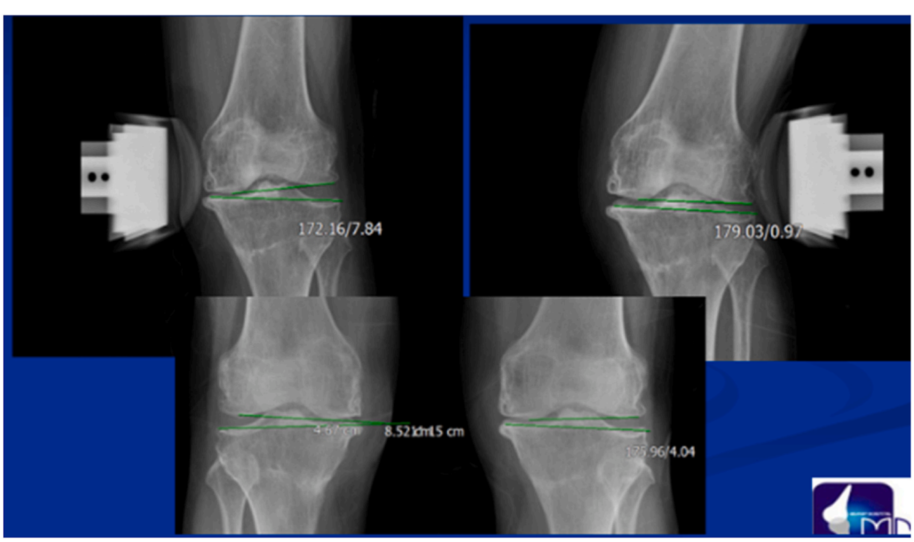

Fig. 1. Pre-operative measurement of laxity by applying varus and valgus force of 10 kDa (kDa).

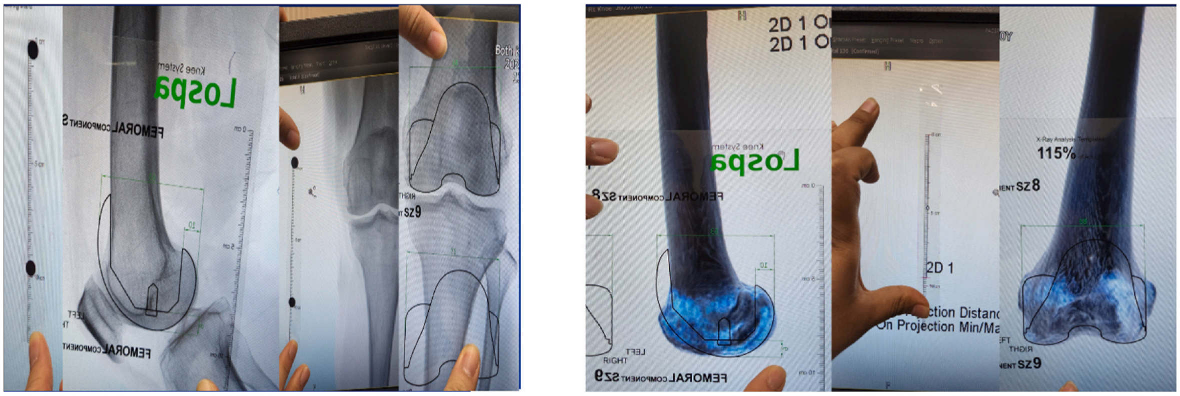

Fig. 2. Pre-operative templating of the knees using computed tomography (CT) scan and X-rays.

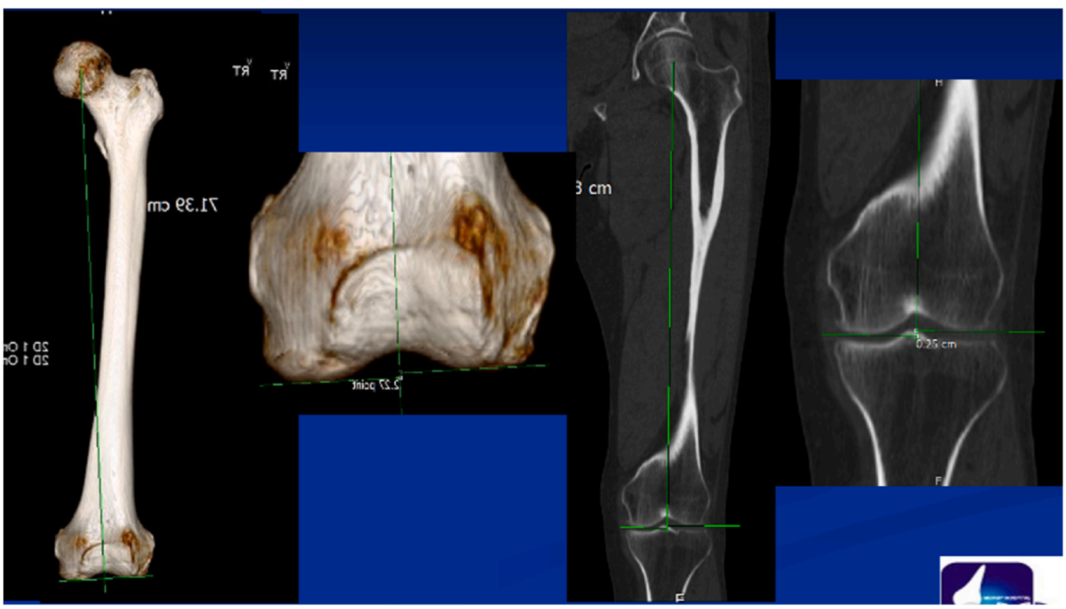

Fig. 3. Measurement of condylar plateau line (CPL) using coronal section of computed tomography scan and three dimensional (3D) CT scan.

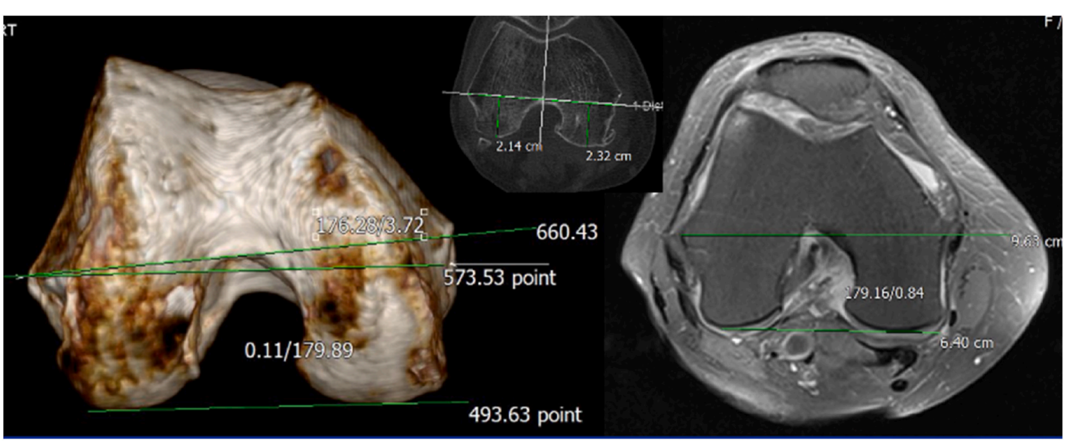

Fig. 4. Measurement of trans-epicondylar axis using computed tomography scan and recheck on magnetic resonance imaging (MRI) scan.

(Fig. 7). Conventional offset-type tensioning devices have been shown to be reliable tools for measuring flexion and extension gaps during TKA, contributing to balanced soft tissue tension and improved surgical outcomes as these devices enhance the accuracy and reproducibility of gap measurements during TKA.[11] To ascertain the accuracy of the robotic system, the surgeon compared the robotic flexion and extension gap measurements with those obtained using the tensor system.

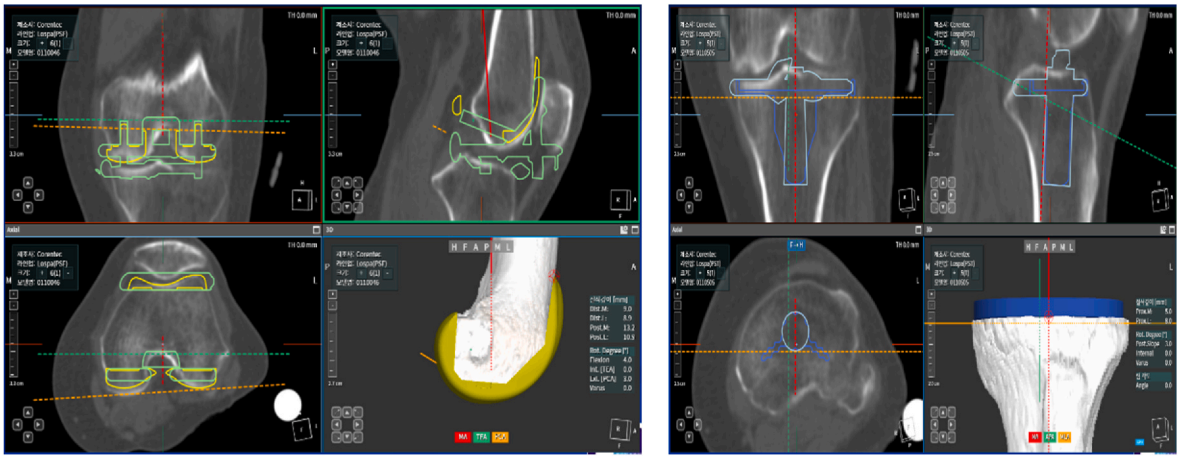

Fig. 5. Pre-operative assessment of bone cuts and prediction of size and alignment of implants by robot software using computed tomography scan.

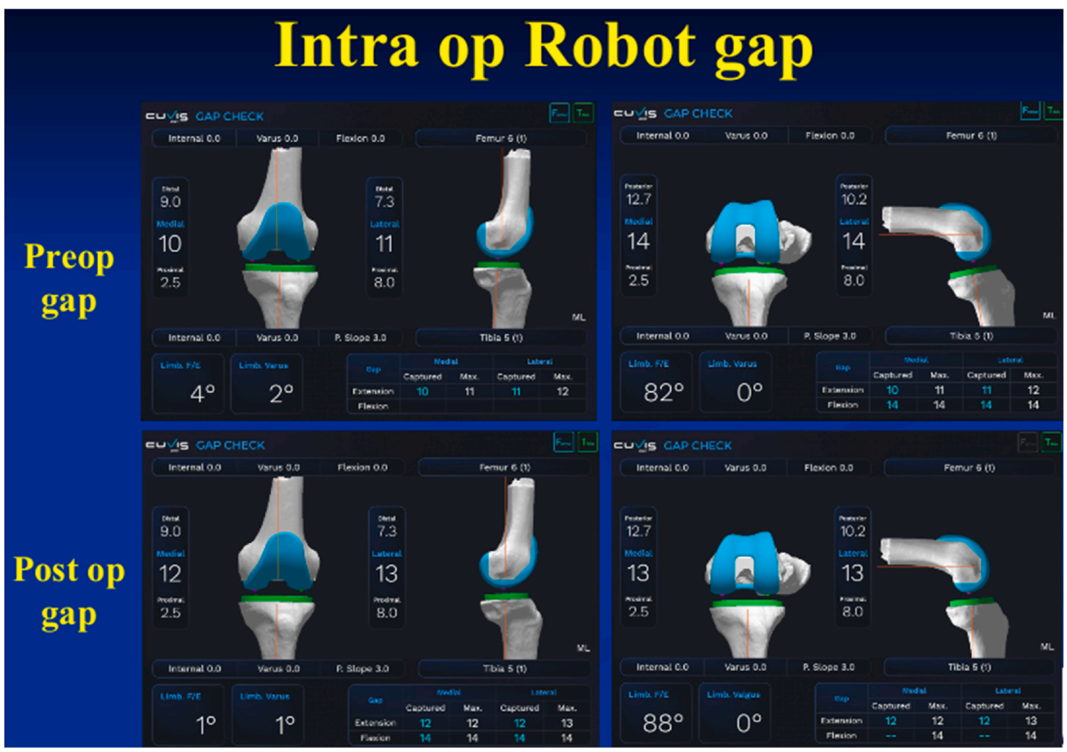

Fig. 6. This figure is showing the gap assessment by the robot before the bone cuts and after bone cuts in flexion and extension.

3. Results

There were total of 159 robotic TKA operated in the year 2023. There were 22 knees of the male patients and 137 knees of female patients. Total numbers of right knees were 78 and left knees were 81. The mean age of the patients involved in the study was 70 $\pm$ 1.026 ($\pm$1.47 % margin of error). The range of the population age involved in the study was from 49 years to 84 years. The average of flexion contracture seen among the patients was 2.84 $\pm$ 1.041 (range -10° to 30°). Medial laxity was found to be present in 31 knees while lateral laxity was present in 32 knees. Laxity of both lateral and medial compartment was present in 18 knees out of 159 patients operated in 2023.

There were 35 knees outliers identified with more than 3 mm mismatch based on offset tensor measurement. Among these 35 cases, 11 knees showed similar readings of outliers as measured by robot and offset tensor. Therefore, after exclusion of these 11 cases, we were left with 24 cases (2 males and 22 females) who exhibited discrepancies between measurements recorded by the robot and those taken by the tensor system, constituting 15 % of all total 159 cases. Among the 24 cases with discrepancies, 9 cases involved valgus knee patients, which accounted for all valgus knee cases in the study of 159 cases, while the remaining 15 cases involved varus knee patients. Among these 24 cases, medial laxity was seen in 7 knees, lateral laxity was seen in 5 knees and laxity of both the compartments was seen in 6 knees.

Out of the 24 cases, there were 20 errors in the robot's ligament gap measurement, 2 errors in balancing measurement, and 2 cases where errors were found in both ligament gap and balancing measurements (Table 1).

Knee gaps were measured with robot and tensor system and compared with standard deviation (SD). In extension, medial gap measurement between robot and tensor showed p-value of 0.0059 (statistically significant) with 95 % confidence interval of this difference from

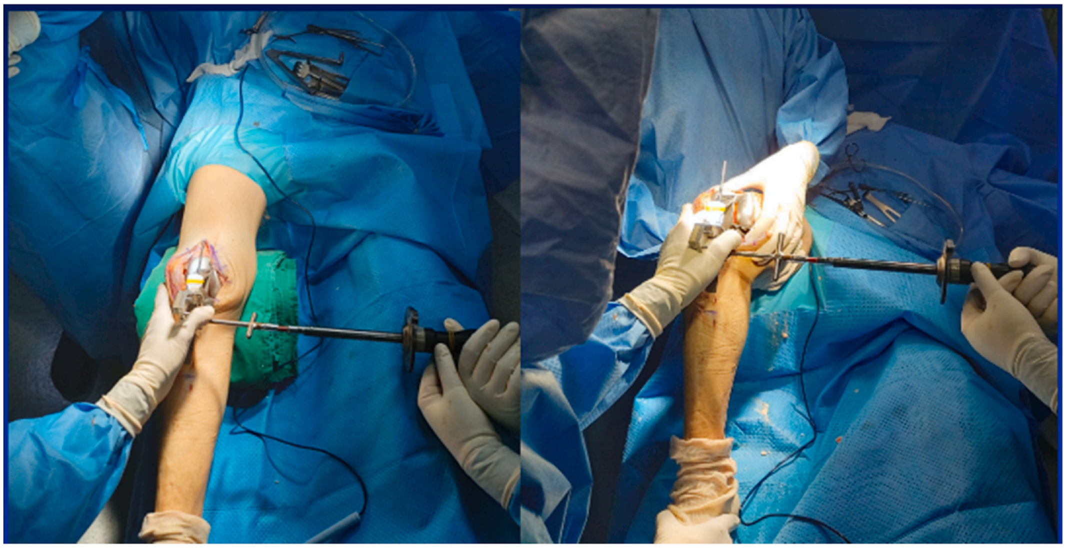

Fig. 7. Offset type tensor system was used to measure the final gaps after all bone cuts.

Table 1
Cases with discrepancies between robotic and offset tensor gap measurements.

Sex	Age	Varus/ valgus	Robot ext gap (mm)		Robot flex gap (mm)		Tensor ext gap (mm)		Tensor flex gap (mm)		Femur/tibial/insert (mm)	Result
			Pre-op	Post-op	Pre-op	Post-op	varus/ valgus	med/ lat	varus/ valgus	med/ lat		
			med/ lat	med/ lat	med/ lat	med/ lat						
F	58	Varus 3°	7 7	15 15	13 10	13 13	0	10 10	0	1717	5 5 10	Robotic gap error
F	72	Varus 17°	10 10	13 13	11 12	13 14	varus 5	7 17	0	17 17	5 5 12	Robotic gap & balancing error
F	68	Valgus 1°	6 6	11 11	13 11	11 13	0	10 10	0	16 16	6 5 10	Robotic gap error
F	65	Varus 11°	7 8	11 12	11 12	12 13	0	12 12	varus 2	15 19	8 9 12	Robotic gap error
F	72	Varus 8°	10 12	15 16	12 13	12 13	0	11 11	varus 1	16 18	5 5 12	Robotic gap error
F	75	Varus 12°	6 9	10 10	12 15	11 11	varus 2	8 12	valgus 1	18 16	6 5 10	Robotic gap error
F	77	Valgus 5°	6 8	12 13	13 12	13 13	valgus 2	14 10	0	16 16	4 4 12	Robotic gap error
M	68	Valgus 2o	10 9	13 12	14 15	13 13	0	14 14	varus 2	16 20	11 11 14	Robotic gap error
F	75	Varus 12°	13 13	13 13	14 14	16 16	valgus 2	19 15	valgus 9	30 12	7 5 16	Robotic gap & balancing error
F	58	Varus 9°	11 12	14 15	12 16	13 15	varus 5	7 17	varus 2	14 18	8 7 12	Robotic balancing error
F	62	Valgus 4°	12 14	12 12	16 11	17 16	0	15 15	0	19 19	5 4 14	Robotic gap error
F	75	Valgus 10°	11 11	16 15	13 14	16 14	varus 4	9 17	0	18 18	6 5 16	Robotic balancing error
F	79	Varus 5°	10 11	12 13	14 14	13 13	varus 1	11 13	0	16 16	6 7 12	Robotic gap error
F	83	Varus 5°	9 12	12 13	14 14	14 13	varus 3	9 15	0	20 20	6 5 12	Robotic gap error
F	71	Varus 10°	11 11	15 15	11 11	15 13	0	15 15	0	21 21	6 7 14	Robotic gap error
F	61	Valgus 5°	12 11	14 14	16 14	13 15	valgus 3	16 10	varus 2	16 20	8 7 12	Robotic gap & balancing error
F	69	Varus 12°	9 11	13 13	12 14	14 12	varus 1	12 14	0	18 18	6 5 12	Robotic gap error
F	68	Valgus 7°	10 9	13 13	18 15	14 14	varus 2	11 15	0	19 19	7 5 14	Robotic gap error
F	68	Valgus 1°	9 9	12 11	14 14	13 13	0	12 12	0	18 18	8 7 12	Robotic gap error
M	68	Valgus 3°	11 10	8 9	8 6	10 10	0	11 11	0	15 15	11 11 12	Robotic gap error
F	70	Varus 8°	11 12	11 13	9 13	13 13	varus 3	9 15	varus 2	14 18	4 4 12	Robotic gap error
F	56	Varus 11°	9 11	9 11	11 14	11 14	varus 1	13 15	0	18 18	6 5 14	Robotic gap error
F	71	Varus 7°	8 7	12 13	10 11	10 11	0	11 11	varus 2	13 17	6 5 10	Robotic gap error
F	71	Varus 5°	8 8	12 13	9 13	12 12	0	10 10	0	15 15	6 5 12	Robotic gap error

Med/Lat = Medial/Lateral, **Ext gap** = Extension gap; **Flex gap** = Flexion gap, **Pre-op/Post-op** = Preoperative and postoperative.

−3.54 to −0.63. In extension, lateral gap measurement by robot and tensor system showed p-value of less than 0.0001 (extremely statistically significant) with 95 % confidence interval of this difference from −4.44 to −1.81. When checked and compared in flexion, medial gap measurement by robot and tensor system showed p-value of less than 0.0001 (extremely statistically significant) with 95 % confidence interval of this difference from −6.65 to −3.18 while lateral gap measurement by two systems showed p-value of less than 0.0001 (extremely statistically significant) with 95 % confidence interval of this difference from −5.97 to −3.53 (Table 2).

On the basis of these findings, the knees which showed discrepancies between the readings of robot and offset tensor (in the same patient) were found to be related to one of the two groups either valgus group or medial release group. Both the groups are associated with the sudden disproportionate increase of the gap (between pre-op gap measurement and post-bone cuts measurement). It was found that knees related to medial release group had pre-op laxity (medial laxity, lateral laxity or both) in most instances.

Table 2
Comparison of Extension and Flexion Gaps Measured by Robotic System vs Tensor Device in Outlier Knees.

Measurement	Mean (mm)	SD (mm)	p-value	95 % Confidence Interval (CI)
Medial Robot Extension Gap	9.42	2.00	0.0059	−3.54 to −0.63
Medial Tensor Extension Gap	11.50	2.90		
Lateral Robot Extension Gap	10.04	2.05	0.0001	−4.44 to −1.81
Lateral Tensor Extension Gap	13.17	2.44		
Medial Robot Flexion Gap	12.38	2.57	0.0001	−6.65 to −3.18
Medial Tensor Flexion Gap	17.29	3.34		
Lateral Robot Flexion Gap	12.79	2.19	0.0001	−5.97 to −3.53
Lateral Tensor Flexion Gap	17.54	2.00		

SD, Standard Deviation. All reported p-values are **statistically significant ($p < 0.05$),** indicating a significant difference between the robotic and tensor measurement methods.

4. Discussion

In our study of 159 patients, robot showed similar coronal or sagittal gaps as checked by offset tensor except in 24 patients. Interestingly these 24 knees found to be from the outlier group of 35 knees as measured by offset tensor system after bone cuts by robotic arm. It was also found that all 9 patients of valgus knees have discrepancies between robotic measurements and tensor system measurements. Among 15 patients of varus knees with discrepancy between readings of robot and tensor, medial laxity was seen in 4 cases, 2 cases had lateral laxity while both medial and lateral laxity was seen in 4 cases.

Contrary to popular belief, a recent study by Kirchner et al. (2024) based on American Joint Replacement registry, states that there are higher chances of post-operative pain and instability in patients with RA-TKA.[12] Their analysis revealed no significant difference between RA-TKA and cTKAs (conventional) regarding the likelihood of revision at the 2-year mark (Odds ratio aka OR for RA-TKA vs. cTKA: 1.0 [95 % CI: 0.8 to 1.3]; p = 0.92). The indications for revision in RA-TKA were comparable to those in cTKA, with the exception of a higher likelihood of instability (OR: 1.6 [95 % CI: 1.0 to 2.4]; p = 0.04) and pain (OR: 2.1 [95 % CI: 1.4 to 3.0]; $p < 0.001$) in the RA-TKA group. There are studies in the literature which showed that even after improved alignments of component and balancing of gaps by RA-TKA, the patients' satisfaction rate failed to correlate as compare to conventional TKA.[13,14] The discrepancy observed between the predicted and actual intraoperative gap measurements in robotic TKA raises important considerations regarding the accuracy of current software algorithms. While our findings of difference in predictive gap versus actual gap by robotic software, are in line with prior reports in patients undergoing robotic TKA, it is important to interpret these observations with caution, as definitive conclusions regarding clinical outcomes require validation through long-term follow-up studies. This finding is opposite of what most of the studies stated in the literature.[3–7]

In their 2019 study on RA-TKA, Shalhoub et al. employed a computer-controlled tensioning device inserted into the knee joint to quantify the knee gap across the range of motion (ROM). The post-op gaps attained closely matched the predicted gaps throughout the ROM. These findings substantiate the hypothesis that post-op knee gaps can be precisely predicted and attained with minimal RMS error across the ROM when utilizing a gap-tensioning device in conjunction with RA-TKA.[15] They supported the use of tensioning device along with robotic system to remove any possibility of errors in gap measurement.

Robot does not have the inbuilt mechanism to detect pre-op laxity which is normally obtain through stress views. Robot can only measure through pre-op CT scan study and intra-op imageless haptic sensors, thus have problem of accurately quantifying gaps in pre-op laxity patients. Intra-operative planning by the Cuvis™ robot of gap measurement was calculated as the distance between two points on the distal cutting surface of the femur and the proximal cutting surface of the tibia, and for flexion gap, two points on the posterior cutting surface of the femur were used (Fig. 8). Tensor has the advantage of quantifying the flexion and extension gap by putting pressure to apart distal femur and proximal tibia to measure the gap which is generally not possible with the robotic system.

Okamato et al. (2013) in their study found that knees with severe varus deformity exhibited larger lateral and medial soft tissue gap after bony cuts in comparison to knees with mild and moderate varus deformity.[16] This finding correlates with our study in which there was sudden disproportionate increase in the gap of some knees (especially valgus and medial release group) resulting in outliers.

Our study found that all the valgus knees were present in the outlier group and they all also had discrepancies between robot and tensor system measurement of the gaps. This finding is supported by the study of Rossi et al. in which they stated that accurate physical examination is mandatory to evaluate a valgus deformity in the knee.[17] Because if a fixed valgus deformity is present, after lateral soft tissue release the knee may be unstable due to medial and lateral structures will no longer be functional.

Another study by McAuliffe et al. also supported our findings of laxity in valgus knees. Their findings indicated that valgus knees undergoing TKA exhibit notable preoperative imbalances in medio-lateral and flexion-extension alignment. In full extension, the medial soft tissues are considerably more lax, while this condition reverses in flexion,

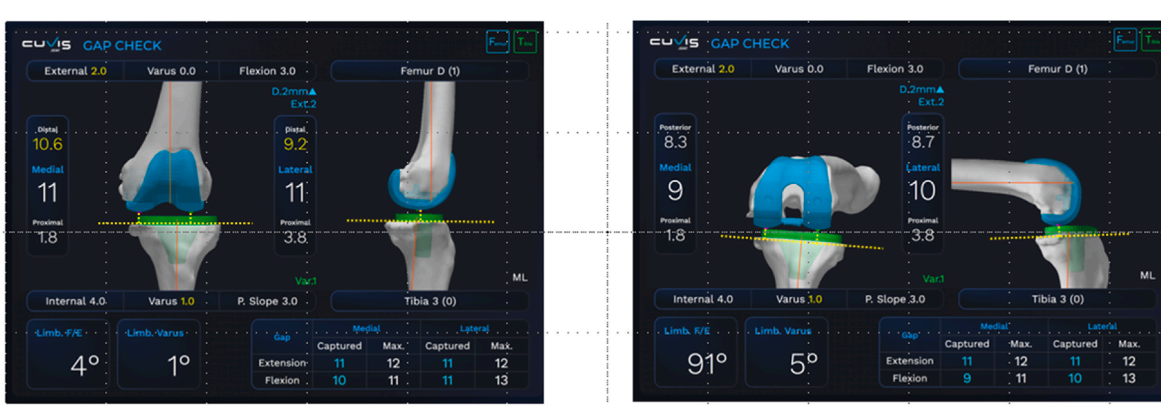

Fig. 8. Gap measurement was calculated as the distance between two points on the distal cutting surface of the Femur and the proximal cutting surface of the Tibia. In the case of a flexion gap, two points on the posterior cutting surface of the Femur are used.

with the lateral tissues becoming significantly more lax. Furthermore, they observed a greater variety of medial and lateral laxity patterns in full extension than previously described in conventional subjective grading systems.[18] Additionally, a study by Favorito et al. identified that a deficient lateral condyle of femur frequently occurs in valgus osteoarthritic knees, contributing to these laxity imbalance.[19] Scanlon et al. in their case report of 2 valgus knee patients who underwent RA-TKA suggested the use of BalanceBot, a type of tensor, to balance the soft tissue correctly.[20]

Through this study, authors suggest to other surgeons that if they are planning RA-TKA for their patients, they should beforehand measure the laxity of their knees and double check every measurement with preoperative templating especially in cases of valgus knees and medial release group patients who have knees with laxity. Authors suggest that on the basis of sudden disproportionate increase of gap, patients can be divided into 2 groups: valgus knees patients and medial release group. Authors recommend that this sudden increase of intraoperative gap during TKA can be reduced by less tibial cut and using one size bigger femoral component. The outliers, especially, in the medial release group can be reduced by performing minimal medial release technique of soft tissue resection in TKA.[21] In this technique, distal part of medial collateral ligament is not resected while balancing the knee.

Limitations: We recognized the limitations of this study. One of the limitations of this study was lack of comparative group. Second, measurements were made in knee extension and 90° flexion due only to the characteristics of the tensor system. We are well aware of the importance of evaluating laxity over the entire range of knee flexion and plan to determine the proper tension in the coronal direction. This study measured the knee joint balance obtained intra-operatively by robot and the tensor system but did not measure any patient-reported outcomes. To better interpret the results, future studies are needed to determine the effect of balance on clinical outcomes.

Future directions: Artificial intelligence, data analytics, and machine learning algorithms have the potential to significantly enhance the management of laxity issues, thereby improving post-operative joint stability. By synthesizing data from a diverse range of RA-TKA studies, these advanced technologies could offer invaluable insights, fostering refinement in surgical techniques to address laxity-related challenges. The future of RA-TKA thus holds the promise of transforming patient care, advancing the field of surgery, and defining the trajectory of knee arthroplasty innovations.

5. Conclusion

According to the observation in this study, authors found that robot-assisted knee arthroplasty excels in terms of bone cutting; however, it is not uncommon for errors to occur in predicting ligament balancing and gaps in some cases, especially valgus knee group and medial release group are very sensitive and are prone for error in gap measurements. Hence, it is strongly advised to exercise utmost caution when considering modification or adaptation to surgical strategies intra-operatively, relying solely on the values provided by the Cuvis™ robotic system. Authors also advocate the need of an in-built tensor system for ligament gap balancing to use intra-operatively in Cuvis™ robot for precise measurement of ligament balancing gap in future to reduce the chances of mismatch of gaps as measured by offset type tensor system and for perfect balancing of the knees.

CRediT authorship contribution statement

Woon-Hwa Jung: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Writing – review & editing, Supervision. **Minseok Seo:** Conceptualization, Formal analysis, Writing – review & editing, Investigation. **Vaibhav Sahu:** Conceptualization, Investigation, Writing – original draft, Writing – review & editing. **Jignesh Tandel:** Formal analysis, Investigation, Writing – review & editing.

Patient consent

The authors declare that they had taken the written informed consent from the patients regarding surgery and also took their approval for publishing this study without disclosing their identities.

Ethical statement

Institutional Ethical Committee approval was taken for this study (MH/2023/IEC/010).

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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