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Evaluation of the safety and efficacy of the fully automated active robotic system in robotic assisted total knee arthroplasty

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ABSTRACT

Background: Use of semi-active and active robotic system for performing Total Knee Arthroplasty (TKA) is increasing. The novel fully automated active robotic system performs milling of the bone surfaces with a high speed burr. The aim of the current study was to assess the safety and efficacy of the system in robotic assisted TKA (RA-TKA).

Materials and methods: A single center clinical trial was conducted following 30 knees undergoing active RA-TKA for 6 months. Inclusion criteria were patients undergoing RA-TKA for end stage arthritis. Patients undergoing conventional TKA and revision TKA were excluded from the study. Sample size was estimated to be 28 patients with α error of 0.05 and β error of 0.2 with power of study being 80. A predefined list of RA-TKA adverse events was employed to study the safety of the system. Efficacy was judged by comparing the planned versus achieved Implant size, alignment and limb alignment on postoperative radiographs. The post-operative clinical evaluation was done by an independent observer who was not part of the operating team. The primary safety and efficacy hypothesis was tested using a one sided Exact binomial test. The p value < 0.05 was considered significant.

Results: Pre-defined adverse events did not occur in any of the 30 RA-TKA (statistically significant p value < 0.001). The implant size accuracy was 100% (30 out of 30 knees) for femoral component and 96.67% (29 out of 30 knees) for tibial component (statistically significant, Chi-squared test, p value 0.0105 and 0.0461 respectively). The implant position and limb alignment was accurate in 100% of patients (p value < 0.001).

Conclusion: Early experience of the use of fully automated active robotic system in TKA shows that it is safe and also is effective in achieving accurate implant size and implant/limb alignment.

1. Introduction

Total knee Arthroplasty (TKA) for end stage (stage 4) degenerative arthritis of the knee is a successful operation. Most of the operated patients experience relief of their knee pain, improved knee function and quality of life after TKA.[1–5] Despite improvements in the implants and surgical techniques, about 20% of patients remain dissatisfied with their primary TKA operation ([6–12]). Accurate implant size/alignment and limb alignment are necessary for the long term survival of the implant and successful outcome.[13,14] Various studies have shown that implant overhang/under sizing and limb malalignment is associated with increased polyethylene wear rate, suboptimal patient reported outcome measures and increased chances of revision of primary TKA.[15,16] The common causes of early revision within two years of primary TKA are infection, instability, aseptic loosening and knee stiffness. They collectively account for almost 50% causes early revisions.[17]

Computer and Robotic assisted TKA (RA-TKA) helps in achieving optimal limb alignment. Robotic assisted technology helps the surgeon in planning the accurate implant size/alignment and limb alignment preoperatively. This is done on the 3D bone model generated with the help of preoperative CT scan. Active Robotic System performs the preplanned bone cuts automatically with the cutting burr. This is done without any human guidance during

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Abbreviations

TKA	Total knee Arthroplasty
RA-TKA	Robotic assisted TKA

femur and tibia preparation.

The active Robotic System for TKA started with the introduction of ROBODOC in 2000. T solution One (TS1, Think Surgical Inc., Freemont, CA), an updated version of the ROBODOC is available since 2019 after getting the Food and Drug Administration (FDA) approval in 2019. The active robot used in this study is a fully automatic active robotic system which executes accurate bone cuts with the help of cutting burr. This is done after the surgeon registers the femur and tibia points during the operation and attaches the robot to the patient.

The aim of the study was 1) To study the safety of the fully automated active robotic system by comparing the incidence of adverse events to the literature control values associated with conventional manual TKA. and 2) To study the effectiveness of the system in predicting the implant size/alignment and limb alignment and compare it with the literature control values for conventional manual TKA. The safety endpoint was assessed against the composite rate of adverse events associated with manual TKA.

2. Materials and Methods

This is single center, same surgical team prospective study involving patients undergoing RA- TKA for end stage (grade 4) arthritis of the knee joint. The sample size was estimated to be 28 patients for anticipated 20% decrease in the composite adverse events associated with the conventional manual TKA with alpha error of 0.05 and beta error of 0.2 with power of study being 80%. The inclusion criterion was patients undergoing primary TKA with fully automated active robot. Patients undergoing conventional TKA, revision TKA, patients with body mass index >40 kg/m2, patients with any type of metallic implants in the to be operated knee were excluded from the study.

All the patients underwent a pre-operative 3 dimensional CT scan. After segmentation of the scan images a bone model was prepared. The operating surgeon along with system specialist did the preoperative planning as regards the implant size/alignment and limb alignment on a computer with specialized software (Fig. 1).

The safety endpoint was assessed against the composite rate of adverse events associated with manual TKA. Healy et al.[18] described the standardized list and the definitions of complications of the manual TKA. These were ratified by the Knee Society and the Association of Bone and Joint Surgeons. They reported the adverse events incidence rate of 7.6%.[18] The adverse events associated with the manual TKA reported in the literature are medial collateral ligament injury (2.7%), extensor mechanism injury (2.1%), nerve injury/palsy (1.3%), femoral/tibial condyle fracture (0.68%), patellofemoral malalignment (0.5%), knee subluxation/dislocation (0.2%) and popliteal vessels injury (0.15%).

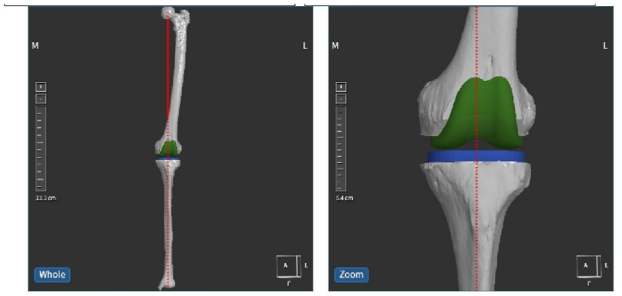
All patients were operated by the same surgical team. Tourniquet was used in all patients. All the patients received posterior stabilized high flexion freedom Total knee implant (Maxx orthopedics, PA, USA). After surgical exposure of the knee joint, the surgeon did registration of 40 points on the femur and the tibia (Fig. 2). Once the actual anatomy of the patient matched with the CT generated bone model as judged by root mean square error (RMSE) < 1, the robot was docked to the patients leg with external fixator pins. Then confirmation was done that the robot has a clear path for milling of the tibia and femur. Finally the fully automated active robot performed the femur and tibia cuts by milling of the bone utilizing high speed burr (Fig. 3). This ensures precise surface dimensions for the pre-planned femur and tibia implant. After completing the bony cuts, trial implantation was carried out. The knee balance in both flexion and extension was checked in real time on the monitor by moving the knee from full extension to maximum flexion. In both flexion and extension only 1 mm of difference was accepted between the medial and lateral joint space (Fig. 4). Beyond this step, cementation of the implants and wound closure was carried out in routine manner. In RA-TKA group of 30 patients the time taken for the insertion of registration pins, bony registration, bone milling with robot and required soft tissue release was measured and was compared with the time for the application of appropriate zigs and execution of the bone cuts and soft tissue releases in the conventional TKA group of 30 patients. All the patients were mobilized on the same evening of the surgery. All patients received thromboprophalaxis in the form of oral rivaraxoban 10 mg one tablet once a day for two weeks. The mean discharge time from the hospital was 3.5 ± 0.5 days. All the patients had long leg AP and lateral x ray to assess the accuracy of the implant size/alignment and limb alignment. Five radiographic markers as described by Peek et al.[19] were used to assess the size and fit of the implant. As regards the femur implant size points considered were presence/absence of femoral notching, gap (>2 mm) between the anterior cortex of the femur and femur implant, posterior femoral contour restoration. Tibia implant size and position was assessed by lateral overhang and cortical contact (<50%). The intra operative and post-operative adverse events and the post-operative x rays were analyzed by an independent observer who was not part of the surgical team. The patients were followed up at 6 weeks, 3 months and 6 months post operatively. The composite adverse events, accuracy of the implants size/alignment and limb alignment with the fully automated RA- TKA system was compared with that of literature control manual TKA. The primary safety hypothesis was tested using a one sided Exact binomial test. Effectiveness of the system in achieving an accurate limb alignment was also tested with primary effectiveness hypothesis using one sided Exact Binomial test. P value < 0.05 was considered significant.

3. Results

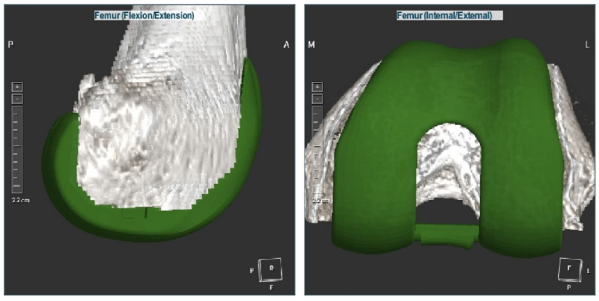
A total of 30 patients (21 females and 9 males) were studied. The average age of the patients was 69 years. The average body mass index of the patients was 29.1 with a range of 20.1–38.5 (Table 1). All the patients were followed up at 6 weeks, 3 and 6 months. None of the 30 patients suffered any of the pre-defined procedure related adverse events. The pre-operative 3D templating was successful in accurately predicting the femur implant in 100% of cases. It accurately predicted the tibial implant in 96.67% of cases (Table 2). In one patient instead of planned size 5, tibial base plate of larger size 6 was used. The time taken in conventional TKA for application of appropriate zigs and execution of the bone cuts and soft tissue releases and in RA-TKA group for the insertion of registration pins, bony registration, bone milling with robot and required soft tissue release was 24.77 ± 1.92 and 25.03 ± 3.27 respectively which is statistically non-significant (p value 0.7086). According to Peek's

Femur Implant	
Model Name	MKUFPSLB00
Manufacturer	MaxxMeril
Lineup	Freedom
Type	PSF
Size (Revision)	B(0)
Femur Resection Depth	
Dist.Med.	8.5 mm
Dist.Lat.	7.5 mm
Post.Med.	9.8 mm
Post.Lat.	7.9 mm
Femur Rotating Degree	
Flex/Ext	Flexion 3.0 °
Int/Ext [TEA]	External 1.5 °
Int/Ext [PCA]	External 2.5 °
Var/Val	Varus 0.0 °

Tibia Implant	
Model Name	MKMTUUX200
Manufacturer	MaxxMeril
Lineup	Freedom
Type	PST
Block	0
Size (Revision)	2 (0)
Tibia Resection Depth	
Prox.Med.	2.0 mm
Prox.Lat.	4.6 mm
Tibia Rotating Degree	
Posterior Slope	5.0 °
Int/Ext	Internal 0.0 °
Var/Val	Varus 0.0 °
Limb Angle	
Limb Angle	0.0



Femur



Tibia

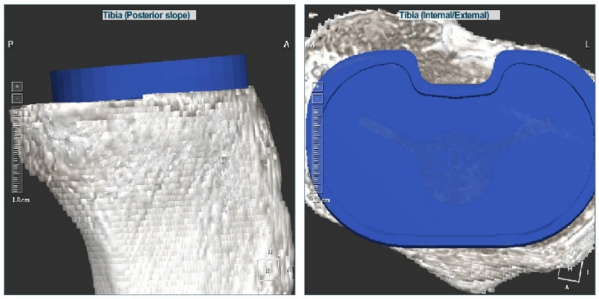


Fig. 1. Pre-Operative 3D CT Scan templating and planning of the RA-TKA.

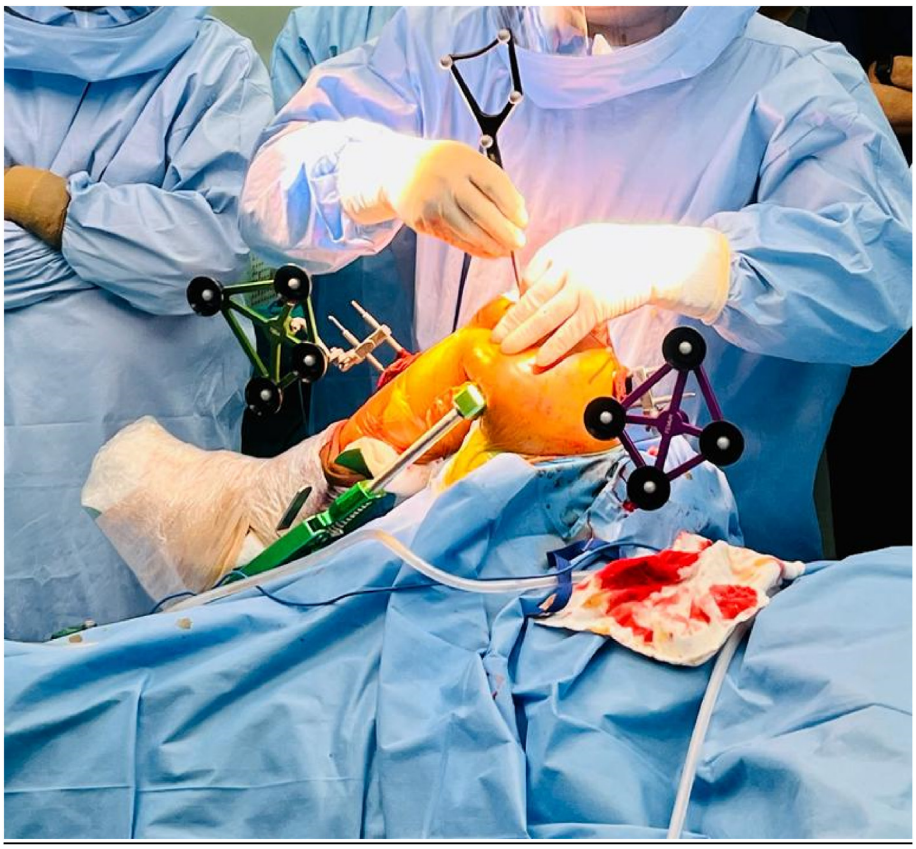


Fig. 2. The Femur and Tibia points being registered in the computer.

criteria no femoral or tibial implant was found to be undersized/oversized. The limb alignment was found to be optimal in all cases (Figs. 4 and 5). No femoral component had anterior cortical notching, and a >2 mm gap between the anterior cortex of femur and the implant was not observed in all cases. All femoral implants restored the posterior condylar contour. As regards the tibial base plate there was no lateral overhang or <50% cortical contact (Table 3). The primary safety hypothesis is met as none of the patients had any predefined adverse events (P value < 0.001). The primary effectiveness hypothesis is also satisfied as all the 30 patients had achieved pre-planned limb alignment on the post-operative x rays (0% malalignment as against literature control rate of 32%.for manual TKA, p value < 0.05). The pre-operative Oxford Knee Score 19.47 ± 1.57 improved to 35.65 ±1.35 at 6 months follow up. (Statistically significant, students *t*-test, p value < 0.001).

4. Discussion

The objective of the current study was to evaluate the safety and efficacy of the fully automated active robotic system for primary TKA. The main finding of the study is no patients in the study group experienced any pre-determined adverse events proving the safety of the system. The pre-operative 3 D CT scan templating was able to accurately predict the femoral implant in 30 out of 30 cases (100%) and tibial implant in 29 out of 30 cases (96.67%). All the post-operative x rays showed acceptable alignment (within −1.5 to +1.5° of desired limb alignment). The most important intimidation point in surgeon's mind in adoption of this new technology is the concern of the increased operative times and reduced efficiency. Our study showed that the active robot specific time for the insertion of registration pins, bony registration, bone milling with robot and required soft tissue release in RA-TKA group was not statistically significantly high as compared to the time taken for application of appropriate zigs and execution of the bone cuts and soft tissue releases in conventional TKA (25.03 ± 3.27 and 24.77 ± 1.92 min statistically non-significant, p value 0.7086).

Only a few studies are available reporting about implant size/alignment and limb malalignment rate with other robotic systems.[20,21] Most of these studies are focused on cadaveric studies. Sires et al.[20] in their study performed post-operative CT scans at mean interval of 5.9 months in 29 patients. They reported 7% malalignment rate (alignment difference ranging from 0 to 7°).

Few studies are available about the clinical results using the predicate device (ROBODOC). Liow et al., in 2014 reported no mechanical axis outliers in their study of 27 patients. In 7.4% (2 out of 27 cases) of their patients they had to abort the robotic procedure.[22] The same group (Liow et al.) in 2017 reported their experiences using the ROBODOC system.[23] They aborted the robotic procedure in 10% of their cases. The mean RA- TKA operative time was 91 min. Stulberg et al.[24] reported a study of 115 patients operated with T Solution One (TSI, THINK Surgical Inc. Freemont,

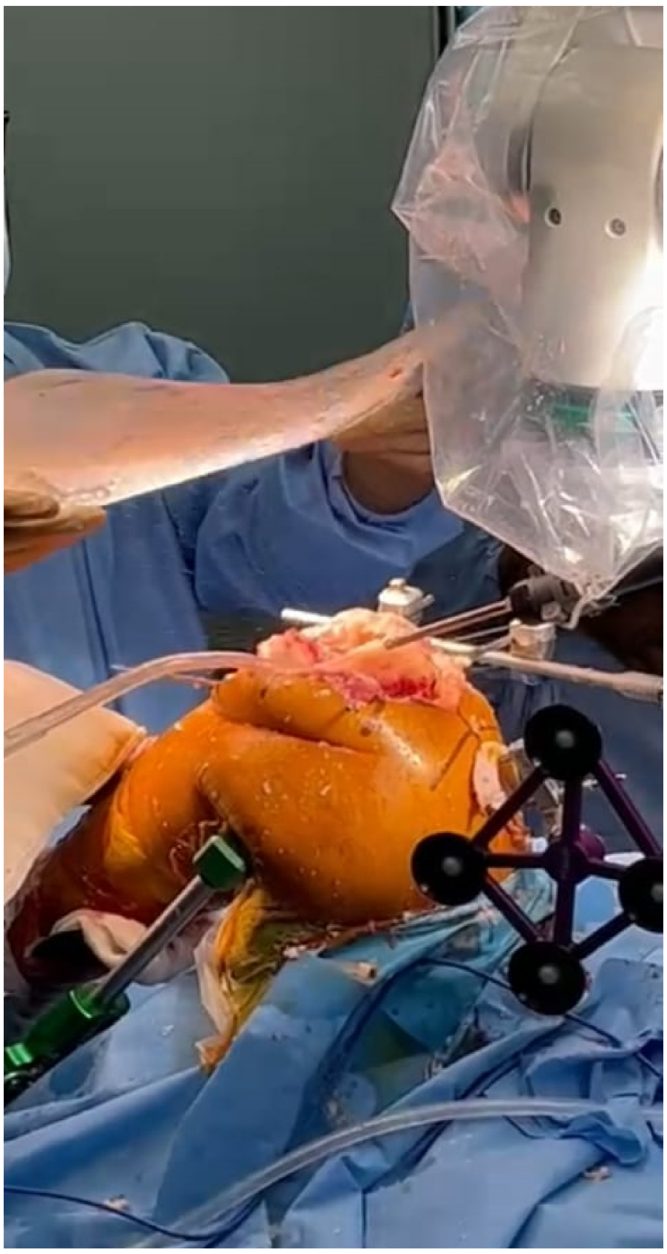


Fig. 3. Fully automatic robotic arm performing distal femur and proximal tibia bone cuts.

CA, USA). In their series eight cases (6.95%) were converted to conventional TKA. Pagani et al.25 reported the adverse events associated with the robotic assisted joint arthroplasty. They analyzed the US Food and Drug administration MAUDE database. The joint arthroplasty included TKA, Total hip arthroplasty and partial knee arthroplasty. The total robotic TKA performed during the study period (January 1, 2020 to July 1, 2021) was 24,000. The total numbers of adverse events in their cases were 204. The majority of the cases were performed with the robot manufactured by Mako Surgical Corp (Stryker, Kalamazoo, MI, USA). The mechanical component was involved in the 122 adverse events whereas software component was involved in 82 of the adverse events. During RA-TKA the most frequent adverse event was unexpected robotic arm movement during the bone cuts (59/204, 28.9%), inaccurate bone cuts (26/204, 12.7%) and leakage of fluid/residue contaminating the robotic component (25/204, 12.3%). The reported conversion to manual TKA was in 23 cases. The primary causes of conversion to manual TKA was unexpected robotic arm movement during bone cuts (6, 26.1%), inaccurate resection (4, 17.4%), inaccurate visual display while cuts (3, 13%), femoral notching (2, 8.7%), locking of the robotic arm (2, 8.7%). Inability to initiate the bone cut and unexplained system shutdown happened in one case each (1, 4.3%). In their analysis the primary types of the reported patient injuries were femoral notching (12, 33.3%), bone pin left in the patient (10, 27.8%), over resection (8,22.2%), check point left in the patient (2, 5.6%), and one incidence each of femur fracture, tibia fracture, Medial collateral ligament laceration (1, 2.8% each). Another important point is the risk of additional radiation due to pre-operative 3 dimensional CT scan in RA-TKA as compared to normal radiograph in conventional TKA. The radiation exposure of the patient is quantified by measuring the Effective dose (ED). Biswas et al.[26] have quantified the ED of radiation exposure associated with the CT scans of the musculoskeletal structures. According to their study, the ED decreases as more distal structures are imaged and CT scan of the distal extremities exposes the patient to less radiation than a posteroanterior radiograph of the chest. Acute exposure over 10 mSv is associated with an increased risk of cancer. The ED for a CT of the lower extremity is estimated to be 0.16 mSv.

The main finding of our study no patient in our study experienced any adverse events related to RA-TKA. Possible reasons for the low incidence of adverse events in the current study could be devise specific and surgeon specific. The devise specific reason could be improvised version of the software of the robotic system, refinement of the operative window of the robotic arm. Improved operative window of the robotic arm leaves behind some bone at the antero-medial, antero-lateral, postero-medial and postero-lateral part of the tibia thereby protecting the collateral ligaments and the posterior structures. The surgeon specific reasons can be

1. Intensive training of the operating team with the help of dry bone models
2. Visitation to the centers of excellence for robotic surgery.
3. Training of the operating surgeon and the system specialist on the pre-operative templating and planning of the TKA on the computer.

Our study has certain limitations. The first limitation is short follow up of 6 months. But the primary aim of our study is to evaluate the safety and efficacy of the fully automated active robotic system. Further long term follow up of this particular cohort is planned and is being studied. Second limitation is that there is no control group of patients who underwent conventional manual TKA with the same surgical team. Instead the safety and efficacy of this robotic system is compared with literature reported control incidence. Only active robot specific time was compared with that of conventional TKA. In future a prospective randomized study comparing the conventional manual TKA and active RA - TKA is necessary to demonstrate improvement in the patient reported outcome measures at intermediate and long term follow up. Strength of our study is to the best of our knowledge ours is the first study which evaluates the safety and efficacy of this fully automated active robotic system in performing RA- TKA in Indian/Asian population.

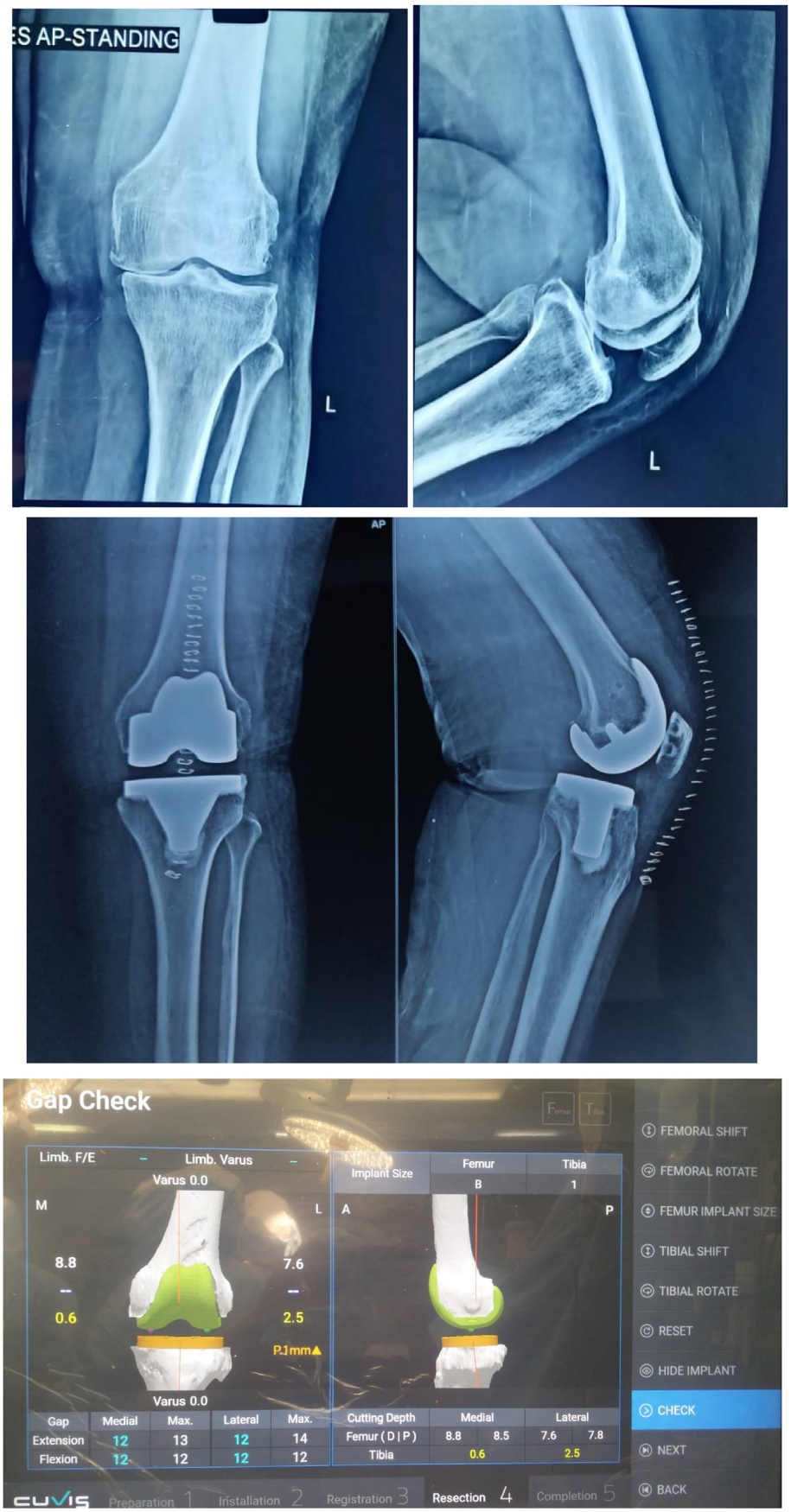


Fig. 4. Pre- Operative and Post-Operative X-Ray and Intra-operative measurement estimation.

Table 1
Pre-operative demographics of patients undergoing Robotic TKA.

PATIENT DERMOGRAPHICS	N = 30
MEAN AGE	69 YEARS
SEX	M 7/F 23
BODY MASS INDEX, Mean, Range	29.1 (20.1–38.5)
SIDE	R 17/L 13
ASA GRADE, Mode, Range	2 (1–3)

Table 2
Comparison between actual and predicted implant.

Sr. no.	Side	Planned femur size	Actual femur size	Planned tibia size	Actual tibia size
1	MS - right	D	D	2	2
2	MS - left	C	C	1	1
3	RJ - right	C	C	2	2
4	RJ- left	C	C	2	2
5	SD - right	C	C	2	2
6	MJ - left	B	B	1	1
7	GK - right	E	E	3	3
8	SD - right	C	C	1	1
9	SB - right	C	C	2	2
10	SB - left	C	C	2	2
11	HS - right	E	E	4	4
12	PM - right	D	D	3	3
13	PM - left	D	D	3	3
14	NJ - right	C	C	3	3
15	NJ - left	C	C	3	3
16	RB - right	C	C	2	2
17	AP - right	F	F	5	6
18	LP - left	C	C	3	3
19	LM - right	C	C	2	2
20	LM - left	E	E	3	3
21	AK - right	F	F	5	5
22	AK - left	F	F	5	5
23	MS - right	D	D	4	4
24	PP - right	C	C	2	2
25	PB - right	F	F	5	5
26	PB - left	F	F	5	5
27	SB - left	D	D	2	2
28	SS - right	C	C	2	2
29	SS - left	C	C	2	2
30	VP - left	C	C	2	2

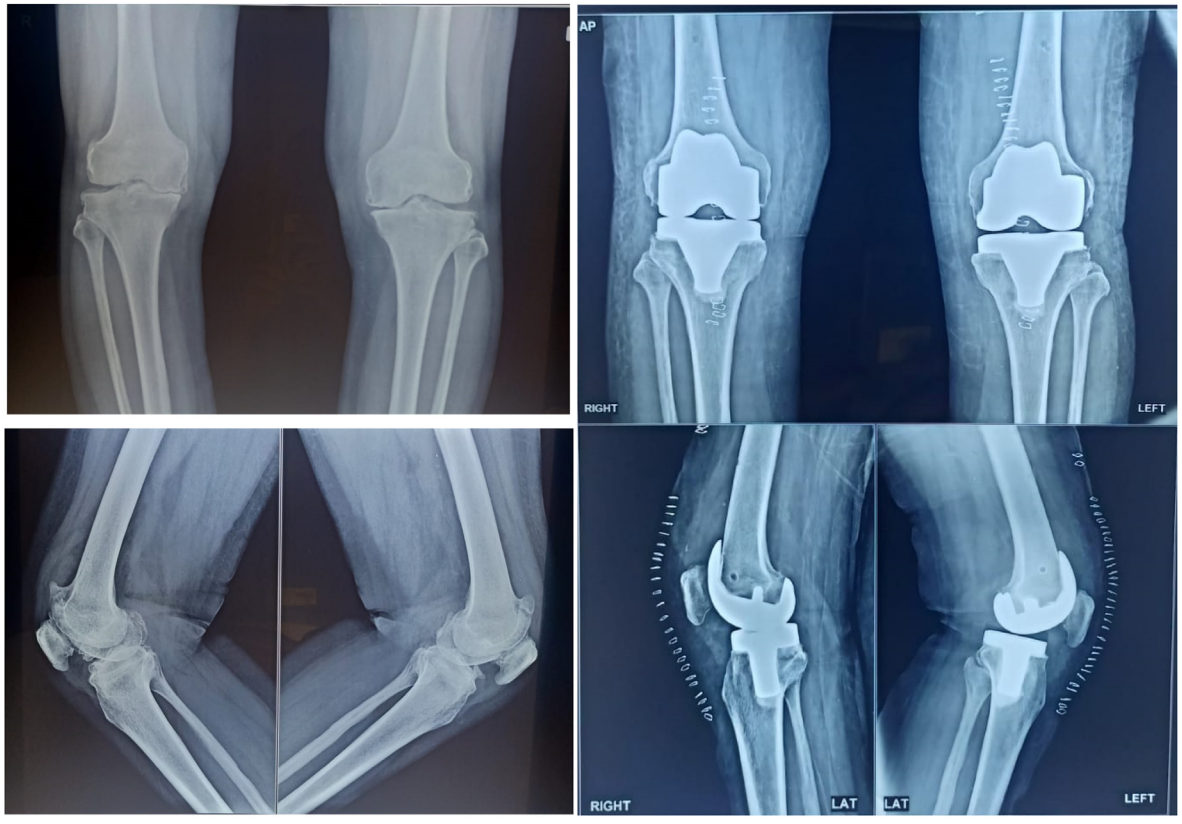


Fig. 5. Pre -operative and post- operative X-Ray.

Table 3
Assessment of the accuracy of the Femur and Tibia implant size and alignment.

Sr. no.	Side	Femur implant size	Tibia implant side	Femur Implant Overhang	Tibia Implant Overhang
1	MS - right	C	2	No	No
2	MS - left	C	1	No	No
3	RJ - right	C	2	No	No
4	RJ- left	C	2	No	No
5	SD - right	C	2	No	No
6	MJ - left	B	1	No	No
7	GK - right	E	3	No	No
8	SD - right	C	1	No	No
9	SB - right	C	2	No	No
10	SB - left	C	2	No	No
11	HS - right	E	4	No	No
12	PM - right	D	3	No	No
13	PM - left	D	3	No	No
14	NJ - right	C	3	No	No
15	NJ - left	C	3	No	No
16	RB - right	C	2	No	No
17	AP - right	F	6	No	No
18	LP - left	C	3	No	No
19	LM - right	C	2	No	No
20	LM - left	C	3	No	No
21	AK - right	F	5	No	No
22	AK - left	F	5	No	No
23	MS - right	D	4	No	No
24	PP - right	C	2	No	No
25	PB - right	F	5	No	No
26	PB - left	F	5	No	No
27	SB - left	D	2	No	No
28	SS - right	C	2	No	No
29	SS - left	C	2	No	No
30	VP - left	C	2	No	No

5. Conclusion

The results of our study clearly demonstrate the safety of the fully automated active robotic system by comparing the incidence of adverse events to the literature control values associated with conventional manual TKA. Also the study shows the effectiveness of the system with the pre-operative 3 D CT scan-based templating in accurately predicting the actual femur and tibia implant sizes and achieving optimal implant position and limb alignment. This has a potential to improve operating room efficiency and achieve long term better patient reported outcomes due to improved implant survival. Continuation of this study is necessary to evaluate the effect of these benefits on long term implant survival and patient reported outcomes.

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Ethics approval

Local ethics committee approval was obtained before the study. Also, all patients consented to participate in the study.

Consent for publication

We hereby give our consent for publication.

Authors' contribution

All the authors have contributed equally in the preparation of the manuscript.

Availability of data and materials

This published article contains all of the data generated or analyzed during this study.

Declaration of competing interest

The authors declare no financial conflicts of interest to disclose.

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