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ORIGINAL ARTICLE

Efficacy of the Pre-operative Three-Dimensional (3D) CT Scan Templating in Predicting Accurate Implant Size and Alignment in Robot Assisted Total Knee Arthroplasty

Sanjay Bhalchandra Londhe[1] · Santosh Shetty[1] · Niraj L. Vora[1] · Ashit Shah[1] · Rakesh Nair[1] · Vijay Shetty[1] · Clevio Desouza[2] · Farheen Shehzad Khan[3]

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Abstract

Background Nearly 20% of Total knee Arthroplasty patients remain dissatisfied. This is a major concern in twenty-first century arthroplasty practice. Accurate implant sizing is shown to improve the implant survival, knee balance and patient reported outcome. Aim of the current study is to assess the efficacy of pre-operative three-dimensional (3D) CT scan templating in a robot-assisted TKA in predicting the correct implant sizes and alignment.

Materials and methods Prospectively collected data in a single center from 30 RA-TKAs was assessed. Inclusion criterion was patients with end stage arthritis (both osteoarthritis and rheumatoid arthritis) undergoing primary TKA. Patients undergoing revision TKA and patients not willing to participate in the study were excluded. Preliminary study of ten patients had indicated almost 100% accuracy in determining the implant size and position. Sample size was estimated to be 28 for 90% reduction in implant size and position error with α error of 0.05 and beta error of 0.20 with power of study being 80. Post-operative radiographs were assessed by an independent observer with respect to implant size and position. The accuracy of femoral and tibial component sizing in the study was compared with the historic control with Chi-squared test. The p value < 0.05 was considered significant.

Results The pre-operative CT scan 3D templating accuracy was 100% (30 out of 30 knees) for femoral component and 96.67% (29 out of 30 knees) for tibial component. The implant position and limb alignment was accurate in 100% of patients. The accuracy of femoral component and tibial component sizing is statistically significant (Chi-squared test, p value 0.0105 and 0.0461, respectively).

Conclusion The study results show the effectiveness of pre-operative 3 D CT scan planning in predicting the implant sizes and implant positioning. This may have a potential to improve the implant longevity, clinical outcomes and patient satisfaction.

Keywords Robotic assisted Total Knee Arthroplasty · Three-dimensional CT · Tibial component · Femoral component

Introduction

About 10–20% of patients remain dissatisfied after Total Knee Arthroplasty (TKA) [1, 2]. Various strategies are adapted to improve the implant survival and patient satisfaction. The things which are tried are modification of the implant design (gender specific implants, patient specific implants) and surgical techniques (minimally invasive subvastus approach, computer assisted TKA). Modifications of implants unfortunately have not shown to modify the outcome of Total Knee Arthroplasty [3]. Various studies have shown that surgical errors while performing TKA are common [4]. It is one of the easily avoidable causes of failed TKA and hence dissatisfaction post-TKA in a patient [5, 6].

The things which need to be carefully executed are achieving accurate implant size, implant positioning, implant/ limb alignment, achieving balanced medial and lateral post bone cut balance and restoration of joint line [7, 8]. TKA implant overhang is the most important cause of knee pain after TKA which accounts for almost 27% cases

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Sanjay Bhalchandra Londhe
sanlondhe@yahoo.com

Extended author information available on the last page of the article

of post-TKA pain [9–11]. Correct sizing of the femoral and tibial component has shown to improve the knee balancing in extension and flexion, postoperative pain, implant survival and patient reported outcome measures (PROM) [12, 13].

Robotic assisted TKA has many advantages as compared to conventional manual TKA [14–17]. The reported clinical advantage of Robotic Assisted TKA is soft tissue protection as it leaves a bony island on the posterior aspect of the tibial plateau protecting the posterior vital structures like the PCL (Posterior cruciate ligament) [15]. Preoperative planning for robot-assisted surgery includes computed tomography (CT) of the surgical limb and three-dimensional (3D) implant templating. Accurate templating has been shown to cut surgical time and reduce costs [18]. The ability to accurately predict implant size preoperatively can improve operative efficiency. Fewer trays can be opened, and sterile final implants can be ready, and this has been shown to decrease operating room time and risk of infection [18].

Marchand et al. [16] in their study found that the mean Western Ontario Macmaster University Arthritis Index pain score (WOMAC) at 6 months post-RA-TKA was significantly better than the manual TKA cohort. They also found that the WOMAC score physical function and overall WOMAC score was also better in RA-TKA cohort than the manual TKA cohort.

The primary objective of the present study is to determine the efficacy of the preoperative CT-based three-dimensional templating in RA-TKA in accurately predicting the femur and tibia implant sizes. The secondary objective is to determine the usefulness of CT-based three-dimensional templating in achieving optimal implant/limb alignment.

Materials and Methods

Our study was a prospective study. The study had the ethics committee approval. An inclusion criterion was patients with end-stage arthritis (both osteoarthritis and rheumatoid arthritis) undergoing primary TKA. Patients undergoing revision TKA and patients not willing to participate in the study were excluded. Preliminary study of ten patients had indicated almost 100% accuracy in determining the implant size and position. Sample size was estimated to be 28 for 90% reduction in implant size and position error with α error of 0.05 and beta error of 0.20 with power of study being 80%. Post-operative radiographs were assessed by an independent observer with respect to implant size and position. The independent observer was not part of the RA-TKA operative team.

All the patients had a pre-operative CT scan of the to-be-operated leg about 1 week prior to the surgery in accordance with the manufacturer's protocol. The to-be-operated leg was scanned in the axial plane in three regions namely hip, knee and ankle. These images were exported in the jpg format. Segmentation and preoperative planning was carried out by utilizing proprietary operating system and dedicated laptops. The planning was done by the operating surgeon along with the trained company engineer. A mechanical alignment and not kinematic alignment philosophy was followed while pre-operative planning of the TKA operation. A neutral alignment of the limb with Hip-Knee-Ankle angle of 0 degrees was the desired limb alignment. The broad steps involved in the planning were, establishment of the hip, knee and ankle center, selection of bony landmarks on the femur and tibia, achieving accurate implant alignment in coronal, sagittal and transverse planes, calculation of the resection values for the tibia (proximal cut) and femur (distal, anterior chamfer, Anterior, box cut, posterior chamfer and posterior cut). On confirming the accuracy of femur and tibia implant sizing without overhang and optimal implant and limb alignment on the summary section of planning software, the plan was approved and saved by the operating surgeon (Fig. 1). When the actual femoral size was in between the two available implant sizes, the software allowed the surgeon to check the implant fit in coronal, sagittal and real-time three-dimensional planes. The implant which fitted the best in all the planes without overhang or notching was selected.

The patients were operated under regional anesthesia (Spinal plus Epidural) with three doses of antibiotic prophylaxis and thromboprophylaxis with oral rivaroxaban. The knee was exposed with a medial parapatellar/subvastus approach. Infrared arrays were placed about 15 cm below joint line in case of tibia and about 12–15 cm proximal to the joint line in case of femur through separate stab incision using 4.5 mm threaded pins. The distal femur and proximal tibia were registered with the operating system. The knee was moved through full extention to flexion and medial and lateral pre-bone cut balance was monitored in real time on the computer. The robot used was fully automated Cuvis joint robot system (Korea). Up to 1 mm of difference in the medial and lateral values in extension and 90° of flexion was accepted as well-balanced knee. The aim was to achieve a sagittal and coronal well-balanced and aligned knee. Then, the robotic arm was registered and was docked to the patient with fixation pins and clamps. The robotic arm then carried out the distal femur and proximal tibia bony cuts. After the completion of the bony cuts, the robotic arm was disengaged from the patient and trial implantation was carried out. Again with the trial femur and tibia implants, the limb was moved from extention through flexion. The post-bone cut medial and lateral gaps were checked in full extention and 90° of flexion to confirm a well-balanced and aligned knee in flexion and extension. All patients were implanted with either a cemented cruciate sacrificing posterior stabilized or cruciate retaining femur implant (Max Freedom Knee). All patients received routine post-operative physiotherapy in

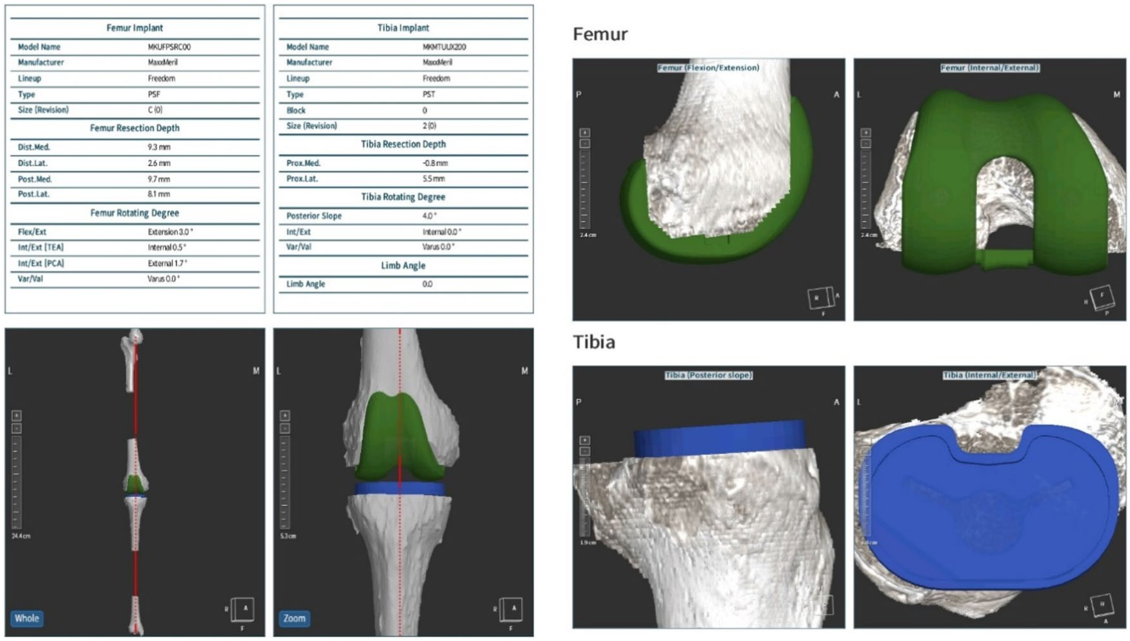

Fig. 1 The analysis of the implant size done by the robotic software pre-operatively

the form of quadriceps and hamstring muscle strengthening exercises and gait training with walker progressing to using a walking stick. The intraoperative data was retrieved and studied by an independent observer who was not part of the planning and surgical team.

The post-operative long leg AP and lateral radiographs were assessed by same independent observer (Figs. 2, 3). While assessing the size and fit of the implant, five radiographic markers as described by Peek et al. [19] were used. The femur implant size was gauged by presence/absence of femoral notching, gap (> 2 mm) between the anterior cortex of the femur and femur implant, posterior femoral contour restoration. The tibia was assessed by lateral overhang and cortical contact (< 50%).

Statistical Analysis: SPSS version 21.0 (IBM Corp) New York was used for statistical analysis.

Results

Our study included 7 male and 23 female patients. The mean age of the study group cohort was 69 years. The mean body mass index (BMI) was 29.1 (range 20.1–38.5) (Table 1). 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 (Table2). In one patient instead of planned size 5 tibial base plate of larger size 6 was used. According to Peek's criteria, no femoral or tibial implant was found to be undersized/ oversized. The limb alignment was found to be optimal in all cases (Figs. 2, 3). No femoral component had anterior cortical notching or > 2 mm gap between the anterior cortex of femur and the implant. All femoral implants restored the posterior condylar contour. The posterior condylar offset ratio was determined to confirm the same. As regards, the tibial base plate there was no lateral overhang or < 50% cortical contact (Table3).

Discussion

Our study clearly demonstrated the efficacy of the preoperative CT-based three-dimensional templating in RA-TKA in accurately predicting the femur and tibia implant sizes. It also shows that preoperative CT-based three-dimensional pre-operative templating is useful in achieving optimal implant/limb alignment. The use of robotic assistance in knee reconstructive procedures potentially enhances not only the accuracy of implant placement but also implant selection and subsequent fit. We report excellent implant positioning in our series of robotic assisted TKAs.

It is of paramount importance that the femur and tibia implant sizing and alignment is accurate for long-term implant survival and clinical outcomes. Various studies have shown that TKA implant component overhang is the cause of knee pain in almost 27% of TKA patients [9–11]. Dennis et al. [20] in his review of the causes of the painful TKA showed that the TKA implant overhang causes impingement of the soft tissue leading to formation of intraarticular

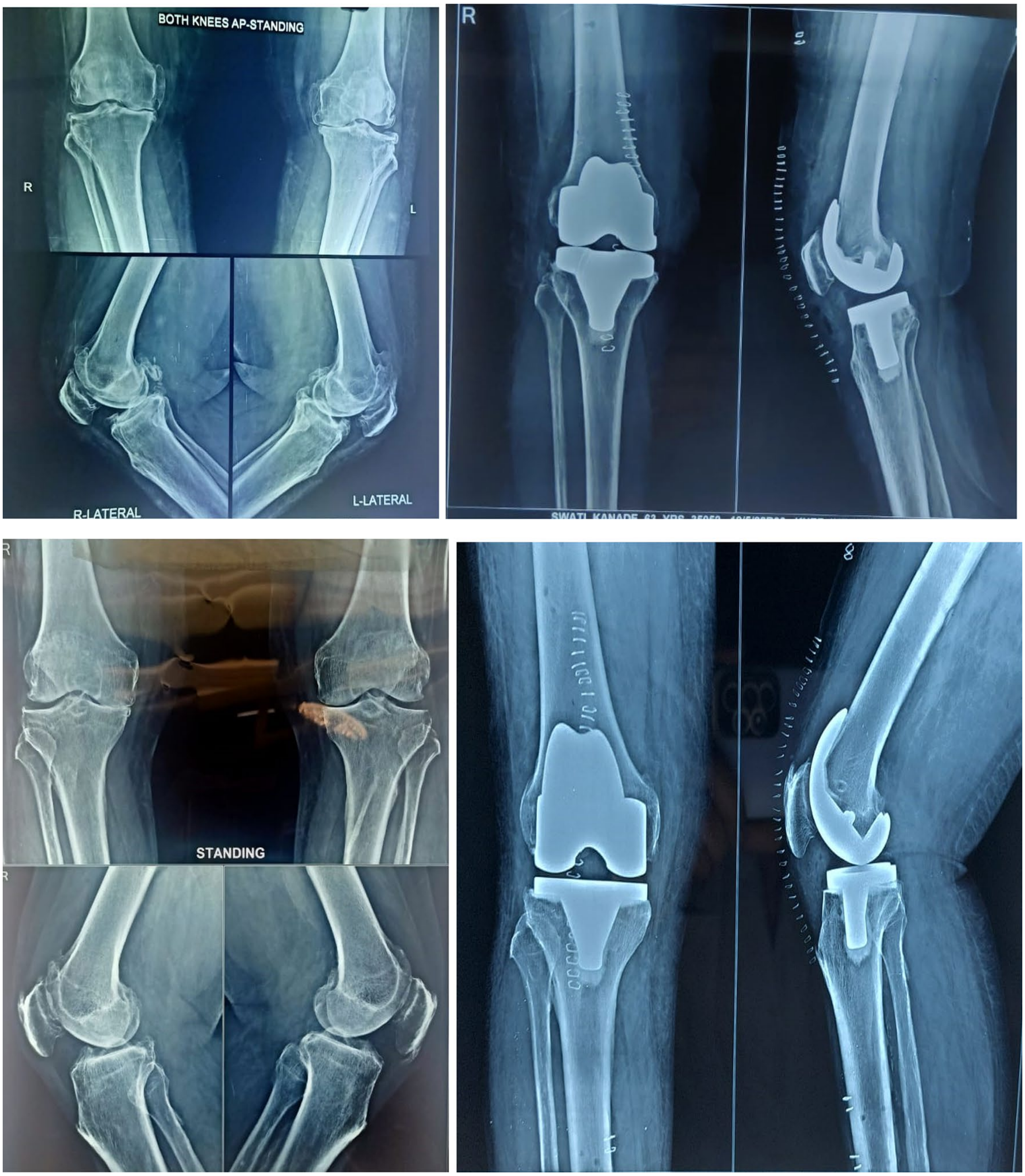

Fig. 2 Pre-operative and post-operative X-rays of robotic assisted total knee arthroplasty

fibrous bands which in turn causes irritation of the tendons and ligaments.

In contrast, under-sizing of the femur component in the AP plane may lead to mid-flexion instability, [21] accelerated osteolysis due to wear debris [22], increase the risk of peri-prosthetic fracture due to anterior femoral cortex notching [23]. Under-sizing of the tibial component has an increased risk of subsidence of the tibial tray as it is resting on the cancellous bone [24]. Bonin et al. in his study [25] documented that implant overhang was present in 66% of femoral component and 60% of tibial component. This results in poor clinical outcomes. Also, the risk of knee pain is doubled if there is more than 3-mm overhang of the femoral component [26]. In obese patients, there is a risk of catastrophic varus collapse if we are to use an undersized tibial component [27].

Similar to the results of this study, other studies have reported substantial advantages of utilizing the robotic assisted device for TKA. Liow et al. [28] in their study reported the comparison between RA-TKA versus manual

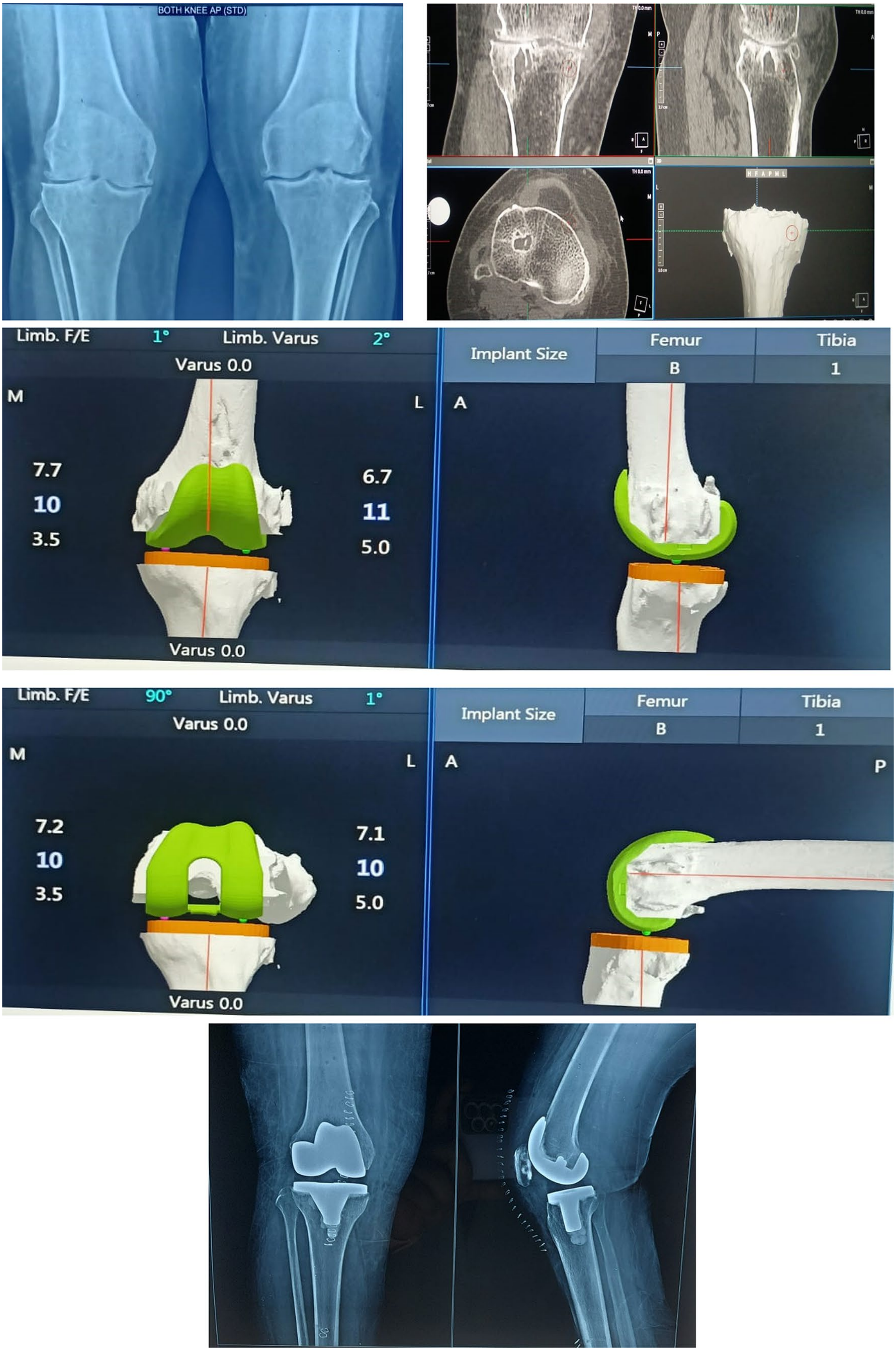

Fig. 3 Pre-operative X-ray and CT scan planning of robotic assisted TKA and post-operative X-ray

Table 1 Pre-operative patient demographic

Patient demographics	$N=30$
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	C	C	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	C	C	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

TKA. They found no malalignment > 3 degrees in RA- TKA whereas 20% of patients with manual TKA had malalignment > 3 degrees. Sodhi et al. [17] in his study reported 0% malalignment in 261 RA-TKA cases. As for overall patient satisfaction and pain, another study by Marchand et al. [29] reported a match-controlled of 20 cemented RA-TKAs to 20

Table 3 Assessment of Femur/Tibia implant size and alignment

Sr. no	Side	Femur implant size	Tibia implant size	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

cemented manual TKAs and found that both patient satisfaction and pain was significantly better in patients who underwent RA-TKAs than patients who underwent manual TKAs.

Our study has certain limitations. First limitation is that the study was conducted at a single centre and all surgeries were performed by one surgical team. However, this eliminates the potential confounding factors that may add intraoperative variables like different surgeons and operating room teams. Second limitation is the study only had patients who underwent RA-TKA and not the manual TKA. Further studies are needed comparing robotic and manual TKA patients.

The strength of our study is to the best of our knowledge, this is the first study which analyses the efficacy of preoperative 3D CT scan planning in accurately predicting the femur and tibia implant sizes and implant and limb alignment in Indian population.

Conclusion

The results of our study clearly demonstrate the efficacy of the pre-operative 3 D CT scan-based templating in accurately predicting the actual femur and tibia implant sizes. Also, the pre-operative templating helps to achieve optimal implant position and limb alignment. This may have 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.

Authors' contribution All the authors have contributed equally in the preparation of the manuscript.

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

Declarations

Conflict of interest The authors declare no financial conflicts of interest to disclose.

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.

Informed consent Informed consent was obtained from all individual participants included in the study.

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Authors and Affiliations

Sanjay Bhalchandra Londhe[1] · Santosh Shetty[1] · Niraj L. Vora[1] · Ashit Shah[1] · Rakesh Nair[1] · Vijay Shetty[1] · Clevio Desouza[2] · Farheen Shehzad Khan[3]

Santosh Shetty
Ask@drsantoshshetty.com

Niraj L. Vora
NLV@drnirajvora.com

Ashit Shah
dr_ashitshah@hotmail.com

Rakesh Nair
drrakeshnair35@gmail.com

Vijay Shetty
vijaydshetty@gmail.com

Clevio Desouza
ceviod@gmail.com

Farheen Shehzad Khan
farheen3129@gmail.com

[1] Orthopedic Surgeon, Criticare Asia Hospital, Teli Galli, Andheri East, Mumbai 400069, Maharashtra, India

[2] Orthopedic Surgeon, Holy Spirit Hospital, Andheri East, Mumbai, India

[3] Meril Life Sciences, Mumbai, India