Indian Journal of Orthopaedics
https://doi.org/10.1007/s43465-023-00970-y

ORIGINAL ARTICLE

Intra-operative Safety of an Autonomous Robotic System for Total Knee Replacement: A Review of 500 Cases in India

P. Chandrashekar[1] · K. Adarsh Babu[1] · H. S. Nagaraja[1] · S. Gangu Hiral[1] · S. Karthikeyan[1] · Supreet Bajwa[2]

Received: 23 April 2023 / Accepted: 1 August 2023
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Abstract

Background Manual total knee arthroplasty (TKA) has been documented several times for their safety and complications data. In contrast, there is a limited evidence-based analysis for safety and complications of autonomous robotic-assisted (RA)-TKA. This study aimed to evaluate the safety features and intra-operative surgical complications associated with the use of Cuvis Joint™ autonomous robotic system for TKA.

Methods The study included 500 consecutive patients who underwent TKA using the Cuvis Joint™ autonomous robotic system from November 2020 to November 2021. All surgeries were performed by a senior surgeon. Patients in whom the surgery was abandoned midway due to technical errors, were excluded from the analysis. In case of unilateral abandonment of the robotic arm during a bilateral RA-TKA, data of the side on which the surgery was completed with robotic assistance was recorded.

Results There was no incidence of neurological injury, vascular injury, extensor mechanism disruption, or medial collateral ligament injury. There was one case of superficial abrasion of the patellar tendon; however, it did not require any intervention. There were no cases of midway abandonment due to threatened soft tissue injury. There was no intra-operative pin loosening or stress-related fractures at the pin sites. There was one case of Steinmann pin breakage and another case of drill bit breakage, which were removed without any damage to the bone.

Conclusion The Cuvis Joint™ autonomous robotic system for TKA is safe with no significant intra-operative complications.

Keywords Autonomous robot · Cuvis Joint · Intra-operative complications · Robotic-arm assisted total knee arthroplasty · Active robotic total knee arthroplasty

Abbreviations

BMM	Bone movement monitor
CT	Computed tomography
3D	3-Dimensional
HKA	Hip knee ankle
ICH-GCP	International Conference on Harmonization Guideline for Good Clinical Practice
MCL	Medial collateral ligament
RA-TKA	Robotic arm-assisted total knee replacement
RMS	Root mean square
TKA	Total knee arthroplasty

Introduction

Conventional total knee arthroplasty (TKA) has been established as an effective and safe alternative for patients with symptomatic end-stage knee osteoarthritis. However, due to complications associated with component malalignment or soft tissue imbalance, patient satisfaction rates after TKA remains between 82 and 89% [1]. Surgical technique has been reported to be the most common cause of failure in TKA. Hence, there is an increased focus on long-term survival, functional outcomes, and satisfaction following TKA [2]. Robotic assisted TKA (RA-TKA) was introduced into orthopedics with an aim to improve accuracy in implant positioning, prosthesis alignment subsequently reducing complication rates [3]. Hence, RA-TKA has been increasingly used in the last 10 years to reduce technical errors [4, 5]. RA-TKA generates a virtual 3-dimensional (3D) model of the patient's anatomy using computer software. This aids the surgeon in pre-planning the bone cuttings, component

✉ Supreet Bajwa
info.bajwasorthopaedic@gmail.com

[1] Institute of Orthopaedics, Sakra World Hospital, Devarabeesanahalli, Bangalore, India

[2] Hip and Knee Specialist, Wockhardt Hospital, 1877, Dr Anandrao Nair Marg, Near Agripada, Mumbai Central, Mumbai, Maharashtra, India

Published online: 05 September 2023

sizing, and its positioning. During the procedure, patient's anatomy is plotted on the surgery plan using navigational software [1]. Robotic systems can be divided into three categories: active, semi-active, or passive. Passive RA-TKA systems are under complete, continuous, and direct surgeon control once the 3D template has been created. Semi-active systems provide haptic auditory, tactile, or visual feedback that notifies deviations from the preoperatively defined boundaries. The system also slows down or completely stops when there is a deviation outside the computer-generated volume or depth of defined bone resection [5]. Active robotic systems operate autonomously without real-time guidance under the surgical supervision. Pre-operative computed tomography (CT) imaging is considered to configure an offline surgical plan using the robotic software. Initial surgical approach by operator includes positioning of the retractors to protect soft tissues, and attachment of the limb to a fixed holding device. After the calibration procedure, the robotic arm independently initiates the femoral and tibial bony resections. Meanwhile, the operator maintains control via an emergency manual override button [1]. Early active robotic systems are no longer used because of higher rates of short-term soft and hard tissue complications [6]. Contemporary active systems use a digitizer to collect data points. The exact anatomical position is identified to autonomously mill joint surfaces for component placement. While the surgeon manually regulates the cutting tool using an override button, the robotic arm independently completes the preparation of bone and executed as planned [7]. However, there are few studies on the safety and intra-operative surgical complications of the contemporary active robotic systems for TKA. The Cuvis Joint™ autonomous robotic system (Curexo Technologies, Seoul, South Korea supported by Meril Healthcare Pvt. Ltd., India) is the latest in line of the fully autonomous robotic system used in our institute since November 2020. This study aimed to evaluate the safety features and intra-operative surgical complications associated with the use of this autonomous robotic system [1].

Materials and Methods

This was a single-center, retrospective, observational study. Overall, 502 patients were assessed for eligibility and 500 consecutive patients with end-stage arthritis (both osteoarthritis and rheumatoid arthritis) who met the inclusion criteria were included in the study. All patients underwent unilateral or bilateral RA-TKA using the Cuvis Joint™ autonomous robotic system from November 2020 to November 2021. The exclusion criteria of the study were: (1) patients who had pre-existing knee arthroplasty and (2) patients who refused to sign the written informed consent form. All surgeries were performed by a senior surgeon. The primary endpoint was safe execution of the surgery. The primary outcome measure is complications associated with active RA-TKA. The incidence of neurovascular injury, extensor mechanism disruption, collateral ligament and other soft tissue injuries, and pin-related injury including intra-operative fractures were studied and the safety features in the autonomous robotic system were analyzed. This study was initiated after the protocol was reviewed and approved by the local ethics committee according to local regulations. The study was carried out in conformity with the protocol and International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP).

Workflow of the Cuvis Joint™ Autonomous Robotic System

The Cuvis Joint™ autonomous robotic system is an image-based closed-platform robotic system. A preoperative CT scan of the lower limb is uploaded to the preoperative planner (J planner™) according to the manufacturer's protocol (Fig. 1).

The software creates a 3D reconstruction of the knee, by auto-segmenting the CT images. Based on the 3D images, the surgeon pre-plans the surgery and determines the following parameters:

1. Center of rotation of the hip, knee, and ankle.
2. Presence of bony deformity.
3. Sizing and positioning of implant.
4. Number of bony cuts required based on the mechanical axis in the frontal and sagittal planes.
5. Marking the femoral and tibial rotation in the axial plane.
6. Registration points required for intra-operative surface registration on the femur.

The software compiles the inputs provided by the surgeon and creates a final alignment report using numerical data, which is then uploaded to the robotic arm console. During the surgery, the technician calibrates the robot to facilitate moving and working with the arm within a defined 3D workspace. Finally, the arm is covered in a sterile drape. The leg of the patient is fixed in a special positioner (De Mayo V2™, Imp incorporation, Plainville, Connecticut, USA) to prevent any untoward movement during surgery (Fig. 2a). After the initial standard exposure, navigation pins with reflective arrays are placed in the femoral and tibial diaphysis, approximately 10 cm from the joint line (Fig. 2b), using a dual pin system on each side provided by the manufacturer (Fig. 2c). The pin size is 4 mm and they are bicortical, as advised by the manufacturer, to prevent pin loosening (Fig. 2d).

This is followed by surface registration of the femur and tibia using a probe. Subsequently, the computer generates

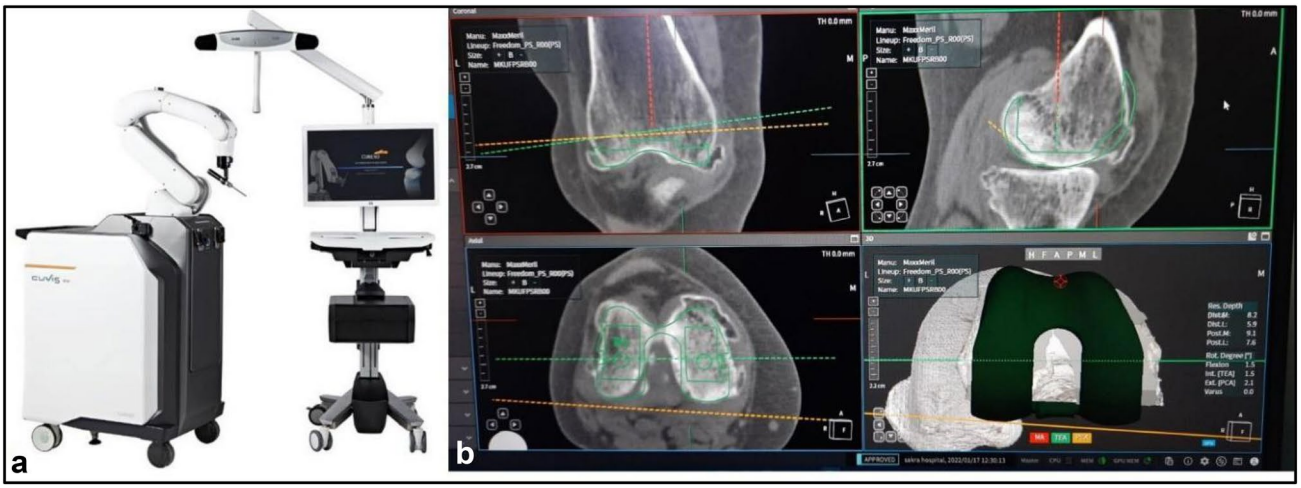

Fig. 1 **a** Cuvis Joint™ autonomous robot, **b** J planner™ software workstation for preoperative planning with real-time numerical data

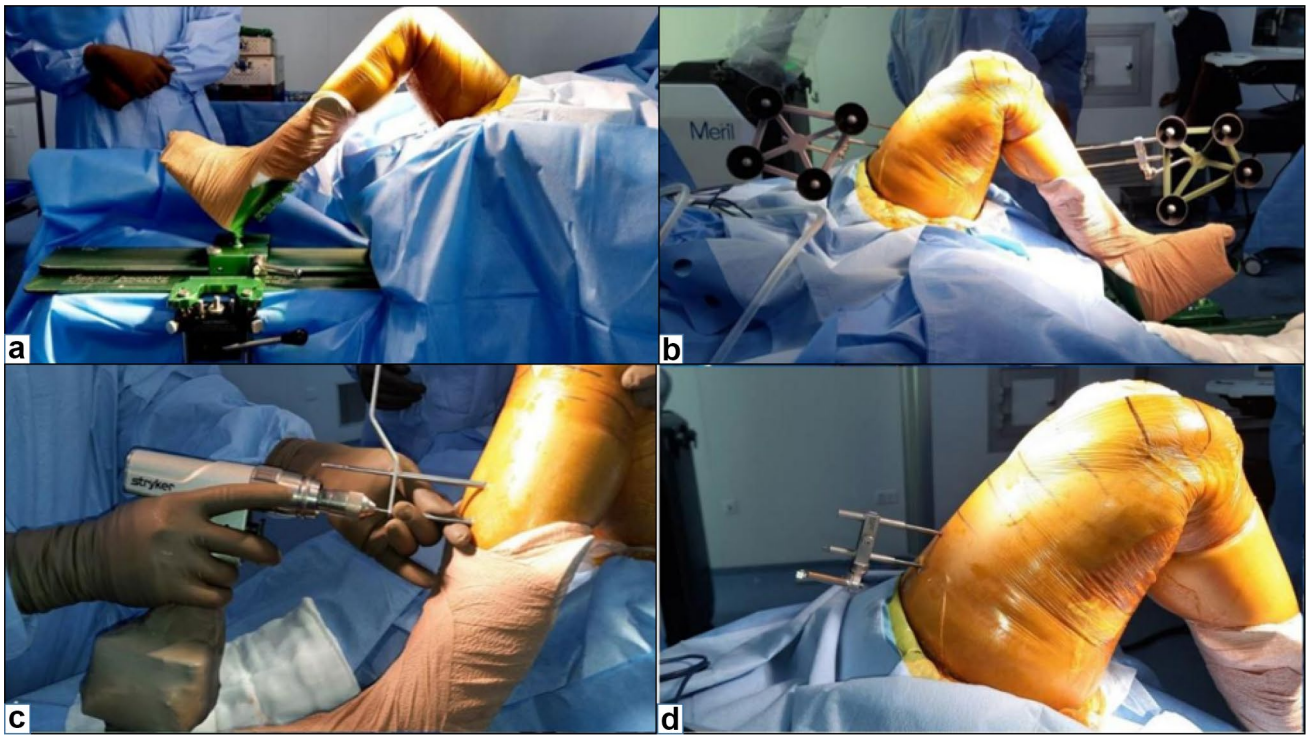

Fig. 2 **a** Leg positioned over a sterile positioner for RA-TKA; **b** drilling the cortex with 2.5 mm drill bit for the insertion of 4 mm unicortical Steinmann pin; **c** dual pins inserted in femur; **d** reflective arrays fixed to the diaphyseal unicortical Steinmann pins

a virtual 3D image of the knee, and the system matches it with the CT images. The registration needs to be precise, which is indicated by a final root mean square (RMS) error of less than 1.

Minimal soft tissue release, osteophytes, and the anterior horns of the menisci can be removed at this stage. The system displays real-time values of the gaps throughout the range of motion and the gaps are balanced according to the surgeon's preference. The robotic arm is on the operating side of the patient and is positioned so that the calibrated robotic workspace overlaps with the surgical workspace; these are visualized on the monitor in real-time. The robotic arm is attached to the patient's leg using metaphyseal hook-type clamps or 6 mm Steinmann pins, one of which is

inserted in the distal femoral and the other in the proximal tibial metaphysis (Fig. 3a).

This step fixes the knee to prevent movement of the leg and aids the robot in monitoring the fine movement of the leg during the procedure- this is known as bone movement monitoring (BMM). When the movement exceeds a certain threshold, the cutting arm freezes (Fig. 4a). The predetermined movement allowed in the Cuvis Joint™ robot is 1 mm, set by the manufacturer. It does not require registration tacks or BMM sensors to be placed on the bone, unlike in the older systems [8].

The type of bone resection is decided by the operating surgeon; it could be either extension surface resection or full surface resection. The robotic arm mills each surface systematically, beginning with the resection of the distal femur. The resection is performed with a 6.2 mm burr with continuous automated saline irrigation that mills the bone at a predefined level, based on the input provided by the surgeon (Fig. 4b).

Being an autonomous system, the robotic arm follows a predefined pathway for milling each surface. Posterior stabilized implants are routinely used; however, the box cut can be avoided in case a cruciate retaining prosthesis is preferred. Though the robotic arm can prepare the keel for the tibial tray, at our center, the senior surgeon uses the robotic arm for cutting and sizing the proximal tibia, but

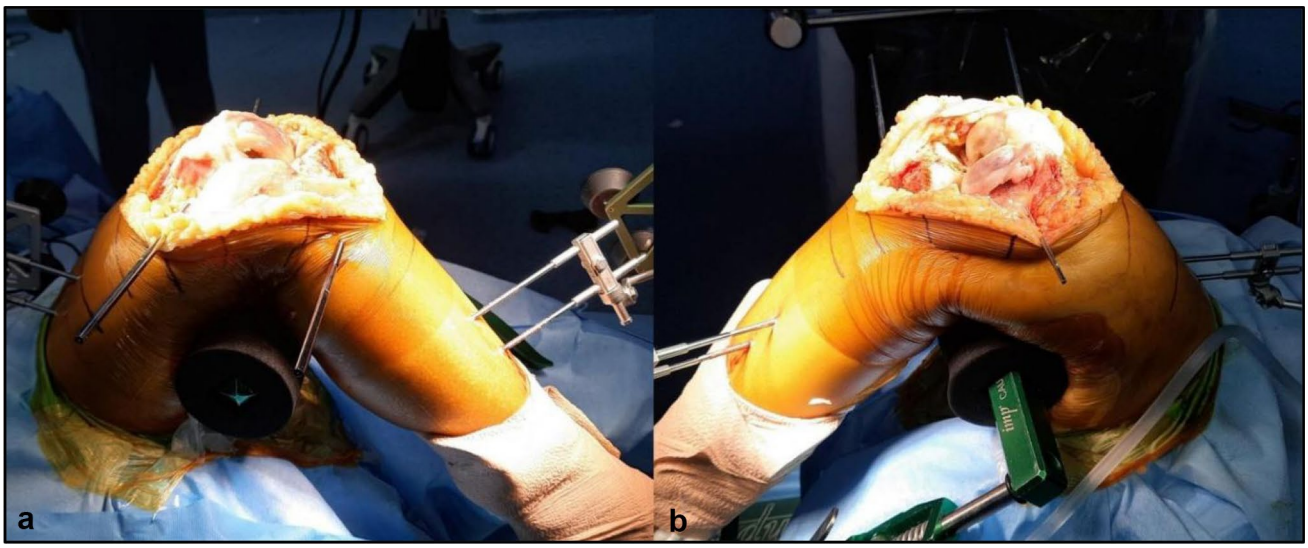

Fig. 3 **a** 6 mm metaphyseal Steinmann pins inserted laterally for the robotic arm to attach to the patient, **b** one 3 mm Kirschner wire inserted in the medial femoral condyle for retraction

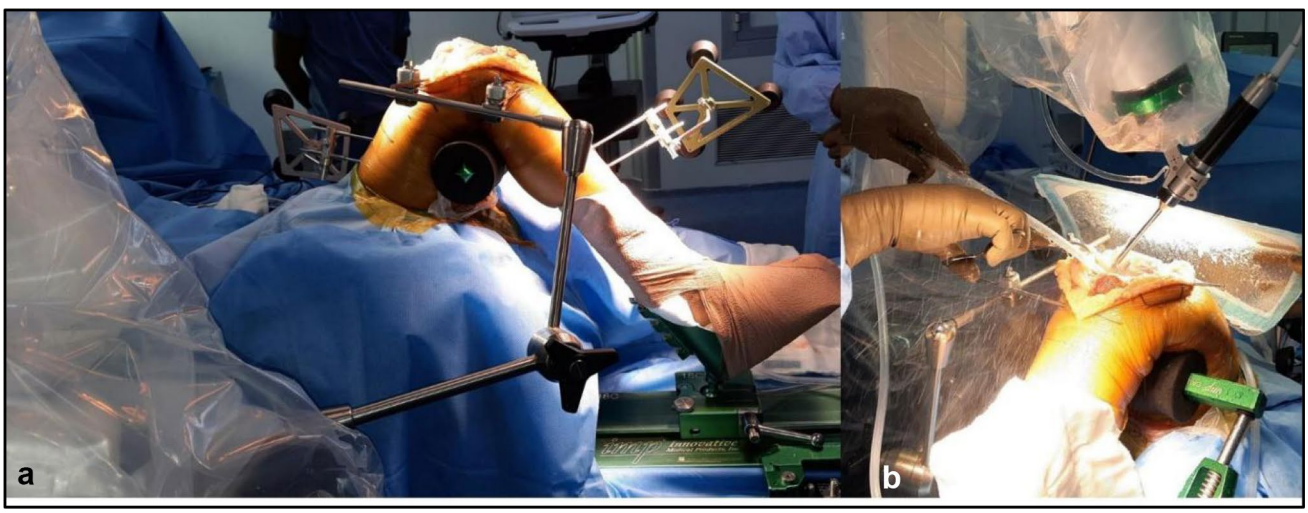

Fig. 4 **a** Robotic console fixed to the patient's body, **b** milling of the femur using 6.2 mm burr with continuous saline irrigation

keel sizing and preparation is performed manually. This helps in soft tissue balancing in case a reduction osteotomy is required. Once all the cuts are completed, the robotic arm is manually detached from the patient's body, and standard procedures such as removal of the remaining bone islands, removal of posterior osteophytes and menisci, and soft tissue release are performed as required. The ligament balance is checked through trials using the values displayed on the monitor and definitive implantation of the knee is initiated [8].

Along with the endpoints indicated above, post-operative radiographs at 6 weeks after surgery were used to determine the accuracy of the overall limb alignment (which the authors intended to be mechanical in principle), as well as the sagittal and coronal component positions. Standing anteroposterior radiographs were utilized to assess the mechanical axis (hip–knee–ankle axis), femur, and tibia coronal (valgus/varus) positioning. Lateral radiographs were utilized to evaluate Tibial sagittal positioning (tibial slope). This finding was used to calculate the mean errors and outliers to determine the accuracy of performing the planned pre-operative surgical plans. Outliers were defined as deviations greater than 3° on each radiograph.

Table 1 Baseline demographic characteristics of patients undergoing RA-TKA with Cuvis Joint™ autonomous robot system

Patient demographic	$n=500$
Mean age (years) (mean ± SD)	65.4 ± 7.5
Gender, *n* (%)	
Male	206 (41.2%)
Female	294 (58.8%)
Body mass index (kg/m^2) (mean ± SD)	28.2 ± 4.2
Operative side, *n* (%)	
Left	217 (43.4%)
Right	283 (56.6%)
American Society of Anaesthesiologists (ASA) grade, *n* (%)	
I	121 (24.2%)
II	326 (65.2%)
III	53 (10.6%)

Results

Baseline demographic characteristics of patients are presented in Table 1. Briefly, 500 consecutive patients' data were recorded with a mean age of 65.4 ± 7.5 years, of which 41.2% were men. Of the total population, 43.4% patients underwent surgery of the left knee, 56.6% of right knee of whom 12.8% ($n=64$) were bilateral simultaneous RA-TKA. There were no cases of midway abandonment due to threatened soft tissue injury. However, two patients encountered midway abandonment from the surgery owing to technical errors (repeated failure of registration process was encountered) and hence, were excluded from the analysis. Also, there was one case of unilateral abandonment (non-sterile pendant malfunctioned) during a simultaneous bilateral RA-TKA and the data of the single side on which the surgery was completed with robotic assistance were included in the analysis. There was no incidence of neurological or vascular injury in our study. There was also no extensor mechanism disruption or medial collateral ligament injury. There was one case of superficial abrasion of the patellar tendon; however, it did not require any intervention as there was no disruption of the integrity of the tendon. There were no cases in which RA-TKA was abandoned midway due to threatened soft tissue injury. There was no intra-operative pin loosening or stress-related fractures at the pin sites. There was one case of Steinmann pin breakage and another case of drill bit breakage extra-articularly, which were removed without any damage to the bone (Table 2).

The post-operative mean HKA axis was 0.9° after utilizing the Cuvis Joint™ fully autonomous robotic system for performing the TKA without any outliers. The coronal and sagittal placement of implants was within 1.2° of the defined value in each case showing high accuracy of component placement after RA-TKA in our series of patients.

Discussion

This study investigated the safety and intra-operative surgical complications associated with the use of the Cuvis Joint™ autonomous system for RA-TKA [9]. However,

Table 2 Radiological results of Mechanical alignment and component positioning using the fully autonomous RA-TKA (Cuvis Joint™ autonomous robot system)

	Pre-operative	Post-operative	Outliers
HKA axis (degrees)	12.4 ± 5.2	0.9 ± 1.2	None
Sagittal inclination of tibial component (posterior slope in degrees)	7.9 ± 2.1	0.4 ± 0.6	None
Coronal inclination of femoral component (degrees)	–	91.2 ± 0.6	None
Coronal inclination of tibial component (degrees)	–	90.6 ± 0.8	None

HKA Hip–knee–Ankle axis

conventional manual TKA achieves this outcome only in 28–85% of cases [10]. In conventional TKA, an inaccuracy of coronal plane angle up to 4° and sagittal plane angle up to 11° is reported in bone cuttings. Additionally, 10–40% of the total cutting error is also reported for guide movement [2]. With the RA-TKA, the cutting errors are eliminated, and outliers are considerably reduced [10]. Hampp et al. reported significantly more accurate bone cuts and implant positioning with RA-TKA compared to conventional TKA [11]. Kayani et al. compared RA-TKA with conventional TKA, and reported improved accuracy of alignment in coronal and sagittal planes in the femoral and tibial components, joint line restoration, tibia slope, and limb alignment compared to conventional TKA [12]. Jeon et al. found an improved accuracy in radiographic alignment of RA-TKA (10.7% coronal outliers) over conventional methods (16.5% coronal outliers) [13]. In a systematic review, Shatrov and Park reported satisfactory femoral component alignment in 95% of cases with RA-TKA versus 84% in the conventional group. Similarly, with the tibial components, malalignment was seen in 21% of cases undergoing conventional TKA versus 5% in RA-TKA [14].

In our report of 500 cases, there was no incidence of neurovascular injury. The incidence of vascular injuries due to conventional TKA is reported to be 0.03–0.2% [15]. The incidence of nerve injury following TKA ranges from 0.3 to 1.3% [16]. RA-TKA allows accurate planning of the milling track and the type of cutting used, which reduces the risk of injury to ligaments, vessels, and nerves compared to the conventional technique [17].

Similarly, there were no cases of medial collateral ligament (MCL) injury or extensor mechanism injury in this study. A superficial patellar abrasion occurred in a short obese female but there was no loss of integrity of the tendon; hence, no intervention was required. Technical errors such as the use of an improper size of oscillating saw as well as ligament and tendon overstretching during bone resection have been associated with ligamentous disruption [18]. Loss of MCL integrity is the most severe problem affecting the postoperative functions and longevity of the implant [19]. The reported incidence of intra-operative MCL injury during TKA is 0.5–3% [19, 20]. The components involved in the extensor mechanism of the knee joint are the quadriceps muscle group, quadriceps tendon, patella, patellar retinaculum, patellar tendon, and tibial tuberosity [15]. During the preparation of patellar components, an excessive bone cutting is associated with patellar fracture which is the most common injury of extensor mechanism [20, 21]. In RA-TKA, appropriate retractor placement and the haptic system that shuts down the saw when the active zone is breached protect the soft tissue [22]. In our patients, the patellar tendon was lifted using a Mayo towel clip when the burr milled the lateral side of the knee, despite the presence of adequate bone island (Fig. 5a).

In this study, RA-TKA was not abandoned midway in any case due to threatened soft tissue injury. RA-TKA causes less soft tissue violation due to the containment of the cutting saw within a fixed stereo-tactic field, based on the 3D images generated [23]. Improvements in implant positioning reduced the need for extensive capsule and ligament release, provided better control over bone cuts, and lessened extensive exposure and crushing of soft tissues [24]. In a retrospective study, Siebert et al. compared 70 patients undergoing RA-TKA vs. 50 undergoing conventional TKA and observed reduced post-operative soft tissue swelling in the robotic cohort [25]. The precise milling by the robot ensures

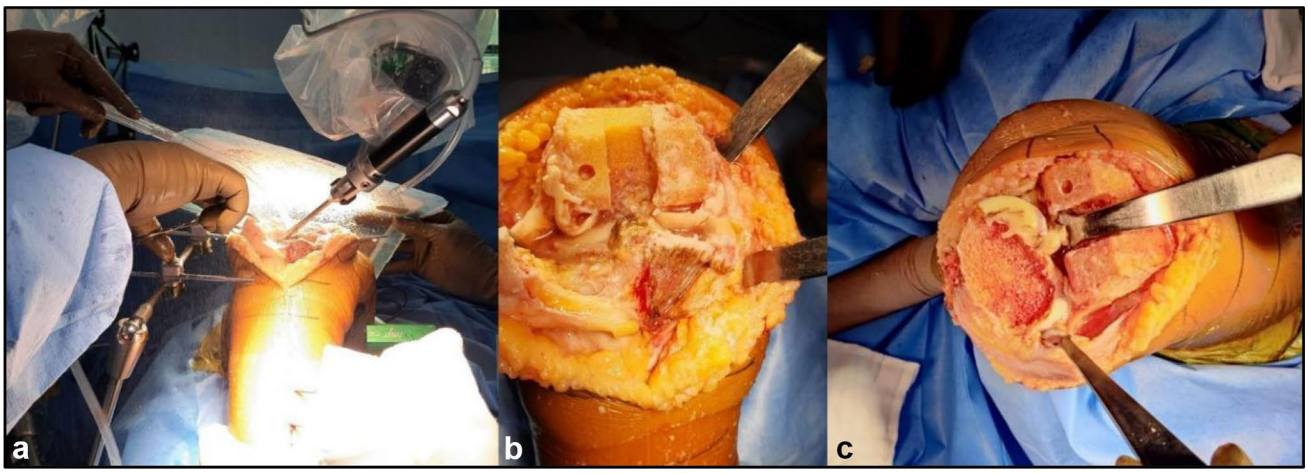

Fig. 5 **a** A Mayo towel clip being used for retraction of the patellar tendon and the more medial pathway taken by the robot to avoid the tendon, **b** and **c** completed resection of the femur and tibia, with robot detached from the body. The bone islands along the periphery untouched by the burr is seen, which shows the precision of milling

the safety of soft tissues. The surface registration compiles 80 points in all, excluding the initial locating points. Then the robot utilizes surface registration for creation of a virtual 3D model of the patient's knee anatomy in accordance with the uploaded CT model. The precision is improved when the RMS error is less than 1. The surgeon also plays a critical role in avoiding soft tissue injury. The preoperative CT scan helps to precisely determine the size and position of the implant. The surgeon ensures that the implant does not overhang the bone in any plane. The software has a failsafe at this juncture- if there is a significant overhang, it alerts the surgeon before finalizing the data. Moreover, the milling is very precise such that the excess bone outside the planned milling is left untouched by the burr. These bone islands help in the natural retraction of the soft tissues and prevent soft tissue injury (Figs. 5b, c, 6).

The robot has another fail-safe mechanism that improves its safety features. It has a BMM that collects data throughout the milling procedure. In case of any untoward movement or bone movement exceeding the defined threshold, the arm freezes and the milling stops, thus avoiding injury. The speed of milling can be modified throughout the process and is under the control of the operator. This provides control over the regions where milling under caution is necessary. Another safety feature includes saline irrigation with an inbuilt motor within the robotic console to ensure no thermal injury to the bone or surrounding soft tissue during the milling process (Fig. 4b). The robot also allows the surgeon to downsize the femoral component intra-operatively but disallows upsizing the component. This feature was designed to prevent any soft tissue injury that might be related to upsizing of the component in case of violation of the bone boundary. In case excessive torque is required during milling either due to dragging of any soft tissues with the burr, sclerotic bone, or pulled up cables, the arm freezes in that position providing another failsafe against tissue injury and improper resection [8].

The milling of the bone surfaces is precise enough to allow for cement-less insertion of the prosthesis, which requires an implant bone gap of 0.1–0.3 mm for osseous integration [27]. Routinely one 3 mm Kirschner wire is used for medial side retraction in thin individuals and two 3 mm Kirschner wires are used in obese individuals in the medial femoral metaphysis. A Mayo towel clip for the patellar tendon retraction during milling on the lateral side and a small-Langenbeck type retractor medially during the posteromedial milling provides an added layer of protection.

Femoral or tibial shaft fracture due to mechanical weakness caused by the pinholes is one of the most dreaded complications of the RA-TKA, with an incidence of 1.4% reported by Beldame et al. [3, 26]. The metaphyseal unicortical Steinmann pin on the lateral side for attaching the robot to the patient provides retraction on the lateral side. Two diaphyseal pins are used on the femur and two on the tibia for navigation array attachment (Fig. 1d) and one metaphyseal unicortical Steinmann pin each on the lateral femoral and lateral tibial condyle for fixing the robot to the patient (Figs. 3a, 4a) during the surgery. For the diaphyseal pins, the first cortex is drilled and a self-drilling self-tapping Steinmann pin through the hole is inserted till the pin touches the opposite cortex. This process is more stable since it is a dual pin system for fixing the markers to the bone. In our study, no registration errors due to the loosening of pins intra-operatively were experienced. A 2.5 mm drill bit is usually used to create a pilot hole before inserting the Steinmann pin, as it is a safer and more secure approach against pin loosening. There was a complication of drill bit breakage and another with the Steinmann pin breakage during insertion (Fig. 7). In Fig. 7, it is noticeable that multiple tracts were made in order to obtain the right axis of insertion. The Steinmann pin

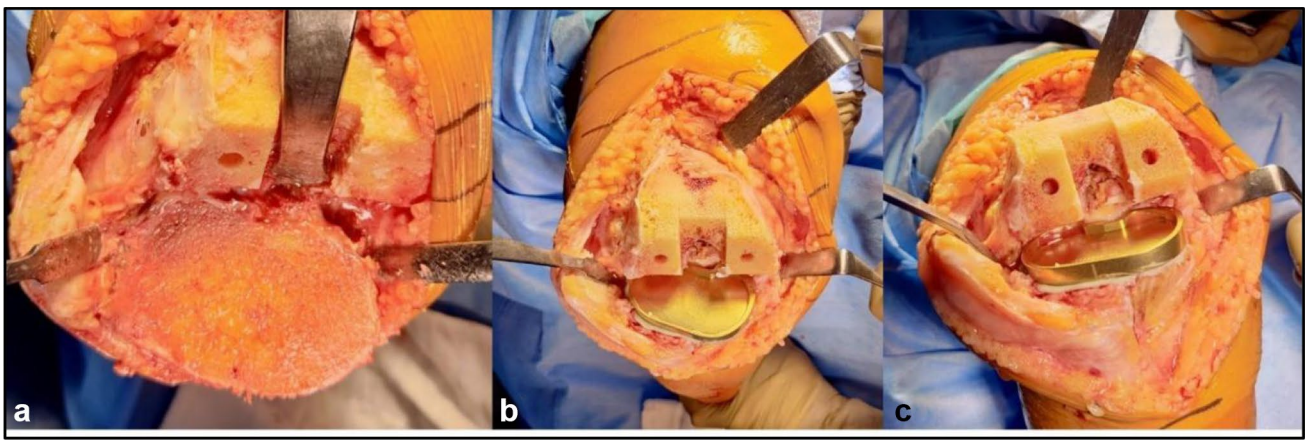

Fig. 6 **a** proximal tibial surface after removing the bone islands and before the manual preparation of keel, image shows the flatness of the cut. **b** and **c** Femoral surface after resection ready for cementing and implantation

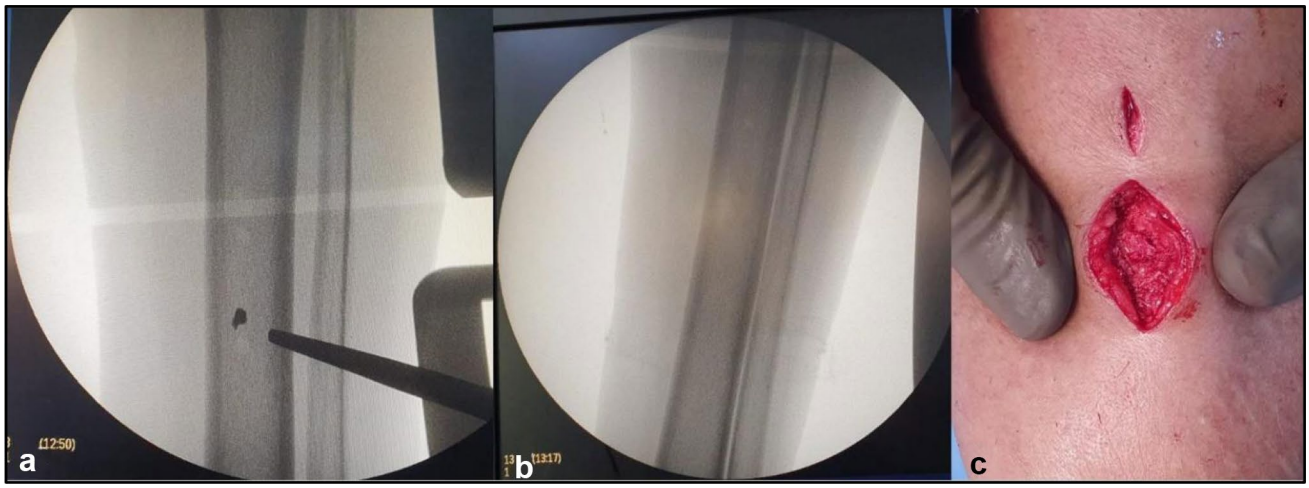

Fig. 7 **a** An image showing the broken tip of Steinmann pin in the tibia, **b** the image after removal of the pin tip, shows intact tibial cortices, **c** clinical picture of the leg showing the incision and the intact cortex

was likely angulated on entry and broke on reapplication in subsequent attempts.

The remnants were retrieved without any damage to the bone. The pins should not be placed trans-cortical or unicortical as these have the highest likelihood of causing stress-related injuries [28] and infection due to thermal necrosis [29]. The minimum follow-up period in our study was 3 months and, to date, no post-operative stress related fracture or pin site infection was seen in any patient. The reported incidence of pin related complications is approximately 1% [30]. In case of apprehension in using metaphyseal pins for stabilizing the bone to the robotic arm, metaphyseal hook-type clams are also available for secure fixation of the leg to the robotic arm.

The ability to use the robotic arm without causing any soft tissue injury in the initial cases required extended operating time and involved pausing the robot in between resections to check the integrity of these tissues. However, with further cases, as our knowledge on safe usage of the robot improved, the operating time reduced considerably. In the last 150 cases, the operating time was consistently less than 90 min, the lowest tourniquet time being 59 min from incision till definitive implantation.

Limitations

It is a retrospective review of single-center experience involving a single RA-TKA device, i.e., Cuvis Joint™ fully autonomous robot system. The study due to its retrospective nature does not include the follow up patient reported outcome measures. The accuracy of implant positioning was done on a post-operative radiograph. Although, this is a large volume (500 patients) single center experience which may generalize the outcome measures and itself proves the safety of RA-TKA, further randomized, multi-center and prospective studies need to be conducted for evaluation of efficacy and performance of the device.

Conclusion

Active robotic arthroplasty involving navigation based minimally invasive surgery, achieves accurate preoperative planning, optimal selection of implants, precise osteotomy, and accurate placement of artificial joints owing to the precise control technology of the robotic arm. The Cuvis Joint™ autonomous robotic system is safe with no intra-operative complications.

Declarations

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Ethics Approval This study was initiated after the protocol was reviewed and approved by the local ethics committee according to local regulations. The study was carried out in conformity with the protocol and International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP).

Informed Consent For this type of study, informed consent is not required.

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