





CLINICAL ARTICLE

A Newly Designed “SkyWalker” Robot Applied in Total Knee Arthroplasty: A Retrospective Cohort Study for Femoral Rotational Alignment Restoration

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Objective: This study explored whether robotic arm-assisted total knee arthroplasty (RATKA) has the advantage of restoring femoral rotational alignment compared to conventional total knee arthroplasty (COTKA).

Methods: Sixty patients (45 women and 15 men) attending our department from May 2019 to December 2020 were selected and divided into two groups, with 30 patients in each group, according to whether they underwent COTKA or RATKA. Femoral rotational alignment results, such as, posterior condylar angle (PCA), patella transverse axis-femoral transepicondylar axis angle (PFA), radiological findings, such as, hip-knee-ankle angle (HKA), lateral distal femoral angle (LDFA), and medial proximal tibial angle (MPTA), and operative data (operation time, intraoperative blood loss, tourniquet time, and length of stay (LOS), and clinical outcomes, such as maximum knee flexion angle (MKFA), Knee Society Score (KSS), and Western Ontario Mac Master University Index Score (WOMAC) were compared within and between the two groups.

Results: PCA and PFA in the RATKA group were $(0.6 \pm 0.3)^\circ$ and $(0.9 \pm 0.3)^\circ$, respectively, which were smaller than $(1.5 \pm 2.0)^\circ$ and $(3.1 \pm 1.1)^\circ$ in the COTKA group ($P < 0.05$), and were closer to 0° ; the differences in HKA, LDFA, and MPTA were not statistically significant. With the exception of the LDFA, the HKA, MPTA, PCA, and PFA improved in both groups after surgery ($P < 0.05$). The blood loss and the LOS of RATKA group were 192.3 ± 23.1 mL and 8.2 ± 1.4 days, which were less than 203.7 ± 29.8 mL and 9.3 ± 1.1 days of the COTKA group, but the operation time showed no statistically significant difference, and the tourniquet time was longer ($P < 0.05$). The MKFA in the RATKA group was $(123.0 \pm 3.7)^\circ$, which was greater than $(116.3 \pm 4.6)^\circ$ in the COTKA group ($P < 0.05$). In terms of scores, the postoperative results were better than the preoperative results in both groups ($P < 0.05$). However, there was no statistically significant difference between the groups.

Conclusion: The accuracy of femoral rotational alignment reconstructed achieved by RATKA is significantly better than that of COTKA and is more conducive to the recovery of knee flexion function after surgery; although RATKA reduces intraoperative blood loss and postoperative LOS, the short-term clinical efficacy comparison has not yet demonstrated the advantages of robotic technology, and a more optimized design is needed to improve the efficiency of RATKA surgery.

Key words: Mechanical axis; Minimally invasive; Robotic arm; Rotational alignment; total knee arthroplasty

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Introduction

Arthroplasty is an effective method to treat end-stage joint disease and damage caused by various reasons and to effectively reconstruct joint function.¹⁻³ It is considered one of the most successful surgical procedures of the 21st century owing to its efficacy and safety.² Total knee arthroplasty (TKA) is a millimeter-scale procedure. Accurate osteotomy and prosthesis implantation are important for improving clinical efficacy and long-term implant survival. Despite continuous improvements in surgical techniques and prosthesis design, the accuracy of surgical resections and the resulting prosthetic malalignment are still high (up to 32%) in conventional TKA (COTKA) procedures, primarily due to the influence of the surgeons' experience.⁴ Aseptic loosening may occur when the alignment deviates by $>3^\circ$. This results in an increased incidence of later revision.⁵ To overcome manual error, a variety of surgical tools have emerged, among which computer navigation and robotic arm technology are the most representative. Robotic arms are a revolutionary technology that have been widely used in the field of joint surgery. The approach utilizes a mechanized device (usually a robotic-arm) that interacts with the environment and sensors and overcomes the errors caused by manual control, and is expected to greatly improve the accuracy of the surgery.

From active robots such as CASPAR and ROBODOC to semi-active robots such as MAKO RIO, many studies have reported that the postoperative lower limb alignment of robotic arm-assisted TKA (RATKA) was more accurate, and deviations in the sagittal, coronal, and transverse planes dropped significantly compared with COTKA. Previous studies have shown that robotic arm-assisted TKA (RATKA) has the following advantages⁶⁻⁸: (i) more precise osteotomy and prosthesis implantation; (ii) better protection of soft tissue around the knee, minimally invasive; (iii) a shorter learning curve; (iv) higher satisfaction of patients; and (v) superior ergonomics, improved efficiency, and reduced labor intensity of surgeons.

However, the above benefits derived mainly from the Robodoc and MAKO systems used. The SkyWalker™ robotic arm system (model OSR-1000, MicroPort (Suzhou, China) OrthoBot Co. Ltd.) evaluated in this study is a new robotic device developed by Chinese researchers. It has the goal of safety, efficiency, and precision in minimally invasive environments, although the efficacy of this new robotic technique still lacks in-depth research.

The aim of this study lies in the following aspects: (i) to evaluate the technical advantages of the newly designed "SkyWalker" robot applied in TKA, especially in improving the deficiencies of conventional surgery in controlling femoral component rotational alignment; (ii) to compare the short-term clinical efficacy between RATKA and COTKA, focusing on comparing the advantages of robotic surgery in improving the maximum knee flexion angle (MKFA) and the accuracy of lower extremity alignment after TKA; and (iii) to observe and verify the feasibility, efficiency and safety of RATKA.

Materials and Methods

This was a retrospective, cohort study. All procedures in this study involving human participants were performed in accordance with the ethical standards of the institutional and/or national research committee standards and the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study was approved by the ethics committee of the hospital (No. KY2019163) and informed consent was obtained from all participants included in this study. The study was registered at <http://www.chictr.org.cn/> (ChiCTR2100054391).

Participants

Eighty-four patients with advanced osteoarthritis (OA) of the knee who underwent primary TKA between May 2019 and December 2020 in our department were retrospectively evaluated. Patients were included according to the following inclusion and exclusion criteria.

The inclusion criteria were as follows: (i) age ≤ 80 years; (ii) patients with only deformity of the knee, varus deformity $\leq 15^\circ$; and fixed flexion deformity $\leq 10^\circ$; (iii) the Kellgren-Lawrence classification Grade IV; (iv) availability of complete follow-up data in the medical records, including operation time, intraoperative blood loss, tourniquet time, length of stay (LOS); MKFA, Knee Society Score (KSS), the Western Ontario Mac Master University Index Score (WOMAC) at 3 months postoperatively, complete full-length weight-bearing radiography (anteroposterior and lateral views), and computed tomography (CT) of the lower extremity; and (v) no severe dysfunction of the contralateral knee or Kellgren-Lawrence classification lower than Grade II.

The exclusion criteria were as follows: (i) patients with large bone defects around the knee; (ii) knee valgus deformities; (iii) severe extra-articular deformities; (iv) patients with periarticular soft tissue dysfunction and neuropathy; and (v) history of autoimmune diseases prior to surgery, such as rheumatoid arthritis and ankylosing spondylitis, involving lesions in multiple joints.

Twenty-four patients were excluded, including eight cases of rheumatoid arthritis, three cases of huge bone defects, nine cases of valgus deformity, and four cases of severe extraarticular deformity.

Ultimately, 60 patients (45 women and 15 men) were included in the study. The patients were divided into two groups according to the surgical method they underwent: 30 patient (30 knees) were included in the COTKA group and 30 patients (30 knees) patients were included in the RATKA group. Patient demographics were recorded before surgery, including age, sex, body mass index (BMI), operation side, mechanical axis (MA), and range of motion (ROM) (Table 1). All patients underwent a CT scan, full-length weight-bearing radiography, and KSS and WOMAC scores were obtained before surgery. All procedures were performed by the same surgeon. The LEGION Total Knee System posterior stabilized prosthesis (Smith & Nephew, Memphis, TN, USA) was used in the COTKA group. An advanced MP prosthesis (MicroPort

TABLE 1 Patient demographics

Item	COTKA group (30 cases)	RATKA group (30 cases)
Age (years)	66.8 ± 6.5	71.3 ± 7.2
Sex (male/female)	8/22	7/23
Operation side (center/right)	17/13	18/12
BMI (kg/m ²)	27.6 ± 3.6	26.8 ± 4.2
ROM (°)	7.3–110.4	10.5–108.7
MA (°)	170.7 ± 2.3	170.8 ± 4.0

Abbreviations: BMI, body mass index; COTKA, conventional TKA; MA, mechanical axis; RATKA, robotic arm-assisted TKA; ROM, range of motion; TKA, total knee arthroplasty.

Orthopedics Inc., Arlington, TN, USA) was used in the RATKA group. In all cases, the patient was placed in the supine position after a combination of lumbar and epidural anesthesia. A tourniquet is placed on the proximal thigh. An anterior central incision of the knee was performed using a standard medial parapatellar approach. No patellar replacements were performed. All participants underwent standardized preoperative education and postoperative rehabilitation.

Newly Designed “SkyWalker” Robot Equipment

Compared with a robotic system equipped with a burr at the end of its arm to perform osteotomy, SkyWalker has

engineered the following improvements in the design: (i) its robotic arm has six motion joints, and the cutting jig is stably connected to the end of the robotic arm, which can improve positioning during the execution of the osteotomy. This differs from the MAKO system, which installs a burr at the end of the robotic arm. A similar design has been adopted for the Praxim surgical robots (OMNI Lifesciences, Bremen, Germany)⁹ and ROSA surgical robots (Zimmer Biomet, Warsaw, IN, USA) and have been successfully applied in surgery. The design of the cutting jigs is closer to the surgical workflow of surgeons, which is conducive to reducing the learning curve and adapting to robotic surgery more quickly.¹⁰ (ii) An eccentric shaft has been added to the cutting jig, which is helpful for the cutting jig to avoid the patella and patellar tendon when it reaches the osteotomy position, so that the surgery can be completed with enhanced minimally invasive exposure. Moreover, the osteotomy can reach closer to the knee joint, thereby reducing the error caused by the vibration of the oscillating saw. (Fig. 1). (iii) The cutting jig was designed with a positioning hole that can be connected to conventional tools. If the robot fails, the surgeon can use the conventional cutting guide and switch to a conventional surgical technique, which can ensure the safety of the surgery, especially for surgeons who are in the early stages of the learning curve (Fig. 2). (iv) After the prosthesis is installed, dynamic measurement of the extension-flexion gap and the medial-lateral



Fig. 1 Innovative design of the SkyWalker™ robotic arm system. The SkyWalker™ robotic arm consists of six joints, with a wide range of motion and flexible operation. The cutting jig is stably connected to the end of the robotic arm. An eccentric shaft is added to the cutting jig, which enables the latter to avoid the patella and patellar tendon to reduce osteotomy errors



Fig. 2 Design of the positioning hole in the cutting jig. A positioning hole (red arrow) was designed in the cutting jig, and the position of the hole is the same as that of the fixing pin (red arrow) on the back of the cutting guide as in conventional surgery. When a malfunction occurs during robotic surgery, with this positioning hole, the surgeon can switch to the conventional cutting guide, fix it on the surface of the femur, and continue with the surgery. This design feature ensures patient safety

gap can be performed by the robotic system to evaluate the soft tissue balance in TKA.

Preoperative Planning

A three-dimensional skeletal model of the affected lower limb was established using thin-slice CT scans (slice thickness, 1 mm). The femoral and tibial horizontal osteotomy in the coronal plane was set perpendicular to the mechanical axis, the femoral osteotomy in the sagittal plane was 3° anteverted to the anatomical axis of the femur, and the tibial osteotomy was 3° retroverted relative to the anatomical axis of the tibia. In the transverse section, the femoral anterior and posterior condyle osteotomy line was parallel to the surgical condyle axis, and the tibial prosthesis rotational alignment was perpendicular to the projected line of the femoral prosthesis's transverse axis and aligned with the medial 1/3 anatomical orientation of the tibial tubercle. The target value of the lower limb alignment was set to 177–180° according to the degree of knee deformity of the patients, which was 180° in 27 cases, 179° in one case, 178° in one case, and 177° in one case. After the completion of the surgical design, the prosthesis installation parameters were determined in the surgical planning system, and the knee osteotomy angle, osteotomy amount, alignment, and rotation of the femoral and tibial prostheses were calculated (Fig. 3).

Preoperative Preparation of the Robotic Arm

Before surgery, the robotic arm was fully prepared, and the procedure was mainly divided into three steps. Step 1: the position of the infrared camera was adjusted to ensure that the limb on the operating side could accept full surveillance and ensure that there were no obstructions in the operative field of view. Step 2: the markers were mounted on the

femoral shaft, tibial shaft, and at the end of the robotic arm. The markers were then registered, located, and validated. Step 3: the pointed probes and blunt probes are prepared. Matching markers were then mounted on the probes (Fig. 4).

Key Points of RATKA

After the knee was fully exposed, the following four steps were performed before the osteotomy. Step 1: the accuracy of the cutting guide was checked. The center point of the femoral head was then identified by flexing the hip in multiple directions. Step 2: the medial and lateral malleoli were palpated using a blunt probe and registered for localization. Step 3: the femoral and tibial checkpoints are determined using a pointed probe, as indicated by the display system. Step 4: forty registration sites are distributed in the distal femur and proximal tibia. The registration of these anatomical sites was collected and verified according to the tips on the display screen (Fig. 5).

The checkpoints of the femur and tibia were verified again, and osteotomy of the distal femur and proximal tibia was performed. First, according to the preoperative planning established based on the navigation system, the valgus resection angle for the distal femur, external rotation resection angle for the posterior condyle, forward flexion resection angle for the anterior condyle, and tibial slope were designed. Simultaneously, the height of the joint line and amount of osteotomy on the medial and lateral sides of the knee were determined. It should be emphasized that the robotic arm could complete 360° rotational and horizontal movements along any plane under predetermined commands. According to the parameters calculated by the computer navigation system, the robotic arm automatically

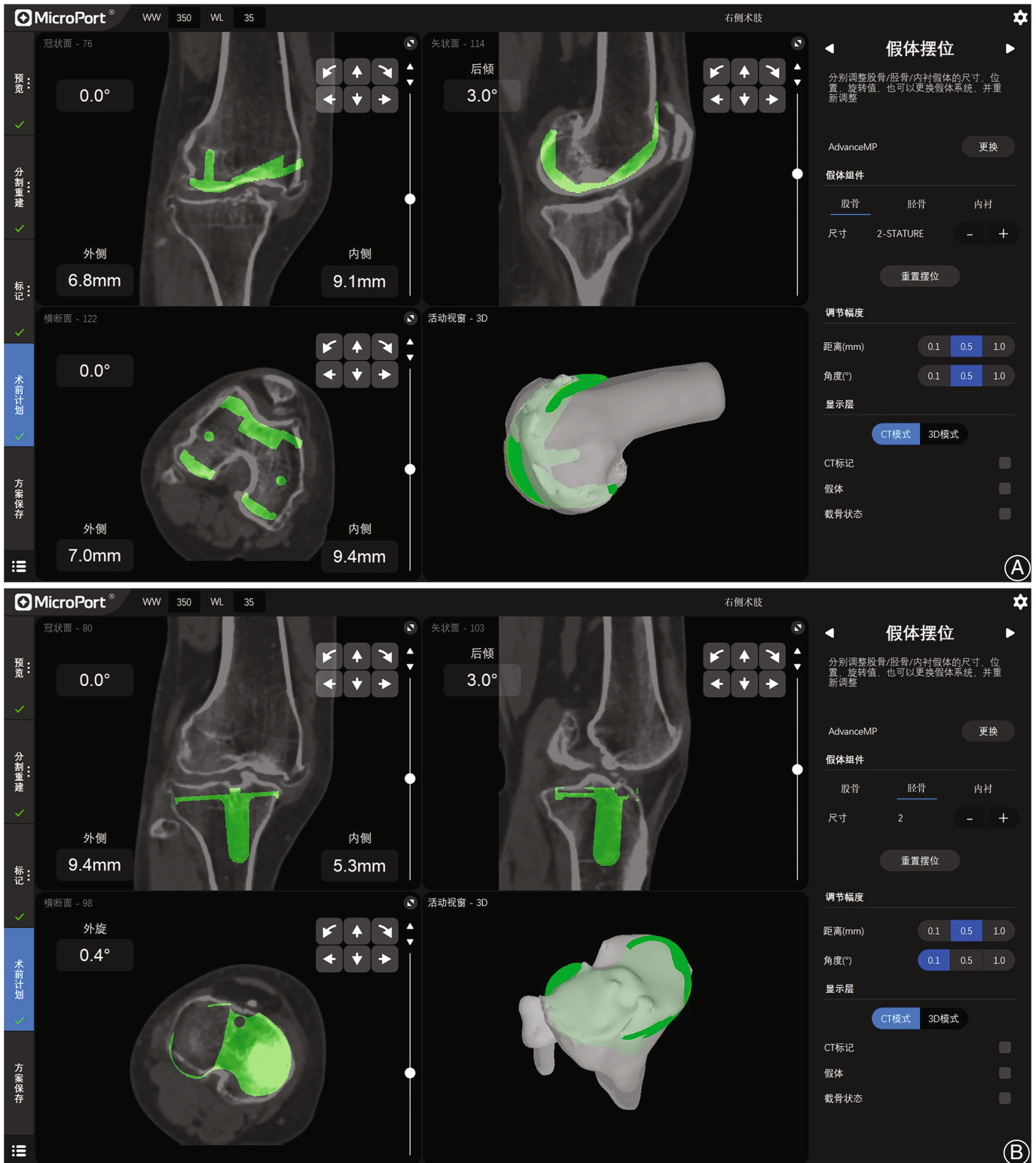


Fig. 3 Preoperative planning of robotic arm-assisted TKA. (A) Preoperative planning for the femur. Coronal plane: LDA 180°, sagittal plane: 3° anteverted to the anatomical axis of the femur, transverse plane: PCA 0°. (B) Preoperative planning for the tibia. Coronal plane: MPTA 180°, sagittal plane: 3° slope, transverse plane: 0.4° external rotation to the AP axis of tibia

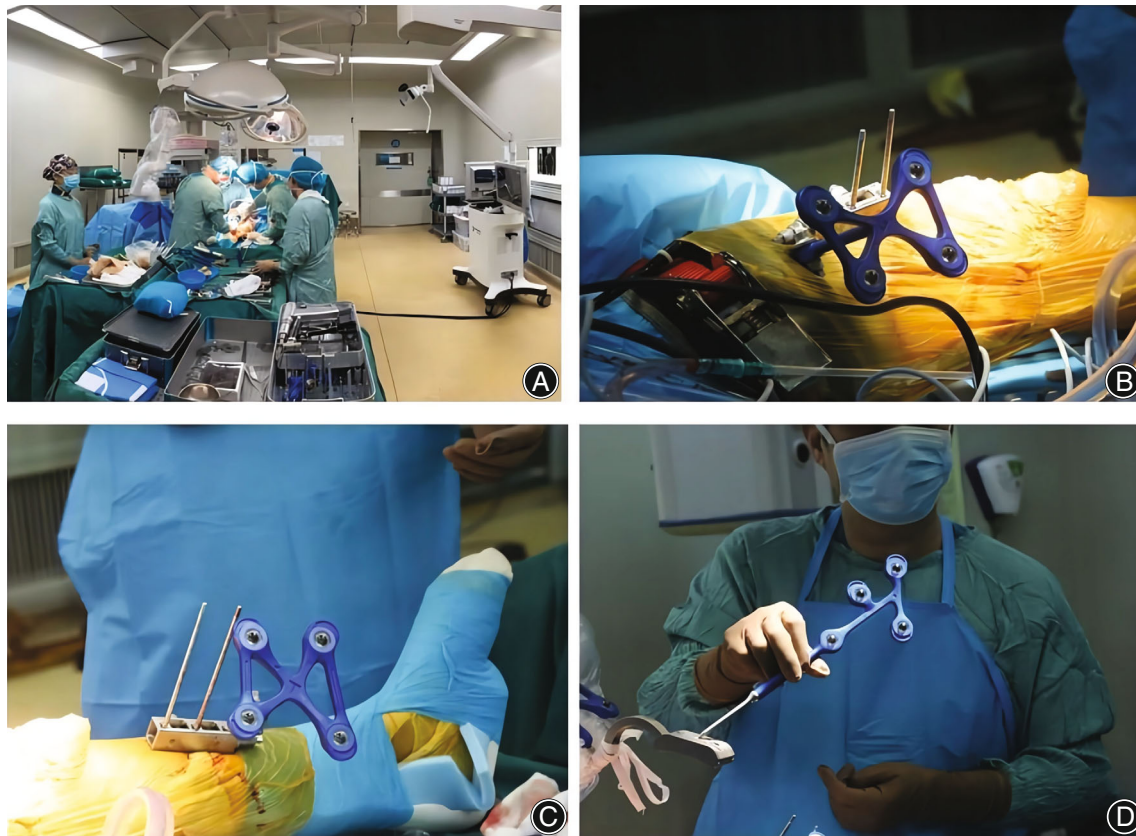


Fig. 4 Preoperative preparation of the robotic arm. (A) The infrared camera position is adjusted. (B) The marker is mounted on the femoral shaft. (C) The marker is mounted on the tibial shaft. (D) The marker is mounted on the probe

arrived at the surgical site directed by the instructions. After confirming the overlap between the actual and simulated planes in the display system, the cutting guide was fixed and the surgeon held a special oscillating saw to complete the osteotomy. Distal femoral osteotomy was first performed, followed by proximal tibial osteotomy. The sequence of the femoral osteotomy was as follows: distal femur, anterior condyle, posterior condyle, posterior oblique osteotomy and anterior oblique osteotomy. After the osteotomy was complete, trials were performed and varus and valgus tests were then performed at different flexion angles of the knee to verify whether the gaps were balanced (Fig. 6).

Key Points of COTKA

The surgeon performed the osteotomy for distal femur first and then for the proximal tibia. A tibial extramedullary guide and a femoral intramedullary guide were routinely used. All participants underwent standard 3° external rotation osteotomy of the posterior condyles to accomplish the surgical procedure. During proximal tibial osteotomy, a 3° posterior tibial slope is maintained in the sagittal plane.

Postoperative Management and Outcome Measurement

All patients were routinely treated for prevention of infection, pain relief, ice compression, and functional rehabilitation. Before discharge, the patients' clinical outcomes were recorded according to the surgical records. One month after surgery, the patients underwent full-length weight-bearing radiography and CT scan to define any interference from metal artifacts and better present the location of the prosthesis. Functional scores were measured 3 months after surgery.

Radiological Results Measurement

The RadiAnt DICOM Viewer (Medixant Ltd., Poznan, Poland) was used to measure and analyze the CT data. PCA was defined as the angle between the surgical transepicondylar axis (sTEA) and the posterior condyle line (PCL) of the femoral component. The sTEA is the line connecting the lowest point of the sulcus on the medial femoral epicondyle and the highest point of prominence on the lateral epicondyle. PFA was the angle between the sTEA and the patella transverse line (PTL), which is the connection between the inner and outer ends of the patella in the transverse plane (Fig. 7).

We used Orthosize-1.3.2-win (Biomet Ltd., Warsaw, IN, USA) to measure and analyze full-length weight-bearing radiographic data. HKA was determined in

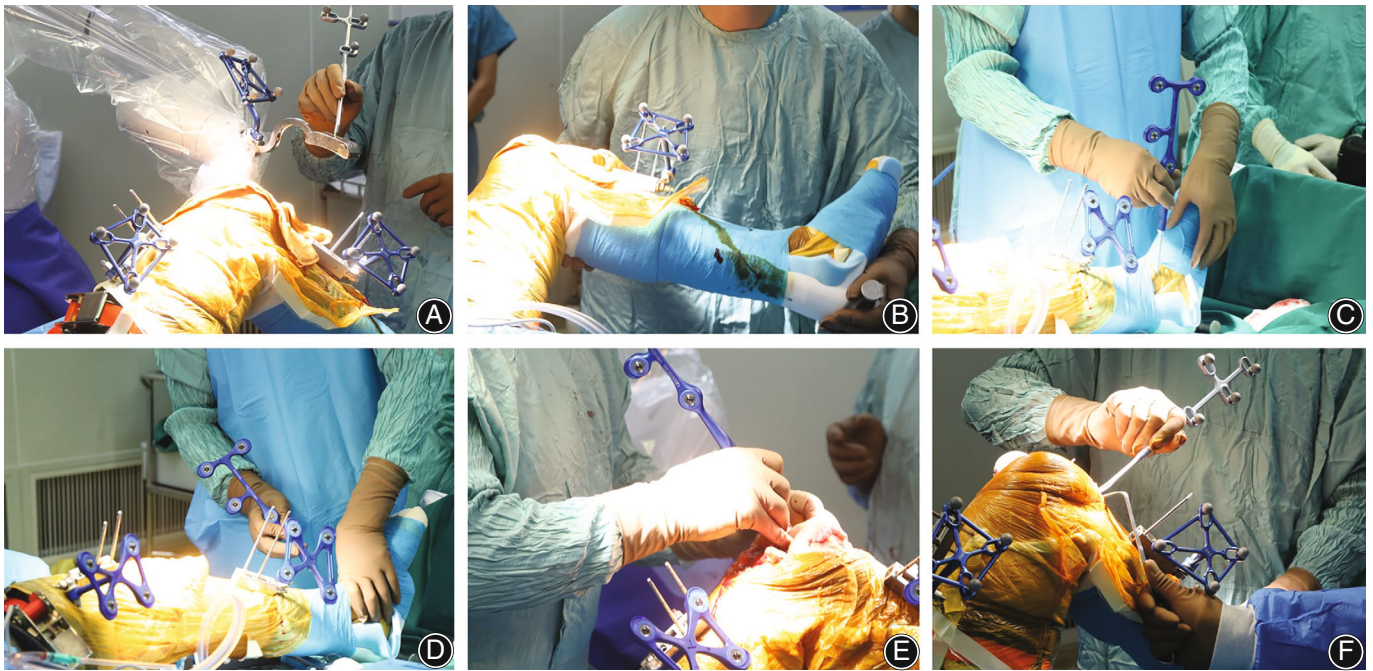


Fig. 5 Preparation for osteotomy. (A) The accuracy of the cutting guide is checked. (B) The center point of the femoral head is identified. (C, D) The medial and lateral malleolus are palpated with a blunt probe. (E) The registration sites are collected and verified on the femur. (F) The registration sites are collected and verified on the tibia

the coronal plane by measuring the angle between the line connecting the center of the femoral head to the center of the knee and the line connecting the center of the knee to the center of the ankle. The lateral distal femoral angle (LDFA) was defined as the lateral angle between the MA and the joint line of the femur. The medial proximal tibial angle (MPTA) was defined as the medial angle between the MA and joint line of the tibia (Fig. 8).

Operative Data Recording

The operation time was defined as the time from skin incision to the completion of suturing of the operative area. Blood loss was calculated based on the amount of blood in the aspirator and the amount of gauze consumed. The tourniquet time was defined as the time from the start of the application to the completion of the capsular suture. The LOS was defined as the time between admission for the preoperative examination and departure from the hospital.

The MKFA defined the angle between the anatomical axis of the tibia and femur when the patient actively flexed the knee. The KSS combines subjective and objective information of the replaced knee and is divided into two subscales: the Knee Score (KSS-K) and Function Score (KSS-F), each ranging from 0 to 100 (representing the worst and the best clinical or functional situations, respectively). The WOMAC is a generalized scoring system for OA, including pain, stiffness, and function, with a total score ranging from 0 to 96. In particular, the lower the score, the better is the result.

Statistical Methods

SPSS v20.0 (IBM, Armonk, NY, USA) was used for statistical analysis. The measurement data of the normal distribution are expressed as the mean and standard deviation. Different statistical test methods were used for statistical analysis between and within groups. A paired *t*-test was used to analyze the intra-group differences in parameters before and after surgery; an independent *t*-test was used to analyze the differences in parameters after surgery between the two groups. Statistical significance was set at $P < 0.05$. All statistical analyses were performed independently by a single doctor who was blinded to the trials. A feasibility study was conducted on a small sample, and after safety was confirmed, the sample size was evaluated according to statistical requirements. Power analysis was conducted with type-I error set at 0.05 ($\alpha < 0.05$) and type-II error at 0.15 (85% power). A minimum sample size of 29 knees was required to detect a significant difference between the two groups based on a two-sample test of proportions and a two-sided test hypothesis using SPSS software.

Results

Comparison of Preoperative Planning and Postoperative Measurement

Compared with the preoperative planning, osteotomy data obtained during surgery were significantly different in the medial and lateral distal femoral osteotomy and femoral

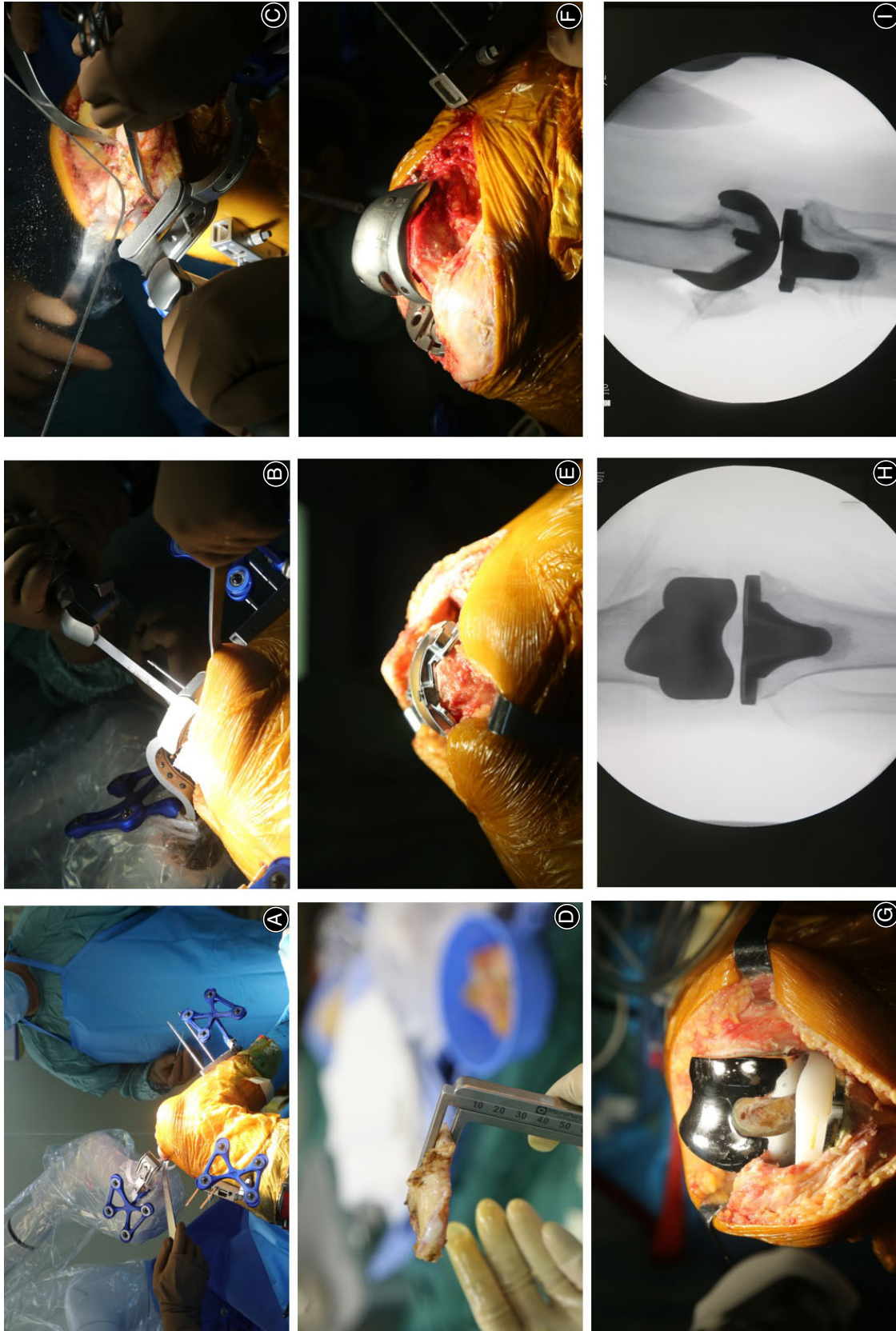
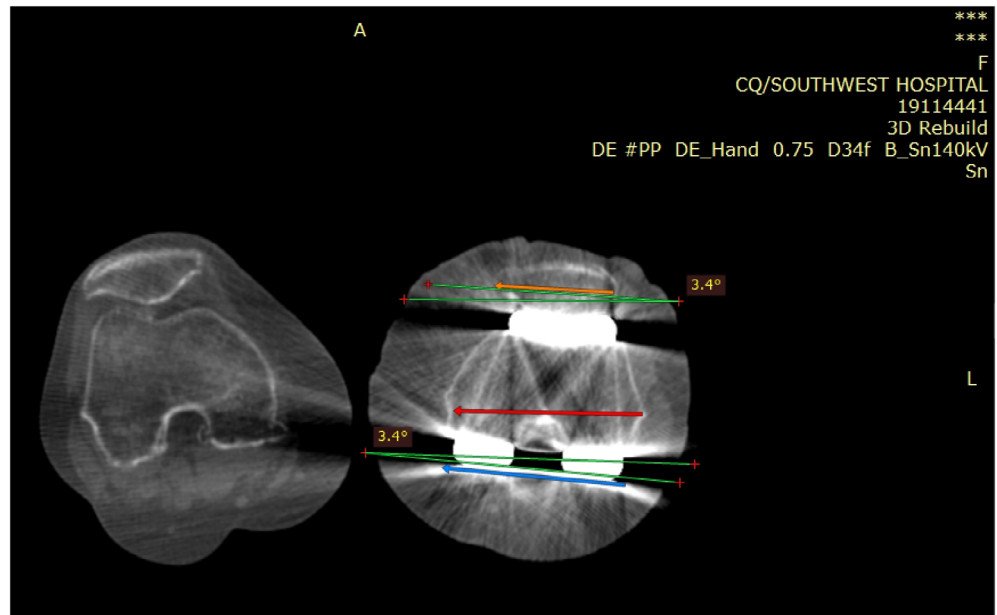


Fig. 6 Key points of robotic arm-assisted TKA. (A) Osteotomy of the distal femur. (B) Osteotomy of the posterior condyle of the femur. (C) Osteotomy of proximal tibia. (D) Measuring the thickness of osteotomy. (E) Intercondylar osteotomy of femur. (F) Trials are installed to verify gap balancing. (G) The prosthesis is installed. (H, I) Radiographs of the knee obtained immediately after surgery

Fig. 7 Measurement of the full-length weight bearing radiograph. The PCA is defined as the angle between the red arrow (sTEA) and the blue arrow (PCL); PFA is the angle between the red arrow (sTEA) and the yellow arrow (PTL); sTEA is indicated by the line connecting the lowest point of the sulcus on the medial femoral epicondyle and the highest point of prominence on the lateral epicondyle; PCL is the posterior condyle line; PTL is the patella transverse line (the connection between the inner and outer ends of the patella in the transverse plane)



medial posterior condyle ($P < 0.05$). The preoperative planning was reduced by 1.24 ± 0.92 mm, the distal lateral femoral condyle osteotomy was reduced by 0.47 ± 1.12 mm, and the femoral medial posterior condyle osteotomy was reduced by 0.59 ± 0.97 mm. There was no significant difference between the lateral osteotomy of the posterior condyle of the femur and the medial and lateral osteotomy of the tibial plateau compared with preoperative planning ($p > 0.05$). Compared with the preoperative planning, the postoperative HKA decreased by an average of $1.2^\circ \pm 1.2^\circ$, with a mean value of $178.3^\circ \pm 0.7^\circ$, and the 95% confidence interval was 0.75° – 1.66° , all within the safe range of $\pm 3^\circ$. In terms of consistency with the preoperative planning, the accuracy of robot-assisted tibial osteotomy (single-plane osteotomy of the tibia) was higher than that of the femur (multi-plane osteotomy for the femur) (Table 2).

Radiological Outcomes

Except for the LDFA, the HKA, MPTA, PCA, and PFA improved in both groups after surgery ($p < 0.05$) (Table 3). The PCA and PFA in the RATKA group were $(0.6 \pm 0.3)^\circ$ and $(0.9 \pm 0.3)^\circ$, which were smaller than $(1.5 \pm 2.0)^\circ$ and $(3.1 \pm 1.1)^\circ$ in the COTKA group ($P < 0.05$), and were closer to 0° ; the differences in HKA, LDFA, and MPTA were not statistically significant (Table 4).

Operative Data

The blood loss and LOS of the RATKA group were (192.3 ± 23.1) mL and (8.2 ± 1.4) days, respectively, which were significantly lower than (203.7 ± 29.8) mL and (9.3 ± 1.1) days of the COTKA group ($P < 0.05$); although there was no significant difference in operation time between the two groups, tourniquet time was significantly increased

in the RATKA group compared to the COTKA group ($P < 0.05$) (Table 5).

Clinical Outcomes

In terms of scores, the postoperative WOMAC, KSS and MKFA results were better than the preoperative results ($P < 0.05$) (Table 6). The MKFA in the RATKA group at 3 months after surgery was $(123.0 \pm 3.7)^\circ$, which was significantly higher than $(116.3 \pm 4.6)^\circ$ in the COTKA group ($P < 0.05$). There were no significant differences in WOMAC and KSS scores between the two groups (Table 7).

Complications

Patients in both groups successfully passed the perioperative period with good incision healing. There was no superficial infection of the incision and periprosthetic joint infection. No incidence of venous thromboembolism, collateral ligament injury, knee extensor mechanism disruption, aseptic loosening of the prosthesis, and fracture around the prosthesis were observed in both groups.

Discussion

To date, three types of robotic arm systems have been developed using active, passive and semi-active technology.¹¹ Among them, semi-active technology is the most mature and widely used robotic arm system in arthroplasty, and the representative products are the RIO (Robotic Arm Interactive Orthopedic System, MAKO Surgical Corp., Fort Lauderdale, USA) and the Acrobot (Acrobot Co., Ltd, London, UK).^{12–14} In this study, a new semi-active robot “SkyWalker” designed by Chinese researchers was used. Compared with other semi-active robots, this robotic system is equipped with a cutting jig, which can ensure accurate

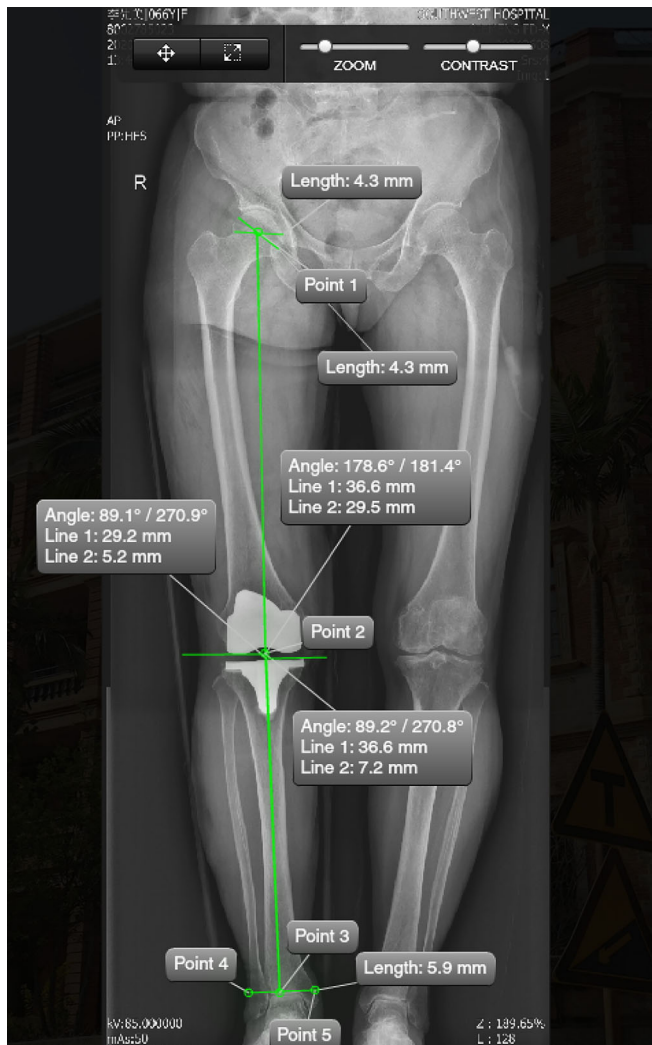


Fig. 8 Measurement for full-length weight bearing radiograph. HKA is determined by measuring the angle between a line connecting point 1 (center of the femoral head) and point 2 (center of the knee), and a line connecting point 2 to point 3 (center of medial malleolus and lateral malleolus, center of point 4 and point 5); LDFA is the lateral angle between the MA and the joint line of the femur; MPTA is the medial angle between the MA and the joint line of the tibia

positioning during surgery, an eccentric shaft, which can help avoid injury to the tendon, and a positioning hole in the cutting jig, which could enable a smooth switch to COTKA if needed.

Based on previous studies, the short-term and medium-term follow-up results were derived mainly from active robotic arm systems such as the Robodoc (Integrated Surgical Systems, Sacramento, CA, USA) and Caspar (URS Ortho GmbH, Rastatt, Germany). There have been few studies evaluating the use of semi-active robotic arm systems, and a large portion of these outcomes has come from

cadaver studies; therefore, the semi-active system needs to be further studied.

In COTKA, the MA deviation was $>9^\circ$ in 7% of patients and 5° in 34% of patients after surgery.¹⁵ However, the MA error of RATKA can be controlled in the neutral position within 1° – 3° .¹⁶ Hampp *et al.* performed surgery on 12 cadavers, six of which underwent RATKA and the other six underwent COTKA. The results showed that the osteotomy thickness in the RATKA group was more consistent with the preoperative plan, the rebuilt MA was more accurate, and the CT results of the RATKA group achieved more satisfactory clinical efficacy.¹⁷ Marchand *et al.* compared MA before and after RATKA in 330 patients. The results showed that the MA of patients with 7° varus deformity was corrected to a neutral position; furthermore, in 96% of patients with valgus deformity $<3^\circ$, the MA was restored to normal.¹⁸ Yang *et al.* reported 10 years of follow-up after RATKA, and the number of cases of MA deviating from the safe zone (neutral position within $\pm 3^\circ$) was less than that in the COTKA group. For the sagittal plane, the location of the prosthesis was more accurate in the RATKA group.¹⁹ Song *et al.* reported 30 patients who underwent bilateral TKA simultaneously, with COTKA on one side and RATKA on the other. The 1-year follow-up after surgery showed no significant difference in function scores or in ROM between the groups, but the restored lower limb alignment was more accurate in the RATKA group.²⁰ The analysis of the function scores and radiological and clinical outcomes is helpful in verifying whether the application of this robotic arm system in TKA has advantages. To our delight, the short-term follow-up outcomes of this study showed that RATKA technology performed better in several aspects as outlined below.

Better Femoral Rotational Alignment and Patellofemoral Tracking

The COTKA requires the following three main references in the reconstruction of the femoral rotational alignment: the TEA, Whiteside's line, and posterior condyle line. In addition, the TEA is divided into the sTEA and the anatomical transepicondylar axis (aTEA), depending on the anatomy of the medial femoral epicondyle. Similar to the preference of most surgeons, the sTEA was chosen in this study as a reference.²¹ Owing to the different wear of the posterior condylar cartilage in different patients, it is not accurate for all patients to determine the alignment by using 3° of external rotation relative to the posterior aspect of the femoral condyles. Previous researchers have reported that the PCA was $3.3^\circ \pm 1.5^\circ$ or $1.6^\circ \pm 1.9^\circ$ in patients with knee OA.²¹ Therefore, rotational alignment based on real-time measurements is more helpful for individualized reconstruction.²²

In this study, the navigation device in the robotic arm system could conduct real-time positioning according to the infrared feedback results of the marker and could thus accurately calculate the thickness of osteotomy on the medial and lateral sides of the posterior condyle to ensure that the bone cutting line was parallel to the sTEA (Check

TABLE 2 Statistical description of the osteotomy accuracy in RATKA (mean \pm SD)

Parameters	Preoperative planning	Postoperative measurements	Actual error	t value	P value	95% CI
Femoral thickness (mm)						
Medial distal	9.23 \pm 0.71	7.99 \pm 1.02	1.24 \pm 0.92	t = 7.32	P = 0.00	0.89–1.58
Lateral distal	6.82 \pm 1.41	6.35 \pm 1.85	0.47 \pm 1.12	t = 2.29	P = 0.02	0.51–0.88
Medial posterior	9.39 \pm 1.05	8.8 \pm 1.37	0.59 \pm 0.97	t = 3.31	P = 0.00	0.22–0.95
Lateral posterior	5.87 \pm 0.91	5.48 \pm 1.22	0.39 \pm 1.07	t = 1.99	P = 0.55	0–0.79
Tibial thickness (mm)						
Medial plateau	4.34 \pm 1.88	4.13 \pm 1.75	0.21 \pm 1.09	t = 1.05	P = 0.32	–1.09 to 0.61
Lateral plateau	8.42 \pm 1.18	8.61 \pm 1.66	–0.19 \pm 1.24	t = –0.83	P = 0.41	–0.65 to 0.27
Lower limb alignment						
HKA	179.73 \pm 0.73°	178.3 \pm 0.7°	1.2 \pm 1.2°	t = 5.42	P = 0.00	0.75–1.66

Note: Statistical method: Paired t-test; statistical significance was set at $P < 0.05$.

TABLE 3 Intra-group comparison of pre- and postoperative radiological results (mean \pm SD)

Item	COTKA group (30 cases)				RATKA group (30 cases)			
	BS	AS	t value	P value	BS	AS	t value	P value
PCA (°)	3.3 \pm 2.5	1.5 \pm 2.0	3.079	0.000	2.9 \pm 1.3	0.6 \pm 0.3	9.442	0.000
PFA (°)	6.0 \pm 1.9	3.1 \pm 1.1	7.235	0.000	5.8 \pm 3.9	0.9 \pm 0.3	6.861	0.000
HKA (°)	170. \pm 2.3	178. \pm 0.7	17.315	0.000	170. \pm 4.0	178. \pm 1.0	10.229	0.000
LDFA (°)	88.5 \pm 2.9	89.4 \pm 1.1	1.589	0.077	88.3 \pm 3.6	89.3 \pm 1.0	1.466	0.113
MPTA (°)	80.6 \pm 3.6	89.2 \pm 0.8	12.773	0.000	81.1 \pm 5.2	89.2 \pm 0.7	8.456	0.000

Note: Statistical method: Paired t-test; statistical significance was set at $P < 0.05$.; Abbreviations: AS, after surgery; BS, before surgery; HKA, hip-knee-ankle angle; LDFA, lateral distal femoral angle; MPTA, medial proximal tibial angle; PCA, posterior condylar angle; PFA, patellar transverse axis-femoral transepicondylar axis angle.

1). The maintenance of the joint line is critical for postoperative knee function. In particular, mid-flexion instability can occur with as little as a 5-mm deviation of the joint line.^{23,24} Studies have shown that RATKA technology demonstrated superior gap balancing and accurate restoration of the joint line while maintaining close-to-normal knee kinematics.^{25,26} In addition, the external rotation angle of the posterior condyle was determined during continuous knee flexion by referring to the results of the distal femur and proximal tibia osteotomy to ensure gap balancing of the entire process (Check 2). This type of “double checking” ensured an accurate femoral rotational alignment. In this study, the PCA in the RATKA group was significantly smaller than that in the COTKA group, indicating that the RATKA technique was advantageous for the reconstruction of femoral rotational alignment. A proper alignment provides several benefits. First, it ensures that the femoral component is in a better position. Second, the correct position of the prosthesis can ensure that the patella is in the center of the trochlear region to obtain better patellar tracking. Moreover, good patellar tracking is helpful for obtaining better outcomes for knee ROM.

In our study, the PFA of the RATKA group was lower than that of the COTKA group, further confirming the above views. In addition, combined with osteophyte removal and

surface shaping, the patella in the RATKA group was in a more neutral position after surgery, avoiding inclination of the medial and lateral sides. The forces on both sides of the patella were more balanced and local stress concentration was avoided, which could reduce the occurrence of further wear and anterior knee pain. Excessive internal or external rotation of the femoral component affects patellar tracking, and excessive internal

TABLE 4 Comparison of postoperative results between groups (mean \pm SD)

Item	COTKA group (30 cases)	RATKA group (30 cases)	t value	P value
Radiological results				
PCA (°)	1.5 \pm 2.0	0.6 \pm 0.3	2.438	0.010
PFA (°)	3.1 \pm 1.1	0.9 \pm 0.3	10.569	0.000
LDFA (°)	89.4 \pm 1.1	89.3 \pm 1.0	0.368	0.984
MPTA (°)	89.2 \pm 0.8	89.2 \pm 0.7	0.001	0.774
HKA (°)	178.3 \pm 0.7	178.5 \pm 1.0	0.897	0.209

Note: Statistical method: independent t-test; statistical significance was set at $P < 0.05$.; Abbreviations: HKA, hip-knee-ankle angle; LDFA, lateral distal femoral angle; MPTA, medial proximal tibial angle; PCA, posterior condylar angle; PFA, patellar transverse axis-femoral transepicondylar axis angle.

TABLE 5 Comparison of operative data between two groups (mean ± SD)

Item	COTKA group (30 cases)	RATKA group (30 cases)	t value	P value
Operation time (min)	119.5 ± 22.5	128.4 ± 18.8	1.663	0.419
Blood loss (mL)	203.7 ± 29.8	192.3 ± 23.1	1.656	0.039
Tourniquet time (min)	74.4 ± 17.3	96.0 ± 15.3	5.123	0.000
Length of stay (days)	9.3 ± 1.1	8.2 ± 1.4	3.384	0.006

Note: Statistical method: Independent t-test; statistical significance was set at $P < 0.05$.

TABLE 7 Comparison of postoperative clinical outcomes between groups (mean ± SD)

Item	COTKA group (30 cases)	RATKA group (30 cases)	t value	P value
MKFA (°)	116.3 ± 4.6	123.0 ± 3.7	6.216	0.000
WOMAC (score)	18.2 ± 3.0	19.5 ± 3.5	1.545	0.496
KSS (score)	88.1 ± 2.2	84.4 ± 3.9	4.526	0.095

Note: Statistical method: Independent t-test; statistical significance was set at $P < 0.05$.; Abbreviations: KSS, knee society score; MKFA, maximum knee flexion angle; WOMAC, Western Ontario Mac Master University Index Score.

rotation may cause patellar dislocation. Berger *et al.* reported that patients with lateral patellar tracking and tilting had an excessive internal rotation of 1°–4°, patellar subluxation at 3°–8°, dislocation at 7°–16°, and component failure at 8°–17°. ²⁷

In terms of standing alignment of the knee, there were no advantages in terms of the HKA, LDFA, and MPTA in the RATKA group, but both groups showed significant improvement after surgery. This indicates that the RATKA technique is comparable to the COTKA technique in restoring the MA to a neutral position and can achieve the goal of correcting varus deformity of the knee.

Satisfactory Short-term Clinical Efficacy

In this study, blood loss in the RATKA group was lower than that in the COTKA group. This is because RATKA can set the osteotomy boundary according to the parameters established preoperatively, and damage to the surrounding soft tissues is reduced. If an error occurs, the robotic action can be stopped by the surgeon at any time within split seconds. Furthermore, accurate osteotomy results in better gap balancing and avoids excessive release and dissection of soft tissues, thus reducing damage to capillaries. Furthermore, we used a small, customized saw to reduce additional damage to the bone; no extra- or intramedullary guides, conventional cutting blocks, or saws were needed.

The RATKA group requires longer operative times in the early stages of surgery as surgeons required more time to learn and adapt to the new technique. Once they become

proficient in COTKA, after adaptive learning and training of 20 cases, the time spent on RATKA should not be different from that of COTKA. ^{28,29} Fleischman *et al.* ³⁰ reported that a surgeon with 10 years of TKA experience and a surgeon with only 2 years of experience performed 48 RATKA procedures. The learning curve of the two studies focused on the first 10–15 patients, and the operative times of the remaining patients showed no difference. ^{28,29}

We found that the RATKA group had a slightly longer time (operation time and tourniquet time) than the COTKA group, with a difference of 10–20 min. This is mainly because the semi-active robotic arm system used in this study is different from the commonly used robot system at present and has not been widely popularized in clinics. For example, the osteotomy process still needs to be completed manually by the surgeon, and it requires time for the markers to be collected to connect with the validation process. The results of this study are similar to those of previous studies. ^{31,32} We found that this robotic arm system provided a short learning curve, with a steady improvement after approximately 15 patients, which was approximately 20 min shorter than previously reported. The MKFA value in the RATKA group was greater than that in the COTKA group and was closely related to the better femoral rotational alignment and patellar tracking in the RATKA group. In addition, owing to the lower postoperative swelling of the knee in the RATKA group, the knee could be passively flexed to approximately 120° earlier, and the LOS was significantly shortened.

TABLE 6 Intra-group comparison of pre- and postoperative results (mean ± SD)

Item	COTKA group (30 cases)				RATKA group (30 cases)			
	BS	AS	t value	P value	BS	AS	t value	P value
Scores								
WOMAC	78.2 ± 6.3	18.2 ± 3.0	47.097	0.000	77.0 ± 5.6	19.5 ± 3.5	47.691	0.000
KSS	55.6 ± 6.2	88.1 ± 2.2	27.058	0.000	59.2 ± 7.3	84.4 ± 3.9	16.677	0.000

Note: Statistical method: Paired t-test; statistical significance was set at $P < 0.05$.; Abbreviations: AS, after surgery; BS, before surgery; COTKA, conventional TKA; KSS, Knee Society Score; RATKA, robotic arm-assisted TKA; WOMAC, Western Ontario Mac Master University Index Score.;

Improved Knee Function

In terms of knee function, there were no statistically significant differences in the postoperative KSS and WOMAC scores between the groups, but the postoperative scores of the two groups were significantly improved compared with those before surgery. This indicated that the RATKA technique could obtain similar short-term clinical outcomes as COTKA and achieve neutral MA of the lower limb, correcting deformity, and improving the function of the affected knee. However, it should be emphasized that these results were only for short-term follow-up, and the final results may vary owing to the different scoring methods used and follow-up periods. Liow *et al.* found that the SF-36 quality-of-life scores of patients in the RATKA group were higher than those in the COTKA group during the 2 years follow-up after surgery, but there was no difference in WOMAC and KSS scores.³³ Therefore, the long-term follow-up results of function scores need to be further studied.

Effect of Different Osteotomy Techniques on Accuracy

In this study, an oscillating saw was used in the osteotomy process. Although the thickness is thinner than that of conventional instruments, it is still not as accurate and minimally invasive as milling devices in other robotic systems. For example, Robodoc and Caspar depend on accurate machining of bone surfaces with a milling device and maintained bone temperature with continuous flow of water during machining to prevent bone injury.^{34,35} Previous studies have shown that bone surfaces cut using a milling tool are more suitable for cementless prosthesis systems. This is important, as bony ingrowth can only occur with a maximum distance of 0.3–0.5 mm between the bone and the implant.^{36,37}

Limitations

This study has the following limitations. First, the follow-up period was short, and the long-term results remain uncertain. Second, the semiactive robot-arm system used in this study is not currently the most commonly used robot system and the rationality of its preoperative design, accuracy of intraoperative navigation, and stability of the software still need to be confirmed by further studies. Third, different types of prostheses were used in both the groups. Because the robotic arm device requires a unique prosthetic system, the prosthesis used in the RATKA group was different from that in the COTKA group. Different prosthesis designs have different requirements for surgical techniques, but it is important to note that the ultimate goal of both prosthesis systems is the same: to achieve a neutral MA and rectangular osteotomy frame in knee flexion. For both prosthetic systems, the aims of implantation are the same: to

restore lower limb alignment on the coronal plane and achieve 180° of HKA, to restore external rotation parallel to the sTEA, and to restore 0° of PCA. Therefore, the two different prostheses do not affect measurements of the femoral rotation alignment but may have some potential impact on clinical outcomes. Fourth, the evaluation of femoral rotational alignment included only PCA and PFA, and CT scans increase the risk of additional radiation exposure. In addition, this study only analyzed the macroscopic results of the knee after surgery, and the kinematics and kinetic parameters that were microscopic and could not be captured by the naked eye should be studied using gait analysis in the future. Large-scale prospective randomized studies are necessary to further evaluate these early results.

Conclusion

This retrospective study explored the clinical efficacy of RATKA. Compared with COTKA, RATKA significantly improved the femoral rotation alignment. The accuracy of this new surgical technique is demonstrated by a small improvement in femoral rotational alignment. This small improvement may positively influence long-term clinical outcomes. Optimal rotational alignment is beneficial for balancing the medial and lateral gaps during knee flexion and may potentially reduce the incidence of aseptic loosening of the prosthesis, wear of the polyethylene liner, instability in mid-flexion, and other adverse events after TKA. In addition, RATKA decreases the variability in alignment when performed by surgeons with different surgical experience. Although RATKA required a longer operative time in this study, the other short-term clinical efficacies were satisfactory.

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Authors Contribution

Li Yang conceived of the idea and developed the rationale. Lin Guo supervised the experimental process and findings. Rui He completed the surgical procedures and wrote the manuscript. Mao-lin Sun performed computations. Ran Xiong collected gait data. Kai Lei and Li-ming Liu collected radiological data and conducted measurements. Peng-fei Yang collected the clinical follow-up data.

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