Journal of Orthopaedic Translation 29 (2021) 143–151

Contents lists available at ScienceDirect

Journal of Orthopaedic Translation

journal homepage: www.journals.elsevier.com/journal-of-orthopaedic-translation

Verification and clinical translation of a newly designed “Skywalker” robot for total knee arthroplasty: A prospective clinical study☆

Runzhi Xia [1], Zanjing Zhai [1], Jingwei Zhang [1], Degang Yu, Liao Wang, Yuanqing Mao, Zhenan Zhu, Haishan Wu, Kerong Dai, Mengning Yan **, Huiwu Li *

Shanghai Key Laboratory of Orthopaedic Implants, Department of Orthopaedic Surgery, Shanghai Ninth People's Hospital, Shanghai Jiaotong University School of Medicine, 639 Zhizaoju Road, Shanghai 200011, People's Republic of China

ARTICLE INFO

Keywords:
Accuracy
Knee osteoarthritis
Robotic surgical procedures
Total knee arthroplasty

ABSTRACT

Objective: To evaluate accuracy of an innovative “Skywalker” system, a newly designed, robot-assisted operation system for orthopaedics via a clinical trial at knee joint.

Methods: We conducted a prospective analysis of the clinical data of 31 patients who underwent total knee arthroplasty assisted by the “Skywalker” robot (Microport, Suzhou, China) from June 2020 to January 2021. Five male patients and 26 female patients aged 69.68 ± 6.11 years (range: 57–79 years) were diagnosed with knee osteoarthritis and indicated for surgery. The “Skywalker” surgical robotic system was adopted to make a preoperative plan for knee arthroplasty. When the robotic arm reached the specified position during the operation, a single surgeon performed the osteotomy with a cutting saw through the cutting jig, and the difference between the actual and the expected resection thickness, and the preoperative and postoperative lower limb alignments were measured.

Results: The actual error of the resection thickness was the difference between the actual and the expected resection thickness. The absolute error of the resection thickness was the absolute value of the actual error of resection thickness. The absolute errors of the resection thickness of the medial and lateral condyle of the distal femur, the medial and lateral posterior condyle of the femur, and the medial and lateral sides of the tibial plateau were 0.87 ± 0.63 mm, 1.02 ± 0.67 mm, 0.74 ± 0.46 mm, 0.98 ± 0.81 mm, 0.92 ± 0.66 mm, and 1.04 ± 0.84 mm, respectively. The absolute angle errors between the actual postoperative angles and the preoperative planned angles of the lower limb alignment angles, coronal femoral component angles, and coronal tibial component angles were 1.46° ± 0.95°, 1.13° ± 1.01°, and 1.05° ± 0.73°, respectively. Besides, 100% of the absolute error of the HKA angles was within 3°. In addition, compared to the preoperative lower limb alignment angle, 90.32% of the postoperative lower limb alignment angles of 31 patients were closer to 180° after the operation. All 31 patients underwent a successful surgery, and no relevant complications occurred after the operation, such as surgical site infection, deep venous thrombosis, or vascular and nerve injury.

Conclusion: The “Skywalker” system has good osteotomy accuracy, can achieve the planned angles well, and is expected to assist surgeons in performing accurate bone cuts and reconstructing planned lower limb alignments in the relevant clinical applications in future.

☆ The translational potential of this article: In recent years, motivated by a desire to improve surgical accuracy and patient satisfaction, many researchers have been focusing on the development of surgical robots and numerous surgical robots have successfully accomplished its clinical translation. However, robotic surgery for total knee arthroplasty is not widely spread. Therefore, we aimed to develop a safe surgical robot to achieve high-precision osteotomy and satisfactory reconstruction of lower limb alignment. Through this prospective clinical study, we have evaluated the accuracy of such total knee arthroplasty robot in detail to further optimize the procedure of robotic surgery clinically in the future.

* Corresponding author.

** Corresponding author.

E-mail addresses: runzhixia@gmail.com (R. Xia), zanjing_zhai@163.com (Z. Zhai), eryijiuyuan@163.com (J. Zhang), ydg163@126.com (D. Yu), wang821127@163.com (L. Wang), yuanqingmao@163.com (Y. Mao), zzajiuyuan@126.com (Z. Zhu), drisland@vip.sina.com (H. Wu), krdai@163.com (K. Dai), yanmengning@163.com (M. Yan), huiwu1223@163.com (H. Li).

[1] First 3 authors are co-first authors and have contributed equally.

https://doi.org/10.1016/j.jot.2021.05.006
Received 24 February 2021; Received in revised form 23 May 2021; Accepted 26 May 2021

1. Introduction

Knee osteoarthritis (OA) is a geriatric disease that may cause pain, aching, stiffness, and associated functional loss. Total knee arthroplasty (TKA) has become a frequent and successful treatment owing to its remarkable progress in recent decades [1]. While manual TKA procedures have demonstrated clinical success in alignment correction, pain relief, and implant survivorship [2], adverse outcomes can occasionally occur. Medial, lateral collateral, or posterior cruciate instability, extensor mechanism disruption, and tibio- or patella-femoral dislocation are among a few of the adverse outcomes [3–5]. Accuracy of implant positioning and lower limb alignment are important prognostic factors that influence patient satisfaction, clinical outcomes, and long-term implant survivorship following TKA [6]. As a result, attention is being given to accurate implant positioning, implant sizing, restoration of the joint line, and soft tissue balancing [7].

A robot-assisted system is a technology designed to minimize the margin of error associated with osteotomy and component placements [8]. Most robot-assisted TKA provides a surgeon the ability to three-dimensionally plan a TKA [9]. During a robot-assisted TKA operation, the surgeon provides the surgical exposure site and then performs surgery as the robot precisely operates according to the plan [10]. Studies have demonstrated that a lack of surgical accuracy in conventional manual TKA can be overcome using robotic technology, which has been reported to provide excellent implant positioning [11,12]. Beyond the accuracy of limb alignments, the postoperative functional scores have been reported to be better for robot-assisted TKA patients compared to manual TKA patients [13]. In addition, the introduction of a robot may diminish the learning curve of surgeons who are in training or acquiring a new technique [14]. Among the robot-assisted TKA systems, the MAKO TKA surgical system (MAKO Surgical Corp, Fort Lauderdale, FL, USA) has the largest market share. At present, a large number of studies have verified its accuracy and postoperative clinical outcomes before routine clinical applications. However, the high cost and the time-consuming preoperative planning of the MAKO system hamper its application on a larger scale, especially in less developed countries. The end of the robotic arm of MAKO is equipped with a burr that is used to perform osteotomy. Comparatively, the Praxim (OMNIlife science, East Taunton, MA) [15] and Rosa (Zimmer Biomet, Warsaw, USA) [16] surgical robots, using a cutting jig to provide positioning for osteotomy, which is different from the MAKO system, also reported similar results. Robots with cutting jigs represent an alternative attractive orientation because they preserve a more natural surgical flow, which is enticing to surgeons.

With the goal of safety, efficiency, and precision in minimally invasive environments, our team has developed a semi-active “Skywalker” robotic system (Microport, Suzhou, China) for TKA. This clinical study aimed to evaluate the accuracy of the system in clinical osteotomy and component placement as this is essential for recommendation to our orthopaedic surgeons for routine clinical applications.

2. Materials and methods

2.1. General information

We conducted a prospective analysis of the clinical data of 31 consecutive patients who had received TKA treatment assisted by the “Skywalker” robot for a knee arthroplasty operation from June 2020 to January 2021. The subjects had to meet all of the following inclusion criteria:

(1) Osteoarthritis of the medial and lateral compartment of the knee joint, which causes pain or dysfunction, and which has undergone ineffective regular and conservative treatment;
(2) Age: 40–80 years old;
(3) BMI ≤ 35 kg/m^2;
(4) An angle of knee varus deformity $\leq 15^\circ$ and a fixed flexion contracture deformity $\leq 15^\circ$;
(5) The knee joint on the operative side has not received surgical treatment before;
(6) The ligament of the knee is in good condition;
(7) No sign of local or systemic infection.

The subjects were not included if they met any of the following exclusion criteria:

(1) The affected knee had been replaced before;
(2) An angle of fixed flexion contracture or varus deformity $> 15^\circ$;
(3) The subject was unable to support and/or fix the component due to diseases (such as tumour, severe osteoporosis, or metabolic bone disease);
(4) The subject was unable to understand the research requirements or complete the follow-up plans.

The operation plan of this study was approved by the Ethics Committee (clinical trial registration number: SH9H-2019-C49-3) and had been carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki), and all patients had signed informed consent for the operation. All 31 patients, including 5 men and 26 women aged 69.68 $\pm$ 6.11 years (range: 57–79 years) reported in this study met above inclusion criteria and underwent knee arthroplasty operation assisted with “Skywalker” robotic system and replaced by Microport total knee component (Microport, Suzhou, China).

2.2. “Skywalker” robot equipment

The “Skywalker” robotic system consists of a robot console, a surgical platform, and surgical accessories. The robot console and the surgical platform of “Skywalker” robot are shown in Fig. 1. The operator needs to operate the robot console to assist the surgeon in completing the operation. The robot console mainly consists of an NDI camera (NewTek, USA), an operator's console, an operator's screen, and a surgeon's screen. NDI camera is used to track the targets used in the operation. During the operation, the operator uses the operator's console to control each step of the robot-assisted TKA operation. The surgeon's screen is completely synchronized with the operator's screen on the operator's console. The surgeon observes the surgeon's screen and performs the operation according to its instructions. The surgical platform mainly includes a robotic arm trolley, robotic arm, and cutting jig. The robotic arm trolley can ensure the stability of the robotic arm. The robotic arm has six motion joints, and the cutting jig is stably connected to the end of the robotic arm, which can provide positioning for the cutting jig during osteotomy. Surgical accessories are used to assist operations, including all types of targets, a lower limb fixator, and mark nails. The targets are used to provide positioning. The lower limb fixator can assist the surgeon in stabilizing the lower limb during osteotomy. Mark nails can be used to verify whether the bone target moves relative to the patient's bone.

2.3. Operation method

According to the requirement of the “Skywalker” surgical robotic system, we collected the preoperative computed tomography (CT) images of the patient's lower limbs. CT scans were taken from about 5 cm above the hip to the bottom of the feet. All CT images were acquired using a Philip iCT CT scanner (Royal Dutch Philips Electronics Ltd., Amsterdam, Netherlands) using a steady protocol (120 kV, 380 mAs, slice collimation 1 mm, supine position). Then, we imported the CT images into the “Skywalker” plan system, and the image data were shown in three views including the coronal, sagittal, and axial planes. In addition, we obtained three-dimensional (3D) models of the tibia, femur, and fibula after the segmentation and reconstruction of the CT images were performed. Then, in this study, a single surgeon manually determined the locations of feature points on the 3D model, which were divided into femoral feature points and tibial feature points, and two specified points can determine a relevant feature line. The determined feature points were used to calculate the required information in the component positioning stage. We used the bone model following the segmentation and reconstruction, selected a suitable type and size for the component, and adjusted its position and posture to obtain proper varus and valgus angles, anteversion and retroversion, internal and external rotation, and the medial and lateral resection thickness. The varus/valgus angle of the femoral component relative to the femur and of the tibial component relative to the tibia should be no more than 3°. Additionally, in the coronal plane, the alignment of the lower limbs should be 180° as much as possible, and the varus/valgus angle should not exceed 3°. A reasonable preoperative planning should allow the femoral and tibial component to almost precisely fit into the shape of the distal femur and tibial plateau, respectively. Thereafter, we calibrated the position of the femoral and tibial component to meet the following condition: the sum of the planned resection thickness of the condyle of the distal femur, the planned resection thickness of the tibial plateau, and the distance between the most convex point of the distal femur and the most concave point of the tibial plateau should be equal to the sum of the thickness of the distal femoral component, the thickness of the tibial component, and the thickness of the tibial bearing. After the resection thickness of the medial and lateral condyle of the distal femur were determined, the osteotomy plane of the posterior condyle of the femur should be adjusted as closely parallel to the transepicondylar line as possible, and the resection thickness of the posterior condyle of the femur should be consistent with that of the condyle of the distal femur as much as possible. Furthermore, we prevented the occurrence of notch or overhang of the anterior condyle of the femur. In this clinical study, the preoperative plan was determined by the same surgeon in all 31 patients. The preoperative planning is illustrated in Fig. 2 and Fig. 3.

During the operation, the patient was placed in the supine position on the operating bed under general anaesthesia, and the patient's lower limb was fixed with a lower limb fixator. Then, we placed the robot console and surgical platform on both sides of the patient and aligned the NDI camera of the robot console to the surgical region. The robotic arm was installed with an aseptic bag to disinfect the patient's surgical region. Then, we registered the target of the robotic arm, inserted the femoral and tibial targets into the patient's femur and tibia, and then inserted femoral and tibial mark nail to serve as a checkpoint, so that it was easy to check any deviations from the bone target at any time. We rotated the femur around the femoral head to calculate the central point of the hip joint and clicked the medial and lateral ankle with the blunt end target pen to calculate the central point of the ankle joint. We reached the knee joint through the patella inside the medial longitudinal incision. We then exposed the surgical region, collected point clouds on the surface of the femur and tibia according to the instructions of the surgeon's screen, and obtained the transfer matrix between the bone target coordinate system and the console CT data coordinate system. We could inspect with the sharp end target pen at any time when the femoral and tibial targets were suspected to have deviated during the operation. According to the surgical plan, the senior joint surgeon could perform the osteotomy with a cutting saw when the robotic arm had moved to the designated position and the cutting jig at the end of the robotic arm was adjusted to the proper position and posture. The osteotomy procedure is shown in Fig. 4. In this clinical study, the intraoperative osteotomy was performed by the same surgeon in all 31 patients. After osteotomy, the osteotomy plane target can be used to evaluate the osteotomy plane of the femur and tibia, including five femoral planes and one tibial plane. After osteotomy was completed on all planes, we tested the component using the conventional method. Then, we flushed the wound with a pulse gun after removing the test mould. We then installed a Microport total knee component (Microport, Suzhou, China) with bone cement after the bone surface was dried. After the bone cement had solidified, we evaluated the soft tissue balance again under valgus stress to the knee. Finally, we removed the bone targets and mark nails on the femur and tibia and closed the surgical incision to complete the operation.

2.4. Postoperative management

Subcutaneous injection of low-molecular-weight heparin was administered to prevent deep vein thrombosis 8 h after the operation. Routine prophylactic antibiotics were administered within 24 h after the operation. Two days after the operation, per the patient's recovery protocol, we required the patient to start to walk on the ground and perform active and passive knee flexion and extension training in non-weight-bearing conditions. We recorded if any complications occurred after the operation, such as surgical site infections, deep venous thrombosis, or vascular and nerve injuries.

2.4. Evaluation index

We recorded the preoperative planned resection thickness of the distal femur, posterior condyle of the femur, and the tibial plateau in the "Skywalker" system. We also recorded the cartilage thickness of the distal

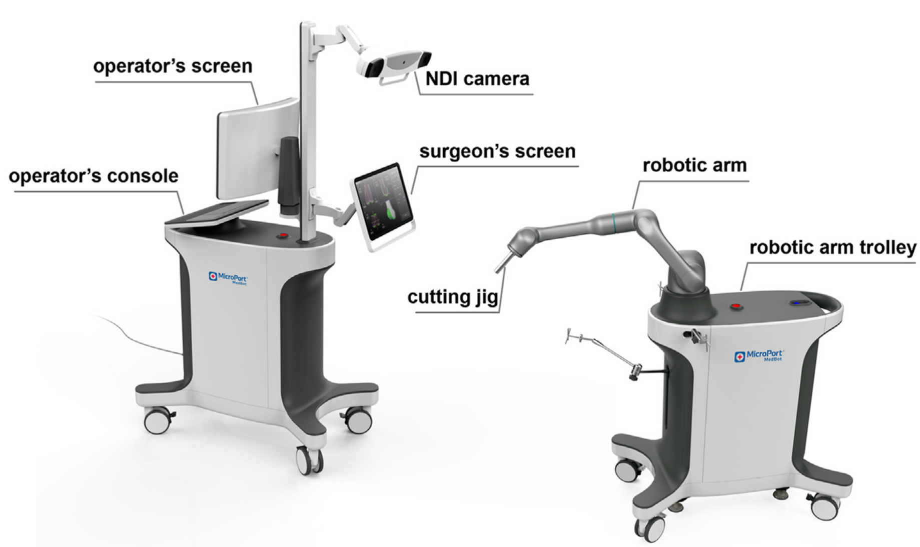

Fig. 1. The robot console and the surgical platform of "Skywalker" robot.

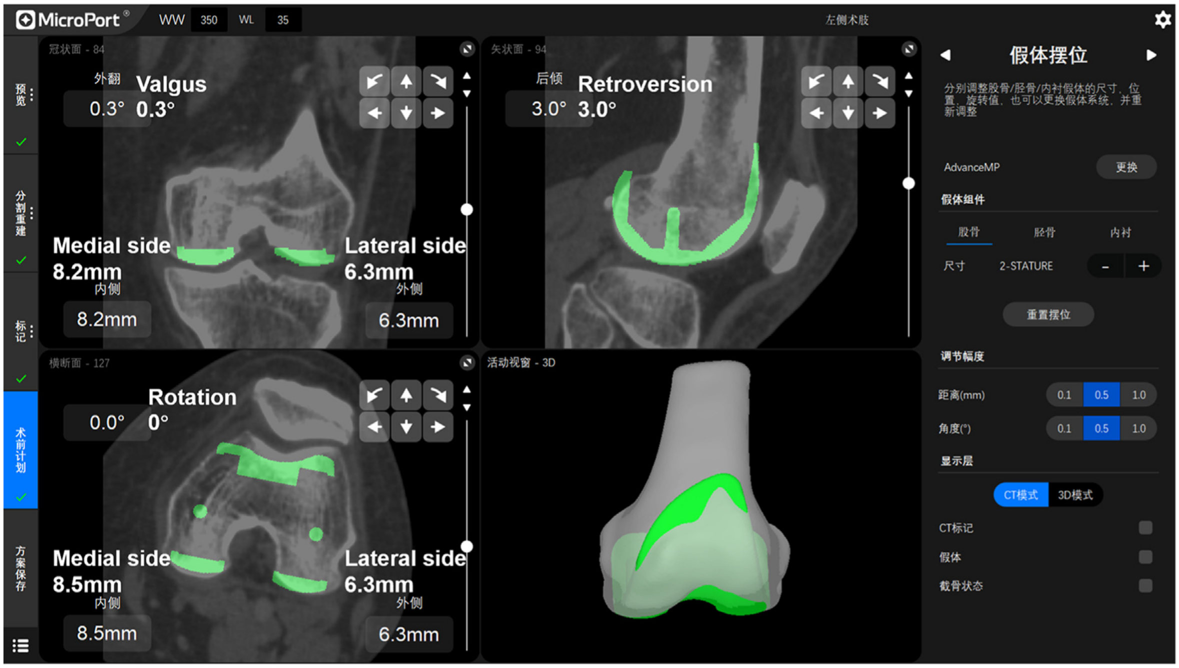

Fig. 2. Preoperatively planned position and posture of a femoral component by the "Skywalker" surgical robot. The planned resection thickness of the medial and lateral condyle of the distal femur and the medial and lateral posterior condyle of the femur were 8.2 mm, 6.3 mm, 8.5 mm, and 6.3 mm, respectively. The planned postures of the femoral component were set at a valgus of 0.3°, retroversion of 3°, and external rotation of 0°.

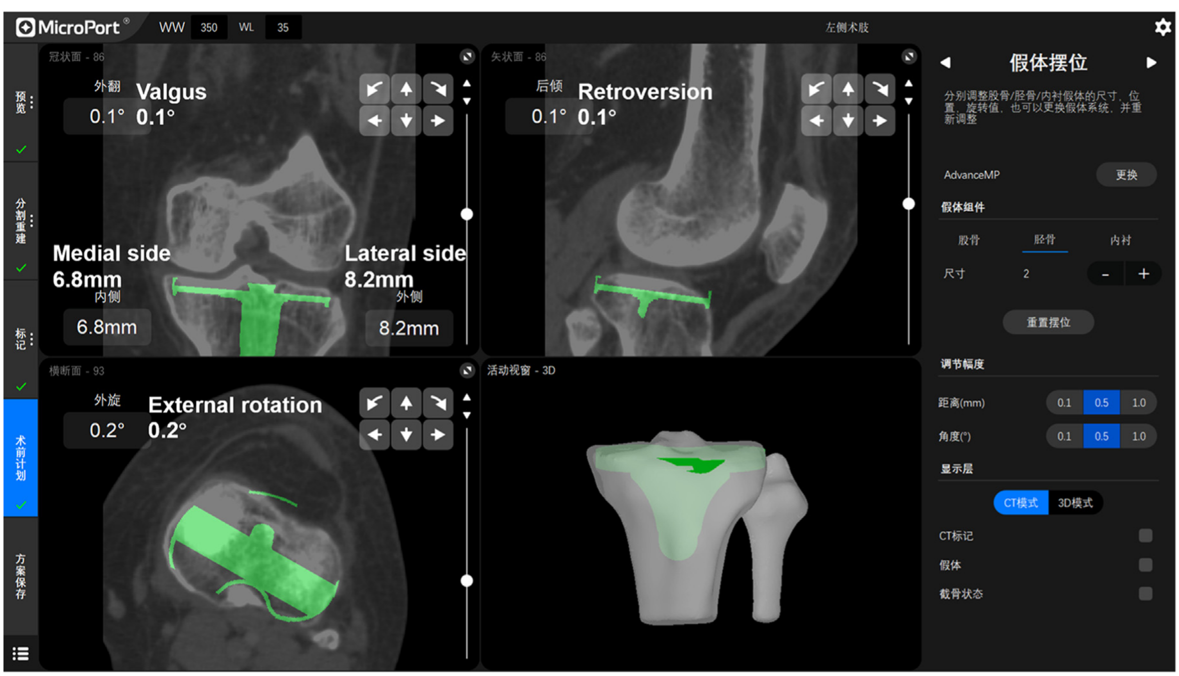

Fig. 3. Preoperatively planned position and posture of a tibial component by the "Skywalker" surgical robot. The planned resection thickness of the medial and lateral sides of the tibial plateau were 6.8 mm and 8.2 mm, respectively. The planned postures of the femoral component were set at a valgus of 0.1°, retroversion of 0.1°, and external rotation of 0.2°.

femur, posterior condyle of femur, and the tibial plateau after the operation, and the actual resection thickness of the distal femur, posterior condyle of femur, and the tibial plateau after the operation. The measurement methods for the actual resection thickness and the cartilage thickness are shown in Fig. 5.

$$\text{Expected resection thickness} = \text{planned resection thickness} + \text{cartilage thickness} - \text{thickness of the gap of the cutting jig.}$$

The thickness of the gap of the cutting jig during the operation was 1.5 mm, the gap of the cutting jig is shown in Fig. 6. The difference between the actual and expected resection thickness were used to evaluate

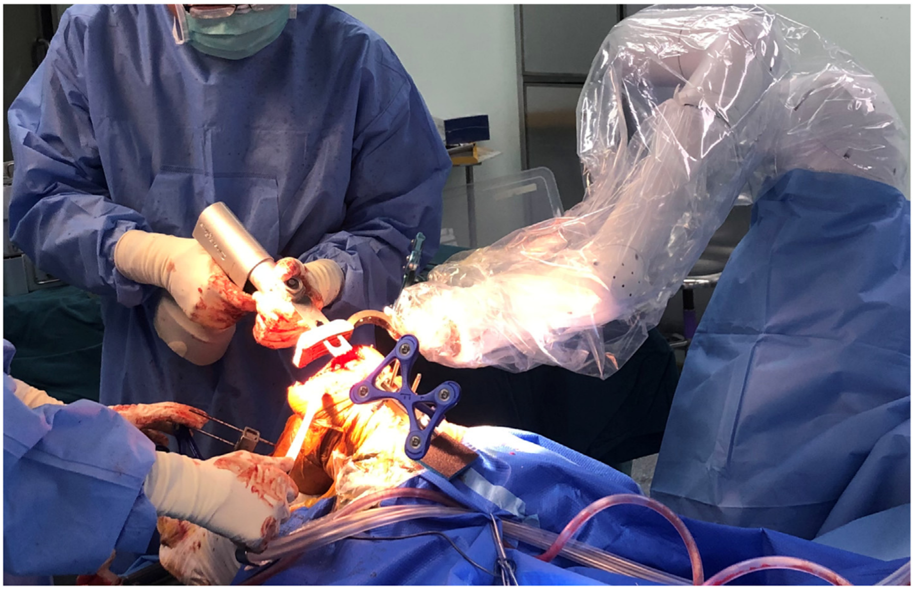

Fig. 4. The osteotomy procedure of "Skywalker" total knee arthroplasty robot. The surgeon can perform the osteotomy with a cutting saw once the cutting jig that is fixed at the end of the robotic arm reaches the planned position.

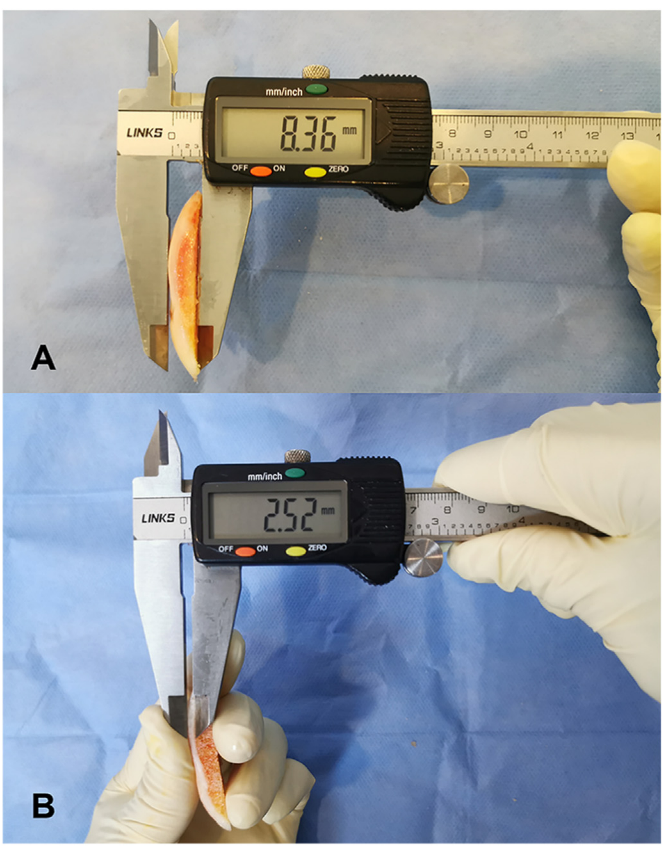

Fig. 5. Measurement methods for the postoperative resection thickness (A) The measurement method for actual resection thickness (B) The measurement method for cartilage thickness.

the actual osteotomy error. The errors of resection thickness on the medial and lateral condyle of the distal femur represented the coronal and sagittal error of resection thickness of the femur. The errors of resection thickness on the medial and lateral condyle of the posterior femur represented the axial error of resection thickness of the femur. The

Fig. 6. The thickness of the gap of the cutting jig.

errors of resection thickness on the medial and lateral tibial plateau represented the coronal and sagittal error of resection thickness of the tibia.

We defined the connection between the centre of the femoral head and that of the knee joint as the femoral mechanical axis, and then defined the connection between the centre of the knee joint and the ankle centre as the tibial mechanical axis. On the coronal plane, we defined the angle between the femoral mechanical axis and the tibial mechanical axis on the medial side of the knee joint as the lower limb hip-knee-ankle (HKA) angle. On the coronal plane, we defined the angle between the femoral mechanical axis and the distal tangent of the femoral component on the medial side as the coronal femoral component angle (CFCA). On the coronal plane, we defined the angle between the tibial mechanical axis and the proximal tangent of the tibial component on the medial side as the coronal tibial component angle (CTCA). Measurement methods for preoperative HKA angle, postoperative HKA angle, postoperative CFCA, and postoperative CTCA are shown in Fig. 7. We recorded the preoperatively planned HKA angle, preoperatively planned CFCA, and preoperatively planned CTCA in the "Skywalker" system. All patients received standard full-length X-ray images of the lower limbs routinely before the operation to measure the varus/valgus angle of the affected knee joint. All patients underwent full-length X-ray images of the lower limbs one

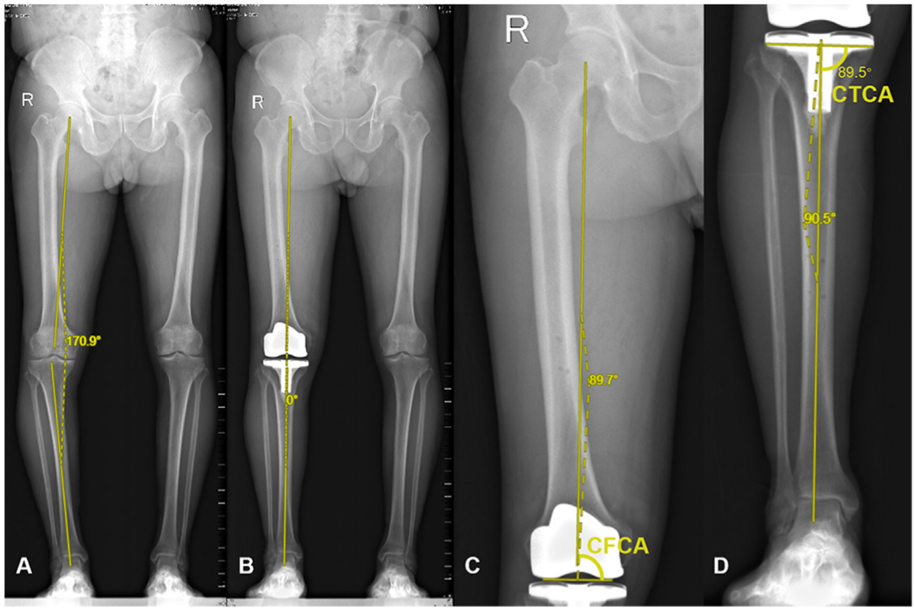

Fig. 7. Measurement methods for angles to be evaluated (A) The measurement method for preoperative HKA angle (B) The measurement method for post-operative HKA angle (C) The measurement method for postoperative CFCA (D) The measurement method for postoperative CTCA.

week after the operation to measure the HKA angle, CTCA, and CFCA of the lower limb that underwent the TKA operation. As for the standard position for taking full-length X-ray images of the lower limbs, nearly 1/3 of the fibular head should overlap with the tibia, and the patella should point straight forward. The angle measurements on the full-length X-ray images of the lower limbs were carried out independently and manually with the PACS System (WinningSoft Software Co., China) by two surgeons who were not involved in the operation, and the average values measured by the two surgeons were taken as the final measurement result.

2.5. Statistical analysis

SPSS 22.0 statistical software (SPSS Inc., Chicago, IL) was used to analyse the data. After checking data normality, descriptive statistics (means, standard deviations, and ranges) were performed. Measurement data conforming to a normal distribution were expressed as ($\overline{x}\pm s$). The difference between the actual and expected resection thickness and the difference between the actual and planned angles were normally distributed, and the paired *t*-test was used to compare the difference between the actual and expected resection thickness and the difference between the actual and planned angles. A P value < 0.05 was considered statistically significant. The proportions of the resection thickness that were within 1 mm and 2 mm from the absolute error were calculated. Similarly, the proportions of angles within an absolute error of 1°, 2°, and 3° were calculated. The 95% confidence intervals for the actual errors of the resection thickness and actual errors of the angles were also calculated to identify the population parameters.

3. Results

The operations were completed successfully in all patients. The average surgical time was 146.13 ± 24.42 min (from the establishment of the aseptic barrier to the completion of the skin suturing of the lower limbs). We measured the planned resection thickness before the operation, the actual resection thickness measured after the operation, and the cartilage thickness measured after the operation in 31 clinical patients. The actual error of the resection thickness represented the difference between the actual and expected resection thickness. The absolute value of the resection thickness was the absolute value of the actual error of the resection thickness. The actual errors of the resection thickness are reproduced in Table 1; the absolute errors of the resection thickness are shown in Table 2. A total of 177 absolute errors from the six positions were recorded in 31 patients, including the medial and lateral condyle of the distal femur, the medial and lateral posterior condyle of the femur, and the medial and lateral sides of the tibial plateau. The mean and standard deviation of the absolute errors at each osteotomy position did not exceed 1.04 mm and 0.84 mm, respectively.

In addition, we also counted the preoperatively planned HKA angles, CFCAs, CTCAs, and two surgeons who were not involved in the operation counted the 31 patients' preoperative HKA angles and postoperative full-length lower limb HKA angles, CFCAs, and CTCAs. We calculated the

Table 1
Statistical description of the actual errors of resection thickness.

Parameters	Mean ± SD (mm)	Range (mm)	P value	95%CI
Femoral				
Medial distal	0.36 ± 1.02	−2.0 to 2.7	0.056	−0.01 to 0.74
Lateral distal	0.60 ± 1.07	−1.4 to 2.9	0.004*	0.21 to 0.99
Medial posterior	0.47 ± 0.74	−1.0 to 2,0	0.001*	0.20 to 0.74
Lateral posterior	0.63 ± 1.12	−1.1 to 3.2	0.006*	0.20 to 1.07
Tibial				
Medial plateau	−0.23 ± 1.13	−2.4 to 1.8	0.306	−0.67 to 0.22
Lateral Plateau	0.32 ± 1.31	−3.5 to 2.6	0.193	−0.17 to 0.82

CI, confidence interval; SD, standard deviation; *, $p < 0.05$.

Table 2
Statistical description of the absolute errors of resection thickness.

Parameters	Mean ± SD (mm)	%Within 1 mm	%Within 2 mm
Femoral			
Medial distal	0.87 ± 0.63	70.97%	96.77%
Lateral distal	1.02 ± 0.67	54.84%	93.55%
Medial posterior	0.74 ± 0.46	74.19%	100%
Lateral posterior	0.98 ± 0.81	64.29%	89.29%
Tibial			
Medial plateau	0.92 ± 0.66	70.37%	88.89%
Lateral Plateau	1.04 ± 0.84	62.07%	89.66%

SD, standard deviation.

differences between the postoperative actual angles and the preoperative planned angles as the actual angle errors, and took the absolute value of the actual angle errors as the absolute angle errors of the surgical robot osteotomy. The actual errors of the angles are reproduced in Table 3, and the absolute errors of the angles are shown in Table 4. The means and standard deviations of the absolute errors of each angle were no greater than 1.46° and 1.01°, respectively. In addition, in comparison to the preoperative lower limb alignment angles, 90.32% of the postoperative lower limb alignment angles from 31 patients were closer to 180° after the operation. All 31 patients underwent a successful surgery, and no relevant complications occurred after the operation, such as surgical site infections, deep venous thrombosis, or vascular and nerve injuries.

Table 3
Statistical description of the actual angle errors between the angles measured from postoperative lower limb X-ray images and the planned angles.

Angles	Mean ± SD (°)	Range (°)	P value	95%CI
CFCA	−0.28 ± 1.50	−4.3 to 3.8	0.307	−0.83 to 0.27
CTCA	0.47 ± 1.21	−2.1 to 3.2	0.038*	0.02 to 0.91
HKA	0.25 ± 1.75	−3.0 to 3.0	0.440	−0.40 to 0.89

CFCA, coronal femoral component angle; CI, confidence interval; CTCA, coronal tibial component angle; HKA, hip-knee-ankle; SD, standard deviation; *, $p < 0.05$.

Table 4
Statistical description of the absolute angle errors between the angles measured from postoperative lower limb X-ray images and the planned angles.

Angles	Mean ± SD (°)	%Within 3°	%Within 2°	%Within 1°
CFCA	1.13 ± 1.01	93.55%	87.10%	54.84%
CTCA	1.05 ± 0.73	96.77%	87.10%	64.52%
HKA	1.46 ± 0.95	100%	70.97%	48.39%

CFCA, coronal femoral component angle; CTCA, coronal tibial component angle; HKA, hip-knee-ankle; SD, standard deviation.

4. Discussion

Mechanical alignments and soft tissue balancing have played major roles in TKA in improving the survival rates of the implants and restoring patient functionality [17,18]. Studies have shown that alignment of the mechanical axis in the coronal plane within a 3° varus/valgus range is associated with increased implant survival rates and improved long-term function [19,20]. To further improve the accuracy of implant alignment and bone resection, various active and semi-active robotic systems for TKA have been developed. Many studies have shown how robot-assisted devices help achieve better knee alignments compared to conventional manual techniques [21–23]. However, the MAKO robot, the most widely used TKA robot, has the disadvantages of high cost and time-consuming preoperative planning. In China, the period of MAKO preoperative planning from sending the patient's CT image to the MAKO engineer to receiving the surgical plan from the MAKO engineer takes about one week. Given the current background, our team has developed a relatively low-cost TKA robot, which is the first TKA robot to be developed and used in clinical operations in China. The initial segmentation of the bone model in “Skywalker” preoperative planning system is based on an automatic segmentation algorithm, which takes about 20 s. A trained engineer then optimizes the segmentation according to the condition of the initial segmentation, which takes about 10–15 min, and generally no more than 50 min. In addition, to finish a preoperative plan, a trained engineer also needs to select feature points on the bone model and adjust component positioning. Finally, these steps are confirmed by the surgeon. Overall, a total preoperative plan takes about 30–50 min, and generally no more than 60 min. Besides, the “Skywalker” cutting jig is stably connected to the end of robotic arm. When the cutting jig reaches the planned position, it does not need to be fixed to the bone like the way Praxim and ROSA robot do, which can avoid pinning to the bone and can also save corresponding surgical time. Moreover, compared with conventional manual TKA, such design can avoid the destruction to the femoral bone marrow caused by the positioning rod. However, the possible risk of this design is that the relative movement of the cutting jig and the patient's bone that could cause the osteotomy to deviate from the operation plan. Therefore, the “Skywalker” surgical robot has a supporting lower limb fixator. During surgery, before osteotomy, a lower limb fixator is used to stabilize the lower limb. The preoperative plan specifies the relative position between the cutting jig and the bone. The NDI camera obtains the position of the cutting jig target and the bone target, and then the robotic system controls the cutting jig to reach the designated position, which meets the preoperative plan of the relative position between the cutting jig and the bone. Researchers emphasized that the robotic arm needs to be able to hold cutting jigs or drilling guides to perform common surgical procedures [24]. Once the cutting jig reaches the designated position, the robotic arm of “Skywalker” locks its joints to ensure the stability of the cutting jig during osteotomy, and as a result of the lower limb fixator and locking of the joints of robotic arm, the cutting jig does not move relative to the patient’ s lower limb. Through this prospective clinical study, we have verified the ability of the “Skywalker” robot to perform an accurate and safe TKA operation.

The surgical plan made by “Skywalker” surgical robotic system is based on CT images. Although this requires more preoperative planning time and registration time, CT images can provide a more detailed 3D skeleton model to define the component placement, including the component alignment of the coronal, sagittal, and axial planes. Before the operation, the surgeon can define the component positioning according to the anatomy of the patient and carry out the preoperative plan precisely with the help of the robotic arm during the operation.

In this clinical study, the mean and standard deviation of the absolute error of each osteotomy position were no more than 1.04 mm and 0.84 mm. The P values of the actual osteotomy errors at the medial condyle of the distal femur and the medial and lateral tibial plateau were greater than 0.05, while the P values of the lateral condyle of the distal femur and the medial and lateral posterior condyle of the femur were less than 0.05. It is worth noting that the points selected in the preoperative surgical plan to calculate the planned resection thickness may not be the actual points measured by a vernier calliper when calculating the actual resection thickness. Currently, as cartilage cannot be segmented from CT images, the preoperative feature points were selected on the bone model segmented from preoperative CT images, whereas the postoperative feature points were selected on the bone pieces with cartilage after osteotomy. The preoperative feature points were all anatomical feature points. The osteotomy process of TKA does not destroy the anatomical feature points of the bone pieces. In this study, the preoperative feature points and the postoperative feature points were determined by the same surgeon. The surgeon selected the postoperative feature points based on the location of the preoperative anatomical feature points. Considering the obvious characteristics of anatomical feature points, we believe the error of point selection was small, although this may affect the calculation of the P values slightly. From the data of all six osteotomy positions, each position ensured that at least 54.84% of the absolute osteotomy errors were within 1 mm, and each position ensured that at least 88.89% of the absolute osteotomy errors were within 2 mm, of which 100% of the absolute resection thickness of the medial posterior condyle of the femur were within 2 mm. Therefore, we believe that the “Skywalker” surgical robot can perform accurate osteotomy. By comparison, in a cadaveric study of ROSA TKA robot [16], the P values of the actual osteotomy errors at the lateral condyle of the distal femur, medial and lateral posterior condyle of the femur, and the lateral tibial plateau were greater than 0.05, while the P values of the medial condyle of the distal femur and the medial tibial plateau were less than 0.05. The medial tibial plateau has the smallest range of actual osteotomy error of −0.6 mm–1.7 mm, and the lateral tibial plateau has the largest range of actual osteotomy error of −3.4 mm–1.8 mm. Among all the six osteotomy positions, 63%–83% of the actual osteotomy errors were within 1 mm, and 93%–100% of the actual osteotomy errors were within 2 mm. The results of this cadaveric study are comparable to our clinical study. However, at present, there is no unified method to evaluate the accuracy of osteotomy of the TKA robots, and other TKA robots have not reported their accuracy of osteotomy like ours.

In this clinical study, the means and standard deviations of the absolute errors of each angle were no greater than 1.46° and 1.01°, respectively. For the actual errors of the angles, the P values of the CFCAs and HKA angles were greater than 0.05, and the P value of the CTCAs was less than 0.05. The preoperative planning angles were calculated based on the custom coordinate system of the “Skywalker” surgical robot, while the postoperative HKA angles, CFCAs, and CTCAs were calculated based on the full-length X-ray images of the lower limbs. The difference between the two calculation methods may affect the P value. In fact, it is challenging to perfectly assess the accuracy of component positioning angle of TKA robot. James et al. [25] claimed that the angle calculated by robot software may be a little bit different from that calculated by CT. They used the navigated probe of MAKO TKA robot to measure the component positioning angle after osteotomy intraoperatively and used CT scan to measure the component positioning angle postoperatively. And they found that, in the coronal plane, the absolute angle errors between intraoperative and postoperative measurements for the femoral component, tibial component, and HKA angles were 1.17° ± 1.10°, 1.03° ± 0.76°, 1.29° ± 1.25°, respectively. Even so, in our clinical study, 54.84% of the absolute errors of the CFCAs were within 1°, 87.10% were within 2°, and 93.55% were within 3°. And 64.52% of the absolute errors of the CTCAs were within 1°, 87.10% were within 2°, and 96.77% were within 3°. In addition, 48.39% of the absolute errors of the HKA angles was within 1°, 70.97% were within 2°, and 100% were within 3°. Therefore, we believe that the “Skywalker” surgical robot can assist surgeons to perform accurate reconstructions of lower limb alignments. It can also be seen from the patients' full-length X-ray images of the lower limbs after the operations that, compared to the preoperative lower limb alignment angle, 90.32% of the postoperative lower limb alignment angles in the 31 patients were closer to 180° after surgery. Actually, coronal alignment is the main consideration in clinical application. The coronal alignment of the femoral and tibial component and the alignment of the lower limb can be easily calculated from standard full-length X-ray images of the lower limbs on the coronal plane. However, knee joints overlap on the sagittal plane of the standard full-length X-ray images of the lower limbs, and calculation of the sagittal alignment of component cannot be performed accurately. In addition, difficulty in defining the position of the patient's lower limbs when taking the axial X-ray images of the knee joint makes it hard to evaluate the axial alignment of the component on the postoperative X-ray images. Further, artifacts of knee components may appear during CT scan, making it impossible to evaluate the alignment of component on sagittal and axial plane based on CT scan.In this clinical study, “Skywalker” -assisted TKA allowed for accurate osteotomy in minimally invasive conditions, achieving the preoperatively planned component placement and proper soft tissue balance with reliable safety. However, this clinical study also has some shortcomings. First, our current osteotomy control group was set as the preoperative planned values, and a conventional operation was not set up as the control group. Second, we have not yet collected clinical scores to evaluate whether accurate component implantation can lead to functional improvements. Therefore, we still need control studies and long-term follow-ups to determine if the clinical effects of the “Skywalker” surgical robot can significantly improve knee-joint functions in the long term.

5. Conclusion

The results of this prospective clinical study demonstrated that, based on robotically positioned and stabilized cutting jig, the “Skywalker” system for total knee arthroplasty is expected to assist surgeons in performing accurate bone cuts and reconstructing planned lower limb alignments in clinical use.

Funding/support statement

This work was supported by the National Key R&D Program of China [grant number 2017YFC0110704].

Authorship

All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing, or revision of the manuscript. Each author certifies that this material or part thereof has not been published in another journal, that it is not currently submitted elsewhere, and that it will not be submitted elsewhere until a final decision regarding publication of the manuscript in Journal of Orthopaedic Translation has been made.

Indicate the specific contributions made by each author (list the authors' initials followed by their surnames, e.g.,Y.L. Cheung). The name of each author must appear at least once in each of the three categories below.

Category 1.

Conception and design of study: RZ. Xia, ZJ. Zhai, JW. Zhang, HW. Li;

Acquisition of data: DG. Yu, YQ. Mao, JW. Zhang, L. Wang

Analysis and/or interpretation of data: HS. Wu, ZA. Zhu, KR. Dai, HW. Li.

Category 2.

Drafting the manuscript: RZ. Xia, ZJ. Zhai, HW. Li, KR. Dai

Revising the manuscript critically for important intellectual content: ZA. Zhu, HS. Wu, YQ. Mao, MN. Yan.

Category 3.

Approval of the version of the manuscript to be published (the names of all authors must be listed):

RZ. Xia, ZJ. Zhai, JW. Zhang, DG. Yu, L. Wang, YQ. Mao, ZA. Zhu, HS. Wu, KR. Dai, MN. Yan, HW. Li.

Declaration of competing interest

A conflict of interest occurs when an individual's objectivity is potentially compromised by a desire for financial gain, prominence, professional advancement or a successful outcome. The Editors of the *Journal of Orthopaedic Translation* strive to ensure that what is published in the Journal is as balanced, objective and evidence-based as possible. Since it can be difficult to distinguish between an actual conflict of interest and a perceived conflict of interest, the Journal requires authors to disclose all and any potential conflicts of interest.

Acknowledgements

All persons who have made substantial contributions to the work reported in the manuscript (e.g., technical help, writing and editing assistance, general support), but who do not meet the criteria for authorship, are named in the Acknowledgements and have given us their written permission to be named. If we have not included an Acknowledgements, then that indicates that we have not received substantial contributions from non-authors.

References

[1] Martelli M, Marcacci M, Nofrini L, LA Palombara F, Malvisi A, Iacono F, et al. Computer- and robot-assisted total knee replacement: analysis of a new surgical procedure. Ann Biomed Eng 2000;28(9):1146–53.

[2] Wijdicks CA, Griffith CJ, Johansen S, Engebretsen L, LaPrade RF. Injuries to the medial collateral ligament and associated medial structures of the knee. J Bone Joint Surg Am 2010;92(5):1266–80.

[3] Siqueira MB, Haller K, Mulder A, Goldblum AS, Klika AK, Barsoum WK. Outcomes of medial collateral ligament injuries during total knee arthroplasty. J Knee Surg 2016;29(1):68–73.
[4] McNabb DC, Kim RH, Springer BD. Instability after total knee arthroplasty. J Knee Surg 2015;28(2):97–104.
[5] Bates MD, Springer BD. Extensor mechanism disruption after total knee arthroplasty. J Am Acad Orthop Surg 2015;23(2):95–106.
[6] Parratte S, Pagnano MW, Trousdale RT, Berry DJ. Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. J Bone Joint Surg Am 2010;92(12):2143–9.
[7] Matsumoto T, Takayama K, Ishida K, Hayashi S, Hashimoto S, Kuroda R. Radiological and clinical comparison of kinematically versus mechanically aligned total knee arthroplasty. Bone Joint Lett J 2017;99-B(5):640–6.
[8] Hampp EL, Chughtai M, Scholl LY, Sodhi N, Bhowmik-Stoker M, Jacofsky DJ, et al. Robotic-arm assisted total knee arthroplasty demonstrated greater accuracy and precision to plan compared with manual techniques. J Knee Surg 2019;32(3):239–50.
[9] Khlopas A, Chughtai M, Hampp EL, Scholl LY, Prieto M, Chang TC, et al. Robotic-arm assisted total knee arthroplasty demonstrated soft tissue protection. Surg Technol Int 2017;30:441–6.
[10] Song EK, Seon JK, Yim JH, Netravali NA, Bargar WL. Robotic-assisted TKA reduces postoperative alignment outliers and improves gap balance compared to conventional TKA. Clin Orthop Relat Res 2013;471(1):118–26.
[11] Park SE, Lee CT. Comparison of robotic-assisted and conventional manual implantation of a primary total knee arthroplasty. J Arthroplasty 2007;22(7):1054–9.
[12] Bellemans J, Vandenneucker H, Vanlauwe J. Robot-assisted total knee arthroplasty. Clin Orthop Relat Res 2007;464:111–6.
[13] Marchand RC, Sodhi N, Anis HK, et al. One-Year patient outcomes for robotic-arm-assisted versus manual total knee arthroplasty. J Knee Surg 2019;32(11):1063–8.
[14] Sodhi N, Khlopas A, Piuzzi NS, Sultan AA, Marchand RC, Malkani AL, et al. The learning curve associated with robotic total knee arthroplasty. J Knee Surg 2018;31(1):17–21.
[15] Clark TC, Schmidt FH. Robot-assisted navigation versus computer-assisted navigation in primary total knee arthroplasty: efficiency and accuracy. ISRN Orthop 2013;2013:794827.
[16] Parratte S, Price AJ, Jeys LM, Jackson WF, Clarke HD. Accuracy of a new robotically assisted technique for total knee arthroplasty: a cadaveric study. J Arthroplasty 2019;34(11):2799–803.
[17] Jakopec M, Harris SJ, Rodriguez y Baena F, Gomes P, Cobb J, Davies BL. The first clinical application of a "hands-on" robotic knee surgery system. Comput Aided Surg 2001;6(6):329–39.
[18] Rodriguez JA, Bhende H, Ranawat CS. Total condylar knee replacement: a 20-year followup study. Clin Orthop Relat Res 2001;388:10–7.
[19] Choong PF, Dowsey MM, Stoney JD. Does accurate anatomical alignment result in better function and quality of life? Comparing conventional and computer-assisted total knee arthroplasty. J Arthroplasty 2009;24(4):560–9.
[20] Ritter MA, Davis KE, Meding JB, Pierson JL, Berend ME, Malinzak RA. The effect of alignment and BMI on failure of total knee replacement. J Bone Joint Surg Am 2011;93(17):1588–96.
[21] Jacofsky DJ, Allen M. Robotics in arthroplasty: a comprehensive review. J Arthroplasty 2016;31(10):2353–63.
[22] Netravali NA, Shen F, Park Y, Bargar WL. A perspective on robotic assistance for knee arthroplasty. Adv Orthop 2013;2013:970703.
[23] Kim SM, Park YS, Ha CW, Lim SJ, Moon YW. Robot-assisted implantation improves the precision of component position in minimally invasive TKA. Orthopedics 2012;35(9):1334–9.
[24] Qin LY, Wen JZ, Chui CS, Leung KS. Housing design and testing of a surgical robot developed for orthopaedic surgery. J Orthop Translat 2016;5:72–80.
[25] Sires JD, Wilson CJ. CT validation of intraoperative implant position and knee alignment as determined by the MAKO total knee arthroplasty system. J Knee Surg 2020. https://doi.org/10.1055/s-0040-1701447.