CLINICAL ARTICLE

Accuracy of a Novel 3D-Printed Patient-Specific Intramedullary Guide to Control Femoral Component Rotation in Total Knee Arthroplasty

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Objective: Total knee arthroplasty (TKA) is one of the most universal and effective means for treating terminal stage osteoarthritis (OA) of knee. Accurate intramedullary guide of femur is the basis for the distal femoral cuts. Determining the surgical transepicondylar axis (sTEA) is the key to reconstruction of the femoral rotational alignment, because the correct rotational alignment can place the femoral component in the right position, balance the flexion gap so that the inner and outer tension is equal, get stability during the flexion process of the knee, and enhance the quality of life of patients. With the development of three-dimensional printing (3DP) technology in the medical domain, the application of patient-specific instrumentation (PSI) in arthroplasty has become more common. The aim of this study was to evaluate the accuracy of a novel 3D-printed patient-specific intramedullary guide to control femoral component rotation in TKA.

Methods: Eighty patients (65 females and 15 males) with knee OA were included in this prospective randomized study. The patients were divided into two groups by random number table method, 40 in each group. TKA assisted by PSI (PSI group) and conventional TKA (conventional group) was performed respectively. Clinical outcomes [operation time, postoperative drainage volume, duration of drainage, Hospital for Special Surgery knee score (HSS), American Knee Society knee score (AKS)] and radiological outcomes [hip-knee-ankle angle (HKA), posterior condylar angle (PCA), patella transverse axis-femoral transepicondylar axis angle (PFA), depth of intramedullary guide] were compared between and within the two groups.

Results: PSI group had less postoperative drainage volume but longer operation time than the conventional group ($P < 0.05$). The AKS and HSS scores after surgery were improved compared with those before surgery in each group ($P < 0.05$). However, there was no significant difference in the duration of drainage and range of motion (ROM) after surgery between the two groups. For the radiological results, the HKA and PFA were improved after surgery in both groups ($P < 0.05$).The postoperative PFA and PCA of the PSI group were closer to 0°, which was better than that of the conventional group ($P < 0.05$). The depth of intramedullary guide in the PSI group was less than the conventional group ($P < 0.05$). But there was no significant difference in HKA before and after surgery between the two groups as well as the preoperative PFA.

Conclusion: The short-term clinical efficacy of TKA assisted by PSI was similar to the conventional TKA. Although TKA assisted by PSI spent more time during operation, it could assist in intramedullary guide and align femoral rotation more accurately.

Key words: 3D Printing; Intramedullary guide; Patient-specific instrumentation; Rotational alignment; Surgical transepicondylar axis; Total knee arthroplasty

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Introduction

With the increase of osteoarthritis (OA) incidence of the knee, more surgeons choose to use total knee arthroplasty (TKA) to solve the pain and deformity issues of patients, and TKA has become a reliable method to treat end-stage knee OA[1–3]. At present, TKA has been widely used. It relieves pain by resecting the worn joint surfaces, removing proliferating inflammatory synovial tissue, and fully succeed indenervating. The joint prosthesis was used to replace the damaged joint surface to reconstruct the function of the knee. On the account of the good postoperative effect, the number of TKA operations increased rapidly. This technology not only solves the pain of patients, but also improves the quality of their daily life, becoming the ultimate choice for patients with advanced knee OA. However, due to the diversity of knee prosthesis design, the patient's ability to adapt, surgical techniques of doctors, basic physical conditions and other factors, patients who receive TKA do not achieve complete satisfaction. More than 20% of the patients are not satisfied with the clinical outcome, resulting in about 35% of revision subjects within 2 years of the primary TKA[4–6]. Increased failure rate has been attributed to several causes, including aseptic loosening, joint instability, infection, malalignment, malposition, arthrofibrosis, periprosthetic fracture, patellar complications, and so on[7–10]. A femoral rotational alignment in transverse plane is necessary for postoperative flexion stability, tibiofemoral and patellofemoral kinematics. Both excessive internal and external rotations have been proved to lead to postoperative dysfunction and even surgical failure[11]. In the meantime, the accurate intramedullary guide of femur is the basis for ensuring the distal osteotomy of the femur. Incorrect intramedullary guide will make it difficult to balance the inner and outer tension in the extension state of the knee, which will further lead to the imbalance of flexion and extension gap and eventually lead to the early failure of TKA. Due to anatomic dysplasia in individuals, the intramedullary guide may be inaccurate. Repeated adjustments during the operation will increase the surgical trauma and the blood loss. Therefore, it is necessary to reduce the number of repeated adjustments during the operation. Furthermore, minimally invasive and accurate surgical methods are increasingly favored by the majority of doctors, and how to reduce additional damage has become the common purpose of them. Therefore, appropriate femoral resection and accurate component rotation are essential for a successful TKA.

The reconstruction of femoral rotational alignment is very necessary to TKA because of its effects on postoperative knee biomechanics and associated functional outcomes. In general, the femoral rotational alignment could refer to bony landmarks which include posterior condylar line (PCL), anteroposterior trochlea axis (Whiteside's line) and sTEA[12]. But the more accurate method for establishing rotational alignment in TKA is still controversial. The most commonly used method to determine the femoral entry point is referring to the insertion point of posterior cruciate ligament on the femur[13]. Accurate intramedullary guide of femur is important for distal femoral cuts, which would determine the lower extremity alignment on the coronal plane[14]. Conventional TKA technique relies heavily on bony landmarks. If anatomical abnormality exists in these references, wrong bone resections would result in malalignment and malrotation of the prosthesis. Hence accurate reconstruction of lower extremity alignment and femoral component rotation is crucial to patients' postoperative functional recovery and satisfaction. Three-dimensional printing (3DP) technology has been widely used in the field of orthopaedics in recent years[15–19]. This technique is mainly applied to preoperative morphological design and tissue repair, such as the reconstruction of large bone defects. The use of 3D-printed products in the field of orthopaedics has further enriched ways and means to solve complex problems in surgery. Meanwhile, patient-specific instrumentation (PSI) is extensively applied in clinical practice, and major breakthroughs have been made in its design and production. This technique is individualized and practical, which could improve surgical accuracy and efficiency[20]. Combined with 3D printing technology and PSI technology, preoperative navigation can be achieved, avoiding the problem of the blocked signal and registration in traditional navigation technology. Standardized surgical procedures cannot satisfy all types of patients, especially for those complicated and special cases, which require more personalized preoperative design by doctors to achieve more satisfactory clinical results. This study explored the practical application of 3D-printed PSI in TKA and its postoperative clinical efficacy. Through comparison with the clinical and radiological outcomes of traditional TKA, the advantages and disadvantages of PSI designed in this study were further explored.

This is a prospective randomized controlled trial (RCT). This study mainly aimed to explore the following three purposes: (i) to evaluate the accuracy of a novel 3DP-designed PSI by comparing its postoperative radiological outcomes with conventional TKA; (ii) to determine whether greater accuracy translated to better clinical outcomes; and (iii) to verify the scientificity and feasibility of PSI through the analysis of its clinical outcomes. The PSI was designed using computer aided design (CAD) software and 3DP technology, and, separately, that the sTEA was used as a reference for the rotational axis of the knee. This study hypothesized that a novel 3DP-designed PSI could assist the intramedullary guide and align femoral rotation more accurately compared with traditional TKA to obtain satisfactory short-term clinical efficacy.

Materials and Methods

This is a prospective randomized controlled trial. All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The present study was approved by the Ethics Committee of the hospital (No. KY201965), and informed consent was obtained from all individual participants included in this study. The research was registered on www.clinicaltrials.gov (NCT04206202).

Participants

One hundred and twenty patients (99 females and 21 males) on the waiting list with advanced OA of knee had been scheduled to prepare for primary TKA between May 2017 and May 2018. Participants of this study were enrolled according to the following inclusion criteria and exclusion criteria (Fig. 1).

The inclusion criteria were: (i) patients with advanced OA of the knee, varus deformity of no more than 15°, flexion-contracture deformity of no more than 10°, without extra-articular deformity of the knee; (ii) weight-bearing radiograph of the X-ray image showed the OA Kellgren-Lawrence classification grade IV; (iii) the treatment for the patient was TKA, whether or not to use PSI depends on the actual grouping; (iv) outcomes are operation time, postoperative drainage volume, duration of drainage, Hospital for Special Surgery knee score (HSS), American Knee Society knee score (AKS), Hip-knee-ankle angle (HKA), the patella transverse axis-femoral transepicondylar axis angle (PFA), posterior condylar angle (PCA), the depth of intramedullary guide; and (v) a prospective study.

The exclusion criteria were: (i) patients with varus deformity of more than 15°, flexion-contracture deformity of more than 10° of the knee; (ii) patients with traumatic arthritis and inflammatory arthritis; (iii) patients with huge bone defects around the knee; (iv) patients who had active infection around the knee; (v) patients with knee valgus deformity; (vi) patients with severe extra-articular deformity; (vii) patients who had previous knee surgery; (viii) patients who had periarticular soft tissue dysfunction and neuropathy; (ix) patients who had poor physical condition and could not withstand the operation; and (x) patients who refused to be followed.

Finally, 80 patients (65 females and 15 males) were enrolled for this study. A prospective randomized single-blind clinical study of the control method was conducted. Patients were unaware of the use of PSI during TKA and assigned to two groups by random number table method, 40 cases in each group. One group was designated as the experimental group (PSI group, performing the TKA assisted by PSI) and the other as the control group (conventional group, performing the conventional TKA). The demographics of the patients were recorded before surgery, including age, sex, body mass index (BMI), the degree of varus deformity, and range of motion (ROM). All patients received the preoperative computed tomography (CT) scan, radiographical examination of the full-length lower limb in standing position, and preoperative HSS and AKS before surgery. One very skilled surgeon who had more than 10 years of TKA experience utilizing same and easy-to-use instrumentation performed all the surgeries in this study in order to eliminate potential inter-individual differences. All patients received the LEGION Total Knee System, posterior stabilized prosthesis (Smith & Nephew, Memphis, USA); in all cases, no patella replacement was performed. All TKA participants took part in a standardized preoperative education and postoperative rehabilitation.

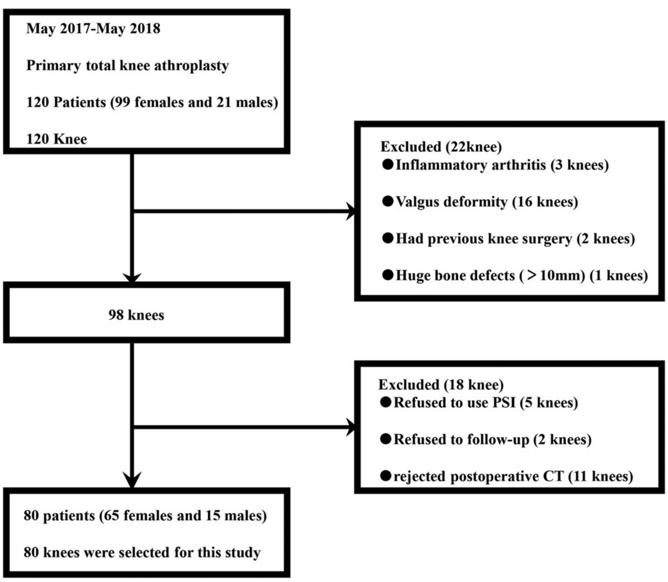

Fig. 1 The study flow diagram.

Preoperative Preparation of PSI

The PSI group underwent 1-mm slice thickness CT scans of the affected knee preoperatively. The data in DICOM (Digital Imaging and Communications in Medicine) format were extracted and imported into the Materialise Interactive Medical Image Control System 19.0 (MIMICS, Materialise Ltd., Belgium) to reconstruct the outline of the distal femur. The data reconstructed by MIMICS were then imported into SIEMENS NX 12.0 (Siemens PLM Software Ltd., Germany) to design the positioning hole of sTEA (diameter: 2 mm) and the location of femoral entry point (diameter: 10 mm). In the standard coordinate system established by the computer, we could find a sulcus on the medial femoral epicondyle and a prominence on the lateral femoral epicondyle. In the MIMICS, we synthesized the sulcus area near the medial epicondyle into a circle, and the center of the circle was the lowest point of the medial epicondyle. In the same way, we could find the highest point of the lateral epicondyle. The sTEA of the femur is determined by connecting the line of the highest point of the lateral epicondyle and the lowest point of the medial epicondyle. Then, the two points on this line were selected as the positioning hole. The femoral intramedullary entry point on distal femur was the projection point of the femoral anatomical axis (Fig. 2A,B). The shape of the PSI was designed by locally increasing the depth of the positioning hole. Furthermore, there were four fixators around the PSI that were in contact with the distal femur and were firmly attached. The four fixators were located at the anterior femoral condyle, the medial and lateral femoral condyle respectively (Fig. 2C–E). Finally, the converted data in STL format were imported into the 3DP system. The laser rapid prototyping printer (UP BOX, Tiertime, China) was used to print the PSI with bio-safe polylactic acid as the material (Fig. 2F–I). The printed PSI was sterilized with ethylene oxide after being sealed and packaged.

Microbiological test of the PSI was performed preoperatively, and the results must be qualified before being used intraoperatively. The surgeon should confirm and take the PSI back on the day of surgery, then the nurse should confirm again that the package was intact and valid. The PSI used in this study was provided free of charge for the patients.

Operative Techniques

The patient was placed in the supine position after the combination of lumbar anesthesia and epidural anesthesia. Surgical area was disinfected and a tourniquet was tied at the root of the thigh. All patients were operated on by the same senior orthopaedic surgeon. The anterior central incision of the knee was performed using a standard medial parapatellar approach and cutting along the medial quadriceps femoris tendon, the medial patellofemoral ligament (MPFL), and the medial patellar tendon. After the joint cavity was fully exposed, the fat pad and the hyperplastic synovial tissue under the patella were resected. Then, the meniscus was removed and the patella was denervated. The patella replacement was not performed in all patients.

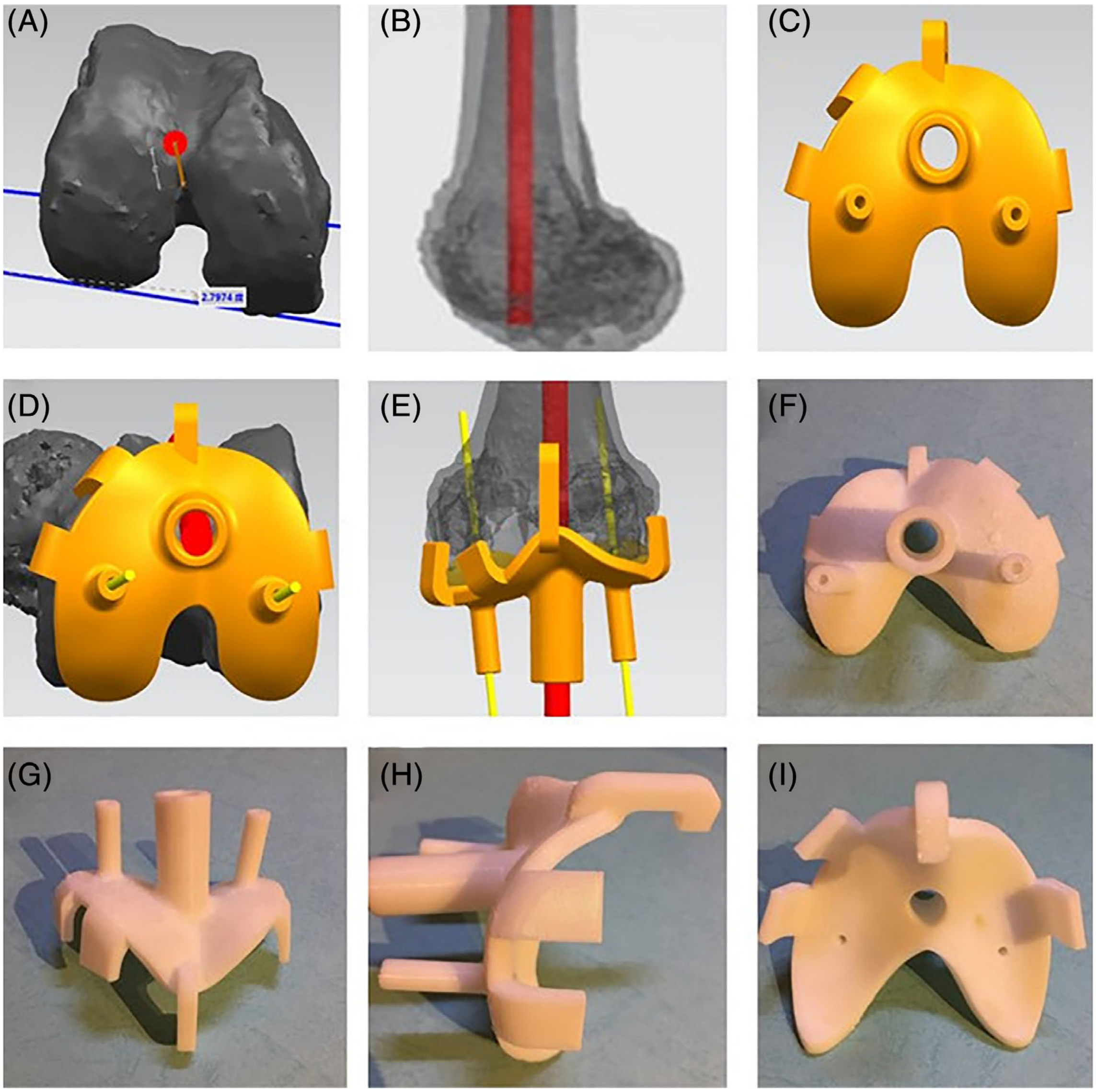

Fig. 2 The process of designing PSI and the morphology of the PSI:(A, B) Finding the sTEA and the location of intramedullary guide; (C–E) The process of designing PSI; (F–I) The morphology of PSI in different perspectives.

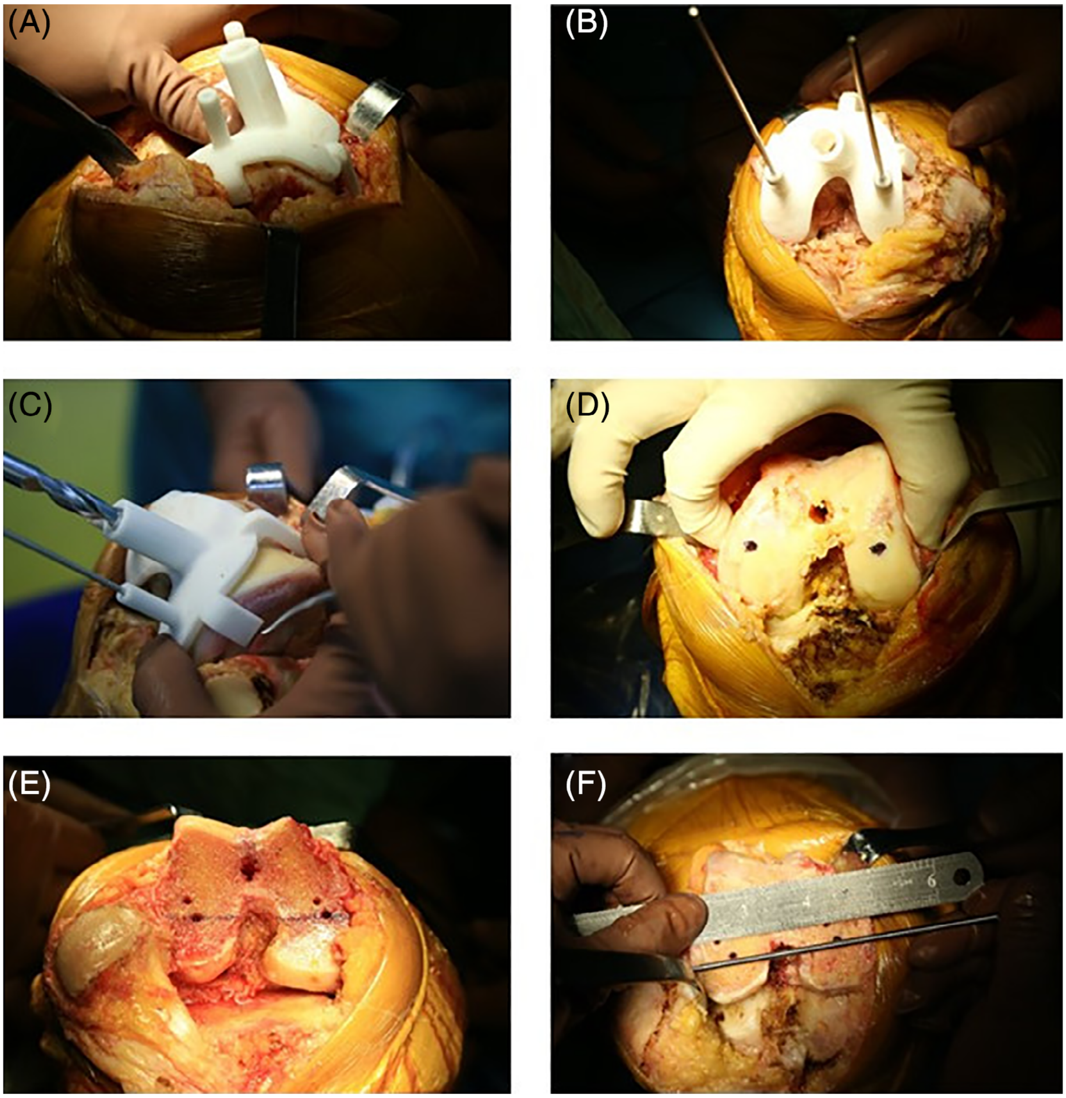

Fig. 3 Steps of the TKA assisted by PSI technology representation: (A) PSI was placed on the distal femur surface; (B) PSI was fixed with Kirschner wire in order to mark the sTEA; (C) Drilling into the distal femur for intramedullary guide; (D) Palpating the medial and lateral epicondyles of the femur and observing the sTEA confirmed by the PSI; (E) Completing the distal femoral cuts; (F) Observing the relationship between the epicondylar axis determined by the femoral rotation guide and the sTEA confirmed by the PSI.

In the PSI group, the PSI was firstly placed on the distal femur surface (Fig. 3A). After confirming the complete matching of the distal femur outline, the PSI was fixed with Kirschner wire to mark the sTEA (Fig. 3B). Then, drilling into the distal femur for intramedullary guide to ensure proper distal femur cuts (Fig. 3C). After removing the PSI, the surgeon should palpate the medial and lateral epicondyles of the femur and observe the sTEA confirmed by the PSI as the first check for the PSI stability, starting with the femoral cut and then the tibial cut (Fig. 3D).The distal femoral cuts and the sTEA confirmed by the PSI were duplicated on the femoral resection plane (Fig. 3E). According to preoperative CT data, the length from the top of the greater trochanter to the lowest point of the intercondylar fossa was calculated, and the depth of intramedullary guide was set at one-third of the length. Then, femoral intramedullary guide was used to resect the distal femur. Next, the surgeon performed the proximal tibia bone cut with the tibial extra medullary guide. The tibial bone cut line was perpendicular to the tibial shaft in the coronal plane and was 3° of the posterior slope in the sagittal plane. The medial and lateral collateral ligaments should be protected during the bone resections. Then, the medial soft tissue was released moderately to balance the extension gap after the bone resections. The femoral rotation guide was placed at the distal femur, and the external rotation was adjusted according to the angle of posterior

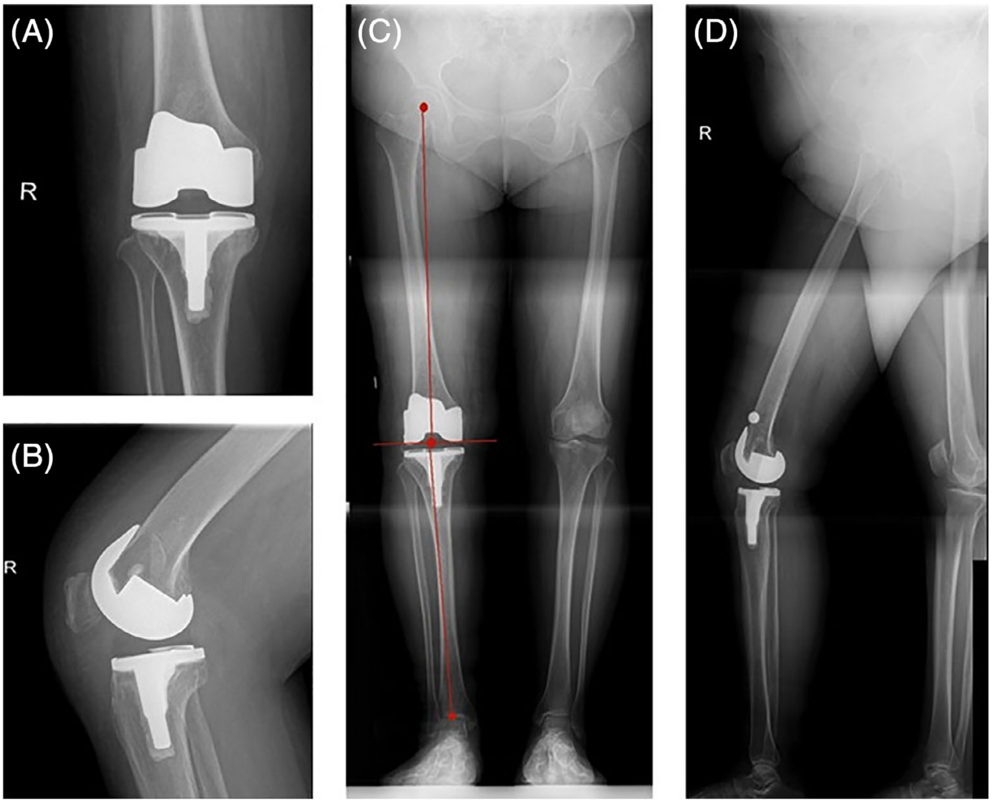

Fig. 4 The postoperative radiographic examination of the knee and the full-length lower limb. HKA was determined in the coronal plane by measuring the angle (blue arrow) between a line connecting the center of the femoral head and the center of the knee (the red line on the side of the femur) and a line connecting the center of the knee to the center of the ankle (the red line on the side of the tibia) in radiographic images of full-length lower limb. HKA, hip-knee-ankle angle.

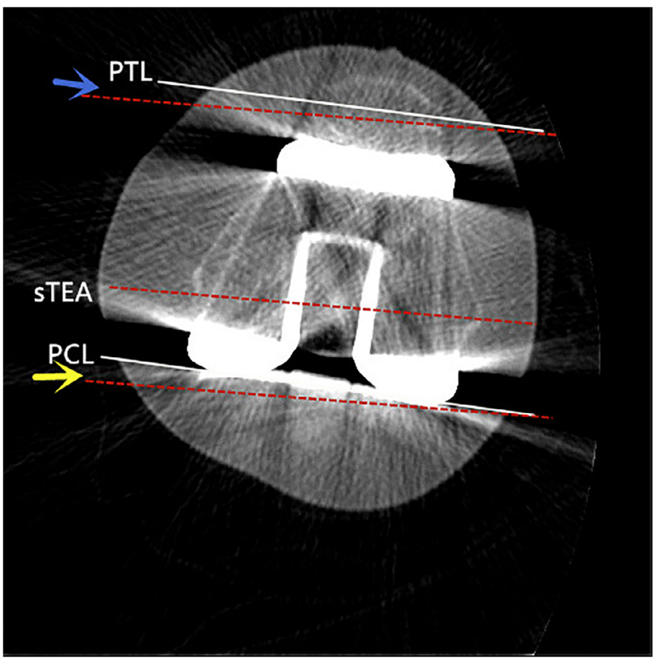

Fig. 5 CT section with reference of axis and angles. PTL, patella transverse line; sTEA, surgical transepicondylar axis; PCL, posterior condyle line; Blue arrow, patella transverse axis-femoral transepicondylar axis angle (PFA); Yellow arrow, posterior condylar angle (PCA).

condylar axis and sTEA measured preoperatively. The relationship between the epicondylar axis determined by the femoral rotation guide and the sTEA confirmed by the PSI were observed as the second check for PSI stability (Fig. 3F). Accomplishing the anterior and posterior femoral cut which paralleled the sTEA by the anteroposterior cutting jig and balancing the flexion gap. Spacer blocks and the trial components were used to test the gap that balanced between flexion and extension. After femoral and tibial cut, bone cement was applied to the distal femur, the proximal tibia, and the inner surface of the prosthesis, then the femoral and tibial components were installed. Finally, the patellofemoral tracking from extension to flexion were observed and the dynamic stability was tested.

In the conventional group, tibial extramedullary guide, femoral intramedullary guide and regular 3° external rotation bone resection were routinely used. The location of intramedullary guide was referring to 1 cm above the insertion point of posterior cruciate ligament on the femur. The surgeon firstly performed the distal femur bone cut and then the proximal tibia bone resection. The anterior and posterior femoral resection was performed routinely 3° externally rotated from the posterior condylar axis.

After the above procedure, tranexamic acid was given intravenously during the operation; the tourniquet was used throughout the procedures and hemostasis should be strictly performed. Finally, tranexamic acid was applied topically through a drainage tube after the capsule was closed. All patients were routinely treated with infection prevention, pain relief, ice compress, and other symptomatic supportive treatment. On the next day after the operation, patients underwent postoperative CT scan. The specific parameters (lower extremity 0.75 mm) and image processing of the CT scan could remove the interference from metal artifacts and better present the location of the knee prosthesis.

Outcome Measures

All patients were followed for 7 to 12 months, with an average of (9.0 ± 3.9) months. The first follow-up was conducted 1 week after the operation, and the operation time, postoperative drainage volume and duration of drainage of the participants were collected according to the operation and nursing records. The second follow-up began 1 month after surgery. The radiographic examination of the knee and the full-length lower limb, as well as the CT scan of knee, were performed. The third follow-up started at 6 months after surgery. HSS score and AKS score were completed by the same researcher to evaluate the clinical outcomes. All the clinical and radiological outcomes were reported at the final follow-up time point.

Hip-Knee-Ankle Angle (HKA)

The HKA was determined in the coronal plane by measuring the angle between a line connecting the center of the femoral head and the center of the knee and a line connecting the center of the knee to the center of the ankle in radiographic images (Fig. 4). Varus defined as HKA is less than 180° and valgus defined as HKA is greater than 180°.

Patella Transverse Axis-Femoral Transepicondylar Axis Angle (PFA)

In the transverse plane of CT images, confirming the sulcus on the medial femoral epicondyle and the prominence on the lateral femoral epicondyle through observing several serial images. Then, look for an image that best shows the outline of the sulcus and prominence in order to determine the sTEA. The patella transverse line (PTL) was the connection between the inner and outer ends of the patella. The PFA was the angle between sTEA and the PTL (Fig. 5). If the PFA opened above sTEA, it was defined as positive; otherwise, it is defined as negative.

Posterior Condylar Angle (PCA)

The PCA was the angle between sTEA and the posterior condyle line (PCL) of the femoral component (Fig. 5). If the PCA opened above sTEA, it was defined as positive; otherwise, it is defined as negative.

Intramedullary Guide Position

The preoperative intramedullary guide position designed by MIMICS and the actual intramedullary guide position displayed by postoperative CT were placed in the same coordinate system by Geomagic Qualify 2013 (Geomagic, Inc., USA), and the relationship between the two positions was compared (Fig. 6). If the "actual position" could completely cover the preoperative "designed position", and presented "concentric circles", and the distance between the two centers was less than the radius of the "actual position", it indicated that the PSI was accurate. If the "actual position" completely deviated from the "designed position", and the distance between the two centers was greater than the radius of the "actual position", it indicated that the PSI was inaccurate.

Depth of Intramedullary Guide

The depth of intramedullary guide was measured in MIMICS Research 19.0 v. We could find the "columnar image" in the coronal CT of the patient after TKA, which was the trauma trace left by intramedullary hemorrhage caused by intramedullary guide rod insertion into the medullary cavity of the femur, and the image with high density on the CT. By using the measuring module of MIMICS, the actual depth of insertion of the guide rod into the medullary cavity in CT could be measured (Fig. 7). The smaller the depth, the smaller the trauma, and the more minimally invasive; otherwise, the greater the trauma. These radiological results were

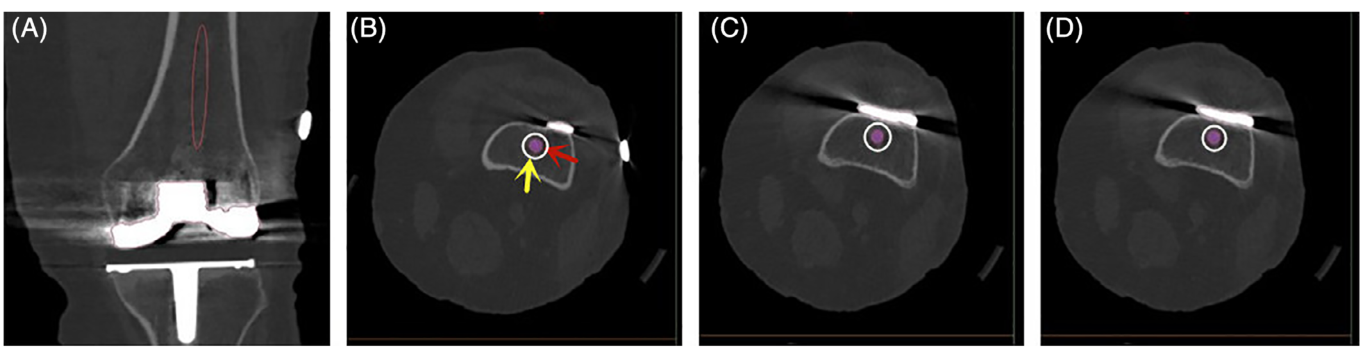

Fig. 6 The location of preoperative designed and actual intramedullary guide: (A) The location of actual intramedullary guide (red circle); (B–D) The relationship between preoperative designed and actual intramedullary guide position on continuous CT level. The purple dot shown by the red arrow is the preoperative designed position, and the white circle area shown by the yellow arrow is the actual position.

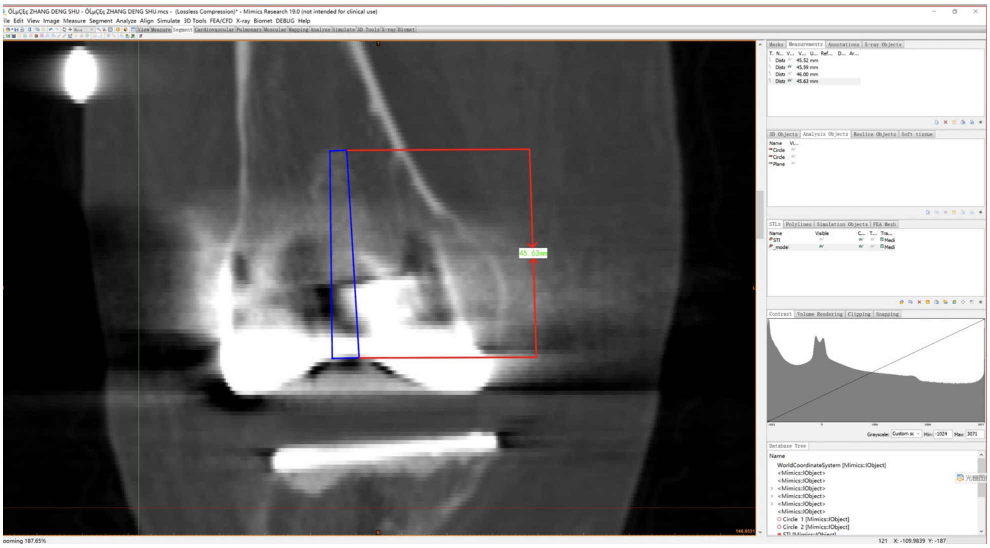

Fig. 7 The method of measuring the depth of intramedullary guide: Blue rectangular area indicated the depth of intramedullary guide.

measured twice with the same method mentioned above by one senior radiologist and the average value of the two measurements were obtained.

Hospital for Special Surgery Knee Score (HSS)
The HSS was used to evaluate postoperative recovery of knee function in an adult population. The HSS score system mainly includes six aspects: pain, function, muscle force, deformity, stability, and the range of motion. The score standard had a maximum of 100 points (best possible outcome). A total score <60 is considered a poor score, 60–69 is fair, 70–85 is good, and 86–100 is excellent.

American Knee Society Knee Score (AKS)
The AKS was used to evaluate postoperative recovery of knee function in an adult population. The AKS score system mainly includes four aspects: pain, stability, range of motion, and function. The score standard had a maximum of 100 points (best possible outcome). A total score <60 is considered a poor score, 60–69 is fair, 70–85 is good, and 86–100 is excellent.

Statistical Methods

SPSS 20.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. The measurement data of normal distribution were expressed as mean and standard deviation. Forty patients were required in each group and different statistical test methods were used for statistical analysis between and within the groups. Paired *t*-test was used to determine the significance of inter-group differences for clinical and radiological outcomes. Independent *t*-test was used to perform the significance of between-group differences for clinical and radiological outcomes. Statistical significance was set at $P <$ 0.05. All statistical analyses were independently performed by one single researcher. Sample size was estimated based on results of the preliminary experiments which accorded to the results of the first 16 patients in this study (first eight cases in each group). According to the results of PCA (PSI group: 0.6 $\pm$ 0.8, conventional group: 1.2 $\pm$ 1.0), the minimum sample size (36 patients in each group) satisfying the statistical significance of the difference between the two groups was calculated (power = 0.8, confidence level 0.05). Considering 20% of patients were lost to follow-up and refused to follow-up, the sample size was finally determined to be 80 (40 patients in each group).

Results

Demographic Results

Eighty patients were enrolled in this study (15 males and 65 females, 80 knees). The age of patients in conventional group was 67.6 $\pm$ 8.4 (range, 55 to 82) years, and 68.7 $\pm$ 9.1 (range, 57 to 80) years in PSI group; there were seven males and 33 females in conventional group, while eight males and 32 females in PSI group; the BMI of patients in conventional group was (26.6 $\pm$ 2.2) kg/m^2, and (25.8 $\pm$ 3.9) kg/m^2 in PSI group; the varus deformity of patients in conventional group was (9.2 $\pm$ 3.6)°, and (8.8 $\pm$ 2.5)° in PSI group; the ROM of the knee in conventional group was (110.6 $\pm$ 20.1)°, and (113.4 $\pm$ 19.7)° in PSI group. No significant difference in demographic results had been found (age: P = 0.576; sex: P = 0.732; BMI: P = 0.263, varus deformity: P = 0.566, ROM: P = 0.531). All characteristics of patients are shown in Table 1.

Clinical Results

Comparison between Groups
The PSI group had less postoperative drainage volume ([258.7 $\pm$ 11.8] mL *vs* [305.6 $\pm$ 10.8] mL) (P = 0.000), but took longer operation time than the conventional group subjects ([87.3 $\pm$ 3.5] min *vs* [73.6 $\pm$ 4.4] min) (P = 0.000).

TABLE 1 Patients demographics in two groups

Indexes	Conventional group (40 cases)	PSI group (40 cases)	P value
Age (years, mean±SD [range])	67.6 ± 8.4 (55–82)	68.7 ± 9.1 (57–80)	>0.05
Sex (male/female)	7/33	8/32	>0.05
BMI (kg/m^2, mean±SD [range])	26.6 ± 2.2 (23.4–28.3)	25.8 ± 3.9 (22.9–27.9)	>0.05
Varus deformity (°, mean±SD [range])	9.2 ± 3.6 (7.4–12.6)	8.8 ± 2.5 (8.2–13.7)	>0.05
ROM (°, mean±SD [range])	110.6 ± 20.1 (89.7–118.2)	113.4 ± 19.7 (87.3–116.4)	>0.05

BMI, body mass index; P > 0.05, no significant difference; PSI, patient-specific instrumentation; ROM, range of motion.

However, there was no statistically significant difference in the duration of drainage (P = 0.355) and preoperative ROM of the knee (P = 0.787) between the two groups. No significant difference in HSS scores (before surgery: P = 0.220; after surgery: P = 0.536) and AKS scores (before surgery: P = 0.487; after surgery: P = 0.373) had been found between the two groups. The detailed results are shown in Table 2.

Comparison within Groups

The postoperative HSS scores ([86.3 ± 7.6] *vs* [58.1 ± 5.4], P = 0.000) and AKS scores ([84.1 ± 7.2] *vs* [55.6 ± 6.2], P = 0.000) were significantly improved compared with that before surgery in conventional group. The HSS scores ([87.4 ± 8.2] *vs* [56.7 ± 4.7], P = 0.000) and AKS scores ([85.7 ± 8.7] *vs* [54.6 ± 6.6], P = 0.000) after surgery were better raised in PSI group. The detailed results are shown in Table 3.

Radiological Results

Comparison between Groups

The measuring results in CT images showed that the PCA of femoral component in PSI group was smaller than that in conventional group ([0.4 ± 0.2]° *vs* [1.7 ± 2.0]°, P = 0.000). The postoperative PFA in PSI group was smaller than that in conventional group ([0.5 ± 0.3]° *vs* [3.1 ± 1.0]°, P = 0.000). The depth of intramedullary guide in PSI group was less than that in conventional group ([9.4 ± 2.5] cm *vs* [20.4 ± 3.6] cm, P = 0.000). However, there was no significant difference in preoperative PFA between the two groups (P = 0.529). The measuring results in radiographic images of the full-length of lower limb showed that no significant

TABLE 2 The comparison of clinical and radiological results between two groups (mean±SD)

Indexes	Conventional group (40 cases)	PSI group (40 cases)	P value
Operation time (min)	73.6 ± 4.4	87.3 ± 3.5	<0.001
Drainage volume (mL)	305.6 ± 10.8	258.7 ± 11.8	<0.001
Duration of drainage (h)	23.6 ± 4.8	24.5 ± 3.8	>0.05
ROM (after surgery, °)	123.4 ± 12.0	124.2 ± 14.3	>0.05
HSS score (before surgery)	58.1 ± 5.4	56.7 ± 4.7	>0.05
HSS score (after surgery)	86.3 ± 7.6	87.4 ± 8.2	>0.05
AKS score (before surgery)	55.6 ± 6.2	54.6 ± 6.6	>0.05
AKS score (after surgery)	84.1 ± 7.2	85.7 ± 8.7	>0.05
PFA (before surgery, °)	5.4 ± 1.2	5.2 ± 1.6	>0.05
PFA (after surgery, °)	3.1 ± 1.0	0.5 ± 0.3	<0.001
HKA (before surgery, °)	170.8 ± 3.6	171.2 ± 2.5	>0.05
HKA (after surgery, °)	178.8 ± 0.8	178.6 ± 0.7	>0.05
PCA (after surgery, °)	1.7 ± 2.0	0.4 ± 0.2	<0.001
Depth of intramedullary guide (cm)	20.4 ± 3.6	9.4 ± 2.5	<0.001

AKS, American Knee Society; HKA, hip-knee-ankle angle; HSS, Hospital for Special Surgery; P > 0.05, no significant difference; PCA, posterior condylar angle; PFA, patella transverse axis-femoral transepicondylar axis angle; PSI, patient-specific instrumentation; ROM, range of motion.

difference in HKA had been found between the two groups in the coronal plane (before surgery: P = 0.566; after surgery: P = 0.238). The detailed results are shown in Table 2.

Comparison between Groups

The outcomes in CT images showed that the postoperative PFA was smaller than that before surgery in conventional group ([3.1 ± 1.0]° *vs* [5.4 ± 1.2]°, P = 0.000), and the postoperative PFA was also smaller than that before surgery in PSI group ([0.5 ± 0.3]° *vs* [5.2 ± 1.6]°, P = 0.000). The measuring outcomes in radiographic images of the full-length of lower limb showed that the postoperative HKA in coronal plane was significantly improved compared with that before surgery in conventional group ([178.8 ± 0.8]° *vs* [170.8 ± 3.6]°, P = 0.000). The HKA after surgery was better than the preoperative result in PSI group ([178.6 ± 0.7]° *vs* [171.2 ± 2.5]°, P = 0.000). The detailed results are shown in Table 3.

Location and Depth of the Intramedullary Guide in PSI Group

The comparison of the relationship between the actual location of intramedullary guide and the results from SIEMENS NX on CT images of the distal femur in PSI group indicated that the intramedullary guide assisted by PSI was accurate.

TABLE 3 The intragroup comparison of clinical and radiological results before and after surgery (mean±SD)

Indexes	Conventional group (40 cases)			PSI group (40 cases)		
	Before surgery	After surgery	*P* value	Before surgery	After surgery	*P* value
HKA (°)	170.8 ± 3.6	178.8 ± 0.8	<0.001	171.2 ± 2.5	178.6 ± 0.7	<0.001
PFA (°)	5.4 ± 1.2	3.1 ± 1.0	<0.001	5.2 ± 1.6	0.5 ± 0.3	<0.001
HSS score	58.1 ± 5.4	86.3 ± 7.6	<0.001	56.7 ± 4.7	87.4 ± 8.2	<0.001
AKS score	55.6 ± 6.2	84.1 ± 7.2	<0.001	54.6 ± 6.6	85.7 ± 8.7	<0.001

AKS, American Knee Society; HKA, hip-knee-ankle angle; HSS, Hospital for Special Surgery; PFA, patella transverse axis-femoral transepicondylar axis angle; PSI, patient-specific instrumentation.

The depth of the intramedullary guide of PSI group was less than conventional group ([9.4 ± 2.5] cm *vs* [15.4 ± 3.6] cm, *P* = 0.000).

In this study, no intraoperative or early postoperative complications occurred in the PSI group and the conventional group.

Discussion

Personalized PCA and Accurate sTEA

The most important finding of this study was that the PCA was 5.2° ± 1.8° instead of the theoretical 3° by measuring the preoperative CT of the 80 patients enrolled. In the European race, PCL was found to be 3° internally rotated from the sTEA in normal population, the femoral posterior condyle resection was performed with PCL as reference at a standard 3° of external rotation in order to get a rectangular mediolateral flexion gap in traditional TKA. Furthermore, tibial plateau in coronal plane is not parallel to the ground, but with a physiological varus angle, an average of 3°[21,22]. Hence, externally rotated bone resection performed at the distal femur can achieve the same tension of the collateral ligaments, and maintain stability during the knee flexion process. Other researchers reported that the PCA was 3.3° ± 1.5°[22] or 1.6° ± 1.9°[23] in patients with OA of the knee. Therefore, conventional rotational alignment with 3° extorsion was not applicable to all patients of knee OA. Preoperative personalized measurement and intraoperative personalized osteotomy could better meet the actual needs of patients. According to the anatomical characteristics of individuals, reconstruction of more accurate rotational alignment is more conducive to the balance of knee flexion gap. In order to achieve more accurate intraoperative localization and osteotomy, more and more surgeons chose to use navigation devices which would prolong the operation time, increase the blood loss volume and the risk of infection[24].

In the current study, the sTEA was designed on the surface of the PSI by SIEMENS NX 12.0 through CT data. The measurement of preoperative CT reduced the intraoperative palpation error of sTEA (Fig. 8A). sTEA was measured on three-dimensional images and designed on PSI to further improve the accuracy of rotational alignment (Fig. 8B). It could be found that PCA measured by two-dimensional CT before surgery was basically equal to that measured by three-dimensional image. Furthermore, the bone cut line of the posterior condyle was basically parallel to sTEA in postoperative CT (Fig. 8C), which further verified the repeatability and accuracy of the PSI. Therefore, the 3DP PSI had certain advantages in assisting the correct femoral posterior condyle bone resections.

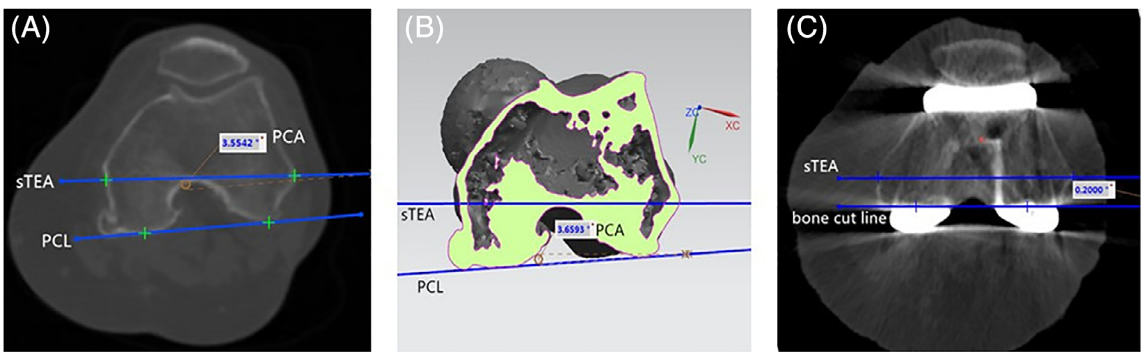

Fig. 8 The measurement of femoral rotational alignment before and after surgery: (A) PCA was measured by two-dimensional CT before surgery; (B) PCA was measured by three-dimensional image before surgery; (C) The bone cut line of the posterior condyle was basically parallel to sTEA in postoperative CT. PCA, posterior condylar angle; sTEA, surgical transepicondylar axis; PCA, posterior condylar angle.

The choice of using sTEA or anatomical transepicondylar axis (aTEA) as a reference to determine PCA varies among joint surgeons. Different options will produce different results in femoral component rotation. Kumar *et al.* found that the mean condylar twist angle (CTA, the angle between the aTEA and PCL) was 5.40° ± 1.88°, mean PCA was 0.71° ± 1.95°, and mean angle between aTEA and sTEA was 4.88°[25]. According to a large number of clinical practices in our center, the sulcus was more easily found in the medial femoral epicondyle than the prominence. Therefore, this study strictly selected the sTEA as the reference axis to determine PCA. In other words, the sTEA was used as a reference for the rotational axis of the knee. Surgeons who chose aTEA as the reference are concerned with the difficulty in determining the sulcus of the medial femoral epicondyle due to the abnormal anatomical structure development. Moreover, sTEA determined by the method of intraoperative palpation is very rough, and is easily affected by the surgeon's experience. Yoshino *et al.* discovered that the medial sulcus could only be determined in 30% of the knees with OA, and the angle between sTEA and aTEA was 3.2° ± 1°[26,27]. Others showed that referring to sTEA could lead to mean femoral component misplacement of 3.5°[28].

Better Patellofemoral Tracking

In this study, PFA after TKA in both the PSI group and the conventional group was significantly improved, which was shown as a reduction in numerical value and a more parallel patella transverse axis to sTEA in postoperative CT. The postoperative PFA of the PSI group was significantly lower than that of the conventional group, and the patella transverse axis was almost completely parallel to sTEA, which proved that the PSI technology had obvious advantages in improving the patellar tracking. This further indicated that the PSI technology had certain preponderance in establishing more accurate rotational alignment while still being scientific and practical in the treatment of knee OA. On the one hand, soft tissues need to be released in order to achieve a balanced flexion gap for compensation when the rotational alignment is wrong, and even excessive releasing can lead to increased trauma, and postoperative pain symptoms persist in patients with low satisfaction. Therefore, an accurate rotational alignment is the key to obtain a rectangular balanced flexion gap. It can also effectively improve patellofemoral tracking, which is crucial for patients after TKA, and reduce the incidence of anterior knee pain. On the other hand, the flexion gap asymmetry could cause maltracking of patella and even early failure of prosthesis[29]. The wrong patellofemoral tracking would limit the flexion and extension of the knee. Patella in the central position of the femoral trochlear can increase the ROM of the knee, reduce the incidence of anterior knee pain, reduce postoperative patella cartilage wear, and optimize the overall function of the knee[28]. Excessive internal or external rotation of femoral component would affect patellar tracking, and excessive internal rotation might cause patella dislocation. Berger *et al.* reported that patients with lateral patellar tracking and tilting had an excessive internal rotation of 1° to 4°, patella subluxation at 3° to 8°, dislocation at 7° to 16°, and component failure at 8° to 17°[30].

Shortening the Depth of the Intramedullary Guide

The intramedullary guide should refer to 1 cm above the insertion point of posterior cruciate ligament[31]. However, due to the influence of osteophytes and anatomical abnormality, the femoral entry point identified during the operation might not be accurate. In conventional TKA technology, intramedullary guide is often inserted deeply into the shaft of the femur, which would increase the surgical trauma. This study found that the depth of intramedullary guide in the PSI group was only half that of the conventional group, which could reduce surgical trauma and postoperative pain around the thigh. TKA assisted by PSI could accurately determine the area and perform intramedullary guide. Through the analysis and reconstruction of preoperative CT data, the MIMICS software could simulate the surface of the distal femur, projecting the anatomical axis onto the surface of it. The area of performing intramedullary guide was lengthened and protruded on the surface of the PSI, which could significantly shorten the depth of the intramedullary guide and accurately determine the anatomical axis of the femur. This study found that the depth of intramedullary guide in PSI group was only half that of the conventional group, which could reduce surgical trauma and postoperative pain around the thigh.

Less Trauma and Satisfactory Short-Term Clinical Efficacy

In the current study, we found that the postoperative drainage volume of patients in the PSI group was significantly lower than that in the conventional group, which further explained that there was less bleeding and trauma through using PSI. Intramedullary guide with PSI could avoid repeated intraoperative modifications and reduced the damage to intramedullary blood vessels, so that the distal femur bone resection could be completed in a single operation. For inexperienced surgeons, especially if there are numerous osteophytes and anatomical abnormalities in the distal femur, PSI technology is a better choice that could reduce the repetition of bone cutting.

We could discover that the TKA assisted by PSI technology took a longer operation time, which was about 15 min more than the conventional group. The reasons for this might be related to the following factors. Firstly, the use of PSI was an additional operation step and took more time to fix PSI to the distal femur. Moreover, the surgeon had a learning curve with this new technology and needed to calibrate the sTEA determined by PSI repeatedly. In terms of other clinical outcomes, there were no statistically significant differences in postoperative HKA, HSS, and AKS scores between the two groups, but the postoperative scores of the two groups were significantly improved compared with those before the surgery. This indicated that the two groups obtained the similar short-term clinical outcomes and could achieve the purpose of recovering the mechanical axis of the lower limb, correcting deformity, and improving the function of the affected limb.

Accurate Alignment

In this study, we also found that the HKA that was reconstructed after surgery is not 180°. The previous studies had shown that the mechanical axis of the lower limb of the normal population was not a straight line, but with a mild varus[32]. For the HKA, it is most clinically relevant to determine the number of outliers greater than 3° of varus/valgus[33].In this study, no outliers that satisfied the conditions were found in postoperative HKA in both groups, and the residual varus of lower extremity alignment was less than 2°, which may be still within the margin for error for the radiological measurement and osteotomy. An accurate rotational alignment can equalize both the inside and the outside of the flexion gap, and make the force on the medial and lateral compartment of the postoperative knee more uniform, which can reduce the wear of the polyethylene bearings and extend the service life of the prosthesis[34]. Liu *et al.* found that in the 32 patients with 46 cases of knee OA, personalized external rotation of the femoral prosthesis according to the direction of sTEA resulted in a better-balanced flexion gap[35].

Limitations

The present study also has some limitations. Firstly, the sample size was relatively small. However, the *post hoc* analysis was performed, and the power was more than 0.8. Secondly, only one angle measuring tool of PACS system (INFINITT Ltd., South Korea) was used for postoperative CT measurement, and only PFA and PCA were used to evalua and only PFA and PCA were used to evaluate the rotational alignment. Previous studies have shown that there are many methods to evaluate rotational alignment and no uniform standard has been established. Several authors have published data using the PCA, while others have used the CTA, thus creating doubts as to the normal femoral component rotation, as these two angles are different. There are many cases in which the medial epicondyle sulcus cannot be identified, and the definition of presence or absence of the sulcus varies according to different researchers who measure CT images at different sections. The results are subjective and without uniform standard, therefore resulting in different outcomes. Previous studies have shown that malrotational alignment could lead to early loosening of the prosthesis, accelerated wear of the polyethylene bearings, and even TKA failure. In this study, CT scans could not show the cartilage of the distal femur and we ignored the influence of the articular cartilage thickness. Using 3DP technology, there was a small gap between the inner side of the PSI printed with CT data and the distal femur, which could not achieve a complete match. The best way was to perform the MRI examination on patients before surgery, and print PSI according to the MRI data. However, due to the personal willingness and financial status of the patients, this plan was not implemented. Since there was no cartilage coverage on the medial and lateral epicondyles of the femur, so the sTEA determined by CT scan data was relatively reliable. Meanwhile, the stability and accuracy of PSI were checked twice during the operation, which could also reduce the error caused by the influence of the residual articular cartilage thickness. Last but not the least, the 6-month clinical scores were considered short-term follow-up scores; it was too short a duration of follow-up and had limited clinical implications. Further studies are needed to confirm the long-term clinical efficacy of the novel 3D-printed patient-specific intramedullary guide.

Conclusion

PSI technology could not only assist in intramedullary guide and align femoral rotation more accurately, but also could potentially improve patella tracking with less trauma compared with conventional TKA. In conclusion, the PSI designed in this study had the advantages of correct alignment, as well as the disadvantages of prolonged operation time and higher cost. The postoperative follow-up proved that the clinical outcomes in the short term of TKA assisted by PSI was satisfactory. However, further studies are needed to confirm the long-term clinical effects.

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