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Original Article

Accuracy and efficacy of osteotomy in total knee arthroplasty with patient-specific navigational template

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Abstract: This study develops and validates a novel patient-specific navigational template for total knee arthroplasty (TKA). A total of 70 patients who underwent TKA were randomized and divided into conventional method group and navigational template group. In the navigational template group, the patient-specific navigational templates were designed and used intraoperatively to assist 35 patients with knee arthroplasty. Information on operation time and blood loss was recorded. After surgery, the positions of the prosthesis were evaluated using CT scan and X-rays. Analysis showed significant differences in errors between the two techniques. In addition, mean operation time and mean blood loss were statistically and significantly lower in the navigational template group than in the conventional group. Overall, the navigational template method showed a high degree of accuracy and efficacy.

Keywords: Total knee arthroplasty, navigation, custom template, rapid prototyping

Introduction

Over the past few decades, correct alignment has been an important factor for total knee arthroplasty (TKA) with good predictable outcomes [1, 2]. Several methods have been used to obtain neutral alignment following TKA. However, the accuracy of the prosthesis with conventional method has reached a bottleneck with little improvement because of the palpating anatomical landmarks in alignment determination [3]. Many studies have indicated that there exists no significant difference between computer-assisted navigated TKA and conventional TKA [4-7] because navigation systems require registration of the bony landmarks identified via the perception and experience of the surgeon. These landmarks are also relatively ambiguous and are subject to errors and require additional instruments and insertion of tracking pins. Potential errors for misalignment may be due to bone anatomy, visual miscalculation of the surgeon and general technical limitations [5, 8, 9].

In addition, conventional techniques generally penetrates the intramedullary canals, increasing the risk of infection and fat embolism. However, the primary limitations of computer-assisted navigational systems include high cost and complexity.

Recently, a patient-specific alignment guide, signature personalized patient care (SPPC) (Biomet Inc., Warsaw, IN) was developed based on a preoperative MRI scan of leg of the patient [10]. Nevertheless, literature has confirmed that bone models generated from MRI scans were dimensionally less accurate than those generated from CT scans. Furthermore, the bone models generated from MRI scans were visibly inferior to those generated from CT scans [11]. Apart from that, SPPC requires 6 weeks of preparation time [10].

Considering these difficulties, we reported a novel patient-specific navigational template based on a preoperative CT scan for TKA in July 2011 [1]. Based on this technique, we present the preliminary results of first 35 consecutive cases operated using this new technique and also compared them with the results from a matched control group operated using conventional intramedullary alignment technique. The surgical duration and degree of blood loss is expected to be lower in the navigational template group as compared to the conventional group. Alignment was expected to be superior

Figure 1. 3D model of the knee. A. Femoral view; B. Tibial view.

in the navigational template group as compared to the conventional intramedullary alignment technique group.

Patients and methods

A total of 70 patients underwent TKA from January 2012 to December 2013. All of them were performed by the same surgeon. The patients were randomly divided into two groups (conventional method group and navigational template method group). Participants were selected from among those patients with indications for primary TKA, including serious knee osteoarthritis. Exclusion criteria included infections, revision surgery, and severe knee instability. Randomization was done using a table of random numbers. In both groups, the same cemented implants (Scorpio Posterior Stabilized System, Stryker, Mahwah, NJ) were used. No exclusions were defined regarding age, gender, degree of leg axis and deviation, or previous surgeries. Written consent was obtained from the participants, and the institutional review board approved the study protocol.

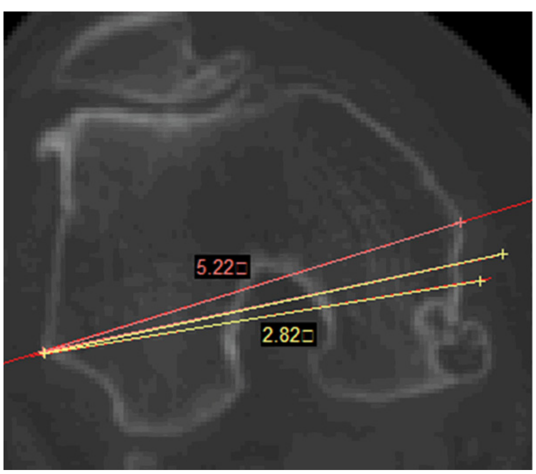

Figure 2. Measuring the rotational angle preoperatively by Reverse Engineering software.

In the navigational template group, 25 female and 10 male patients were included. The mean age was 68.5±4.8 years (range: 63 to 75 years), and the mean preoperative deviation of leg axis was 6.1°±4.2° (range: 16° varus to 14° valgus).

In the conventional group, 26 female and 9 male patients were included. The mean age was 67.8±3.4 years (range: 64 to 72 years), and the mean preoperative deviation of the leg axis was 6.5°±4.4° (range: 17° varus to 18° valgus).

A spiral 3D CT scan (LightSpeed VCT, GE) was performed preoperatively on the lower limb of each patient with 0.625 mm slice thickness and 0.35 mm in-plane resolution. The images

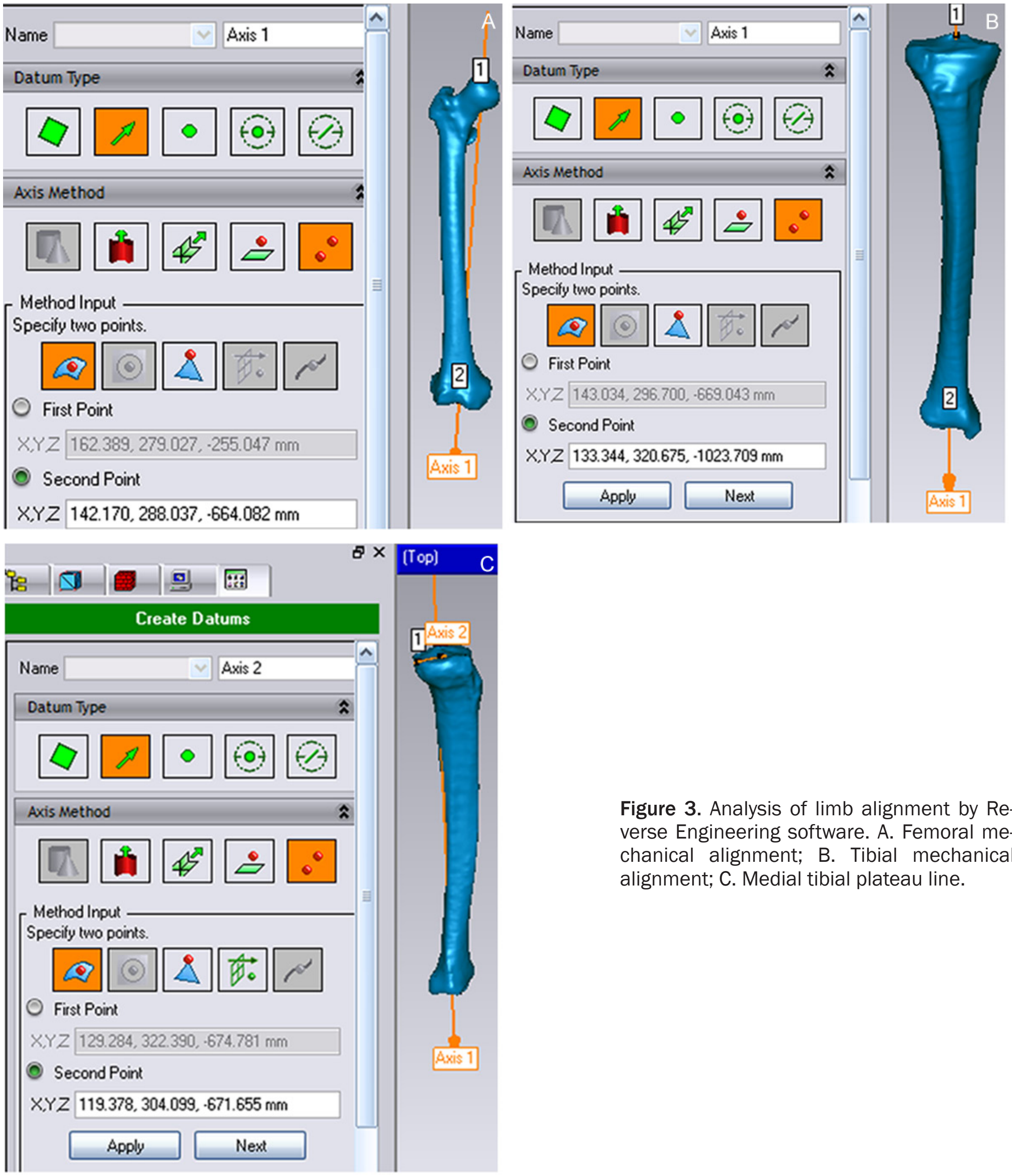

Figure 3. Analysis of limb alignment by Reverse Engineering software. A. Femoral mechanical alignment; B. Tibial mechanical alignment; C. Medial tibial plateau line.

were stored in DICOM format and transferred to a workstation running MIMICS 10.01 software (Materialise, Belgium) to generate a 3D reconstruction model of the desired tibia and femur (**Figure 1**). The femoral external rotation angle of the patients were positioned and measured in the 2D image of the MIMICS before surgery (**Figure 2**).

The lower limb 3D model was exported in stereolithography (STL) format to a workstation running the reverse-engineering software, Launch Geomagic Studio10.0 (Geomagic Inc.,), to determine the optimal mechanical alignment. Using the Geomagic Studio software, the femoral head was regarded as a sphere, and its center could be identified. The femoral center is located under the roof of the intercondylar notch. The femoral mechanical axis lies between the center of the femur and the center of the femoral head (**Figure 3A**). The tibial mechanical axis is the line connecting the prox-

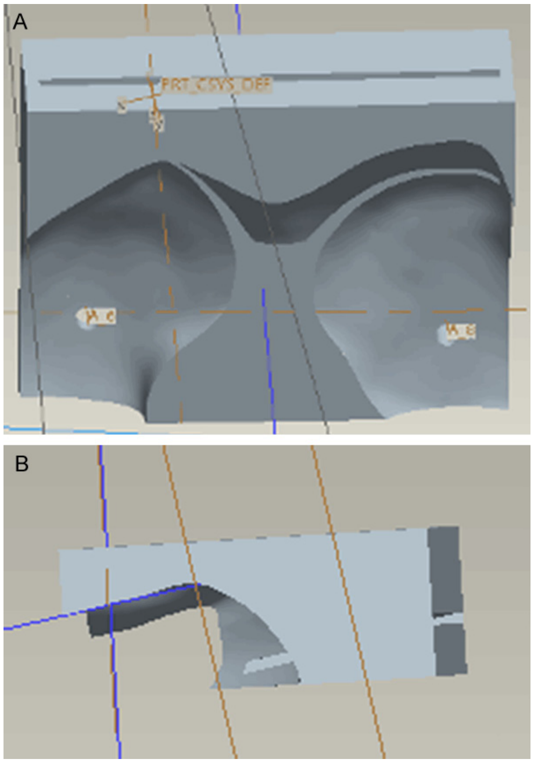

Figure 4. Design of the navigational templates. A. Virtual femoral template. B. Virtual tibial template.

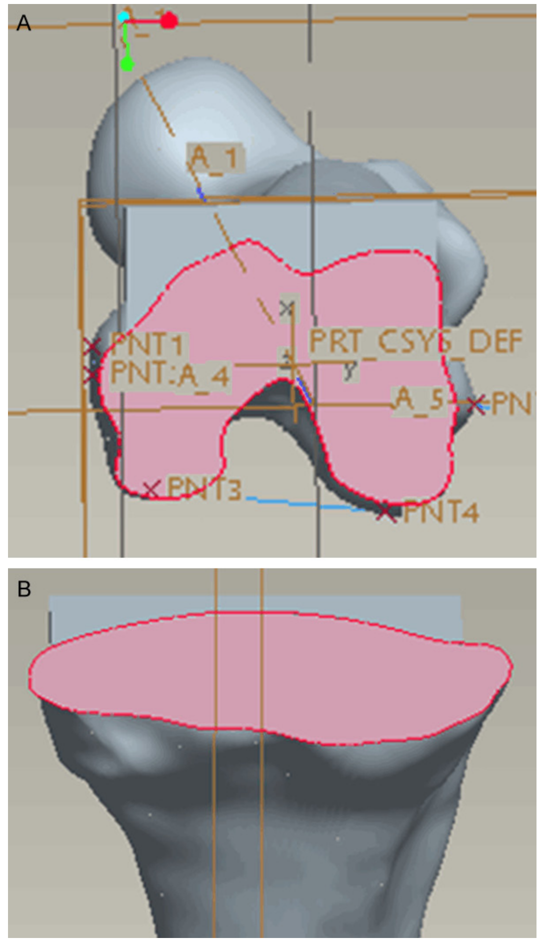

Figure 5. Surface shape after virtually cutting the distal femur and proximal tibia.

imal tibial and the ankle centers (**Figure 3B**). The proximal tibial center is located at the intersection of the transcondylar and the anterior/posterior axes. The ankle center is the midpoint of the bimalleolar axis. In the study, the medial tibial plateau line was chosen to measure the posterior slope angle of the tibia (**Figure 3C**). Subsequently, curved surface reconstruction was performed based on the point cloud data of the STL models. Finally, the curved surface was exported in an initial graphics exchange specification format to a workstation running the reverse-engineering software, Pro ENGINEER Wildfire 4.0 (Pro/E, PTC, USA), to determine the optimal rotational alignment and the position of osteotomy.

Following the identification of the optimal alignment and position of osteotomy, a navigational template was constructed with a 10 mm thick osteotomy gap. Two drill guides were used to define the rotational alignment of the femur. Another tibial template was constructed with an 8 mm thick osteotomy gap and inherent posterior slope angle. The template surfaces were created as the inverse of the distal femur and proximal tibia surface, thereby potentially enabling a near-perfect fit (**Figure 4**). By using a computer, the distal femur and proximal tibia were cut along the gap to acquire their virtual surfaces to measure the degree of match after actual osteotomy (**Figure 5**).

The femur and tibia navigational template and the verification templates based on the virtual surfaces of femur and tibia after osteotomy were produced in acrylate resin (Somos 14120, DSM Desotech Inc,) by using stereolithography, a rapid prototyping (RP) technique (Hen Tong Company, China).

All TKA procedures were performed using a medial parapatellar arthrotomy with patellar eversion under pneumatic tourniquet control. All operations were performed by the same surgeon, Dr. Ding. In the conventional group, 35 patients underwent TKA by using standard instrumentation (an intramedullary guide for distal femoral resection and an extramedullary

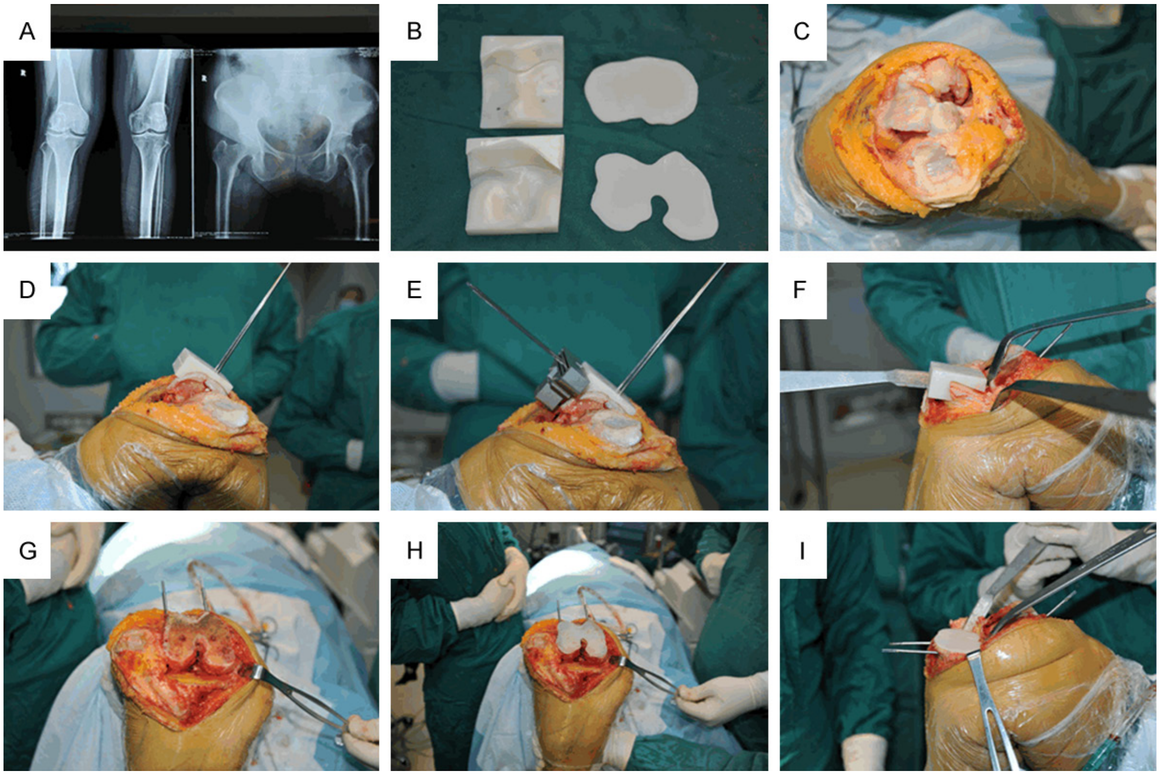

Figure 6. Total knee arthroplasty was performed on a female patient diagnosed with severe knee osteoarthritis. In this case, the right knee was in pain significantly, and the left knee experienced minimal pain. Subsequently, her right knee was replaced; A. The X-ray shows knee degenerative changes and hyperplasia, especially the right knee; B. RP model of femur and tibia navigational template, and the verification template; C. Actual cartilage degeneration; D. Navigational template fitted the femoral condyle perfectly; E. Positioned distal femur osteotomy plane and external rotation axis; F. Navigational template fitted the tibial plateau perfectly; G-I. Actual surface of the distal femur and the proximal tibia after osteotomy matching with the surface shape in the virtual setting by using the navigational template.

guide for proximal tibial resection). All anatomical landmarks and alignments were obtained by palpating.

In the navigational template group, TKA was performed on 35 patients after locating the axis and osteotomy plane by navigational template (**Figure 6**). First, the femoral navigational template was placed on the femoral condyle by the surgeon. Two K-wire drill guides marked the position of the rotational alignment. Subsequently, the Stryker instrument was placed along the osteotomy gap of the navigational template. By removing the two K-wires, the surgeon cut the distal femur by using an electric saw along the gap. Finally, the verification template was placed to validate whether the actual section matched the surface cut in the virtual setting. The surgeon then measured the femoral size and placed the cutting block according to the located rotational alignment to cut the anteroposterior condyle. The tibial navigational template was subsequently placed on the tibial plateau to locate the osteotomy plane and posterior slope. The Johnson instrument was placed, and the proximal tibia was cut along the gap. Finally, the verification template was placed to validate the fit of the actual section to the surface cut in the virtual setting (**Figure 6**).

A tourniquet tied to the thigh was inflated to 350 mmHg when the surgery began. Blood loss (ml of blood in the suction device, prior to application of a tourniquet and prior to rinsing the knee) and operation time (min. from incision until the bandage was placed) were recorded by an independent OR nurse.

The postoperative radiograph assessment was identical to the preoperative assessment, including the gemstone energy spectrum CT scan and X-rays. All radiographs were analyzed by one surgeon (Dr. Xu) blinded to the surgical technique used. The mechanical axis was the angle among the centers of the femoral head,

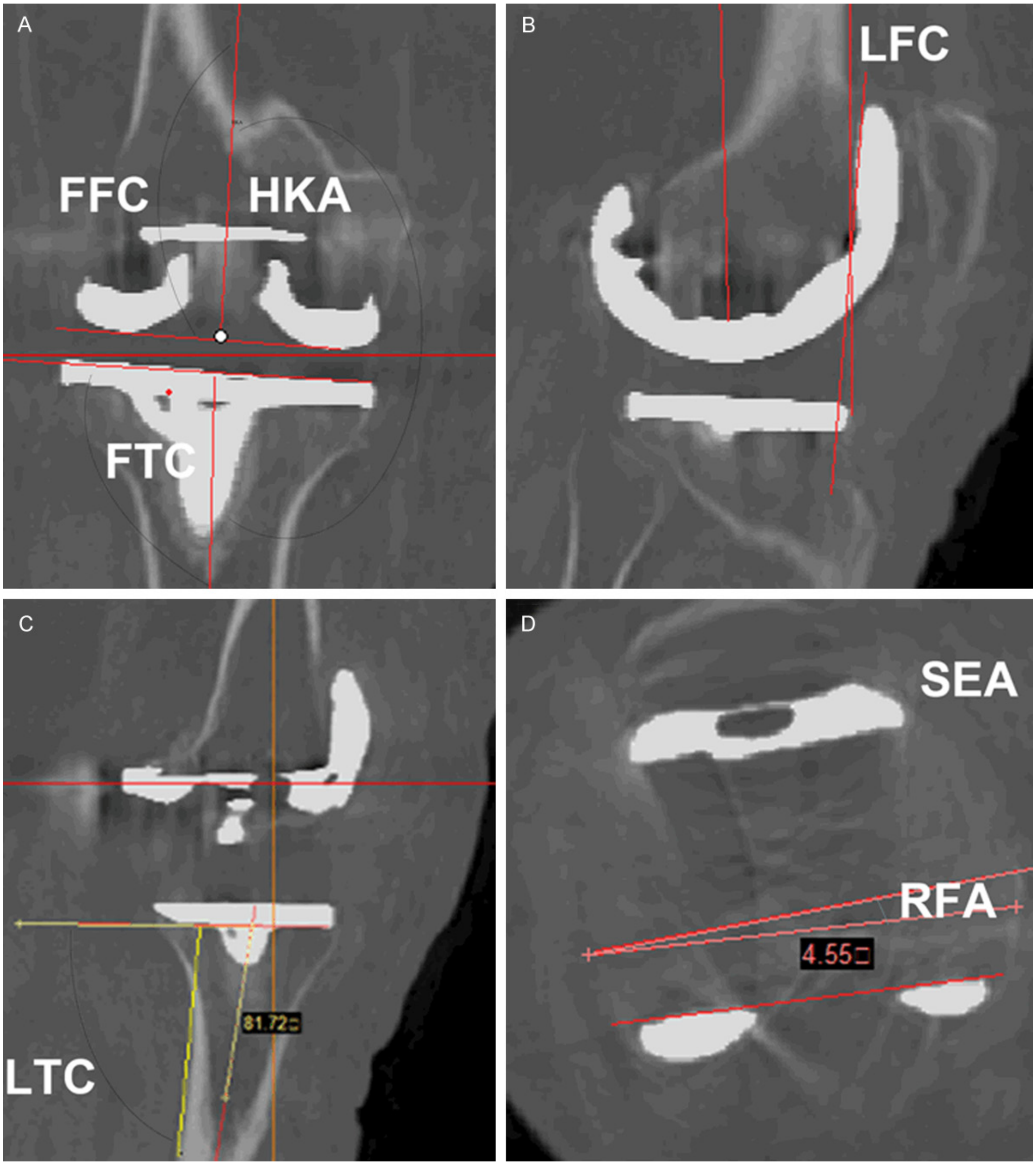

Figure 7. Imagic examination shows good positioning of the prosthesis. A. Distal resection of the femur and the proximal resection of the tibia is almost perpendicular to the mechanical axis of the leg in the coronal plane (FFC, FTC, HKA); B and C. Analysis of the angle in the sagittal plane (LFC, LTC); D. The posterior surface resection is parallel to the transepicondylar axis (RFA).

knee, and ankle. Alignment of the femoral and tibial components were measured as recommended with respect to the mechanical axis in the frontal plane and the longitudinal axis of the shaft of the femur and tibia, respectively, for the two components in the sagittal plane. For the mechanical axis of the leg and frontal alignment, the following angles were measured: the hip-knee-ankle angle (mechanical axis of the leg), the frontal femoral component (FFC) angle, and the frontal tibial component (FTC) angle (**Figure 7A**). For the sagittal plane, the following angles were measured: the lateral femoral component (LFC) angle and the lateral tibial component (LTC) angle (**Figure 7B**, **7C**). The LFC angle was measured between the anterior cor-

Table 1. Mechanical axis

	Navigational (n=35)	Conventional (n=35)	*P*-value
Mean (SD)	181°	177°	<0.001
Range	176°-183°	170°-187°	
Number of outliers >3°	1/35	8/35	<0.001

Table 2. FFC and FTC

	Navigational (n=35)	Conventional (n=35)	*P*-value
FFC, Deviation	1.0°±0.8°	2.6°±1.8°	<0.001
FFC, Range	87°-92°	84°-98°	
FFC, Number of outliers >3°	1/35	9/35	<0.001
FTC, Deviation	1.2°±1.0°	2.8°±1.5°	<0.001
FTC, Range	87°-95°	85°-96°	
FTC, Number of outliers >3°	1/35	10/35	<0.001

tex of the distal femur and the shield of the femoral component. The LTC angle was measured in relation to the posterior tibial cortex. In addition, we measured the rotational femoral angle (RFA) by knee reconstruction (**Figure 7D**).

Statistical analysis

Student's t-test was used to compare blood loss, operation time, and alignment of the mechanical axis and individual femoral and tibial components between the navigational template group and the conventional method group. Differences were considered significant at P<0.05. All analyses were performed using SPSS software.

Results

Patients and preoperative mechanical leg axis

The preoperative deviation of the mechanical leg axis was not significantly different between the navigational template group and the conventional group (P>0.05). No significant differences were found for age and gender distribution between both groups (P>0.05).

Accuracy and efficacy of the navigational template

The accuracy of the navigational template was examined before operation by placing it on the femoral condyle and tibial plateau. Each of the navigational templates was found to fit its corresponding biomodel appropriately without any free movement.

During the operation, manually finding the best fit for the template was easy because no significant free motion of the template was observed. The template was positioned and pressed slightly against the femoral condyle and tibial plateau. Therefore, the navigational template fulfilled its purpose for *in situ* osteotomy. Visual inspection showed that the actual surfaces after distal femur and proximal tibia osteotomy were found to perfectly match the templates of the virtual surfaces without any violation.

Postoperative mechanical leg axis

In the navigational template group, 97.1% of the patients (34/35) had a postoperative leg axis within the range of ±3° compared with 77.1% (27/35) in the conventional group (P<0.001). The mean value of the mechanical axis in the navigational template group was 181° and ranged from 3° valgus to 4° varus, whereas the mechanical axis in the conventional group was 177° and ranged from 7° valgus to 10° varus (**Table 1**).

FFC and FTC angles

In the navigational template group, the FFC angle was observed in 97.1% of patients (34/35) with a varus/valgus alignment within the range of ±3° compared with 71.4% (25/35) in the conventional group. The mean deviation from the neutral axis was 1.0° (±0.8°, range: 3° valgus to 2° varus) in the navigational template group and 2.6° (±1.8°, range: 6° valgus to 8° varus) in the conventional group (P<0.001) (**Table 2**).

The FTC angle had a varus/valgus alignment within the range of ±3° in 97.1% of patients (34/35) in the navigational template group compared with 74.3% (26/35) in the conventional group. The mean deviation from the neutral position was 1.2° (±1.0° range 3° valgus to 5° varus) in the navigational template group and 2.8° (±1.5°, range 5° valgus to 6° varus) in the conventional group (P<0.001) (**Table 2**).

LFC and LTC angles

The mean LFC angle was 4.5° (±3.2°, range: 2° extension to 9° flexion) in the navigational template group, whereas the LFC angle in the conventional group was 9.3° (±4.3°, range: 4° flexion to 12° flexion) (P<0.001) (**Table 3**).

Table 3. LFC and LTC

	Navigational (n=35)	Conventional (n=35)	*P*-value
LFC, Deviation	4.5°±3.2°	9.3°±4.3°	<0.001
LFC, Range	2°-9°	4°-12°	
LTC, Deviation	5.3°±2.1°	3.6°±2.7°	<0.001
LTC, Range	85°-90°	86°-95°	

Table 4. RFA

	Navigational (n=35)	Conventional (n=35)	*P*-value
Preoperative	4.8°±1.1°	4.5°±0.8°	>0.05
Postoperative	5.0°±0.6°	2.3°±1.2°	<0.001

Table 5. Operation time and Blood loss, Mean (SD)

	Navigational	Conventional	*P*-value
Operation time, min	45 (8)	60 (10)	<0.001
Blood loss, ml	200 (45)	290 (60)	<0.001

The navigational template patients had a posterior slope of the tibial component of 5.3° (±2.1° range: 3° to 8°), whereas those in the control group had 3.6° (±2.7° range: 0° to 7°) (P<0.001). The mean LTC angle was 84° (±2.9° range: ventral 85° to 90° dorsal) in the navigational template group compared with 87° (±2.5° range: 86° to 95°) in the conventional group (**Table 3**).

RFA angle

The mean values of preoperative and postoperative RFA angle measured on the CT image were 4.5°±0.8° and 2.3°±1.2° in the conventional group and 4.8°±1.1° and 5.0°±0.6° in the navigational template group. The difference between the two groups was statistically significant (**Table 4**).

Using this novel custom-fit navigational template, the operation was simplified and made accurate. The operation time was considerably reduced. On average, each TKA was completed for approximately 45 min. The navigational template technique does not penetrate the intramedullary canals and thereby reduces blood loss, risk of infection, and marrow embolization. Mean operation time and mean blood loss were statistically and significantly lower in the navigational template group than the conventional group (**Table 5**). Currently, the production time for the RP model is approximately 2 d, and the cost is approximately USD 60 per template. This cost can be reduced in the future. In addition, the cost can be reduced to USD 40 if the RP model of the knee is deemed unnecessary.

Discussion

An important factor for the TKA to succeed is the reconstruction of the lower limb mechanical axis during surgery. Biomechanics and biotribology research demonstrated that restoring the lower extremity precisely can be a very effective method to avoid polyethylene wear. Liau et al. used 3D finite element analysis techniques to study the effect of lower extremity malalignment on the part of the tibial polyethylene liner. The results indicated that compared with the neutral position of the lower limb alignment, analog 5° varus tilt on the line increases the contact pressure to 145.9%. Increased contact pressure will inevitably lead to increased polyethylene wear, causing periprosthetic osteolysis and will eventually lead to the loosening of the prosthesis and TKA failure [12]. The clinical long-term follow-up also confirmed that the incidence of aseptic loosening with limb alignment deviation postoperatively increased, which is consistent with the findings of Liau et al. Many scholars reported that less than 3° varus–valgus alignment of the lower limb in the frontal plane was optimal. Rand and Coventry found that the 10-year survival of patients with axis deviation of <4° is 90%. In contrast, if the axis deviation was >4°, the 10-year survival of patients with varus was reduced to 75%, and the survival of valgus patients was reduced to 71% [13].

In perfect TKA surgery, the distal femoral osteotomy should be perpendicular to the mechanical axis of the femur, and the proximal tibia in the coronal plane should be perpendicular to the mechanical axis of the tibia [14-18]. The angle between the femur anatomical axis and the mechanical axis reflects an aligned lower limb. The technique is often used to determine the valgus angle of the distal femoral osteotomy when employing intramedullary positioning. Currently, all TKA systems assume that the angle of all femur anatomical–mechanical axis changes from 5° to 6°. Therefore, fixed osteotomy angle positioning, which is contrary to the anatomical differences between individuals, destroys the normal knee biomechanical characteristics [19].

In this study, the navigation template was designed preoperatively and positioned precisely by professional engineering software. The production model was matched with the bone completely. Using the navigation template, 97.1% of patients achieved a varus-valgus alignment deviation of less than 3°. Less than 77.1% of the patients had a deviation alignment of less than 3° through traditional surgery. Only 83% of patients had an alignment deviation of less than 3° using the navigation system [5-7].

The navigation template not only ensures the osteotomy surfaces of the distal femur and proximal vertical tibia with lower limb mechanical axis, but also enables the precise positioning of the external rotation axis. The standard of conventional unified 5° posterior slope osteotomy violated the anatomy differences in patients. The navigation template measures and positions the tibial plateau posterior slope angle preoperatively for different individuals. Therefore, the navigation template achieves the principles of individualized osteotomy and guarantees TKA patient biomechanics to avoid prosthesis aseptic loosening rate because of the deviation of limb alignment.

The accuracy of traditional, unarmed positioning osteotomy completely depends on personal experiences and imaging equipments, and the disadvantages of navigation systems include high cost, operation complexity, and poor stability. The technique is still difficult to proliferate and apply. The design of the navigation template is feasible for the surgeon as long as the template and femoral condyle and tibial plateau fit precisely. This template can position the axis and osteotomy plane, does not rely on personal experiences, assists new doctors to overcome the discomfort of positioning lower limb mechanical axis and external rotation axis, and shortens the learning time of new doctors in knee replacement, which also significantly reduces the duration of the surgery. Operations can also be simulated in the preoperative stage. Furthermore, the prosthesis model can be predicted, thereby avoiding excessive osteotomy and iatrogenic errors. The individualized custom template is accurate, has low cost, and provides a new approach for knee replacement.

Traditional intramedullary technology significantly increases the amount of blood loss because of the interference of the marrow cavity [20]. The risk of infection increases with the insertion of the implant into the medullary cavity. Implant insertion will also increase the pressure in the bone marrow cavity, which inevitably leads to a spillover of fat droplets and increase the incidence of fat embolism [21]. However, the designed individualized navigation template without interfering the marrow cavity avoids medullary cavity bleeding, reduces the amount of blood loss, and significantly reduces the risk of infection and incidence of fat embolism.

Compared with the template based on a preoperative MRI scan of the leg of the patient, the production time for our navigational template is approximately 2 d to less than six weeks. Literature has confirmed that bone models generated from MRI scans were dimensionally less accurate than those generated from CT scans. Furthermore, the bone models generated from MRI scans were visibly inferior to those generated from the CT scans [11]. Therefore, CT is likely to provide the optimum surgical outcome when used to manufacture patient-specific templates.

In this study, modern digital technology was applied to explore full knee replacement axis positioning by using reverse engineering principles. Modern digital technology was also employed to design individualized positioning and navigation template. The method has been applied in experimental and clinical applications and has been found to be feasible with promising prospects.

Disclosure of conflict of interest

None.

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