

Original Article

Alignment results of infrared computer-assisted navigation of total knee arthroplasty for end-stage knee osteoarthritis

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Abstract: Objective: Total knee arthroplasty (TKA) is one of the most conventional surgeries used to solve dyskinesia caused by knee joint degeneration; however, ambiguous prosthesis position and angle after TKA can cause serious complications. This study evaluated the outcomes of infrared computer-assisted navigation (ICAN) of TKA for end-stage knee osteoarthritis. Methods: Forty-six end-stage knee osteoarthritis patients who underwent TKA were randomly divided into computer-assisted orthopedic surgery (CAOS) (n = 23) and non-CAOS (n = 23) groups. The intraoperative conditions, postoperative complications, soft tissue balancing, functional scores, and X-ray data were compared between groups. Results: The CAOS group showed longer surgery time and higher range of motion than the non-CAOS group. No significant differences in American Knee Society Score (AKSS) and Oxford Knee Score were observed between the two groups. Compared to those in the non-CAOS group, the error of the lower limb line, angle of soft tissue balancing, separation of soft tissue, and angular deviation (α , β , γ , δ) of the implants were much lower in the CAOS group. Conclusion: The ICAN system for TKA surgery was associated with less intraoperative blood loss and suitable position and angle in patients with end-stage knee osteoarthritis.

Keywords: End-stage knee osteoarthritis, total knee arthroplasty, computer-assisted navigation system, limb alignment

Introduction

Total knee arthroplasty (TKA) is one of the most common surgical procedures in the orthopedics field. The procedure is frequently performed in elderly patients although increasing incidence of postoperative infection have been reported [1, 2]. TKA is one of the main treatment methods for knee joint degeneration including telophase osteoarthritis and severe joint deformity [3]. However, a Chinese report demonstrated that only 70-85% of patients who received traditional TKA showed satisfying lower limb alignment [4]. Serious complications can occur due to ambiguous prosthesis position and angle after TKA [5].

Compared to the conventional technique, some reports have suggested that computer-assisted orthopedic surgery (CAOS) could improve the alignment of the components in TKA [6, 7].

A meta-analysis showed an increased rate of outliers (defined as valgus or more than 3° malalignment varus) for the tibial and femoral component following CAOS [8]. Therefore, whether the use of CAOS can help to improve the radiological outcome of TKA remains controversial [9]. There is also debate regarding whether a perfect alignment should be the target for TKA outcome assessment [10]. Currently, a good alignment in combination with good function has been proposed to be of great importance for clinical outcomes and implant longevity in TKA patients [11-13]. To our knowledge, few clinical trials have assessed alignment outcomes for use of CAOS during TKA.

This retrospective cohort study compared clinical and radiographic results to assess differences in functional results between traditional TKA and CAOS methods.

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Table 1. Comparisons of basic information between the CAOS and non-CAOS groups

Index	CAOS (n = 23)	Non-CAOS (n = 23)	χ^2/t value	P value
Sex (male/female)	10/13	8/15	0.365	0.546
Age (years, $\bar{x} \pm s$)	64.16 \pm 6.26	65.21 \pm 6.73	-0.548	0.587
Body mass index (kg/m ² , $\bar{x} \pm s$)	24.53 \pm 4.62	25.73 \pm 4.73	-0.870	0.389
Preoperative AKSS score ($\bar{x} \pm s$)	35.41 \pm 6.72	34.68 \pm 5.83	0.394	0.696
Preoperative Oxford score ($\bar{x} \pm s$)	21.64 \pm 5.82	20.86 \pm 5.43	0.470	0.641

Abbreviations: CAOS, computer-assisted orthopedic surgery; AKSS, American Knee Society Score.

Materials and methods

Patients

This retrospective cohort study was supported by the hospital committee for medical experimental ethics.

From January 2017 to January 2018, a total of 112 patients with end-stage knee osteoarthritis underwent TKA. All signed the informed consent document.

The inclusion criteria were patients (1) diagnosed with end-stage knee osteoarthritis as defined previously [14]; (2) with confirmed TKA adaptation disease. The exclusion criteria were patients with (1) ankylosing hip or ankle joints; (2) abnormal cardiopulmonary function; or (3) history of knee surgery.

Grouping

The 112 eligible patients were randomly divided into the CAOS (treatment with infrared computer-aided navigation, n = 23) and non-CAOS (n = 89) groups according to the treatment method. All surgeries were completed by an experienced surgeon. Both groups received the same rehabilitation schedule. Basic information such as age, sex, body mass index (BMI), preoperative American Knee Society Score (AKSS) score, and Oxford Knee Score (OKS) was recorded. Propensity score matching (PSM) of patients in the two groups was carried out by using a maximum of 1:1 matching of clinical baseline characteristics to make the groups comparable. After matching, the CAOS and non-CAOS groups included 23 (10 males and 13 females) and 23 (8 males and 15 females) patients, respectively. The basic clinical data are described in **Table 1**. There were no significant differences in any indexes between the two groups ($P > 0.05$).

Surgical methods

CAOS group: This study used an Ortho-Pilot TKA v5.1 (Swabs company, Melsungen, Germany) infrared computer-aided navigation system. As in the non-CAOS group, an infrared signal reflector was placed on the thighbone and tibia. The patients' lower limb alignment was recorded after confirmation of the center in the femoral head, ankle joint, and knee joint. Osteotomy of the tibia and the thighbone was completed using a template with an infrared signal reflector. The infrared computer-aided navigation system can be used to accurately and quickly adjust the osteotomy range and thickness to acquire an optimal movement locus and lower limb alignment. Next, the lower limb prosthesis that can generate net positive mechanical work was installed for test mode. The knee joint prosthesis (bone cement, PS type, Biostat, Melsungen, Germany) was implanted after determining the optimal install angle for prosthesis position under monitoring system navigation and adjustment of the soft tissue balance. Finally, the postoperative knee joint sport and alignment-related parameters were recorded after bone cement solidification.

Non-CAOS group: Patients in the non-CAOS group were maintained in a horizontal position with their knees bent after anesthesia. A 12-cm incision was made in neutral alignment to the knee plane to release the soft tissue. After dislocation of the knee joint, osteotomy was performed in the proximal tibia and distal femur via extra- or intramedullary locations. The joint motion and lower limb alignment were monitored after the prosthesis was implanted. During this process, the knee ligament was kept balanced when the knee joint was in complete extension or 90° flexion. The total knee prosthesis (Columbus PS type, Biostat,

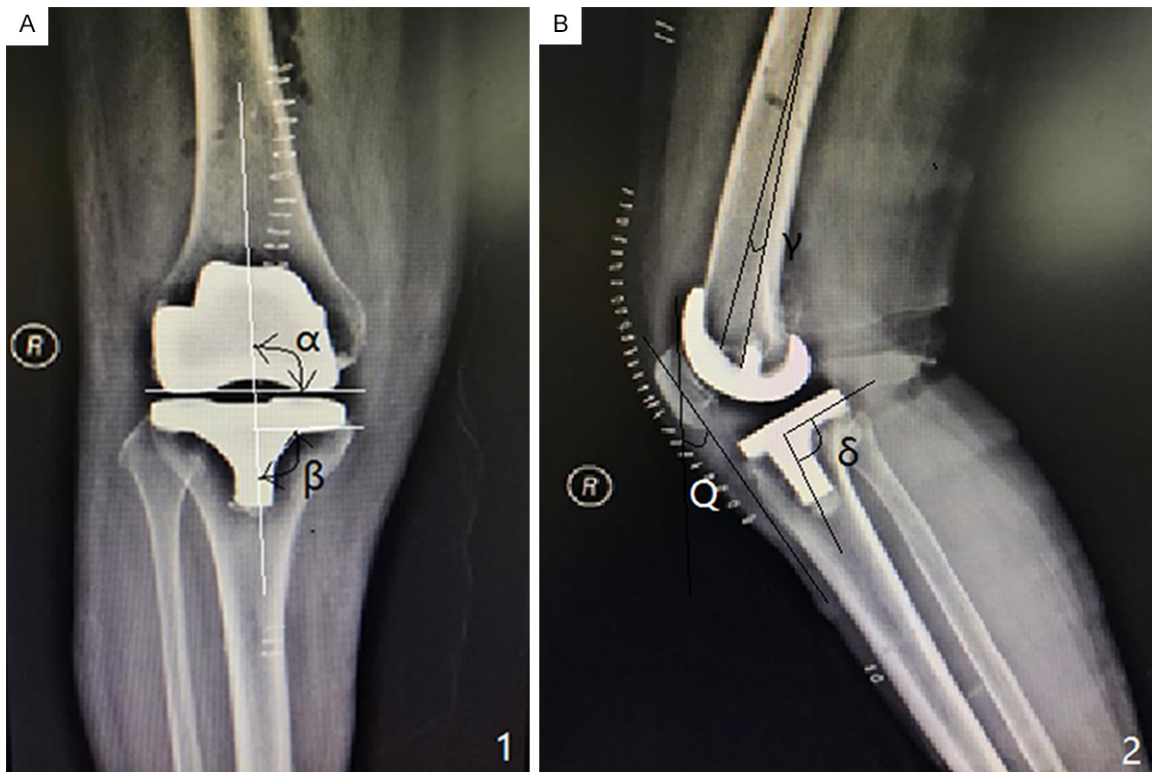


Figure 1. Radiographic measurements. α is defined as the angle between the mechanical axis of the femur and the tangent of the femoral component (from the standard of 180°); β is defined as the angle between the line parallel to the tibial tray and the mechanical axis of the tibia (from the standard of 180°); γ is the angle between the slope of the distal femoral cut and the longitudinal axis of the femur (from the standard of 90°); and δ is the angle between the slope of the proximal tibial cut and the posterior cortex of the tibia (from the standard of 30°). Q is defined as the angle between the anatomical axis of the patella and the tangent of the sagittal plane femoral prosthesis (from the standard of 30°). A. Front view; B. Lateral view.

Melsungen, Germany) was then installed, followed by surgical drainage and sutures.

Postoperative drainage of the knee arthroplasty was placed for 24 h to prevent infection and alleviate pain. Antibiotics and nonsteroidal anti-inflammatory and analgesic drugs were administered as necessary. Twelve hours after surgery, the patients were subcutaneously injected with low molecular-weight heparin for prevention of deep venous thrombosis with oral rivaroxaban substitution after hospital discharge. All patients started standardized exercises and rehabilitation training on the first postoperative day.

Evaluation index

The surgical time, intraoperative blood loss, and drainage volume at 24 h after surgery were recorded. Functional scores including the range of motion (ROM), AKSS, and OKS were deter-

mined. X-rays of whole lengths of both lower limbs and frontal/lateral knee joints under weight-bearing conditions were obtained. A picture archiving and communication system (PACS) was used to measure the lower limb alignment (hip-knee-ankle, HKA), angle of soft tissue balancing (the inclination of the distal femur relative to the femoral mechanical axis), and variable separation of soft tissue (the distance between the tangents described above and the intersection point of the femoral condyle and tibial plateau).

The mechanical axis, femoral angles (α), and coronal tibial angles (β) were measured based on the standing long radiographs, while the femoral angles (γ) and sagittal tibial angles (δ) were measured from lateral knee radiographs (**Figure 1**). α was defined as the angle between the mechanical axis of the femur and the tangent of the femoral component; β was defined as the angle between the line parallel to the

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Table 2. Comparisons between the CAOS and non-CAOS groups during the perioperative period

Index	CAOS group (n = 23)	Non-CAOS (n = 23)	t value	P value
Surgery time (min)	76.53 ± 10.82	58.49 ± 9.37	6.045	< 0.001
Preoperative bleeding (mL)	251.45 ± 32.27	354.62 ± 41.73	-9.381	< 0.001
Postoperative drainage (mL)	296.62 ± 121.54	416.83 ± 133.78	-9.962	< 0.001

Abbreviation: CAOS, computer-assisted orthopedic surgery.

Table 3. ROM, AKSS, and Oxford scores at the last follow-up

Index	CAOS group (n = 23)	Non-CAOS (n = 23)	t value	P value
ROM score (°)	113.43 ± 4.62	108.80 ± 3.73	3.715	0.008
AKSS score	80.42 ± 9.11	78.51 ± 9.22	0.704	0.485
Oxford score	37.51 ± 9.62	36.22 ± 9.33	0.466	0.643

Abbreviations: ROM, range of motion; AKSS, American Knee Society Score; CAOS, computer-assisted orthopedic surgery.

group was significantly higher than that in the non-CAOS group (76.53 ± 10.82 vs. 58.49 ± 9.37 min, $P < 0.05$) while preoperative bleeding and postoperative drainage were lower in the CAOS group (both $P < 0.05$) (**Table 2**).

tibial tray and the mechanical axis of the tibia; γ was the angle between the slope of the distal femoral cut and the longitudinal axis of the femur; δ was the angle between the slope of the proximal tibial cut and the posterior cortex of the tibia. Q was defined as the angle between the anatomical axis of the patella and the tangent of the sagittal plane femoral prosthesis. In this study, all patients in both groups received total knee-joint prostheses with a 3° shim inclination. The mechanical axis α , β , and δ were measured from 90°, γ was measured from 3°, and Q was measured from 30°.

Statistical analysis

All analyses were performed using IBM SPSS Statistics for Windows, version 21.0 (IBM Corp., USA). Measured data, including patient age, BMI, surgical time, intraoperative blood loss, postoperative drainage volume, AKSS, OKS, lower limb alignment data, α , β , γ , δ , and Q angular deviation were expressed as means ± standard deviation ($\bar{x} \pm s$) and were compared between groups by *t*-tests. Count data such as sex were expressed as percentages and analyzed by χ^2 tests. $P < 0.05$ was considered statistically significant.

Results

Results during the perioperative period

The surgery was successfully completed in both groups. No patient had nerve or blood vessel injury. The surgery time in the CAOS

Two days after surgery, the patients were rechecked by X-ray and the wounds were primarily healing. No patients experienced cardiovascular events, infections, or fractures. Lower extremity blood vessel color doppler ultrasound revealed deep venous thrombosis in one case in the non-CAOS group on the seventh day. He was advised to elevate the limb for rehabilitation and was administered rivaroxaban for anticoagulation. Two weeks later, the thrombus had disappeared.

Follow-up results

All patients in both groups were followed up for 3-24 months (average 12.4 months). During this time, one case in the non-CAOS group complained of knee joint pain on day 172 after surgery. After rehabilitation, all patients recovered well without any infection or prosthetic loosening. On the last follow-up examination, all injured limbs in the two groups could walk well and perform squats.

The ROM, AKSS, and OKS on the last follow-up are listed in **Table 3**. The ROM in the non-CAOS group was significantly higher than that of the CAOS group ($P < 0.05$). However, the AKSS and OKS did not differ significantly between the two groups ($P > 0.05$).

Evaluation of the imaging

On the last follow-up, the limb alignment error, soft tissue balancing angle, and soft tissue separation variable were significantly less in the CAOS group than those in the non-CAOS group ($P < 0.05$, **Table 4**).

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Table 4. Errors in limb alignment, angles of soft tissue balancing, and soft tissue separation variable on the last follow-up visit

Index	CAOS group (n = 23)	Non-CAOS group (n = 23)	t value	P value
Error in limb alignment (°) From the standard of 180°	1.56 ± 0.18	4.08 ± 1.04	-11.451	< 0.001
Angle of soft tissue balancing (°)	1.05 ± 0.13	2.84 ± 0.46	-8.354	< 0.001
Soft tissue separation variable (mm)	3.34 ± 0.65	6.03 ± 0.71	-13.402	< 0.001

Abbreviation: CAOS, computer-assisted orthopedic surgery.

Table 5. Comparisons of implant alignment and positioning between the CAOS and non-CAOS groups

Index	CAOS group (n = 23)	Non-CAOS (n = 23)	t value	P value
α angle deviation (°) From the standard of 90°	1.97 ± 0.21	5.02 ± 0.58	-18.798	< 0.001
β angle deviation (°) From the standard of 90°	2.03 ± 0.36	4.93 ± 0.33	-17.873	< 0.001
γ angle deviation (°) By the standard of 3°	2.56 ± 1.54	5.58 ± 1.42	-18.614	< 0.001
δ angle deviation (°) From the standard of 90°	2.02 ± 0.36	3.93 ± 0.69	-11.772	< 0.001
Q angle deviation (°) From the standard of 30°	4.03 ± 0.66	4.11 ± 0.21	-0.493	0.585

Abbreviation: CAOS, computer-assisted orthopedic surgery.

Table 5 shows the implant alignments and positioning. Due to the double-column prosthesis design, with a 3° shim inclination, the target angle for measurement of α and β was 90°, while those for γ and Q were 3° and 30°, respectively. The α, β, γ, and δ deviations in the CAOS group were significantly lower than those in the non-CAOS group. No significant difference in Q angle deviation was observed between the two groups. A typical case is shown in **Figure 2**. The TKA navigation system diagram is shown in **Figure 3**.

Discussion

TKA is one of the most conventional surgeries used to treat dyskinesia caused by knee joint degeneration. The use of TKA can significantly increase patient quality of life [15]. Outliers appear not only owing to the alignment system but also due to factors associated with surgeons and patients [16]. For TKA, surgeons should consider patient selection, surgical skill, and prosthesis installation [17]. The clinical outcomes of traditional TKA depend on the surgeon's experience; thus, accurate osteotomy positioning, balanced and stabilized soft tissue, and precise prosthesis implantation are essential to recovering biomechanical function

in patients undergoing TKA [18, 19]. However, errors arising from the precision of bone cuts and implantation might be related to suboptimal alignment in traditional TKA [20]. Some studies have reported that approximately 5-8% of failed surgeries were caused by prosthesis loosening [21].

Both patellar tracking and ligament balance are important for corrective rotational alignment during TKA. We observed significantly reduced intraoperative bleeding and postoperative drainage with the use of the CAOS system compared to those in patients receiving traditional treatment; however, the surgical duration was much longer in the CAOS group in the present study. During the CAOS procedure, the HKA angle should be located by the infrared reflector to reduce outliers, so that the impact could survive well in long time duration. That might explain why CAOS required a longer surgical time and more accurate alignment. In computer-assisted navigation, initial lower limb alignment is required after movement locus registration to guide the osteotomy and identify a suitable implant [22]. We observed a much higher ROM in the CAOS group than that in the non-CAOS group. Therefore, we believe that computer-assisted navigation for TKA surgery

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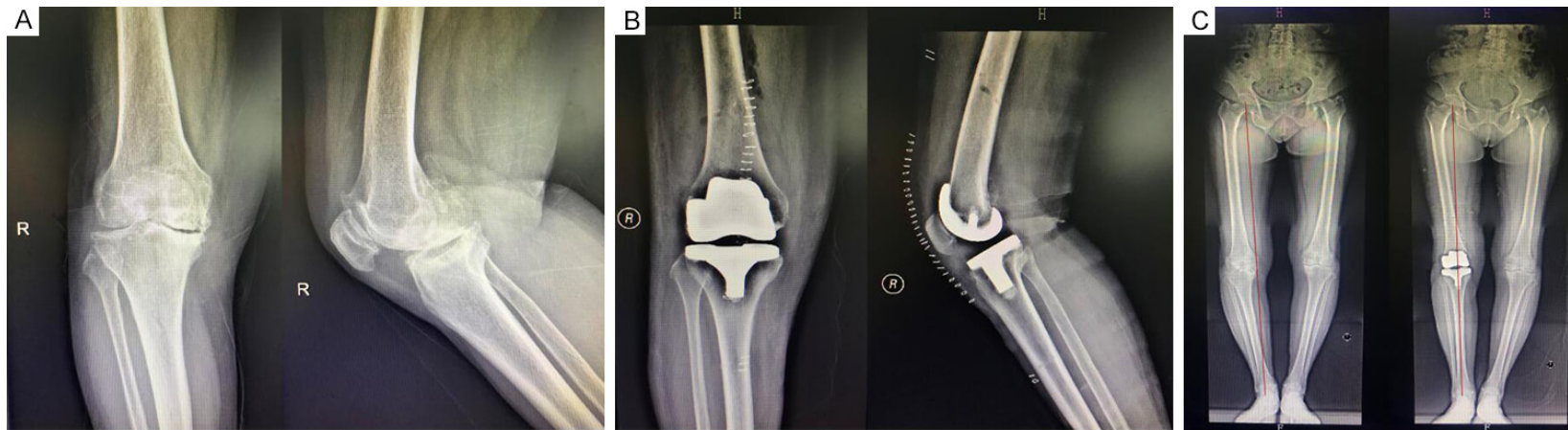


Figure 2. A 67-year-old woman with right knee end-stage osteoarthritis who underwent total knee arthroplasty (TKA) surgery assisted by infrared computer navigation. A. Preoperative X-ray anteroposterior image; B. Lateral X-ray anteroposterior image; C. Comparison of pre-operative and postoperative lower limb alignment.

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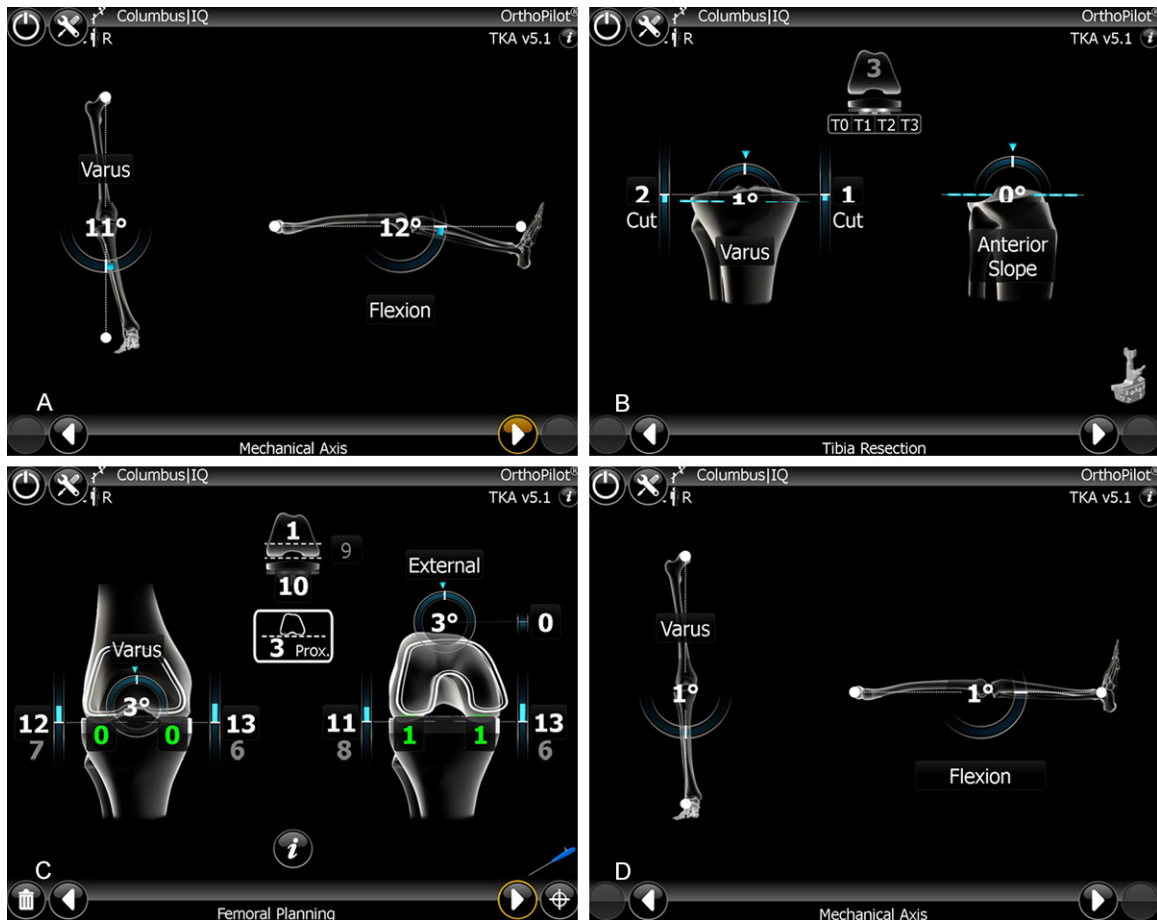


Figure 3. Diagram of total knee arthroplasty (TKA) surgery assisted by infrared computer navigation. A. Initial lower limb alignment; B. Tibial osteotomy planning; C. Femur osteotomy planning; D. Postoperative lower limb alignment; the correction effect of lower limb alignment was satisfactory.

helps to improve the matching of score knee joint prostheses and restoration of knee function.

In clinical practice, many surgeons align the femoral component to the external rotation from the posterior condylar axis by using the cutting guide systems to make it parallel to the surgical transepicondylar or clinical transepicondylar axes [23, 24]. However, articular cartilage wear in the hemi-compartment might result in inaccurate femoral rotation, which will finally lead to early loosening and residual pain [25]. Previous studies have reported that CAOS did not increase postoperative infection rate [26]. Similarly, we also did not observe significant difference between CAOS and traditional surgery. A clinical study showed that both the superficial medial ligament and posteromedial corner release were related to external femoral

rotation (2.4°) in knee flexion [27]. According to the cartilage thickness, a nearly $4\text{--}5^\circ$ external rotation might arise, which can lead to soft tissue looseness in knee flexion. Our comparisons of implant alignment and positioning in patients with or without computer-assisted navigation revealed no significant difference in Q angle between the two groups. This finding indicated that computer-assisted TKA avoided femoral prosthesis and patella misalignment as well as did traditional TKA. In this study, the use of an infrared computer-aided navigation system allowed real-time monitoring of the kinestate during $0\text{--}90^\circ$ extension and flexion of the knee joint. We also observed significantly lower soft tissue balancing and soft tissue variable separation than those in the non-CAOS group ($P < 0.05$). Although remain controversies regarding alignment and prosthesis survival, an alignment within 3° of the mechanical axis is gener-

ally accepted as the limit of alignment [28]. Compared to traditional TKA, the α , β , γ and δ angular deviation in the CAOS group were much lower, indicating a more accurate implant. Theoretically, great alignment might require less ligament balancing, thereby reducing tissue softening, bleeding, and post-operative pain [13].

While CAOS offers several advantages, it is not suitable for surgery of the hip or in patients with ankle stiffness due to deformity [29]. Additionally, this technology is expensive for patients. The limitations of this study include its retrospective cohort design, with fewer cases and shorter follow-up time; therefore, a large number of clinical evaluations, different tools for evaluation, and longer follow-up durations are required as different navigation systems and other implants may show different results.

Conclusion

In conclusion, the use of the ICAN system was associated with lower intraoperative blood loss and suitable position and angle in patients with end-stage knee osteoarthritis; therefore, it may be a useful tool for clinical TKA surgery.

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Disclosure of conflict of interest

None.

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