Comparison of Alignment and Prosthesis Positioning Accuracy Between Robotics and Personalized 3D Preoperative Planning in Total Knee Arthroplasty

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Research article

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Abstract

Purpose: Lower limb alignment is crucial in total knee arthroplasty (TKA). Previous studies have shown that robotics and personalized three-dimensional (3D) preoperative planning could improve postoperative alignment accuracy compared with conventional TKA, but comparison between the above two techniques has never been reported. The purpose of this study was to compare the alignment and prosthesis positioning accuracy between robotics and personalized 3D preoperative planning in TKA.

Methods: A consecutive series of patients who received TKA in our Center from September 2020 to January 2021 were enrolled. After 1:2 matching, 52 and 104 patients were eventually included in robotics group and personalized 3D preoperative planning group, respectively. Multiple postoperative alignment variables, operation time, tourniquet time, length of hospital stay, hemoglobin (Hb) decrease at 1 and 3 days after operation were recorded and compared.

Results: Compared with personalized 3D preoperative planning, robotics had significantly lower frontal tibial component (FTC) angle absolute deviation (P<0.001) and less FTC outliers (P<0.05). The postoperative hip-knee-ankle (HKA) angle and frontal femoral component (FFC) angle were different between two groups, while the absolute deviations were similar. Hb decreases of robotics were significantly lower than those of personalized 3D preoperative planning (P<0.001), while the operation time and tourniquet time were longer (P<0.001).

Conclusion: Compared with personalized 3D preoperative planning, robotics has more accurate tibial component coronal alignment and less postoperative Hb decrease, while the operation time is significantly longer.

Trial registration: The Chinese Clinical Trial Registry, ChiCTR2000036235. Registered 22 August 2020, http://www.chictr.org.cn/showproj.aspx?proj=59300

Introduction

Substantial studies have demonstrated that accurate alignment and prosthesis positioning in total knee arthroplasty (TKA) are closely related to satisfactory postoperative outcomes and prosthesis longevity[1–5]. Although contemporary prosthesis designs have enhanced durability, the longer life expectancies of patients put higher demands on prosthesis survivorship[6]. In addition, postoperative dissatisfaction following TKA is still up to 20%[7, 8]. TKA is one of the most effective interventions for end-stage knee osteoarthritis, while improvements in surgical technique remain a necessity[9]. In order to improve alignment and prosthesis positioning accuracy, thereby reducing revision and improving outcomes, some advanced techniques have been adopted, such as computer-navigation[10], patient-specific instrumentation (PSI) [11] and robot-assisted surgery[12].

The alignment and prosthesis positioning accuracy among navigation, PSI, robotics and conventional TKA were compared in the previous large sample meta-analyses[13, 14]. A total of 73 randomized controlled trials (RCTs) with 4,209 TKAs were included in the Bayesian network meta-analysis conducted by the authors' team. And it could be found that robotics could significantly reduce the occurrence of malalignment and malposition compared with conventional TKA[13]. Bouché et al. reached similar conclusions[14]. However, expensive medical costs and longer operation time greatly limit the application of robotics during TKA[9, 15, 16].

To achieve accurate alignment and prosthesis positioning as cost-effectively as possible, a verified technique named personalized 3D preoperative planning was introduced[17], which could be considered as a simplified PSI without cutting guides. During the intraoperative implementation, multiple markers such as the femoral entry point and the fix point of tibial plateau extramedullary guide pin were used for positioning by conventional osteotomy instruments according to the personalized 3D preoperative planning, rather than the patient-specific cutting guides. The advantages of this technique include personalized preoperative planning, relatively precise intraoperative positioning, no need to purchase new equipment, better control of the surgical time and cost, and easier application due to similar procedures with conventional TKA[17].

The previous study only confirmed that personalized 3D preoperative planning could improve osteotomy accuracy compared with conventional TKA[17], while the comparison of alignment and prosthesis positioning accuracy between robotics and personalized 3D preoperative planning has never been reported, to our knowledge. The purpose of this study was to investigate the above issues. The authors hypothesized that robotics was superior to personalized 3D preoperative planning in terms of postoperative alignment and prosthesis positioning in primary TKA.

Materials And Methods

Medical records and imaging data were retrospectively collected from a consecutive series of TKA performed at our Center from September 2020 to January 2021. The robotics group included patients with knee osteoarthritis, who underwent TKA with the Skywalker™ robotics system (MicroPort® OrthoBot Co., Ltd., Suzhou, China); The 3D preoperative planning group included patients who underwent TKA with personalized 3D preoperative planning due to knee osteoarthritis. The exclusion criteria for both groups were: 1) patients whose pre- and post-operative full-length weight-bearing radiographs (FLX) of the lower limbs were not available or did not meet Paley's criteria[18], which would affect the measurement; 2) in bilateral TKA, the side (left or right) with better postoperative outcomes was excluded in the study. Finally, a total of 52 cases were enrolled in the robotics group and 196 cases in the 3D preoperative planning group.

To reduce the influence of selection bias and potential confounding factors in this retrospective study, the gender, left or right, age, body mass index (BMI) and preoperative hip-knee-ankle angle (HKA) were selected to perform a 1:2 matching with the "nearest" method by R software (Version 4.0.4, R foundation for statistical Computing, Vienna, Austria). Finally, 52 robot-assisted TKA and 104 personalized 3D preoperative planning TKA were compared in this study.

The personalized 3D preoperative planning [17] and Legion® primary total knee prosthesis (Smith-Nephew, Inc., Memphis, IN, USA) were used in the 3D preoperative planning group. The lower limb full-length Computed Tomography (CT) data of patients was collected to performed 3D reconstruction with Mimics Research 19.0. With the CATIA 5.20 and NX12.0 software, the engineers and surgeons at our Center formulated the personalized 3D preoperative planning, which should include the following key information: the femoral entry point, the coronal projection angle of the Hip-Knee-Shaft (HKS), the transverse projection angle of the posterior condylar angle (PCA), the fix point of the tibial plateau extramedullary guide pin, the volume of femoral and tibial osteotomy, etc. [17] During the intraoperative implementation, the femoral entry point was strictly located according to the preoperative plan, and the coronal projection angle of HKS and the specific osteotomy volume were used in the distal femoral osteotomy. And the femoral rotatory osteotomy was guided by the transverse projection angle of PCA. Similarly, the tibial osteotomy was conducted based on the key information presented in the personalized 3D preoperative planning, including the fix point of the tibial plateau extramedullary guide pin, the tibial osteotomy volume, etc.[17] For more details on personalized 3D preoperative planning TKA, please refer to the authors' previous article[17].

The Skywalker™ robotics system and Advance® medial-pivot knee prosthesis (MicroPort Orthopedics Inc., Arlington, TN, USA) were used in the robotics group. A patient-specific 3D model was formulated automatically after importing the patients' lower limb CT data into the Skywalker™ robotics system. Multiple feature points were marked in the 3D model, such as the center point of femoral head, knee joint and ankle joint, the most prominent point of lateral femoral epicondyle, the most concave point of medial femoral epicondyle, etc. Then, the appropriate prosthesis positioning and alignment parameters were selected in real-time preview to complete the preoperative planning. During the surgery, the navigation markers made by radix lens (a wipeable retro-reflective lens for use with optical measurement applications) were installed and the patient's anatomical characteristics were registered, to ensure accurate knee recognition. With the help of optical measurement technology, the robotic arm automatically moved to the appropriate position in strict accordance with the preoperative plan, and assisted the surgeons to complete accurate osteotomy (Figure. 1).

In both groups, the nerve block anesthesia and Insall's medial parapatellar approach were conducted for all patients. A tourniquet was applied before the skin incision and released after the joint cavity was rinsed. In order to reduce total blood loss, tranexamic acid was routinely used. No patella replacement was performed in all cases. Discharge criteria included no obvious swelling, no extension lag, active bending ≥ 90°, walking distance with assistance ≥ 200 m and VAS-pain score ≤ 4. Patients who met all the above criteria could be discharged, which meant the hospital stay included postoperative rehabilitation programmes.

Preoperative FLX (within 1 month before surgery) and FLX of the latest follow-up were collected. Preoperative HKA and postoperative frontal femoral component (FFC) angle, frontal tibial component (FTC) angle, lateral femoral component (LFC) angle, lateral tibial component (LTC) angle and HKA (Figure. 2) were measured three times by two raters independently[17], with an interval of more than 15 days. The targets in all cases for postoperative HKA, FFC, FTC, LFC and LTC were 180°, 90°, 90°, 90° and 87°, respectively. Values exceeding the target by 1, 2 and 3 degrees were recorded as outliers (± 1°), outlier (± 2°) and outlier (± 3°), respectively. Meanwhile, medical records such as gender (male or female), side (left or right), age (years), BMI (kg/m^2), operation time (min), tourniquet time (min), hospital stay (day), hemoglobin (Hb) decrease at 1 and 3 days after operation (g/L) were collected via the electronic medical record management system.

The χ^2 test and T-test was respectively used for categorical and continuous variables. Intraclass correlation coefficient (ICC) was used to evaluate intra-rater and inter-rater consistency in FLX measurement. ICC values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 were indicative of poor, moderate, good and excellent reproducibility, respectively[19]. Statistical analysis was performed by SPSS 25.0 (SPSS Inc., Chicago, IL) and $P < 0.05$ was considered statistically significant.

This study has been approved by the Ethics Committee (SH9H-2019-C49-4, QX202004) and registered in the Chinese Clinical Trial Registry (ChiCTR2000036235).

Results

All baseline characteristics were similar between two groups after 1:2 matching (Table I).

The intra-rater and inter-rater consistency in FLX measurement was excellent (ICC > 0.9, $P < 0.05$). Although postoperative HKA and FFC were significantly different between two groups ($P < 0.05$), the absolute deviations from the target value were similar. The two groups had similar postoperative FTC, but the robotics group was significantly better than the 3D preoperative planning group in FTC absolute deviation (1.1°±0.9° *vs* 1.8°±1.3°, $P < 0.001$). There were no statistical differences between two groups in LFC, LTC and corresponding absolute deviations. Besides, the robotics group had significantly less FTC outliers compared with the 3D preoperative planning group($P < 0.05$), regardless of whether the outliers were defined as exceeding the target value by 1, 2, or 3 degrees. There were no statistical differences between two groups in outliers of the other four angles (Table II).

The operation time, tourniquet time in the 3D preoperative planning group were significantly shorter ($P < 0.001$), while the robotics group had lower Hb decrease at 1 and 3 days after operation ($P < 0.001$) (Table III).

Discussion

TKA has significantly improved patients' quality of life, but even after decades of progress and development, some patients are still dissatisfied with their arthroplasty[7, 8, 20]. Malalignment and malposition still persist despite the continuous improvement of surgical techniques[21], so accurate alignment and prosthesis positioning remain one of the most attractive issues of TKA[9]. The most important finding of this study was that robotics had more accurate tibial component coronal alignment and less Hb decrease compared with the personalized 3D preoperative planning in TKA, while the operative time was significantly longer.

It could be found that robotics had more accurate FTC alignment than the personalized 3D preoperative planning (Table II). Born for accurate alignment and prosthesis positioning, robotics has the advantages of intraoperative real-time navigation, secondary calibration and sensitive feedback[22–24], with the help of robotic arm and optical measurement technology. On the contrary, although there were multiple key points to reduce surgeons' subjective evaluation during intraoperative implementation in the 3D preoperative planning TKA[17], arthroplasty was still partly dependent on surgeons' observation and manual operation, which might result in inaccuracy.

Besides, the Hb decrease at 1 and 3 days after operation was significantly lower in robotic group ($P < 0.001$) (Table III), mainly because opening of femoral medullary canal was not required in robot-assisted TKA. An RCT conducted by Kuo et al. found that avoiding opening medullary cavity could significantly reduce blood loss and transfusion rate in TKA[25]. And Rathod and Schnurr et al. reached the similar conclusions[26, 27].

Due to additional procedures such as intraoperative registration, the operation time of robotics group was significantly longer than that of 3D preoperative planning group (92.2min ± 16.4min *vs* 130.1min ± 26.9min, $P < 0.001$) (Table III). Song et al. had demonstrated that robot-assisted TKA required an additional 25 minutes of operation time compared with conventional TKA, even after surmounting the learning curve[28, 29]. And the authors' previous study had shown that personalized 3D preoperative planning TKA took an average of 13 minutes less than conventional TKA[17]. The longer operation time of robotics group in this study was logically consistent with the above articles.

Multiple limitations of this study must be noted before revealing the clinical relevance. Firstly, the Skywalker™ robotics system currently is exclusive for MicroPort® prosthesis. Separate MicroPort® prosthesis are not available in the authors' hospital (not on the hospital centralized procurement list of medical supplies), and could only be implanted together with the robotics system as a clinical trial project. Except for different surgical techniques, the above details would lead to differences in prostheses between two groups. Although different prostheses types had no effect on the comparison of alignment accuracy between robotics and the personalized 3D preoperative planning, this made the comparison of postoperative outcomes meaningless, because various prosthesis design might have an impact on patient reported outcome measures (PROMs) and component coverage[30–32]. Secondly, the long-term prosthesis survivorship between the two techniques remains to be further explored, to make this study more valuable and practical. Thirdly, as a retrospective study, although potential biases were reduced through 1:2 matching, the conclusion of this study still needs to be verified by subsequent researches.

Robotics could significantly improve alignment accuracy, but the expensive start-up costs (equipment purchase and maintenance fees, often up to $800,000[33]) discourage many smaller-scale clinics. Similarly, excessive operating costs (advanced preoperative imaging and cleaning fees, quoted at over $1,200 per case[33]) also make many patients feel overburdened, especially when the extra costs cannot be covered by medical insurance. The personalized 3D preoperative planning was slightly weaker than robotics in alignment accuracy, but better than conventional TKA [17], with a much lower extra cost compared with robotics (no more than $280 per case). Coupled with the advantage of shorter operation time, the excellent cost performance of personalized 3D preoperative planning might make it still attractive to many surgeons.

Conclusion

Compared with personalized 3D preoperative planning, robotics has more accurate tibial component coronal alignment and less postoperative Hb decrease, while the operating time is significantly longer.

Abbreviations

TKA
total knee arthroplasty; *3D*:three-dimensional; *CT*:computed tomography; *FLX*:full-length radiograph; *PSI*:patient-specific instrumentation; *HKA*:hip-knee-ankle angle; *FFC*:frontal femoral component angle; *FTC*:frontal tibial component angle; *LFC*:lateral femoral component angle; *LTC*:lateral tibial component angle; *ICC*:intraclass correlation coefficient; *BMI*:body mass index; *Hb*:hemoglobin; *RCT*:randomized controlled trial.

Declarations

Ethical approval and consent to participate

Ethical approval was obtained from the ethical committee (SH9H-2019-C49-4, QX202004). All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Consent for publication

All authors read, approved the final manuscript, and consented to publication. The Authors consent to publication of the current work in *Journal of Orthopaedic Surgery and Research* and declare that this work is not being concurrently submitted to any other publisher.

Availability of data and materials

All data and materials of the present study were in full compliance with the journal’s policy.

Competing interests

The authors declare that they have no competing interest.

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Authors’ contribution

KL composed the manuscript, LML and KL participated in the measurement work, PFY and LY collected the data, PFY and RX completed the statistical analyses, RH and LG conceived the idea of the study; all authors contributed to the writing of the manuscript and approved the final manuscript.

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Tables

Table I. Baseline characteristics before and after 1:2 matching.

Characteristics	Before PSM (n = 248)			After PSM (n =156)		
	3D preoperative planning group (n = 196)	Robotics group (n = 52)	*P-value*	3D preoperative planning group (n = 104)	Robotics group (n = 52)	*P-value*
Gender (Male: Female)	52:144	11:41	0.428[b]	23:81	11:41	0.891[b]
Side (Left: Right)	95:101	31:21	0.153[b]	61:43	31:21	0.908[b]
Age (years)	69.3±8.4	66.1±7.9	**0.016[a]**	66.9±9.4	66.1±7.9	0.585[a]
BMI (kg/m^2)	25.6±3.2	26.0±4.2	0.472[a]	26.0±3.5	26.0±4.2	0.988[a]
Pre-HKA (°)	170.6±8.8	172.4±6.4	0.110[a]	172.1±9.1	172.4±6.4	0.857[a]

HKA: Hip-Knee-Ankle angle. **[a]** stands for t-test, **[b]** stands for χ^2 test.

Table II. Comparison of postoperative alignment.

	3D preoperative planning group (n = 104)	Robotics group (n = 52)	*P-value*
HKA	179.2°±3.0°	180.60°±2.5°	**0.002**[a]
FFC	90.3°±1.9°	89.6°±1.7°	**0.026**[a]
FTC	89.5°±2.1°	90.0°±1.4°	0.076[a]
LFC	87.8°±3.0°	88.1°±3.2°	0.586[a]
LTC	86.0°±2.7°	86.5°±2.9°	0.240[a]
HKA absolute deviation	2.3°±2.2°	2.1°±1.5°	0.520[a]
FFC absolute deviation	1.6°±1.0°	1.4°±1.0°	0.184[a]
FTC absolute deviation	1.8°±1.3°	1.1°±0.9°	**<0.001**[a]
LFC absolute deviation	3.0°±2.1°	3.0°±2.2°	0.883[a]
LTC absolute deviation	2.3°±1.8°	2.4°±1.7°	0.777[a]
HKA outlier (±3°)	30/104	11/52	0.304[b]
HKA outlier (±2°)	43/104	26/52	0.305[b]
HKA outlier (±1°)	65/104	39/52	0.118[b]
FFC outlier (±3°)	13/104	6/52	0.863[b]
FFC outlier (±2°)	38/104	13/52	0.148[b]
FFC outlier (±1°)	66/104	32/52	0.815[b]
FTC outlier (±3°)	18/104	2/52	**0.018**[b]
FTC outlier (±2°)	35/104	9/52	**0.032**[b]
FTC outlier (±1°)	69/104	23/52	**0.008**[b]
LFC outlier (±3°)	47/104	22/52	0.732[b]
LFC outlier (±2°)	65/104	32/52	0.907[b]
LFC outlier (±1°)	83/104	42/52	0.887[b]
LTC outlier (±3°)	31/104	15/52	0.901[b]
LTC outlier (±2°)	49/104	28/52	0.428[b]

LTC outlier (±1°)	71/104	38/52	0.537[b]

HKA: hip-knee-ankle angle; FFC: frontal femoral component angle; FTC: frontal tibial component angle; LFC: lateral femoral component angle; LTC: lateral tibial component angle. Values exceeding the target value by 1, 2 and 3 degrees were recorded as outliers (±1°), outlier (±2°) and outlier (±3°), respectively. **a** stands for t-test, **b** stands for χ^2 test.

Table III. Comparison of surgical data.

	3D preoperative planning group (n = 104)	Robotics group (n = 52)	*P-value*
Operation time (min)	92.2±16.4	130.1±26.9	**<0.001**
Tourniquet time (min)	56.6±13.5	96.1±15.1	**<0.001**
Length of hospital stay (day)	8.3±1.5	8.5±3.2	0.532
Hb decrease 1 day (g/L)	19.5±9.7	9.6±9.1	**<0.001**
Hb decrease 3 days (g/L)	35.6±13.9	22.9±13.6	**<0.001**

The t-test was used for all.

Figures

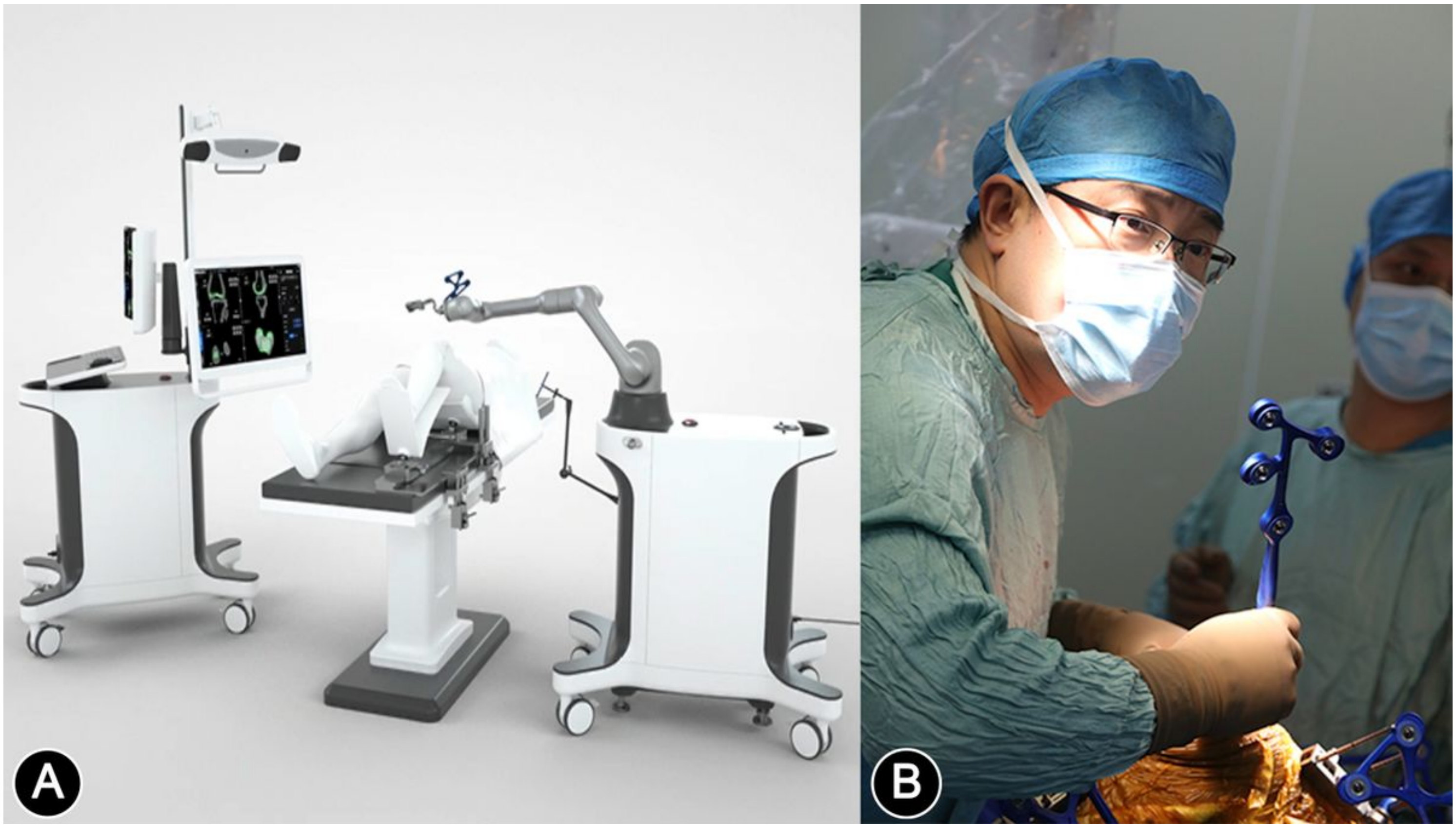

Figure 1

MicroPort® Skywalker™ robotics system and its intraoperative registration.

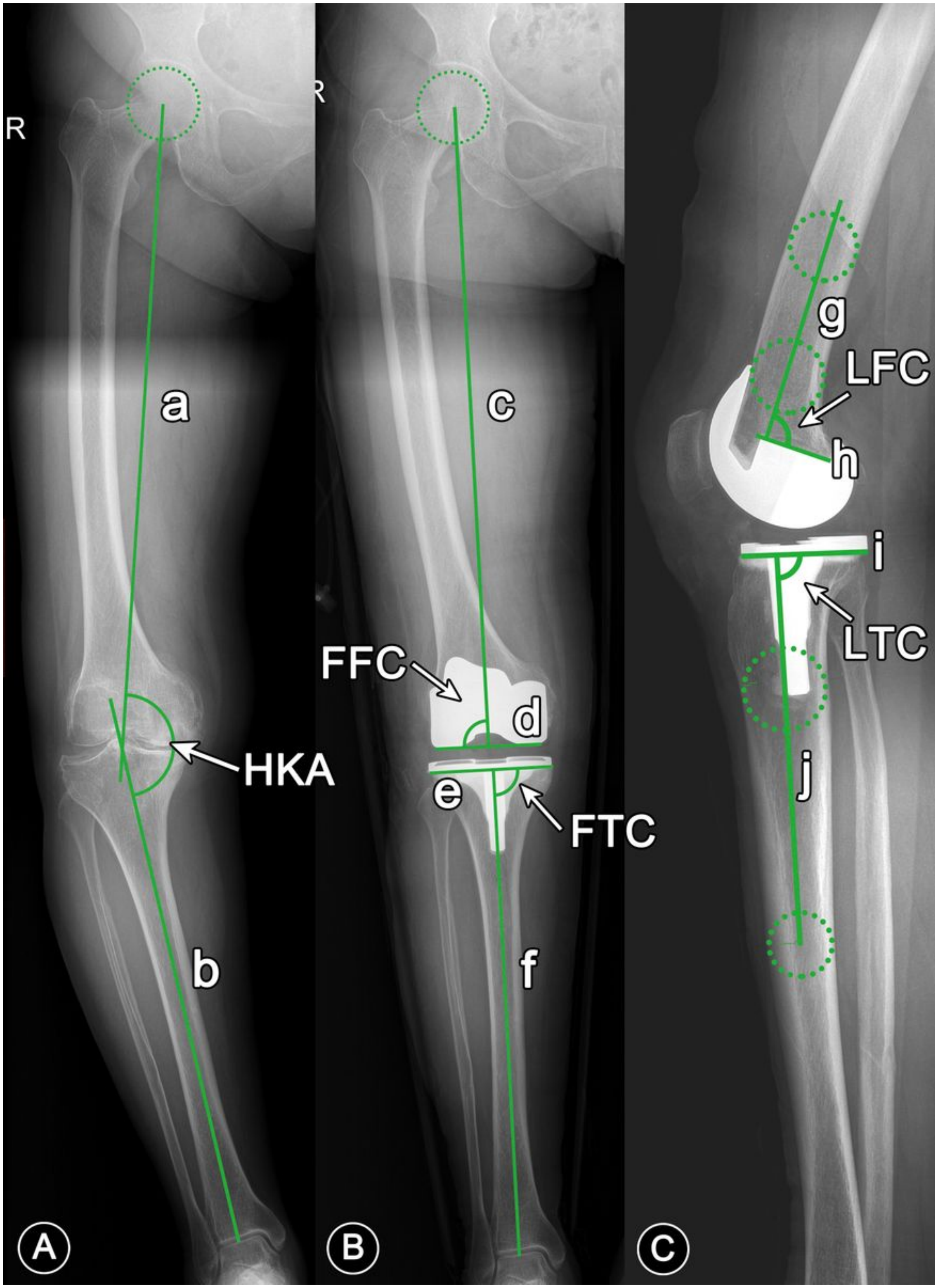

Figure 2

Measurement of HKA, FFC, FTC, LFC and LTC. HKA: Hip-Knee-Ankle angle; FFC: frontal femoral component angle; FTC: frontal tibial component angle; LFC: lateral femoral component angle; LTC: lateral tibial component angle. (Fig.2A) Preoperative HKA: the medial angle formed between the femoral mechanical axis (line a) and the tibial mechanical axis (line b). (Fig.2B) Line c: postoperative femoral mechanical axis; line d: the line across the bottom of the femoral condyles; line e: the line across the bottom of the tibial plateau on the anteroposterior radiograph; line f: the postoperative tibial mechanical axis; FFC: the lateral angle between line c and line d; FTC: the medial angle between line e and line f; postoperative HKA: the medial angle between line c and line f. (Fig.2C) Line g was the line connecting the center points of the femoral shaft at 0 cm and 5 cm above the implant, line h was the line across the bottom of the femoral implant; Line i: the line across the bottom of the tibial plateau on the lateral radiograph; line j: the line connecting the center points of the tibial shaft at 5 cm and 15 cm below the joint line; LFC: the posterolateral angle between line g and line h. LTC: the posterolateral angle between line i and line j.