



Original article

The application of 3D printing patient specific instrumentation model in total knee arthroplasty

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ABSTRACT

The application of 3D printing patient specific instrumentation model in total knee arthroplasty was explored to improve the operative accuracy and safety of artificial total knee arthroplasty. In this study, a total of 52 patients who need knee replacement were selected as the study objects, and 52 patients were divided into experimental group and control group. First, the femoral mechanical-anatomical angle (FMAA), lateral femoral angle (LFA), hip-knee-ankle angle (HKA), femorotibial angle (FTA) of research objects in both groups were measured. Then, the blood loss during the operations, drainage volume after operations, total blood loss, hidden blood loss, and hemoglobin decrease of the experiment group and the control group were measured and calculated. Finally, the postoperative outcomes of patients who underwent total knee arthroplasty were evaluated. The results showed that before the operations, in the PSI group, the femoral mechanical-anatomical angle (FMAA) was $(6.9 \pm 2.4)^\circ$, the lateral femoral angle (LFA) was $(82.4 \pm 1.6)^\circ$, the hip-knee-ankle angle (HKA) was $(166.4 \pm 1.4)^\circ$, and the femorotibial angle (FTA) was $(179.5 \pm 7.3)^\circ$. In the CON group, the FMAA was $(5.8 \pm 2.4)^\circ$, the LFA was $(81.3 \pm 2.1)^\circ$, the HKA was $(169.5 \pm 1.9)^\circ$, and the FTA was $(185.4 \pm 5.4)^\circ$. The differences in these data between the two groups were not statistically significant ($P > 0.05$). After the operations, in the PSI group, the total blood loss, the hidden blood loss, and the hemoglobin (Hb) decrease were respectively (420.2 ± 210.5) , (240.5 ± 234.5) , and (1.7 ± 0.9) ; in the CON group, the total blood loss, the hidden blood loss, and the Hb decrease were respectively (782.1 ± 340.4) , (450.9 ± 352.6) , and (2.9 ± 1.0) . These data of both groups were statistically significant ($P < 0.05$). Therefore, it can be seen that the 3D printing patient specific instrumentation model can effectively simulate the lower limb coronal force line and was highly consistent of the preoperative software simulation plan. In addition, the random interviews of patients who underwent total knee arthroplasty showed that the knees of patients had recovered well. The application of 3D printing patient specific instrumentation model in artificial total knee arthroplasty can effectively improve the operative accuracy and safety, and the clinical therapeutic effects were significant.

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1. Introduction

In recent decades, the total knee arthroplasty (TKA) has been recognized as one of the most effective methods for the treatment of advanced knee diseases all over the world (Zhou et al., 2018). A large number of patients all around the world receive TKA and benefit from it every year (Zhou et al., 2018).

Traditional artificial knee arthroplasty is not only limited in accuracy but also has certain traumatic injuries to patients (Gaillard et al., 2017). In the past five years, the survival rate of patients underwent TKA was about 95% (Lin et al., 2016). The researchers also reported that nearly 70% of patients underwent retrospective studies (Zou et al., 2017), and the survival rate of the prosthesis and the recovery of the lower extremity physiological axis and mechanical axis were closely related (Du et al., 2017). The line from the center of the femoral head to the center of the ankle joint should pass through the center of the knee joint; thus, this line is called the neutral force line axis (Li et al., 2017). Studies have shown that the maximum acceptable angle for the varus or valgus of the lower limb as the axial force line should be less than 3° (Abreusilva and DiasT, 2016), the aseptic loosening of the prosthesis after knee replacement and the force line deviation of the

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knee joint reconstruction were closely related, if the lower limb force line deviation was less than 3° (Snoap and Jaykel, 2017), the aseptic loosening rate of the prosthesis after operation would be 4%. If the lower limb force line deviation was less than 3° , the aseptic loosening rate of the prosthesis after the operation would be 23%. It can be seen that in order to reduce the aseptic loosening rate of the prosthesis, the precise lower limb force line should be reconstructed (Ha et al., 2014).

Based on the above discussions, through the measurement of long leg weight bearing radiographs in combination with the knee joint computed tomography (CT) scanning data, the 3D model of the knee joint was reconstructed; in addition, through the utilization of 3D printing patient specific instrumentation (PSI) model, the effects of 3D printing PSI on the operative accuracy and safety of artificial total knee arthroplasty (TKA) were explored; consequently, through the comparisons between the preoperative and postoperative HSS (Score of hospital for special surgery), KSS (American knee society knee score), ROM (pain and range of motion of knee were assessed with Lequesne index), WOMAC (the western Ontario and McMaster universities osteoarthritis index), and VAS (visual analogue scale) scores, the clinically therapeutic effects were evaluated, which provided certain theoretical guidance for the future treatments of knee arthritis.

2. Method

2.1. Experimental subject

A total of 52 research objects were selected in the experiment and were divided into the experiment group (the PSI group) and the control group (the CON group). Patients selected in the PSI group were treated with TKA for the first time, while patients selected in the CON group were treated with LINK knee joint prosthesis replacement, as shown in Fig. 1. In the PSI group, 7 patients were male and 12 were female, in which the operative sites of 11 patients were the left knees and 8 were the right knees. The average age of the entire PSI group was (70.2 ± 8.4) years old, and the average body mass index (BMI) was (24.2 ± 3.4) Kg/m². The scores of preoperative HSS, KSS, ROM, WOMAC, and VAS were respectively (57.7 ± 11.2) , (43.6 ± 14.7) , (103.1 ± 20.6) , (60.4 ± 6.5) , and (5.8 ± 1.2) . In the CON group, 10 patients were male, and 23 patients were female, in which the operative sites of 15 patients were the left knees and 18 were the right knees. The average age of the entire CON group was (68.6 ± 7.1) years old, and the average BMI was (25.4 ± 2.8) Kg/m². In the PSI group, 1 patient had a previous history of cardiac stenting, thereby the patient was treated with tranexamic acid both intraoperatively and postoperatively. In the control group, only 17 patients underwent re-examinations of long leg weight bearing radiographs, thereby only

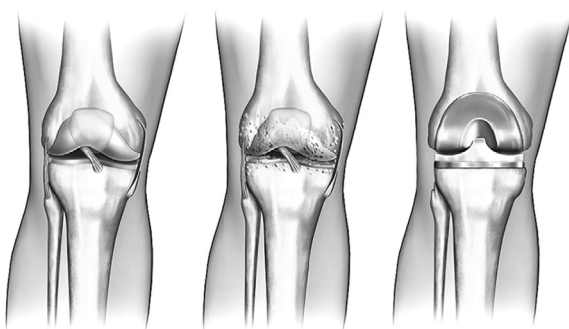


Fig. 1. Schematic diagram of knee joint replacement.

17 cases were included in the calculation of the lower limb force line (see Figs. 2–4).

The inclusion criteria of the experiment were as follows. First, the patients must be diagnosed as degenerative knee arthritis through the examinations before the object selection, with no obvious or poor therapeutic effects after a stage of treatments, and were scheduled for TKA operations, whose deformity angles of varus or valgus joint was less than 30° and the deformity angle of fixed flexion contracture was less than 20° . Then, before the TKA operations, patients were submitted to examinations and detections of blood routine, C-reactive protein, erythrocyte sedimentation rate, D-dimer, and coagulation function; next, patients were submitted to imaging detections such as color Doppler ultrasonography, echocardiography, electrocardiogram, and chest radiography. If the results of the above examinations and detections indicated no abnormalities, the patients would be included as research objects. Finally, the BMI of included patients must be less than 30 Kg/m². Only if the above conditions were met can patients be included in the experiment (see Tables 1–4).

The exclusion criteria of the experiment were as follows. First, patients with confirmed medical histories of open operations, severe bone defects, and knee joint extra-articular deformations without any corrections were excluded from the experiment; in addition, patients who were confirmed to undergo knee joint puncture operations recently should be excluded; then, patients had neither preoperative complete long leg weight bearing radiographs and lateral X-ray radiographs nor postoperative long leg weight bearing radiographs and lateral X-ray radiographs should be excluded; finally, patients who did not meet the above inclusion criteria were excluded.

In this study, informed consent has been signed with patients and their families and the study has been approved by the hospital ethics committee.

2.2. Preoperative preparations

Before the operations, the relevant routine examinations were carried out, and ultrasound and magnetic resonance were utilized for imaging. First, the image data and measurement parameters were obtained through the long leg weight bearing radiographs and computed tomography (CT) knee joint scans.

Then, Mimics 16.0 software was used to locate the DICOM files scanned by CT, and remove the irrelevant images after seg-

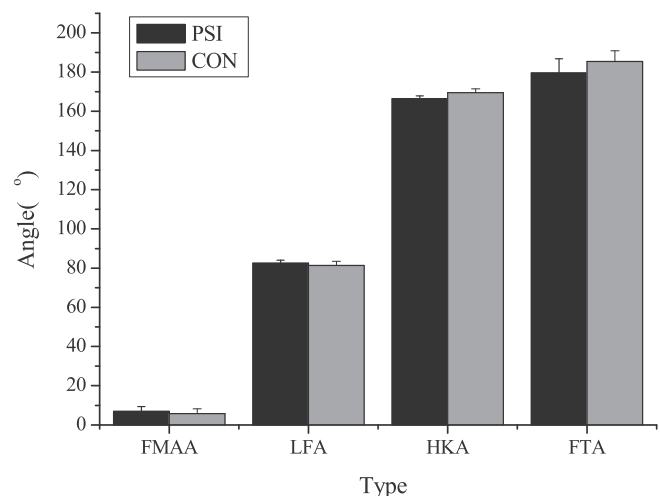


Fig. 2. Coronal force line comparison between the PSI group and the CON group before operations.

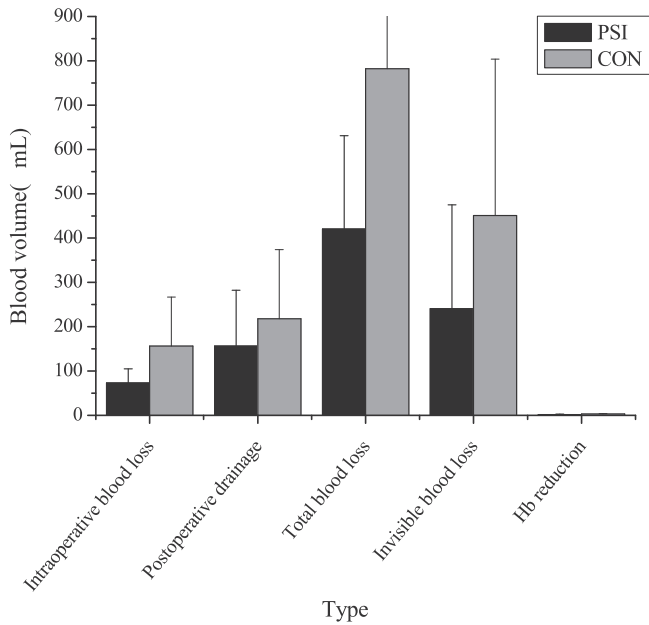


Fig. 3. Comparison of blood loss between the PSI group and the CON group.

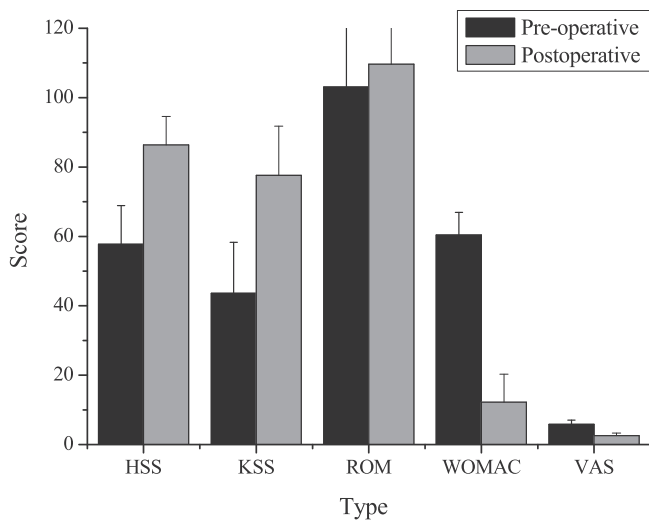


Fig. 4. Clinical evaluation of three months after operation in the PSI group.

mentation. The 3D images of the distal femurs were preserved, and the original CT images of the knee joints were reconstructed as 3D models by using Mimics Research software to obtain the 3D reconstructed models of distal femurs. Next, based on the angles provided by the 3D models and the angles provided by the long leg weight bearing X-ray radiographs, the osteotomy surfaces could be determined; thus, according to the osteotomy surfaces, the PSI plastic guide plates could be made; the fitness degree between distal femoral models and the PSI plastic guide plates were pre-examined; once the correctness was confirmed, the PSI guide plates for surgical treatments were printed. While printing the PSI plastic guide plates, the nylon powder should be selected as the raw material of printing; the reason was that the nylon powder had a small diameter, high production strength and accuracy, high melting point, high-temperature resistance, corrosion resistance, and deformation resistance, and was difficult to break.

2.3. Evaluation of therapeutic effects

The postoperative outcomes of patients who underwent TKA operations were evaluated. In the PSI group, the accuracy of lower limb force line corrections was compared. After operations, patients were randomly interviewed. The preoperative and postoperative HSS, KSS, WOMAC, and VAS scores of patients, as well as ROM, were compared. The blood loss during the operations and the drainage volume after operations of the experiment group and the control group were recorded. Then, based on the given conditions, the hidden blood loss, total blood loss, and hemoglobin (Hb) decrease were calculated. It was worth noting that in the experiment, during the operations, the femoral medullary cavities of patients in the PSI group were not opened, while the femoral medullary cavities of patients were opened.

2.4. Statistical method

The measurement data were expressed by the mean number ± the standard deviation ($\bar{x} \pm s$), which were all tested by the normality test. The obtained data were statistically processed by using the SPSS 22.0 software. The multi-sample mean comparison was tested by Chi-square test. The two independent samples were tested by *t*-test, $P < 0.05$ indicated obvious differences, and the differences were statistically significant.

Table 1 Comparison of general data between the two groups ($\bar{x} \pm s$).

	PSI	CON	χ^2	t	p
Gender (male/female)	7/12	10/23	0.502	–	0.479
Site (left/right)	11/8	15/18	0.326	–	0.564
Age (years old)	70.2 ± 8.4	68.6 ± 7.1	–	0.572	0.578
BMI (Kg/m ²)	24.2 ± 3.4	25.4 ± 2.8	–	–1.935	0.081
Total	19	33	–	–	–

Table 2 Coronal force line comparison between the PSI group and the CON group before operations ($\bar{x} \pm s$).

Before operations	PSI	CON	t	p
FMAA	6.9 ± 2.4	5.8 ± 2.4	1.034	0.325
LFA	82.4 ± 1.6	81.3 ± 2.1	0.412	0.679
HKA	166.4 ± 1.4	169.5 ± 1.9	–0.462	0.653
FTA	179.5 ± 7.3	185.4 ± 5.4	–2.024	0.052

Table 3
Comparison of blood loss between the PSI group and the CON group ($\bar{x} \pm s$).

Groups	PSI	CON	t	p
Blood loss during the operations	73.4 ± 31.3	156.3 ± 110.6	-4.2	0
Drainage volume after operations	156.2 ± 126.3	217.8 ± 155.9	-1.534	0.132
Total blood loss	420.2 ± 210.5	782.1 ± 340.4	-4.214	0
Hidden blood loss	240.5 ± 234.5	450.9 ± 352.6	-2.347	0.023
Hb decrease	1.7 ± 0.9	2.9 ± 1.0	-4.002	0

Table 4
Clinical evaluation of three months after operation in the PSI group ($\bar{x} \pm s$).

	Before operations	After operations	t	p
HSS	57.7 ± 11.2	86.4 ± 8.2	-10.372	0
KSS	43.6 ± 14.7	77.6 ± 14.2	-7.352	0
ROM	103.1 ± 20.6	109.7 ± 12.3	-1.429	0.18
WOMAC	60.4 ± 6.5	12.2 ± 8.1	12.236	0
VAS	5.8 ± 1.2	2.5 ± 0.8	7.521	0

3. Results

3.1. Comparison of general data

Through the comparison of general data, all the data comparisons between the groups were tested by Chi-square test. Based on the inclusion criteria, 52 research objects were selected, including 17 males and 35 females. All the research objects were aged 45–85 years old. As can be seen from the table below, in the PSI group, 7 patients were male and 12 were female, in which the operative sites of 11 patients were the left knees and 8 were the right knees. The average age of the entire PSI group was (70.2 ± 8.4) years old, and the average body mass index (BMI) was (24.2 ± 3.4) Kg/m². In the CON group, 10 patients were male, and 23 patients were female, in which the operative sites of 15 patients were the left knees and 18 were the right knees. The average age of the entire CON group was (68.6 ± 7.1) years old, and the average BMI was (25.4 ± 2.8) Kg/m². It could be seen from the table that there was no significant difference in gender, age and location between the PSI group and the CON group, which was not statistically significant.

3.2. Comparison of lower limb coronal force line between the PSI group and the CON group before operations

As can be seen from the table below that before the operations, in the PSI group, the femoral mechanical-anatomical angle (FMAA) was (6.9 ± 2.4)°, the lateral femoral angle (LFA) was (82.4 ± 1.6)°, the hip-knee-ankle angle (HKA) was (166.4 ± 1.4)°, and the femorotibial angle (FTA) was (179.5 ± 7.3)°. In the CON group, the FMAA was (5.8 ± 2.4)°, the LFA was (81.3 ± 2.1)°, the HKA was (169.5 ± 1.9)°, and the FTA was (185.4 ± 5.4)°. The differences in these data between the two groups were not statistically significant ($P > 0.05$).

3.3. Statistical analysis of blood loss of the PSI group and the CON group

As can be seen from the table below, in the PSI group, since the femoral medullary cavities of patients were not opened, the blood loss during the operations was relatively less, which was (73.4 ± 31.3) mL; in the CON group, since the femoral medullary cavities of patients were opened, the blood loss during the operations was (156.3 ± 110.6) mL; thus, the differences in blood loss during the operations between the two groups were obvious, which were statistically significant ($P < 0.05$). In the PSI

group, the drainage volume at 24 h after operations was (156.2 ± 126.3); in the CON group, the drainage volume at 24 h after operations was (217.8 ± 155.9); through comparisons, the differences of these data were not obvious, which were not statistically significant ($P > 0.05$). After the operations, in the PSI group, the total blood loss, the hidden blood loss, and the hemoglobin (Hb) decrease were respectively (420.2 ± 210.5), (240.5 ± 234.5), and (1.7 ± 0.9); in the CON group, the total blood loss, the hidden blood loss, and the Hb decrease were respectively (782.1 ± 340.4), (450.9 ± 352.6), and (2.9 ± 1.0), and these data of both groups were statistically significant ($P < 0.05$). It could be seen that the safety and the degree of injury to human body of PSI operation method were significantly lower than that of CON operation method, which could prove the feasibility and excellence of PSI operation method.

3.4. Data comparison of the PSI group before and after operations

The US Hospital for Special Surgery (HSS) knee scores could comprehensively evaluate the recovery of short-term functions of the patellofemoral joint and femorotibial joint after operations, as well as the comparisons with the articular motions before the operations. The judgment criteria of clinical efficacy were that: greater than 85 points indicated excellent, between 70 and 80 points indicated fine, between 60 and 69 points indicated fair, and less than 59 points indicated poor. The Knee Society Score (KSS) was used to evaluate the clinical efficacy. 85–100 points were recorded as excellent, 70–84 points were recorded as fine, 60–69 points were recorded as fair, and less than 60 points were recorded as poor. The evaluation method of the Visual Analogue Scale (VAS) had high sensitivity and comparability. A line segment with a length of 10 cm was drawn on the paper and was divided into 10 scales. One end of the scale was recorded as 0, and the other end was recorded as 10, in which 0 indicated no pains, 10 indicated severe pains, and the middle part indicated different degrees of pains. The WOMAC rating scale was utilized to evaluate the preoperative and postoperative structures and functions of hip-knee joints through the aspects of pain, rigidity, and articular functions.

As can be seen from the table below, the preoperative scores of HSS, KSS, ROM, WOMAC, and VAS were respectively (57.7 ± 11.2), (43.6 ± 14.7), (103.1 ± 20.6), (60.4 ± 6.5), and (5.8 ± 1.2); the postoperative scores of HSS, KSS, ROM, WOMAC, and VAS were respectively (86.4 ± 8.2), (77.6 ± 14.2), (109.7 ± 12.3), (12.2 ± 8.1), and (2.5 ± 0.8). The data of preoperative and postoperative data in the PSI group were significantly different ($P < 0.05$); however, the differences of preoperative and postoperative knee joint activities were not statistically significant ($P > 0.05$). It could be seen that

through PSI treatment, it could greatly improve the flexibility of patients' joints and reduce patients' pain.

4. Discussion

Through the comparisons of perioperative time between the experiment group and the control group, it was found that the operation time of the CON group was significantly higher than that of the PSI group by 0.5 h. Through the measurements of long leg weight bearing X-ray radiographs, in the lower limb force line corrections of the two groups, no significant differences were found in HKA, FMAA, and FFA ($P > 0.05$); however, through further calculations, the outliers of HKA were 0% in the PSI group and 18.8% in the CON group; in addition, compared with the CON group, the FFA of the PSI group was closer to the ideal value; meanwhile, the differences in LFA and FTA between the two groups were statistically significant ($P < 0.05$), and the LFA and FTA of the PSI group were closer to normal values; thus, it could be considered that the coronal force line recovery in the PSI group was more accurate than that in the CON group. The lateral cortical line of distal femoral was almost parallel to the distal anatomical axis of the femur and could be used as a reference line for distal femoral extramedullary localization. The 3D printing PSI model could effectively simulate the lower limb coronal force line and was highly consistent of the preoperative software simulation plan. In conclusion, compared with the traditional knee joint replacement surgery, 3D printing personalized distal femoral osteotomy guide plate model can greatly improve the safety of knee joint replacement surgery, can reduce the pain of patients, and has important clinical application value. The deficiencies of the experiment were that the number of research objects was not enough, and the postoperative long leg weight bearing X-ray radiographs were less, which made it impossible to further accurately compare the sagittal force lines of the two groups. Thus, subsequent experiments would continue

to increase the cases for control studies. 3D printing technology has high application values in orthopedic operations. Therefore, in future research, the application of 3D printing technology in orthopedic operations should be further researched and explored to make more patients benefit from clinical treatments.

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