RESEARCH ARTICLE

Effectiveness and Accuracy of a Patient-Specific Instrumentation System for Total Hip Arthroplasty

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Objective: Traditional total hip arthroplasty (THA) is often performed by visual inspection due to the lack of reliable reference, which results in inappropriate position of prosthesis and poor outcomes. This study attempts to introduce a novel patient-specific instrumentation (PSI) system and assess its effectiveness and accuracy compared with freehand operation and robot system through bone model experiments.

Methods: Equally divide 30 sawbone models into the freehand group, PSI group, and robot group. Ten sets of prosthesis parameters were randomly generated as planning, and the three groups underwent simulated THA depending on these parameters. After the placement of the femoral prosthesis, the acetabular anteversion plan was adjusted in the PSI and robot groups so that the combined anteversion was maintained before and after adjustment. After the surgery, the actual prosthesis parameters of all bone models were measured and analyzed statistically.

Results: No statistically significant difference was found in femoral anteversion error among the three groups ($p = 0.951$). The errors of acetabular cup anteversion, acetabular cup abduction, and combined anteversion in PSI group were 3.92° (2.94°, 4.62°), 5.65° (4.63°, 6.70°), and 3.93° (2.94°, 4.62°), respectively, which were significantly smaller than those in the freehand group [11.84° (9.92°, 13.87°), 13.54° (9.81°, 15.21°), 16.04° (8.18°, 19.25°), respectively, $p < 0.05$], but significantly larger than those in the robot group [1.34° (0.98°, 1.70°), 1.80° (1°, 2.02°), 1.34° (0.98°, 1.70°), respectively, $p < 0.05$].

Conclusion: Compared with the traditional freehand operation, the patient-specific instrumentation system is feasible in total hip arthroplasty because it improves the accuracy of prosthesis placement. In addition, the rapid measurement of intraoperative femoral prosthesis parameters can help surgeons optimize preoperative planning.

Key words: Combined Anteversion; Patient-Specific Instrumentation; Robotics; Surgical Navigation; Total Hip Arthroplasty

Background

Total hip arthroplasty (THA) is the most effective treatment for degenerative hip diseases. With the aging of the global population, the number of THA cases has sharply increased. Depending on statistics, the annual total number of arthroplasty cases in China has reached nearly 400,000, of which almost 60% are hip arthroplasties.

Position of the prosthesis is one of the key factors that affect surgical outcomes. Inappropriate position often leads to impingement, dislocation, limited range of motion, reinforced wear of the prosthesis, and so forth,[1,2] and eventually instability and failure,[3,4] which require revision surgery. This exerts substantial physical and financial burdens on the patient.[5]

Traditional THA has some notable problems. First, given the limited exposure to the surgical area and the lack of reliable references, surgeons place prostheses with reference to the operating bed or ground, which generates errors caused by the patient's movement. Second, during the operation, the direction of the position of the prosthesis was mostly obtained by the surgeon's visual inspection. Fujishiro measured prosthesis parameters in 1411 patients who underwent primary THA and revealed a very wide error range.[6]

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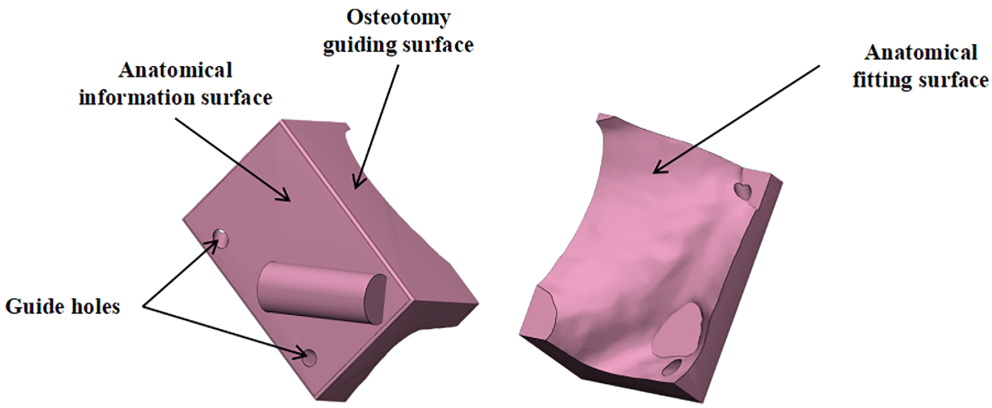

FIGURE 1 Femoral base tool

Lastly, with the in-depth study of postoperative THA complications, the correlation between the femoral prosthesis and acetabular cup prosthesis gained attention. Ranawat popularized the concept of combined anteversion[7]; that is, the sum of femoral anteversion and cup anteversion should satisfy a specific range. Dorr proposed that the safety zone of combined anteversion should be between 25° and 50° (37° ± 12°),[8] which is widely accepted and still used today. Subsequent studies have disagreed on the definition of combined anteversion and safe zone, but authors were convinced that prosthetic parameters play a crucial role in avoiding hip impingement.[9,10] Therefore, the safe zone of the acetabular cup is relevant to the femoral prosthesis, which requires surgeons to measure parameters after femoral prosthesis placement and adjust the surgical plan of the acetabular cup accordingly.

With the rapid development of computer navigation and robot technology, medical surgical robots have been used in orthopaedic surgery.[11] With the help of optical real-time tracking technology and the stable operation of the mechanical arm, the accuracy of orthopaedic surgery can be greatly improved.[12] However, robots are bulky, complicated to operate, and most importantly, expensive, which only a few hospitals can afford.[13]

In conclusion, there is a clinical need for a cheap, convenient, and relatively accurate auxiliary tool, so we designed a novel patient-specific instrumentation (PSI) system for THA. This system utilizes 3D printing technology and sensors to achieve prompt measurement of prosthesis parameters and real-time navigation of THA. The objectives of this study were: (i) to assess the effectiveness and accuracy of the PSI system; (ii) to analyze results of this PSI system; and (iii) to discuss advantages and disadvantages of the PSI system in THA application.

Materials and Methods

Materials, Instruments, and Software

Bone models (Sawbones® USA), coordinate measuring machine (Absolute arm, Hexagon Manufacturing Intelligence [Qingdao] Co. LTD, China), PSI system, bench clamp, THA surgical tool (Zimmer Biomet Holdings, Inc., USA), Xishan Surgical Power Unit (DK-O-MCS, Chongqing Xishan Technology Co. LTD, China), THA robot system (TiRobot Recon, Beijing TINAVI medical Technology Co. LTD, China), Materialize mimics (Version 21.0, Materialize, Belgium), Materialize 3-Matic (Version 13.0, Materialize, Belgium), SPSS (Version 26.0, IBM, USA).

PSI System

The PSI system included base and standard tools. Base tools include femoral and acetabular base tools in accordance with the site of action. Femoral base tools include the anatomical fitting surface, osteotomy-guiding surface, and anatomical information surface (Figure 1). Acetabular base tools include the anatomical fitting surface and the anatomical information surface (Figure 2). Standard tools consist of the femoral information reading tool, femoral neck axis reading tool, pelvic information reading tool, and acetabular navigation tool (Figure 3).

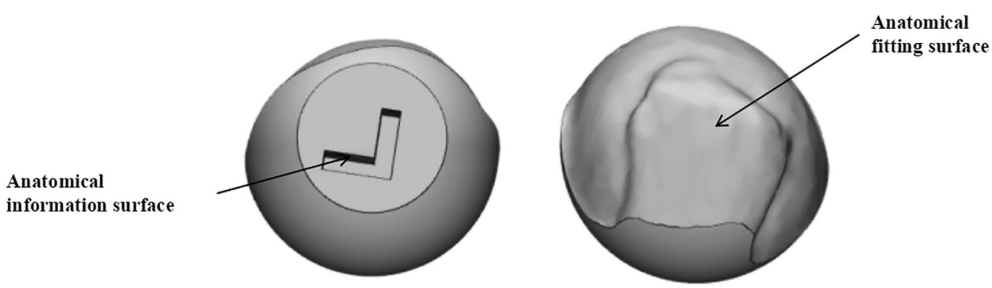

FIGURE 2 Acetabular base tool

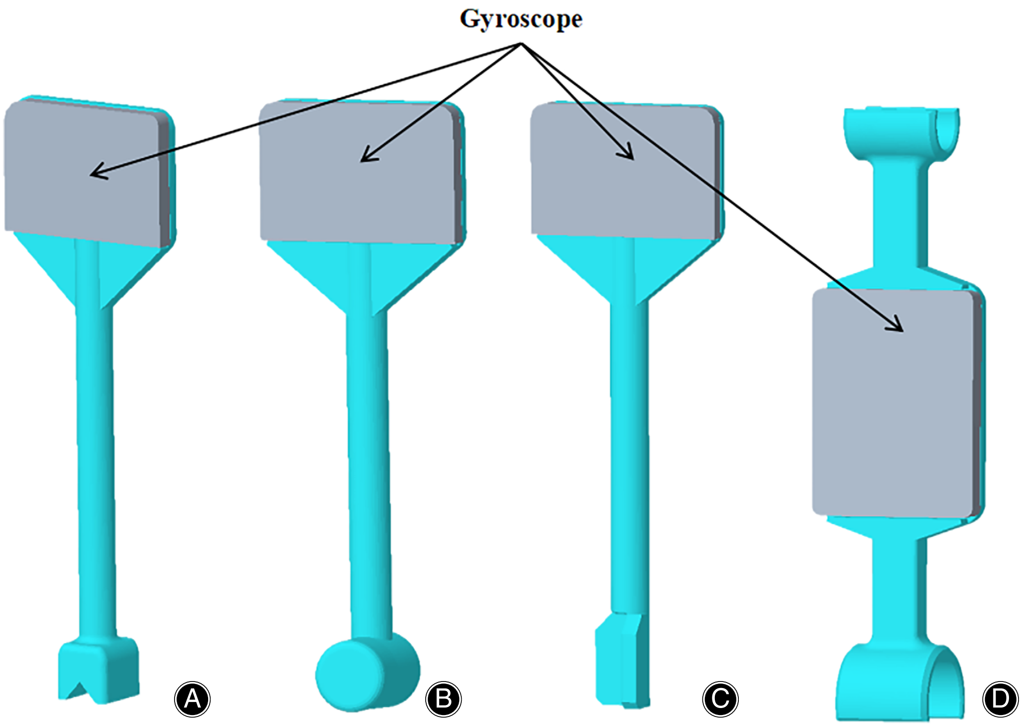

FIGURE 3 Standard tool (A) Femur information reading tool; (B) Neck axis reading tool; (C) Pelvic information reading tool; (D) Acetabular cup navigation tool

The design process of base tools is similar to the traditional 3D printing femoral osteotomy guide plate and acetabular positioning tool. The bone model was scanned by CT. Digital imaging and communications in medicine (DICOM) data were imported to the Mimics 21.0 software for segmentation and 3D reconstruction. Transfer reconstruction model into the 3-Matic software for base tools design.

Femur side: The frontal surface and anatomical axis of the femur model were fitted as references for base tool design. The femoral intertrochanteric crest was used as the target area for the femoral base tool. Because this area can be completely exposed, it has less soft tissue attachment and strong anatomical specificity. The anatomical information surface of the femoral base tool was designed to parallel the femoral frontal surface, which can be used as a reference for femoral anteversion measurement. The osteotomy-guiding surface is coplanar with the planned osteotomy surface. A cylinder was designed on the anatomical information surface with its axis parallel to the anatomical axis of the femur, which can be used as a reference for the measurement of the

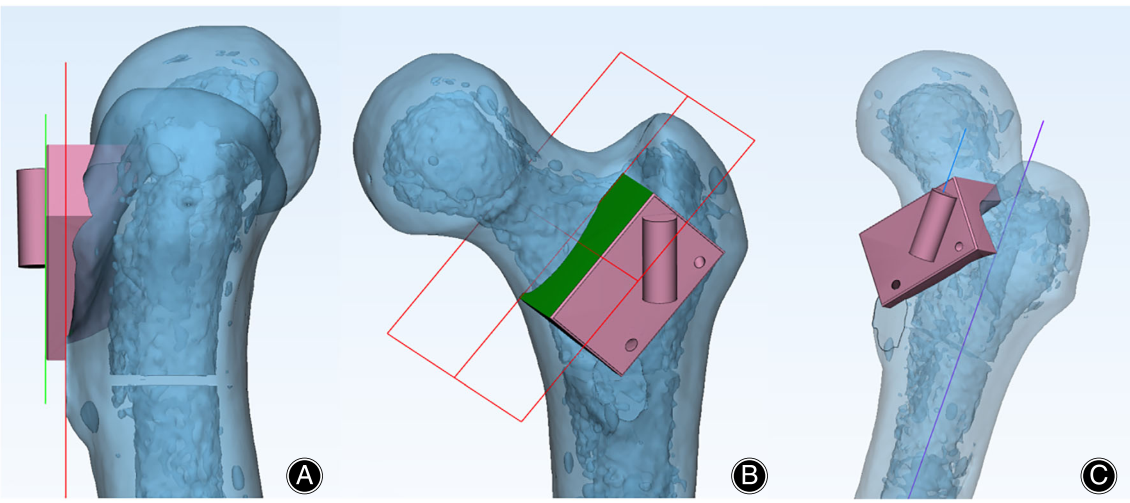

FIGURE 4 (A) Anatomical information surface (green) is parallel to the femoral frontal surface (red); (B) Osteotomy guiding surface (green) is coplanar with the planned osteotomy surface (red); (C) The cylinder axis was parallel to the anatomical axis of the femur

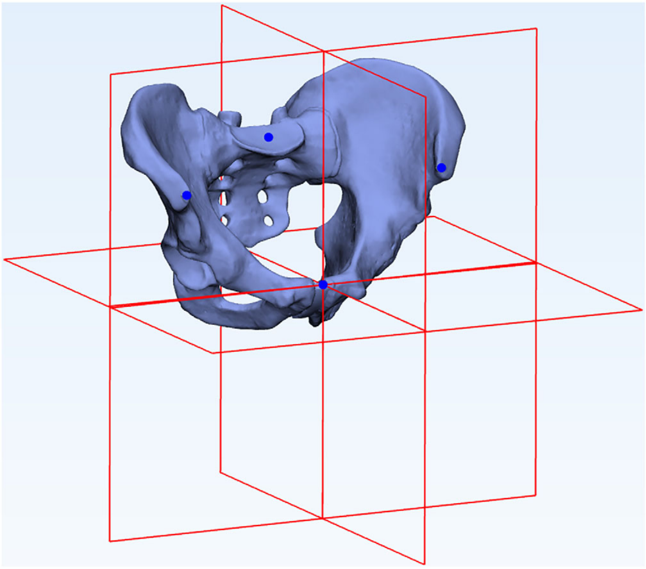

FIGURE 5 Pelvic segmentation and reference frame establishment

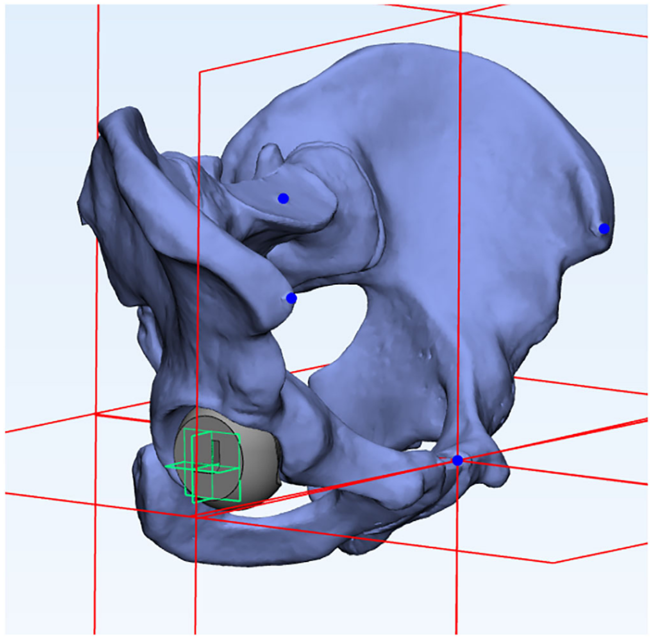

FIGURE 6 The acetabular base tool anatomical information surface (green) is parallel to the pelvic reference surface (red), respectively

femoral neck shaft angle (not used in this experiment) (Figure 4). The anatomical fitting surface was obtained by Boolean subtraction. Guide holes were designed so that the direction of the Kirschner wires would not influence prosthesis placement.

Acetabular side: The anterior pelvic plane (APP), created from the bilateral anterior superior iliac spine to the pubic symphysis, was used as the pelvic coronal surface. Combined with the upper surface midpoint of the S1 vertebral body, the sagittal plane and cross-section were drawn to establish a spatial reference frame (Figure 5). This reference frame is rigidly related to the pelvis. No matter how the pelvis translates or rotates, the parameters of the acetabular cup prosthesis have fixed values to avoid placement errors due to the postural factors of the patients. The acetabular fossa was taken as the target area of the acetabular base tool, which was also fully exposed during surgery, without excess soft tissue coverage, and had strong morphological specificity. In designing the acetabular base tool, the three planes of the "L-shaped" groove in the anatomical information surface should be parallel to the APP, sagittal plane, and cross-section of the pelvis (Figure 6). The anatomical fitting surface was also obtained by Boolean subtraction.

According to the application design, standard tools can be subdivided into information reading tools and navigation tools. Each standard tool has two parts: the functional part and the gyroscope part. For information reading tools, the functional part was designed to read the reference information in the anatomical information surface of the corresponding base tool (Figure 7). In addition, the functional part of the navigation tool can be fixed to the operation rod so that the axis of the operating rod was kept parallel to the gyroscope axis.

Experimental Procedure

Marking bone models: Drill a 2 mm-deep hole at each anatomical mark of bone models. Place a 2 mm-diameter steel ball and seal the hole with hot melt adhesive (Figure 8). This is to provide a fixed and unified reference frame for each group during the succeeding parameter measurement process.

Thirty sawbone models were equally divided into three groups: freehand group, PSI group, and robot group. Before the operation, bone models were firmly fixed to the experimental table using the bench clamp.

Ten sets of parameters were randomly generated with femoral anteversion, acetabular anteversion, and acetabular abduction as one set, in which the femoral anteversion was fixed at 15°, the acetabular cup abduction ranged from 30° to 50°, and the acetabular cup anteversion ranged from 5° to 25°. Then, the combined anteversion of each group was obtained.

Freehand group: According to the planning parameters, the THA was simulated by freehand on the femoral and pelvic models (Figure 9).

PSI group: Design and print the base tool. First, accomplish operational steps on the femoral side. Place the femoral base tool on the femoral intertrochanteric crest. Use 2-mm Kirschner wires fixed to the femoral base tool of the femur via the guide holes. Perform femoral neck osteotomy along the osteotomy-guiding surface and complete femoral prosthesis placement as in a routine operation. Use the femoral information reading tool and femoral neck axis reading tool to calculate the femoral prosthesis anteversion (Figure 10). Adjust the acetabular cup anteversion plan so that combined anteversion

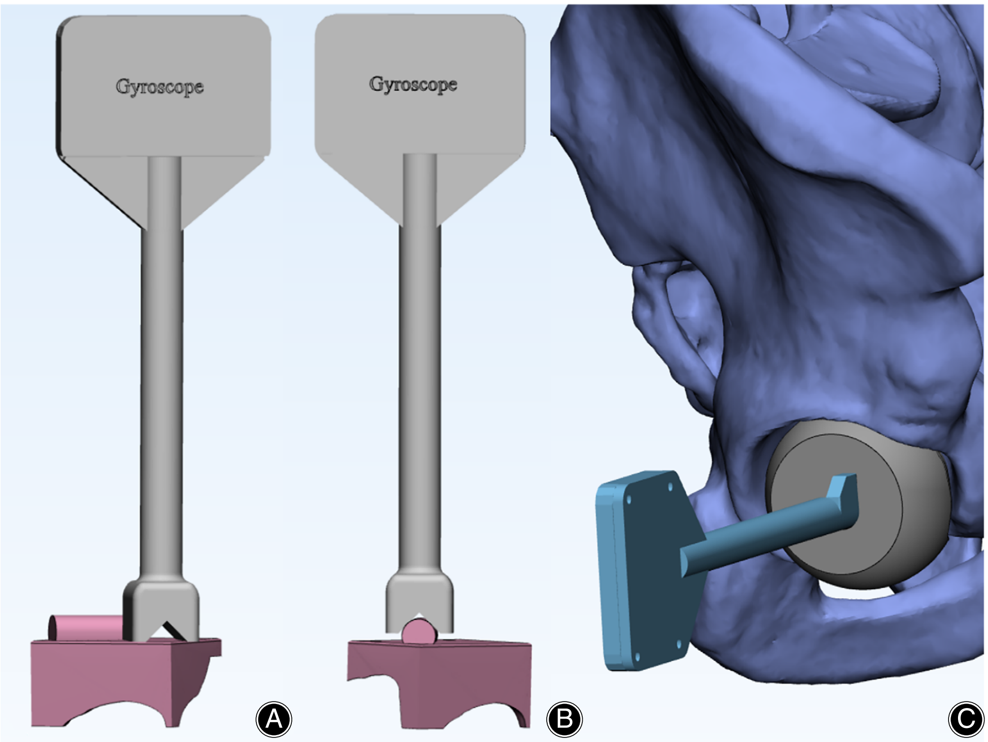

FIGURE 7 Operation method of information reading tools (A) Read information of femoral frontal plane; (B) Read information of femoral axis; (C) Read information of pelvic reference frame

was maintained before and after adjustment. Record adjusted acetabular anteversion parameters. Perform the procedures on the acetabular side. Place the acetabular base tool in the acetabular fossa. Insert the pelvic information reading tool into the "L-shaped" groove of the acetabular base tool and transfer the pelvic reference plane information to a computer. Subsequently, during acetabular grinding and prosthesis placement, fix the acetabular navigation tool to the operation rod. By calculating the angle between the axis of the operating rod and the reference surface recorded before, realize the real-time navigation and complete prosthesis placement according to the adjusted plan (Figure 11).

Robot group: Conduct CT of the bone models. Import DICOM data into the robot system. Perform preoperative image processing. Install a tracker on the lateral side of the

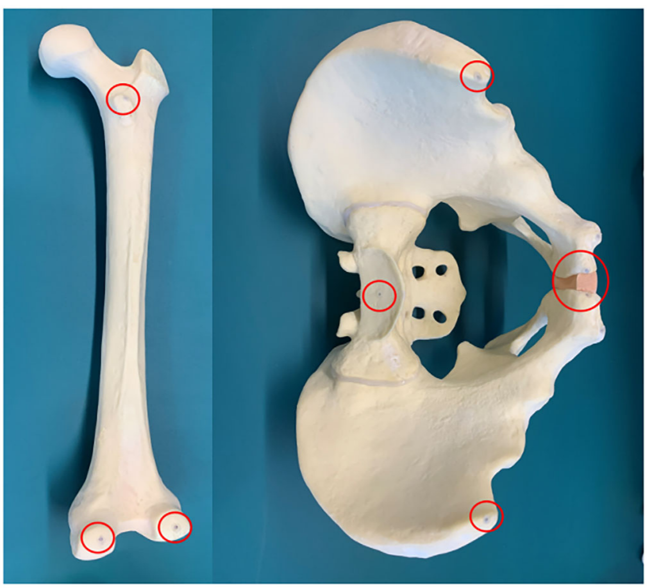

FIGURE 8 Model bone mark

FIGURE 9 THA were simulated by freehand

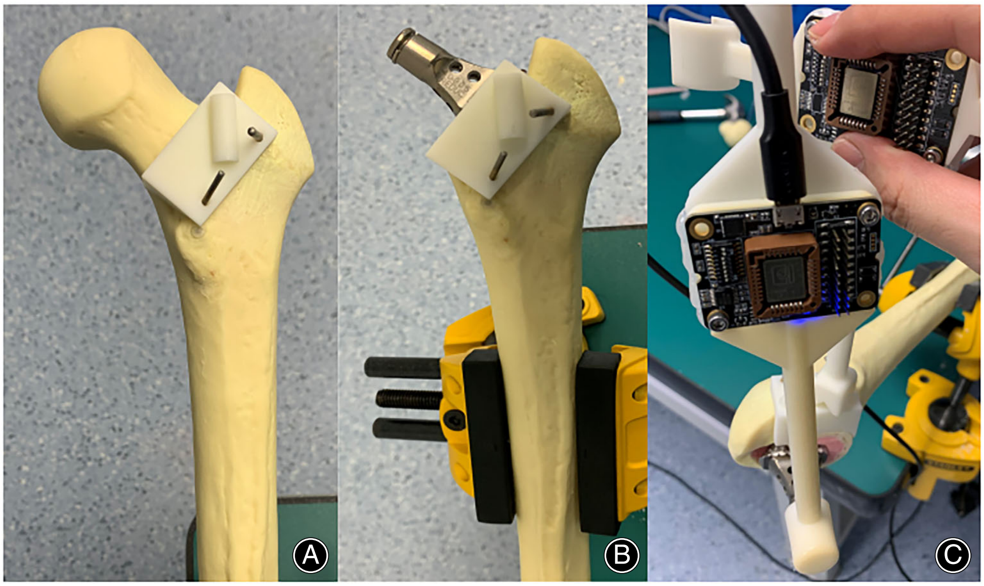

FIGURE 10 PSI group femoral operation process (A) Base tool placement; (B) Prosthetic placement; (C) Femoral prosthesis anteversion measurement

femoral trochanter. Accomplish femur registration by the probe. Set the osteotomy line under navigation and then perform a femoral neck osteotomy. Implant the femoral prosthesis by the freehand technique. Measure the femoral parameters using the corresponding tools. Similar to the PSI group, adjust the acetabular cup anteversion plan so that the combined anteversion was maintained before and after adjustment. Record all parameters.

Operational steps on the acetabular side: Install a tracker on the iliac crest. Accomplish pelvic registration by the probe. Run the robotic arm in the direction of the adjusted plan. Accomplish acetabular cup grinding and acetabular cup prosthesis placement with the assistance of the robotic arm. Lastly, measure postoperative parameters of the acetabular cup prosthesis (Figure 12).

Parameter Acquisition

To ensure that the parameters of each group were comparable, each parameter was clearly defined. For the acetabular

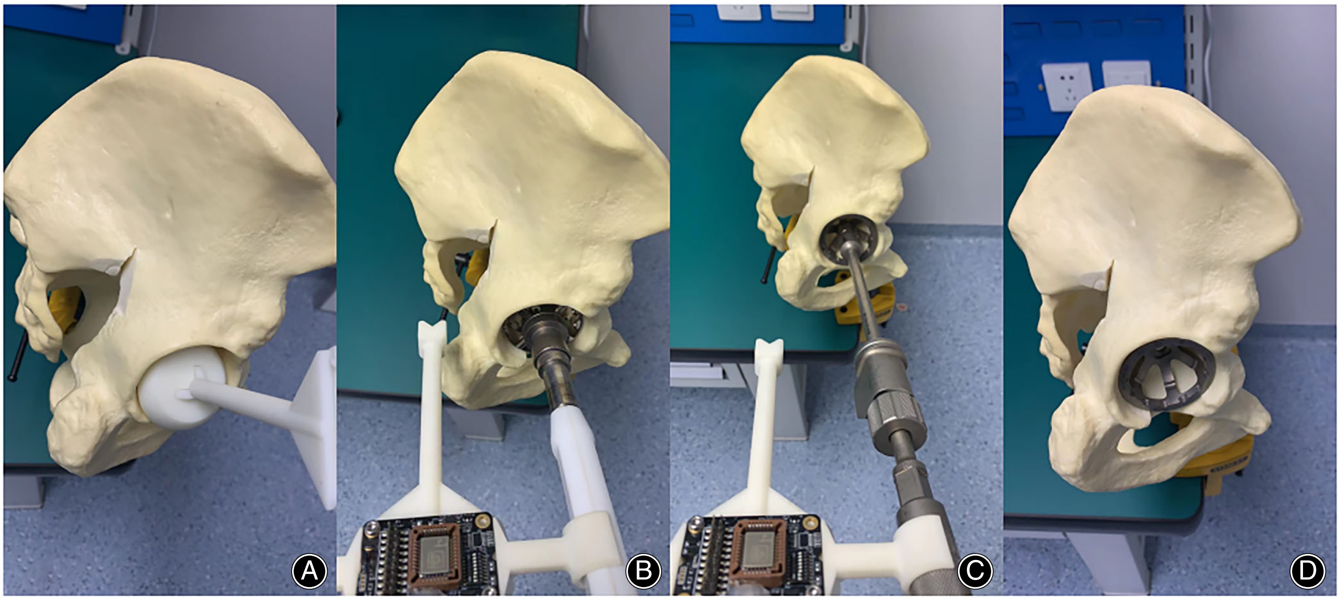

FIGURE 11 PSI group acetabular operation process (A) Base tool placement and reading reference surface information; (B) Acetabular grinding under navigation; (C) Cup prosthesis placement under navigation; (D) Cup prosthesis placement completed

FIGURE 12 RA group operation process
(A) Robot-assisted femoral neck osteotomy;
(B) Femoral anteversion measurement;
(C) Robot-assisted acetabular grinding;
(D) Cup parameters verification

cup parameters, we used the radiological definition proposed by Murray.[14]

i. Femoral anteversion: The angle between the femoral neck axis and the femoral frontal plane.
ii. Acetabular cup anteversion: The angle between the coronal plane and the acetabular cup axis.
iii. Acetabular cup abduction: The angle between the sagittal plane and the projection of the acetabular cup axis on the coronal plane.
iv. Combined anteversion: The sum of femoral anteversion and acetabular cup anteversion.

Use coordinate measuring machine to measure the prosthesis parameters of all postoperative bone models, include femoral anteversion, acetabular anteversion, and acetabular abduction. During the measurement process, the metal balls in the previous marking bone models step could be selected to fit the required reference surface for parameter measurement.

We used the parameter error—the absolute value of the difference between the actual parameter and the planned parameter—to analyze the accuracy and difference in each group (note that the acetabular cup anteversion errors of the PSI and robot groups are the absolute values of the difference between the actual acetabular cup anteversion and adjusted acetabular cup anteversion).

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows Version 26 (IBM Corp., Armonk, NY, USA). Kruskal–Wallis test was used for non-normal variables, which were expressed as median (interquartile range). A value of $p < 0.05$ was considered significant.

Results

Overview of Parameters in each Group

We finished with a total of 30 THA operations of bone models. Random parameters and actual prosthesis parameter results of each group are shown in Table 1.

TABLE 1 Summary of parameters results [median (Q1, Q3)]

Parameters	Random plan	Freehand group	PSI Group	Robot group
Femoral prosthesis antevesion (°)	15 (15, 15)	18.08 (12.53, 21.91)	16.76 (12.67, 21.40)	18.08 (12.49, 21.19)
Acetabular cup anteversion (°)	17.5 (12.75, 21.25)	29.27 (22.64, 35.50)	21.32 (8.1, 28.42)	17.82 (9.88, 19.66)
Adjusted Acetabular cup anteversion (°)	NA	NA	18.99 (5.7, 23.42)	16.58 (7.97, 20.1)
Acetabular cup abduction (°)	40.5 (35.75, 45)	52.51 (51.16, 57.98)	46.02 (41.25, 51.18)	42.48 (37.48, 46.07)
Combined anteversion (°)	32.5 (27.75, 36.25)	48.57 (41.46, 51.12)	37.57 (31.26, 41)	32.83 (28.54, 37.66)

TABLE 2 Parameter error results of each group [median (Q1, Q3)]

	Freehand group	PSI group	Robot group	Statistics	*p* value
Femoral anteversion error (°)	4.02 (2.15, 6.91)	4.78 (2.17, 6.40)	4.35 (2.42, 6.19)	$H = 0.101$	0.951
Acetabular cup anteversion error (°)	11.84 (9.92, 13.87)	3.92 (2.94, 4.62)	1.34 (0.98, 1.70)	$H = 24.792$	<0.001
Acetabular cup abduction error (°)	13.54 (9.81, 15.21)	5.65 (4.63, 6.70)	1.80 (1, 2.02)	$H = 25.806$	<0.001

Prosthesis Anteversion Error

For the femoral prosthesis anteversion error, no significant differences were found among the groups ($p = 0.951$). This result was expected because the insertion of the femoral prosthesis was performed under visual inspection in all groups. At the same time, the target parameters of femoral anteversion were consistent in each group, and the error gradually became stable after the first few attempts.

In comparison of errors of acetabular cup parameters, either anteversion or abduction, significant differences were found among the three groups ($p < 0.001$). Statistical results are shown in Table 2.

Post hoc multiple comparisons showed that the robot group had the highest accuracy of the acetabular cup parameters among the three groups. The errors of the acetabular cup parameters of the PSI group were smaller than those of the freehand group. All differences were statistically significant ($p < 0.05$). Statistical results are shown in Table 3.

The comparison results of the combined anteversion error were similar to those of acetabular cup parameters. It takes a combined anteversion error of 16.04° (8.18°, 19.25°) in freehand group, 3.93° (2.94°, 4.62°) in PSI group, and 1.34° (0.98°, 1.7°) in robot group. Thus, the combined anteversion error in the PSI group was smaller than that in the freehand group ($p = 0.033$), but larger than that in the robot group ($p = 0.044$).

Discussion

Accuracy of Novel PSI System

In this study, we introduced our novel PSI system and compared the accuracy of freehand, PSI, and robot-assisted THA on prosthesis implantation through bone model experiments. For femoral prosthesis implantation, neither PSI nor robot improved accuracy compared with freehand operation because every group placed prosthesis under visual inspection. However, in the acetabular cup placement, the accuracy of PSI and robot is significantly superior to freehand operation due to the stable reference surface and the real-time navigation function. Because of this, PSI system and robot can better ensure that the combined anteversion angle of the prosthesis is within the acceptable error range of plan. The results also revealed that PSI was less accurate than the robot, and there is still room for improvement.

Significance of Novel PSI System

It is clinically desirable to accurately place the prosthesis in a safe zone to avoid postoperative complications.[15,16] But patients have unique spinopelvic movements that can affect the safe zone of the acetabular cup.[17] Therefore, to find the most suitable prosthesis position for patients, it is necessary to identify, reconstruct, and simulate the multimodal information of patient anatomy, biomechanics, and kinematics and then calculate the personalized specific safe zone of the acetabular cup.[18] Moreover, the femoral

TABLE 3 Post hoc multiple comparison results of the acetabular cup parameters

	Freehand group vs. PSI group		PSI group vs. robot group		Robot group vs. freehand group	
	Statistics	*p* value	Statistics	*p* value	Statistics	*p* value
Acetabular cup anteversion error	$H = -2.565$	0.031	$H = 2.413$	0.047	$H = 4.978$	<0.001
Acetabular cup abduction error	$H = -2.54$	0.033	$H = 2.54$	0.033	$H = 5.08$	<0.001

prosthesis position is influenced by the femoral neck physiological anteversion, proximal femoral anterior arch, proximal femoral morphology of the medullary cavity, and other related factors. Relatively, acetabular prosthesis parameters are more controllable. Therefore, we recommended placing the femoral prosthesis first and the acetabular cup prosthesis according to the parameters of the femoral prosthesis. However, surgeons still need tools to avoid visual errors during acetabular cup prosthesis placement.

In recent years, 3D printing technology experienced dramatic improvements in methodology, accuracy, and material quality. It has been widely used in orthopaedic surgery[19]; 3D printing models are used to simulate surgery,[20] such as 3D printing custom implant[21] and 3D printing surgical guide plate.[22] Studies have proved that THA using a 3D printing guide plate can significantly improve the accuracy of surgery.[23] However, once the surgical guide plate is printed, it cannot be changed. The surgeon must follow the planned procedure based on the surgical guide plate and cannot adjust the surgical plan according to the actual intraoperative situation.

The PSI system for THA used in this study was independently designed by our team. To realize its measurement function, an anatomical information module was added to the base tool. Anatomical information required for the measurement of prosthesis parameters is integrated into the tool. To read the integrated anatomical information, the reading tools for the corresponding structures were made. In addition to the navigation tool, all the aforementioned tools make up the complete PSI system. This system realizes parameter measurement function and real-time navigation, which can better provide the basis for intraoperative operation and avoid blind operation.

Advantages and Disadvantages of Novel PSI System

As mentioned before, the PSI system can greatly improve the accuracy of surgery compared with traditional freehand operation. Although the accuracy of the PSI system is not as good as that of the robot, it also has some advantages that the robot cannot match. First, the PSI system is cheaper. Except for the base tools that need to be printed in 3D and customized, standard tools can be reused. The cost of the entire set of the PSI system is less than 2000 RMB, which can greatly reduce medical expenses compared with robots that cost millions of dollars. Second, the PSI system is easy to operate and saves surgical time. The design of the PSI system is completed before surgery. Surgeons only need to perform a few simple steps to use it during surgery without changing their surgical habits. Compared with the complex steps of RA surgery, such as registration, running of the robotic arm, and repeated disassembly and assembly of tools, the PSI system may be more acceptable to clinicians.

However, this PSI system has several limits. First, in this system, we used gyroscopes for angle measurement. Gyroscopes will produce drift errors during long periods of use. To decrease the effect of drift errors, we added a reset command in the supporting software for automatic calibration before each use. In addition, magnetic fields should be avoided around the gyroscope. Second, resulting from the functional limitations of the gyroscope, this PSI system can only perform measurements of angular parameters. However, in actual clinical surgery, surgeons often give attention to acetabular grinding depth, femoral offset, limb-length discrepancy, and other distance parameters. To make the tool system more functional, we have begun developing a new version of PSI systems using magnetic navigation or augmented reality and virtual reality technology to help clinicians better.

Strength and Limitations

To our knowledge, this is the first study to combine 3D printing technology and sensor in THA. However, this experiment has some limitations. First, during this experiment, the experimental operator can see the whole bone model, making it a good reference. But it will not happen in the real surgical scene. Second, femoral models cannot simulate unique femoral anatomical morphology in different patients, which explains why freehand femoral anteversion in previously published clinical research articles showed a wider range of results than in the present study.[6,24] Therefore, further clinical PSI experiments are necessary.

Conclusion

Compared with freehand operation, PSI has significant advantages in accuracy. Anatomical reference surface information is integrated into the base tool in advance by 3D printing, which is read by the gyroscope during operation, and the rapid measurement of prosthesis parameters and intraoperative navigation are realized. Even not as accurate as the robot, the PSI system can be an excellent alternative to THA in primary hospitals that cannot afford a robot because of its simple design, high accuracy, and low price.

Author Contributions

Teng Zhang: Writing—Original Draft, Investigation, Methodology; Zhao Jia: Writing—Review & Editing, Data Curation; Junqiang Wang and Wei Han: Supervision, Validation; Jinqi Li: Formal analysis, Data Curation; Maoqi Gong: Project administration; Xieyuan Jiang: Funding acquisition, Conceptualization. All authors read and approved the final manuscript.

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Conflict of Interest

All authors disclosed no relevant relationships.

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