Design of Custom-made Navigational Template of Femoral Head and Pilot Research in Total Hip Resurfacing Arthroplasty

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Research article

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Abstract

Background

To develop a novel custom-made navigational template for accurate prosthesis implantation in total hip resurfacing arthroplasty (THRA) by computer-aided technology.

Methods

The template was produced based on data preoperatively acquired with computed tomography (CT) scan. The position of the drill guide was chosen as the anatomical axis of the femoral neck which was defined by the ligature between the center of the femoral head and another point on the centerline of proximal femoral neck. And the final direction of the drill guide was confirmed by a small valgus angle. The surface of the template was constructed as the inverse of the femoral neck surface. Then each template was formed from acrylate resin by using rapid prototyping (RP) technique. Finally, the template was tested in 18 cadavers scheduled for THRA and postoperative medical imaging was used to evaluate the accuracy and validity of the template.

Results

The template had a near-prefect fit with the femoral neck surface. There were no guide failures. Postoperative evaluation revealed that the Kirschner wires pass through the center of the femoral head, have a relative valgus angle to the central axis of the femoral neck and have no obvious varus-valgus angles or anterior/posterior inclination angles. So, the Kirschner wires achieved the expected implant requirement.

Conclusion

This study shows a novel way of guiding the prosthesis implantation accurately in THRA. The template is an excellent medium for preoperative planning and intraoperative technique, and embodies the development tendency of Computer Assisted Surgery.

1. Background

Total hip resurfacing arthroplasty (THRA) is an old concept in orthopedic surgery. Early resurfacing is no longer used because of inappropriate variations in prosthetic materials [1]. However, the use of THRA has been reinstated after the University of California designed and applied a third generation metal-on-metal surface arthroplasty prosthesis system in 1966 [2]. To date, metal-on-metal hip resurfacing arthroplasty (MM-RA) has become the preferred alternative for young, active patients for the improvement of prognosis of future hip joint arthroplasties [3–6]. Nevertheless, the main conditions that cause the failure of THRA include femoral neck fracture, aseptic loosening of the femoral prosthesis, and hip varus–valgus. These complicated diseases are closely related to the location of the femoral prosthesis implant. Several studies have shown that early postoperative femoral neck fracture is related to proximal femoral bone fracture and is biomechanically influenced by improper surgical operations and femoral prosthesis implantations [7,8]. Thus, the location of the femoral prosthesis is vital for implant survival. However, only a few methods have been developed for guiding the orientation of the femoral prosthesis [9].

The demand for accurate joint replacement has been increasing continuously, particularly for prosthesis location. Considering the different anatomical forms of the hip joint, only individual treatment can adapt and accurately treat physiological joint activities. In this study, we develop a novel patient-specific navigational template for accurate prosthesis implantation in THRA by computer-aided technology and reverse engineering (RE). Consequently, individual treatment is achieved accurately and effectively.

2. Methods

2.1 Data Acquisition

A total of 18 specimens with the lower extremities of ten males and eight females aged 45 years to 65 years were obtained from the Department of Anatomy at Kunming Medical University. All specimens were examined by fluoroscopy to exclude other hip diseases and deformities. A spiral 3D computed tomography pelvic scan (Light Speed VCT, General Electric, USA) was performed on each specimen with a 0.630 mm slice thickness and 0.35 mm in-plane resolution (100 mA tube current; 120 kV tube voltage; 15 s to 20 s scan time; 512 × 512 scan matrix). All scans were performed with the specimens in a supine position. All imaging data were stored in the DICOM (digital imaging and communications in medicine) format. The need for ethics approval was deemed unnecessary for this cadaver research by the Ethics Committee of 920th Hospital of Joint Logistics Support Force.

2.2 Preoperative Planning

MIMICS10.01 software (Materialise, Belgium) was used on the images to generate a 3D reconstruction model of the desired hip joint. First, the femur was segregated from the 3D model. We obtained the spherical center, which was considered the center of the femoral head, by fitting a suitable sphere (Figure 1a). We selected a point from the centerline of the proximal femur that had rounder and finer local as the center of the femoral neck (Figure 1b). The coordinates of the two points were multi-calculated by the same person, and the mean values were obtained. We achieved the central axis of the femoral neck by the ligature of the two points.

A virtual drill guide with a 4 mm diameter was placed according to the location of the femoral neck axis for placement simulation to obtain the optimal Kirschner wire trajectory on the 3D femoral model. The final direction of the drill guide was confirmed by a small valgus angle of 5° to 10°, which served as the original point of the femoral head center on the femoral coronary surface (Figure 2). The optimal length of the drill guide was determined based on the measurement.

Second, the femur model was exported in stereolithograph (STL) format to a workstation running Geomagic Studio 12 software (Geomagic Inc., USA) to create the custom-made template surface according to the optimal drill guide trajectory. The surface was constructed as the inverse of the femoral neck surface, thus, a near perfect fit was established (Figure 3). We also ensured that the template did not overlap onto the adjacent segments.

Finally, a virtual custom-made navigational template that fit the bone surface closely was constructed with a drill guide as the navigational channel for the Kirschner wire. This custom-made template represented the femoral head prosthesis stem.

The bio-model of the novel navigational template was produced with medical-grade acrylic resin (Somos 14120, DSM Desotech Inc., USA) by stereolithography, which is a RP technique (Bing Chuang Company, China) (Figure 4). System parameters were set as follows: 0.1 mm processing layer thickness, 450 mm/s processing speed, and 45 °C ± 2 °C temperature.

2.3 Surgery

All surgeries were performed in a laboratory by the senior author (LJL, GXJ) by using the following procedures. Bodies were placed in a lateral position on a table and exposed as necessary prior to hip joint dislocation (Figure 5a). The navigational template was then matched to the femoral head surface accurately. Thereafter, a high-speed drill was used to drill the trajectory of the Kirschner wire along the guidance hole (Figure 5b). Finally, a Kirschner wire was inserted into the femoral head as the expected channel of prosthetic implantation.

2.4 Statistical Methods

The positions of the Kirschner wires after the surgeries were evaluated by x-ray and CT scan. All data were measured by AutoCAD2010 (Auto Desk, USA) and presented in the form of mean ± standard deviation (SD). T-test was performed by using Prism 6.0 software. Measurement indices included the following: (1) Stem-shaft angle (SSA), which is the angle between the axial line of the femur and extension line of the Kirschner wire; (2) lateral offset, which is the acute angle between the central axis of the femoral neck and the implanted Kirschner wire in the coronal surface; (3) horizontal offset, which is the acute angle between the central axis of the femoral neck and implanted Kirschner wire in the transverse surface.

3. Results

During the operation, we easily achieved the best fit for the manual positioning of the template. No significant free motion existed when the template was placed into position and pressed slightly against the femoral head and neck. Thus, the template can be used as an in- situ drill guide for position fixation.

Visual inspections show that the actual surfaces match perfectly to the template of the virtual surface without any restrictions.

A total of 18 cases were instrumented with Kirschner wires by using the novel navigational templates. In the coronary surface of the femur, the Kirschner wires passed through the center of the femoral head (16 cases), had relative valgus angles (14 cases) ranging from 6.2° to 12.3°, had varus angles (2 cases) with the central axis of the femoral neck, paralleled the central axis of the femoral neck (2 cases), and had no significant valgus or varus angle. In the horizontal surface of the femur, the Kirschner wires passed through the center of the femoral head (17 cases), paralleled the central axis of the femoral neck (15 cases), had no obvious horizontal offset, and exhibited slight anteversion (2 cases) and retroversion (1 case). The average valgus angles of the Kirschner wires (8.7° ± 1.7°) were obtained by comparing the preoperative average neck-shaft angle（NSA） (141.2° ± 6.0°) with the postoperative average Stem-shaft angle (SSA) (146.1°± 6.6°) of all samples (Figures 6 to 8).

4 Discussion

THRA is an alternative method to THA for young, active patients with hip diseases [10–12]. THRA enables the preservation of an intact femoral bone, potentially improves the prognosis of future hip joint arthroplasties, closely mimics the normal anatomy of the proximal part of the femur for hip articulation, optimizes stress transfer, and offers inherent stability and optimal range of movement [13,14]. The main factors that cause the failure of THRA include femoral neck fracture and the aseptic loosening of the femoral prosthesis [15]. The femoral neck notch and varus position of the prosthesis caused by improper operation increases the risk of failure [16–18]. Implant position significantly influences implant survival, patient function, and prosthesis life span [19]. Only careful and individualized preoperative planning ensures proper implant position because of the different anatomies of the hip joint [12].

In conventional THAR, the surgeon usually achieves the implant channel for the prosthesis component according to manual measurements and operative experience [20]. Thus, accumulated experience is important before a surgeon can apply THAR. Furthermore, the alteration of the position can cause negative effects on the accuracy of the prosthesis [1]. The offset of the femoral neck central axis always occurs when a traditional localizer is used, thus increasing the risk of fracture. Computer-aided technology lacks the capability for long-term investigations of bulk cases in clinical trials [1]. Computer-aided technology also requires additional system components, such as displays, sensors, and robot systems, for the intraoperative registration of bone structures. Only a few hospitals can meet the costs of these equipments [12]. Therefore, no simple and effective method can be used to ensure the accurate implantation of hip resurfacing systems in contemporary medicine.

We utilized computer-aided technology, RP, and RE to design a novel navigational template to eliminate the need for expensive and complex equipments, facilitate accurate placement, and achieve satisfactory results. The spherical center of the fitting globe approaches significance to the anatomical center of the femoral head by using the contour lines of the femoral head cortex. Despite of the irregular geometry of the femoral neck, the centerline inevitably passes the center of each tangent plane and is perpendicular to the major axis of the femoral neck and shaft of the proximal femur. Thus, we chose a point on the centerline of the femoral neck of a rounder and finer tangent plane with the fitting center of the femoral head to determine the implant channel of the prosthesis. The template also has an unlimited oncoming meaning between the anatomical axis of the femoral neck and ligature of the two points. More accurate results can be achieved by repeated calculation and fitting.

Several studies have emphasized the importance of the valgus orientation of the femoral component relative to the native femoral neck [21,22]. When the valgus angle is set to approximately 140° or is anatomically anteverted, lateral neck and head interfacial stresses will be minimized. Excessive varus–valgus angles increase the rate of femoral neck fractures and prosthetic loosening [23]. Excessive anterior and posterior inclination angles change the optimal pathway of biomechanics. Thus, the final direction of the drill guide was confirmed by an appropriate valgus angle to mimic closely the pre-disease physiological status of the proximal femur. Considering that all performances were based on preoperative CT scan, we obtained the individualized preoperative implant planning. Postoperative evaluation reveals that the Kirschner wires pass through the center of the femoral head, have a relative valgus angle to the central axis of the femoral neck and have no obvious valus–valgus angles or anterior/posterior inclination angles. Thus, the Kirschner wires achieved the expected requirement.

Sheng Lu et al. [12] regarded the femoral head region as the inverse of the template surface. Considering the obvious anatomical mark, easy exposure, and less cartilage, we chose the femoral neck region as the inverse of the template surface. The anatomical marks of the capsular space and osteophyma of the femoral head under pathological status are abnormal, and the articular cartilage can have a negative effect on the matching accuracy. Thus, more perfect fitness would be achieved.

RP is a digital modeling technique based on the principle of separation and involves the accumulation of materials to create a prototype. RP is controlled by a computer and is based on computer-aided design models or imaging data from CT or magnetic resonance imaging (MRI). The manufacturing technique is precise to the point of 0.1 mm or less. Thus, the manufactured inverse surface of the template is the accurate replica of biological objects with similar morphologies. We can also conduct virtual surgeries in MIMICS10.01 software, simulate operative procedures, observe the implant locations of prosthesis, evaluate results, and modify procedures. The advantages of computer-aided technology embody the development tendency of digital orthopedic systems.

In summary, our navigational template system serves as a novel alternative for the placement of hip resurfacing prosthesis. Our system is easy to implement, appropriate for surgeons without special training, eliminates time-consuming procedures in the operating room. The time consumed from the design to the production of one template is approximately 3 h. The cost of a novel template is the sum of all material costs and 3D printer fees. The addition of software expenses increases the price of the template. However, the software can be used in other research and clinical work, thus reducing the cost of the template in the long term. Our template is a simple and low-cost solution for the accurate, safe, and rapid implementation of elective surgery on bone structures.

The errors in this study are derived from various factors. First, the articular cartilage is not imaged by CT, thus causing a negative impact on matching accuracy. We can delineate the thickness of the articular cartilage via MRI in further research. Second, the design procedure of the template, including reconstruction and fitting, requires manual or automatic segmentation, which causes errors. Third, the bio-model of the template can deviate from the computer 3D model. This kind of error is related to the RP equipment and material. We controlled the precision within 0.1 mm in the rapid formation. Finally, the template should adhere tightly to the osseous marker during surgery because any movement between the bones affects the accuracy. This type of error represents the largest source of error in the entire process and should be controlled precisely.

Our study is a pilot trial with a limited number of cases. The application of this study only remains in basic research. Further studies are necessary to determine the appropriate values for clinical applications.

5 Conclusion

We developed a custom-made navigational template for hip resurfacing system placement by using computer-aided technology. Postoperative CT scan and x-rays reveal that the individualized template enables a near perfect fit with the femoral neck and guides the implantation of the femoral components accurately. Our template is an excellent medium for preoperative planning and intraoperative operations and embodies the development tendency of Computer Assisted Surgery.

Declarations

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Conflict of interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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This study has been performed within an appropriate ethical framework in accordance with the Declaration of Helsinki. The need for ethics approval was deemed unnecessary for this cadaver research by the Ethics Committee of 920th Hospital of Joint Logistics Support Force. We all agree to publish this article if it is accepted. All the data are authentic and reliable.

I declare that the authors have no competing interests as defined by Nature Research, or other interests that might be perceived to influence the results and/or discussion reported in this paper.

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In this study, JL Liang, YQ Xu, and S Lu conceived the study. JL Liang wrote the manuscript text. YH Zhao collected data. XJ Gao, XW Fang analyzed results. JL Liang, YH Zhao and S Lu performed Cadaveric Study, YQ Xu, S Lu technical support. All authors reviewed the manuscript.

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Figures

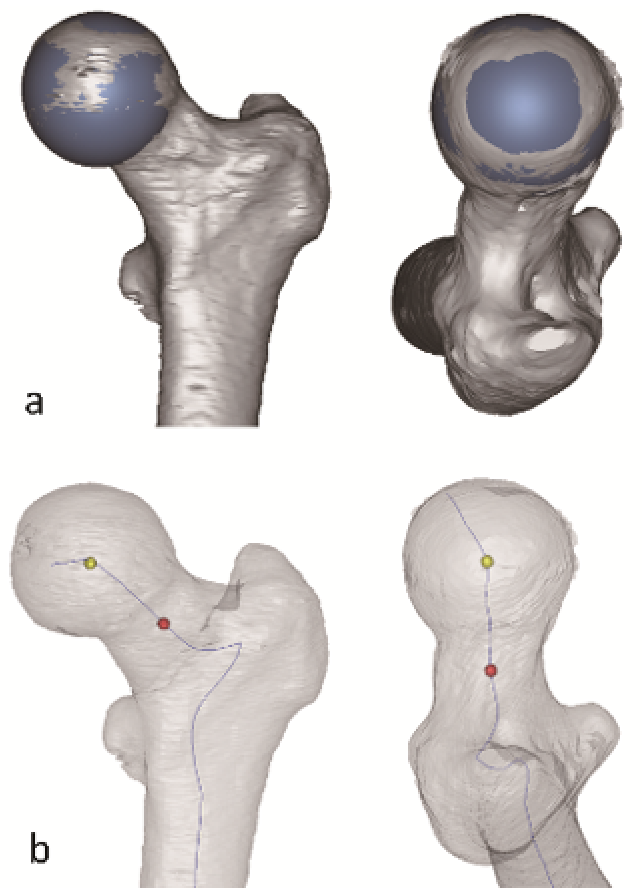

Figure 1

Calculating the anatomical central axis of femoral neck. (a) Calculating the center of the femoral head by fitting a suitable sphere. (b) Calculating the centerline of the proximal femur.

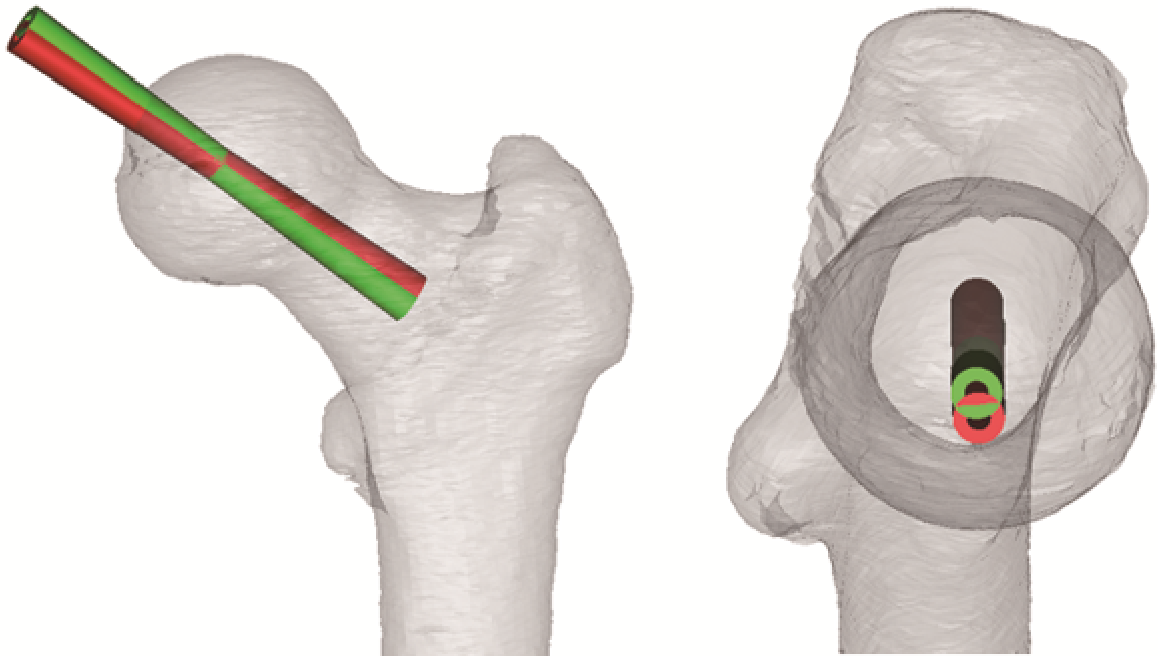

Figure 2

The position of drill guide. The initial position (red one) was consistent in the central axis of the femoral neck. The final direction (green one) was confirmed by a small valgus angle of 5° to 10°.

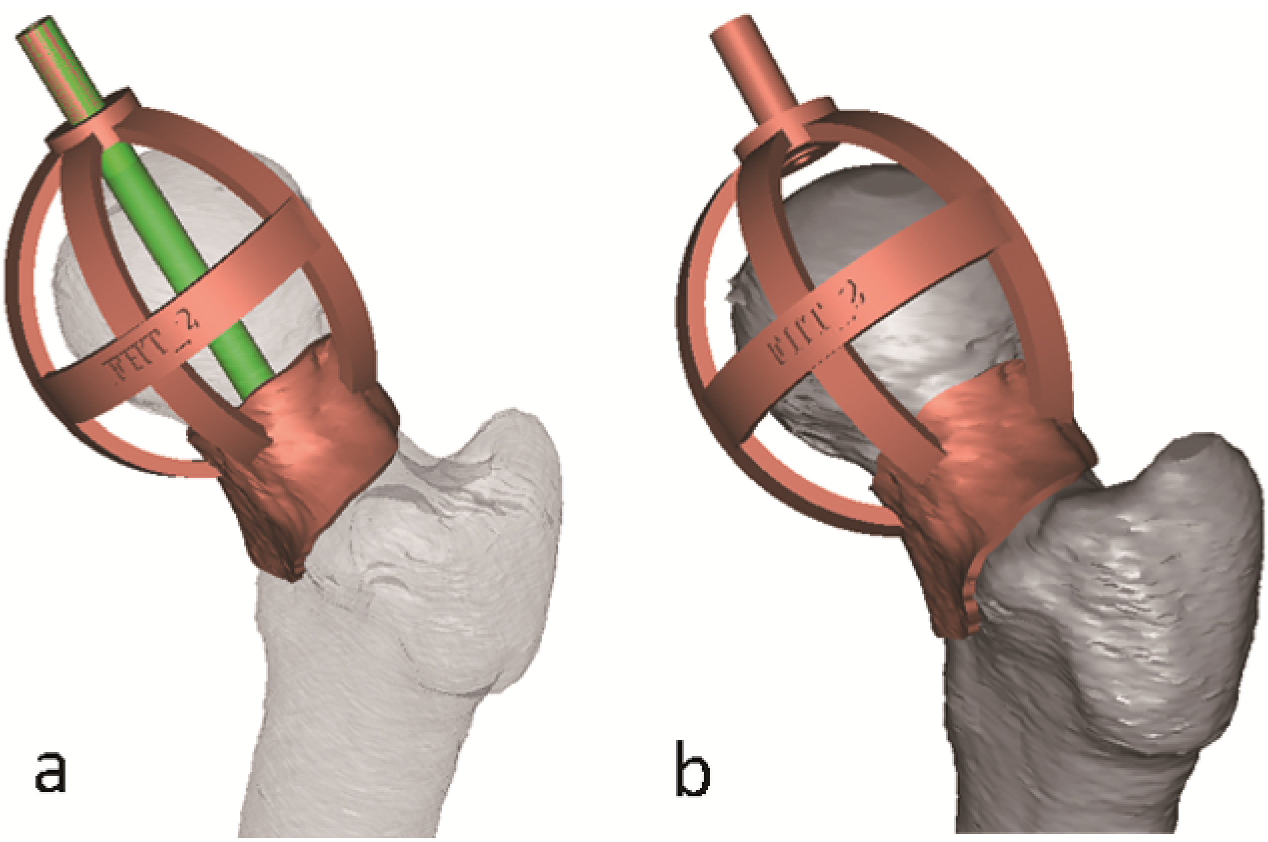

Figure 3

The design of navigational template. (a) The direction of the template was consistent in the drill guide. (b) The virtual surface of template matched perfectly to the surface of the femoral neck.

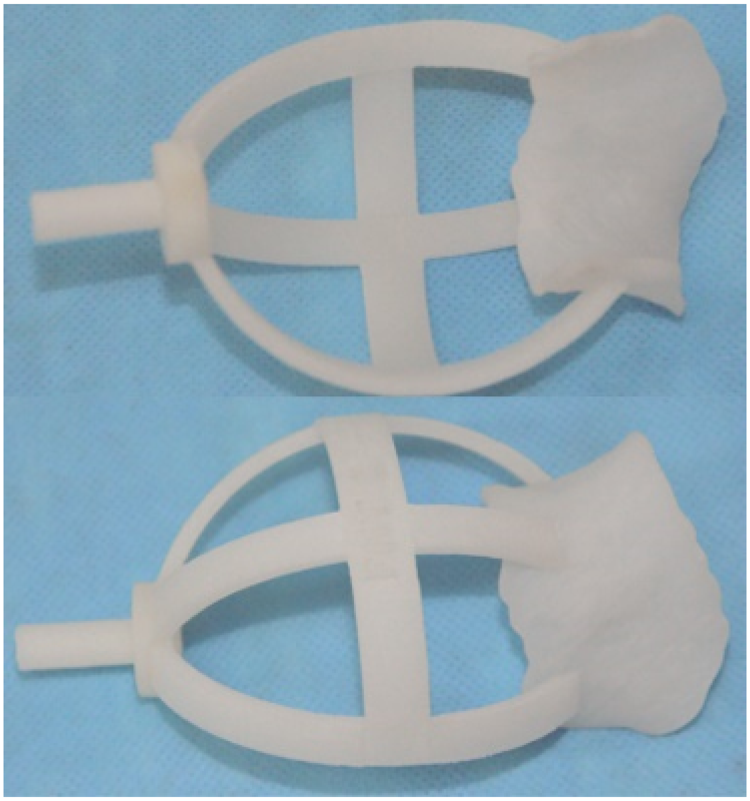

Figure 4

The RP model of the navigational template.

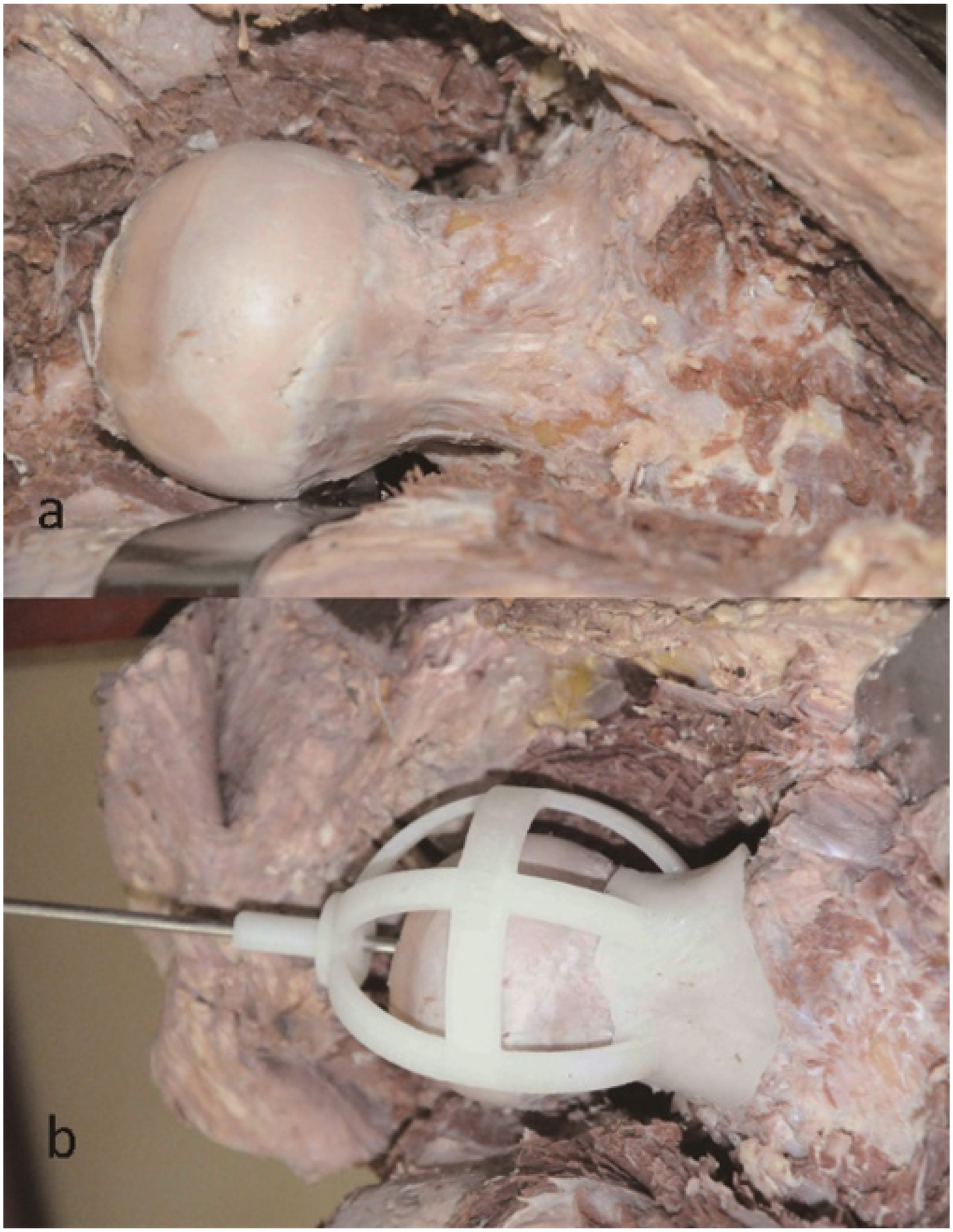

Figure 5

Cadaveric experiment. (a) The exposure and dislocation of the femoral head. (b) The navigational template fitted the femoral neck perfectly and a Kirschner wire was nailed on for fixation.

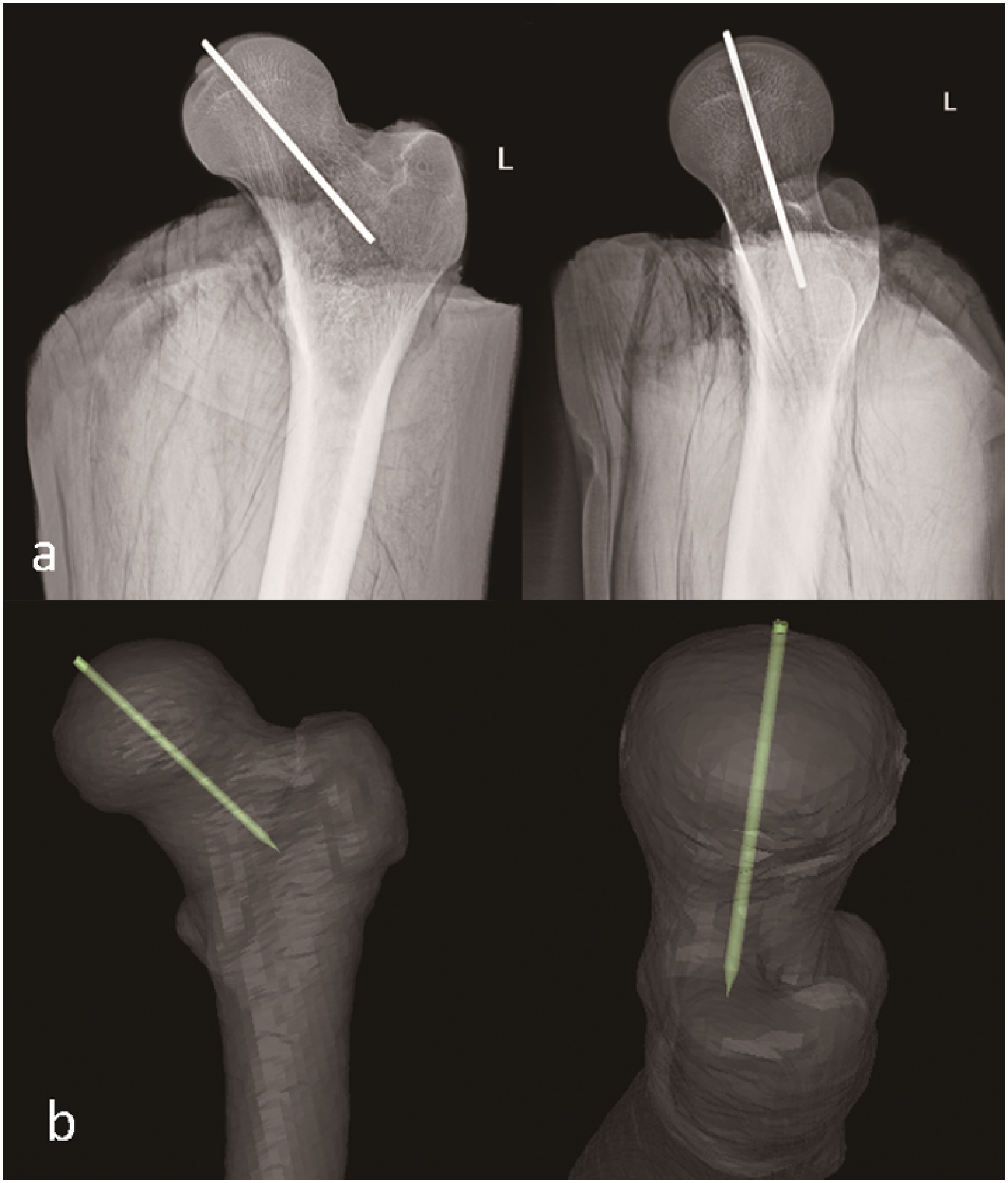

Figure 6

Postoperative x-rays and CT scan show the perfect and accurate position of Kirschner wire. (a) Postoperative x-rays show the anteroposterior and lateral position of the Kirschner wire. (b) 3D reconstruction of postoperative CT scan shows the optimal postion of the Kirschner wire.

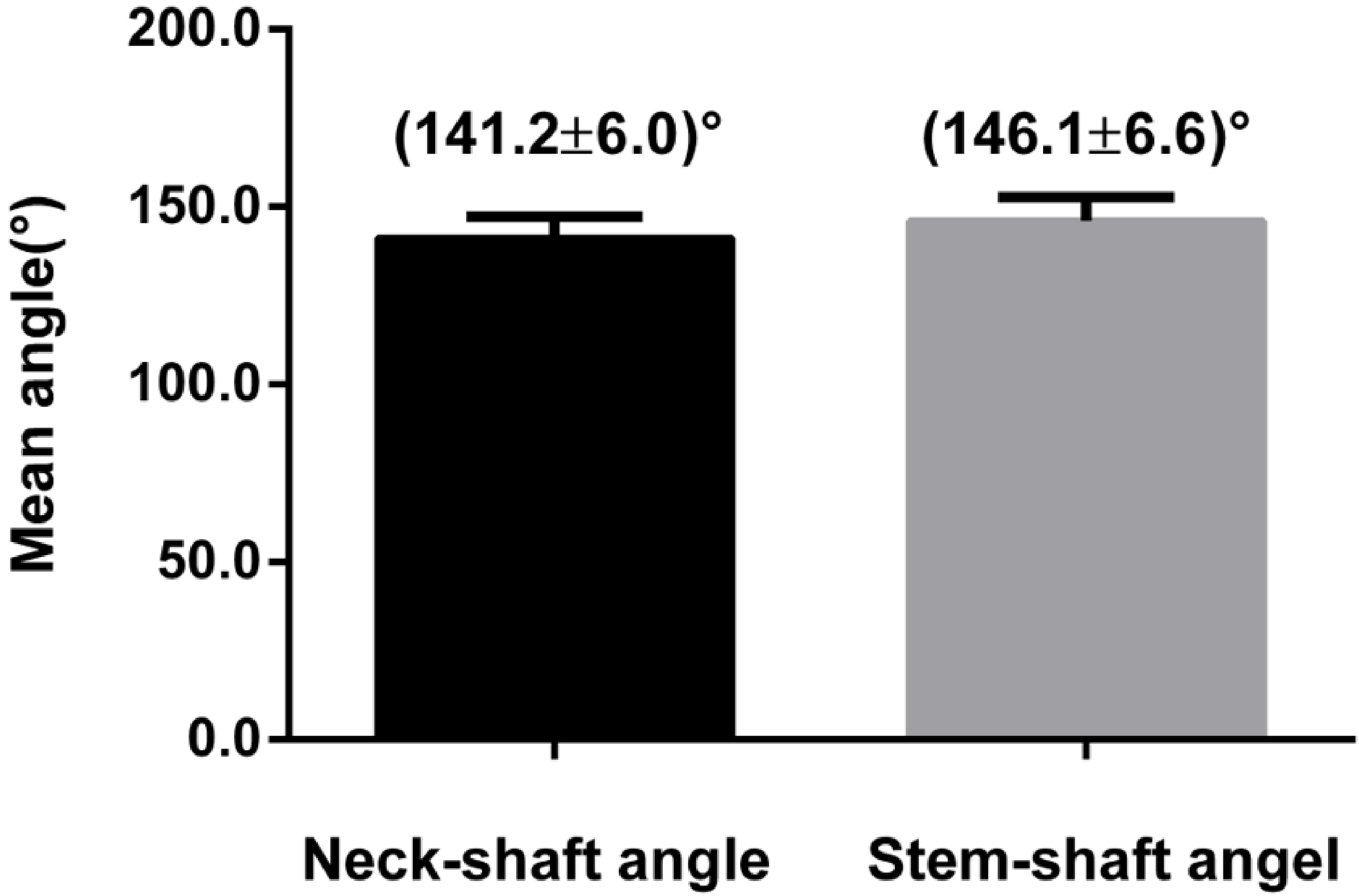

Figure 7

The NSA and SSA. data are expressed as mean ± SD. And there is no significant difference (P > 0.05).

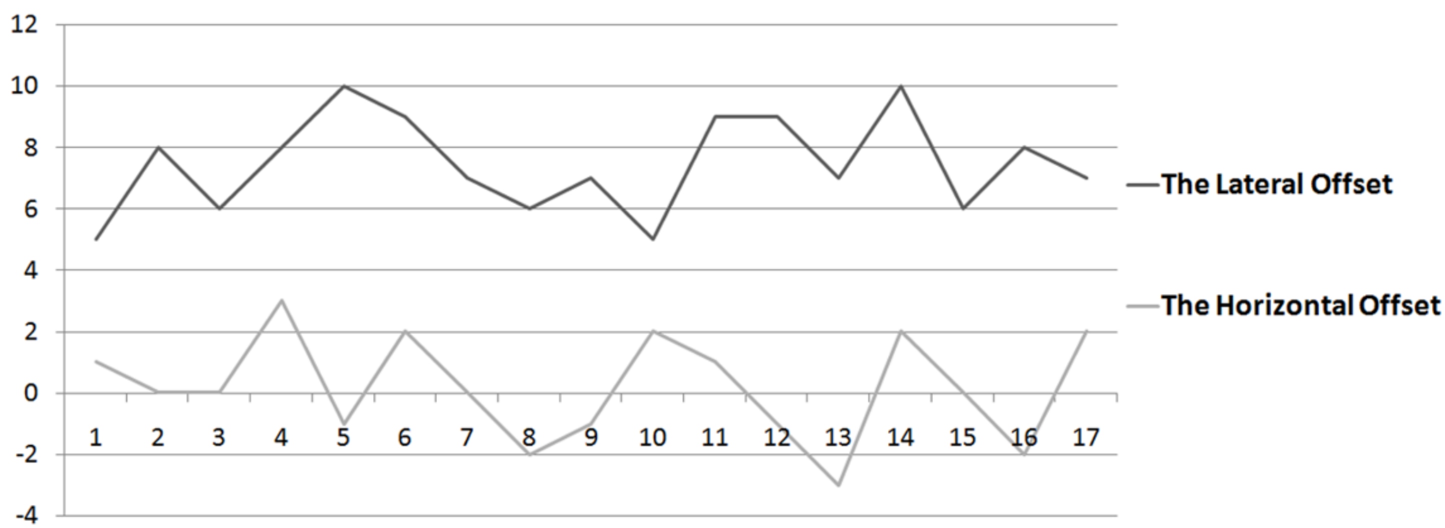

Figure 8

Folded diagram of the lateral offset and the horizontal offset. The lateral offset shows the expected requirement of relative valgus angle was achieved. The horizontal offset shows no obvious anterior/posterior inclination angles.