Clinical Application of Orthopedic Robot Navigation and Positioning System

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Abstract. To investigate the orthopedic robot navigation system fracture clinical application of the cannulated screw fixation in femoral neck. 40 patients were randomly divided into the robot operation group and the traditional operation group, namely 20 cases for each group. The frequency of fluoroscopy, the time of operation and the number of drill holes in the two groups were measured. The parallelism between the cannulated screws was measured. The deviation angle between the cannulated screws and femoral neck-shaft angle or anteversion angle was measured. The difference between the two groups was compared with the statistical methods. There were significant differences in the operation time, the frequency of fluoroscopy and the number of drill holes in the two groups (P <0.05). The difference of the parallelism and the deviation angle between the cannulated screws in the two groups were statistically significant (P <0.05). The operation time was short, the radiation in the operation was less, the mechanical distribution of the cannulated screws was better, the safety and accuracy of the operation were improved, when the orthopedic robot navigation and positioning system assisted the cannulated screw fixation in femoral neck fracture.

1. Introduction
With the rapid development of science and technology in 21 Century, surgical operation has entered the era of minimally invasive biological intelligence, which is integrated by biology, information science and physics. Computer Assisted Orthopaedic Surgery (CAOS), which combines imaging, information science, robot technology and remote control technology, has emerged as the times require. It has a significant advantage in improving the accuracy of operation, reducing the surgical trauma, improving the success rate of the operation and reducing the radiation damage in the operation. It has satisfied the patients and doctors with the requirements for the safety and effectiveness of the surgery [1]. In our hospital, the orthopedics robot navigation and positioning system was used to assist 20 cases of femoral neck fracture with hollow screw internal fixation.

2. Data and Methods
2.1. General Information
40 patients with femoral neck fracture of Garden I and II type fracture of the femoral neck were selected from January 2017 to January 2018 in China -Japan union Hospital of Jilin University.
According to the treatment methods, the patients were randomly divided into the robot operation group (the orthopedics robot navigation and positioning system assisted hollow screw internal fixation) and the traditional operation group (traditional hollow screw internal fixation), namely 20 cases for each group. The patients included 22 males and 18 females, aged 25-80 years, with an average age of 55 years. The exclusion criteria include unstable femoral neck fractures, other fractures of the femur confirmed by imaging, severe osteoporosis, and other diseases that are difficult to tolerate the operations.

2.2. Experimental Instrument
The German SIEMENS C-arm fluoroscopy machine; the biplane surgical robot of Beijing Tian Zhihang medical Polytron Technologies Inc (model GD-2000).

2.3. The Administration Methods

2.3.1. Robot Operation Group. The system is mainly composed of two parts of the workstation and the navigation robot (positioning system). The workstation is mainly processed in the background, which is responsible for the image acquisition, the calculation and planning of the operation path. The navigation robot is the executive part of the system, which is responsible for the output of the final surgical path and is responsible for completing the navigation and positioning of the guiding needle during the operation. The orthopedics robot system used in our hospital has a positioning accuracy of 0.4-0.8 mm, which can meet the needs of CAOS. The robot uses a double plane algorithm, which is composed of the splicing of different modules. The mechanical structure is similar to a frame in general. The two mechanical arms and their hole tongs make up 6 freedom motion spaces. The robot is operated by the passive operation, that is, the robot will automatically give the puncture path by the principle of two points, and the robot will take it. With modular design, different fracture sites can be performed through different splicing methods.

After subarachnoid block anesthesia or general anesthesia in the ordinary operating bed, the patients were placed in the orthopedics traction bed, and the fracture was repaired by manipulation and adjustment, and the anatomical reduction of the fracture was confirmed by the positive and lateral perspective of the C-arm. According to the operative site of the patient, the corresponding double plane positioning ruler is installed. The positioning ruler is closely combined with the robot assembly, and the workstation completes the calibration of the ruler. After adjusting the positioning ruler to the appropriate position, the X-ray positive and lateral images were captured and the software was introduced into the workstation programming software. The interactive software was operated, the marking points were picked up and the placement planning path and the simulated figure of the three screws were completed, and the length of the hollow screws was calculated. The robot arm of the starting robot navigates and locates each hollow screw guide needle, moves the manipulator to the position of the guide needle, then installs the needle sleeve, cards the guide sleeve into the positioning card slot, and locates the skin in the operation area along the sleeve, and makes the small incision 1cm long, the blunt separation of the skin and the fascia, and inserts the sleeve to the tip to the lateral bone surface of femur. 3 guided needles were drilled into the bone surface in turn. Positive and lateral fluoroscopy was performed after each implantation. After verification, the sleeve was pulled out and the guide needle was cut off outside the skin to remove the robot. After that, 3 cannulated screws with the right length were selected and placed in accordance with the routine procedure. After positive and lateral fluoroscopy, the incision was sutured by layer.

2.3.2. Traditional Operation Group. Conventional reduction operation was used for internal fixation with cannulated screws. The mode of anesthesia and the body position were the same as the operation group of the robot. After the reduction of C-arm fluoroscopy fracture, 3 Kirschner pins were first inserted into the inverted shape and 2 millimeter. The positive and lateral position of the hip joint were re-examined with the C-arm. The position and depth of 3 Kirschner pins were observed. If the position
was bad, the direction of the Kirschner needle was pulled out, and the needle tip was 0.5 millimeters under the cartilage of the femoral head. After the position was satisfied, 3 Kirschner pins were measured into the length of the neck of the femur, and the hollow drill was expanded along 3 Kirschner pins. Finally, the length of the hollow screw was placed in order, and the Kirschner needle was removed. After another perspective, stitch the incision.

2.4. Data Processing
The operation time, the number of fluoroscopies in operation and the number of drill holes in the two groups were measured. After the operation, the immediate positive and lateral positions DICOM file of two groups of patients in the C-arm was derived, and the angle of the screw and the axis of the femoral shaft was measured by Image-pro plus 6.0 software. The angle between the three screws and the femoral shaft were recorded as $\alpha_1$, $\alpha_2$ and $\alpha_3$, and the parallelism between the studs was calculated by the algorithm proposed by Liebergall [2]. The specific algorithm is: the parallelism of the screw is: 

$$
\frac{|\alpha_1-\alpha_2|+|\alpha_1-\alpha_3|+|\alpha_2-\alpha_3|}{3};
$$

the angle between the axis of 3 hollow screws and the axis of the neck of the femoral neck is measured respectively in the positive and lateral positions: $\beta_1$, $\beta_2$, $\beta_3$, $\beta_4$, $\beta_5$, $\beta_6$, that is, the deviation angle between the hollow screws and femoral neck-shaft angle or anteversion angle.

2.5. Statistical Treatment
SPSS 13.0 statistical software is adopted for data analysis. The enumeration data is tested by $\chi^2$. The measurement data is expressed by mean standard deviation ($\bar{X} \pm S$). The intra-group comparison is tested by matching t; intra-group comparison is analyzed by one-way variance, $P<0.05$ meaning significant differences.

3. Results
Compared with the traditional surgery group, the robotic surgery group had shorter operation time and less C-arm fluoroscopy and fewer intraoperative drilling. The difference was statistically significant ($P<0.05$), was shown in table 1. The positive and lateral parallelisms of patients in robotic operation group were smaller than those in traditional operation group ($P<0.05$), was shown in table 2. The deviation angle between cannulated screw and femoral neck-shaft angle or anteversion angle in robotic operation group was smaller than that in traditional operation group ($P<0.05$), was shown in table 3.

| Table 1. The general clinical data of two groups of patients ($X \pm S$, n=20) |
|---------------------------------------------------------------|
| **Group** | **Operation Time (min)** | **Fluoroscopes number** | **Drilling time** |
|-----------------|-----------------|-----------------|-----------------|
| Robot Operation Group | 36.15±13.30\textsuperscript{a} | 14.77±6.62\textsuperscript{b} | 4.05±1.45\textsuperscript{c} |
| Traditional Operation Group | 58±19.02 | 50.86±5.12 | 13.14±2.35 |

Compared with Traditional Operation Group, $P^{abc}<0.05$.

| Table 2. Screw parallelism of two groups of patients ($X \pm S$, n=20) |
|---------------------------------------------------------------|
| **Group** | **Positive screw parallelism** | **Lateral screw parallelism** |
|-----------------|-----------------|-----------------|
| Robot Operation Group | 0.31±0.49\textsuperscript{d} | 0.67±0.52\textsuperscript{e} |
| Traditional Operation Group | 1.38±0.46 | 2.70±0.39 |

Compared with Traditional Operation Group, $P^{de}<0.05$. 

3
Table 3. Screw deviation contrast of two groups of patients ( $\bar{x} \pm s$, n=20)

| Group                        | Deviation neck-shaft angle | Deviation anteversion angle |
|------------------------------|----------------------------|-----------------------------|
| Robot Operation Group        | 2.8±1.6                   | 5.13±1.54                  |
| Traditional Operation Group  | 7.2±1.8                   | 8.95±4.35                  |

Compared with Traditional Operation Group, $P^{0.05}<0.05$.

4. Discussion
The femoral neck fracture is treated by closed reduction and hollow screw internal fixation, and the fracture requires anatomical reduction so as to achieve the goal of loosening and firm fixation. The application of hollow screw internal fixation technology is strict, the accurate selection of entry point and implantation of the best position are the key to successful operation [4]. However, the visual error and the instability of human hands make it difficult for Department of orthopedics doctors to ensure that each screw is in the best position, and the re-nailing is more common. At the same time, as the number of hours of operation is longer and the time is longer, patients and medical staff increase the radiographic damage caused by repeated fluoroscopy.

Computer Assisted Orthopaedic Surgery (CAOS) navigation system is equivalent to the doctor's "brain" and "eye" [5]. The principle of "brain" is to match patients' preoperative or intraoperative image data (such as CT data, MRI data, etc.) and the X-ray plain film of the patients in the operation to accurately match the registration algorithm or perspective relationship, to help doctors understand the internal dissection of the patients who are unable to see directly. The navigation module is equivalent to the doctor's "eye" [6]. It can track the movement of the surgical instruments in real time and display the position and posture of the surgical instruments in the display in the form of the same instrument model. Thus, the operation process is more simple and intuitionistic, the accuracy of operation is improved and the operation time is shortened. The robot [7], the mechanical arms, are equivalent to the hand of the doctor. The high precision operation and the full stability can solve the operation problem. The manipulator has the multi degree of freedom similar to the arm. It can realize the accurate and fixed three-dimensional space motion, and the optical navigation positioning can adjust the space position by real-time feedback, and can adjust the space position by real time feedback. To avoid errors due to damage and instability caused by handheld devices, can significantly improve the fine operation predictability, accurate and minimally invasive, so as to effectively compensate for the lack of traditional operation method, has important clinical value and economic value of the orthopedics surgery, is an important development direction in the future of medicine.

The continuous exertion of external force during the operation of the femoral neck fracture may cause stress concentration near the nail point of the subtrochanteric screw, and multiple boreholes may lead to the femoral subtrochanteric fracture and intertrochanteric fracture. The hip and the femur, as bearing and moving structure, have complex physiological structure and mechanical distribution, in which the calcar femorale is an important bone structure with a typical mechanical bearing in the neck of the femur. When the human body is upright, gravity shifts from the femoral head to the compression trabeculae and the calcar femorale, and to the femoral axis. The medial side of the calcar femorale is a compact bone tissue, with 3 thin layers of 5 to the outside. The anatomical characteristics of the calcar femorale shorten the actual length of the neck of the femur and reduce the bending distance of the trunk of the neck of the femur, which is an important part of the structure of the internal weight of the proximal femur. Therefore, when the femoral neck fracture is known, the position of the best hollow screw needs to conform to the direction of the compression trabeculae, and the screw parallel to the fixation of the femur is the best internal fixation effect, that is, the smaller the deviation of the hollow screws and the femoral neck-shaft angle is the better. When the hollow nail is inserted, it should follow the anatomical position of the calcar femorale, close to the cortical bone below the femoral neck, and pass through the fracture line. In this way, the internal fixation screws can obtain strong supporting compressive stress and reduce the shear stress of the fracture obviously. At present, 3 screws are placed in an inverted triangle [8], which two are located in the proximal end of
the femoral neck and one close to the thighbone [9], which is parallel to each other, and the best deviation is not more than 10 degrees [10]. According to this principle of operation, it is difficult for the C-arm to guide the percutaneous accurate implantation of the 3 screws. And because the arm fluoroscopy can only get a single plane at one time, the operator must need to change the position and angle of the fluoroscopy many times for the purpose of the operation, and the non-avoidable repeated drilling in the neck of the femur is not only costly. It is time consuming and increases the risk of postoperative complications, while doctors and patients are exposed to larger radiation. In this experiment, we found that in the application of the surgical robot, the operation navigation part can be completed after 2 X-ray imaging. The parallelism of the screws placed in the robotic operation group is obviously superior to the parallelism of the traditional group, and the robot group has obvious advantages over the deviation from the neck-shaft angle and anteversion angle. The screws placed in the robot are more consistent with the standard of the hollow screw placement, and have better internal fixation effect and biomechanical distribution, and to a certain extent, reduce the incidence of complications.

The application of the robot navigation and positioning system in the domestic orthopedics surgery is still in the early stage, and many operations need to be further explored. But for the high required fracture alignment operation, because of its precise navigation ability, the robot has a higher advantage, which greatly reduces the risk of surgical failure and iatrogenic radiation damage. Nevertheless, surgical robots, as a combination of medicine and computer science, still face some problems, such as complex operation of the system, complicated operation, if the operator is not familiar with the whole operation process, it will increase the operation time and the number of fluoroscopy. The learning curve of the operating robot is relatively slow, and the specialized doctors in general need to understand the principle of the operation of the surgical navigation. After three stages of learning, the first is to use the operation of the bones of the corpse, and then used skillfully as a candidate system and contrast observation. It can be applied to clinical practice more skillfully, and now the technology update rate is faster than that of doctors, so that doctors face greater challenges. The system occupies a large amount of space in the crowded operation room, which increases the chance of infection and complicated cable. It also increases the risk of medical staff. At this stage, the reason for the limitation of the operating robot is due to the high price of the whole solution. Although there is a great improvement in the accuracy of the operation, the type of operation can be limited, which makes the operation robot slightly lower. However, the navigation technique is a useful tool for Department of orthopedics surgery. It must be improved along with the development of other disciplines. With the continuous improvement and extension of navigation technology, it is foreseeable that the clinical utility of CAOS will be greatly improved.

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