


GUIDELINE

Guidance for the Treatment of Femoral Neck Fracture with Precise Minimally Invasive Internal Fixation Based on the Orthopaedic Surgery Robot Positioning System

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Femoral neck fractures are among the most common fractures in orthopaedics. There are many surgical methods for the treatment of femoral neck fracture. Percutaneous cannulated lag screw fixation for the treatment of femoral neck fractures is favored by orthopaedic doctors because of its characteristics of being minimally invasive, with less bleeding and firm fixation. However, traditional freehand screw placement is limited by many factors, and the screw malposition rate is very high, which directly leads to the reduction of its biomechanical stability, and even leads to the ischemic necrosis of the femoral head caused by damage to blood vessels. In addition, excessive attempts to drill holes can damage cancellous bone and affect the screw's holding force, which reduces the stability of internal fixation and increases the risk of failure. At the same time, too much radiation exposure to medical personnel and patients also causes great damage to the body. Robot-assisted orthopaedic surgery combines the mechanical "eye" (an infrared ray tracking device) and the mechanical "hand" (six degrees of freedom mechanical arm), and through the process of preoperative planning, intraoperative assistance in screw placement, and postoperative confirmation, provides a more minimally invasive and precise treatment method for this kind of surgery, and significantly reduces radiation exposure. This guide uses the TiRobot system as an example to describe the robot surgery in detail, aiming at standardizing the application of robots in orthopaedic surgery.

Key words: Femoral neck fracture; Internal fixation; Precise minimally treatment

Introduction

Femoral neck fracture is a common injury in orthopaedics, accounting for approximately 3.6 percent of all fractures. It often occurs in elderly patients with osteoporosis, mostly with low energy injuries. In addition, it is also found in young adults with high energy injuries.

There are various surgical treatments for femoral neck fractures, among which percutaneous cannulated screw internal fixation is the main method for the treatment of femoral neck fractures in young people and non-displaced femoral neck fractures in the elderly due to its advantages of being minimally invasive, less bleeding, and reliable fixation. At present, the most commonly used cannulated screw configuration is an inverted triangle, which requires three

cannulated screws to be distributed in parallel and dispersion as close as possible to the femoral neck cortex and subchondral bone of the femoral head to obtain ample pullout strength, providing good biomechanical stability. In addition, four screws were fixed (three parallel dispersions + one vertical fracture line)¹. Biplanar double supported screw fixation² and other configurations were studied to provide better stability.

Traditional freehand cannulated screw placement has many shortcomings, such as that inexperienced surgeons cannot carry out preoperative planning depending on the dissection shape of the femoral neck, the unstable controlling guide wire direction when drilling, repeated drillings lead to bone damage, and screws penetrate the cortex because of

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malposition; these factors can directly or indirectly cause postoperative complications, such as fracture nonunion, femoral head necrosis, and internal fixation failure, which influence function prognosis³. Furthermore, in determining the position of the guide wire and screws, frequent intraoperative fluoroscopy increases the radiation exposure of medical staff and patients.

With the development of imageology and computer, robot and other technologies, orthopaedic robots can improve the accuracy of operations and the effect of surgical treatment, meanwhile reducing the radiation exposure of medical staff and patients⁴ and truly achieving precision therapy for fractures. China has intellectual property rights for the “Tianji” orthopaedic surgery robot (TiRobot), which is the first universal orthopaedic navigation robot so far and has been certified by the China Food and Drug Administration (CFDA). It can be used for cannulated screw internal fixation treatment of femoral neck. To standardize the application of orthopaedic surgical robots in the internal fixation of pelvic acetabular injuries and so that the orthopaedic precision therapy benefits more patients, the present paper will use TiRobot as an example to elaborate on the technical points of robot-assisted percutaneous cannulated screw internal fixation in the treatment of femoral neck fractures and guide the clinical application.

Introduction of Orthopaedic Surgery Robot

Structure Composition

The orthopaedic surgical robot system consists of surgical planning and control software, host, mechanical arm, optical tracking system, surgical tool kit and accessories.

TiRobot (Fig. 1): The product consists of a host, a robotic arm, surgical planning and control software, an optical tracking system, a console vehicle, and a navigation and positioning kit.

Medical device classification directory: Usually consists of a host, a tracking and locating device, functional software, locating framework, adapter, markers, and accessories. There is optical navigation and electromagnetic navigation. Part of the navigation system has mechanical arms.

Working Principle

Robot-assisted orthopaedic surgery, like conventional surgery, is a process of eye-brain-hand coordination.

Eye of Orthopaedic Surgery Robot: Image Acquisition and Recognition

As the most commonly used diagnostic method in orthopaedics, X-ray and C-arm CT can provide more information to doctors without exposing the wound. For orthopaedic surgery robots, obtaining this digital image information can provide more information and enable more accurate minimally invasive treatment in orthopaedic surgery. The intraoperative C-arm CT image data can undoubtedly obtain more complete and accurate 3D information, to better serve



Fig. 1 TiRobot orthopaedic surgery robot system.

the high-precision orthopaedic surgery. However, due to radiation, the intraoperative location, and other reasons, intraoperative X-rays are more widely used. Therefore, the compatibility of multimodality images largely influences the versatility of orthopaedic surgical robots.

To make better use of image information and realize spatial localization, some localization markers are placed in the field during image acquisition to develop on the image. The orthopaedic surgery robot can quickly and accurately realize the identification and location of marks through a software recognition algorithm, thus preparing for registration. Just as human eye vision affects precision surgery, image quality greatly affects the registration accuracy of the robot. Therefore, in 2D image acquisition, the high-precision and low-distortion digital flat C arm is more suitable for orthopaedic surgery than the ccd-type C arm.

Brain of Orthopaedic Surgery Robot: Surgical Design and Registration

After an accurate image is obtained, the robot hosts will be allowed to produce a surgical design based on the medical image data, and the robot will be assigned to achieve spatial registration. With a human-computer interaction interface, doctors can perform surgical design before or during surgery, depending on the circumstances. According to the different images obtained, the surgical design can be divided into two dimensions and three dimensions. In general, the screw channel planning of the positioning robot usually follows a

2D surgery design, and the entry point and terminal point of the screw can be planned in multiple images. The joint robot is mainly based on the 3-D surgical design to achieve a good match between the joint surface of the implant and the bone surface.

Registration algorithms are another core technology of orthopaedic surgery robots, and their essence is to completely and accurately present the surgical plan designed by doctors in the image space to the actual operation space. Due to the different medical image data used, the robot registration algorithm is quite different. The X-ray image commonly used in traumatic orthopaedics is calibrated using the C-arm calibration method. The principle is to calculate the relative spatial relation of the C-arm's emitter source, marker point, and designed screw insertion and terminal point through the marker points of a specific structure, to become the identifiable kinematic parameters of the robot and guide the robot motion. For CT/C-arm CT image data, 3D registration is needed to obtain the robot kinematics parameters. The more advanced technique is to use X-ray and preoperative CT to achieve 2D/3D registration, which not only retains a lot of 3D spatial information but also reduces the intraoperative fluoroscopy time to the greatest extent. However, such technology is not yet advanced enough to be put into clinical use.

Hand of Orthopaedic Surgery Robot: Tool Tracking and Navigation

After obtaining the robot's kinematics parameters, the robot can accurately place the surgical tools (e.g. drill and milling cutter) on the surgical site. This process is called robot navigation. Theoretically, the robot can complete navigation and positioning independently due to its own position information. However, the absolute positioning accuracy of the robot does not meet the requirements of clinical surgery at the present time. Therefore, additional external equipment is needed to improve the accuracy of the robot navigation. An optical capture system is a common precision compensation device. A real-time optical tracking guide robot can reduce the positioning precision from 1–2 mm to less than 1 mm. At the same time, important functions such as displacement compensation and breathing compensation can be realized. It should be noted that the optical capture system has certain requirements on the capture field, and reasonable robot positioning can largely avoid the tracking failure caused by occlusion of surgical tools.

The orthopaedic surgical robot has a mechanical emergency brake switch, which ensures that the robot can stop immediately during the navigation process to avoid injury in any dangerous situation. In addition, due to safety concerns, orthopaedic surgical robots, especially orthopaedic positioning surgery robots, are mostly used as auxiliary equipment for surgery, only guiding accurate and safe screw channels for doctors, instead of performing autonomous drilling operations. Through the only drilling channel, doctors perform the autonomous and controllable screw implant operation

to complete the high-precision and difficult orthopaedic surgery.

Indications and Contraindications of Surgical Robots

Indications

The robot-assisted internal fixation of femoral neck fractures is suitable for femoral neck fractures that involve a small displacement or for closed/limited open reduction.

Contraindications

1. Unclear image collection caused by hardware or patient factors preventing safe planning.
2. The fracture cannot be effectively fixed using the percutaneous cannulated screw technique.
3. There may be important tissues, such as blood vessels and nerves, that cannot be avoided in the path planned by the robot.
4. The mechanical arm cannot be moved to the planned site: for example, multiple doctors are required to coordinate to complete the reduction during the operation, the tracer is blocked, or due to the patient's posture or surgical bed.
5. The tracer cannot be effectively fixed: for example, if a patient has severe osteoporosis, or multiple doctors are required to cooperate to complete the reduction and maintain the reduction due to the influence of respiratory magnitude.
6. Through planning, the angle between the guide wire and bone surface is too small to complete the fixation of the entry point, resulting in unavoidable error.

Procedure for Robot Operation Preparation

Preparation

After successful anesthesia, the patient was placed on a traction bed. The affected limb was pulled along the long axis of the body, and the healthy limb was opened at an angle.

Fracture Reduction

Restore the normal anatomical structure of the fracture as far as possible by means of traction closed reduction or limited open reduction under fluoroscopy and establish bone channels for cannulated screw internal fixation.

Preparation of the Robot

After routine disinfection and draping, all parts of the robot and the C-arm are placed in the appropriate position to ensure the working space of the robot arm can reach the operation area. The optical tracking camera was placed on the foot of the patient, and the mobile C-arm was placed on the opposite side of the surgeon.

Image Collection and Registration

The patient tracer was fixed on the anterior superior iliac spine of the affected side; the robot arm was fixed with a sterile protective sleeve and the robot tracer was assembled,

to establish a sterile working environment for the mechanical arm surgery. The C-arm is used to obtain the intraoperative fluoroscopy image containing the robot positioning marking points and transmit it to the master workstation software for registration calculation.

Image Collection Requirements for Traumatic Femoral Neck Channel Screw Surgery

1. The screw bone channel has a complete and clear display.
2. As far as possible, the projection perspective images are perpendicular to each other, which is conducive to establish the construction of three-dimensional spatial relations by computer.
3. Tab ruler should be placed inside the image without overlapping.

Navigation Image Acquisition

Recommended intraoperative image of femoral neck: anteroposterior of femoral neck (AP view); lateral of femoral neck (lateral view).

Key Points of Perspective Image Recognition

The AP view of the femoral neck (in the supine position of the patient, the X-ray image intensifier is perpendicular to patient plane) showed the full length of the lateral cortex of the femur to the femoral head (Fig. 2).

The lateral view of the femoral neck (in the supine position of the patient, the X-ray image intensifier is perpendicular to the femoral neck channel plane) showed the full length of the lateral cortex of the femur to the femoral head (Fig. 3).

Surgical Path Planning

According to the AP view image collected, based on typical identification points and bone marker structure, surgical screw path planning is performed on the master control system planning software. The femoral neck screw channel is confirmed by the biplanar image; that is, the AP view of the femoral neck screw channel and the lateral view of the femoral neck screw channel. Surgical safety and optimal

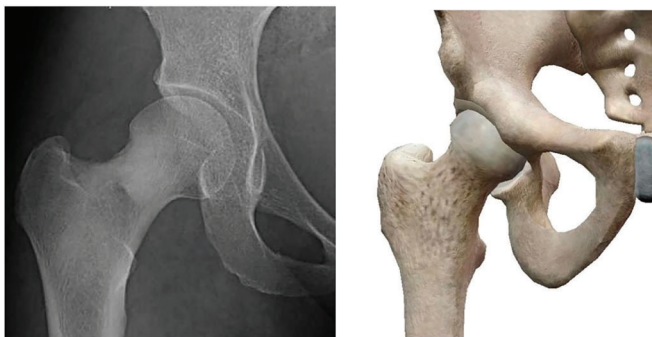


Fig. 2 Standard anteroposterior view of the femoral neck and its 3D representation.



Fig. 3 Standard lateral view of the femoral neck and its 3D representation.

mechanical distribution of screws should be considered in the surgical design. The AP view confirms that the screw was between the upper and lower cortical boundaries of the femoral neck and the relationship between the screw and fracture line (Fig. 4); the lateral view confirms that the screw was between the anterior and posterior cortical boundaries of the femoral neck and the relation between the screw and the anteversion angle (Fig. 4), finally, the length of the screw was adjusted according to the tip-apex distance (TAD).

Mechanical Arm Operation

The mechanical arm posture simulation module of planning software is used to simulate the operation posture of the mechanical arm. After confirming that the mechanical arm posture is suitable for follow-up surgery, the control software of the main control system controls and monitors the movement of the mechanical arm along the planning path to the target position. The guide sleeve is installed at the end of the mechanical arm, and the guide sleeve is positioned according to the following principles: (i) the guide sleeve is always moving in the clean area, and enough operating space is reserved; (ii) leave room for the operator to implant the guide wire; and (iii) ensure that the guide sleeve and patient tracer can be tracked by the optical tracker in real time to facilitate real-time monitoring accuracy.

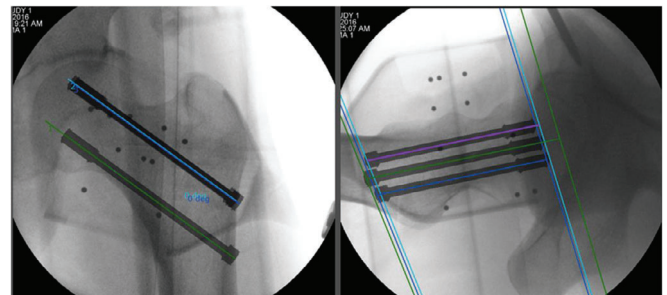


Fig. 4 Screw position planning at AP view and lateral view respectively.

Guide Wire Placement

Make a 2-cm incision in the entry points, with blunt separation of subcutaneous tissue. The sleeve is inserted to touch the bone cortex. Confirm whether entry point and direction of virtual guide wire is in accordance with the plan; if not, the surgeon can fine-tune the path with the robot. Anteroposterior and lateral view images are verified through after the guide sleeve touches the bone surface, to ensure that the implanted path is consistent with the planning path (Figs. 5,6). After confirming that the path is accurate, the guide wire is drilled into the bone passage through the sleeve under fluoroscopy monitoring.

Screw Placement and Verification

After confirming the position of the guide wire, place the cannulated screw. Finally, after confirming the good position of the cannulated screw, remove the guide wire and rinse the incision for suture.

Matters Needing Attention

Personnel Requirements

1. With the experience of open reduction surgery, when any problem occurs, the surgery can be completed without being limited to robot assistance.
2. Skill of closed reduction, internal fixation, and scientific surgical planning.

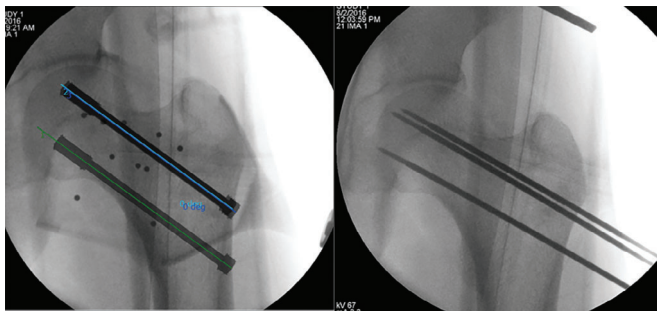


Fig. 5 Intraoperative verification at AP view.

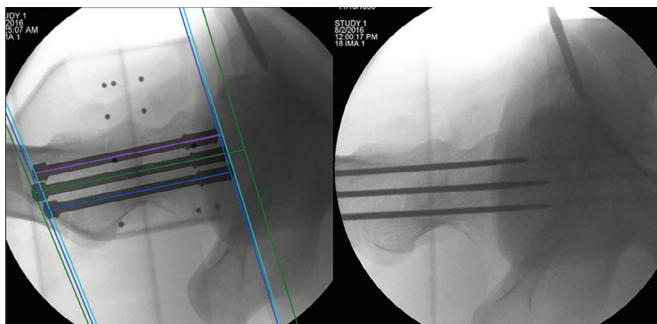


Fig. 6 Intraoperative verification at lateral view.

3. Familiar with the basic principles of robot work and can correctly complete the acquisition of robot images.
4. Pay attention to the position of the tracer during the operation to minimize the interference of any factors on the tracer and reduce errors.
5. When the guide device and the guide wire are inserted, try to avoid the impact of soft tissue tension on the premise of reducing local trauma.

Image Collection Requirements

1. All bone structures and anatomic landmarks of the surgical area are included, ensuring the bone pathways are continuous and complete.
2. The positioning registration component is clearly displayed in the perspective image.
3. The navigation camera can simultaneously identify and capture the spatial location information of the patient tracer and the robot tracer.
4. Collect the images in sequence according to requirements of different surgical methods, making clear the corresponding relation between the planned position image and the verified position image.

Image Drift

The accurate placement of the screw depends on the spatial position of the surgical site matching the image. Various factors, such as excessive traction during the operation, can lead to a change in the spatial position of the surgical site, or the relative displacement of the patient tracer and the surgical site, or interference of the transmission path between the tracer and the infrared optical tracker camera, which can cause the image to be inconsistent with the surgical site, which is called image drift. Surgeons should be able to determine whether the image drift occurs during the operation and verify it. If the image drift cannot be corrected, the image should be collected again.

Surgical Path Review

1. During the robot-assisted operation, surgeons should always monitor the running of the system, and take emergency measures immediately in case of, for instance, unexpected movement or equipment failure. Stop the robot and remove all contact parts with the patient for corresponding treatment.
2. During the implantation placing, C-arm fluoroscopy should be used for process monitoring, and surgery only can be completed after the implantation is confirmed to be correct.

Operating Room Requirements

1. The operating room area should be greater than 30 m², with a good grounding system and power supply conditions.
2. The operation table should meet the requirements of body position and image collection.

Equipment Maintenance

1. Use in strict accordance with the operation manual, and use is prohibited without training.
2. The system has precision components, and the transportation and storage process should be conducted in strict accordance with the requirements of the operation manual.
3. Carry out regular maintenance and calibration.
4. Prevent the power supply voltage from being too high or too low. Check the grounding regularly to ensure safety.
5. When using fumigation for disinfection, the equipment should be pushed out of the fumigation room to avoid corrosion or damage of circuit boards and components.
6. Attention should be paid to dust prevention and dust should be wiped away frequently.
7. Electric power shall be applied to dehumidify and moisture-proof when idle for a long time, especially in the humid southern areas, at least once a week, 2 to 3 h each time, to avoid damage from damp.

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