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A clinical study on robot navigation-assisted intramedullary nail treatment for humeral shaft fractures

Hongfei Qi^{1†}, Xianjie Ai^{1†}, Taotao Ren^{1†}, Zhong Li¹, Chengcheng Zhang¹, Bo Wu¹, Yu Cui¹ and Ming Li^{1*}

Abstract

Background The purpose of this study was to evaluate the advantages of robot navigation system-assisted intramedullary nail treatment for humeral shaft fractures and compare its efficacy with that of traditional surgical intramedullary nail treatment.

Materials and methods This was a retrospective analysis of patients with humeral shaft fractures who received intramedullary nail treatment at our centre from March 2020 to September 2022. The analysis was divided into a robot group and a traditional surgical group on the basis of whether the surgery involved a robot navigation system. We compared the baseline data (age, sex, cause of injury, fracture AO classification, and time of injury-induced surgery), intraoperative conditions (surgery time, length of main nail insertion incision, postoperative fluoroscopy frequency, intraoperative bleeding), fracture healing time, and shoulder joint function at 1 year postsurgery (ASES score and Constant–Murley score) between the two groups of patients.

Results There was no statistically significant difference in the baseline data or average fracture healing time between the two groups of patients. However, the robotic group had significantly shorter surgical times, longer main nail incisions, fewer intraoperative fluoroscopies, and less intraoperative blood loss than did the traditional surgery group ($P < 0.001$).

Conclusion Robot navigation system-assisted intramedullary nail fixation for humeral shaft fractures is a reasonable and effective surgical plan. It can help surgeons determine the insertion point and proximal opening direction faster and more easily, shorten the surgical time, reduce bleeding, avoid more intraoperative fluoroscopy, and enable patients to achieve better shoulder functional outcomes.

Keywords Orthopaedic robot navigation, Humerus fracture, Intramedullary nail fixation

Introduction

Humerus fracture is a common type of fracture, and with the continuous growth of the elderly population, the incidence of osteoporosis-related humeral fractures is increasing [1]. Nonsurgical treatment of humeral fractures can lead to serious complications, such as nonunion, malunion, and traumatic arthritis; therefore, surgical treatment is increasingly being chosen [2–4]. The proportion of fractures in the humeral shaft is relatively high. In recent years, with the increasing number of surgical patients for

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humeral shaft fractures, surgical methods and internal fixation choices for humeral shaft fractures have become a focus of attention. The two common surgical methods are open reduction with bone plate fixation and intramedullary nail fixation [5], whereas the other surgical methods include closed reduction with percutaneous internal fixation and joint replacement surgery [6, 7]. In the past, open reduction with bone plate internal fixation was the most common surgical method, but open reduction with bone plate internal fixation has the disadvantages of a large surgical incision and high degree of intraoperative bleeding. With improvements in intramedullary nails, various types of humeral fractures can be fixed [8]. Intramedullary nails are fixed at the centre, causing less damage to the blood flow around the fracture. Compared with eccentric fixation with a bone plate, intramedullary nails have greater resistance to internal and external inversion and rotational stress [9–11]. Therefore, intramedullary nails can replace locking plates for the treatment of humeral shaft fractures.

The humeral intramedullary nail has advantages such as minimal invasiveness, central fixation, and good therapeutic effects and has gradually become the preferred internal fixation method for humeral shaft fractures. During this surgery, determining a good needle insertion point and direction is a key factor in ensuring surgical efficacy and reducing post-operative complications. The traditional surgical method involves repeatedly comparing X-rays located in the anterior and lateral positions during intraoperative fluoroscopy, especially for obese or difficult-to-reposition patients. This poses certain difficulties and requires repeated attempts, which can exacerbate bleeding and damage the rotator cuff and surrounding soft tissues. Robot navigation technology is minimally invasive and precise, and its application in orthopaedics is becoming increasingly widespread [12]. Common uses include assisting in the placement of pedicle screws in spinal surgery [13, 14] and assisting PFNA (proximal femoral antirotation intramedullary nail) fixation in elderly patients with intertrochanteric fractures of the femur [15, 16]. At present, no studies have explored the efficacy of robot navigation system-assisted intramedullary nail fixation for humeral shaft fractures. To our knowledge, this is the first relevant study.

The purpose of this study was to evaluate the advantages of robot navigation system-assisted intramedullary nail treatment for humeral shaft fractures and compare its efficacy with that of traditional surgical intramedullary nail treatment. The specific research process is as follows.

Materials and methods

Inclusion criteria: 1. Age > 18 years; 2. Unilateral fracture of the humeral shaft; 3. The surgical method used is traditional intramedullary nail fixation or robot navigation-assisted intramedullary nail fixation; 4. Injury within 2 weeks.

Exclusion criteria: 1. History of trauma or functional impairment in the affected limb; 2. Pathological orthopaedics; 3. Patients with combined radial nerve injury; 4. Failure to cooperate during follow-up or follow-up time < 12 months.

This was a retrospective study involving samples from patients who underwent intramedullary nail treatment for humeral shaft fractures at our centre from March 2020 to September 2022. Robotic navigation can be divided into two groups according to whether it is used during the surgical process: the robot group and the traditional surgical group. The surgical method used in the robot group was to fix humeral shaft fractures with intramedullary nails assisted by robot navigation, whereas the surgical method used in the traditional surgical group was to fix fractures with traditional intramedullary nails. This study was approved by the Ethics Committee of Xi'an Hong Hui Hospital (20,200,206), and all patients included in the study signed informed consent forms.

Materials and methods

Surgical techniques

Robot group

All patients underwent surgery in the beachchair position under general anaesthesia, and the upper arm was extended backwards to guide the needle into the insertion point. We inserted a positioning ruler into the proximal end of the fracture, ensuring that the positioning ruler was placed on the same fracture fragments as the needle insertion point. The surgical robot utilized was the Tianji orthopaedic robot (manufactured by Beijing Tianzhihang Company). We obtained imaging data of the proximal humerus in both the anteroposterior and lateral positions via a C-arm machine. We uploaded these data to the orthopaedic robot workstation (Fig. 1a) and planned the insertion point and direction of the intramedullary nail guide. We ensured that the guide direction was centred on the humeral head and medullary cavity, as seen on the anteroposterior and lateral X-ray images of the proximal humerus (Fig. 1b-c). We then activated the robotic arm, moved it to the needle insertion point on the body surface, and inserted the needle percutaneously along the robotic arm (Fig. 1d). We used a C-arm machine to confirm the position of the guide needle through fluoroscopy (Fig. 1e). We made a 3 cm skin incision along the guide pin and exposed the shoulder sleeve layer by layer. We

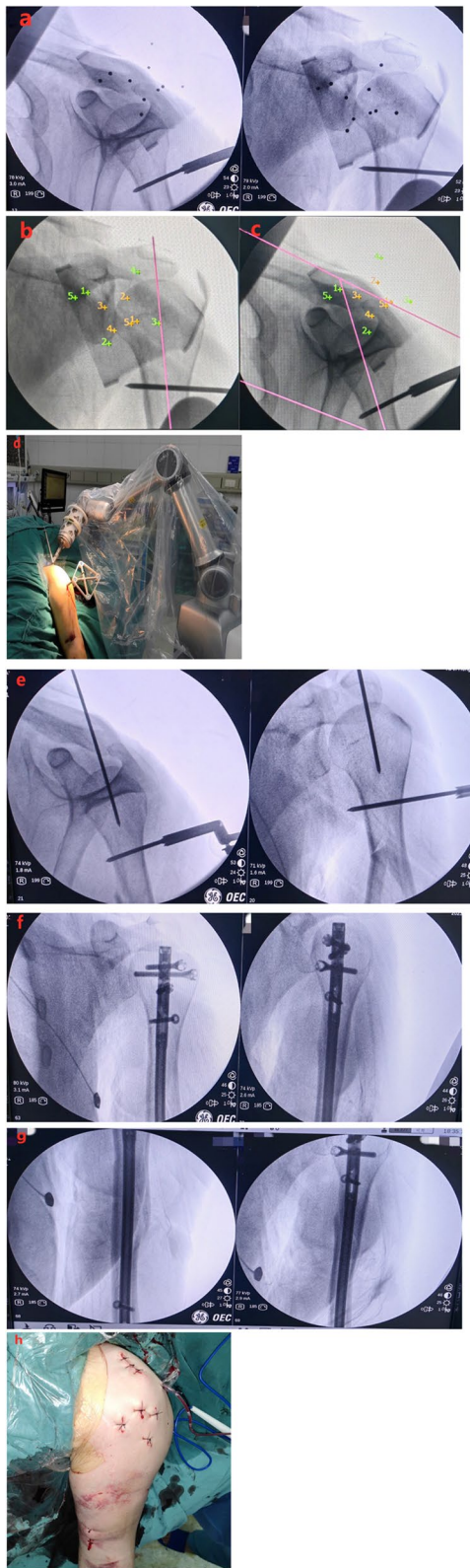


Fig. 1 Intraoperative photographs of the robot group. **a** First, we obtained standard anterior posterior and lateral X-images of the affected limb's shoulder joint. **b-c** We designed the ideal needle opening direction and channel on a computer host. **d-e** We inserted the guide pins along the direction of the robotic arm. **f-g** We inserted intramedullary nails and placed locking nails after expanding the medullary cavity. **h** Clinical photograph after suturing the wound

split 1 cm of the shoulder sleeve along the guide needle, inserted a protective sleeve, and opened the proximal end of the intramedullary nail along the guide pin. After the gold finger was inserted for closed reduction, the marrow was gradually expanded, and the main nail of the humeral bone marrow intramedullary nail (produced by Tianjin Zhengtian Company) was inserted. We inserted locking screws at the far and near ends (Fig. 1e-f), placed drainage tubes, and closed the wound layer by layer (Fig. 1g).

Traditional surgical group

In the traditional surgical group, patients also took a beach chair position and extended their upper arm backwards. Guide pins were inserted and X-ray images in the anterior posterior and lateral positions of the proximal humerus were repeatedly compared to ensure that the guide pin direction was located in the centre of the medullary cavity in both the anterior posterior and lateral positions of the proximal humerus. After the position of the guide pin was satisfactory, the skin was cut open layer by layer to expose the rotator cuff. The rotator cuff was split open, and a protective sleeve was inserted for proximal opening. After closed reduction, the medullary cavity gradually expanded. After the main nail of the humeral bone marrow was inserted, interlocking screws were placed at the far and near ends for fixation, drainage tubes were placed, and the wound was closed layer by layer.

Postoperative treatment

We removed the drainage tube 24 h to 48 h after surgery. On the second day after surgery, pendulum movements of the shoulder joint and passive lifting and external rotation movements of the shoulder joint started. The shoulder abduction brace was worn for six weeks after surgery, after which active shoulder joint training was initiated.

Outcome measures

The intraoperative outcomes mainly included intraoperative bleeding, intraoperative fluoroscopy frequency, operative time, and the length of the incision used for inserting the main nail.

The postoperative outcome was evaluated by one doctor with 15 years of experience in orthopaedic surgery. Fracture union was evaluated via radiographs. We define

fracture healing as when a mature callus forms a bridge across the fracture in the radiological view [17]. We assessed shoulder functional outcomes at the 12th month after surgery via the American shoulder and elbow surgeons (ASES) rating scale and the Constant–Murley score.

The ASES score includes two parts: pain (50%) and daily living function (50%), with a maximum score of 100 points. The higher the score is, the better the shoulder joint function. The Constant–Murley score consists of four aspects: pain (15 points), muscle strength (25 points), functional activity (20 points), and shoulder joint range of motion (40 points). The higher the score is, the better the function of the shoulder.

Statistical analysis

To achieve the purpose of this study, we compared various indicators of intraoperative and postoperative recovery between two groups of patients. Continuous variables are expressed as the means ± standard deviations. Continuous variables are first subjected to a normality test. Variables that follow a normal distribution are subjected to two independent sample t-tests, while variables that are not normally distributed are subjected to the Mann–Whitney U test. The chi-square test (χ^2) was used to compare the count data of the two groups of patients. $P < 0.05$ indicated a statistically significant difference between the two groups.

Results

This study included a total of 76 patients, including 38 in the robot group and 38 in the traditional surgical group. There was no statistically significant difference in the baseline data between the two groups (Table 1). All patients completed at least 12 months of follow-up, and the fractures healed smoothly. No patients reported complications such as deep infection or internal fixation failure. Compared with the traditional surgical group, the robot group had a shorter surgical time, less intraoperative blood loss, less frequent intraoperative fluoroscopy, a shorter main nail incision length, and better shoulder functional scores one year after surgery (Table 2).

All patients completed at least 12 months of follow-up, and the fractures healed smoothly. No patients reported serious complications, such as deep infection or internal fixation failure.

Compared with the traditional surgical group, there was no statistically significant difference in fracture healing time between the robot group and the traditional surgical group. However, there were significant differences in surgical time, intraoperative blood loss, intraoperative fluoroscopy frequency, main nail incision length, ASES score and Constant-Murley score at 12 months after surgery (Table 2). Overall, patients in the robot group had shorter surgical times, less intraoperative blood loss, less intraoperative fluoroscopy

Table 1 Comparison of the general characteristics and baseline data between the two groups of patients

General information	Robot Group (n = 38)	Traditional surgical group (n = 38)	t or χ^2	P
Age (years)	40.4 ± 8.5	38.9 ± 7.4	0.820	0.415
Sex (male/female)	24/14	30/8	2.303	0.129
Cause of injury (fall/traffic injury/other)	19/15/4	20/16/2	0.725	0.696
AO classification (2A/2B/2C)	10/19/9	13/18/7	0.668	0.716
Injury to surgery time (days)	4.6 ± 0.9	5.0 ± 1.3	-1.559	0.123

Table 2 Comparison of the intraoperative conditions and prognoses between the two groups of patients

General information	Robot group (n = 38)	Traditional surgical group (n = 38)	t or χ^2	P
Surgical time (min)	52.6 ± 9.7	73.7 ± 10.4	-9.146	< 0.001
The length of the incision for inserting the main nail (cm)	3.2 ± 1.0	5.8 ± 1.2	-10.261	< 0.001
Number of intraoperative fluoroscopies	10.42 ± 0.78	16.8 ± 3.4	-11.274	< 0.001
Intraoperative bleeding (ml)	47.8 ± 6.2	56.6 ± 11.8	-4.069	< 0.001
Fracture union time (months)	5.2 ± 1.7	5.4 ± 1.4	-0.559	0.577
ASES Score	89.3 ± 5.6	85.8 ± 6.7	2.470	0.015
Constant-Murley Score	92.4 ± 6.2	89.3 ± 7.1	2.027	0.046

frequency, shorter main nail incision lengths, and better shoulder joint function one year after surgery.

Discussion

Fixation of humeral shaft fractures can be performed via two main methods: intramedullary nails and bone plates. Intramedullary nails are a type of central fixation, whereas bone plates are eccentric fixation. The intramedullary nail is inserted into the medullary cavity along the long axis of the humeral shaft, and its locking screw force arm is significantly smaller than that of eccentrically fixed bone plate screws [11]. It has advantages such as minimal trauma, reliable fixation, and fewer complications. In patients with humeral shaft fractures combined with humeral head fractures, intramedullary nail fixation may be more advantageous. The results of a previous meta-analysis also indicate that the fixation effect of intramedullary nails is better than that of bone plates [18]. Therefore, intramedullary nails are increasingly becoming the preferred choice for the fixation of humeral shaft fractures. The key to intramedullary nail fixation lies in the accurate insertion point and direction. Unlike PFNA fixation for intertrochanteric fractures of the femur, surgeons can roughly determine the insertion point and direction of the guide wire by touching the vertex of the greater trochanter. The insertion point of the humeral intramedullary nail does not have obvious anatomical landmarks, and intraoperative fluoroscopy is required to compare the shoulder joint anteroposterior and lateral X-ray films repeatedly.

The robot navigation system combines the robotic arm, imaging data, and patients together. Surgical doctors can locate the robotic arm on the surface of the skin or bone tissue on the basis of the patient's imaging data and obtain an ideal needle insertion point and direction [19]. The robot navigation system can improve the efficiency and accuracy of surgery, with accuracy reaching the millimetre level. In addition, it can also detect the movement of the guide needle in real time and adjust the path on its own [20]. The use of robot navigation systems to assist doctors in surgical operations can ensure consistency between the planned path and the surgical path, which cannot be achieved in traditional surgical operations [21]. Due to these advantages, robot navigation systems can be used for surgical operations in high-risk areas (such as pelvic sacroiliac screw insertion) [22] and for minimally invasive fixation for the closed reduction of fractures. Our previous study also revealed that the use of robot navigation technology for PFNA fixation in elderly patients with intertrochanteric fractures can reduce the incidence of intraoperative bleeding and transfusion. Surgical doctors rely on robot navigation systems to plan the insertion point and direction of

the guide needle on the image. The robotic arm can be accurately located above the humeral head, helping doctors quickly and accurately find the insertion point and direction of the humeral intramedullary nail. Traditional surgery requires repeated comparisons of anterior, posterior, and lateral X-rays of the shoulder joint because the guide needle not only needs to be in the centre position on anterior and posterior lateral X-rays of the shoulder joint but also needs to be in the centre position on lateral X-rays. Repeated attempts not only prolong the surgery time but also increase bleeding and damage to surrounding soft tissues [23, 24]. During this process, there may be a risk of damaging the radial nerve if the guide needle penetrates from the fractured end of the fracture. Therefore, traditional surgery requires greater skill and experience from doctors, and the speed and efficacy of surgery highly depends on their experience and skills. The robot navigation system can substantially reduce the number of attempts to insert the guide needle and improve the accuracy of inserting the guide needle into the medullary cavity. Minimally invasive and precise advantages are precisely what is needed for the operation of humeral intramedullary nails. Robot navigation systems assisted by intramedullary nails can simplify surgical operations, reduce trauma, and improve patient prognosis in the field of humeral orthopaedics. The most common complications of humeral intramedullary nails are postoperative shoulder joint pain and limited shoulder joint function. The use of retrograde humeral intramedullary nails can reduce this occurrence. The pain and limited function of the shoulder joint after surgery are largely related to rotator cuff injury. Rotator cuff injury is caused mainly by inaccurate positioning of the needle insertion point in traditional surgery, and repeated attempts have exacerbated damage to the rotator cuff. Robot navigation technology can minimize damage to the rotator cuff to the greatest extent possible. In addition, the robot navigation system can reduce the frequency of intraoperative fluoroscopy and reduce the harm of X-ray radiation to patients and medical personnel [25, 26]. The cost of robot navigation systems is relatively high, which may, to some extent, affect their popularity.

Our research revealed that there was no significant difference ($P > 0.05$) between the robot group and the traditional surgical group in terms of fracture healing time. There were significant differences ($P < 0.05$) in surgical time, length of the main nail incision, number of intraoperative fluoroscopies, intraoperative blood loss, and shoulder joint function one year after surgery. The robot group had a shorter surgical time, less intraoperative bleeding, shorter main nail incisions, fewer intraoperative fluoroscopies, and better shoulder joint function one year after surgery. These findings are consistent with the

results of previous research on robot navigation systems [26, 27].

Our study also has certain shortcomings. First, it is a retrospective controlled study without randomized grouping and double-blind treatment. Second, as a single centre study with small sample sizes, we require further large sample and multicentre studies to confirm the conclusions of this study. Finally, the patient follow-up time is relatively short, and longer follow-up may lead to different conclusions.

Conclusion

Robotic navigation system-assisted intramedullary nail fixation for humeral shaft fractures is a reasonable and effective surgical plan. It can help surgeons determine the insertion point and direction faster and more easily, shorten the surgical time, reduce bleeding, avoid more intraoperative fluoroscopy, and enable patients to achieve better shoulder joint function.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12891-024-07848-6>.

Supplementary Material 1.

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Clinical trial number

Not applicable.

Authors' contributions

Hongfei Qi and Ming Li were responsible for the study design, the definition of intellectual content, and the literature research. Xianjie Ai and Taotao Ren analysed and interpreted the data. Hongfei Qi drafted the manuscript. Chengcheng Zhang, Bo Wu and Yu Cui revised the manuscript. Zhong Li is responsible for coordinating, guiding, and correcting some of the difficulties in research process. All authors read and approved the final manuscript.

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Availability of data and materials

The data are available from the corresponding author upon reasonable request.

Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study was performed in accordance with the principles of the Declaration of Helsinki. This study was approved by the ethics committee of Hong Hui Hospital, Xi'an Jiaotong University (Xi'an, Shaanxi, China; 20200206). All patients provided informed consent prior to participation in the study.

Competing interests

The authors declare no competing interests.

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