Robot-assisted core decompression combined with bone grafting can improve the early clinical results in femoral head necrosis: a prospective cohort study

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Research Article

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Abstract

Background: To explore the clinical effect of robot-assisted core decompression combined with bone grafting in the treatment of femoral head necrosis involved in early stage.

Methods: This study is a prospective cohort study. The study included 49 patients (78 hips) who attended the Department of Orthopedics and Joint Surgery of the Second Affiliated Hospital of Xi'an Jiaotong University from August 2019 to February 2021. All the patients suffering Association Research Circulation Osseous (ARCO) Ⅱ stage of femoral head necrosis underwent core decompression and bone grafting. Among the patients undergoing surgery, 30 patients (54 hips) were treated with traditional surgical methods, and 19 patients (24 hips) were assisted by the made-in-China orthopedic robot system. All operations were performed by the same operator. The baseline data of the two groups of patients, the time of unilateral operation, the number of unilateral X-ray fluoroscopy, the Harris hip score (HHS) at the last follow-up after surgery, the visual analog score (VAS), and the collapse rate at the last follow-up were collected and compared.

Results: A total of 41 patients (70 hips) were followed up, including 24 cases (42 hips) in the traditional surgery group and 17 cases in the robot-assisted group (28 hips). The average follow-up time of all cases was (13.9±3.4) months (range: 8-18 months). At the last follow-up, a total of 13 patients (13 hips) suffered femoral head surface collapse, including 11 patients in the traditional surgery group (11 hips) and 2 patients in the robot-assisted group (2 hips). The rate of femoral head collapse between the two groups had statistical difference. The average operation time of unilateral hip in the traditional operation group was (22.5±5.5) min, and (18.2±4.0) min in the robot-assisted group, with significant difference. The number of X-ray fluoroscopy of unilateral hip in the traditional operation group was (14.7±3.1) times, and (10.1±3.1) times in the robot-assisted group, with significant difference. The HHS before surgery in the traditional surgery group was (63.8±3.2) points, and (84.6±3.4) points at the last follow-up,while the preoperative HHS of the robot-assisted surgery group was (65.5±3.5) points, and (85.9±3.1) points at the last follow-up. The HHS at the last follow-up of the two groups were significantly different from those before the operation, but there was no difference between the two groups. The preoperative VAS of the traditional surgery group was (4.8±0.8) points, and (1.7±1.2) points at the last follow-up. The preoperative VAS of the robot-assisted surgery group was (5.0±0.7) points, and (0.9±0.7) points at the last follow-up. At the last follow-up of the two groups, there were significant differences in VAS, and significant difference between the two groups was also detected.

Conclusion: Core decompression combined with bone grafting have a definite effect in the treatment of femoral head necrosis at early stage. Compared with traditional surgery, robot-assisted surgery can achieve better short-term results and head preservation rate.

Trial registration: the research has been registered in China National Medical Research Registration and Filing System

Background

Osteonecrosis of femoral head (ONFH) remains a major challenge to orthopedic surgeons due to its unclear pathogenesis(1). Clinically, most patients with ONFH have progressed to the stage of collapse at the time of treatment, and the normal structure of the hip joint is destroyed, resulting in secondary hip arthritis. The vast majority of patients need to receive joint replacement therapy, which brings serious burden to the family and society(2). Therefore, how to intervene ONFH before the collapse of the femoral head, delay or even reverse the process of femoral head necrosis, and delay the time of joint replacement are urgent clinical problems to be solved.

Core decompression is an important means for early intervention of femoral head necrosis(3). In order to enhance the decompression effect, a large number of studies have focused on the implant, but the improvement of the surgical technique itself has been neglected(4, 5). With the gradual application of intelligent robots and navigation technologies in clinical practice, some achievements have been made in the field of orthopedic surgery assisted by robots(6). Due to the congenital advantages of orthopedic robots in the operation of bone tissues, they have been widely used in the fields of trauma, spine suegery and joint replacement, and have obtained good results(6, 7). The Second Affiliated Hospital of Xi 'an Jiaotong University is one of the few hospitals owning made-in-China orthopedic robots. The robots have helped complete a large number of minimally invasive fracture surgery, pedicle screw implantation and other operations. Since August 2019, we have completed a number of core decompression and bone grafting of femoral head using the orthopedic robots, and conducted a retrospective study on the patients. The results are reported as follows.

Methods

Research object

This study was a retrospective analysis. A total of 49 patients (78 hips) who underwent core decompression and bone grafting for femoral bone necrosis at the International Society of Bone Circulation (ARCO) II stage in the Department of Bone and Joint Surgery, the Second Affiliated Hospital of Xi 'an Jiaotong University from August 2019 to February 2021 were included. All hip joints were examined by X ray, computed tomography(CT) and MRI before operation, which indicated different scope and degree of femoral head necrosis. According to the treatment, the hip joints were divided into two groups. Inclusion criteria: patients with femoral head necrosis diagnosed by history, symptoms, signs and MRI, all patients were fully informed of the risks of surgery and signed surgical informed consent. Exclusion criteria: a. patients diagnosed with ARCO stage III or above; b. patients with serious cardiovascular and cerebrovascular diseases or tumors; c. people with mental illness; d. refusal to operate. Ultimately, 41 patients (70 hips) were followed up, including 24 patients (42 hips) in the conventional surgery group and 17 patients (28 hips) in the robot-assisted group. There was no significant difference in preoperative data between the two groups (p<0.05).

Surgical Procedure

All surgical procedures were performed by the same team of doctors. Surgical operations in the robot-assisted group: Preoperative CT scan of the hip joint (thickness: 0.625mm) was completed, and DICOM data were obtained and imported into the robot, and surgical channel planning was carried out in advance. The patient was supine on a traction bed with both lower limbs abducted and the affected side was elevated. The required equipment was placed in place and connected. The surgical area was routinely sterilized and covered with sterile surgical towels to fully expose the affected surgical area. After install sterile of C arm, the hip X-ray was taken under the two different positions, and the X-ray data was imported to the host to fit with the preoperative CT reconstruction data. When achieving the condition of the optimal fitting, according to the preoperative planning, the surgical path and the nail entry point were fine-tuned, then the data were transmitted back to the manipulator controller. On the operating table, computer was used to simulate the movement process of the manipulator arm. After confirming that the movement process and direction were correct, the manipulator arm were operated. The robot arm automatically run the guide needle and cannula to the skin surface according to the planned direction and the needle feeding point, and the screw could be inserted into the patient's body through this point and direction. The surgeon made an incision at the skin of the needle insertion point, bluntly separated the soft tissue, inserted the kirschner wire along the guide needle trocar, and then inserted the hollow drill bit with a diameter of 10 mm along the direction of the kirschner wire to below the bone cortex. After the length and position were determined by perspective, the kirschner wire and the hollow drill bit were pulled out. After fully scraping the surrounding dead bones with trephine and scraping spoon, allogeneic bone grains were taken for pressure bone grafting. After confirming the bone grafting amount under fluoroscopy, 10mm nano-bone rods were screwed in. After confirming the position through fluoroscopy again, the wound was rinsed, hemostatic thoroughly, and the incision was sutured. The operation time, the number of fluoroscopy and the amount of blood loss were counted. The surgical procedure is shown in Figure 1.

In the conventional group, the patients were supine in traction bed, and the lower limbs were abducted in traction bed. Locating the greater trochanter on the surface through C-arm fluoroscopy. Longitudinally cut the skin in length outside the hip joint along the lower edge of the greater trochanter of femur. Blunt dissected the subcutaneous fascia, muscle and periosteum. Confirming the direction of kirschner wire drilling by C-arm fluoroscopy. The kirschner wire was inserted into the bone about 4cm, and then the hollow brick with a diameter of 10mm was drilled into the femoral head to the position below the femoral head cortex. After the fluoroscopic positioning of the length and position was satisfactory, kirschner wire and the hollow bit were pulled out. After fully scraping the surrounding dead bones with trephine and scraping spoon, allogeneic bone grains were taken for pressure bone grafting. After confirming the bone grafting amount under fluoroscopy, 10mm nano-bone

rods were screwed in. After confirming the position through fluoroscopy again, the wound was rinsed, hemostatic thoroughly, and the incision was sutured. The operation time, the number of fluoroscopy and the amount of blood loss were counted.

Postoperative Management

All patients were treated with prevention of infection and analgesia after operation. Postoperative X-ray and CT were reviewed 3 months after surgery. All patients in the two groups exercised half weight bearing activities with crutches until 3 months after surgery.

Statistical analysis

All data were processed by statistical software SPSS 22.0. The measurement data were expressed as Mean±SD and t test was used. Counting data were compared by R×C contingency table chi-square test, $p<0.05$ was considered significant difference.

Results

Basic Information

Forty-one patients (70 hips) were finally included in this study. Baseline data of the robot-assisted and convention groups were collected and compared. No significant difference was detected in age (43.2±11.9 vs. 46.0±12.6, p=0.477), gender (15/9 vs. 10/7, p =0.811), BMI(23.9±4.0 vs. 22.3±3.2, p = 0.185), follow-up time of (13.9±3.6 vs. 13.9 ±3.3, p = 0.982), preoperative Harris score (65.5± 3.5 vs. 63.8 ± 3.2, p = 0.095), preoperative VAS (5.0 ±0.7 vs. 4.8± 0.8, p =0.407).(Table 1)

Table 1
Baseline data of two group

	Robot-assisted group(17 cases/28 hips)	Conventional Group(24cases/42 hips)	P value
Age	42.1±6.4	40.8±8.1	0.569
Gender(M/F)	15/9	10/7	0.811
BMI(kg/m^2)	24.1±3.4	23.2±5.8	0.535
Follow-up Time(month)	15.2±4.6	14.1±5.2	0.479
Pre-operation HHS	68.4±4.5	67.2±3.9	0.380
Pre-operation VAS	4.8±1.7	5.1±1.5	0.563

Comparison Of Intraoperative Statistical Indicators

After intraoperative data were collected for all enrolled patients, we counted the duration time of unilateral hip surgery, the amount of intraoperative blood loss, and the number of unilateral hip fluoroscopy. The final results showed significant differences in the duration of surgery (18.2±4.1 vs. 22.5±5.5) and the number of fluoroscopy (10.1±3.1 vs. 14.7±3.1) in the robot-assist group when compared to the conventional group ($p<0.001$), and there was no significant difference in intraoperative blood loss between the two groups ($p = 0.051$).(Table 2)

Table 2
Comparison of intraoperative factors between the two groups

	Robot-assisted group	Conventional Group	pvalue
Operation time (min)	18.2±4.1	22.5±5.5	0.009*
Blood loss(ml)	54.3±27.8	56.6±26.1	0.789
Number of fluoroscopy	10.1±3.1	14.7±3.1	<0.001*

Comparison Of Postoperative Follow-up Data

The Harris hip score, VAS score and the number of collapsed hip joints of all enrolled patients at the last follow-up were further analyzed. The results showed that at the last follow-up, a total of 13 patients suffered hip collapse, including 11 patients in the traditional surgery group and 2 patients in the robot-assisted group. There was a statistical difference in the collapse rate between the two groups ($\chi^2=4.031$). At the last follow-up, there was no significant difference in Harris score between the two groups, while there was a statistical difference in VAS score ($t=3.920$).(Table 3)

Table 3
Comparison of the two groups at the last follow-up

	Robot-assisted group	**Conventional Group**	**p**
Collapse of the hips	11	2	0.045*
HHS	85.9±3.1	84.6±3.4	0.238
VAS	0.9±0.7	1.7±1.2	0.038*

Clinical Data Of A Woman With Femoral Head Necrosis

Patient A, male, 43 years old who suffered femoral head necrosis due to the use of steroid. Preoperative X-ray revealed normal morphology of the right femoral head, while CT and MR showed typical necrosis of the femoral head in the weight-bearing area. This patient underwent robot-assisted core decompression and bone grafting. Postoperative X-ray showed that the implant accurately reached the necrotic area, and CT at 8 months postoperatively showed good repair of local necrotic area.(Figure 2)

Discussion

A total of 41 patients (70 hips) with ARCO stage II were included in this study, including 24 patients (48 hips) in the traditional surgery group and 17 patients (22 hips) in the robot-assisted group. The mean follow-up time was (14.6±4.8) months. To the last follow-up, a total of 13 patients (13 hips) suffered collapse of femoral head, including 11 cases (11 hips) in traditional surgery group, and 2 cases (2 hips) in robot-assisted group. The collapse rate of femoral head in traditional surgery group was in agreement with other previous reports(8), and the collapse rate of femoral head in robot-assisted group was significantly lower than that of other previous studies. In addition, robotic surgery was superior to traditional surgery in terms of operation time, number of intraoperative X-ray fluoroscopy and postoperative pain improvement. At the last follow-up, Harris hip score was better in both groups than before, but there was no significant difference between the traditional surgery group and the robot-assisted group.

There are many classification criteria for femoral head necrosis. In this study, the 2019 revised ARCO staging system was used to regularly classify the included patients. In the 2019 revision of the ARCO staging system, stage 0 was removed, and the location and size of necrotic lesions were not used as staging criteria(9). In this study, a total of 13 hips progressed to ARCO III with collapse at the last follow-up. After case summary of these 13 hips, it was found that the area of femoral head necrosis of 9 hips exceeded 30%, which was classified as ARCO IIc of 1994 edition. Eight patients received hormone therapy again during the follow-up period due to primary disease progression. For the hip joint which necrotic area of the femoral head exceeds 30%, the necrotic bone cannot be completely removed, which leaded to the lack of bone grafting through the core decompression canal. The size of necrotic area in the femoral head before operation and the amount of necrotic bone remaining during operation will affect the success rate of surgery. Landgraeber et al. suggested that a better surgical efficiency could be achieved when the postoperative residual dead bone was less than 1000mm^3(10). Compared with traditional surgery, robot-assisted surgery can reach the necrotic area more accurately and remove the necrotic bone to the maximum extent. However, at present, the related instruments of robot-assisted surgery are still scarce, which cannot give full play to the advantages of precision of robots(11). In addition, for the hip joint with large necrosis area of the femoral head, a simple working path for decompression cannot completely remove the dead bone. In this case, robot-assisted decompression combined with arthroscopic removal of dead bone and bone grafting of the hip joint or open surgery are required to ensure better surgical results(12, 13).

In this study, the postoperative Harris score and VAS score of patients in the two groups were significantly improved compared with the preoperative score, while the VAS score was significantly different at the last follow-up between the two groups, and the Harris score was not significantly different. Patients with early necrosis of the femoral head usually present with pain in the hip joint without significant range of motion limitation. Therefore, for the evaluation of the treatment effect of early femoral head necrosis, the improvement of VAS is more significant. Among the 41 patients included in this study, a total of 29 patients underwent simultaneous surgical treatment for bilateral femoral head necrosis. For this part of patients, Harris score could not evaluate the function of a single hip joint very well, which affected the final results. The VAS score can be used to evaluate the unilateral hip joint without being affected by the contralateral hip joint. At present, there is a lack of independent comprehensive evaluation criteria for bilateral hip joint.

The robot used in this study is an orthopedic surgery robot made entirely in China, which is mainly used in trauma, spine and other fields. Till now, there is a lack of relevant research on decompression treatment of femoral head necrosis. As such robots has natural advantages for bone tissues, through a combination of preoperative CT data and intraoperative real-time X-ray image, the robot can help complete core decompression precisely and convenient with a more minimally invasive surgical incision. According to the follow-up data, robot-assisted operation can achieve superior outcome, and effectively reduce the number of intraoperative radiation exposure, intraoperative bleeding, reduce the operation time, and complications related to drilling. By fitting the preoperative CT-based reconstruction image with the intraoperative X-ray image, the robot system can realize the drilling point of femoral under the intraoperative three-dimensional field of vision. At the same time, for some necrotic areas that are difficult to reach, traditional surgery requires repeated puncture to determine the drilling path, which increases the risk of vessel and nerve damage and steel needle fracture. Traditional surgery usually requires a 5cm surgical incision below the greater trochanter and partial dissection of the gluteus medius, which may result in decreased hip abductor strength. The robot-assisted system has been proved to be able to perfectly avoid these complications in other clinical operations(14, 15), and no related complications occurred in this study.

Traditional core decompression combined with bone grafting is usually performed under direct vision or fluoroscopy with low grafting strength. The virtual wall technology of the robot can effectively and accurately implant the graft material into the necrotic decompression area, which will ensure the support strength and avoid iatrogenic collapse. In terms of implant material, we chose the commonly used nano-bone rod which had been introduced in our former research. This bone rod can provide excellent biocompatibility, mechanical compatibility and bioactivity to avoid the possible rejection of other endoplants in our previous study(16), while good ability of bone ingrowth is one of the important factors for successful hip preservation(17, 18). At the last follow-up, the collapse rate of the robot group was significantly lower than that of the traditional surgery group, suggesting that accurate removal of dead bones and high strength mechanical support can bring better clinical results. In this study, 2 patients with post-operative collapse chose hip replacement, during which a layer of fibrous tissue was found between the implanted rod and the bone, and no bone ingrowth occurred. How to induce better osteogenesis and bone ingrowsion is an important research direction for achieving better results of core decompression surgery(19, 20).

There are still some problems in this study. First of all, since the robot needs to use intraoperative X-ray and preoperative CT reconstruction data for fitting, even slight changes in posture will lead to deviation of the results after the X-ray image of hip joint is obtained. Secondly, there is still a lack of robotic core decompression equipment, which can not give full play to the characteristics of robotic surgery. Thirdly, the number of cases included in this study is still small, the follow-up time is not long, and the medium and long term results are still to be observed.

Conclusions

The results of this study suggest that robot-assisted core decompression and bone grafting can reduce the operative time, reduce the number of intraoperative X-ray fluoroscopy, relieve pain, and possibly improve the surgical efficiency.

Abbreviations

ARCO:Association Research Circulation Osseous;

HHS:Harris Hip Score;

VAS: Visual Analog Score;

ONFH: Osteonecrosis of Femoral Head;

CT: Computed Tomography

Declarations

Ethics approval and consent to participate: This study was approved by the Medical Ethics Committee of the Second Affiliated Hospital of Xi 'an Jiaotong University(No.2020001). The written informed consent was obtained from all participants. All methods were performed in accordance with the Declaration of Helsinki and “Ethical Review of Biomedical Research involving Human Beings (Trial)” issued by the Ministry of Health P.R.China at 2019.

Consent for publication: All patients in the study agreed to publish all results of the study.

Availability of data and material：The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: On behalf of all authors, the corresponding author states that there is no conflict of interest.

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Authors' contributions：TR and YP designed the research, TR and LS conducted the follow-up, TR, LS and WCS analyzed the data, WKZ offered technical guidance.

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Figures

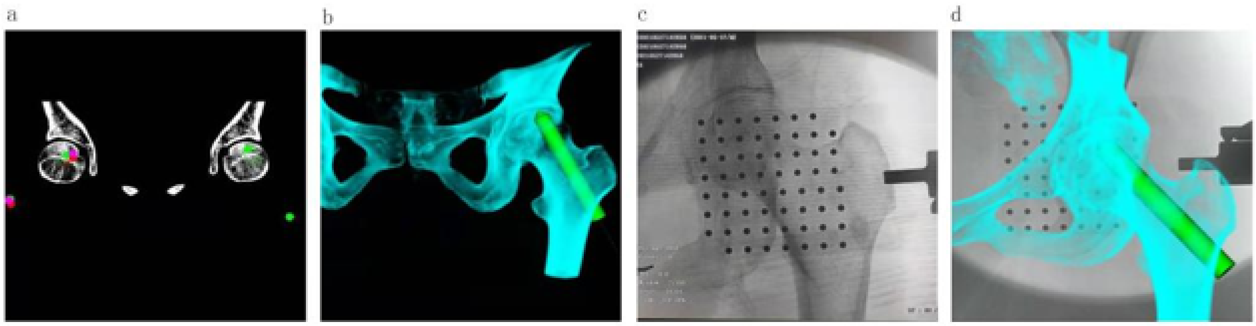

Figure 1

Surgical demonstration of robot-assisted core decompression and bone grafting. a: After obtaining the preoperative CT data of the patient's hip joint, the decompression path was planned in the coronal position; b: Verify decompression path after 3D reconstruction of CT data; c: Intraoperative hip X-ray; d: After fitting intraoperative X-ray and preoperative CT data, the decompression path was fine-tuned, and the decompression was assisted by a mechanical arm.

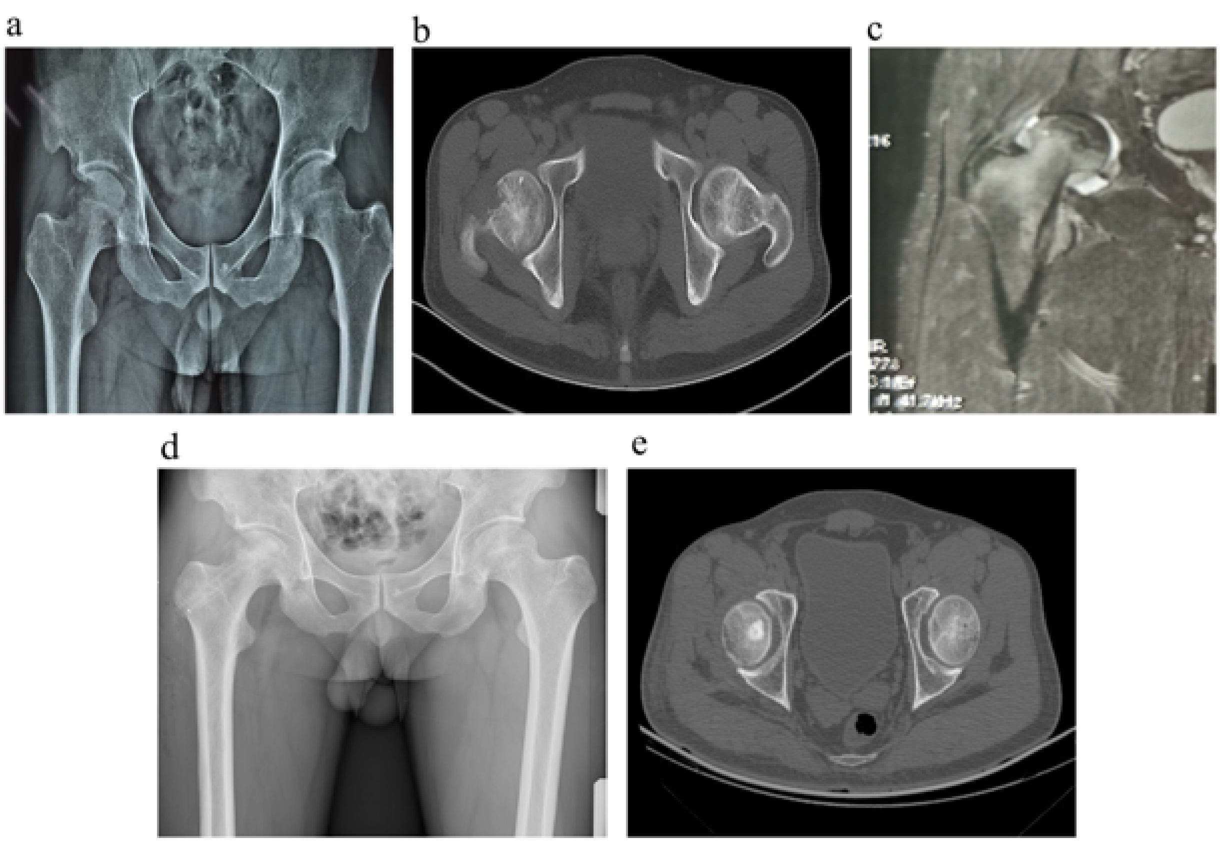

Figure 2

Imaging data of a patient with femoral head necrosis undergoing robot-assisted core decompression and bone grafting. a,b,c: X-ray, CT scan and MRI of the lesion side; d: X-ray of the lesion side 8 months after operation; e: CT-scan of the hip 8 months after operation.