

Original Article

Minimally invasive technology combined with titanium rod support in the treatment of early osteonecrosis of the femoral head

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Abstract: Osteonecrosis of the femoral head (ONFH) is a common and refractory disease that progresses quickly. It can progress to the collapse of the femoral head or to secondary arthritis in a short period of time without timely treatment. This study recruited 39 patients with ONFH from January 2012 to June 2017 and implemented minimally invasive technology combined with titanium rod support to treat their ONFH, and the related indicators were observed. After the operations, the patients' pain was significantly relieved, and their hip joint function was significantly enhanced. After the arthroscopic debridement, the surface of the femoral head cartilage was modified and smooth. Positive and lateral x-ray examinations 12 months after the operations showed that the titanium nails were well supported, and the weight-bearing areas of the femoral heads were not collapsed. After 12 months, two cases progressed from stage II b to stage II c, two cases progressed from stage II c to stage III, with femoral head collapse, so total hip replacements were necessary. This therapy can serve as a reliable and remarkable method for treating ONFH.

Keywords: Minimally invasive technology, titanium rod, osteonecrosis of the femoral head (ONFH)

Introduction

Osteonecrosis of femoral head (ONFH) is a common and refractory disease in orthopedics departments. ONFH is especially common in young and middle-aged people from 20 to 40 years old [1-4]. The disease progresses quickly. If it is not treated in time, it can progress to a collapse of the femoral head or to secondary arthritis in a short period of time, such that joint replacement may be needed. And in recent decades, the prevalence rate of ONFH has increased yearly [5]. Therefore, it is particularly important to actively find an effective technology for the treatment of early ONFH.

The preservation of the patient's own femoral head is the main purpose of the treatment of early necrosis of the femoral head [6], but the ideal treatment should be carried out from two aspects in the early stages. On the one hand, the goal is to enhance the local bone repair

ability of femoral head, that is, the tissue-engineered bone inoculated with autologous red bone marrow to repair the cystic lesion area of the femoral head, and the procedure's mechanism and efficacy have been reported by the authors [7-10]. On the other hand, it is treated by maintaining the local mechanical strength, that is, employing a hollow titanium rod to support the femoral head to prevent collapse before repairing the bone defect area [11-13]. In order to enhance the osteogenic repair ability of the diseased area of the femoral head and to prevent its collapse, the preferred methods reported in the domestic and overseas medical literature are core decompression focus debridement with or without bone transplantation [14, 15], vascularized fibula transplantation [16], allogeneic fibula transplantation [17], or tantalum rod implantation [18, 19]. The clinical results of core decompression focus debridement are uncertain and lack structural supports, and even combined bone transplanta-

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Table 1. Disease inducements and ARCO staging (hip)

Inducements	I c stage	II a stage	II b stage	II c stage	Hips (cases)
Corticosteroids	2	5	7	3	17 (13)
Alcohol	4	6	6	2	18 (16)
Trauma	1	1	1	2	5 (5)
No inducement	1	0	2	2	5 (5)
χ^2					0.068
P					0.798

tion lacks long-term mechanical support, resulting in a collapse of the femoral head. Vascularized fibula transplantation needs to expand the surgical process, and the donor site has the disadvantages of high morbidity and a long rehabilitation time, as well as the risk of proximal femoral fracture. Allogeneic fibula transplantation is more expensive and has the possibility of an absorption and rejection reaction, which can increase the technical difficulty of future hip replacement. The above methods are traumatic and have disadvantages such as repair wounds and insufficient donor sources. Although the tantalum rod recently used at home and abroad has a supporting effect, it is expensive and difficult for patients to accept, so it is not suitable for the vast majority of domestic consumers, resulting in its limited application. The purpose of this study is to explore the clinical efficacy of minimally invasive technology combined with titanium rod support in the treatment of early ONFH.

Materials and methods

General data

From January 2012 to June 2017, 39 patients with ONFH were treated using minimally invasive technology combined with titanium rod support in the Orthopedics Department of The First Affiliated Hospital of Hebei North University. Case inclusion criteria: (1) patients with stages I and II ONFH as the primary disease according to the Association Research Circulation Osseous (ARCO); (2) ONFH patients treated with minimally invasive technology combined with titanium rod support for the first time; (3) patients who were in stable condition and capable of grading relevant scores; (4) patients who were informed and signed the consent form. Exclusion criteria: (1) patients with collapsed femoral heads, immature bone development, stage III-VI ONFH, patients who used immunosuppressants, patients who un-

derwent inline fixation treatment for femoral neck fracture, patients with a past or present infection history; (2) patients with cognitive and speech disorders; (3) patients who had fractures caused by trauma; (4) patients who were incapable of walking before surgery. There were 22 hips in 20 males and 22 hips in 19 females. The patients had an average age of 37.5 ± 6.4 years. The course of disease lasted for 27 months with an average of 17

months. The inducement of treatment and the corresponding clinical stage of ARCO are shown in **Table 1**. The treatments for all the patients were authorized by the ethics committee of the First Affiliated Hospital of Hebei North University, and we informed the patients and their families, and they signed the informed consent form. The patients in the two groups were routinely examined, including examinations of their anterior and lateral hip joints, hip joint MRIs and pelvic positions, and the ONFH was confirmed through intraoperative pathology. Before their operations, all the patients were evaluated for the Harris score of hip joint function (a score < 70 indicated poor, a score 70-80 indicated medium, a score 80-90 indicated good, a score > 90 indicated excellent) and for the visual analogue scale (VAS) score (draw a 10 cm horizontal line on the paper, one end of the horizontal line is 0, indicating no pain; the other end is 10, indicating severe pain; the middle part represents varying degrees of pain).

Main materials

An arthroscope was purchased from the Beijing Stryker Medical Equipment Co., Ltd. The supporting material hollow titanium rod was made by Jiangsu Zhangjiagang Xinxin Medical Equipment Co., Ltd., the rod body has a diameter of 10 mm, the hollow diameter was 1.35 mm (a smooth rod); the rod tail had a length of 16-20 mm with a coarse thread, the thread core diameter was 10 mm, the thread diameter was 11 mm, the thread spacing was 1.75 mm, the whole rod length was 75-110 cm, and there was a large, inner hexagonal notch at the end [20].

Minimally invasive technology and methods

The external condition of the femoral head was observed using arthroscopy, the condition of the joint capsule was observed, and the degree

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of core decompression was accurately observed. Under C-arm X-ray fluoroscopy, a 2 mm guide needle was drilled into the center of the cystic disease area of the femoral head at 2 cm under the greater trochanter, the skin was cut longitudinally, the fascia lata and the lateral femoral muscle were separated, and a working tube with a diameter of 1.5 cm was inserted. 6, 8, and 10 mm hollow drills were used to remove the bone to the cystic degeneration area in turn. Through this bone tunnel, a special long handle curette or grinding drill was inserted, and the tissue in the femoral head was scraped under the guidance of fluoroscopy, which was routinely sent for histological examination, and arthroscopy was used to observe whether the tumor-like tissue or sclerosed bone or necrotic bone in the diseased area were all scraped off until there was fresh bleeding on the bone surface of the diseased area. The impactor was used to transplant the bone into the scraped area of the femoral head through the tunnel and pressed properly. Then a hollow titanium rod of the appropriate length was selected and slowly inserted along the core decompression hole to the beginning of the coarse thread of the nail tail under the guidance of the navigation system and perspective, and then it was screwed into the coarse thread to make the tip of the rod placed in the focus area of the femoral head, that is, under the cartilage of the femoral head, to support the subchondral bone and suture the incision. All the operations were performed by the same surgeon.

Postoperative treatment

The patients were given functional exercises of the hip and knee joints on the day after operation. The patients who underwent single hip operations could carry out non-weight-bearing activities on double crutches two weeks after their operations, and weight-bearing activities on single crutches three months after their operations. The patients who underwent double hip operations could carry out weight-bearing activities on single crutches three months after their operations, and the time they needed to use crutches was six months. All the patients were treated with hyperbaric oxygen therapy and an oral administration of simvastatin 10 mg every day after operation.

Evaluation index of efficacy

One year after the treatment, follow-up and X-ray positive and lateral examinations were

performed to observe the sizes of the lesions, the degree of collapse of subchondral bone, whether the nail was loose, and whether there was radiation transmission in the area around the nail. No change in the above items was considered to be stable; progress of the lesion, loosening of the nail, and radiation transmission in the area around the nail rod, but no withdrawal of the nail, no perforation, and no collapse of subchondral bone were considered to be unstable; nail withdrawal or piercing, or a collapse of the subchondral bone was considered a failure.

Harris scoring and VAS scoring of the hip joint function were performed to evaluate the improvement of the patients' hip joint function.

The clinical efficacy was evaluated using the above two indicators. Improvement: postoperative pain relief $\geq 50\%$, functional improvement $\geq 50\%$, and the x-ray showed stable. No change: postoperative pain relief $< 50\%$, functional improvement $< 50\%$, and the x-ray showed stable or unstable. Aggravation: the postoperative pain of the affected hip was worse than that before the operation, the function was worse than it was before operation, and the x-ray showed a worsened condition.

Statistical processing

SPSS software was used to complete the statistical processing. One-way analyses of variance and SNK-q tests were used to compare the measurement data, χ^2 tests were used to compare the count data, and rank sum tests were used to compare the rank data. $P < 0.05$ indicated that a difference was statistically significant.

Results

All the cases were followed up for 24-36 months, with an average of 30 months. The postoperative pathological results showed ONFH.

Preoperative ONFH imaging examinations

As shown in **Figure 1**, A: The preoperative x-ray examinations of the left femoral heads showed that the weight-bearing area of the left femoral head was cystic and there was ischemic sclerotic bone in the periphery and center. B: The patients underwent preoperative pelvic CT

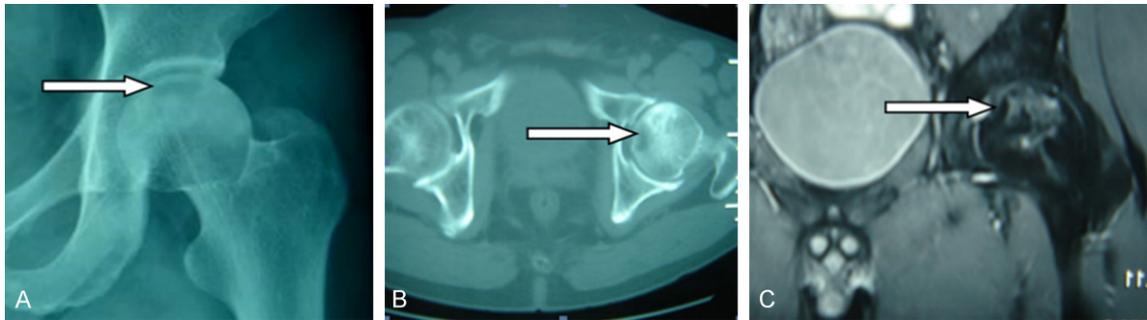


Figure 1. Preoperative imaging examination of ONFH. A: Preoperative X-ray examination of the left femoral head showed that the weight-bearing area of the left femoral head was cystic and there was ischemic sclerotic bone in the periphery and center. B: Preoperative pelvic CT examination showed cystic degeneration of the left femoral head and ischemic sclerotic bone around it. C: Preoperative hip joint MRI showed an abnormal signal area in the upper and outer front of the left femoral head.

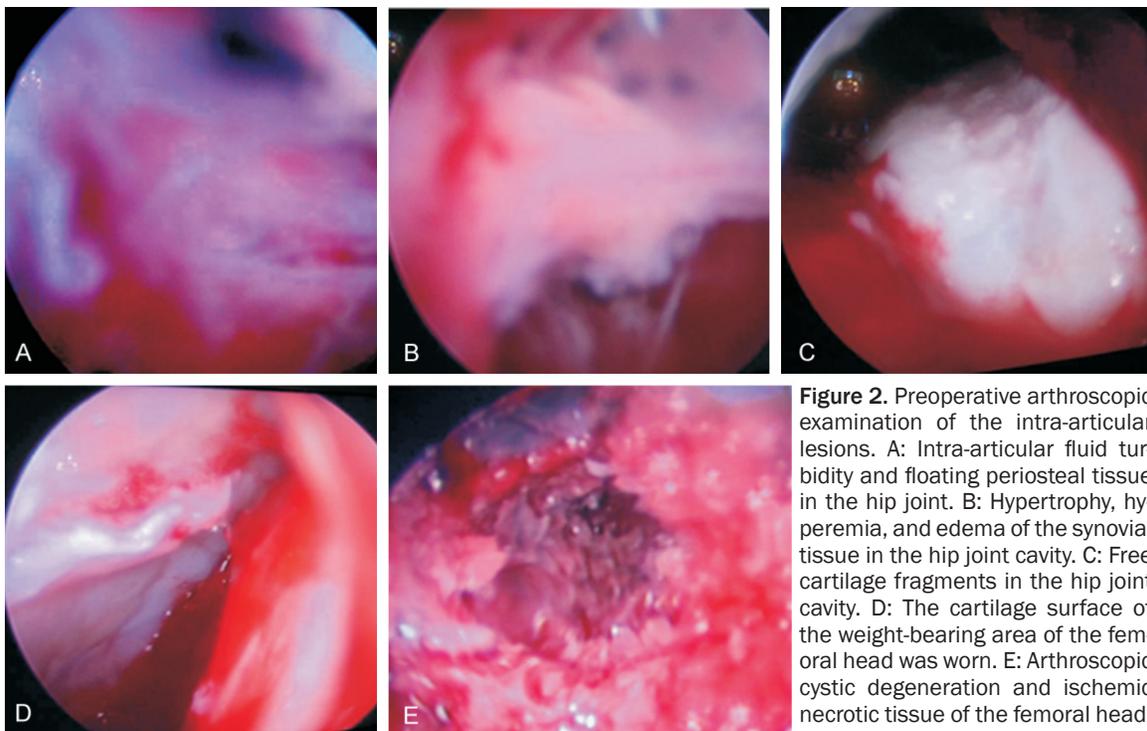


Figure 2. Preoperative arthroscopic examination of the intra-articular lesions. A: Intra-articular fluid turbidity and floating periosteal tissue in the hip joint. B: Hypertrophy, hyperemia, and edema of the synovial tissue in the hip joint cavity. C: Free cartilage fragments in the hip joint cavity. D: The cartilage surface of the weight-bearing area of the femoral head was worn. E: Arthroscopic cystic degeneration and ischemic necrotic tissue of the femoral head.

examinations, which showed cystic degeneration of the left femoral head and ischemic sclerotic bone around it. C: The patients' preoperative hip joint MRIs showed abnormal signal areas in the upper and outer front of the left femoral heads.

Preoperative arthroscopic examinations of the intra-articular lesions

The preoperative arthroscopic examinations showed that the synovial fluid in the hip joint cavity was turbid, there were floating periosteal tissues and free cartilage fragments, and there was synovial tissue hyperplasia and hypertro-

phy accompanied by hyperemia and edema. The surface of the cartilage in the weight-bearing area of femoral head was worn, and cystic lesions and ischemic necrotic tissue could be seen inside the femoral head (**Figure 2**).

Intraoperative arthroscopic debridement of the femoral head

Intraoperative arthroscopic debridement of the surface and inside of femoral head was performed. It was observed that the cartilage of the femoral head was smooth after the arthroscopy, and fresh blood exudated from the wound bone after the curettage in the femoral head,

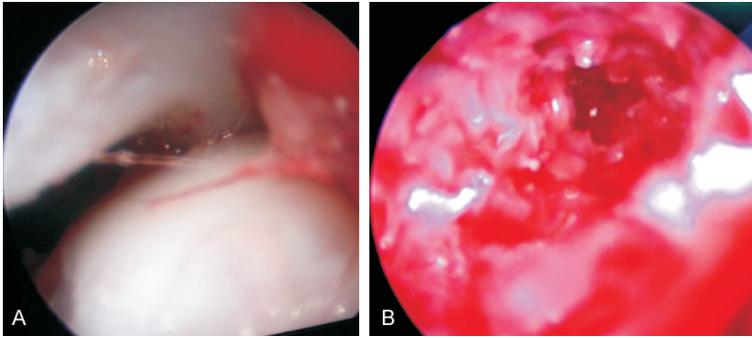


Figure 3. Intraoperative arthroscopic debridement of the surface and the inside of the femoral head. A: The surface of the diseased cartilage of the femoral head was smooth after the correction. B: Fresh blood exudated from the wound bone after the curettage in the femoral head.



Figure 4. A, B. Positive and lateral x-ray examinations of the patient 12 months after the operation showed that the titanium nail was well supported and there was no collapse in the weight-bearing area of the femoral head.

Table 2. Changes in the patients' x-ray staging before and after their operations

Operation staging	Postoperative staging					Hips
	I c	II a	II b	II c	III	
I c	8	0	0	0	0	8
II a	0	10	0	0	0	10
II b	0	0	14	2	0	16
II c	0	0	0	7	2	9
χ^2						3.226
P						0.312

indicating that the femoral head was cleaned (**Figure 3**).

The preoperative and postoperative results of the anterior and lateral X-ray examinations and the x-ray staging

One year after the treatment, follow-up and x-ray positive and lateral examinations were

performed to observe the size of the lesion, the collapse degree of the subchondral bone, whether the nail was loose, and whether there was radiation transmission in the area around the nail. **Figure 4:** The positive and lateral x-ray examinations of the patient 12 months after operation showed that the titanium nail was well supported and there was no collapse in the weight-bearing area of the femoral head.

As shown in **Table 2**, at 12 months after the operations, two cases progressed from stage II b to stage II c, and two cases progressed from stage II c to stage III, with collapses of the femoral head, so total hip replacements were necessary.

Preoperative and postoperative results of the Harris hip scores

As shown in **Table 3**, the patients' VAS scores at 6 and 12 months after the operations were significantly lower than they were before the

operations, and the difference was statistically significant, indicating that the degree of pain was significantly reduced after the operations. The patients' Harris scores at 6 and 12 months after the operations were significantly higher than they were before the operations, and the difference was statistically significant, indicating that the hip joint function was significantly enhanced after the operations.

Total clinical efficacy of the postoperative follow-up

During the follow-up at 12 months after the operations, there was no significant difference in the clinical efficacy or total improvement rate among the preoperative stages I c, II a, II b and II c ($P > 0.05$, **Table 4**).

Discussion

Although joint replacement has become a recognized and established method for the treat-

Table 3. Preoperative and postoperative VAS scores and Harris hip scores

Test time	VAS score	Harris score
Preoperative	4.8±1.2	77.5±3.5
6 months after operation	4.0±1.2*	86.7±1.2*
12 months after operation	2.1±0.6*#	98.0±2.4*#
F	101.065	567.798
P	< 0.001	< 0.001

*P < 0.05, compared with before the operation; #P < 0.05, compared with 6 months after the operation.

Table 4. Comparison of the patients' total clinical efficacy followed up at 12 months after their operations

Preoperative	Hips	Improved	No change	Aggravated	Improved (hips, %)
I c	8	8	0	0	8 (100.0)
II a	12	10	2	0	10 (83.3)
II b	16	14	0	2	14 (87.5)
II c	9	6	1	2	6 (66.7)
Hc/ χ^2		3.435			3.226
P		0.336			0.312

ment of ONFH [21], young and middle-aged patients need to undergo multiple joint revisions, which is unacceptable for many patients, so preserving the femoral head is the preferred goal. The design significance of this subject is to find a new treatment method that is new, scientific, practical, feasible, with a high cure rate, less surgical trauma, less pain, fewer complications, low cost, no need for joint replacement, easy for patients to accept, simple and easy to carry out.

ARCO stage II belongs to the early stage of ONFH, when osteonecrosis and cystic degeneration have appeared on the femoral head [22]. If it is not treated in time, the trabeculae in the weight-bearing area will be fractured, broken, or absorbed. At this time, the most effective method is to support the osteonecrosis but not a collapse of the femoral head, instead of joint replacement. Many studies have reported similar methods for the treatment of early ONFH, but the application of minimally invasive technology combined with titanium rod support in the treatment of early ONFH has not been reported. As a minimally invasive technology, arthroscopy is widely used in the field of orthopedics. The main purpose of the application of arthroscopy is to observe the bone lesions inside the femoral head through the femoral

neck decompression tunnel and to enter the hip joint space percutaneously to observe the intra-articular structure and femoral head and joint surface. As shown in **Figure 2**, the preoperative arthroscopic examinations showed that the synovial fluid in the hip joint cavity was turbid, with floating periosteal tissue and free cartilage fragments and synovial tissue hypertrophy with hyperemia and edema. The surface of the cartilage of the femoral head was worn, and cystic lesions and ischemic necrotic tissue could be seen inside the femoral head. Arthroscopy can be used to clear the lesions on the damaged joint surface and inside the joint visually, which avoids the blindness of simple C-arm cleaning [23]. In addition, some foreign scholars believe that the disease involves not only avascular necrosis of the femoral head, but also total joint disease [24-26]. In the treatment process, we can effectively

remove the turbid suspended tissue in the joint cavity and clean the surface of femoral head, which is very effective at improving the healthy environment of the whole joint and has practical value in improving the accuracy and effectiveness of the treatment for ANFH stage II.

In addition, this study found that the aggravation of patients in stages II b and II c after the operations was greater than it was in stages I c and II a, which suggests that patients with ONFH should be identified and treated as soon as possible, for it is beneficial to their postoperative recovery and long-term wellbeing. After the operations, two cases progressed from stage II c to stage III, and their femoral heads collapsed, and all the patients who needed total hip replacement were corticosteroid ONFH. It has been found that because of the action of hormones on osteoblasts, the formation of osteoblasts is inhibited and osteoblast apoptosis is promoted, resulting in osteonecrosis of the femoral head as a serious complication in the process of hormone therapy, with a high disability rate [27-30]. This study also found that minimally invasive technology combined with titanium rod support therapy is effective in the treatment of hormonal ONFH, but the effect is lower than the effects of other etiologies.

To sum up, the hollow titanium rod designed in this project to support the collapse of the femoral head has the advantages of low cost and definite efficacy. The hollow titanium rod can be implanted into the neck of the femoral head and the cystic degeneration area of the femoral head using minimally invasive technology, without leading to lesions at the donor site, and with only minor local complications, a convenient operation, and better clinical practicability and efficacy.

In conclusion, minimally invasive technology combined with titanium rod support in the treatment of early ONFH provides good short-term results and a good prospect for clinical application. However, due to the limited sample size and time, there may be bias in the results, so further research should be undertaken in the future.

Disclosure of conflict of interest

None.

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