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Research article

Comparison of minimally-invasive fibular supporting of T-type with traditional bloody iliac flap metastasis for osteonecrosis of the femoral head at ARCO stage II

Yanfang Zhang, Mengnan Li, Sikai Liu, Bo Liu, Xiaobo Wu, Yongtai Han, Tao Wu *

Department of Bone Disease, Third Hospital of Hebei Medical University, No. 139 Ziqiang Road, Qiaoxi District, Shijiazhuang 050051, Hebei Province, China

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ABSTRACT

Purpose: Our research mainly evaluates the clinical efficacy of two surgical methods in the treatment of osteonecrosis of the femoral head (ONFH) at ARCO stage II, aiming to provide optimal hip-preserving treatment of ONFH.

Method: From October 2018 to September 2020, 48 patients (59 hips) met the inclusion criteria and randomized. 24 cases (29 hips) in experimental group were treated with minimally-invasive fibular supporting of T-type; 24 cases (30 hips) in control group were treated with traditional bloody iliac flap metastasis. We will compare some intraoperative and postoperative conditions.

Result: The operation time in experimental group was 37 (6) minutes, in control group was 130 (21.75) minutes; the length of surgical incision in two groups was 3.7 (0.7) cm and 12.85 (2.68) cm. The intraoperative blood loss in two groups was 69 (21) ml and 363 (87) ml; the postoperative VAS score of the experimental group on day 1, day 3, day 7 after surgery was 5.5 (2), 3.5 (1), 0 (1); the control group was 6 (1.75), 4 (1), 3 (1). The data differences between above groups have statistically significant. The follow-up time of two groups was (33.86 $\pm$ 5.66) months and (35.67 $\pm$ 4.69) months. The bone graft healing time in two groups was (14.21 $\pm$ 1.93) months and (13.83 $\pm$ 2.34) months. The Harris hip scores of two groups at the last follow-up were 90 (7.5) and 86.5 (8.5). The survival rates of two groups were 79.31% (23/29) and 76.67% (23/30). The difference was no statistically significant in above groups ($P > 0.05$).

Conclusion: The two different bone graft implantation showed satisfactory early outcomes. Compared to the control group, the experimental group has the advantages of lesser pain, lesser blood loss, lesser trauma and shorter operation time. It may be a choice as bone graft for the treatment of ONFH at early stage.

1. Introduction

ONFH is a disabling disease whose processes include destruction of the femoral head, degeneration and necrosis of bone cells, subchondral bone collapse, and ultimately articular cartilage degeneration and osteoarthritis [1]. At present, the treatment of ONFH is still a worldwide problem. Many studies have confirmed that if medical intervention is not actively given in the early stage, hip replacement will be the final destination of most patients [2, 3, 4]. The reported peak age of ONFH onset is younger patients, especially men in their 40 s and women in their 30 s, who have reached the peak of their occupational and physical development [5]. Total hip arthroplasty (THA) is the first choice for the treatment of middle-advanced ONFH [6]. However, young and middle-aged patients will undergo one or more revisions due to prosthesis wear and loosening [7, 8]. The significance of hip preservation therapy for young and middle-aged patients with ONFH is undoubted. It can improve their quality of life and avoid or delay the frequency and time of artificial hip replacement [9]. Many studies have demonstrated that hip-sparing surgery is effective in promoting revascularization, repairing bone tissue, providing mechanical support, and preventing femoral head collapse [10, 11, 12]. Many scholars have conducted useful explorations on this, including core decompression, free bone graft, vascularized bone graft, and proximal femoral rotational osteotomy [13, 14]. Professor Zhao Dewei's team used vascularized iliac bone flap or greater trochanter bone flap transplantation to treat femoral head necrosis, and the curative effect was definite [15, 16]. Prof. Phemister first

* Corresponding author.
E-mail address: wutaodoctor@163.com (T. Wu).

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reported the Phemister technique for the treatment of nonunion of femoral neck fractures and femoral head necrosis using core decompression and autologous cortical bone grafting [17]. This technique has been improved by many scholars and is widely used in the treatment of ONFH. The technique named Advanced Core Decompression (ACD) is a modified procedure of core decompression which can allow better removal of the necrotic lesion by using the new percutaneous expandable reamer. This surgery consists of removing the necrotic tissue and subsequently refilling the defect. However, if the decompression range is large but the support is insufficient, which is more likely to cause collapse. To address the limitation, we introduced a novel minimally-invasive fibular supporting of T-type for early stage ONFH. In this study, we compared the clinical effects of minimally-invasive fibular supporting of T-type with traditional bloody iliac flap metastasis for osteonecrosis of the femoral head at ARCO stage II.

2. Materials and method

2.1. General information

From October 2018 to September 2020, in the Department of Orthopedics, the Third Hospital of Hebei Medical University, a total of 48 cases (59 hips) were treated by the same operation group, all of whom were young and middle-aged non-traumatic ARCO stage II patients. ONFH patients, who met the inclusion criteria of this study, used a prospective randomized controlled study. Among them, 24 cases (29 hips) including 22 males (27 hips) and 2 females (2 hips) in experimental group were treated with minimally-invasive fibular supporting of T-type. The age ranged from 21 years old to 46 years old, with an average age of 34.29 ± 6.89 years. The Harris hip score was 70.59 ± 5.14. In the control group, 24 cases (30 hips) were treated with iliac bone flap transfer with ascending branch of lateral femoral circumflex artery for the treatment of femoral head necrosis, including 21 males (26 hips) and 3 females (4 hips); the age ranged from 20 years to 45 years old, with an average of 34.42 ± 5.96 years. The Harris hip score was 69.13 ± 5.30. Before surgery, the two groups of patients were routinely performed bilateral hip anteroposterior position, frog-shaped X-ray films, CT and MRI examinations. The volume of the patient's necrotic lesion was calculated the percentage of the necrotic area in the MRI image (necrotic area/whole femoral head area in the MRI image). And the degree of necrosis was measured according to the Steinberg classification (Grade A, <15%; Grade B, 15%–30%; Grade C, >30%). There was no statistical difference in general data such as age, gender and the volume of necrotic lesion between the two groups ($P > 0.05$) (Table 1).

This study was approved by the Medical Ethics Committee of the Third Hospital of Hebei Medical University.

Table 1. Basic conditions of the experimental group and the control group before surgery.

Item		Experimental group (n = 24)	Control group (n = 24)	P value
Gender	Male	22	21	>0.999
	Female	2	3	
Age (years)		34.29 ± 6.89	34.42 ± 5.96	0.394
Alcoholism	Yes	20	22	0.663
	No	4	2	
Smoking	Yes	19	20	>0.999
	No	5	4	
Glucocorticoid adminstration	Yes	1	0	>0.999
	No	23	24	
Osteoporosis	Yes	1	2	>0.999
	No	23	22	
Harris hip score		70.59 ± 5.14	69.13 ± 5.30	0.806
Necrotic area*	Grade A	3	6	0.208
	Grade B	15	9	
	Grade C	11	15	

*: Grade A, <15%; Grade B, 15%–30%; Grade C, >30%.

2.2. Patients

2.2.1. Inclusion criteria

① Age:18–45 years old; ② radiographic femoral head with no collapse; ③ the time of pain in the affected hip joint is ≤6 months; ④ no history of surgical treatment for ONFH; ⑤ provision of informed consent for study participation; ⑥ follow-up can be adhered to after operation and compliance is good.

2.2.2. Exclusion criteria

① Active infection or coagulopathy; ② inability to tolerate surgery due to other diseases or poor overall condition; ③ weak subjective desire to preserve the hip; ④ the patients could not be followed up according to the doctor's orders after discharge, and the compliance was poor.

2.3. Surgical technique

In experimental group: Under C-arm fluoroscopy, a guide pin was percutaneously inserted into the center of the necrotic area along the femoral neck at 4–6 cm below the lateral side of the greater trochanter (Figure 1a). The pin was stopped at 3–5 mm below the cartilage of the femoral head. About 4-cm longitudinal skin incision was made and the greater trochanter of the femur was exposed. A triangular window was made at the slope below the greater trochanter, and the cancellous bone was reserved for femoral head bone grafting. Under the monitoring of the C-arm machine, we used hollow drills of different diameters to drill a channel along the guidewire (Figure 1b). The change of different drills was stopped until the 12 mm hollow drill was reamed to the subchondral bone, and a V-shaped tunnel was constructed in the necrotic area (Figure 1c-e). Put an appropriate amount of autologous cancellous bone into the necrotic area under the cartilage and press it. According to the preoperative plan, an allogeneic fibular rod with a length of 1.5–2.0 cm was pushed into the channel and placed horizontally (Figure 1f). After pressing firmly, the remaining autologous cancellous bone was placed on the both ends of the transverse fibular rod. The longitudinal fibular rod was implanted along the tunnel of the femoral neck and fixed with a cancellous bone screw (Figure 1g, h). The area where cancellous bone was taken from the greater trochanter was filled with allogeneic bone. Finally, the incision was routinely irrigated and sutured. Figure 1i–l shows the schematic diagram of T-type allograft of fibula under minimally invasive procedure.

In control group: The affected hip was raised in a 45° supine position, and an anterolateral S-shaped incision was made about 10–15 cm in length. The lateral femoral cutaneous nerve should be protected in the subcutaneous tissue. To expose the ascending branch of the lateral circumflex femoral artery along the space between the rectus femoris and tensor fascia lata and vein, and mark them. The superficial layer of the tensor fascia lata was freed and the ascending branch of the lateral femoral circumflex artery was used as the vascular pedicle (Figure 2a). The 1 cm sleeve of the tensor fascia lata muscle was reserved, and it was freed to the ilium behind the anterior superior iliac spine. The iliac bone flap with vascular pedicle (about 2.0 × 2.0 × 2.5 cm) was made by a sharp osteotome. Meanwhile, some cancellous bone was reserved. The junction of the femoral head and neck was exposed and the necrotic tissue was cleaned with a high-speed drill and a curette until the fresh blood oozes out (Figure 2b). To place the cancellous bone into the head firstly and press it moderately. Then, the vascularized iliac bone flap was transferred into the femoral head and fixed by one absorbable screw (Figure 2c). It was confirmed that the position of bone graft was intact using the C-arm machine (Figure 2d). Finally, the incisions were routinely closed sequentially.

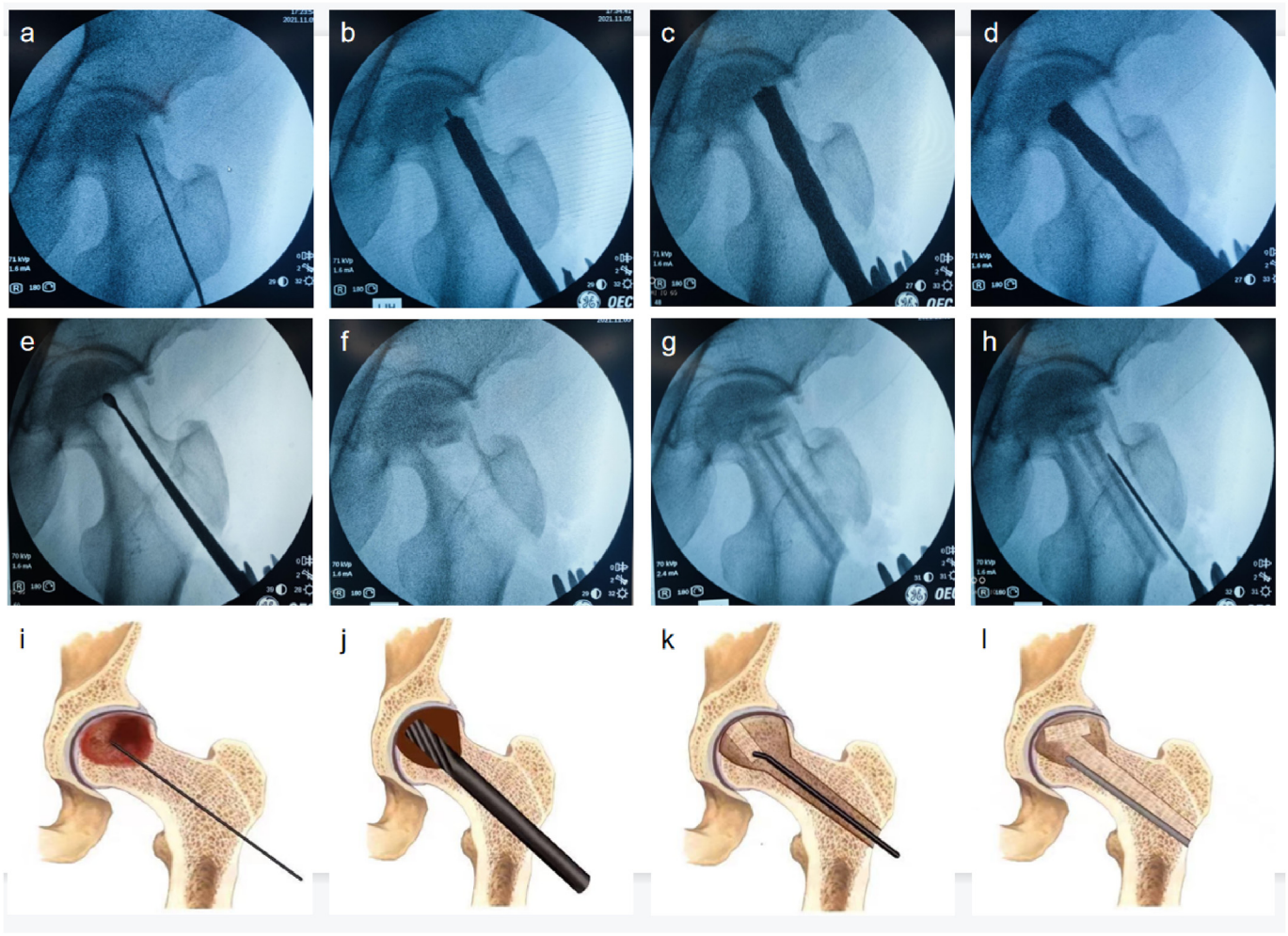

Figure 1. Operation diagram (a–h) and Schematic diagram (i–l) of T-type allograft of fibula under minimally invasive procedure.

No traction therapy was performed in the two groups after operation. In the early stage, ankle-foot dorsiflexion and lower-limb abduction function exercises were performed same in everyone. The patients in the experimental group who underwent hip-sparing surgery on one side began to walk with the aid of crutches without weight-bearing on the affected limb 3–4 days after the operation, while the patients in the control group who underwent hip-sparing surgery on one side began to walk with the aid of crutches without weight-bearing on the affected limb 2–3 weeks after the operation. After operation, professional doctors evaluated the healing degree of femoral head bone graft based on imaging, and determined the time of standing with crutches and abandoning crutches.

Routine re-examinations were performed at 4, 12, 24, and 48 weeks after operation, and every 6–12 months after 1 year. Routine X-ray and three-dimensional CT examinations of the hip were performed to dynamically evaluate the changes of femoral head morphology and bone graft healing.

2.4. Efficacy evaluation

The Harris hip score was used to evaluate the preoperative hip function and postoperative treatment effect. All radiographs were evaluated independently by three of the authors. A radiographic failure was defined as the onset of collapse [18]. Clinical failure was defined as a Harris hip score below 80 points or if the patients had the radiographic failure. Survival analysis was performed based on collapse of the femoral head. The clinical survival was compared between the groups with Kaplan-Meier survival analysis.

2.5. Statistical methods

Data were processed and analyzed by SPSS 26.0 statistical software package. Two-sample t-test was used to compare measurement data with normal distribution, two-sample rank-sum test was used to compare measurement data with skewed distribution, and chi-square test was used to compare count data between groups, and $p < 0.05$ was considered statistically significant., and $p < 0.05$ was considered statistically significant.

3. Results

3.1. General results

There was no nerve and blood vessel injury, infection and serious complications such as lower extremity deep vein thrombosis in both groups. Follow-up time: the experimental group was 24–45 months, with an average of (33.86 ± 5.66) months; the control group was 25–45 months, with an average of (35.67 ± 4.69) months, there was no significant difference between the two groups ($t = -1.336$, $p = 0.187$).

3.2. Intraoperative comparison

All operations were performed by the same surgeon in the same surgical team. The operation time of the experimental group was 30–50 min, with an average of 37 (6) min, and the operation time of the control group was 110–160 min, with an average of 130 (21.75) minutes, and the difference was statistically significant ($z = -6.599$, $p = 0.00$). The length

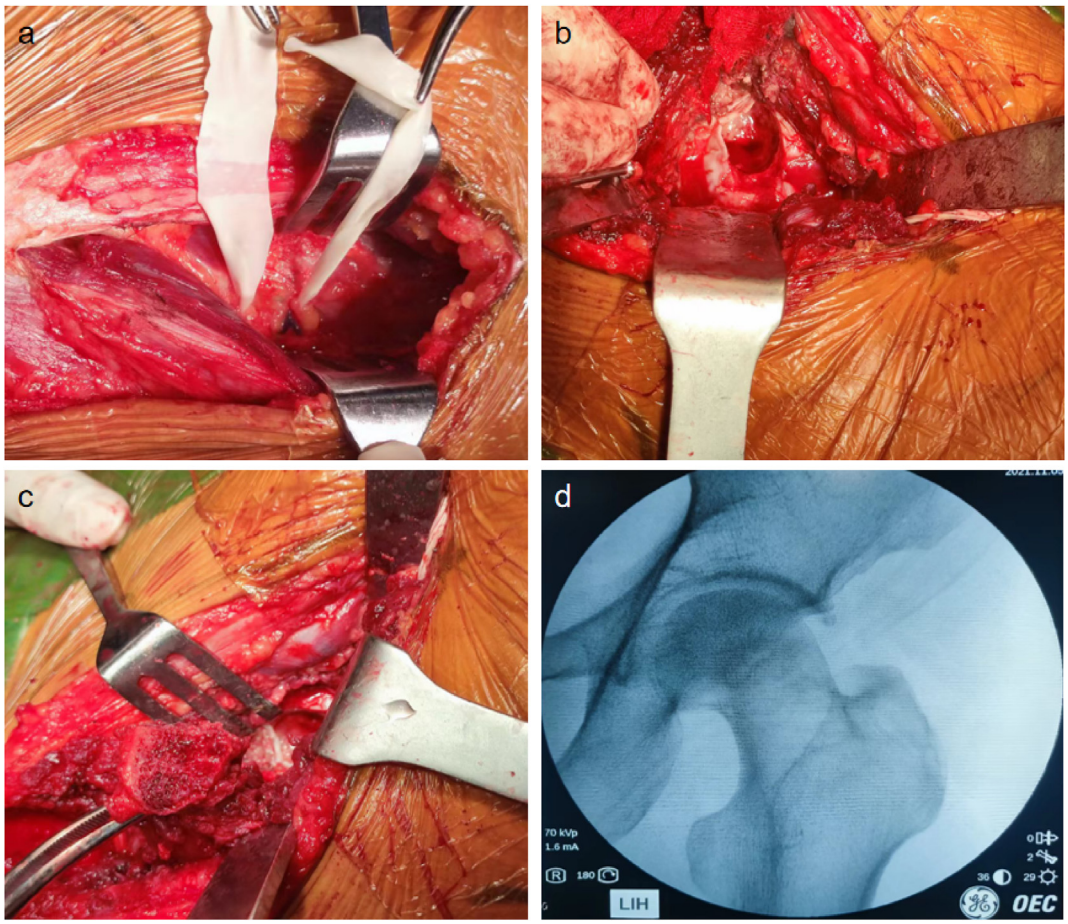

Figure 2. (a–c): Operation diagram of iliac bone flap transfer with ascending branch of lateral femoral circumflex artery (d): intraoperative X-ray.

of the surgical incision in the experimental group was 3–5 cm, with an average of 3.7 (0.7) cm. The control group was 10–15 cm, with an average of 12.85 (2.68) cm, and the difference was statistically significant ($z = -6.599$, $p = 0.00$). The bleeding during surgery in the experimental group was 50–100 ml, with an average of 69 (21) ml, and the control group was 300–500 ml, with an average of 363 (87) ml, and the difference was statistically significant ($z = -6.597$, $p = 0.00$). Furthermore, the experimental group did not require a drainage tube at the end of the procedure, but the control group did. And the control group often required blood transfusion during the operation, refer to Table 2 for details. We have compared the VAS score on postoperative day 1, day 3, and day 7, which can be seen in Figure 3.

3.3. Bone graft healing

Review X-ray films showed that the cystic degeneration area of the femoral head disappeared in the two groups, and the bone density in the bone graft area was increased, achieving bone graft healing. The bone graft healing time in the experimental group was 11–18 months, with an average of (14.21 ± 1.93) months. The bone graft healing time in the control group was 10–19 months, with an average of (13.83 ± 2.34) months, and the difference was no statistically significant ($t = 0.668$ $p = 0.507$).

Table 2. Intraoperative conditions in the experimental and control groups.

Item	Experimental group (n = 29)	Control group (n = 30)	*P value*
Operation time (min) M (IQR)	37 (6)	130 (21.75)	<0.001
The length of the surgical incision (cm) M (IQR)	3.7 (0.7)	12.85 (2.68)	<0.001
Bleeding during surgery M (IQR)	69 (21)	363 (87)	<0.001
Drainage (yes: no)	0:29	30:0	<0.001
Intraoperative blood transfusion (yes: no)	1:28	25:5	<0.001

3.4. Evaluation of hip function

The Harris hip scores of the experimental group at the last follow-up were 90 (7.5) and the control group were 86.5 (8.5), and there was no significant difference between the two groups ($z = -1.818$ $p = 0.069$).

3.5. Evaluation of failure rate

Femoral head collapse occurred in 6 hips in experimental group and 7 hips in the control group. During the 2-year follow-up, no radiological evidence of disease progression was identified in 79.31% (23/29) of cases in experimental group. The clinical failure cases included that 1 case progressed in 6 months postoperatively, 2 cases progressed in 1 year postoperatively and 3 cases progressed in 2 years postoperatively. In control group, the hip survival rate was 76.67% (23/30) of cases. The clinical failure cases included that 4 cases progressed in 1 year postoperatively and 3 cases progressed in 2 years postoperatively. Kaplan-Meier survival analysis showed there was no significant difference in the survival time between the two groups (Figure 4). However, total hip arthroplasty was only performed in 2 cases in experimental group and 4 cases in control group. The remaining patients who progressed to collapse were treated conservatively.

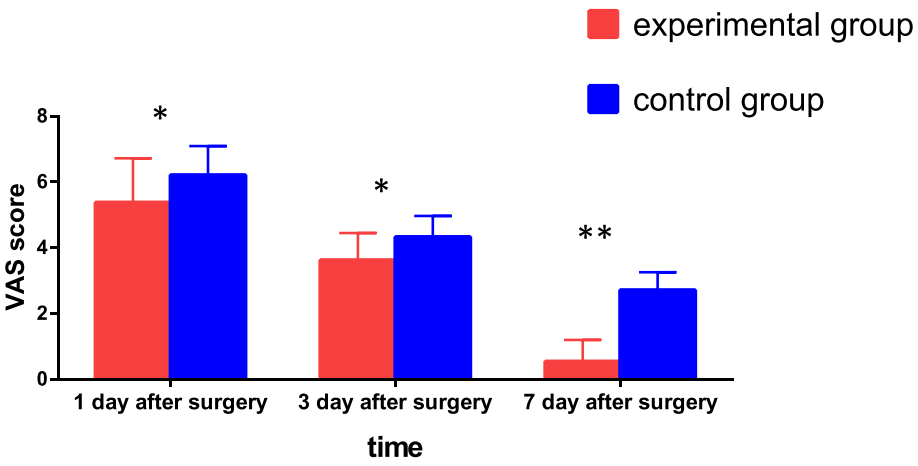

Figure 3. Comparison of postoperative VAS scores between the two groups, "*" indicates the difference was statistically significant.

4. Discussion

ONFH is a common refractory disease in orthopaedics. Trauma, long-term drinking and use of corticosteroids are currently recognized as the main causes of ONFH [19]. If there is no early diagnosis and treatment of ONFH, it will progress to the point of femoral head collapse, or even total hip arthroplasty. However, THA is not the best choice for the patients with early stage ONFH, especially for young and middle-aged patients [20]. Therefore, early diagnosis of ONFH in young and middle-aged patients is very important [21], and early surgical intervention can effectively delay the progression of necrosis and osteoarthritis [22, 23]. Vascularized bone grafting has been described to treat the pre-collapse and early post-collapse cases of ONFH, which has satisfactory long-term outcome. Lau et al. found that vascularized iliac bone grafting was effective in treating patients with pre-collapse in ONFH at a long-term follow-up of 17 years [24]. Therefore, we chose this technique as the control group and hip preservation survival rate is 76.67% in this study. However, the vascularized bone grafting is characterized by major trauma, complicated techniques, a significant number of complications and prolonged operation; so many surgeons began to introduce the non-vascularised bone grafting [25, 26]. There are three major techniques for non-vascularised bone grafting: the "light bulb procedure" through a window at the femoral head-neck junction, the trapdoor procedure via cartilage of the femoral head, and the core decompression via the lateral side of the greater trochanter of the femur [27]. The core decompression was initiated by Phemister, referred to as cortival strut grafting, was first described in 1949 [17]. However, we consider that the drawbacks of the traditional Phemister method are that it cannot sufficiently decompress and provide effective support. In this study, we introduced a new method for ONFH. After sufficiently decompressing the necrotic area of the femoral head using the Advanced Core Decompression introduced in the literature [28], we used the T-shaped support method in the tunnel theory for reference to provide strong support. A long-term comparative study of allogeneic fibular grafts versus non-vascularized autologous for ONFH found no significant differences in the HHS (82.4 $\pm$ 13.6 and 80.3 $\pm$ 14.5 respectively) and survival rate (86% and 84.1% respectively) [29]. Our findings were in agreement with that results. In this study, there was no significant difference in the HHS (90 (7.5) and 86.5 (8.5) respectively) and survival rate (79.31% and 76.67% respectively) between the two surgical approaches for the treatment of ONFH at ARCO stage II. However, compared with the traditional bloody iliac flap metastasis, the minimally-invasive fibular supporting of T-type had some advantages, such as less trauma, less blood loss, shorter operation time, less pain and so on. Femoral head collapse firstly occurred six months after operation in the experimental group. It may be related to the premature landing of the patient, and the fibular rod support has not reached bone fusion after full decompression. When the bone grafts reached bone fusion, the survival rates of the two groups was 93.1% and 86.66% respectively in 1 year postoperation, and 79.31% and 76.67% respectively in 2 years postoperation, which were in agreement with the results of other researchers [30]. The collapse of the femoral head is not directly related to

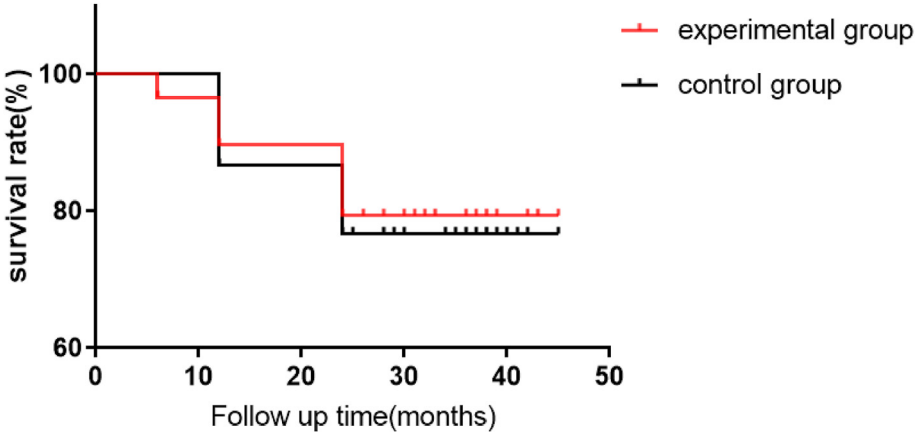

Figure 4. Kaplan-Meier survivorship analysis showed there was no significant difference between the two groups.

the occurrence of THA. In this study, only 6 cases underwent THA, although there were 13 hips progressed to collapse. Because the patients obtained good HSS after hip preservation surgery, so they refused to accept THA.

The allograft fibula T-type support structure belongs to the beam-column structure in the architectural engineering profession. This simple beam-column structure with one beam and one column can increase the lateral force area, support a large vertical load, improve the effect of mechanical support, and stabilize the biomechanical support of early postoperative femoral head necrosis to the greatest extent. Under the condition that the fibula T-beam-column structural support fully guarantees the initial mechanical stability of the femoral head, an ideal internal environment is created for the reconstruction, repair and revascularization of femoral head necrosis, which is in line with the principle of hip-preserving treatment. Since the position of the pressing support channel was moved down, autologous cancellous bone grafts could be chiseled at the ipsilateral greater trochanter during the operation. In view of the excellent inducibility, osteogenic ability and osteoconductivity of autologous cancellous bone, it is helpful to reverse or delay the natural course of ONFH [11].

There are still many shortcomings in this study: (1) this study only compared the early efficacy of minimally invasive allogeneic fibula T-braced bone grafting and transfer of iliac bone flap with ascending branch of lateral circumflex femoral artery in the treatment of ARCO stage II young and middle-aged patients with ONFH. But the long-term efficacy still needs to be followed up in the later period. (2) The sample size of this study is relatively small, and it is necessary to increase the sample size in order to obtain a more objective and fair conclusion.

5. Conclusion

As we all know, ARCO stage II ONFH is easy to collapse, and the collapse rate is high, but if effective measures can be taken in the early stage for active intervention, satisfactory curative effects can be obtained. There was no significant difference in outcome between the two surgical approaches for the treatment of ONFH at ARCO stage II. However, the minimally-invasive fibular supporting of T-type has some advantages, such as less trauma, less intraoperative blood loss, shorter operation time, no postoperative lower drainage, less pain after the operation, no strict bed rest in the early postoperative period, and can be routinely non-weight-bearing. Therefore, minimally-invasive fibular supporting of T-type can promote the repair of osteonecrosis in the early stage, which may be a choice as bone graft for the treatment of ONFH at early stage.

Declarations

Author contribution statement

Yanfang Zhang: Contributed reagents, materials, analysis tools or data; Wrote the paper.

Mengnan Li: Contributed reagents, materials, analysis tools or data.

Sikai Liu; Bo Liu: Analyzed and interpreted the data.

Xiaobo Wu: Conceived and designed the experiments; Performed the experiments.

Yongtai Han: Performed the experiments.

Tao Wu: Conceived and designed the experiments; Performed the experiments; Wrote the paper.

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Data availability statement

Data included in article/supp. material/referenced in article.

Declaration of interest's statement

The authors declare no conflict of interest.

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