

Original Article

Multi-directional core decompression apparatus with impaction bone grafting for the treatment of femoral head osteonecrosis

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Abstract: *Background:* Core decompression (CD) is one of the most widespread interventions for osteonecrosis of the femoral head (ONFH), but the biomechanical structure of the femoral head is severely destroyed in conventional techniques. A new surgical intervention of core decompression (CD) using self-designed multi-directional CD apparatus combined with impaction bone grafting and the fibular allograft implantation is reported, attempting to seek an innovative intervention for patients suffered early stages of ONFH. *Material and methods:* Fifty-eight affected hips in 53 patients with early stages of ONFH were involved in our prospective study of either core decompression using conventional drill combined with the fibular allograft implantation (control group) or this new surgical technique (experimental group). Outcome assessment included the Harris hip score (HHS), VAS score and X-ray performance. *Results:* The total of fifty patients finished a mean 42.7 months follow-up. There was significant statistical difference of postoperative HHS score between specific experimental group and control group. The VAS score was also statistically different. The clinical failure rates of the two groups were 6.9% and 19.2%, respectively. The postoperative X-ray performance of the experimental group were evaluated as improved in 18 (62.0%), unchanged in 8 (27.6%) and worse in 3 (10.3%) affected hips; while that of the control group were improved in 10 (38.5%), unchanged in 9 (34.6%) and worse in 7 (26.9%) affected hips. The new surgical technique had a higher improved rate and a lower failure rates. *Conclusion:* Multi-directional CD apparatus combined with impaction bone grafting and the fibular allograft implantation is an effective alternative treatment, even with large lesion area and irregular shape. It's technically feasible and may be superior in removing the necrotic bone and providing reliable biomechanical structure support for the femoral head. *Level of evidence:* Level II, low-powered prospective randomized trial.

Keywords: Osteonecrosis of femoral head, core decompression, impaction bone grafting

Introduction

Osteonecrosis of the femoral head (ONFH) remains difficult to treat even though numerous studies have been focused on treatment using various techniques [1]. Core decompression (CD) of the femoral head is one of the most widespread interventions, and there was a considerable success rate if the client chose reasonably [2-6]. As a result, reduction of the intramedullary pressure will help to restore blood supply and relieve pain. The key is that consideration must be given to both complete necrotic bone removal and biomechanical structure protection [7]. CD using large-diameter drilling

does well on removing the necrotic bone completely [8]. However, it severely destroys the biomechanical structure of the femoral head. Though a number of scholars have advocated using multiple small-diameter drillings for CD [9, 10], it also has some limitations. The fact stated all above reveals that further optimization of surgical intervention is needed.

This study used a self-designed multi-directional CD apparatus (This apparatus had won the national utility model patent certificate, patent No. ZL 200920350211.2. **Figure 1**). It could remove the necrotic bone completely in multi-direction, multi-angle and multi-depth by adjust-

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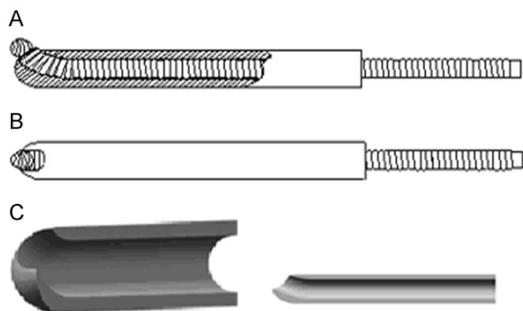


Figure 1. The new multi-directional CD apparatus. This apparatus is constituted by special designed tube within a flexible drill. Frontier of the tube has a side port to going through the drill. Rotate of the tube part plus forward and back the drill part may guide the drill in different direction in core decompression, which would innovatively avoid unnecessary injures. A. Lateral view. B. Aerial view. C. Detailed structure of the tube part.

ing the drilling direction and depth. And it was combined with impaction bone grafting and fibular allograft implantation, which could provide biomechanical structural support to the subchondral bone. The purpose of the present study was to report this new surgical intervention of CD using the new self-designed multi-directional CD apparatus combined with impaction bone grafting and fibular allograft implantation, and compare its clinical and radiographic outcomes with those of CD using conventional drilling combined with fibular allograft implantation. The hypothesis was that this new surgical intervention was technically feasible and may be superior in removing the necrotic bone completely and providing reliable biomechanical structure support for the femoral head.

Materials and methods

This study was approved by the institutional subcommittee and ethics committee. All the procedures were approved by the institutional review board and informed consents were obtained.

From Jan, 2009 to Jun, 2010, a total of 202 patients of ONFH were treated in our department, among them 101 patients met the indication of core decompression surgery. Diagnosis had been established on these patients by their clinical and radiographic features. Before surgery, all the patients were told both the advantages and disadvantages of each surgical method. They selected surgical method based on their understanding about the information

from the surgeons. Only patients with stage II and III ONFH according to the Steinberg classification were included in this study. Exclusion criteria included patients whose MRI images showed necrotic lesion had been close to the articular surface of the hip joint (the distance was less than 0.5 mm), or had already invaded into the articular surface, or had been larger than 30% of the whole articular surface. Patients with active infection, myelodysplastic syndrome, coagulation, anemia, or had a previous treatment to the affected hip, or with age above 65 years were also excluded.

Following the criteria of a prospective non-randomized study, finally, a total of 53 patients (58 affected hips) with early stages of ONFH were included in this study. Twenty-seven patients (30 affected hips) underwent CD using multi-directional CD apparatus combined with impaction bone grafting and fibular allograft implantation (the experimental group). While 26 patients (28 affected hips) underwent CD using conventional drilling combined with fibular allograft implantation (The control group). They entered into this study voluntarily and signed an informed consent before enrollment. **Table 1** outlines details on preoperative demographic and baseline characteristics of the two groups with no significant difference ($P>0.05$).

Surgical technique

The surgeries involved in this study were performed by the same senior surgeon assisted by his colleagues. All surgical procedures were conducted according to the operating instructions.

After resecting subcutaneous tissue and blunt dissecting vastus lateralis muscle, the patient was placed with the affected limb intorted for $10^{\circ}\sim 15^{\circ}$ to eliminate the effect of anteversion angle of femoral neck. Through a lateral approach, a 2-mm guide pin was inserted into the centre of the osteonecrotic region under fluoroscopic guidance. Along the guide pin, a 10-mm tunnel to a depth of approximate 5~7 mm beneath the articular cartilage surface was created with the help of reamers. The normal particulate bone obtained during this procedure should be kept for autogenous bone grafting. After that, patients of the experimental group underwent CD using self-designed multi-directional CD apparatus. Insert the apparatus into the bone tunnel and remove the necrotic bone

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Table 1. Demographic and baseline characteristics of included patients

Characteristic	Experimental group	Control group	Statistic value*	P value
Mean age (years)	37.67 ± 8.05 (20~62)	36.92 ± 7.30 (18~60)	0.352	0.726
Gender, cases (%)			0.232	0.630
Male	17 (63.0)	18 (69.2)		
Female	10 (37.0)	8 (30.8)		
Hips, cases (%)			0.000	1.000
Unilateral	24 (88.9)	24 (92.3)		
Bilateral	3 (11.1)	2 (7.7)		
Etiology, cases (%)			2.804	0.423
Steroid	10 (37.0)	9 (34.6)		
Alcohol	7 (25.9)	6 (23.1)		
Trauma	8 (29.6)	5 (19.2)		
Idiopathic	2 (7.4)	6 (23.1)		
Steinberg stage, hips (%)			0.259	0.611
Stage II	13 (43.3)	14 (50.0)		
Stage III	17 (56.7)	14 (50.0)		
Follow-up (months)	41.1 ± 7.5	43.9 ± 5.3	1.544	0.130
Lesion volume (cm ³)	4.15 ± 1.20	4.39 ± 1.63	0.634	0.528

*t for continuous variables and with the χ^2 for categorical variables.

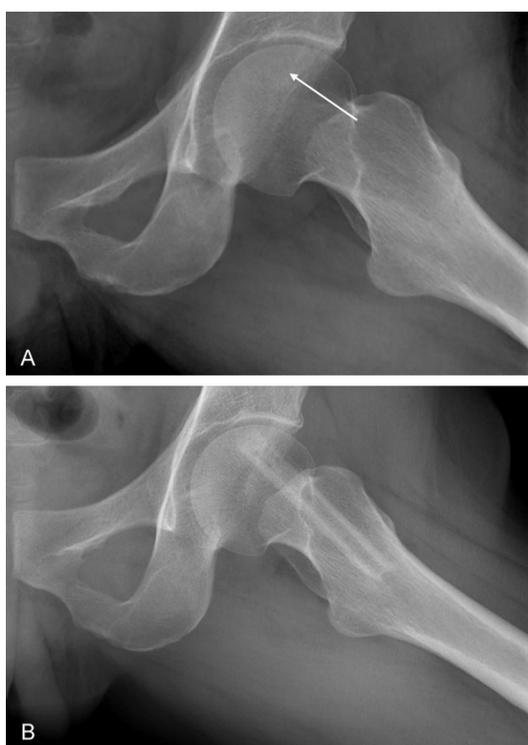


Figure 2. Radiographs of a 38-year-old male with osteonecrosis of the left femoral head (Steinberg Stage II) in experimental group. A. Preoperative radiograph showing a necrosis area. B. Radiograph taken after surgery.

by adjusting the direction and depth of drilling under fluoroscopy guidance. Then particulate

bone harvested was impacted into the full depth of the bone tunnel. If graft was not enough, the tunnel could be packed with a combination of autogenous iliac crest bone and harvested bone. After autogenous bone impaction grafting, create a tunnel to a depth of 5~7 mm beneath the articular cartilage surface along the track of the bone tunnel created before, the diameter of which related to the fibular allograft, and then measure the length. The fibular allograft confirmed could be well rotated into the lateral cortex of the femur after properly tapping (**Figure 2**). In control group, all the patients underwent fibular allograft implantation after CD using conventional drill (**Figure 3**). The detailed procedures were mentioned above and we left them out.

Postoperative rehabilitation

Postoperative care consisted of prophylactic intravenous antibiotic and anticoagulation therapy. Patients were instructed to walk with two crutches, and non-weight bearing should be made on the affected hip during the three postoperative weeks. Afterwards weight bearing should be increased gradually. Full weight bearing as tolerated was allowed at the third postoperative month. Follow-up should be performed every month during the three postoperative months. Thereafter, it was performed every three months.

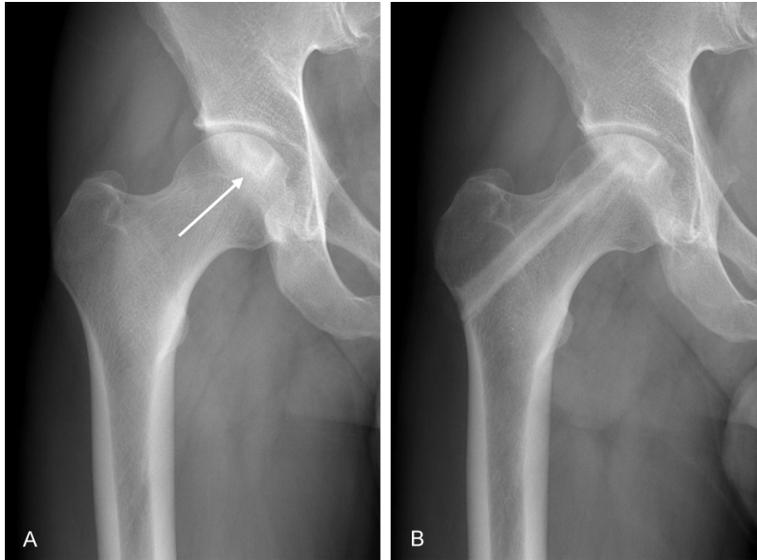


Figure 3. A 34-year-old male with osteonecrosis of the right femoral head (Steinberg Stage III) in convention group showed that an inaccurate angle of drilling may bring a residual because of its low tolerance of direction. A. Preoperative radiograph showed a necrosis area. B. Radiograph taken after conventional surgery.

Assessment

All patients were evaluated clinically and radiographically before and after operation. Follow-up assessment was performed by the same experienced surgeon. Outcome assessment included the Harris hip score (HHS), Visual analogue pain scale (VAS) score and imaging evaluation (X-ray and Magnetic resonance imaging (MRI) performances). The HHS and VAS scores were obtained before operation and at the time of follow-up or just before conversion to a Total Hip Arthroplasty (THA). The total HHS >90 points was considered as excellent, 80-89 points as good, 70-79 points as fair, and ≤69 points as poor. VAS scores ranged from 0 to 10, 0 was defined as no pain, 1-3 as mild pain, 4-6 as endurable pain affecting sleep, and 7-10 as unendurable severe pain. Clinical failure was defined as patient with HHS below 70 points or underwent THA for any reason [11]. X-ray images were obtained in anterior-posterior, and frog position at the time of follow-up. Radiographic outcomes could be divided into 3 grades. ① Improved: The necrotic lesion was healed and replaced with new bone. ② Unchanged: No change happened. ③ Worsened: Onset of the progression of collapse or progressive osteoarthritis (OA), and it was defined as radiographic failure [8].

All patients underwent high-resolution MRI with a 1.5-Tesla imager (Signa; GE Medical Systems, Milwaukee, Wisconsin) preoperatively and post-operatively using at least two protocols, i.e. coronal T1-weighted imaging and coronal short T inversion recovery (STIR). Coronal STIR images were obtained using repetition time (TR) 2,560 ms and echo time (TE) 108 ms, while coronal T1-weighted sequences (TR 400/TE 8.6/Ef) were obtained using a pelvic phased array coil. Images of 4-mm thickness with 1-mm gaps and a 34×34-cm field of view were obtained using a 256×192 matrix. Measurement of the volume of osteonecrosis was carried out on coronal T1-weighted images.

The area of osteonecrosis was considered to be the sector demarcated by the serpiginous line corresponding to the band-like hypointense margin [26]. The outer border of this low-intensity region was assumed to represent the edge of the necrotic area. For each coronal slice, the area of osteonecrosis was outlined using an image analysis program (SYNAPSE 3.2.1; FUJIFILM Medical System, Inc., U.S.A.), and the volume of osteonecrosis was calculated by multiplying the area of osteonecrosis by the thickness (thickness of the slice plus the gap). The total volume of necrotic bone was the sum of the individual volumes of all slices [27]. The percentage changes in the lesion size from the baseline were calculated by dividing the differences in lesion volume between the baseline and the follow-up scans by the baseline lesion volume and multiplying by 100%. ONFH was arbitrarily estimated to be improved or worsened if there was a >15% change in the necrotic volume, while changes of ≤15% were considered to be “no change” [28, 29].

Statistical analysis

Statistical analyses were performed using SPSS 22.0 statistical software. A comparison of the differences between the groups was made with the independent two-sample *t* test for

Table 2. Clinical results

A. Harris hip score						
	Preoperative HHS (points)		Postoperative HHS (points)		t value	P value
Experimental group	66.75 ± 6.48		87.83 ± 7.95		11.068	<0.001
Control group	64.82 ± 8.03		80.79 ± 9.71		6.464	<0.001
t value	0.986		2.953		-	-
P value	0.328		0.005		-	-
B. Harris Hip Score scale						
	Excellent, Hips (%)	Good, Hips (%)	Fair, Hips (%)	Poor, Hips (%)	Z value	P value
Experimental group	16 (55.2)	8 (27.6)	3 (10.3)	2 (6.9)	2.049	0.040
Control group	8 (30.8)	8 (30.8)	5 (19.2)	5 (19.2)		
C. VAS						
	Control group (n=26)		Postoperative (points)		t value	P value
Experimental group (n=29)	6.7 ± 2.3 (4~9)		1.5 ± 1.4 (0~4)		10.767	<0.001
Control group (n=26)	6.1 ± 1.7 (4~9)		3.1 ± 1.6 (0~6)		6.566	<0.001
t value	1.448		3.971		-	-
P value	0.154		<0.001		-	-

continuous variables and with the chi-square test and Fisher exact test for categorical variables. The Wilcoxon rank test was used to evaluate the X-ray performance and HHS scale. Continuous variables were presented as mean ± standard deviation, whereas categorical variables were presented as number and percentage. Multivariable linear regression was performed to demonstrate possible factors influencing post-operative outcome (Harris score and VAS score). All statistical assessments were two-sided and evaluated at the 0.05 level of statistical significance.

Results

Demographics

With an average follow-up of 42.7 months (range, 24-52 months), 50 patients finished follow-up of at least 2 years and included in final analysis. The experimental group and the control group each have 26 patients (29 hips) and 24 patients (26 hips). Unfortunately, one patient (1 hip) in the experimental group and two patients (2 hips) in the control group were lost to follow-up. Of these patients, one was dead and the others refused to attend our follow-up for some personal reasons. These patients were excluded.

Clinical outcomes

Table 2 outlines the details about the clinical outcomes. At the most recent follow-up or just

before conversion to a THA, all the patients showed a marked improvement in HHS. The majority reported substantial relief of pain and less restricted hip motion. The two groups had comparable preoperative HHS ($P=0.328$). The post-operative HSS was increased greater than the pre-operation both in experimental group and control group, however, significant statistical difference was observed in the postoperative HHS between two groups ($P<0.05$) (**Table 2A**).

As **Table 2C** show, no significant statistical difference was observed in the preoperative VAS scores ($P=0.281$), nevertheless, the postoperative VAS scores differed significantly at the time of final follow-up between two groups ($P<0.001$), showing the experimental group had a lower level of pain than the control group.

Multivariate linear regression also confirmed that surgical procedures and pre-operative score was all correlated with post-operative score (Harris and VAS) ($P<0.05$). Furthermore, the steinberg stage and follow-up time were found associated with post VAS score. None of other factors were associated with post-operational score (**Table 4**).

The poor outcomes in HHS score of the two groups were 6.9% and 19.2%, respectively (**Table 2B**). THA was performed in one patient (1 hip) of experimental group and in four patients (5 hips) of control group. One reason for THA

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Table 3. Radiological assessment

A. Postoperative X-ray assessment							
	Total, hips	Improved, hips (%)	Unchanged, hips (%)	Worse, hips (%)	Z value	P value	Failure rate* (%)
Experimental group	29	18 (62.1)	8 (27.6)	3 (10.3)	1.912	0.056	10.3
Control group	26	10 (38.5)	9 (34.6)	7 (26.9)			26.9

*Radiological failure rate.

B. Pre- and postoperative MRI assessment			
	Changes (hips)		
	Worsened	No change	Improved
Experimental group	1	24	4
Control group	2	21	3
Z value	0.553		
P value	0.580		

Table 4. Results of multivariable linear regression analyses for post-operative scores (Harris score and VAS score)

	Post-Harris score			Post-VAS score		
	B	t value	P value	B	t value	P value
Age	-0.158 ± 0.123	-1.283	0.206	-0.014 ± 0.019	-0.703	0.486
Gender	2.263 ± 1.978	1.144	0.259	-0.209 ± 0.308	-0.678	-0.501
Etiology	-0.528 ± 0.948	-0.557	0.580	-0.228 ± 0.148	-1.542	0.130
Follow-up time	0.005 ± 0.136	0.034	0.973	-0.047 ± 0.021	-2.209	0.032
Steinberg stage	3.622 ± 2.157	1.679	0.100	0.528 ± 0.336	2.535	0.015
Surgical Group	-4.623 ± 1.895	-2.440	0.019	2.232 ± 0.295	7.559	0.000
Pre-Harris score	0.673 ± 0.136	4.952	0.000	0.014 ± 0.021	0.679	0.500
Pre-VAS score	0.941 ± 0.476	1.978	0.054	0.535 ± 0.074	7.221	0.000

B: Unstandardized coefficients.

was progression of the lesion (1 hip in experimental group and 4 hips in control group). Another failure of the control group was conducted THA because of sepsis.

Imaging performance

Postoperative X-ray performance is outlined in **Table 3**. Although no significant statistical difference was observed, the *p* value was so close to 0.05 and there were more improved hips and less worse hips in experimental group with a better radiographic failure rate that we could probably concluded that the postoperative X-ray performance of experimental group was better. In addition, lesion volume changes was in non-significant different between two groups (**Table 3**).

Until the final follow-up, no complications were seen except subtrochanteric fracture occurred to one patient of control group. The implant was removed and the fracture was treated with op-

en reduction and internal fixation. The patient was graded as a failure case.

Discussion

As originally pioneered by Ficat and Arlet, CD is a most widespread conventional procedure to treat ONFH [12]. Though the efficacy of CD in preventing disease progression has been questioned for a long time [11, 13], we mustn't overlook its success in reduction of the intramedullary pressure which will help to restore blood supply and relieve pain, especially on patients with early stages of ONFH. To get more desirable outcomes, surgical intervention based on CD procedure must be further optimized.

All in all, incomplete necrotic bone removal is the main point leading to the failure. At the repair stage of ONFH, the stress concentration generates potential between necrotic bone and new-formed bone, which was reported as the major risk factor leading to the progression

[14]. It will not only affect the local stress distribution, but also block the reconstruction of new bone tissue. As a result, it raises the difficulty in repairing subchondral bone and the possibility of trabecular bone fracture, finally leading to the failure. Therefore, in order to eliminate stress concentration around, surgical intervention should be emphasized on complete necrotic bone removal. However, the necrotic lesion area of the femoral head is irregular in shape and scope. Since the traditional CD procedure is limited in scope of decompression, remove the necrotic bone effectively becomes a tough task. Sometimes, enlarge the diameter of drilling is necessary [8], nevertheless, which advance the weakness of biomechanical support within the femoral head. Though a number of scholars have advocated CD using multiple small-diameter drillings and thought it is as effective as CD using large-diameter drilling [9, 10], as far as I am concerned, its limited capacity of removing the necrotic bone will restrict its widely application. Taking it into consideration, a self-designed multi-directional CD apparatus was used in present study. Within the single bone tunnel created, the apparatus can remove the necrotic bone around the bone tunnel in multi-direction, multi-angle and multi-depth by adjusting the drilling direction and depth. It contributes to avoiding fracture of trabecular bone within the femoral head resulting from stress concentration and thus advancing reconstruction of self bone tissue.

Even though the lesion was non-significant, with an aim at removing necrotic bone and reducing the intraomedullary pressure completely, large diameter of lesion in traditional group would bring a residual because of its low tolerance of direction technically (**Figure 3**). Yet, in comparison with experiment group, traditional procedure will possibly bring a massive invasion with a completely removal, calling large-diameter reamers and curettes employed. These all do greatly harm to the biomechanical structural integrity of the femoral head, especially in the cases of steroid-induced ischemic ONFH with severe osteoporosis [15]. The weakened structural support and inner instability advances the progression of proximal femur fracture and collapse of the cartilage surface [16, 17]. This may gives an explanation for the failure of isolated CD procedure even with complete removal of necrotic bone. What's more, Ficat emphasized bone tissue reconstruction

induced after CD procedure was not dependable [18]. With the revascularization of necrotic femoral head, the increment in activity of osteoclast and velocity of bone resorption were faster than that of new bone tissue formation during the repair process. Some studies found the surgical site underwent CD procedure showed a sight of loose fibrous scar tissue without new bone formation [17, 19]. Therefore, inducing the bone reconstruction, restoring the biologic environment and biomechanical support to the proximal femur are the key points of surgical intervention [10, 20].

Since isolated CD is relating to the problems of a lack of structural support, the surgical technique was modified by additional interventions such as implantation of growth factors, bone marrow mononuclear cells, fibular grafting, tantalum rod implantation or others [1, 2, 10, 21-24]. CD using large-diameter drilling combined with fibular allograft implantation has obtained satisfactory clinical outcomes recently [1-3, 6, 25]. This surgical combination can be used not only on the patients at pre-collapse stage as a salvage intervention, but also on the patients at post-collapse stage for the purpose of delaying THA. In order to resist the decrement of biomechanical properties and avoid the occurrence of collapse, beside fibular allograft implantation, we performed impaction bone grafting procedure using autogenous bone to fill up the bone cavity formed after decompression process. Particulate bone has strong osteoinductive and osteoconductive properties [2, 17, 20, 25], and its porous structure is suitable for surrounding bone tissue growing in. After particulate bone compacting tightly with surrounding bone, the stress would disperse into surrounding uniformly, which averts the generation of stress concentration. As the graft exists, it also could help to repair bone defects and restore bone stock faster. After impaction bone grafting, we did fibular allograft implantation on the patients of experimental group. As the fibular allograft could be surrounded by bone graft with no cavity existing, the biomechanical structure support was well reconstructed and strong osteoinductive property was ensured at the same time.

In conclusion, the new multi-directional CD apparatus used in present study helped to remove the necrotic bone completely within single bone tunnel. As the reduction of intraomedul-

lary pressure and no stress concentration generation, it promoted revascularization of the necrotic femoral head and new bone formation effectively. Followed impaction bone grafting and fibular allograft implantation filled up the bone defects which provided conditions for bone healing and effective biomechanical support to avoid collapse of the femoral head. After we finished a mean 42.7 months follow-up, the clinical and radiographic outcomes of the experimental group were better than those of the control group. Though long-term follow-up and large sample size are needed, sincerely, the authors recommend multi-directional CD apparatus combined with impaction bone grafting and fibular allograft implantation as an effective alternative treatment for patients with early stages of ONFH. It's technically feasible and may be superior in removing the necrotic bone completely and providing reliable biomechanical structure support for the femoral head.

Disclosure of conflict of interest

None.

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