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HIP ARTHROPLASTY

Core decompression in combination with nano-hydroxyapatite/polyamide 66 rod for the treatment of osteonecrosis of the femoral head

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Abstract
Background The aim of this study was to investigate the effectiveness of core decompression in combination with a nano-hydroxyapatite/polyamide 66 (n-HA/PA66) rod and a porous bioglass bone graft for the treatment of osteonecrosis of the femoral head (ONFH).
Methods Sixty-four patients (84 hips) with ONFH were allocated to a program of either core decompression (CD) in combination with a n-HA/PA66 rod and a porous bioglass bone graft (treatment group) or CD with an autologous cancellous bone graft (control group). Clinical and radiographic retrospective follow-ups were performed on all patients with the prospectively collected data.
Results The overall clinical failure rate in the treatment group (9/38, 23.68 %) was lower than that of the control group (24/46, 52.17 %) ($p < 0.05$). Harris hip scores (HHS) were significantly increased in both groups post-surgery ($p < 0.05$). There was a significant difference between the two groups on HHS improvement for Steinberg IIC and IIIA ($p < 0.05$ and $p < 0.001$, respectively). The visual analogue scale (VAS) was significantly decreased in both groups post-surgery ($p < 0.05$). Especially, significant difference in the VAS improvement was observed between the groups for IIB, IIC and IIIA ($p < 0.05$, $p < 0.05$ and $p < 0.01$, respectively).
Conclusions Core decompression combined with the implantation of a n-HA/PA66 rod and a bioglass bone graft can significantly decrease hip pain, improve hip function, and prevent the collapse of the femoral head in patients with ONFH. As the effectiveness of this approach appears to vary with Steinberg stage, we suggest that this treatment procedure may be suitable for patients with early to middle stage ONFH.

Keywords Osteonecrosis of the femoral head · Core decompression · Biomaterials · Bone graft · Follow-up

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Introduction

Osteonecrosis of the femoral head (ONFH) is a progressive disease that generally affects patients between 30 and 50 years of age and has significant impacts on the work and leisure activities of these patients [1]. It has been well documented that without surgical intervention, approximately 70–80 % of hips with clinically established ONFH experience radiological and clinical progression, leading to the collapse of the femoral head [2]. Several prophylactic procedures have been performed in these patients in the early stages of the disease in an attempt to halt progression and to encourage repair. Of these procedures, core decompression (CD), which was introduced by Ficat and Arlet, works by the reduction of intra-medullary pressure, is the most frequently used [3]. Although CD has been used for approximately three decades and there are numerous publications analyzing its efficacy, there is no general consensus among investigators regarding either the indications for this procedure or the specific technique used to optimize its results [4–8]. One of the possible causes of failure of this approach is that CD may not adequately promote

osteogenesis and may not provide enough mechanical support for the necrotic area.

Here, we report short-term results in patients with painful non-traumatic ONFH. Patients were surgically treated with CD in combination with implantation of a n-HA/PA66 rod and a resorbable bioglass bone graft. All the patients were followed for an average of 2 years. The aim of this study was to introduce this surgical technique and its rationale. We hypothesize that this treatment procedure may be suitable for patients with early to middle stage ONFH.

Patients and methods

All procedures used in this study were reviewed and approved by the Institutional Review Board of the Second Affiliated Hospital of Medical College of Xi'an Jiaotong University. We also obtained approval from The Ethics Committee of the Second Affiliated Hospital of Medical College of Xi'an Jiaotong University. All patients provided their written informed consent to participate in this study.

Patients and groups

This study was a retrospective study of prospectively collected data. 91 patients with ONFH treated with CD in our department between January 2009 and July 2013 were systematic evaluated. The inclusion criteria for this study were as follows: (1) no history of trauma or malignancies; (2) radiographic criteria of Steinberg stage I, II, or IIIA; (3) persistent hip pain for at least 6 months without significant improvement after conservative treatment; (4) patient age of <55 years; (5) informed consent for this study. The exclusion criteria for this study were as follows: (1) patient history of traumatic intracapsular hip fracture; (2) inability to walk; (3) active infection, disturbance of blood coagulation.

Finally, 64 patients (84 hips) of ONFH were included in this study those fulfilled all the inclusion and exclusion criteria mentioned above. Generally, 35 patients (46 hips) who received the autologous cancellous bone graft in combination with CD were set to the control group, and the other 29 patients (38 hips) underwent CD in combination with the implantation of a n-HA/PA66 rod and resorbable bioglass bone graft were included in the treatment group. For each patient, diagnosis confirmation and clinical Steinberg classification [9] were performed in a blind manner by two senior surgeons (Table 1). Harris hip score (HHS), visual analogue scale (VAS) [4], high quality anteroposterior position (AP) X-rays and magnetic resonance images (MRI) were obtained preoperatively. Table 2 outlines the patient demographics.

Table 1 A quantitative Steinberg classification system ONFH

Stages	Description
Stage 0	Normal or non-diagnostic radiograph, bone scan and MRI
Stage I	Normal radiograph, abnormal bone scan and/or MRI
	IA: Mild, femoral head affected <15 %
	IB: Moderate, femoral head affected between 15 and 30 %
	IC: Severe, femoral head affected >30 %
Stage II	Abnormal radiograph showing 'cystic' and sclerotic changes in femoral head
	IIA: Mild, femoral head affected <15 %
	IIB: Moderate, femoral head affected between 15 and 30 %
	IIC: Severe, femoral head affected >30 %
Stage III	Subchondral collapse producing a crescent sign
	IIIA: Mild, femoral head affected <15 %
	IIIB: Moderate, femoral head affected between 15 and 30 %
	IIIC: Severe, femoral head affected >30 %
Stage IV	Flattening of the femoral head
	IVA: Mild, femoral head affected <15 %
	IVB: Moderate, femoral head affected between 15 and 30 %
	IVC: Severe, femoral head affected >30 %
Stage V	Joint narrowing with or without acetabular involvement
	VA: Mild, femoral head affected <15 %
	VB: Moderate, femoral head affected between 15 and 30 %
	VC: Severe, femoral head affected >30 %
Stage VI	Advanced degenerative changes

Artificial bone grafts

The porous resorbable bioglass bone graft [Cuboid shape: (7 × 8 × 23 mm)] were produced by NovaBone™ Products (FL, USA). It was reported that bioglass has good biocompatibility, osteoconduction and osteoinduction [10]. The n-HA/PA66 rods (Sichuan National Nano Technology Co., Ltd, Chengdu, China) used in the study were composed of the inorganic material n-HA and the organic polymer material PA66. The compound biomaterials have been demonstrated as attractive material candidates because of their chemical similarity to the inorganic phase of natural bone, favorable biocompatibility, osteoconductivity and bioresorbable [11, 12]. The rod has a cylindrical shape with an outer diameter of 8 mm and a wall thickness of 3 mm. The lengths of the rods range from 70 to 100 mm, with increments of 5 mm (Fig. 1a). The hollow center of the rod and the pores in its wall facilitate the ingrowth of the host bone. The mechanical properties were as follows: elastic modulus (6.25 ± 0.82) GPa; bending strength (85.14 ± 12.13) Mpa; compressive strength (100.12 ± 18.95) MPa.

Table 2 Demographics and baseline characteristics of each group

Characteristics	Treatment group	Control group	*p* value
Number of patients	29	35	
Age (years)	35.49 ± 6.13	37.12 ± 5.80	
Sex *n* (%)			
Male	21 (72.41)	23 (65.71)	0.565[b]
Female	8 (27.29)	12 (34.29)	
Number of hips	38	46	
Hips *n* (%)			
Unilateral	20 (68.97)	24 (68.57)	0.973[b]
Bilateral	9 (31.03)	11 (31.43)	
Etiology			
Corticosteroid	17 (58.62)	19 (54.29)	0.802[b]
Alcohol	5 (19.24)	5 (14.28)	
Idiopathic	7 (24.14)	11 (31.42)	
Clinical stage			
Steinberg IB	3 (42.86)	3 (37.50)	0.999[b]
Steinberg IC	4 (57.14)	5 (62.50)	
Steinberg IIA	8 (21.05)	9 (19.57)	
Steinberg IIB	10 (26.32)	12 (26.09)	
Steinberg IIC	8 (21.05)	11 (23.91)	
Steinberg IIIA	5 (13.16)	6 (13.04)	
Clinical symptom			
Inguinal pain	19 (65.51)	20 (57.14)	0.876[b]
Hip joint pain	25 (86.21)	32 (91.42)	
Knee joint pain	6 (20.69)	6 (17.14)	
Mean BMI	24.89 ± 3.91	26.13 ± 4.82	0.229[a]
VAS	6.42 ± 1.08	6.74 ± 0.95	0.156[c]
HHS	56.54 ± 8.95	59.24 ± 6.57	0.115[c]

Data were presented as mean ± SD or *n* (%)

BMI body mass index, *VAS* visual analogue scale, *HHS* Harris hip score

Statistical analysis were performed between the groups using [a] independent two-sample *t* test, [b] Chi-square test or [c] linear mixed model

Procedure and surgical technique

The schematic diagram demonstrates the surgical procedure performed on patients in the treatment group (Fig. 1b, c). All the operations of each patient in both groups were conducted by the same group of surgeons (PY and CB). There is general agreement that the procedure should be performed with fluoroscopic guidance under the AP or a frog leg position to prevent the penetration the joint line. A straight lateral longitudinal incision within 3 cm was performed. Subsequently, a 2.0-mm diameter Kirschner needle was drilled along the femoral neck axis toward the ONFH area until the subchondral lamella of the femoral head was reached. A cannulated driller (8.0 mm) was inserted via a Kirschner needle to obtain a canal of 8 mm in diameter, and the k-wire was removed.

In the control group, a curette was used to debride the necrotic bone in the necrotic area. After irrigating the canal with saline, the viable autologous cancellous bone obtained from the intertrochanteric region was thinned with a rongeur and placed very loosely into the canal.

In the treatment group, advanced debridement was carried out using an expandable reamer instrument. Briefly, the reamer instrument was inserted into the canal to reach the necrotic area. The reamer was then expanded by turning the blade control knob clockwise. During expansion, it is necessary to confirm blade position under the AP or a frog leg position frequently (Fig. 1d, e). When the desired reamer expansion was achieved, the advanced debridement was completed by rotating the entire instrument several full revolutions. Once the advanced debridement was complete, the cuboid-shaped NovaBone™ was press-fit into the necrotic area via the canal and the n-HA/PA66 rod was also inserted at a proper length.

Postoperative management and rehabilitation

Weight bearing was not allowed within the first 3 months post-surgery, in the meantime, quadriceps isometric contraction exercise was essential to prevent the disuse muscle atrophy. Partial weight-bearing crutch walking was allowed thereafter, and full weight bearing was allowed 6 months after surgery. Patients were allowed to engage in physical activities and sports 12 months after surgery.

Clinical and radiographic follow-up measures

All patients were followed-up clinically and radiographically by one of the authors every 3 months during the first year, every 6 months in the second year and yearly thereafter. The clinical follow-up consisted of the determination of the serial HHS and VAS. The radiographic follow-up consisted of serial AP position radiographs and MRI.

A radiographic failure was defined as the onset or the progression of collapse or progressive OA according to follow-up radiographic examinations. A clinical failure was defined as an HHS below 80 points [13] or if the patient needed further surgical procedure such as total hip arthoplasty (THA) or osteotomy for any reason.

In the present study, the HHS and VAS at the time of the pre-operation and last follow-up (defined as 36 months or the time of the patient quit the study due to the radiographic or clinical failure) of each patient were used for statistical analysis.

Statistical analysis

Data analysis was performed with SPSS for Windows 12.0 (SPSS Inc. IL, USA). Continuous and categorical

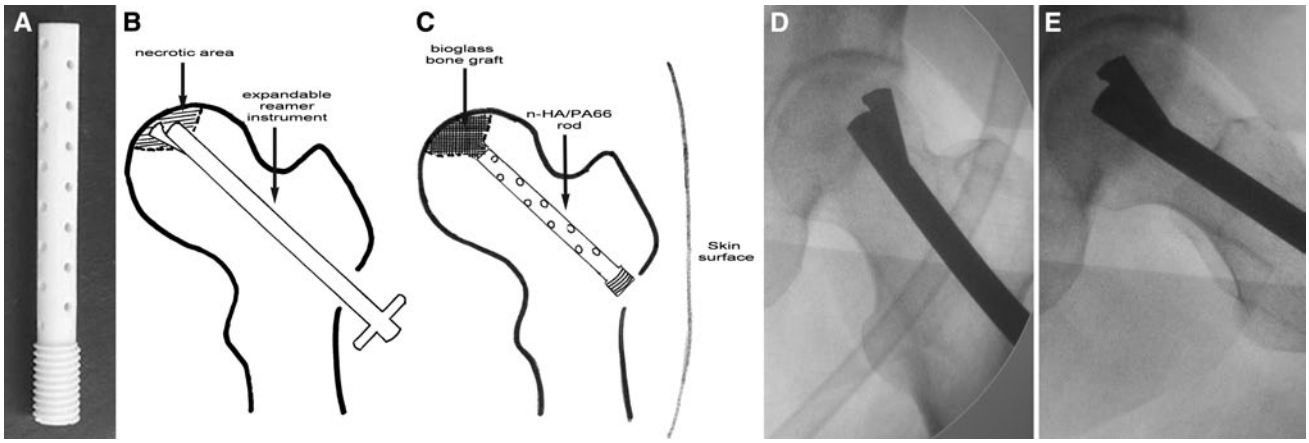

Fig. 1 **a** Gross view of the n-HA/PA66 rod. **b** Schematic diagram demonstrating CD was performed using an expandable reamer instrument. **c** Schematic diagram demonstrating the bioglass was press-inserted into the necrotic area, and the n-HA/PA66 rod was inserted into the canal for mechanical support. **d**, **e** An X-ray view of AP and frog leg position showed expandable reamer instrument that was used to debride the sequestrum and sclerotic bone in the necrotic area of the femoral head

demographic and baseline measurements were compared between the groups by the independent two-sample *t* test and Chi-square test, respectively. Continuous variables are presented as the mean ± standard deviation, whereas categorical variables are presented as a number and percentage. The statistical analysis between the preoperative and postoperative HHS and VAS was based on linear mixed models and was used to compare changes in the HHS and VAS between the two groups. Continuous clinical variables were presented as the mean ± standard error. Survival analysis was performed using the Kaplan–Meier method. $p < 0.05$ was considered significant.

Results

Demographics and baseline characteristics of the patients

Demographics and baseline characteristics were obtained for each patient in each group (Table 2). There were no significant differences in any demographic parameters ($p > 0.05$). The duration of follow-up ranged from 5 to 36 months with a mean follow-up of (21.78 ± 8.46) months in the treatment group and 9–36 months with a mean follow-up of (23.24 ± 9.32) months in the control group. In addition, no difference on the duration of follow-up was observed between the groups ($p > 0.05$). Two patients in the treatment group suffered superficial wound infection and were treated with prolonged antibiotic therapy for 5 days.

VAS and HHS changes post-surgery

As anticipated, there was a significant difference between the pre-operation and last follow-up HHS in both groups, and a significant difference was observed between the groups in the last follow-up HHS (both $p < 0.05$). Furthermore, the HHS improvement in the treatment group was significantly greater than that in the control group (27.19 ± 2.79 vs. 15.58 ± 2.93, $p < 0.001$) (Fig. 2a).

There was a significant difference between the pre-operation and last follow-up VAS in both groups, and a significant difference was observed between the groups in the last follow-up VAS (both $p < 0.05$). A significant difference was also observed in the VAS improvement between the treatment group and the control group (3.17 ± 0.34 vs. 1.97 ± 0.30, $p < 0.01$) (Fig. 2b).

No significant difference in the HHS improvement was observed between the treatment group and control group for Steinberg IB, IC, IIA and IIB ($p = 0.58$, $p = 0.32$, $p = 0.86$ and $p = 0.42$, respectively); however, there was a significant difference between the two groups for Steinberg IIC and IIIA ($p < 0.05$ and $p < 0.001$, respectively) (Fig. 2c).

No significant difference in the VAS improvement was observed between the treatment group and control group for Steinberg IB, IC and IIA ($p = 0.56$, $p = 0.31$ and $p = 0.35$, respectively); however, there was a significant difference between the two groups with Steinberg stage IIB, IIC and IIIA ($p < 0.05$, $p < 0.05$ and $p < 0.01$, respectively) (Fig. 2d).

Radiological analysis

In the treatment group, 21.05 % (8/38) of hips exhibited collapse or aggravated collapse of the femoral head in the weight-bearing area. Hip OA was detected in four of the eight failed hips, and THA was performed for all eight hips. Furthermore, the radiological failure rate of the different

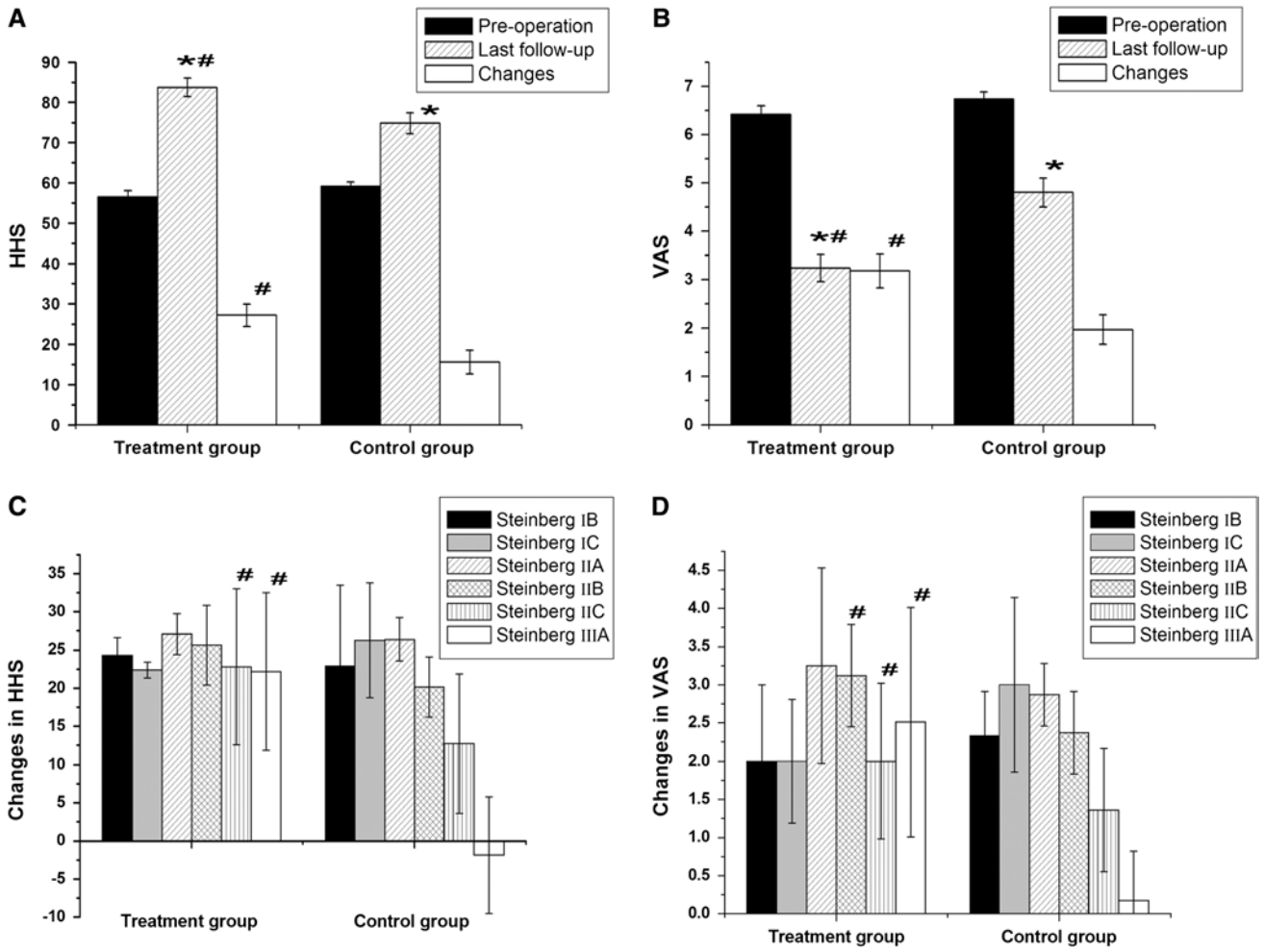

Fig. 2 **a**, **b** Showed the results of statistical analysis of the pre-operation and last follow-up HHS and VAS in both groups. **c**, **d** Showed the results of statistical analysis of changes in the HHS and VAS for different Steinberg stages in both groups. Data are presented as the mean ± standard error and were compared using a linear mixed model. *Asterisk* indicates a statistically significant difference between pre-operation and last follow-up ($p < 0.05$). # indicates a statistically significant difference between the treatment group and the control group ($p < 0.05$)

Steinberg stages was as follows: Steinberg IB, 0 % (0/3); Steinberg IC, 0 % (0/4); Steinberg IIA, 12.50 % (1/8); Steinberg IIB, 20.00 % (2/10); Steinberg IIC, 37.5 % (3/8); and Steinberg IIIA, 40.00 % (2/5).

In the control group, 45.65 % (21/46) of hips exhibited collapse or aggravated collapse of the femoral head in the weight-bearing area. Hip OA was detected in 15 of the 21 failed hips, and THA was performed for 19 of the 21 failed hips. The residual two failed hips received conservative therapy due to the economic cause. Furthermore, the radiological failure rate of the different Steinberg stages was as follows: Steinberg IB, 0 % (0/3); Steinberg IC, 20.00 % (1/5); Steinberg IIA, 22.22 % (2/9); Steinberg IIB, 50.00 % (6/12); Steinberg IIC, 63.63 % (7/11); and Steinberg IIIA, 83.33 % (5/6).

Obviously joint effusion was observed in the 21 of 29 (72.41 %) radiological failed hips of the two groups at the time of last follow-up. All the affected hips were classified as Steinberg IIA (2/21, 9.52 %), Steinberg IIB (4/21, 19.05 %), Steinberg IIC (9/21, 42.86 %) and Steinberg IIIA (6/21, 28.57 %).

Representative radiographic images of a successful case (Steinberg IIC) in the treatment group are presented in Fig. 3. Representative radiographic images of an unsuccessful case (Steinberg IIC) in the treatment group are shown in Fig. 4. In the retrieved sample from the failed patient undergoing THA, the host bone was observed to have infiltrated the hollow part of the rod (Fig. 5).

Survivorship analysis

Based on Kaplan–Meier survival estimates, the radiological failure rate was significantly lower in the treatment group

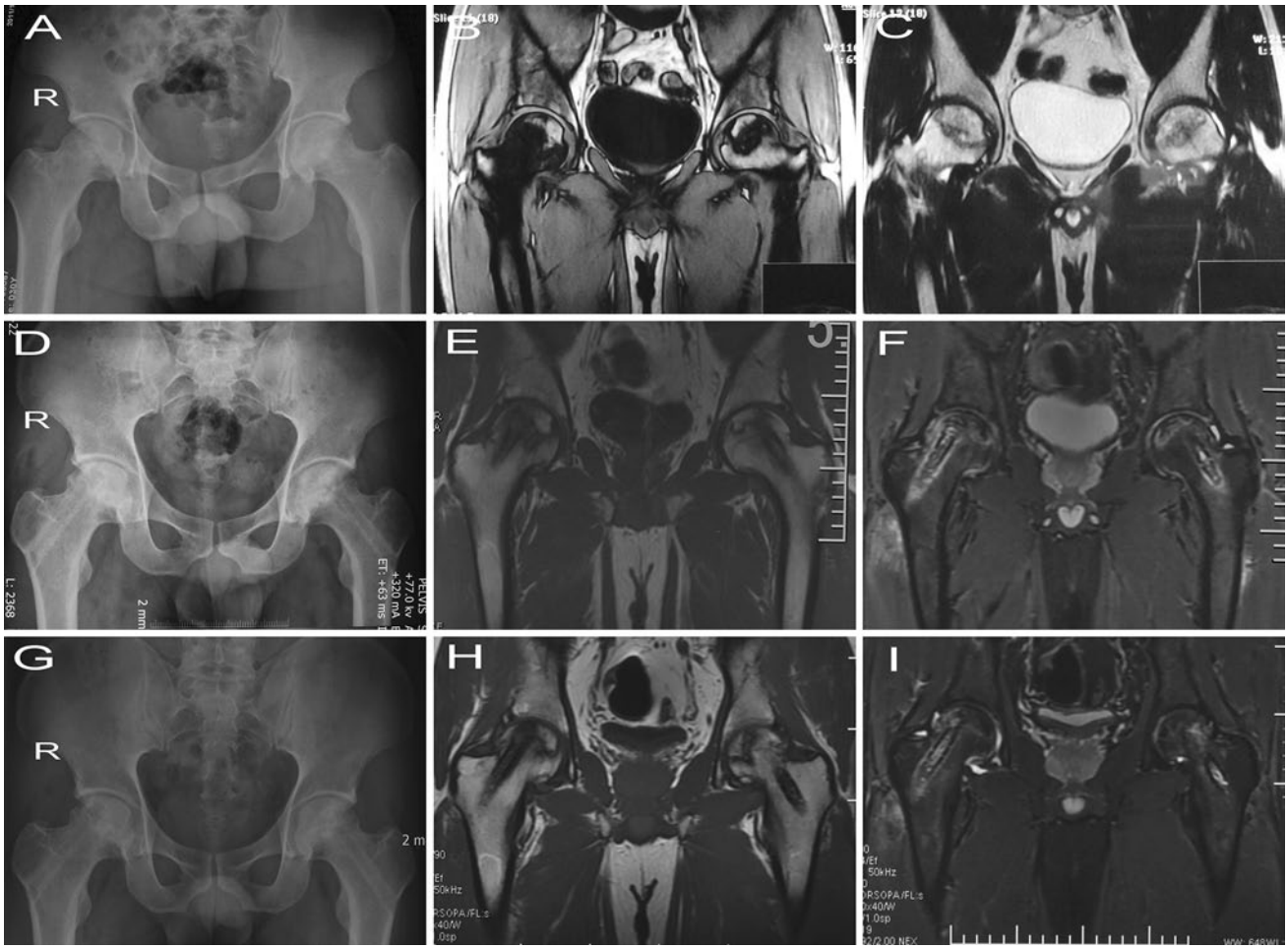

Fig. 3 Representative radiographs from a bilateral case with Steinberg stage IIC that was successfully treated with CD in combination with a n-HA/PA66 rod and bioglass bone graft. X-ray and MRI (T1 and T2) taken before surgery (**a**–**c**), 6 months post-surgery (**d**–**f**) and 24 months post-surgery (**g**–**i**) are shown

(8/38, 21.05 %) compared to the control group (21/46, 45.65 %) ($p < 0.05$). The clinical failure rate in the treatment group (9/38, 23.68 %) was also lower than that of the control group (24/46, 52.17 %) ($p < 0.05$) (Fig. 6).

Discussion

Although joint replacement procedures have been very successful in the treatment of ONFH [14], the patient population tends to be younger and their life expectancy exceeds the "life span" of the biomaterials used in joint prostheses. Therefore, these younger patients will likely need one or more revision surgeries in the future. As a result, the goal of surgical procedures in patients with ONFH is to preserve the femoral head rather than replace it.

Several prophylactic procedures have been performed in patients with the earlier stages of ONFH in an attempt to halt disease progression and to encourage repair [15, 16]. Of these procedures, CD is the most frequently used [3]. Although CD has been used for approximately three decades and there are numerous publications analyzing its efficacy, there is significant variation in the published data regarding the efficacy of CD for the treatment of ONFH. Mont et al. [17] reported that 63.5 % of 1,166 reviewed hips between 1960 and 1993 achieved a satisfactory clinical result after CD, Steinberg stage influenced the clinical outcome, with a survival rate of 84 % of hips with stage I disease, 65 % of hips with stage II disease and 47 % of hips with stage III disease. Fairbank et al. [18] reported the similarity clinical outcome, 88 % in hips in stage I, 72 % in stage II and 26 % in stage III. In 1997, Powell et al. [19] presented 66 % "good-to-excellent" clinical results. In contrast, several more recent reports showed less favorable results. Marker et al. [20] reported that 19/31 hips (61 %) were presented radiographic failure. After the follow-up of 120–240 months of 121 hips, Hernigou et al. [21] concluded that further

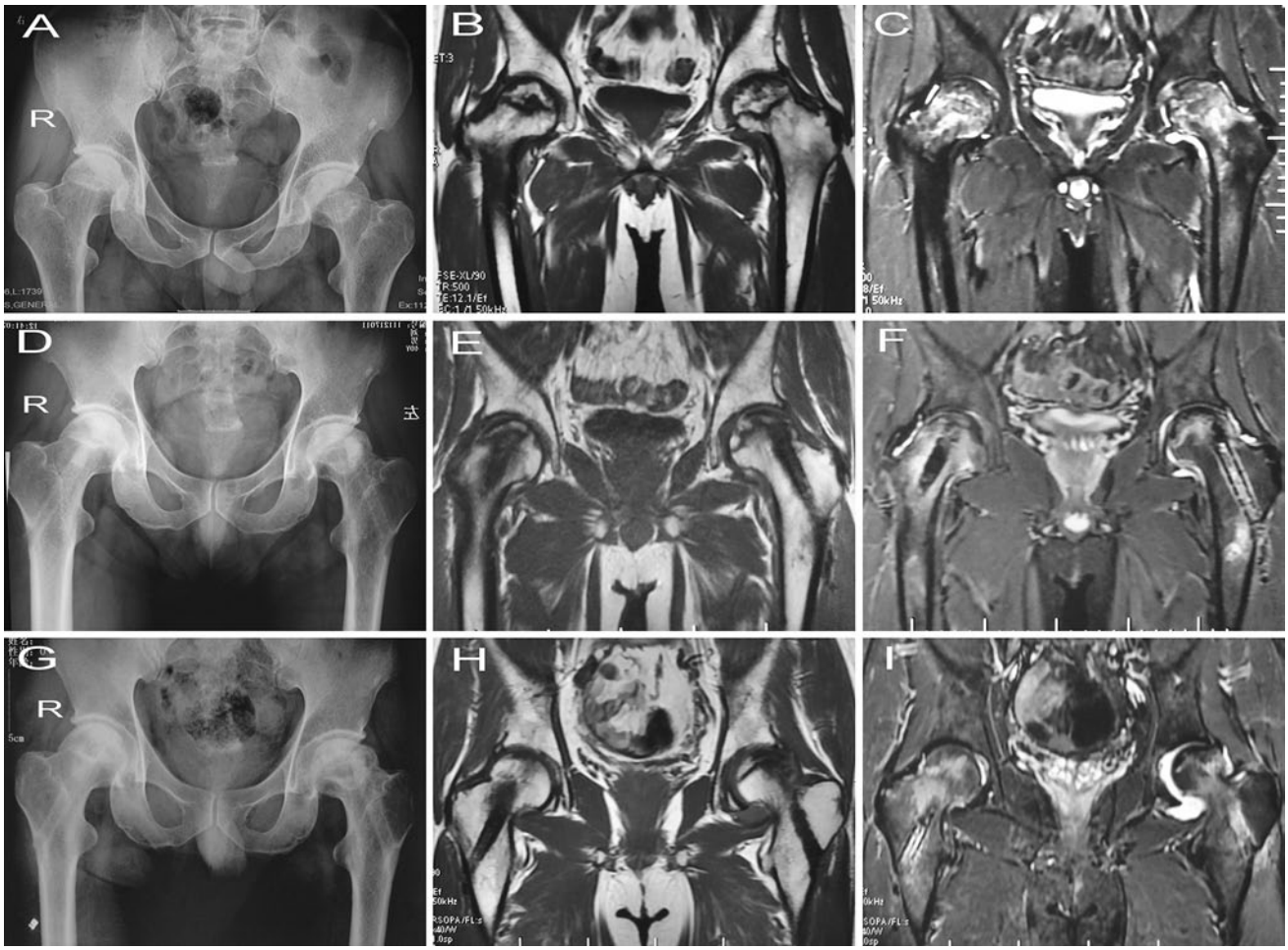

Fig. 4 Representative radiographs from a bilateral case with Steinberg stage IIC. The right hip was successfully treated following treatment with CD in combination with a n-HA/PA66 rod and bioglass bone graft. But the left hip was failed with the procedure, femoral head collapse was observed 10 months post-surgery. X-ray and MRI (T1 and T2) taken before surgery (**a**–**c**), 6 months post-surgery (**d**–**f**) and 10 months post-surgery (**g**–**i**) are shown

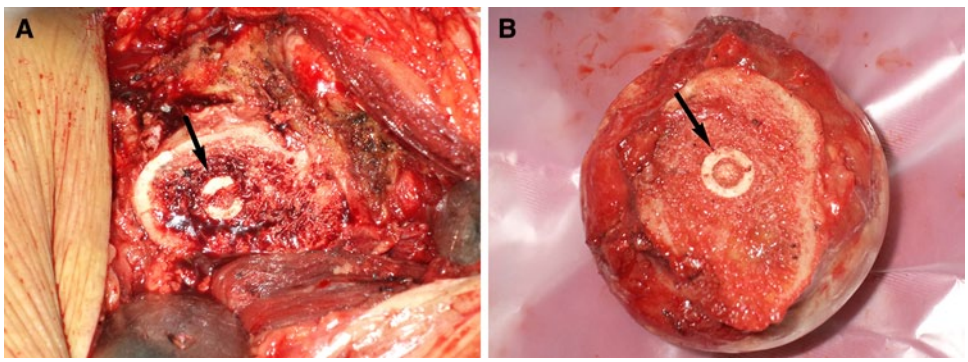

Fig. 5 After the femoral head was retrieved at THA, the hollow part of the n-HA/PA66 rod was filled with host cancellous bone. *Arrow* indicates the implanted n-HA/PA66 rod

surgery was necessary for 91 hips (75 %). Ha et al. [22] had similar results in 18 hips with 78 % classified as failures. The present study demonstrated that the overall successful rate was around 76 % for the treatment group and 50 % for the control group.

It is not clear why this disparity exists among the various reports on the outcome of CD. Unfortunately, it is difficult to compare these studies because many different variables are presented such as technical factors, inclusion criteria, the methods for following progression or

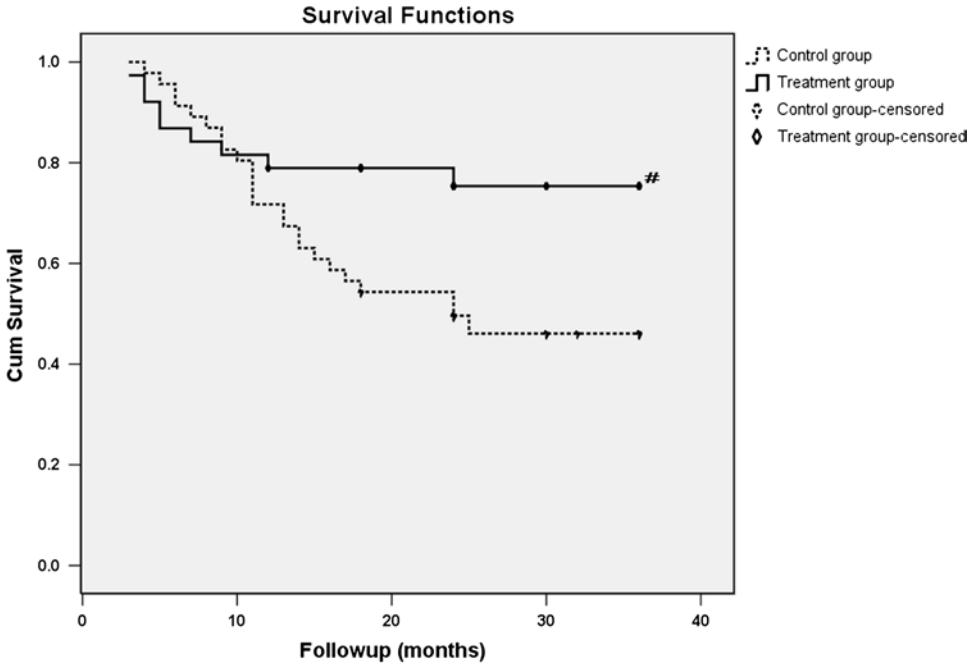

Fig. 6 Kaplan–Meier survival curves (time in months) in the treatment group and control group. # indicates a statistically significant difference between the treatment group and the control group ($p < 0.05$)

resolution, demographic differences, and the means used to determine the outcome.

One of the possible causes for the failure of this approach is that a traditional CD procedure may not adequately promote osteogenesis in the necrotic area and may not provide enough mechanical support for the subchondral surface [23, 24]. In the control group, the overall failure rate almost reached 50 %. The negative results may attribute to the reasons of loosely filled autologous cancellous bone could not provide rapidly recovery of mechanical support of the femoral head. Vascularized bone grafts (such as free vascularized fibular grafting) combined with CD have been shown to incorporate more rapidly and to provide structural support. However, several disadvantages have restricted the clinical application of this combined procedure such as the technical expertise required, a prolonged surgical and rehabilitation time and donor site morbidity [15].

The present study attempted to integrate several treatment principles for early stage to middle stage ONFH. We used a special expandable reamer instrument to debride the necrotic bone. Bioglass was subsequently pressed into the necrotic area, and a n-HA/PA66 rod was inserted into the core to provide mechanical support. The goal was to tip the balance of the creeping substitution process by accelerating bone healing while also providing enough structural support to the articular cartilage. The theoretical foundation for this combined procedure was based on the following hypotheses: (1) to relieve pain by decreasing the intraosseous pressure through CD, (2) to debride the sequestrum of necrotic bone that might inhibit revascularization of the femoral head, (3) to fill the structural deficit with osteoinductive and osteoconductive stuff biomaterials and (4) to support the subchondral surface by using supporting biomaterials.

Large diameter CD was used for all the patients in the present study. It is generally recognized that small diameter CD is suitable for pre-collapsed lesions with a small range of necrosis. We suggest that patients with early and middle stage ONFH should be treated with conventional large diameter CD due to two advantages. First, large diameter CD may achieve sufficient decompression of the high pressure within the necrotic femoral head. Second, the unique expandable reamer instrument we used can completely debride the sequestrum and fatty marrow within the necrotic area.

The synthetic bioglass material adopted in the present study has been used extensively as a bone graft substitute [10]. We press-filled a bioglass bone graft substitute into the necrotic area to accelerate new bone formation. Earlier studies have also demonstrated that a n-HA/PA66 cage is an effective device for reconstruction after anterior vertebral resection [11, 25]. The hollow, porous, cylindrical structure of the n-HA/PA66 rod used in the present study facilitated the ingrowth of host bone. In a retrieved sample from a failed patient undergoing THA, the host bone was observed to have infiltrated the hollow part of the rod. In addition, when the patient requires THA, metal materials like tantalum rod may influence the osteotomy of the femoral neck, but not these biomaterials.

The major objective of this innovative procedure is the prevention of subchondral collapse based on the

excellent biomechanical properties. It was clearly demonstrated that CD combined with a n-HA/PA66 rod and bioglass was more effective than the traditional procedure for patients with early to middle stages of ONFH. Importantly, in Steinberg IIIA, only two of five hips failed in the treatment group, while five of six hips failed in the control group. The overall differences of HHS and VAS improvement between the groups were only 11.61 points and 1.21 points, respectively. But when statistical analysis was conducted by the different Steinberg stage, the differences of HHS improvement between the groups were 1.39, −3.88, 0.69, 5.48, 10.07 and 24.06 for Steinberg IB, IC, IIA, IIB IIC and IIIA, respectively; statistical differences were observed in the Steinberg stage IIC and IIIA. The same trends were also observed in VAS improvement in different Steinberg stage. These results suggested that CD combined with a n-HA/PA66 rod and bioglass would more effective in the middle stage of ONFH. The limitations of the present study, including the small number of patients in each group or stage and short-term follow-up, do not allow us to make any definitive conclusions. A retrospective trial to assess mid- and long-term clinical and imaging outcomes is currently underway.

Interestingly, obviously joint effusion was observed in the 72.41 % radiological failed hips of the two groups, our results confirmed that joint effusion can be served as the valuable parameter to evaluate the clinical outcome.

In conclusion, we have found that CD in combination with the implantation of a n-HA/PA66 rod and a bioglass bone graft can significantly decrease hip pain, improve hip function and prevent the collapse of the femoral head in patients with ONFH. As the effectiveness of this approach appears to vary with Steinberg stage, we suggest that this treatment procedure may be suitable for patients with early to middle stage ONFH.

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Conflict of interest The authors declare that they have no conflict of interest. All the costs of each patient were covered by the basic medical insurance of China.

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