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Biomechanics of treating early-stage femoral-head osteonecrosis by using a β-tricalcium phosphate bioceramic rod system: a 3-dimensional finite-element analysis

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Abstract

The effect of implanting a β-TCP bioceramic rod system (BRS) can be observed with using the 3-dimensional (3D) finite-element method on the biomechanics of early-stage osteonecrosis of the femoral head (ONFH), to provide a theoretical basis for the biomechanics of applying the β-TCP BRS in the treatment of ONFH.

A healthy 172 cm tall male adult volunteer (age: 40 years, weight: 70 kg, and femoral diameter: 50 mm) was selected for this study. The volunteer had no history of diseases in the hip, lower back, and lower limbs. He also had no history of trauma and surgery and had no lesions in the femoral head.

A finite-element model of the normal proximal femur was constructed, and on this basis, 4 ONFH finite-element models were constructed, which had 15% and 30% necrotic areas in the superolateral area and 2 and 4 mm collapse in the weight-bearing area of the femoral head, respectively.

This process was followed by simulated implantation of the β-TCP BRS in the finite-element models of the femoral head. Changes in the stress and displacement of the femoral head were observed before and after treatment with the β-TCP BRS, and the risk of femoral-head collapse was assessed.

Under an applied walking load, the stress concentration on the femoral head was alleviated after treatment. Moreover, the stress and collapse values of the weight-bearing area decreased compared with those before treatment, and the differences were statistically significant ($P < .05$); the risk of collapse was also lower than that before treatment. As the area of the necrosis increased, the collapse value also increased, and the risk of collapse increased. More severe preoperative collapse implied that a greater risk of postoperative recollapse exists.

This case report was written for 4 purposes: Implantation of the β-TCP BRS could effectively improve the internal mechanical properties of ONFH, enhance the support capacity of bones in the weight-bearing area in ONFH, reduce the compressive stress on the necrotic bone, and lower the risk of collapse in ONFH.

Abbreviations: 3D = 3-dimensional, BRS = bioceramic rod system, DICOM = Digital Imaging and Communications in Medicine, ONFH = osteonecrosis of the femoral head, TCP = the β-tricalcium phosphate.

Keywords: β-tricalcium phosphate, bioceramics, displacement, finite-element analysis, ONFH, stress

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This study was only the primary research, and further study is in progress.

This study was approved by the Ethics Committee of Guizhou Provincial People's Hospital.

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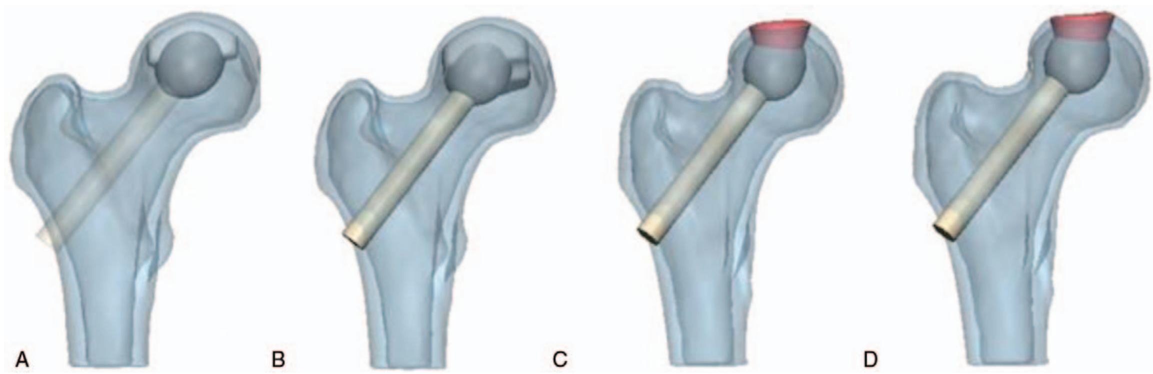
1. Introduction

Osteonecrosis of the femoral head (ONFH) is a complex disease that mainly occurs in adults aged 30 to 50 years. Its pathological features include local ischemic necrosis and damage to cells related to bone formation, which disrupts the dynamic equilibrium of bone formation. This problem will in turn lead to the destruction of the bone internal structures, resulting in the formation of necrotic lesions, sparse and fragmented trabeculae with microfractures, and separation of the cartilage and subchondral bone.[1–3] The primary causes of ONFH are trauma, steroid medications, and alcohol use.[4,5] Without effective treatment, ONFH could become a catastrophic illness, leading to the destruction in the hip-joint structure and loss of function. In severe cases, patients may need to undergo artificial hip replacement.[6–8]

In recent years, the β-tricalcium phosphate (TCP) bioceramic rod system (BRS) has been applied in clinical practice as a new method for treatment of early ONFH. It has ideal mechanical properties as well as good biological properties; hence, it is fast becoming a novel technique for the treatment of early to intermediate-stage ONFH. Owing to their high mechanical strength, dense ceramic granules can provide mechanical



A B C D

Figure 1. (A) Postoperative geometric model with 15% superolateral necrosis. (B) Postoperative geometric model with 30% superolateral necrosis. (C) Postoperative geometric model with 2 mm collapse. (D) Postoperative geometric model with 4 mm collapse.

support. On the contrary, porous ceramic granules and porous ceramic rods have excellent microporous structures, which are conducive to inducing vascularization, bone ingrowth, and nutrient transport. Following ONFH core decompression, the β-TCP porous BRS can simultaneously provide mechanical support, material degradation, and bone fusion. During the early stages of implantation, the dense ceramic granules can provide excellent mechanical support for the necrotic region, whereas the porous ceramic granules and rods can fill bone defects, and their porous structure induces bone formation. With the repair of osteonecrosis at the later stages of implantation, the formation of a new bone and material degradation will gradually achieve the objectives of biomechanical support and fusion. To date, no studies have been conducted that explore the biomechanics of implanting the β-TCP BRS in ONFH.

2. Case report

2.1. Ethical review

A healthy 172 cm tall male adult volunteer (age: 40 years, weight: 70 kg, and femoral diameter: 50 mm) was selected for this study. This study was approved by all patient consents.

2.2. β-tricalcium phosphate bioceramic rod system

The β-TCP porous BRS used in this study was provided by Shanghai Bio-Lu Biomaterials Co, Ltd. (Shanghai, China). The porosity of the porous ceramics was approximately 70%, the pore size was approximately 500 μm, and the pore interconnection diameter was approximately 150 μm. The elastic modulus of the dense ceramic granules was 749 MPa, and that of the porous ceramic granules was 20 MPa.

2.3. Data collection

A SOMATOM Definition dual-source computed tomography scanner (Siemens, Berlin, Germany) was employed for thin-slice scanning to obtain the raw data. The raw imaging data were then stored on a disk in a DICOM format.

2.4. Study procedures

The acquired DICOM data of a normal femoral head were imported and opened in the Mimics image processing software. Then, images of the femoral-head surface and cancellous-bone contours were extracted and exported to establish 3D geometric models. Subsequently, the Geomagic software was employed for sampling, smoothing, and surface fitting of the geometric models. Then, 4 ONFH models were designed, which had 15% and 30% necrotic areas in the superolateral area and 2 and 4 mm collapse in the weight-bearing area of the femoral head, respectively. The ceramic granules formed an ellipsoidal shape, and their volume was consistent with the size of the scraper, which has long and short diameters of 32 and 29 mm, respectively. A cylindrical ceramic rod with a diameter of 10 mm was connected to the ceramic granules. Then, ONFH models implanted with the bioceramic rod were designed (Fig. 1). The ellipsoidal mixed ceramic granules were placed at the center of the necrosis, which is inferior to the cortical bone beneath the subchondral bone. The models were imported into the Hypermesh software for meshing, followed by mechanical analysis of the ONFH finite-element models using the Abaqus software.

2.5. Material attributes and value assignment of the finite-element models

In terms of the assignment of values for the material parameters, the results obtained by early scholars in biomechanics, namely Anderson et al,[9] Brown and Hild,[10] and Lee et al[11] were used to assign different material properties to each component. The cortical bone was assigned an elastic modulus of 15,100 MPa and a Poisson ratio of 0.3. The cancellous bone was given an elastic modulus of 445 MPa and Poisson ratio of 0.22. The necrotic bone was provided with an elastic modulus of 124.6 MPa and a Poisson ratio of 0.152. The dense ceramic granules were provided with an elastic modulus of 749 MPa. The porous ceramic granules were assigned an elastic modulus of 20 MPa and a Poisson ratio of 0.3. The dense and porous ceramic granules were mixed at a volume ratio of 10:9, and the elastic modulus of the light bulb-shaped mixed ceramic granules was 403.7 MPa.

3. Main outcome measures

The variations in stress and displacement of the ONFH models before and after surgical implantation of the BRS were observed. The stress and collapse values in the weight-bearing and necrotic areas of the femoral head were randomly measured 20 times before and after surgery.

4. Statistical analysis

The SPSS22.0 statistical software (IBM SPSS Statistics 22.0, Chicago, IL) was used for data processing. All data were expressed

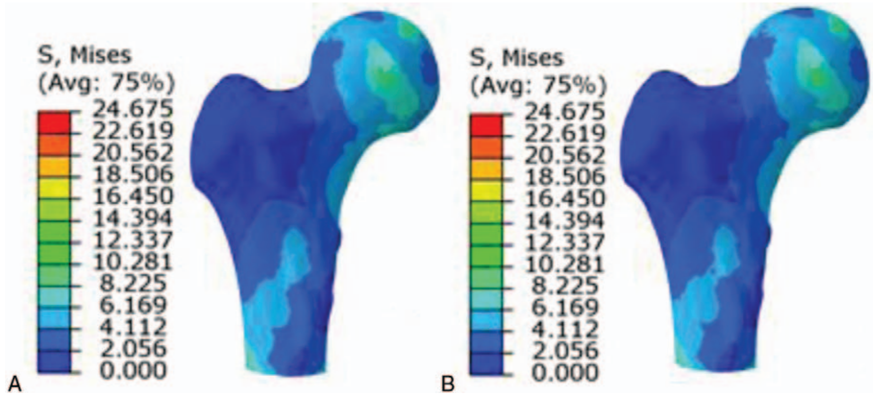


Figure 2. Pre- and postoperative stress distributions of the femoral head in 15% superolateral osteonecrosis (A, Preoperative; B, Postoperative).

as mean and standard deviation. The pre- and post-treatment data were analyzed using paired *t* tests. All statistical testing activities were conducted using 2-tailed hypothesis testing, and $P<.05$ indicated that the differences were statistically significant.

5. Results of the finite-element analysis

5.1. Pre- and postoperative finite-element analysis of bioceramic granules and rod implantation in 15% superolateral ONFH

When the femoral head showed 15% superolateral osteonecrosis and a normal walking load was applied (i.e., 2.5 times the body weight), the preoperative stress in the weight-bearing area at the interface between the cortical bone and necrotic area did not show proper stress conduction. Clear concentrations of the stress were observed (light yellow and dark green areas), and the maximum stress in this area was 11.592 MPa. The stress concentration was somewhat alleviated after surgery, and the maximum stress in this area was 10.08 MPa. The preoperative stress value of the weight-bearing area was 8.125 ± 1.284 MPa, which decreased to 7.056 ± 1.120 MPa after surgery. The difference was statistically significant ($P<.05$), which indicates that the necrotic area showed greater support capacity after being filled with bioceramic granules, effectively dispersing the stress on the surface of the femoral head. The preoperative collapse value was 0.617 ± 0.207 mm, which was reduced to 0.456 ± 0.153 mm after surgery. The difference was statistically significant ($P<.05$), which indicates that the risk of bone collapse after surgery was lower than that before surgery (Figs. 2 and 3 and Tables 1–3).

5.2. Pre- and postoperative finite-element analysis of bioceramic granules and rod implantation in 30% superolateral ONFH

When the femoral head showed 30% superolateral osteonecrosis, the preoperative stress in the weight-bearing area at the interface between the cortical bone and necrotic area did not show proper stress conduction. Clear concentrations of the stress were observed (light yellow and dark green areas), and the maximum stress in this area was 15.743 MPa. The stress concentration was slightly alleviated after surgery, and the maximum stress in this area was 14.748 MPa. The preoperative stress value of the weight-bearing area was 10.761 ± 1.445 MPa, which decreased to 9.813 ± 1.354 MPa after surgery. The difference was statistically significant ($P<.05$). Despite the increase in the necrotic area to 30%, the bioceramic granules still enhanced the support capacity of the necrotic area, and the stress was effectively dispersed on the surface of the femoral head. The preoperative collapse value was 0.893 ± 0.357 mm, which was reduced to 0.732 ± 0.374 mm after surgery. The difference was statistically significant ($P<.05$), which indicates that the risk of bone collapse

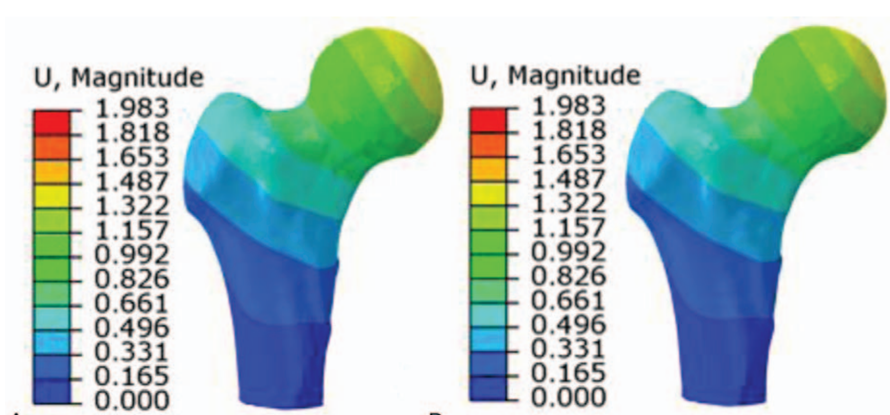


Figure 3. Pre- and postoperative displacement distributions of the femoral head in 15% superolateral osteonecrosis (A, Preoperative; B, Postoperative).

Table 1

Pre- and postoperative collapse values ($\bar{x} \pm s$).

Collapse value, mm	Pre-op	Post-op	T	P
15% superolateral necrosis	0.617 ± 0.207	0.456 ± 0.153	2.119	.041
30% superolateral necrosis	0.893 ± 0.257	0.732 ± 0.274	2.271	.029
2 mm collapse	0.985 ± 0.142	0.855 ± 0.148	2.833	.007
4 mm collapse	1.153 ± 0.151	1.045 ± 0.142	2.110	.041

Table 2

Pre- and postoperative stress values of weight-bearing area ($\bar{x} \pm s$).

Stress value of weight-bearing area, MPa	Pre-op	Post-op	T	P
15% superolateral necrosis	8.125 ± 1.284	7.056 ± 1.120	2.811	.008
30% superolateral necrosis	10.761 ± 1.445	9.813 ± 1.354	2.138	.039
2 mm collapse	10.938 ± 1.894	9.751 ± 1.430	2.239	.031
4 mm collapse	11.152 ± 1.690	10.089 ± 1.616	2.028	.049

after surgery was lower than that before surgery (Figs. 4 and 5 and Tables 1–3).

5.3. Pre-and postoperative finite-element analysis of bioceramic granules and rod implantation in ONFH with 2 mm collapse

When the femoral head showed a 2 mm collapse, the preoperative stress in the weight-bearing area at the interface between the cortical bone and necrotic area did not show proper stress conduction. Clear concentrations of the stress were observed (light yellow and dark green areas), and the maximum stress in this area was 16.051 MPa. The stress concentration was slightly alleviated after surgery, and the maximum stress in this area was 15.193 MPa. The preoperative stress value of the weight-bearing area was 10.938 ± 1.894 MPa, which decreased to 9.751 ± 1.430 MPa after surgery. The difference was statistically significant ($P < .05$). In the case of a minor collapse, the bioceramic granules enhanced the support capacity of the necrotic area and alleviated the stress concentration on the surface of the femoral head. The preoperative collapse value was 0.985 ± 0.142 mm, which was reduced to 0.855 ± 0.148 mm after surgery. The difference was statistically significant ($P < .05$), which indicates that the risk of recollapse after surgery was lower than that before surgery (Figs. 6 and 7 and Tables 1–3).

Table 3

Pre-and postoperative maximum stress values of weight-bearing area.

Maximum stress value of weight-bearing area, MPa	Pre-op	Post-op
15% superolateral necrosis	11.592	10.080
30% superolateral necrosis	15.743	14.748
2 mm collapse	16.051	15.193
4 mm collapse	16.425	15.662

5.4. Pre- and postoperative finite-element analysis of bioceramic granules and rod implantation in ONFH with 4 mm collapse

When the femoral head showed a 4 mm collapse, the preoperative stress in the weight-bearing area at the interface between the cortical bone and necrotic area did not show proper stress conduction. Clear concentrations of the stress were observed (light yellow and dark green areas), and the maximum stress in this area was 16.425 MPa. The stress concentration was slightly alleviated after surgery, and the maximum stress in this area was 15.662 MPa. The preoperative stress value of the weight-bearing area was 11.152 ± 1.690 MPa, which decreased to 10.089 ± 1.616 MPa after surgery. The difference was statistically significant ($P < .05$). Despite a larger degree of collapse, the bioceramic granules still provided a certain level of support in the necrotic area, and the postoperative stress was still lower than the preoperative stress. The preoperative collapse value was 1.153 ± 0.151 mm, which was reduced to 1.045 ± 0.142 mm after surgery. The difference was statistically significant ($P < .05$), which indicates that the risk of recollapse after surgery was lower than that before surgery (Figs. 8 and 9 and Tables 1–3).

6. Discussion

The femoral-head collapse mainly results from the common effect of biological and biomechanical factors, to improve biomechanical factors that can efficiently prevent the increase in the scope of necrosis and the occurrence of femoral head collapse.[12,13] Currently, no studies are available related to the biomechanics of

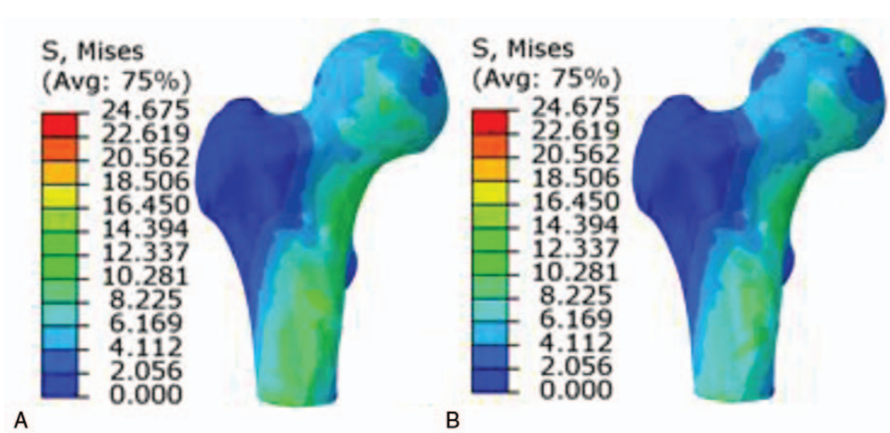


Figure 4. Pre- and postoperative stress distributions of the femoral head in 30% superolateral osteonecrosis (A, Preoperative; B, Postoperative).

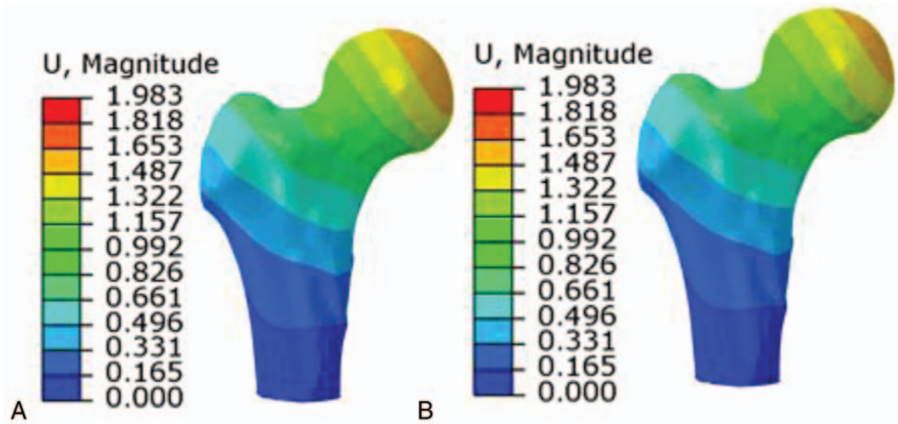


Figure 5. Pre- and postoperative displacement distributions of the femoral head in 30% superolateral osteonecrosis (A, Preoperative; B, Postoperative).

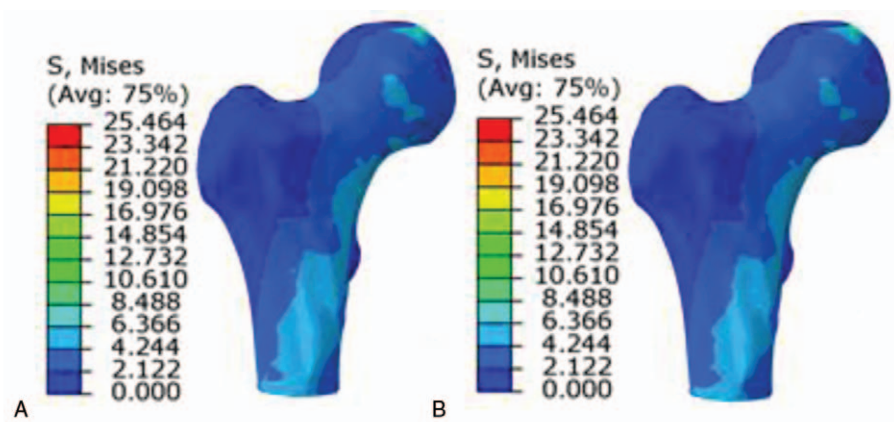


Figure 6. Pre- and postoperative stress distributions of the femoral head with 2 mm collapse (A, Preoperative; B, Postoperative).

the β-TCP BRS for the treatment of ONFH. The obstacle of treatment of osteonecrosis is the repair of necrotic bone, and the fundamental part is to prevent and correct femoral head collapse, while the therapy goal is to avoid collapse of the femoral head and the development of advanced arthritis.[14] A proximal femur model of a healthy individual was established in this study, which was used as the basis for setting the different areas of necrosis and magnitudes of the collapse, followed by implantation of the BRS in the necrosis models. Subsequently, finite-element analysis was performed before and after implantation to evaluate the biomechanical effects of the BRS on the femoral head. This process enables us to determine the optimal timing for the surgery and provide guidance for the clinical application of this method in ONFH treatment.

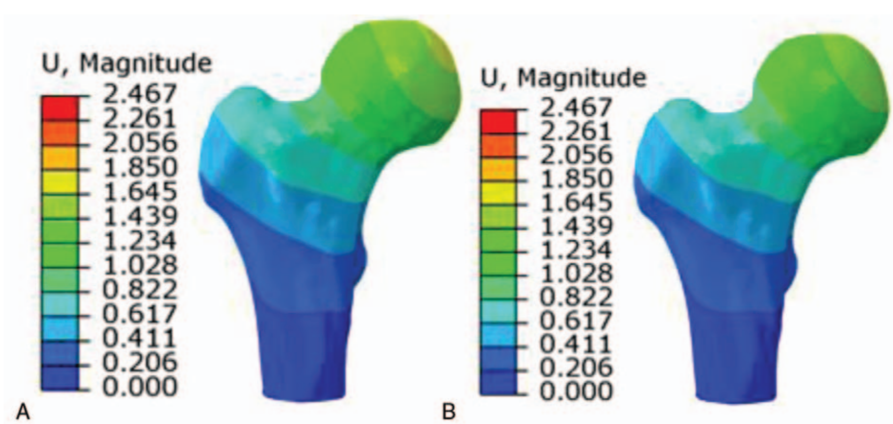


Figure 7. Pre- and postoperative displacement distributions of the femoral head with 2 mm collapse (A, Preoperative; B, Postoperative).

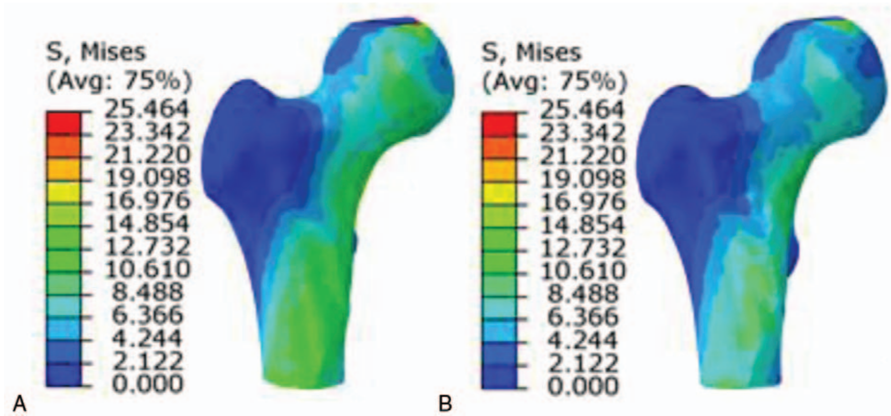


Figure 8. Pre- and postoperative stress distributions of the femoral head with 4 mm collapse (A, Preoperative; B, Postoperative).

The collapse value for the 30% necrosis was larger than that for the 15% necrosis, which indicates that the risk of bone collapse becomes greater as the size of the necrosis increases. Lesion size is an important factor that affects the prognosis of ONFH. Some scholars have discovered that patients with an ONFH area greater than 30% were more susceptible to femoral-head collapse.[12] An ONFH area of 30% is crucial to the prognosis of ONFH because an area over 15% will lead to exacerbation in the radiographic progression of ONFH.[15] A 4 mm collapse in the weight-bearing area showed a greater collapse value than the 2 mm collapse. Thus, a higher collapse magnitude leads to a higher risk of bone recollapse, which indicates that the structural damage to the femoral head caused by a collapse results in poor mechanical support, increasing the risk of recollapse.

After implantation of the bioceramic granules and the rod when the necrotic area was 15%, the risk of femoral-head collapse significantly decreased compared with that before treatment. As the necrosis size increased, the postoperative risk of collapse increased, whereas the efficacy of implanting the bioceramic granules and rod also decreased. When the necrosis size was 30%, the postoperative collapse value was lower than that before surgery, but the preoperative value was already relatively large. Hence, the mechanical support provided by filling the necrotic area with bioceramic granules was insufficient to bear such loads and required the repair of the bone structure in the necrotic area to enhance the mechanical support. In the weight-bearing area of the femoral head with 2 mm collapse, its postoperative collapse value was significantly lower than its preoperative value; hence, the risk of recollapse was lower than that before surgery. With the 4 mm collapse, despite the lower postoperative collapse value than its preoperative value, the collapse value was still larger than that of the 2 mm collapse, which indicates that as the magnitude of the collapse increased, the damage to the mechanical support structure in the femoral head became more severe. Hence, although the implantation of the bioceramic granules decreased the risk of collapse compared with that before surgery, its support capacity was still limited, and collapse could not be prevented. Hence, the chances of recollapse were very high.

After the implantation of the bioceramic granules and rods in the ONFH with different necrosis sizes and different collapse magnitudes, the finite-element analysis revealed that defect filling of the necrotic areas in the femoral head with bioceramic granules alleviated the concentration of stress on the surface of the femoral head. Thus, the stress levels on the weight-bearing area and the displacement of the femoral head decreased, which led to statistically significant differences before and after surgery in the various ONFH models. The compression trabeculae of the femoral head are mainly concentrated in the weight-bearing area; hence, as the main load-bearing region of the femoral head, the stress is mostly concentrated in the femoral head. By filling the

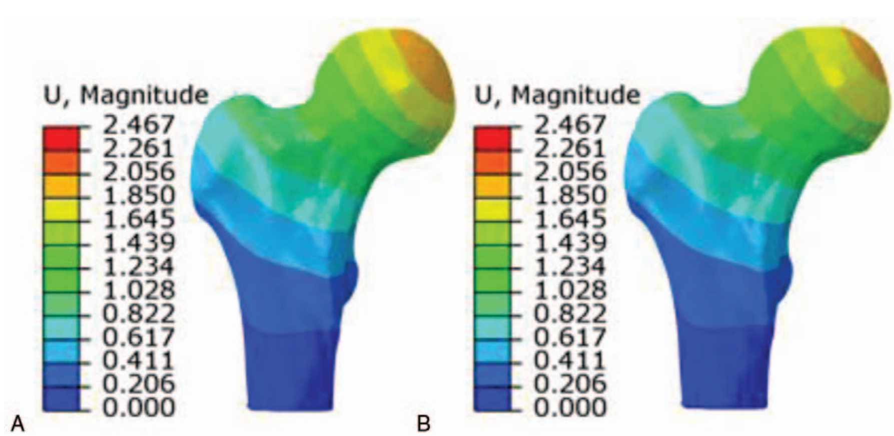


Figure 9. Pre- and postoperative displacement distributions of the femoral head with 4 mm collapse (A, Preoperative; B, Postoperative).

necrotic area in the femoral head with bioceramic granules, we were able to alter the mechanical structure of the femoral head, strengthen the stress capacity of its load-bearing region, reduce the compressive stress on the necrotic bone, and reduce the stress transferred to the distal femur. These processes, in turn, effectively reduce the stress on the weight-bearing area of the femoral head, which is conducive to the repair of peripheral bone tissue and reduction in the collapse value, thereby reducing the probability of further femoral collapse. Therefore, our results have provided a theoretical support for the application of the implantation of the BRS.

Collapse in ONFH is the result of changes in the biomechanics of the femoral head. Its main cause is the decrease in the stress levels in and the stress concentration around the necrotic area, and its pathological basis is the microfracture of the trabeculae. Its essence is a type of biomechanical instability. The femoral head collapse often occurs in the necrotic area of the subchondral bone plate, and the geometry and size of the lesion determine whether the lesion in the deep cancellous bone area collapses. Motomura et al[16] found that the extent and area of the femoral head collapse were affected by the necrosis area. Yang et al[17] suggested that the extent and location of necrosis affected the necrosis of the femoral head collapse, if in the small scope of bone necrosis or subchondral integrity, the collapse was not prone to occur; although in the case of a large necrosis range or involving to the weight zone, the collapse can easily occur. Volokh et al[18] demonstrated that the support of normal cancellous bone was an important foundation to limit the cortical deformation. Ohzono et al [19] found that collapse of femoral head necrosis was due to fatigue fracture of the internal trabecular bone caused by the internal stress altering of the femoral head necrosis. Kim et al[20] indicated that the subchondral and deep cancellous bones were very significant for the mechanical support of the internal structure of the femoral head, and the necrotic bone reduced the mechanical supporting ability, also leading to local stress concentration, continuous human pressure that will inevitably result in progressive increase in femoral head necrosis. Researchers have found that even with a relatively large area of necrosis, the stress load on various parts of the femoral head does not reach the yield strength. The femoral head would collapse once this level is exceeded, and the sites most susceptible to collapse are the surfaces with significant stress concentration and the interface between the necrotic and surviving tissue.[15] The support provided by implanting the BRS alleviates the stress concentration effect and reduces the risk of fatigue fractures, thereby also reducing the risk of femoral-head collapse. In early-stage implantation of the BRS, using mixed bioceramic granules with elastic modulus and strength similar to those of the trabeculae will reconstruct the mechanical support structure of the femoral head to a certain extent, thereby restoring its biomechanical properties. When the necrosis size is relatively large, the effects of the bioceramic granules and rod implantation were significantly poorer than those of smaller necrotic areas because an excessively large area of osteonecrosis will lead to a considerable loss in the support structure and the supporting effects of the bioceramic granules will be effectively insufficient to compensate for this loss. With regard to the femoral head with severe preoperative collapse, a serious damage to the internal structure of the femoral head implies that the supporting effect of the bioceramic granules will be extremely limited.

This study verified that β-tricalcium phosphate ceramic rod system can improve the biomechanical properties of necrotic femoral head. More specifically, with the femoral head lesion and the structure of the intrinsic trabecular lesion increased, the progressive risk of necrosis of the femoral head collapse was raised. Simultaneously, we can grasp the best treatment time of the femoral head necrosis, to determine the clinical effect and prognosis with certain guidance significance. In clinical treatment, when the lesion was less than 15% or the collapse was less than 2 mm, the choice of ceramic rod surgery was very suitable. If the lesion was greater than 30% or the collapse was greater than 4 mm, the operation was unsatisfied. If the indications can be properly chosen and the appropriate patients can be selected, β-tricalcium phosphate ceramic rod system for treatment of femoral head necrosis was a good choice.

This study was based on the finite element analysis of biomechanical studies. Compared with the traditional biomechanical researches, it cannot be subject to conditions, such as the values can be arbitrarily assigned to simulate a variety of complex environments and other advantages. However, the basis of the analysis comes from the traditional biomechanics, the accuracy of the data is not as comparative as the traditional biomechanical studies. Therefore, in order to facilitate research, discover fundamental law and principles, and simplify conditions, we only investigated a law and phenomenon instead of solving a specific value. Of course, the clinical effect and prognosis were also related to the patient's age, BMI, etiology, and other factors, and further clinical studies were eventually required to further observe its efficacy and prognosis.

7. Conclusion

When the lesion size was approximately 15% or lower, or when the collapse was less than or equal to 2 mm, β-TCP bioceramic granules and rod implantation could provide sufficient mechanical support and facilitate the preservation of mechanical stability in ONFH. When the lesion size was almost or exceeded 30% or when the collapse was great than or equal to 4 mm, the β-TCP bioceramic rod implantation had limited effectiveness in improving the internal mechanical properties of ONFH. Although decreases in the stress and displacement occurred, the postoperative risk of collapse in ONFH could not be effectively reduced. In the treatment of ONFH by β-TCP bioceramic rod implantation, the BRS only provided limited biomechanical support. As the load increased, the risk of femoral-head collapse also increased. Its effects in ONFH with a small necrotic area and minor collapse were superior to that in ONFH with large necrotic areas and major collapse. In clinical treatment, the results of this study can guide the choice of appropriate indications for this surgical modality and predict outcomes.

Author contributions

Conceptualization: Bo Li.
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Formal analysis: JinMin Zhao.
Funding acquisition: RuYin Hu.
Methodology: RuYin Hu.
Project administration: RuYin Hu.
Supervision: JinMin Zhao.
Visualization: Rui Luo.
Writing – original draft: Bo Li.
Writing – review & editing: Bo Li.

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