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# High energy focused extracorporeal shock wave therapy for early and mid-stage femoral head necrosis: A single center retrospective cohort study

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## Abstract

**Background:** Research has shown that extracorporeal shock wave therapy has a certain therapeutic effect on the osteonecrosis of the femoral head (ONFH). However, the sample sizes are relatively small.

The aim of this study is to evaluate and investigate the clinical efficacy and safety of high-energy extracorporeal shock wave treatment (ESWT) in the management of early and mid-stage ONFH by observing a large size clinical sample.

**Materials & Methods:** 453 patients with stage I–III ONFH treated ESWT in our hospital between June 2019 to August 2021, are included. The visual analog pain scale (VAS), Harris hip score, radiography, and magnetic resonance imaging were used to estimate treatment results. The progression of ONFH was evaluated by imaging examination and clinical outcomes.

**Results:** The mean follow-up was 39.81±7.94 months (range 26 to 50 months). The mean VAS decreased from 5.54 ± 1.19 before ESWT treatment to 1.92 ± 0.43 points at the 12 months follow-up ($p < 0.001$). The mean Harris hip score improved from 75.51 ± 5.14 before ESWT treatment, to 92.21 ± 4.53 at the 12 months follow-up ($p < 0.001$). The clinical success(improvement) was observed in 85.71% of ARCO stage I patients, 48.09% of ARCO stage II patients, and 49.15% of ARCO stage III patients. Imaging success (no worsening of clinical images) was observed in 12.38% stage I hips, 28.37% of stage II hips, and 27.12% of stage III hips, respectively. The hip joint survival rate of stage II and stage III patients was 86.51% and 77.97% ($P<0.05$).

**Conclusions:** The result of the current study suggests that ESWT definitely represents an effective, reliable, and safe therapeutic method for early and middle stages of ONFH with bone marrow edema syndrome (BMES), and should be recommended as a therapeutic option.

**Keywords:** High-energy extracorporeal shock wave therapy, Osteonecrosis, Femoral head, Bone marrow edema

## Introduction

Osteonecrosis of the femoral head (ONFH) is one of the most common causes of hip joint disability in young adults[1].The incidence rate of adult non-traumatic ONFH in China is 0.725%. It has been estimated that about 8.12 million Chinese adults (15 years or above) suffered from ONFH with a significant higher prevalence in males[2].Currently, the commonly used hip joint preservation surgical approaches mainly includes core decompression, non-vascularized bone transplantation, vascularized bone transplantation, tantalum rod implantation, and osteotomy. Conservative treatments such as NSAID, physical therapy, and protected weight bearing are also used for treatment ONFH. However, there is still no completely satisfactory method to treat bone necrosis[3]. Early diagnosis, early rational and effective treatment may be the best way to preserve the patient's own joints as much as possible under the current technological level. In recent years, the development of diagnosis has effectively solved the problem of early detection of femoral head necrosis. Therefore, orthopedic physicians should adopt active and effective treatment methods based on the patient's own situation and disease stage, under the premise of clear early diagnosis, in order to achieve better treatment results. Furthermore non-surgical treatment for early ONFH has received increasing attention. The comprehensive treatment of ONFH through a combination

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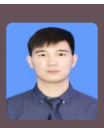
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**Figure 1:** A. High-energy focused extracorporeal shock wave therapy equipment used in the current study (Dornier Compact Delta II, Dornier MedTech GmbH, Wessling, Germany).
B. Extracorporeal shock wave photograph with precise localization and real-time monitoring of the impact site.

of drugs and physical therapy, often achieves good clinical results, delaying or even avoiding surgical treatment. Safe, effective, and non-invasive non-surgical hip preservation treatment methods have always been the goal pursued by orthopedic physicians and the urgent need of patients. Since the early 1990s when literature reported the application of extracorporeal shock wave technology (ESWT) to promote fracture healing [4], there has been a gradual increase in reports on the treatment of musculoskeletal disease using this technology and it has become a research hotspot [5-6]. Previous studies have shown favorable results on the efficacy of ESWT in the treatment of early ONFH, delayed and non-healing fractures, knee joint bone marrow edema and other diseases [7-10]. However, the sample sizes were relatively small, and the scientific evidence was not high. In addition, according to our knowledge, current research reports mostly use of radial pressure waves therapy for early and mid-stage ONFH, and there are relatively few clinical reports on focused high-shockwaves energy. It is precisely for these reasons that we designed this study with the aim of evaluating and investigating the clinical efficacy and safety of focused high-energy ESWT for early and mid-stage ONFH by observing a large clinical sample and providing a precise clinical treatment plan for early clinical treatment of ONFH.

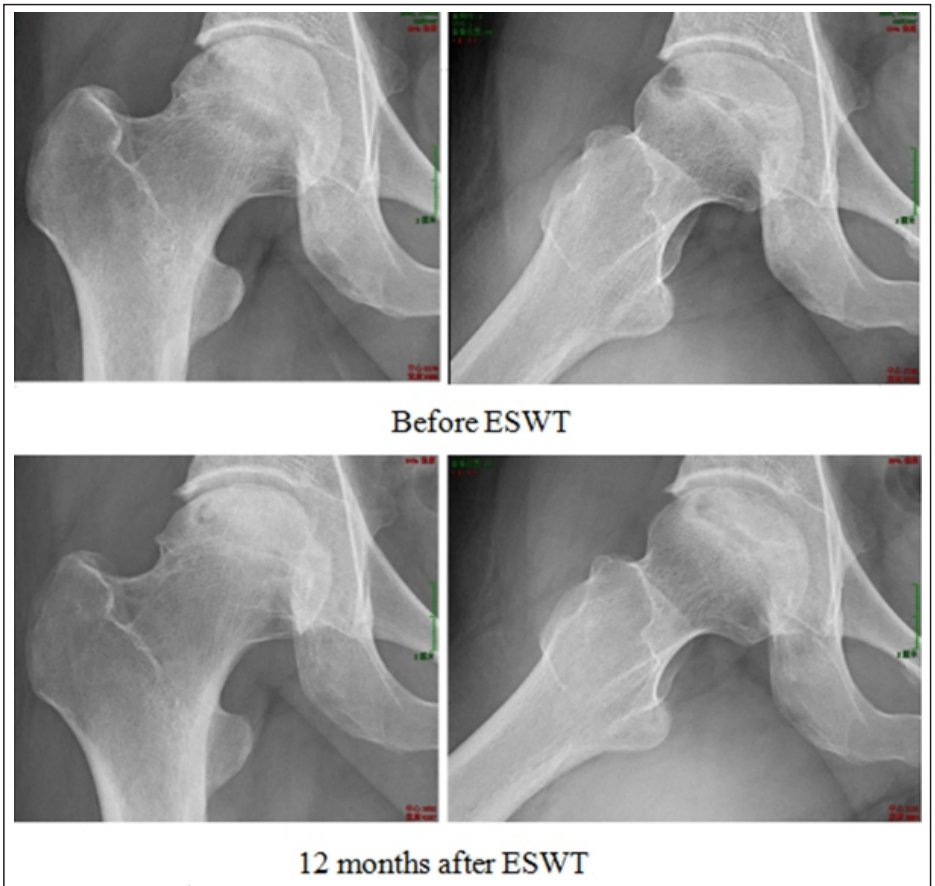


**Figure 2:** Radiographs (AP + frog position) of the right hips before and 12 months after ESWT treatment in a 23-year-old male patient with osteonecrosis of the femoral head showing that the necrotic area within the femoral head has undergone significant bone repair, and the cystic area within the femoral head has been replaced by continuous bone trabeculae. Moreover, the morphology of the femoral head has not changed, and the femoral head has not collapsed, resulting in a significant increase in bone density.

## Materials And Methods

This study was approved by the institutional Clinical Trials and Biomedical Ethics Committee of Luoyang Orthopedic Hospital of Henan Province (20190601). Written informed consents were obtained from all patients for participating and using their clinical data for the present study.

### Clinical Data

We have extensively recruited non traumatic femoral head necrosis patients who visited our center from June 2019 to August 2021, aged 18-60 years old, regardless of gender. All patients underwent laboratory tests (blood routine, biochemistry, bone metabolism, coagulation, etc.) and imaging examinations (X-ray, CT, and MRI) to clarify the diagnosis and staging of the disease. The diagnosis of ONFH was based on history, clinical examination, and imaging assessment. The staging of femoral head necrosis is based on the ARCO staging developed by the International Association for Research on Circulation (ARCO)[11].We have also established exclusion criteria as follows:①femoral head necrosis ARCO IIIB and ARCO IV; ②Patients with severe illnesses such as heart, liver, kidney, and hematopoietic system diseases;③Patients with tumors, infections, lower limb thrombosis, and coagulation dysfunction;④Patients diagnosed with severe osteoporosis through lumbar and hip bone density examinations; ⑤Mental illness patients and those with poor compliance.

### Basic treatment and clinical education

We have specially arranged for a professional physician and nurse to provide relevant knowledge and health education to all patients receiving treatment. Firstly, how to use crutches reasonably and effectively to help reduce hip load and avoid strenuous activities; Secondly, for patients with a Body

| Table 1: Patient demographic characteristics | |
|---|---|
| Variable | Values |
| Patients/hips (no.) | 453/697 |
| Age (years) | 35.42±7.24(Rang 18-60) |
| Male/female (no. of patients) | 270/183 |
| Right/left (no. of hips) | 342/355 |
| Bilateral disease (no. of patients) | 244 |
| Duration of symptoms (months) | 7.9±2.36 |
| ARCO stage, n | |
| I | 105 |
| II | 289 |
| III | 59 |
| Etiology, n | |
| Steroid | 163 |
| Alcohol 11 | 149 |
| Trauma 23 | 96 |
| Idiopathic 8 | 45 |
| Duration of follow-up, months | 39.81±7.94(range 26-50) |

Mass Index (BMI) greater than 25, nutritionists provided professional guidance and adjusted their dietary structure, developed recipes, and controlled their weight. Thirdly, informed patients to quit smoking and drinking. Fourth, targeted lipid-lowering treatment and control of primary diseases related to abnormal bone metabolism based on the patient's comorbidities.

**Shock Wave Treatment**

According to the signing informed consent, all patients were treated with focused high-energy focused ESWT (Dornier Compact Delta II, Dornier MedTech GmbH, Wessling, Germany) with two fixed physicians as shock wave therapists (fig 1). The treatment plan was as follows: on the first day of hospitalization, relevant examinations were completed, and patients were screened. Before treatment, it was conducted a detailed evaluation of patient's condition, including stage and area of necrosis, the position to be adopted during the treatment process, etc. It was explained to the patient the varying degrees of pain that may occur during shock wave treatment to alleviate their tension. If necessary, patients received oral NSAIDs two hours before treatment to alleviate the pain during the treatment process. Secondly, we marked the treatment points on the femoral head based on the necrosis and bone marrow edema areas provided by the patient's MRI before treatment. They are usually 3-4 treatment points, as a reference for the therapist during the treatment process. Thirdly, during treatment, patients generally adopted a supine position on the treatment bed, with both lower limbs in abduction and internal rotation of 15 degrees, for better treatment results. Finally, during the treatment process, the intensity of the shock wave is adjusted based on the patient's tolerance to pain, and the following treatment parameters are set and recorded: energy level (2-3); number of pulses (500 impacts per treatment point for a total of 2000 impacts), energy flux density (0.50 mJ/mm2), and a frequency of 2-3Hz. One course of treatment is 15 days, with a total of 2 courses. The interval between the two courses is 30 days, and the treatment period is a total of 12 weeks.

Before and after treatment, patients were asked to assist using crutches. It is important to ensure strict weightlessness within one month after treatment. Partial weight-bearing is allowed 2-3 months after treatment. The traditional Chinese medicine for tonifying the kidney and promoting blood circulation (femoral head necrosis healing capsule,0.75g p.o. Bid for 12months, internal use of traditional Chinese medicine preparations in hospitals) and Risedronate Sodium Tablets (35 mg p.o. q.w. for 9 months) were administered to each patient.

The patients were followed, examined and evaluated by the same physician at the outpatient department at 3, 6, and 12 months after the second procedure. Pain was calculated through the Visual Analog Scale (VAS) in millimeters, clinical functional assessment was made by the Harris Hip Scores (HHS). Imaging examination including pelvic radiograph X-ray (Anteroposterior (AP) + frog position) were used to assess the size and location of the lesion, congruency of the femoral head, presence of a crescent sign, and degenerative changes of the hip joint. X-rays and double hip MRI were performed at 3 months, 6 months, and 12 months after treatment and at the final follow-up, evaluating the changes in lesion size, the congruency of the articular surface, and the presence of bone marrow edema. The severity of bone marrow edema is described as 5 levels: graded 0 for no bone marrow edema, 1 for perinecrotic bone marrow edema, 2 for bone marrow edema extended into femoral head, 3 for bone marrow edema extended into neck of femur, and 4 for bone marrow edema extended into intertrochanteric region [12]. We also focused on clinical safety and the recording and management of adverse events during the treatment process. The primary endpoint of the study was the need for surgery, including hip preservation surgery and total hip arthroplasty (THA) during the follow-

| Table 2: The VAS and Harris hip scores before and after ESWT | | | | |
|---|---|---|---|---|
| | Before ESWT | | After ESWT (months) | |
| Variable | T0 | T1(3 month) | T2(6 month) | T3(12month) |
| VAS* | 5.54±1.19 | 2.34±0.61 | 1.97±0.74 | 1.92±0.43 |
| *P* value | <0.001 | <0.001 | <0.001 | <0.001 |
| HSS* | 75.51±5.14 | 90.05±3.72 | 92.36±2.47 | 92.21±4.53 |
| *P* value | <0.001 | <0.001 | <0.001 | <0.001 |
| VAS: visual analog scale; ESWT: extracorporeal shock wave therapy; and HSS = Harris hip score. | | | | |

**Table 3: Overall clinical outcomes after ESWT.**

| Clinical outcome | ARCO grade I | ARCO grade-II | ARCO grade-III |
|---|---|---|---|
| | no. (%) | no. (%) | no. (%) |
| Improved | 90(85.71%) | 139(48.09%) | 29(49.15%) |
| Unchanged | 13(12.38%) | 82(28.37%) | 16(27.12%) |
| Worse | 2(1.90%) | 68(23.53%) | 14(23.73%) |
| Total hip arthroplasty | 0(0%) | 39(13.49%) | 13(22.03%) |

ESWT: extracorporeal shock wave therapy; ARCO: the Association Research Circulation Osseous.

**Table 4: Changes on radiograph and MR image before and after treatment**

| Variable | Before ESWT | After ESWT | P-value |
|---|---|---|---|
| ON lesion (%) | 42.57±3.76 | 34.41±4.35 | 0.074 |
| Bone marrow edema | | | |
| Grade 0 | 133 | 309 | 0.027 |
| Grade 1 | 46 | 47 | |
| Grade 2 | 142 | 64 | |
| Grade 3 | 100 | 26 | |
| Grade 4 | 32 | 7 | |

T values, given as the mean and standard deviation with the range in parentheses, represent the percentage of the involved area of the femoral head.
ESWT: extracorporeal shockwave therapy; ONFH = osteonecrosis of the femoral head.

up. The clinical outcome description refers to these standards[13]:"improved": clinical success was defined when there were significant improvements in pain and function of the affected hip after treatment; "unchanged": imaging ,success was defined when there were very little or no changes after treatment; "worsened": was defined when more pain and less function were noted after treatment.

**Statistical Analysis**

SPSS 19.0 software (Chicago, IL) were applied to analysis clinical data of patients. The mean and standard deviations (SD) were calculated for the HHS and VAS scores before and after the shock wave treatment using t-tests. The overall clinical outcomes and the changes in lesion size were compared statistically using a chi-square test for statistical significance using a 95% confidence interval ($p<0.05$).

## Results

A total of 453 patients (270 males, 183 females) with ONFH were enrolled during the period from June 2019 to August 2021. The mean follow-up duration was 39.81±7.94 months (range 26 to 50 months), (Table 1).

Compared with pretherapy (T0), the pain was alleviated to varying degrees, the HHS was significantly improved, and the VAS was significantly reduced at T1-2 (3- and 6-months post-treatment) after therapeutic intervention ($P<.05$). In the VAS and HHS score during the peri-treatment time, the mean improvement between T0 and T1, T2, T3 (12 months post-treatment), and between T1 and T2 had significant statistical significance ($P<.05$), and the HHS of T1 and T3 also had significant statistical significance ($P<.05$), while the mean VAS and HHS improvement between T2 and T3 had no significant statistical significance, (Table 2).

The clinical success (improvement) was observed in 85.71% of ARCO stage I patients, 48.09% of ARCO stage II patients, and 49.15% of ARCO stage III patients. Imaging success (unchanged) was observed in 12.38% stage I hips, 28.37% of stage II hips, and 27.12% of stage III hips, respectively. Thirteen patients in ARCO stage III and thirty-nine patients in ARCO stage II underwent THA during the follow-up because of aggravated disease with unacceptable pain and hip dysfunction. The hip joint survival rate of stage II and stage III patients was 86.51% and 77.97%, respectively, (Table 3).

The follow-up results of AP pelvic and frog position X-ray showed that after treatment, most of the patient's femoral head morphology was still acceptable, and the area of femoral head necrosis did not change significantly. However, satisfyingly, there was significant bone repair in the area of femoral head necrosis, bone density had increased, and X-ray showed obvious hardening of the necrotic area boundary (Fig 2). MRI examination results indicated mild or no obvious bone marrow edema in the femoral head and neck, and a small amount of fluid accumulation in the hip joint cavity. The clinical results before and at final follow up are shown in table 4.

We did not find any serious adverse events in this study. A common complication is that some patients may experience temporary bruising and mild local swelling after treatment, but these events will be relieved within a few days. During the treatment process, we did not observe any significant vascular or neurological damage during the treatment process, nor did we find any systemic issues related to ESWT.

## Discussion

ONFH is a chronic progressive disease, with a hidden onset and high disability rate. A high incidence of ONFH is reported in young and middle-aged people [1,14]. The lack of an effective treatment leads to a severe collapse of the femoral head within 1 to 4 years, resulting in joint dysfunction, and requiring total hip arthroplasty (THA) [15-16].When middle-aged and young people underwent their first THA, they will be exposed to one or even multiple joint revisions in the future, which will have a significant impact on the patient's personal physical and mental health, family economic burden, and social development.

At present, although many hip preservation surgical procedures have been proposed, both domestically and internationally, scientific evidence is insufficient, clinical reports are uncertain, and surgical costs are high. Patients still have many problems and complications after surgery, such as how to balance bed rest and mobility, and the chance of further worsening and collapse of the femoral head after non arthtoplasty surgery. These problems need to be faced and solved, and further exploration is needed.

Due to the incomplete elucidation of the pathogenesis of ONFH, it is difficult to prevent and treat it from the source.

Therefore, early diagnosis and effective treatment are the key to treating early femoral head necrosis. Considering that femoral head necrosis tendency to appear in younger patients, to carry out reasonable and effective hip preservation treatment is still an urgent problem that orthopedic physicians need to solve. In the face of the current situation, as orthopedic physicians, we have a responsibility to help ONFH patients overcome the pain of bone necrosis, explore its pathogenesis, and find more effective early hip preservation treatment methods to save more ONFH patients' femoral heads.

In recent years, ESWT has been widely used in clinical practice because of its safe and non-invasive effects, as well as the minimal complications associated with its use [5]. Scientific literature suggests that ESWT is an effective non-invasive intervention in the early stages of ONFH with good therapeutic effects. A recent meta-analysis study[17] indicates that ESWT has an effect on pain relief and has a limited effect on motion and function. Its effect may be better than in the surgical groups (core decompression and core decompression with bone grafting). Unfortunately, shock waves cannot decrease the lesion area in the femoral head as shown in MRI and stop disease progression. Alkhawashki, Hazem M et al[18] assessed the effectiveness of ESWT in reducing pain, improving range of motion (ROM) and delaying the surgical intervention in 24 patients with AVN of femoral head and recommended the use of ESWT in treating AVN of bone whether of femoral head or other sites prior to the collapse of the articular surface. Fuqiang Gao et al. [19] applied focused high-energy extracorporeal shock wave therapy to 335 patients (528 hips) with ONFH, and the research result showed that the clinical effect of high-energy extracorporeal shock wave therapy on ONFH was significant, effectively relieving pain and improving hip joint function. A prospective randomized controlled trial confirms that high energy ESWT can be successfully used to reduce the probability of glucocorticoid induced ONFH. ESWT can be recommended for the prevention and intervention of ONFH in high-risk populations receiving high-dose glucocorticoid therapy[20].

Our research results indicate that compared with before treatment, Harris scores at all stages of follow-up after treatment were significantly improved and VAS scores were significantly decreased. VAS scores decreased from 5.54 ± 1.19 to 1.92 ± 0.43, and Harris scores increased from 75.51 ± 5.14 to 92.21 ± 4.53 ($P<0.001$). The hip joint survival rate of stage II and stage III patients was 86.51% and 77.97% ($P<0.05$). ESWT also showed a significant impact on the area of femoral head bone marrow edema, significantly reducing the area of femoral head bone marrow edema. Hip bone marrow edema is the main cause of hip pain, which confirms that ESWT can significantly provide pain relief and enabling functional recovery by reducing it. This is consistent with previous research results[21-22].

Although the clinical efficacy is satisfactory, the mechanism of ESWT in the treatment of ONFH is not completely clear, yet [23]. Zhai L, et al proposed that moderate extracorporeal shock wave intensity can enhance mesenchymal stem cells (MSCs) proliferation, inducing the development of MSCs into osteoblasts, and preventing them from converting in adipocytes[24]. Previous studies have also shown that shock waves can induce osteoblast activity in osteoporotic bone during the regulation of bone metabolism and inhibit osteoclasts [25,26]. Relevant animal experiments have shown that ESWT significantly reduced IL-1α, IL-4, IL-6 and other proinflammatory cytokines in mice on the sixth day after treatment[27]. Ma, Huan-Zhi et al. [28] conducted a histomorphometric analysis on the necrotic femoral head of rabbits treated with ESWT and confirmed that the bone mass of necrotic femoral heads treated with shock waves increases, and further confirmed that ESWT may promote bone repair in necrotic femoral heads through the proliferation and activation of osteoblasts.

## Conclusion

Our research evidence supports that ESWT definitely represents an effective, reliable, and safe clinical treatment therapeutic method for early and middle stages of ONFH with BMES. It is necessary to conduct multicenter randomized controlled trials to ultimately demonstrate the efficacy of ESWT.

**Declaration of patient consent:** The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

**Conflicts of Interest:** Nil. **Source of Support:** None.

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