

Guidelines for High-energy Focused Shock Wave Therapy in Non-traumatic Osteonecrosis of the Femoral Head in Adults (2025 Edition)

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Abstract

Non-traumatic osteonecrosis of the femoral head (NONFH) is a common and refractory orthopedic disease that leads to disability and is a frequent cause of hip joint dysfunction and pain. This condition imposes a significant burden on patients, their families, and society. Extracorporeal shock wave therapy (ESWT) is a non-invasive, safe, and effective treatment that has been widely used in the clinical management of musculoskeletal diseases, including NONFH. However, the current application of ESWT for NONFH lacks a unified consensus regarding treatment protocols and evaluation methods, limiting its widespread adoption. Consequently, developing standardized, scientific, and effective ESWT interventions for patients with early- and mid-stage NONFH remains a critical concern for clinicians. These guidelines have been developed under the organization of the Third Medical Center of the Chinese PLA General Hospital and the China-Japan Friendship Hospital, with contributions from the Shock Wave Medical Professional Committee of the Chinese Research Hospital Association and experts in ONFH and ESWT. It references the latest domestic and international literature, integrates domestic clinical experience and actual conditions, and employs the modified 2011 Oxford Centre for Evidence-Based Medicine (OCEBM) levels of evidence and grades of recommendation. Guidelines are developed under the guidance of the WHO Handbook for Guideline Development (2014 Edition) and the Chinese Principles for the Development and Revision of Clinical Guidelines (2022 Edition). The Appraisal of Guidelines for Research and Evaluation II (AGREE II), Reporting Items for Practice Guidelines in Healthcare, and the Appraisal of Guidelines for Research and Evaluation in China (AGREE-China) were also referenced for evaluation. Nine clinical questions of utmost concern to physicians were selected, leading to the formation of nine evidence-based recommendations. These guidelines aim to provide constructive recommendations and a basis for the promotion and application of ESWT in the treatment of NONFH, thereby enhancing the scientific rigor and standardization of ESWT.

Keywords: Shockwave, Extracorporeal shock wave therapy, Osteonecrosis of the femoral head, Evidence-based medicine, Physical therapy

Introduction

Osteonecrosis of the femoral head (ONFH) is a common yet refractory disease that may cause physical disability. It is also the leading cause of hip joint dysfunction and local pain. Its primary histological characteristic can be described as the progression where progressive tissue necrosis and bone trabeculae fractures caused by death of osteocytes and bone marrow ischemia, attributed to local obstruction of blood supply, eventually lead to bone structure deformation and partial collapse [1]. ONFH can be described as traumatic and non-traumatic based on etiological differences, whereas non-traumatic ONFH (NONFH) is considered more widespread and obtains a high incident rate. Therefore, the following guidelines will

focus on the ESWT intervention for NONFH.

NONFH has an early onset age. The disease progresses insidiously, mainly affecting the young and middle-aged population, causing collapse of the femoral head, joint damage, and secondary hip-joint arthritis. The pathogenesis of NONFH is currently under debate. Popular hypotheses include coagulation disorders, lipid metabolic dysfunction, osteogenesis disorders, and vascularization impairment. The 2015 Chinese nationwide epidemiological investigation of NONFH shows that the overall prevalence of NONFH in the Chinese population over 15 years old was 0.725%. Among these, systemic steroid treatment, habitual drinking (alcohol abuse), smoking, hip trauma (dislocation or fracture), abnormal lipid metabolism,

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decompression sickness, and radiation exposure are the top causes [2]. NONFH can cause physical disability if there is a lack of early intervention, which may lead to total hip arthroplasty (THA), bringing a heavy burden to the patients and their families. Therefore, it is high time to call for appropriate therapeutic techniques for the early diagnosis and treatment of NONFH, halting disease progression, and postponing the timing of THA.

As a non-invasive, safe, and effective therapeutic strategy, extracorporeal shock wave therapy (ESWT) has been widely applied to the clinical treatment of multiple musculoskeletal disorders, including NONFH. Previous clinical practices and studies suggest that ESWT serves as a fair technique for early non-invasive intervention of NONFH due to its improvement in the patients' hip function, pain, and bone marrow edema [3]. However, there is still an absence of consensus on the indications, indexes, and assessment protocols of ESWT, restricting its promotion and application. For the purposes of elevating the efficacy, scientific nature, and standardization of ESWT for NONFH, the Third Medical Center of the General Hospital of CPLA and China–Japan Friendship Hospital (CJFH) have organized Chinese experts on ONFH and ESWT, referenced the latest literature while combining clinical experience and actuality to jointly develop the Guidelines for High-energy Focused Shock Wave Therapy in Nontraumatic Osteonecrosis of the Femoral Head in Adults (2025 edition). These guidelines aim to provide constructive recommendations and a basis for the promotion and application of ESWT for NONFH.

Materials and Method

Institutions and members of the expert committee

These guidelines have been developed under the organization of the Third Medical Center of the Chinese PLA General Hospital and the

CJFH, with contributions from the Shock Wave Medical Professional Committee of the Chinese Research Hospital Association and experts in ONFH and ESWT. The program was launched on December 18, 2024, and finished on August 31, 2025. Guidelines are developed jointly by experts in orthopedics, rehabilitation, evidence-based medicine, etc. Working groups include the steering committee for guideline development, the expert committee for guideline development, the working group for evidence evaluation and writing, and the working group for methodology and coordination. All members of the expert committee have no conflicts of interest related to these guidelines. Conflicts of interest forms were completed.

Methodology

Guidelines are developed under the guidance of the WHO Handbook for Guideline Development (2014 Edition) and the Chinese Principles for the Development and Revision of Clinical Guidelines (2022 Edition) [4]. The Appraisal of Guidelines for Research and Evaluation II (AGREE II) [5], Reporting Items for Practice Guidelines in Healthcare [6], and the Appraisal of Guidelines for Research and Evaluation in China (AGREE-China) were also referenced for evaluation. The development plan was strictly followed throughout the process.

Target users

These guidelines were developed for physicians, medical professionals, researchers, and instructors in the field of ONFH or ESWT.

Proposal, selection, and determination of the clinical questions

The expert committee primarily proposed 12 clinical questions at the launch meeting through brainstorming [7]. Nine questions were

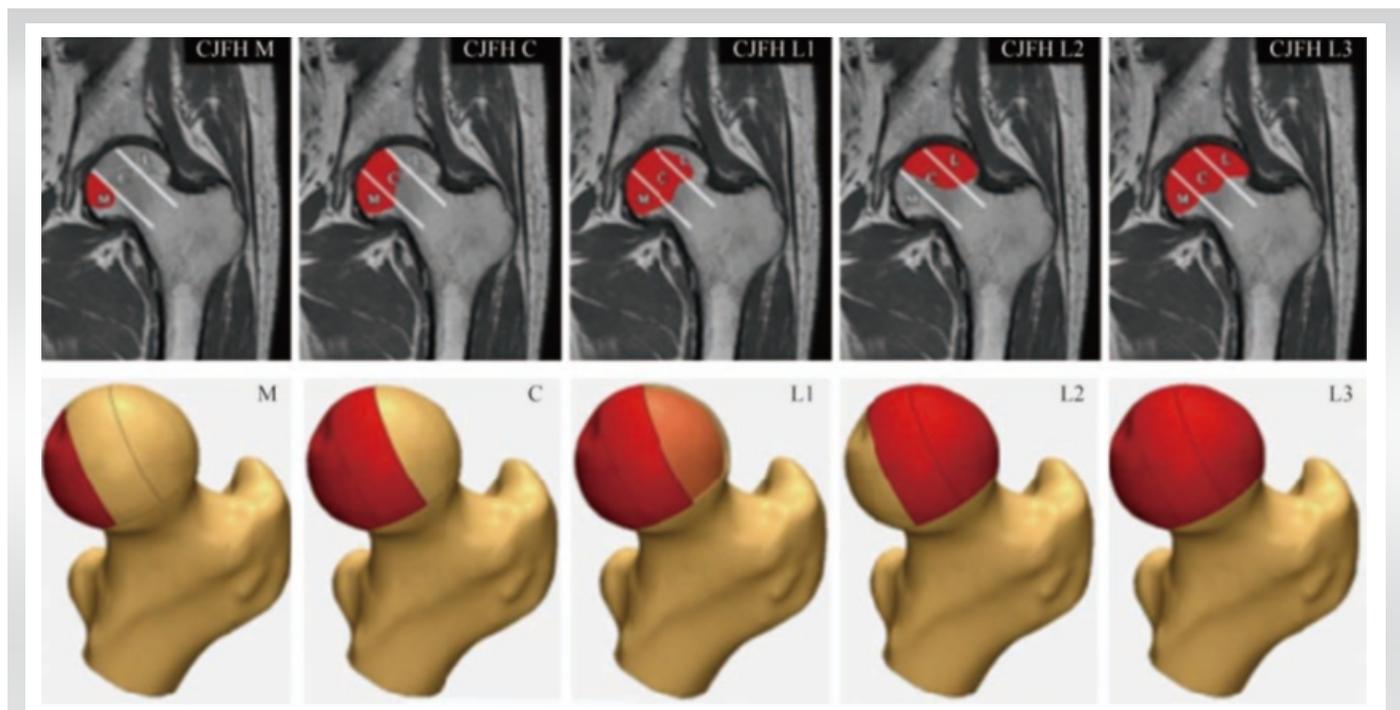


Figure 1: Schematic for China–Japan Friendship Hospital classification [13].

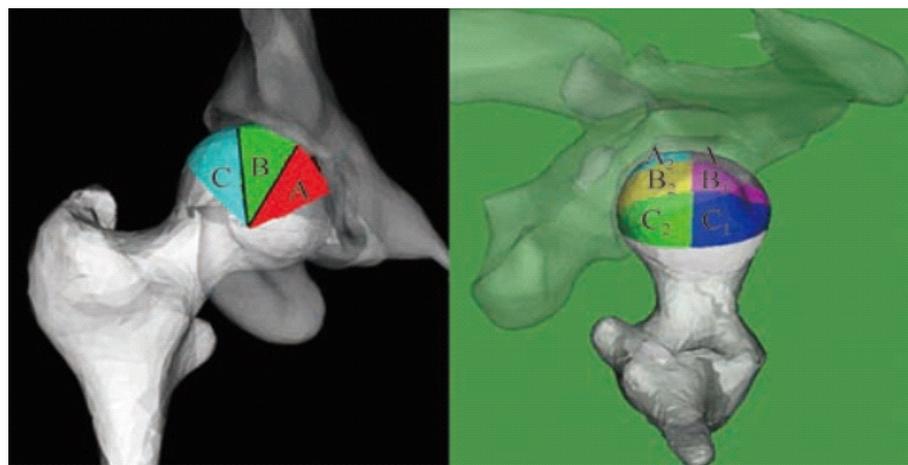


Figure 2: Schematic for three-dimensional magnetic resonance imaging reconstruction classification.

selected to be included after further discussion and investigations by the guideline working groups.

Strategies for literature search

The expert committee deconstructed the nine clinical questions mentioned previously based on the Population, Intervention, Comparison, and Outcome (PICO) principle into population, intervention, comparison, and outcome. In these guidelines, P refers to patients with NONFH, I to high-energy focused ESWT, C to other non-surgical interventions, and O to improvements or reductions in joint function, pain, and imaging outcomes.

A systematic search of the English and Chinese literature before November 1st, 2024 was carried out using keywords following the PICO principle in databases including Medline, Web of Science, the Cochrane Library, China National Knowledge Infrastructure, Wanfang Data, the Chinese Biomedical Literature Database, the National Institute for Health and Clinical Excellence, the National Guideline Clearinghouse, and the official website of the World Health Organization. Systematic reviews and meta-analyses were prioritized as the primary types of included literature; supplements include original studies (including randomized controlled trials, cohort studies, case-control studies, case series, and epidemiological surveys), and relevant guidelines in the ONFH field. Studies with low quality or methodological errors were excluded. Terms used as keywords include “non-traumatic osteonecrosis of the femoral head,” “non-traumatic avascular necrosis of the femoral head,” “shockwave,” “shock wave,” “NONFH,” and “NANFH,” among others. The retrieved literature was screened based on the inclusion and exclusion criteria stated.

Standards for evidence levels and strength of recommendation

These guidelines adopt the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence on therapy/prevention/etiology/harm [8]. Adjustments were made according to the specific circumstances of the field by means of the nominal group technique.

Evidence levels

1a: Systematic reviews of homogeneous randomized controlled trials (RCTs) or systematic reviews of well-conducted cohort studies. 1b: Individual RCTs with a narrow 95% confidence interval or individual cohort studies with consistent baseline characteristics and follow-up rates >80%. 1c: Universal failure with conventional treatment or case series reporting uniform outcomes, such as complete mortality or survival.

2a: Systematic reviews of homogeneous cohort studies, or systematic reviews of retrospective cohort studies or RCTs with untreated control groups. 2b: Individual cohort studies and lower-quality RCTs, individual retrospective cohort studies, or RCTs with untreated control groups. 2c: Outcome studies.

3a: Systematic reviews of homogeneous case-control studies. 3b: Individual case-control studies.

4: Case series or lower-quality case-control studies; series with low-quality cohorts or follow-up rates <80%.

5: Expert opinions without analytical evaluation or opinions based on pathophysiological reasoning.

Strength of recommendations

- Grade A: Recommended. Recommendations with highly effective evidence (evidence level 1).
- Grade B: Recommended under specific conditions. Recommendations with effective evidence (evidence levels 2 and 3). These recommendations may be altered accordingly with the emergence of higher-quality evidence in the future.
- Grade C: Results should be applied with caution. Recommendations with evidence are effective under specific conditions (evidence level 4).
- Grade D: Results can only be applied under specific circumstances. Evidence with limited effectiveness (evidence level 5).

Formation of opinions

Nine recommendations were formed by the expert committee based on the quality of evidence. The preferences and values of Chinese patients, as well as the cost-effectiveness and benefit-risk balance of interventions, were carefully considered. These recommendations were discussed and reviewed during face-to-face meetings, leading to consensus on the final contents and stances of the recommendations.

Publication and update of the guidelines

These guidelines will be disseminated after publication through various channels, including academic conferences or workshops, printed media, and the Internet. These guidelines will be updated every 2 years following the international guideline update process for revision.

Guideline registration

These guidelines have been registered through the platform of

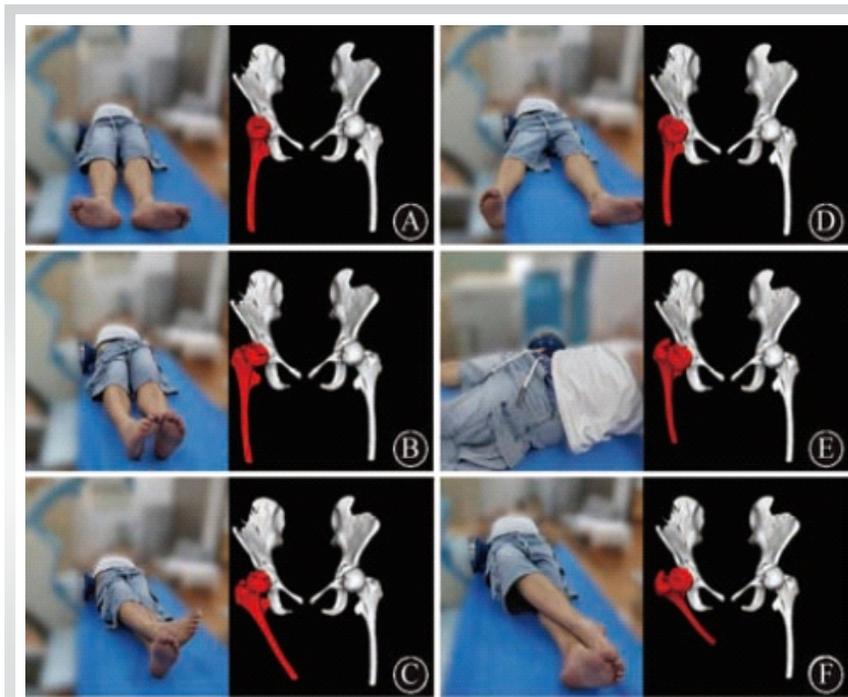


Figure 3: Treatment positions for different areas guided by extracorporeal simulation software. (a) External rotation for anterior medial area; (b) Supine position for anterior central area; (c) Adduction-internal rotation position for anterior lateral area; (d) Extension – external rotation position for posterior medial area; (e) Extension position for posterior central area; (f) adduction-extension-internal rotation position for posterior lateral area [4,15].

Practice Guideline Registration for Transparency (PREPARE).
Registration number: PREPARE-2024CN1206.

Clinical Staging and Classification of NONFH

Staging

Currently, there are various staging methods for NONFH, including the commonly adopted Ficat-Arlet staging [9], Steinberg staging [10], the Association Research Circulation Osseous (ARCO) staging, and the Chinese staging [11,12]. The ARCO staging was developed in 1991 by the ARCO committee based on the Ficat-Arlet, Steinberg, and the Japanese Bone Necrosis Study Group staging. Compared to previous staging systems, it is more systematic, comprehensive, and practical, offering significant improvements in diagnosis, treatment evaluation, and prognosis. Guidelines recommend using the 2019 version of the ARCO staging (Table 1) when assessing the indications for ESWT in ONFH, which was approved at the 2019 ARCO Annual Meeting held in Dalian, China.

Classification

CJFH Classification

In 2014, the Joint Surgery Branch of the Chinese Orthopaedic Association organized Chinese experts in the field of osteonecrosis research and treatment to develop the clinical diagnosis and treatment Guidelines for ONFH, which were later updated in 2016. Among these, the use of the CJFH classification for prognostic evaluation and treatment assessment was advised. As a subtype of ONFH, NONFH is also adaptable to the CJFH classification.

The CJFH classification [13] utilizes the magnetic resonance imaging (MRI) or computed tomography scan images in the coronal median

plane, dividing the coronal median section of the femoral head into the medial, central, and lateral pillars along the anterior and posterior margins of the round ligament. Based on the involvement of these three columns by the necrotic area, ONFH is further classified into five types (Fig. 1): Type M, necrosis confined to the medial pillar; type C, necrosis occupying only the medial and central pillars; and type L, necrosis occupying varying degrees of the lateral pillar. While type L was further divided into three subtypes: type L1, three pillars involved, but the lateral pillar is partially preserved; type L2, the entire lateral pillar and part of the central pillar are involved; and type L3, the whole femoral head is involved. The CJFH classification can be easily applied as it avoids defects in anatomical variation or poor alignment of the hip. The reliability and repeatability of its predictions regarding ONFH collapses make it a useful guide for selecting treatment strategies.

Three-dimensional (3D)-MRI reconstruction classification

To improve the accuracy of necrotic area assessment and efficacy of ESWT, Ding et al. [14], inspired by the Japanese Investigation Committee classification, proposed a 3D reconstruction classification for ONFH based on MRI (Table 2 and Fig. 2). This 3D-

MRI reconstruction classification divides the weight-bearing area of the femoral head into anterior and posterior parts along the central coronal line. The front area is zone 1, and the posterior area is zone 2. In addition, the area of weight on the acetabulum is divided into three parts: the inner part is the A zone, the outer part is the B zone, and above the acetabular covering part is the C zone. This results in six regions: anterior medial (A1), posterior medial (A2), anterior central (B1), posterior central (B2), anterior lateral (C1), and posterior lateral (C2). This classification takes the energy attenuation of shock waves (SW) within the femoral head fully into account, making it more suitable for ESWT treatment, providing valuable insights to personalized ESWT for NONFH.

Physics of SW

SW is a special type of mechanical wave with acoustic characteristics. As an effective mechanical stimulus, SW can reach deep tissues by penetrating media. SW propagates through alternating decompression and compression (rarefaction and condensation) of the media, creating cavitation, tensile forces, and shear forces to provide non-damaging mechanical stimulation to surrounding cells [16]. Thus, triggering the self-healing mechanisms of tissues results in various biological effects, such as tissue repair, physical-mechanical action, anti-inflammation, nerve block, and vasodilation [17]. The main physical characteristic of SW is stated as follows:

A. Mechanical effect: SWs release energy mostly at the interfaces of tissues with different densities in the human body, generating mechanical forces such as compression and shear.

B. Cavitation: Micro-bubbles or cavitation bubbles in the interstitial

Table 1: The 2019 revised ARCO staging for osteonecrosis of the femoral head [12]

ARCO stage	Image findings
I	X-ray: Normal
	MRI: Low-signal band on T1-weighted MRI
II	X-ray: Abnormal
	MRI: Abnormal
III	Subchondral fracture on X-ray or CT
IIIA (early)	Femoral head depression ≤ 2 mm
IIIB (late)	Femoral head depression >2 mm
IV	X-ray: Osteoarthritis

ARCO: Association Research Circulation Osseous, MRI: Magnetic resonance imaging, CT: Computed tomography.

process of ESWT into four distinct phases: The physical phase, physicochemical phase, chemical phase, and biological phase. During this process, SW penetrates tissue layers, generating significant pressure within the femoral head, which induces mechanical stimulation and subsequently promotes tissue repair. These mechanical effects primarily occur in regions with significant impedance gradients, such as the interface between bone and soft tissue or the sclerotic zone surrounding the necrotic area of the femoral head. At the interface between normal and necrotic tissues, SW induces energy deposition, enabling the transformation of mechanical effects into biological effects through mechanical conduction [21-23]. Previous studies have shown that ESWT may regulate various cytokines, such as von Willebrand factor (vWF), vascular endothelial growth factor, bone morphogenetic protein-2, osteocalcin, and insulin-like growth factor-1, which play critical roles in the healing process. Meanwhile, the unique nerve-blocking property of SWs

fluid collapse and expand under the influence of SWs, generating localized effects as the energy of SW accumulates in the area.

C. Thermal effect: The mechanical effect and cavitation result in energy transformation into heat jointly within the human body [18,19].

Based on generation strategies, SWs can be classified into electrohydraulic SW, piezoelectric SW, electromagnetic SW, and pneumatic ballistic SW. SWs can also be categorized into focused SW or radial SW according to the means of propagation.

The main physical parameters of SW involved in the treatment process include SW energy, pressure field, and energy flux density (EFD). Pressure field refers to the symmetrical region surrounding the rear of the SW generator, and its shape varies depending on the type of therapeutic devices. In general, the pressure field shape of electrohydraulic SW is elliptical, electromagnetic SWs have spindle-shaped ones, while piezoelectric SWs have spherical-shaped pressure fields. SW energy is calculated by performing a time integration of the pressure/time function at a specific location within the pressure field, followed by volume integration. SW energy is expressed in millijoules (mJ). EFD refers to the energy passing through an area unit on the vertical cross-section in the direction of SW propagation, representing the concentration of SW energy. It is commonly expressed in millijoules per square millimeter (mJ/mm²), which is widely used to describe the treatment dose during ESWT [20].

Mechanisms of ESWT in Treating NONFH

The biological effects of SWs primarily include the following six aspects: Tissue repair and reconstruction, release of tissue adhesions, vasodilation and angiogenesis, analgesia and nerve block, disintegration of high-density tissues, and reduction of inflammation and infection.

Traditional theories categorize the therapeutic

contributes to the immediate alleviation of localized pain associated with ONFH, leading to improved joint function in NONFH patients [23,24].

Propagation of ESWT in the Femoral Head

During the treatment of NONFH, SW originates from the tip of the generator and sequentially passes through multiple tissue layers, including the skin, fat, muscle, joint capsule, and cartilage, before reaching the necrotic lesion within the femoral head. During the process, SW undergoes attenuation of energy, which is closely related to the impedance of the propagation media. Theories suggest reflection and scattering occur when SW crosses tissue interfaces, leading to energy loss. The greater the impedance difference, the higher the energy attenuation. Experiments demonstrate that focused SW experiences a loss of more than 50% of its energy for every 1 cm of tissue penetration [25,26]. Therefore, while radial SW can produce

Table 2: 3D-MRI reconstruction classification of ONFH [15]

Classification	Area	Explanation
A1	anterior medial	Anterior side of the femoral head + 50% inner side of the weight-bearing area
A2	posterior medial	Posterior side of the femoral head + 50% inner side of the weight-bearing area
B1	anterior central	Anterior side of femoral head + necrosis $\geq 50\%$ outer side of the weight-bearing
B2	posterior central	Posterior side of femoral head + necrosis $\geq 50\%$ outer side of the weight-bearing
C1	anterior lateral	Anterior side of femoral head + non-weight-bearing area
C2	posterior lateral	Posterior side of femoral head + non-weight-bearing area

3D: Three-dimensional, MRI: Magnetic resonance imaging, ONFH: Osteonecrosis of the femoral head

biological effects such as those of focused SW, it cannot provide the same therapeutic effect. As a result, the relative position of the SW source and the necrotic lesion in terms of direction and depth significantly affects the efficacy of ESWT. To maximize therapeutic outcomes, SW should propagate through the least number of tissue layers and cover the shortest distance to reach the necrotic lesion.

As previously mentioned, SWs can be categorized as focused SW or radial SW based on their generation strategies. Unlike radial SW, focused SW forms a parabolic lens to concentrate dispersed energy onto a single point [27]. To sum up, focused SW should be employed during treatment for its concentrated energy and strong penetration capability to ensure sufficient energy density at the target area.

Recommendation

- Background question 1: Why a high-energy focused shock wave?

Recommendation: High-energy focused SW is capable of performing sufficient propagation depth and energy density to produce a therapeutic effect in NONFH treatments. (Evidence level 1b, grade A recommendation)

Previous studies and clinical practices indicate that SW should perform sufficient propagation depth and energy density to produce a therapeutic effect in NONFH treatments. Both focused SW and radial SW possess distinct physical characteristics. Focused SW features high energy and a concentrated focus, whereas radial SW has lower energy but a broader effect area. Consequently, both types are suited for different clinical scenarios. Apart from a limited number of studies and case reports using radial SW for the treatment of NONFH [28], most research has employed focused SW, which has consistently shown favorable therapeutic outcomes. The femoral head is located deep within the body, and although radial SW can stimulate similar biological effects as focused SW, the attenuation of energy during propagation makes it challenging for radial SW to achieve therapeutic effects at the site of necrosis [22]. Therefore, the treatment of NONFH requires the use of medium- to high-energy focused SW with a propagation depth exceeding 10 cm. It is essential to note that some SW devices produce waves with sufficient propagation depth, such as focused SW, but fail to deliver adequate energy at the treatment target. Such devices are also unsuitable for treating NONFH.

- Background question 2: Can high-energy focused ESWT improve the clinical symptoms of NONFH?

Recommendation: High-energy focused ESWT has shown significant efficacy in the treatment of NONFH. High-energy focused ESWT reduces pain and improves joint function effectively in early- and mid-stage NONFH. (Evidence level 1a, grade A recommendation)

The biological effects of high-energy focused ESWT are believed to promote effective tissue repair, nerve block, and local inflammation reduction theoretically. Multiple clinical trials and meta-analyses [3,29-34] indicate that ESWT significantly improves Harris Hip Score (HHS) and reduces Visual Analog Scale (VAS) scores, showing alleviation in joint pain and enhancement in hip function among NONFH patients. A recent meta-analysis [30] reported that compared to control groups, patients receiving ESWT showed significant improvements in HHS (MD = -33.38; 95% CI: -46.31--20.45) and a marked reduction in VAS scores (MD = 4.64; 95% CI: 3.63-5.64). Another network meta-analysis suggests that

ESWT shows better pain relief effects than core decompression therapies, recommending ESWT for both short-term and long-term intervention [35].

- Background question 3: Can high-energy focused ESWT improve radiographic outcomes of NONFH?

Recommendation: High-energy focused ESWT can delay the radiographic progression of NONFH and reduce bone marrow edema. Growing evidence has shown its ability to reverse structural changes caused by necrosis. (Evidence level 2a, grade B recommendation)

Several clinical studies have proved that high-energy focused ESWT can delay the collapse of the femoral head and improve the survival rate of native hips. While theoretical studies suggest that ESWT can repair tissue damage caused by NONFH through various biological means, clinical studies have only shown improvement in bone marrow edema and trends of reduction in necrotic lesions. These limitations are often caused by trial design, follow-up duration, and sample size [30,31,36-38]. However, there has been growing evidence showing lesion reduction after ESWT. A 2-year follow-up conducted by Liu et al. found a significant reduction in the necrotic area after focused ESWT [34]. The latest meta-analysis conducted by Garcia et al. showed promising results. A decrease was found in the percentage of lesions at 12 months after ESWT, though with significant heterogeneity [39], which, on the other hand, supports the previously proposed limitations.

- Background question 4: Which types of NONFH are suitable for high-energy focused ESWT?

Recommendation: High-energy focused ESWT is suitable for adult NONFH patients in ARCO stages I to IIIA, especially those classified as type C, M, and some type L1-L2 patients under the CJFH classification. Therapeutic efficacy decreases with the advancement of stages and classifications. ESWT may also be used as a symptomatic treatment for ARCO IIIB-IV patients who refuse surgical intervention (Evidence level: 1a, grade A recommendation).

Although studies suggest that high-energy focused ESWT shows better therapeutic outcomes than core decompression and bone grafting in improving hip joint function during early-stage ONFH [40-42], there is no single treatment that is suitable for all ONFH types and stages. For NONFH cases that have progressed to the pre-collapse stage (some ARCO stage III-IV), particularly those classified as L3 under the CJFH classification, ESWT cannot replace surgical intervention, as it is unlikely to prevent collapses [40]. Based on these considerations, ESWT can be integrated as part of a cocktail therapy to alleviate pain, improve joint function, and accelerate bone healing for patients who cannot avoid surgical intervention [24].

- Background question 5: Can high-energy focused ESWT be used for the prevention of steroid-induced NONFH?

Recommendation: High-energy focused ESWT combined with pharmacological treatment can serve as an effective prevention strategy for steroid-induced NONFH. (Evidence level 2b, grade B recommendation)

A prospective randomized controlled trial investigated the effect of preventive high-energy focused ESWT combined with oral bisphosphonates and traditional Chinese medicine (for activating blood circulation, removing blood stasis, and liver-kidney nourishing) on the incidence of steroid-induced NONFH in patients receiving

high-dose steroid therapy. The results indicated that the incidence of NONFH in the treatment group was significantly lower than that in the control group within a year [43]. Therefore, we recommend using high-energy focused ESWT as a primary prevention strategy for patients undergoing high-dose steroid therapy. However, there is currently a lack of independent studies that investigate other risk factors and EFD in similar contexts.

• Background question 6: What are the contraindications for NONFH treatment with high-energy focused SW?

Recommendation: Absolute contraindications: Coagulation disorders, presence of thrombosis in the treatment area, severe cognitive impairments, or mental disorders.

Relative contraindications: Severe arrhythmias, poorly controlled severe hypertension, patients with pacemakers, patients with metastatic malignant tumors, pregnant women, patients with sensory dysfunction, and acute gout attacks.

Acute soft-tissue infections or skin lesions within the treatment area.

(Evidence level 5, grade D recommendation).

Clinical practices have shown that ESWT is a safe and effective treatment for NONFH with significant advantages [44]. In clinical trials and practice, common complications from high-energy focused ESWT for NONFH are usually limited to mild symptoms such as local ecchymosis or bruising [32]. However, the potential risks of ESWT should not be overlooked, especially for treatments with high-energy focused SW. It is recommended that clinicians be familiar with hip joint anatomy to avoid potential damage. There is currently a lack of specific studies on contraindications, and the guidelines and recommendations for this are mainly generated from previous guidelines, expert opinions, and clinical practices [19,45,46].

• Background question 7: How should EFD, shock number, and treatment courses be planned when using high-energy focused SW for NONFH?

Recommendation: EFD should start from a low-energy level and gradually increase based on the patient's endurance to pain. Generally, a medium to high EFD level is recommended, with a range greater than 0.28 mJ/mm^2 . The shock number should be adjusted based on the patient's recovery progress. For each treatment session, 3 to 5 treatment targets should be selected, focusing on the necrotic lesion and its edges. Each target should receive 500 to 1000 shocks per treatment. High-energy focused ESWT can be performed on a daily or every other day basis, with a total of five sessions per course. The total number of shocks per course should range from 8000 to 15,000. It is suggested to complete 5–8 treatment courses, with intervals of 2–3 months between each course. (Evidence level 2a, grade B recommendation)

Previous literature and clinical studies have shown that sufficient energy must be provided to achieve the desired effect of promoting NONFH repair. Recent research indicates a dose-dependent effect during ESWT [47]. The latest meta-analysis revealed that high EFD SWs are more effective than low EFD in terms of pain relief, functional improvement, and delaying disease progression. However, current studies are unable to establish a precise dose-response relationship between EFD and treatment efficacy [48]. Current guidelines suggest starting with low energy levels during NONFH treatment and gradually increasing to medium-high intensity SW, with the aid of VAS scores for guidance. According to the experience from multiple clinical

centers, the EFD for treating NONFH should not be $<0.28 \text{ mJ/mm}^2$. A multiple-session approach based on the patient's recovery is generally adopted. Treatment targets are selected around the necrotic area and its edges, with 3-5 targets per session, and each target receives 500–1000 shocks. Treatment is generally conducted on a daily or every other day basis, with a total of five sessions per course. The total number of shocks per course should range from 8000 to 15,000 [19,24]. This approach can be adjusted based on the patient's condition. Patients are recommended to avoid weight-bearing for 3 months and reduce weight-bearing for 6 months. Treatment courses should be repeated 5–8 times, with intervals of 2–3 months to ensure adequate tissue repair.

• Background question 8: How to select and locate the treatment target during focused ESWT properly?

Recommendation: For routine treatment, a localization method utilizing body landmarks and radiographic imaging methods can be used to position the treatment probe in the anterior or lateral aspect of the joint. The positioning of the patient should ensure the maximum exposure of the necrotic area and minimize SW attenuation. The patient can be guided to perform combined movements such as hip abduction, external rotation, adduction, and internal rotation, to form positions like the frog-leg posture or supine position. It is recommended to prioritize MRI-guided localization if allowed, combined with 3D reconstruction techniques to improve treatment accuracy. 3D-MRI reconstruction classification is also recommended for location guidance. Additionally, visual navigation technology can be adopted to develop a personalized treatment plan. Regardless of the localization method, it is always essential to ensure that the SW focus coincides with the necrotic area shown on the imaging, while avoiding critical blood vessels, nerves, and internal fixation, and promptly correcting any changes in the focus position. (Evidence level 2b, grade B recommendation)

As a non-invasive, non-surgical treatment, traditional focused ESWT often uses body landmarks or ultrasound for the selection of treatment sites. Because of the anatomical characteristics of the hip joint, it is recommended to select the operation sites in the anterior or lateral aspects of the joint, perpendicular to the femoral head. Studies have shown that imaging-assisted localization is more effective than pain-point localization in ESWT [49]. Other literature indicates that visual navigation helps improve the effectiveness of ESWT [14,50]. This approach aligns with the opinions in Chinese and international musculoskeletal disease treatment guidelines [19,51]. Since the femoral head, especially the weight-bearing area, with a high necrosis rate, is covered and obstructed by the acetabulum, significant energy attenuation can occur during treatment. A retrospective study showed that using 3D-MRI reconstruction classification for localization could reduce energy loss caused by anatomical obstruction effectively and improve the efficacy of ESWT in the early stages of ONFH [14,15] (Fig. 3).

Background question 9: How to evaluate the efficacy of high-energy focused ESWT for NONFH?

Recommendation: It is recommended to perform hip joint radiographic examinations before, immediately after, and at 3, 6, and 12 months after treatment. MRI should be used for patients in ARCO stage II. Other evaluations should include the HHS and VAS scores. It is recommended to describe the disease using the ARCO staging and

the CJFH classification when evaluating. (Evidence level 3a, grade B recommendation).

The commonly used assessment indicators for ONFH include symptoms (hip pain, joint function) and radiographic progression. While the HHS, VAS scores, and radiographic examinations are most frequently used in clinical practice and research, there is currently a lack of reliability and repeatability evaluations of these indicators in the assessment of ESWT efficacy. In terms of disease evaluation, the ARCO staging is a comprehensive and practical approach with high application value in diagnosis, treatment evaluation, and prognosis. It is universally recognized and commonly used in various clinical studies [1,12]. The imaging-based CJFH classification is also a convenient, accurate approach in predicting collapse, and is not influenced by anatomical variations or the patient's position. Studies have shown that the CJFH classification is reliable and highly repeatable, providing significant practical value in guiding treatment selection and prognosis analysis [52].

Challenges and prospects of high-energy focused ESWT for NONFH

In recent years, ESWT has been widely applied as a safe and effective treatment for musculoskeletal diseases, including NONFH. Previous clinical practices and research have demonstrated the efficacy of high-energy focused ESWT in improving the clinical symptoms and radiographic findings of NONFH through mechanical effects and biological mechanisms. The Chinese Technical Specifications for Construction of Shockwave Therapy Center [53] proposed in 2024 further promoted the standardization and application of ESWT in China. However, ESWT for ONFH still faces certain challenges and difficulties in clinical practice.

On one hand, the large volume, extensive range, and irregular shape of necrotic lesions in NONFH present challenges for precise targeting during high-energy focused ESWT. Localization methods are currently limited to relatively low precision. A single treatment target cannot cover the entire necrotic area, which may reduce the effectiveness of the therapy. On the other hand, the anatomical characteristics of the hip joint bring difficulties in energy delivery during the treatment process. The acetabulum and non-necrotic regions of the femoral head obstruct the necrotic lesions, resulting in significant energy loss and insufficient energy density on site. These challenges increase the requirements for selecting appropriate treatment sites. Moreover, we have seen evidence emerging in recent years showing the ability of ESWT in reducing the size of bone lesions and edema in ONFH, which was previously considered uncertain. It can be foreseen that with the continuous standardization of clinical practice and progress in further studies (especially ones with long-period follow-ups), better clinical outcomes of ESWT for NONFH will be seen in the near future.

In summary, achieving full coverage of NONFH necrotic lesions and minimizing energy loss during high-energy focused ESWT are key directions for future research. The introduction of 3D-MRI reconstruction classification for NONFH provides a novel approach to addressing these challenges. Pre-operative and intraoperative 3D reconstruction planning based on imaging, coupled with artificial intelligence (AI)-assisted ESWT, are to become promising trends in the future. By combining 3D techniques with AI-assisted localization

and energy control, it will be possible to guide optimal exposure of the bone necrosis area, reduce propagation distance of SW, and improve both the clinical and radiographic outcomes of NONFH. These approaches will achieve a "holistic treatment," addressing both the symptomatic and pathological changes.

This guideline is intended as expert advice and should not be considered mandatory requirements or legal grounds. It can be adapted to local conditions and tailored to suit the specific circumstances during clinical practice.

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