

Authors:

Yue Wen Ma, MD
Dong Lei Jiang, MM
Dai Zhang, MM
Xiao Bei Wang, MM
Xiao Tong Yu, MD

Affiliations:

From the Departments of Rehabilitation Medicine (YWM, DLJ, DZ) and Nuclear Medicine (XBW), the First Affiliated Hospital of China Medical University, Liaoning; and Institute of Meta-Synthesis Medicine, Beijing, China (XTY).

Correspondence:

All correspondence and requests for reprints should be addressed to: Yue Wen Ma, MD, Department of Rehabilitation Medicine, The First Affiliated Hospital of China Medical University, Shenyang 110001, Liaoning, China.

Disclosures:

Financial disclosure statements have been obtained, and no conflicts of interest have been reported by the authors or by any individuals in control of the content of this article.

Editor's Note:

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.ajpmr.com).

0894-9115/16/9509-e133

American Journal of Physical Medicine & Rehabilitation

Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially.

DOI: 10.1097/PHM.0000000000000484

CASE REPORT**OPEN**

Radial Extracorporeal Shock Wave Therapy in a Person With Advanced Osteonecrosis of the Femoral Head

ABSTRACT

Ma YW, Jiang DL, Zhang D, Wang XB, Yu XT: Radial extracorporeal shock wave therapy in a person with advanced osteonecrosis of the femoral head. *Am J Phys Med Rehabil* 2016;95:e133–e139.

This case report describes the first patient with avascular necrosis of the femoral head of Association Research Circulation Osseous stage IV, treated with radial extracorporeal shock wave therapy. By contrast, previous studies demonstrated the efficacy of a single treatment of focused extracorporeal shock wave therapy in improving pain and Harris Hip Scale in patients with avascular necrosis of the femoral head of Association Research Circulation Osseous stage I to III. The affected hip was treated with 6000 impulses of radial extracorporeal shock wave therapy at 10 Hz and an intensity ranging from 2.5 to 4.0 bar at 7-day intervals for 24 mos. The Harris Hip Scale values were 33, 43, 56, 77, 81, 88, and 92 at baseline and 1, 3, 6, 12, 18, and 24 mos, respectively. The radiographs showed that the subluxation of the right hip was slightly aggravated. Joint effusion was reduced, bone marrow edema disappeared, the density became more uniform, and the gluteal muscles were more developed based on magnetic resonance imaging. Increased tracer uptake was evident along the joint margin and superolateral aspect of the head both before and after radial extracorporeal shock wave therapy. This case report demonstrates the feasibility of long-term radial extracorporeal shock wave therapy in Association Research Circulation Osseous stage IV patients.

Key Words: Radial Extracorporeal Shock Wave, Avascular Necrosis of the Femoral Head, Association Research Circulation Osseous Stage IV

Avascular necrosis of the femoral head (AVNFH) is caused by insufficient blood supply and is histologically associated with osteocyte death, followed by osteoclastic resorption of dead trabeculae and apposition of new bone tissue,^{1,2} with risk factors of corticosteroid use, trauma or surgery at the hip, alcoholism, coagulopathy, and even genetic polymorphisms.³ The collapse of the femoral head is a result of mechanically weak bone subjected to weight-bearing, which is considered Association Research Circulation Osseous (ARCO) stage IV and can be

associated with incapacitating pain and immobility. Total hip arthroplasty (THA) is considered the most reliable option for patients with collapse of the femoral head.⁴ Extracorporeal shock wave therapy (ESWT), a biophysical modality, was reported to successfully treat patients with ARCO stages I–III, yielding an improvement in pain symptom, and mobility, higher scores on the Harris Hip Scale (HHS), and partial or complete healing as shown by magnetic resonance imaging (MRI).^{5–13} The exact mechanisms of the ESWT benefits in AVNFB remain unknown, although it is thought that shock waves may cause an increase in neovascularization and the expression of angiogenesis-related growth factors, in addition to bone remodeling and regeneration.^{9,12} In addition, ESWT significantly upregulates the expression of BMP-2 in necrotic femoral heads, and the process of the repair of femoral head necrosis is thus accelerated.¹⁰ The ESWT reported in the existing literature is the focused form. In this study, radial extracorporeal shock waves broadcasted by a ballistic shock wave generator was first used, which is safer and simpler to operate with the similar therapy mechanism.^{14,15} Radial ESWT (RSWT) has been widely used in musculoskeletal disorders, such as tendinopathies and bone defects^{16–19} and was cleared by the Food and Drug Administration for muscle pain and local blood circulation (as class I). A patient with AVNFB with ARCO stage IV who was treated successfully after 24 mos of RSWT is described.

CASE DESCRIPTION

The patient was a 57-yr-old woman who was diagnosed with congenital hip dysplasia with subluxation and AVNFB classified as ARCO stage IV 2.5 yrs before receiving RSWT, with no history of hypertension, cardiovascular disease, diabetes mellitus, corticosteroid therapy, trauma, use of anticoagulant drugs, smoking, or drinking. The patient reported that her main complaints were difficulty in walking and sitting and disturbed sleep because of right hip pain. The patient opted to undergo RSWT in lieu of THA.

The shock waves were applied using a radial extracorporeal shock wave generator (MASTERPULS MP100, STORZ MEDICAL AG, Switzerland). The frequency applied was 10 Hz, with a pressure starting at 2.5 bar and gradually increasing to 4.5 bar depending on the patient's tolerance without local anesthetics. If the patient did not feel pain or soreness at the time of or the day after RSWT, the intensity would either be increased by 0.2 bar or be

maintained. The procedure was performed once a week for 24 mos as follows. (1) Shock waves were focused around the middle lateral one-third point of the right groin with the R15 (diameter, 15 mm) transmitter for 2000 pulses with the patient in the supine position. (2) The patient was asked to lie on her healthy side with the hip and knee at approximately 90 degrees of flexion. The shock waves were focused approximately 5 cm medial and anterior to the greater trochanter of the femur, including the tender points, with the D20 (diameter, 15 mm) transmitter for 1000 pulses. This is a dynamic process in which the area of maximum tenderness is treated circumferentially, starting from the most painful site. (3) Finally, the D20 transmitter was exchanged with a deep transmitter (diameter, 15 mm), which was focused on the same area as the D20 transmitter for 3000 pulses. The treatment area was prepared with a coupling gel to minimize the loss of shock wave energy at the interface between the head of the device and the skin.

The patient underwent physical examinations and questioning to elicit information that enabled the authors to rank the patient using the HHS²⁰ before and at 1, 3, 6, 12, 18, and 24 mos after beginning treatment. The HHS gives 91 points for assessment of pain and function and 9 points for range of motion and deformity. Higher values are better. The intensity of pain was recorded on a visual analog scale (VAS), and standardized manual muscle testing (MMT) was performed as reported by Palmer and Epler.²¹ Neutral anteroposterior and lateral radiographs were obtained before RSWT and 12 and 24 mos afterward and MRI was performed before RSWT and 24 mos afterward. The patient underwent planar bone scintigraphy before and after the 24-mo-long course, and single-photon emission computed tomography/computed tomography was performed after the second bone scan. Semiquantitative evaluation of the planar bone scintigraphy images of the lesion was performed by drawing an irregular region of interest (ROI). First, the ratio of the mean uptake count of the ROI of the lesion relative to the mirror contralateral site was calculated. Second, the highest uptake count in the ROI of each side was automatically determined with the workstation, and the ratio of the highest uptake count of the lesion site relative to the contralateral site was also calculated.

The 24-mo-long RSWT was completed without complications, and the pain or soreness occasionally caused by RSWT usually disappeared within 3 days. There was improvement in the VAS and HHS scores after 1 mo, and evaluation at 3, 6, 12, 18, and

TABLE 1 The pain visual analog scale and HHS in each time point

	Baseline	1 Mo	3 Mos	6 Mos	12 Mos	18 Mos	24 Mos
Pain score (10)	8	6	3	2	0	0	0
Harris hip score (100)	33	43	56	77	81	85	92
Pain (44)	20	30	30	40	44	44	44
Stairs (4)	0	0	2	2	2	4	4
Public transportation (1)	0	0	0	1	1	1	1
Sitting (5)	0	0	3	5	5	5	5
Activities-shoes, socks (4)	4	4	4	4	4	4	4
Limp (11)	0	0	5	8	8	8	8
Distance walked (11)	2	2	5	8	8	8	11
Support (11)	3	3	3	5	5	7	11
Articular malformation (4)	1	1	1	1	1	1	1
Motion (5)	3	3	3	3	3	3	3

24 mos showed further improvement in performing functional activities (Table 1). The participant reported complete resolution of pain during routine clinical evaluations at the 12th month. The MMT results are shown in Table 2. On average, the subject's MMT grade improved by nearly three grades. The right lower limb was able to move against gravity after 6 mos of therapy and could perform resistance exercise after 12 mos according to MMT. The difference in the left and right thigh circumference decreased from 4.5 to 1.5 cm after 24 mos. The subjective reports that the feelings of her hip and strength gradually improved, and she replaced the crutch with a walking stick after 8 mos of treatment. As the treatment went on, she was able to walk without a stick most of the time after 18 mos. At the 24th month, she told that she could travel for more than 2 hrs without feeling lower extremity fatigue and pain.

The original radiograph showed subluxation and osteoarthritis of the right hip with decreased joint space and articular collapse. As in the plain film, MRI images showed right femoral head deformation, and the acetabulum was shallow with subchondral cyst formation, joint effusion, and joint space narrowing. The radiographs showed that the

subluxation of the right hip was slightly aggravated (Figs. 1A–C). Joint effusion was reduced, bone marrow edema disappeared, the density became more uniform, and the gluteal muscles were more developed based on the MRI (Figs. 1A, B). Increased tracer uptake was evident along the joint margin and superolateral aspect of the head both before and after RSWT, as shown in planar bone scintigraphy and single-photon emission computed tomography/computed tomography (Fig. 2). There was no apparent difference in the mean uptake of the ROI between the pretreatment and posttreatment in planar bone scintigraphy, whereas the maximum uptake count decreased significantly with the ratio of right/left decreasing from 4.250 to 3.271 (Table 3).

DISCUSSION

Our results support the efficacy and need for RSWT in this patient and others like her who opt not to have THA for their late-stage AVNFB, as demonstrated in the authors' previous randomized controlled study that RSWT for four times was significantly more effective for reducing pain and improving the function of lower extremity for advanced AVNFB than general physical therapy.²² In

TABLE 2 The MMT in each direction

Movements Tested	Baseline	1 Mo	3 Mos	6 Mos	12 Mos	18 Mos	24 Mos
Hip flexion	2	2	2	3	4	5	5
Hip abduction	2	2	2	3	4–	4+	5
Hip internal rotation	2	2	3	3	4	4	5
Hip external rotation	2	2	2	3	4	4	5
Hip extension	3	3	3	4–	4–	4	5
Hip adduction	2	2	2	3	4–	4	4+

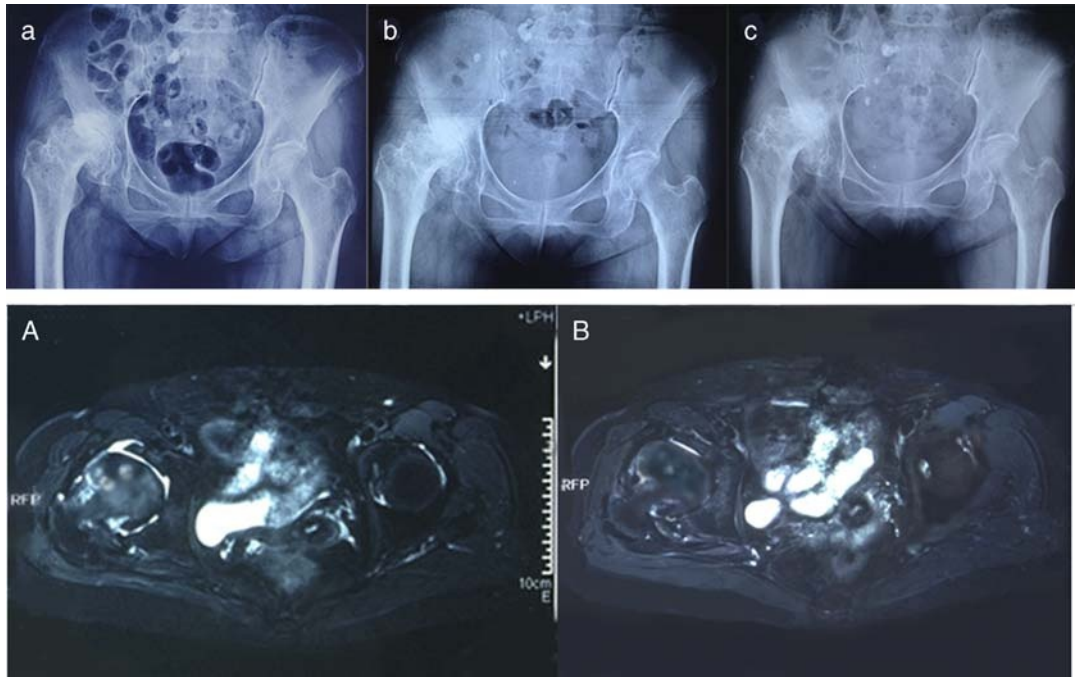


FIGURE 1 Radiographs of the hip before (a) RSWT and 12 (b) and 24 (c) mos later. The images show a collapse and osteophyte in the right femoral head with joint space narrowing. The subluxation of the right hip was slightly aggravated. MRI: fat saturated T2-weighted image (A) before RSWT shows right femoral head deformation with subchondral cyst formation, bone marrow edema, joint effusion, and joint space narrowing. The image (B) after RSWT demonstrates that the joint effusion and bone marrow edema decreased, the density became more uniform, and the gluteal muscles were more developed.

this study, the patient tolerated the 24-mo-long RSWT very well. The positive results of improved HHS, decreased pain VAS score, increased lower

extremity strength, and improvements in physical status helped to improve the overall quality of life for this individual. Because the quality of life

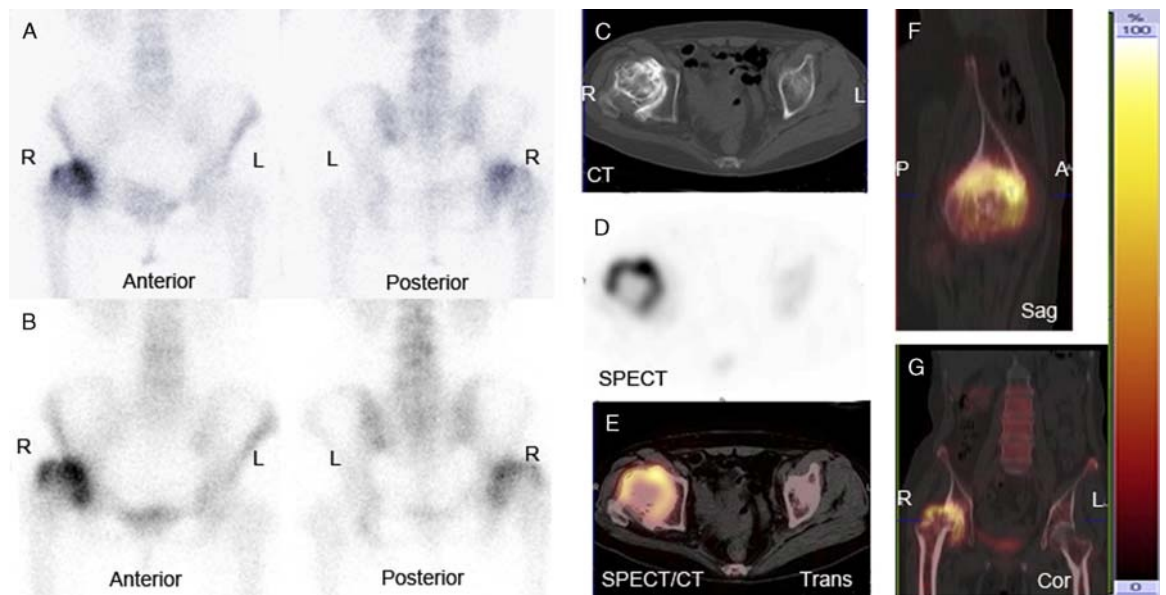


FIGURE 2 Planar bone scintigraphy: Increased tracer uptake is evident along the joint margin and superolateral aspect of the head before and after RSWT (A, B). The single-photon emission computed tomography/computed tomography (SPECT/CT) fusion image (C, D, E, F, G) obtained after the second bone scan showed the anatomy and an increase in uptake in the right femoral head. The increased uptake in the joint corresponds to joint space narrowing, subchondral sclerosis, and subchondral cyst formation.

TABLE 3 The ratio of right/left for ROI uptake count and the highest uptake count from the planar bone scintigraphy before and after the 24 mos of treatment

	Pre Right/Left	Post Right/Left
ROI uptake count	3.877	3.921
Highest uptake count	4.250	3.271

improved significantly, there is currently no need for THA.

THA is considered the most reliable option for ARCO stage IV of AVNFB. However, some patients are not selected for THA because they have a condition, such as poor cardiopulmonary function, that increases the risk, and THA is not performed in young patients because of the limited service life of artificial hips. Although the results of THA have considerably improved in the past few years, some patients require revision because of dislocation and aseptic loosening.²³⁻²⁵ The poor bone quality secondary to corticosteroid use, lack of weight bearing, or the underlying disease (i.e., rheumatoid arthritis) also causes surgical challenges. Conservative treatment for AVNFB has been shown to be an important alternative for those who cannot or do not opt for surgical treatment. ESWT in ARCO stages I-III may help to prevent progression of the area of avascular necrosis, manage pain, improve the function of hip,⁹⁻¹³ and even completely heal the early lesion.⁷ Moreover, ESWT seemed to be more effective than core decompression and nonvascularized fibular grafting, which are two usual treatments for the early stages of osteonecrosis of the femoral head.⁵ The exact mechanisms of the ESWT benefits in AVNFB remain unknown, although it is thought that shock waves may cause an increase in neovascularization and the expression of angiogenesis-related growth factors, in addition to bone remodeling and regeneration.²⁶⁻²⁸ On the basis of previously mentioned several good effects on clinical symptoms, imaging, and molecular biology in early-stage AVNFB, the authors speculate that ESWT is possible effective for advanced AVNFB. Most of the existing studies on AVNFB used focused shock waves broadcast by electromagnetic⁶ or electrohydraulic^{5,7,8,11-13} shock wave generators, which are generally used in conjunction with general or regional anesthesia and under radiographic guidance. What's more, the location of some arteries and nerves should be located with an ultrasound Doppler scan to avoid any direct

shock wave contact. In contrast, the ballistic shock wave source is radial, and the procedure can be performed without general or regional anesthesia, exact location to be determined with imaging, nor locating the blood vessels and nerves to keep them from being damaged. In addition, the functioning range of ballistic shock wave therapy is larger than that of the focused form, including the soft tissue around the femoral head, which may be important in the repair process. Patients do not need to worry that RSWT will interfere with walking or increase pain, nor do they have to walk with partial weight-bearing on the affected leg after RSWT as in the case of focused ESWT. In this study, any complications that may be associated with the use of RSWT, such as edema, increased pain, and congestion, were not observed. Although the pain sometimes became worse as the intensity increased, the treatment usually resulted in greater relief of pain afterward. Moreover, the cost of RSWT is lower than that of focused ESWT.

The initial x-ray film showed a slight subluxation of the right hip, so the patient was not treated with joint mobilization therapy. The aggravated subluxation of the right hip, as demonstrated by radiographs and the increase in the joint motion range, may have resulted from the antifibrosis effect of RSWT. Multiple ESWT is reported to be capable of degrading fibrotic tissue, which seems to be associated with inhibition of inflammation and synergistic alterations of profibrotic and antifibrotic proteins (transforming growth factor β 1 and matrix metalloproteinase 2, respectively).²⁹ The authors speculate that for AVNFB patients with limited joint mobility and without subluxation, RSWT in combination with joint mobilization therapy would be more effective.

Increased tracer uptake in the initial bone scan was evident along the joint margin, particularly corresponding to osteoarthritic changes,³⁰ with clinical manifestations of pain and motion limitation. The maximum uptake count decreased in the second bone scan, indicating an improvement of osteoarthritis, which was consistent with the clinical improvement and the decrease in joint effusion seen on MRI. From the planar bone scintigraphy and single-photon emission computed tomography/computed tomography, there was no change in the mean uptake of the ROI and no increase in cold areas during the 24-mo-long therapy, which indicated that RSWT can promote and maintain the reparative process.

This study's findings encourage the collection of group data in randomized controlled trials to

assess the efficacy of RSWT in rehabilitation to decrease pain and promote motor function in advanced AVNFH. This novel modality resulted in significant pain relief and functional improvement of the hip in this patient. It was surmised, on the basis of radiographic, MRI, and bone scan findings, that there were advantageous biologic effects as well. RSWT has the potential to delay the need for THA in young patients and to provide an effective noninvasive option for those who are intolerant of surgery or unwilling to accept THA. Additional studies are needed to further determine the optimal dose and define the optimal treatment interval to shorten the treatment period.

Supplementary Checklist

CARE Checklist: <http://links.lww.com/PHM/A220>

REFERENCES

- Chandler F: Coronary disease of the hip. *J Int Coll Surg* 1948;11:34–6
- Bradway JK, Morrey BF: The natural history of the silent hip in bilateral atraumatic osteonecrosis. *J Arthroplasty* 1993;8:383–7
- Malizos KN, Karantanas AH, Varitimidis SE, et al: Osteonecrosis of the femoral head: Etiology, imaging and treatment. *Eur J Radiol* 2007;63:16–28
- Zalavras CG, Lieberman JR: Osteonecrosis of the femoral head: Evaluation and treatment. *J Am Acad Orthop Surg* 2014;22:455–64
- Wang CJ, Wang FS, Huang CC, et al: Treatment for osteonecrosis of the femoral head: Comparison of extracorporeal shock waves with core decompression and bone-grafting. *J Bone Joint Surg Am* 2005; 87:2380–7
- Vulpiani MC, Vetrano M, Trischitta D, et al: Extracorporeal shock wave therapy in early osteonecrosis of the femoral head: Prospective clinical study with long-term follow-up. *Arch Orthop Trauma Surg* 2012; 132:499–508
- Parsons JS, Stelle N: Osteonecrosis of the femoral head: Part 2—Options for treatment. *Curr Orthop* 2008;22:349–58
- Ludwig J, Lauber S, Lauber HJ, et al: High-energy shock wave treatment of femoral head necrosis in adults. *Clin Orthop Relat Res* 2001;387:119–26
- Wang CJ, Wang FS, Ko JY, et al: Extracorporeal shockwave therapy shows regeneration in hip necrosis. *Rheumatology (Oxford)* 2008;47:542–6
- Ma HZ, Zeng BF, Li XL, et al: Temporal and spatial expression of BMP-2 in sub-chondral bone of necrotic femoral heads in rabbits by use of extracorporeal shock waves. *Acta Orthop* 2008;79:98–105
- Hsu SL, Wang CJ, Lee MS, et al: Cocktail therapy for femoral head necrosis of the hip. *Arch Orthop Trauma Surg* 2010;130:23–29
- Ma HZ, Zeng BF, Li XL: Upregulation of VEGF in subchondral bone of necrotic femoral heads in rabbits with use of extracorporeal shock waves. *Calcif Tissue Int* 2007;81:124–31
- Alves EM, Angrisani AT, Santiago MB: The use of extracorporeal shock waves in the treatment of osteonecrosis of the femoral head: A systematic review. *Clin Rheumatol* 2009;28:1247–51
- Ibrahim MI, Donatelli RA, Schmitz C, et al: Chronic plantar fasciitis treated with two sessions of radial extracorporeal shock wave therapy. *Foot Ankle Int* 2010;31:391–7
- Gerdesmeyer L, Frey C, Vester J, et al: Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: Results of a confirmatory randomized placebo-controlled multicenter study. *Am J Sports Med* 2008; 36:2100–9
- Speed C: A systematic review of shockwave therapies in soft tissue conditions: Focusing on the evidence. *Br J Sports Med* 2014;48:1538–42
- Schmitz C, Császár NB, Rompe JD, et al: Treatment of chronic plantar fasciopathy with extracorporeal shock waves (review). *J Orthop Surg Res* 2013; 8:31
- Gollwitzer H, Gloeck T, Roessner M, et al: Radial extracorporeal shock wave therapy (rESWT) induces new bone formation in vivo: Results of an animal study in rabbits. *Ultrasound Med Biol* 2013;39: 126–33
- Notarnicola A, Tamma R, Moretti L, et al: Effects of radial shock waves therapy on osteoblasts activities. *Musculoskelet Surg* 2012;96:183–9
- Harris WH: Traumatic arthritis of the hip after dislocation and acetabular fractures: Treatment by mold arthroplasty: An end-result study using a new method of result evaluation. *J Bone Joint Surg Am* 1969;51:737–55
- Palmer ML, Epler ME: *Fundamentals of Musculoskeletal Assessment Techniques*, ed 5. Philadelphia, PA: Lippincott, Williams & Wilkins; 1998
- Ma YW, Jiang DL, Yu XT: Effect of extracorporeal shock wave on avascular necrosis of femoral head of stage IV. *Zhongguo Kangfu Lilun Yu Shijian* 2015; 21:348–52
- Ortiguera CJ, Pulliam IT, Cabanela ME: Total hip arthroplasty for osteonecrosis: Matched-pair analysis of 188 hips with long-term follow-up. *J Arthroplasty* 1999;14:21–8
- Kim SM, Lim SJ, Moon YW, et al: Cementless modular total hip arthroplasty in patients younger than fifty with femoral head osteonecrosis: Minimum fifteen-year follow-up. *J Arthroplasty* 2013;28:504–9
- Bedard NA, Callaghan JJ, Liu SS, et al: Cementless THA for the treatment of osteonecrosis at 10-year

- follow-up: Have we improved compared to cemented THA? *J Arthroplasty* 2013;28:1192–9
26. Wang CJ, Wang FS, Yang KD: Treatment of osteonecrosis of the hip: Comparison of extracorporeal shockwave with shockwave and alendronate. *Arch Orthop Trauma Surg* 2008;128:901–8
 27. Lin PC, Wang CJ, Yang KD, et al: Extracorporeal shockwave treatment of osteonecrosis of the femoral head in systemic lupus erythematosus. *J Arthroplasty* 2006;21:911–5
 28. Wang CJ, Ko JY, Chan YS, et al: Extracorporeal shockwave for hip necrosis in systemic lupus erythematosus. *Lupus* 2009;18:1082–6
 29. Fischer S, Mueller W, Schulte M, et al: Multiple extracorporeal shock wave therapy degrades capsular fibrosis after insertion of silicone implants. *Ultrasound Med Biol* 2015;41:781–9
 30. Lee A, Emmett L, Van der Wall H, et al: SPECT/CT of femoroacetabular impingement. *Clin Nucl Med* 2008;33:757–62