

Peer Review File

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Reviewer Comments

We appreciated very much your research in ESWT.

Find below my comments:

I. Shockwave: preferred termed by ISMST in one word

Response 1: Thanks for the professional advice, we have changed the word "shock wave" to "shockwave".

changes in the text: We have modified our text as advised (see line 1, 36, 47, 49, 58, 59, 95, 148, 228)

II. First page: Wei Sun (as other physicians): if he is MD, he should be graduated as MD, PhD

Response 2: Wei Sun was graduated as MD, and "PhD" has been changed to "MD".

changes in the text: We have modified our text as advised (see page 1, line 4, 14)

III. Abstract:

- Pp 2 line 35 (and line 147): "Considering an extensive application of ESWT, orthopedists should pay attention to the rare complication of contact dermatitis, and the dosage of ESWT should be strictly controlled to avoid unexpected complications". This complication is really rare, so, in my opinion, the conclusion's message should be: Although bone pathologies should be treated with high energy, the patient should be informed on this rare complication. (See: ISMST International Society for Medical Shockwave Treatment. Consensus statement on ESWT indications and contraindications. https://www.shockwavetherapy.org/fileadmin/user_upload/dokument/e/PDFs/Formulare/ISMST_consensus_statement_on_indications_and_contraindications_20161012_final.pdf).

Response 3: Thanks for the professional advice, the conclusion has been changed to "Although bone pathologies should be treated with high energy, patients should be informed on this rare complication".

changes in the text: We have modified our text as advised (see page 3, line 45, 46).

IV. Introduction

- Pp 2 54 line: "ESWT is a kind of pulsed mechanical wave with great energy": focused SW does not always imply great energy, may be low or medium energy

Response 4.1: Thanks for the professional advice, "ESWT is a kind of pulsed mechanical wave with great energy" has been changed to "Extracorporeal shockwave therapy (ESWT) uses pulsed mechanical waves which release energy when the shockwaves propagate to the interface between the bone and soft tissue."

changes in the text: We have modified our text as advised (see page 4, line 58-60).

- Pp 3 line 62: “cost-effective physiotherapy”: the title reference mentioned by the authors is ESWT for orthopedic conditions: “Efficacy and safety of extracorporeal shock wave therapy for orthopedic conditions” (see reference Schmitz n° 6, line 184). I suggest to change the word physiotherapy for “tool” or better “treatment modality”.

Response 4.2: Thanks for the professional advice, the words “cost-effective physiotherapy” have been changed to “cost-effective treatment modality”.

changes in the text: We have modified our text as advised (see page 4, line 66-67).

V. Case presentation:

- Pp 4 line 93: “Low-energy ESWT (0.15 mJ/mm²). Bone pathologies should be treated with high energy (as already mentioned the link on ISMST) and usually this indication requires anesthesia or some kind of sedation. This skin complication was not expected. Never heard or read before.

Response 5.1:

Thanks so much for the comments. Adherence to guidelines, bone pathologies really should be treated with high energy and requires anesthesia. However, in our center, we do not usually use anesthesia or some kind of sedation in clinical ESWT practice, even sometimes the energy fluid density (EFD) of per shockwave is high. For example, we used high-energy ESWT for the treatment of osteonecrosis of the femoral head and other bone diseases [1, 2] (Fig 1). We must admit that our procedures were not standard. In our actual clinical practice, the energy of ESWT usually starts from a low level, and most of patients can tolerate the pain. After getting comfortable, we increase the energy gradually until a higher level.

2.2. Shock Wave Treatment. Although small areas of necrosis may remain asymptomatic and resolve spontaneously, most

All ESWT procedures were performed once without general or regional anesthesia by experienced physicians with the patient in supine position on the operation table. ESWT

Fig 1

In this case presentation, the patient was so sensitive to the pain or may be too nervous that he could just tolerate relatively low energy (0.15 mJ/mm²) when he first received the ESWT. After treatment, the groin pain alleviated immediately though the energy was not high and no local or systematic adverse reactions occurred. However, the patient presented with sever local skin complications after a second session of high-energy ESWT (0.28 mJ/mm²), which was not expected. We have discussed this point in the "potential limitations" part.

changes in the text: We have modified our text as advised (see page 11, line 156-160).

- Pp 4 line 96: “Three months later, he was subjected to a second session of high-energy ESWT (0.28 mJ/mm²)”. It is strange to wait 3 months for next session, it is not the recommended ISMST and German SW protocol, suggesting to apply ESWT with an interval between 1 - 2 weeks.

Response 5.2: In our center, the time interval between two ESWT therapy sessions

was one week for the treatment of osteonecrosis of the femoral head [1] (Fig 2). However, the patient did not follow the doctor's advice for a second session treatment because the pain was relieved. Until three months later, he come to for the second session of ESWT. We have discussed this point in the "case presentation" and "potential limitation" part.

3000–4000 impulses at a frequency of 2-3 Hz. Each patient underwent two therapy sessions (the time interval between successive procedures was one week). After ESWT treatment, patients were instructed to walk on crutches with partial weight bearing on the affected leg for 4–6 weeks. Alendronate sodium tablets (70 mg p.o. q.w. for 12 months) were administered to each patient. Nonnarcotic analgesics such as celecoxib were prescribed for pain. Patients were followed up at the outpatient department at 3, 6, and 12 months after the second procedure. An assessment of pain intensity (visual analogue scale, VAS) and hip function (Harris hip score, HHS)

Fig 2

changes in the text: We have modified our text as advised (see page 7, line 101-103; page 11, line 161-162).

- Pp 5 line 141: “who suffered a lot” this is not scientific.

Response 5.3: As suggested, “who suffered a lot” has been changed to “and the course of skin damage was long and severe”.

changes in the text: We have modified our text as advised (see page 10, line 154-155).

References:

1. Gao F, Sun W, Li Z, Guo W, Wang W, Cheng L, Wang B. High-Energy Extracorporeal Shock Wave for Early Stage Osteonecrosis of the Femoral Head: A Single-Center Case Series. *Evid Based Complement Alternat Med.* 2015;2015:468090.
2. Shi L, Gao F, Sun W, Wang B, Guo W, Cheng L, Li Z, Wang W. Short-term effects of extracorporeal shock wave therapy on bone mineral density in postmenopausal osteoporotic patients. *Osteoporos Int.* 2017;28(10):2945-2953.

VI. Discussion:

- Pp 5 line 119. there are more complications described in the literature. Not updated, but see those I knew, if it would help for discussion:

1. Durst HB, Blatter G, Kuster MS. Osteonecrosis of the humeral head after extracorporeal shock-wave lithotripsy. *J Bone Joint Surg Br* 2002;84(5):744-6. doi: 10.1302/0301-620X.84B5.12282
2. Erduran M, Akseki D, Ulusal AE. A complication due to shock wave therapy resembling calcaneal stress fracture. *Foot Ankle Int.* 2013 Apr;34(4):599-602. doi: 10.1177/1071100712470917. Epub 2013 Jan 28.
3. Haake M, Böddeker IR, Decker T et al. Side-effects of extracorporeal shock wave therapy (ESWT) in the treatment of tennis elbow. *Arch Orthop Trauma Surg* 2002;122(4):222-8. doi:10.1007/s00402-001-0362-7
4. Hansen L, Thøger Persson Krogh, Torkell Ellingsen, Lars Bolvig, Ulrich

Fredberg. Long-Term Prognosis of Plantar Fasciitis: A 5- To 15-Year Follow-up Study of 174 Patients with Ultrasound Examination. *Orthop J Sports Med.* 2018 Mar 6;6(3). Doi: 10.1177/2325967118757983.

5. Kiessling MC, Milz S, Frank HG et al. Radial extracorporeal shock wave treatment harms developing chicken embryos. *Sci Rep* 2015;5:8281. doi: 10.1038/srep08281

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7. Liu HM, Chao CM, Hsieh JY, Jiang CC. Humeral head osteonecrosis after extracorporeal shock-wave treatment for rotator cuff tendinopathy. A case report. *J Bone Joint Surg Am* 2006;88:1353-6. doi: <http://dx.doi.org/10.2106/JBJS.E.00868>.

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9. Nouri-Majalan N, MasoumiR, Halvani A, Moghaddasi S. Lung contusion and cavitation with exudative plural effusion following extracorporeal shock wave lithotripsy in an adult: a case report *J Med Case Reports* 2010;4:293. doi: 10.1186/1752-1947-4-293.

10. Ohmori K, Matsuda T, Horii Y et al. Effects of shock waves on the mouse fetus. *J Urol* 1994;151(1):255-258. doi: 10.1016/s0022-5347(17)34927-3.

11. Shim JS, Chung SG, Bang H et al. Ulnar Neuropathy After Extracorporeal Shockwave Therapy: A Case Report. *PM R* 2015;7(6):66770. doi: 10.1016/j.pmrj.2015.01.019.

12. Sistermann R, Katthagen BD. Complications, side-effects and contraindications in the use of medium and high-energy extracorporeal shock waves in orthopedics. *Z Orthop Ihre Grenzgeb* 1998;136(2):175-8. doi:10.1055/s-2008-1051302.

Response 6.1: Thanks very much for these references, which are of great help to us. After reading each article carefully, we added some content about the complications of ESWT in the discussion section.

changes in the text: We have modified our text as advised (see page 9, line 132-139).

- Pp 5 line 133: “second session was much larger”: in my opinion it should be shorter, as first session 3 Hz, and second 4 Hz, so faster the second one.

Response 6.2: We are sorry that the unclear description has caused a misunderstanding. What we want to say is that the total energy of ESWT in the second session was much larger than that in the first session.

changes in the text: We have modified our text as advised (see page 10, line 146-147).

Other important considerations:

1. Level of energy is medium, it should be high.

Response 1: This comment was similar to the above one: *V. Case presentation, Pp 4 line 93*, “Low-energy ESWT (0.15 mJ/mm²). Bone pathologies should be treated with high energy).

We have made our correspondingly answer in that section, and discussed this point in the "potential limitation" part.

changes in the text: We have modified our text as advised (see page 11, line 156-160).

2. The interval period between the 2 treatments of 3 months is too high.

Response 2: This comment was similar to the above one: *V. Case presentation, Pp 4 line 96: "Three months later, he was subjected to a second session of high-energy ESWT (0.28 mJ/mm²)". It is strange to wait 3 months for next session, it is not the recommended ISMST and German SW protocol, suggesting to apply ESWT with an interval between 1 - 2 weeks.*

We have made our correspondingly answer in that section, and discussed this point in the "potential limitation" part.

changes in the text: We have modified our text as advised (see page 11, line 161-163).

3. The author do not inform on clinical and radiological follow-up. What was the follow-up? How pain and necrosis evolve? Did the injury evolve into a scar?

Response 3: We conducted a follow-up in August 2020, and the specific results of the follow-up were presented in the section of case presentation. The patient's condition was stable, his hip pain was relieved, and physical examination of hip joint function was normal, with no impact on his everyday activities. Imaging examinations showed that there was no progress in ONFH, the femoral head was intact and there was no collapse, and the clinical stage was still ARCO IIB stage. The skin lesions returned to normal and there was no scar residue.

changes in the text: We have modified our text as advised (see page 8-9, line 120-125).

4. Authors should inform as a limitation or on discussion section, that although bone pathologies should be treated with high energy, this patient was treated with medium energy in the first session. What was the objective? Maybe to alleviate pain?

Response 4: Why low energy is used in the first treatment has been described as a limitation section in the text as suggested. In this case presentation, the patient was so sensitive to the pain or may be too nervous that he could just tolerate relatively low energy (0.15 mJ/mm²) when he first received the ESWT. After treatment, the groin pain alleviated immediately though the energy was not high and no local or systematic adverse reactions occurred.

changes in the text: We have modified our text as advised (see page 11, line 156-160).

5. Another limitation should be the approach: the ideal approach in the treatment of osteonecrosis of femoral head (ONFH) is the anterior with external rotation of the femur (be careful on neurovascular system of scarpa triangle). The authors used posterior approach (pp 4 line 88). By using this posterior approach, ESWT does not reach the target. ESWT would hit the external part of the head and a large part of the trochanter, but the external part of the head is generally less affected by necrosis.

Response 5: The ESWT the approach has been described as a limitation section in the

text as suggested.

changes in the text: We have modified our text as advised (see page 11, line 163-164).