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Efficacy of high-energy, focused ESWT in treatment of lumbar facet joint pain: a randomized sham-controlled trial

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Objective: Lumbar facet joints (FJs) are a common source of chronic low back pain (LBP). Focused extracorporeal shock wave therapy (ESWT) has demonstrated potential in the treatment of musculoskeletal disorders due to its deeper tissue penetration and safety profile. This study aimed to evaluate the efficacy and safety of ESWT in the management of lumbar facet joint pain.

Methods: A prospective, randomized, sham-controlled trial was conducted in 128 patients with chronic lumbar facet syndrome confirmed by medial branch block. Patients were randomized to receive either focused ESWT (Group A, n = 64; 0.35 mJ/mm^2, 1200 shocks/session = 600 shocks per segment, 5 weekly sessions) or sham therapy (Group B, n = 64). Pain intensity (VAS), disability (ODI), and neuropathic pain features (PainDETECT questionnaire) were assessed at 2, 6, and 12 months. Lumbar spine MRI was performed at baseline and 6 months post-treatment.

Results: Group A showed significant reductions in VAS scores at 6 and 12 months (mean 64.4% reduction at 12 months, $P<0.01$), with an effect size (Cohen's d = 1.12). ODI decreased by 42.3% in Group A compared to 12.5% in the sham group. Neuropathic pain symptoms improved significantly only in Group A (PD-Q reduction from 18.3 ± 2.4 to 10.2 ± 1.9; $P<0.01$). MRI follow-up demonstrated resolution of bone marrow edema in 58.8% of ESWT-treated patients versus none in the control group. No adverse effects were reported.

Conclusions: High-energy focused ESWT is a safe and effective non-invasive therapy for chronic lumbar facet joint pain, showing sustained improvements in pain, function, and neuropathic symptoms. MRI findings support its biological effect on joint-related bone marrow edema. ESWT represents a promising alternative to interventional pain procedures.

Keywords: bone marrow edema, facet joint pain, focused extracorporeal shockwave therapy, modic changes, neuropathic pain, non-invasive therapy

Introduction

Anatomically, a motion segment of the lumbar spine consists of an intervertebral disc and two facet (zygoapohyseal) joints, with ligaments and muscular tissue. Traditionally, pain of neuropathic origin in this area has been correlated mainly with radiculopathy, which is caused by nerve root compression. A common cause is disc prolapse or foraminostenosis originating from chondral plate degeneration and spurs in the affected facet joints (FJs). FJ may also play a role in local neuropathic pain development, usually combined with a nociceptive component[1,2]. Facet joints bear more than 20% of the weight of the upper trunk; therefore, degeneration, destruction of the chondral plate, and development of spurs and calcifications[3] lead to an inflammatory cascade in the joints and surrounding soft tissues. This may develop into a painful vicious cycle of neurogenic inflammation and/or mechanical compression of the medial branch of the dorsal nerve root. Progressive FJ degeneration is not only an

HIGHLIGHTS

- First RCT to evaluate focused ESWT in lumbar facet joint pain treatment.
- ESWT is safe, non-invasive, and effective short- and long-term.
- ESWT may serve as an alternative to invasive pain interventions.
- MRI showed reduction of bone marrow edema after ESWT.
- Suggests broader biological effects beyond pain relief.

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issue in the elderly population but also in young active individuals with a predisposition to low back pain. The prevalence of chronic low back pain of FJ origin is very high, and according to the literature, it contributes to 31% of chronic low back pain[4]. Lumbar facet joint syndrome, which was originally described 80 years ago[5], is characterized by localized para-axial or lateral low back pain, elicited by hyperextension or rotation in the lumbar area, with a typical referred pattern of pain to the buttocks and posterior or anterolateral thigh. Patients usually do not describe pain irradiation below the knee[6]. In some patients, signs of neuropathic pain sensation are also present, including numbness, paresthesia, or allodynia, and more rarely, they develop trophic changes[1].

Diagnosis of facet-mediated LBP remains challenging. Imaging (MRI, CT) provides limited specificity. Therefore, diagnostic medial branch blocks (MBBs) under imaging guidance remain the gold standard for confirming facetogenic pain. A ≥50% reduction in pain following ultrasound- or fluoroscopy-guided local anesthetic injection is generally accepted as a positive criterion[7,8]. Differential diagnosis must exclude discogenic, myofascial, and radicular pain syndromes using clinical, imaging, and where appropriate, electrophysiological criteria. Bone hypermetabolism evaluation via bone scintigraphy and single-photon emission computed tomography may offer additional information about inflammatory activity around the affected FJ and for the exclusion of mass lesions and possible red flags in low back pain[9,10].

Interventional therapeutic approaches in FJ pain include FJ intra-articular injections with limited evidence III, medial branch anesthetic block with a level of evidence II-1 or II-2[8] with shorter term pain relief, and radiofrequency medial branch neurotomy [RMBN], considered as a gold standard in lumbar FJ pain with a longer-lasting analgesic effect (6 months to almost 2 years), with a level of evidence II-1[11]. Various types of guidance, including fluoroscopy, CT, and, more recently, ultrasound guidance, are used for accurate needle placement[12]. However, both steroid injections and RMBN are percutaneous interventional procedures and may carry a non-negligible risk of complications, such as pyogenic infections[13], chemical meningitis[14], bleeding[15], and rare but possible damage to neural structures. In mild cases, multifidus muscle atrophy has been observed[16]. In cases of inappropriate needle or electrode placement, sensory or motor loss due to nerve root damage has been described[17].

Other treatment options for FJ pain may include pharmacological treatment – third-generation anticonvulsant pregabalin, NSAIDs, and/or opioids. Certain rehabilitation techniques, exercise therapy, or spinal manipulation may have an additional positive effect on the treatment of this common painful condition[2,18].

Extracorporeal shockwave therapy (ESWT), originally developed for lithotripsy, is increasingly explored as a treatment for musculoskeletal conditions. ESWT includes two types of energy delivery: focused (ESWT) and radial pressure waves (RPWs), which differ in penetration depth and physical properties. Focused ESWT, due to its greater tissue penetration, has demonstrated efficacy in deeper tissues, including subchondral bone[19]. It is, however, unclear how the different characteristics of ESWT are related to clinical effectiveness.

Studies on the biological effects of shockwave therapy have mainly used ESWT, showing a number of effects of shockwaves on biological tissues. The effect of ESWT is created by a direct mechanical load on the structure, which can be used in the disintegration of calcifying processes, such as shoulder calcifying tendonitis. The biological effects of ESWT have been observed in tendon tissue healing[19,20], cartilage repair[21], osteogenesis[22], and pain modulation[23]. ESWT has also been shown to improve motor function and pain in animal studies looking at osteoarthritis[24]. Complex interactions between the mechanical load and tissue response are sometimes described as mechanotransduction[25].

In animal and *in vitro* studies, the authors also investigated the direct effect of ESWT application on neural structures. Murata *et al*[23] studied the expression of activating transcription factor 3 (ATF3) and growth-associated phosphoprotein (GAP-43) as markers of nerve injury and axonal regeneration in experimental rats. In conclusion, ESWT application can lead to desensitization of the area of exposure. Mense *et al*[26] observed that significant improvements in nerve regeneration were observed in a rodent model of nerve compression using low-energy ESWT. Another study[27] reported improvements in sciatic nerve regeneration due to neurotrophin-3 expression in experimental sciatic nerve lesions in rats. Similar pathophysiological principles, such as arthritis, chondral plate damage, nerve fiber inflammation, and entrapment, play an important role in the pathophysiology of FJ pain development.

Recent studies also investigated effects of ESWT on the spine. In a rat model of spinal disc degeneration, low-energy shockwaves promoted disc regeneration (restoring disc height and hydration) and improved the microenvironment for repair[28]. Similarly, in a spinal cord injury model, repeated ESWT reduced tissue inflammation and enhanced neural tissue regeneration, leading to improved locomotor function[29]. These findings suggest that ESWT may attenuate chronic inflammation in the spine and facilitate tissue healing.

Human clinical studies have also shown significant effects of ESWT on peripheral nerve regeneration. Multiple papers[30–32] have described the positive effects of ESWT on clinical and electrophysiological variables in patients with carpal tunnel syndrome (CTS). Recent meta-analyses on carpal tunnel syndrome have shown that both focused ESWT and RPW are more clinically effective than controls in symptom relief, functional enhancement, and electrophysiologic parameter improvement for patients with mild-to-moderate CTS at any time point of follow-up; however, larger and higher quality RCTs with more stringent design and longer follow-up are recommended for clear results[33].

With regard to spine ESWT treatment, a prospective randomized controlled trial[34] found positive short-term results of ESWT in sacroiliac joint pain. There is also evidence of ESWT efficacy for myofascial low back pain[35] and a randomized controlled trial on ESWT in coccydynia[36]. Recent meta-analyses have also described ESWT as a safe and effective approach for different kinds of non-specific chronic low back pain[29,37,38]. Newer studies also pointed out both the short- and long-term pain relief of focused ESWT[39]. One study[40] compared quadratus lumborum trigger point injections to ESWT and found that ESWT was more efficacious than corticosteroid TPI in improving quality of life and disability and was related to a greater likelihood of at least a 30% decrease in pain intensity and disability and at least a 20% improvement in quality of life in treated patients compared to corticosteroid TPI.

Several trials have tested ESWT as an adjunct or alternative to conventional therapies. Lee *et al*[41] divided 28 chronic low back pain patients into two groups: both groups received a 6-week

exercise therapy program, but one group also received weekly ESWT sessions. The ESWT + exercise group had greater pain relief and improved dynamic balance ability compared to exercise alone.

Notably, one clinical trial found that ESWT not only reduced back pain but also improved nerve conduction velocities in peripheral nerves[42]. The authors randomized 30 patients to either ESWT or a standard exercise rehabilitation program. After 1 and 3 months, the ESWT group showed significantly lower pain scores and disability indices (Roland–Morris and Oswestry scores) than the exercise group. Moreover, nerve conduction studies in the ESWT group demonstrated improved sensory and motor nerve function, whereas the exercise group had no significant EMG changes. These findings highlight ESWT's ability to provide not just symptomatic relief but also potential physiological improvement. Liu *et al*[37] performed a comprehensive meta-analysis of 12 RCTs (632 patients) specifically to evaluate ESWT in chronic low back pain. The results showed significantly greater pain relief and improvements in the disability index with ESWT than with control interventions at both 4 weeks and 12 weeks follow-up. Overall, the authors concluded that ESWT provides better pain and function outcomes than placebo or standard care in chronic back pain, reinforcing it as a valuable non-invasive treatment.

ESWT seems to be effective in treatment of bone marrow edema (BME) in various locations[43]. The mechanism of its action may include promoting a tissue's self-healing capabilities[44]. In bone tissue, this involves stimulation of osteoblasts and periosteal cells, differentiation of stem cells, and increased secretion of nitric oxide synthase and vascular endothelial growth factor, thus leading to increased neovascularization[45]. ESWT has been also proven to be effective in conservative treatment of avascular necrosis of the femoral head[46]. In lower back pain, BME is represented by Modic I changes – specific hyperintense T2-weighted abnormalities on magnetic resonance imaging (MRI) – which were shown to represent bone marrow edema and inflammation[47]. Studies using MRI T2-weighted fat-suppressed sequences have demonstrated facet joint BME in 14% to 41% of patients with chronic low back pain[48,49]. Up to date, no clinical trials investigated ESWT effects on spine BME so far.

In our previous retrospective pilot study[50], we confirmed the efficacy of RPW on long-term pain relief and quality of life in patients with lumbar facet joint pain against standard treatment options for FJ pain – medial branch anesthetic block and radiofrequency neurotomy. The shockwave group achieved superior long-term pain relief compared to the injection group and only slightly less pain relief than the radiofrequency group. Importantly, both the ESWT and radiofrequency groups showed significant long-term improvement in daily functional activities, whereas steroid injections yielded more transient benefits. No adverse effects were observed with ESWT. This study suggested that non-invasive shockwave therapy could provide lasting relief comparable to the "gold-standard" medial neurotomy, concluding ESWT as a safe and promising option for lumbar facet joint pain. However, from some perspectives, RPW did not succeed. We did not observe a significant long-term effect in patients with a high BMI (BMI>30), and only a negligible influence on neuropathic pain was found.

Based on these findings, we designed a prospective, randomized sham-controlled trial to assess the efficacy and safety of high-energy fESWT in patients with chronic unilateral FJ pain. Our primary objectives were to evaluate changes in nociceptive and neuropathic pain, quality of life, and imaging findings in short- and long-term follow-up.

Study objective and inclusion and exclusion criteria

This prospective, randomized, sham-controlled clinical trial enrolled 128 patients diagnosed with chronic, unilateral lumbar FJ pain. Recruitment was conducted between February 2020 and March 2022 at a single specialized outpatient center for spine disorders and pain medicine.

The study aimed to evaluate the efficacy of high-energy, focused ESWT in reducing pain and disability in this patient population.

Inclusion criteria required patients experiencing chronic persistent or intermittent, but recurrent localized lumbar pain persisting for ≥3 months, without radiation below the knee, and showing mechanical provocation (e.g. pain on extension and rotation). All patients underwent standardized diagnostic ultrasound-guided medial branch nerve block, using 5 mL of 1% trimecaine per segment, to confirm facet-mediated pain[51]. Blocks were applied to two adjacent medial branches innervating the target FJ to cover both ascending and descending fibers, consistent with established techniques for facet joint innervation patterns. Patients were considered eligible only if they achieved a reduction of ≥50% in pain intensity on the visual analog scale (VAS) within 60 minutes after injection[52]. This diagnostic threshold aligns with international recommendations and clinical practice guidelines[7]. To avoid short-term anesthetic interference with subsequent treatment, shockwave therapy was initiated a minimum of three weeks after diagnostic block administration.

Rigorous **exclusion criteria** were applied to minimize confounding pain sources. Patients were excluded if they presented with

- Clinical signs of radiculopathy, including dermatomal sensory deficits, motor weakness, or positive nerve tension signs.
- Abnormal findings on electromyography (EMG), including evidence of polyneuropathy, plexopathy, or radicular lesion.
- Radiographic findings of lumbar disc herniation, nerve root compression, spinal stenosis, vertebral instability, spondylolisthesis, fractures, or tumors on MRI.
- Metabolic comorbidities such as diabetes mellitus or thyroid dysfunction, due to their potential influence on peripheral nerve function and neuropathic pain profiles.

This strict selection protocol was designed to isolate lumbar facet joint pain and avoid confounding from overlapping musculoskeletal or neuropathic conditions.

Methods

This study enrolled 128 patients with chronic, unilateral lumbar facet joint (FJ) pain who responded to diagnostic ultrasound-guided medial branch block, as described in the previous section. All procedures were conducted at a single outpatient pain medicine center. The study protocol was reviewed and approved by the local ethics committee in January 2020.

Patients were randomly assigned in a 1:1 ratio to one of the two groups:

Group A (Treatment Group): high-energy, focused extracorporeal shockwave therapy (ESWT).

Group B (Control Group): sham treatment

Each group included 64 patients with comparable demographic profiles (Group A: 33 men, 31 women; mean age: 44 years; Group B: 35 men, 29 women; mean age: 39 years). All participants underwent comprehensive clinical assessment by a neurologist and a rehabilitation physician. This included spinal range-of-motion evaluation, assessment of muscle spasm and trigger points, motor strength testing, deep tendon reflexes, and sensory evaluation (tactile discrimination and vibration testing). Magnetic resonance imaging (MRI) of the lumbar spine was performed prior to treatment and repeated six months after study completion to evaluate safety and structural changes. All patients underwent conduction and needle electromyography (EMG) studies to exclude polyneuropathy, radiculopathy, or plexopathy. Blood panels included renal, hepatic, glycemic, electrolyte, and thyroid function (FT3, FT4, TSH) parameters.

To minimize variability, all participants were instructed to discontinue other conservative therapies, including NSAIDs, physical therapy, or spinal manipulation, during the study. Only a standardized home-based exercise therapy protocol was permitted, consisting of core stabilization and lumbar extension exercises administered at the same frequency and intensity across both groups. Compliance was monitored at follow-ups via self-report and therapist feedback. This study was conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines[53].

Randomization protocol

Randomization was performed using a computer-generated sequence with random block sizes (2–4), stratified by site. Allocation was concealed using sealed opaque envelopes managed by a study coordinator, who was not involved in treatment or assessment. Patients were blinded to group allocation, and outcome assessors were likewise blinded. Treating providers, trained and certified for the use of focused ESWT electromagnetic device, were not blinded due to the physical setup requirements of the device.

Pain and outcome measurement

Pain intensity was measured using the Visual Analog Scale (VAS, 0–10 cm) at baseline, and at 2, 6, and 12 months post-treatment. Disability related to low back pain was assessed using the Modified Oswestry Disability Index (ODI) at the same intervals. Neuropathic pain features were assessed using the PainDETECT Questionnaire (PD-Q), a validated tool in study participants' native language (Czech), which quantifies clinical signs of neuropathic pain such as burning, allodynia, paresthesia, and numbness[54] to measure neuropathic pain.

Statistical analysis

Statistical analysis was conducted using SPSS Statistica v10 (SPSS Inc., Chicago, IL, USA). Between-group comparisons were performed using one-way analysis of variance (ANOVA)[55]. Repeated measures ANOVA were used to assess changes over time. Significance was set at $P < 0.05$, and 95% confidence intervals (CIs) were reported where appropriate. Subgroup analyses (e.g. neuropathic pain and evaluation in overweight patients, BMI >28) were pre-planned.

Therapeutic protocol

Focused ESWT was administered using the Storz Duolith SD-1 electromagnetic device (Storz Medical AG, Tagerwilen, Switzerland). The energy flux density (EFD) was set at 0.35 mJ/mm^2, with a frequency of 4 Hz. Each session included 1200 shocks, delivered over five weekly sessions.

Ultrasound guidance was used to identify the facet joint orientation and target depth, and the optimal angle of the applicator head was marked on the skin to ensure consistent positioning throughout treatment [see Figs 1 and 2].

According to the manufacturer information (Storz Medical Duolith SD-1, rev. 26 140.0002), the applicator head used in this study produces a focal zone at 65 mm with a therapeutically effective penetration depth (5 MPa) reaching up to 125 mm. Given that the facet joints receive dual segmental innervation, treatment was applied at both the affected segment and the adjacent superior level (600 shocks per level). For example, for L4/L5 FJ pain, the L3/L4 and L4/L5 medial branch regions were targeted. The setup was similar to diagnostic block[51].

Sham control group device setup

In Group B (sham treatment), the same device was used with identical settings for frequency, energy, and session length. However, a custom-designed, slim air-filled polyurethane interface was inserted between the applicator head and the skin, effectively absorbing the shockwaves and preventing energy transmission into the tissues. The Pat approach has been validated in previous placebo-controlled ESWT trials and was designed to mimic the auditory and tactile sensations of real treatment without delivering therapeutic energy[32,56]. Post-treatment, patients were asked to guess their group assignment to assess the effectiveness of blinding.

Adverse events and Safety

No serious adverse events were reported in either group. Eight patients experienced mild-to-moderate pain flare within 24 hours after treatment (six in Group A, two in Group B), which was successfully managed with a single dose of oral NSAIDs or paracetamol. All symptoms resolved spontaneously. No clinical neurological deficits and skin or soft tissue injuries were observed.

Results

Data from all 128 enrolled participants (n =64 in each group) were included in the final analysis, with no dropouts or missing follow-up points.

Pain intensity (VAS)

At baseline, the mean Visual Analog Scale (VAS) score was 5.9 ± 1.0 cm in the ESWT group (Group A) and 6.5 ± 1.8 cm in the sham group (Group B). Both groups exhibited statistically significant reductions in VAS scores at the 2-month follow-up (Group A: $P = 0.03$; Group B: $P = 0.01$). However, only Group A demonstrated sustained pain reduction at 6 and 12 months

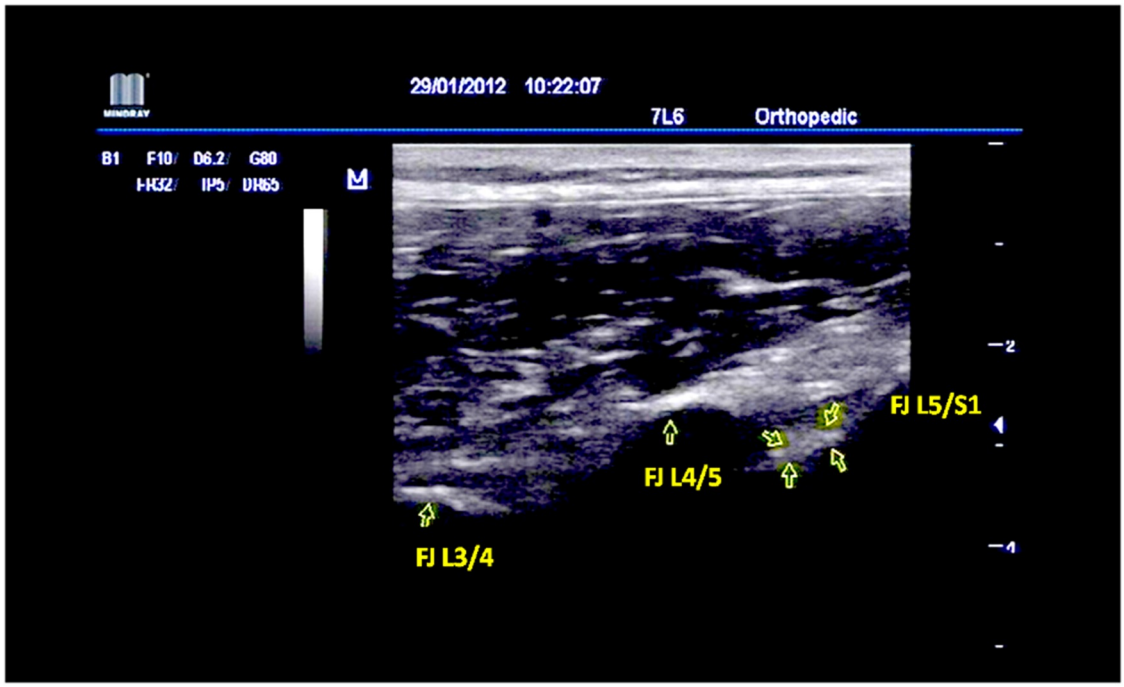

Figure 1. In-plane ultrasound visualisation of lumbar facet joint. Linear probe, 5 MHz, focus depth set to 28 mm. FJ – corresponding facet joints. A position of facet joints and appropriate segment was marked on the skin, maintaining the same position for treatment [image from author´s archive].

(Group A: $P < 0.01$), whereas pain scores in Group B returned toward baseline by 12 months [Fig 3].

The mean VAS score in Group A declined to 3.0 ± 1.4 at 6 months and 2.1 ± 1.2 at 12 months, representing a **64.4% reduction from baseline**. In contrast, Group B showed only a transient decrease (mean 3.8 ± 1.5 at 2 months), followed by partial relapse (5.5 ± 1.6 at 12 months). The between-group difference in VAS at 12 months was 3.4 cm (95% CI: 2.8–4.1; $P < 0.01$), Cohen's d = 1.12.

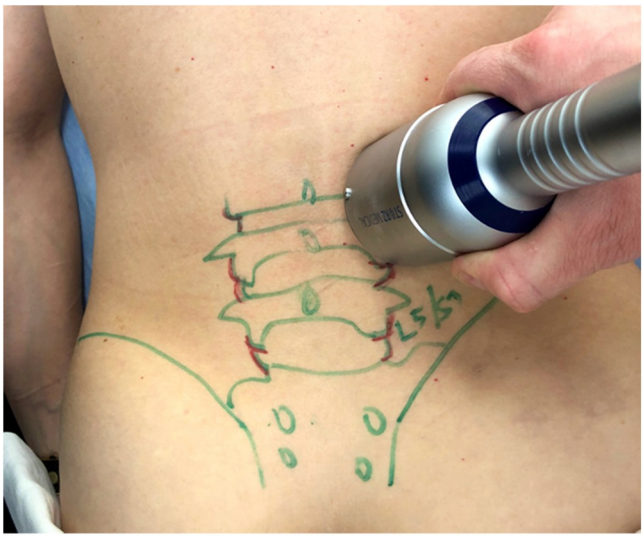

Figure 2. Scheme of application head (Storz Duolith) positioning. We used ultrasound (see Image 1) as well as clinical focusing – elicited pain in treatment area). After delivering 600 shocks to affected segments, we have moved the head upwards to treat the upper segments.

Disability index (Modified Oswestry Disability index—ODI)

The Modified Oswestry Disability Index (ODI) improved significantly in both groups at 2 months ($P < 0.05$). However, continued improvement was seen only in the ESWT group, with sustained reduction in disability scores at 6 and 12 months [Fig 4a]. In the control group, ODI returned close to baseline values by 12 months. The ESWT group exhibited a mean ODI reduction of 42.3% at 12 months, compared to 12.5% in the control group.

Neuropathic pain intensity (PainDETECT Score)

The PainDETECT (PD-Q) neuropathic pain questionnaire[57] was used to quantify the clinical signs of neuropathic pain (i.e. irradiating pain, itchiness, dull pain, paresthesia, or numbness). Among all participants, 27 patients in Group A and 22 in Group B (total n = 49) exhibited baseline neuropathic pain symptoms according to the PainDETECT Questionnaire (PD-Q).

Baseline PD-Q scores in this subgroup were 18.3 ± 2.4 (Group A) and 17.9 ± 2.6 (Group B). Over the 12-month follow-up, only the ESWT group demonstrated a significant reduction in PD-Q scores (to 10.2 ± 1.9; $P < 0.01$), with no significant change in Group B. Subgroup analysis confirmed this effect persisted even after adjusting for baseline PD-Q severity [Fig 4b]. These results support the hypothesis that ESWT may exert therapeutic effects on neuropathic pain components in lumbar facet joint syndrome.

BMI-dependent response

Subgroup analysis of patients with **BMI >28** (n =34 in Group A, n =31 in Group B, n =65 in both groups) demonstrated significantly better pain reduction in the ESWT group compared to controls ($P < 0.01$), suggesting greater tissue penetration with focused energy may be especially beneficial in overweight

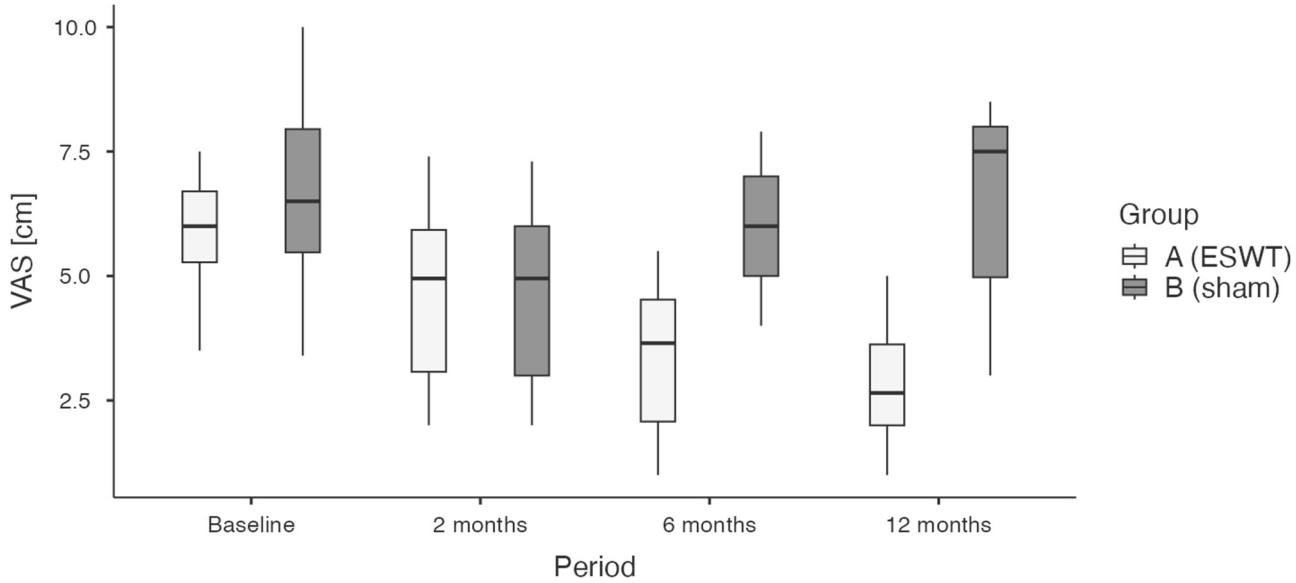

Figure 3. VAS [cm] values comparison between Group A – ESWT (on the left side, "a") and Group B – sham- ESWT (on the right side, "b") at 2, 6, and 12 months follow-up. Mean, maximum, and minimal values for each parameter are stated graphically, as well as 3Q and 2Q box plots. Significant results [$P<0.05$] marked with *.

individuals. The mean VAS reduction in this subgroup was 65.7% in Group A vs. 17.4% in Group B at 12 months [Fig 4c].

MRI findings and safety

All patients underwent lumbar MRI at baseline and ≥6 months post-treatment. No structural damage (e.g. hemorrhage, fracture, spine instability, or soft tissue injury) attributable to shockwave therapy was observed in either group, supporting the safety profile of high-energy, focused ESWT at 0.35 mJ/mm^2.

As a secondary output, among 17 patients in Group A with baseline bone marrow edema in the facet joints or vertebral bodies (Modic changes), 10 patients (58.8%) demonstrated substantial resolution of edema at follow-up. This resolution was defined as a ≥ 50% reduction in the hyperintense area on T2-weighted MRI imaging, confirmed by two blinded radiologists. Inter-rater reliability evaluating the MRI was high (Cohen's $\kappa = 0.87$), confirming the consistency of imaging evaluations.

In contrast, no significant MRI changes were seen in the 20 patients with bone marrow edema in the control group. Representative imaging changes are shown in Fig 5.

These findings support the hypothesis that bone marrow edema contributes to nociceptive sensitization in facet joint pain[58] and that its resolution may represent a biological correlate of ESWT therapeutic effect[43].

Discussion

This randomized, sham-controlled trial provides evidence supporting the efficacy and safety of high-energy, focused ESWT in the treatment of chronic lumbar facet joint pain. The study demonstrated clinically meaningful improvements in pain intensity, disability, and neuropathic pain features, with sustained long-term effects up to 12 months. Furthermore, this study introduces novel, clinical, and imaging-based insights into the modulation of bone marrow edema (BME) in the spine by focused ESWT.

Focused ESWT vs. radial shockwave and invasive interventions

Previous studies evaluating radial pressure wave (RPW) therapy in low back pain, including our own retrospective analysis[50], reported moderate pain relief, with notable limitations in patients with higher body mass index (BMI) or deeper facet joint involvement. Radial shockwaves, limited to superficial tissue penetration (~3–6 cm), may not adequately reach the joints and its innervation, particularly in overweight or obese individuals.

In contrast, the current study used focused ESWT with a focal depth of 6.5 cm and penetration depth (5 MPa area) of up to 12.5 cm, effectively addressing this limitation. Our results showed a 65% reduction in mean VAS scores at 12 months (95% CI: 58–72%; $P < 0.01$), which compares favourably with typical outcomes reported for radiofrequency medial branch neurotomy (RMBN), where pain relief often ranges from 50% to 60%[7,11]. Unlike RMBN, however, ESWT is non-invasive, does not carry the risks of nerve damage, bleeding, infection, or post-procedural muscle atrophy, and does not require fluoroscopic guidance or sedation. Regarding the depth and targeting of therapeutic energy in the current study, ultrasound-guided applicator positioning was used, maintaining the position of FJ in the optimal angle and focus depth of the ESWT applicator.

While prior studies of Notarnicola *et al* and Lee *et al*[41,42] have reported the benefits of ESWT in non-specific chronic low back pain, this is the first prospective randomized trial focusing on imaging-confirmed, anesthetic block-positive lumbar facet syndrome. It also advances the field by refining patient selection, targeting protocols, and outcome assessment over an extended follow-up period.

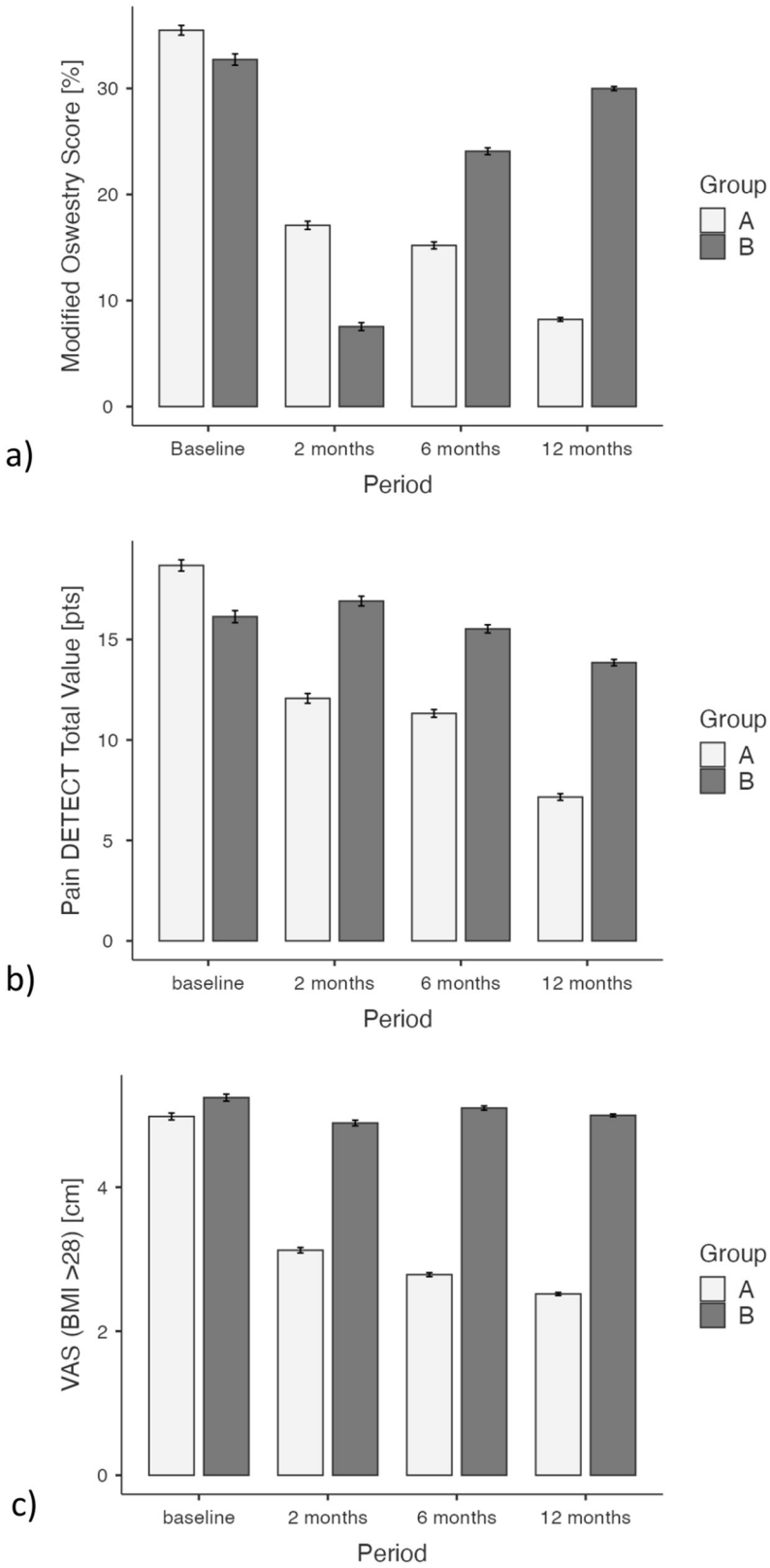

Figure 4 (A) Modified Oswestry score [%] values comparison between treatment Group A and control Group B at baseline, 2, 6, and 12 months follow-up. Mean, maximum, and minimal values for each parameter are stated graphically. Significant results [$P<0.05$] marked with *. (B): Pain DETECT neuropathic pain questionnaire (PD-Q) values comparison between treatment Group A and control group B at baseline, 2, 6, and 12 months follow-up. (C) Visual Analog Scale (VAS) values in BMI >28 patients – comparison between treatment Group A and control Group B at baseline, 2, 6, and 12 months follow-up.

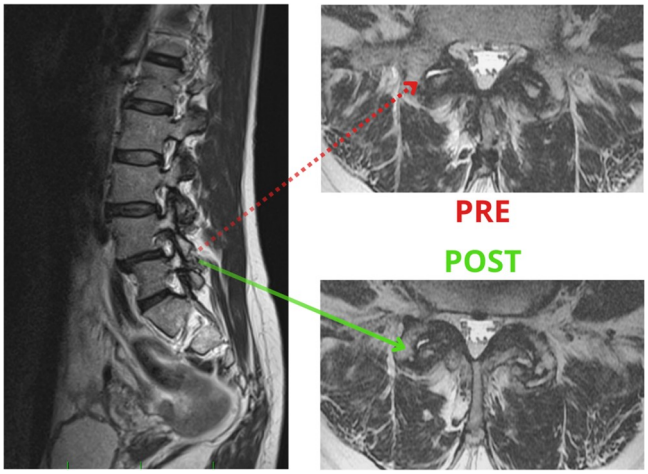

Figure 5. MRI findings of bone marrow edema reduction within the articular process of treated FJ L4/5, 12 months follow-up after the treatment [image from author's archive].

Neuropathic pain modulation and mechanistic insights

A significant finding in our study is the reduction in neuropathic pain symptoms, as measured by the PainDETECT questionnaire. Nearly one-third of patients exhibited neuropathic components, and ESWT significantly improved PD-Q scores at 12 months, a result not observed in the sham group. Although the presence of neuropathic pain in facet joint degeneration may be debated, our findings, as aligned with preclinical and clinical evidence, support a neuromodulatory effect.

Animal studies have demonstrated that ESWT promotes peripheral nerve regeneration, reduces inflammatory mediators, and enhances neurotrophin expression (e.g. NT-3, GAP-43, and ATF3). Mense *et al* and Murata *et al*[23,26] showed improved nerve repair and function in models of nerve compression following ESWT. *In vitro*, ESWT has been shown to enhance Schwann cell proliferation, axonal elongation, and remyelination through upregulation of VEGF and modulation of the ERK/MAPK signaling pathways[27,46]. These changes are consistent with improved functional recovery observed in animal models of nerve injury.

Clinically, studies of Ke *et al*, Wu *et al*, and Zhang *et al*[30,31,33] reported improved electrophysiological markers and pain scores in carpal tunnel syndrome following focused ESWT and RPW, further validating its effect on neural tissue. Our study contributes to this body of work by providing new evidence for similar effects in a spinal application, suggesting that ESWT may benefit patients with facet joint-related neuropathic pain.

Although we did not perform post-treatment electrophysiology, our exclusion of peripheral nerve involvement at baseline (polyneuropathy and radiculopathy), combined with PD-Q result analysis, ensures the maximum diagnostic relevance and may provide a clinical basis for future studies.

Bone marrow edema (BME): a novel imaging correlate

A particularly novel contribution of this study, considered as an important secondary outcome, is the observation of BME resolution in lumbar facet joints and adjacent vertebrae following focused ESWT. Among 17 patients with Modic type I or II changes at baseline, 10 showed substantial reduction in edema, defined as a visible reduction or disappearance (≥50% decrease) of the hyperintense signal in the affected region, as evaluated independently using a binary scoring system (present/absent). These results may suggest a biological influence of ESWT on vertebral body and articular inflammatory processes.

Modic changes, particularly type I, have been implicated as pain generators in chronic low back pain, associated with both mechanical and inflammatory pathways. Studies of Alpayci *et al* and Suri *et al*[49,58] emphasized the relationship between BME and facet joint degeneration. While ESWT has previously been shown to reduce subchondral BME in weight-bearing joints such as the knee and hip, including in osteoarthritis and avascular necrosis of the femoral head, the devices used in those studies were similarly high-energy, focused systems. For example, Häußer *et al*[43] demonstrated reduction of BME in the femoral head in avascular necrosis using a focused ESWT device. Similarly, Gao *et al*[45] showed reduced knee BME in osteoarthritic patients following focused shockwave therapy. These parallels suggest a shared biological mechanism across joints: mechanotransduction-induced angiogenesis, osteoblast activation, and reduced subchondral inflammation.

Our findings represent the first application of this approach in the spine, extending the therapeutic potential of focused ESWT to spinal joint-related BME. Conversely, imaging alone is not definitive evidence of therapeutic success. However, our imaging findings parallel clinical outcome improvements and suggest that structural changes may reflect underlying biological modulation rather than placebo effects. The durability of clinical effects observed at long-term follow-up of 12 months further supports this conclusion.

Study limitations and future research directions

Our study has certain limitations. First, while EMG and imaging were used to exclude confounding diagnoses at baseline, we did not include follow-up electrophysiological assessments. Incorporating post-treatment EMG and nerve conduction studies would provide objective validation of the neuromodulatory effects indicated by PD-Q score reductions. Specific neurophysiological protocols including F-wave latency, sensory conduction velocity, and quantitative EMG and evaluation of paraspinal muscles could help confirm the neural impact of fESWT and should be analyzed in relation to affected dermatomes and facet innervation patterns.

Second, the study was conducted as a single center, and the results may not be fully generalizable to more diverse populations or healthcare settings.

Third, our cohort was selected based on positive response to diagnostic medial branch blocks, which, although a gold standard for facet pain diagnosis, may limit extrapolation to patients with mixed lower back pain pathologies.

Future research should include multi-center trials, broader patient populations, and direct comparisons, i.e. with other non-invasive modalities such as pulsed electromagnetic field therapy (PEMF) or high-intensity focused ultrasound (HIFU) or complex exercise techniques, which were also reported as effective in facet joint pain management.

Conclusion

This randomized, sham-controlled trial demonstrated that high-energy, focused extracorporeal shockwave therapy (ESWT) is a safe and effective non-invasive treatment for chronic lumbar facet joint pain. Statistically and clinically significant improvements in pain intensity, functional disability, and neuropathic pain symptoms were sustained over a 12-month follow-up period.

Focused ESWT showed particular efficacy in subgroups with elevated BMI and those exhibiting neuropathic pain features – populations in whom traditional treatments often underperform. A novel contribution of this study is the observation of spinal bone marrow edema including Modic change resolution on MRI following ESWT, the first such report in the literature. This finding, in parallel with clinical improvements, supports the biological plausibility of ESWT-mediated modulation of joint inflammation and nociceptive and neuropathic sensitization.

While promising, these findings should be interpreted with caution. Larger, multi-center trials with longer-term follow-up and more complex endpoints are needed to confirm and extend these results. Overall, ESWT represents a promising non-invasive treatment modality with the potential to address multiple dimensions of facet joint pain through a non-invasive, well-tolerated intervention.

Ethical approval

The study was approved by the ethical committee.

Consent

Each patient signed informed consent to take a part of the study.

Sources of funding

There was no financial support for the study.

Author contributions

Concept/idea/research design: T.N., Writing: T.N., P.H., K.K., Data collection: T.N., J.N., Data analysis: J.K., Project management: T.N., J.N., Fund procurement: T.N., Providing participants: T.N., J.N., Providing facilities/equipment: T.N., J.N., Consultation (including review of manuscript before submitting): K.K.

Conflicts of interest disclosure

There is no conflict of interest in any of the authors.

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Presentation

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References

[1] Fukui S. Distribution of referred pain from the lumbar zygapophyseal joints and dorsal rami. Clin J Pain 1997;13:303–07.
[2] Nedelka T, Nedelka J, Schlenker J, Mazanec R. Neuropathic component of chronic low back pain (in Czech. Neurol.Prax 2011;12:104–09.
[3] Selby DK, Paris SV. Anatomy of facet joints and its clinical correlation with low back pain. Contemp Orthop 1981;3:1097–103.
[4] Manchikanti L, Boswell MV, Singh V, Pampati V, Damron KS, Beyer CD. Prevalence of facet joint pain in chronic spinal pain of cervical, thoracic, and lumbar regions. BMC Musculoskelet Disord 2004;28:15.
[5] Ghormley RK. Low back pain with special reference to the articular facets, with presentation of an operative procedure. Jama 1933;101: 1773–77.
[6] Marks R. Distribution of pain provoked from lumbar facet joints and related structures during diagnostic spinal infiltration. Pain 1989;39: 37–40.
[7] Cohen SP, Raja SN. Pathogenesis, diagnosis, and treatment of lumbar zygapophysial (facet) joint pain. Anesthesiology 2007;106:591–614.
[8] Datta S, Lee M, Falco FJ, Bryce DA, Hayek SM. Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions. Pain Physician 2009;12:437–60.
[9] Khazim R, Zaidan AA, Ravi K, Toma T. Single photon emission computerized tomography (SPECT) scan- positive facet joints and other spinal structures in a hospital-wide population with spinal pain. Makki D Spine J 2010;10:58–62.
[10] Pneumaticos SG, Chatziioannou SN, Hipp JA, Moore WH, Esses SI. Low back pain: prediction of short-term outcome of facet joint injection with bone scintigraphy. Radiology 2006;238:693–98.
[11] Manchikanti L. Medial branch neurotomy - systematic review of the evidence. Pain Physician 2002;5:405.
[12] Peh WCG. Image-guided facet joint injection. Biomed Imaging Interv J 2011;7:e4.
[13] Muffolerro AJ, Nader R, Westmark RM, Nauta HJ, Garges KJ, Hadjipavlou AG. Hematogenous pyogenic facet joint infection of the subaxial cervical spine. A report of two cases and review of the literature. J Neurosurg Spine 2001;95:135–38.
[14] Berrigan T. Chemical meningism after lumbar facet joint block. Anesthesia 1992;7:905–06.
[15] Raj PP, Shah RV, Kay AD, Denaro S, Hoover JM. Bleeding risk in interventional pain practice: assessment, management, and review of the literature. Pain Physician 2004;7:3–52.
[16] Dreyfuss P, Stout A, Aprill C, Pollei S, Johnson B, Bogduk N. The significance of multifidus atrophy after successful radiofrequency neurotomy for low back pain. PMR 2009;1:719–22.
[17] Kornick CA, Kramarich SS, Lamer TJ, Sitzman BT. Complications of lumbar facet radiofrequency denervation. Spine 2004;29:1352–54.
[18] Jones TR, James JE, Adams JW, Garcia J, Walker SL, Ellis JP. Lumbar zygapophyseal joint meniscoids: evidence of their role in chronic intersegmental hypomobility. J Manipulative Physiol Ther 1989;12:374–85.
[19] Wang CJ. Extracorporeal shockwave therapy in musculoskeletal disorders. J Orthop Surg Res 2012;20:7–11.

[20] van der Worp H1, van den Akker-scheek I, van Schie H, Zwerver J. ESWT for tendinopathy: technology and clinical implications. Knee Surg Sports Traumatol 2013;21:1451–58.
[21] Wang CJ, Sun YC, Wong T, Hsu SL, Chou WY. Chang HW. Extracorporeal shockwave therapy shows time- dependent chondroprotective effects in osteoarthritis of the knee in rats. J Surg Res 2012;178: 196–205.
[22] Qin L, Wang L, Wong MW, *et al*. Osteogenesis induced by extracorporeal shockwave in treatment of delayed osteotendinous junction healing. J Orthop Res 2010;28:70–6.
[23] Murata R, Ohtori S, Ochiai N, *et al*. Extracorporeal shockwaves induce the expression of ATF3 and GAP-43 in rat dorsal root ganglion neurons. Auton Neurosci 2006;128:96–100.
[24] Ochiai N, Ohtori S, Sasho T, *et al*. Extracorporeal shock wave therapy improves motor dysfunction and pain originating from knee osteoarthritis in rats. Osteoarthritis Cartilage 2007;15:1093–96.
[25] Jaalouk DE, Lammerding J. Mechanotransduction gone away. Nat Rev Mol Cell Biol 2009;1:63–73.
[26] Mense S, Hoheisel U. Shock wave treatment improves nerve regeneration in the rat. Muscle Nerve 2013;47:702–10.
[27] Lee JH, Kim SG. Effects of extracorporeal shock wave therapy on functional recovery and neurotrophin-3 expression in the spinal cord after crushed sciatic nerve injury in rats. Ultrasound Med Biol. 2015;41:790–96.
[28] Che YJ, Hou JJ, Guo JB, *et al*. Low energy extracorporeal shock wave therapy combined with low tension traction can better reshape the microenvironment in degenerated intervertebral disc regeneration and repair. Spine J 2021;21:160–77.
[29] Hsu CC, Wu KLH, Peng JM, *et al* Low-energy extracorporeal shockwave therapy improves locomotor functions, tissue regeneration, and modulating the inflammation induced FGF1 and FGF2 signaling to protect damaged tissue in spinal cord injury of rat model: an experimental animal study. Int J Surg 2024:110:7563–72.
[30] Ke MJ, Chen LC, Chou YC, *et al*. The dose-dependent efficiency of radial shock wave therapy for patients with carpal tunnel syndrome: a prospective, randomized, single-blind, placebo- controlled trial. Sci Rep 2016;6:38344.
[31] Wu YT, Ke MJ, Chou YC, *et al*. Effect of radial shock wave therapy for carpal tunnel syndrome: a prospective randomized, double-blind, placebo-controlled trial. J Orthop Res 2016;34:977–84.
[32] Vahdatpour B, Kiyani A, Dehghan F. Effect of extracorporeal shock wave therapy on the treatment of patients with carpal tunnel syndrome. Adv Biomed Res 2016;5:120.
[33] Zhang L, Yang T, Pang L, *et al*. Effects of extracorporeal shock wave therapy in patients with mild-to-moderate carpal tunnel syndrome: an updated systematic review with meta-analysis. J Clin Med 2023;12: 7363.
[34] Moon YE, Seok H, Kim SH, Lee SY, Yeo JH, Extracorporeal shock wave therapy for sacroiliac joint pain: a prospective, randomized, sham-controlled short-term trial. J Back Musculoskelet Rehabil 2017;30: 779–84.
[35] Oh Hong Jin, Sang Park Joon, Geun Jeon Dae, Wang Hyeon Yoon, Jung Hyun Park. Extracorporeal Shock Wave Therapy Versus Trigger Point Injection in the Treatment of Myofascial Pain Syndrome in the Quadratus Lumborum. Ann Rehabil Med 2017;41:582–88.
[36] Lin SF, Chen YJ, Tu HP, *et al*. The effects of extracorporeal shock wave therapy in patients with coccydynia: a randomized controlled trial. PLoS One 2015;10:e0142475.
[37] Liu K, Zhang Q, Chen L, *et al*. Efficacy and safety of extracorporeal shockwave therapy in chronic low back pain: a systematic review and meta-analysis of 632 patients. J Orthop Surg 2023;18:455.
[38] Wu YT, Ke MJ, Chou YC, Chang CY, Lin CY, Li TY, Shih FM, Chen LC. Ferdinandov D.Focused extracorporeal shockwave therapy for the treatment of low back pain: a systematic review. Front Med 2024;11:1435504.
[39] Rajfur K, Rajfur J, Matusz T, *et al*. Efficacy of focused extracorporeal shock wave therapy in chronic low Back pain: a prospective randomized 3-month follow-up study. Med Sci Monit Int Med J Exp Clin Res 2022;28:e936614.
[40] Eftekharsadat B, Fasaie N, Golalizadeh D, *et al*. Comparison of efficacy of corticosteroid injection versus extracorporeal shock wave therapy on inferior trigger points in the quadratus lumborum muscle: a randomized clinical trial. BMC Musculoskelet Disord 2020;21:695.
[41] Lee S, Lee D, Park J. Effects of extracorporeal shockwave therapy on patients with chronic low back pain and their dynamic balance ability. J Phys Ther Sci 2014;26:7–10.
[42] Notarnicola A, Maccagnano G, Gallone MF, *et al*. Extracorporeal shockwave therapy versus exercise program in patients with low back pain: short-term results of a randomised controlled trial. J Biol Regul Homeost Agents 2018;32:385–89.
[43] Häußer J, Wieber J, Catalá-Lehnen P. The use of extracorporeal shock wave therapy for the treatment of bone marrow oedema - a systematic review and meta-analysis. J Orthop Surg Res 16:369.
[44] D'Agostino MC, Craig K, Tibalt E, Respizzi S. Shock wave as biological therapeutic tool: from mechanical stimulation to recovery and healing, through mechanotransduction. Int J Surg 2015;24:147–53.
[45] Gao F, Sun W, Li Z, Guo W, Kush N, Ozaki K. Intractable bone marrow edema syndrome of the hip. Orthopedics 2015;38:e263–70.
[46] Chen J-M, Hsu S-L, Wong T, Chou W-Y, Wang C-J, Wang F-S. Functional outcomes of bilateral hip necrosis: total hip arthroplasty versus extracorporeal shockwave. Arch Orthop Trauma Surg 2009;129:837–41.
[47] Rahme R, Moussa R. The modic vertebral endplate and marrow changes: pathologic significance and relation to low back pain and segmental instability of the lumbar spine. AJNR Am J Neuroradiol 2008;29:838–42.
[48] Lakadamyali H, Tarhan NC, Ergun T, *et al*. STIR sequence for depiction of degenerative changes in posterior stabilizing elements in patients with lower back pain. AJR 2008; 191:973–79.
[49] Suri P, Dharamsi AS, Gaviola G, *et al*. Are facet joint bone marrow lesions and other facet joint features associated with low back pain? A pilot study. PMR 2013;5:194–200.
[50] Nedelka T, Nedelka J, Schlenker J, Hankins C, Mazanec R. Mechanotransduction effect of shockwaves in the treatment of lumbar facet joint pain: comparative effectiveness evaluation of shockwave therapy, steroid injections and radiofrequency medial branch neurotomy. Neuro Endocrinol Lett 2014;35:393–97.
[51] Gofeld M, Bristow SJ, Chiu S. Ultrasound-guided injection of lumbar zygapophyseal joints: an anatomic study with fluoroscopy validation. Reg Anesth Pain Med 2012;37:228–31.
[52] Van Zundert J, Vanelderen P, Kessels A, van Kleef M. Radiofrequency treatment of facet-related pain: evidence and controversies. Curr Pain Headache Rep 2012;16:19–25.
[53] Schulz KF, Altman DG, Moher D. for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. Ann Int Med 2010;152:726–32.
[54] Freynhagen R, Baron R. The evaluation of neuropathic components in low back pain. Curr Pain Headache Rep 2009;13:185–90.
[55] Freedman David A, Pisani R, Purves R. Statistics. 4th edition. New York, NY: W.W. Norton & Company;2007
[56] Ioppolo F, Rompe JD, Furia JP, Cacchio A. Clinical application of shock wave therapy (SWT) in musculoskeletal disorders. Eur J Phys Rehabil Med 2014;50:217-30.
[57] Freynhagen R, Baron R, Gockel U, Tölle TR. painDETECT: a new screening questionnaire to identify neuropathic components in patients with back pain. Curr Med Res Opin 2006;22:1911–20.
[58] Alpayci M, Bulut MD, Yazmalar L, *et al*. The relationship between facet joint osteoarthritis and Modic changes of the lumbar spine: a retrospective magnetic resonance imaging study. Turk J Phys Med Rehab 2016;62:308–13.