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Case Series

Can Focal Extracorporeal Shock Wave Therapy Promote Bone Consolidation and Improve Pain and Functionality? – A Case Series

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Abstract

Background: Nonunion bone fractures cause chronic pain and disability, posing a significant burden on healthcare systems. Extracorporeal Shockwave Therapy (ESWT) has emerged as a promising non-invasive treatment, with studies showing bone healing success rates between 50% and 100%.

Methods: This study aims to evaluate the efficacy of focal ESWT (fESWT) in improving bone consolidation, pain, and functionality in patients with nonunion bone fractures, and to identify potential predictive factors of the treatment success rate. Inclusion criteria included nonunion bone fractures persisting over 9 months, pain and/or functional limitation, and skeletal maturity. Exclusion criteria included bone tumors, infected nonunions, instability of fixation devices, fracture gap size larger than 5mm, blood coagulation disorders, and pregnancy. Ultrasound was used to assess fracture depth, select the appropriate stand-off, and define the treatment area. The protocol involved three sessions of fESWT at one-week intervals. Patients underwent clinical and radiological evaluations at 3-, 6-, and 9-months following treatment.

Results: The study included 7 patients (5 males and 2 females, mean age 56.14 ± 18.68 years). Treatment was successful in 4 patients (57.1%) at 9 months post-treatment. NRS mean scores decreased significantly at 9 months, at rest and during movement, with overall reductions of 1.43 and 4.14 points, respectively. At 9 months, the qDASH mean score improved by 18.15 points, and the LEFS mean score increased by 22.20 points. Even in persistent nonunions after treatment, the NRS mean score at rest decreased by 1.67 points and during movement by 3.33 points. Additionally, functional outcomes improved, with the qDASH score increasing by 18.15 points and the LEFS score by 32.00 points. No adverse effects were observed. Patient satisfaction with the fESWT was "very good" in 42.9% of cases, "satisfactory" in 42.9%, and "good" in 14.3%.

Conclusions: fESWT is a safe and effective treatment for fracture nonunions in selected patients, including atrophic cases, with significant pain and functional improvement, even in persistent nonunions. Standardizing procedures is essential. Choosing fESWT may reduce healthcare costs by avoiding more invasive treatments.

Keywords: *Nonunion, Extracorporeal Shock Wave Therapy, Bone Consolidation, Pain, Functionality*

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Introduction

Nonunion bone fractures represent a chronic medical condition that causes pain and functional impairment, with a significant impact on health systems and society.[1] The FDA defines nonunion as a fracture that is at least nine months old and has not shown any evidence of healing for three consecutive months.[1] It is a multifactorial pathologic process and affects up to 15% of patients.[2] The occurrence of nonunion is influenced by injury-related factors like trauma severity, as well as environmental conditions, which encompass systemic issues such as chronic illnesses and malnutrition, the use of specific medications, alcohol consumption, and local factors like irradiation and peripheral vascular disease.[1]

Extracorporeal shockwave therapy (ESWT) has emerged as a promising noninvasive method for promoting fracture healing. The impact of shock waves on bone consolidation was first recognized in 1988 when it was shown that patients receiving lithotripsy treatment exhibited an enhanced osteogenic response in the pelvic region.[3,4] Initially, the hypothesis regarding the mechanism of shockwave therapy suggested that it creates micro-lesions in the treated bone without harming adjacent soft tissue, triggering the stimulation of bone healing in nonunion fractures. However, Tischer[5] raised doubts about this principle by demonstrating new bone formation in healthy rabbit femora without any micro-lesions. Animal studies have demonstrated that effective osteoneogenesis can be stimulated even at lower intensities of 0.25 to 0.3 mJ/mm², using approximately 3000 pulses, without causing any mechanical damage.[6] Wang [7], a leading pioneer in shockwave therapy, further transformed this understanding by showing that shockwaves induce significant neovascularization in the treated tissue without causing deterioration. This occurs through the upregulation and expression of various pro-angiogenic and pro-osteogenic growth factors, which strongly stimulate bone healing.[4,8] Recent clinical studies have reported healing rates using ESWT ranging from 50% to 100%.[1,9-14] Considerable variation exists in the inclusion criteria and treatment protocols for delayed unions across different studies, particularly concerning the types of ESWT devices used (hydraulic, electromagnetic, or piezoelectric; radial or focal), the frequency of treatment sessions, the number of shock waves per session, and the total energy flux density applied.

There are two types of wave technology: focal and radial. While they share some indications, there are numerous differences in terms of the type of generator, physical characteristics, mechanism of action, and associated risks.[15]

Focal Extracorporeal Shockwave Therapy (fESWT) represents the conventional shock waves. There is ongoing research on its mechanism of action, revealing a biological response to mechanical stimuli known as mechanotransduction, which operates at the cellular, molecular, and tissue levels.[15] The therapeutic benefits of fESWT encompass analgesic, osteogenic, and tissue-repairing effects.[4] The intensity used is adjusted based on the desired therapeutic outcome: 0.1 to 0.3 mJ/mm² for cell regeneration, 0.1 to 0.5 mJ/mm² for pain management, 0.3 to 1.0 mJ/mm² for osteogenesis and 0.5 to 3.6 mJ/mm² for lithotripsy.[6]

Sharing the experience and detailed treatment protocol of a hospital center aims to encourage broader adoption of fESWT in clinical practice.

Objective

This study aims to evaluate the efficacy of fESWT in improving bone consolidation (*primary endpoint*), pain, and functionality (*secondary endpoints*) in nonunion bone fracture patients, and to identify potential predictive factors of the treatment success rate.

Methodology

Since February 2023, fESWT has been used in the Physical and Rehabilitation department of a hospital center, to treat nonunion bone fracture patients.

The study protocol was conducted according to Good Clinical Practice guidelines and the Declaration of Helsinki and previously approved by the Committee of Ethics for Health of the Hospital where the study took place (Ethics approval number: 03/21/04/2023).

In this study, nonunion was defined as a fracture without any progress toward healing on radiographs at least 9 months following treatment. Inclusion criteria were patients with nonunion bone fractures with fracture gaps of less or equal to 5mm, accompanied by pain and/or functional limitation, and skeletal maturity. Both hypertrophic and atrophic nonunions were considered. Exclusion criteria were bone tumors, infected nonunions, instability of fixation devices, blood coagulation disorders and pregnancy.[9,13]

Patients were referred by the attending orthopedic physician. During the follow-up period, none of the patients underwent any additional treatments. All patients provided informed consent and received explanations about the treatment and potential local complications.

Initial evaluation

At the initial consultation, the evaluation included discerning injury mechanisms, identifying the type and location of the fracture, and reviewing both surgical and nonsurgical prior interventions. Additionally, assessments were conducted for baseline metabolic conditions such as osteoporosis and diabetes, nutritional status (body mass index), immunological status, and tobacco and alcohol use habits. A comprehensive neurovascular examination was also performed, which focused on the soft tissue and assessment of joint range of motion, particularly in the joints above and below the fracture.

An initial anteroposterior and lateral radiograph for evaluation and characterization of the type of nonunion was requested. Laboratory tests included: complete blood count, electrolyte panel, C-reactive protein, erythrocyte sedimentation rate, hemoglobin A1c, thyroid stimulating hormone, free T4, parathyroid hormone, and also calcium, phosphorus, and vitamin D, serum levels of activated partial thromboplastin time, prothrombin time and fibrinogen levels.

Shock-Wave Therapy

All patients were treated with three sessions of focal electromagnetic extracorporeal shock wave therapy (fESWT) – DUOLITH SD1 T-TOP (Storz Medical AG, Tägerwilen, Switzerland) - with one-week intervals, according to The International Society for Medical Shockwave Treatment (ISMST) guidelines for Pseudarthrosis and Delayed Healing Bone Fractures.

The fractures were first evaluated using ultrasound imaging to determine their distance from the skin, facilitating appropriate selection of the stand-off. A longer stand-off head is recommended when the fracture is closer to the skin (Fig 1). When osteosynthesis material was present, the entry zone for shock waves was carefully chosen to avoid areas with plates. The fracture site was marked on the skin to guide the positioning of the fESWT equipment, and coupling gel was applied to minimize shock wave energy loss. The treatment protocol involved applying fESWT to multiple points along the cortical bone near the fracture. The number of pulses and their intensity were adjusted based on patient tolerance, and all treatment parameters were documented for each session. No local anesthesia was used.
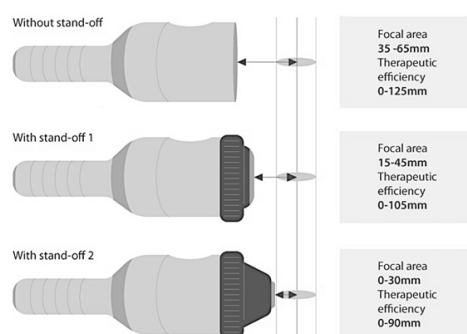

Fig 1. *Characteristics of the transducer (adapted from: Dreisilker, U., Shock Wave Therapy In Practice. 1st Edition ed. 2010: Walter Medien GmbH).*

The treatment parameters were as follows: [2,9-11,13,14,16-19]

- Short bones: frequency of 1-4Hz, delivering 1000-2500 pulses at an energy density of 0.1-0.35 mJ/mm².

- Long bones: frequency of 1-4Hz, delivering 2000-6000 pulses at an energy density of 0.3-0.55 mJ/mm².

Patients were instructed to avoid the use of Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) during the treatment period. Weight-bearing was allowed for lower limb non-unions as tolerated, while upper limb non-union patients were encouraged to engage in normal activities if pain-free.

Outcome measures:

All patients were evaluated 3, 6, and 9 months after treatment.

- **Primary endpoint**

The *primary endpoint* of this study was bone consolidation, assessed through radiographic evidence of bone-healing at 9 months after fESWT.

Assessments of anteroposterior and lateral radiographs, along with clinical examinations, were conducted at four-time points: before treatment, and at 3, 6, and 9 months after treatment. A nonunion was considered healed when 4 cortices (two visible on the anteroposterior radiograph and two on the lateral radiograph) were bridged or if no gap could be detected.

- **Secondary endpoints**

The *secondary endpoints* of this study were functional status and pain levels, measured at four-time points: before treatment, and at 3, 6, and 9 months after treatment.

Functional status was evaluated using one of two questionnaires: Quick Disabilities of the Arm, Shoulder, and Hand (qDASH) questionnaire (first component) for upper-limb nonunions, and Lower Extremity Functional Scale (LEFS) for lower-limb nonunions. The qDASH is an 11-item self-administered survey assessing upper extremity disability referenced over a 7-day period prior to administration. The resultant score is reported on a scale of 0 to 100, where 0 represents no disability and 100 represents total disability. The LEFS is a self-administered questionnaire containing 20 questions about a person's ability to perform everyday tasks. The scale ranges from 0 to 80, with higher scores indicating better function.

Pain levels were assessed using the Numeric Rating Scale (NRS), which rates pain severity on a scale from 0, indicating "no pain", to 10, representing "the worst pain imaginable". This assessment was conducted through axial loading of the involved extremity (movement) and at rest.

- **Patient satisfaction with the treatment**

At the 10-month follow-up evaluation, patients rated the overall treatment efficacy as "very good", "good", "satisfactory" or "poor".

Statistical Analysis

Descriptive statistics measures (absolute and relative frequencies, measures of central tendency and dispersion) were used to describe the studied population, nonunion, prior treatments, and fESWT treatment characteristics, through SPSS 28.0.

Results

Characteristics of the study population

The study population comprised 5 males (71.4%) and 2 females (28.6%) with an average age of 56.14 ± 18.68 years (Table 1). All 7 patients were followed for ten months, with no dropouts. Only 1 patient had alcohol consumption habits, and 2 patients were active smokers. One patient had osteoporosis and was already on medication. There were no diabetic patients or individuals with regular use of corticosteroids or NSAIDs; there was 1 patient with ankylosing spondylitis. All women (n=2) and most men (n=3) exhibited vitamin D deficiency (71.4%). No patient showed an increase in inflammatory parameters or other significant changes in their laboratory results.

Nonunion characteristics and prior treatments

All patients had trauma-induced fractures, including one open fracture (Table 2). Fractures occurred mainly in the lower limbs (71.4%). The average fracture gap size was 3.06 ± 0.92 mm. Most patients (6) had atrophic nonunions. Only 2 patients received conservative treatment with cast immobilization. Regarding previous surgical procedures related to the fracture, 3 patients had undergone two prior surgeries, while 2 had undergone one prior surgery. Fixation methods included arthrodesis (1), intramedullary nailing (1), and plates and screws (3). Only 1 patient had osteosynthesis material removal.

The interval from fracture occurrence to the initiation of ESWT sessions ranged from 9 to 17 months, with a mean time of 12.86 ± 3.02 months. The number of pulses and their intensity were adjusted based on patient tolerance, and all treatment parameters were documented for each session (Table 3).

Outcome Characterization

- **Primary endpoint**

Data for the *primary endpoint* is shown in Table 4. Bone healing was achieved in 4 patients (57.1%) at 9 months post-treatment (Figures 2, 3 and 4).

- **Secondary endpoints**

Data for the *secondary endpoint* is shown in Table 5, Figure 5 and 6. At rest, the NRS mean score decreased from 1.71 at baseline to 0.29 at 9 months, with an overall reduction of 1.43 points. Similarly, the NRS mean score during movement decreased from 4.43 at baseline to 0.29 at 9 months, with an overall reduction of 4.14 points. The qDASH mean score improved from 29.55 at baseline to 11.40 at 9 months, with an overall improvement of 18.15 points. The LEFS mean score increased significantly from 43.60 at baseline to 65.80 at 9 months, with an overall improvement of 22.20 points.

Table 1. Baseline patients' characteristics (n=7).

Sex – n (%)	
Female	2 (28.6)
Male	5 (71.4)
Age (years) - mean±sd	56.14±18,68
BMI (kg/m²) - mean±sd	27.35±2,68
Smoking habits – n (%)	2 (28.6)
Alcohol use habits – n (%)	1 (14.3)
Osteoporosis – n (%)	1 (14.3)
Autoimmune disease – n (%)	1 (14.3)
Regular use of corticosteroids, NSAIDs or other analgesics – n (%)	0 (00.0)
Diabetes – n (%)	0 (00.0)
Vitamin D deficiency – n (%)	5 (71.4)

Table 2. Baseline nonunions' characteristics (n=7).

Site of nonunion – n(%)	
Tibia (diaphyseal region)	2 (28.6)
Metatarsus (base of the 5th)	1 (14.3)
Metatarsophalangeal joint (arthrodesis)	1 (14.3)
Fibula (malleolus)	1 (14.3)
Humerus (diaphyseal region)	2 (28.6)
Fracture gap size (mm)- mean±sd	3,06±0,92
Type of nonunion – n(%)	
Hypertrophic	1 (14.3)
Atrophic	6 (85.7)
Traumatic fracture- n(%)	7 (100)
Open fracture- n(%)	1 (14.3)
Previous surgical procedures – n(%)	
None	2 (28.6)
One	2 (28.6)
Two	3 (42.9)
Extraction of osteosynthesis material- n(%)	1 (14.3)
Time between fracture and the first fESWT session (months)- mean±sd	12,86±3,02
Stand off - n(%)	
without stand off – (35-65 mm)	2 (28.6)
with stand off 2 – (0-30 mm)	5 (71.4)
Osteosynthesis material present at time of fESWT- n(%)	4 (57.1)

Table 3. Parameters of Focal Extracorporeal Shock Wave Therapy applied to each patient and time of nonunion.

Site and duration of nonunion (parameters)	Total energy (J)			Consolidation
	First session	Second session	Third session	9 Mo
Humerus - 17 months post-fracture (3-4 Hz, 0.3-0.55 mJ/mm², 3000 pulses) *Without stand off*	46.086	43.739	43.184	No
Metatarsus, base of the 5th **-** 9 months post-fracture (3-4 Hz, 0.1-0.35 mJ/mm², 2500 pulses) *Stand off 2*	23.095	25.167	21.309	Yes
Metatarsophalangeal joint (arthrodesis) **-** 14 months post-fracture (3-4 Hz, 0.1-0.35 mJ/mm², 1500 pulses) *Stand off 2*	19.143	20.309	19.855	No
Tibia - 9 months post-fracture (3-4 Hz,0.35-0.55mJ/mm², 2500 pulses) *Stand off 2*	45.334	37.450	44.445	Yes
Tibia - 14 months post-fracture (3-4 Hz,0.35-0.55mJ/mm²,1500-3000 pulses) *Stand off 2*	35.239	31.514	44.975	Yes
Fibula - 12 months post-fracture (3-4 Hz,0.35-0.55mJ/mm²,2500-3000 pulses) *Stand off 2*	29.755	42.666	41.568	Yes
Humerus - 15 months post-fracture (3-4 Hz,0.35-0.55mJ/mm², 3000 pulses) *Without stand off*	45.334	37.450	44.445	No

Table 4. Fracture consolidation in the studied patients, before and after shock-wave therapy (at 3, 6 and 9 months) (n=7).

	Baseline	3 Mo	6 Mo	9 Mo
Primary endpoint				
Fracture consolidation - n(%)				
Yes	0 (0.0)	0 (0.0)	2 (28.6)	4 (57.1)
No	7 (100)	7 (100)	5 (71.4)	3 (42.9)

Table 5. NRS, qDASH and LEFS mean scores in the studied patients, before and after shock-wave therapy therapy (at 3, 6 and 9 months) (n=7).

	Baseline	3 Mo	6 Mo	9 Mo	Overall*
Secondary endpoints					
NRS score- mean±sd					
Rest	1.71±2.75	0.57±1.13	0.29±0.76	0.29±0.76	-1.43±2.15
Movement	4.43±2.15	3.00±1,63	1.00±1.53	0.29±0.76	-4.14±2.34
qDASH score-mean±sd	29.55±6.43	12.50±4.81	11.40±0.00	11.40±0.00	-18.15±6.43
LEFS score- mean±sd	43.60±9.32	49.40±13.68	54.60±14.74	65.80±15.79	22.20±16.50

Table 6. NRS, qDASH, and LEFS mean scores in patients with consolidated and non-consolidated fractures, before and after treatment.

	Baseline	3 Mo	6 Mo	9 Mo	Overall*
Secondary endpoints – *consolidated* fractures (n=4)					
NRS score- mean±sd					
Rest	1.25+1.89	0,75+1.50	0.00+0.00	0.00+0.00	-1,25+1.89
Movement	4.75+2.50	3.75+0.957	0.75+0.957	0.00+0.00	-4.75+2.5
LEFS score (n=4) - mean±sd	39.50+1.92	53.00+12.78	56.75+16.09	64.75+18.02	25.25+17.35
Mo - months. sd - standard-deviation. * difference between 9 Mo and baseline.					
	Baseline	**3 Mo**	**6 Mo**	**9 Mo**	**Overall***
Secondary endpoints – *non consolidated* fractures (n=3)					
NRS score- mean±sd					
Rest	2.33±4.04	0.33±0.58	0.67±1.16	0.67±1.16	-1.67±2.89
Movement	4.00±2.00	2.00±2.00	1.33±2.31	0.67±1.16	-3.33±2.31
qDASH score (n=2) -mean±sd	29.55±6,43	12.50±4,81	11.40±0,00	11.40±0,00	-18,15±6,43
LEFS score (n=1)	38.00	35.00	46.00	70.00	32.00
Mo - months. sd - standard-deviation. * difference between 9 Mo and baseline.					

Table 7. Patient satisfaction with the treatment (n=7).

	10 Mo
Patients' perception - n(%)	
Poor	0 (00.0)
Satisfactory	3 (42.9)
Good	1 (14.3)
Very good	3 (42.9)

Fig 2. Serial radiographs of a right tibial hypertrophic nonunion in a seventy-one-year-old man. A: before fESWT (14-months post-fracture). B: 9-months after fESWT.

Fig 3. *Serial radiographs of a right fibula atrophic nonunion in a sixty-two-old woman. A: before fESWT (12-months post-fracture). B: 9-months after fESWT.*

Fig 4. *Serial radiographs of a right metatarsus atrophic nonunion in a thirty-year-old woman. A: before fESWT (9-months post-fracture). B: 9-months after fESWT.*
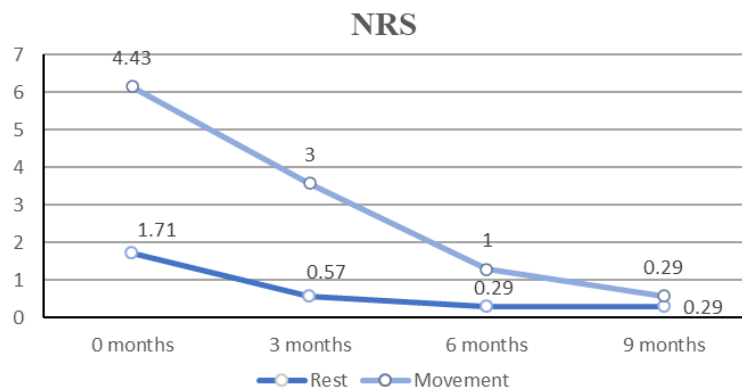

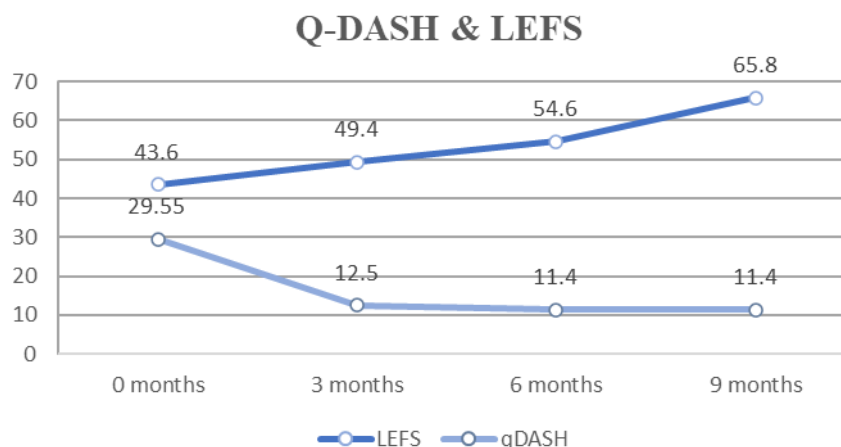**Fig 5.** *Variation of NRS mean score over the 9-month period.*

Figure 6. Variation of Q-DASH & LEFS mean scores over the 9-month period.

- **Subanalysis of the secondary endpoints in consolidated versus non-consolidated fractures**

The subanalysis of the secondary endpoints in consolidated versus non-consolidated fractures is shown in Table 6. For *consolidated* fractures, the NRS mean score at rest decreased from 1.25 at baseline to 0.00 at 9 months, with an overall reduction of 1.25 points. During movement, the NRS mean score decreased from 4.75 at baseline to 0.00 at 9 months, with an overall reduction of 4.75 points. The LEFS mean score improved significantly from 39.50 at baseline to 64.75 at 9 months, showing an overall improvement of 25.25 points. The qDASH was not assessed in the sub-analysis of consolidated fractures, as the sample did not include any upper limb fractures.

For non-consolidated fractures, the NRS mean score at rest decreased from 2.33 at baseline to 0.67 at 9 months, with an overall reduction of 1.67 points. During movement, the NRS mean score decreased from 4.00 at baseline to 0.67 at 9 months, with an overall reduction of 3.33 points. The qDASH mean score improved from 29.55 at baseline to 11.40 at 9 months, showing an overall improvement of 18.15 points. The LEFS mean score for non-consolidated fractures increased from 38.00 at baseline to 70.00 at 9 months, with an overall improvement of 32.00 points.

Adverse effects

No local complications or neuromuscular, systemic, or device-related adverse effects were observed.

Patient satisfaction with the treatment

Patient satisfaction with the fESWT was "very good" in 42.9% of cases, "satisfactory" in 42.9%, and "good" in 14.3% (Table 7).

Discussion

Bone consolidation is a unique biological process involving the coordinated participation of specific cell types and inflammatory factors. This biological process can be stimulated by fESWT, an attractive therapeutic option due to its non-invasiveness, low complication rates, and high bone healing rates. [10,11,16,20] Studies with Level I and II evidence have shown efficacy comparable to surgical intervention in the treatment of pseudarthrosis.[10,12] A 2023 systematic review and meta-analysis by Valerio et al.[21] concluded that fESWT is a promising approach to treating long bone nonunions successfully, with healing rates comparable to surgery but without the risk of complications. Additionally, the lower cost is noteworthy.[16,22]

The pathophysiology of nonunion is multifactorial, with inadequate fracture stabilization and impaired blood supply being key factors. To address these contributing issues, comorbidities and habits affecting vascularization and bone healing were optimized. Vitamin D deficiency, identified in 71.4% of patients, was addressed through supplementation, and all smokers were counseled on smoking cessation.

The classification of bone nonunions includes hypertrophic and atrophic types. Hypertrophic nonunions are characterized by extensive callus formation and adequate bone vascularity, indicating a good healing potential but insufficient mechanical stability. In contrast, atrophic nonunions lack callus formation and occur in cases with inadequate biological healing and poor blood supply.[23]

Treatment of nonunions is complex and requires a highly individualized approach. Based on the "diamond concept", treatment options are guided by the *mechanical* and *biological* characteristics of the nonunion and may include stabilization, deformity correction, infection management, soft tissue coverage, and staged bone grafting.[2,7,16]

The ISMST guidelines[24] suggest that, after fESWT, immobilization may be required in cases where osteosynthesis devices are absent or provide inadequate fracture fixation to achieve full stabilization of the nonunion, which may be considered, especially in hypertrophic nonunions. In this study, only patients with nonunion with fracture gaps of less or equal to 5mm and no instability were included. Therefore, it was determined, together with the attending orthopedic surgeon, that immobilization or orthotization after treatment did not provide any additional benefit. Infections were excluded through laboratory analysis. Understanding these factors is essential for developing effective treatment strategies for nonunion, requiring a comprehensive approach to address each contributing element.

Primary endpoint

Analyzing the *primary endpoint*, the bone-healing success rate (57.1%) was slightly lower than reported in the literature (70-100%). This can be partially explained by the inclusion of predominantly *atrophic* nonunions (n=6).

It appears that the effectiveness of shock waves in the treatment of bone consolidation problems depends on the type of nonunion. *Hypertrophic* long bone nonunions have an improvement rate of 80% to 100% with shock waves, while *atrophic* nonunions have a lower response rate estimated to be around 23% to 27%.[3]

Nonunion rates are highest in bones with poor vascularity, such as the scaphoid, 5th metatarsal, tibia, fibula and femur.[1] In our study, the positive results observed in *atrophic* nonunions may be attributed to the intensities used (0.1-0.55 mJ/mm²), which likely improved the biological and environmental conditions at the fracture site, facilitating bone consolidation.[6,7]

Additionally, the average referral time for fESWT was 13 months, indicating that good outcomes can still be achieved even with delayed treatment.

The consolidation rates observed at 3 months (0.0%), 6 months (28.6%), and 9 months (57.1%), based on serial X-ray analysis, suggest that performing X-rays too early for result evaluation may not be beneficial.

Possible Factors for Poor Response to fESWT

Three nonunions persisted after fESWT. Possible causes for variations in treatment response were analyzed.

The increasing number of orthopedic surgeries before ESWT correlates with the failure of nonunion healing, likely related to the severity of the injury and/or periosteal disruption, as well as impaired perfusion resulting from operative trauma.[11] In our patients, all persistent nonunions (n=3) occurred in fractures previously treated surgically: metatarsophalangeal joint - arthrodesis (n=1) and diaphysis of the humerus - plates and screws (n=2). It's worth noting that the humeral diaphyseal fractures underwent two prior surgical interventions each.

The non-consolidated humeral fractures were located in the diaphysis. According to Dahm et al., fractures in the diaphysis of the humerus are a negative predictive factor for a successful ESWT outcome.[25] Additionally, weight-bearing is known to play a key role in promoting bone healing, which likely explains why patients with upper limb fractures have worse consolidation outcomes compared to those with lower limb fractures.

These patients had no relevant comorbidities impacting bone consolidation, although one was an active smoker. Since smoking significantly hinders the healing process, it may have contributed to the lack of consolidation.

The other persistent nonunion was in a patient with prior arthrodesis of the 1st metacarpophalangeal joint, who had several potential factors compromising the effectiveness of therapy, including ankylosing spondylitis and osteoporosis. Union rates for arthrodesis nonunion after fESWT are inferior to those for fracture nonunion reported in the literature.[16] Additionally, this patient posed more technical challenges.

Another possible factor that may have contributed to the non-consolidation of fractures is their later referral for fESWT (14, 15 and 17 months).

Pain and Functionality Outcomes

The analgesic effect of fESWT is explained by the activation of inhibitory mechanisms of pain message transmission at the level of the posterior roots of the spinal cord. This reduction in pain perception allows for gradual increases in intensity over time, as repeated stimulation progressively raises the pain threshold and enhances tolerance.[6]

Additionally, fESWT exerts long-term analgesic effects by depolarizing large-diameter nerve fibers, leading to decreased substance P at the application site, activation of the serotonergic system, selective reduction of unmyelinated C fibers, and reduced expression of calcitonin gene-related peptide in the dorsal root ganglia, all contributing to sustained pain relief.[4,10,16]

No oral analgesics or nerve blocks were needed, as the treatment was well tolerated. This avoided the confounding effect of anesthesia when analyzing pain improvement with fESWT.

Functionality, measured by the Q-DASH and LEFS scores, showed notable improvements over time after fESWT. One of the key findings from this study is that even in non-consolidated fractures there was a significant reduction in pain and improvement of function which reinforces the idea of independent mechanisms of action for bone consolidation and pain management. The early clinical differences (at 3 and 6 months) may be attributable to the direct and indirect actions that shockwaves have on pain mechanisms, as reduced pain leads to improved limb function.

Strengths and Limitations

Although the evidence supporting the effectiveness of shockwaves seems clearly favorable, there is a lack of unified protocols to be able to draw solid conclusions. The strengths of the study include a detailed description of the methodology and protocol used. This work aims to present our clinical experience and encourage the implementation of similar protocols in other clinical settings.

Most studies report using fluoroscopy for the procedure; however, in our protocol, only a physician experienced in clinical ultrasound and pre-treatment X-rays was required to target the cortical bone, which makes the treatment much more feasible and accessible.

It is important to underline that no adverse effects were reported, which strongly suggests that fESWT is a safer alternative to the surgical treatment of delayed unions and nonunions.

Lastly, the study truly reflects clinical practice and considers patient outcome measures, assessing improvement through pain and functionality scales and patient-reported feedback.

However, we should note some limitations, including the lack of a control group, a small sample size, and the inclusion of various bone types.

Conclusion

This case series offers valuable insights into clinical practice, confirming that fESWT is a reliable and effective treatment for nonunions with fracture gaps of less or equal to 5mm, including atrophic cases. Even in persistent nonunions after treatment, significant pain relief and functional improvement were observed.

In our practice, ultrasound guidance ensured accurate targeting of the fracture site for precise application of fESWT. The outpatient nature of the treatment improves patient accessibility and eliminates costs associated with operating room procedures, such as surgery, anesthesia and hospitalization.

By reducing the need for more invasive treatments, fESWT has the potential to lower healthcare costs. However, further research is needed to determine the optimal treatment parameters and identify patient-specific factors that can improve outcomes. Standardizing procedures for treatment application will be essential to ensure consistency in clinical results and contribute to more robust clinical conclusions.

Conflict of Interest

The authors declare no conflict of interest.

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