

Radial Shockwave Therapy: A Non-Invasive Breakthrough for Nonunion Fractures

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Abstract

Background: Nonunion bone fracture treatment often requires complex surgical procedures, including osteosynthesis material replacement, bone resection and bone grafting, among others. Radial extracorporeal shockwave therapy (rESWT) is emerging as a non-invasive, safe and effective alternative.

Methods: This article reports nonunion bone fracture cases successfully treated with rESWT, demonstrating improvements in bone consolidation, pain reduction and functionality. Ultrasound was used to localize the fracture site and define the treatment area. The protocol consisted of six weekly rESWT sessions. Patients underwent clinical and radiological evaluations at 3, 6, and 9 months post-treatment.

Results: Seventeen patients (9 males, 8 females; age range: 16-65 years) were included. At 9 months post-treatment, 13 patients (76.4%) achieved successful bone healing. The tibia was the most commonly treated site (9/17), with 66.6% of tibia nonunion healing after six sessions. Functional assessment using the Patient-Specific Functional Scale showed an 82% improvement.

Conclusions: Radial ESWT is a safe and effective treatment for both superficial and deep bone fractures. It should be considered by orthopedic surgeons as an early intervention for delayed fracture healing.

Keywords: Bone, Radial extracorporeal shockwave therapy, Fracture, nonunion.

Introduction

Delayed bone healing remains one of the most complex challenges in orthopedic surgery, with postoperative pseudoarthrosis occurring in 5-10% of long bone fractures. [1] Pseudarthrosis is defined as the failure of fracture consolidation beyond nine months post-injury, and is evidenced radiographically by a persistent fracture line. [2] However, in clinical practice, fractures may be treated as pseudoarthrosis as early as six months post-injury, while delayed healing can be detected between three and six months. [3] Patients with nonunion bone fractures often experience associated pain, functional impairment, and reduced mobility, which can contribute to opioid overuse, mental health complications, and persistent pain even after fracture consolidation.

The gold standard procedures described for nonunion bone fractures include: fracture fixation dynamization, exchange nailing, augmentation plating, external fixators, and bone grafting. However, treatments are generally performed only after pseudoarthrosis is established (beyond nine months) and are associated with complications such as deep infections, persistent wound drainage, hematoma formation, sensory loss, chronic pain, and recurrent nonunions. [4]

Extracorporeal shockwave therapy (ESWT) has emerged as a promising noninvasive alternative for promoting fracture healing. The osteogenic effects of shockwaves were first observed in 1988 when lithotripsy patients exhibited enhanced bone formation in the pelvic region. [5,6]

ESWT is classified into two types: focal (fESWT) and radial (rESWT) differing in generator type, physical characteristics, mechanism of action, and associated risks. [7]

The therapeutic benefits of ESWT include analgesic, osteogenic, and tissue-repairing effects. [8]

The intensity of ESWT used is adjusted based on the desired therapeutic outcome:

- 0.1-0.3 mJ/mm² for cell regeneration
- 0.1-0.5 mJ/mm² for pain management
- 0.3-1.0 mJ/mm² for osteogenesis
- 0.5-3.6 mJ/mm² for lithotripsy [9]

For delayed fracture consolidation, fESWT with three sessions at 0.1-0.55 mJ/mm² has shown a success rate of 57.1%. [10]

Comparable results were obtained with rESWT, where six sessions (3000 impulses at 0.18mJ/mm²) using the EMS Swiss Dolorclast device achieved a success rate of 73% in superficial bones. [11]

Objective

To evaluate the outcomes of rESWT in cases of delayed consolidation and propose its use as an early intervention (3-6 months post-fracture) to promote healing and prevent pseudoarthrosis.

Methodology

This retrospective case series includes 17 patients treated with rESWT for nonunion fractures between March 2019 and July 2024. The cohort consisted of 8 females and 9 males (age range: 16-65 years).

Definition of Nonunion: A nonunion was defined as a fracture that:

Failed to show cortical continuity in three out of four cortices after ≥ 6 months of surgical or nonsurgical treatment.

Showed no radiographic improvement for three consecutive months with clinical signs such as inability to bear weight, pain on palpation/percussion, or movement at the fracture site. [11,12]

Inclusion criteria:

Nonunion fractures with gaps ≤ 5 mm, associated pain and/or functional limitations. Both hypertrophic and atrophic nonunions.

Exclusion criteria:

Bone tumors, infected nonunions, instability of fixation devices, blood coagulation disorders and pregnancy.

All patients had undergone initial surgical fracture treatment and were referred to our clinic by their treating orthopedic surgeons due to persistent pain, functional impairment, and lack of consolidation on X-rays or CT scans.

Fracture Sites

Tibia shaft (7 patients)

Distal tibia (2 patients)

Fibula (1 patient)

Femur (3 patients)

Humerus (3 patients)

Fifth metatarsal (1 patient)

Fracture Type:

Closed fractures: 15 cases

Open fractures: 2 cases (both tibia)

Previous Surgical Procedures

Closed fractures: Internal plates, intramedullary nails, and internal screw fixation

Open fractures: External fixators

Initial evaluation

During the initial consultation, a thorough assessment was conducted to determine the injury mechanism, fracture type and location, and prior surgical or nonsurgical interventions. Additional evaluations included baseline metabolic conditions (e.g., osteoporosis, diabetes), nutritional status, and lifestyle factors such as tobacco and alcohol use.

A comprehensive neurovascular examination was performed, with particular attention to soft tissue integrity and joint range of motion in adjacent joints.

Vitamin D levels were not tested due to social security coverage limitations and associated costs. However, based on previous studies indicating a high prevalence of Vitamin D deficiency in patients with delayed fracture healing—especially women [10], all patients were prescribed Vitamin D3 (one pill per month for three months).

Lifestyle Modifications

Patients were advised to optimize nutrition, hydration, and eliminate harmful habits such as smoking and alcohol consumption:

One daily smoker quit during treatment.

Three patients with regular alcohol consumption were encouraged to stop or significantly reduce intake.

Several patients regularly took NSAIDs for pain and were instructed to avoid them during treatment, as they may impair bone healing.

Weight-bearing guidelines:

Lower limb nonunions: Allowed as tolerated.

Upper limb nonunions: Patients were encouraged to engage in normal activities if pain-free.

Shockwave Therapy Protocol

All patients underwent rESWT treatment between March 2019 and July 2024.

The standard protocol consisted of six consecutive weekly sessions in an outpatient setting, performed without anesthesia using a Swiss DolorClast EMS device.

- Each session delivered 4,000 radial extracorporeal shockwave pulses.
- Energy setting: 4 bar air pressure (equivalent to 0.4 mJ/mm²)
- Frequency: 8 Hz
- Handpiece: EvoPower with a 15-mm applicator [Fig. 1]

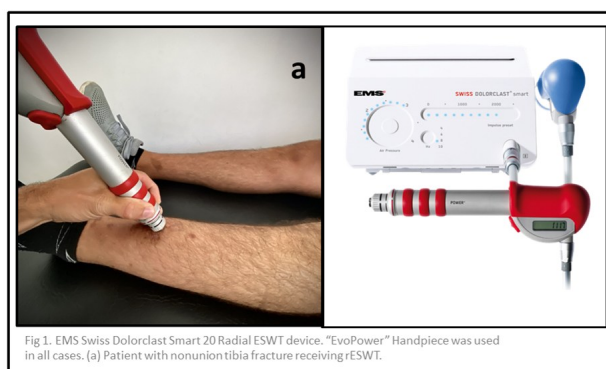


Fig 1. EMS Swiss Dolorclast Smart 20 Radial ESWT device. "EvoPower" Handpiece was used in all cases. (a) Patient with nonunion tibia fracture receiving rESWT.

As the treatment could be painful initially, impulses were gradually increased from the lowest intensity until reaching 4,000 impulses at 4 bars of pressure (0.4 mJ/mm²).

To ensure precise application, ultrasound guidance was used in all cases to identify the treatment site before rESWT administration [Figs. 2, 3]



Outcome measures:

All patients underwent evaluation at 3, 6, and 9 months after treatment through physical examination and anteroposterior and lateral radiographs.

A positive therapy outcome was defined as radiographic evidence of bone consolidation along with the absence of pain and functional limitations at 9 months following the initiation of rESWT.

The primary endpoint of this study was bone union, assessed through radiographic evidence of bone healing at 9 months post-rESWT. A nonunion was considered healed if four cortices had successfully united (two visible on anteroposterior radiographs and two on lateral radiographs) or if no detectable gap was present.

Additionally, the study aimed to assess pain levels and functional status of the affected limb before treatment and at 3, 6, and 9 months after treatment. Pain was measured using the Visual Analogue Scale (VAS), while functional status was evaluated with the Patient-Specific Functional Scale.

Table1. Patient Specific Functional Scale.

Patient-specific activity scoring scheme (Point to one number):

0	1	2	3	4	5	6	7	8	9	10
Unable to perform activity										Able to perform activity at the same level as before injury or problem

Activity	Initial	3 months	6 months	9 months
1.				
2.				
3.				

Methods

Each patient was assigned three activities based on whether the injury affected the upper or lower limb. These activities were selected according to the patient's progression level, as some could not bear weight on the affected limb, while others could walk with crutches or even normally, though with pain.

The evaluated activities included:

- Lifting an object, such as a bag of groceries, from the floor.
- Performing routine work, household, or school activities.
- Engaging in usual hobbies, recreational, or sports activities.
- Pushing up with the hands (e.g., from a bathtub or chair).
- Preparing food (e.g., peeling, cutting).
- Driving.
- Walking without crutches.
- Walking two blocks.
- Walking one mile.
- Standing for one hour.
- Climbing up or down ten stairs (approximately one flight).

These activities were assessed at 3, 6, and 9 months after initiating rESWT. Each was scored from 0 (unable to perform) to 10 (fully able to perform). For example, a patient progressing from a score of 2 to 8 in the PSFS would demonstrate a 75% improvement (a change of 6 out of a possible 8).

Results

The study included 17 patients (8 females, 9 males) aged 16 to 65 years, all with trauma-induced fractures, including two cases of open fractures. The tibia was the most frequently affected site (52.9%), with positive outcomes observed in 6 out of 9 cases (66.6%). Most patients (58%) had hypertrophic nonunions.

Patients began rESWT between 4 and 24 months post-fracture, with an average of 9.5 months. Nearly half (47%) were using NSAIDs for pain management. One patient, a smoker, quit during treatment. Three patients reported regular alcohol consumption and were advised to stop or minimize intake.

The first noticeable improvements were observed between the second and third rESWT sessions, as pain symptoms and mobility difficulties started to subside. Patients with lower-limb injuries began to tolerate weight-bearing, allowing them to discontinue crutch or cane use.

At follow-up evaluations conducted 3, 6, and 9 months after treatment:

At 6 months, 12 out of 17 patients (70.5%) demonstrated positive outcomes, characterized by radiographic bone consolidation and the absence of pain or functional limitations during weight-bearing activities.

One patient showed partial improvement at 6 months, still experiencing pain and requiring a cane, with incomplete consolidation on X-ray. By 9 months, radiographic consolidation was confirmed, and all symptoms had resolved.

Overall, 13 out of 17 patients (76.4%) achieved bone consolidation following six sessions of rESWT, with an average resolution of 82% (ranging from 50% to 95%).

The treatment was well tolerated, with manageable pain being the most commonly reported side effect. No skin injuries, hematomas, or ecchymoses were observed during or after rESWT sessions. No statistically significant differences in age or gender were noted between patients with positive and negative outcomes.

Adverse Effects

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

Table 2. Patients' characteristics.

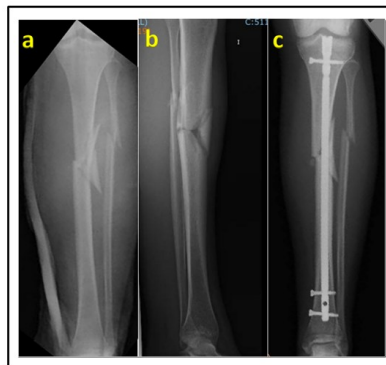
Sex	
<i>Female</i>	8
<i>Male</i>	9
Range Age	16 to 65
Smoking habits	1
Alcohol use habits	3
Autoimmune disease	0
Regular use of NSAIDs	8
Diabetes	0

Table 3. Nonunions' characteristics.

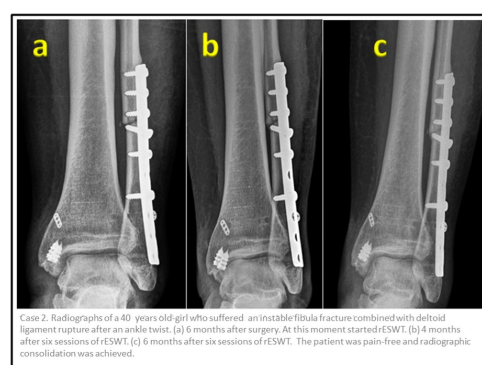
Site of nonunion	
<i>Humerus</i>	3
<i>Femur</i>	3
<i>Tibia diaphysal</i>	7
<i>Distal tibia</i>	2
<i>Fibula</i>	1
<i>5th Metatarsus</i>	1
Fracture gap	≤5mm
Type of nonunion	
<i>Hypertrophic</i>	10
<i>Atrophic</i>	7
Traumatic fracture	17
Open fracture	2
Previous surgical procedure	
Internal fixation	15
External fixation	2
Time between fracture and the first fESWT session (months)	9.5

Cases.

Below are presented 5 representative cases of nonunion fractures treated with rESWT and satisfactory results.



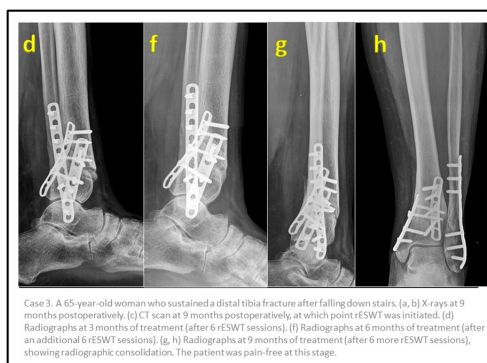
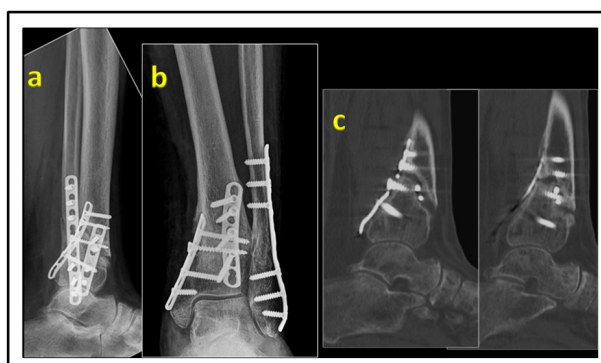
Case 1. Radiographs of a 34-year-old woman who sustained a combined fracture of the left tibia and fibula during a football match. (a, b) Initial X-rays at 1 month postoperatively. (c) X-ray at 7 months postoperatively. At this stage, the patient had severe leg edema, pain, and difficulty bearing weight. rESWT was initiated at this point. (d, e) Radiographs at 6 months of treatment (after 6 rESWT sessions), showing fracture consolidation. The patient was pain-free, and radiographic healing was achieved.



Case 2. Radiographs of a 40-year-old girl who suffered an unstable fibula fracture combined with deltoid ligament rupture after an ankle twist. (a) 6 months after surgery. At this moment started rESWT. (b) 4 months after six sessions of rESWT. (c) 6 months after six sessions of rESWT. The patient was pain-free and radiographic consolidation was achieved.

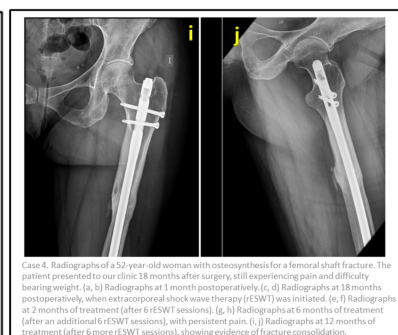
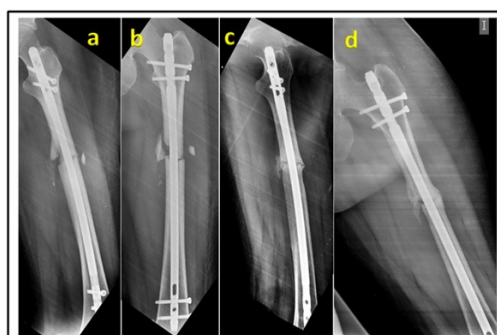
Case 1

Case 2



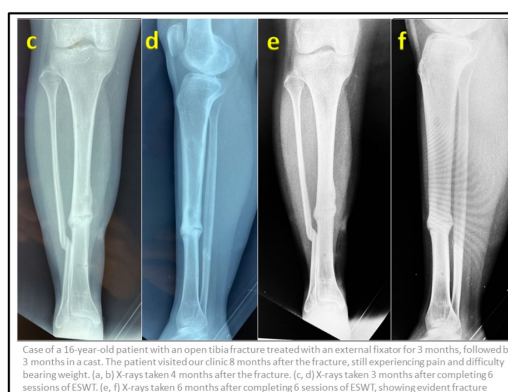
Case 3. A 65-year-old woman who sustained a distal tibia fracture after falling down stairs. (a, b) X-rays at 9 months postoperatively. (c) CT scan at 9 months postoperatively, at which point rESWT was initiated. (d) Radiographs at 3 months of treatment (after 6 rESWT sessions). (f) Radiographs at 6 months of treatment (after an additional 6 rESWT sessions). (g, h) Radiographs at 9 months of treatment (after 6 more rESWT sessions), showing radiographic consolidation. The patient was pain-free at this stage.

Case 3



Case 4. Radiographs of a 52-year-old woman with nonunion for a femoral shaft fracture. The patient presented to our clinic 18 months after surgery, still experiencing pain and difficulty bearing weight. (a, b) Radiographs at 1 month postoperatively. (c, d) Radiographs at 18 months postoperatively, when extracorporeal shock wave therapy (rESWT) was initiated. (e, f) Radiographs at 2 months of treatment (after 6 rESWT sessions). (g, h) Radiographs at 6 months of treatment (after an additional 6 rESWT sessions), with persistent pain. (i, j) Radiographs at 12 months of treatment (after 6 more rESWT sessions), showing evidence of fracture consolidation.

Case 4



Case of a 16-year-old patient with an open tibia fracture treated with an external fixator for 3 months, followed by 3 months in a cast. The patient visited our clinic 8 months after the fracture, still experiencing pain and difficulty bearing weight. (a, b) X-rays taken 4 months after the fracture. (c, d) X-rays taken 3 months after completing 6 sessions of ESWT. (e, f) X-rays taken 6 months after completing 6 sessions of ESWT, showing evident fracture consolidation.

Case 5

Discussion

Thirteen out of 17 patients (76.4%) achieved successful bone consolidation following rESWT, as confirmed by radiographic evaluation at the 6- and 9-month follow-ups. No complications were reported, and anesthesia was not required during treatment. Tibial nonunions were the most common, with 66.6% healing within six months of rESWT.

These findings support the consideration of ESWT as a first-line therapy for fracture nonunions. However, proper application is crucial. Whether using fESWT or rESWT, the procedure should be performed by physicians experienced in managing delayed fracture healing to ensure optimal treatment and minimize risks.

Kertzman's case series highlights a significant correlation between treatment timing and fracture healing success, emphasizing the importance of early intervention. [11] Based on this, the recommendation includes both superficial and deep, as well as early and late, fracture nonunions. Upon diagnosing nonunion, early fESWT should be prioritized if available. If not, early rESWT should be considered before opting for surgical intervention. For refractory cases involving superficial bones, surgery remains a necessary alternative.

Conclusions

This case series suggests that rESWT is a safe and effective option for treating delayed fracture healing. By using rESWT, surgical interventions such as osteosynthesis replacement, bone grafting, and their associated hospitalization, medication, and anesthesia costs can potentially be avoided. Orthopedic surgeons should consider rESWT before surgical treatment when signs of delayed union emerge between the 3rd and 4th postoperative month, aiming to intervene before pseudoarthrosis develops.

Conflicts of Interest

The authors declare no conflicts of interest.

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