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Original Article

Shock wave therapy in foot and ankle nonunion fractures: case series

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Abstract

Objective: Report a case series of five patients with foot and ankle nonunion fractures treated with radial-type extracorporeal shock wave therapy.

Methods: This retrospective study described the evolution of five patients diagnosed with foot and ankle nonunion fractures, radiologically and clinically, treated with radial shock wave therapy, admitted from September 2021 to August 2022 with outpatient follow-up.

Results: After the stipulated treatment sessions, all patients showed radiographic signs of bone callus, with improved pain and good functional results. Comprehensively, treatment with radial shock waves for foot and ankle nonunion fractures was effective and did not require intervention.

Conclusion: Radial-type shock wave therapy, especially in places of greater bone prominence, seems effective in treating nonunion fractures, exposing the patient to a lower risk of complications than surgical treatment.

Level of Evidence IV; Therapeutic Study; Case Series.

Keywords: Pseudarthrosis; Fractures, bone; Foot; Extracorporeal shockwave therapy.

Introduction

Extracorporeal shock wave therapy (ESWT) was initially applied to treat ureteral lithiasis, such as lithotripsy, and over time, they observed a possible effect on osteogenesis[1-3]. The use of ESWT in orthopedics included treating inflammatory soft tissue conditions, tendinopathies, avascular necrosis of the femoral head, and nonunion[1].

The shock wave is a three-dimensional kinetic energy pulse of high amplitude and short microseconds duration, which can be generated by different means, transforming electrical energy into mechanical energy[1,2,4]. It is classified according to the density of the energy flow in relation to the direction of propagation, low or high energy, and the type of wave, focal or radial[1].

Focal shock waves are generated by unique acoustic pulses generated by a sparkler (electro-hydraulic principle), similar to a speaker (electromagnetic principle), while radial shock waves come from a mechanism similar to ballistics, in which compressed air or a magnetic field launches a pulse in a tube until it reaches the wave applicator on the skin, which converts the stress waves into pressure waves[1,5].

Radial waves tend to be lower energy, do not require anesthesia for application, and are cheaper than focal waves[1]. They also have more consistent effects on tissue dissipation than focal waves if they encounter obstacles such as calcifications or bone tissue[5].

The application is performed by placing the device on the injury topography to treat the skin perpendicular to it. The practicability varies according to the wave type, application time, and number of sessions. These factors are still being studied to define and specify the best treatment according to the diagnosis and the effectiveness of the type of shock waves to be used[6].

Study performed at the Hospital de Urgências de Goiânia, Goiânia, GO, Brazil.

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Focal waves are widely used due to their greater intensity and tissue penetration and can reach the tissue to be treated between 0.5 and 5 cm deep. Radial waves, which were used in this study, have a lower penetration, causing less tissue damage and reaching more superficial tissues between 0.5 and 1.5 cm[3].

Extracorporeal shock wave therapy affects the production of microfractures in the sclerotic bone ends, forming a subperiosteal hematoma of the cortical bone and stimulating neoangiogenesis and bone consolidation[1]. Shock waves also indirectly affect bone tissue called a cavitation bubble, which consists of partial apoptosis of the osteocytes and production of osteoblasts[1,2,4,7,8]. In addition, low-energy shock waves stimulate progenitor and differentiated stem cells[3,7].

The main benefit of ESWT in bone tissue is mainly osteoblastic stimulation for osteogenesis and not just a mechanical action of periosteal detachment promoting bone consolidation[4]. Indications of ESWT also include soft tissue lesions, acting as a stimulus to increase the production of vascular endothelial growth factor in cartilage, nerve, and connective tissues, promoting angiogenesis and cell regeneration, and blocking the pain cascade[4,6].

Radial-type ESWT is easy to perform treatment in an outpatient setting, without analgesics and its potential risks of a surgical procedure, even though it may cause hematoma and mild pain during application[5]. On the other hand, the use of focal shock waves is usually performed under sedation or analgesics in a hospital environment, with greater cost and risk to the patient, and may cause greater soft tissue edema, fractures, intraosseous bleeding, and thromboembolism[1,2,4].

The presence of an epiphyseal plate or malignant tumor in the affected area, acute infection, and pregnancy are general contraindications for shock waves, with coagulopathy or use of anticoagulants being a relative contraindication for high-energy ESWT[1].

Extracorporeal shockwave therapy has been used in cases of nonunion fractures, a condition in which the fracture shows no sign of bone consolidation evolution on radiographic examination in the expected time. The presence of sclerotic edges, absent bone callus, and persistence of the fracture focus result in pain and instability[8,9].

In the scientific literature, most reports regarding the efficacy of ESWT in treating nonunion fractures refer to long bones and upper limbs and the use of focal waves, and data regarding the use of ESWT in foot and ankle nonunion fractures are scarce.

The objective of this study is to report a case series of five foot and ankle nonunion fractures treated with radial-type extracorporeal shockwave therapy.

Methods

The study was approved by the Institutional Review Board, and the Informed Consent Form was not necessary due to the unidentifiable data extraction, without the name or any data that would allow their identification. All patients admitted for treatment of nonunion fractures and under conservative treatment were included, and those using calcium or bone-forming medications or with previous use of bisphosphonates were excluded.

This study is a retrospective analysis of five patients admitted with foot and ankle nonunion fractures. Data regarding age, sex, elapsed fracture time, fracture site, comorbidities, and signs of consolidation after shock wave therapy were collected from the hospital's electronic medical record.

All patients were followed clinically and submitted to radiographs at all outpatient follow-ups at each ESWT session and after four weeks, eight weeks, and one year of treatment. During the ESWT sessions, the load was maintained with partial support from a robofoot. From the fourth session, all patients were released to full load with a robofoot for four weeks, as they presented good callogenesis, and the robofoot was removed after this period.

Descriptive analysis of patient data was performed using Microsoft Excel version 16.54 (2021) and IBM SPSS Statistics version 23 (2015).

Results

Five patients with foot and ankle nonunion fractures were admitted between September 2021 and August 2022, presenting an absence of bone consolidation, diastasis of the fracture focus, and complaints of pain.

All patients were submitted to four sessions of radial-type ESWT, performed on an outpatient basis, under the protocol of four sessions of 2500 shots per session, with an intensity of 1.5 to 3.0 bar and a frequency of 10 to 14 Hz, at a weekly interval between them, and comparative radiographs were performed after each session. At the end of this period, improvement in pain was reported by the patients, and good bone consolidation was observed on the radiographs, which were then released for full load. The patients maintained outpatient follow-up after treatment, showing the effectiveness of the treatment performed.

Females were the most prevalent (60%), the left side was the most affected (60%), and the mean age was 49.2 years (range 32 to 61 years), with a median of 55 years and a standard deviation of 11.9. The fractures were due to low-energy traumas, such as a rotational mechanism of the foot or ankle; all were closed type. The mean fracture time was 64.4 days, with a standard deviation of 38.81 (Table 1). Figure 1 shows the radiographic evolution of the patient with nonunion medial malleolus fracture before the first session and 1, 2, and 6 months of evolution.

Discussion

The discovery of the effect of focal-type ESWT on bone tissue dates back to 1991. Valchaneau et al.[10] initially described its applicability in treating delayed consolidation in fractures and pseudoarthrosis, demonstrating the efficacy of ESWT on osteogenesis stimulation by several mechanisms.

Table 1. Patient description

Patient	Sex	Laterality	Age	Fracture time	Place	Shock wave type	Number of sessions	Comorbidity	Signs of bone consolidation
1	Female	Right	42 years	42 days	Medial malleolus	Radial	4	No	Yes
2	Male	Left	32 years	30 days	5th metatarsal base	Radial	4	No	Yes
3	Female	Left	56 years	120 Days	5th metatarsal base	Radial	4	Kidney transplantation (chronic kidney disease)	Yes
4	Female	Right	61 years	40 days	5th metatarsal base	Radial	4	No	Yes
5	Male	Right	55 years	90 days	5th metatarsal base	Radial	4	No	Yes

Figure 1. Radiographs of nonunion fracture of the medial malleolus before and after shock wave therapy. (A) Before therapy; (B) four weeks after therapy; (C) eight weeks after therapy; (D) six months after therapy.

Since then, EWST has been used for several musculoskeletal pathologies, from soft tissue injuries (such as tendinopathies, epicondylitis, and fasciitis) to bone injuries, such as fractures without deviation and delayed bone consolidation. Currently, the study with radial waves has been enhanced to improve its applicability and ensure cost reduction and the decreased rate of side and tissue effects[5].

Wuerfel et al.[7] conducted a systematic review, including 180 studies published between 1988 and 2021, that addressed the ESWT effects on connective tissue and muscle/nerve tissue. The ESWT effect on bone and cartilage tissue was described in 100 studies published over 33 years, with most of the studies (64%) performed in animal models and the others in primary or secondary cell culture. The authors noted that ESWT still needs further studies to establish optimal treatment settings, intensity, duration, location, and applied energy, although it is a safe and effective treatment option for various musculoskeletal system pathologies.

In parallel with this study, Schmitz et al.[5] conducted a systematic review to evaluate whether ESWT would be an effective and safe non-invasive treatment option for tendons and other musculoskeletal system pathologies based on data from the Physiotherapy Evidence Database (PEDro). One hundred and six studies were included in the qualitative synthesis, from which the authors established the following statements, based on randomized clinical trials, about radial and focal ESWT. Extracorporeal shockwave therapy is effective and safe, but the application of local anesthesia and insufficient energy negatively affects the outcome. No scientific evidence of the results using radial or focal ESWT was observed. The ideal treatment protocol for ESWT appears to be three treatment sessions at one-week intervals, with 2,000 shots per session and the application of the highest possible energy flux density.

Yue et al.[6] presented a case report of delayed mid-clavicle fracture consolidation and highlighted the use of focal waves in treating nonunion due to its dangerous side effects, mainly due to the proximity of the clavicle to vital organs, such as the lung. However, radial waves, in addition to presenting superficial adverse reactions, present cell proliferation, and similar results, compared to the configuration of focal waves, with greater capacity to induce angiogenesis, improving tissue perfusion. In superficial musculoskeletal disorders, greater pain relief was observed.

Tam et al.[11] investigated the effect of shock waves on cells extracted from the normal human periosteum to study possible response mechanisms and determine optimal treatment settings. The authors observed that ESWT can promote biochemical changes in periosteal cells and that lower doses, applied with a greater number of shocks and sessions, are more favorable to stimulating the activity of periosteal cells, inducing greater cell proliferation, with more viable cells, greater calcium deposit, and fewer side effects.

Kwok et al.[1] presented a broad review of ESWT in treating foot and ankle nonunion fractures. Among the eight studies evaluated, there was consolidation of 61 of the 65 metatarsal fractures (93.8%), 12 of the 13 ankle fractures (92.3%), and two talus fractures (100%), except for a single navicular fracture. The consolidation rate in the radial shockwave used in nine types of fractures was 77.8%, and in the focal shockwave, in 57 fractures, 94.7%. In the other 14 fractures reported in the studies, the type of shock waves was not specified. The efficacy of shock waves as a treatment choice for non-union fracture was demonstrated, but it proved to be unsatisfactory when comparing wave types due to the discrepancy in the sample.

Furia et al.[12] compared intramedullary screw fixation and high-energy shockwave treatment for pseudoarthrosis in the metaphyseal-diaphyseal region of the 5th metatarsal. Among the patients in the shockwave group, 86.9% were successful in the treatment, and in the fixation group, 90%. Regarding complications, only one patient in the ESWT group presented petechiae. On the other hand, for the 11 patients in the fixation group, one patient with refracture, one with cellulitis, and nine symptomatic hardware were identified. Thus, it was concluded that both treatments were effective. However, surgical treatment is more often associated with complications that result in a surgical reapproach.

Alkhawashki[13] used ESWT in the treatment of nonunion fractures in 44 patients (49 bones), with fractures in the femur and tibia and a single treatment session in 39 fractures. Consolidation was successful in 75.5% of cases at a mean time of 10.2 months. In cases where ESWT was unsuccessful, a gap of more than 5 mm, instability, vascularization impairment, and low-grade deep infection were observed.

Similar to our study, Kertzman et al.[14] also described the lack of substantial evidence using radial shockwave therapy in the treatment of nonunion fractures and performed the analysis of this treatment in 22 patients for nonunion fractures in superficial bones (including tibia and foot and ankle bones), despite previous surgical fixation in most cases. A protocol was performed with three weekly radial sessions with 3000 pulses each. Patients were followed clinically and radiologically, with treatment success in 73% at six months, with no side effects. It was concluded, therefore, that radial ESWT seems to be an effective and safe alternative in the management of nonunion fractures of superficial bones if diagnosed early.

Another more recent and valuable study, also published by Kertzman et al.[14], presented the largest prospective case series of radial shock waves and observed that both focal and radial waves influence osteoblast stimulation, good quality callogenesis, and resistance. The authors demonstrate that the use of this treatment is effective and safe and that, despite the idea that radial waves are superficial, there are studies that demonstrate that they can reach up to 4 cm in depth. They also exposed that many *in vitro* and animal studies have proven the ability of ESWT to stimulate consolidation, as seen in the study by Ramesh et al.[15], with the stimulation of chondrocyte production and bone growth in growth plates.

Our study reports a case series of five patients with ankle and/or base of the 5th metatarsal nonunion fractures presenting local pain. Shock wave treatment was applied as the treatment of choice for bone consolidation due to its less invasive methodology, and the radial wave type was used for its lower side effects in soft tissues. Despite the small sample size, all patients presented good clinical and radiological results after the fourth shockwave session, thus demonstrating that the method is effective, minimally invasive, and safe, with high chances of success.

As in the case reports described by Yue et al.[6] and Kertzman et al.[14], it can be suggested the efficacy of the radial wave in anatomically more superficial bones, with only subcutaneous coverage, such as clavicle and foot and ankle bones. Satisfactory bone consolidation was observed without complications that could exist if a more invasive surgical procedure and bone graft removal were used. Extracorporeal shock wave therapy should be considered for patients with clinical comorbidities who have contraindications to surgical treatment, such as patients in our report who had chronic kidney disease.

Conclusion

Radial-type shock wave therapy, especially in places of greater bone prominence, seems to be effective for treating nonunion fractures, exposing the patient to a lower risk of complications compared to surgical treatment. More robust studies with better and more compatible methodological designs are necessary for developing and specifying ideal treatment configurations, with a greater possibility of early and safe functional rehabilitation.

Authors' contributions: Each author contributed individually and significantly to the development of this article: GFR *(https://orcid.org/0000-0003-4979-7826) Conceived and planned the activities that led to the study, participated in the review process, data collection, survey of the medical records, formatting of the article and approved the final version; JSM *(https://orcid.org/0000-0003-4742-1905) Conceived and planned the activities that led to the study, interpreted the results of the study, participated in the review process, performed the surgeries, data collection, statistical analysis, bibliographic review, survey of the medical records, formatting of the article, clinical examination and approved the final version; ARNL *(https://orcid.org/0000-0002-0715-6417) Conceived and planned the activities that led to the study, interpreted the results of the study, articipated in the review process, data collection, statistical analysis, bibliographic review, survey of the medical records, formatting of the article and approved the final version; SEK *(https://orcid.org/0000-0003-3132-924X), and ACA *(https://orcid.org/0000-0002-9983-1888) Conceived and planned the activities that led to the study, interpreted the results of the study, participated in the review process, data collection, statistical analysis, bibliographic review, survey of the medical records, formatting of the article and approved the final version; ABA *(https://orcid.org/0009-0009-3962-4025), and LST *(https://orcid.org/0009-0009-5170-7608) Conceived and planned the activities that led to the study, interpreted the results of the study, participated in the review process, data collection, statistical analysis, bibliographic review, survey of the medical records, formatting of the article and approved the final version; LRD *(https://orcid.org/0000-0002-3830-0848) conceived and planned the activities that led to the study, bibliographic review and approved the final version. All authors read and approved the final manuscript. *ORCID (Open Researcher and Contributor ID) iD.

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