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Review

Extracorporeal shock wave treatment in foot and ankle fracture non-unions — A review

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ABSTRACT

Background: The authors reviewed the current evidence and conducted a comprehensive review on the use of extracorporeal shock wave therapy (ESWT) in the treatment of foot and ankle fracture non-unions.

Methods: Four databases were searched to identify relevant studies in the available literature.

Results: Eight studies were reviewed, demonstrating union rates of 65%–100% and 90–100% at 3- and 6-months following ESWT treatment respectively. No major complications were seen in any of the studies. Minor complications included local soft tissue swelling, petechiae, bruising and pain.

Conclusions: The literature that is currently available is limited to case series of relatively small sample sizes, highlighting the need for a prospective randomised controlled trial to further investigate the efficacy of ESWT in the treatment of foot and ankle fracture non-unions.

1. Introduction

Extracorporeal shock wave therapy (ESWT) was first introduced in routine medical practice in the 1980s as lithotripsy to break up calcific deposits in the body such as renal calculi. It was noted in 1988 the time that patients treated with shock waves during lithotripsy demonstrated an increase in pelvic osteogenic response [1]. Since the 1990s, its application has expanded across a range of medical disciplines. Its use in trauma and orthopaedics includes the treatment of soft tissue disorders (such as elbow epicondylitis, plantar fasciitis and tendinopathies), avascular necrosis of the femoral head and bony non-unions [2]. The International Society for Musculoskeletal Shockwave Therapy (ISMST) was set up in 1997 to guide the research and development of the use of ESWT in musculoskeletal conditions.

ESWT is thought to promote bone healing by inducing micro-fractures of sclerotic bone ends, producing microfissures and thereby enhancing the blood supply. The production of small fragments of bone has a stimulating effect on osteogenesis, promoting union at the fracture site [3]. Traditionally, symptomatic fracture non-union is treated with surgical stabilisation with or without bone graft augmentation. ESWT has emerged as an efficient, non-invasive and cost-effective alternative. A meta-analysis conducted by Ogden showed that in 1737 patients with delayed union or non-union of the long bones and small bones of the hands and feet, healing success rates ranged from 62% to 83% [4]. Several other authors have also demonstrated the effectiveness of ESWT in the treatment of long bone and upper limb fracture non-unions [2,3], however, its use in the foot and ankle is largely limited to soft tissue pathologies such as plantar fasciitis and tendinopathies. There is a paucity of evidence in the use of ESWT in fracture non-unions pertaining to foot and ankle fractures specifically. This paper aims to review the current literature on shock wave treatment, and published results of its use in foot and ankle fracture non-unions to date.

1.1. Principles and types of shock waves

The basic mechanism of shock waves consists of a single-impulse acoustic wave with a high amplitude and short duration [5]. These are produced by commercially available shock wave generators. Two forms of ESWT are available, focused (fESWT) or radial (rESWT).

fESWT has three methods of shock wave generation, all of which convert electrical energy to mechanical energy. These are the piezo-electric, electrohydraulic (use of a spark gap) and electromagnetic (analogous to a loud speaker) principles; Each device utilises a different technique to generate a shock wave. For shock waves to be clinically effective, the maximally beneficial pulse energy must be focused at the point of intended treatment – in this case, the fracture site – by means of reflectors.

In contrast to the above focused shock wave generators, radial shock

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wave generators utilise a ballistic principle. It consists of a handpiece with a projectile fired within a guiding tube that strikes a metal applicator placed on the skin. The projectile generates stress waves in the applicator that transmits pressure waves into tissue.

The amount of energy delivered during ESWT can be divided into low and high energy shockwaves. Different manufacturers of shock wave machines with differing methods of shockwave production make standardisation difficult. There is currently no consensus amongst manufacturers and users of ESWT regarding the criteria to differentiate between low, medium or high energy levels. Rompe defined energy levels at the focus area of up to 0.08 mJ/mm^2 as low, up to 0.28 mJ/mm^2 as medium and over 0.6 mJ/mm^2 as high energy [6]. Furia et al., on the other hand, defined low energy ESWT as <0.2 mJ/mm^2 and high energy as >0.2 mJ/mm^2 [7]. Radial shock waves tend to be of lower energy imparted in multiple sessions, and generally do not require anaesthesia. Maximum energy is transferred more superficially in subcutaneous tissue, and is therefore more commonly used for soft tissue disorders. High energy shock waves are generally performed under sedation or anaesthesia – either regional or general – with deep penetration for treatment deeper structures, such as bony pathology. The advantages of low energy radial shockwave therapy is the ability to provide treatment in the outpatients setting without the use, and potential risks of general or regional anaesthesia.

The energy flux density (EFD) is the amount of energy in a given amount of tissue at a given point in time, measured in mJ/mm^2. This quantifies the total amount of energy delivered in a treatment session.

$$\text{EFD } (\text{mJ/mm}^2) = \text{Energy per shock} \times \text{Total number of shocks delivered}$$

In some devices, the EFD is not defined and the energy level of shock waves is specified in kilovolts instead. Treatment parameters include the total amount of energy per treatment, number of shocks per session (EFD), frequency of shocks, energy per shock, number of treatments, and interval between treatments. Each parameter can be manipulated to modulate the clinical response [7].

1.2. Biologic effects of ESWT

Shock waves have a direct and indirect effect on treated tissues [7]. The absorbed shock waves produce a tensile force, accounting for the direct effect which leads to cortical bone subperiosteal haematoma formation at the periosteal interface. Shock waves also stimulate the formation of cavitation bubbles – this indirect cavitation effect causes partial osteocyte death, followed by migration of osteoblasts to stimulate new bone formation [8,9].

Effectiveness of ESWT in treatment of non-unions is dependent of the type of non-union, hypertrophic or atrophic. Union rates of hypertrophic non-union in long bones have been reported to be 80% to 100%, whereas that of atrophic non-unions are lower at 23%–27% [10,11].

1.3. Procedure of ESWT

Low energy ESWT can be administered on an outpatient basis without anaesthesia, whereas high energy ESWT may require sedation, regional or general anaesthesia. The area for treatment is examined and area of maximal pain and tenderness marked. This can be supplemented by image guidance to identify the area of interest for application for ESWT. An ultrasound gel is applied to the patient's skin overlying the bone, and the probe of the shockwave generator is aimed at the fracture non-union site. The probe is applied centrally at the point of maximal tenderness, then circumferentially, so that all pathologic tissues are treated. Depending on the size of the targeted bone, the treatment area is usually several centimetres in length and width [7].

After the procedure, the area of skin and soft tissue is inspected for any signs of swelling, haematoma or ecchymosis prior to discharge.

1.4. Contraindications

According to the ISMST guidelines, patients on anticoagulants or have a pre-existing bleeding disorder have a relative contraindication to ESWT, as bleeding can occur with high energy ESWT. Other contraindications include the epiphyseal plate being within the shock wave field, acute infection, pregnancy or malignant tumour within the shock wave field. During ESWT application, large vessels and nerves should be avoided. Some of these are less of a concern in the foot and ankle.

2. Methods

2.1. Search strategy

PubMed, MEDLINE and EMBASE and Google Scholar databases were searched in December 2019 to identify relevant studies in the available literature. The inclusion criteria consisted of studies on the usage of ESWT on the use of fracture non-union in the foot and ankle. Keywords used for the search were "shockwave" OR "shock wave" OR "ESWT" AND "nonunion" OR "union" OR "fracture". The references of the relevant articles were screened to find further papers.

2.2. Eligibility criteria

Searches were limited to human and English studies published in peer-reviewed journals. Non foot and ankle applications, non-English articles and animal studies were excluded.

2.3. Data extraction

The titles and abstracts of the identified articles were reviewed by three authors (IK, EL, MA). After initial screening, full texts of the relevant studies were obtained and reviewed. A PRISMA flowchart illustrating the search strategy and study selection process is included in Fig. 1.

A total of 8 studies were identified. The majority of studies included fracture non-unions elsewhere in the body, and therefore only data on foot and ankle cases were extracted from those studies. Data extracted included: publication year, study design, number of patients (sample size), location of fracture non-union, duration of non-union at the time of ESWT, type and energy level of shock wave used, fracture union rate, time to radiological and/or clinical union, complications of treatment (Table 1).

2.4. Search results - quality assessment

There were no randomised controlled trials. There was one comparative cohort study by Furia et al. [12], the rest were all case

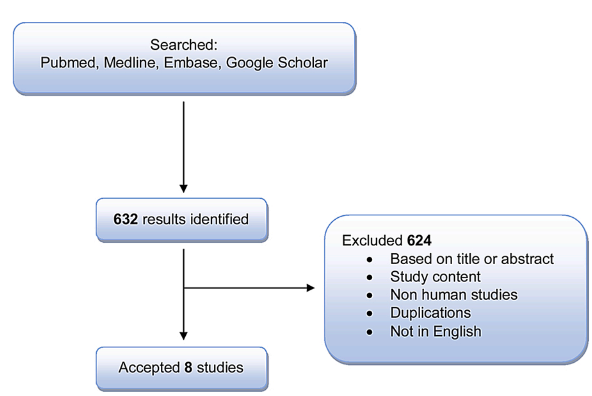

Fig. 1. Flow diagram illustrating the decision making process in the selection of studies.

Table 1
Summary of studies and study characteristics.

Study	n	Type of study	ESWT type (fESWT/ rESWT)	Energy level	Duration of non-union (months)	No. of treatment sessions	Location of fracture non-union	Previous surgery	Anaesthetic used	Mean follow up (months)	No. united/ total no. at final follow up	Union rates	Complications
Alkhawashki (2015)	1	R	fESWT	4Hz at 26kV	NS	1	Metatarsal	No	NS	18 (18–24)	1/1	100%	NS
Alvarez et al. (2011)	34	P	fESWT	0.22–0.51 mJ/mm^2	6.8 +/- 3.9	NS	Metatarsals	No	GA RA	12	18/20	71% at 3/12 89% at 6/12 90% at 12/12	Swelling Petechiae Bruising
Furia et al. (2010)	23	R	fESWT	0.18 mJ/mm^2	10.4 +/- 7	1 (21) 2 (1)	Metatarsals	No	GA (15) RA (6) LA (2)	64.7 (6–11)	22/22	87% at 3/12 95% at 6/12 100% at 7/12	Petechiae
Kertzman et al. (2017)	7	R	rESWT	0.18 mJ/mm^2	6–17	3 (6) 4 (1)	Malleolus (3) Navicular (1) Metatarsals (3)	Yes (7) No (1)	None	6	2/3 0/1 3/3	71% at 6/12	Pain (bearable)
Schaden et al. (2001)	12	NS	NS	0.25–0.35 mJ/mm^2	>3	NS	Ankle (9) Talus (2) Midfoot (3)	NS	GA RA LA	18 (3–48)	9/9 2/2 2/3	93%	Petechiae
Silk et al. (2012)	2	R	rESWT	0.2 mJ/mm^2	24 (1 patient) 6 (1 patient)	3	Metatarsals	No	None	12	2/2	100% at 3/12	None
Vulpiani et al. (2012)	5	P	NS	0.25–0.84 mJ/mm^2	>6	3 to 5	Metatarsals	NS	None	12	NS	NS	Swelling
West et al. (2007)	28	P	fESWT	14–24kV	13.2 Range, 2.3 to 192	NS	Metatarsals	Yes (Some, NS)	GA RA	12	13/14	65% at 3/12 80% at 6/12 93% at 12/12	Pain

n = no. of foot and ankle fracture non-unions; R = retrospective; P = prospective; NS = not specified; () = number of patients; GA = general anaesthetic; RA = regional anaesthetic; LA = local anaesthetic.

series with small sample sizes (n = 1–34). There were three prospective studies [13–15], four retrospective studies [12,16–18] and one non-specified [19].

2.5. Data synthesis

The aim of the synthesis was to identify trends and gaps in the evidence and identify implications for future research. A narrative and tabular summary of the studies was undertaken (Table 1). Where there was excess heterogeneity between the study characteristics, results were reported separately.

3. Results

3.1. Study characteristics

In total, 114 fracture non-unions in the foot and ankle were described in the eight studies. Anatomical areas treated included 14 ankles, 4 midfoot and 96 metatarsals. Follow up time ranged from 6 to 111 months.

Two studies described their fracture non-unions as hypertrophic in nature [16,18], one study included both hypertrophic and atrophic non-unions [17], and the remainder did not specify the type of non-union. The duration of non-union at the time of ESWT application ranged from 6.8 to 24 months.

3.2. ESWT usage

Four studies used fESWT [12,13,15,16], two studies used rESWT [17,18] and two studies did not specify the type of ESWT used [14,19]. A variety of low and high energy ESWT protocols were used, ranging from an EFD of 0.18 mJ/mm^2 to 0.84 mJ/mm^2. Three studies did not require any use of anaesthesia [14,17,18], whereas the others used required general, regional or local anaesthesia during application of ESWT. The number of treatment sessions used ranged from one to 5.

3.3. Clinical outcomes

3.3.1. By anatomical area

At final follow up, 61 of the 65 metatarsal fractures united following ESWT, giving a union rate of 93.8%. Twelve of the 13 ankle/malleolus fractures united, giving a union rate of 92.3%. Of the two talus fracture non-unions, both had united. And the only one navicular fracture union described did not unite following ESWT. One paper did not specify the union rates of fractures specific to its individual anatomical area [14]. Of note, some papers had patients that were lost to final follow up [13,15].

3.3.2. By shockwave type

In terms of the type of shockwave used, fESWT achieved fracture union in 54 out of 57 fractures (94.7%), whereas rESWT achieved fracture union in 7 out of 9 fractures (77.8%). Type of shockwave usage was not specified in the 14 fractures reported in two studies [14,19].

3.3.3. Overall union rates

Fracture union rates ranged from 65% to 100% at 3 months following ESWT [12,13,15,18]. At 6 months, union rates reached 90%–100% [12,13,15]. Most papers did not specify whether the treated fracture non-unions were of the hypertrophic or atrophic subtype, therefore comparisons between their respective union success rates could not be drawn.

No major complications were reported in any of the studies. Minor complications included local soft tissue swelling [13,14], petechiae or bruising [12,13,19], and pain during application of ESWT [15,17].

4. Discussion

ESWT has attracted significant interest in the field of trauma and orthopaedics in recent years. Unfortunately, its rapid application has not been matched by sufficient high quality studies, leading to its scepticism regarding its efficacy in the treatment of more specific musculoskeletal conditions, such as fracture non-unions in the foot and ankle. Whilst surgery remains the gold standard for the treatment of symptomatic fracture non-unions, with successful union rates between 74%–95%, it is not without the risk of complications. Where autologous bone grafting is required for treatment of non-unions, major complications (such as infection, prolonged wound drainage, haematomas, further surgery and persistent pain) of up to 8.6% and minor complications (such as superficial wound infection, temporary sensory loss and mild pain) in over 20% have been reported [20]. ESWT is non-invasive and has low risk of complications, rendering it an attractive non-operative treatment option. Our data from current available studies show that whilst there is huge heterogeneity between the type and energy level of shock wave used, the number of sessions and requirement for anaesthesia, union rates following treatment in all studies are high at three and six months. This is in keeping with current literature on the successful treatment of long bone non-unions [21,22].

One limitation of this study is the lack of high level evidence in the individual studies included. Apart from the study by Furia et al. [12], all the studies were small retrospective case series (level 4 evidence) with no control groups. Also, the definition of non-union was not always specified in the studies. Some cases may therefore be delayed unions rather than true non-unions, and therefore the natural history of these may have been wrongly attributed to the effects of ESWT. Standardisation of the terminology and the inclusion of a clear definition of non-union is therefore paramount in future studies when looking at the effectiveness of ESWT. Post treatment rehabilitation protocols (for example, any immobilisation in a cast or a boot and its duration) should be clearly set out as part of the study design.

Two of the included studies had high loss to follow up rates of the patients, at 41% and 50% [13,15]. Possible reasons may include patients with persistent non-unions having sought further treatment elsewhere, or patients who have achieved fracture union not attending further follow up appointments. Not considering the reasons for loss of follow up could have biased the results.

Other factors that contribute to fracture healing, such as patient's medical comorbidities, steroid use, smoking history and nature of the injury have not been mentioned and accounted for either. These confounders can be significant and ought to be taken into account. Subdividing non-unions into hypertrophic and atrophic types are also important, given that the effectiveness of ESWT appears to be significantly higher in the former compared to the latter [21–23]. The difference in fracture healing potential between low and high energy shockwaves has previously been demonstrated in rabbit models, showing a dose dependent effect on bone mass, callus formation, and modulus of elasticity [24]. Promising results have also been shown in treatment of fracture non-unions in humans with higher energy ESWT [3,25], however these studies did not have a comparative low energy group. Given that application of high energy ESWT necessitates the use of regional or general anaesthesia, there needs to be better evidence of its efficacy over low energy ESWT before it is recommended, especially in the foot and ankle where bony non-unions are relatively superficial and subcutaneous compared to long bones. Further research into the use of ESWT in the elective setting – such as non-union following arthrodesis – in foot and ankle surgery should also be considered.

5. Conclusions

A review of ESWT in non-unions specifically in the foot and ankle was carried out. It was populated that the data to reflect this specifically in this group of patients, and the effectiveness of ESWT does appear promising with the current level 4 evidence. No serious adverse events have been reported. There is, however, significant heterogeneity in the current literature, in particular to the definition of a non-union, the type of fractures which are treated with ESWT, as well as other patient factors and comorbidities. Strict definitions of non-union and its type ought to be specified, as well as standardisation of the type, dosage and regime of ESWT used. There is a definite need for more robust evidence to support its use in the form of a prospective, randomised trial with a control group. Nonetheless, this current evidence demonstrating the success rates of ESWT in non-unions in the foot and ankle is of value to foot and ankle surgeons, particularly during the consenting process.

6. Brief summary

What we already know

- Success and effectiveness of ESWT in treating delayed or non-union of long bones and small bones of the hands and feet have been shown to range from 62 to 83%.
- Use of ESWT has largely been limited to soft tissue pathologies so far.
- Little work has been performed on the use of ESWT in the treatment of foot and ankle fracture non-unions.

What this study adds

- Union rates of 65–100% and 90–100% in foot and ankle fracture non-unions can be achieved 3- and 6-months following ESWT treatment respectively.
- No major complications of ESWT have been reported.
- The current evidence is based on case series of relatively small sample sizes, therefore prospective randomised controlled trials are required to provide more robust evidence.

Conflict of interest

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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