British Medical Bulletin, 2015, **116**:115–138
doi: 10.1093/bmb/ldv047
Advance Access Publication Date: 18 November 2015

Efficacy and safety of extracorporeal shock wave therapy for orthopedic conditions: a systematic review on studies listed in the PEDro database

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Accepted 12 October 2015

Abstract

Background: Extracorporeal shock wave therapy (ESWT) is an effective and safe non-invasive treatment option for tendon and other pathologies of the musculoskeletal system.

Sources of data: This systematic review used data derived from the Physiotherapy Evidence Database (PEDro; www.pedro.org.au, 23 October 2015, date last accessed).

Areas of agreement: ESWT is effective and safe. An optimum treatment protocol for ESWT appears to be three treatment sessions at 1-week intervals, with 2000 impulses per session and the highest energy flux density the patient can tolerate.

Areas of controversy: The distinction between radial ESWT as 'low-energy ESWT' and focused ESWT as 'high-energy ESWT' is not correct and should be abandoned.

Growing points: There is no scientific evidence in favour of either radial ESWT or focused ESWT with respect to treatment outcome.

Areas timely for developing research: Future randomized controlled trials should primarily address systematic tests of the aforementioned optimum treatment protocol and direct comparisons between radial and focused ESWT.

Key words: ESWT, RSWT, PEDRo, musculoskeletal system

Introduction

Extracorporeal shock wave therapy (ESWT) has been successfully used for over 20 years to manage a variety of orthopedic conditions.[1–3] A byproduct of extracorporeal shock wave lithotripsy (ESWL), ESWT has emerged as an acceptable and popular non-invasive management option for tendon and other pathologies of the musculoskeletal system. Prior studies on tendinopathy showed that ESWT can be as or more effective than other forms of treatment including eccentric exercise, traditional physiotherapy, steroid injections, injections of platelet-rich plasma and surgery.[4–7]

One of the primary reasons for the underuse of ESWT is a generalized unfamiliarity with the technique. Prior systematic reviews support the widely accepted notion that ESWT is safe, technically easy to perform and helpful in some conditions.[2,3,8] That said, many of these reviews are dated and have also added to the already pre-existing confusion regarding terminology, protocols, energy levels and treatment parameters. The studies that form the basis of these reviews differ greatly in regards to design, protocol, application technique and length of follow-up. This heterogeneity makes it difficult for the practitioner to adopt a 'best practice' approach.

Yet there is no shortage in information. A search in PubMed on 'shockwave OR shockwaves OR shock wave OR shock waves OR shock-wave OR shock-waves NOT urol* NOT stone NOT stones' on May 17, 2015 yielded over 5000 citations. For this and the above-mentioned reasons, there remains a need for a concise summary of the evidence for the use of ESWT in clinical practice, as well as for developing a generally applicable 'best practice' protocol for ESWT.

The PEDro database (www.pedro.org.au, 23 October 2015, date last accessed) is a freely available database of over 31 000 randomized controlled trials (RCTs), systematic reviews and clinical practice guidelines in physical and rehabilitation medicine. For each RCT, review or guideline, the PEDro database provides the citation details, the abstract and a link to the full text, where possible. All RCTs listed in the PEDro database (henceforth referred to as 'RCTs in PEDro') are independently assessed for quality (the assessment criteria are summarized in Table 1). All but two of the PEDro scale items are based on the Delphi list.[9] PEDro is currently the largest independent database on topics related to physical and rehabilitation medicine and is often used by investigators in Norway, Australia and New Zealand; less so by other European and North American investigators.

The present systematic review used data derived from the PEDro database according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines[10] to compare (i) ESWT with other non-operative treatment for tendon and other pathologies of the musculoskeletal system, (ii) radial ESWT with focused ESWT (see Figs. 1 and 2) and (iii) high-energy ESWT with low-energy ESWT.

Materials and methods

An evidence-based systematic review of literature was performed according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines[10] to examine efficacy and safety of ESWT for orthopedic conditions.

Data source

The PEDro database (www.pedro.org.au, 23 October 2015, date last accessed) was searched from its date of inception to May 17, 2015 to find potentially relevant publications.

Study selection

A first search addressed the key terms shock wave, shock waves, shockwave, shockwaves, lithotrypsy and lithotrypter. Based on the outcome of the first search (as outlined in detail in the next paragraph), a second search was performed on the key terms plantar, Achilles, epicondylitis, subacromial, non-calcific and calcifying.

Table 1 Assessment criteria of the PEDro database (modified from www.pedro.org.au, 23 October 2015, date last accessed)

Part 1: Criteria for inclusion of clinical trials in PEDro (all criteria must be fulfilled)

- The trial must involve comparison of at least two interventions. One of these interventions could be a no treatment control or a sham treatment.
- At least one of the interventions being evaluated must be currently part of physiotherapy practice or could become part of physiotherapy practice. However, the study need not be carried out by physiotherapists.
- The interventions should be applied to subjects who are representative (or who are intended to be representative) of those to whom the intervention might be applied in the course of physiotherapy practice.
- The trial should involve random allocation or intended-to-be-random allocation of subjects to interventions.
- The paper must be a full paper (not an abstract) in a peer-reviewed journal.

Part 2: Assessment criteria of clinical trials included in PEDro

No.	Assessment criterion
1[a]	Eligibility criteria were specified.
2	Subjects were randomly allocated to groups.
3	Allocation was concealed.
4	The groups were similar at baseline regarding the most important prognostic indicators.
5	There was blinding of all subjects.
6	There was blinding of all therapists who administered the therapy.
7	There was blinding of all assessors who measured at least one key outcome.
8	Measures of at least one key outcome were obtained from >85% of the subjects initially allocated to groups.
9	All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analysed by 'intention to treat'.
10	The results of between-group statistical comparisons are reported for at least one key outcome.
11	The study provides both point measures and measures of variability for at least one key outcome.

[a]This criterion influences external validity, but not the internal or statistical validity of the trial. It has been included in the PEDro scale so that all items of the Delphi scale[9] are represented on the PEDro scale. This item is not used to calculate the PEDro score.

Data extraction

The outcome of the first search is shown in Figure 3. We identified $n = 209$ records in the PEDro database of which $n = 47$ were duplicates. All reviews ($n = 48$) were excluded, as well as records that did not address ESWT ($n = 3$).[13–15] Furthermore, all ESWT studies on wound healing and chronic decubitus were excluded ($n = 5$).[16–20] The remaining records ($n = 106$) were divided into studies on (i) radial ESWT with positive outcome (i.e. radial ESWT significantly better statistically than either placebo or alternative treatment modalities) (rESWT+; $n = 23$), (ii) radial ESWT with negative outcome (i.e. radial ESWT not significantly better statistically than either placebo or alternative treatment modalities) (rESWT−; $n = 3$), (iii) focused ESWT with positive outcome (fESWT+; $n = 66$) and (iv) focused ESWT with negative outcome (fESWT−; $n = 15$) (note that one RCT[12] addressed both radial and focused ESWT and, thus, was listed in both groups rESWT+ and fESWT+).

For each of these groups (i.e. rESWT+, rESWT−, fESWT+ and fESWT−), mean and standard error of the mean (SEM) of the following variables were calculated: (i) number of treatment sessions; (ii) interval between treatment sessions for those RCTs with more than one treatment session; (iii) number of impulses per treatment session; (iv) energy flux density (EFD) of the impulses; (v) total EFD that was applied (calculated as the product of the number of treatment sessions, the number of impulses per treatment session and the EFD of the impulses) and (vi) PEDro score (between 0 and 10). Comparison of groups was performed using Kruskal–Wallis test (non-parametric analysis of variance) followed by pairwise comparisons using Dunn's multiple

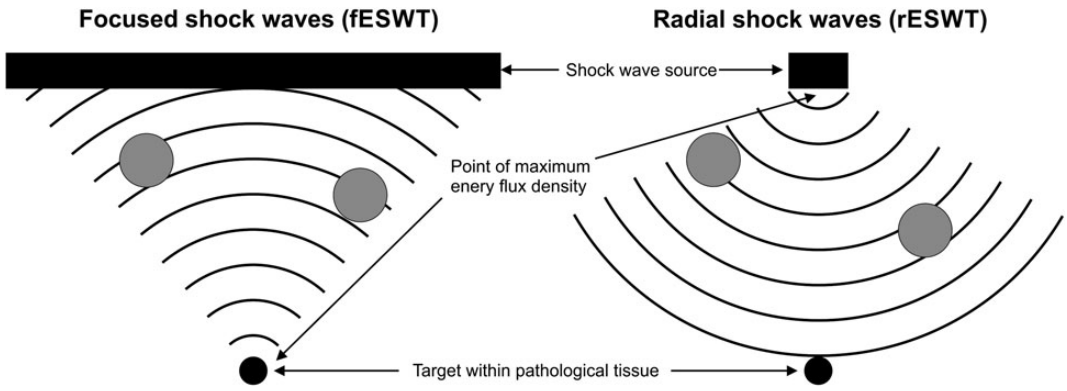

Fig. 1 Working principle of focused and radial extracorporeal shock wave technology. In case of focused shock waves, single acoustic pulses are generated either with a spark-gap (electrohydraulic principle), a technology similar to a loudspeaker (electromagnetic principle) or piezocrystals (piezoelectric principle) (details are provided in Fig. 2). By means of reflectors of certain shape, the acoustic pulses are converted into a focused acoustic pressure wave/shock wave with a point of highest pressure at the desired target within pathological tissue. In case of radial shock waves, a projectile is fired within a guiding tube that strikes a metal applicator placed on the skin. The projectile generates stress waves in the applicator that transmit pressure waves into tissue. It is of note that any disturbance in the pathway of the acoustic pulses between a focused shock wave source and the target within tissue (such as bone, calcifications, etc.; grey dots in the figures) may result in some parts of the acoustic pulse not reaching the target and, thus, weakening the shock wave energy (i.e. the energy flux density) at the target. The same disturbances would not impact the energy of radial shock waves at the target. This is most probably the reason why in muscle tissue, the energy of focused shock waves was found to be decreased by >50% compared with measurements in water, whereas for radial shock waves, measurements in muscle tissue and water were consistent.[11]

comparison test. Many RCTs in PEDro did not specify whether the reported EFD was the positive EFD (EFD_+) or the total EFD (EFD_{total}) (details about EFD_+ and EFD_{total} are provided in Refs.[21,22]). Accordingly, calculations of mean EFDs were based on mixed EFD_+ and EFD_{total} data.

Furthermore, absolute and relative numbers of studies performed with, respectively, electrohydraulic, electromagnetic or piezoelectric shock wave generators were calculated. This was done separately for the groups fESWT+ and fESWT−. Comparison of groups was performed using χ^2 test.

All calculations were performed with GraphPad Prism (version 5.00 for Windows; GraphPad Software, San Diego, CA, USA). A P-value of <0.05 was considered statistically significant.

Finally, we investigated which orthopedic conditions were repeatedly (i.e. more than two times) addressed in the retrieved RCTs on ESWT in PEDro. This was the case for the indications plantar fasciopathy, Achilles tendinopathy, lateral epicondylitis, subacromial pain syndrome, non-calcific supraspinatus tendinopathy and calcifying tendonitis of the shoulder. On this basis, a second search in the PEDro database was performed. For each of the key terms plantar, Achilles, epicondylitis, subacromial, non-calcific and calcifying, we calculated (i) the total number of records, the number of reviews and the number of RCTs in PEDro, (ii) the number of RCTs in PEDro that addressed the corresponding condition and (iii) the number of RCTs on ESWT in PEDro for the corresponding condition. Full-text articles were not assessed for eligibility during the second search.

Results

All studies included in the qualitative synthesis of the first literature search are listed in Tables 2 and 3. The average number of treatment sessions among all RCTs on ESWT in PEDro was 2.88 ± 0.15 (mean ± SEM; range: 1–12), with highest numbers in RCTs on rESWT+ and lowest numbers in RCTs on fESWT+ (Fig. 4A). The difference in the mean number of treatment sessions between these two groups was statistically significant ($P < 0.01$).

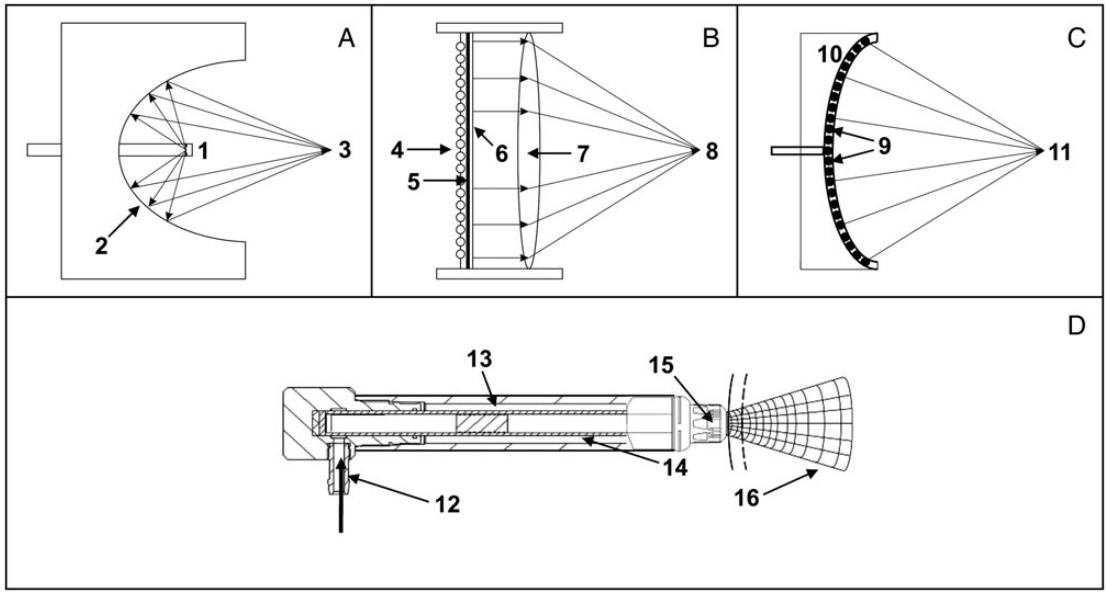

Fig. 2 Schematic representation of the mode of operation of focused (**A**–**C**) and radial (**D**) extracorporeal shock wave generators. (A) Electrohydraulic principle (fESWT): a high voltage discharges rapidly across two electrode tips (spark-gap) (*1*) that are positioned in water. The spark-gap serves as the first focal point (*1*). The heat generated by this process vaporizes the surrounding water. This generates a gas bubble centered on the first focal point, with the gas bubble being filled with water vapor and plasma. The result of the very rapid expansion of this bubble is a sonic pulse, and the subsequent implosion of this bubble causes a reverse pulse, manifesting a shock wave. By means of reflectors of certain shape (*2*), this shock wave can be converted into a convergent/focused acoustic pressure wave/shock wave with a point of highest pressure at the second focal point (*3*). (B) Electromagnetic principle (fESWT): a strong, variable magnetic field is generated by passing a high electric current through a coil (*4*). This causes a high current in an opposed metal membrane (*5*), which causes an adjacent membrane (*6*) with surrounding liquid to be forced rapidly away. Because the adjacent membrane is highly conductive, it is forced away so rapidly that the compression of the surrounding liquid generates a shock wave within the liquid. By means of an acoustic lens (*7*) of certain shape, this shock wave can be converted into a convergent/focused acoustic pressure wave/shock wave with a point of highest pressure at a focal point (*8*). (C) Piezoelectric principle (fESWT): a large number of piezocrystals (*9*) are mounted in a bowl-shaped device (*10*); the number of piezocrystals can vary from a few to several thousands (typically between 1000 and 2000). When applying a rapid electrical discharge, the piezocrystals react with a deformation (contraction and expansion), which is known as the piezoelectric effect. This induces an acoustic pressure puls in the surrounding water that can steep into a shock wave. Because of the design of the bowl-shaped device an acoustic pressure wave/shock wave can emerge with a point of highest pressure at a focal point (*11*). (D) Ballistic principle (rESWT): compressed air (pneumatic principle; *12*) or a magnetic field (not shown) is used to fire a projectile (*13*) within a guiding tube (*14*) that strikes a metal applicator (*15*) placed on the patient's skin. The projectile generates stress waves in the applicator that transmit pressure waves into tissue (*16*).

Among those RCTs on ESWT in PEDro with more than one treatment session, the average interval between treatment sessions was 9.13 ± 0.66 days (range: 1–42 days). On average, the longest intervals between treatment sessions were reported for Group fESWT− and the shortest intervals for Group rESWT −. However, there were no statistically significant ($P < 0.05$) differences between the groups (Fig. 4B).

The average number of impulses per treatment session among all RCTs on ESWT in PEDro varied only slightly among the groups rESWT+, rESWT−, fESWT+ and fESWT−, with a mean value of 2029 ± 96 (range: 250–6000). There were no statistically significant ($P < 0.05$) differences between the groups (Fig. 4C).

The EFD of the impulses applied in all RCTs on ESWT in PEDro was on average 0.19 ± 0.01 mJ/mm^2 (range: 0.03–0.78), with the highest mean value in Group fESWT+ and the lowest mean value in Group rESWT+ (Fig. 4D). The difference in the mean EFD

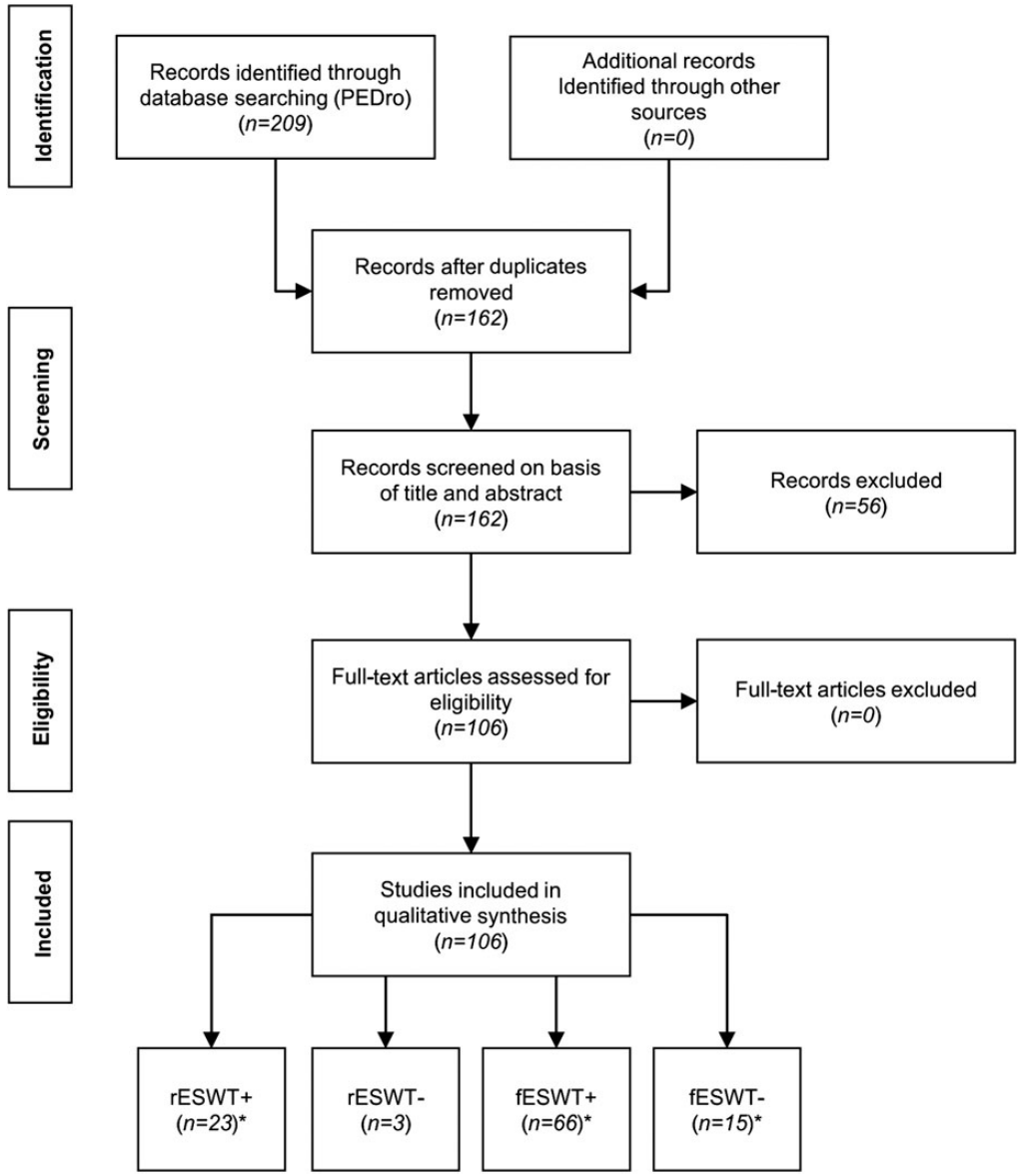

Fig. 3 Systematic review flow chart of the first literature search according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.[10] *, one study[12] addressed both radial and focused ESWT and, thus, was listed in both categories rESWT+ and fESWT+.

between these two groups was statistically significant ($P < 0.01$). However, one cannot exclude that this resulted from the fact that for many RCTs in Groups fESWT+ and fESWT−, it remained unclear whether the reported EFD was EFD_+ or EFD_{total} (which is higher than EFD_+; c.f. Refs.[21,22]). In contrast, for most studies in Groups rESWT+ and rESWT−, it was known that the reported EFD was EFD_+.

Among all RCTs on ESWT in PEDro, the average total EFD applied (calculated as the product of the number of treatment sessions, the number of impulses per treatment session and the EFD of

Table 2 RCTs on radial ESWT listed in the PEDro database included in the present systematic review

Ps	Indication	Study	O	Device	T	EFD	*S*	*I*	Impulses	PEDro assessment criteria									
										2	3	4	5	6	7	8	9	10	11
9	Calcifying tendonitis of the shoulder	Cacchio *et al.*[23]	+	Not specified (Elettronica Pagani)	R	0.10 (EFD_+)	4	7	2500	+	+	+	+	−	+	+	+	+	+
	Plantar fasciopathy	Gerdesmeyer *et al.*[24]	+	DolorClast (EMS)	R	0.16 (EFD_+)	3	14	2000	+	+	+	+	−	+	+	+	+	+
		Ibrahim *et al.*[25]	+	DolorClast (EMS)	R	0.16 (EFD_+)	2	7	2000	+	+	+	+	−	+	+	+	+	+
8	Achilles tendinopathy	Rompe *et al.*[26]	+	DolorClast (EMS)	R	0.10 (EFD_+)	3	7	2000	+	+	+	−	−	+	+	+	+	+
		Rompe *et al.*[27]	+	DolorClast (EMS)	R	0.12 (EFD_+)	3	7	2000	+	+	+	−	−	+	+	+	+	+
		Rompe *et al.*[5]	+	DolorClast (EMS)	R	0.10 (EFD_+)	3	7	2000	+	+	+	−	−	+	+	+	+	+
	Plantar fasciopathy	Rompe *et al.*[28]	−	DolorClast (EMS)	R	0.16 (EFD_+)	3	7	2000	+	+	+	−	−	+	+	+	+	+
		Lohrer *et al.*[12]	+	Duolith SD 1 radial part (Storz)	R	0.17 (EFD_{total})	3	7	2000	+	−	+	+	−	+	+	+	+	+
	Proximal hamstring tendinopathy	Cacchio *et al.*[29]	+	DolorClast (EMS)	R	0.18 (EFD_+)	4	7	2500	+	+	+	−	−	+	+	+	+	+
	Subacromial pain	Engebretsen *et al.*[30]	−	DolorClast (EMS)	R	0.1–0.16 (EFD_+)	4–6	7	2000				−	−					
7	Calcifying tendonitis of the shoulder	Kolk *et al.*[31]	−	DolorClast (EMS)	R	0.11 (EFD_+)	3	12	2000	+	+	+	+	−	−	−	+	+	+
	Subacromial pain	Engebretsen *et al.*[32]	−	DolorClast (EMS)	R	0.1–0.16 (EFD_+)	3	5	2000	+	+	+	−	−	−	+	+	+	+
	Lateral epicondylitis	Gündüz *et al.*[33]	+	Not specified	R	'1.4 bar'	10	1	500	+	+	+	−	−	+	+	−	+	+
	Plantar fasciopathy	Chow and Cheing[34]	+	DolorClast (EMS)	R	0.05 to max. tolerable EFD_+	3	7	1000	+	−	+	+	−	+	+	−	+	+
6	Plantar fasciopathy	Shaheen[35]	+	DolorClast (EMS)	R	0.06–0.14 (EFD_+)	3	7	2000	+	−	+	+	−	+	−	−	+	+
5	Non-specific shoulder pain	Damian and Zalpour[36]	+	Masterpuls MP 200 (Storz)	R	Not specified	5.5	7	?	+	−	+	−	−	−	+	−	+	+
	Primary long bicipital tenosynovitis	Liu *et al.*[37]	+	DolorClast (EMS)	R	0.12 (EFD_+)	4	7	1500	+	−	+	−	−	−	+	−	+	+
		Cho *et al.*[38]	+		R	0.12 (?)	1		1000	+	−	+	−	−	−	+	−	+	+

Table continues

Table 2 Continued

Ps	Indication	Study	O	Device	T	EFD	*S*	*I*	Impulses	PEDro assessment criteria									
										2	3	4	5	6	7	8	9	10	11
	Myofascial pain syndrome			JEST-2000 (Joeunmedical, Korea)															
	Lateral epicondylitis	Sarkar *et al.*[39]	+	Masterpuls MP 100 (Storz)	R	0.06 (?)	3	7	2000	+	−	+	−	−	−	+	−	+	+
	Lateral and medial epicondylitis	Lee *et al.*[6]	+	DolorClast (EMS)	R	0.06–0.12 (EFD_+)	3	7	2000	+	−	+	−	−	−	+	−	+	+
	Greater trochanteric pain syndrome	Rompe *et al.*[40]	+	DolorClast (EMS)	R	0.12 (EFD_+)	3	7	2000	−	−	+	−	−	−	+	+	+	+
	Plantar fasciopathy	Grecco *et al.*[41]	+	DolorClast (EMS)	R	0.12 (EFD_+)	3	7	2000	+	−	+	−	−	−	+	−	+	+
		Greve *et al.*[42]	+	DolorClast (EMS)	R	0.12 (EFD_+)	3	7	2000	+	−	+	−	−	−	+	−	+	+
		Marks *et al.*[43]	−	DolorClast (EMS)	R	0.16 (EFD_+)	3	3	2000	+	−	+	−	−	+	+	−	−	+
4	Plantar fasciopathy and tennis elbow	Mehra *et al.*[44]	+	DolorClast (EMS)	R	0.10 (EFD_+)	3	14	2000	+	−	−	−	−	−	+	−	+	+
	Spasticity	Vidal *et al.*[45]	+	DolorClast (EMS)	R	0.10 (EFD_+)	3	7	2000	+	−	−	−	−	+	−	−	+	+

Ps, PEDro score; O, outcome; +, rESWT significantly better statistically than either placebo or alternative treatment modalities; −, rESWT not significantly better statistically than either placebo or alternative treatment modalities; T, shock wave technology; R, radial; EFD, energy flux density; EFD_+, positive EFD; EFD_{total}, total EFD; (?), not specified whether EFD_+ or EFD_{total}; *S*, number of treatment sessions; *I*, interval between treatment sessions (days). The PEDro assessment criteria 2–11 are outlined in detail in Table 1. Note that the first PEDro assessment criterion (Eligibility criteria were specified) is not used to calculate the PEDro score.

Table 3 RCTs on focused ESWT listed in the PEDro database included in the present systematic review

Ps	Indication	Study	O	Device	T	EFD	*S*	*I*	Impulses	PEDro assessment criteria									
										2	3	4	5	6	7	8	9	10	11
9	Calcifying tendonitis of the shoulder	Gerdesmeyer *et al.*[46]	+	Epos Ultra (Dornier)	EM	0.08–0.32 (?)	2	14	1500 or 6000	+	+	+	+	−	+	+	+	+	+
	Lateral epicondylitis	Rompe *et al.*[47]	+	Sonocur Plus (Siemens)	EM	0.09 (EFD_{total})	3	7	2000	+	+	+	+	−	+	+	+	+	+
		Pettrone and McCall[48]	+	Sonocur Plus (Siemens)	EM	0.06 (?)	3	7	2000	+	+	+	+	−	+	+	+	+	+
	Patellar tendinopathy	Zwerver *et al.*[49]	−	Piezowave (Wolf)	PE	0.068–0.40 (EFD_{+})	3	7	2000	+	+	+	+	−	+	+	+	+	+
	Achilles tendinopathy	Rasmussen *et al.*[50]	+	Piezoson 100 (Wolf)	PE	0.12–0.51 (?)	3	7–14	2000	+	+	+	+	−	+	+	+	+	+
	Plantar fasciopathy	Buchbinder *et al.*[51]	−	Epos Ultra (Dornier)	EM	0.02–0.33 (?)	3	7	2000 or 2500	+	+	+	+	−	+	+	+	+	+
		Kudo *et al.*[52]	+	Epos Ultra (Dornier)	EM	0.36 (EFD_{+})	1		3500	+	+	+	+	−	+	+	+	+	+
		Gollwitzer *et al.*[53]	+	Duolith SD 1 (Storz)	EM	0.25 (EFD_{total})	3	7	2000	+	+	+	+	−	+	+	+	+	+
8	Calcifying tendonitis of the shoulder	Schmitt *et al.*[54]	−	Minilith SL 1 (Storz)	EM	0.11 (EFD_{+})	3	7	2000	+	+	+	+	−	+	+	−	+	+
		Haake *et al.*[55]	+	Minilith SL 1 (Storz)	EM	0.78 (EFD_{total})	2	7	2000	+	+	+	+	−	+	+	−	+	+
		Ioppolo *et al.*[56]	+	Modulith SLK (Storz)	EM	0.10 and 0.20 (?)	4	7	2400	+	+	+	−	−	+	+	+	+	+
		Albert *et al.*[57]	+	Modulith SLK (Storz)	EM	0.45 (?)	2	14	2500	+	−	+	+	−	+	+	+	+	+
	Lateral epicondylitis	Speed *et al.*[58]	−	Sonocur Plus (Siemens)	EM	0.18 (?)	3	28	1500	+	−	+	+	−	+	+	+	+	+
		Staples *et al.*[59]	−	MedTech Epos (Dornier)	EM	Maximum tolerable	3	7	2000	+	−	+	+	−	+	+	+	+	+
		Haake *et al.*[60]	−	Various devices	EM/PE	0.04–0.22 (EFD_{+})	3	7	2000	+	+	−	+	−	+	+	+	+	+
		Chung and Wiley[61]	−	Sonocur Basic (Siemens)	EM	0.03–0.17 (?)	3	7	2000	+	+	+	−	−	+	+	+	+	+
	Plantar fasciopathy	Buch *et al.*[62]	+	Epos Ultra (Dornier)	EM	0.03–0.36 (?)	1		3800	+	+	+	+	−	+	+	−	+	+
		Haake *et al.*[63]	−	Epos Ultra (Dornier)	EM	0.08 (EFD_{+})	3	14	4000	+	−	+	+	−	+	+	+	+	+
		Speed *et al.*[64]	−	Sonocur Plus (Siemens)	EM	0.12 (?)	3	28	1500	+	−	+	+	−	+	+	+	+	+
		Lohrer *et al.*[12]	+	Duolith SD 1 (Storz)	EM	0.20 (EFD_{total})	3	7	2000	+	−	+	+	−	+	+	+	+	+

Table continues

Table 3 Continued

Ps	Indication	Study	O	Device	T	EFD	*S*	*I*	Impulses	PEDro assessment criteria									
										2	3	4	5	6	7	8	9	10	11
7	Calcifying tendonitis of the shoulder	Peters *et al.*[65]	+	Minilith SL 1 (Storz)	EM	0.15 and 0.44 (?)	5	42	1500	+	+	−	+	−	+	+	−	+	+
		Hearnden *et al.*[66]	+	Not specified		0.28 (?)	1		2000	+	+	−	+	−	+	+	−	+	+
		Pleiner *et al.*[67]	+	Orthospec (Medispec)	EH	0.28 (?)	2	14	2000	+	−	+	−	+	+	+	−	+	+
		Tornese *et al.*[68]	+	Epos Ultra (Dornier)	EM	0.22 (?)	3	7	1800	+	−	+	−	−	+	+	+	+	+
		Sabeti-Aschraf *et al.*[69]	+	Modulith SLK (Storz)	EM	0.08 (?)	3	7	1000		+	+	−	−	−	+	+	+	+
						0.20 (?)	2	7	2000										
	Non-calcific supraspinatus tendinopathy	Haake *et al.*[70]	+	Minilith SL 1 (Storz)	EM	0.33 (EFD_+)	3	7	2000	+	−	+	−	−	+	+	+	+	+
		Groß *et al.*[71]	−	Minilith SL 1 (Storz)	EM	0.33 and 0.44 (EFD_+)	3	7	2000	+	−	+	−	−	+	+	+	+	+
		Galasso *et al.*[72]	+	Modulith SLK (Storz)	EM	0.068 (?)	2	7	3000	+	−	+	+	−	+	+	−	+	+
	Plantar fasciopathy	Rompe *et al.*[73]	+	Sonocur Plus (Siemens)	EM	0.16 (?)	3	7	2100	+	+	+	−	−	+	+	−	+	+
		Ogden *et al.*[74]	+	Ossatron (HMT)	EH	0.22 (?)	1		1500	+	+	+	+	−	+	+	−	+	−
		Theodore *et al.*[75]	+	Epos Ultra (Dornier)	EM	0.36 (?)	1		3800	+	−	+	+	−	+	+	−	+	+
		Porter and Shadbolt (2005)[76]	−	Not specified	EH	0.08 (?)	3	7	1000	+	+	+	−	−	+	+	−	+	+
		Liang *et al.*[77]	+	Piezoson 100 (Wolf)	PE	0.12 and 0.56 (EFD_{total})	3	7	2000	+	+	+	−	−	+	+	−	+	+
		Malay *et al.*[78]	+	Orthospec (Medispec)	EH	Not specified	1		3800	+	−	+	+	−	+	+	−	+	+
		Vahdatpour *et al.*[79]	+	Duolith SD 1 (Storz)	EM	0.20 (?)	3	7	4000	+	−	+	+	−	−	+	+	+	+
		Radwan *et al.*[80]	+	Ossatron (HMT)	EH	0.22 (?)	1		1500	+	+	+	−	−	−	+	+	+	+
	Knee osteoarthritis	Chen *et al.*[81]	+	Piezowave (Wolf)	PE	0.275 (EFD_+)	6	7	2000	+	+	+	−	−	−	+	+	+	+
6	Myogelosis of the masseter muscle	Kraus *et al.*[82]	+	Sonocur Plus (Siemens)	EM	0.04 (?)	1		250	+	−	−	+	−	+	+	−	+	+
	Calcifying tendonitis of the shoulder	Pan *et al.*[83]	+	Orthospec (Medispec)	EH	0.26–0.32 (?)	2	14	2000	+	−	+	−	−	+	+	−	+	+
		Perlick *et al.*[84]	+	Lithostar (Siemens)	EM	0.33, 0.42, 0.54 (?)	2	21	2000	+	+	+	−	−	−	+	−	+	+

		Sabeti-Aschraf *et al.*[85]	+	Modulith SLK (Storz)	EM	0.08 (?)	3	7	1000	+	−	+	−	−	+	+	−	+	+
	Lateral epicondylitis	Rompe *et al.*[86]	+	Osteostar (Siemens)	EM	0.08 (?)	3	7	1000	+	−	+	−	−	+	+	−	+	+
		Haake *et al.*[87]		Various devices	EM/PE	0.04–0.22 (EFD_+)	3	7	2000	+	−	+	+	−	−	+	−	+	+
		Melikyan *et al.*[88]	−	Epos Ultra (Dornier)	EM	333 (total EFD delivered) (?)	3	?	?	+	−	+	+	−	+	+	−	+	−
		Melegati *et al.*[89]	+	Epos Ultra (Dornier)	EM	0.16 (?)	3	7	1800	+	−	+	+	−	−	+	−	+	+
	Long bone fracture	Wang *et al.*[90]	+	Ossatron (HMT)	EH	0.62 (?)	1		6000	+	−	+	−	−	+	+	−	+	+
	Achilles tendinopathy	Costa *et al.*[91]	−	Modulith SLK (Storz)	EM	0.20 (?)	3	28	1500	+	+	−	−	−	+	+	−	+	+
	Plantar fasciopathy	Ogden *et al.*[92]	+	Ossatron (HMT)	EH	0.22 (?)	1		1500	+	−	+	+	−	+	+	−	+	−
		Rompe *et al.*[93]	+	Osteostar (Siemens)	EM	0.08 (?)	3	7	1000	+	+	−	−	−	−	+	+	+	+
		Chew *et al.*[94]	+	Epos Ultra (Dornier)	EM	0.42 (?)	2	7	2000	+	+	+	−	−	+	−	−	+	+
		Tornese *et al.*[95]	+	Epos Ultra (Dornier)	EM	0.22 (?)	3	7	1800	+	−	+	−	−	+	+	−	+	+
		Saxena *et al.*[96]	+	Duolith SD 1 (Storz)	EM	0.24 (EFD_{total})	3	7	2000	+	+	+	−	−	−	+	−	+	+
	Spasticity	El-Shamy *et al.*[97]	+	Modulith SLK (Storz)	EM	0.03 (?)	12	7	1500	+	+	+	−	−	+	−	−	+	+
5	Calcifying tendonitis of the shoulder	Cosentino *et al.*[98]	+	Orthima (Direx Medical) EH	EH	0.28 (?)	4	5.5	1200	+	−	+	+	−	+	−	−	+	−
		Hsu *et al.*[99]	+	OrthoWave (MTS)	EH	0.55 (?)	2	14	1000	−	−	+	+	−	+	+	−	+	−
		Farr *et al.*[100]	+	Modulith SLK (Storz)	EM	0.30 (?)	1		3200	+	−	−	−	−	+	+	−	+	+
						0.20 (?)	2	7	1600										
	Tenonitis of the rotator cuff	Speed *et al.*[101]	−	Sonocur (Siemens)	EM	0.12 (?)	3	28	1500	+	−	+	−	−	−	−	+	+	+
	Lateral epicondylitis	Rompe *et al.*[102]	+	Osteostar (Siemens)	EM	0.08 (?)	3	7	1000	+	−	+	−	−	+	−	−	+	+
		Rompe *et al.*[103]	+	Sonocur (Siemens)	EM	0.16 (?)	3	7	1000	−	−	+	−	−	+	+	−	+	+
		Chung *et al.*[104]	−	Sonocur Basic (Siemens)	EM	0.03–0.17 (?)	3	7	2000	+	−	+	−	−	−	+	−	+	+
	Lateral epicondylitis	Ozturan *et al.*[105]	+	Stonelith V5 (PCK)	EH	0.17 (?)	3	7	2000	+	−	+	−	−	−	+	−	+	+
	Patellar tendinopathy	Wang *et al.*[106]	+	Ossatron (HMT)	EH	0.18 (?)	1		1500	−	−	+	+	+	+	+	−	+	+
	Plantar fasciopathy	Rompe *et al.*[107]	+	Osteostar (Siemens)	EM	0.08 (?)	3	7	1000	+	+	+	−	−	−	−	−	+	+
	Plantar fasciopathy	Krischek *et al.*[108]	+	Osteostar (Siemens)	EM	0.08 (?)	3	7	500	+	−	+	−	−	−	+	−	+	+
	Plantar fasciopathy	Cosentino *et al.*[109]	+	Orthima (Direx Medical)	EH	Between 0.03 and 0.4 (?)	6	8.5	1200	+	−	+	+	−	−	+	−	+	−

Table continues

Table 3 Continued

Ps	Indication	Study	O	Device	T	EFD	*S*	*I*	Impulses	PEDro assessment criteria									
										2	3	4	5	6	7	8	9	10	11
	Plantar fasciopathy	Hammer *et al.*[110]	+	Piezoson 300 (Wolf)	PE	0.20 (?)	3	7	3000	+	−	+	−	−	−	+	−	+	+
4	Calcifying tendonitis of the shoulder	Seil *et al.*[111]	+	Piezolith 2501 (Wolf)	PE	0.10 and 0.30 (?)	3	7	5000	+	−	+	−	−	−	+	−	+	−
							1		5000										
		Loew *et al.*[112]	+	MFL 5000 (Philips) and Compact (Dornier)	EH	0.10	1		2000	−	−	+	−	−	−	+	−	+	+
			+	MFL 5000 (Philips) and Compact (Dornier)	EM	0.3	1		2000										
			+	MFL 5000 (Philips) and Compact (Dornier)	EM	0.3	2	7	2000										
	Supraspinatus tendon syndrome	Schmitt *et al.*[113]	−	Minilith SL1 (Storz)	EM	0.33 (EFD_+)	3	7	2000	+	−	−	−	−	−	+	−	+	+
	Lateral epicondylitis	Haake *et al.*[114]	−	Minilith SL 1 (Storz)	EM	0.22 (EFD_+)	3	7	2000	−	−	+	+	−	−	−	−	+	+
	Osteonecrosis of the femoral head	Wang *et al.*[115]	+	Ossatron (HMT)	EH	0.62 (?)	1		6000	−	−	+	−	−	−	+	−	+	+
	Plantar fasciopathy	Rompe *et al.*[116]	+	Osteostar (Siemens)	EM	0.06 (?)	3	7	1000	+	−	+	−	−	−	−	−	+	+
		Wang *et al.*[117]	+	Ossatron (HMT)	EH	0.32 (?)	1		1500	−	−	+	−	−	−	+	−	+	+
		Yucel *et al.*[118]	+	Stonelith V5 (PCK)	EH	Not specified	1		3000	+	−	+	−	−	−	−	−	+	+
		Hammer *et al.*[119]	+	Piezoson 300 (Richard Wolf)	PE	0.20 (?)	3	7	3000	+	−	+	−	−	−	+	−	−	+
	Achilles tendinopathy	Notarnicola *et al.*[120]	−	Minilith SL1 (Storz)	EM	0.06 (?)	3	3.5	1600	+	−	+	−	−	−	−	−	+	+
3	Calcifying tendonitis of the shoulder	Rompe *et al.*[121]	+	Not specified (Siemens)	EM	0.06 and 0.28 (?)	1		1500	+	−	−	−	−	−	−	−	+	+
	Lateral epicondylitis	Crowther *et al.*[122]	+	Minilith SL1 (Storz)	EM	0.10 (?)	3	7	2000	+	+	−	−	−	−	−	−	+	−
	Lateral epicondylitis	Rompe *et al.*[123]	+	Osteostar (Siemens)	EM	0.08 (?)	3	7	1000	+	−	+	−	−	−	−	−	+	−
	Lateral epicondylitis/ tendinosis calcarea of the shoulder	Rompe *et al.*[124]	+	Not specified (Siemens)	EM	0.08 (?)	3	7	1000	+	−	−	−	−	−	+	−	−	+

1	Rotator cuff lesions	Saggini *et al.*[125]	+	Evotron (HMT)	EH	0.132 (?)	3	7	600	+	–	–	–	–	–	–	–	–	–

Ps, PEDro score; O, outcome; +, fESWT significantly better statistically than either placebo or alternative treatment modalities; –, fESWT not significantly better statistically than either placebo or alternative treatment modalities; T, shock wave technology; EH, electrohydraulic; EM, electromagnetic; PE, piezoelectric; EFD, energy flux density; EFD_+, positive EFD; EFD_{total}, total EFD; (?), not specified whether EFD_+ or EFD_{total}; *S*, number of treatment sessions; *I*, interval between treatment sessions [days]. The PEDro assessment criteria 2–11 are outlined in detail in Table 1. Note that the first PEDro assessment criterion (Eligibility criteria were specified) is not used to calculate the PEDro score.

the impulses) was 0.99 ± 0.08 J/mm^2 (range: 0.01–3.72 J/mm^2), with the highest mean value in Group fESWT+ and the lowest mean value in Group rESWT+. However, there were no statistically significant ($P < 0.05$) differences between the groups (Fig. 4E).

The average PEDro score among all RCTs on ESWT in PEDro was 6.33 ± 0.17 (range: 1–9), with the highest mean score in Group fESWT– and the lowest mean score in Group fESWT+ (Fig. 4F). The difference in the mean PEDro score between these two groups was statistically significant ($P < 0.01$).

Furthermore, in 17 RCTs on fESWT with positive outcome in PEDro, an electrohydraulic (EH) device was used, in 42 RCTs an electromagnetic (EM) device and in 6 RCTs a piezoelectric (PE) device (in 1 RCT both EH and EM device were used). For the RCTs on fESWT with negative outcome in PEDro, the corresponding numbers were 1 (EH), 13 (EM) and 2 (PE) (1 study with both EH and EM devices). The distribution of numbers of EH, EM and PE devices was not statistically significant ($P = 0.229$) between RCTs on fESWT with positive outcome and RCTs on fESWT with negative outcome.

The results of the second search are summarized in Table 4. For the key word plantar, 82 out of 288 records (28.5%) in the PEDro database were RCTs on plantar fasciopathy, of which 41 (41/82 = 50%) had a PEDro score of 6 or higher. For the other key words, the corresponding numbers were as follows: Achilles: 44/130 = 33.8% RCTs on Achilles tendinopathy, among them 27/44 = 61.4% with PEDro score ≥6. Epicondylitis: 106/106 = 100% RCTs on lateral epicondylitis, among them 48/106 = 45.3% with PEDro score ≥6. Non-calcific: 3/8 = 37.5% RCTS on non-calcific supraspinatus tendinopathy, among them 2/3 = 66.6% with PEDro score ≥6. Calcifying: 16/21 = 76.2% RCTs on calcifying tendonitis of the shoulder, among them 9/16 = 56.3% with PEDro score ≥6. Subacromial: 63/76 = 82.9% RCTS on subacromial pain syndrome, among them 40/63 = 63.5% with PEDro score ≥6.

For plantar fasciopathy, 41.5% of the RCTs listed in the PEDro database were RCTs on ESWT (56.1% of the RCTs with PEDro score ≥6). For other

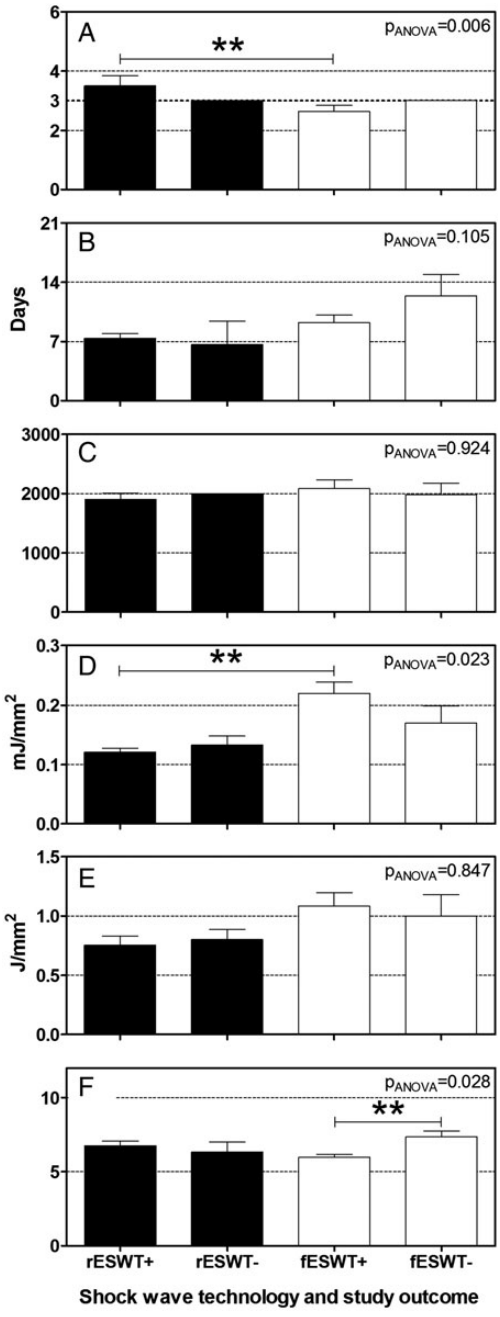

Fig. 4 Mean and standard error of the mean (SEM) of the number of treatment sessions (**A**), interval between treatment sessions (**B**), number of impulses per treatment session (**C**), energy flux density of the impulses (**D**), total energy flux density that was applied (**E**) and the PEDro score of all RCTs on radial (rESWT) and focused (fESWT) extracorporeal shock wave therapy with positive (+) or negative (−) outcome listed in the PEDro database (deadline: May 17, 2015). Details are provided in the main text.

indications, the corresponding relative numbers of RCTs on ESWT were as follows: Achilles tendinopathy: 11.4% of all RCTs, and 18.5% of those RCTs with PEDro score ≥6. Lateral epicondylitis: 15.1% of all RCTs, and 18.8% of those RCTs with PEDro score ≥6. Non-calcific supraspinatus tendinopathy: 100% of all RCTs. Calcifying tendonitis of the shoulder: 81.3% of all RCTs, and 77.8% of those RCTs with PEDro score ≥6. Subacromial pain syndrome: 4.8% of all RCTs, and 7.5% of those RCTs with PEDro score ≥6.

Discussion

Methodological considerations

Prior systematic reviews attempted to assimilate the raw data from hundreds of studies investigating ESWT so as to draw meaningful conclusions. Unfortunately, many of these reviews, by not defining terminology, and by not drawing a distinction between the various types of ESWT have at times added to the confusion. Concepts such as radial ESWT, focused ESWT, low-energy ESWT and high-energy ESWT have clinical, practical and economic implications and therefore need explanation by reviewers.

The reliability of the PEDro scale for rating the quality of RCTs was demonstrated[126] and subsequently confirmed independently.[127] Using RCTs derived only from the PEDro database, we sought to (i) clarify some common misconceptions regarding ESWT and (ii) for specific indications, compare ESWT with other forms of non-operative treatment.

A meta-analysis is often very helpful when the efficacy of an intervention is not known. The preponderance of the RCTs derived from our search of the PEDro database demonstrated that ESWT is better than placebo, no treatment or an alternative treatment (>80% of all studies on ESWT in PEDro). However, there are substantial differences among RCTs on ESWT listed in PEDro with regard to clinical condition, study design, ESWT technology and device, treatment protocol and follow-up period. Therefore, we felt a clinical review would be the more appropriate format for our purposes.

We have derived 10 main statements about ESWT based on the RCTs on rESWT and fESWT in PEDro

Table 4 Results of the second search of the PEDro database split up according to key words as outlined in detail in the main text (deadline: May 17, 2015)

	Plantar		Achilles		Epicondylitis		Non-calcific		Calcifying		Subacromial	
Records	288		130		135		8		21		76	
Reviews	42		31		29		3		5		13	
RCTs	246		99		106		5		16		63	
Ps	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**	**A**	**B**
10	1	0	2	0	0	n/a	0	n/a	0	0	0	n/a
9	7	71.4	1	100	3	66.7	0	n/a	1	100	4	0
8	9	55.6	5	60.0	9	44.4	0	n/a	3	100	10	10.0
7	13	61.5	11	0	17	5.9	2	100	4	75.0	15	13.3
6	11	45.5	8	12.5	19	10.5	0	n/a	1	0	11	0
5	13	46.2	6	0	24	20.8	1	100	3	100	11	0
4	16	25.0	8	0	14	7.1	0	n/a	3	66.7	7	0
3	8	12.5	3	0	7	14.3	0	n/a	1	100	1	0
2	2	0	0	n/a	3	0	0	n/a	0	n/a	2	0
1	1	0	0	n/a	3	0	0	n/a	0	n/a	0	n/a
CE	1	0	0	n/a	7	0	0	n/a	0	n/a	2	0
Total-1	82	**41.5**	44	**11.4**	106	**15.1**	3	**100**	16	**81.3**	63	**4.8**
Total-2	41	**56.1**	27	**18.5**	48	**18.8**	2	**100**	9	**77.8**	40	**7.5**

Records, total number of records; Reviews, number of reviews; RCTs, number of RCTs. Ps, PEDro score; A, absolute number of RCTs addressing the corresponding indication (i.e. plantar fasciopathy, Achilles tendinopathy, lateral epicondylitis, non-calcific supraspinatus tendinopathy, calcifying tendonitis of the shoulder and subacromial pain), split up according to PEDro scores; B, relative number of RCTs on ESWT addressing the corresponding indication; split up according to PEDro scores; CE, currently evaluated by PEDro. Total-1, total and relative numbers of RCTs in categories A and B; Total-2, total and relative numbers of RCTs in categories A and B with a PEDro score of 6 or higher.

(Table 5). Each statement is briefly substantiated by scientific evidence developed in the present systematic review. References to studies not listed in PEDro were kept at the absolute minimum and marked by an asterisk.

ESWT is effective

The efficacy of ESWT is clearly supported by the cumulative data. 88.5% (23 out of 26) of all RCTs on rESWT and 81.5% (66 out of 81) of all RCTs on fESWT in PEDro had positive outcome (i.e. rESWT or fESWT significantly better statistically than either placebo or alternative treatment modalities).

ESWT is safe

The safety of ESWT was also clearly supported by the cumulative data. There were no reports of serious adverse events in any of the studies included in this analysis.

For certain orthopedic conditions, RCTs on ESWT were the predominant type of RCT listed in the PEDro database and/or obtained the highest PEDro scores among all investigated treatment modalities

Both criteria (i.e. predominant type of RCT in PEDro, and highest PEDro scores among all investigated treatment modalities) were fulfilled for the indications plantar fasciopathy, non-calcific supraspinatus tendinopathy and calcifying tendonitis of the shoulder (Table 4). For Achilles tendinopathy and lateral epicondylitis, respectively, 11.4 and 15.1% of all RCTs in PEDro were RCTs on ESWT, but these RCTs also obtained among the highest PEDro scores among all investigated treatment modalities for these conditions.

For other indications (greater trochanteric pain syndrome, patellar tendinopathy, knee osteoarthritis, long bone fracture, osteonecrosis of the femoral head, proximal hamstring tendinopathy, primary long bicipital tenosynovitis, myofascial pain syndrome,

Table 5 Main statements about ESWT based on the RCTs on rESWT and fESWT listed in the PEDro database

No.	Statement
1	ESWT is effective.
2	ESWT is safe.
3	For certain orthopedic conditions, RCTs on ESWT were the predominant type of RCT listed in the PEDro database and/or obtained the highest PEDro scores among all investigated treatment modalities.
4	There was no difference in the 'quality' of RCTs on ESWT in PEDro with positive or negative outcome.
5	Application of local anesthesia adversely affects outcome of ESWT.
6	Application of insufficient energy adversely affects outcome of ESWT.
7	There is no scientific evidence in favor of either rESWT or fESWT with respect to treatment outcome.
8	The distinction between radial ESWT as 'low-energy ESWT' and focused ESWT as 'high-energy ESWT' is not correct and should be abandoned.
9	There is no scientific evidence that a certain fESWT technology is superior to the other technologies.
10	An optimum treatment protocol for ESWT appears to be three treatment sessions at 1-week intervals, with 2000 impulses per session and the highest energy flux density that can be applied.

myogelosis of the masseter muscle and spasticity), there are not enough RCTs on rESWT and fESWT in PEDro to draw meaningful conclusions regarding the significance of ESWT for the corresponding conditions.

There was no difference in the 'quality' of RCTs on ESWT in PEDro with positive or negative outcome

RCTs on ESWT with either positive or negative outcome had almost the same averaged PEDro scores. This finding contradicts the belief that 'better' RCTs (i.e. RCTs with a higher PEDro score) generally demonstrate that ESWT is not effective.

Application of local anesthesia adversely affects outcome of ESWT

Two studies[128*,129*] demonstrated that application of local anesthesia in the area of treatment (as done in Refs.[54,63]) adversely affects outcome of ESWT. The molecular mechanisms underlying this phenomenon are not yet fully understood, but substantial evidence points to a central role of the peripheral nervous system in mediating molecular and cellular effects of shock waves applied to the musculoskeletal system.[*130–132*] These effects could be blocked by local anesthesia.[133*] Thus, it is now generally recommended to apply shock waves without local anesthesia to the musculoskeletal system.

Application of insufficient energy adversely affects outcome of ESWT

The averaged EFD applied in all RCTs on rESWT and fESWT for calcifying tendonitis of the shoulder with positive outcome in PEDro ('averaged EFD') was 0.28 ± 0.04 mJ/mm^2. This was ~2.6 times more than the EFD applied in a negative RCT on rESWT for this indication (EFD = 0.11 mJ/mm^2).[31] A similar situation was found for treating plantar fasciopathy. Here, the averaged EFD was 0.19 ± 0.02 mJ/mm^2, which was more than two times the EFD applied in a negative RCT on fESWT[63] as well as in another negative RCT on fESWT[76] (0.08 mJ/mm^2). Regarding Achilles tendinopathy, averaged EFD was equal to 0.17 ± 0.04 mJ/mm^2 in RCTs on ESWT with positive outcome in PEDro, compared with EFD = 0.06 mJ/mm^2 applied in an RCT on fESWT with negative outcome.[120]

There is no scientific evidence in favor of either rESWT or fESWT with respect to treatment outcome

'Which is better, rESWT or fESWT?' A review of the PEDro database demonstrated no scientific evidence in favor of either rESWT or fESWT with respect to treatment outcome. There are very few studies comparing the two techniques. In one such study,[12] better results were reported with fESWT than with rESWT for treating patients with plantar fasciopathy

(EFD was higher in fEWST than in rESWT in this study[12]). However, using the same rESWT and fESWT devices than in Ref.[12] and the same EFD in fESWT and rESWT, other authors found no difference in effectiveness between rESWT and fESWT for patients with patellar tendinopathy.[134]*

The distinction between radial ESWT as 'low-energy ESWT' and focused ESWT as 'high-energy ESWT' is not correct and should be abandoned

Rompe *et al.*[8] arbitrarily defined an EFD of 0.2 mJ/mm^2 as the margin between low- and high-energy shock wave treatments. Following this definition, 100% of the RCTs on rESWT, ~45% of the fESWT+ RCTs and ~77% of the fESWT− RCTs in PEDro were performed with low-energy shock waves (c.f. Tables 2 and 3). However, other definitions of the margin between low- and high-energy shock wave treatments were published[135]*,[136]* (Table 6). Accordingly, it is not correct to characterize rESWT as low-energy shock wave treatment and fESWT as high-energy shock wave treatment, as different authors have used different thresholds for this distinction. Because there is no consensus in the literature about the difference between low- and high-energy ESWT, this distinction appears arbitrary and should be abandoned.

There is no scientific evidence that a certain fESWT technology is superior to other technologies

Focused shock waves can be produced by electrohydraulic, electromagnetic and piezoelectric shock wave generators. In 2001, Ogden *et al.*[92] in an early review of ESWT technology stated that 'the electrohydraulic method . . . has been shown to be superior to other generation methods (electromagnetic, piezoelectric)'. These authors[92] used literature derived from urology (i.e. from ESWL) to substantiate this claim. However, we found no statistically significant ($P < 0.05$) difference in the distribution of numbers of RCTs on fESWT in PEDro using electrohydraulic, electromagnetic and piezoelectric shock wave generators among studies with positive outcome and studies with negative outcome. Hence, the RCTs on fESWT in PEDro do not indicate an advantage of a certain fESWT technology over other technologies.

An optimum treatment protocol for ESWT appears to be three treatment sessions at 1-week intervals, with 2000 impulses per session and the highest EFD that can be applied

This recommendation is based on the quantitative analysis shown in Figure 4 and reflects the average number of treatment sessions and the average interval between treatment sessions among all RCTs on ESWT in PEDro. With respect to the EFD of the impulses (to be as high as possible, i.e. what can be tolerated by the individual patient without application of local anesthesia), this recommendation is based on findings of one study on rESWT for plantar fasciopathy with positive outcome[34] and another study on fESWT for calcifying tendonitis of the shoulder with positive outcome[112] that 'more is better'. There is not a single RCT on ESWT in PEDro, contradicting this 'more is better' recommendation.

Limitations

There are three main limitations inherent to the present systematic review on ESWT. First, with few

Table 6 Percentage of studies on ESWT listed in the PEDro database that would be considered 'high-energy ESWT' according to different definitions of the margin between low- and high-energy shock wave treatments in the literature

References	Margin [mJ/mm^2]	rESWT+ (%)	rESWT− (%)	fESWT+ (%)	fESWT− (%)
Rompe *et al.*[8]	0.20	0	0	54.7	23.1
Neufeld and Cerrato[135]*	0.12	57.1	66.6	73.4	61.5
Lei *et al.*[136]*	0.10	90.5	100	78.1	76.9

exceptions, only RCTs on ESWT in PEDro were considered. This approach was adopted to minimize selection bias by using the selection process and criteria of an independent third party that has never been involved in planning, performing and funding any study on ESWT, and to rely on the proven reliability of the PEDro scale for rating the quality of RCTs. Accordingly, all analyses, interpretations and conclusions of the present study are only valid for those RCTs on ESWT in PEDro.

Second, no meta-analysis was performed. This was because of the substantial differences among RCTs on ESWT in PEDro with regard to clinical condition, study design, ESWT technology and device, treatment protocol and follow-up period.

Third, because of the first and second limitations, all conclusions of the present study are only valid for those shock wave generators that were used in the RCTs on ESWT in PEDro (Tables 2 and 3). This is particularly important considering the substantial variability in treatment success and rates of unwanted side effects found when treating the same clinical condition (lateral epicondylitis) with different electromagnetic and piezoelectric fESWT devices operated at comparable energy settings.[60,87]

Conclusion

ESWT has been proven as effective and safe non-invasive treatment option for tendon and other pathologies of the musculoskeletal system in a multitude of high-quality RCTs. For plantar fasciopathy, non-calcific tendinopathy of the supraspinatus tendon and calcifying tendonitis of the shoulder RCTs on ESWT are the predominant type of RCT in PEDro and obtained the highest PEDro scores among all investigated treatment modalities for these conditions. The latter criterion was also achieved for Achilles tendinopathy and lateral epicondylitis, albeit in a smaller number of RCTs. Therefore, ESWT should be considered by medical doctors, therapists, patients and payers when discussing treatment options for certain musculoskeletal pathologies. Future RCTs on ESWT should primarily address systematic tests of the optimum treatment protocol identified in this systematic review (three treatment sessions at 1-week intervals, with 2000 impulses per session and the highest EFD that can be applied) and direct comparisons between radial and focused ESWT.

Conflict of interest statement

N.B.M.C., S.M., M.S., J.-D.R. and J.P.F. declare that no competing financial interests exist. C.S. serves as a paid consultant for and receives benefits from Electro Medical Systems (Nyon, Switzerland), the manufacturer and distributor of the Swiss DolorClast radial shock wave device. However, C.S. has not received any honoraria or consultancy fee in writing this manuscript. No other potential conflicts of interest relevant to this article were reported.

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