

A systematic review of shockwave therapies in soft tissue conditions: focusing on the evidence

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ABSTRACT

Background ‘Shock wave’ therapies are now extensively used in the treatment of musculoskeletal injuries. This systematic review summarises the evidence base for the use of these modalities.

Methods A thorough search of the literature was performed to identify studies of adequate quality to assess the evidence base for shockwave therapies on pain in specific soft tissue injuries. Both focused extracorporeal shockwave therapy (F-ESWT) and radial pulse therapy (RPT) were examined.

Results 23 appropriate studies were identified. There is evidence for the benefit of F-ESWT and of RPT in a number of soft tissue musculoskeletal conditions, and evidence that both treatment modalities are safe. There is evidence that F-ESWT is effective in the treatment of plantar fasciitis, calcific tendinitis, and that RPT is effective in plantar fasciitis. Where benefit is seen in F-ESWT, it appears to be dose dependent, with greater success seen with higher dose regimes. There is low level evidence for lack of benefit of low-dose F-ESWT and RPT in non-calcific rotator cuff disease and mixed evidence in lateral epicondylitis.

BACKGROUND

Extracorporeal shockwave therapy (ESWT) has been used in the treatment of soft tissue and bone-related musculoskeletal disorders for over 20 years. In an overview of this treatment modality by this author in 2004, the heterogeneous evidence base and the diversity of treatment types and protocols that were in use were discussed.¹ At that time, there was evidence of benefit of focused ESWT (F-ESWT) in the treatment of calcific rotator cuff tendinopathy and in plantar fasciitis.¹ In the time ensuing, although there has been much research activity and an expansion in publications, interpreting the current literature has become even more challenging. This in part relates not only to the study design and study populations but also to the increasing array of shockwave (SW) systems, treatment protocols and, importantly, basic differences in forms of ‘shock waves’ used. The aims of this update were to summarise and clarify the current evidence base relating to ESWT, current treatment systems and the differences between different forms of therapy.

ESWT: definitions

SWs are three-dimensional pressure pulses of micro-second duration with peak pressures of 35–120 MPa. The more established form of medical ESWT involves focused SWs. These are concentrated into small focal areas of 2–8 mm diameter in order to optimise therapeutic effects and minimise effects on

other tissues.² Many of the physical effects are considered to be dependent on the energy delivered to a focal area. The concentrated SW energy per unit area, the *energy flux density*, (EFD, in mJ/mm^2), is a term used to reflect the flow of SW energy in a perpendicular direction to the direction of propagation and is taken as one of the most important descriptive parameters of SW ‘dosage’.³ There remains no consensus as to the definition of ‘high and ‘low’ energy ESWT, but as a guideline, low-energy ESWT is $\text{EFD} \leq 0.12 \text{ mJ}/\text{mm}^2$, and high energy is $>0.12 \text{ mJ}/\text{mm}^2$.⁴

Focused SW systems differ in their design and in particular whether the SWs are generated by electrohydraulic, electromagnetic or piezoelectric mechanisms (table 1). The waveform characteristics, focal area and tissue penetration of SWs—and hence their effects on tissue—are influenced by this. Regardless of the method of SW generation, SWs are concentrated by means of focusing reflectors to the target site. The proposed mechanisms for the benefit of F-ESWT on musculoskeletal tissue include direct effects on tissue calcification, alteration of cell activity through cavitation, acoustic microstreaming, alteration of cell membrane permeability and effects on nociceptors through hyperstimulation, blocking the gate control mechanism.^{1–5}

Another form of treatment, often described as ‘radial shock wave therapy’, is better termed ‘radial pulse therapy’ (RPT). Some studies of ‘low energy ESWT’ are in fact referring to the use of RPT.^{6–7} Their description as SWs is inappropriate and has caused much confusion in interpreting the literature. Radial ‘shock’ waves are generated by a ballistic source and do not have the characteristics of real medical SWs. They are not focused and it has been demonstrated that they do not have a penetrating effect on tissue, but rather act superficially.⁸ The mechanisms of action of RPT on musculoskeletal tissues are as yet unclear. The increasing

Table 1 Examples of ESWT and radial systems

| Type of system | Manufacturer/system |
|--|--|
| Focused ESWT—electromagnetic | Epos Ultra (Dornier, Germany), Sonocur systems (Siemens, Erlangen, Germany) ² |
| Focused ESWT—electrohydraulic | OssaTron (HealthTronics, USA) Orthospec (Medispec Ltd, USA) |
| Focused ESWT—piezoelectric | Piezoson (Wolf, Germany) |
| Radial pulse therapy (Radial ‘Shock’ wave therapy) | Doloclast (EMS, Switzerland) |

ESWT, extracorporeal shockwave therapy.



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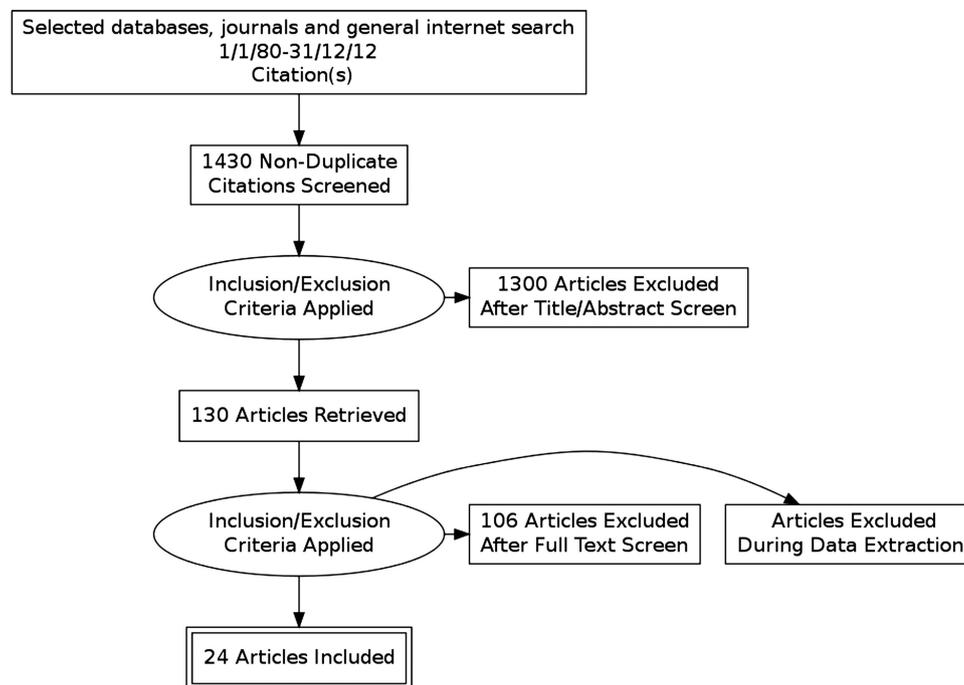


Figure 1 Study selection pathway.

popularity of radial ‘shock’ wave systems is predominantly related to their lower cost.

No direct comparison of F-ESWT with RPT has been performed, although a study design for such a trial in patella tendinopathy has been published.⁹

METHODOLOGY OF THIS REVIEW

A thorough search of the literature was performed, using PubMed, EMBASE, the Cochrane database, and orthopaedic, rheumatology and sports medicine journals, references in review

articles and SW literature and the general internet for all papers published on the subject between the years 1980 and 2012. Search term variables for which data were sought (PICOs): adults, SW, ‘shockwave’, ESWT, radial, focused, Achilles, plantar fasciitis, rotator cuff, supraspinatus, calcific, elbow, common extensor, tendon, pain, function.

The principle outcome measure evaluated was patient’s pain at 12 weeks. Main inclusion criteria were the language publications of studies of SW therapy (radial, focused or unstated) in the treatment of Achilles tendinopathies, rotator cuff (calcific,

Table 2 Studies of F-ESWT and RPT in chronic recalcitrant plantar fasciitis: 12-week follow-up

| Treatment | Ref | Study design | System type | N | Regime | Significant benefit at 12 weeks (or other time frame as stated)? |
|---------------------------------|-----|--------------|-------------|-----|--|---|
| F-ESWT low to high as tolerated | 21 | DB-RCT | EH | 172 | 1 session, 3800 pulses, starting at low dose, increasing to high as tolerated* | Yes. Mean reduction in pain at 3 months 3.39 (TG) vs 1.78 (CG); p<0.001 |
| | 22 | DB-RCT | EM | 178 | 3 once weekly sessions, 2000–2500 shocks from 0.02 mJ/mm ² increasing as tolerated* | No. Mean (SD) change in pain: 26.3(34.8) (TG) vs 25.7 (34.9) |
| F-ESWT low | 23 | DB RCT | EM | 227 | 3 once weekly sessions, 4000 shocks, 0.08 mJ/mm ² | No. ‘Success’ in 34% (TG) vs 30% (CG); 95% CI: –8 to 15% |
| | 13 | DB RCT | EM | 88 | 3 once monthly sessions, 1500 shocks, 0.12 mJ/mm ² | No. Mean (SD) VAS Pain: 73.6 (20.1; 23–100) to 41.4 (27.4; 0–97) in TG vs 70 (20.1; 9–98) to 47.1 (31.5; 0–100). Those achieving 50% improvement from baseline 37% (TG) vs 24% (CG) |
| F-ESWT high | 24 | DB RCT | EH | 293 | 100 shocks @ 0.12, 1400@0.22 mJ/mm ² | Yes. Mean pain: 8.02 baseline to 3.48 12 weeks (TG) vs 8.14 to 4.20 (CG) |
| | 25 | DB-RCT | EM | 150 | 3800 shocks (3500 shocks @ 0.36 mJ/mm ² | Yes. Mean (SD) change in pain VAS TG: 3.4(2.7) vs CG: 4.1 (3.1), p=0.0435 |
| | 26 | DB RCT | EM | 40 | 3 once weekly sessions, 2000 @ 0.25 mJ/mm ² | Yes. % reduction in VAS composite score: 73.2% (TG) vs 40.5% (CG), p=0.0302. MW effect size 0.6737 |
| | 27 | DB-RCT | EM | 114 | 1 session, 3800 shocks @ 0.34 mJ/mm ² (implied) | Yes. Mean (SD) VAS pain: 7.5(1.5) to 3.9 (3.2) vs 7.9 (1.5) to 5.3 (2.7); p<0.0001 |
| RPT | 28 | DB-RCT | RPT | 245 | 3 sessions once every 2 weeks of 2000 pulses @ 0.16 mJ/mm ² | Yes. Reduction in VAS composite score 72.1% vs 44.7%, p=0.0220. MW effect size 0.5753 |
| | 29 | DB-RCT | | 50 | 2 sessions, 1 week apart, of 2000 shocks @ 0.16 mJ/mm ² | Yes, at 24 weeks. Mean (SD) VAS pain 8.5 (0.3) to 1.1 (0.3) (TG) vs 8.9 (0.2) to 7.7 (0.2) |

N=total number of patients DB-RCT.

*High variation in total dose administered between patients.

CG, control group; DB-RCT, double-blind randomised controlled trial; EH, electrohydraulic; EM, electromagnetic; F-ESWT, focused extracorporeal shockwave therapy; RPT, radial pulse therapy; SB, single-blind randomised controlled trial; TG, treatment group.

Table 3 Studies of ESWT and RPT in chronic recalcitrant mid portion Achilles tendinosis

| Treatment | Ref | Study design | System type | N | Regime | Significant benefit at 12 weeks (or other time frame as stated)? |
|-------------|-----|--------------|-------------|----|---|--|
| F-ESWT low | 31 | DB-RCT | EM | 49 | Once monthly, 1500 up to max 0.20 mJ depending on tolerance | No |
| F-ESWT high | 32 | DB-RCT | Not stated | 48 | 2000 shocks @ 0.12–0.51 mJ/mm ² | Yes. Mean (SD) AOFAS scale pain, function, alignment: 70 (6.8) to 88(12) vs 74 (12) to 81 (16) |

RPT: no studies met inclusion criteria.

DB-RCT, double-blind randomised controlled trial; F-ESWT, focused extracorporeal shockwave therapy; RPT, radial pulse therapy.

non-calcific) tendinopathies, tennis elbow and plantar fasciitis. Information extracted from each study included study design, inclusion criteria, number of patients, statistical analysis, treatment regimes, outcome measures, follow-up duration and results. Only those studies without exclusion criteria were included. Exclusion criteria were as follows: uncontrolled studies and those without a control involving a suitable sham treatment, those with methodological errors including no formal randomisation process, different baseline characteristics of study groups, mixed study populations (wide age range, different pathologies, coexisting disease, acute and chronic disease mix), patients no blinding, inappropriate statistical analysis or no details given, unvalidated outcome measures, follow-up <12 weeks, loss of patients to follow-up at 12 weeks, >20%, significant variation in follow-up points between patients and total sample size <40.^{10–18} Levels of evidence were defined according to the US Preventative Tasks Force Classification.¹⁹

High-quality studies (randomized controlled trials (RCTs)) are comparatively rare.¹⁸ As others have reported, heterogeneity of systems, study methodologies, outcome measures, treatment protocols and study populations make pooling of data and meta-analysis inappropriate.^{14–18 20} However, those studies that provide best current levels of evidence for benefit or inefficacy are summarised below, and study quality, treatment regimes and systems used are highlighted. In the absence of double-blind RCTs for specific conditions, other less optimal studies are included to highlight to the reader the current evidence level for use. Summary tables are provided, and help to illustrate the diversity of regimes and systems used and levels of evidence in different conditions.

RESULTS

A flow diagram illustrating the process of identification and screening of the literature is given in figure 1. Of 130 articles retrieved, 104 were excluded. Principle reasons for exclusion were uncontrolled study/lack of appropriate sham control (67); small sample size (3); statistical errors (6); high dropout (5); lack of blinding (4); randomisation errors (2); lack of similarity of groups at baseline (4); and miscellaneous (eg, wrong condition, review articles, not in English language) (13).

Twenty-six studies satisfied the criteria for inclusion in the review: plantar fasciitis (10 studies), insertional (1) and mid portion (3) Achilles tendinopathy, calcific rotator cuff/supraspinatus tendinopathy (4), non-calcific rotator cuff tendinopathy (3), tennis elbow (5).

Plantar fasciitis

There is level 1 evidence for the benefit of focused high energy F-ESWT in the treatment of chronic recalcitrant plantar fasciitis (table 2). One study indicates the benefit from low moving to high-dose F-ESWT. One study also provides level 1 evidence of benefit with RPT. There is also level 1 evidence for the lack of benefit of low-dose F-ESWT in this condition.

Achilles tendinopathies

The evidence base for F-ESWT and RPT in both mid-portion and insertional Achilles tendinopathies is currently very limited. There are no high-quality studies of large populations (tables 3 and 4). Studies of RPT do not satisfy the criteria for this review as they are unblinded and/or uncontrolled.^{6 7 30}

There is evidence of benefit with high-energy F-ESWT in mid portion disease from one small double-blind RCT³¹ and for the lack of benefit of low-dose F-ESWT from one small double-blind RCT.³² Clearly, further research in this condition is warranted.

Calcific tendinopathy of the rotator cuff

There is consistent level 1 evidence of midterm (at least 6 months) effectiveness of F-ESWT—in particular high-dose regimes—in reducing pain and improving shoulder function for patients with chronic calcific tendinopathy (table 5).

The evidence base for RPT in this condition is, by comparison, much less robust. There are no double-blind RCTs. Cacchio *et al*³⁶ performed a single blind study of 90 patients with chronic calcific tendinopathy comparing RPT (2500 shocks at increasing intensity) once weekly for 4 weeks. ‘Control’ patients received ‘less active treatment’—45 shocks of RPT at low intensity, not a true sham. Significant differences between the groups were noted at a follow-up at 6 months. UCLA Shoulder rating scale changed from 10.25±2.08 to 32.12±3.02 (p=0.115) in the treatment groups and 10.14±0.96 to 10.57

Table 4 Studies of ESWT and RPT in chronic recalcitrant insertional Achilles tendinopathy

| Treatment | Ref | Study design | System type | N | Regime | Significant benefit at 12 weeks (or other time frame as stated)? |
|-------------|-----|--------------|-------------|----|--|--|
| F-ESWT high | 30 | RCT | EM | 68 | 1 session 3000 @ 0.21 mJ/mm ² | Yes, benefit at 3 and 12 months. Mean (SD) VAS pain TG: 7.9(2) to 2.9 (2.1) p<0.001 vs CG: 8.6 (1.1) to 7.2 (1.3) p>0.05 |

RPT: no studies met inclusion criteria.

F-ESWT, focused extracorporeal shockwave therapy; RPT, radial pulse therapy.

Table 5 Studies of F-ESWT in the treatment of calcific rotator cuff tendinopathy

| Ref | Design | System type | N | Regime | Significant benefit at 12 weeks (or other time frame as stated)? |
|-----|--------------------------------------|-------------|-----|--|---|
| 33 | Single-blind RCT | EH | 70 | 4 sessions: 1 using 12 shocks, 0.03 to 0.28 mJ, 3 sessions of 1200 shocks at 0.28 mJ (4–7-day interval) | Loss of 2/3 control patients to follow-up at 24 weeks. At 4 weeks: CMS TG: 45–74 at 4 weeks and 76 at 12 weeks; CG 48–46 at 4 weeks |
| 34 | Single-blind RCT | EM | 80 | 2 sessions at 2 week interval 2500 shocks @ up to 0.45 mJ/mm ² | Yes. Benefit at mean follow-up 110 days (note significant range; 41–255 days). CMS: TG: 50.7 (33.7–70.2) to 63.2 (23.8–90), p<0.0001 vs CG: 50.3(28.2–83.8) to 54.8 (19.9–86.8), p=0.061 |
| 35 | Multicentre RCT. High vs low vs sham | Not stated | 144 | Two sessions, interval 12–16 days. 1500 shocks @ 0.32 mJ/mm ² vs 6000 shocks @0.08 mJ/mm ² vs sham | Yes. Benefit in both treatment groups at 6 and 12 months, superior in high-dose. Change in CMS at 6 months in control, low, high-dose groups: 6.6 (1.4–11.8), 15 (10.2–19.8), 31 (26.7–35.3) p<0.001 between control and each treatment group and between high and low energy |

Twelve-week follow-up (unless stated otherwise).

N=total number of patients. DB-RCT: double-blind randomised controlled trial.

EH, electrohydraulic; EM, electromagnetic; F-ESWT, focused extracorporeal shockwave therapy; SB, single-blind randomised controlled trial.

±3.96 (p=0.3302) in the ‘control’ group (p=0.0023). Pain scales changed from 7.96±0.88 to 0.95±0.99 (treatment) and 7.72±1.03 to 6.84±2.44 (less ‘control’). There are other reports of RPT in this condition, but did not meet the criteria for inclusion in this review.³⁷

National Institute of Health and Care Excellence guidance on the treatment of calcific rotator cuff tendinopathy of the shoulder supports the use of F-ESWT in those cases recalcitrant to conservative measures such as NSAIDs, analgesics, corticosteroids, aspiration or lavage.¹⁷

Non-calcific rotator cuff tendinosis

In non-calcific RC-tendinosis, there is no evidence in favour of low-dose or high-dose F-ESWT versus placebo, each other or other treatments. In fact, there is some limited evidence for inefficacy (table 6). There are no studies of RPT.

Lateral epicondylitis (common extensor tendinopathy)

The evidence is conflicting in relation to the effects of low-dose F-ESWT in common extensor tendinopathy (table 7). Three of the five studies that met the criteria for this review indicate lack of benefit; however, two studies demonstrate superiority of the treatment over placebo. Other trials are limited by the lack of proper blinding, lack of study control groups, the methods of randomisation and analysis.⁹ There is a need for high-quality studies of high-energy F-ESWT and RPT in this condition.

DISCUSSION AND CONCLUSION

Although research into the effects of SW therapies has been performed for over two decades, the heterogeneity of systems, treatment protocols and study populations, continue to make it difficult to gain an overall insight into the efficacy of the

modality.^{14–18 20} In 2004, there was some evidence of benefit for F-ESWT in calcific rotator cuff tendinopathy and in plantar fasciitis.¹ A summary of findings with research to date in 2012, and the influence on clinical practice, is given in boxes 1 and 2.

Studies of SW therapies involve unvalidated outcome measures such as ‘composite scores’ representing the combination of a number of outcome measures into one measure.^{26 28} Empirical definitions of ‘success’ have been used by some as defined by achieving a given percentage improvement, rather than utilising basic changes in patient-rated outcomes such as pain, the latter more suitable especially in smaller samples.²³ Sample sizes are often small and power calculations not provided. Perhaps inevitably, some studies are industry sponsored, introducing the chance of bias. Those studies with positive findings on the effects of SW therapy are more likely to be readily available and open access.

Current treatment guidelines in use do not differentiate between forms of therapy, systems and protocols,^{14 –17} but rather treat SW as a universal form of therapy. Clearly, this is not appropriate. As with any treatment, evaluation of SW should clarify the form and the strength and the frequency of treatment being discussed.

There are a number of steps that could be taken to clearly establish the role that specific forms of SW therapy have to play in the management of musculoskeletal conditions. Double-blind RCTs of specific types of SW therapy, with adequate sample size to ensure adequate statistical power, validated outcome measures, reliable sham controls, involving tightly defined study populations, with minimal loss to follow-up are clearly still needed. Effect sizes should be included in results to allow greater insight for the clinician. The emphasis should be on studies comparing SW therapies to placebo at this stage, and an

Table 6 Studies of F-ESWT in recalcitrant non-calcific rotator cuff tendinopathy

| Treatment | Ref | Design | System type | N | Dose regime | Significant benefit at 12 weeks (or other time frame as stated)? |
|--------------------|-----|--------|-------------|----|---|---|
| F-ESWT low energy | 11 | DB-RCT | EM | 74 | 1500 shocks @ 0.12 mJ/mm ² once monthly×3 | No. Mean (SD) SPADI TG: 53.6 (20.2) to 34.7 (26.6) vs CG: 59.5 (16.1) to 39.7 (27.7) |
| | 38 | DB-RCT | EM | 40 | 2000 shocks @0.11 mJ/mm ² once weekly×3 | No. Mean (SD) CMS: 42.2(13.04) to 64.39 (32.68) vs CG: 40.7 (13.29) to 66.5(37.92) |
| F-ESWT high energy | 39 | DB-RT | EM | 40 | 6000 shocks @0.78 mJ/mm ² versus 6000@0.33 mJ/mm ² (ie, both high dose) | No. Mean (SD) CMS: TG: 46.37 (22.47) to 79.77(35.47) vs CG: 49.06 (20.52) to 67.89(32.94) |

DB-RCT, double-blind randomised controlled trial; DB-RT, double-blind randomised trial; EM, electromagnetic; F-ESWT, focused extracorporeal shockwave therapy.

Table 7 F-ESWT in the management of chronic recalcitrant common extensor tendinopathy

| Treatment* | Ref | Study type | System type | N | Regime | Significant benefit at 12 weeks (or other time frame as stated)? |
|------------|-----|------------|-------------|-----|---|---|
| F-ESWT low | 40 | DB-RCT | EM | 271 | 3, once weekly sessions 2000 shocks @ 0.07–0.09 mJ/mm ² | No. Mean (SD) pain 65.9(19.4) to 38.3 vs CG: 60.6(25.5) to 50.4 (29.4) |
| | 12 | DB-RCT | EM | 75 | 1500 shocks @ 0.12 mJ/mm ² once monthly×3 | No. 'Success' TG: 25.8% vs CG: 25.4% |
| | 41 | DB-RCT | EM | 78 | 3, once weekly sessions 2000 shocks 0.09 mJ/mm ² (NB Tennis players only) | Yes. Significantly higher improvement in pain during resisted wrist extension in TG: 3.5 (2.0) vs CG: 2.0 (1.9); p=. 65% >50% reduction of pain in 65% (TG) vs 28% (CG) |
| | 42 | DB-RCT | EM | 114 | 3, once weekly sessions 2000 shocks @ 0.06 mJ/mm ² | Yes. Significant difference in pain reduction at 12 weeks: improvement of pain score by >50% seen in 61% TG vs 29% CG |
| | 43 | DB-RCT | EM | 60 | 3, once weekly sessions, 2000 shocks @ 0.03–0.17 mJ/mm ² (NB No previous treatments) | Success rate >50% improvement 39% TG vs 31% CG |

*High-dose F-ESWT and RPT: no studies met inclusion criteria.

DB-RCT, double-blind randomised controlled trial; F-ESWT, focused extracorporeal shockwave therapy; RPT, radial pulse therapy.

Box 1 'Shock wave' therapies in musculoskeletal conditions: what have we learned?

Focused extracorporeal shockwave therapy (F-ESWT) and radial pulse therapy (RPT) should be considered as different treatment modalities.

There continues to be a lack of large well-designed RCTs in general in F-ESWT and RPT.

Where benefit has been demonstrated further research into the most effective regimes is needed.

There is evidence for use in specific conditions (box 2).

'industry standard' sham therapy should be established. There is the potential for using both forms of therapy in combination. Again, studies are required.

Research to date though has been helpful in defining the potential forms of 'shock waves' that are worth exploring

Box 2 Extracorporeal shockwave therapy (ESWT) and radial pulse therapy (RPT) in current clinical practice

There is good evidence for:

- ▶ Benefit for high-dose focused ESWT (F-ESWT) and for RPT in plantar fasciitis.
 - Lack of benefit for low-dose F-ESWT in plantar fasciitis.
 - F-ESWT in calcific tendinopathy of the rotator cuff, especially in high dose.

There is some evidence for:

- ▶ Benefit for high-dose F-ESWT in mid portion and insertional Achilles tendinopathies.
 - No benefit in low-dose F-ESWT in this condition.
 - Benefit of RPT in calcific tendinopathy.
 - Lack of effect of F-ESWT in non-calcific tendinopathy of the rotator cuff and for low-dose F-ESWT in common extensor tendinopathy.

There is no evidence to support not refute the effects of F-ESWT nor RPT in other conditions.

There is mixed evidence for the effects of low-dose F-ESWT in common extensor tendinopathy.

further, and in demonstrating that the types of regimes used can significantly influence outcome. It has also been demonstrated over the past few decades that SW is a safe treatment with adverse effects typically being minor, and occurring rarely. It is clear from the data presented here that there is evidence for the benefit of F-ESWT and of RPT in a number of soft tissue musculoskeletal conditions, and that both treatment modalities are safe. Where benefit is seen in F-ESWT, it appears to be dose dependent, with greater success seen with higher dose regimes. Both treatments offer an alternative to surgery in the management of recalcitrant conditions. While the focus to date has been on the use of SWs in only chronic cases recalcitrant to other medical interventions, its use in advance of some treatments—for example, steroid injections—should be considered, given the proposed mechanisms of action, at least in F-ESWT, its non-invasive characteristics and excellent safety record.

Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

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