3.3 Shock Wave Therapy

Effectiveness and safety of extracorporeal shock wave therapy for disorders of the tendons: A systematic review of studies listed in the PEDro database

3.3.1 Introduction

Extracorporeal shock wave therapy (ESWT) has been used successfully for over 20 years in the treatment of a wide variety of indications in the musculoskeletal system – in particular in tendinopathies. Initially developed as a by-product of extracorporeal shock wave lithotripsy (ESWL), ESWT soon established itself as a non-invasive, effective method of treatment for tendinopathies and other disorders of the musculoskeletal system. Initial studies into the treatment of tendinopathies showed a therapeutic outcome for ESWT at least equal to or better than that for other treatment forms (e.g. eccentric exercises, traditional physiotherapy, steroid injections and surgical interventions).

The term extracorporeal shock waves in medicine today is a general grouping for solitary acoustic waves for therapeutic application. In order to gain a better understanding of what this means, one could imagine a pressure wave caused by a supersonic aircraft. If it were possible to utilise this pressure wave for therapeutic purposes, it would fall under the term extracorporeal shock waves. In contrast to therapeutic ultrasound, in which a million or more acoustic waves are applied per second, extracorporeal shock waves are concerned with a single event. It also follows however that the energy transmitted per solitary wave in extracorporeal shock waves is many times higher than that transmitted in therapeutic ultrasound. The matter is complicated by the fact that the term "shock wave" does not mean precisely the same thing in medicine as the definition of shock waves in physics. In order to understand this, we come back to our example of the supersonic aircraft. The movement of the aeroplane through the air causes a pressure wave which moves away from the aircraft in all directions. If the aircraft flies at subsonic speeds, the pressure waves are also able to move away from the aircraft in the direction of flight because they propagate more quickly than the speed of the aircraft. If the aircraft flies at exactly the speed of sound then this is no longer possible. A shock wave is now generated instead. In physics this is referred to as non-linear acoustics.

Note: This text is based on the following extensive study in English: Schmitz et al.: Efficacy and safety of extracorporeal shock wave therapy for orthopaedic conditions [33].
The physical characteristics of the first extracorporeal shock waves used in medicine (in order to break down kidney stones) were similar to the shock waves of a supersonic aircraft. In their medical application, these physical characteristics were achieved by focusing solitary acoustic waves. The result is that the terms "focused shock waves" and "genuine shock waves in the physical sense" are often still used synonymously in medicine today. This also applies to electrohydraulic (EH) shock wave devices. For electromagnetic (EM) and piezoelectric (PE) shock-wave devices, however, this is not necessarily the case with low energy levels [34, 35]. In this case, the shock waves are indeed focused, but are not genuine shock waves in the physical sense. It may be assumed that the majority of focused shock waves applied to tendons today are not genuine shock waves in the physical sense.

In the case of radial extracorporeal shock waves, no focusing takes place. Here, the solitary acoustic waves propagate away from an applicator (usually metal), whereby the waves are generated by the percussion of a projectile on the applicator. The term "radial" however is not scientifically correct. In fact, pressure measurements taken at various distances from the applicator show that the wave does not propagate away from the applicator in a spherical pattern [36].

Again and again in medicine we come across attempts to differentiate between radial shock waves and focused shock waves by describing radial shock waves as "pressure pulses" or "pressure waves". However, as explained above, this is scientifically incorrect. Instead, the following classification should apply [35]:

– focused shock waves, which are genuine shock waves in the physical sense,
– focused shock waves, which are not genuine shock waves in the physical sense, and
– radial shock waves, which are not genuine shock waves in the physical sense.

The fact that all these forms of shock waves are currently in use in the treatment of tendinopathies makes it clear that the question of whether the waves are genuine shock waves in the physical sense or not must not be the focus of our thinking when it comes to evaluating the suitability of a particular shock-wave device for the treatment of tendinopathies.

The question of whether shock waves in tendinopathies are making use of molecular or cellular mechanisms is of only very limited help. For many of the shock-wave devices on the market today, there is very little relevant data available or none at all. In addition, this field is undergoing a very rapid transformation in basic research. In general it can be said that shock waves can be effective through several different mechanisms in the case of disorders of the tendons [37 – 41]:

– pain relief through the reduction of substance P in C-nerve fibres.
– interrupting neurogenic inflammation,
– activating the proliferation of fibroblasts,
– supporting inflammatory mechanisms and catabolic processes implicated in the removal of damaged extracellular matrix components, and
– (in the case of insertion tendinopathies) the building of new bone substance in the area of the tendon insertion.
One of the main reasons for the nevertheless decidedly limited therapeutic use of ESWT may be a general lack of knowledge of how to use this technique. Although earlier reviews supported the widely accepted finding that ESWT is safe, easy-to-use and helpful for particular indications, many of these reviews are now outdated and at the same time contributed to the still widespread uncertainty with regard to terminology, therapy protocols, the energy flux density to be used and other treatment parameters. This uncertainty may make it difficult for the user to establish a best practice protocol. For these reasons there is now an urgent need for a precise summary of the available evidence for the use of ESWT in tendinopathies in everyday practice on the one hand and the development of generally applicable treatment guidelines on the other.

The PEDro database (www.pedro.org.au, hereinafter abbreviated to “PEDro”) is a totally independent, publicly accessible and now the largest online database on the subject of physical and rehabilitation medicine (PRM). PEDro currently makes available the precise citation, abstract and a link to the original publication for over 31,000 randomised, controlled clinical trials (RCTs), systematic reviews and clinical guidelines. In addition, all RCTs in PEDro are subjected to an independent quality check based on a total of 11 evaluation criteria, the majority of which are on what is known as the Delphi list. A quality score is calculated on the basis of these evaluation criteria, with 0 being the worst and 10 being the best score. In many countries PEDro is today considered the first point of reference for literature on PRM, but in German-speaking countries has so far been little utilised.

This systematic review is based on data taken from PEDro and complies with the PRISMA guidelines (Preferred Reporting Items for Systematic Reviews and Meta-Analyses). In particular we have (i) compared ESWT with other, non-operative treatment methods for tendinopathies and other disorders of the musculoskeletal system as well as (ii) radial ESWT (rESWT) with focused ESWT (fESWT) and (iii) so-called high-energy ESWT with so-called low-energy ESWT.
3.3.2 Types of RCT

The following four types of RCT concerning the treatment of tendinopathies with ESWT were extracted from PEDro: (1) rESWT with positive result (i.e. rESWT showing statistically significant advantage when compared with placebo and/or other treatment methods) (rESWT+; n = 23); (2) rESWT with negative result (i.e. rESWT showing no statistically significant advantage when compared with placebo and/or other treatment methods) (rESWT –; n = 3), (3) fESWT with positive result (fESWT+; n = 66); and (4) fESWT with negative result (fESWT–; n = 15). It was noticeable here that in only a few of these RCTs was it clearly specified whether the energy flux densities (EFD) described were the positive part (EFD+) or the total EFD (EFD total).

3.3.3 Key statements concerning ESWT

A detailed analysis of these in total 107 RCTs in PEDro concerning ESWT in tendinopathies (see table 3.2) led to the following 10 key statements:

(1) ESWT is effective
The effectiveness of ESWT is clearly supported by the cumulative data. 88.5% (23 out of 26) of all RCTs in PEDro concerning rESWT in tendinopathies and 81.5% (66 out of 81) of all RCTs in PEDro concerning fESWT in tendinopathies achieved a positive result when compared with placebo and/or other treatment methods.

(2) ESWT is safe
The safety of ESWT is similarly clearly proven by the cumulative data in PEDro. There were no reports of any serious undesired side effects in any of the RCTs investigated.

(3) For particular indications (all tendinopathies) studies into ESWT are the dominant RCTs in PEDro and/or achieved the highest PEDro quality score amongst all treatment methods investigated
Both criteria (dominant type of RCT in PEDro and highest PEDro quality score amongst all treatment forms investigated) are met in the case of plantar fasciopathy, non-calcific tendinopathy of the supraspinatus tendon and calcific shoulder tendinitis. For tendinopathies of the Achilles tendon (insertion and mid portion tendinopathies) and lateral epicondylitis (tennis elbow) 11.4% and 15.1% of all RCTs in PEDro were carried out with ESWT. These also achieved the highest PEDro quality scores amongst all investigated treatment methods used for these indications. For other indications (greater trochanteric pain syndrome, patellar tendinitis, knee joint arthrosis, fractures of the long bones, femoral head necrosis, tenosynovitis of the long biceps tendon, myofascial pain syndrome, myogelosis of
the masseter muscle and spasticity) there are insufficient RCTs concerning ESWT in PEDro to draw conclusions about the relevance of ESWT in these disorders.

(4) In the statistical centre there is no difference in scientific quality between RCTs in PEDro concerning ESWT with positive or negative result. RCTs concerning ESWT, producing both positive and negative result, almost all achieved the same average PEDro quality scores. This finding clearly contradicts the assumption which sometimes arises that "better" RCTs (i.e. RCTs with a higher PEDro quality score) generally show that ESWT is not effective in the case of tendinopathies.

(5) Local anaesthetic has a negative impact on the results of ESWT. Two clinical studies (neither of which are however listed in PEDro) have shown that the use of local anaesthesia has a negative influence on the results of ESWT [42, 43]. The molecular mechanisms underlying this phenomenon are not yet fully understood. The available evidence, however, points overwhelmingly to a significant role being played by the peripheral nervous system in the transmission of the molecular and cellular effects of ESWT on the musculoskeletal system. These effects can be suppressed by local anaesthesia (in very brief summary, C-fibres which transmit pain cannot be activated by ESWT and deactivated by local anaesthesia at the same time). ESWT without local anaesthesia is therefore generally recommended.

(6) Using an insufficient energy flux density has a negative effect on the results of ESWT. The average energy flux density (EFD) that was applied in all RCTs in PEDro concerning ESWT in cases of calcific shoulder tendinitis (with both rESWT and fESWT) and which achieved positive results was 0.28 ((± 0.04) mJ/mm². This is equal to almost 2.6 times the energy flux density that was applied in an RCT in PEDro for rESWT in a case of calcific shoulder tendinitis with negative result (EFD = 0.11 mJ/mm²) [44]. A similar situation was found in the treatment of plantar fasciopathy. Here, the average EST in all positive RCTs in PEDro for ESWT was 0.19 (± 0.02) mJ/mm², which is more than double the EFD applied into RCTs for fESWT in cases of plantar fasciopathy with negative result [45, 46]. With regard to tendinopathies of the Achilles tendon, the average EFD of all positive RCTs in PEDro for ESWT was 0.17 (± 0.04) mJ/mm², compared with an EFD of only 0.06 mJ/mm², which was used in an RCT concerning fESWT used in this disorder with a negative result [47].
(7) There is no scientific evidence in favour of rESWT or fESWT with regard to treatment results in cases of tendinopathy

"Which is better, rESWT or fESWT?" We are asked this question almost daily. Our systematic study of RCTs in PEDro has clearly shown that in cases of tendinopathy there is no scientific evidence in favour of one or the other form of ESWT with regard to treatment results. In one of the few studies carried out directly comparing these two techniques, better results were reported using fESWT over rESWT in the treatment of patients with plantar fasciopathy [48]. However, a higher EFD was used in the fESWT than in the rESWT. Other authors who used precisely the same EFD in fESWT and rESWT in the treatment of patellar tendinitis (and the same ESWT device as in the first study on plantar fasciopathy mentioned), found no difference in effectiveness between the two techniques [49].

(8) The widespread differentiation between rESWT as "low-energy ESWT" and fESWT as "high-energy ESWT" is arbitrary and should be abandoned

In 2007 a group of authors defined an EFD of 0.2 mJ/mm² as the cut-off point between low-energy ESWT and high-energy ESWT [50]. According to this definition, 100% of the RCTs in PEDro concerning rESWT, 45% of the RCTs in PEDro concerning fESWT with positive result and approx. 77% of the RCTs in PEDro concerning fESWT with negative result were carried out using low energy ESWT. Consequently it is incorrect to describe rESWT as low-energy ESWT and fESWT as high-energy ESWT. Other recent arbitrarily suggested cut-off points between low-energy ESWT and high-energy ESWT [51, 52] are similarly unable to contribute to a differentiation between RCTs in PEDro concerning rESWT and fESWT. Accordingly, these kinds of differentiations should no longer be used.

(9) There is no scientific evidence for the superiority of a particular fESWT technology over other fESWT technologies

Focused shock waves can be generated using electrohydraulic (EH), electromagnetic (EM) and piezo electric (PE) shock wave generators. A review concerning ESWT published in 2001 came to the conclusion that the electrohydraulic method is better than the other methods [53]. To support this statement, the authors of that review referred to literature concerning ESWL in which considerably higher EFDs were used at that time than are now commonly used in ESWT. In our own investigation, we found no statistically significant difference in the distribution of the number of fESWT+ and fESWT− RCTs in PEDro, which were carried out with either EH, EM or PE shock-wave generators. Accordingly, RCTs concerning fESWT in PEDro shown no advantage of one particular fESWT technology over the other technologies.

(10) An optimum treatment protocol in cases of tendinopathy appears to be three treatments at one week intervals with 2000 impulses per session and the highest possible energy flux density
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This recommendation is based on our quantitative analysis and reflects both the average number of treatments and the average period between treatments in all RCTs concerning ESWT in PEDro. With regard to the EFD of the impulses (as high as possible, i.e. whatever the individual patient will tolerate without the administration of local anaesthesia) the recommendation "more is better" is based amongst other things on the positive results of an RCT in PEDro concerning rESWT in the case of plantar fasciopathy [50] and an RCT in PEDro concerning fESWT in the case of calcific shoulder tendinitis [55]. There is not one RCT concerning ESWT in PEDro which contradicts this recommendation ("more is better").

3.3.4 Conclusion

Extracorporeal shock wave therapy has been shown in a number of high-quality RCTs to be an effective, safe and non-invasive treatment method in cases of tendinopathy and other disorders of the musculoskeletal system. For the indications plantar fasciopathy, tendinopathy of the supraspinatus tendon and calcific shoulder tendinitis, RCTs concerning ESWT are now the predominant RCTs in PEDro and received the highest PEDro quality scores of all treatment methods investigated. The latter criterion was also achieved for tendinopathies of the Achilles tendon (insertion and mid-portion tendinopathy) and lateral epicondyritis, if in a lower number of RCTs. As a whole, ESWT should be considered by doctors, therapists and patients in the treatment of tendinopathies and other disorders of the musculoskeletal system. Future RCTs concerning ESWT should above all include systematic tests with regard to the optimum treatment protocol as identified in this systematic study (three treatments at one week intervals with 2000 impulses per session and the highest possible EFD), as well as direct comparisons between rESWT and fESWT.