

● *Review*

CLINICAL APPLICATION OF EXTRACORPOREAL SHOCK WAVE THERAPY IN ORTHOPEDICS: FOCUSED VERSUS UNFOCUSED SHOCK WAVES

CASPER BINDZUS FOLDAGER,^{*†§} CATHAL KEARNEY,[‡] and MYRON SPECTOR^{*§}

^{*}Department of Orthopedics, Brigham & Women's Hospital, Harvard Medical School, Boston, MA; [†]Orthopaedic Research Laboratory, Aarhus University Hospital, Aarhus, Denmark; [‡]Harvard School of Engineering and Applied Sciences, Cambridge, MA; and [§]Tissue Engineering Labs, VA Medical Center, Boston, MA

(Received 12 July 2011; revised 2 June 2012; in final form 10 June 2012)

Abstract—For the past decade extracorporeal shock wave therapy has been applied to a wide range of musculoskeletal disorders. The many promising results and the introduction of shock wave generators that are less expensive and easier to handle has added to the growing interest. Based on their nature of propagation, shock waves can be divided into two types: focused and unfocused. Although several physical differences between these different types of shock waves have been described, very little is known about the clinical outcome using these different modalities. The aim of the present review is to investigate differences in outcome in select orthopaedic applications using focused and unfocused shock waves. (E-mail: foldager@ki.au.dk) © 2012 World Federation for Ultrasound in Medicine & Biology.

Key Words: Focused shock waves, Unfocused shock waves, Plantar fasciitis, Achilles tendinopathy.

INTRODUCTION

Extracorporeal shock waves (ESWs) were initially introduced to the clinic in the 1980s for lithotripsy to break up kidney stones (Chaussy et al. 1984). After establishing the beneficial effects of ESWs on plantar fasciitis, numerous groups and clinicians have investigated the use of ESW for treatment of many musculoskeletal disorders (Ogden et al. 2001a). Within the field of orthopedics, ESWs devices have been approved by the U.S. Food and Drug Administration (FDA) for treatment of plantar fasciitis (Dorotka et al. 2006; Kudo et al. 2006; Malay et al. 2006; Gollwitzer et al. 2007; Liang et al. 2007; Gerdesmeyer et al. 2008; Hofling et al. 2008; Marks et al. 2008; Chuckpaiwong et al. 2009; Greve et al. 2009; Dogramaci et al. 2010; Ibrahim et al. 2010; Lohrer et al. 2010; Metzner et al. 2010; Othman and Ragab 2010) and lateral epicondylitis (Rompe and Maffulli 2007). Off-label use of ESW therapy has been described for a wide range of indications including Achilles tendinopathy (Furia 2006; Rompe et al. 2007b; Fridman et al. 2008; Furia 2008; Rasmussen et al. 2008; Rompe et al. 2008; Rompe et al. 2009a; Saxena et al. 2011), pseudarth-

rosis and fracture nonunion (Cacchio et al. 2009; Wang et al. 2009b; Xu et al. 2009; Elster et al. 2010; Stojadinovic et al. 2011), femoral head necrosis (Wang et al. 2008a, 2008b; Wong et al. 2008; Chen et al. 2009; Wang et al. 2009a; Hsu et al. 2010; Wang et al. 2011a), tibial stress syndrome (Rompe et al. 2010a), greater trochanter pain syndrome (Rompe et al. 2009b), delayed bone-tendon healing (Wang et al. 2008c), subacromial pain (Engebretsen et al. 2009), calcific tendinitis of the shoulder (Hearnden et al. 2009), rotator cuff tendinopathy (Schofer et al. 2009), patellar tendinopathy (van Leeuwen et al. 2009) and osteoporosis (van der Jagt et al. 2009).

The purpose of the present review is to provide a clinical update of the outcomes of the clinical use of shock wave treatment of the most frequently reported musculoskeletal disorders, distinguishing results of focused *versus* unfocused ESWs. Over the years, the features of the shock waves generated by a wide array of devices have been defined, and the biological effects *in vitro* and in different tissues in animal models have been described. What has been less quantified in a systematic fashion is the outcome of the application of ESWs for the treatment of specific clinical problems.

EXTRACORPOREAL SHOCK WAVES

The typical waveform of a shock wave therapy device has a compressive phase followed by a tensile

Address correspondence to: Casper Bindzus Foldager, Tissue Engineering Labs, VA Medical Center, 150 South Huntington Avenue, Building 1A, Boston, MA 02130. E-mail: foldager@ki.au.dk

phase. Detailed descriptions can be found elsewhere of the physical properties of shock waves (Ogden et al. 2001b; Cleveland and McAteer 2006; Cleveland et al. 2007) and the waveforms generated by specific devices (Cleveland et al. 2007). Issues related to the specific features of a waveform that qualify it as a shock wave (*viz.*, rise time) have been discussed previously, and are outside the scope of this review, which deals with apparatus marketed as shock wave devices.

At the interface of two tissues with different acoustic impedances, part of the shock wave will be reflected at the boundary and part will be transmitted, and biological effects are often found to occur at these interfaces (Ogden et al. 2001b; Kearney et al. 2011). The outcome has been found to be dependent on several variables: the energy flux density (EFD) in mJ/mm^2 , which is the amount of acoustic energy per unit area per pulse (the pulse intensity integral) (Cleveland and McAteer 2006); the number of shocks; and the rate in Hz (shocks per second). A prior *in vitro* study demonstrated the value of computing the total energy dose (TED) delivered per treatment by multiplying the energy flux density by the total number of shocks (Tam 2005). This metric has been adopted for this review as a convenient comparator of the ESW dose used in the various clinical studies.

Based on their propagation pattern, shock waves can be divided into two categories: focused and unfocused. Unfocused shock waves are often referred to in the literature as *radial shock waves*. For clinical applications, focused shock waves were traditionally produced by electrohydraulic generation of pressure waves but are now also produced by electromagnetic and piezoelectric modalities. Unfocused shock waves are produced pneumatically: Analogous to a jackhammer, a projectile is accelerated onto a solid applicator that is in contact with the skin. In contrast to the focused shock wave applicator, which contains a curved reflecting surface in a fluid-filled balloon (*viz.* inside the head of the focused device), the cylindrical piston of the unfocused shock wave head may be only millimeters in diameter.

METHODS

The inclusion criterion for this review was clinical studies published in English from 2006–2011 using ESWs for treatment of musculoskeletal disorders. We excluded reviews and case reports in the present review. A MEDLINE search was performed on March 17, 2011 using the keywords shock+wave or shockwave combined with: tendinopathy, plantar+fasciitis, plantar+fasciopathy, pseudoarthrosis, non-union and non-union and femoral+head. To identify articles using unfocused shock waves, we performed an additional search for shock+wave or shockwave in combination

with radial; non-focused, nonfocused, unfocused and un-focused; and pneumatic. Indications with five or more studies are shown in Table 1 and are included in the comparison. Eight studies investigating the effect of focused ESWs were identified for both femoral head necrosis and pseudoarthrosis/nonunion fracture. No studies using unfocused ESW were found for these disorders. Other indications identified were patellar tendinopathy, rotator cuff tendinopathy, calcifying tendinitis of the shoulder, subacromial pain, greater trochanter pain syndrome, tibial stress, osteoporosis and treatment of hamstrings. From our search results we included the two disorders using both focused and unfocused shock waves. The studies were ranked by level of evidence I, II, III, IV, or V (Wright et al. 2003).

RESULTS

The ESW values for the various studies are based on the information provided in the papers by the authors of the respective studies. The TEDs for each type of ESW treatment for the two clinical indications are shown in Figure 1.

Achilles tendinopathy

The studies treating Achilles tendinopathy used shock waves with an EFD within the range of 0.1–0.21 mJ/mm^2 . Two studies did not mention EFD in mJ/mm^2 . Focused and unfocused ESWs were used for treatment of both insertional and noninsertional Achilles tendinopathy (Table 2).

Focused ESWs. Furia et al. (2006, 2008) showed a positive effect of focused ESWs for both insertional and noninsertional Achilles tendinopathy in reducing pain, compared with no treatment in two case-control studies with up to one year of follow-up. In these studies focused ESWs were administered in single-session treatments of 3000 shocks with an EFD of 0.21 mJ/mm^2 (TED of 630 mJ/mm^2). A significant reduction in pain after four months was also shown in a cohort study of 23 patients. The shock waves were given in a single session of 2000 shocks with 21 kV (Fridman et al. 2008).

Unfocused ESWs. Rompe et al. published three randomized, controlled trials for treatment of Achilles tendinopathy using three weekly sessions of treatments,

Table 1. Orthopaedic indications for both focused and radial ESW therapy with a total number of five or more articles identified from 2006–2011

Indication	Focused	Unfocused
Plantar fasciitis	9 (+1)	6 (+1)
Achilles tendinopathy	3	5

One paper on plantar fasciitis used both focused and unfocused ESW.

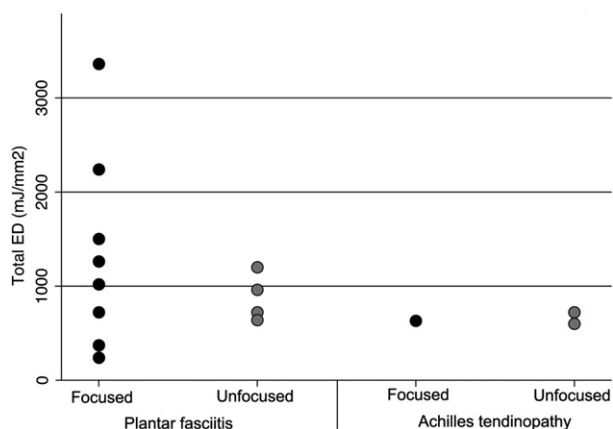


Fig. 1. Scatter plot showing the TED for the selected applications in Table 1 using either focused or unfocused shock wave therapy. One study using unfocused ESWs for Achilles tendinopathy applied a TED within a range of 480–2040 mJ/mm², which is not depicted in the figure.

each of 2000 shocks and an EFD of 0.1–0.12 mJ/mm² (TED 600 to 720 mJ/mm²) (Rompe *et al.* 2007b, 2008, 2009a). Unfocused ESW treatment was compared with eccentric loading exercises in all studies, and one study also compared ESW to “wait-and-see.” The outcome was evaluated four months after treatment (Rompe *et al.* 2007b). There was a significant improvement of symptoms for both insertional and noninsertional Achilles tendinopathy in the ESW group. There was no difference in the outcome comparing eccentric loading exercises and ESWs for insertional Achilles tendinitis, but the exercises were inferior to unfocused ESWs for noninsertional Achilles tendinitis. The combination of unfocused ESWs and eccentric loading tended to provide faster symptom relief compared with treatment alone, but no difference in outcome was found after one year (Rompe *et al.* 2009a).

Rasmussen *et al.* (2008) enrolled 48 patients in a placebo-controlled, double-blinded trial. The patients

Table 2. Articles from 2006–2011 on Achilles tendinopathy

Author	Year	ESW type	n*	TED	Level of evidence
Furia <i>et al.</i>	2006	Focused	35	630	III
Furia <i>et al.</i>	2008	Focused	34	630	III
Fridman <i>et al.</i>	2008	Focused	23	n/a	IV
Rompe <i>et al.</i>	2007	Unfocused	25	600	I
Rompe <i>et al.</i>	2008	Unfocused	50	720	I
Rasmussen <i>et al.</i>	2008	Unfocused	48	480–2040	II
Rompe <i>et al.</i>	2009	Unfocused	34	600	I
Saxena <i>et al.</i>	2011	Unfocused	74	n/a	II

TED measured in mJ/mm². Studies for which EFD is not given in the manuscript in mJ/mm², or where a TED cannot be calculated are listed as n/a.

* In ESW group at inclusion.

Table 3. Articles from 2006–2011 on plantar fasciitis

Author	Year	ESW type	n*	TED	Level of evidence
Dorotka <i>et al.</i>	2006	Focused	41	240	I
Malay <i>et al.</i>	2006	Focused	115	n/a	I
Kudo <i>et al.</i>	2006	Focused	58	2240	II
Gollwitzer <i>et al.</i>	2007	Focused	20	1500	I
Liang <i>et al.</i>	2007	Focused	53	720, 3360	I
Höfling <i>et al.</i>	2008	Focused	20	n/a	II
Chuckpaiwong <i>et al.</i>	2009	Focused	225	1260	II
Metzner <i>et al.</i>	2010	Focused	63	361	IV
Yucel <i>et al.</i>	2010	Focused	33	n/a	II
Gerdesmayer <i>et al.</i>	2008	Unfocused	129	960	I
Marks <i>et al.</i>	2008	Unfocused	16	720	II
Greve <i>et al.</i>	2009	Unfocused	16	n/a	I
Dogramaci <i>et al.</i>	2010	Unfocused	25	n/a	I
Ibrahim <i>et al.</i>	2010	Unfocused	25	n/a	I
Rompe <i>et al.</i>	2010	Focused	48	960	I
Lohrer <i>et al.</i>	2010	Focused and unfocused	19, 20	1020, 1200	I

Studies in EFD cannot be identified (in mJ/mm²) in the manuscript and TED that could not be calculated are denoted with “n/a.”

* In ESW group at inclusion.

were divided into two groups of 24 patients; one group received 2000 shocks with a large variation in EFD 0.12–0.51 mJ/mm² (TED 480 to 2040 mJ/mm²) and the other group received a sham dose of 2000 shocks with 0 mJ/mm². The authors found a significant positive effect of ESW using the American Orthopaedic Foot and Ankle Society score (AOFAS) at 12 weeks, but they found no difference in pain reduction between the intervention and sham-treated groups. In a prospective cohort study with 60 patients (74 tendons), Saxena *et al.* (2011) found a significant improvement in the Roles & Maudsley score after a minimum of one year of follow-up using three treatment sessions one week apart with 2500 shocks at 2.4 Bar.

Comparison of focused and unfocused ESWs. Unfocused and focused ESWs were shown to have a significant benefit of treating insertional and non-insertional Achilles tendinopathy. The total TED in the above studies was within a narrow range (600 to 720 mJ/mm²), except in the study by Rasmussen *et al.* (2008), in which the variation in EFD was high among the study subjects.

Plantar fasciitis

Nine studies used focused ESWs, six studies used unfocused ESWs and one study compared the two types of shock wave treatment. In one study, the type of ESW could not be determined (Othman and Ragab 2010). In six studies we were not able to calculate the TED based the information in the papers (Table 3).

Focused ESW. Three randomized, placebo-controlled, double-blinded trials investigating the effect

of focused ESW for plantar fasciitis have been published since 2006. Malay et al. (2006) published the largest of the studies with a 2:1 randomization with 115 in the ESW group and 57 in the placebo group. The patients were treated in a single session with 3800 shocks. Unfortunately, the EFD was not reported. They found a significant effect of ESWs in terms of a blinded assessor's and the patient's subjective assessment of heel pain at two- and three-month follow-up. In addition, Kudo et al. (2006) found a significant reduction in heel pain after six weeks and three months in a double-blinded, multicenter, randomized, controlled trial using focused ESW. They administered approximately 3500 shocks with an EFD of 0.64 mJ/mm^2 to 58 patients (total energy 2240 mJ/mm^2). Gollwitzer et al. (2007) performed the smallest of the three trials in a study investigating the effect of three treatments with one week between the treatments using focused ESWs on 20 patients. The ESW treatment was given in sessions of 2000 shocks with 0.25 mJ/mm^2 (total energy 1500 mJ/mm^2), thus lower than in the study by Kudo et al. (2006). Gollwitzer et al. found a greater decrease in heel pain in the ESW group compared with untreated controls after 12 weeks, but the effect was just outside statistical significance.

In studies with no untreated controls, Dorotka et al. (2006) applied 1000 pulses with the lowest EFD in this review— 0.08 mJ/mm^2 —at three separate sessions one week apart, and they observed only minor improvements after 6 and 12 weeks. Metzner et al. (2010) used between 1000 and 3500 focused shock waves with 0.35 mJ/mm^2 on 63 patients (73 heels) in one session (15 patients received 2 sessions and 2 patients received 3 sessions). They found a significant positive effect in pain relief using the visual analog scale (VAS) at six weeks and at 18- and 72-month follow-ups, with $>50\%$ improvement in the VAS in 90% of the patients at the last follow-up. Höfling et al. (2008) similarly reported an effect of focused ESW on heel pain but did not report the EFD dose.

Comparing the above studies raises the natural question of a dose-response effect of high versus low EFD. Liang et al. compared focused low-energy shock waves (EFD 0.12 mJ/mm^2) to high-energy shock waves (EFD 0.56 mJ/mm^2) for plantar fasciitis in 53 patients. ESWs were administered in three weekly sessions of 2000 shocks each. Both EFDs resulted in a significant decrease in pain (recorded by the VAS) and improvement in outcome by the SF-36 survey at both three and six months post treatment. Even though the higher-energy group had less heel pain at follow-up, there was no difference in success rate between the two dosages, on the basis of the SF-36 survey score (Liang et al. 2007).

Chuckpaiwong et al. identified the following as predictors influencing the outcome of focused ESW for

plantar fasciitis in a large retrospective study: age, hours spent walking per day, diabetes mellitus and the presence of a documented psychological disorder. Treatment consisted of a single treatment session composed of 3800 shocks (300 shocks of increasing intensity and 3500 shocks at 0.36 mJ/mm^2). At the three-month follow-up, treatment was successful in 70% of the patients (Chuckpaiwong et al. 2009). The above studies all indicate an effect of focused ESWs in treating plantar fasciitis and, importantly, in a study by Yucel et al. (2010), the effect was found to be comparable with intralesional corticoid injections.

Unfocused ESW. The range of doses of TED reported in the studies using unfocused ESW is narrower than that of the studies using focused ESW: 720–960 versus 361–3360 mJ/mm^2 .

Gerdesmeyer et al. (2008) performed the largest study in this category, treating 115 patients in three sessions of 2000 shocks each with an EFD of 0.16 mJ/mm^2 (TED 960 mJ/mm^2). In this randomized, placebo-controlled, double-blinded, multicenter study they found a significant reduction in pain at 12-weeks follow-up compared with untreated controls. Using the same treatment regime, Rompe et al. (2010b) compared unfocused ESW with plantar-specific stretching and found that both treatments showed improved outcome at two-month follow-up. The largest improvement was seen in the stretching group, but two thirds of the patients needed to revert to their exercises to maintain their outcome (Prisk 2010).

In two smaller randomized, double-blinded, placebo-controlled trials with 25 patients in the treatment group, the authors also found positive effects in terms of reduction in heel pain after six months in one study (Dogramaci et al. 2010) and an additional improvement in the Roles & Maudsly score at 12- and 24-week follow-up in another study (Ibrahim et al. 2010).

The only study that did not detect an efficacy of unfocused ESWs for plantar fasciitis was by Marks et al. (2008), who published a small randomized, double-blinded, placebo-controlled trial using unfocused shock waves in 16 patients, 9 of whom were in the control group. The treatment was applied in three sessions starting with 500 shocks in the first session and 2000 in the following two sessions, three days apart (EFD 0.16 mJ/mm^2 ; total TED 720 mJ/mm^2). The authors found no significant difference between the treated and control groups. In addition, Greve et al. (2009) found that, although effective, unfocused ESW did not perform better than physiotherapy in a small study with 16 and 10 patients in the two groups, respectively.

Comparison of focused and unfocused ESWs. Lohrer et al. (2010) compared unfocused and focused ESWs in

a pilot randomized, controlled trial of 39 patients. Shock waves were applied at three sessions with weekly intervals. The EFDs were comparable—0.20 mJ/mm² for focused and 0.17 mJ/mm² for unfocused shock waves (total energies of 1200 and 1020 mJ/mm²). In this comparison, the TED for unfocused ESWs was higher than any of the studies investigating only unfocused ESW. A rate of 10 Hz was used for both treatments. There were significant improvements in both groups after the treatment. Based on age-adjusted multivariate analysis, the authors showed a “small” superiority of focused shock waves by the Mann-Whitey estimator.

In the aforementioned studies one study from the focused group and one study from the unfocused ESW group were not able to reveal significant positive effects of the ESW modality applied. The only shared feature of these studies was that they were both the smallest in their category in terms of patients included. It can therefore not be ruled out that they might have been underpowered.

DISCUSSION

ESW therapy is a noninvasive and low-cost treatment that has shown significant positive clinical effects in a wide range of connective tissue pathologies. Traditional conservative treatments for plantar fasciitis and Achilles tendinopathy are time consuming and of uncertain benefit, and surgical treatments have variable outcomes. These shortcomings have motivated the search for new treatment methods such as ESW therapy (Rompe *et al.* 2007a; Kearney and Costa 2010). Both focused and unfocused ESW treatments have generally provided beneficial clinical outcomes. The present review has not been able to show specific differences in the outcome of focused *versus* unfocused shock wave therapy for Achilles tendinopathy or plantar fasciitis. The treatment variables in the present review included EFD, number of treatment sessions, the time between treatments, the number of shocks per treatment and the type of shock wave applied. The general efficacy, issues and controversies of ESW therapy for treatment of Achilles tendinopathy and plantar fasciitis have been addressed in previous reviews and will not be discussed here (Rompe *et al.* 2007a; Magnussen *et al.* 2009; Wilson and Stacy 2010). We dealt with comparison of the different types of shock waves in relation to the TED delivered, and thus the additional variables above might come to serve as confounders, limiting the ability to compare the studies directly and draw stronger conclusions.

We chose to use the TED applied as a comparator knowing that the waves propagate differently and that the energy reaching the target might defer based on these propagation patterns. Using TED allowed for integration

of the EFD and the number of pulses, which has been proposed as a good predictor correlating the variables to tissue response (Tam 2005). Another shock wave parameter that may be responsible in part for the biological response is the rate at which the shocks were applied, in shocks per second (Hz). However, there has not been a systematic evaluation of the effects of the rate in the clinical treatment of specific disorders, and this parameter often is not reported in clinical studies.

Selecting the appropriate shock wave generator and the combination of EFD and total energy delivery for the treatment by adjusting number of pulses and sessions are likely to be interconnected for an optimal response. Because of differences in wave propagation by focused and unfocused generators, differences in the energy distribution may intuitively apply. Although the location of the tissue receiving the highest energy exposure by use of focused shock wave can be changed by the definition of the focal area, the highest dose of energy using unfocused shock waves from ballistic sources is delivered at the surface of the skin. The propagation of the unfocused shock wave from this area fixed at the skin surface is followed by a steep fall-off in energy. Thus, requirements of high energy for desired tissue response in deep zones will lead to very high energy delivery at the skin surface using unfocused ESWs as opposed to focused ESWs. Unfocused ESW treatments are thus especially applicable if the region of interest is close to the skin surface, such as in tendons, ligaments and bone close to the skin. However, osseous sites like the costae and the clavulae are not currently suitable for any type of ESW treatment due to their proximity with the air-filled lung tissue providing large difference in acoustic impedance. As has been noted, “when shock waves encounter a tissue-air interface, the release of shock wave energy at the interface will result in tissue injury” (Eroglu *et al.* 2007). This was demonstrated in rabbits (Eroglu *et al.* 2007) and in dogs (Delius *et al.* 1987), where ESW-induced hemorrhages and tissue damage in the lungs were reported using focused ESW. Despite the rapid increase in applications of ESWs, no specific safety studies have been conducted in humans, and the safety relies on the reports of adverse effects in the clinical trials. Future research with unfocused ESW would be required to confirm that there is no propagation of the waves to the lungs, but safety issues related to its use in this region need to be considered carefully. In selecting focused ESWs for treatment, consideration should be given to the fact that tissues and organs beyond the target tissue, but still in the focal zone, will be exposed to shock waves of the same EFD.

The primary adverse effects of ESW treatment in orthopedic use are pain, swelling, reddening and hematoma at the application site, although these are considered

relatively rare (Ogden et al. 2001a). High-energy shock waves (e.g., $\sim 55 \text{ mJ/mm}^2$) are usually administered after injection of local anesthesia to prevent pain during treatment. No adverse effects on the articular cartilage adjacent to the treatment site have been reported (Vaterlein et al. 2000) and recent studies even suggest chondroprotective effects of ESWs (Wang et al. 2011b, 2011c). Certain factors related to the application of ESWs need to be balanced: whereas the impact of low-energy ESWs (e.g., $\sim 15 \text{ mJ/mm}^2$) is too limited to provide a treatment effect, high-energy ESWs have been shown to induce injury to tendinous tissue in animal studies (Maier et al. 2001). In addition, it has been shown that in cambium cells the TED is a better predictor for the impact on viability than EFD or number of pulses alone (Tam et al. 2005).

In the present review we chose to assign the ESW apparatus into two categories based on the propagation of the wave as previously described. However, the many different sources of ESWs available limit the comparison of shock wave types, and some devices are even able to produce both focused and unfocused shock waves. It can also be argued whether ESW produced by ballistic sources are in fact shock waves because of the slower rise time and lower amplitude (Cleveland et al. 2007), but the identification of waves from ballistic sources as shock waves remains used widely. In our comparison we used TED, which does not include the frequency, and is another important parameter as previously discussed.

The foundation of evidence-based medicine is that the prescribed treatment should be selected on the basis of the best evidence available. For select applications, both focused and unfocused shock wave treatments have generated positive outcomes. As often happens in comparing the efficacies of other types of clinically available therapies, a direct comparison between these two types of shock wave treatments for any clinical application has been confounded by factors that include incomplete dose-response profiles for the different types of shock waves, variations in the generated waveforms among the different focused shock wave devices and among the nonfocused apparatus and differences in the patient selection criteria. As the importance of shock wave therapy becomes more widely appreciated, systematic comparisons of the various apparatus are sure to be performed.

Based on our review, no evidence in terms of outcome clearly favors one type of shock wave over the other, and the best clinical practice subsequently relies on the clinician's ability to choose either modality based on other factors. For example, the heads of focused devices are traditionally larger, which may prevent the application of focused shock wave treatment to select locations. Additional considerations are associated costs

related to the apparatus itself and the personnel available in the daily practice. The managing board of the International Society for Medical Shockwave Treatment has suggested that piezoelectric-, electromagnetic- and electrohydraulic-generated shock waves can be administered only by trained physicians, whereas pneumatic unfocused shock waves can be applied by trained technicians and nurses as well (Board 2011). Decision making based on the available basic science that in theory might favor one over the other, such as penetration depth of the energy as earlier discussed, is of low evidence but may be the clinician's last option.

CONCLUSION

As noted at the outset, the purpose of this review was to provide a clinical update of the clinical outcomes from shock wave treatment for select applications. Positive clinical outcomes have been reported for both focused and unfocused shock waves for several disorders, demonstrating that these treatment modalities can play an important role in the clinic. There are not yet sufficient data to allow a direct comparison of focused and unfocused shock wave therapies for a particular clinical application.

Level I and level II studies were available for comparison of unfocused and focused ESWs for plantar fasciitis, whereas the comparison of these two modalities for Achilles tendinopathy was limited because of less evidence available for focused ESW (levels III and IV). Hence, the present review does not provide a definite answer to whether focused or unfocused shock wave application provides the best outcomes for treatment of plantar fasciitis and Achilles tendinopathy. The understanding of the technical and biological backgrounds might provide a theoretical understanding for selection of appropriate treatment strategies.

Acknowledgments—A postdoctoral research fellowship for C. B. Foldager at Brigham & Women's Hospital and Harvard Medical School was funded by an Elite Research Scholarship from the Danish Minister of Science, Technology and Innovation. M. Spector is supported by a Research Career Scientist Award from the Department of Veterans Affairs.

REFERENCES

- Cacchio A, Giordano L, Colafarina O, Rompe JD, Tavernese E, Ioppolo F, Flamini S, Spacca G, Santilli V. Extracorporeal shock-wave therapy compared with surgery for hypertrophic long-bone nonunions. *J Bone Joint Surg Am* 2009;91:2589–2597.
- Chaussy C, Schuller J, Schmiedt E, Brandl H, Jocham D, Liedl B. Extracorporeal shock-wave lithotripsy (ESWL) for treatment of urolithiasis. *Urology* 1984;23:59–66.
- Chen JM, Hsu SL, Wong T, Chou WY, Wang CJ, Wang FS. Functional outcomes of bilateral hip necrosis: Total hip arthroplasty versus extracorporeal shockwave. *Arch Orthop Trauma Surg* 2009;129:837–841.

- Chuckpaiwong B, Berkson EM, Theodore GH. Extracorporeal shock wave for chronic proximal plantar fasciitis: 225 patients with results and outcome predictors. *J Foot Ankle Surg* 2009;48:148–155.
- Cleveland RO, McAteer JA. Physics of Shock Wave Lithotripsy. In: Smith AD, (ed). *Smith's textbook of endourology*. 2nd edition. Hoboken, NJ: Wiley-Blackwell; 2006. p. 317–332.
- Cleveland RO, Chitnis PV, McClure SR. Acoustic field of a ballistic shock wave therapy device. *Ultrasound Med Biol* 2007;33:1327–1335.
- Delius M, Enders G, Heine G, Stark J, Remberger K, Brendel W. Biological effects of shock waves: Lung hemorrhage by shock waves in dogs—pressure dependence. *Ultrasound Med Biol* 1987;13:61–67.
- Dogramaci Y, Kalaci A, Emir A, Yanat AN, Gokce A. Intracorporeal pneumatic shock application for the treatment of chronic plantar fasciitis: A randomized, double blind prospective clinical trial. *Arch Orthop Trauma Surg* 2010;130:541–546.
- Dorotka R, Sabeti M, Jimenez-Boj E, Goll A, Schubert S, Trieb K. Location modalities for focused extracorporeal shock wave application in the treatment of chronic plantar fasciitis. *Foot Ankle Int* 2006;27:943–947.
- Elster EA, Stojadinovic A, Forsberg J, Shawen S, Andersen RC, Schaden W. Extracorporeal shock wave therapy for nonunion of the tibia. *J Orthop Trauma* 2010;24:133–141.
- Engelbrechtsen K, Grotle M, Bautz-Holter E, Sandvik L, Juel NG, Ekeberg OM, Brox JI. Radial extracorporeal shockwave treatment compared with supervised exercises in patients with subacromial pain syndrome: Single blind randomised study. *BMJ* 2009;339:b3360.
- Eroglu M, Cimentepe E, Demirag F, Unsal E, Unsal A. The effects of shock waves on lung tissue in acute period: An in vivo study. *Urol Res* 2007;35:155–160.
- Fridman R, Cain JD, Weil L Jr, Sr Weil L. Extracorporeal shockwave therapy for the treatment of Achilles tendinopathies: A prospective study. *J Am Podiatr Med Assoc* 2008;98:466–468.
- Furia JP. High-energy extracorporeal shock wave therapy as a treatment for insertional Achilles tendinopathy. *Am J Sports Med* 2006;34:733–740.
- Furia JP. High-energy extracorporeal shock wave therapy as a treatment for chronic noninsertional Achilles tendinopathy. *Am J Sports Med* 2008;36:502–508.
- Gerdesmeyer L, Frey C, Vester J, Maier M, Weil L Jr, Sr Weil L, Russli M, Stienstra J, Scurren B, Fedder K, Diehl P, Lohrer H, Henne M, Gollwitzer H. Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: Results of a confirmatory randomized placebo-controlled multicenter study. *Am J Sports Med* 2008;36:2100–2109.
- Gollwitzer H, Diehl P, von Korff A, Rahlfs VW, Gerdesmeyer L. Extracorporeal shock wave therapy for chronic painful heel syndrome: A prospective, double blind, randomized trial assessing the efficacy of a new electromagnetic shock wave device. *J Foot Ankle Surg* 2007;46:348–357.
- Greve JM, Grecco MV, Santos-Silva PR. Comparison of radial shock-waves and conventional physiotherapy for treating plantar fasciitis. *Clinics (Sao Paulo)* 2009;64:97–103.
- Hearnden A, Desai A, Karmegam A, Flannery M. Extracorporeal shock wave therapy in chronic calcific tendonitis of the shoulder—is it effective? *Acta Orthop Belg* 2009;75:25–31.
- Höfling I, Joukainen A, Venesmaa P, Kroger H. Preliminary experience of a single session of low-energy extracorporeal shock wave treatment for chronic plantar fasciitis. *Foot Ankle Int* 2008;29:150–154.
- Hsu SL, Wang CJ, Lee MS, Chan YS, Huang CC, Yang KD. Cocktail therapy for femoral head necrosis of the hip. *Arch Orthop Trauma Surg* 2010;130:23–29.
- Ibrahim MI, Donatelli RA, Schmitz C, Hellman MA, Buxbaum F. Chronic plantar fasciitis treated with two sessions of radial extracorporeal shock wave therapy. *Foot Ankle Int* 2010;31:391–397.
- Kearney CJ, Lee JY, Padera RF, Hsu HP, Spector M. Extracorporeal shock wave-induced proliferation of periosteal cells. *J Orthop Res* 2011;29:1536–1543.
- Kearney R, Costa ML. Insertional achilles tendinopathy management: A systematic review. *Foot Ankle Int* 2010;31:689–694.
- Kudo P, Dainty K, Clarfield M, Coughlin L, Lavoie P, Lebrun C. Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracorporeal shock-wave therapy (ESWT) device: A North American confirmatory study. *J Orthop Res* 2006;24:115–123.
- Liang HW, Wang TG, Chen WS, Hou SM. Thinner plantar fascia predicts decreased pain after extracorporeal shock wave therapy. *Clin Orthop Relat Res* 2007;460:219–225.
- Lohrer H, Nauck T, Dorn-Lange NV, Scholl J, Vester JC. Comparison of radial versus focused extracorporeal shock waves in plantar fasciitis using functional measures. *Foot Ankle Int* 2010;31:1–9.
- Magnussen RA, Dunn WR, Thomson AB. Nonoperative treatment of midportion Achilles tendinopathy: a systematic review. *Clin J Sport Med* 2009;19:54–64.
- Maier M, Saisu T, Beckmann J, Delius M, Grimm F, Hupertz V, Milz S, Nerlich A, Refior HJ, Schmitz C, Ueberle F, Weiler C, Messmer K. Impaired tensile strength after shock-wave application in an animal model of tendon calcification. *Ultrasound Med Biol* 2001;27:665–671.
- Malay DS, Pressman MM, Assili A, Kline JT, York S, Buren B, Heyman ER, Borowsky P, LeMay C. Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: Results of a randomized, placebo-controlled, double-blinded, multicenter intervention trial. *J Foot Ankle Surg* 2006;45:196–210.
- Managing Board of the International Society for Medical Shockwave Treatment (ISMST), Consensus Statement, Linz, 2011.
- Marks W, Jackiewicz A, Witkowski Z, Kot J, Deja W, Lasek J. Extracorporeal shock-wave therapy (ESWT) with a new-generation pneumatic device in the treatment of heel pain. A double blind randomised controlled trial. *Acta Orthop Belg* 2008;74:98–101.
- Metzner G, Dohnalek C, Aigner E. High-energy extracorporeal shock-wave therapy (ESWT) for the treatment of chronic plantar fasciitis. *Foot Ankle Int* 2010;31:790–796.
- Ogden JA, Alvarez RG, Levitt R, Marlow M. Shock wave therapy (Orthotripsy) in musculoskeletal disorders. *Clin Orthop Relat Res* 2001a;22–40.
- Ogden JA, Toth-Kischkat A, Schultheiss R. Principles of shock wave therapy. *Clin Orthop Relat Res* 2001b;8–17.
- Othman AM, Ragab EM. Endoscopic plantar fasciotomy versus extracorporeal shock wave therapy for treatment of chronic plantar fasciitis. *Arch Orthop Trauma Surg* 2010;130:1343–1347.
- Prisk VR. Commentary on an article by J.D. Rompe, MD, et al.: Plantar fascia-specific stretching versus radial shock-wave therapy as initial treatment of plantar fasciopathy. *J Bone Joint Surg Am* 2010;92:e26.
- Rasmussen S, Christensen M, Mathiesen I, Simonson O. Shockwave therapy for chronic Achilles tendinopathy: A double-blind, randomized clinical trial of efficacy. *Acta Orthop* 2008;79:249–256.
- Rompe JD, Cacchio A, Furia JP, Maffulli N. Low-energy extracorporeal shock wave therapy as a treatment for medial tibial stress syndrome. *Am J Sports Med* 2010a;38:125–132.
- Rompe JD, Cacchio A, Weil L Jr, Furia JP, Haist J, Reiners V, Schmitz C, Maffulli N. Plantar fascia-specific stretching versus radial shock-wave therapy as initial treatment of plantar fasciopathy. *J Bone Joint Surg Am* 2010b;92:2514–2522.
- Rompe JD, Furia J, Maffulli N. Eccentric loading compared with shock wave treatment for chronic insertional achilles tendinopathy. A randomized, controlled trial. *J Bone Joint Surg Am* 2008;90:52–61.
- Rompe JD, Furia J, Maffulli N. Eccentric loading versus eccentric loading plus shock-wave treatment for midportion achilles tendinopathy: A randomized controlled trial. *Am J Sports Med* 2009a;37:463–470.
- Rompe JD, Furia J, Weil L, Maffulli N. Shock wave therapy for chronic plantar fasciopathy. *Br Med Bull* 2007a;81–82:183–208.
- Rompe JD, Maffulli N. Repetitive shock wave therapy for lateral elbow tendinopathy (tennis elbow): A systematic and qualitative analysis. *Br Med Bull* 2007;83:355–378.
- Rompe JD, Nafe B, Furia JP, Maffulli N. Eccentric loading, shock-wave treatment, or a wait-and-see policy for tendinopathy of the main body of tendo Achillis: A randomized controlled trial. *Am J Sports Med* 2007b;35:374–383.

- Rompe JD, Segal NA, Cacchio A, Furia JP, Morral A, Maffulli N. Home training, local corticosteroid injection, or radial shock wave therapy for greater trochanter pain syndrome. *Am J Sports Med* 2009b;37:1981–1990.
- Saxena A, Ramdath S Jr, O'Halloran P, Gerdesmeyer L, Gollwitzer H. Extra-corporeal pulsed-activated therapy ("EPAT" sound wave) for achilles tendinopathy: A prospective study. *J Foot Ankle Surg* 2011;50:315–319.
- Schofer MD, Hinrichs F, Peterlein CD, Arendt M, Schmitt J. High-versus low-energy extracorporeal shock wave therapy of rotator cuff tendinopathy: A prospective, randomised, controlled study. *Acta Orthop Belg* 2009;75:452–458.
- Stojadinovic A, Kyle Potter B, Eberhardt J, Shawen SB, Andersen RC, Forsberg JA, Shwery C, Ester EA, Schaden W. Development of a prognostic naive bayesian classifier for successful treatment of nonunions. *J Bone Joint Surg Am* 2011;93:187–194.
- Tam KF, Cheung WH, Lee KM, Qin L, Leung KS. Delayed stimulatory effect of low-intensity shockwaves on human periosteal cells. *Clin Orthop Relat Res* 2005;438:260–265.
- van der Jagt OP, van der Linden JC, Schaden W, van Schie HT, Piscaer TM, Verhaar JA, Weinans H, Waarsing JH. Unfocused extracorporeal shock wave therapy as potential treatment for osteoporosis. *J Orthop Res* 2009;27:1528–1533.
- van Leeuwen MT, Zwerver J, van den Akker-Scheek I. Extracorporeal shockwave therapy for patellar tendinopathy: A review of the literature. *Br J Sports Med* 2009;43:163–168.
- Vaterlein N, Lussenhop S, Hahn M, Dellling G, Meiss AL. The effect of extracorporeal shock waves on joint cartilage—an in vivo study in rabbits. *Arch Orthop Trauma Surg* 2000;120:403–406.
- Wang CJ, Wang FS, Ko JY, Huang HY, Chen CJ, Sun YC, Yang YJ. Extracorporeal shockwave therapy shows regeneration in hip necrosis. *Rheumatology (Oxford)* 2008a;47:542–546.
- Wang CJ, Wang FS, Yang KD, Huang CC, Lee MS, Chan YS, Wang JW, Ko JY. Treatment of osteonecrosis of the hip: Comparison of extracorporeal shockwave with shockwave and alendronate. *Arch Orthop Trauma Surg* 2008b;128:901–908.
- Wang L, Qin L, Lu HB, Cheung WH, Yang H, Wong WN, Chan KM, Leung KS. Extracorporeal shock wave therapy in treatment of delayed bone-tendon healing. *Am J Sports Med* 2008c;36:340–347.
- Wang CJ, Ko JY, Chan YS, Lee MS, Chen JM, Wang FS, Yang KD, Huang CC. Extracorporeal shockwave for hip necrosis in systemic lupus erythematosus. *Lupus* 2009a;18:1082–1086.
- Wang CJ, Yang KD, Ko JY, Huang CC, Huang HY, Wang FS. The effects of shockwave on bone healing and systemic concentrations of nitric oxide (NO), TGF-beta1, VEGF and BMP-2 in long bone non-unions. *Nitric Oxide* 2009b;20:298–303.
- Wang CJ, Yang YJ, Huang CC. The effects of shockwave on systemic concentrations of nitric oxide level, angiogenesis and osteogenesis factors in hip necrosis. *Rheumatol Int* 2011a;31:871–877.
- Wang CJ, Weng LH, Ko JY, Sun YC, Yang YJ, Wang FS. Extracorporeal shockwave therapy shows chondroprotective effects in osteoarthritic rat knee. *Arch Orthop Trauma Surg* 2011b;131:1153–1158.
- Wang CJ, Weng LH, Ko JY, Wang JW, Chen JM, Sun YC, Yang YJ. Extracorporeal shockwave shows regression of osteoarthritis of the knee in rats. *J Surg Res* 2011c;171:601–608.
- Wilson M, Stacy J. Shock wave therapy for Achilles tendinopathy. *Curr Rev Musculoskelet Med* 2010;4:6–10.
- Wong T, Wang CJ, Hsu SL, Chou WY, Lin PC, Huang CC. Cocktail therapy for hip necrosis in SARS patients. *Chang Gung Med J* 2008;31:546–553.
- Wright JG, Swiontkowski MF, Heckman JD. Introducing levels of evidence to the journal. *J Bone Joint Surg Am* 2003;85-A:1–3.
- Xu ZH, Jiang Q, Chen DY, Xiong J, Shi DQ, Yuan T, Zhu XL. Extracorporeal shock wave treatment in nonunions of long bone fractures. *Int Orthop* 2009;33:789–793.
- Yucel I, Ozturan KE, Demiraran Y, Degirmenci E, Kaynak G. Comparison of high-dose extracorporeal shockwave therapy and intralesional corticosteroid injection in the treatment of plantar fasciitis. *J Am Podiatr Med Assoc* 2010;100:105–110.