Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis: Literature Review

Subhash Regmi, MS, MSc; Ishor Pradhan, MBBS, MS

Department of Orthopaedics, B & B Hospital, Gwarko, Lalitpur, Nepal

Address of Correspondence

Subhash Regmi, MBBS, MS, MSc

Department of Orthopaedics, B & B Hospital, Gwarko, Lalitpur, Nepal

Email: itsmesubu@gmail.com

Plantar fasciitis (PF) is a chronic degenerative condition of plantar aponeurosis which results in significant pain and functional disability. Although majority of patients respond well to non-steroidal anti-inflammatory drugs (NSAIDs), stretching exercise, and insoles, 10% remain symptomatic and require further intervention. The treatment of chronic PF is often challenging, and several options, such as corticosteroid injection (CSI), autologous whole blood injection (AWBI), platelet rich plasma injection (PRPI), botulinum toxin A injection (BTX-A), dry needling (DN), ultrasound therapy (UT) and extracorporeal shock wave therapy (ESWT), have been described. Out of several options, ESWT has become popular because it is non-invasive and cost-effective. However, there is considerable variation among published studies regarding the application of shock waves and their biological effects. Literature also lacks enough synthesis on the efficacy of ESWT in terms of long-term pain relief and functional recovery. Furthermore, the protective effects of ESWT on disease pathology is not well established. Therefore, this review aims to evaluate the efficacy of ESWT, in terms of pain reduction, functional recovery, and improvement in disease pathology in treating patients with chronic PF.

Keywords: fasciopathies, FSWT, Roles and Maudsley (RM) scores, RSWT, VAS.

Plantar fasciitis (PF) is a degenerative disease involving plantar aponeurosis at bony insertion site, and the pathological process involves overuse or repetitive microinjuries resulting in collagen necrosis, calcification, and thickening of plantar fascia.[1] It is the most common cause of heel pain, and the peak incidence is seen between 45 and 65 years of age.[1] Clinical features include heel pain and walking difficulties, and imaging findings include identification of heel spurs in plain radiograph, thickened (>0.4cm) plantar facia in ultrasound (US) and high-signal intensity areas (HSIA) and oedema around plantar fascia in magnetic resonance imaging (MRI).[2,3] Treatment is mostly supportive with non-steroidal anti-inflammatory drugs (NSAIDs), stretching exercises, and insoles, because the condition is often self-limiting.[2] However, around 10% of the patients with PF remain symptomatic for >3 months, also known as chronic PF, which often requires further interventions.[4]

Chronic PF is commonly managed non-surgically, and surgical release is the last resort because of higher incidence of complications.[5] Several non-surgical treatment options have been described, such as corticosteroid injection (CSI), autologous whole blood injection (AWBI), platelet rich plasma injection (PRPI), botulinum toxin A injection (BTX-A), dry needling (DN), ultrasound therapy (UT) and extracorporeal shock wave therapy (ESWT).[5,6] Out of which, ESWT has gained popularity in recent years, because of its non-invasiveness and cost-effectiveness. However, there is considerable variation among published studies regarding the application of shock waves for the treatment of chronic PF, and the biological effects of shock waves are not clearly understood.

Li et al.[7] in a meta-analysis including 41 clinical trials involving 2889 patients compared the efficacy of eight non-surgical treatment options, including NSAIDs plus exercise, ESWT, CSI, AWBI, PRPI, BTX-A, DN and UT, versus placebo in treating chronic PF and found that compared to placebo, only ESWT was significantly better in reducing pain scores at both 4 and 12 weeks. This suggests that there is strong evidence regarding the efficacy of ESWT in providing short-term pain relief. However, literature lacks enough synthesis on the efficacy of ESWT in providing long-term pain relief. In addition, the functional recovery following ESWT and its protective effects on disease pathology is not well established. Therefore, this review aims to evaluate the efficacy of ESWT, in terms of long-term pain relief, functional recovery, and improvement in disease pathology.

Mechanism of action of ESWT

Types and dosage

There are two types of ESWT available for clinical use in patients with fasciopathies and tendinopathies: focused shock wave therapy (FSWT) and radial shock wave therapy (RSWT)[8]. FSWT propagates shock waves more concentrated towards the depth of affected tissues whereas RSWT delivers the waves superficially covering the larger surface area.[7] In FSWT, the point of maximum density of shock waves is at the target tissue and in RSWT, the point of maximum density of shock wave is at the device.[8]

Shock waves generated during ESWT, either FSWT or RSWT, are measured using energy flux density (EFD) and expressed in unit mJ/mm^2, and are classified into three classes based on EFD: low-density (<0.08 mJ/mm2), medium-density (<0.28 mJ/mm2) and high-density (<0.60 mJ/mm2).[9] Wang et al.[10] in a meta-analysis of 14 clinical trials observed that the therapeutic shock wave densities ranged from 0.04 to 0.36 mJ/mm^2. However, Rompe et al.[9] in a pre-clinical study, observed negative histological changes, such as marked inflammation and fibrinoid necrosis in the Achilles tendon and paratenon of rabbits using high-density shock waves (0.28 to <0.60 mJ/mm^2). In addition, Zhu et al.[11] in human-based study, observed significant increase in soft-tissue oedema and slight increase in bone marrow oedema in immediate magnetic resonance imaging (MRI) evaluation following treatment with high-density shock waves (>0.3 mJ/mm^2, at 1500 cycles, 18kV) in 16 patients with chronic PF. This suggests that high-density shock waves should not be preferred whenever possible. There is a continuous debate among orthopaedic surgeons regarding the method of shock wave delivery and requirement of anaesthesia. Chow et al.[12] observed the difference of 17% in pain reduction and 112% in increase in walking/standing duration between maximum tolerable density group and fixed density group. This suggests that the maximum tolerable density shock wave results in better pain relief and walking/standing tolerability compared to fixed low-density shock waves. Similarly, Rompe et al.[13] observed no significant difference in pain reduction and patient satisfaction following repetitive FSWT (3 cycles, 0.20 mJ/mm^2, at 2000 impulses per cycle) with (n=41) and without (n=45) anaesthesia. This suggests that medium-density shock waves can be applied without anaesthesia.

Biological effects

For the treatment of plantar fasciitis, shock waves generated in the ESWT device are perpendicularly delivered to the affected tissue[8]. After delivery, shock wave causes

two main effects: direct pressure effect by hitting the tissue depth with high impact during positive phase or depolarization and indirect tensile effect during negative phase or repolarization **(Figure 1)**.[8,14]

Initially, the direct pressure effect of shock waves was thought to be responsible for achieving desired therapeutic effect by destroying nerve endings.[9] However, later, pre-clinical studies.[15,16] have found that indirect tensile effects of shock waves initiate immune-mediated reaction and result in selective degeneration of painful nerve endings. Kenmoku et al.[15] observed significant reduction in the amplitude of compound muscle action potential (CMAP) in shock wave treated calf of healthy rats compared to untreated contralateral calf, suggesting the role of ESWT in selectively destroying nerve end plates. Similarly, Takahashi et al.[16] observed 18% reduction in the amount of fluorogold-labelled calcitonin gene related peptide (CGRP) immunoreactive dorsal root ganglion (DRG) neurons in hind paw of shock wave (0.08 mJ/mm^2, 1000 impulses) treated rats compared to untreated rats, suggesting that ESWT reduces pain by activating immunomodulatory reactions at the nerve endings. Hence, tensile effect of shock waves is more responsible for providing pain relief than direct pressure effect.

It is known that fibroblasts play major role in the healing and remodelling of affected aponeurosis or tendons by synthesizing extracellular matrix proteins, such as collagen[17]. Berta et al.[18] investigated the effect of ESWT on human fibroblasts *in vitro* and observed significant increase in the proliferation of fibroblasts when treated with shock waves (0.22 mJ/mm^2, 1000 and 2000 impulses) compared to untreated fibroblasts in same culture medium. In addition, microRNA expressions for collagen type I and III were also significantly higher in treated fibroblasts compared to untreated controls. Similarly, Vetrano et al.[19] observed elongated

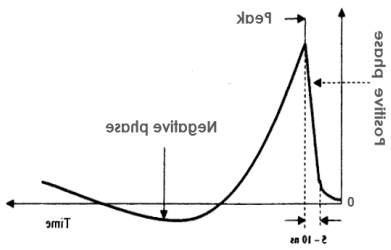

Figure 1: Graphical representation of positive (depolarization) and negative phases (repolarization) of shock waves. Peak represents the maximum density of shock wave at the target tissue.

fibroblast-like morphological changes in human tenocytes, harvested from semitendinosus muscle of 3 different healthy donors, in standard culture medium when treated with shock waves (0.14 mJ/mm^2, 1000 impulses) compared to untreated tenocytes which showed ovoid *tenoblast-like* morphology. In addition, the total collagen concentration was significantly higher (difference ranged 100-170 µg/ml) in shock wave treated tenocytes compared to untreated tenocytes. This suggests that shock waves can promote tendon remodelling via fibroblasts proliferation/differentiation and collagen synthesis. ESWT is also found to effective in promoting tissue regeneration by activating various cell signalling pathways[14]. Weihs et al.[20] in an experiment using rodent ischemic excision wound healing model observed that shock waves, 10-300 impulses of 0.03 to 0.19 mJ/mm^2 generated using electrohydraulic machine, triggered adenosine triphosphate (ATP) release and MAPK/ERK1/2 signalling pathways to promote the proliferation of residing mesenchymal stem cells (MSCs) *in vitro*, and the application of shock waves resulted in significantly better wound healing *in vivo*. Similarly, Wang et al.[21] investigated the angiogenetic effect of shock waves in Achilles tendon of rabbits and observed significant increase in the number of blood vessels (histological) and angiogenic markers, such as vessel endothelial growth factor (VEGF), endothelial nitric oxide synthase (eNOS), and proliferating cell nuclear antigen (PCNA) in Achilles tendon insertion site treated with shock waves, 500 impulses of 0.12 mJ/mm^2, compared to untreated Achilles tendon contralateral leg. In addition, they did not observe any signs of oedema, hematoma, and restriction of movement in treated limb. This suggests that ESWT facilitates tissue regeneration via neo-vascularization and stem cell proliferation.

Efficacy of ESWT in treating patients with chronic PF Effects on long-term pain reduction Most studies [7,22] reporting chronic PF agreed that the endpoint duration should be 24 weeks or more to be considered as long-term outcomes. The studies [23–25] reporting long-term outcomes of ESWT regarding pain relief are shown in **(Table 1)**. Okur et al.[23], in a prospective RCT including 83 patients (40 RSWT and 43 custom foot orthosis), observed around and 3 points reduction in mean visual analogue scale (VAS) scores for pain during walking from the baseline at 48 weeks with RSWT and orthosis, respectively. The reduction of 2 points in VAS values (0 to 10) from the baseline following 3 cycles of RSWT is a clinically significant reduction.[26] Similarly, Ibrahim

Author(s)	Study design	ESWT	Dosage	N#	Mean (SD) resting VAS BL	End-point (m)	Mean VAS final	Mean (SD) Dif. from BL
Konjen et al., 2015	RCT	RSWT	6 cycles, 0.09 mJ/mm^2, 1 cycle/wk	15	85.86 (0.98) (0 to 100)	6	16.00 (1.39)	**69.87****
Okur et al., 2019	RCT	RSWT	3 cycles, 0.09 mJ/mm^2, 1 cycle/wk	40	7.2 (2.3) (0 to 10)	12	5.5 (2.1)	**1.7****
Ibrahim et al., 2017	RCT	RSWT	2 cycles, 0.16 mJ/mm^2, 1 cycle/week	23	8.52 (0.34) (0 to 10)	24	1.44 (0.32)	**7.08****

RCT randomized control trials, **RSWT** radial shock wave therapy, **ESWT** extracorporeal shock wave therapy, **N** number of participants, **#**numbers in treatment group, **SD** standard deviation, **wk** week, **m** months, **VAS** visual analogue scale, **BL** baseline, **Dif.** difference, ******p<0.001

Table 1: Studies reporting long-term resting VAS outcomes (>6 months) following ESWT for chronic PF

et al. in a double-blind RCT including 47 chronic PF patients (23 RSWT and 24 placebo) observed reduction of around 7 points in VAS scores (0 to 10) from the baseline in patients who received two cycles of medium density RSWT and the reduction of around 3.5 points in patients who received placebo at 2-year follow-up. The difference of around 3.5 points in VAS reduction between RSWT and placebo at 2-year suggests that RSWT can effectively provide long-term pain reduction.

Author(s)	Study design	ESWT	Dosage	N	Mean Baseline score	End-point (wk)	Success rate (%)
Kudo et al., 2003	RCT	RSWT	1 cycle, 0.36 mJ/mm^2, 3500 impulses*****	58	3.8	12	40
Gollwitzer et al., 2007	RCT	FSWT	3 cycles, 0.25 mJ/mm2, 2000 impulses per cycle	20	3.8	12	60
Gerdesmeyer et al., 2008	RCT	RSWT	3 cycles, 0.16 mJ/mm2, 2000 impulses per cycle	125	3.5	12	59
Chukpaiwong et al., 2009	Case series	RSWT	1 cycle, 0.36 mJ/mm2, 3500 impulses*****	225	3.7	12	71
Ibrahim et al., 2010	RCT	RSWT	2 cycles, 0.16 mJ/mm2, 2000 impulses per cycle	126	3.6	12	68
Radwan et al., 2012	RCT	FSWT	1 cycle, 0.22 mJ/mm2, 1500 impulses*****	34	4	12	64
Gollwitzer et al., 2015	RCT	FSWT	3 cycles, 0.25 mJ/mm2, 2000 impulses per cycle	125	3.6	12	55

N number of participants, **wk** weeks, **RCT** randomized control trials, **ESWT** extracorporeal shock wave therapy, **RSWT** radial shock wave therapy, **FSWT** focused shock wave therapy, *****performed under anaesthesia, **RM** Roles and Maudsley

Table 2: Studies reporting the success rate of ESWT according to RM scoring system evaluation in patients with chronic PF.

Author(s)	Study design	ESWT	Dosage	N	Mean baseline scores	End-point (wk)	Mean scores	Improvement From baseline
Chukpaiwong et al., 2009 [44]	Case series	RSWT	1 cycle, 0.36 mJ/mm2, 3500 impulses*	225	46	12	77	31
						52	78	32
Radwan et al., 2012 [46]	RCT	FSWT	1 cycle, 0.22 mJ/mm2, 1500 impulses*	34	43	12	80	37
						52	87	44
Chew et al., 2013 [53]	RCT	FSWT	1 cycle, 0.02 to 0.42 mJ/mm2, 2000 impulses	19	62	12	85	23
						52	90	28

N number of participants, **wk** weeks, **RCT** randomized control trials, **ESWT** extracorporeal shock wave therapy, **RSWT** radial shock wave therapy, **FSWT** focused shock wave therapy, *****performed under anaesthesia, **AOFAS** American Orthopaedics Foot and Ankle Society

Table 3: Studies reporting AOFAS hind-foot scores following ESWT in patients with chronic PF

Effects on function

Roles and Maudsley (RM) score is the most widely used scoring system to evaluated functional status of the patients with tendinopathies[27]. Seven studies. [28–34] have used RM scoring system to evaluate the functional recovery in a total of 713 patients with chronic PF who failed to prior treatment with NSAIDs, stretching exercises and insoles. The average pre-treatment RM scores ranging from 3.5 to 4. The success of the treatment was determined as improvement of RM scores to 1 or 2 at 12 weeks post-treatment. After 12 weeks of ESWT, the success rate in achieving satisfactory functional status ranged from 40 to 71%. This suggests that ESWT provides satisfactory functional outcomes.[35]

American Orthopaedic Foot and Ankle Society (AOFAS) has provided hind-foot functional scoring system for the evaluation of functional status of the patient suffering from foot and ankle conditions[36,37]. AOFAS hind-foot scoring is better predictor of functional outcome compared to RM scores because it also evaluates the hind-foot structural alignment apart from pain and disability[37]. Three studies[28,33,38] have reported functional outcomes of 278 chronic PF patients who received ESWT using AOFAS hid-foot scores **(Table 3)**. The patient selection criteria were similar across all three studies, such as disease duration of >6 months, RM scores of 3 or 4, no comorbidities, and those who did not

respond to NSAIDs, stretching exercise, insoles, and CSI therapy. The baseline AOFAS scores ranged from 46 to 62, which represented significant disability[37]. After 12 weeks of ESWT, the score improved by 23 to 37 points, which is a clinically significant improvement[39]. The improvement also persisted up to 1 year, and the final scores ranged from 78 to 90. This suggests that ESWT can provide satisfactory functional recovery both short-term and long-term in patient with chronic PF.

Effects on disease pathology

X-rays, US (gold standard), and MRI are commonly used investigation modalities to evaluate plantar fascia pathology before and after intervention.[2,3] Hammer et al.[40] evaluated the effect of ESWT (3 cycles, 0.2 mJ/mm^2, 3000 impulse/cycle) on plantar fascia thickness of 22 patients with chronic PF (>6months, failed NSAIDs, physiotherapy and insoles) who had thicker plantar fascia compared to normal contralateral side in US measurements (mean difference of 1.0 mm, $p<0.05$) and observed no significant difference (mean difference 0.1mm, $p>0.05$) in facia thickness between affected foot and normal foot at 6 months of treatment. The thickness of affected side reduced by 0.9mm, which was significant ($p<0.05$). Although there is a possibility of measurement bias in the study because the operator was not blinded, the reduction of around 1.0 mm was clinically significant. This suggests that ESWT can significantly improve plantar facia thickness in patients with chronic PF. Similarly, Maki et al.[41] evaluated MRI findings in 23 patients with chronic PF (>3months, failed NSAIDs, insoles and CSI therapy) who underwent ESWT (1 cycle, 0.03 to 0.36 mJ/mm^2, 3800 impulses) and observed significant improvement in HSIA and oedema around plantar fascia and calcaneum bone marrow oedema, and all these MRI findings had positive correlation with reduction in pain scores. This suggests that ESWT has some role in modifying disease pathology, and MRI findings, such as bone marrow oedema and HSIA are predictors for symptomatic outcomes. However, they found no significant reduction in plantar fascia thickness at 6 months, and there was variance in the use of shock wave, as the densities ranged from 0.03 to 0.36 mJ/mm^2) and there is a risk of measurement bias, as the measurement process was not blinded.

Furthermore, Ulusoy et al.[42] observed significant reduction in plantar fascia thickness, with mean difference of 0.86mm from baseline ($p<0.001$), at 1 month following ESWT (1 cycle, 0.25 mJ/mm^2, 2000 impulses) in 20 patients with chronic PF (>6 month previously untreated). They also found positive correlation of reduction

of plantar fascia thickness and reduction in pain scores. This suggests that ESWT can reduce plantar fascia thickness and the reduction in thickness can be a predictor for symptomatic improvement. However, the level of evidence is weak, because of the variance in patient selection, dosing of ESWT, and duration of follow-up and study limitations. Hence, further high-quality studies with proper patient selection are required to evaluate the effect of ESWT on plantar fascia pathology and to establish the association of reduction in plantar fascia thickness and symptomatic improvement.

Conclusion

ESWT is a reliable treatment option for patients with chronic PF. There is weak evidence regarding the superiority of FSWT over RSWT, especially for short-term outcomes. Maximum tolerable density shock waves are found to be safe, and effective than fixed density shock waves and shock waves can be applied effectively without anaesthesia.

ESWT can provide long-term pain relief and the overall success rate of achieving satisfactory functional recovery at 12 weeks ranged from 40 to 70%. However, the evidence regarding the effectiveness of ESWT in improving disease pathology is weak because of some inherent limitation of published studies regarding study design, selection criteria, and outcome evaluation. Hence, further high-quality studies evaluating the long-term effect of ESWT on disease pathology using imaging modalities, such as X-ray, US, or MRI and including control groups are required.

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