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The Effectiveness of Extracorporeal Shock Wave Therapy on Chronic Achilles Tendinopathy: A Systematic Review

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Abstract

Background: Achilles tendinopathy is a pathological state resulting from repetitive loading or stress on the tendon. Extracorporeal shock wave therapy (ESWT) is hypothesized to be an effective alternative intervention to surgery when other conservative therapies fail. This systematic review investigated the effectiveness of ESWT in the treatment of insertional and noninsertional Achilles tendinopathies.

Methods: Articles were electronically searched from the Cochrane Controlled Trials Register, MEDLINE, CINAHL, EMBASE, and SPORTDiscus using a comprehensive search strategy. Studies were included if they were prospective clinical trials examining the effectiveness of ESWT for insertional or noninsertional Achilles tendinopathies. Methodological quality of included studies was assessed using PEDro scale and Modified McMaster tool. The strength of the evidence was reported using the National Health and Medical Research Council body of evidence framework. A narrative summary of the findings was presented.

Results: Four of the included studies were randomized controlled trials, and 2 were pre-post study designs. Common methodological deficiencies included not blinding the clinician and participants. There was consistent evidence from 4 reviewed studies on the effectiveness of ESWT in the management of patients with chronic Achilles tendinopathies at a minimum 3 months' follow-up.

Conclusion: Overall, our review showed satisfactory evidence for the effectiveness of low-energy ESWT in the treatment of chronic insertional and noninsertional Achilles tendinopathies at a minimum 3 months' follow-up before considering surgery if other conservative management fails. However, combining ESWT with eccentric loading appears to show superior results.

Level of Evidence: Level 1, systematic meta-analysis.

Keywords: Achilles, chronic, extracorporeal, shock wave, tendinopathy

Achilles tendinopathy is one of the most frequently encountered overuse injuries, especially in the athletic population,[3] accounting for 5% to 18% of all running injuries. Tendinopathy was described by Cook and Purdam[5] as a pathological state of the tendon that results from repetitive loading or stress shielding that may lead to a catabolic effect on tendon integrity. There are 3 stages to tendon pathology: early reactive, disrepair, and degenerative. The management for tendinopathies depends on the stage of pathology and should consider factors such as age, repetitive loading, and the presence of bony spurs.[5]

Achilles tendinopathy may involve lesions in the tendo-achilles, the enthesis organ, the surrounding peritendinous structure, or a combination of these structures.[24] The impairments associated with this condition include loss of muscle power, pain, and stiffness of surrounding soft tissues. As a result, patients with this condition often experience limitations in their ability to walk, run, climb, and perform household activities and sports.[3]

In recent years, there has been substantial investigation to understand tendon pathophysiology, which has led to a change in management strategies for Achilles tendinopathies. The management of chronic Achilles tendinopathies has shifted from passive inflammation management only to active exercises and pharmacological interventions.[1] Extracorporeal shock wave therapy (ESWT) is a recent addition to the list of management choices and has shown promising outcomes such as a decrease in pain and an improvement in functional scores in managing chronic tendinopathies.[5]

A number of systematic reviews have been published in the past 10 years reporting the effectiveness of different management approaches to Achilles tendinopathy. In 2001, McLauchlan and Handoll[13] reviewed clinical trials that

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investigated the effectiveness of various treatment interventions for acute and chronic Achilles tendinitis. This review found insufficient evidence to determine which method of treatment is most appropriate for Achilles tendinitis.

A recent review on insertional Achilles tendinopathy management[9] reviewed both surgical and conservative approaches for treating the condition. This review aimed to include only prospective trials, but it also included 1 retrospective cohort study to review ESWT. A review by Magnussen et al[12] evaluated the effects of nonsurgical interventions, including ESWT, for noninsertional Achilles tendinopathies. Their review included 2 trials on ESWT, one of which included a mixed population of tendons and could have been excluded according to their mentioned criteria.[6] A guideline published by Carcia et al[3] addressed Achilles tendinopathy with a wider scope to suggest examination choices and treatment recommendations but included only 2 studies on ESWT. Since there are no high-quality reviews on this topic and methodological issues in the ones available in literature, there is need for a systematic review focusing on the effect of ESWT on both insertional and noninsertional chronic Achilles tendinopathies. This review aimed to explore the effectiveness of ESWT in the treatment of chronic insertional and noninsertional Achilles tendinopathy

Methods

Search Strategy

As a first step in the systematic review process, we framed our review question using the PICOT (population, intervention/exposure, comparison, outcome, time frame) framework (Table 1). A range of keywords was identified and grouped into 2 categories to ensure that a broad search would be conducted. Category 1 represented key words within the concept of "Achilles tendinitis" (OR "Achilles tendinopathy"). Category 2 represented key words within the concept of "shock wave therapy" ("extracorporeal shock wave therapy" OR "ESWT"). Wildcards and truncations symbols were used as appropriate across different databases.

We conducted a comprehensive search using the following electronic databases: MEDLINE, EMBASE, SPORTDiscus, CINAHL, and the Cochrane Controlled Trials Register. Reference lists of all relevant articles were examined for additional studies that may not have been indexed in the electronic databases.

Study Selection

We considered all experimental designs in this review because of a limited number of studies with high methodological quality. Our review examined studies that investigated the effects of ESWT on insertional and/or noninsertional Achilles tendinopathy. Only articles published in English within the past 10 years were included.

Table 1. The PICOT Format

Population	Male or female adults aged 18 years or older with chronic Achilles tendinopathy (both insertional or noninsertional)[a]
Intervention/exposure	Extracorporeal shock wave therapy
Comparison	Any conservative treatment or sham
Outcome	Pain Foot/ankle or lower extremity function score
Time frame	Short term and long term (postintervention follow-up for 3 months or longer)

Abbreviation: PICOT, population, intervention/exposure, comparison, outcome, time frame.
[a]*Chronic* is defined as a condition lasting for more than 3 months. *Achilles tendinopathy* is defined as an overuse tendon injury and can be classified according to the location of the pathology into insertional, which is close to the calcaneus, and noninsertional (also called midportional), which is found 2 to 6 cm proximal to the calcaneus.

Two reviewers independently (H.A. and J.V.S.) scrutinized the titles and the abstracts to determine eligibility for inclusion. Full texts of potentially relevant papers were retrieved for a more detailed examination. The decision to include or exclude studies, based on the set criteria, was made independently by the same authors. Differences in opinions were resolved by discussion until a consensus was reached.

Methodological Quality Assessment

The methodological quality of all included studies was independently assessed by 2 authors (H.A. and J.V.S.). The PEDro scale, which is scored out of 10, was used to examine the quality of the randomized controlled trials (RCTs). It is an assessment scale of the methodological quality and risk of bias of clinical trials.[17] Non-RCTs were assessed using the Modified McMaster Quantitative Critical Appraisal Tool.[7] This tool yields a maximum score of 15. It contains a generic quantitative appraisal scale. Differences in scoring between reviewers were resolved by discussion until a consensus was reached.

Data Extraction and Synthesis

The first author (H.A.) extracted data from individual studies and included characteristics of the population studied, description of the intervention, outcomes assessed, and results of individual studies. All extracted data were double-checked by the second author (J.V.S.) for rigor. This extracted data were compiled into a tabular form (Table 2).

Data were synthesized using a qualitative/narrative approach. Synthesis of collected data was then collectively reviewed. This step included comparing the studies and then discussing the quality of evidence, clinical impact, consistency of findings, generalizability of the results, and the recommendations based on the National Health and

Table 2. Characteristics of Studies and Intervention Details

Author	Year	Group	N	Age, y, Mean ± SD or (Range)	Duration of Symptoms, mo, Mean ± SD	Shock Wave Application	No. of Impulses and Dosage (Energy Flux Density)	No. of Sessions	Interval Between Sessions	Other Interventions
Vulpiani et al[23]	2009	Shock wave therapy	127[a]	47.8 ± 12.8	>6	Using ultrasonography guidance to focus the shock waves on insertional or midportion tendinopathy or calcified area	1500-2500 impulses, 0.08-0.33 mJ/mm^2 for midportion; 1500-2500 impulses, 0.12-0.40 mJ/mm^2 for insertional calcific tendinopathy	4 (range, 3-5)	Average 2 d (range, 2-7)	None
Rompe et al[20]	2008	Shock wave therapy	25	40.4 ± 11.3	26.3 ± 10.7	Area of maximal tenderness was treated in a circumferential pattern, starting at the point of maximum pain	2000 impulses, 0.12 mJ/mm^2	3	1 wk	
Rasmussen et al[18]	2008	Shock wave therapy	24	49 ± 9	>3	Delivered to the area of swelling and tenderness	2000 impulses, 0.12-0.51 mJ/mm^2, 50 Hz	4	1 wk	Stretching and eccentric loading training
Rompe et al[21]	2007	Shock wave therapy	25	51.2 ± 10.3	12.5 ± 6.8	Area of maximal tenderness in a circumferential pattern, starting at the point of maximum pain level	2000 impulses, 0.1 mJ/mm^2	3	1 wk	None
Costa et al[6]	2005	Shock wave therapy	22	58.7 ± 10.8	17.8 ± 10.1	Treatment area was identified using patient's tenderness and ultrasound as a guide	1500 impulses, 0.2 mJ/mm^2	3	1 mo	None
Lakshmanan and O'Doherty[10]	2004	Shock wave therapy	16[a]	48.5 (35-77)	>6	Painful area in the Achilles tendon with constant motion of probe around the lesion under 2.5 bar pressure in a continuous mode pattern	2000 impulses, 6-10 Hz	3	1 wk	None

[a]No. of tendons.

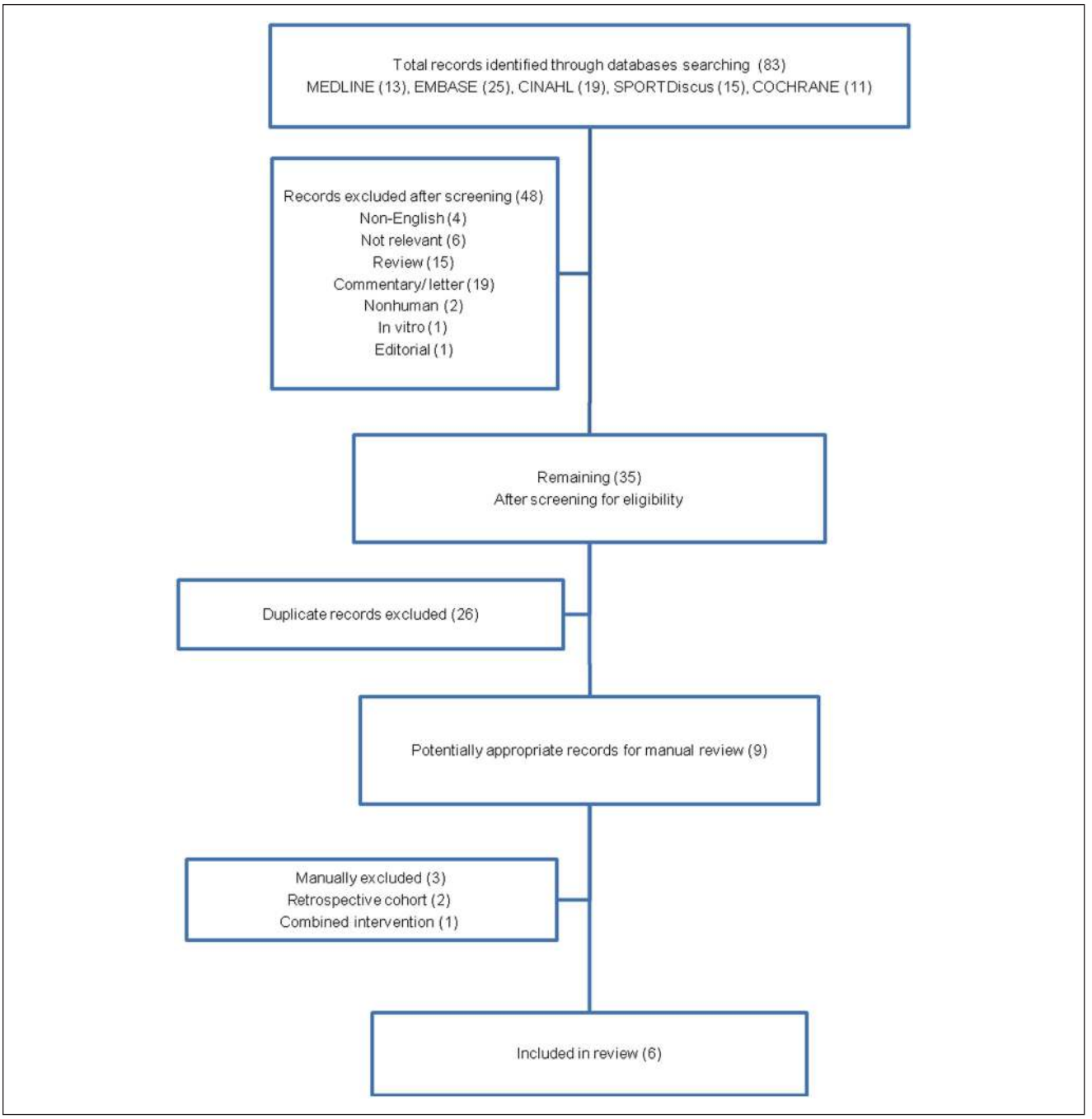

Figure 1. CONSORT diagram.

Medical Research Council (NHMRC)[14] strength of the body of evidence matrix.

Results

Search Results

An overview of the search results is outlined in Figure 1. The selection of studies was based on the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) guidelines. Of the initial 83 titles identified from the databases, 48 were excluded as they did not satisfy the inclusion criteria, leaving 35 studies for possible inclusion in the review. Upon examination, 26 were duplicates and 2 were nonexperimental studies. One article was excluded as contamination of data occurred with combined interventions. Therefore, studies included in the review comprised 4 RCTs and 2 pre-post studies.

Participants' Characteristics

The number of participants for each study varied from 16 to 127, and a total of 365 tendons were available for analysis. Table 2 provides a summary of the participants' characteristics. Of the 6 studies reviewed, 2 dealt exclusively with noninsertional Achilles tendinopathy,[10,21] 1 on insertional tendinopathy,[20] and 2 articles included both types of tendinopathies.[6,23] The study by Rasmussen et al[18] did not specify the type of tendinopathy in their inclusion criteria. The age of participants ranged between 35 and 69.5 years. The duration of symptoms varied widely across studies, ranging between 3 and 42 months. Overall, there was lack of consistency in the characteristics of participants across studies.

Treatment Parameters

Table 3 outlines the treatment parameters used by individual studies. The majority of the studies described the application of ESWT at the area of maximal tenderness or swelling.[10,18,20,21] Two others[6,23] used ultrasound guidance to focus shock waves on tendinopathy or calcified areas. The dosage of ESWT differed among studies, with energy levels ranging between 0.08 and 0.51 mJ/mm^2 (reported in energy flux density) and impulses per session varying between 1500 and 2500 impulses. In all studies, the number of treatment sessions was either 3 or 4, except for 1 study[23] that reported a variable number of sessions. The time interval between treatments was 1 week in most studies,[10,18,20,21] whereas Costa et al[6] used a 1-month interval, and Vulpiani et al[23] reported intervals between 2 and 7 days. Most studies examined ESWT as a single intervention.[6,10,21,23] Two studies had cointerventions; 1 study allowed the use of analgesics as necessary,[20] whereas another administered stretching and an eccentric loading training program to all participants.[18]

Outcome Measures

Pain outcomes were expressed using either a visual analog scale (VAS)[6,10,18,23] or the Numerical Rating Scale (NRS).[20,21] All studies reported pain outcomes after 3 to 4 months of follow-up, wherein 2 had a longer term follow-up of 12 to 24 months.[10,23] The VISA-A (Victorian Institute of Sport Assessment–Achilles) was used to evaluate function in 3 studies.[10,20,21] Other measures of function were reported by other studies such as the Disability Rating Index/Functional Index for Lower Limb Injuries (FIL),[6] the American Orthopaedic Foot and Ankle Society (AOFAS) score,[18] and the Ankle Hindfoot Scale (AHS).[10]

All outcome measures used have been tested for validity and reliability and have shown good responsiveness to change.

Effects of ESWT on Achilles Tendinopathy

Pain. Of the 6 studies, 4[10,20,21,23] reported statistically significant improvements in pain scores (VAS or NRS) at a minimum of 4 months despite the variability in ESWT application parameters between these studies. The study by Rasmussen et al[18] showed no difference in the change of pain measure between ESWT and control. Costa et al[6] reported no significant difference between groups on VAS score during walking or rest at the 3-month follow-up. However, pain scores during sports activity showed improvement with 13 of 41 tendons becoming pain free at the 1-year follow-up.

Function. Functional outcomes were assessed in 5 studies, and 4 showed statistically significant improvement.[10,20,21,23] Costa et al[6] reported no change in the FIL measure. All outcome measures for function were measured at a minimum period of 3 months from baseline.

Methodological Quality

The quality of the included studies is summarized in Tables 4 and 5. Four studies were RCTs, and 2 were pre-post design.

Scores of RCTs on the PEDro scale ranged between 7-9 and 10. All studies reported random allocation of participants, similar groups at baseline, assessor blinding, adequate follow-up, and intention-to-treat analysis. Concealed allocation was undertaken by all studies, except for one.[18] None of the studies had therapist blinding, and only 2 reported participant blinding.[6,18] All studies reported between-group statistical analysis using both point measures and measures of variability except for one.[18]

The 2 pre-post studies were appraised using the Modified McMaster Quantitative Critical Appraisal Tool. These studies obtained a score of 9 out of 14 and 11 out of 14, respectively. Both reported adequately on details of intervention, dropouts, and clinical importance. There was clear reporting of study purpose and sample characteristics, with appropriate conclusions. Results of both studies were reported in terms of statistical significance. However, neither provided adequate background literature review nor justified the sample size. Only 1 study used valid and reliable outcome measures and appropriate statistical methods.[10] Cointervention was avoided in only 1 study.[23]

Overall Appraisal of Evidence

Summary of the strength of evidence is provided in Table 6. There is an overall satisfactory level of evidence for the effectiveness of ESWT for the treatment of chronic Achilles tendinopathies on pain and function. Despite inconsistencies in the inclusion criteria, type of tendinopathy, and area of application, 4 of 6 studies showed significant positive outcomes except for Costa et al[6] and Rasmussen et al.[18]

Table 3. Outcome Measures

Author, Year	SWT Group	Outcome	Period, mo	Follow-up: Baseline to Follow-up, Mean ± SD (90% CI)	*P* Value: Within Group	*P* Value: Between Group
Vulpiani et al, 2009[23]	SWT	VAS (0-10)	12	2.88 ± 3.1	<.01	NA
		VAS (0-10)	24	2.6 ± 3.3	<.01	
Rompe et al, 2008[20]	SWT	VISA-A (0-100)	4	79.4 ± 10.4 (34-100)	NR	.005
		Likert scale (1-6)		2.8 ± 1.6 (1-6)		.043
		NRS (1-10)		3.0 ± 2.3 (0-8)		.004
		Pain threshold (kg)		3.5 ± 1.1 (1.5-5.2)		.002
		Tenderness at 3 kg measured on NRS (0-10)		2.4 ± 4.2 (1-7)		.021
Rasmussen et al, 2008[18]	SWT	AOFAS (0-100)	3	88 ± 10	.05	.04
		VAS (0-10)		NR	NR	NS
Rompe et al, 2007[21]	SWT	VISA-A (0-100)	4	70.4 ± 16.3 (34-100)	NR	<.001
		Likert scale (1-6)		2.9 ± 1.5 (1-6)		.001
		NRS (1-10)		4.0 ± 2.2 (0-8)		<.001
		Pain threshold (kg)		2.8 ± 0.9 (1.5-4)		.008
		Tenderness at 3 kg measured on NRS (0-10)		2.6 ± 4.2 (0-5)		.260
Costa et al, 2005[6]	SWT	Pain during walking (100-mm VAS)	3	34.5 ± 34.2	NR	.127
		Pain at rest (100-mm VAS)		27.3 ± 30.6		.408
		FIL		0.95 ± 0.96		.137
Lakshmanan and Doherty, 2004[10]	SWT	AHS (0-100)	20-22	87.0 ± 11.4	<.001	NA
		VISA-A (0-100)		75.9 ± 19.1	<.001	
		VAS (0-10)		0.7 ± 1.2	<.001	

Abbreviations: AHS, Ankle-Hindfoot Scale; AOFAS, American Orthopaedic Foot and Ankle Society score; FIL, Functional Index for Lower Limb Injuries; NA, not applicable; NR, not reported; NRS, Numerical Rating Scale; NS, reported as not significant (*P* value not given); SWT, shock wave therapy; VAS, visual analog scale; VISA-A, Victorian Institute of Sport Assessment–Achilles.

Discussion

To date, this is the first systematic review that reports the effectiveness of ESWT for the treatment of chronic insertional and noninsertional Achilles tendinopathies. The evidence for ESWT suggests that it can be considered an alternative to surgery for patients who fail to respond to conservative management. This finding concurs with other systematic reviews that report the effectiveness of ESWT on other conditions, including shoulder calcified tendinitis,[11] patellar tendinopathies,[22] and chronic proximal plantar fasciitis.[15]

Achilles tendinopathy has been shown to cause pain because of the presence of neuropeptides (eg, substance P and calcitonin gene–related peptide [CGRP]) and neurotransmitters (eg, glutamate), altered collagen fiber structure, and increased interfibrillar ground substance.[2] Öhberg et al,[16] on the other hand, demonstrated the presence of neovessels in pathological tendons using color Doppler and identified them as a potential cause of pain. According to Cook and Purdam,[5] Achilles tendinopathy in the late disrepair stage has some chance for reversing the change to cellular matrix, and thus a treatment algorithm focusing on better conservative methods must be tried before surgery is considered. Extracorporeal shock wave therapy fits within this paradigm of treatment. Low-energy ESWT has been speculated in the short term to produce an analgesic effect by altering the permeability of neuron cell membranes and in the long term to increase inflammation by causing increased blood flow in the chronic tendinopathy and improve the symptoms. High-energy ESWT is believed to be able to cause destruction of neovessels, but the risk of tissue damage is too high[4] and therefore not included in this review. Furia[8] cited a study on rat tendons that found low-energy ESWT causes an increase in neovessel formation and angiogenesis, which may facilitate a positive effect overall. This may contradict the earlier belief on neovessels being the source of the pain in this pathology, and this may indicate a lack of consensus on the behavior of pain and effect of shock wave in altering it.

Table 4. PEDro Scale for Randomized Controlled Trial Studies

PEDro Criterion	Costa et al, 2005[6]	Rasmussen et al, 2008[18]	Rompe et al, 2008[20]	Rompe et al, 2007[21]
Eligibility criteria	1	1	1	1
Random allocation	1	1	1	1
Concealed allocation	1	0	1	1
Baseline comparability	1	1	1	1
Blind subjects	1	1	0	0
Blind therapists	0	0	0	0
Blind assessors	1	1	1	1
Adequate follow-up	1	1	1	1
Intention-to-treat analysis	1	1	1	1
Between-group comparisons	1	1	1	1
Point estimates and variability	1	0	1	1
Total	9/10	7/10	8/10	8/10
Percentage score	90	70	80	80

Item 1 eligibility criteria is not used to calculate the PEDro score.

Table 5. Modified McMaster Quantitative Critical Appraisal Tool

Criterion	Lakshmanan and O'Doherty, 2004[10]	Vulpiani et al, 2009[23]
Study purpose stated clearly	1	1
Relevant background literature reviewed	0	0
Research design appropriate	1	1
Sample described in detail	1	1
Sample size justified	0	0
Outcome measures reliable	1	0
Outcome measures valid	1	0
Intervention/exposure described in detail	1	1
Contamination avoided	NA	NA
Cointervention avoided	0	1
Results were reported in terms of statistical significance	1	1
Appropriate analysis methods	1	0
Clinical importance reported	1	1
Dropouts reported	1	1
Appropriate conclusions	1	1
Total	11/14	9/14
Percentage score	79	64

Abbreviation: NA, not applicable.

All studies reviewed in this article were not strictly consistent in their treatment parameters, but most agreed on the number of sessions and interval between sessions. Costa et al[6] chose a lower dosage and longer intervals between sessions, thus delivering a lower energy to the tissue. Two studies by Rompe et al[20,21] were most consistent in their treatment parameters and achieved similar findings throughout their studies. Thus, the similar parameters reported in the majority of the studies support a dose-effect relationship. Although the average age of patients in the ESWT groups was slightly higher in all reviewed studies, Costa et al[6] had a larger range of ages and experienced poor results. These differences in their study methods may explain their lack in demonstrating positive findings compared with the other studies.

None of the reviewed studies found serious complications with ESWT except for one,[6] which reported tendon rupture. In this study, tendon rupture was attributed to the severity of condition and age of patients. Both patients were older than 60 years and had advanced tendinosis. Furthermore, the actual rupture happened during trivial incidents and not during treatment, and thus drawing a conclusion becomes difficult. The most common reaction experienced by patients was transient reddening of the skin. The ESWT treatment in all studies used low-energy shock waves, which could explain why application was safe and comfortable in most patients. In addition, movement of the treatment head over the affected tendon distributes the energy evenly, which could prevent tendon rupture.[19]

Limitations in our review might be the exclusion of 2 non-English studies that may result in language bias. Other limitations are the relative inconsistencies in adhering to a treatment dosage among all studies, which could have made drawing a strong recommendation easier. However, keeping in mind that the tendons were at different levels of severity and at different stages of symptoms, dosages may be varied to suit the client.

Overall, the literature supports the use of ESWT in the treatment of chronic insertional and noninsertional Achilles tendinopathy. The dosage likely to produce positive effects can be between 1500 and 2500 impulses per session administered at a flux density of 0.1 to 0.5 mJ/mm^2. A minimum of 3 sessions, with an interval of 1 week between sessions, can

Table 6. National Health and Medical Research Council Body of Evidence Framework

Component	Grade	Comments
Evidence base	A = excellent	Total of 6 studies Level II: 4 studies Level IIIc: 2 studies Quality of studies: low risk of bias
Consistency	C = satisfactory	There was variability in the reporting of site of intervention, dosages, and sample population characteristics (eg, age, length of symptoms)
Clinical impact	C = satisfactory	Two high-quality studies and 2 other experimental lower quality studies reported statistical significant improvement in pain and function parameters at follow-up period ranging from 3 to 24 months
Generalizability	A = excellent	Subjects studied are similar in characteristics to patients seen in clinical practice
Grades of recommendation	C = satisfactory	Overall, the existing body of evidence provides some support for recommending use of extracorporeal shock wave therapy on chronic Achilles tendinopathies, but care should be taken in its application

be expected to improve pain and function in this patient group. An increase in the frequency of sessions did not seem to have any additional effect on outcomes. The risk of ESWT is reported to be transient skin reddening in most studies. However, there was evidence for possible tendon rupture in patients older than 60 years with advanced tendinosis.

Conclusion

Our review showed satisfactory (grade C—NHMRC recommendation) evidence with the majority of the studies reporting satisfactory consistent findings for the effectiveness of low-energy ESWT in the treatment of chronic insertional and noninsertional Achilles tendinopathies. Studies show improved pain and functional outcomes for a minimum of 3 months, and therefore ESWT may be considered before surgery if other conservative management fails. The dosages applied may be varied within the parameters found in this review according to the length, severity, and irritability of patient symptoms. Further research needs to be done into the long-term outcomes of ESWT on Achilles tendinopathy, in addition to establishing if there exists a clear dose-effect relationship by comparing high-intensity ESWT with low-intensity ESWT. Future research should explore the effects of ESWT on Achilles tendinopathy on different age groups, as well as duration and severity of symptoms.

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