

# Extracorporeal shockwave therapy for Achilles tendinopathy

Interventional procedures guidance

Published: 21 December 2016

[www.nice.org.uk/guidance/ipg571](http://www.nice.org.uk/guidance/ipg571)

## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG312.

# 1 Recommendations

- 1.1 The evidence on extracorporeal shockwave therapy (ESWT) for Achilles tendinopathy raises no major safety concerns. Current evidence on efficacy of the procedure is inconsistent and limited in quality and quantity. Therefore, ESWT for Achilles tendinopathy should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to do ESWT for Achilles tendinopathy should:
- Inform the clinical governance leads in their NHS trusts.
  - Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
  - Audit and review clinical outcomes of all patients having ESWT for Achilles tendinopathy (see section 7.1).
- 1.3 NICE encourages further research into ESWT for Achilles tendinopathy, which may include comparative data collection. Studies should clearly describe patient selection, treatment protocols, use of local anaesthesia and the type and duration of energy applied (see section 3). Studies should include validated outcome measures and have a minimum of 1 year of follow-up. NICE may update the guidance on publication of further evidence.

## 2 Indications and current treatments

- 2.1 Achilles tendinopathy is characterised by chronic degeneration of the Achilles tendon and is usually associated with injury or overuse. Symptoms include pain, swelling, weakness and stiffness over the Achilles tendon and tenderness over the heel. Achilles tendinopathy is classified as insertional or non-insertional. Insertional Achilles tendinopathy occurs at the bone–tendon junction in more active people, and non-insertional (or mid-portion) Achilles tendinopathy occurs more proximally in older, less active and overweight people.
- 2.2 Conservative treatments include rest, application of ice, non-steroidal anti-inflammatory drugs (NSAIDs), orthotic devices and splints, physiotherapy, Achilles tendon exercises or stretching, topical nitroglycerin, low-level laser therapy and injections with corticosteroid or autologous blood. Surgery may rarely be considered in patients with refractory symptoms with the aim of repairing partial tears in the Achilles tendon.

## 3 The procedure

- 3.1 Extracorporeal shockwave therapy (ESWT) is a non-invasive treatment in which a device is used to pass acoustic shockwaves through the skin to the affected area. Ultrasound guidance may be used to assist with positioning of the device. The shockwaves can be either focused or unfocused (often referred to as radial shock waves). The focused shockwaves are generated using electrohydraulic, electromagnetic or piezoelectric energy. The unfocused shockwaves are generated pneumatically.
- 3.2 Treatment protocols for ESWT vary according to the energy density and frequency of shockwaves. ESWT may be applied in a series of treatments or a single session. Local anaesthesia may be administered before treatment because high-energy ESWT ( $>0.12 \text{ mJ/mm}^2$ ) can be painful; however, there is evidence that the use of local anaesthesia may adversely influence the outcome of ESWT. Low-energy ESWT ( $\text{EFD} \leq 0.12 \text{ mJ/mm}^2$ ) can be used repeatedly and does not need local anaesthesia.

3.3 The mechanism by which this therapy might affect tendinopathy is not known.

## 4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

### Extracorporeal shockwave therapy (ESWT) for non-insertional (mid-portion) Achilles tendinopathy

- 4.1 In a systematic review and meta-analysis on ESWT (n=633), evidence for mid-portion Achilles tendinopathy (tendinopathy 2 to 6cm from the insertion into the calcaneus) was reported from 2 randomised controlled trials (RCTs) of 75 and 68 patients respectively (Rompe 2007, Rompe 2009). The RCT of 75 patients (Rompe 2007) compared ESWT (n=25) with eccentric loading exercise (n=25) and found no statistically significant effects on pain and functional outcomes at 4-month follow-up (Visual analogue scale [VAS] score standard mean difference [SMD] 0.17, 95% confidence interval [CI] -0.38 to 0.73; Victorian institute of sport assessment questionnaire–Achilles [VISA-A] score SMD 0.29, 95% CI -0.27 to 0.85; Likert scale risk ratio 1.20, 95% CI 0.64 to 2.25). The study also compared ESWT (n=25) with a 'wait and see' group (no-treatment control, n=25) and found statistically significant effects that favoured ESWT at 4-month follow-up (VAS score SMD -0.93, 95% CI -1.52 to -0.34; VISA-A score SMD -1.03, 95% CI -1.62 to -0.44; Likert scale risk ratio 0.63, 95% CI 0.40 to 1.00). The RCT of 68 patients (Rompe 2009) comparing combined ESWT and eccentric loading exercise in mid-portion Achilles tendinopathy (n=34) with eccentric loading exercise alone (n=34) found greater improvement in pain and function at 4-month follow-up (VAS score SMD -0.53, 95% CI -1.01 to -0.05; VISA-A score SMD -0.76, 95% CI -1.25 to -0.27; Likert scale risk ratio 0.40, 95% CI 0.18 to 0.91).
- 4.2 The systematic review also reported evidence from a case-control study of 68 patients (Furia 2008) comparing ESWT (n=34) with conservative treatment including rest, footwear modification, anti-inflammatory medication, and gastrocnemius-soleus stretching and strengthening (n=34) and found that ESWT

was statistically significantly better in improving pain and functional outcomes at 3-month follow-up (VAS score SMD  $-3.75$ , 95% CI  $-4.56$  to  $-2.95$ ; Roles and Maudsley score SMD  $0.20$ , 95% CI  $0.09$  to  $0.46$ ) and after follow up of at least 12 months (VAS score SMD  $-3.42$ , 95% CI  $-4.18$  to  $-2.66$ ; Roles and Maudsley score risk ratio  $0.20$ , 95% CI  $0.09$  to  $0.46$ ).

## ESWT for insertional Achilles tendinopathy

4.3 In the systematic review and meta-analysis on ESWT ( $n=633$ ), evidence for insertional Achilles tendinopathy (tendinopathy up to 2 cm from the insertion into the calcaneus) was reported from 1 RCT of 50 patients (Rompe 2008) comparing ESWT ( $n=25$ ) to eccentric loading exercise ( $n=25$ ). It found statistically significant improvement for outcomes of pain and function at 4-month follow-up (VAS score SMD  $-0.86$ , 95% CI  $-1.44$  to  $-0.27$ ; VISA-A score SMD  $-1.54$ , 95% CI  $-2.18$  to  $-0.91$ ; Likert scale risk ratio  $0.50$ , 95% CI  $0.28$  to  $0.89$ ). The systematic review also reported evidence from 1 case-control study of 68 patients (Furia 2006) comparing ESWT ( $n=34$ ) with conservative treatment including rest, footwear modification, anti-inflammatory medication, and gastrocnemius-soleus stretching and strengthening ( $n=34$ ) and found that ESWT was statistically significantly better in improving pain and functional outcomes at 3-month follow-up (VAS score SMD  $-2.42$ , 95% CI  $-3.05$  to  $-1.78$ ; Roles and Maudsley score SMD  $0.28$ , 95% CI  $0.13$  to  $0.62$ ) and after follow-up of at least 12 months (VAS score SMD  $-2.39$ , 95% CI  $-3.02$  to  $-1.76$ ; Roles and Maudsley score risk ratio  $0.28$ , 95% CI  $0.13$  to  $0.62$ ). The effect of ESWT was diminished when a local anaesthetic was administered before treatment in this study.

## ESWT for non-insertional (mid-portion) or insertional Achilles tendinopathy

4.4 In a systematic review and meta-analysis of 246 patients, evidence from meta-analysis of data from 2 RCTs (Rompe 2007, patients with mid-portion tendinopathy; Rompe 2008, patients with insertional tendinopathy) found no significant effects on pain and functional outcomes at 16-week follow-up (VISA-A score SMD  $-0.55$ , 95% CI  $-2.21$  to  $1.11$ ).

- 4.5 In the systematic review and meta-analysis on ESWT (n=633), evidence for mid-portion or insertional Achilles tendinopathy was reported from 2 RCTs of 49 and 48 patients respectively (Costa 2005, Rasmussen 2008) comparing ESWT with no treatment (placebo). The RCT of 49 patients (Costa 2005) found no significant difference between ESWT (n=22) and sham treatment (n=27) at 3-month follow-up (VAS score SMD -0.44, 95% CI -1.01 to 0.13; Functional index of lower limb activity [FILA] SMD -1.05, 95% CI -1.65 to -0.45; EQ-5D SMD -0.21, 95% CI -0.77 to 0.36). The RCT of 48 patients (Rasmussen 2008) used the same intervention as Costa 2005 but with a higher energy level and an extra treatment session. It found that patients in the ESWT group had significantly better American orthopaedic foot and ankle society (AOFAS) scores than the sham group at 3-month follow-up (SMD -0.52, 95% CI -1.09 to 0.06). The 3 prospective studies (Firdman 2008, Saxena 2011, Vulpiani 2009) included in this systematic review reported improvements in pain and functional outcomes at an average follow up of 20 to 24 months.
- 4.6 The specialist advisers listed key efficacy outcomes as pain reduction, pain relief and improved function.
- 4.7 Twelve commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

## 5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 Transient skin reddening occurred in all patients treated by extracorporeal shockwave therapy (ESWT) in 1 RCT (Rompe 2007) and in 3 patients each in the 2 case-control studies (Furia 2006 and 2008) included in a systematic review of 11 studies. Some patients reported the presence of cutaneous bruises after the applications of ESWT in the case series of 102 patients with Achilles tendinopathy (number not reported).
- 5.2 Pain during ESWT in 2 patients and transient numbness for 24 hours after ESWT

- in 1 patient was reported in a case-control study (Furia 2006) included in the systematic review of 11 studies.
- 5.3 Calf ache was reported in some patients who had eccentric loading exercise in 1 RCT (Rompe 2007, numbers not reported), and in an equal number ('the majority') of patients in both groups in another RCT (Costa 2005, numbers not reported) included in the systematic review of 11 studies.
- 5.4 Achilles tendon rupture 2 weeks after the first ESWT treatment session, associated with falls, was reported in 2 patients in 1 RCT (Costa 2005) included in the systematic review of 11 studies.
- 5.5 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers considered that the following were theoretical adverse events: persistent or worsening symptoms and damage to the soft tissues.
- 5.6 Twelve commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

## 6 Committee comments

- 6.1 The committee was informed by specialist advisers that low energy devices are now more commonly used and may be associated with less procedural pain.
- 6.2 The committee noted that patient commentary was mixed in terms of the benefits of the procedure and noted that some patients found the treatment painful.
- 6.3 The committee noted that there were occasional reports of tendon rupture in treated patients, although this can also happen when the procedure has not been used.
- 6.4 The committee found it difficult to interpret the evidence because of the diversity

of treatment protocols and comparators used, varying reported end points, and inconsistencies in use of local anaesthesia and energy type.

## 7 Further information

- 7.1 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an [audit tool](#) (which is for use at local discretion).

### Information for patients

NICE has produced information on this procedure for patients and carers ([information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-2240-6

### Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).