

National Institute for Health and Care Excellence
IP719/2 – Extracorporeal shockwave therapy for Achilles tendinopathy
Consultation Comments table
IPAC date: 8 September 2016

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
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1	Consultee 1 NHS Professional	1	<p>I have already provided this comment as part of the BOFAS Scientific Committee group. ESWT has now been around for 15 years. I agree there is legitimate debate around efficacy which warrants further research, particularly for calculating cost effectiveness for NHS recommendations. However with regards safety ESWT has been around for over 15 years - long enough to know about side effects. I am aware of only 2 achilles tendon ruptures in the literature and none in my own or other colleagues practice, which in a population of patients with Achilles tendon disease is not surprising. The other side effects are, in my experience and the literature reports, minor and transient. As such I see no need for recommending universal data collection or extra monitoring for side effects. Equally with regards consent, written documentation of risks and the evidence with regards efficacy is essential. I disagree that signed written consent needs to be obtained as this is not required for other such non-invasive procedures. ESWT is less invasive, and probably safer, than some injections and many other procedures for which verbal, documented consent is required but not written consent.</p>	<p>Please respond to all comments</p> <p>Thank you for your comments.</p> <p>1.3 recommends further research on efficacy but cost effectiveness is not in the remit of IP programme.</p> <p>Section 1.1 states <i>'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.</i></p> <p>Section 5 described the safety events from the published literature. In addition anecdotal and theoretical adverse events listed by specialist advisers are also listed in 5.5.</p> <p>The committee recommended data collection by audit because the quantity of the evidence is currently inadequate and there are significant inconsistencies in the evidence on the efficacy of the procedure. With regard to patient consent, the recommendations are intended to address the practical steps that clinicians should take to carry out the procedure safely in relation to the hospital's clinical governance arrangements, the patient consent process and the collection of data. IPAC has not specified written consent is required, but have indicated providers should implement the guidance with "special arrangements" for clinical governance, consent and audit or research.</p>

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2	Consultee 2 Healthcare Other	General	Extracorporeal shock wave therapy (ESWT) has been successfully used in soft-tissue pathologies like lateral epicondylitis, plantar fasciitis, tendinopathy of the shoulder and also in bone and skin disorders. Conclusive evidence recommending ESWT as a treatment for Achilles tendinopathy is still lacking. In plantar fasciitis as well as in calcific shoulder tendinopathy shock wave therapy is recently the best evaluated treatment option. This analysis the evidence based literature of ESWT in chronic Achilles tendinopathy. Recently published data have shown the efficacy of focused and radial extracorporeal shock wave therapy.	<p>Please respond to all comments</p> <p>Thank you for your comments.</p> <p>Section 1 of the guidance states that <i>‘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’.</i></p> <p>Published data on the efficacy of focused and radial ESWT (Mani Babu 2015) has been included in table 2 in the overview.</p>

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3	Consultee 1 NHS Professional	4	In the third paper a review of 20 studies were identified, with 13 providing sufficient data to compute effect size calculations. The energy level, number of impulses, number of sessions, and use of a local anesthetic varied between studies. Additionally, current evidence is limited by low participant numbers and a number of methodological weaknesses including inadequate randomization. Moderate evidence indicates that ESWT is more effective than home training and corticosteroid injection in the short (<12 months) and long (>12 months) term for GTPS. Limited evidence indicates that ESWT is more effective than alternative nonoperative treatments including nonsteroidal anti-inflammatory drugs, physical therapy, and an exercise program and equal to patellar tenotomy surgery in the long term for PT. Moderate evidence indicates that ESWT is more effective than eccentric loading for insertional AT and equal to eccentric loading for midportion AT in the short term. Additionally, there is moderate evidence that combining ESWT and eccentric loading in midportion AT may produce superior outcomes to eccentric loading alone.	Please respond to all comments Thank you for your comments. Evidence from Mani Babu et al (2015) has been included in section 4 of the guidance and also table 2 in the overview. The committee reviewed this paper but did not feel it changed their recommendation.
4	Consultee 1 NHS Professional	General	Extracorporeal shock wave therapy is an effective intervention and should be considered for GTPS, PT, and AT particularly when other nonoperative treatments have failed.	Thank you for your comments. This guidance is on the treatment of Achilles tendinopathy only.

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5	Consultee 1 NHS Professional	General	<p>Add the following literature:</p> <ol style="list-style-type: none"> 1. Gerdesmeyer L, Mittermayr R, Fuerst M, Al Muderis M, Thiele R, Saxena A, Gollwitzer H. Current evidence of extracorporeal shock wave therapy in chronic Achilles tendinopathy. <i>Int J Surg.</i> 2015 Dec;24(Pt B):154-9. 2. Kvalvaag E, Brox JI, Engebretsen KB, Sjøberg HL, Bautz-Holter E, Råde C. Is radial Extracorporeal Shock Wave Therapy (EWST) combined with supervised exercises (SE) more effective than sham rESWT and SE in patients with subacromial shoulder pain? Study protocol for a double-blind randomised, sham-controlled trial. <i>BMC Musculoskelet Disord.</i> 2015 Sep 11;16:248. 3. Mani-Babu S, Morrissey D, Waugh C, Screen H, Barton C. The effectiveness of extracorporeal shock wave therapy in lower limb tendinopathy: a systematic review. <i>Am J Sports Med.</i> 2015 Mar;43(3):752-61. 4. Notarnicola A, Maccagnano G, Tafuri S, Fiore A, Margiotta C, Pesce V, Moretti B. Prognostic factors of extracorporeal shock wave therapy for tendinopathies. <i>Musculoskelet Surg.</i> 2016 Apr;100(1):53-61. 	<p>Please respond to all comments</p> <p>Thank you for your comments.</p> <p>Reference 1 (Gerdesmeyer et al 2015) has been picked up in our update search and has been added to appendix A in the overview.</p> <p>Reference 2 (Kvalvaag 2015) is a protocol on EWST for a different indication and is outside the scope of this review. Therefore will not be considered.</p> <p>Reference 3 (Mani Babu 2015) has been included in table 2 in the overview.</p> <p>Reference 4 (Notarnicola 2016) will be not considered for this review as patients with different tendinopathies were included in the study.</p> <p>The committee reviewed the additional relevant papers but did not feel they changed their original recommendation.</p>

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