

**National Institute for Health and Clinical Excellence**

**773 – Extracorporeal shockwave therapy for refractory tennis elbow**

**Consultation Comments table**

**IPAC date: Friday 15<sup>th</sup> May 2009**

*Please note that some comments from Consultee 2 relate to all three shockwave therapies.*

*The comments have been included in each table in their entirety and the response clearly indicates which procedure the comment applies to.*

<b>Com. no.</b>	<b>Consultee name and organisation</b>	<b>Sec. no.</b>	<b>Comments</b>	<b>Response</b> <b>Please respond to all comments</b>
1	Consultee 1 NHS Professional	1	It is agreed that further research on ESWT in this condition is necessary. This is mainly to identify the most suitable patient population for its use. The current evidence base is adequate to support its use, but given that many cases will settle without intervention, it should be reserved for those cases with symptoms beyond 3 months - as indeed should be the case for steroid injections.	Thank you for your comment. Section 1.3 of the guidance encourages further research with clearly described patient selection and treatment protocols. This guidance describes the use of ESWT for tennis elbow in patients who are refractory to conservative treatments, including corticosteroid injection.
2	Consultee 3 BUPA employee	1	Bupa agrees that the evidence is inadequate to support routine use. Specifying the use of validated outcome measures and a minimum of 1 year follow up is useful.	Thank you for your comment.
3	Consultee 1 NHS Professional	2.1	Corticosteroid injection has no proven benefit in outcome studies of tennis elbow. The Committee should consider this when assessing the relative benefit of interventions. In comparison, the published literature on ESWT shows beneficial effects. The implication is therefore that ESWT should be considered in preference to steroid injection.	Thank you for your comment. Corticosteroid injection is generally accepted as one of the primary treatments for tennis elbow. This. The IP programme does not compare the efficacy and safety of interventions against comparator interventions.

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4	Consultee 3 BUPA employee	2.1	No comment, thank you	Thank you for your comment.
5	Consultee 1 NHS Professional	2.2	Animal and human studies indicate three main mechanisms: denervation, stimulation of healing and decalcification. Calcium in soft tissue conditions can be categorised as that in acute calcific tendinitis or dystrophic calcification - commonly noted in chronic soft tissue injuries and is considered a source of pain. The treatment rational is greater for ESWT than surgery and steroid injection, which has little logical basis for use in chronic conditions.	Thank you for your comment. The IP programme does not compare the efficacy and safety of interventions against comparator interventions.
6	Consultee 2 Manufacturer	2.2.2	Furthermore, all documents state that "Local anaesthesia may be used because high-energy ESWT can be painful". This should be interpreted as lack of knowledge or neglect of what is known about the negative influence of local anaesthesia on the actions of extracorporeal shock waves on the musculoskeletal system. The negative impact of local anaesthesia on the efficacy of extracorporeal shock wave treatment was already addressed in detail by Rompe and Maffuli (Br Med Bull 2007; 83: 355–378) (pp. 373 f):  "One of the most interesting questions is whether application of an LA [ <i>local anaesthesia</i> ] has a negative effect on the outcome of tendinopathies after SWT. <sup>47</sup> [Rompe et al., Br Med Bull 2007;81–82: 183–208]. These interventions are sometimes used as the treatment, which is	Thank you for your comment. There is insufficient evidence on the effect of local anesthesia and energy type on ESWT. Section 1.3 and 2.5.1 of the guidance will be changed.  The referenced papers will be added to Appendix A of the appropriate overview, expect the non peer-reviewed study. The NICE IP methods guide highlights hat efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee.

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			<p>uncomfortable and sometimes painful. Recently, two interesting papers were published, comparing the use of SWT with and without local anaesthesia in patients with chronic plantar fasciopathy.</p> <p>Labek <i>et al.</i><sup>48</sup> [<i>Z Orthop Ihre Grenzgeb</i> 2005; 143: 240–246] reported that they had enrolled 60 patients with a chronic plantar fasciitis in a triple-arm randomized trial. Patients were randomly assigned to receive repetitive low-energy SWT without local anaesthesia (group I) or repetitive SWT (energy flux density doubled) with local anaesthesia (group II) or repetitive low-energy SWT with local anaesthesia (group III). At 6 weeks, there was significant improvement in pain during first steps in the morning in all groups, by 4.2 points in group I, by 2.6 points in group II and by 2.4 points in group III. A reduction in pain of at least 50% was achieved in 60% of patients in group I, in 36% of patients in group II and in 29% of patients in group III. In conclusion, at 6 weeks, success rates after low-energy SWT with local anaesthesia were significantly lower than that after identical low-energy SWT without local anaesthesia.</p> <p>A current randomized-controlled study from Germany<sup>49</sup> [<i>Rompe et al., J Orthop Res</i> 2005; 23: 931–941] confirmed their observation. The average pain score for patients who received SWT without local</p>	

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			<p>anaesthesia (group I) was 6.9 points at baseline and 2.2 points at 3 months. The average pain score for patients who received SWT with local anaesthesia (group II) was 6.7 points at baseline and 4.1 points at 3 months. At 3 months in group I, 67% of patients achieved at least a 50% reduction in pain, compared with 29% of patients in group II.</p> <p>In the only human experiment in this field so far, Klonschinski <i>et al.</i><sup>50</sup> [<i>Presentation at the 7th EFORT Congress, 4–7 June 2005, Lisbon, Portugal</i>] investigated whether the biological effects of SWT differ between application with and without an LA in humans. SWT was applied to the skin after local pre treatment either with lidocain cream LA or without LA to the corresponding location of the contralateral limb. Increasing energy flux density led to a significant increase of pain. LA significantly attenuated this pain and significantly inhibited C-fibre activity, with a significant reduction in local vasodilation. Reduction in vasodilation correlated positively with the amount of energy flux density applied. SWT without LA resulted in a dose-dependent lower pressure pain threshold, i.e. sensitization, than did SWT with LA. Together, SWT in a dose-dependent fashion activated and sensitized primary afferent nociceptive C-fibres in human skin. LA substantially altered the biological responses after SWT."</p>	

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7	Consultee 3 BUPA employee	2.2	No comment	Thank you for your comment.
8	Consultee 1 NHS Professional	2.3	There is adequate evidence in the literature to support its use - in particular when compared to other treatments that are considered by NICE to be adequate to be used as standard approaches.	Thank you for your comment. NICE supports use of this procedure under the conditions set out in section 1 of the guidance. The Committee's judgement of the evidence and Specialist Advice did not find that safety and efficacy were sufficiently established for the procedure to be used unconditionally.
9	Consultee 3 BUPA employee	2.3	Might 2.3.4 say "...key outcomes as sustained (eg at least 12 months after treatment) relief of symptoms....."	Thank you for your comment. Section 2.3.4 is the opinion of the Specialist Advisers.
10	Consultee 1 NHS Professional	2.4	Rupture of the CET is extremely rare and it is questionable that ESWT would be responsible. It is more likely to be due to repeated steroid injections performed prior to ESWT, as they cause tissue atrophy.	Thank you for your comment. The overview provides more details about individual studies and Specialist Advisor opinion's.
11	Consultee 3 BUPA employee	2.4	No comment	Thank you for your comment.
12	Consultee 1 NHS Professional	2.5	Further research should focus on best treatment regimes. Efficacy has been well demonstrated.	Thank you for your comment. Section 1.3 of the guidance encourages further research.
13	Consultee 2 Manufacturer	2.5.2	Para 2.5.2 reads identical in all three documents addressing "Plantar fasciitis".	Thank you for your comment. This was a mistake and has been corrected.
14	Consultee 3 BUPA employee	2.5	In view of what you say in 2.5, should 1.1 end "only be used in the context of research"?	Thank you for your comment. The Committee considered a recommendation for use in the context of research only but considered that the evidence on efficacy and safety was sufficiently strong to recommend use under special arrangements.

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15	Consultee 2 Manufacturer	General	<p>I read with interest you IPAC review for Extracorporeal Shockwave Therapy for Plantar Fasciitis, Achilles Tendonopathy and Tennis Elbow, however, in my view these documents are of little help to assess the clinical efficacy of extracorporeal shock wave treatment of chronic plantar fasciitis, Achilles tendonitis and tennis elbow. There are several key points I would like to highlight pertaining to IP252/2, IP773 and IP719.</p> <p>Primarily the summary document does not provide an accurate and balance review of ESWT. This is in principle due to the fact that there is evidence that the NICE committee used the same text three times and just exchanged some single words and a few paragraphs, in the wrong manner for the public consultation documents. (Please see detailed comments below).</p>	Thank you for your comment. The Committee recommendations are similar for all three shockwave therapies, but not the same. There are differences throughout the documents demonstrating that the Committee did consider the procedures separately.
16	Consultee 2 Manufacturer	General	There was no differentiation between radial and focused low energy and high energy shockwave therapy. There are clear differences and treatment protocol requirements and safety for all stakeholders in providing this treatment prior to surgery.	Thank you for your comment. The Committee discussed these issues and decided that there was insufficient evidence to produce recommendations on different types of energy. The Committee has recommended research to determine the best treatment protocols. A further statement about the effect of energy type on ESWT will be added to 1.3 and 2.5.1
17	Consultee 2 Manufacturer	General	The data reviewed reflected a lack of knowledge and awareness of the use of local anaesthesia, clearly the evidence suggests it's use has a negative effect in conjunction with the treatment, yet your review board included these such trials in your review, clearly this will influence the overall results	Thank you for your comment. The Committee has recommended research to determine the best treatment protocols. A statement about the effects of local anaesthesia on ESWT will be added to 1.3 and 2.5.1

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18	Consultee 2 Manufacturer	General	In summary, these documents cannot be assessed as a scientifically sound evaluation of the current knowledge about efficacy of extracorporeal shock wave treatment of chronic plantar fasciitis, Achilles tendonitis and tennis elbow. An immediate re-review appears favourable for public consultation.	Details of the criticism have been considered and changes made where the Committee felt it was appropriate.
19	Consultee 2 Manufacturer	General	<p data-bbox="678 507 1279 536"><i>Please see separate comment 19.</i></p> <ol data-bbox="725 772 1279 1414" style="list-style-type: none"> <li data-bbox="725 772 1279 970">1. Buch M, Knorr U, Fleming L, Theodore G, Amendola A, Bachmann C, Zingas C, Siebert WE. Extracorporeal shockwave therapy in symptomatic heel spurs. An overview. Orthopade;31:637-644.</li> <li data-bbox="725 975 1279 1377">2. Gerdesmeyer L, Frey C, Vester J, Maier M, Weil L Jr, Weil L Sr, Russlies M, Stienstra J, Scurran 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 [Epub ahead of print Oct 1].</li> <li data-bbox="725 1382 1279 1414">3. Kudo P, Dainty K, Clarfield M,</li> </ol>	<p data-bbox="1301 507 2121 635">Thank you for your comment. There is insufficient evidence on the effect of local anesthesia and energy type on ESWT and section 1.3 and 2.5.1 of the guidance will be changed to reiterate this.</p> <p data-bbox="1301 683 1462 711">References:</p> <ol data-bbox="1491 751 2121 1423" style="list-style-type: none"> <li data-bbox="1491 751 2121 810">1. This is not included in the overview as it falls outside the scope of the procedure.</li> <li data-bbox="1491 815 2121 874">2. Reference number 3 in overview for IP 252/2 EWST for refractory plantar fasciitis.</li> <li data-bbox="1491 919 2121 1015">3. This paper is in Appendix A of the overview for IP 252/2 ESWT for refractory plantar fasciitis.</li> <li data-bbox="1491 1059 2121 1187">4. This paper did not appear in our original literature search. It will be included in Appendix A of the overview for IP252/2 ESWT for refractory plantar fasciitis.</li> <li data-bbox="1491 1232 2121 1295">5. Reference number 1 in overview for IP 252/2 EWST for refractory plantar fasciitis.</li> <li data-bbox="1491 1334 2121 1423">6. This paper was excluded from the overview for IP 252/2 EWST for refractory plantar fasciitis but will be added to Appendix A.</li> </ol>

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			<p>Coughlin L, Lavoie P, Lebrun C. Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracorporeal shockwave therapy (ESWT) device: a North American confirmatory study. J Orthop Res 2006;24:115-123.</p> <p>4. Ogden JA, Alvarez R, Levitt R, Cross GL, Marlow M. Shock wave therapy for chronic proximal plantar fasciitis. Clin Orthop Relat Res 2001;(387):47-59.</p> <p>5. Ogden JA, Alvarez RG, Levitt RL, Johnson JE, Marlow ME. Electrohydraulic high-energy shock-wave treatment for chronic plantar fasciitis. J Bone Joint Surg Am 2004;86-A:2216-2228.</p> <p>6. Rompe JD, Furia J, Weil L, Maffulli N. Shock wave therapy for chronic plantar fasciopathy. Br Med Bull 2007;81-82:183-208.</p> <p>7. Theodore GH, Buch M, Amendola A, Bachmann C, Fleming LL, Zingas C. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. Foot Ankle Int 2004;25:290-297.</p>	<p>7. This paper is in Appendix A of the overview for IP 252/2 ESWT for refractory plantar fasciitis.</p>

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*