Extracorporeal Shock Wave Therapy

for treating musculoskeletal conditions.

First Update.

By

WCB Evidence Based Practice Group

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Clinical Services,
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Background:

Extracorporeal Shock Wave Therapy (ESWT) was introduced in the early 1990s as a spin-off of urological lithotripsy[(1)]. Since then, ESWT has been applied to treat various musculoskeletal conditions, including lateral epicondylitis, plantar fasciitis, calcific tendonitis of the shoulder, delayed union and non-union of bone fractures.

In December, 2002, the Evidence Based Practice Group (EBPG) published a systematic review and the result of a pilot study conducted among chronic lateral epicondylitis claimants treated with Extracorporeal Shock Wave Therapy[(2)]. At the time, the EBPG concluded that:……..

- at present the literature is too 'scattered' with too many variables being present to suggest this modality of treatment is effective

- the WCB should not be the 'leading edge' in accepting new health technologies (assessment, treatment or otherwise) until the evidence is relatively clear that they are of benefit and such technologies are accepted and established within the medical / surgical communities

- the WCB should re-view this topic as the literature develops (which is quite rapidly doing so).

In June 2004, the issue regarding the reimbursement status of ESWT for treating various chronic musculoskeletal conditions and lateral epicondylitis, in particular, has been brought up again by the Sonorex® provider to the attention of the Chief Executive of the WCB of BC. Hence, the EBPG feels the need to update the 2002 systematic review on the effectiveness of ESWT in treating various chronic musculoskeletal conditions.

It should be noted that there are two different kind of ESWT machines available based on the level of energy applied, i.e. **high** (e.g. OssaTron®) or **low** (e.g. Sonocur®) **energy level**. Typically, a high energy protocol consists of a single treatment of high energy shock waves (1300mJ/mm2). This painful procedure requires anesthesia. Typically, a low energy protocol consists of multiple treatments, spaced one week to one month apart, in which a lower dose of shock waves is applied (e.g. 1405mJ/ mm2 over three sessions). This protocol does not require anesthesia. The objective of this paper is to conduct a systematic review on the effectiveness of ESWT, with emphasize on **low energy** ESWT, in treating lateral epicondylitis, plantar fasciitis and calcific tendonitis of the shoulder.

Methods:

Literature searches were undertaken on commercial medical literature databases (up to week 2 June 2004), including Cochrane Database of Systematic Reviews, ACP Journal Club, Database of Abstracts of Reviews of Effectiveness (DARE), Cochrane Central Trial Registry, BIOSIS, CINAHL, EMBASE and Ovid MEDLINE. Searches were also done on other databases including Bandolier, the US Agency for Healthcare Research and Quality and the England and Wales National Institute for Clinical Excellence; websites of members of the International Network of Agencies for Health Technologies Assessment (including CCOHTA Canada, the US Department of Veterans Affairs, the UK, New Zealand, Australia, Sweden, Austria, the Netherlands and Denmark); websites of BC, Alberta and the Quebec Office of Health Technology Assessment; websites of other WCBs in Canada (including Yukon and Northwest Territories, Alberta, Saskatchewan, Manitoba, Nova Scotia, Newfoundland, PEI, Quebec and Ontario) and in the US (Washington State and Colorado); private health insurance companies (including Aetna, Blue Cross Blue Shields, Regence Group, Humana, Permanente Medical group, Tuft and Western Health Advantage)

Searches were undertaken in order to identify published reviews or systematic reviews, controlled trials, clinical trials or randomized controlled trials. These searches were done by employing a combination of medical subject heading and keywords of; (extracorporeal shock wave therapy OR extracorporeal shockwave treatment OR sonocur OR sonorex) AND (lateral epicondylitis OR plantar fasciitis OR shoulder calcific tendonitis OR shoulder calcific tendonitis OR musculoskeletal).

Inclusion criteria: publications were selected if they involved human subjects. There was no restriction placed on the year of publication. Publications were restricted to those where at least the abstract was available in English.

Exclusion criteria: for the review or systematic review, the publications were excluded if the methodology used to evaluate the quality of the primary studies were not transparent. By definition the application of ESWT on delayed union or non-union fractures and renal calculi were excluded.

Appendix 1 provides the interpretation of level of evidence as adopted by the EBPG.

Fourteen (one is an up-date[11] and four in German language[12-15]) reviews and systematic reviews[1,3-15] on the application of ESWT for musculoskeletal conditions, dating from 1998 - 2004, were found. With the exception of the reviews/systematic reviews published in German language[12-15], 10 reviews/systematic reviews were fully retrieved and appraised. German language articles were summarized based on the information available from the abstracts. Published randomized controlled trials (RCT) (level 1 evidence) were then checked with the primary studies included in the systematic reviews. In this report, current RCTs that were published after the inclusion criteria of the most current published systematic reviews[11] were then appraised separately and presented, if applicable after critical appraisal.

Appendix 1 provides the information on level of evidence that is adopted by the EBPG. This report focuses on available level 1 evidence found on this topic.

Results.

A. Systematic reviews (level 1 evidence):

A.1. Articles in German:

1. Heller and Niethard[14] (1998) published the earliest meta analysis on the effectiveness of ESWT in treating various musculoskeletal conditions, including plantar fasciitis, lateral epicondylitis, calcific tendonitis and non-union. 105 papers on the area of ESWT and locomotor system were retrieved and 55 papers (4825 cases) were appraised according to the critical appraisal criteria developed by the American Association of Spine Surgery. Only 24 papers (1585 cases) (33%) were considered to be of sufficient quality according to the American Association of Spine Surgery type A and B criteria. The authors stated that majority of papers, especially in the area of non-union and other tendonitis, hardly lived up to scientific standards. No serious complications were reported. The authors concluded that recent increase in the use of ESWT had no scientific indication in numerous cases as conservative methods are not used consequently.
2. Fritze[15] (1998) conducted a 'selective review' on the application of ESWT in orthopaedics cases. The author searched the Medline database for articles on the efficacy of ESWT in treating non-unions, calcifying tendonitis of the shoulder, lateral epicondylitis and plantar fasciitis. 25 articles were retrieved. In conclusion, Fritze emphasized the need of properly conducted double blind RCTs to confirm the efficacy of ESWT. Further, the author suggested the importance of establishing a rational and standardized dosing of ESWT.
3. Boddeker and Haake[16] (2000) conducted a 'systematic' literature review on the effectiveness of ESWT in treating lateral epicondylitis. 20 articles were retrieved and appraised according to the biometrical criteria for the conduct of therapeutic trials. None of these studies fulfilled all the criteria. The authors concluded that the efficacy of ESWT in treating lateral epicondylitis could neither be confirmed nor excluded.
4. Haake et al[17] (2002) conducted a 'systematic review' on the effectiveness of ESWT in treating lateral epicondylitis. 20 studies were identified and only 2 were judged to be of good quality. The authors concluded that the effectiveness of ESWT in treating lateral epicondylitis has not been proven. The authors suggested that ESWT should not be applied clinically as a matter of course but only as a part of high quality studies with an adequate control group, blinding and appropriate follow-up. Due to pain incurred by patients given ESWT, the authors suggested that further studies should check on the status of the blinding of the patients.

It should be noted that the EBPG cannot provide/evaluate the proper level of evidence on these four reviews that are available in German due to the lack of information, especially surrounding study's methodology, which was available in the English abstracts.

A.2. Articles in English:

1. Wild et al[1] (2000) from the Institute of Technology Assessment at the Austrian Academy of Sciences conducted an assessment of emerging technology in the form of a systematic review (level 1 evidence) on the application of ESWT in orthopedics, including calcifying tendonitis of the shoulder, plantar fasciitis, lateral epicondylitis and fracture non-union. This article was based on the original systematic review published in German[18]. The purpose of this review was to provide information for health insurance companies on whether to reimburse ESWT and to counsel the Austrian Ministry of Health whether the Ministry should invest in the ESWT machines.

   Three hundred articles, representing all available information on ESWT at the time were collected. The authors did not mention the databases that were searched, criteria of inclusion and exclusion, date of publication (probably up to 1996) and the review methods. Interestingly, the authors stated that the conclusion of this review was based mainly on 2 unpublished systematic reviews that had been done by the German Medical Services of the Health Insurers (representing the health insurers point of view) and the Swiss Evaluation Study conducted by Dubs et al (representing the orthopaedists point of view).

   Wild et al concluded that at the time the quality of the published studies on the application of ESWT on various conditions were severely deficient. Unless more research of good quality was undertaken, the reluctant attitude of the health decision makers to reimburse ESWT was not likely to change.

   It should be noted that the English version of this systematic review did not provide clear information on the methodology employed by the authors in conducting this review.

2. The Cochrane based systematic review (level 1 evidence) on the effectiveness of shock wave therapy for lateral elbow pain (tennis elbow) by Buchbinder et al[3] (2001) was the basis of the previously published review on ESWT conducted by the EBPG[2]. This is a Cochrane standard review on the effectiveness and safety of ESWT for patients with tennis elbow.

   In this review, various databases (from 1966 to 2001), including Medline, Embase, CINAHL and SciSearch were searched by employing the Cochrane Musculoskeletal Review Groups to identify all possible RCTs in combination with keywords to identify tennis elbow. Inclusion and exclusion criteria were defined. Article selection, review process and data extraction were clearly described. Nineteen published articles were identified. Seventeen studies were excluded, mainly due to the fact that these studies were not RCTs. Two randomized placebo controlled trials were included in this systematic review.

   Both RCTs were similar in characteristics of the study population, including the inclusion criteria. However, one trial demonstrated highly significant differences in favor of ESWT for all outcome measurements, including pain at rest, pain with resisted wrist extension and pain with resisted middle finger extension, while the other trial did not show any difference between groups for any of the measured

endpoints. The RCT which showed significant differences was lacking in quality, namely an unclear randomization process, as well as the data were not analyzed according to 'intention to treat' principle, as compared to the RCT which showed no difference. Interestingly, when the results of the 2 RCTs were pooled in a meta-analysis, the positive results from one of the RCT diminished. The pooling of the 2 RCTs showed that there was no significant difference between patient with lateral elbow pain treated with ESWT and placebo with regard to pain with pain at rest, pain with resisted wrist extension, pain with resisted middle finger extension at 6, 12 and 24 weeks.

Cautiously, Buchbinder et al concluded that the effectiveness of ESWT in treating lateral elbow pain was unclear. Further trials were needed to clarify the value of ESWT for lateral elbow pain.

The most common side effects of the ESTW identified in one of the study included transitory reddening of skin (21.1%), pain (4.7%), small haematomas (3.5%), migraine (1.5%) and syncope (1.1%).

It should be noted that this is a Cochrane based quality systematic review in which the authors rigorously followed an established methodology in conducting systematic reviews.

3. In 2001, Boddeker et al[4] published a systematic review on the quality of study design employed (biometric evaluation) in the conduct of studies in the effectiveness of ESWT in treating plantar fasciitis. The authors also intended to provide a comprehensive survey of those published in English and German according to sound methodological criteria.

Boddeker et al searched Medline and the Cochrane Library (up to August 2000) for English and German full articles (abstracts were excluded) on clinical trails of ESWT in patients with heel spurs or plantar fasciitis. Manual searches were undertaken based on references available from retrieved articles. Biometric evaluation was done based on the criteria developed by Schäfer et al[4]. These criteria have been supported by the German Society of Medical Informatics, Biometry and Epidemiology, by the German Region of the International Biometric Society, and by the German Society of Social Medicine and Prevention.

Twenty one articles were identified, 7 articles showed duplication, as such only 17 articles were reviewed. None of these 17 articles fulfilled all the criteria for good quality clinical trials developed by Schäfer et al. The one article, by Rompe et al[4] (in German language) fared best with regard to the biometric evaluation. Rompe et al showed that ESWT was significantly better with regard to pain and subjective improvement at 6 weeks and 12 weeks. However, it should be noted that the study was only single blinded (either patient or investigator) and the study also showed that after 1 year ⅓ of the control subjects improved significantly.

Boddeker et al concluded that the study by Rompe et al provided preliminary evidence on the effectiveness of ESWT in treating plantar fasciitis but, because of the methodological problems inherent in all of the evaluated studies, the effectiveness of ESWT could neither be confirmed nor excluded on the basis of the available data.

It should be noted that Boddeker et al followed a clear and thorough methodology in conducting this systematic review.

4. Ogden et al[5] (2001) up-dated a previous meta analysis conducted by Heller and Niethard[12] in 1998, in particular, due to the vast amount of new research published after 1997, development of focus groups on ESWT and their subsequent publications (such as the International Society for Musculoskeletal Shock Wave Therapy) and the current approval given by the US Food and Drug Administration for ESWT to treat certain musculoskeletal conditions. Expanded classification schemes proposed by the American Association for Spine Surgery was employed in classifying study designs in the published literature on the subjects (the original classification scheme was employed by Heller and Niethard). In this, rather complicated and not necessarily clearly explained criteria, expanded scheme, studies were categorized into type A to H according to various criteria such as time direction, availability of controls, follow-up data, recall of patients and podium presentations. For example, type A studies were prospective randomized, double blind cross over, statistically validated differences between patients who receive a placebo and follow-up studies of sufficient scope and duration, with all patients being treated by exactly the same protocols; type B studies were defined as prospective study with appropriate control group, non randomized, adequate analysis and follow-up of sufficient scope and duration in which neither study subjects nor treating and evaluating physicians were blinded to actual treatment and the treating and evaluating physicians maybe the same individual; type C were prospective studies without a control group, but with adequate analysis and follow-up of sufficient scope and duration and type F were retrospective data analysis studies that might include patients treated by one or more physicians, and often have variations in treatment that the patient received, which might or might not involve an attempt to actually assessed the patients to obtain accurate, up to date outcome data, and might include meta analysis and evidence based medicine reviews.

   The authors did not provide information on data sources, search criteria, inclusion-exclusion criteria, review procedures and the meta analysis procedure. The 'meta analysis' was limited to the application of ESWT in treating plantar fasciitis, lateral epicondylitis, delayed union and non union, calcific tendonitis of shoulders, other enthesopathies and additional skeletal applications.

   There was no report on the number of studies retrieved, reviewed and included in this analysis (the authors provided the number of patients, based on reference numbers quoted in each disease category, the number of primary research included might be extrapolated). Further, there was no information on individual primary studies provided in this 'meta analysis' to provide the opportunity for independent analysis by the reader

   It should be noted that this 'meta analysis' lacked transparency in its methodology and provided no evidence on its search strategy for primary research on the subject. The primary study classification scheme (that relate to the level of evidence) employed is confusing and may contradict the current widely adopted study design/level of evidence scheme (type C).

5. The England and Wales National Institute for Clinical Excellence (NICE) conducted a systematic review on the effectiveness of ESWT in treating calcific tendonitis[6] (2002).

A systematic search on various databases (from inception until October 2002), including Medline, Premedline, EMBASE, Current Contents, Pub Med, Cochrane Library and Science Citation Index, using Booleans search terms was conducted. Other databases, including The York Centre for Reviews and Dissemination database, Clinicaltrials.gov, National Research Register, SIGLE and Grey Literature Reports, relevant online journals and the Internet were also searched. There was no language limitation in these searches. Searches followed protocols developed by NICE in conducting rapid reviews. There was no limitation on the primary study design to be included in this rapid review. However, if there was ≥ 5 RCTs only these were reported. Non-English papers were included if they contained safety and efficacy data and were considered to add substantively to the English language evidence base. Five RCTs were identified, retrieved and included in this rapid review (3 English-language RCT, 1 foreign language RCT and 1 quasi RCT). The search also revealed that at the time there was no registry or trial being performed on the application of ESWT among patients with calcific tendonitis.

Four of these trials showed that ESWT treated patients had increased function and a reduction in pain compared to the control groups. However, these studies suffered from various methodological weaknesses especially in their randomization practices that might lead to bias in outcomes. Further, the effect of dose of energy used on efficacy outcomes was unclear. The Specialist Advisor Group, from the British Orthopaedic Association, examining the evidence concluded that the efficacy of ESWT in treating calcific tendonitis was still unclear. Few complications, including subcutaneous haematoma (most common), aseptic necrosis of the humeral head and tendon disruption, were reported in the literature. It was not known whether this was because complications were uncommon or because complications were not well reported in the studies being reviewed.

It should be noted that this rapid review was conducted in adherence to a comprehensive and methodologically rigorous protocol developed by the NICE group.

6. The Technology Evaluation Center at the Blue Cross Blue Shield Association (TEC-BCBS) in the US conducted a systematic review on ESWT for musculoskeletal indications (2002)[7]. The purpose of this review was to investigate whether ESWT improved pain and functioning for patients with chronic musculoskeletal conditions that were unresponsive to conservative treatments. Typically, Blue Cross - Blue Shield Technology Assessment makes conclusions based on 5 categories, including that:

- technology must have final approval from appropriate governmental regulatory bodies
- the scientific evidence must permit conclusions concerning the effect of the technology on health outcomes

- the technology must improve health outcome
- the technology must be as beneficial as any established alternatives and
- the improvement must be attainable outside the investigational settings.

The authors searched Medline and Current Content, from 1980 - March 2002, by employing keywords: (ESWT OR shock waves OR extra-corporeal shock wave therapy OR OssaTron) AND (plantar fasciitis OR heel spur OR calcaneal spur OR musculoskeletal OR tendonitis OR non-union OR fractures). The search was limited to English language primary researches on human subjects. Manual searches were done on bibliographies of selected references, Cochrane Reviews by Crawford et al[9] and prior technology assessment by Blue Shield California. 85 citations were found. The abstracts of these articles were reviewed and those relevant articles were reviewed in full. Studies were included in this review if it was published in peer-reviewed English language journals, patient population of individuals with chronic musculoskeletal disorders unresponsive to conservative therapy, study design was prospective controlled trial in which one group was treated with ESWT and the other with placebo or alternative treatments, reported quantifiable pre- and post-treatment measurements of pain, disability and/or functional status, and it involved at least 10 patients in each group. Six articles, 3 studies on plantar fasciitis and 3 studies on tendonitis of the shoulder, met these inclusion criteria.

The 3 studies on plantar fasciitis (total of 96 patients with heel spur and 260 patients without heel spur) were rated fair (i.e. did not meet all quality criteria but was not 'fatal'). All three studies reported that ESWT led to superior improvement on pain and activity scales as compared to sham ESWT. Even though these 3 studies had methodological flaws, the authors concluded that ESWT might be efficacious in reducing heel pain and improving activity for patients with chronic plantar fasciitis that was unresponsive to prior treatments. However, it should be noted that these studies employed OssaTron® which is categorized as **high energy level** extracorporeal shock wave therapy as compared to Sonocur® which is a **low energy level** extracorporeal shock wave therapy.

The three studies on tendonitis of the shoulder involved 199 patients. Only one of the 3 studies was a randomized, double blind trial and it was rated as 'good' (i.e. meets all quality criteria). The other two studies were non-randomized and were rated as 'poor' (i.e. these studies had 'fatal' flaws such as inadequate randomization and high loss of follow-up). The only 'good', randomized double blind trial showed that both groups of patients with shoulder tendonitis showed improvement on the pain and functional status measures. However, there was no significant difference between the ESWT treatment group and the placebo groups. In the 'poor' rated studies, the ESWT group showed statistically greater improvements as compared to the non ESWT group with regard to pain and functional outcomes.

Most of the included studies did not report adverse events related to ESWT treatments. Adverse events that were reported included failure of the device, local trauma (e.g. swelling, bleeding), neurological symptoms (primarily numbness and/or tingling at the treatment site) and local pain. The incidence of adverse events reported in one of these studies was 6.5% for ESWT and 4.1% for sham ESWT. All of these adverse events resolved without any residual problem.

The TEC-BCBS team concluded that it is likely that ESWT is efficacious in reducing heel pain and improving activity for patients with chronic plantar fasciitis that is unresponsive to prior treatments. With regard to shoulder tendonitis, the team concluded that there is not sufficient evidence to suggest ESWT is of benefit to patients with chronic shoulder tendonitis unresponsive to prior treatments. With regard to their conclusion on the effectiveness of ESWT in treating plantar fasciitis, once again the EBPG would like the reader to be aware that, the device being tested was of the **high energy** type of ESWT (OssaTron®).

7. Ogden et al[8] (2002) conducted another meta analysis on the effectiveness of ESWT for chronic proximal plantar fasciitis which was an update, essentially of a previously published 'meta analysis' by Heller and Niethard[12] in 1998.

The authors searched the Medline database from 1990 to 2000 for studies applying ESWT for musculoskeletal conditions, particularly plantar fasciitis. There was no restriction with regard to language. Manual searches were conducted based on cited references in the individual papers. Searches on book titles were also done in order to identify topics on clinical applications of ESWT.

The same expanded classification scheme proposed by the American Association for Spine Surgery was employed in categorizing study design. The authors did not mention any specific methodology on how the meta analysis would be conducted (as it was in the previous meta analysis[5]). Further the results were presented in narrative format.

This 'meta-analysis' has serious methodological flaws as compared to internationally recognized standards and as such will not be commented on further.

8. Crawford and Thompson[9] (2003) conducted a Cochrane based systematic review on the effectiveness of available interventions for treating plantar fasciitis. The study was conducted according to rigorous criteria set up by the Cochrane Musculoskeletal Injury Group. The purpose of the review was to identify and evaluate available evidence on the effectiveness of treatments for plantar fasciitis.

The authors searched the Cochrane Musculoskeletal Injuries Group specialized registries (on available reviews and protocols, up to September 2002), the Cochrane Central Register of Controlled Trials (on primary controlled trial studies), Medline (1966 - Sept 2002), EMBASE (1988 to Sept 2002). Manual searches were also done including on reference list of articles and dissertations, as well as 4 podiatry journals. Contact with all UK schools of podiatry and investigators were also made in order to identify dissertations on the management of heel pain, unpublished data or research in progress. An optimum search strategy, as proposed by Dickersin, combined with subject specific search terms to identify plantar fasciitis was employed[9]. No language restriction was put in place. Only randomized or quasi randomized controlled trials in adults with plantar fasciitis were included in this review.

Twenty five RCTs were identified on which 6 where excluded from further analysis. Of the remaining 19 RCTs, 5 RCTs using different doses, 2 were un-blinded, dealt with the issues on the effectiveness of ESWT in treating plantar fasciitis. Based on these studies, the authors concluded that there was conflicting

evidence for the effectiveness of **low energy** ESWT in reducing night pain, resting pain and pressure pain in the short term (6 and 12 weeks). The trial on high energy ESWT showed that high energy ESWT was more effective than placebo in reducing heel pain. However, the means difference between ESWT treated and placebo with regard to heel pain was only 6%. This study on high energy ESWT was part of the US FDA approval for the marketing of OssaTron® in the US; methodological flaws were found in the published study including inconsistencies with the intended protocol.

9. Perez et al[10] (2003) published a review on the ESWT for plantar fasciitis. Even though this review was listed as systematic review, upon examination of the full article, the EBPG concluded that this was not the case. All of the primary controlled trials cited in this review were already evaluated and cited on the Cochrane systematic review by Crawford and Thompson[9], above. As such, the EBPG will not present further the review by Perez et al[10].

10. In January 2003, the Office of the Medical Director of the Washington State Department of Labor and Industries conducted a 'Stage One'[19] health technology assessment on ESWT for the treatment of musculoskeletal disorders, including plantar fasciitis, shoulder tendonitis, lateral epicondylitis and non-union[11] (the original review). This review was then up-dated in March 2004[12] (the update review). It should be noted that within the Washington State Department of Labor and Industry, 'Stage One' Technology Assessment program is the first stage in their technology assessment program. The purpose of 'Stage One' is to make a threshold decision as to whether or not the technology under review should be investigated fully under 'Stage Two'. In order to reach this decision, the staff of the Office of the Medical Director will assemble and present a report for the Medical Director in order for the Medical Director to make a decision as to whether or not the device under review should be evaluated further. It should be noted that the 'Stage One' process is not comprehensive, but sufficient enough so that an educated decision can be made on whether to commit further resources in researching the device. In 'Stage One', information that is readily available is assembled. Detailed searching and analysis is reserved for 'Stage Two'.

    In the original review[11], the authors presented available evidence of various levels, including case reports, case series, randomized/controlled/clinical trials in narrative format. The musculoskeletal disorders included in this review are plantar fasciitis, shoulder tendonitis, lateral epicondylitis and non-union. Primary studies included in this review were as follows:

    - 3 non randomized trials, 6 randomized controlled trials and 3 systematic reviews[4,8,9] on the application of ESWT in treating patients with plantar fasciitis
    - 2 non randomized trials, 4 randomized controlled trials and 1 systematic review[3] on the application of ESWT in treating patients with lateral epicondylitis

- 4 non randomized trials and 5 randomized controlled trials on the application of ESWT in treating patients with shoulder tendonitis. It should be noted that the authors did not include systematic reviews on the effectiveness of ESWT in treating shoulder tendonitis conducted by the UK National Institute for Clinical Excellence.

Based on the available evidence, the authors concluded that:

- The exact mechanism of action of ESWT in treating plantar fasciitis, shoulder tendonitis and lateral epicondylitis (and non union) was unknown
- Treatment protocols and exact patients inclusion and exclusion criteria varied between studies
- Both the ESWT and placebo groups in these trials experienced relief of pain and clinical improvement (as measured by various methods)

Overall, the authors concluded that the evidence establishing the effectiveness of ESWT in treating plantar fasciitis, shoulder tendonitis, lateral epicondylitis were inconclusive.

11. In March 2004, the Office of the Medical Director of the Washington State Department of Labor and Industries conducted an update review[12] on the effectiveness of ESWT in treating plantar fasciitis, shoulder tendonitis and lateral epicondylitis.

On this update, the authors searched PubMed and the Centre for Reviews and Dissemination databases (DARE) for any articles published in English between January 2003 and February 2004 by employing keywords "extracorporeal", "shockwave", or "ESWT". Hand searching for articles was also conducted based on the reference lists of the resulting database searches. The update included any type of study design[20].

The results of this update included:

- Second premarket approval from the US Food and Drug Administration (FDA), in March 2003, for OssaTron® (high energy ESWT) for the treatment of chronic lateral epicondylitis. It should be noted that OssaTron® received the first FDA approval, in October 2000, for treatment of plantar fasciitis. EPOS Ultra Device (low energy ESWT) was granted first FDA approval for treatment of plantar fasciitis in January 2002. Sonocur (low energy ESWT) was granted first FDA approval for treatment of chronic lateral epicondylitis in 2002.
- Secondary data analysis (non-randomized placebo controlled trial) from the OssaTron® FDA trial showed that there was no significant different in the fragmentation or disappearance of heel spur at 3 and 12 months between ESWT treated and placebo treated patients with plantar fasciitis. Other studies based on this expanded OssaTron® FDA trial data showed that there was no significant different between ESWT and placebo treated patients with plantar fasciitis with regard to patient rated outcome (categorized as excellent to failure). This study also showed that there was no association between the likelihood of positive response to ESWT

treatment with the duration of symptoms among patients with plantar fasciitis.

Two double blind RCTs (one with **high energy** and one with **low energy** ESWT) on the application of ESWT among patients with plantar fasciitis showed no meaningful improvement in clinical outcomes in patients treated with ESWT compared to patients in the placebo group.

One, single blind, RCT, with cross over control group, on **low energy** ESWT showed significant differences, with regard to walking time, between ESWT and iontophoresis/oral NSAID group at 12 weeks (i.e. prior to cross over into ESWT for the control group).

Another single blind RCT, conducted among recreational athletes who ran > 30 miles/week and diagnosed with plantar fasciitis showed a modest beneficial effect (mean pain, 10 point based VAS, on first walking in morning) of 3 points at 1 year follow up among patients treated with **low energy** ESWT.

A case control study showed that painful plantar fascia was ultrasonographically thicker than pain free comparison heels. After being treated with ESWT, decreases in thickness as well as pain improvement were statistically significant.

- As part of the FDA pre-market approval trial for its second application, OssaTron® submitted double blind RCT data on the effectiveness of this **high energy** ESWT in treating lateral epicondylitis. This study showed that at week 8 post treatment, there was a significant difference between ESWT and placebo group with regard to investigator assessment on pain. However, at 8 weeks, there was no significant different between ESWT and placebo groups with regard to patient rated pain (VAS) and pain medication use.

  Another double blind RCT showed that there was no significant difference between lateral epicondylitis patients treated with ultrasound guided high energy ESWT and placebo with regard to pain scores, Disabilities of Arm, Shoulder and Hand (DASH) score and analgesic use at 3 and 12 months.

- Three RCTs on the effectiveness of ESWT in treating shoulder tendonitis were presented in this update.

  One double blind three armed RCT[21] applied high energy, low energy and placebo in patients with shoulder tendonitis. This trial showed that, even though the high energy and low energy group received the same total acoustic energy, the clinical and radiological outcomes of these intervention groups were different. At 6 months follow-up, patients treated with high energy ESWT had the highest Constant and Morley score (CMS) (measuring shoulder function) compared to low energy and placebo groups. The authors concluded that at 6 months, high and low energy ESWT showed clinically significant benefit, as measured by CMS, compared to placebo group with significantly better outcomes associated with high energy ESWT. Upon individual appraisal of this particular RCT by

Gerdemeyer et al[21], the EBPG concluded that this trial is of high quality level 1 evidence (Appendix 2).

There were 2 additional RCTs presented in this update review and were appraised individually by the EBPG[22,23].

In a single blinded RCT, Cosentino et al[22] compared low energy ESWT with placebo in treating calcific shoulder tendonitis. Seventy consecutive calcific shoulder tendonitis patients were randomly assigned to receive either low energy ESWT or placebo. Various inclusion and exclusion criteria were implemented. CMS was measured at baseline, end of treatment, one and six months post treatment and intended as the outcome measure. The authors observed that there was a significant decrease of pain and significant increase in shoulder function among the ESWT group that was not observed among the placebo group. The authors concluded that ESWT could be considered as an alternative treatment for chronic calcific shoulder tendonitis. It should be noted that the authors did not provide information on all eligible and recruited patients and the difference between those excluded/refused and those included in the trial. The authors did not state the primary outcome and reflected this in a stated hypothesis with the corresponding sample size calculation. Further the statistical analysis presented in this primary research did not take into account the nature of multiple comparisons presented in the results section as well as adopting intention to treat analysis.

In a non-blinded RCT, Pan et al[23] compared the effectiveness of low energy ESWT with TENS in treating calcific shoulder tendonitis. Chronic calcific shoulder tendonitis patients attending a government outpatient clinic from January 2001 to January 2002 were recruited for this study. Various inclusion and exclusion criteria were set up and implemented. All patients were randomly assigned to ESWT or TENS. CMS were measured at baseline, 2, 4 and 12 weeks post treatment. It should be noted that patients on TENS received TENS treatment for only 20 minutes on each session, 3 times per week for 4 weeks. It is most likely that the TENS group did not receive adequate treatment. The authors stated that in both groups, the CMS improved significantly at 2, 4 and 12 weeks follow up. The authors concluded that ESWT was more effective in the treatment of chronic calcific shoulder tendonitis than was TENS. However, in this paper, the authors did not provide any information on the number of eligible, recruited and participated patients. Further the statistical analysis presented did not take into account the nature of multiple comparisons presented in the result section as well as adopting intention to treat analysis.

Based on the EBPG appraisal these 2 RCTs[22,23] would be rated as low quality.

12. Harniman et al[13] (2004) conducted a systematic review on the effectiveness of extracorporeal shock wave therapy in treating calcific and non calcific tendonitis of the rotator cuff.

The authors searched for articles in English or French in various databases including Medline (up to April 2003), EMBASE (up to May 2003), CINAHL (up to May 2003) and Evidence Based Medicine (Cochrane Database of Systematic Reviews, ACP Journal Club, DARE and Cochrane Controlled Trials Register). Manual searches were also undertaken based on references available from the initial retrieved articles. The authors did not provide information on the specific search strategy. However, they did note that the search strategy was available upon request. The EBPG has appraised this systematic review as comprehensive and transparent.

There were a total of 87 citations retrieved. Sixteen articles, included 6 case series/cohort studies, 5 controlled trials and 5 RCTs, fulfilled the inclusion criteria and were assessed further. The authors concluded that there was:

- moderate evidence (i.e. one trial, 50 patients followed to one year) that **high energy** ESWT focused on the calcific deposit provided long term effective treatment for chronic calcific shoulder tendonitis
- moderate evidence that **low energy** ESWT had no effect in chronic noncalcific shoulder tendonitis

It should be noted that the one high quality RCT on the subject by Gerdesmeyer et al[21] (discussed earlier) was published after the search inclusion period of this systematic review. As such, this article was not included in Harniman's review.

B. Other studies (RCT and Cost analysis studies):

B.1. The EBPG is aware of an RCT undertaken Pettrone et al[24] on the effectiveness of ESWT for chronic lateral epicondylitis that was presented at the February 13 - 17 2002 Annual Meeting of the American Academy of Orthopaedic Surgeons in Texas, USA. The authors concluded that ESWT was a safe and effective treatment for chronic lateral epicondylitis. It should be noted that all of the authors were associated with Siemens, the company who produced Sonocur®. To date, the EBPG has been unable to retrieve the full publication of this paper. As such, this primary research cannot be appraised properly and will not be discussed further in this review.

B.2. A recent paper by Melegati et al[25] (2004) compared the effectiveness of ultrasound guided two different ESWT location on treating patients with lateral epicondylitis. Patients diagnosed with lateral epicondylitis from June to October 2002 at a sport rehabilitation centre were recruited. Forty one patients were available and were then randomized into two groups of lateral tangential focusing ESWT or back tangential focusing ESWT. The purpose of this study was to

investigate the impact of different placement of the ESWT device. This study did not employ any control group in the manner of a conventional effectiveness study. Given the objective of this whole review by the EBPG was to investigate the effectiveness of ESWT, this particular study by Melegati et al[25] will not be appraised further.

B.3. In 2001, Haake et al published, perhaps the only, cost analysis study on ESWT compared to surgery among patients with shoulder tendonitis. The costs presented in this analysis included procedure costs (ESWT or surgery), procedure-related hospital stays, physiotherapy and so called 'unfitness for work' costs (presumably equivalent to wage loss). As such, the cost analysis may bear some resemblance to the direct cost incurred by the WCB of BC.
A convenient sample of 60 patients (30 in each treatment group) was used to assemble the associated costs. The authors concluded that the cost per case ranged from € 2,700 to € 4,300 per patient for ESWT and from € 13,400 to € 23,450 per patient for surgical treatment, depending on the cost calculation methods. Approximately 65% of per patient cost was attributable to productivity loss in the workplace. The cost ranged presented above was already adjusted to the number of probable treatment success, in each treatment group, as defined by the Subjective Shoulder Rating System score.
It should be noted that, methodologically, the most appropriate investigation to conduct cost related analysis is by attaching economic study in a properly conducted randomized controlled trial due to various sources of bias. As such, this economic study by Haake et al cannot be seen as conclusive evidence on the relative cost-effectiveness of ESWT vs. surgery in treating shoulder tendonitis. In the evidence rating scheme adopted by the EBPG, this article is rated as level 3 or 4 evidence only.

C. ESWT policy from other workers' compensation board in Canada and the US:

C.1. Workers' compensation board in Canada.
The EBPG searched the websites of various workers' compensation boards in Canada, including Yukon[27], Nunavut[28], Alberta[29], Saskatchewan[30], Manitoba[31], Ontario[32], Nova Scotia[33], New Brunswick[34], Newfoundland[35] and Prince Edward Island[36]. The purpose of this exercise was to find information on the reimbursement policy of these boards regarding ESWT in treating various musculoskeletal conditions. This searching failed to identify any information in that regard.

C.2. Workers' compensation board in the US.
1. Washington State Department of Labor and Industry[37].
Based on the initial[11] and updated review[12] of published literature on ESWT, on which ESWT did not substantially show effectiveness for treating plantar fasciitis or lateral epicondylitis, the department stated that ESWT was not a

covered therapy for any indication, including plantar fasciitis, lateral epicondylitis, shoulder tendonitis and delayed fracture union or non-union.

2. Colorado State Department of Labor and Employment[38].
   The department stated that ESWT has not been shown to have an advantage over other conservative treatment for lateral epicondylitis. As such, the department did not recommend ESWT as a passive treatment modality for lateral epicondylitis.

3. Ohio Bureau of Workers' Compensation[48].
   The Bureau stated that studies have not demonstrated consistent results or efficacy in the treatment of plantar fasciitis, epicondylitis and non-calcific tendonitis of the shoulder. ESWT is considered unproven and investigational for these services.

D. Private health insurance reimbursement policy on ESWT:

D.1. Aetna[39, 40].
Based on the available published literatures, Aetna concluded that there was insufficient evidence of the effectiveness of ESWT in treating plantar fasciitis[39], epicondylitis[40], shoulder tendonitis[40], Achilles tendonitis[40] or other musculoskeletal conditions[40]. Aetna considered ESWT, both **low** and **high** energy, as experimental/investigational treatment modality, and would therefore not provide coverage.

D.2. The Regence Group[41].
Based on the available published literature, the Regence Group considers ESWT (both **low** and **high** energy), investigational for all indications, including plantar fasciitis, lateral epicondylitis, tendinopathies including calcific tendonitis of the shoulder, stress fracture, delayed union, non-union and avascular necrosis of the femoral head.

D.3. Tufts Health Plan[42].
Tufts Health Plan considers the application of ESWT (both **low** and **high** energy) for treating plantar fasciitis and other musculoskeletal conditions as experimental or investigative. A diagnosis or treatment method is considered as investigative or experimental when 'reliable evidence' shows that prevailing opinion among experts regarding the treatment is that more studies or clinical trials are necessary to determine its safety, efficacy, toxicity, maximum tolerated dose, or its efficacy as compared to standard means of treatment or diagnosis.

D.4. BlueCross of California[43].

California BlueCross views ESWT as investigational or not medically necessary in treating plantar fasciitis, lateral epicondylitis, tendinopathies including the supraspinatus and calcific tendonitis of the shoulder, stress fracture, delayed union, non-union and avascular necrosis of the femoral head.

D.5. Wellmark BlueCross BlueShield of Iowa and South Dakota[44].

ESWT might be considered medically necessary for the treatment of chronic proximal plantar fasciitis as an alternative treatment to surgery. Patients must meet the following criteria:

- Patients diagnosed with plantar fasciitis received prior approval
- Symptoms persists for at least 6 months
- Lack of response to at least 3 other conservative treatment such as rest, physical therapy, anti-inflammatory medications, local corticosteroids, or heel orthotics.

A second treatment might be covered up to 16 weeks after the first treatment if the initial response was not acceptable. There would be no coverage for a third treatment if the first two were ineffective, as it would not be medically necessary.

However, ESWT was considered investigational for the treatment of all other musculoskeletal conditions, including epicondylitis, tendinopathies including calcific tendonitis of the shoulder, stress fracture, delayed union and nonunion of fractures, and avascular necrosis of the femoral head.

D.6. The US Medicare and Medicaid[45-47].

US Medicare and Medicaid Services provide coverage for ESWT when undertaken with FDA approved devices, when the approved devices were used only for their specific FDA approved indications. At present, only plantar fasciitis and lateral epicondylitis are covered indications for use of this modality. All other conditions were considered investigational and not covered.

ESWT might be medically indicated for treatment of plantar fasciitis or lateral epicondylitis when all of the following criteria were met:

a. The patient had been symptomatic for at least six (6) months.
b. There had been a lack of response for at least the last two months to conservative measures, including – rest, physical therapy, anti-inflammatory medications, local corticosteroid injections, heel orthotics or forearm sleeve (as applicable).
c. The patient would otherwise be considered a candidate for surgical treatment.

For treatment plans that were based on a treatment protocol using **high energy** ESWT:

- Only one treatment would be covered per anatomical site in any six (6) month period
- No more than two treatments would be covered for any site in a calendar year

- Repeat treatments might be medically necessary and might be covered if the following conditions were met:
  - previous treatment resulted in significant improvement in symptoms and function
  - the criteria for initial treatment had been met
  - for repeat treatment, documentation had to be submitted with each claim to support medical necessity.
  - anesthesia, such as local or regional blocks, when performed by the operating physician, would not be reimbursed separately. If medical necessity for administration of anesthesia by an anesthesiologist was presented, this might be covered separately if sufficient documentation was presented to justify medical necessity.

For treatment plans that were based on a treatment protocol using **low energy** ESWT:

- No more than three treatments would be covered for any single anatomical site during a six month period
- No more than six treatments would be covered per year per anatomical site
- Repeat treatments might be medically necessary and covered if the following conditions were met:
  - previous treatment resulted in significant improvement in symptoms and function
  - the criteria for initial treatment had been met
  - for repeat treatment, documentation had to be submitted with each claim to support medical necessity.
  - anesthesia, such as local or regional blocks, when performed by the operating physician, would not be reimbursed separately. Because anesthesia was rarely required for this application, anesthesia performed by any provider other than the operating physician would be considered only on a case by case basis for medical necessity.

The Centers for Medicare and Medicaid contracted this service to other private health insurance companies, such as Cigna Medicare in North Carolina[46] or Cahaba GBA in Georgia[47].

Summary - Conclusion.

- ESWT has been applied to treat various musculoskeletal conditions, including lateral epicondylitis, plantar fasciitis, calcific and non calcific shoulder tendonitis, delayed fracture union and fracture non-union, stress fracture and avascular necrosis of the femoral head.
- Prior to 2000, published literature on these topics were appraised as low quality and experts stressed the importance of conducting proper controlled trials in order to assess the efficacy of ESWT in treating various musculoskeletal conditions.

- Based on published systematic reviews (level 1 evidence)[1,3,4,6,7,9,11,12,13] and one RCT[21], currently the evidence on the effectiveness of ESWT in treating:
    - Lateral epicondylitis - inconclusive
    - Plantar fasciitis - no evidence or inconclusive at best for **low energy** ESWT. However, **high energy** ESWT probably is effective.
    - Shoulder tendonitis - moderate evidence that **low energy** ESWT does not have any effect. There is moderate evidence that **high energy** ESWT has effect.
- There is no information available on the status of the ESWT coverage on the websites of WCBs in Canada.
- The Washington State and Colorado State Department of Labor and Industries specifically state that ESWT is not covered therapy for various musculoskeletal conditions, including lateral epicondylitis, plantar fasciitis, calcific and non calcific shoulder tendonitis, delayed fracture union and fracture non-union.
- The US private health insurance companies, including Aetna, the Regence Group, Tufts and BlueCross of California, consider the application of ESWT in treating lateral epicondylitis, plantar fasciitis, calcific and non calcific shoulder tendonitis, delayed fracture union and fracture non-union, stress fracture and avascular necrosis of the femoral head to be investigational or not medically necessary. As such, to date, these companies did not provide coverage for ESWT.
- Wellmark BlueCross BlueShield of Iowa and South Dakota provide limited coverage of ESWT, as somewhat the last treatment resort prior to surgery, for patients with plantar fasciitis. The company did not mention whether the coverage involve **high** or **low** energy ESWT.
- The US Medicare - Medicaid provides limited coverage for ESWT for patients with plantar fasciitis and lateral epicondylitis. The coverage includes **low** and **high** energy ESWT.

Both high-dose and low-dose protocols have been investigated. A high-dose protocol consists of a single treatment of high energy shock waves (1300mJ/mm2). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced one week to one month apart, in which a lower dose of shock waves is applied (1405mJ/ mm2 over three sessions). This protocol does not require anesthesia.

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Appendix 1.

Workers' Compensation Board of BC - Evidence Based Practice Group. Grades of quality of evidence [adapted from 1,2,3,4].

1	Evidence from at least 1 properly randomized controlled trial (RCT) or systematic reviews of RCTs.
2	Evidence from well-designed controlled trials without randomization or systematic reviews of observational studies.
3	Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group.
4	Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.
5	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

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