Summary

- Electrohydraulic, electromagnetic, or piezoelectric devices are used to translate energy into acoustic waves during extracorporeal shock wave treatment (ESWT) for chronic rotator cuff tendonitis (shoulder pain). The acoustic waves may help to accelerate the healing process of chronic rotator cuff tendonitis via an unknown mechanism.

- ESWT, which is performed as an outpatient procedure, is intended to alleviate the pain due to chronic rotator cuff tendonitis.

- Limited evidence from a German study indicates that the cost of ESWT for rotator cuff tendonitis is one-fifth to one-seventh the cost of surgical treatment, with longer recovery time and time off work in the surgical treatment group accounting for about two-thirds of the overall cost.

- The evidence reviewed for this bulletin supports the use of high-energy ESWT for chronic calcific rotator cuff tendonitis, but not for non-calcific rotator cuff tendonitis. High-quality RCTs with larger sample sizes are needed to provide stronger evidence.

The Technology

Shock waves are sound waves that are characterized by a high peak pressure, short rise time, and short lifecycle. These large changes in pressure produce strong waves that can travel through the human body. The sound waves are produced using a generator and then focused at the target tissue using an elliptical reflector or an acoustic lens. The energy at the focal point, which is called the energy density, is measured in joules per area (mJ/mm²). Low energy density is <0.2 mJ/mm², whereas high energy density occurs at 0.2 mJ/mm² to 0.4 mJ/mm².

The number of impulses and the energy density define the total energy of a treatment.

ESWT, which is performed as an outpatient procedure, has been promoted as an alternative to surgical intervention for rotator cuff tendonitis that does not respond to conventional conservative therapies. The belief is that ESWT provides long-lasting analgesia and stimulates the healing process, although the mechanism for this is unclear.

The rotator cuff is a confluence of tendons from four shoulder muscles that stabilize the shoulder joint. Shoulder pain due to rotator cuff tendonitis is one of the most prevalent and costly work-related musculoskeletal disorders. Calcific rotator cuff tendonitis occurs in 7% to 17% of cases.

Regulatory Status

Health Canada licensed SONOCUR Basic (Siemens), Epos Ultra (Dornier MedTech), and Orthospec (Medispec) extracorporeal shock wave units in July 1999, July 2004, and March 2005 respectively.

Patient Group

According to Welfling, calcific tendonitis was detected using radiology in 2.7% to 20% of patients with asymptomatic rotator cuff tendonitis. This disorder affects mainly women, and those with sedentary professions seem to be the most susceptible. The Orthopedic Extracorporeal Shock Wave societies are proposing the use of ESWT for calcific tendonitis of the shoulder in patients with
pain lasting >6 months and Gartner radiologic stages I and II,\(^9\) and where >3 conservative measures have been applied, including obligatory physiotherapy and cortisone or local anesthetic injections.\(^10\) (In the Gartner radiological classification of calcific tendonitis of the shoulder,\(^9\) stage I is homogenous structure, sharp outline, stage II is inhomogeneous structure, sharp outline, or homogeneous structure, no defined outline, and stage III is inhomogeneous structure, no defined outline.) Patients with calcific tendonitis represent a small percentage of the group of patients with shoulder pain, much of which is the result of the degenerative joint disease associated with aging.\(^11\)

**Current Practice**

Non-surgical, conservative approaches in the management of shoulder tendonitis include activity modification, physiotherapy, non-steroidal anti-inflammatory drugs (NSAIDS), corticosteroid injections, and ultrasound. Surgery may be used when these modalities fail. ESWT, which has been suggested for patients who do not respond to conventional conservative therapies, is positioned at the end of the conservative treatment spectrum.\(^2\)

**The Evidence**

Randomized controlled trials (RCTs) published from 2000 to 2006 were reviewed. Five RCTs compared ESWT with placebo (418 participants),\(^12-16\) four RCTs compared different levels of energy (280 participants),\(^12,16-18\) one RCT compared ESWT with transcutaneous electric nerve stimulation (60 participants),\(^19\) and one RCT compared ESWT with radiotherapy (30 participants).\(^20\) The main outcomes that were measured were pain, function, and adverse effects. The degree of calcific resorption was also measured in the studies that targeted calcific tendonitis. These efficacy endpoints were measured from one to 12 months after treatment.

All six RCTs that examined the efficacy of ESWT compared to placebo or transcutaneous electrical nerve stimulation for calcific tendonitis, favoured ESWT for relieving pain, improving function, and reducing the size of calcific deposits. Most of the comparisons were statistically significant.\(^12,14,16-19\)

**Adverse Effects**

No serious adverse effects were reported, although hematomas and petechial bleeding occurred more often with high energy levels compared to low energy levels (the statistical tests were not performed).\(^12,18\)

**Administration and Cost**

Treatment protocols for ESWT depend on the energy category.\(^2\) When high-energy machines are used, the treatment course usually consists of one treatment of 1,000 pulses to 1,500 pulses, with an optional additional treatment. With high-energy therapy, at least a local anesthetic is required, and imaging technology is used to locate the treatment area. When low-energy machines are used, the treatment course consists of three treatments of 2,000 pulses to 3,000 pulses with an optional two additional treatments. No anesthesia is required for low-energy therapy, and the treatment area is located based on the patient’s feedback regarding the area of most discomfort.

A 2001 study in Germany assessed the direct and indirect costs during the first 12 weeks after the initiation of ESWT treatment or surgical treatment for shoulder tendonitis. Results showed that the average cost per case ranged from €1,940 to €3,180 for ESWT and from €13,347 to €22,735 for surgical treatment, depending on the value associated with a lost workday. The cost differences between ESWT and surgery were primarily the result of the greater productivity losses associated with surgical trauma. The average number of lost workdays for surgical and ESWT patients were 66.9 and 7.7 respectively.\(^21\)

The Canadian list price of the SONOCUR Basic unit is approximately C$100,000 (Bert Stadler, Siemens Canada, Edmonton: personal communication, 2006 Nov 8). The Orthospec unit costs about C$200,000 (Lui Mattiazzi, Osis Medical, Toronto, ON: personal
communication, 2006 Oct 15). The cost of the Epos Ultra unit was unavailable.

## Concurrent Developments

Prolotherapy (injection of a dextrose or other “proliferant” solution into the ligaments or tendons) is being promoted as an alternative treatment for rotator cuff tendonitis, although there is little evidence to support its use for this condition.\(^{22}\)

## Rate of Technology Diffusion

ESWT has been used in orthopedic practice over the past 10 years. The conflicting evidence regarding its clinical effectiveness has limited its diffusion in some countries. The increase in the number of applications for the reimbursement of costs related to ESWT for orthopedic indications and the unlimited expansion of the indications for this therapy led to a re-evaluation of ESWT in Germany in 1999 and the conclusion that “neither the benefit, nor the medical necessity, nor the efficiency” of ESWT had been proven.\(^{10}\) A similar assessment in Switzerland prompted a unanimous resolution by the Commission of Health Insurers to exclude ESWT in their cost catalogue.\(^{10}\) According to a US review, most insurers do not cover ESWT for musculoskeletal indications.\(^{23}\) A few insurers have begun covering ESWT for calcific rotator cuff tendonitis that has been confirmed using x-rays and that has not responded to >3 non-surgical treatments, for example, exercise, physiotherapy, anti-inflammatory drugs, or steroid injections.\(^{23,24}\)

## Implementation Issues

The widespread implementation of ESWT for the treatment of rotator cuff tendonitis is impeded by limitations in the research completed to date. These limitations include a lack of appropriate control groups, inadequate randomization, small sample sizes, and funding from manufacturers. A 2004 systematic review\(^{25}\) (which excluded six RCTs that were reviewed in this bulletin\(^{12,16-20}\)) showed data that favoured high-energy ESWT for treating chronic calcific rotator cuff tendonitis. The current evidence supports the use of high-energy ESWT for chronic calcific rotator cuff tendonitis that is recalcitrant to conventional conservative treatment, although more high-quality RCTs with larger sample sizes are required to provide more convincing evidence. Because current evidence does not support the use of ESWT to treat other musculoskeletal conditions,\(^{26,27}\) health care providers may be reluctant to buy this technology for the use of the small group of patients with chronic calcific rotator cuff tendonitis who might benefit.

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