Summary

Electrohydraulic, electromagnetic, or piezoelectric devices are used to translate energy into acoustic waves during extracorporeal shock wave treatment (ESWT) for chronic lateral epicondylitis (CLE) of the elbow (elbow tendonitis or tennis elbow). These waves may help to accelerate the healing process via an unknown mechanism.

Results from randomized controlled trials have been conflicting. Half of the studies showed statistically significant improvement in pain in the treatment group, and half of the studies had data showing no benefit over placebo for any measured outcomes.

Limited evidence shows that ESWT is cheaper than arthroscopic surgery, open surgery, and other conservative therapies, such as steroid infiltrations and physiotherapy, that continue for more than six weeks.

The lack of convincing evidence regarding its effectiveness does not support the use of ESWT for CLE.

The Technology

Shock waves are sound waves that are characterized by a rapid increase in pressure. They 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.

Electrohydraulic, electromagnetic, or piezoelectric methods can be used for shock wave generation and delivery. These methods involve the conversion of electrical energy into mechanical energy through the generation of shock waves that are focused on a specific region of tissue and transmitted to the patient through a coupling gel. This is believed to provide analgesia and stimulate the healing process.

Chronic lateral epicondylitis (CLE) is an occupational and sports-related condition that is caused by the overuse of the lower arm muscles. This induces inflammation and pain in the tendons on the outside of the elbow. The diagnosis of CLE is straightforward, but the most effective treatment for this condition is unclear.

ESWT, which is performed as an outpatient procedure, is used in the treatment of lateral elbow pain when other conservative therapies have failed.

Regulatory Status

Health Canada licensed SONOCUR® Basic (Siemens), Epos Ultra® (Dornier MedTech), and Orthospec™ (Medispec) for marketing in Canada, in July 1999, July 2004, and March 2005 respectively.

Patient Group

The prevalence of chronic lateral epicondylitis is 1% to 3% in the general population. This increases to 19% among those who are 30 years old to 60 years old. The Orthopedic Extracorporeal Shock Wave societies propose the use of ESWT for epicondylitis in patients with pain lasting >6 months, in patients who have undergone unsuccessful regular treatment over the last three months, or in patients for whom surgery was unsuccessful.

Current Practice

The management of lateral elbow pain consists of conservative and invasive therapies. Oral or topical non-steroidal anti-inflammatory drugs (NSAIDs) and
corticosteroids (taken orally or through local injection) offer short-term treatment for pain, although there are questions about the effectiveness of corticosteroid injections. Long-term treatment modalities include laser therapy, acupuncture, muscle strengthening, massage, elbow straps, and high-voltage galvanic stimulation. Patients who are unable to function after undergoing conservative treatments are candidates for surgical interventions. 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.11

### The Evidence

Randomized controlled trials (RCTs) published from 2000 to 2006 were reviewed. Seven RCTs compared ESWT with placebo (802 participants),12-18 one RCT compared ESWT with steroid injection (93 participants),19 and one RCT compared ESWT with minimal dosage of shock waves (75 participants).20 Two trials did not report the energy level used,13,20 one used a medium energy level,18 one used varied energy levels,15 and the remaining five trials used a low energy level.12,14,16,17,19 The main outcomes that were measured were pain at rest (100-point scale), pain with resisted wrist extension (10-point visual analog scale), functional assessment (Upper Extremity Function Scale), grip strength (by dynamometry), and adverse effects. These efficacy end points were measured at three months after treatment.

The trials reported conflicting results regarding the clinical effectiveness of ESWT. Four trials reported data that favour ESWT over placebo or minimal dosage of shock waves for most of the efficacy outcomes that were measured.12-14,20 Three trials12,14,20 showed a statistically significant improvement in pain during resisted wrist extension in the treatment group (p<0.05) and a statistically significant increase in the number of patients achieving at least a 50% reduction of pain at three months after treatment (p<0.05). The other small trial13 reported benefit on a 10-point scale at six months in the treatment group (10/13 participants) compared with the placebo group (1/11 participants).

Four trials showed no benefit from using ESWT compared with placebo for any measured outcomes.15-18 In these trials, no significant difference was shown between the treatment groups based on the changes in pain scores over the study period.

In one RCT, data showed that those patients with lateral elbow pain who were treated with local steroid injection were more likely to achieve a 50% reduction of pain at three months after the end of treatment than those treated with ESWT.19

Among the nine RCTs reviewed in this bulletin, four received funding or other support from the manufacturers,12,13,15,16 four declared that they had received no assistance,14,17-19 and one did not indicate the funding source.20

Most of the published studies on ESWT for chronic lateral epicondylitis are homogenous in quality. While the recommended energy density for ESWT in orthopedic practice ranges from 0.01 ml/mm² to 0.28 ml/mm², of the nine included RCTs, no studies compare the effect of using different energy levels. No published studies evaluate whether there is a dose-response relationship between the energy received by a patient and the clinical outcome.

### Adverse Effects

No serious adverse effects were observed in the included studies. One trial14 reported temporary reddening at the treatment area in all patients. In the same trial, 95% of patients reported pain during ESWT compared to 53% in the placebo group, and 21% of patients in the ESWT group reported nausea. Another trial12 reported temporary moderate pain in 50% of patients in the ESWT group compared to 22% in the placebo group, and 18% of patients in the ESWT group experienced nausea.

### Administration and Cost

Treatment protocols for ESWT depend on the energy category.11 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.

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.

A 2000 Austrian cost estimate study indicated that ESWT is less expensive than arthroscopic surgery, open surgery, and other conservative therapies, such as steroid infiltrations and physiotherapy, that continue for >6 weeks.10

Concurrent Developments

Other treatments for CLE that are being investigated include the use of prolotherapy (injection of a dextrose or other solution into the ligament) and dexamethasone iontophoresis (delivery of a corticosteroid drug through the skin using an electrical charge).21-23

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. In Germany, in 1999, ESWT was re-evaluated because of the large increase in the number of applications for the reimbursement of costs related to orthopedic ESWT and the unlimited expansion of its indications. It was concluded that “neither the benefit, nor the medical necessity, nor the efficiency” of this therapy had been proven.10 After an assessment of ESWT in 1998, the Swiss Commission of Health Insurers reached a unanimous decision to exclude ESWT from publicly funded benefits.10

Implementation Issues

There is a lack of evidence to support the use of ESWT for chronic lateral epicondylitis.24 The small, randomized, controlled trials show conflicting results, and there is no standard treatment plan for delivering this therapy. Recent assessments by the UK National Institute for Health and Clinical Excellence (NICE) and the US Blue Cross Blue Shield have also concluded that the current evidence does not support the use of this treatment.25,26

References


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