

EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR CHRONIC TENDINITIS AND RELATED DISORDERS

REVIEW OF THE MEDICAL LITERATURE FOR EFFICACY, SAFETY, AND COST-EFFECTIVENESS

BACKGROUND

Low energy ESWT is a byproduct of the high energy lithotripters that have been used for decades in the treatment of kidney stones. That technology requires a large machine and an anesthetized patient, and is very expensive.

About 12 years ago smaller, low energy, ESWT devices were developed in Europe to treat common painful tendon conditions that often resulted in calcium stones being deposited in the tendons. It was found that, after ESWT treatment, the calcium deposits often disappeared along with the pain.

The following literature summary involves the use of low energy ESWT devices supplied by several different manufacturers.

The last section compares two devices now approved in the United States: 1) the OssaTron (High Medical Technology), which is a high-energy ESWT device approved by the FDA in 2000, and 2) the Sonocur (Siemens A.G.), a low energy ESWT device approved by the FDA in July, 2002. Studies using a Siemens (Sonocur) machine are marked with an asterisk (*).

A. EFFICACY

Elbow

1.* *Analgesic Effects of Extracorporeal Shock-Wave Therapy on Chronic Tennis Elbow.* J. D. Rompe, C. Hopf, K. Küllmer, J. Heine, and R. Bürger. *Journal of Bone and Joint Surgery*, Volume 78-B, 1996, pp.233-237.

100 patients with tennis elbow for more than a year randomized to either real ESWT or a sham treatment in which the patients were connected to the device but did not get a real ESWT session. Every patient had 3 treatment sessions one week apart. At six-month follow-up, 48% of the ESWT patients had a “good” or “excellent” outcome, and another 42% an “acceptable” result, while 6% of the control group had a good or excellent result. Overall, 90% of the ESWT patients were better, compared to 30% of those treated with sham ESWT.

2.* *Low-energy extracorporeal shock wave therapy for persistent tennis elbow.* J.D. Rompe, et al. *International Orthopedics*, Volume 20, 1996, pp.23-27.

50 consecutive patients who had failed conservative treatment for at least 12 months were studied according to the protocol in Reference 1 above. Follow-up assessment at 3 months showed a 70% decrease in night pain compared to before treatment, while those in the sham group had a 25% increase in night pain. Use-related pain decreased by 54% at 3 months in the ESWT group, while it increased by 9% in the control group. Overall, 56% of patients reported a good or excellent (no pain) outcome, with 76% responding to some degree, and none reporting a “poor” result. In the controls, there were no excellent responders, and almost half had a “poor” response.

3. *Extracorporeal Shock-Wave Therapy for Chronic Lateral Tennis Elbow – Prediction of Outcome by Imaging.* M. Maier, M. Steinborn, C. Schmitz, et al. Archives of Orthopedics and Trauma Surgery, Volume 121, 2001, pp.379-384.

42 consecutive patients were assessed before and after ESWT treatment, with a mean follow-up period of 18 months. All patients had pre-treatment MRI's. Overall 84% of the men but just 52% of the women had a good outcome. Those patients, male and female, who had the most abnormal tendons on MRI were the patients most likely to respond to ESWT. The authors concluded that those tendons that were thickened or swollen with fluid had the greatest potential to regenerate after ESWT.

Foot and Heel

4. *Extracorporeal Shock Wave Application for Chronic Plantar Fasciitis Associated with Heel Spurs: Prediction of Outcome by Magnetic Resonance Imaging.* M. Maier, M. Steinborn, C. Schmitz, et al. Journal of Rheumatology, Volume 27, 2000, pp.2455-2462.

Using the same methods described in Reference 5 above, the authors evaluated 43 patients with 48 painful heels from refractory plantar fasciitis (duration > 6 months) before and after ESWT. After a mean 19 months of follow-up, 75% had an excellent or good outcome. The MRI analysis showed that those patients who had edema of the bone marrow in the painful heel were most likely to respond (94% good or excellent outcome).

5. *Efficacy of Extracorporeal Shock-Wave Treatment in Calcaneal Enthesophytosis.* R. Cosentino, P. Falsetti, S. Manca, et al. Annals of the Rheumatic Diseases, Volume 60, 2001, pp.1064-1067.

This study of 60 patients with at least 6 months of heel pain required the presence of a bone spur on the symptomatic heel visible on X-ray. Patients were randomly assigned to 6 weekly treatments of real or sham ESWT. Treated patients were significantly better at 1 and 3 months in terms of rest pain, morning pain, and pain after normal activities. No significant improvement in any of these outcomes was seen in the control group. Ultrasound study showed that inflammation was reduced in 40% of

the treatment group at 1 month, but only 7% in the controls. 30% of the ESWT group also showed a decrease in the size of the heel spur on X-ray at 1 month after treatment.

6.* *Evaluation of Low-Energy Extracorporeal Shock-Wave Application for Treatment of Chronic Plantar Fasciitis.* J. D. Rompe, C. Schoellner, and B. Nafe. *Journal of Bone and Joint Surgery*, Volume 84-A, 2002, pp.335-341.

100 consecutive patients with heel pain of averaging 9 months in duration (range 6-20 months) were randomly assigned to receive 3 weekly sessions of ESWT or sham therapy. Patients were assessed up to 5 years after treatment. At 6 months there was a mean 75% pain reduction in the treatment group, versus no improvement in pain in the controls ($p < .0001$). 50% of the ESWT patients were completely pain free, while none of the controls were. At the 5-year follow-up, there was a further reduction in pain (mean of 88%). 13% of the ESWT patients eventually had heel surgery, while 58% of the sham treated patients had been operated on.

Shoulder

7. *Shock-wave Therapy is Effective for Chronic Calcifying Tendinitis of the Shoulder.* M. Loew, W. Daecke, D. Kusnierczak, et al. *Journal of Bone and Joint Surgery*, Volume 81-B, 1999, pp.863-867.

This was a two-part study, with 80 patients randomly assigned to ESWT or sham in the first part, and 115 patients treated with 1 or 2 ESWT sessions in the 2nd part. Results were better in the treatment group, and dependent on the amount of energy (treatments) received. At 6-month follow-up, up to 58% of the treated patients had complete or substantial pain relief, compared to none in the controls. 77% of the patients who had 2 treatment sessions showed disintegration or disappearance of calcium deposits on X-ray.

8.* *Shock Wave Therapy Versus Conventional Surgery in the Treatment of Calcifying Tendinitis of the Shoulder.* J. D. Rompe, J. Zoellner, and B. Nafe. *Clinical Orthopedics and Related Research*. Number 387, June, 2001, pp.72-82.

79 consecutive patients who had failed conservative methods (medications, injections, P.T.) were randomized to arthroscopic shoulder surgery or a single ESWT treatment and followed for 24 months. Both groups received 4-6 weeks of P.T. following the procedure. Pain relief was similar at 1 year, but better in the surgically treated group at 2 years. At 1 year 75% of the surgical group and 64% of the ESWT group had good or excellent results. Analysis of the data showed that patients who had a solid calcium deposit did better with surgery, while those with scattered deposits did as well or better with ESWT. Also, only one ESWT treatment session was used in this study, while later studies tended to use 2 or 3 sessions.

9. *Low-energy Extracorporeal Shock-wave Treatment (ESWT) for Tendinitis of the Supraspinatus.* J. Schmitt, M. Haake, R. Hildebrand, et al. *Journal of Bone and Joint Surgery*, Volume 83-B, 2001, pp.873-876.

This was a randomized controlled study of 40 patients with non-calcific tendinitis of the supraspinatus tendon of the shoulder, comparing 3 sessions of ESWT with 3 sham procedures. There was no significant difference between the groups in terms of function or pain at 6 month follow-up. Interestingly, both groups got significantly better after treatment, even though all patients had been in pain an average of nearly 2 years and had failed conservative therapy before study.

10. *Exact Focusing of Extracorporeal Shock Wave Therapy for Calcifying Tendinopathy.* M. Haake, B. Deike, A. Thon, and J. Schmitt. *Clinical Orthopedics and Related Research*, Number 397, 2002, pp.323-331.

This randomized study of 50 patients with calcific shoulder tendinitis looked at results of treatment whether the treatment was aimed at a specific calcium deposit, or whether the ESWT lens was focused on the origin of the supraspinatus tendon. Each patient had 2 treatment sessions. Both groups were significantly improved after 1 year, but the patients whose treatment was focused on the calcium deposit did better. The authors recommended that, whenever possible, ESWT be focused exactly on the area where calcium deposits are found, rather than where the tendon is attached to bone.

B. SAFETY

No serious side-effects have ever been reported in any of the studies using low-energy ESWT. Transient after-effects include redness of the skin for a few days, or minor bruising at the treatment site. Post-treatment pain at the site of ESWT application is common, but is generally no more severe than the pain experienced by the patient during use of the affected area.

C. COST EFFECTIVENESS

11.* *Shock Wave Therapy Versus Conventional Surgery in the Treatment of Calcifying Tendinitis of the Shoulder.* [Same as Reference 8 above]

The 79 patients randomized to arthroscopic surgery or ESWT treatment were evaluated at the end of two years. Direct medical costs were \$2,970 more in the surgically treated group. This group also averaged more than 9 weeks of lost work time, compared to 2.5 weeks in the ESWT group. Indemnity costs in the surgical group were \$9,240 per patient more than the ESWT group. Overall, arthroscopy cost \$12,000 more than ESWT.

12. *Assessment of the Treatment Costs of Extracorporeal Shock Wave Therapy Versus Surgical Treatment for Shoulder Disease.* M. Haake, M. Rautmann, and T. Wirth. International Journal of Technology Assessment in Health Care. Number 4, 2001, pp. 612-617.

60 patients were evaluated, half with surgery, half with 2 ESWT treatments. At follow-up, both treatments were equally effective. Direct medical costs averaged \$4,298 (1Dollar = 1 Euro) for the surgical group, while ESWT cost \$875 on average. Lost work time cost \$10,000 (range \$2,400-\$25,200) for surgery, and \$1,190 (range \$300-\$25,200) for the ESWT patients. Overall the surgically treated patients cost more than 7 times as much as the ESWT-treated patients.

D. COMPARISON OF THE SONOCUR AND OSSATRON DEVICES

Because there are only 2 FDA-approved ESWT devices available in the United States, it is important to compare and contrast the treatment protocols and results of scientific studies where available.

The OssaTron was approved in 2000 for treatment of plantar fasciitis (heel pain), while the Sonocur was approved in 2002 for treatment of lateral epicondylitis (tennis elbow). It is quite legal to use either device for treatment of other conditions, as long as the patient receives informed consent.

	OssaTron	Sonocur
Treatment Site	Surgery Center	Office or Clinic
Anesthesia Required?	Yes	No
Total Time per Treatment	About 2 hours	15-30 minutes
Number of Treatments	1 or 2 per area	1-3 per area
Cost per Treatment	~\$3,500	~\$1,000

Side Effects The limited published reports on use of the OssaTron show that it is generally safe, with no significant side-effects. However, the OssaTron is a high energy ESWT device, and use of high energy ESWT has resulted in damage to bone in the form of periosteal detachment and small cortical fractures (see Reference 6 above). As stated above (page 4), no significant side effects with use of the Sonocur have ever been reported.

One randomized controlled trial of the OssaTron has been reported in English:

13. *Shock Wave Therapy for Chronic Proximal Plantar Fasciitis.* J. A. Ogden, R. Alvarez, R. Levitt, et al. *Clinical Orthopedics and Related Research*, Number 387, 2001, pp.47-59.

302 patients with chronic heel pain (6-18 months duration) were randomized to ESWT or a sham procedure. One or 2 treatment sessions were administered. At 3 month follow-up, 47.1% of the treated patients were better, compared to 30.2% of the controls, which was a significant difference.

A MedLine computer search of the medical literature turned up 2 more studies, both done by the same investigators in Taiwan. Both were consecutive patient studies, and neither study had a control group to compare the results, which showed a significant benefit from the treatment. One study reported on treatment of heel pain, and the other studied lateral epicondylitis:

Chen HS, Chen LM, Huang TW. Treatment of painful heel syndrome with shock waves. *Clin Orthop and Related Res.* 2001; (387):41-46.

Ko JY, Chen HS, Chen LM. Treatment of lateral epicondylitis of the elbow with shock waves. *Clin Orthop and Related Res.* 2001;(387):60-67.

E. CONCLUSIONS

Who is likely to benefit from ESWT?

1. Patients who have failed conservative treatment, which is usually defined as anti-inflammatory medications, corticosteroid injections into the painful area, and/or physical therapy. Failure can be described as continued symptoms which impair work or home activities after at least 3 months of treatment. Another definition of failure may be no response or relapse of symptoms after 2 corticosteroid injections. Patients who are still symptomatic after 2 injections are unlikely to respond to any more conservative treatment.

2. Patients with objective abnormalities on physical examination or imaging studies. As the literature reviewed above shows, those patients with calcium deposits in or about tendons seem to respond very well to ESWT, as do patients with objective signs of tendon abnormalities such as swelling or crepitus. Ultrasound or MRI may demonstrate abnormalities, but should not be necessary if the physical exam reveals more than just tenderness at the painful location.

What body areas are likely to respond to treatment?

The controlled studies reviewed here are almost all positive with respect to a significant benefit in terms of pain relief, improved function, and cost when compared to conservative or surgical treatment of tendinopathies around the elbow, shoulder, and heel. Studies have suggested that non-calcific tendinitis of the shoulder does not respond to ESWT as well as surgical intervention.

Theoretically, any near-bone tendinopathy may respond to ESWT, but probably 90% of all refractory cases will involve these 3 body areas. Other areas to consider ESWT for are chronic tendinitis of the knee (quadriceps and patellar tendinitis), the hip, and the wrist.

Which ESWT device to use in the United States?

Much more literature is available on the use of low energy ESWT treatment using the Sonocur device than with the higher energy OssaTron. There are 4 controlled clinical trials of Sonocur treatment, in 3 body regions (elbow, heel, and shoulder), all with significantly positive results.

There is only 1 controlled clinical trial of the OssaTron and that for the heel only. In addition, the Sonocur treatment of heel pain (Reference 6) appeared to be superior to the OssaTron (Reference 13), although the methods of evaluation were not identical. In the Sonocur trial, there was an average 75% reduction in pain, with 57% showing a good or excellent outcome, while none of the controls had an excellent outcome, and only 10% had a good outcome at 6 months. The OssaTron trial had only a 3 month follow-up, and only 47% of the treated patients were better, with a mean pain relief of 56%. 30% of the control group had also improved, resulting in only a small difference in improvement between the groups.

The OssaTron carries with it the risk and discomfort of an anesthetic, is more than 3 times as expensive, and takes more time than the Sonocur. These factors lead us to favor the use of the Sonocur device. Reports from physicians in Canada, who have had experience with ESWT for musculoskeletal conditions since 1997, show very wide and broad patient and physician acceptance of the Sonocur.