

## TECHNIQUE

# Shock Wave Therapy for Treatment of Foot and Ankle Conditions

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## ABSTRACT

Shock wave therapy is a relatively new treatment of foot and ankle pain. An acoustic sound wave similar to one used for lithotripsy can cause a hyperanalgesia effect reducing pain and can cause breakdown and neovascularization of chronically damaged tissue. Three commercial sources are available for musculoskeletal applications. To date, the treatment seems to be effective for soft tissue pain. Within the United States shock wave therapy has been licensed for plantar fasciitis and has been used outside the United States for other foot and ankle tendonopathies. The pain must be well localized to 1 area for effective treatment. This article reviews the physics, indications, techniques, and documented outcomes to date.

**Keywords:** plantar fasciitis, shock wave therapy, extracorporeal, tendonitis, fasciitis

## HISTORICAL PROSPECTIVE

Extracorporeal shock wave therapy (ESWT) was used initially in the fragmentation of renal stones in the kidney and urinary tract for the treatment of renal colic. The first machine was produced commercially by Dornier in 1984.<sup>1,2</sup> Stones in the gall bladder, pancreas, bile ducts, and salivary glands have been treated by lithotripsy using ESWT. Observation showed that while in some cases the stone did not fragment or pass, the patient had significant symptom relief. The effect of shock waves was used in an animal model in 1986 to determine the effects on skin defect healing: Low doses having a positive effect and high doses inhibiting healing.<sup>3</sup> The technology was applied thereafter to the treatment of delayed bone healing and pseudoarthrosis after appropriate animal studies.<sup>3-5</sup> Treatments started in 1988, with 70 of 82 nonunions being successfully treated.<sup>6</sup> Other bony orthopedic applications included

loose hip arthroplasties, and osteochondrosis including OCD lesions of the knee and talus, and Kohler, Perthes, and Osgood-Schlatter diseases.<sup>3</sup>

Subsequently, the treatment was applied to tendonopathies including plantar fasciitis, shoulder impingement, and tennis elbow.<sup>7,8</sup> Dahmen<sup>3</sup> wrote the first paper in 1992 on shock wave treatment of tendonopathies, with 30 different syndromes being included in a 512 patient series.

The urological generators were not ideal for musculoskeletal treatments, hence newer generations of impulse generators were developed for treatment of musculoskeletal conditions (Fig. 1). Siemens produces the Soncur (Sonorex, Vancouver, British Columbia, and Siemens, Erlagen, Germany), Dornier the Epos Ultra (Dornier Medtech America Inc, Kennesaw, GA, USA, and Dornier Medtech, Wessling, Germany), and Healthtronics the OssaTron (High Medical Technologies, Lengwil, Switzerland, and Healthtronics, Austin, TX, USA). FDA approval has been granted for Sonocur treatment of lateral epicondylitis. The Epos Ultra and OssaTron have been approved for treatment of chronic plantar fasciitis with symptoms present for 6 months and failure of conservative treatment.

## PHYSICS

The therapeutic ultrasound wave has a fast pressure rise and a high pressure maximum. This transfers energy to the focused area within the patient. The shock wave generator must be coupled to the patient using a fluid barrier. In urology this is achieved by immersing the patient in water. In the generators developed for musculoskeletal applications, the coupling has been achieved using a water-filled diaphragm applied to the skin with acoustic gel placed on the skin surface. The generator and coupling device are all on the end of an articulating arm and on a mobile base, allowing the machine to be positioned to precisely deliver the shock wave to the area of discomfort.<sup>2</sup>

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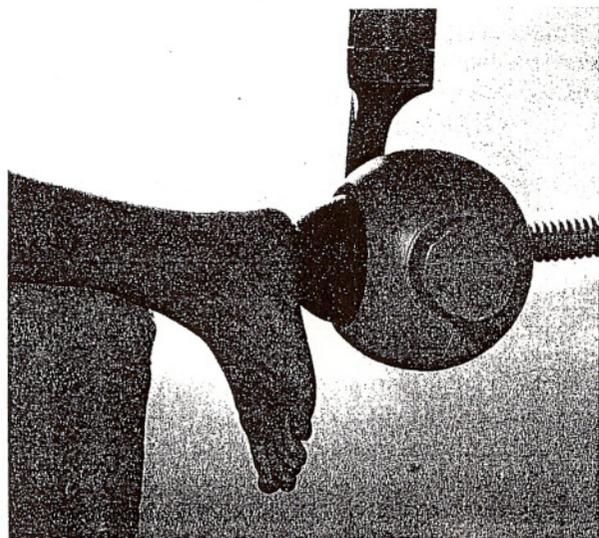


FIGURE 1. A patient undergoing low dose shock wave therapy treatment of the heel showing the coupling head, bellows, and gel.

The actual shock wave is generated within the machine by either an electromagnetic, electrohydraulic, or piezoelectric system. The electrohydraulic wave is generated similar to an automobile spark plug; the piezoelectric system uses oscillation of quartz crystals, and the electromagnetic generator uses deflection of a metal membrane similar to a speaker for a sound system.<sup>2</sup> The source causes a membrane to be rapidly repelled, the shock wave traveling through water to an acoustic focusing lens. The shock wave has a sudden pressure increase causing the local tissue effect (Fig. 2). The lens focuses the shock wave to a focal point at a known distance from the lens. All devices have water-filled coupling bellow that can vary the distance between the lens and the skin surface. This allows the operator to vary the depth of the focal point within the patient. Shocks can be varied in intensity and frequency.<sup>9</sup>

Subsequent developments have focused on methods of application and determining the correct dose size and frequency to achieve a maximal clinical effect.

### Cellular Effects

The effect at the cellular level is related to dose, with high energy levels causing significant cell necrosis. Lower doses cause cellular changes. These include enhanced membrane permeability, mitochondrial, endoplasmic reticulum, and cell nucleus changes. These include vacuolation within the cytoplasm and lesions in the actin and vimentin filaments.<sup>2</sup>

### Bone Effects

Within bone this cellular damage results in microfractures and osteoblast stimulation. Hematomas can be created. Increased neovascularization at a bone tendon

interface is seen in rabbits<sup>10</sup> and in dogs.<sup>11</sup> Within bone, high doses can cause avascular necrosis and hematoma formation in animal studies. Only hematoma formation has been seen in doses used in patients.

### Soft Tissue Effects

Within muscle and tendons, shock wave increases TGF- $\beta$  and IL-1 expression in rat Achilles tendonitis model.<sup>12</sup> Paratenon fluid is also seen after treatment, and an increased diameter in the tendon. Histological changes included fibrinoid necrosis, fibrosis in the paratenon, and infiltration of inflammatory cells.<sup>13</sup>

Shock wave therapy is thought to be effective in pain relief by a counter irritation or hyperstimulation analgesia effect. For low doses the hyperstimulation activates nonmyelinated C fibers, causing inhibition of further pain reception by inhibitor fibers. At moderate energy intensity, pain may be relieved by direct and indirect mechanisms. The direct effect includes disruption of the mechanical source of pain, such as scar formation in the Achilles insertion, or calcification within a tendon or fascia. Neovascularization removes the breakdown products of the scar or calcification. Indirectly, including the hyperstimulation analgesia, vascularization and macrophage immigration induces cellular repair of the degenerate tissue.<sup>2</sup>

### INDICATIONS

FDA approval has been obtained for plantar fasciitis for OssaTron in 2000 (high energy), Dornier Epos for plantar fasciitis in 2002, and Siemens Sonocur (low energy) for lateral epicondylitis in 2002. The FDA approval includes at least 6 months of existence of disease and failure of conservative treatment.

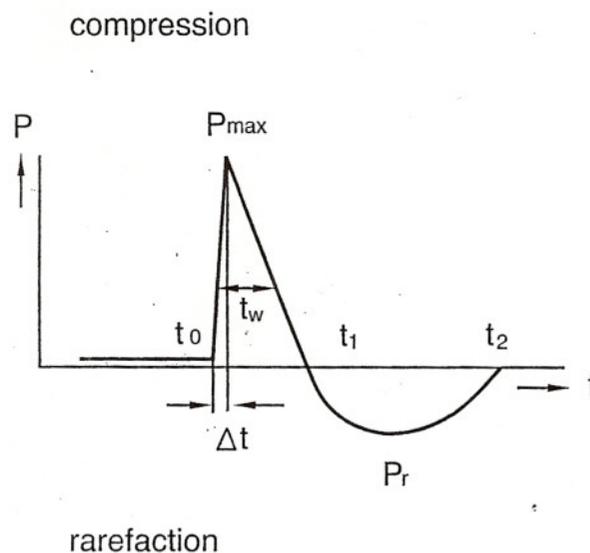


FIGURE 2. The shock wave profile.

Outside the United States, shock wave therapy within foot and ankle is used to treat Achilles tendonitis, Morton neuroma, stress fractures, peroneal, and tibialis posterior tendonitis. In general, shock wave therapy is used for treatment of enthesopathies, tendonopathies, and overuse injuries.

### ■ CONTRAINDICATIONS

Patients on anticoagulants or with a known clotting disorder have a relative contraindication to shock wave therapy as bleeding may be stimulated by the treatment. Pregnancy is considered a contraindication as the effect of shock wave on pregnancy has not been evaluated. Infection in the site or an open wound over the treatment site excludes the patient from shock wave therapy.

Otherwise patients unable to localize pain have a relative contraindication to treatment. These include patients with Alzheimer disease or other brain conditions preventing pain localization, or patients with diffuse pain, or many sites of pain making localization of the origin impossible.

### ■ PRETREATMENT PLANNING

Low energy shock wave therapy requires that the pain be well localized to 1 or 2 discrete areas. The area should be identifiable by palpation. There should be an anatomic correlation to the pain, the area of pain should be consistent, and the patient should be able to cooperate in the localization of the area of discomfort.

Patients should be imaged before treatment to rule out any malignancy. This may include plain radiographs and MRI.

Conservative treatment should be exhausted before treatment. For plantar fasciitis this should include anti-inflammatories, physiotherapy and stretching, activity modification, and orthotics, but not necessarily steroid injections.<sup>14</sup>

Contraindications to treatment include poorly localized pain, pregnancy, malignancy, age under 18, and bleeding disorders. Patients on Coumadin should suspend anticoagulation if shock wave therapy is performed to prevent hematoma formation.

### ■ TECHNIQUE OF TREATMENT

#### Types of Musculoskeletal Source

Energy source may be low or high energy: Low energy is applied by a technician, requires no anesthesia or imaging, and has a lower cost using 3 treatment regimes. The lower energy sources allow the technician to focus the signal onto the area of maximum discomfort as no anesthetic is used. The Sonocur plus is a low energy source.

High energy requires a physician to operate it and anesthesia is required as it is painful. Imaging is required to focus the beam. For the Epos Ultra local anesthetic is instilled in the heel before treatment. For the Epos ultra uses an electromagnetic generator. The OssaTron uses a spark plug. All generators use water-filled diaphragms to contact the skin. The OssaTron is more painful and therefore requires a greater degree of anesthesia, increasing the cost. The water-filled diaphragm can be changed in depth focusing the beam within the patient.

The operator can direct the shock wave at the area of discomfort and can also vary the depth of penetration of the wave. For the Epos Ultra, the area of tenderness is identified using clinical exam, and an ultrasound probe is used to confirm the positioning of the center of shock wave application. For the OssaTron, the area is identified before anesthesia and the physician directs treatment to the area. The higher dose may result in a higher field being affected, causing a greater degree of pain relief.

For the Sonocur, direct feedback is used, as no anesthesia is required, the operator changing the depth and direction of treatment to hit the area of maximum pain.

Gel is applied to the area to couple the diaphragm to the skin preventing shock wave attenuation. The diaphragm of the device is applied to the skin and the depth of penetration altered until the area of discomfort has been localized. This is harder to achieve for the OssaTron. The Epos Ultra uses ultrasound to focus the beam, whereas patient feedback is used for the Sonocur. The energy level of the shock wave is increased and 2000 shocks are applied per treatment. The source is adjusted during treatment to ensure that the area of maximum tenderness is treated. The treatment is repeated up to 3 times.

#### Complications—transient

In the FDA study, the patients reported a number of adverse events. This included pain, nausea, and reaction at the application site, sweating, and dizziness. Some reactions were the same in the control group. Other reported complications include petechiae, skin discoloration, dull pain, and paraesthesia.

#### Posttreatment Management

Patients activity can be as tolerated after treatment. One of the major benefits of shock wave therapy is that patients can continue activities immediately after treatment and minimal time off work is required compared with a surgical release. Adjuvant treatments are continued during and after treatment, including ice and physiotherapy. There is no literature to date documenting any particular risk of rupture after shock wave therapy so physiotherapy and activities are encouraged to be continued as normal.

### Delayed Imaging

MRI before and immediately after treatment shows increase in soft tissue oedema but not bone oedema: high energy.<sup>15</sup>

Ultrasound at 6 months shows significant attenuation of signal after shock wave therapy compared with before-treatment approaches same as opposite side. Thickness of plantar fascia correlated with the degree of pain.<sup>16</sup>

### SUMMARY OF OUTCOME DATA TO DATE

Two papers have shown no difference between treatment groups: one published in the *Journal of the American Medical Association*,<sup>17</sup> the second in the *British Medical Journal*.<sup>18</sup> Both used the Dornier Epos Ultra with local anesthetic block. The *JAMA* paper used

a low dose versus regular dose treatment, and the *BMJ* article used a polyethylene foil in the control group. Both papers studied patients early in the treatment or with minimal symptoms, potentially confounding the results. The *JAMA* article used 6 weeks instead of 6 months as an inclusion criterion. The *BMJ* article had only 1 patient in each group going on to surgery and did not outline the duration of prior treatment. Ultrasound and MRI abnormalities may not be the main area of pain and as a result may have missed the source of pain.

Most papers apart from these 2 have shown successful outcome of treatment. The studies have been of higher quality in general, being prospective and randomized controlled studies for the most part. The Cochrane database felt there was little evidence for its use but set a very high standard for inclusion criteria for the papers.<sup>19</sup> Otherwise, weaker literature evidence presently exists for the surgical treatment of planar fasciitis so that the

TABLE 1. Summary of prospective papers for plantar fasciitis

Date	Journal	Author	Device energy	Study	No. patients	Design	Result
2002	Journal of Bone and Joint Surgery	Rompe <sup>21</sup>	High	Low vs high dose	115	Random	+ve
1995	Archives of Orthopedic and Trauma Surgery	Rompe <sup>22</sup>	High	Low vs no treatment	30	Random	+ve
2003	Archives of Orthopedic and Trauma Surgery	Hammer <sup>16</sup>	Shock wave therapy	Plantar fascia thickness	44	nil	Decreased fascia thickness
2002	JAMA	Buckbinder <sup>17</sup>	Dornier Epos Ultra	Low vs high	165	Random	-ve
2002	Foot & Ankle International	Alvarez <sup>23</sup>	High	Case series	20		+ve
2002	Journal of Foot and Ankle Surgery	Wang <sup>11</sup>	High	Case series	85		+ve
2002	Foot & Ankle International	Ogden <sup>14</sup>	all	Meta-analysis			+ve
2001	Clinical Orthopaedics and Related Research	Ogden <sup>24</sup>	High	Low vs high	322	random	+ve
2005	Journal of Orthopaedic Research	Rompe <sup>25</sup>	low	Local anesthetic vs no local	86	random	+ve
2003	American Journal of Sports Medicine	Rompe <sup>26</sup>	Low	Low vs placebo runners	45	random	+ve
2005	Journal of Foot and Ankle Surgery	Hyer <sup>27</sup>	Dornier Epos	Case series	35		+ve
2004	Foot and Ankle International	Theodore <sup>28</sup>	Dornier Epos	Treatment vs sham	150	Random blinded	?+ve
2004	Journal of Bone and Joint Surgery	Ogden <sup>29</sup>	High energy	Treatment vs sham	293	Random blinded cross	+ve
2003	Journal of Orthopaedic Research	Speed <sup>30</sup>		Treatment vs sham	88	Random blinded	?+ve
2003	Foot and Ankle International	Lee <sup>31</sup>	Low energy	Treatment vs sham	435	Random	
2003	Foot and Ankle International	Hammer <sup>32</sup>		Crossover	47	Random	+ve
2003	BMJ	Haake <sup>18</sup>	Dornier Epos		256		-ve
2003	Cochrane Database of Systematic Reviews	Crawford <sup>19</sup>	Meta-analysis				-ve

conclusion of the Cochrane review needs to be taken in context.

In the treatment of failed plantar fasciitis, the comparative treatment, open surgery, has not had nearly the same rigorous outcome analysis. The only comparative series on shock wave therapy against surgery performed was a study on lateral epicondylitis in worker's compensation patients. This study supported the use of ESWT over surgery but has not as yet been published.<sup>20</sup> Seventy-six percent of the ESWT group returned to work by 6 months compared with 30% in the surgery group. Low dose source without anesthesia is effective, and high dose with anesthesia is effective. Low dose with anesthesia is not effective, as shown in a prospective randomized trial by Rompe.<sup>25</sup> Summaries of outcomes to date are in Table 1.

## CONCLUSION

Shock wave therapy seems to be a viable treatment alternative for plantar fasciitis. Outcome studies in general have supported a positive outcome. Shock wave therapy has been used for treatment of well-localized tenopathies and soft tissue pain outside the United States. For example, insertional Achilles tendonitis can be treated with shock wave therapy as an alternative to surgery. FDA approval for foot and ankle presently only covers plantar fasciitis. Shock wave therapy should be offered as a second line of treatment to patients with plantar fasciitis, possibly before steroid injection, as the complication rates may be lower and the therapeutic effect higher. Shock wave therapy may have better outcomes than surgery for plantar fasciitis. Comparative studies are needed (surgery vs shock wave therapy) before absolute conclusions can be reached. However, few patients would agree to have the invasive treatment of surgery if shock wave therapy is also available.

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