shockwave therapy

Medical Information for Specialists in Orthopaedics / Rheumatology / Traumatology

High Medical Technologies

Sequence of events in a typical treatment situation

Prerequisites

- The condition to be treated has been reliably diagnosed
- The patient has been given sufficient information about shock-wave therapy and been instructed on possible adverse reactions
- The case has been reviewed thoroughly to exclude contraindications to shock-wave treatment.

Patient preparation and ROI locating

A distinction is made between soft-tissue and bone indications.

Soft-tissue indications

In patients presenting with these indications, the treatment area is located via ultrasound or palpation and marked on the skin. X-rays, which are usually available for patients with calcifying tendinitis or plantar fasciitis, facilitate the locating of the region of interest (ROI). The penetration depth of the OssaTron can be selected from 0-100 mm via stepless adjustment and monitored via the laser locating system. To make the treatment as pleasant as possible for the patient, it is carried out in most cases under local anaesthesia.

Bone indications

Because higher energy levels are required to treat bone, this type of treatment is usually carried out under general or spinal anaesthesia. The focus is positioned via x-ray locating. The OssaTron comes equipped with a locating bow with two target markings. With the aid of these target markings, it is possible to bring the shock-wave focus directly over the ROI under x-ray control.

Treatment

To guarantee optimal transmission of shock waves, ultrasound gel is placed as a coupling medium between the therapy head and the patient's skin. The zone between the skin and the membrane of the therapy head should be free of air bubbles. Depending on the particular indication, a specific number of shock waves are emitted onto the treatment area at a specified energy level. The treatment takes between 4 and 30 minutes.

Follow-up care

In most cases, ESWT is administered in an outpatient setting. Immobilization of the extremities is necessary only in patients with pseudarthroses without osteosynthesis material or in cases with insufficient stability. In all other cases, the patient can be sent home again after a short rest period, the length of which depends on the type of anaesthesia used.

Adverse reactions

- The patients may experience pain directly during, or as a result of the treatment; as a rule this pain subsides directly after the treatment or within a few days
- In individual cases, erythema and petechia may occur in the skin area where the shockwave coupling membrane was applied. Hematomas have been observed only in exceptional cases

Indications and Contraindications

Indications

Soft-tissue indications

- Calcifying tendinitis
- Epicondylitis
- Plantar Fasciitis
- Achillodynia
- Patellar tip syndrome
- Induratio Penis Plastica (Peyronie's Disease)

Bone indications

- Pseudarthrosis and delayed fracture healing
- Avascular necrosis (AVN)
- Osteochondrosis Dissecans (OD)

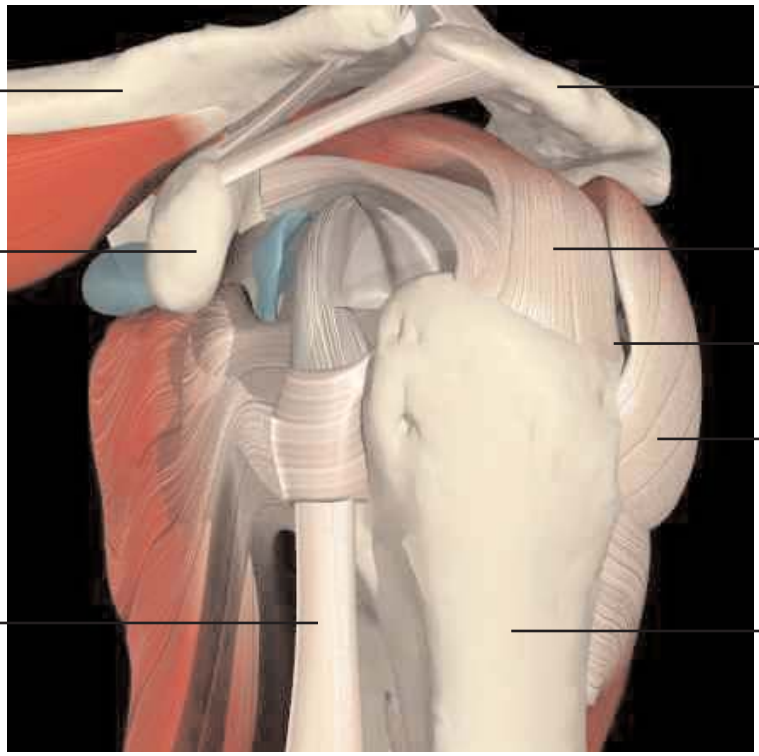
Contraindications

- Bone structures at locations such that lung tissue could lie in the path of the converging or diverging shock waves
- Coagulation disorders
- High-risk patients
- Osteomyelitis
- Open epiphyseal plates in children
- Infected pseudarthrosis

Until sufficient clinical experience has been gained with the safe use of ESWT to treat the following conditions, they must be viewed as contraindications to shockwave therapy:

- pregnancy
- patients with pacemakers
- placement of the therapeutic focus over large vessels because of the danger of thrombosis
- placement of the therapeutic focus over major nerves
- treatment of vertebrae because of the lack of information on the effect of shock waves on the spinal cord
- treatment of skull bones because of the lack of information on the effect of shock waves on the cerebral system

Calcifying tendinitis



Anatomical picture of the rotator cuff

Calcifying tendinitis

Calcifying tendinitis is a chronic inflammation of the insertion of the supraspinatus tendon, the infraspinatus tendon or the long biceps tendon; it can cause symptoms ranging from shoulder pain to limitation of movement. This condition can occur with or without calcific deposits. The possible causes include overuse, e.g. due to excessive athletic activity after a long period of inactivity, or trauma.

Treatment

The treatment area can be reliably located with ultrasonic or x-ray methods. Treatment is usually carried out under local anaesthesia.

Success rate

In 88 % of the patients treated, a distinct improvement or complete recovery was observed after six months. In 73 % of the patients treated, disappearance or decrease in size of the calcific deposits could be demonstrated on x-ray. The retreatment rate was approx. 1.6 treatments per patient on average.

Reference

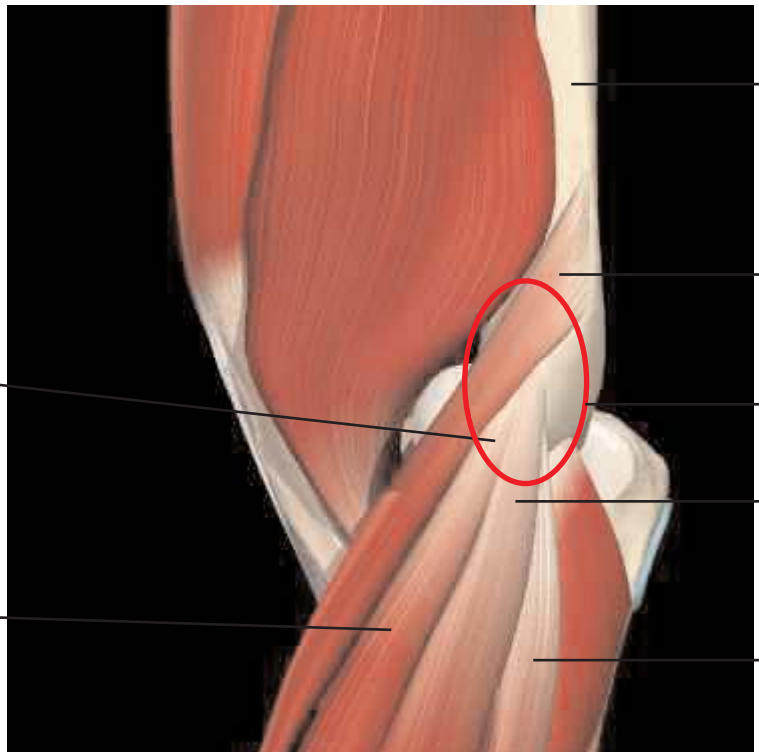
- R.Thiele: The german extracorporeal shock wave society; W. Siebert, M.Buch: Extracorporeal shock waves in orthopaedics, pp. 189-200, Springerverlag, 1997

Calcifying tendinitis

Before treatment

8 weeks after treatment

Epicondylitis radialis



Anatomical picture of the elbow (side view)

Epikondylitis radialis

As a result of constant excess strain and micro-traumas causing tears in the tendons, inflammatory or degenerative changes take place on the epicondyle. These are accompanied by severe tenderness and pain on movement at the common origin of the extensor digitorum communis and the extensor carpi radialis brevis muscles (epicondylitis humeri radialis). The extensor muscles are responsible for grasping and rotary movements of the hand; in patients with epicondylitis, these movements may be restricted and painful.

Treatment

The treatment area can be reliably located by palpation or ultrasonic methods. Treatment is usually administered under local anaesthesia.

Success rate

In 73.1 % of the patients treated, a distinct improvement or complete recovery was noted after six months. The retreatment rate was 1.2 treatments per patient on average.

Reference

- J-Y. Ko et al.: Treatment of Lateral Epicondylitis of the Elbow with shock-waves; CORR 387, pp. 60-67, 2001

FDA study

In order to obtain FDA approval for the OssaTron, a multicentric, randomized, double-blind, placebo-controlled study was carried out. A total of 209 patients participated in this study, during which a success rate of 66 % was achieved in patients with epicondylitis radialis after a single treatment session. The retreatment rate was 1.13 treatments per patient on average.

Anatomical picture of the sole of the foot

Plantar fasciitis (painful heel syndrome)

The plantar aponeurosis is a wide band of thick fibrous tissue extending from the calcaneus to the toes. It lies superficially on the flexor digitorum brevis muscle and is covered by subcutaneous fatty tissue. Overuse of the plantar aponeurosis (e.g. as a result of talipes planus, obesity, etc.) may result in inflammation of the attachment of the plantar fascia and thus to pain in the heel or midfoot region; this pain is most noticeable in the morning, when the patient first places weight on the foot. In about 50 % of the patients with this condition, a bony spur can be detected on the calcaneus by x-ray. However, spurs have also been found in patients lacking the symptoms described above.

Treatment

The treatment area can be reliably located by ultrasonic or x-ray methods. Treatment is usually administered under local anaesthesia.

Success rate

In 87 % of the patients treated, a distinct improvement or complete recovery was noted after six months. The retreatment rate was 1.3 treatments per patient on average.

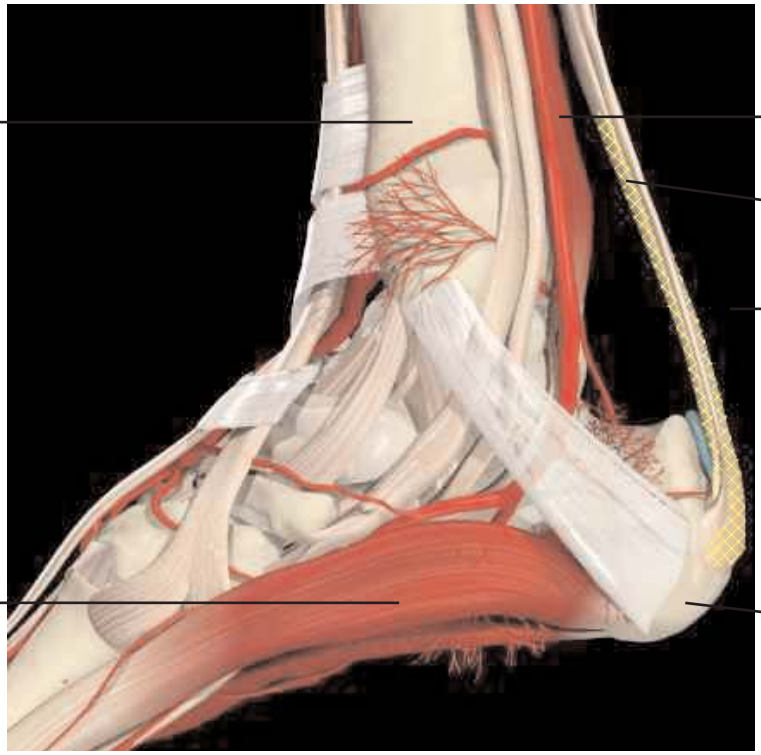
Reference

H-S. Chen et al.: Treatment of painful heel syndrome with shock waves; CORR 387, pp. 41-46, 2001

FDA study

In order to obtain FDA approval for the OssaTron, a multicentric, randomized, double-blind, placebo-controlled clinical study was carried out. A total of 276 patients participated in this study, during which a success rate of 76 % was achieved in patients with plantar fasciitis after a single treatment. The retreatment rate was 1.07 treatments per patient on average.

Achillodynia



Anatomical picture of the foot (side view). The yellow-shaded areas is the Achilles tendon.

Achillodynia

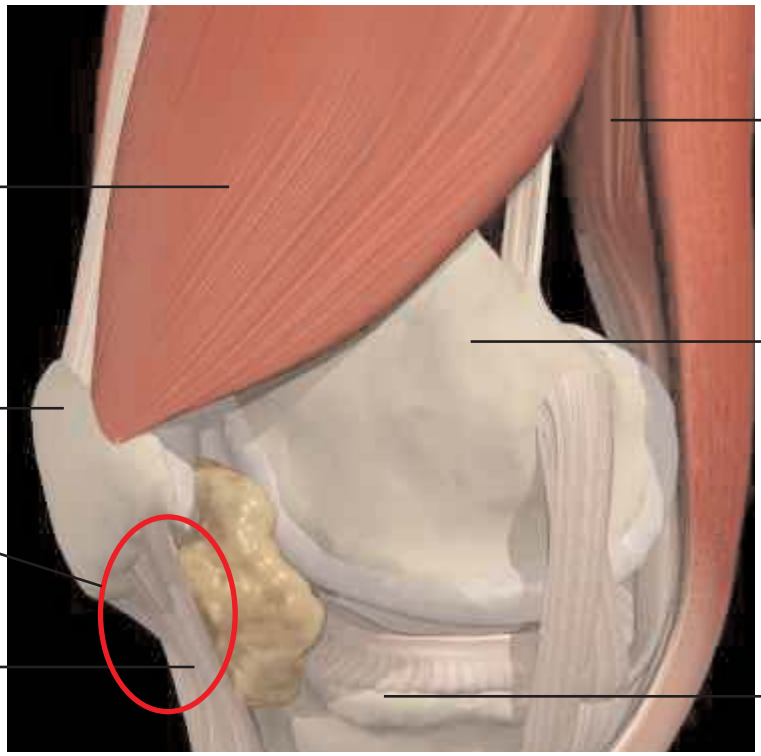
In most cases the pain syndrome in the Achilles tendon region is caused by overuse or trauma. A thickening of the tendon near the tendon insertion can usually be detected by palpation or imaging techniques. This thickening leads to massive pain and limitation of movement. The Achilles tendon is the thickest and strongest tendon in the body. It is about 12 to 15 cm long and represents a fusion of the aponeurosis of the gastrocnemius and soleus tendons.

Treatment

The treatment area can be reliably located by ultrasonic or x-ray methods. Treatment is usually administered under local anaesthesia.

MRI-Image of the heel

Patella-Spitzen-Syndrom (Jumper`s Knee)



Anatomical picture of the knee (side view)

Patellar tip syndrome (jumper's knee)

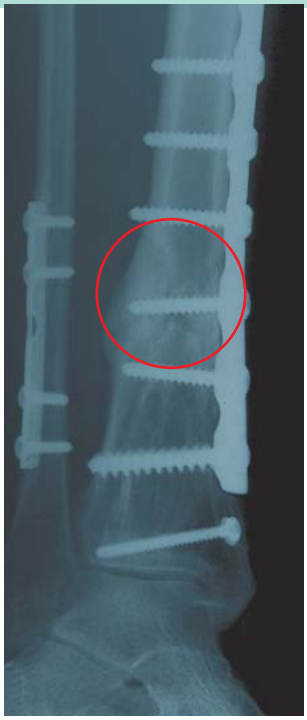
In most cases of patellar tip syndrome, the proximal insertion of the patellar tendon is inflamed and thickened, causing massive pain and restriction of movement. This disease usually occurs among athletes, especially those engaging in sports involving jumping.

Treatment

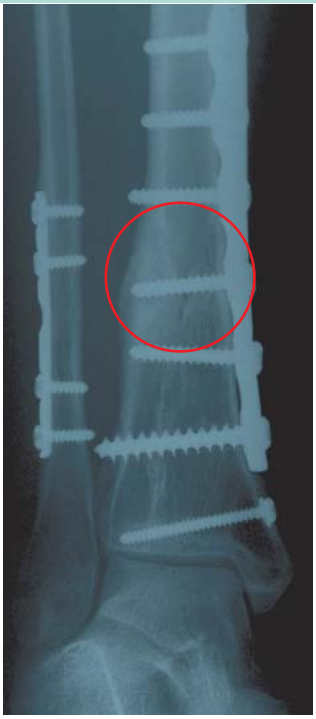
The treatment area can be reliably located by ultrasonic or x-ray methods. Treatment is usually administered under local anaesthesia.

Pseudarthrosis

Before shock wave therapy, 7 month after fracture.



6 month after a single shock wave therapy with the OssaTron, complaint free, full weight-bearing is possible.



Final control: 12 month after shock wave therapy, removal of the osteo synthesis material one day after control.

Pseudarthrosis

The term "pseudarthrosis", or non-union, is used to describe a fracture characterized by an absence of bony union or unstable healing six months or longer after the fracture. Patients with this diagnosis usually experience pain upon weight-bearing; the affected bone displays abnormal mobility. Pseudarthrosis may be caused by mechanical factors, deficient callus formation, infections or insufficient blood circulation.

Treatment

Clinical studies have shown that hypertrophic and defect pseudarthrosis have a better response to treatment and a higher success rate than atrophic pseudarthrosis.
The size of the fracture gap ≤ 5 mm - also has a favorable effect on the outcome following ESWT.

The treatment area is located via radiological techniques. Depending on the particular bone involved, the treatment is carried out under general or regional anesthesia (e.g. spinal).
In most cases, one shock wave treatment is sufficient; an additional treatment is required only in exceptional cases.

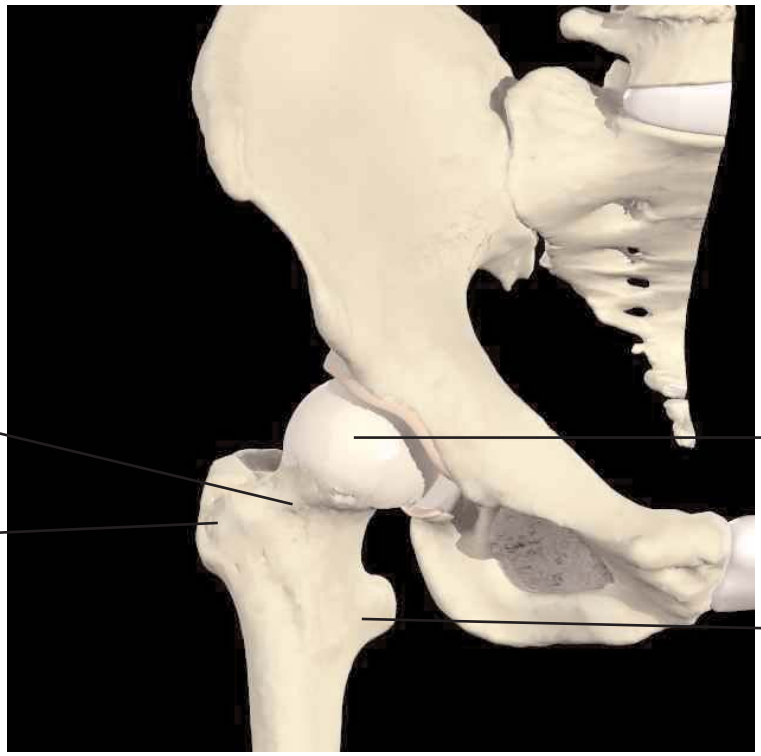
Success rate

in 80% of patients treated a bony union was noted after one year. The retreatment rate was 1.1 treatments per patient on average.

Source

Wang et al.: Treatment of Nonunions of long bone fractures with shock waves; CORR 387, pp. 95-101, 2001

Avascular femoral head necrosis



Anatomical picture of a hip joint

Avascular femoral head necrosis

In patients with this disease, impaired blood circulation leads to the death of bone cells in the femoral head. These changes do not show up on x-ray until relatively late; however, they can be detected at a very early stage by MRI. The impaired blood circulation may be due to trauma or to non-traumatic causes such as idiopathic diseases, alcoholism or drug abuse. Patients with AVN suffer from pain and limited movement. As the disease progresses, incomplete fractures occur in the femoral head; the resulting "unround" shape of the hip joint results in increasingly impaired joint function. At this stage of the disease, the patient has pain even at rest.

Treatment

The results of clinical studies indicate that ESWT offers good prospects for success in patients with AVN at ARCOR stage 2 or below. The treatment area is located by x-ray; treatment is carried out under general anaesthesia.

Success rate

In 66.6% of the patients treated, a distinct improvement or complete recovery was observed after one year.

Reference

- J.Ludwig et al.: High-energy shock wave treatment of femoral head necrosis in adults; CORR 387, pp. 119-126, 2001

Osteochondrosis dissecans (OD)

Anatomical picture of the knee

Osteochondritis dissecans (OD)

Osteochondritis dissecans is a process during which fragments of the joint cartilage, and attached bone, start to separate from the rest of the joint surface. Although this process can take place in any large joint, it most frequently occurs in the knee joint. The injury is usually unilateral and may remain asymptomatic. However, it is heralded in most cases by symptoms such as swelling and pain. Advanced stages of the disease are characterized by phenomena such as the sudden "giving way" of the knee or joint locking.
The two main hypotheses put forth on the pathogenesis of OD are a) mechanical injury or overuse and b) necrosis and detachment due to bone infarcts caused by insufficient blood circulation.

Treatment

The treatment area is located by x-ray; therapy is carried out under general anaesthesia or regional anaesthesia (e.g. spinal).

MRI image of a knee with OD

Reference:

S. Heiersdorf et al:.
Osteochendritis dissecans;
Coombs, Schaden, Zhen:
Musculoskeletal Shockwave Therapy,
pp. 255-264; GMM 2000

OssaTron - Soft-tissue indications

Indication	Energy level	Number of shock waves
Calcifying tendinitis	14 - 16 kV	800 - 1000 [1,2]
Epikondylitis radialis	16 - 18 kV	1000 [1]
Achillodynia	14 - 16 kV	1000
Patellar tip syndrome	14 - 16 kV	1000
Plantar fasciitis	14 - 16 kV 18 kV	1000 [1, 3] 1500 [4]

Literature:

- **1)** Thiele: The German Extracorporeal Shock Wave Society, in W. Siebert, M. Buch: Extracorporeal Shock Waves in Orthopaedics, Springerverlag 1997, pp. 189 - 200
- **2)** J-Y. Ko et al.: Treatment of Lateral Epicondylitis of the Elbow With Shock Waves, in CORR Nr. 387, pp. 60-67; 2001 Lippincott Williams & Wilkins, Inc.
- **3)** H-S. Chen et al.: Treatment of Painful Heel Syndrome With Shock Waves, in CORR Nr. 387, pp. 41 - 46; 2001 Lippincott Williams & Wilkins, Inc.
- **4)** FDA-Studie: Extracorporeal shock wave therapy for chronical heel pain syndrome

OssaTron - Bone indications

Pseudarthrosis	Energy level	Number of shock waves
Humerus	28 kV	3000 [5]
Ulna, Radius	24 kV	2000 [5]
Femur, Tibia	28 kV	6000 [5]
Metatarsal	20 kV	1000 [5]
Further Bone indications		
AVN	28 kV	4000 [6]
Osteochondrosis dissecans	20-28 kV	2000-3000 [7]

Literature:

- **5)** C-J. Wang et al.: Treatment of Nonunions of Long Bone Fracture With Shock Waves, in CORR Nr. 387, pp. 95 -101; 2001 Lippincott Williams & Wilkins, Inc.
- **6)** J. Ludwig et al.: High-Energy Shock Wave Treatment of Femoral Head Necrosis in Adults, in CORR Nr. 387, pp. 119 - 126; 2001 Lippincott Williams & Wilkins, Inc.
- **7)** S. Heidersdorf et al.: Osteochondritis dissecans, Coombs, Schaden, Zhen (eds), Musculoskeletal Shockwave Therapy, pp. 255 - 264, GMM 2000

EvoTron

Indication	Penetration depth	Number of shock waves
Epicondylitis radialis	5 - 15 mm	1200
Tendinosis calcarea	15 - 25 mm	1500
Plantar Fasciitis	15 - 25 mm	1200

The typical way of treating Plantar fasciitis and Tendinosis calcarea is to increase the penetration depth after a few hundred shocks from 10 mm penetration depth up to 15 or 20 mm.