

What is Extra-corporeal Shock Wave Therapy (ESWT) ?

It was in the early 80's that it became possible for urologists to remove kidney stones without open surgery ; instead of the traditional scalpel they used shock waves, generated by a special device, called Lithotripter ; the energy of the shockwaves directed and focused at the renal stone, entered the body via a special water cushion and caused its des-integration after a certain number of shocks ; the des-integrated parts leave the body via the natural way.

This new procedure was called Extra-corporeal Shock Wave Lithotripsy (ESWL).

At a later stage it was observed that certain healing effects took place around the area where the shockwave energy was directed, involving bone and soft tissue areas. Under the guidance of Orthopedists and Traumatologists, these healing effects were studied and first experiments were done applying these particular waves to chronic orthopedic diseases ; in parallel a development started for shockwave equipment that complied with orthopedic requirements, which by nature differ from the urologists needs and characteristics.

In line with ESWL this new procedure was called Extra-corporeal Shock Wave Therapy (ESWT).

HMT High Medical Technologies AG in Switzerland unveiled their first system for ESWT, called OssaTron, in 1991. To this day, this system is widely in operation due to its technical characteristics and ease of operation, and last but not least, undisputable clinical results.

With the ReflecTron HMT presents a smaller unit especially designed for the present requirements in hospitals and private practices ; to meet with the requirements of the orthopedist attending in various clinics in different locations, HMT launched a portable unit, called EvoTron, meeting with the same characteristics as the ReflecTron.

For the Veterinarian Specialist, HMT developed a EquiTron which due to its robust design is intended for the outdoor medical procedures with animals, in particular horses ; likewise with human orthopedy, HMT developed a portable shockwave system for veterinarian use in laboratories and surgical centers, and called this VersaTron and VersaTron 4 Paws.

It is important to understand that all HMT systems satisfy the strict requirements imposed by the DIGEST Organization who controls and allows certification seals only to those systems that comply with the standards as far as the physical principles and characteristics of a shockwave are concerned, and which are accepted by the industry and medical society.

(see <http://www.digest-ev.de/> sub "Technik".)

What are the Indications for ESWT ?

Following ESWT indications are accepted by the International Society for Musculoskeletal Shock Wave Therapy (ISMST) :

- Tendopathies of the shoulder with or without calcification *)
- Epicondylitis humeri radialis (tennis elbow) and ulnaris (Golfer's elbow) *)
- Plantar fasciitis (heel spur) with or without calcification
- Non-unions, pseudarthrosis, delayed fracture healing
- Avascular Necrosis of the head of the femur
- Osteochondrosis dissecans
- Achillodynia
- Patella tip syndrome Jumper's knee)

*) These diseases are known as RSI symptoms - "RSI" stands for Repetitive Strain Injury -- an umbrella term covering all kinds of work-related injuries to the muscles, nerves, and tendons of the upper limbs. It includes, for instance, Carpal Tunnel Syndrome, Bursitis, Tendonítis, Tenosynovitis, Shoulder Calcification, and Epicondylitis.
Although many kinds of repetitive work can bring on RSI symptoms, computer users are particularly at risk ; they tend to work for periods without a break, sometimes in slumping or "crouching" postures which add to the strain on muscles and tendons.

How does ESWT work ?

Unlike ESWL for urinary stones, where the mechanical effect of the shockwave is important, the results of the basic ESWT research today show a growing consensus that shockwaves cause changes in the molecular biological structures and produce enzymatic effects; there are several theses :

1. Shock waves stimulate a metabolic reaction of tissue (chemical / physical changes) - stimulating a series of regenerative processes of the tissue ;
2. Shock waves induce neo-vascularisation [1] in the treated site which in turn relieve pain and improve tissue regeneration and repairing.
3. Shock waves induce an analgesic effect (= reduced response to painful stimuli) by over stimulating the nerves. This effect is described as "Gate Control Effect" in the literature.

[1] Wang et al.; Shock Wave Enhanced Neo-vascularisation At The Tendon-Bone Junction - An Experiment In Dog Model. Presented at the 3rd Congress of the International Society for Musculoskeletal Shockwave Therapy in Naples, June 1 - 3, 2000

Who is a candidate for ESWT?

In general ESWT is recommended for patients who have not responded to conservative treatments like physical therapy, infiltration etc. and surgery is considered the next option.

Criteria of the ISMST (International Society for Musculoskeletal Shockwave Therapy) :

pain over a period of at least 6 months
unsuccessful, regular prior treatment over a period of at least 3 months, or
unsuccessful operation

at least 3 of the following conservative measures must be carried out, whereby the first two treatments are mandatory.

- Physiotherapy
- Injections (cortisone, local anesthetics)
- Medication
- Electrotherapy
- Ultrasound
- Thermotherapy / frigo-therapy
- Neural therapy
- Acupuncture
- X-ray treatment (not recommended)
- Resting of the shoulder joint (not recommended)

How is the treatment performed?

ESWT treatment is a non-invasive procedure, i.e. it does not involve surgery. The average treatment time is about 10 - 20 minutes. HMT's operational protocols are based on single session procedures giving a success rate of over 70% for most cases; a second procedure may be required in case a first procedure is not successful; localization of the treatment area is accomplished using palpation or X-Ray, whereas the medical doctor may use fluoroscopy or ultrasound for a further diagnosis and monitoring.

What are the Results?

Success rates for ESWT are good to excellent. In the case of Tendinitis, the OssaTron / ReflecTron, using a single treatment, have a success rate of approximately 75%. In the case of shoulder calcification, the single treatment success rate is close to 80%. Generally, the patients become pain free within 3 - 4 weeks post treatment. Calcific deposits may disappear after 6 - 8 weeks.

For the OssaTron, the success rate for the healing of non-unions (= failure of normal healing of a fractured bone) may exceed the range of 80% ; this even for non-unions, that, in some cases have been present for many years.

ESWT is a useful non-invasive therapy for patients suffering from chronic pain and an alternative prior to surgery.

FDA approval for the ESW treatment of chronic heel pain syndrome with HMT's shock wave device OssaTron

In October 2000 the Food and Drug Administration (FDA) approved the OssaTron for severe heel pain.

A multi-center, randomized, placebo-controlled, double blind clinical study was performed in 7 institutions in the USA to determine the safety and effectiveness of extracorporeal shock wave therapy (ESWT) with the OssaTron of chronic heel pain syndrome (plantar fasciitis) involving 302 patients who failed other treatments in the previous six months. Half were treated with the OssaTron; half received a sham treatment ; all were given a local anesthesia or an ankle block before treatment.

The success rate following a single treatment with the OssaTron is 76 %. The success rate for patients undergoing repeat treatment, following a failed primary treatment, is 81 % based on investigator's assessment The complication rate is 4.7 % and the re-treatment rate 10.7 %.

It was concluded that a single ESWT procedure with the OssaTron is an effective treatment for chronic heel pain syndrome.

In March 2003 the FDA approved the OssaTron for chronic lateral epicondylitis.

A multi-center, randomized, placebo-controlled, double blind clinical study was performed in 7 institutions in the USA to determine the safety and effectiveness of extracorporeal shock wave therapy (ESWT) with the OssaTron of chronic lateral epicondylitis involving 225 patients who failed other treatments in the previous 6 months or more.

The comparison of the clinical and statistical results between active treatment patients and Placebo-treated patients was highly significant according to the statistical analysis. 90% of the treated patients received a benefit from the treatment and 64% had an excellent or good outcome. The complication rate was 4,7% and the re-treatment rate 12,9%. The energy delivered was 1500 shocks at 18 kV.

It was concluded that a single ESWT procedure with the OssaTron is an effective treatment for chronic lateral epicondylitis.

Shockwave properties and significance on Clinical Results

1. Energy Flux Density

The Energy Flux Density (EFD) is probably the most used parameter in discussions about shockwave and shockwave devices. However EFD is only one single parameter and not enough to characterize a shockwave due to the fact that only the energy flux through 1 mm² of a medium is described ; additionally only the highest value is numbered. However there is a certain distribution throughout the total focus. This is important since not only 1 mm² of tissue is covered and treated.

A high EFD results in an increased potential of tissue and cell damage. It was reported that in experimental studies no irreversible tissue damage was observed up to 0.6 mJ/mm² EFD. (1)

In this context shockwaves are considered “Low Energy” when the energy flux density ranges from 0.05 mJ/mm² to 0.10 mJ/mm². “Medium Energy” shockwaves range from 0.10 to 0.28 mJ/mm² and “High Energy” shockwaves are existent when the EFD is > 0.28 mJ/mm².

Neither the OssaTron, ReflecTron nor the EvoTron do have Energy Flux Density of more than 0.4 mJ/mm². Therefore there is no risk of tissue damage or irreversible cell damage by HMT devices. Other systems as the Eledromagnetic shockwave or piezoelectric shockwave have significant higher EFD than HMT's Orthopedic devices. Therefore the risk of cell damages with those systems is far bigger than with HMT devices, if not used properly.

¹ Dose-related effects of shock waves on rabbit tendo Achillis. A sonographic and histological study
Rompe JD, Kirkpatrick CJ, Kullmer K, Schwitalle M, Kirschek O.
J Bone Joint Surg Br. 1998 May; 80(3):546-52

2. Focal Energy

As far as clinical effectiveness concerns the focal energy of the shock wave is the most important parameter because the energy is responsible for clinical data, like:

- success rate
- number of shocks per treatment
- retreatment rate

Due to the character of the generated shockwave and the bigger focus size, HMT systems have a significant high total energy per shockwave ; at the same time HMT devices have a lower EFD based on 1 mm². Because of the much bigger focus size of the OssaTron, Reflectron and EvoTron, HMT applies high energy on a large focus volume.

3. Clinical effectiveness

There are some significant differences in terms of clinical effectiveness – success rate, between the different ESWT systems :

- a) **number of treatments**
- b) number of **shockwaves** per treatment
- c) applied **energy level**



More information can be found in the sites of

ISMST under <http://www.ismst.com/>

DIGEST under <http://www.digest-ev.de/>

Ondas de Choque under <http://www.ondasdechoque.com.br/>

And the links mentioned in our site under <http://www.hmtbr.com.br/>