shockwave therapy

Clinical studies about orthopaedics

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Studies and Research on Extracorporeal Shock-Wave Therapy

Introduction

Shock waves have been used routinely for about 20 years to desintegrate stones in the kidneys and ureters. For approximately eight years, they have also been used to treat orthopaedic disorders. During lithotripsy procedures, the shock waves break a stone, or urinary calculus, into fragments small enough to leave the body via normal routes. In the field of orthopaedics, however, shock waves are used to initiate healing processes in patients with chronic diseases of bone or soft tissue. At the beginning of the 1980s, the first experiments were carried out to investigate the impact of shock waves on the pelvic bones. It was feared that shock waves administered to break down calculi in the ureters could cause damage to the pelvic bones. However, the results of these experiments showed that the shock waves did not cause any damage to intact bones.

1985

In this year the first systematic animal studies got underway to investigate the effects of shock waves on bone. These studies were carried out at University Hospital Bochum by Prof. Senge and Prof. Richter in cooperation with Dr. Schwarze, one of the founders of HMT AG. The experiments showed the osteogenic effect of shock waves on bone and the stimulation of fracture healing. Additional histological studies verified the activation of osteoblasts by shock waves.

1988

In 1988 the first successful shockwave treatments of human pseudarthroses were carried out in Germany (in Bochum) and Bulgaria. In the early 1990s, the first reports were published on the clinical use of shock waves to treat soft-tissue diseases. At that time these shockwave treatments were carried out with lithotripter units, which usually have a fixed therapy head. In contrast to the urological applications for shock waves, which were limited to the kidneys and ureters, the orthopaedic applications of shockwave therapy were distributed over the entire body.

1993

In this year HMT had the distinction of being the first manufacturer to put a special orthopaedic shockwave unit on the market with a movable therapy arm. This made it possible for the first time to bring the shockwave unit to the patient instead of requiring the patient to come to the shockwave unit. This kind of flexibility is especially important for the treatment of bone disorders, which is usually carried out under general or spinal anaesthesia.

Clinical studies

It has been shown, in a large number of clinical studies, that the administration of shockwave therapy for the known orthopaedic indications is very safe and effective. Ultimately, the value of a therapy or a treatment method has to be demonstrated by controlled cohort studies.
Together with its American partner, HealthTronics, HMT is conducting clinical studies on the use of ESWT to treat chronic plantar fasciitis, lateral epicondylitis and delayed fracture healing. The results of the study on the use of the OssaTron to treat chronic plantar fasciitis are already available. This was the first clinical study on orthopaedic shockwave treatments which met the requirements of GCP und evidence-based medicine. The results clearly demonstrate the safety and effectiveness of ESWT treatment administered with the OssaTron. As a direct result of this study, HMT gained FDA approval for the OssaTron, the first orthopaedic shockwave unit to be approved for the U.S. market.

Results of the plantar fasciitis study:
After a single treatment with the OssaTron, a success rate of 76% was achieved in patients with plantar fasciitis.

Plantar Fasciitis	Criteria for Success	Success Rate in %	Combined Success Rate in %
Complaint free	4/4	51%	76%
Significant improvement	2/4, 3/4	25%	
Slightly improvement	1/4	10%	24%
No improvement	0/4	14%	

Results of the epicondylitis study:
In January 2002 the results of the HMT study on the use of the OssaTron to treat chronic lateral epicondylitis were submitted to the American Food and Drug Administration (FDA). This study was also designed and carried out in conformance with the principles of good clinical practice (GCP).
A single treatment with the OssaTron yielded a success rate of 66%.

Epicondylitis	Criteria for Success	Success Rate in %	Combined Success Rate in %
Complaint free	**3/3**	46%	66%
Significant improvement	2/3	20%	
Slightly improvement	1/3	23%	34%
No improvement	0/3	11%	

In addition to these studies, a large number of clinical studies have been carried out worldwide, in cooperation with HMT, on the use of the OssaTron to treat a wide range of orthopaedic indications. Several representative studies are listed in the Annex.

New indications:
A number of studies are now underway to expand the range of orthopaedic applications for ESWT beyond the applications known so far. These new applications include avascular femoral head necrosis, osteochondritis dissecans, patellar tip syndrome and achillodynia.

Effect:
The actual mechanism of action responsible for the effect of shock waves on bone or soft-tissue has still not been fully explored. The activities of research teams worldwide which are investigating the effect of shockwave therapy on various orthopaedic disorders show the strong interest of both patients and doctors in the new method.

Scientists from HMT have been active participants in these research projects. The clinical effect of shock waves on pseudarthrosis is characterized by the formation of callus and bony remodelling. Petechial bleeding and small haematomas are the most common adverse reactions to this treatment. In animal experiments conducted on the use of shock waves to treat disorders of bone, the following effects were observed

- formation of hematomas in surrounding tissue
- haematoma formation and haemorrhage in bone marrow
- intensified new bone formation (osteogenesis)

On the basis of these observations, the following mechanism of action has been postulated:
The shock waves create small injuries at fracture ends, thus stimulating new bone growth. Some of the bone cells at the focus are destroyed by the shock waves. The surviving bone cells exhibit increased proliferation, thereby creating new osseous material

The use of ESWT to treat diseases of tendons and tendon insertions has the following clinical effects:

- breakdown of calcific deposits
- pain relieve
- local swelling which subsides after a short time

Histological studies have shown clearly that shock waves promote the creation of new vessels (neovascularisation). This process causes inflammations at the tendon-bone junction to subside. These inflammations at the tendon insertion points are the cause of the patients symptoms.

The future

Future studies will be aimed at directly measuring shock waves in vivo to determine actual physical quantities such as pressure, energy and focal volume. Previous measurements of shock waves have been carried out in vitro. Because shock waves change their properties as they pass through different tissue layers, in vitro results are not sufficient to explain clinical results, differences between the various shock wave generation systems, and the mechanism of action of shock waves. According to the most recent clinical studies, there are marked differences between the individual shockwave generation systems with respect to the number of treatments required and the success of shock wave treatment. The impact of shock wave therapy is due to the direct and indirect effects exerted by shock waves on bone and other tissue. The direct effect is characterized by a positive pressure amplitude and a short wave rising time. The indirect effect is due to the formation of cavitations in a liquid environment. The phenomenon of cavitation was observed during studies on the use of shock waves to treat kidney stones. It is not yet known whether cavitation also occurs during the administration of shockwave therapy to treat orthopaedic disorders and, if so, what role it plays.

Next to physical studies on shock waves, animal experiments are of great importance. Histological, biochemical and biomechanical studies are carried out to determine the effect of shock waves on bone and soft tissue. An important part of these studies is the determination of the dose-effect relationship, i.e. how many shock waves and how many treatments are required for a certain indication and a certain unit in order to achieve the highest possible success rate. The objective of HMT is to make shock wave units available which achieve satisfactory results for the patient with only one treatment if possible.

Furthermore, clinical studies are underway to develop new therapeutic concepts for known indications and to assess the effectiveness of shock wave therapy for new indications.

Annex: Literature

Treatment of Painful Heel Syndrome With Shock Waves
Han-Shiang Chen, Liang-Mei Chen, Ting-Wen Huang
Clinical Orthopedics and Related Research, Number 387, pp. 41-46

Shock Wave Therapy for Chronic Proximal Plantar Fasciitis
John A. Ogden, Richard R. Alvarez, Richard Levitt, G. Lee Cross, Marie Marlow
Clinical Orthopedics and Related Research, Number 387, pp. 47-59

Treatment of Lateral Epicondylitis of the Elbow With Shock Waves
Jih-Yang Ko, Han-Shiang Chen, Liang-Mei Chen
Clinical Orthopedics and Related Research, Number 387, pp. 60-67

Correlation Between the Duration of Pain and the Success of Shock Wave Therapy
K. Helbig, C. Herbert, T. Schostok, M. Brown, R. Thiele
Clinical Orthopedics and Related Research, Number 387, pp. 68-71

Treatment of Calcifying Tendinitis of the Shoulder With Shock Wave Therapy
Ching-Jen Wang, Jih-Yang Ko, Han-Shiang Chen
Clinical Orthopedics and Related Research, Number 387, pp. 83-89

Extracorporeal Shock Wave Therapy of Nonunion or Delayed Osseous Union
W. Schaden, A. Fischer, A. Sailler
Clinical Orthopedics and Related Research, Number 387, pp. 90-94

Treatment of Nonunions of Long Bone Fractures With Shock Waves
Ching-Jen Wang, Han-Shiang Chen, Chin-En Chen, Kuender D. Yang
Clinical Orthopedics and Related Research, Number 387, pp. 95-101

High-energy shock wave treatment of femoral head necrosis in adults
J. Ludwig, S. Lauber, H. J. Lauber, U. Dreisilker, R. Raedel, H. Hotzinger
Clinical Orthopedics and Related Research, Number 387, pp. 119-126, 2001