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Shock and Pressure Waves - Magic Tools in Medicine

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Twenty-five years ago extracorporeally generated shock waves revolutionized urological stone therapy. Ten years later healing effects of shock waves were recognized and musculoskeletal indications became an important field of shock wave application. Recently pneumatically generated pressure waves were successfully applied to various maladies such as plantar fasciitis and achillodynia. Although the characteristics of pressure waves and their mechanism of generation significantly differ from shock waves, medical effects seem to be similar at least for superficial applications.

Shock waves are characterized by high peak pressure ($\sim$ 10-100 MPa), short rise time (tr $\sim$ 10 ns) and low tensile wave components. The mechanism of generation requires supersonic processes like explosions ($>$ 1500 m/s in water) or steep increases propogated by non-linear waves. Due to the short pulse duration (td $<$ 1 μs) shock waves may be focused to small areas ($<$ 10 mm). Shock waves are generated by electro-hydraulic, piezoelectric or electromagnetic principles. Pressure waves are often generated by low velocity impact of masses (v $\sim$ 1 m/s) and feature lower peak pressure ($\sim$ 0-10 MPa), longer rise times (tr $\sim$ 500 ns) and longer pulse duration (td $\sim$ 200-2000 μs). Contrary to the above mentioned shock waves, focussing of this type of pressure waves to small treatment areas is not possible. Present pressure wave devices utilize pneumatically accelerated pistons which transmit pressure pulses by impact on a bounce plate in close contact with the skin surface. Important parameters to characterize shock and pressure waves are peak pressure (positive and negative), energy and energy flux density. In the case of shock waves, focal size defined as -6dB isobar-lines and 5 MPa isobar-lines is used to describe the dimensions of the treatment area. The technical differences result in diverse device concepts with or without localization modalities.

Shock Wave Energy Deflection due to the Presence of a Model Bone

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The success of Shock Wave Therapy (SWT) for treating various musculoskeletal conditions has been mixed. Fundamentally, the physical mechanisms leading to observed biological responses are not understood. While basic research into specific biological pathways has been gaining momentum, no research is being performed to characterize shock wave propagation through heterogeneous musculoskeletal tissues, and cavitation and shear waves generated by SWT devices. Without an understanding of the physical characteristics and effects of shock wave interactions at the bone interface, it will be difficult to understand (and thus optimize) biological responses. Disarticulated model hard plastic bones were used in these studies. The simple structure of a calcaneus provides a good starting point for model validation and study. An electro hydraulic source was used for cavitation studies, while a ballistic source was used in the pressure field. A high speed camera was used to capture cavitation bubbles generated by SWT, and a needle hydrophone measured the pressure field. High-resolution numerical simulation of SW pulses propagating from a water pillow from an electro hydraulic source into an ankle were performed using the software package CLAWPACK. All three methods (simulations, cavitation and pressure field measurements) show that the presence of bone deflects the energy of the shock wave. Modelling the interaction of the SW with bone yields important information about SW deflection. The degree of deflection will depend on the relative orientation of the SW axis of symmetry and bone structure. These results suggest that focused energy may arise at unexpected locations.
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Extracorporeal Shockwaves Manifest Themselves as Biological Mechanotransduction

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The impact of extracorporeal shockwaves (ESWs)on living tissue results in the conversion of mechanical stimuli into biochemical and/or molecular-biological signals. These signals in turn induce a certain flow of information. Subsequent signals are viewed as a biological information unit that brings about certain biological changes in the cell itself for which the signals are meant. This sequence is referred to as mechanotransduction. The tissue structures mainly involved in mechanotransduction are part of the extra cellular matrix that transfers information via so-called adhesion molecules, principally integrins and cadherins, as connecting links to the cytoskleton. The signals are transmitted to the cell nucleus via the constituent components of the cytoskeleton (i.e. microtubules, actinomicrofiliaments and intermediary filaments), thereby inducing gene transcription and expression. In the case of destruction of the cytoskleton, mechanotransduction is rendered impossible. Specific so-called mechanogated membrane ion channels which belong to the DEG/ENaC super-family are responsible for initial and fast prompting of mechanotransduction. Relevant for mechanotransduction are the frequency, amplitude, intensity and duration of the extracorporeal stimuli which determine - as if by code - the concentration of certain second messengers and, thus, turn on the gene expression. To date, arguably the most prominent example of mechanotransduction through ESWs is the effect on migration activity of mesenchymal stem cells as proven for the first time by the authors. The effect of ESWs on living tissue constitutes a complex, signal-inducing stress situation which manifests itself on several interconnected levels. Additional phenomena are observed and established which at present cannot be exactly classified in the overall context of mechanotransduction. The activation of the, in evolutionary terms, very old protection and defense mechanism of living organisms through ESWs, the so-called heat shock protein system, is an example. As far we are aware, we were the first to produce experimental evidence.

A Trial on the Mechanotransductional Influence of ESWT on Pig Skin and Fibroblastic Activity under the Aspect of Energy Flux Density and Frequency

Author: S. Marx[1], H.G. Neuland[2], H.J. Duchstein[3], R. Thiele[1]

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The fundamental assumption for the mechanical effect applying extracorporal generated shockwaves was in the common opinion replaced by a microbiological working mechanism. Hereafter the effect of shockwave is explained in the formation of new blood-vessels while a number of growth-factors are released.
How this mechanism is transformed and where the boarders are, is subject of a number of basic-research studies performed in the society of shockwave application.
Referring to the microbiological working mechanism of ESW the following knowledge is state of the art.
The application of shockwaves induces the release of biologically active substances as NO, VEGF, BMP and further growth-factors. Research work has shown these substances increased during and after shockwave-treatment. This effect is named "bioengineering", meaning to induce the tissue to produce and release biological active substances by itself after stimulation by an outside trigger.
The process of transformation of a mechanic stimulus into a biologic answer is united in the collective name of mechanotransduction. The phenomenon of mechanotransduction is well known, yet not completely understood. It is part of our daily experience of hearing and touching. It also plays a crucial role in the regulation of cell-volume, -shape, -motility and -differentiation. Cells in general may respond to mechanical stresses transmitted over cell surface receptors that physically couple the cytoskeleton to extra cellular matrix or to other cells. Molecular biological and electrophysiological investigations indicate that this rapid process of signal transduction is mediated by mechano-gated membrane ion channels.
Although the effects of mechanical stress could be mediated in part by activation of mechano-sensitive ion channels or by locally and systemically released growth factors, studies have demonstrated that mechanical input itself is able to trigger cellular signalling mechanisms through the process of mechanotransduction.
Sensitivity to mechanical forces appears in all adhesion-dependent cells. This gets evident in the mechanocytes or cells routinely subjected to mechanical forces, such as skeletal muscle cells, osteocytes, chondrocytes, airway smooth muscle cells, cardiomyocytes, vascular endothelial and smooth muscle cells.
Trying to understand these effects and the mode of action we started a number of clinical trials showing the effect of ESW.
In order to show mechanical influence affecting organic-tissue this trial was performed in Hamburg at Beiersdorf giving the opportunity to work with UPE and singulet-oxygen-detecting devices showing the Triboluminiszenz-Effect.
Triboluminiszenz is the emission of elektromagnetic radiation in UV-, VIS or IR-spectrum appearing if activated atoms or molecules rearrange to there former status. This can be detected by UPE - ultraweak Photoemission - quantifying the measure of physical stress.
The stimulation of the pig-skin is performed with the Orthowave by MTS using a regular focussed and a defocused application-head and the Piezoson by Wolf.
ESW as a form of mechanical stress will rise the biosynthetic activity of cells by mechanotransduction. Is the mechanical stress too high this will lead to a reduction of biosynthesis and damage might be caused to treated tissue. The variables in this trial are the Frequency and the Energy Flux Density of different devices. Aim is to show a gradient for the highest stimulation of the treated tissue regarding that different tissues will react in different ways and it seems as if every indication will need its own curve. Knowing these curves

a dose-effect-relationship could be realized and therapeutic application could be regulated for the highest induction of cell-proliferation and -regeneration. Of course this will only give a little step in this direction but once understanding the working mechanism of ESW and calculating the biologic answer research will be even more transparent and aimed.

Nitric Oxide and Shock Waves: Another Brick in the Wall

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The clinical observation of immediate vasodilatation and laboratory findings of enhancement of angiogenesis around the ESW-treated area immediately give rise to the hypothesis that ESW may modulate the production of NO. Recently, we have showed that ESW quickly enhance eNOS activity and NO production in human umbilical vein endothelial cells (HUVEC) under either normal or inflammatory conditions. However, we could not show the effect of ESW treatment on iNOS expression. Massive amounts of NO produced by iNOS are potentially harmful. Therefore, evaluation of the ESW effect on iNOS expression is fundamental in further assessing the molecular mechanism of clinically-observed anti-inflammatory action of ESW.
Rat glioma cell line C6, cultured in DMEM supplemented with 10% fetal calf serum, was treated with an electromagnetic lithotripter (MODULITH SLK device Storz Medical AG, Swizerland) as described (FEBS letters 579 2005 6839-6845). Protein extract was subjected to electrophoresis and blotted to a PVDF membrane. Membranes were incubated with anti-eNOS antibody and successively incubated with enhanced chemiluminescent detection reagents. nNOS activity was estimated by measuring the conversion of L-2,3,4,5-[3H]arginine to L-2,3-[3H]citrulline. The production of NO was assayed using the DAF-2DA detection system. NF-kB activation was evaluated by Electrophoretic Mobility Shift Assay. iNOS expression was analyzed by Northern blotting and RT-PCR analysis.
In this study we show that ESW at a low energy density value quickly increase nNOS activity and basal NO production in the rat glioma cell line C6. In addition, the treatment of C6 cells with ESW reverses the decrease of nNOS activity and NO production induced by a mixture of lipopolysaccharides (LPS), interferon-gamma (IFN-gamma) plus tumour necrosis factor-alfa (TNF-alfa). Finally, ESW treatment efficiently suppresses NF-kB activation and NF-kB-dependent gene expression, including iNOS and TNF-alfa.
This report suggests a possible molecular mechanism of the anti-inflammatory action of ESW treatment. Further studies are needed to investigate this mechanism in vivo.

Biological Mechanism of Shockwave in Fracture Healing

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The purpose of this study was to investigate the biological mechanism of shock wave treatment in bone healing in rabbits.
A closed fracture of the right femur was created with a three-point bend method and the fracture was stabilized with an intra-medullary pin. Shock waves were applied one week after the fracture. Twenty-four New Zealand white rabbits were randomly divided into three groups. Group 1 (the control) received no shock waves; group 2 received low-energy and group 3 high-energy shock waves. The animals were sacrificed at 24 weeks, and a 5-cm segment of the femur bone including the callus was harvested. The specimens were studied with histomorphological examination, biomechanical analysis and immunohistochemical stains.
The results showed that high-energy shockwaves improved bone healing with significant increase in cortical bone formation and the number of neovascularization in histomorphology, better bone strength and bone mass in biomechanics, and increased expressions of angiogenic growth markers including BMP-2, eNOS, VEGF and PCNA than the control and low-energy shock wave groups. The effect of shock wave treatment appears to be dose-dependent. In conclusion, high-energy shock waves promote bone healing associated with ingrowth of neovascularization and increased expressions of angiogenic growth factors.

Radial Extracorporeal Shock Wave Therapy (rESWT) Induces Bone Formation in Vivo

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Extracorporeal shock wave therapy (ESWT) is presently applied to a variety of bone and soft tissue pathologies in orthopaedics. Compared to the commonly used focused shock waves, radial ESWT (rESWT) is characterized by a larger treatment area, which simplifies application and reflects the pathology zone rather than a point. Therefore, rESWT is expected to be at least as effective as focused ESWT. The purpose of the study was to evaluate if rESWT can induce new bone formation at low energy flux densities and to study the time course of rESWT-induced osteogenesis. New Zealand white rabbits (n=13) were used for the animal model after approval by the responsible ethics committee. After the adaptation phase, radial extracorporeal shock waves (rESW) were applied with the Swiss Dolorclast shock wave device (EMS Electro Medical Systems, Nyon, Switzerland) to one randomized femur of each animal, while the contralateral side served as an intraindividual control. Four thousand pulses of rESW with an energy flux density of 0.16mJ/mm2 were applied twice with standard parameters (8Hz, 4 bar, 7-day interval). Animals were sacrificed at 1 week (n=4), 3 weeks (n=4) and 5 weeks (n=5) after the second rESWT. Sections of all femora (thickness 75 microm) were investigated with broad-band fluorescence microscopy (H3 filter, JUST filter) and contact micro radiography for new periosteal and endosteal bone and callus formation, periosteal detachment and cortical and trabecular fractures. Integration of the fluorescent dyes into bands of newly deposited bone could be observed under fluorescence microscopy and were significantly increased after rESWT. Shock wave-induced osteogenesis was already visible at week 1 however, new bone formation was even more pronounced and significantly different to the control group after 3 and 5 weeks. Furthermore we could demonstrate both endosteal and periosteal new bone formation at the dorsal femoral cortex after rESWT, but not in the control. No calcified bone remodelling, resorption or callus formation could be shown in contact micro radiography. Furthermore, neither trabecular nor cortical fractures were observed. No side effect was found but there was some haematoma at the application site.
rESWT offers new perspectives in the therapy of bone pathologies as larger tissue areas could be effectively treated. The osteogenetic effect is a shock wave induced biochemical response resulting from the total energy applied per area rather than high energy-related local mechanical effects found in focused ESWT.

Influence of ESWT on Migration, Cell-Formation and Cell-Differentiation of Endothelial Progenitor-Cells

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The microbiological working-mechanism of ESW has developed to be the main working hypothesis in the last years to understand how shockwaves induce all our good results in clinical studies pointing out different indications to be treated.
At this point mainly the release of several growth-factors could be shown and therefore the model of bioengineering replaced the mechanical effect postulated in the early stages of shockwave application.
It has been shown that shockwave application induces the release of biologically active substances such as NO, VEGF, bFGF.
Our group is following a working-model on mechanotransduction which underlines the direct effect of ESW on the cell. Mechanotransduction does play a role in the regulation of cell-volume, -shape, -motility and -differentiation.
As stem- and progenitor-cells have shown their role in cell and tissue-regeneration we tried to point out the influence of a mechanical stress on endothelial progenitor cells (EPC), induced by shockwaves. These effects are shown in an in-vitro-Trial.
We have shown an induction of endothelial progenitor cells by ESW. This could be related to a vessel-protective and -regenerative effect of shockwave. The positive influence of ESW could be generated by the activation of stem- and progenitor-cells as well as the release of the mentioned biological active substances, VEGF, EPO, bFGF.
These factors have proved their influence on migration and cell differentiation to the endothelial cell-type.
The influence of shockwave on progenitor-cells together with the idea of a chemotactic influence activating the treated tissue and supporting the migrative activity will be one of the points of interest understanding the working-mechanism of shockwaves.

The Effect of Focused Extracorporeal Shockwaves on Migration Activity of Mesenchymal Stem Cells (MSCs) Ex-vivo.

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In contrast to the omnipotent embryonic stem cells which can differentiate into all types of tissue, the so-called adult MSC's, which are primarily found in bone marrow, exhibit a limited potential of differentiation. They can mainly differentiate into muscle, cartilage and bone tissue as well as into connective and fatty tissue. Thus to regenerate these tissues, MSC'S are required. The question arises as to which mechanism provides the route to the locus where they are needed. Up to now, a direct effect on the migration activity of MSC'S through high physical strain in sports activities was established only by one researched team at the Sports University of Cologne. Based on these findings we set out to produce a similar effect through the impact of external mechanical stress. And indeed, through the use of focused extracorporeal shockwaves (ESWs) we were the first to increase significantly the migration of MSC's. The proof was obtained by means of the Boyden-Chamber assay in a pig skin model. The fact that targeted and well-defined activation of MSC's is possible opens up the possibility to observe and monitor further signal and differentiation paths of MSC's. This potentially provides tremendous scope not only for therapeutic benefits of ESWs in the orthopaedic surgical domain, but also for cardiovascular regeneration.

Stem cell De-Programmation by Shockwaves

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We submitted in vitro cell cultures of human precursors from bone and heart to SW treatment, to evaluate the effects on bone mineralization and Extra Cellular Matrix deposition as well as on the activation of regeneration potential of human heart precursors.
Cultures of human osteoblasts and cardiac cell lineages were submitted to SW and compared to control untreated groups. We studied Ca++ deposition, ALP and NOS activities, growth rate and differentiation of human osteoblasts. The precursors and progenitors of cardiomyocyte, smooth muscle, fibroblasts and endothelial cells were identified by immunocytochemistry, and the expression of mRNA and proteins was studied by western blot and RT-PCR.
Shockwaves can inhibit both growth rate and Ca++ deposition. They modulate the osteoblasts NOS activity presumably affecting ALP. SW changed the relative number of cardiac precursors and progenitors of all cardiac cell lineages and enhanced the expression of cytoplasmic proteins. The low rate of Ca++ deposition may be due to changes in Ca++ intra and extracellular flow as well as to decreased enzymatic activities, such as ALP activity, linked to bone mineralization retardation. In regard to the human heart, SW positively influence the differentiation of cardiac primitive cells and could possibly inhibit or retard pathological remodelling and functional degradation of the heart.

Orthopaedic Lithotripsy in Chronic Tendinopathies

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Chronic tendinopathies are very frequent but not a serious problem. Generally, chronic tendinopathies or tendinoses are the consequence of an acute event managed in an incorrect way. The tendon tissue loses elasticity, vascularity and develops angiofibroblastic degeneration. The results of traditional methods such as NSAID's and analgesic drugs or physical therapy, have not proven favorable, leading some patients to surgical procedures. Extracorporeal Shock Wave Therapy is a relatively new procedure (in Mexico since 2002). This treatment method causes neovascularization and biomechanical recovery of tendons. Its mechanisms of action are basically two fold: the direct (traumatic) and the indirect (cavitational) effects, the last being the most important. Shock waves have been used successfully in acute tendinopathies and in recent years they have shown good effectiveness in treating chronic tendinopathies.
In this work we present our experience in the treatment of 40 patients with chronic tendinopathies such as rotator cuff tendonitis, tennis elbow and plantar fasciitis. General indications were reviewed and, based on our results, we discuss the future of this therapeutic option.
We have had good or excellent results in most of our patients, with a minimal rate of complications. The procedure is well tolerated and accepted by our patients.
We found shockwave therapy to be a good option in our patients with chronic tendinopathies. This first case series in Mexican patients is the base for a controlled study in order to determine precise parameters of clinical success.

Therapy with Radial ESWT Combined with Physiotherapy in the Treatment of Soft Tissue Diseases

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The aim of this study was to clinically evaluate the effectiveness of Extracorporeal Shockwave treatment in soft tissue pathologies.
The study was conducted in the Clinic of Physiotherapy and Sports Injuries Rehabilitation in Athens in collaboration with METROPOLITAN HOSPITAL utilizing the EMS device. From January 2005 until June 2005 we treated 42 patients (7 women and 35 men) with Radial Shockwaves for the following diseases: 27 Patients with Plantar Fasciitis (10 athletes basketball A1 category, 8 athletes A2 category, 2 athletes soccer, 1athlete tennis National team level, 6 patients non-athletes) 8 patients with calcanear tendonitis, 4 patients with Epicondylitis, 3 patients with Tibial periostitis (1 athlete basketball, 2 athletes tennis) Inclusion criteria were at least 3 months of unsuccessful conservative treatment (cortisone injection, ultrasound, microwaves). The mean follow-up was 9 months. To evaluate the intensity of pain the outcome was assessed in 4 categories using the VAS (Visual analog scale) and Roles and Maudsley. The protocol of treatment included 5-7 treatments with shockwaves 2 times per week. In each treatment we applied 1,700 shockwaves with an intensity of 1.8 bar for the first 600 shocks and 2.5 bar for the remaining 1,100. Once a week kinesiotherapy and massage were applied for the Plantar Fasciitis in the Guff region and Achilles tendon as well as in the fascia around this region. No local or other anaesthesia was administered. All the participants signed an agreement to participate in this study.
The results of the study were as follows: Diseases/Results excellent good moderate poor Plantar Fasciitis 58,3% 25% 6,7% 0 Tendinitis Calcanear 33,4% 33,4% 22,1% 11,1% Epicondylitis 50% 25% 0 25% Periostitis 100% 0 0 0.
The results of this study lead us to the conclusion that treatment of the above diseases with the use of Radial Extracorporeal Shockwave combined with physiotherapy is safe and effective.

Sport's Injuries of Tendons: our Experience with ESWT with Ultrasound Guide in Line

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The aim of this study is to show our experience utilizing ESWT to treat on tendonopathies of athletes from various sports. Each treatment was performed using ultrasound guide in line to ensure maximum efficiency.
From February 2004 to September 2004, 99 athletes with chronic tendon injuries were treated with ESWT. The age of the patients was between 15 and 35 years (average age = 23.16 years) .The treatments were performed with a piezoelectric device (WOLF PIEZOSON 300) with US-imaging guide in line. We performed the treatments in 3-4 sessions (one session weekly or every 2-3 days) using low and mid-level energy. The follow up was performed with the VAS scale 30, 60, 90 and 120 days after the end of therapy.
The best results were reported for enthesitis of the patellar tendon (95% reduction of pain); 30% of the athletes experienced chronic enthesitis of the anterior cruciate ligament using the patellar tendon. For shoulder impingement of the rotator cuff we observed 66% reduction of pain (volleyball, baseball and rugby players); and 100% reduction of pain was reported for enthesitis of the pubic bone (soccer players).
The best results were reported for patellar tendon enthesitis and pathologies of the pubic bone. In these pathologies the injury and area of pain are very small, therefore utilizing a guide with Ultrasound imaging on line in real time increases the effectiveness of the therapy and reduces its side effects (shock waves on the bone, movement of the patient).

Shockwave Biosurgery in Insertional Tendinopathies: Our Experience in Ecuador

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Tendineous pain during sports and daily activities is a major cause of incapacity, and is often hard to manage for patients and physicians alike, as it causes functional disabilities and sometimes leads to pharmacological overuse, or even surgery. Two decades ago ESWT was developed, and has been used successfully in many centers throughout the world. Shockwave Bio surgery started as a treatment option in Ecuador in March 2004.

We have treated 97 patients between 18 and 75 years of age with chronic tendinopathies. Our patients had a diagnosis of Lateral Epicondylitis (22), Patellar Tendonitis(27), Achilles Tendonitis (9), Plantar Fasciitis (36) and Supraspinatus Tendonitis (3). We excluded patients with previous surgical procedures and patients treated with ESWT and Autologous Growth Factors (AGF) combined therapy. We applied 2,000 radial shockwaves (Swiss Dolor Clast - EMS) as analgesia and 2,000 impulses at therapeutic levels (0.06-0.18 mJ/mm2) without anaesthesia, in two sessions at one week intervals.

We have followed 97 patients for an average of 18 months. The average pain score before treatment was 8/10, and became 2/10 after the follow up (80% reduction). All our patients experienced pain relief to some degree and were satisfied with the procedure. Most of them recovered enough to restart their basic daily activities and even sports.

ESWT was effective for most of our patients. By using this technique that is not only non-invasive, but also well tolerated, we avoided the possible complications of surgical procedures and reduced costs in our hospital. We will continue with these protocols and report further results.

Radial Shock Wave Therapy (RSWT) for the Treatment of Chronic Tendonopathies - our Experience

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The aim of this prospective study was to analyze the results obtained during treatments with RSWT for chronic tendonopathy pathologies.
Prospective study. Between January 2002 and December 2004, 112 patients (mean age = 45+/- 14 years) with a diagnosis of chronic tendonopathy pathologies (patellar tendon, Achilles tendon, lateral epicondylitis, plantar heel pain, supraspinatus tendon with or without calcific deposit and bursitis trochanterics), a history of chronic symptoms for at last 4 month (mean chronicity =18.22±17.67 months), and failure of or poor results from two conventional treatments were treated in our clinic with a radial shock wave device Swiss Dolor Clast (EMS, Switzerland). Of the total patients, 4 did not complete the treatment protocol and 13 could not be evaluated in the follow up period (15% lost patients). The other 95 patients were treated in 3 sessions, at intervals of one week, with 2,000 impulses per session at 2.5-3.5 bars of intensity (energy flux density = 0.1-0.16 mJ/mm2) and a frequency of 6 Hz. A visual analogue scale (VAS) evaluated the pain intensity during diary life activity (DLA) and sports activity (SA). Functional impairment of the corporal segment injured was evaluated by using functional tests according to the indicated pathology. Evaluation was performed immediately before treatment and at 4, 26 and 52 weeks after the final session. During follow up the patients' satisfaction was evaluated on the Roles and Maudsley scale (RM).
The no parametric Wilcoxon test for dependent samples to compare means of VAS and functional test. The pain intensity of DLA and SA decreased significantly ($p< 0{,}001$) and functional tests showed significant improvement ($p<0{,}001$) at 4, 26 and 52 weeks post RSWT. The excellent and good results obtained in 68 patients (73%) at 4 weeks post RSWT remained approximately constant at 26 weeks (74%) and 52 weeks (70%) after treatment. Only minor side effects such as swelling, petechea and discomfort during treatment were reported.
Radial shock wave therapy is an effective and safe method (minor side effects) for the treatment of chronic tendonopathy pathologies with a history of chronic symptoms for at last 4 month and failure of or poor results from two conventional treatments.

Shockwave Therapy for Achilles Tendonopathy: Retrospective Study

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The aim of this study was to evaluate the efficacy and safety of extracorporeal shock wave therapy for the treatment of Achilles tendonopathy in two Brazilian Orthopaedics Clinics. In a multi-center, retrospective study, the effect of shockwave therapy was investigated in 101 cases of 90 patients with Achilles tendon calcifying (or not) tendinosis treated during a period of 37 months, from May 2002 to June 2005. Eleven patients received bilateral treatment. There were 34 women and 56 men with an average age of 58 (range, 33-87) years. The criteria for inclusion were at least three months of unsuccessful conservative therapy or six months of pain. Criteria for exclusion were inflammatory arthritis, corticosteroid injection within the previous 6 weeks, neurological abnormality, gout, malignant diseases, blood coagulation disorders and previous Achilles tendon rupture. Each patient was treated with 1,000 shock waves, a 05 mm focus depth, and with an energy flux density of no more than 0.13 mJ/mm2 after local or regional anaesthesia. One treatment was performed on 91 cases, 7 underwent a second treatment and 3 cases underwent a third treatment. The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score and subjective outcome on Visual Analogue Scale (VAS) analysis 45, 90 and 180 days after the end of the therapy. The study showed the efficacy and safety of ESWT were excellent in 21.8%, good in 47.5%, acceptable in 19.8%, and poor in 10.9%, 180 days after ESWT.

Efficacy of Extracorporeal Shockwave Therapy (ESWT) in the Treatment of Tendinopathies and Enthesiopathies

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ESWT has been increasingly used to treat tendinopathies and enthesiopathies. A retrospective review of patients who underwent ESWT at our centre was conducted to establish the efficacy and safety of this treatment modality.

The records of patients treated with ESWT between April 2004 and October 2005 were reviewed. All had lesions that were documented on ultrasound sonography. Each course of treatment comprised two sessions performed one week apart. At each session, 2,000 focal shock wave pulses were administered under ultrasound guidance at increasing energy flux densities (between 0.03 mJ/mm2 and 0.28 mJ/mm2). No sedation or anaesthetic agents were used, and all patients received a two-week course of non-steroidal anti-inflammatories. Pain was assessed using the Visual Analogue Scale (VAS).

A total of 639 treatments were performed on 264 sites. The patients were predominantly male (62.1%) with a mean age of 42 years (range 13-73 years). Plantar fasciitis (47.7%) was the most common indication, followed by medial/lateral epicondylitis of the elbow (17.8%), patellar tendinopathy (11.4%), supraspinatus tendinopathy (9.8%) and Achilles enthesiopathy (9.1%). Of the treatments, 518 (81.1%) were first courses, 98 (15.3%) were second courses, and 23 (3.6%) were third courses. For all sites, the pre-treatment mean VAS score was 5.4. This was significantly reduced after one session (3.8) and at the two-week (3.0) and three-month (2.5) follow-up. Proximal plantar fascia swelling was also significantly reduced (5.7 mm pre-treatment vs. 4.6 mm after one course). No adverse events were reported.

ESWT is an effective and safe treatment modality for chronic and painful lesions at bone-tendon junctions.

Beginning of Analgesia as a Key Variable in Shockwave Biosurgery

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Even though the therapeutic success of shockwaves in urology, orthopaedics and plastic surgery is a fact, and that new applications under research in cardiology and infectology are promising, there are still tendencies of insurance companies of not approving treatments, perhaps by novelty and cost issues. There is a clear necessity of establishing parameters for the creation of homogenous protocols for ESWT as well as to predict evolution.

We performed an experimental study from September 2004 to May 2005 in 127 patients who received ESWT for different pathologies. Clinical and radiographic parameters, VAS, and patient's satisfaction level were evaluated. Follow up was performed every six weeks for a total period of six months (first stage of study). Descriptive and inferential statistical analysis was performed, based on Pearson's coefficients of correlation and Chi Square analysis.

There was a low correlation (0,02) between number of waves necessary for beginning of analgesia and time of evolution. There also was a clear dependency between level of satisfaction and number of waves at the beginning of analgesia. This last parameter was also dependent with the type of pathology (significance level of 0.001).

The number of necessary waves for the beginning of analgesia, as well as the total number of shockwaves is variable and depends on each pathology, but not on time of evolution. The number of necessary shockwaves for beginning of analgesia could be an useful parameter in predicting the evolution, and treatment protocol in each case. However, further studies are necessary to validate this variable.

Why are Extracorporeal Shock Waves the Last Alternative Therapy?

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The terms tendonitis, tendinosis and paratendonitis or an association of them, should be reserved to specific histopathological features of tendon conditions. Unfortunately the term tendonitis is used in a clinical context and it refers to a clinical syndrome and not to a specific histopathological entity. Tendinosis represents a chronic musculoskeletal disorder that can cause pain and impaired function. Tendon healing is a complex process requiring inflammatory response, neoangiogenesis, fibrillogenesis and matrix remodeling (Enwemeka 1989). Many events can happen to impair the normal healing of tendons. One of them is persistent overuse in sports without time to recover and it can induce the degenerative process.
The term tendinosis, first used by Puddu (Puddu 1976), implies tendon degeneration without clinical or histological signs of intratendinous inflammation and is the final result of a number of pathological processes with slightly different histological manifestations. Many therapeutic options are used by doctors but none of them with optimum results.
Extracorporeal shock waves are used only after other therapies have failed, despite experimental studies demonstrating significant improvement in patellar tendinosis (Wen-Wei Hsu 2004) and promoting healing of collagenase-induced Achilles tendonitis and increased TGF ß1 and IGF-I expression (Chen and Wang 2003). Tendon healing in the early stages depends on the tenocytes growth and neovascularization. The tenocytes have been found to convert biophysical stimulation into a biochemical response leading to release of growth factors and cellular adaptation. TGF ß and IGF I can promote tendon regeneration by regulating collagen metabolism and tenocytes proliferation. It is important to avoid repetitive chronic inflammation because this can develop non-healing stages and promote alterations in growth factors. Collagen synthesis is strongly influenced by a number of growth factors. These include TGF ß, IL -1, IL-4, PDGF, IGF 1-2 and EGF. In a study on collagen production on rabbits, it was found that TGF ß1 and IGF-2 not only increases collagen production but also differentially affects the ratios of collagen I and III. These effects were most pronounced in 3 week-old scars and were observed to have a decreasing effect at 6 -12 weeks. I believe that to produce a better scar it is necessary to begin with ESWT before the first month.
The best healing is the faster healing and ESWT is an option to promote better results.

Evaluation with Ultrasound and Color Doppler of the Results of Extracorporeal Shock Wave Therapy for the Control of Hyper Vascular Areas in Tendinosis (Preliminary Study)

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There is considerable controversy regarding the origin of insertional pain in chronic tendinosis. Even though tendon biopsies having shown an absence of inflammatory cell infiltration. Recent studies indicate that this pain is closely related to the presence of hypervascularization of the tendon.
We studied patients with chronic tendinosis. Tendon hypervascularization was rated mild, moderate, or intense based colour Doppler ultrasound findings. The effect on pain during Achilles tendon loading activity was evaluated using a visual analogue scale (VAS). In this study 14 Achilles tendons in 10 patients with a long duration of pain-symptoms from the mid-portion of the Achilles tendon were included in the investigation. At follow-up, all patients answered a questionnaire assessing their satisfaction with the result of the treatment, the level of present tendon loading activity, and tendon related symptoms.
Clinical and ultrasound follow-up three to six weeks after three treatment by shock wave sonographically-guided , we compare if result indicate an effect on the neovessels similar Eccentric training or US- and CT-guided injections of the sclerosing agent Polidocanol. Neovascularisation was found inside and outside the ventral side of the region with structural tendon changes in all tendons with chronic painful mid-portion Achilles-tendinosis. Before treatment, the mean VAS-score, evaluating the amount of pain during Achilles tendon loading activity, was 70. At the six weeks follow up, 8/10 patients were satisfied with the treatment and mean VAS score had decreased to 10, and in the majority of the tendons all neovessels had decreased. In the 2/10 patients who were not satisfied with the treatment (remaining tendon pain), multiple neovessels remained.
This pilot study indicates an effect of ESWT on the neovessels well correlated with reduced pain but further randomised controlled trials are needed to prove this findings.

Treatment of Chronic Lumbar Pain with Radial Shock Waves

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This paper is about one year experience using radial shock waves as treatment for lumbar pain with trigger-points.

We treated patients with chronic resistant lumbar pain who had no neurological compression or others diseases. We identified the trigger points with clinical examination and perform the treatment using radial shock waves in conjunction with needles. We repeated the application every week for 2 months (8 sessions) with 3,000 shocks.

We evaluated 30 patients using clinical patient opinion relative to pain during activities such as standing, walking and night pain . After 8 sessions, 25 of 30 patients were satisfied with the results. Three months after treatment the patients were still satisfied.

This is an initial report of our experience. More research pre and post treatment needs to be done. We have performed the inactivation of trigger points with needles for the last 8 years with good results. The association with radial shock waves is safe, less invasive and, in our initial opinion, a new option for these hard-to-treat patients.

Morton's Neuroma: Treatment with Extracorporeal Shock Wave Therapy

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Morton's Neuroma is a common pathology of the forefoot. It is characterized by plantar forefoot pain, neuralgia affecting spaces of the toes, burning sensation that increases with digital pressure in between the toes, and a solid node in the proximal space of the toes is evident on the ultrasonographic exam. The conservative treatment is usually successful, however, when it fails, the surgical removal of the tumor can be indicated. While surgery has proven effective, it comes with the risks and complications associated with surgery and necessitates a prolonged recovery.
We reviewed the records of 20 patients presenting with Morton's Neuroma between July 2003 and September 2005. All patients answered a questionnaire regarding satisfaction, pain, restriction of footwear and activity. All patients (20) had tried conservative treatment for a minimum of 6 months without success. Eleven patients (13 feet) were treated with ESWT (1,500 pulses at 0.3 mJ/mm2), on an Orthima-Direx device (electrohydraulic), from directly plantar to the Morton's Neuroma. The mean follow-up was 15.9 (5 - 30) months. Of the total, 61.4%(8 feet) were satisfied and 38.3%(5 feet) were dissatisfied with the outcome, 4 of which underwent surgical treatment. Of the 9 patients (10 feet) submitted to surgical approach through a dorsal incision, 90% (9 feet) were satisfied. The mean follow-up was 16.8 (5-29) months in this group. One patient complained of paraesthesia on the toe 6 months after surgery.
ESWT can be considered an option in the treatment of painful Morton's Neuroma. It does not have complications associated with surgery.

Focused Shock Waves in the Treatment of the Sesamoiditis of the Hallux

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Sesamoiditis is usually present as pain in the plantar base of the first metatarsal, and is often a hidden and ignored pathology.
From September 2004 to February 2005, 44 patients (73% male, 27% female) with an average age of 47 years (range 19-57) with a diagnosis of sesamoiditis were included in the study. Fifty-four percent had sesamoiditis associated with proximal plantar fascitis and 18% had sesamoiditis associated with hallux valgus. Forty-five percent were active athletes. Patients received ESWT with a focused Orthospec (Medispec) generator, at 0.08-0.16 mJ/mm^2 with 120 shockwaves/minute in a single session. Follow up was done by analyzing clinical and radiological variables, VAS, gait foot-takeoff analysis, tolerance to mobility and patient's satisfaction. Patients were followed up with every six weeks for a nine month period. Descriptive and inferential statistical analyses were performed, as well as coefficients of correlation and Chi Square analysis, with a significance level of 0.05. We used the beginning of analgesia as a primary variable for evaluation.
Our results showed that the beginning of analgesia was achieved with an average of 494 shockwaves. The average total number of shockwaves per treatment was 930. After a 9-month follow up our patients showed 82% excellent/good results (n=26), 9% fair (n=4), and 9% poor (n=4). VAS showed statistically significant differences, with a variation between initial and end values of p=0.024 and association VAS End satisfaction level p=0.000.
Our results showed a significant improvement in both pain control and patient satisfaction in sesamoiditis treatment, however further studies are necessary to determine a final protocol.

Radial Shockwave Therapy for the Treatment of Rotator Cuff Rupture and Pericapsulitis: A Case Report

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At the international ISMST congress in Vienna, the consensus for shoulder tendinopathies treatment was oriented to focal shockwave therapy. However, there are no scientific publications to our knowledge describing the treatment of rotator cuff rupture and pericapsulitis with RSWT. We present a 57-year-old woman with a rotator cuff rupture of the left shoulder one year after an accidental fall. She received multiple unsuccessful treatments until she was booked for surgery by the orthopaedist. The patient chose a non-surgical treatment before the procedure. Physical examination showed pain (VAS) at rest (3/10), at any movement (9/10), pressure (7/10) and abduction shoulder rise (10/10). There was a clear hyperalgesic area at the deltoid area. She could perform shoulder motion actively against gravity. The MRI reported a subacromial impingement, rotator cuff rupture and biceps tendonitis. We applied RSWT without anaesthesia, with 2,000 impulses at 2.5 BAR maximum and 8 Hz in 3 sessions at one week intervals. We prescribed analgesics, ice packs and pendulum and stretching exercises.

After one month the patient had no hyperalgesia, no pain at rest or starting any movement. She had pain after flexion over 90°. We observed an increase in range of motion. She could raise her hand over 90° of flexion, 70°-80° of abduction and initiate rotation. She still had capsular adhesion but physical therapy could be restarted.

Our findings in this patient showed good results using RSWT in rotator cuff rupture with pericapsulitis. We believe it could be safely used when the conditions are not optimum for surgery.

Clinical Investigation into the Effects of Extracorporeal Shock Waves on Skeletal Muscle Dysfunctions in Patients Affected by Cerebral Palsy

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For some time shock waves have been employed in the management of post-traumatic skeletal muscle injuries to treat contracture. Recently ESWT has found new medical applications and, among these, one of the most interesting is the treatment of muscular contraction in patients affected by Cerebral Palsy (CP). In our department we have been treating equine foot in children with CP for several years with very encouraging results. Nevertheless it is difficult to evaluate objectively the effects of shock waves on skeletal muscle. For this reason we have performed a clinical investigation on the effects of ESWT in skeletal muscle dysfunctions in patients affected by CP by means of gait analysis.
Sixteen patients affected by monolateral equine foot as a complication of CP were treated by ESWT and rehabilitation according to our usual protocol, which consists of 1-5 sessions of treatment at very low energy followed by Physiokinesitherapy. Each patient underwent quantitative gait analysis before and after treatment. Quantitative gait analysis is useful in objective documentation of walking ability in patients with Cerebral Palsy. In all the cases, we observed increased improvement of time, space and kinematics variables at the suffering side; a greater balance between the affected limb and the contralateral was achieved in all areas of measurement. Moreover the overall patient satisfaction level for this treatment modality was high. Once the clinical validity of this methodology is proved, a pathological study of the relationship between shock waves and skeletal muscle tissue will be necessary (and we are already working on this). At the same time we are also evaluating the possibility of applying this methodology to other muscular dysfunctions such as dystrophy.

Shockwave Biosurgery and Autologous Growth Factors Combined Therapy in Equine Suspensory Ligament Injuries

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The use of ESWT in equine tendinopathies results in a good or excellent outcome in most cases. However, some horses have difficulty recovering from swelling and lameness, especially those with an echographic diagnosis of a tendinous defect.
We treated 12 horses with a diagnosis of suspensory ligament injuries graded between 2 and 4, and lameness during daily work graded between 2.5 and 3.5/5. Swelling and pain were present in the proximal metacarpal area. Ultrasound showed intrasubstance defects in the ligament that were also palpable. Before the treatment, we obtained 50 cc of blood and we prepared Autologous Growth Factors (AGF) in a double centrifuge process. In one session and under sedation, we applied 4,000 radial shockwaves to the defect area using a Swiss Dolor Clast Veterinary unit (EMS Switzerland). We used a pressure of 2-4 bar at 6-10 Hz. After shockwave application, the area was disinfected and the activated AGF was injected. We developed and standardized a 2-month workout protocol that progressively allows the horses to walk, trot and gallop under veterinary care and echographic controls.
All horses showed improvement in pain, gait, trot and gallop. Swelling decreased significantly in the first two weeks, and did not recur after the workout protocol. There were no complications. Our encouraging results may reduce the treatment protocols to a single session, improve outcome in tendinopathies with a detectable defect and allow faster recovery of severe suspensory ligament injuries in horses.

Duration of Analgesia Resulting from Extracorporeal Shockwave Therapy in Unilateral Lameness in Horses

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In addition to the potential therapeutic value of ESWT in horses is the consideration of the analgesic affect. The risks to both horse and rider when working without full comprehension of pain is significant. The objective of the study reported here was to determine the short term effect of ESWT on lameness by force plate evaluations.

In the study, 9 horses that had chronic unilateral lameness localized to the forelimb were used. All horses had lameness localized by perineural and/or intraarticular anaesthesia and confirmation of the specific lameness aetiology by radiographic evidence. Force plate data was obtained daily for each horse for 3 days (day -3 to -1) prior to ESWT. In addition, following the force plate analysis on the first day (day -3), local anaesthesia was used to alleviate the lameness and a force plate analysis was completed. On day 0 ESWT was done in the morning and the first post treatment force plate analysis was completed 7 to 8 hours later. Force plate analysis was repeated daily though day 7. A matched pairs t test was used to compare between baseline, the post-block measurement and post-treatment measurements day 0 through 7.

There was a significant difference between baseline PVF and PVF on day 0 (0.003) and 2 (0.0156). The PVF after local anaesthesia was not significantly different (0.14) than the day 2 post-treatment PVF.

There was a significant analgesia following ESWT from 8 hours through 48 hours after treatment. These data can be utilized in the formation of regulations concerning ESWT.

ESWT Treatment in Delayed Union and Pseudoarthrosis

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During 2004 in our Institute we investigated the effectiveness of extracorporeal shock wave therapy in pseudoarthrosis and delayed union of long bones in 30 patients. We extended our work to a total of 80 patients till Jan 2006. This study shows our experience as Radiologists with ESWT.
Our study, started in 2004 with 30 patients, continued till Jan 2006 collecting a group of 80 patients to valuated the effectiveness of ESWT in treatment of pseudoarthrosis and delayed union. We treated 53 males and 27 females (age ranging from 15 - 68 years), of whom 44 suffered of pseudoarthrosis and 36 of delayed union. Shock wave treatment was administered with a "REFLECTRON" (HMT- System). The protocol consisted in 4 treatments (one per week) with 3000 shocks (frequency 240 shocks/min) each. The target area was selected under fluoroscopic guidance drawing a pen-point on the corresponding skin area. Treatment was given without anesthesiological support, hospitalisation nor immobilisation.
Our experience confirms the primary role of ESWT in the conservative treatment of pseudoarthrosis and delayed union of long bones.

Shockwave Biosurgery and Autologous Growth Factors Combined Therapy in Minimally Invasive Treatment of an Intertrochanteric Fracture Non-union: a Case Report

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A significant number of hip fractures are produced by high energy trauma that causes complex fractures which are difficult to manage with closed or open reduction and internal fixation. Some patients present low energy trauma fractures that are mostly incomplete or not displaced. These fractures are difficult to diagnose and can lead to complications like pseudarthrosis, non-unions or fracture displacement.
We treated a 38-year-old man with a non-displaced intertrochanteric fracture non-union. The first treatment option was to perform an open reduction with cure of pseudarthrosis and bone grafting. However, the adequate stability of the fracture and the difficulty in performing surgery on an overweight patient led us to propose a non-invasive treatment option. Given our experience with RSWT & Autologous Growth Factors (AGF) combined therapy, we choose such a treatment for this patient. We applied 4,000 shockwaves at 4 BAR at the trochanteric area without anaesthesia. Previously, we obtained 30 cc of blood that was processed in a double centrifuge process. The AGF was activated and mixed with morselized bone allograft, and applied percutaneously into the non-union. Our patient was allowed to walk with crutches post-treatment. Pain was controlled and no complications occurred. X-rays showed bone bridges after 2 weeks and a solid bone callus after 4 weeks.
RSWT and AGF combined therapy may be a useful procedure to treat non-unions of intertrochanteric non-displaced fractures. We believe this therapy could be performed in acute incomplete or not displaced fractures of the hip.

The Effects of Extracorporeal Shockwaves on Acute High-Energy Long Bone Fractures of the Lower Extremity

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Institution: Chang Gung Memorial Hospital-Kaohsiung Medical Center Kaohsiung, Taiwan

High-energy long bone fractures of the lower extremity are at risk of poor fracture healing and high rate of non-union. Extracorporeal shockwaves have proven to be effective to heal non-union of long bone fractures. However, the effect of shockwaves on acute fractures is unknown. The purpose of this study was to investigate the effects of shockwaves on acute high-energy fractures of the lower extremity. Materials and Methods: Between January and October 2004, 56 patients with 59 acute high-energy fractures were enrolled in this study. Patients were randomly divided into two groups: 28 patients with 28 fractures in the study group and 28 patients with 31 fractures in the control group. Both groups showed similar age, gender, type of fracture and follow-up time. Patients in the study group received open reduction and internal fixation and shockwave treatment immediately after surgery on odd-numbered days of the week, whereas patients in the control group received open reduction and internal fixation without shockwave treatment on even-numbered days of the week. The evaluation parameters included clinical assessments of pain score and weight bearing status of the affected leg and serial radiographs at 3, 6 and 12 months. The primary end-point is the rate of non-union at 12 months, and the secondary end point is the rate of fracture healing at 3, 6 and 12 months. Results: At 12 months, the rate of non-union was 11% for the study group versus 20% for the control group ($P < 0.001$). A significantly better rate of fracture healing was noted in the study group over the control group at 3, 6 and 12 months ($P < 0.001$). Conclusion: Extracorporeal shockwave is effective in promoting fracture healing and decreasing the rate of non-union in acute high-energy fractures of the lower extremity. High-energy long bone fractures of the lower extremity are at risk of poor fracture healing and high rate of non-union. Extracorporeal shockwaves have proven to be effective to heal non-union of long bone fractures. However, the effect of shockwaves on acute fractures is unknown. The purpose of this study was to investigate the effects of shockwaves on acute high-energy fractures of the lower extremity. Between January and October 2004, 56 patients with 59 acute high-energy fractures were enrolled in this study. Patients were randomly divided into two groups: 28 patients with 28 fractures in the study group and 28 patients with 31 fractures in the control group. Both groups showed similar age, gender, type of fracture and follow-up time. Patients in the study group received open reduction and internal fixation and shockwave treatment immediately after surgery on odd-numbered days of the week, whereas patients in the control group received open reduction and internal fixation without shockwave treatment on even-numbered days of the week. The evaluation parameters included clinical assessments of pain score and weight bearing status of the affected leg and serial radiographs at 3, 6 and 12 months. The primary end-point is the rate of non-union at 12 months, and the secondary end point is the rate of fracture healing at 3, 6 and 12 months. At 12 months, the rate of non-union was 11% for the study group versus 20% for the control group ($P < 0.001$). A significantly better rate of fracture healing was noted in the study group over the control group at 3, 6 and 12 months ($P < 0.001$). Extracorporeal shockwaves are effective in promoting fracture healing and decreasing the rate of non-union in acute high-energy fractures of the lower extremity.

Standard of Care for the Treatment of Non-Unions

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Considering that non-union results from one or both factors (instability and impaired vascularization), the treatment is directed to overcome the causing factors. Many non-unions have been existing for long time, and some with previous surgeries. The consequences are that beside the lack of bone union, it may be present misalignment, skin scars, dead bone, loose implants and particularly important bone atrophy (disuse) and joint stiffness (or impaired ROM). Treatment must consider all these parallel factors, which have to be overcome in order to bring back to the patients the best possible conditions to achieve better daily activities, and even going back to sports. Diagnosis is usually easy to be established through plain X-Rays, moreover if they are consecutive. Seldom it is necessary to have CT scan or MRI. Assessment of function pre-op is mandatory. Treatment objectives are to correct not only non-union, but also to restore length, angulations and rotational deformities, and especially articular function. Today the best way to fulfill these requirements is with surgical treatments, which offer required stability so bone can heal, correct deformities, allow to add bone graft when necessary and permits early movements of joints. All these factors together offer good results in over 80% in surgically treated non-unions with stable osteosynthesis.

Extracorporeal Shockwave Therapy for Non-Unions and Delayed Healing Fractures

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The objective of every fracture treatment is to reunite the fracture fragments in an anatomical position and completely restore the function of the injured portion of the skeleton as quickly as possible. Despite today's sophisticated technologies and good primary treatment, 1-3% of all bone fractures develop into pseudarthrosis. Surgical treatment with debridement of the pseudoarthrotic tissue, cleaning of the fragment edges, insertion of autologous spongiosa and stabilization with osteosynthesis material is considered the "gold standard" for the treatment of pseudarthrosis. However, these surgical procedures are extremely traumatic for the patient. They are also costly, time-consuming, and associated with a high rate of complications. Therefore in December 1998, after successful pilot studies, the Trauma Centre Meidling commenced a large-scale prospective study using shockwave therapy to treat non-unions.

To date, more than 1,100 non-unions have been treated with shockwave therapy in the Trauma Centre Meidling. We have used different electrohydraulic devices (Orthowave 280, MTS; OssaTron, HMT) and have even compared different technologies by also using an electromagnetic device (Modulith, Storz Medical) from April 2004 until January 2005.

From the start of the study, more than 50 patient-specific data items were stored in a database developed especially to permit the combination of a broad range of parameters. This database structure serves as the basis for quality assurance measures and enables the researchers to determine the optimal treatment parameters and other important criteria. This database containing a documentation of the treatment of pseudarthrosis with ESWT is made available to all interested parties free of charge; it can be ordered from the authors.

Treatment was basically envisaged as a single treatment. Depending on the region to be treated, shockwave therapy is administered under general, regional or local anaesthesia. The patients are positioned such that the pseudarthrosis gap is clearly visualized in the anterior-posterior projection. The shockwave focus is positioned on the pseudarthrosis gap and between 2,000 and 4,000 pulses are applied (1,000 pulses per treatment location). We use an energy flow density (EFD) of 0.3 to 0.4 ml/mm2 for all bone treatments.

Following shockwave therapy the pseudarthrosis is immobilized like a fresh fracture. This is usually done with a plaster cast or plastic splint; in 7 patients with especially mobile tibia non-unions, an external fixator was used. Fixation is not necessary when the pseudarthrosis has been treated with appropriate osteosynthesis material and this material exhibits no signs of loosening upon clinical or radiological examination. It can be assumed that the healing process is initially accompanied by neovascularization; for this reason, we try to prevent micro-movements of the non-union during the first 3-4 weeks after treatment to preclude tearing of the new capillaries. It may be necessary, in some cases, for the patient to avoid full weight bearing on the affected extremity during this period. The patient's cooperation must be elicited by a detailed briefing since most patients are asymptomatic directly after the treatment, owing to the analgesic effects of the shockwaves, and want to put their full weight on the affected extremity again.

If the cardinal symptoms (i.e. pain upon bending or compression, swelling, reddening and hyperthermia) subside during the early post-treatment phase (i.e. the first 2-3 months after ESWT), the physician can afford to take a "wait and see" attitude. This applies even if the x-ray findings are ambiguous, since the clinical findings constitute a more reliable measure of therapeutic success at this stage.

A pseudarthrosis gap with a width greater than 5 mm shows a poor prognosis.

In cases where bony remodelling of the non-union could not be demonstrated after 3 to 6 months, patients were given the option of surgical repair. Numerous patients, especially those who had undergone multiple

operations previously, refused this option. This led to a relatively high number (18%) of repeat treatments. In exceptional cases, a third or fourth (and in one instance, even a fifth) treatment was performed. The group of patients undergoing repeat ESWT included patients for whom a complicated pseudarthrosis operation was contraindicated for internal reasons or could have been done only at considerable risk to the patient.
Osseous union was achieved in 67% to 75% (depending on the device) of the pseudarthroses. As expected, the best therapeutic results were obtained in patients with delayed osseous union - in this group, ESWT was administered 3-6 months after the injury or the last operation on bone - and healing was achieved in 75% to 85% of these patients. Of the patients with pseudoarthrosis with an onset more than six months previous, 60% to 70% experienced osseous union.
Among the more than 1,100 patients treated at the Trauma Center Meidling, no complications occurred other than the adverse reactions that have already been observed following shockwave therapy (i.e. local swelling, petecheal bleeding, haematoma). Even though the mechanism of action of shockwave therapy has not yet been fully explored, we are convinced that ESWT is an effective, inexpensive and time-saving therapeutic modality with an almost zero rate of complications. Therefore we consider ESWT as the first choice thrapy for non-unions and delayed unions that do not require surgical realignment.

Standard of Care for the Treatment of Avascular Necrosis (AVN) of the Femoral Head

Author: Dr. João Matheus Guimarães

Avascular necrosis (AVN) of the femoral head is a pathologic process resulting from interruption of blood supply to bone.
AVN of the hip is poorly understood but is the final common pathway of traumatic or non-traumatic factors that compromise the already precarious circulation of the femoral head. Femoral head ischemia results in the death of bone marrow and osteocytes and usually results in the collapse of the necrotic segment.
AVN of the femoral head is a debilitating disease that usually leads to osteoarthritis of the hip joint in relatively young adults .The goal in treating avascular necrosis is to improve the patient's use of the affected joint, stop further damage to the bone, and ensure bone and joint survival.
Non-operative treatment and surgical treatment options are available, their risks and benefits, potential limitations and complications will be discussed.

Treatment for Osteonecrosis of the Femoral Head: Comparison of Extracorporeal Shock Waves with Core Decompression and Bone-Grafting

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There is continuing controversy regarding the optimal treatment for patients with symptomatic earlystage osteonecrosis of the femoral head. We compared the results of noninvasive treatment with extracorporeal shock waves with those of core decompression and bone-grafting in similar groups of patients.

Patients with stage-I, II, or III osteonecrosis were randomly assigned to be treated either with shock waves or with core decompression and nonvascularized fibular grafting. The shock-wave group consisted of twenty-three patients (twenty-nine hips), and the surgical group consisted of twenty-five patients (twenty-eight hips). The patients in the two groups had similar demographic characteristics, duration and stage of disease, and duration of follow-up. The patients in the shock-wave group received a single treatment with 6000 impulses of shock waves at 28 kV to the affected hip. The evaluation parameters included clinical assessment of pain with a visual analog pain scale, Harris hip scores, and an assessment of activities of daily living and work capacity. Radiographic assessment was performed with serial plain radiographs and magnetic resonance imaging.

Before treatment, the two groups had similar pain and Harris hip scores. At an average of twenty-five months after treatment, the pain and Harris hip scores in the shock-wave group were significantly improved compared with the pretreatment scores (p ¡ 0.001). In this group, 79% of the hips were improved, 10% were unchanged, and 10% were worse. Of the hips treated with a nonvascularized fibular graft, 29% were improved, 36% were unchanged, and 36% were worse. In the shock-wave group, imaging studies showed regression of five of the thirteen lesions that had been designated as stage I or II before treatment and no regression of a stage-III lesion. Two stage-II and two stage-III lesions progressed. In the surgical group, four lesions regressed and fifteen (of the nineteen graded as stage I or II) progressed. The remaining nine lesions were unchanged.

Extracorporeal shock-wave treatment appeared to be more effective than core decompression and nonvascularized fibular grafting in patients with early-stage osteonecrosis of the femoral head. Long-term results are needed to determine whether the effect of this novel method of treatment for osteonecrosis of the femoral head endures.

New Application of Shock Waves in Arthritis and other Osteochondropathies: Clinical Data, Biological Considerations and Future Perspectivies

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Recent reports in medical literature have shown that pain in arthritis and osteochondropathies, not to mention inflammation, can be due to bone marrow oedema. The aim of our study was to examine the effects of Extracorporeal Shock Waves (ESW) on these pathologies and to underline their potential positive interference on the evolution of chondro-osseous degeneration.
Forty-five patients suffering from knee, ankle or foot pain due to arthritis or other degenerative osteochondropathies, all of them characterized by bone marrow oedema, were subjected to high energy ESW (1 or more series of 3 treatments; 4,000 - 5,000 shocks/treatment; 0.15 - 0.4 mJ/mm2). After each treatment, patients were on crutches for 20 - 25 days. Results were evaluated according to subjective and objective clinical findings and MRI imaging (pre and post treatments).
More than two-thirds of the patients reported positive results after ESW, in regard to pain, swelling or joint stiffness, and bone marrow oedema. Pain resolution was strictly related to an improvement of MRI imaging ($> 90\%$). No local nor general side effects were reported.
Bone marrow oedema, responsible for pain in arthritis and other osteochondropathies, recently has been described as a negative prognostic factor regarding their degenerative evolution. According to our promising data, ESW seems to positively interfere not only with symptoms but also with the pathogenetic mechanism of degeneration. The authors are going to explain the rationale of this new therapeutic application, of which its "protective" effects against tissue degeneration are underlined.

Osteochondral Lesions as an Indication for ESWT

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The treatment of osteochondral lesions is realized in the field of high-end-technologies. In arthroscopic techniques the cartilage tissue is refreshed by abrasion and retrograde drilling. For the localized chondral defect various types of cartilage-transplantation such as OATS and mosaic-plasty are applied.
Aim of the treatment of cartilage damage of the joint always is to restore the congruent surface of the joint and the complete covering with cartilage tissue. ESW showed in vitro a proliferation of chondrocytes and even in vivo we were able to show these results in single-case-publications. The idea of the working-mechanism of extracorporal shockwaves has expelled from primarily assumptions of the mechanical destruction of the treated tissue and therefore causing a remodelling process. The shockwave rather shows an aimed induction of bioengineerin process in the sense of activating the cell metabolism via "second-messenger"-cascades. Mediators like NO appeared in the focus of interest. Such signal transducing substances are able to cause a transformation of transmembranous proteins and activating them. By "second-messenger"-Pathways the intracellular metabolism is affected. The transformation of mechanical stress, produced by ESW, into a cellular answer is named mechanotransduction. Regarding the cartilage-tissue cell-regeneration is induced by the mechanical stress. Chondrocytes have a very slow metabolism. In terms of an intact tissue-formation an expanding growth is not necessary. This information is processed by the intracellular and transmembranous adhesion-molecules. If there is a defect detected this will lead to the activation of repairing processes. In cartilage-tissue this process remains slowly and therefore shows a remaining defect or a less thickened coverage of the joint. The aim is to stimulate these mechanisms by ESW and therefore gaining a thickened covering of the chondral defect with a primary cartilage tissue. The shockwave treatment is performed in combination with a diagnostic arthroscopy in order to get a documentation of the chondral defect of the surface and the stage of the osteochondrosis. The study included 87 patients, 59 male and 28 female. Following to the pictorial report the patients with an OD or a degenerative/traumatic chondral lesion receive a single treatment with an electrohydraulic generated shockwave in general anaesthesia.
After shockwave treatment an immobilisation of the joint and a waiting period for sportive activities is performed for 2-6 weeks. Clinical controls and MRI-examination show the outcome. If the patients agree a "second-look"-arthroscopy and histologic findings will be performed, but in reality most of the now pain-free patients do not agree to undergo a second arthroscopy. As shown in previous publications the treatment of the OD shows a very good and good result in 70% and in another 14% the progression of the affected area could be stopped. Additional to the good subjective results we have never seen any treatable side effects.
At this time we are not able to reveal valid data on the treatment of degenerative/traumatic chondral lesions and therefore we can only show single-cases.
For treating chondral-lesions in the sense of arthritic disease there will be further pilot-trials that are performed in the mean-time. It is to be shown how the microbiologic effects of shockwaves are transformed to the cells, hardening the hypothesis of a bioengineering effect of shockwaves. Afterwards a valid animal-experiment has to be studied. In the scientific research and clinical studies the positive effect of shockwaves on cartilage has been shown. These effects and the hypothesis of a mechanotransductional effect are to be investigated in comprehensive study. In order of the efficacy, the lack of complications and the slight effort applying shockwaves this could be a sensible alternative to the acknowledged methods in the treatment of chondral damage.

Effectiveness of Shock Waves in Bone Marrow Edema Syndrome of the Hip: new Cases and More Pathogenetic Hypothesis

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"Bone Marrow Oedema Syndrome of the Hip" (BMESH) is a painful syndrome of still unknown origin. The aim of our study was to examine the efficacy of Extracorporeal Shock Waves (ESW) in rapidly relieving this condition and to underline some important biological implications.
A total of 110 patients, affected by BMESH, were subjected to high energy ESW (1 - 2 series of 2 - 3 treatments; 3,000 - 4,000 shocks; 0.3 - 0.6 mmJ/mm^2). After treatment, patients went on crutches for approximately 25 - 30 days. Patients were evaluated before and after treatment by Visual Analog Scale for pain and by MRI imaging for bone marrow oedema.
ESW showed to have rapid positive effects in almost 80% of the patients, with regard to both pain and bone marrow oedema. Few patients showed aseptic osteonecrosis of the femoral head after bone marrow oedema resolution. No local nor general side effects were recorded after ESW. BMESH, according to some of the authors, if it persists, may produce aseptic osteonecrosis of the femoral head. It can have spontaneous resolution, but it takes many months. Medical and surgical therapies are reported to be effective, but take a relatively long time as well. From our study, ESW seems to be a valid, safe, non- invasive tool in rapidly relieving BMESH. Moreover, on the basis of clinical data, the authors are going to propose ESW as first therapeutic choice, due to the potential protective effect against further vascular impairment and irreversible tissue damage.

Two-Year Results of Patients with Gonarthrosis Treated with Intermittent Extracorporeal Shockwaves and Intra-Articular Application of Hyaluronic Acid

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Within the scope of a multicenter study about the effects of extracorporeal shockwaves in combination with intra-articular applications of hyaluronic acid, 9 patients were observed for a period of over two years. After MRI examination, the sensivity to pain was proved by VAS (visual analogue scale) and the functional maximum load by Lysholm and HSS (hospital of special surgery) score. ESWT was applied using Piezoson 100 (Fa.Wolf, Knittlingen, Germany) on 9 patients (5 women,4 men) between 29 and 75 years of age. The treatment was performed five times at one-week intervals. Three patients (2 women, 1 man) who were under medical supervision for 30 months reported total elimination of their pain with a significant improvement of the Lysholm and HSS-score. Two patients had a significant and two a mediocre improvement in their pain. Two patients required surgery.
The treatment of gonarthrosis in a not-so-advanced state that combines ESW with intra-articular hyaluron acid injection seems to be a good alternative to other therapies.

Histological Findings in Human Osteoarthritis (OA) Treated with ESWT

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Institution: Santiago - Chile

ESWT has been used for treatment in different pathologies that compromise cartilage and corresponding subchondral bone . The aim of this report is to evaluate the effects of shock waves on this special anatomical region and compare them with our histopathological results in ESWT-treated soft-tissue shoulder pathologies. From July 2004 to November 2005 , 15 patients (6 male , 9 female, mean age = 61 years.) with knee OA (13), elbow OA (1) and trapezius-mtc OA (1), were accepted for a single treatment of shockwaves (2,000 shocks /0.33mJ/mm2, Orthospec/Medispec) focused on the area of OA clearly displayed in MRI-gadolinium. According to protocol, these patients underwent delayed arthroscopic treatment and osteochondral biopsies (6 to 10 weeks post-ESWT application). During the same period we collected 15 osteochondral biopsies from patients with OA, and 5 osteochondral samples from patients with prosthetic solutions for complex joint fractures. All biopsies underwent the same treatment of habitual stains for this kind of tissue and examination under light microscope.
HISTOLOGICAL RESULTS: 1. There were no differences in the histopathological aspect of OA between the treated and control cases, suggesting that ESWT does not produce distortion or more damage in these tissues. 2. In the cartilage of OA-ESWT cases there was no observed necrosis of cartilage cells or damage to isogenic groups, which were surrounded by a normal matrix with normal collagen arcades as in normal control cases. 3. Cartilage in treated cases remained quiescent with no observation of mitosis, but in some patients there was an intense matrix basophilic reaction. 4. The review of subchondral bone and bone marrow features between three groups of samples depicted no large differences; however in some material there was an observed increase of neo-hypermuskularized active vessels with more cellularity associated in bone marrow areas, quite similar to those seen in shoulder tendinosis treated with ESWT. 5. There was no evidence of scarring, fibrosis, necrosis or anaplasia- displasia phenomena.
The reactive features of bone marrow blood-vessels are quite similar to those found in others ESWT-treated tissues. The fact that some blood vessels cross over to rest in calcified cartilage (Clark ,1990) and the probable relationship between these blood vessels and the reparative process in this special anatomical area are particularly interesting in light of our findings that shockwaves could improve epiphyseal microcirculation. This deserves more research efforts. Our histological observations in different human tissues indicate that ESWT treatment does not cause more structural damage or cellular lesions and that the neo-vascular response is consistent in doses of 2,000 to 4,000 shocks at $0.33/\mathrm{mJ/mm^2}$.

Standard of Care for Lateral Epicondylitis

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Lateral epicondylitis, or tennis elbow, is the most common overuse syndrome of the elbow. A bit of controversy exists about not only the treatment of this condition but also the exact pathophysiology. Most often this injury is encountered in industrial workers and also has been encountered in professional musicians, people who spend a great deal of time at a computer or keyboard that is set up with poor ergonomics and the tennis' s player or racquet sports. Discontinuing activities that cause the pain is the first step to proper treatment of Lateral Epicondylitis and due recurrence of this condition is common, return to activity should not occur too quickly, and preventive exercises should be done consistently.
Treatment is aimed at pain relief and reducing inflammation and the conservative treatment include nonsteroidal anti-inflammatory medications ,local injection of cortisone, immobilization of the forearm and elbow and physical therapy.
The surgical treatment is available to treat tennis elbow if the conservative treatment fails and a variety of procedures have been designed to excise the inflammation and scar tissue. We will discuss the efficacy and risks of the surgical treatment.

Shockwave Therapy for Lateral Epicondylitis of the Elbow : Retrospective Study

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The aim of this study was to evaluate the efficacy and safety of extracorporeal shock wave therapy for the treatment of Lateral Epicondylitis of the elbow in three Brazilian Orthopaedics Clinics.
In a multi-center, retrospective study, the effect of shockwave therapy was investigated in 93 elbows of 89 patients with Lateral Epicondylitis of the elbow treated for a period of 51 months, from March 2001 to June 2005. Four patients received bilateral treatment. There were 37 women and 52 men with an average age of 51 (range, 33-74) years. The criteria for inclusion were at least three months of unsuccessful conservative therapy or six months of pain. Criteria for exclusion were inflammatory arthritis, corticosteroid injection within the previous 6 weeks, acute infection, gout, malignant diseases or blood coagulation disorders. Each patient was treated with 1,200 shock wave impulses, a 5 mm focus depth, and with an energy flux density of no more than 0.13 mJ/mm2 after local or regional anaesthesia. One treatment was performed on 80 elbows, 12 elbows underwent a second treatment and 1 a third. The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score and subjective outcome on Visual Analogue Scale (VAS) analysis, 45, 90 and 180 days after the end of the therapy. The study showed the efficacy and safety of ESWT were excellent in 39.8%, good in 32.3%, acceptable in 10.8%, and poor in 17.1%, 180 days after ESWT.

Radial or Focused Shockwave Biosurgery In Lateral Epicondylitis?

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In this review we present our case series of RSWT and compare them with our 2003 Focused Shockwave Bio surgery results. In 134 cases of lateral epicondylitis treated with RSWT we used a two-session protocol with 4,000 shockwaves progressing from less than 2 Bar (¡0.06mJ/mm2) and 10Hz to 4bar (0.18mJ/mm2) and 4Hz, without anaesthesia. We evaluated patients at three, six and twelve months with VAS, ASES-e score, and the ability to return to sports. After three months 97 patients showed a VAS pain reduction of 68%, 62% returned to sports at a similar level, 32% at a lower level, and 6% had persistent pain. Sixty-five percent had good or excellent functional scores. After twelve months, 89 patients showed a VAS pain reduction of 61%, 70% returned to sports at a similar level, 26% at a lower level and 4% had persistent pain. No patients required surgery, and the functional scale analysis improved to 84% with good or excellent results.
Similar results were reported after one year for both types of shockwaves. We found some differences: RSWT allowed a shorter treatment time, a variation in energy and frequency, and the ability to quickly change the point of application. Treatment with focused shockwaves is better for immediate pain relief, is a hand-free procedure for the operator, and patients feel they are receiving more an orthopaedic procedure rather than physical therapy. Economic issues are beyond this paper. Having both devices allows our unit to use Shockwave Bio surgery in a wide variety of applications.

Recommendation for the Treatment of Tennis Elbow with ESWT

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Over the past decade in Germany extracorporeal shock wave therapy (ESWT) has become a serious alternative in the treatment of the tennis elbow.
In the last 10 years, we have observed the results of ESWT in 272 athletes who have had Epicondylitis Humeri Radialis (EHR). We applied 1,500 impulses with an energy of 0.08mJ/mm2 on different areas of the lateral epicondyle in relation to the individual pain sensation of the patient. The treatment was done at weekly intervals.
The evaluation of the results with various times of observation showed that directly after ESWT 171 athletes (approx. 63%) reported good to very good results. A slight improvement was reported in 27.2% (74). Nearly 10% (27) of the athletes showed no improvement. During the first evaluation 6 weeks post-treatment, the good and excellent results increased from 63% to 72.1%. After 6 months the increase of good to excellent results reached 76.1% (207 PB). After more than 3 years, 72% (195 PB) of the athletes showed a good to excellent result. Only 12 of the athletes had a recurrence. After more than 10 years we were able to reach nearly 80% (151 PB) of the athletes who showed good to excellent results in the 3 year follow up. Only 9 (6%) had a recurrence.
Due to our 13 years experience we recommend that ESWT should be done without local anaesthesia because in such cases the patient is not able to give exact feedback regarding his individual pain areas. The shockwaves should be applied on different areas of the lateral epicondyle in relation to the individual pain sensation of the patient (Dynamical Treatment). The final results should be evaluated after a time period of more than 3 months, because of the long term effect of ESWT.