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Abstracts 1

of the 4th International Congress of the ISMST

Berlin

Shockwave therapy for painful heel spur: results of a prospective randomized double blind study

measuring plantar heel pressure with a Novel Emed AT-4 pedograph system

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Background:

In spite of the widespread use of extracorporeal shock wave therapy for patients with painful heel and calcaneal spur, the literature offers no double blind study regarding this matter. We investigated the effects of ESWT on different aspects of pain as well as the plantar heel pressure for normal walking.

Methods:

32 patients suffering from persistent symptoms for more than five months qualified for low-energy ESWT and were assigned at random to two groups, real (Group I, n = 17) and simulated ESWT (Group II, n = 15). Any other therapy was stopped six weeks before initial ESWT. Depending on clinical response patients received one or two times 1000 impulses of 0,08 mJ/mm² with six weeks in between (Ossatron OSA 120, HMT AG, Switzerland). Each patient was examined clinically, on VAS (0-10), Roles and Maudsley Score and walked barefoot at individual speed on a floorway with an embedded Emed AT-4 pedograph system (Novel GmbH, Munich). Follow up examinations took place 19, 32 and 48 weeks after the initial ESWT. All patients received prescriptions for custom made in shoe orthoses which were renewed ½ year later. No other treatment was allowed for the time of the study.

Results:

Tolerable puncture pressure at the plantar area applied with a 1 cm² stamp increased from 116,7/140,3 N (Group I/II) to 223,2/159,3 N after 48 weeks (p = 0,02). Morning pain decreased from 5,7/5,3 down to 0,7/2,2 (p = 0,04). Resting pain showed improvement from 4,6/3 down to 0,7/1,8 (p = 0,02). Painfree barefoot walking for 60 or more minutes was possible for 17,6/13,3 % of group I /II and increased to 64,7/46,7 %. Painfree walking with

shoes and orthoses for 60 or more minutes was possible for 58,8/46,7 % of group I/II and improved to 100/86,7%. The mean plantar pressure for the affected side started initially at 13,5/14,2 N/cm² increasing to 17,7/17 N/cm², results for peak pressure were 25,1/28,4 N/cm² and increased in both groups to 35,3/34,6 N/cm². Pressure Time Integral started at 6,4/8,6 Ns/cm² and showed 7,8/9 Ns/cm² in the end. Patients reported averaged 1,5/2,9 points at the Score according to Roles and Maudsley (one = painfree, four = same condition as before treatment)

Conclusion:

The treatment group improved significantly better than the placebo group for puncture pressure, morning- and resting pain, barefoot and shoe-walking as well as for Roles and Maudsley score. Regarding the foot pressure at normal gait we observed a clear pattern towards putting more load on the heel parallel to pain relief but without a significant difference between both groups. Looking at the clinical outcome ESWT seems to have significantly more impact on pain at plantar fasciitis with calcaneal spur than conservative treatment.

Experimental study in sciatic nerve and aquiles tendon in rabbit. Preliminary results

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The objective is to study the effects of the shockwaves on tendon and peripheno nerve, to determinate the biological actions on them. We have used the Aquiles tendn and the ciatic nerve on rabbit.

This is an experimental comparative and double blind study.

Material:

50rabbits. Same sex. General anesthetic. Sonocur plus Siemens.

Methods:

First location of the estructures with lineal ultrasonographic image. Second location with the head of Sonocur of the area to treat.

Application of ESW on the different areas in three different sessions, with a lapsus of 48 hours. At 96h we proceed to sacrify the animal in accordance with the ethic committee of the University Hospital. There are four groups of animals, treated with shockwaves and a control group.

Results:

1° Ultrasonographic study. 2° Necropsy. Macroscopic study. 3° Microscopic study.

At present we have complete the 1° and 2° and 80% of the optic microscopic. We hope to present the results in the congress as a work in progress.

Effect of shockwaves on calcaneal spurs

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Atlanta Medical Center

In a study of 321 patients with chronic proximal plantar fasciitis 197 (65%) had a heel spur prior to acceptance for treatment with extracorporeal shockwave therapy. At evaluation three months after receiving a shockwave treatment, 10 of 130 (7.7%) patients who received shockwaves had disappearance of the heel spur, while 12 of 129 who had a placebo treatment also had disappearance of the heel spur (9.2%).

The results showed no correlation between post-treatment disappearance of the heel spur and the outcome. Further, the vast majority of treated subjects (93%) who had a successful outcome at 3 months still has an obvious heel spur present on the post-treatment radiographic study. Accordingly, while the heel spur may be an additive factor in the patients evaluation, the presence or disappearance of the heel spur following treatment with extracorporeal shockwaves had no correlation with successful outcome.

Effects of unfocussed shockwave treatment in human soft tissue: preliminary study

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In this study the AA. studied the possible structural and ultrastructural changes in the human soft tissues (ligament and muscle) treated with radial shockwaves.

The radial shockwaves are pneumatically generated and emitted at the tip of the applicator and coupled into the human tissue, until to a depth of up to 35mm.

A patient, affected by an impingement syndrome at the right shoulder and treated with shockwaves therapy three months before, was underwent an operation, in the course of which we performed a biopsy of the subacromial ligament and supraspinatus muscle.

For light microscopy the tissue are fixed in 10% formaldehyde and embedded in paraffin. 5 μ sections was stained with hematoxylin and eosin and Mallory trichrome stain. For the electron

microscopy the tissues were fixed in isotonic buffered glutaraldehyde 3% for 5 hours at 20 ° C and rinsed in 0,1 M cacodylate buffer. After dehydration of the specimens, cross-sections of 0,04 µ were stained.

At the light microscopy examination we have not observed evidence of inflammation in both tissues. In the ligament we revealed a slight stromal sclero-hyalinosis with an increase of collagenous production and activated fibroblasts, including plentiful wrinkled endoplasmic reticulum. In the muscle we observed an increase of the interstitial connective tissue with fiber cell, including a lot of subsarcolemmal mitochondria and a slight increase of lipid.

These preliminary observations on the human soft tissues, treated with shockwaves demonstrated the absence of inflammatory figures in the ligament with remedying changes. The evidence in the muscle of the subsarcolemmal mitochondria accumulation is probably connected to the development of a "fibrositis".

Extracorporeal shock wave therapy

Introduction into basic physics and quantification of the sonic field

Author: Anna Tóth-Kischkat

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Shockwaves are short high pressure sonic pulses expanding concentrically. Their impact has been used very successfully in lithotripsy, before they were entered into orthopedics were again they produced convincing results. While the medical process induced in lithotripsy is fairly simple this is not the case in orthopedics. In order to correlate physical input with medical results it is particularly important to understand the physics involved and to quantify the sonic field.

There are three methods of shockwave generation

- * spark gap
- * electromagnetic
- * piezoelectric

For optimization of impact and minimalization of losses and possible side effects the output energy is focused into the area, where it is medically needed. The physical data in this focal area have been measured for the different devices and are published and continuously updated on our website: <http://www.shockwave-therapy.net>.

Low-energy shockwaves therapy in 87 cases of insertional tendinous pathology

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Purposes:

On the basis of our experience in the use of a III generation lithotripter: LITHORING multione (Medas, Genoa) in operation care of our Institute since May 1993 we conducted a preliminary experience in the treatment of the tendinous pathology, using a portable shock-waves litotripter, designed for low energy, non invasive treatment without the aid of a local anaesthetic in the majority of cases.

Material and Methods:

We examined patients (58 males and 29 females average 62.0 years old) in the period from July 1999 to January 2001 using the "Orthima" lithotripter marketed by "Direx medical systems". This is a lithotripter of the electro-hydraulic type. The pulsation frequency is 120 pulses a minute and the energy supplied can vary from 0.0003 up to 0.5 mj/mm² with a maximum penetration capacity up to 65 mm. In all cases a preliminary diagnostic examination was carried out (RX or, when necessary, US and/or NMR). Each treatment includes a series of sessions varying, case by case between 5 and 10 with intervals of 3-5 days, depending on the clinical progress and the type of pathology (maximum of 10 sessions for pubic pain, 8 for plantar fasciitis and calcaneal entesopathy, a maximum of 5 sessions per series for all other pathologies).

Results :

The target was pain absence-reduction. We obtained satisfying results in 70% (61 patients) of cases and lack of success in 30% (26 case) of the patients treated, with no side effects.

Conclusions:

Keeping in mind the repeatability of the therapeutic cycles, usually well tolerated by the patients, we believe that low-energy shock waves, also in consideration of the low costs involved and user-friendliness, represent an excellent alternative to the conservative analgic treatments with osteoarticular surface pathologies wherever surgical treatment is not recommended.

Extracorporeal shockwave treatment (ESWT) in plantar fasciitis

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Prof. Dr. V. Lök Izmir/Turkey, H. Aydinok, MD; Izmir/Turkey

This study aimed at determining the results of ESWT in cases of plantar fasciitis (PF) as well as delineating the indications of treatment.

ESWT has been administered to a total 148 patients, 11 of which actively participated in sports in Nürnberg Germany and Izmir Turkey. Average age being 53 (range 22-84) 76 patients were female (%68) and 36 were male (%32) . ESWT has been administered following a period of minimum 6 months of unsuccessful conservative treatment which consisted of longitudinal arch support, anti-inflammatory medications, local steroid administration and physical therapy (electrotherapy, therapeutic ultrasound, heat and cold applications).

ESWT consisted of 16-18 kilovolts and 100-200 impulses per minute adding were found to be sufficient to obtain results. treatments were limited to four sessions and terminated with resolutions of pain. Although local anesthesia is preferable during treatment, general and epidural approaches are also feasible.

Complete resolution of symptoms were observed in 101 (%68) patients. In 33 (%22) patients severity of symptoms declined without complete resolution. 14 patients (%10) did not respond to treatment.

Radial extracorporeal shock wave therapy for chronic insertion desmopathy of the equine suspensory ligament – a controlled study .

Authors: K. J. Boening, DVM, MS, Dipl. ECVS; S. Löffeld, DVM; K. Weitkamp, DVM; S. Matuschek, Dipl. Biol.

In human medicine, extra corporal shock wave lithotripsy is an established therapeutic procedure for treatment of renal calculi. In the last few years extra corporal shock wave therapy (ESWT) also has been used in human orthopaedic treatment, especially chronic insertion tendopathy/desmitis such as "tennis elbow", tendinosis calcarea and pseudarthrosis.¹

In the veterinary field, the use of ESWT is still right at the beginning.

So far, there is little information about different indications, treatment regimens and long term results. Controlled studies are completely missing.

Since June 1998, at the Tierklinik Telgte, Germany, horses with different orthopaedic conditions have been treated with radial Extra corporal Shock Wave Therapy . The aims were first to collect experiences with the new therapy; and second to establish the treatment as standard indication for special problems.

Therapy of chronic insertion desmitis/desmopathy of the proximal suspensory ligament in the equine front and hind limb is somewhat frustrating. This condition is characterised by a high rate of recurrence and low long term success. Systemic or local application of antiphlogistics and corticoids, blistering combined with long periods of rest and low grade training and finally surgery (peripheral neurectomy) are described in literature and documented.²⁻⁵

Long term follow up information about the treatment of chronic longstanding high suspensory desmitis are still missing in veterinary literature. This condition seemed to be ideal for ESWT treatment evaluation, for ESWT is known as a safe, alternative, non-invasive therapy without serious side effects.

In the present controlled study the results of radial ESWT for the treatment of chronic proximal suspensory ligament desmitis are documented.

31 horses with chronic proximal suspensory desmitis and which have already been treated by conventional methods were treated by radial ESWT .

The clinical diagnosis was supplemented by radiographs and ultrasonographic examinations, in a few cases also by scintigraphy. The horses got usually 2 to 3 sessions of shock wave therapy.

The horses were followed up within time frames of 4 weeks and 6 months after the final treatment. In this control examination not only clinical improvement but also radiographic and ultrasonographic changes were recorded. The criteria for success of treatment was free of lameness and return of the horses to full performance.

A retrospective control group consisted of 30 horses with chronic disease of proximal suspensory desmitis that were only treated by conventional methods. This group was used to compare the rate of success between radial ESWT and the outcome of conventional methods of treatment.

71 % (22 out of 31) of the horses treated by radial ESWT resumed full work 6 months after treatment. In the control group there were only 50 % (15 out of 30) that returned to full work.

Additional to the compare of the two groups the influence of different parameters, for example the index of lameness, the affected leg, the kind of use and the results of the radiographic and ultrasonographic examinations, on the outcome of treatment are discussed.

Based on the outcome of this study the radial ESWT seems to be an effective treatment for chronic, therapy resistant cases of proximal desmitis if the suspensory ligament in the horse.

Literature:

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Prospective randomized placebo controlled double blind multicenter study to evaluate safty and efficacy of extracorporeal shockwave therapy (ESWT) in chronic plantar fasciitis

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Problem:

ESWT has been used since 1995 to treat patients with plantar fasciitis who have failed available

conventional therapies. Previous studies for this condition using this therapy conducted in Europe have not been carried out as a placebo controlled study.

Method:

A total of 150 patients met the inclusion/exclusion requirements and were enrolled into this study at 6 sites (76 randomized to the active group, 74 randomized to the sham group). A single treatment was performed (3800 shock waves, 0.36 mJ/mm²) with regional anaesthesia. Ultrasound controlled focussing was performed. The Sham treatment was achieved by the placement of a thin foam cushion on the therapy head preventing the shock waves from being delivered to the patient. Follow up was performed at 3-5 days, 6 weeks, 3 months, 6 months and 12 months post treatment. Sham patients meeting defined criteria were offered an active treatment at 3 months. Primary Efficacy Outcome was the difference between the Active treatment and the Sham treatment in the change from baseline in the VAS score for pain while walking for the first few minutes in the morning through three months post treatment. Primary Safety Evaluation was the number of adverse effects and severity of complications that were related to ESWT as assessed at three months by the investigator. Secondary Efficacy Outcomes included pain evaluation from the AOFAS Ankle-Hindfoot Scale Score, Roles and Maudsley score, the SF-12 score, pain measurement on palpation (point of tenderness) with an algometer, and the ROM Assessment from the AOFAS Ankle-Hindfoot. An independent statistical consultant performed the statistical analysis.

Result:

At 3 months 73 patients in the Active group and 73 patients in the Sham group were available for analysis. Four (4) patients discontinued the study prior to the 3 month follow up visit. The results of the study demonstrate that patients treated with ESWT have statistically and clinically significant improvements in the primary outcome parameter ($p=0.01$). The Roles and Maudsley score was statistically and clinically significant between treatment groups at 3 months post treatment ($p= 0.03$). Treatment related side effects are mild and of low incidence and included pain, ecchymosis, and edema.

Cavitation dynamics induced by extracorporeal shockwaves

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Cavitation has been identified as one of the possible mechanisms in lithotripsy both for kidney stone destruction and tissue damage. Cavitation bubbles generated by lithotripsy shock waves have been detected in vitro and in vivo. The cavitation bubbles are excited by the negative pressure (tensile-stress) of the shock waves and can grow up to 1000 times their initial diameter. Upon collapse, bubbles close to solid surfaces can develop micro-jets of fluid on the order of 100 m/s which can damage the solid material. In free fluid, bubbles can collapse spherically inducing enormous localised pressures and shear forces that can damage tissue.

We demonstrate how cavitation can be detected and localised in vitro and in vivo using multiple detectors. The theoretical models applicable to bubble dynamics are presented and we show

excellent agreement between numerical predictions and measurements of cavitation fields in both electrohydraulic and electromagnetic shock wave lithotripters. The computational model predicts that violent cavitation will also occur in orthopaedic devices (OssaTron and Reflectron, HMT). Cavitation may play a role in the performance of orthopaedic devices; either in a beneficial manner, e.g., breaking up calcifications or in a detrimental manner by damaging healthy tissue.

Shockwaves therapy in the treatment of Osgood Schlatter disease out

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Introduction:

Among juvenile osteochondritis, also known like nucleus-apophysitis of the growth, Osgood Schlatter disease is one of the most frequent; this illness affects mainly sporting teen-agers, that practise soccer, artistic gymnastic, volleyball or other sports implying a functional overload on the knee extensor apparatus. Treatment of Osgood Schlatter disease is mainly conservative in view of its favourable development. Therapy consists on temporary abstention from sport activities and rarely on immobilisation of the limb by means of stiff knee-pads. In some rare cases the persistence of the pain with an X-ray image of ossification in the context of the rotuleus-pretibialis tendon could be observed in spite of an adequate treatment.

Material and Methods:

The Authors present the results achieved in the treatment of Osgood Schlatter disease output by means of Shock Waves. 28 patients, with age included between ten and sixteen years, no responders to conservative therapy and free from treatment for at least two months, have been treated.

Results:

In 8 patients the complete disappearance of the ossification combined with the total pain solving has been achieved. In 10 cases the Authors observed a notable reduction of the calcification size and of the pain level. In the remaining patients no changes have been observed either about the ossification or about the pain.

Conclusions:

Shockwave therapy is an effective aid for the specialist which has to treat the strongest shapes of the Osgood Schlatter disease.

Efficacy of extracorporeal shockwave therapy in the treatment of calcaneal enthesophytosis

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Objective:

The aim our study was to evaluate the efficacy of extracorporeal shock wave therapy (ESWT) in the treatment of calcaneal enthesophytosis.

Method:

60 patients (43 females and 17 males) were examined, showing talalgia associated with enthesophytosis of the plantar fascia or Achilles tendon. A single blind randomized study was performed with 30 patients undergoing a regular treatment (group 1) and 30 a simulated one (shocks of 0 mj/mm² energy were applied) (group 2).

A ESWT system was utilised "Orthima" by Direx Medical System Ltd. that is characterised by an electrohydraulic shock wave source assembled on a mobile arm with full possibility of movement, it is also equipped with a sonographic system with Linear Array and 7.5 MHz probe. Symptomatology variations were evaluated by Visual Analog Scale (VAS). Variations in the dimension and density of enthesophytosis were evaluated by x-ray and dual x-ray absorptiometry (DXA) respectively. Variations in the grade of enthesitis were evaluated by sonography.

Results:

A significant decrease of VAS was observed in group 1. Examination by x-ray showed morphological modifications (reduction of the bigger diameter >1 mm) of the enthesophytosis in 30% of cases

(9 patients), densitometry showed a reduction of bone mineral density (BMD) and bonemineral content (BMC), sonography did not show significant changes in the grade of enthesitis just after the end of the treatment; although after 1 month sonography showed a significant reduction in the grade of enthesitis. In the control group no significant decrease of VAS was observed. No modifications were observed in the calcified enthesitis by x-ray, densitometry or sonography.

Conclusion:

Our results showed that ESWT has a safe and efficacious effect on the symptoms of most patients with a painful heel, that it can also bring about a structural modification of enthesophytosis and that it reduces inflammation of the enthesitis.

Shock wave therapy: a new strategy for the treatment of algodystrophyc syndrome

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Algodystrophy, known also as Sudeck's disease, Reflex Sympathetic Dystrophy (RDS) or, more recently, Complex Regional Pain Syndrome (CRPS), is a clinical entity of still unclear pathophysiology, which can result in persistent disability.

Aim of this paper is to present the preliminary but very encouraging results about the possibility to successfully treat by means of shock wave therapy (SWT) some classic algodystrophic syndromes, as well as a particular form of CRPS known as "Transient Osteoporosis of the Hip" (TOH) (characterized from bone marrow edema of the femoral head).

From 1999 until now 15 patients were subjected to SWT (Epos, Dornier) for an algodystrophic syndrome: ten patients suffered from TOH, 3 patients from post traumatic CRPS of foot and ankle, 2 patients from post traumatic CRPS of the hand and wrist.

Each patient was subjected to a total number of 3 application (weekly frequency): each session consisted of 2000 shots for TOH (0.5 mJ/mm²), while 3000 shots in the other cases (0.08 – 0.12 mJ/mm²).

Significative improvement was observed already after the first application in all of the patients: 70 – 80% reduction of pain and limp in the group of TOH, as many as in the group of CRPS (relief of pain, edema, vasomotor and trophic changes, as well as of articular stiffness).

All patients within 30 –40 days were able to walk and move their affected limb free of discomfort, to discharge crutches and eventually to take sport activities again.

Up to now all patients have been free of symptoms and in most of them (checked by means of MR imaging) bone marrow edema disappeared.

On our opinion, these preliminary results are of particular interest, especially for therapeutic implication in TOH, whose recommended treatment, until now is still the surgical one ("bone core decompression").

If further observations will confirm our preliminary results, in the nearer future SWT is going to replace the invasive treatment of TOH, with a remarkable and obvious advantage for the patient, especially if one considers that TOH is considered by some of the authors as the preliminary phase of aseptic osteonecrosis of the femoral head.

We would like to underline also the possibility to significantly accelerate, by means of SWT, the clinical and therapeutical course of other forms of CRPS .

Long-term follow-up of shockwave treatment on heterotopic ossifications and new radiologic methodologies for evaluation

Authors: Dr. M. De Pretto, Dr. G. Ferrari , Dr. I. Dalla Valle, Dr. R. Saggini

ITALY

Aim of the study:

Presenting our achieved experience regarding the shockwave treatment on patients, who are affected by paraosteo- arthropaties (POA), paraplegic, tetraplegic or spinal cord injured with coma outcomes. Presenting the new identification methodology before the treatment for the area of main interest by means of multislice CT scan with tridimensional reconstructions.

Materials and methods:

From February 1998 till today 150 patients, between 20 and 60 years old, have been treated with shockwave therapy. After an immediate check, 60 patients received a long-term follow-up, among which 10 after a period between 2 and 2 years and an half following the treatment, 38 after a period between 1 and 2 years and 12 after a period shorter than one year.

The treatment has been performed with the use of lithotripsy device OSSATRON at the maximum power, for 4000 shock waves in one session, after radiographic positioning.

All the patients have been evaluated both with clinical, laboratory investigations and with diagnostic radiologic and MR examinations.

Results:

There has been a better result on the POA at first appearance, than in stabilized ones. In all the treated heterotopic ossifications at their beginning a successful outcome has been achieved with the stop of the evolution and a ROM increase, which have kept themselves in time.

In the greater part of cases the results maintain themselves, as there is no POA restarting. The patients who have been treated after a distance of time are very few, and only for capsular or muscle retractions or for analgesic purpose. We may assume from this that there's no need to treat again the heterotopic ossifications. Complications on osseous level, like fractures, necrosis or other haven't occurred. In the stabilized POA, where there was a more reduced benefit of the shockwave treatment, we have applied to 20 patients in the last three months a new evaluation methodology before the treatment of the osteophytes, which have more significance for the joint ankylosis.

Tridimensional reconstructions have been used after the acquisition of CT scan images with simulator and images' subtraction, in order to stress the most approving condition for joint release.

Conclusion:

Following the comparison of the treatments directed to patients with stabilized POA, before and after the introduction of tridimensional simulation, we may deduce from the post-treatment clinical tests, though our limited experience to a small group of patients, that it is an effective and innovative methodology in the radiographic positioning and in the study of POA.

The long-term follow-up confirms the usefulness of shockwave therapy on heterotopic ossifications, the improving results on the POA at their beginning and the complete absence of complications even following long-term assessments.

2-year-follow-up after ESWT treatment of a heel spur

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233 patients with and without a chronic Fasciitis plantaris were questioned by an impartial, none-treating colleagues, that is not in their practice, to ensure a neutral opinion and to stay in line of objectivity. The ESWT took place during 1995 through 1998 in 7 different practices after a 6 months successful treatment according the guidelines of the DIGEST conservative method. Out of 290 patients 57 could not be reached, so that 233 patients were questioned, representing 80.3%.

The average age was 59.9 years. The follow-up period averaged 37.9 months. The questionnaire was developed in connection with the Simple-Shoulder-Test of the University of Washington, modified for the heel-spur disease. The test is adequate for individual judgement and practice parameter. Modifications and changes before and after treatment can be shown and allow to identify a failure in treatment.

Technique: Treatment with Monolith Fa. Storz and Sonocur Fa. Siemens

Amount of Energy: 0.30mf/mm² treatment, total energy in average.

Taking into consideration 2.95 treatments, then the total amount of energy results in 0.885mf/mm² per patient.

During the time of follow-up 161 (69%) of the patients claimed to have no pain, 24 (10%) had almost no pain, 8 (3%) permanent (chronic) pain. The rest of 18% showed little or unsatisfactory results. 79% showed a positive result with no pain. Thus it can be stated that 74% had been without pain walking for an unlimited time. 12% of the patients showed pains after 2-3 hours walking. 67% of the patients showed and confirmed a positive result of the ESWT treatment. 10% of the patients seldom or very rarely showed pain. 7% complained heavily. In conclusion one can say that the percentage of improvement with similar questions was very narrow. Improvement was achieved by 30% at once, 15% showed improvement after one week, and 23% showed improvement after one month. After 3 months even 18% showed improvement.

204 did not need further treatment after ESWT. No patient required an operation

The ESWT was applied to 168 patients without an anaesthesia and 65 received a local or regional anaesthesia. 81 patients felt the treatment to be very painful and unbearable. This is most half of the treatment without anaesthesia. The question here to be discussed as to the ideal method of anaesthesia to garant a treatment without pain and without the risk to lose the ideal target of treatment .

174 patients would undergo ESWT immediately and 32 patients would most likely undergo a treatment with ESWT.

Prior to treatment 34% of the patients were on sick leave between several days up to 6 weeks, after treatment with the ESWT only 11% were on sick leave, that means an improvement of 23%.

Efficacy and economical aspects: Comparison ESWT versus alternate therapies in the treatment of calcifying tendinitis

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Aim:

Efficacy and costs of ESWT still are in the center of interest of medical persons and insurances as well. During our 'Swiss Multicenter Study' we evaluated different medical and economical aspects. Some of them will be presented in the following report.

Patients and method:

From fall 1998 to fall 2000, we treated a group of 105 patients (av. age 50.3 y, 47 m, 58 f) suffering by calcifying tendinitis with ESWT (2 x 2000 Shockwaves, 0.2 mJ/mm², Interval 1 week). We compared the efficacy and the costs with a control group consisting of 58 patients (av. Age 51.9 y, 22 m, 36 f). They had the same indication but could at last not be treated by ESWT due to the fact that insurance didn't pay this therapy. Inclusion and exclusion criteria in both groups was following to the international standards. Results of efficacy concerning anamnesis, daily function, mobility and strength was quantified by VAS-scores.

We defined the criteria of success as follows:

1. Score-decrease 0 – 30% = no significant improvement
2. Score-decrease 31% - 89 % = significant improvement
3. Score resting 10% or less = successful treatment

Findings and results:

Results	successful	Significant improved	No signif.improv.	totally
ESWT group	39 (37%)	47 (45%)	19 (18%)	105 (100%)
Control group	18 (31%)	22 (38%)	18 (31%)	58 (100%)

Costs:

Patients and method:

The same two groups were analysed concerning economic aspects as well. In the ESWT-group we evaluated the costs of two treatments including controls. The amounts based on the official tarification in the cantons of Zurich and Lucerne. The costs of diagnostics, pre-evaluation and possible previous treatments of all patients in both groups are not included in the following calculations. They are assumed as the same in both groups because separation happened directly before decision to treat by ESWT or alternate methods.

Findings and results:

In the ESWT-group every patient caused costs of 2 sessions of ESWT and controls for average sFr. 2841.50 (approx. 1670 US\$)

In the control group the following treatments (sometimes repeatedly) was applied instead of ESWT (after separation in two groups!):

mode of treatment	persons	painfree	better	unchanged	worse	Total treatm.
no treatment	12	4	4	4	0	-
physiotherapeutical treatments (massage, gymnastics, novodyn etc)	25	1	5	19	6	31
corticosteroid injections	15	0	2	21	0	23
'needling'	23	3	6	16	0	25
arthroscopy	9	3	2	4	0	9
arthrotomy	14	7	7	0	0	14

If a treatment caused only temporary improvement and pain returned again after some time the result was considered as 'unchanged'.

We evaluated the average costs of the alternate treatments including necessary controls and costs for absence of work as follows:

treatment	definition	sFr.	n	sFr.	% of tot amt.
physical therapy:	9 sessions + 1 consultation	600.-	31	18'600.00	5.2
steroid-Injection:	1 consultation + Injection + medicament	60.-	23	1'150.00	0.3
needling:	Basics + x-rays + punktion + medicament + 1 control + 1 day absence of work in 50% of patients	700.-	25	17'500.00	4.8
arthroscopy:	1 operation incl. anesthesia + 2 days hospitalisation + 1 week absence of work in 50% of patients	5'000.-	9	45'000.00	12.4
arthrotomy:	1 operation incl. anesthesia + 6 days hospitalisation + 4 week absence of work in 50% of patients	20'000.-	14	280'000.00	77.3
Total costs for control group of 58 persons				362'250.00	100.0
Calculated costs for 1 patient of control group				6'245.70	

Every patient in the control group caused costs of sFr. 6'245.70 (approx.. 3670 US\$).

Savings per patient: sFr. 6'245.70 - sFr. 2'841.50 = sFr. 3'404.20 (approx. 2000 US\$)

Discussion:

In our study ESWT was unsuccessful only in 18% in comparison with 31% of the patients from

the control group with alternate treatments. Full success was possible in 37% of the ESWT-group, only in 31% of the control group.

At the same time and in the same groups we evaluated that ESWT can save sFr. 3'404.20 per patient (approx. 2000 US\$) in comparison with alternate therapies.

Even if both groups were statistically small, the differences showed a high significance of the results. We respect that in other countries the amount of the costs can differ. Nevertheless the relation of the costs between the two groups should be of similar linearity.

Conclusion:

We recommend the following strategy: After unsuccessful conservative treatment in calcifying tendinitis, ESWT should be evaluated before any operation. Our results support this suggestion from medical and economical aspects as well.

The frozen shoulder: indications for extracorporeal shockwave therapy

Authors: C. de Durante, MD, B. Corrado, MD, O. Galasso MD, M.R. Carillo, MD.

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Authors here report their experience in the treatment of frozen shoulder by ESWT.

Twenty patients suffering from chronic tendinopathy of the rotatory cuff with a frozen shoulder at clinical examination have been selected. The tendinopathy lasted at least six months. All patients have been subjected to MRI in order to exclude lesions of the rotatory cuff and calcifications of the tendon or of subacromial bursa.

A consistent reduction of the articular range motion was observed at clinical examination: a mean of 20°-50° of abduction and 20-40° of extrarotation were reported.

Patients have been subdivided in two groups (A, B). The Group A was treated by 4 applications of shock waves (2 sittings per week). The energy level for each application was set between 0.07 and 0.11 mj/mm², the number of shoots was 2500, shock waves were focused via anterior and lateral. All patients of group A have been subjected to physiokinesitherapy of the shoulder three times a week for two months.

Group B was treated by physiokinesitherapy only.

Follow-up was carried out at 1 month and six months. Authors judged the total recovery of the articular range motion as excellent result, a 60-80% recovery of the a.r.m. as good result, a 60-40% recovery of the a.r.m. as sufficient result, and a recovery of the a.r.m. less than 40% as poor result.

Group A		Group B	
1 month	6 months	1 month	6 months

Excellent 1 (10%)	3 (30%)	0	1 (10%)
Good 3 (30%)	3 (30%)	2 (20%)	2 (20%)
Sufficient 1 (10%)	1 (10%)	6 (60%)	6 (60%)
Poor 5 (50%)	3 (30%)	2 (20%)	1 (10%)

Results achieved let to consider shock waves an useful therapy to manage patients suffering from frozen shoulder: this technique reduces the recovery time and increases the clinical success rate. However, physiokinesitherapy remains the main treatment for such disease.

Clinical results of the use of extracorporeal shockwave therapy in the treatment of plantar fasciitis

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The object of this study was to determine the safety and effectiveness of extracorporeal shockwave treatment for chronic plantar fasciitis.

This phase I/II pilot dose-response study was performed from June 24, 1997 to October 12, 1999 utilizing standard spark-gap renal lithotripsy equipment to which was added an acoustic coupling device. This coupling device was added so as to accurately locate the F2 or treatment location. Without this added coupling device, the treatment area would be positioned too deep for accurate and appropriate treatment of the foot. This is due the fact that the standard lithotripsy device takes into account the thickness of the patient's flank when performing a renal stone lithotripsy treatment, and it is not suited for therapy of sites which are more superficial.

The procedure was performed under intravenous sedation with a local anesthetic ankle block. The area of maximum pain was marked with a radiopaque marker and then located in two planes utilizing the fluoroscopy unit which is attached to the lithotripor. The treatment was begun at 14kV and increased 1kV every 200 shocks until 22kV was reached. A total dose of 1500 to 2000 shocks were delivered. The patients were allowed to return to normal pretreatment activities the following day including work and/or exercise activities. A second treatment was delivered in three weeks if the patient continued to have pain. If, necessary, the study protocol permitted a third treatment to be delivered following the six weeks postoperative examination. This approach provided the ability to analyze patients response to dose escalation.

The study consisted of 16 patients with 20 feet (four patients were treated for bilateral plantar fasciitis). Of these 20 feet, 12 cases involved the right foot and 8 cases involved the left foot. Thirteen of the patients were female (17feet) and three patients were male (3feet). The patient's range in age was from 25 years to 63 years, with a mean age of 43. The range of the condition prior to the procedure was from 3 months to 84 months, with a mean average of 23 months.

Seven patients (7feet) underwent one treatment. Eight patients (ten feet) underwent two treatments and two patients (three feet) underwent three treatments.

The mean Body Mass Index (BMI) was calculated for each patient. The mean BMI for those patients who had one treatment (Group 1) was found to be 29. The mean BMI for those patient who had two treatments (Group 2) was found to be 32 and those patients who had three treatments (Group 3), the mean BMI was calculated to be 46.

At 12months, the post-procedure mean improvement for Group 1 was 83%, ($p < .001$), and Group 2, ($p < .003$), the mean improvement was 72%. At 6 months post-procedure, Group 3 had a mean improvement of only 21%, ($p = .29$). All of the patients in Group 3 elected to drop out of the study after 6 months and all underwent an open plantar fasciotomy procedure.

No complications were noted in this study and no statistical difference between Group 1, who received 2000 shocks and Group 2, who received 4000 shocks was noted.

Our study demonstrates that extracorporeal shockwave therapy appears to be a safe and effective means of treating chronic plantar fasciitis that has failed conservative therapy.

Shockwave lithotripsy (SWL) induces significant structural and functional changes in the kidney

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Early clinical studies suggested that SWL was free of bioeffects. Subsequent studies have clearly documented acute and chronic renal changes. The foundation for understanding the characteristics and consequences of clinical SWL-injury has been well-controlled renal structural and functional studies in the pig, a model that closely mimics the human kidney. Our studies show that a clinical dose (2000 shocks at 24 kV) of SWL administered by the Dornier HM3 induces a predictable, unique vascular injury at F2 that is associated with transient renal vasoconstriction, seen as a reduction in renal plasma flow, in both treated and untreated kidneys. The SWL-induced trauma is associated with an acute inflammatory process, termed "Lithotripsy Nephritis" and tubular damage at the site of damage that leads to a focal region of scar formation. While lesion size increases with kV level and shockwave number, the pronounced vasoconstriction has a much lower threshold. Preliminary unilateral renal denervation studies suggest that the fall in blood flow in the untreated kidney is mediated by stimulation of autonomic nerve activity in the treated kidney. In addition, there are risk factors including kidney size and pre-existing renal disease (e.g. pyelonephritis), that exaggerate the predicted level of impairment of renal tubular and hemodynamic function induced by a clinical dose of SWL. Studies from our group suggest that the mechanisms of soft tissue injury probably involves acoustic cavitation and shear stress while stone breakage is caused by cavitation bubble collapse and spallation. Preliminary analysis of the pressure waveform generated by the OssaTron ESWT device shows similarities to the HM3 pressure pulse. This suggests that ESWT shockwaves have the potential to induce tissue trauma involving similar mechanisms to those at play in lithotripsy.

Tennis elbow: evidence-based medicine

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Tennis elbow is a quite common disease with a life-time prevalence of about 4%. Based on the incidental observation of analgesic effects shock wave therapy has recently been proposed as a therapeutic approach especially in refractory cases. This approach has rapidly penetrated the health care market. Following the regulations of the German physicians' schedule of charges shock wave therapy in orthopedic indications is as costly as in the treatment of urolithiasis. Therefore, the question of efficacy deserves special scrutiny. Private health insurers owe the reimbursement of medically necessary treatment to their clients. According to the insurance contract medical necessity is defined hierarchically and quite similar to the levels of evidence on which evidence-based medicine relies.

Being a subjective experience heavily influenced by circumstantial factors pain is prone to a considerable placebo response. Thus, any treatment of the tennis elbow is subject to all sources of bias, be it on the side of the investigator or the patient (selection bias). Therefore, strict methodology has to be required for efficacy trials in tennis elbow, i.e. randomized, double-blind, placebo-controlled trials. The ideal design is a three-armed trial comparing sham shock-wave therapy with active shock-wave therapy and standard treatment (the latter obviously non-blind).

A systematic research of the literature in terms of a Health Technology Assessment (HTA) revealed that none of the published studies sufficiently adheres to established methodological recommendations (e.g. ICH guidelines). Of the 17 studies published to date only three used a control group with randomized allocation although an explicit description of the way of randomization is nevertheless lacking; the studies have been single-blind, on the side of the investigator, which can hardly help in this indication. The number of studies may actually be lower due to unspecified double publication. All studies completely ignore confounding variables. Thus, shock-wave therapy of tennis elbow still waits for its proof of efficacy although the data published look promising.

Effectiveness of ballistic shock waves, a prospective controlled study

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The efficacy and the fast effect of extracorporeal shock wave therapy have won it an extensive place in orthopaedics in the treatment of bone pseudoarthrosis, osteonecrosis and tendon diseases. Therefore, during the last few years, new therapeutic waves called ballistic or radial waves have been proposed to treat some orthopaedic diseases. Physic characteristics (peak pressure, duration time, focusing, propagation front) make ballistic waves fundamentally different from shock waves.

To verify whether ballistic waves could be useful in orthopaedics Authors here report a

prospective controlled study. Sixty patients suffering from different soft tissues diseases have been selected. Patients have been subdivided in two homogeneous groups. Group A has been treated by shock waves, group B by ballistic waves. The number of applications (four), the interval between each sitting, the number of pulses and the firm producing the two devices were the same. Follow up has been carried out at 1 month and six months.

Authors compare results achieved using the different techniques and discuss about limits and indications of ballistic waves.

The influence of cortical bone on acoustical parameters of shockwave focus

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Germany

Purpose :

The aim of the study was to evaluate the influence of cortical bone on the properties of extracorporeal shock waves and to find out, if the focus get any alterations after passing the bone.

Materials and methods:

Shock waves are measured at 2 intensities, 8 and 14 kV. First of all it was necessary to indicate pressure diagrams of the sound field of the lithotripter Dornier Epos UltraO in water as reference values. Then the attenuation of the shock waves was determine after passing cortical bone. In this study a fibre-optic probe hydrophone, the FOPH 300 from the physical institution of the university of Stuttgart was used to characterize the size and intensity of the focus.

Pre tests showed the signal size in pure water. The mean value of the measurements in vitro for the positive peak pressure was about 56.27 MPa at 14 kV and 7.49 MPa at 8 kV. The mean values for the peak-negative pressures were -11.7 MPa at 14 kV and -5.2 MPa at 8 kV and for the energy flux density 0.51 mJ/mm² at 14 kV and 0.04 mJ/mm² at 8 kV. The same technique was used to measure the focus characteristics after passing the cortical bone of a femur. To analyse the attenuation these results were compared with the pre strudy reference-parameters.

Results:

After the shock wave passed the cortical bone, there was no measurable signal found, by using the fibre optic hydrophone system after 8 KV shock waves have passed the bone. The findings on the energy level of 14 KV showed, that the maximum P⁺ was attenuate to 8 Mpa, the P⁻ to - 3 Mpa. The ED⁺ was reduced to 0,025 mJ/ mm² and ED⁻ attenuated to 0.01 mJ/ mm².

Discussion

This investigation demonstrates the attenuative effect of cortical bone on shock waves. Regarding the current concepts in fracture healing and treatment of pseudarthrosis, it seems to be improbable, that shock waves were able to induce mechanical effects after they have passed cortical bone. In the treatment of bony leasions, it is imperative to use an exact control system

as x-ray to hit the small gap into the pseudarthrosis, where no cortical bone prevent the intrance of shock waves.

The relationship of clinical outcome of lateral epicondylitis after ESWT and number of treatments

Authors: L.Gerdesmeyer, MD, R. Garve, MD, R. Gradinger, MD.

Germany

Purpose :

The aim of the study was to evaluate the influence of extracorporeal induced shock wave therapy (ESWT) on the lateral epicondylitis, and to investigate the influence of the number of ESWT settings on the clinical outcome.

Materials and methods:

543 patients were treated with extracorporeal shockwaves, emitted from the COMPACT S (Dornierâ). For evaluation the effects the visuel-analogue-scale and the Roles and Maudsley score were used. The ESWT was indicated, after failed non-operative treatment. 2,6 ESWT settings were done with a FU of 20,9 month.

Results:

2 years after the last ESWT, the patients reported a severe decrease in pain with reduction on VAS ($p < 0.01$). The difference between pre ESWT und post ESWT were independant from number of ESWT settings. No more statistical decrease could be shown after repetitive ESWT. These results were stabel in course of time. Over 2 years after ESWT 68% were excellent/good and 32% just satisfied/worse

Discussion:

This investigation demonstrates the positive effect on lateral epicindylitis without severe side effects. All results concerning the improvement in discomfort/pain were statistically high significant ($p < 0.01$). The results differ from other authors reporting better clinical outcome in dependance of repetitive ESWT. The ESWT is indicated to treat the lateral epicondylitis. Because of missing severe side effects and the proved efficiency, the ESWT is indicated before operative intervention.

High energy S.W.T. in treatment of diaphysical non unions: evaluations of prognostic factors

Authors. S. Gigliotti, MD, C.De Durante, MD, M.Rizzo, MD

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The type of non unions, the stability between fragments and the presence of internal or external devices can influence the results in treatment of non unions and can be the reason of failure of shockwave therapy. In six years we have treated by shockwaves 196 diaphyscal long bone non unions (51 cases of tibia, 37 of femur, 20 of humerus, 24 of cubitus, 21 of radius, 10 of fibula, 11 of clavícula, 17 of metacarpal and metatarsal, 5 of phalanx).

We have used an electromagnetic litotryptor (by Storz Medical) with an "in line" radiographic and ultrasound localisation of non union area. From 4 to 6 sessions of treatment were applied; in each 4000 impulses were shot at energy from 0,5mmJ/mm² to 1mmJ/mm². We have obtained the total fusion in 67% of cases, the partial fusion in 19% of cases and the absence of fusion in 14% of cases.

In hypertrophic non unions the results were better (81% of total fusion) than in atrophic non unions (22,5% of total fusion). The percentage of total fusion was greater than 50% in all non unions (from 89% of clavícula non unions to 58% of tibia non unions) except for humerus non unions (44,5%). In cases treated by plates we have recorded an incidence of partial fusion (24%) greater than in non unions treated by external devices (9,5%) nail because of impossibility to hit the circumference of bone totally with focal point of pressure field. In cases treated by cast we have recorded results like in cases treated by plates but with lower percentage of non fusion. Good results we have recorded in cases of non unions of leg treated by functional cast bracing or by walking cast after shockwave treatment (57% of total fusion and only 22% of no fusion).

Not satisfactory results we have recorded in humeral non union not surgically stabilised (75% of no fusion) before ESWT, because of impossibility to achieve an adequate stability by casting but also with medullary nail the results are not good (only 20% of total fusion), so the best treatment is with plate and screws or with external device. Presence of medullary nail does not prevent treatment in non unions of femur but it is necessary to focalise the shockwaves on cortical bone and results improve if the static fixation is converted to a dynamic state 1-2 months after ESWT.

Extracorporeal shock wave therapy (ESWT) in the treatment of calcifying tendinitis – importance of focussing

Authors : M. Haake, MD, B. Deike, MD, A. Thon, MD, J. Schmitt, MD.

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A controlled prospective randomised study was designed to analyse the effect of ESWT on calcifying tendinitis of the shoulder either focused to the calcified area or to the origin of the supraspinatus tendon.

Fifty patients were included in the study and treated with a Storz Minilith SI-1 shock wave generator. The intervention group received 4000 impulses (ED_{50} 0.78 mJ/mm²) in 2 therapy sessions after local anaesthesia focused on the origin of the supraspinatus tendon. Patients in the control group received ESWT focused to the calcified area. Follow-up examinations were performed 12 weeks and 1 year after treatment by an independent observer.

We found an increase of function and a reduction of pain in both groups. Statistical analyses showed a significant superiority of ESWT application focused to the calcified area in all observed parameters (e.g. Constant-score at primary endpoint $p = < 0,001$). After one year all patients (25/25) of the group with focus to the deposit were rated as success according to the age-corrected Constant Score, but only 10/24 patients in the group with focus to the insertion of the supraspinatus tendon.

ESWT with 2 x 2000 impulses of an energy flux density (ED_{+}) of 0.78 mJ/mm² was found highly effective in the treatment of calcifying tendinitis of the supraspinatus muscle, when it was exactly focussed under fluoroscopic control at the calcific deposit. It should not longer be applied without exact focussing as a bio-feedback procedure to the insertion of the muscle. Lithotripter building companies should change their instruction manuals and provide appropriate shock wave generators with the ability of fluoroscopic imaging

Extracorporeal shock wave therapy (ESWT) in the treatment of tennis elbow – a prospective randomised placebo-controlled multicentre trial

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ESWT is used frequently as an alternative therapy in the treatment of chronic lateral epicondylitis of the elbow. Up to now, there is no firm evidence of efficacy of ESWT from well-designed randomised clinical trials.

Aim of the study is to show superiority of ESWT in combination with local anaesthesia over placebo-ESWT plus local anaesthesia.

A prospective, single-blind multicenter trial with a randomised two-sample parallel- group design (ESWT vs. Placebo) and blinded independent observer was conducted in Germany and Austria. Primary endpoint was the success rate 3 months after intervention. 272 patients from 15 centres were allocated at random to active ESWT (3 x 2000 pulses, energy flux density ED_{+} 0.04 to 0.22 mJ/mm²) or placebo ESWT. The results of 399 ESWT and 402 placebo treatments were analysed, the drop out rate was 9.2%. at the primary endpoint.

Overall therapeutic success rate in the ESWT-group was 25.8% and 25.4% in the Placebo-group. 95% confidence interval of the difference was +/- 11.07%. There was no difference in the secondary endpoints Roles and Maudsley score, subjective pain ratings or grip strength between both groups. Very few side effects were reported.

ESWT as applied is ineffective in the treatment of lateral epicondylitis. Previously reported success of ESWT is due to inappropriate study designs.

Extracorporeal shockwave therapy of osteoarthritis of the knee

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Background:

Osteoarthritis, the most common joint disease is a major cause of morbidity and dysfunction, especially among the elderly population. The knee joint is very frequently involved.

Clinically there is localized pain, tenderness, diminished range of motion and various degrees of inflammation.

Methods:

We conducted a pilot study of extracorporeal shock wave therapy (ECST) using the Orthospec™, manufactured by Medispec, for osteoarthritis of the knee. Our assumption of a possible beneficial effect was based on the known analgesic effect of ECST, the anti-inflammatory effect (used in the treatment of tennis elbow and calcaneal spur) and the microfracture theory of cartilage cell growth stimulation and matrix formation.

A group of 24 patients, 11 men and 13 women, with severe osteoarthritis of the knee, who went through most of the conventional treatments without success and were candidates for total knee replacement surgery, were treated with ECST once a month for three consecutive months. The follow-up was conducted with the 'KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE (KOOS)' (which is based on the WOMAC questionnaire) before each treatment and one month and three months after the last one.

Results :

According to the repeated measure statistical test, there was a significant difference ($p=0.001$, $f=8.932$) between the scores of the five questionnaires given. Using the paired comparison test to measure the strength of the differences on a time scale, comparing the pretreatment score to the score three months after the last treatment, we found out that ECST produced a statistically significant improvement in pain ($P=0.001$ $F=14.082$) and function ($P=0.001$, $F=12.449$).

Conclusions:

According to the clinical and statistical findings, ESCT has a beneficial effect on osteoarthritic knees. Being a pilot study, more research should be carried out in order to strengthen our results, establish the optimal level of energy of the shock waves, the ideal dosage and interval between treatments and by a longer follow-up find out how long the beneficial effect lasts. However, our findings give a new encouraging direction to conservative treatment of osteoarthritis that is efficient, cost effective and improves compliance.

Comparison of different energy settings for different indications.

Analysis based upon literatur. Future requirements for ESWT – systems. Technical presentation of OrthoWave

Author: N.Hopfenzitz, MTS Medical Technologies & Services GMBH, Germany

The comparison of the recent studies shows a very wide range of energy setting for the different indications. As very low energy is required for the treatment of different chronic inflammations, high energy ESWT is used for calcifications, non -unions and necrosis. To meet all requirements MTS will present new technical modifications of OrthoWave.

Shockwave treatment enhances mechanical strength during early fracture healing: An animal study

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Purpose:

To evaluate the effect of shock-wave treatment on the mechanical strength and the bone mineral density of tibial diaphyseal osteotomy in a rabbit model.

Material and method:

18 adult New Zealand rabbits received right tibial diaphyseal transverse osteotomy and external fixation at Day 0. In the experimental group, the 12 rabbits received 5000 impulses, 0.32mJ/mm² shock-wave treatment by Orthospec™ at the osteotomy site at Day 7 and Day 21. In the control group, the 6 rabbits did not receive any treatment on the osteotomy site. Serial plain X-ray examinations and measurements of bone mineral density by dual-energy X-ray absorptionometry (DEXA) on bilateral tibias were performed at Day-7, Day 0, Day 14, Day 21, and Day 28. At Day 28, rabbits of the control group and 6 rabbits of the experimental group were sacrificed. The remaining 6 rabbits were sacrificed at Day 42. The bilateral tibias were sent for torsional test by using Material Testing System (MTS) machine. Histologic examination of the osteotomy site was performed after the mechanical tests were completed.

Result:

On plain X-ray film, the osteotomy gaps at Day 28 completely healed in 3 of the control group (50%) and 8 of the experimental group (66.7%). Lower limb alignment of the two groups are both normal. There is no difference on the change of percentage of bone mineral density of bilateral tibial diaphysis of the two groups from Day 0 to Day 28. The percentage of maximum torque of bilateral tibial diaphysis of experimental group at Day 28 is significantly higher than that of control group (55.9% versus 31.0%, P<0.05). The percentage of maximum torque of bilateral tibial diaphysis of experimental group at Day 42 is significantly higher than that at Day

28 (74.3% versus 55.9%, $P < 0.05$). There is no significant correlation between values of maximum torque and values of bone mineral density (correlation coefficient = 0.56, $P = 0.055$). Histologic examination is in progressing.

Conclusion:

Shock-wave treatment has positive effect on early healing of bone fracture by demonstrating superior mechanical torsional strength and higher union rate of fracture healing, but is ineffective in increasing bone mineral density. Long-term effect of shock-wave treatment on fracture healing is deserved to be studied. The influence of shock-wave treatment on bone metabolism is in need of further investigations.

Key word shock-wave treatment, diaphyseal osteotomy, bone mineral density, biomechanical testing

Extracorporeal shockwave promotion of osteogenic cells proliferation and bone related proteins expression

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We aimed to elucidate the effect of extracorporeal shockwave treatment on osteogenic lineages growth and bone-related protein expression in vivo. Male Sprague-Dawley rats were treated with 0,16 mJ/mm² ESW at 500 impulses on the left femurs for studies. Femoral bones were subjected to immunohistological assay after 1,3,7,14 and 21 days ESW treatment.

Results showed that ESW induced periosteal hematoma and subperiosteal detach from cortex in 1 day and cell proliferation on subperiosteal and cortex site in 3 days as determined with anti-proliferated cell nuclear antigen (PCNA) expression.

There was significant more osteochondrocytes and osteoblasts as demonstrated by anti-chondromeyte proteoglycan monomer antibody and anti-bone alkaline phosphatase antibody within inner cortex in comparison with the controls.

In addition ESW treatment significantly promoted collagen type I, collagen type III expressions in 3 days and osteocalcin expression in 7 days. Interestingly, ESW induced rapidly and strongly TGF- β 1 expression in the treatment site 1 day. Results suggested that ESW promotion of osteogenesis were via enhancement of osteochondrocytes and osteoblasts proliferation association with TGF- β 1 induction and bone-related protein expressions.

Effectiveness of extracorporeal shockwave therapy for chronic calcific

tendinitis of shoulder : a preliminary report of a prospective blinded randomized control trial

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Objective:

To compare the effectiveness of different levels of energy extracorporeal shock wave therapy (ESWT) on 50 patients with tendinitis of shoulder with calcific deposit.

Design:

A prospective, blinded, randomized control trial against a control group.

Subjects and selection criteria:

We enrolled 50 consecutive patients for shoulder pain secondary to calcific tendinitis (diagnosed using x-ray, MRI or USS) and refractory to nonsurgical therapy (corticosteroid injections or physiotherapy). History of pain greater than 4 months or a restricted range of motion of the affected shoulder. Gärtner type I or II calcific deposit on X-ray. Patients with rotator cuff rupture, local arthritic changes, pregnancy, infection or coagulation disorders were excluded. All patients consented to enter the study after detailed explanation of the techniques, the possible risks of shock wave therapy, and the alternative management.

Methods Patients were randomized into five groups. The random sequence was generated using random number tables. The patients, and the evaluator were all unaware of the treatment. The control group I (n=8) received a sham treatment of 2000 shocks with negligible energy flux density of 0.03mJ/mm². Group II (n=13) received 2000 shocks fixed at 0.11mJ/mm². Group III (n=11) received 2000 shocks at 0.11mJ/mm² in two occasions (every 7 days). Group IV (n=8) received 2000 shocks at 0.44mJ /mm². Group V (n=10) received 2000 shocks at 0.44mJ /mm² in two occasions (every 7 days). For occasional pain relief, patients could take an analgesic drug after therapy (usually tramadol). Nonsteroidal anti-inflammatory drugs were allowed. All patients used local ice 15 minutes the first day after therapy.

Shock wave therapy was given using an electromagnetic lithotripter (Compact Delta, Dornier MedTech®, Wessling, Germany) with X-ray diagnosis system. All treatments were performed as outpatients procedures by the same Physician and technician, after topic applications of ethyl chloride. This started with low shock wave intensities which increased to the planned energy level within the first 200 impulses. No complications were recorded. The selection and follow-up were done by different physiatrist and blind to treatment. Outcome assessments were carried out 8 weeks after randomization. The evaluation was measured by scores on scales (Constant Morley shoulder assessment score). Statistical analysis was performed blind to treatment group. All hypothesis tests were two tailed with p<0.05. Analyses were carried out with SPSS version 8.0.

Results:

The results of 50 patients at 8 weeks follow-up showed a significant improvement in 82 % and unchanged in 18%. Constant score improved from 64.16 ± 13 to 84.07 ± 15 . Pain, Activities of daily living, range of motion and torque experienced significant improvement. A statistically significant difference was observed between the five groups. The effectiveness of one or two session was similar. Complete absorption or partial resorption of the deposit of calcific was observed in 56.2%. The control group experienced no significant improvement. A significant correlation between the dose of energy and effectiveness also was observed.

Conclusion: Extracorporeal shock wave therapy is a successful nonsurgical method in treatment of shoulder pain and elimination of the calcific deposit .Also this preliminary results shown that should be considered increase the energy flux of density and the number of waves per session in order reduce or eliminate the calcific deposit.

Our experience with ethyl chloride for local anesthesia in the treatment of tendinopathies with shockwave therapy

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Objective:

To evaluate the effectiveness of ethyl chloride application for local anesthesia during application of shock wave therapy at different levels of energy.

Subjects and selection criteria:

From April 2000 to December 2000 Ethyl Chloride was applied in 578 patients for local anesthesia during treatment with shock wave therapy. All patients was affected by tendinopathies in different locations and refractory to nonsurgical therapy (corticosteroid injections or physiotherapy). We treated tendinosis calcarea, supraespinatus tendinitis, epicondylitis, heel spur, trochanteritis and others tendinopathies. History of pain greater than 4 months or a restricted range of motion of the affected shoulder, elbow or hip. Patients with rotator cuff rupture, local arthritic changes, pregnancy, infection or coagulation disorders were excluded. All patients consented to enter the study after detailed explanation of the techniques, the possible risks of shock wave therapy, and the alternative management.

Patients were treated for a minimum of 1 and maximum of 4 sessions, 2000 impulses each. The energy flux density was between $0.03\text{mJ}/\text{mm}^2$ and $0.44\text{mJ}/\text{mm}^2$. For occasional pain relief, patients could take an analgesic drug after therapy (usually tramadol). Nonsteroidal antinflamatory drugs were allowed. All patients used local ice 15 minutes the first day after therapy.

Material and methods:

Ethyl Chloride (Chloroethane) (Cloretilo Chemirosa Ern®,SA. Laboratorios) is a vapocoolant

(skin refrigerant) intended for topical application to control pain associated with injections, minor surgical procedures (such as lancing boils, incisions and drainage of small abscesses) and for the temporary relief of minor sports injuries. When used to produce local freezing of tissues, adjacent skin areas should be protected. Ethyl Chloride is contraindicated in individuals with a history of hypersensitivity to it. Use: Have the patient assume a comfortable position. Take precautions to cover the patient's eyes, nose and mouth if spraying near the face. Spray Ethyl Chloride on the target area continuously for 3 to 7 seconds from a distance of 3 to 9 inches (8 - 23 cm.). Spray the target area until the skin just begins to turn white; do not frost the skin. The anesthetic effect of Ethyl Chloride lasts more than 7-10 minutes. This time interval is usually sufficient to use shock wave therapy. Shock wave therapy was given using an electromagnetic lithotripter (Compact Delta, Dornier MedTech®, Wessling, Germany) with X-ray diagnosis system. All treatments were performed as outpatient procedures by the same Physician and technician, after topic applications of ethyl chloride. This started with low shock wave intensities which increased to the planned energy level within the first 200 impulses. Some very small haematomas were seen after high energy applications, but no other complications were recorded.

Results:

We observed side effects of ethyl chloride (Cutaneous sensitization may occur, but appears to be extremely rare. Freezing can occasionally alter pigmentation) and evaluated the session under local anesthesia with ethyl chloride as satisfactory or excellent (85%), bad (2%), moderate (13%). No side effects derived of application of ethyl chloride were observed.. All patients tolerated the energy without subcutaneous anesthesia.

Conclusion:

We can affirm that this kind of local anesthesia is safety was very useful and very comfortable for patients avoid subcutaneous infiltration of local anaesthetic. We have been used this topic anaesthetic with high flux energy without necessity of infiltration. It is recommended as an alternative method in the local anesthesia in patients using shock wave therapy.

Effectiveness of low-energy extracorporeal shock wave therapy on tendinitis of shoulder without evidence of calcific deposit : a preliminary report of a prospective blinded randomized control trial

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Objective:

To compare the effectiveness of different low-energy extracorporeal shock wave therapy (ESWT) on 83 patients with tendinitis of shoulder without evidence of calcific deposit.

Design:

A prospective, blinded, randomized control trial against a control group.

Subjects and selection criteria:

we enrolled 83 consecutive patients for shoulder pain secondary to supraespinatus tendinitis (diagnosed using MRI or USS) without calcification and refractory to nonsurgical therapy (corticosteroid injections or physiotherapy). History of pain greater than 4 months or a restricted range of motion of the affected shoulder. Patients with rotator cuff rupture, local arthritic changes, pregnancy, infection or coagulation disorders were excluded. All patients consented to enter the study after detailed explanation of the techniques, the possible risks of shock wave therapy, and the alternative management.

Methods: Patients were randomized in four groups of 21 patients. The random sequence was generated using random number tables. The patients and the evaluator were all unaware of the treatment. All patients received low-energy shock waves with a focal EFD of less than $0.11\text{mJ}/\text{mm}^2$. The control group I (n=21) received a sham treatment of 2000 shocks with negligible energy flux density of $0.03\text{mJ}/\text{mm}^2$. Group II (n=21) received 2000 shocks fixed at $0.07\text{mJ}/\text{mm}^2$. Group III (n=21) received 2000 shocks at $0.11\text{mJ}/\text{mm}^2$. Group IV (n=20) received 2000 shocks in two occasions at $0.07\text{mJ}/\text{mm}^2$ (every 7 days). For occasional pain relief, patients could take an analgesic drug after therapy (usually tramadol). Nonsteroidal antiinflammatory drugs were allowed. All patients used local ice 15 minutes the first day after therapy.

Shock wave therapy was given using an electromagnetic lithotripter (Compact Delta, Dornier MedTech®, Wessling, Germany) with X-ray diagnosis system. The same physician and technician performed all treatments as outpatient's procedures, after topic applications of ethyl chloride. This started with low shock wave intensities, which increased to the planned energy level within the first 200 impulses. No complications were recorded. The selection and follow-up were done by different physiatrist and blind to treatment. Outcome assessments were carried out 8 weeks after randomization. The evaluation was measured by scores on scales (Constant Morley shoulder assessment score). Statistical analysis was performed blind to treatment group. All hypothesis tests were two tailed with $p=0.05$. Analyses were carried out with SPSS version 8.0.

Results:

The results of 83 patients at 8 weeks follow-up showed significant improvement in 63,9 % and unchanged in 36,1%. Constant score improved from 63.31 ± 12 to 73.68 ± 15 . Pain, Activities of daily living, range of motion and torque experienced significant improvement. A statistically significant difference was not observed between the four groups. The effectiveness of the treatments is similar.

Conclusion:

Tendinitis of shoulder without evidence of calcific deposit is one of the most important cause of shoulder pain. Their management includes advice, analgesics, non-steroid anti-inflammatory drugs, steroid injections, and physiotherapy. Evidence from randomized clinical trials on shoulder disorders shows small effects favoring the effectiveness of non-steroid drugs and steroid injections. This preliminary results suggest that the use of low-energy extracorporeal shock wave therapy is an alternative method for tendinitis of shoulder without evidence of calcific deposit. It is necessary to define sham treatment in ESWT and further research is also needed to determine the most efficient energy densities and the number of shock waves.

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