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# Physical Principles of Shock Waves and Pressure Waves Different Technical Solutions for Medical Applications

Author: O. Wess

Institution: Storz Medical AG, Kreuzlingen Switzerland

Shock waves in medicine are utilized for different applications such as fragmentation of kidney stones, stimulation of healing processes and as treatment option for certain chronic pain diseases. Shock waves are generated mainly by three different physical principles: electro-hydraulic, electromagnetic and piezo-electric mechanisms. They are characterized by a high peak pressure (P+=5-100 MPa), steep rise of pressure amplitude (Tr << 1 Microsecond), short time duration (Td < 1 Microsecond) and low tensile pressure amplitudes (P-<10% P+). Extracorporeally generated shock waves are generated within in a tissue like medium (usually water) to be transmitted into the body without significant reflection losses. Shock waves are distributed over a large surface area for gentle and lesion free transmission and are concentrated (focused) to ensure high treatment efficiency within the target zone. Whenever required, defined treatment zones may be selected within predetermined and localized regions of the body. As long as energy transmission is not obstructed by bony or gas filled organs remote tissue areas may be reached.

Although often mixed up, shock waves can be clearly differentiated from lower amplitude pressure waves, not featuring the above mentioned typical characteristics of shock waves. These types of pressure waves are usually generated by mechanical impact of colliding bodies resulting in extended pressure pulses ( $\mathrm{Td} > 200$  Microseconds) superposed by a small ultrasonic vibration in the range of 100 kHz containing only a small part of the applied energy.

In spite of being physically different from shock waves as defined above, pressure waves may also be efficiently used for stimulation of healing processes and pain therapy, but not for stone fragmentation in distant locations. Effective energy application is limited to superficial areas close to the point of skin contact.

Stone fragmentation is based on the disintegration power of shock waves. Stimulating effects and tissue engineering qualities of shock waves require a different mechanism. Reorganisation of pathological reflex patterns on a neuronal memory level may be an important mechanism involved and followed by biochemical reactions and improved metabolism. The hypothesis of modulation of reflex patterns by shock waves is briefly outlined.

# Treatment of Painful Heel Syndrome With Shockwaves

Author: Dr K. Raveendran

Institution: Hospital Fatimah, Ipoh, Perak, Malaysia

A prospective non-randomised clinical study on the effectiveness of shockwaves for painful heel syndrome was done on 126 patients. There were 57 males and 69 females. There were 22 cases with bilateral treatments making a total of 148 treatments. Each heel had 800 impulses. All patients presented with plantar tenderness and heel pain.

89 (71%) patients were examined or contacted at a minimum 6 months follow up. 74% had no pain or minimal pain. 3 patients said they were worse off after the treatment.

18 patients had no improvement and had a second treatment. None of the patients had more than 2 treatments.

No systemic or local complications were noted.

Shockwave therapy has been the most effective modality for treatment of the recalcitrant painful heel syndrome in Malaysian patients compared to physiotherapy and steroid infiltration used prior to the advent of shockwave therapy.

# Shockwave Therapy for plantar fasciitis: retrospective study

Authors: P Rockett, A Souza, P Santos

Institution: Ortosom, Porto Alegre, Brazil

Cortrel, Rio de Janeiro, Brazil Orthomaster, São Paulo, Brazil

## Aim:

The aim of this study was to evaluate the efficacy and the safety of extracorporeal shock wave therapy for the treatment of plantar fasciitis in three Brazilian Orthopaedics Clinics.

### Material and Methods:

In a multi-center, retrospective study, the effect of shockwave therapy was investigated in 103 patients with plantar fasciitis treated in the period of 39 months from March 2001 to May 2004. There were 55 women and 48 men with an average age of 56 (range, 31-90) 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, previous corticosteroid injection, acute infection, neurological abnormality, gout, malignant diseases, blood coagulation disorders and ruptures of the plantar fascia. Each patient was treated with 1200 - 1500 impulses of shock wave, a 20 mm focus depth, and with an energy flux density of no more than 0.14 mJ/mm after local anaesthesia or ankle block. One treatment was performed on 96 patients, 6 patients underwent a second treatment and 1 patients underwent a third treatment. The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score, subjective outcome on Visual Analogue Scale (VAS) analysis, 45, 90 and 180 days after the end of the therapy.

**Results**: The study showed the efficacy and safety of ESWT were excellent in 36.9%, good in 32%, acceptable in 9.7%, and poor in 21.4%, 180 days after ESWT.

# Extracorporeal Shockwave Therapy (ESWT) in The Treatment of Plantar Fasciitis

Authors: P.Papandrea MD, M. Ciurluini MD, A. Ferretti MD

Institution: "Kirk Kilgour" Sports Injury Center,

Department of Orthopaedic Surgery

St. Andrea Hospital, University of Roma "La Sapienza", Italy

Objectives: evaluate medium-term clinical results of symptomatic treatment of plantar fasciitis.

## Methods and Measures:

From October 1998 to December 2004, 82 patients affected by plantar fasciitis, 14 of whom with a bilateral pathology, for a total of 96 cases, were treated with ESWT. On the basis of the inclusion criteria indicated by ISMST, 58 patients (67 cases) were included in the study. 44 patients (29 males and 15 females) aged between 21 and 77 years (average 56 year) were reviewed at 1 month, 4 month, 17-month follow up. 9 patients were affected by bilateral plantar fasciitis, for a total of 53 cases re-examined. 25 patients (30 cases) played sports activity. X-rays showed the presence of calcaneal spur in 34 patients.

In the pre-treatment phase, the symptomathology was classified into 5 stages according to the severity of pain and its effects on daily activities.

- a. Stage 0: lack of pain;
- b. Stage 1: pain only after intense physical activity or after playing sports;
- c. Stage 2: pain and stiffness during intense physical activity or during sports;
- d. Stage 3: pain during daily activities;
- e. Stage 4: pain at rest and at night.

An average of four sessions (min 3, max 5) of shockwaves were administered (power from 0.04 to 0.250 mJ/mm2, 2000-2.500 impulses for each session).

Clinical outcomes were evaluated according to the following criteria (based on the symptomathological classification mentioned above):

- Excellent: lack of pain (stage 0);
- Good: stage I with an improvement of at least two stages;
- Fair: improvement of one stage;
- Poor: no improvement.

#### Results:

At 1 month follow-up, 49% of patients reported satisfactory results (excellent and good results), at 4 months follow-up the percentage increased to 68%, at 17 month follow-up to were 81%. At 40 month f. up it was possible to review 15 patients (19 cases), satisfactory results were 84%.

Regarding the 34 patients affected by plantar fasciitis in association with calcaneal spur, at 17 month follow-up satisfactory results were 73%, no radiological evidence of disappearing of the spur was obtained. Among the 25 sport players (30 cases) satisfactory results were 57% at 1 month, 80% at 4 month, 90% at 17 month follow-up.

#### Conclusion:

Shockwave therapy represents a valid, non-invasive symptomatic treatment for patients with plantar fasciitis.

# Extracorporeal Shock Wave Therapy (ESWT) in the Treatment of Recalcitrant Plantar Fasciitis - Affecting Factors For the Results

Authors: Ki-Won Young, M.D., Kyoung-Tai Lee, M.D., Jae-Young Kim, M.D., Seung-Do Cha, M.D.,

Eung-Soo Kim, M.D

**Institution**: Department of Orthopedic Surgery

Eulji University, School of Medicine

Seoul, Korea

## Purpose:

The plantar fasciitis is the most common cause of heel pain. Standard treatment of plantar fasciitis is a conservative therapy and include nonsteroidal anti-inflammatory drugs(NSAID), heel cups, night splints, orthoses, electrotherapy, physiotherapy with stretching exercises and local steroid injections. After unsuccessful conservative treatment of at least 6 months, surgery is eventually recommended. The aim of this study was to investigate the results of extracorporeal shock wave therapy and various affecting factors to the results in patients with a previous unsuccessful no surgical treatment of at least 6 months.

#### Materials and Methods:

63 patients with a previous unsuccessful no surgical treatment of at least 6 months were included. A clinical investigation was carried out before ESWT and at follow-up appointments(1, 3, 6 months). Patient satisfaction, pain caused by manual pressure, pain on walking were scored with visual analogue scale(VAS). And the patients estimated the comfortable walking time. The mean duration of follow-up was 5.5 weeks(range, 3 11). Body weight, age, previous treatment, duration of symptom as clinical factors were estimated and calcaneal spur size in simple X-ray, thickness of plantar fascia and soft tissue oedema in ultrasonography. Treatment comprised 1000 impulses of shock wave at 14-16 kV(OssaTron) in local block.

# Results:

At sixth months, the rate of good and excellent outcomes was 36.5% and 22.3% of patients was not changed. After ESWT pain caused by manual pressure decreased from 75 point to 34 point on the visual analogue scale(VAS) and pain on walking from 72.5 point to 38 point. The comfortable walking time had increased from 0.3 hour to 3.4 hours. The rate of good and excellent outcomes in patients with non-invasive previous treatment was 66.6% and 47.8% in calcaneal spur size less than 5mm. It seemed that the result was more improved as less as the steroid injection number. No adverse events were reported after 3 months follow-up visit.

## Conclusions:

The non-invasive nature and minimal complications of appropriately applied ESWT are its primary advantages. The effects of ESWT seems to be time dependent. Steroid injection and large calcaneal spur might effect on less satisfactory results.

# Extracorporeal Shock Wave Therapy applied to chronic plantar hell pain

Authors: BF. Meyer, KK. Simões, E. Thober, M. Meyer

**Institution**: Centro de Ondas de Impacto(COI)

Porto Alegre, Brazil

Sociedade Brasileira de Terapia por Ondas-de Choque(SBTOC)

The Chronic Plantar Heel Pain (CPHP) can be incapacitating to patients and a challenge to doctors. This is reported at about 20% of general population. The most common local pain is the insertion of plantar fascia in the medial tuberculum of the calcaneum bone, being the Fasciitis Plantar the most common diagnosis. Histological evaluation in patients with CPHP demonstrate changes like: proximal thicken of plantar fascia, vascularization decrease, inflammation of peri-tendon, decrease of flexibility and modification in the nocireceptors. The objective of this study was to evaluate the effectiveness of the Extracorporeal Shock Wave Therapy (ESWT) in the treatment of CPHP. Patients with minimum age of 18 years old and symptoms for more than six months were included, with no success on conservative treatments. Twelve months of minimum time of attendance after the first application of ESWT. It was excluded patients with contra-indications to ESWT and received local corticoid infiltration at least one month. It was used the evaluation functional protocol of AOFAS Score. The equipment used was the ORTHIMA(Direx), that uses an electrohydraulic generator. The treatment consisted of 1500 impulses, with energy of 0.35 mJ/mm2, being accomplished between 1 to 3 sessions with interval of 60 days; however we only repeat sessions on those patients that persist with incapacitating pain. The focus was the site of maximum reproduction of local pain at digit-pressure. No anesthesia was dispensed. It was treated 104 patients, and 94 patients answered the questionnaire. Seven cases were bilateral, that totalized 101 feet in this study. Were evaluated 34 men and 60 women, with 57,3 average age, 79,68 kg average weight and 22,87 months of previous pain. The time of attendance after-ESWT was 19.14 months. 63\% received only a single application. Subjectively 80\% were satisfied in relation of pain relief. There was a significant increase of the AOFAS Score in 94% of the patients (pi0.001). The Extracorporeal Shock Wave Therapy is an alternative of the effective treatment of the Chronic Plantar Heel Pain.

# Radial Shock Wave Therapy for chronic hell pain

Authors: J. Ritz, L. Guiloff, A. Baar, E. Botello, M. Brañes.

Institution: Occupational Medicine. Facultad de Medicina.

Pontificia Universidad Católica de Chile.

## Purpose of the study:

Evaluation of the effect of Unfocused or Radial Shock Wave Therapy (RSWT) on chronic plantar heel pain.

#### Materials and Methods:

Since July 2002, a prospective study was conducted including 74 heels in 63 patients with a minimum of 6 months of pain. All patients had a definite indication for open surgery after at least two unsuccessful different conservative treatment approaches. Informed consent of the patients was gained. There were 24 females and 39 males with an average age of 50 (17-79). History and physical examination were recorded in detail. The patients were asked to determine the effect of RSWT by a visual analogue scale (VAS) for walking, at rest and at night. The walking distance, onset of pain and return to daily activities or sports were registered as well as objective findings. All patients received 2000 shockwaves at a frequency of 5Hz and a work pressure of 2, 5 Bars, without local anaesthesia, in 3 weekly sessions. After each session, patients were given non-narcotic analysic and an ice pack. All the patients tolerated the treatment well, and the majority were able to retake daily activities again. There were neither systemic nor local complications after treatment. No patient showed any kind of deterioration. Two independent orthopaedic surgeons did the follow up. At 12-month follow-up, and using the VAS a reference, the pressure-elicited pain decreased from 6.9 to 2 (p 0.05), the pain in sports decreased from 6.8 to 2.1 (p 0.05). Night complaints improved from a VAS score of 2,6 to 1,4 (p 0,05). Pain at daily activities also improved from 4,8 to 1,8 (p 0,05). Before the RSWT, only 17 patients were pain-free after walking more than 1000 meters. After the treatment, 38 patients were able to walk more than 1000 m without pain.

### **Conclusions:**

The Unfocused o Radial Shock Wave Therapy (RSWT) is an attractive non-invasive and highly economical alternative for open surgery. The cost of the device is far cheaper than focused extracorporeal machines (ESWT). The results are very satisfactory and reduce the need for surgery in a high percentage of patients.

# Two Year follow up: Ultrasound Measurements Post ESWT Plantar Fascia

Authors: Rob Gordon, Eric Crawford, Joey Pratile

Kanada

## Purpose:

To determine whether ESWT is effective in decreasing the thickness of the plantar fascia as measured by the ultrasound.

# Introduction:

Plantar fasciitis has exhibited hyaline degeneration ultrasound studies have shown thickening of the plantar fascia in patients with plantar fasciitis. This study attempts to determine whether ESWT alters the thickness of the plantar fascia.

## Material and methods:

30 patients were treated with ESWT at 18 KV 1500 shocks. Pre and post ultrasounds were taken of a minimum of 1year later. VAS was also recorded.

#### Results:

Minimum 1-year follow up shows that ESWT can decrease the plantar fascia thickness and VAS scores.

## Conclusion:

ESWT is effective in decreasing pain and plantar fasciitis thickness in patients with plantar fasciitis.

# ESWT - A Prospective Double Blind Study on Bilateral Plantar Fasciitis

Authors: Lowell Weil, Jr., DPM, MBA, FACFAS

Institution: Weil Foot & Ankle Institute, Des Plaines, Illinois, USA

### Introduction:

Extracorporeal Shock Wave (ESWT) has become a common treatment modality for chronic plantar fasciitis worldwide. All studies in the literature evaluate ESWT for unilateral plantar fasciitis with comparisons to placebo control on another subject.

## Purpose:

The purpose of this study was to use a patient as their own control to assess the value of ESWT in chronic bilateral plantar fasciitis.

# Patients, Material, Methods:

36 patients with bilateral plantar fasciitis of greater than 6 months duration and pain of greater than 6 on a VAS on both feet and that failed to respond to conservative care were eligible to participate. Additional systemic and neurologic causes of heel pain were ruled out in all cases. Patients were anesthetized with intravenous sedation and an infiltrative local block to both heels. Computer randomization then determined which foot was to be treated actively while the other was left as placebo Utilizing an Ossatron by Healthtronics, the appropriate foot was treated with 2000 pulses at 19 kV from two different positions Patients were evaluated at 1 week, 6 weeks and 12 weeks by a blinded investigator. End point evaluation parameters were reduction in VAS and Roles and Mauldsey quality of life assessment.

### Results:

The treated foot improved 70% of the time while the Sham foot improved 52% of the time. 67% of the treated feet improved by >50%, while 47% of the Sham feet improved by >50%. 65% of the treated feet attained a VAS of <3, while only 39% of the Sham group achieved <3 on a VAS. In 39% of the patients, both feet improved and in 4% of the patients, neither foot improved.

## Conclusion:

This study, utilizing patients as their own control, shows that ESWT is a valuable and efficacious treatment for chronic plantar fasciitis. Placebo success is significant but not equal to treated subjects following ESWT for plantar fasciitis.

# Economic Randomization of ESWT With Dolorclast And Ossatron Results

Authors: Rob Gordon, Kanada

Purpose:

To determine the efficiency of the Ossatron to the Dolar clast in the treatment of plantar fasciitis.

# Introduction:

The efficiency of the Ossatron has been shown to be effective for the treatment of plantar fasciitis. A pilot study was determined to see the effectiveness of the Dolarclast machine in treating plantar fasciitis.

### Materials and Methods:

Prospective Patients were asked to choose treatment by either the Dolarclast or Ossatron by economic reasons.

### Results:

Both the Ossatron and Dolarclast improved pain relief for plantar fasciitis.

## Conclusion:

Economics and perceived gold standard play a role in the treatment of plantar fasciitis. Both the Ossatron and Dolarclast appear to improve symptoms of plantar fasciitis.

# Radial extracorporeal shock wave therapy (rESWT) in chronic plantar heel pain - a RCT

Authors: L.Gerdesmeyer, L.Weil, B.Scurran, J.Stienstra, C.Frey, K.Fedder,

M. Maier, M.Henne, M.Russlies, H.Lohrer, J.Vester

Institution: Technical University Munich

Dept. of Orthopedic Surgery and Sportstraumatology

Ismaninger Str. 22, D-81675 München

**Aim**: The study has to determine the effectiveness of rESWT for chronic plantar heel pain.

#### Materials and methods:

A total of eight study centers enrolled 254 patients in this study, 252 patients were randomized, 251 patients received assigned treatment (129 active-ESWT, 122 Placebo-ESWT). All patients were suffering from painful heel syndrome for at least 6 month, all of them previously get unsuccessful conservative treatments. Basically the radial extracorporeal shock wave therapy was performed without local anesthesia. 2000 treatment-impulses were applied with the working pressure of 0.4 MPa (4 bar). Subjects received 3 shock wave treatments with 2000 therapeutical shock wave impulses each. Between each treatment, a treatment-free interval of 2 weeks was observed.

The primary Criteria were: Heel pain when taking the first steps of the day (VAS) and Heel pain while doing daily activities (VAS). Second criteria were defined as: Pain on pressure, measured with standardized pressure device (Dolormeter), Roles and Maudsley-Score, SF-36, physician's global judgment of effectiveness, subject's satisfaction with the outcome of the treatment, Subject's willingness to recommend treatment. The primary point in time for comparison of groups was three months after last treatment.

The patients of the ITT (intention-to-treat) population were defined in the final blind review report (individual listing) before blind was broken. A total of 125 ESWT patients (96.9% of all treated ESWT patients) and 118 placebo patients (96.7% of all treated placebo patients) were evaluated for the ITT analysis.

The size of the treatment effects were quantified using the Mann-Whitney superiority measure with associated confidence intervals. Efficacy was analysed by comparing the success rates between the treatment and placebo groups, with success being defined on a per patient basis for each of the two primary efficacy criteria as at least a 60% reduction in VAS pain scores from baseline to 3 month after ESWT.

The study was performed in accordance to GCP guidelines.

## Results:

With regard to the demographic criteria, sex, BMI, age and other baseline characteristics including the baseline efficacy criteria, groups are well comparable, all effect sizes are denoting only marginal group differences, all p-values are statistically not significant (p ; 0.1).

With regard to the primary criteria the analysis showed statistically significant results (P = 0.0059, one-sided, ESWT success rate 55.20% vs. placebo success rate 38.98With regard to the secondary criteria the clinical relevant data criteria mental/physical health score of the SF36, the Roles and Maudsley Score, global judgment of effectiveness, therapy satisfaction and therapy recommendation all showed better outcome at the primary endpoint in favour to the ESWT group ( $P \mid 0.025$  one-sided) and all effect sizes (Mann-Whitney) denote more than small superiority of the ESWT group.

The a priori ordered hypotheses of the final statistical analysis plan are statistically significant (P ; 0.025 one-sided): Composite score (sum score) of heel pain (VAS) when taking first steps of the day, heel pain (VAS) 'while doing daily activities and heel pain (VAS) after application of the Dolormeter (P = 0.0220 one-sided, MW = 0.5753, LB-CI = 0.5023). Overall success rate with regard to heel pain defined as percentage decrease of heel pain larger than 60% from baseline at visit 7 for at least two of the three heel pain (VAS)

measurements (P = 0.0020 one-sided, MW = 0.5937, LB-CI = 0.5314).

The other criteria also demonstrate superiority of the ESWT group with p-values below the level of significance. All effect sizes (Mann-Whitney) denote more than small superiority of the ESWT group.

Only minor side effects as petecheal bleeding, swelling and discomfort during treatment were detected.

# Shockwave Therapy for tendinosis calcarea of the shoulder: retrospective study

Authors: P Rockett, A Souza, P Santos

Institution: Ortosom, Porto Alegre, Brazil

Cortrel, Rio de Janeiro, Brazil Orthomaster, São Paulo, Brazil

## Aim:

The aim of this study was to evaluate the efficacy and the safety of extracorporeal shock wave therapy for the treatment of tendinosis calcarea of the shoulder in three Brazilian Orthopaedics Clinics.

## Material and Methods:

In a multi-center, retrospective study, the effect of shockwave therapy was investigated in 119 patients with tendinosis calcarea of the shoulder treated in the period of 38 months from April 2001 to May 2004.

There were 64 women and 58 men with an average age of 56 (range, 37-79) years.

The criteria for inclusion were at least three months of unsuccessful conservative therapy or six months of pain and calcifications grade I or II from Gartner's classification. Criteria for exclusion were inflammatory arthritis, previous corticosteroid injection, acute infection, gout, malignant diseases and, blood coagulation disorders.

Each patient was treated with 1500 - 2000 impulses of shock wave, a 35 mm focus depth, and with an energy flux density of no more than 0.14 mJ/mm after local anaesthesia.

One treatment was performed on 111 patients and 8 patients underwent a second treatment.

The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score, subjective outcome on Visual Analogue Scale (VAS), X-rays and ultrasound analysis, 45, 90 and 180 days after the end of the therapy.

## Results:

The study showed the efficacy and safety of ESWT were excellent in 26.9%, good in 37%, acceptable in 12.6%, and poor in 23.5%, 180 days after ESWT.

# Extracorporeal shockwave therapy in rotator cuff calcific tendinitis.

Authors: M., Pinho Teixeira Alves

Institution: HOSPOR - Santiago Hospital,

Department of Orthopaedics,

Setúbal, Portugal.

The author present the preliminary results of his study on the treatment of shoulder periarticular calcification with extracorporeal shock waves.

Fourteen patients suffering from subacromial impingement syndrome, with radiographic evidence of calcification inside the supraspinatus tendon and subacromial bursa, were studied. All patients were submitted to musculoskeletal echography in order to exclude rotator cuff tears. All patients presented with a painful reduction of shoulder range of motion, especially abduction and external rotation. Nocturnal pain was found in all patients. The analogic pain scale was used to evaluate the patients's pain. The treatment consisted of three sessions of extracorporeal shock waves (power of 0.2 mJ/mm2 - 11,2 KV), one per week, each session of 2000 shots, in a 120 shockwaves per minute frequency. The equipment used was Siemens LithostarUro ®, with Siemens Siremobil Image Intensifier ® and Siemens Adara Echograph ®.

Follow up in two weeks after treatment and two months later showed in 86% of cases a reduction of pain and increase of shoulder range of motion. The nocturnal pain disappeared in 86% of patients. The analogue pain scale improved from a medium of 7 to 1,5. One patient (7%) abandoned the treatment. One patient (7%) was submitted to surgical treatment. X-rays two months after treatment showed a initial fragmentation of calcification in one case (there was a 1,5 cm calcification) and total resorption in the other cases, with smaller calcifications.

The author considers the technique a valid treatment method of subacromial impingement syndrome with periarticular shoulder calcifications.

# Musculoskeletal Shockwave Therapy in Tendinosis Calcarea of The Shoulder Six Years of Experience

Authors: Dr. José Eid, Dr. Paulo Kertzman

Introduction:

The treatment of tendinosis calcarea goes since fisiotherapy, non anitiinflamatory drugs, infiltrations and surgical procedure to remove the calcification. We present the results of extrashockwavetherapy (ESWT) in 79 patients with tendinosis calcarea.

#### Material and Methods:

From 1998,october to 2004, March, we treated 129 patients with tendinopathy of the shoulder with ESWT. We have done 387 aplications with 3 sessions per patient. Tendinosis calcarea was present in 79 patients, 48 women and 31 men, ages between 38 and 78 years. The treatment was done under the guideline conditions of the ISMST( International Society) and SBTOC (Brazilian Society) protocol, i. e., all the patients showed pain and limitation of motion for at least 6 months, in spite of traditional treatment. The device used was an eletromagnetic generator from Dornier (Compact S and Epos Ultra) and the focus was done by radioscopy or Ultrassonography of 7,5 Mhz. We did 237 applications, 3 sessions in each patient, with 2000 shockwaves (SW) in each session, in intervals of 7 day.

### Results:

Patients were reviewed clinical with the Roles and Maudsley functional scale and through X-Rays and or Ultrassonography in the first 3 months, 6 months and 1 year. We observed a great improvement of pain and function in 63 patients. Resoption of calcification occurred in 54 patients.

## **Conclusions:**

ESW is a therapy that shows effective in the treatment of tendinosis calcarea. We observed a great improvement of function and pain even in a safety and effective way, even in cases without resorption.

# Complications of extracorporal shockwave therapy in the treatment of calcifying tendinitis of the shoulder

**Authors**: Sabeti M MD<sup>(1)</sup>, Dorotka R MD<sup>(1)</sup>, Schatz KD MD<sup>(1)</sup>, Schubert S<sup>(1)</sup>, Ebenbichler G<sup>(2)</sup>, Trieb K MD<sup>(3)</sup>

Institution: (1) AKH WienOrthopädie

(2) Physikalische Medizin und Rehabilitation

(3) Klinikum Frankfurt a.d. Oder Orthopädische Abteilung

## Objective:

Study investigates complications of the application of shockwaves in the treatment of shoulder joint disorders. To our knowledge, no one has investigated side effects of this treatment modality at the shoulder.

## Design:

In this retrospective study, 130 patients were treated with extracorporal shock wave therapy for symptomatic calcifying tendonitis between January 2000 and April 2003. The energy flux density applied was in the low or mid- energetic range (0.012-0.2 mJ/mm2). The evaluation of side effects and treatment complications was performed clinically during each treatment session, and clinically and radiologically 6 and 12 weeks after the end of therapy, respectively. Clinical assessment comprised patient- reaction for complications, pain assessment using Visual Analogue Scale and the assessment of the Constant and Murley Score. In cases of persisting pain after therapy additional radiographs were made.

### Results:

Local erythema at the interface of skin and lithotripter occurred in 97% of the population. Pain due to lithotriptic therapy was observed in 10 of 130 patients. No other side effects, especially no bony alterations were observed.

### Conclusion:

Low and mid- energetic shockwave therapy for calcifying tendonitis of the shoulder appear to be a safe conservative treatment modality.

# Treatment of shoulder pathologies with ESWT

Authors: Paulo F. Kertzman Institution: São Paulo Brasil

This paper is about the treatment of shoulders calcification of supraspinatus and subscapularis tendons and "frozen" shoulder with ESWT. We use and Orthima-Direx device and treat patients with at least six months with pain and no good results with traditional treatments and surgical indication. We do not use anaesthesia, we do the localization of the point of treatment with palpation of the shoulder and all of the cases have good xray and ultrasound documentation. We make 1500 shock waves ( 300 level 1 low energy, 300 level 2 medium energy, 400 level 3 medium energy and 500 hundred level 4 high energy ) anr repeat after 3 and 6 weeks. We treat 35 patients between 2003 and 2004. 30 patients with supraspinatus calcificatin, 2 with subsacapularis and 3 with frozen shoulder. After treatment we make x-ray after 2 months, 6 months and one year. On the patients with supraspinatus qe have firs improvement of pain and movement and after progressive reabsortion of the calcium deposits in 25 ( 80% ) of the 30 patients after at least one year of treatment. on the 2 cases of subscapularis calcification we have good results and on the 3 cases of frozen shoulder in 2 we have after 3 months no more pain and progressive better movements. We conclude that ESWT on shoulder chronic pathologies is very safe and has very good results.

# Extracorporeal Shock Wave Therapy for soft tissue diseases in shoulder with ultrasonographic localization technique

Authors: Gengyan Xing, Rufang Jing

**Institution**: Orthopeadic Department, The General Hospital of CPAP,

Bejing, 100039, China

# Introduction:

Subacromial bursitis (SB) is a common condition that affects the shoulder joint. Subacromial bursitis is caused by overuse or repetitive movement of the shoulder (this may include an occupation which requires lifting, working above the head, etc.). Symptoms may include localized shoulder pain and tenderness. The pain will be worse when the arm is raised to the side. Inflammation of the long head of the brachial biceps muscle (ILBM) is a relatively common cause of shoulder pain. It is localized to the anterior face of the shoulder, is exacerbated especially by anterior elevation and external rotation. The biceps muscle splits into two tendons at the shoulder. A long one and a short one. The long tendon runs over the top of the humerus bone (upper arm) and attaches to the top of the shoulder blade. Inflammation of this tendon is a fairly common complaint especially with swimmers, rowers, throwers, golfers and weight lifters. Both Subacromial bursitis and Inflammation of the long head of the brachial biceps muscle (ILBM) can be treated with ESWT.

## Objective:

In order to reveal the effect of Extracorporeal Shock Wave Therapy (ESWT) with ultrasonographic localization technique for subacromial bursitis (SB) and inflammation of long tendon of biceps muscle (ILBM), the comparative study was used between ultrasonographic localization technique and pain-point localization technique.

## Method:

151 cases, 65 cases of SB and 86 cases of ILBM were treated with ESWT. 25 of 65 cases of SB were referred with ESWT of ultrasonographic localization technique, other 40 with ESWT of pain-point localization technique. 31 of 86 cases of ILBM were referred with ESWT of ultrasonographic localization technique, other 55 cases with ESWT of pain-point localization technique. Shoulder function and pain (visual analogue scale, VAS) were assessed before treatment and at one week and six months after treatment. The satisfied rate were compared between the ESWT with ultrasonographic localization technique and ESWT with pain-point localization technique in SB and ILBM .

## Results:

Through 6 mouths follow up, the results showed that the satisfactory rates were respective 89.6% (SB) and 92.3% (ILBM) in the cases with the ESWT of ultrasonographic localization technique, the satisfactory rates were respective 76.9% (SB) and 79.1% (ILBM) in the cases with ESWT of pain-point localization technique. The difference of satisfactory rates were significant between two ESWT groups (ultrasonographic localization technique group and )in SB and ILBM cases, (Pi0.05).

# Conclusion:

Through the study, we considered that the effect of the ESWT with ultrasonic localization technique was better than the ESWT with pain-point localization technique for SB and ILBM. The ultrasonic localization technique is of important role in advance of satisfactory rate in ESWT.

# Shockwave Therapy for Lateral Epicondylitis of the elbow: retrospective study

Authors: A. Souza, P. Rockett, P. Souza

Institution: Ortosom, Porto Alegre, Brazil

Cortrel, Rio de Janeiro, Brazil Orthomaster, São Paulo, Brasil

## Aim:

The aim of this study was to evaluate the efficacy and the safety of extracorporeal shock wave therapy for the treatment of Lateral Epicondylitis of the elbow in three Brazilian Orthopaedics Clinics.

### Material and Methods:

In a multi-center, retrospective study, the effect of shockwave therapy was investigated in 65 patients with Lateral Epicondylitis of the elbow treated in the period of 39 months from March 2001 to May 2004. There were 25 women and 40 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, previous corticosteroid injection, acute infection, gout, malignant diseases and blood coagulation disorders. Each patient was treated with 1200 impulses of shock wave, a 05 mm focus depth, and with an energy flux density of no more than 0.13 mJ/mm after local or regional anaesthesia. One treatment was performed on 55 patients and 10 patients underwent a second treatment. The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score, subjective outcome on Visual Analogue Scale (VAS) analysis, 45, 90 and 180 days after the end of the therapy.

### Results:

The study showed the efficacy and safety of ESWT were excellent in 43%, good in 30.8%, acceptable in 10.8%, and poor in 15.4%, 180 days after ESWT.

# Treatment of Soft Tissues Pathologies with Extracorporeal Shockwave Therapy

Authors: Santos Paulo Roberto

Institution: Hospital Santa Rita - São Paulo - Brazil

## Introduction:

The purpose of this study was to clinically evaluate the efficacy of Extracorporeal Shockwave Therapy using an electro hydraulic shockwave device to treat soft tissue pathologies.

### Materials and Methods:

The study was conducted in Hospital Santa Rita in São Paulo where an Ossatron - HMT is installed. From January 2002 to December 04, 132 patients (63 female and 59 male), with an average age of 51 years (min 28 and max 83 years) were submitted to shockwave therapy in the following soft tissues pathologies: 32 tendinitis calcarea of the shoulder, 13 tendinosis of the shoulder, 36 plantar fasciitis, 19 epicondylitis, 18 Achilles tendon tendinosis, 12 trochanteric bursitis of the femur, 2 patelar tendinosis.

Inclusion criteria were at least 6 months of unsuccessful conservative treatment. To evaluate the intensity of pain, the outcome was assessed in four categories using Roles and Maudsley and VAS (visual analogue scale). One to three sessions of shockwave therapy were performed using the standard protocols; patients were reviewed at 3-6 weeks, 3 and 6 months after treatment. Local anaesthesia and/or general anaesthesia was performed.

#### Results:

Twelve patients were excluded because of inadequate follow-up, 120 patients were included in the analysis. The results were as follows:

Pathologies / Results excellent good poor nil tendinitis calcarea of the shoulder 64% 13,3% 11,6% 11,1% tendinosis of the shouder 54,5% 18% 18,5% 9% plantar fasciitis 54% 10% 18% 18% Achilles tendon tendinosis 60% 10,7% 17,6% 11,7% trochanteric bursitis 70% 8,4% 5% 16,6% patelar tendinosis 50% 50% 0 0 Epicondylitis 58,7% 16,3% 10% 15%

### Conclusions:

The results of the study showed that extracorporeal shockwave therapy is an effective and safe treatment for entesopathies.

# ESWT for Lateral Epicondylitis and Heel - Our New Protocol of Anaesthesia

Authors: A.C. Souza, P.Rockett, P.R. Santos, F. Arkader, R. Badaró.

Institution: Ortosom, Porto Alegre, Brazil Cortrel, Rio de Janeiro, Brazil Orthomaster, São Paulo, Brazil

Recent clinical observation indicates the beneficial effect of shock wave on inflammatory region of soft tissues. We started a protocol of treatments with no sedation or general anaesthesia, using local anaesthetics at the doctor's office. However, some studies showed that the simultaneous use of local anaesthesia has a negative influence on repetitive low-energy shock wave therapy for chronic plantar fasciitis and results without local anaesthesia have been significantly better than with local anaesthesia even in higher energy-treatment. The purpose of the study is to demonstrate a new protocol of anaesthesia with a regional block of the elbow and of the ankle, to treat lateral epicondylitis, Achilles tendinopathies and plantar fasciitis; a procedure that can be done in doctor's office. We started this new protocol to observe if there was or not, influence between the use of local anaesthesia in the our follow-up results and to further prospective studies to evaluate this influence.

# Influence of Energy and Local Anesthesia on the outcome of Low Energy Extracorporeal Shockwave Therapy (ESWT) on Plantar Heel Spur.

Authors: Gerold Labek, V. Auersperg M. Ziernhöld, N Poulios,

A. Handelbauer, N. Böhler

**Institution**: AKH Linz, Orthopaedic Department Krankenhausstrasse 9, 4020 Linz, Austria

The question of doing low energy ESWT with or without local anaesthesia is still in discussion and hasn't been validated in a randomised comparing trial yet. In the large multicenter-trials of the German orthopaedic society (DGOOC) local anaesthesia has been used for blinding. The results of the study concerning tennis elbow have been controversially to the average outcome results in literature. Aim of this pilot study has been to evaluate the influence of local anaesthesia on the clinical outcome of ESWT.

We have started a prospective, randomised trial on plantar heel spur including patients, who have been unsuccessfully treated conservatively but sufficiently according to the guidelines of the International Society of Muskuloskeletal Shockwave Therapy (ISMST). Severe low back pain, segmental pain in L5/S1 level or no clearly definable pain by local pressure has been excluded. Treatment has been done with a Sonocur Plus (Siemens) device. Follow-up-time have been minimum 6 weeks. Three groups have been randomised:

- Group A (20 patients, 24 heels): No local anaesthesia, energy flux density (EFD) 0,04 mJ/mm<sup>2</sup>.
- Group B (20 patients, 22 heels): With local anaesthesia by 4 ml 2% Scandicain, EFD 0,09 mJ/mm<sup>2</sup>.
- Group C (20 patients, 24 heels): With local anaesthesia by 4 ml 2% Scandicain, EFD 0,04 mJ/mm<sup>2</sup>.

For evaluation parameters we have chosen VAS (visual analogue scale) in weight bearing and non weight bearing situations as well as pain under pressure, addition-ally the need of further therapy at the moment of follow up.

We have registered a significant better result in VAS (p < 0,016 to p < 0,009 in different situations of weight bearing) and need of further therapy (p < 0,01) in group A (no local anaesthesia) in comparison to group C (local anaesthesia, same EFD) in a 6-weeks follow up. Similar results we found between groups A and B (VAS p<sub>i</sub> 0,026 to p<sub>i</sub> 0,003). There has been no significant difference between groups B and C. Successful therapy (painless or low pain and no further therapy needed) in Group A has been reported in 65,3%, in groups B and C with local anaesthesia only in 36,3% (p<0,01) and 29,2% (p<0,001). The results have been stable in a long term follow up too.

In our pilot study the results of ESWT on plantar heel spur without local anaesthesia have been significantly better than with local anaesthesia even in higher energy-treatment of group B. We have found strong clues, that blinding by local infiltration is influencing the results in a negative way and has to be assessed as a systematic error in study design. Even some articles were published supporting our results further investigations concerning the influence of local anaesthesia on the results of ESWT are recommended.

# Outcome of surgery after failed ESWT

Authors: Gerold Labek, V. Auersperg, N. Poulios,

E. Hinterreiter, A. Handelbauer, N. Böhler

Institution: Orthopaedic Department, AKH, Linz

## Introduction:

ESWT is used in the therapeutic spectrum in our department for patients, which have done intensive conservative treatment for months without any success. This procedure and ESWT might lead to a selection process for patients. Aim of this retrospective study was to evaluate, if the chance for success of surgical interventions are decreased by this process and to evaluate the outcome of surgery after failed ESWT to these patients.

## Material and Methods:

From 1993 to 2002 760patients have been treated by ESWT at AKH Linz. 189 of them for lateral Epicondylitis and 183 for plantar fasciitis. 53% of EHR and 80% of plantar fasciitis treatment were successful according to Auersperg - Score levels 6 and 7, which includes only excellent and good results. Out of the patients with failed treatments 34 patients suffering lateral epicondylitis and 18 patients suffering plantar fasciitis have been treated by a surgical procedure, most of them in our clinic. EHR was treated by a Hohmann operation (originally described by G. Hohmann: Das Wesen und die Behandlung des sogenannten Tennisellenbogens. Münch Med Wochenschr 1933; 80: 250-252), plantar fasciitis by a tenotomy of the plantar fascia and denervation of the calcaneal periosteum.

13 patients (out of 18) suffering plantar fasciitis and 26 (out of 34) suffering EHR could be evaluated by a follow up period of at least 1 year after operation. Auersperg-Score and VAS was recorded.

## Results:

# Plantar Fasciitis:

6 Patients were pain free, 4 reported major improvement without need of further therapy. 3 patients has no or unsatisfying improvement by the operation. 76% of the patients had satisfying benefit by a Hohmann operation after failed ESWT.

#### EHR:

17 patients were pain free, 7 reported major improvement without need for further therapy, 2 patients had no or unsatisfying improvement by the operation. 92% of the patients had satisfying benefit by a tenotomy procedure after failed ESWT. This is similar to reported success rates in the literature without ESWT before.

## Conclusion:

Low Energy ESWT seems not to influence the success of surgical procedures by selection of patients or other reasons. Further studies should be performed for more detailed evaluations. Larger multicentre databanks for recruitment and description of patients would be recommended.

# Validation of a "Patient-Rated Tennis Elbow Evaluation" (PRTEE) Questionnaire

Authors: Jan D. Rompe, B. Nafe, C. Theis, T. J. Overend, J. C. MacDermid

**Institution**: Dept. of Orthopaedic Surgery,

Johannes Gutenberg University School of Medicine,

Langenbeckstr. 1, D-55131 Mainz

## Background:

Though the most often diagnosed pathology of the upper extremity there is no consensus on how to measure treatment outcome for lateral elbow tendinosis (LET). The aim of the study was to determine the reliability of a questionnaire designed specifically to assess forearm pain and function in patients with a chronic tennis elbow.

## Methods:

Seventy-eight patients with chronic, unilateral MRI-confirmed LET (of whom 78 were studied twice without therapy and 38 were studied 3 months after appropriate treatment) completed the 3-section, 15-item patient-rated tennis elbow questionnaire.

### Results:

The test-retest reliability coefficient of determination ( $R^2 = 0.95$ ) and internal consistency (Cronbach's alpha = 0.94) were both good. Convergent validity was attested by good correlations with the Disabilities of Arm, Shoulder and Hand Questionnaire (DASH), and the Numeric Rating Scale-based Thomsen test ( $R^2 = 0.75$  and 0.87, P < 0.0001). Only a poor correlation was found with the Roles and Maudsley Score and the Upper Extremity Function Scale ( $R^2 = 0.02$  and 0.03, P = 0.2767 and 0.1798). Sensitivity to change was demonstrated by correlating pre-treatment - post treatment changes to those in DASH and Thomsen test ( $R^2 = 0.66$  and 0.84, P < 0.0001).

## Conclusion:

The patient-rated forearm evaluation questionnaire for LET is an internally consistent score, correlating well with other, non-elbow specific scores, and is sensitive to change on treatment.

## Clinical Relevance:

Reliability of the score for lateral elbow tendinosis has been confirmed independently in North America, Asia, and Europe. It is therefore recommended as standard scoring system in future clinical trials on tennis elbow.

# Extracorporeal Shock Wave Therapy for Treatment of Navicular Syndrome.

Authors: S.R. McClure, DVM, PhD; R.B. Evans, PhD; K.G. Miles, DVM; E. L. Reinertson, DVM, MS; \*J. F. Hawkins, DVM; +C. M. Honnas, DVM.

#### Institution:

From the Department of Veterinary Clinical Sciences, College of Veterinary Medicine; Department of Veterinary Diagnostic and Production Animal Medicine, Iowa State University, Ames, Iowa 50011-1250, \*Department of Veterinary Clinical Sciences, School of Veterinary Medicine, Purdue University, West Lafayette IN 47907-1250, Department of Large Animal Medicine and Surgery, College of Veterinary Medicine, \*Texas A&M University, College Station TX 77843-4475

Navicular syndrome is a common cause of chronic lameness in horses. The exact aetiology of navicular syndrome is unknown. Mechanisms of disease onset proposed include bone remodelling, ischemia, and chronic bursitis. The objective of this study was to evaluate ESWT in decreasing the lameness associated with navicular syndrome. Case records of horses that were diagnosed with navicular syndrome and treated with ESWT from June 1999 to August 2001 were evaluated for this study. Each navicular bone involved was treated with 2000 pulses (1000 pulses through the frog and 1000 through the heel) at 0.89 mJ/mm2 by an electrohydraulic shock wave generator. A follow-up examination was performed 6 months post-treatment. Further follow-up information was obtained by repeated clinical evaluation of the horse and by telephone and/or personal interview with the owner or trainer. Outcome was evaluated three ways: 1) unmasked veterinary evaluation, 2) client perception of lameness, and 3) masked evaluation of video tapes taken preand 6 months post treatment. A series of radiographs were taken of each foot for evaluation of the navicular region prior to treatment and 6 months post-treatment for the 16 horses with follow-up. A radiologist blinded as to outcome or pre- or post- treatment evaluated the radiographs and scored them from 0 = normal to 3 =dramatic changes for; 1) medullary sclerosis, 2) distal border synovial invaginations, 3) flexor cortex erosions, 4) abaxial margins, 5) medullary cysts, and 6) the deep digital flexor tendon. Extracorporeal shock wave therapy was effective in decreasing the lameness associated with navicular syndrome in 81% of the horses as determined by an unmasked evaluator and in 56% of the horses with masked evaluators. There was no significant change in the radiographic scores between pre- and post- treatment (P=0.54). There was no significant relationship between pre-treatment radiographic score and outcome for lameness evaluation by the 3 masked graders for trotting at hand (r2=0.019, P=0.92) or in a circle (r2=-0.23, P=0.26). Extracorporeal shock wave therapy provided a non-invasive, effective mechanism to decrease the lameness associated with navicular syndrome. There were no complications associated with the procedure. Lameness in horses that responded to treatment did not regress in the year following treatment. The results of this study indicate that ESWT should be considered as a viable non-invasive mechanism to navicular syndrome in horses.

# Radial Shock Wave Therapy for chronic insertion desmopathy of the proximal suspensory ligament in sports horses.

Authors: A. Morral\*, J. Grau\*\*, L. Mata\*\*, J. Viu\*\*, M. Prades\*\*\*, T.Ramon\*\*\*

## Institution:

- \*EUIF Blanquerna. Universitat Ramon Llull.
- \*\*Clínica Equina Jordi Grau.
- \*\*\*Facultat de Veterinària. Universitat Autònoma de Barcelona. Spain.

# Introduction:

Suspensory ligament desmopathy is a common disease causing primary and compensatory lameness in the sport horse. The disease can cause long-term lameness restricting the horse's ability to perform at the level of competition achieved prior to the onset of lameness. Current medical treatment options include confinement and rest, controlled exercise protocols, intralesional injections, corticosteroid therapy, anti-inflammatory therapy, bone marrow injection, and corrective shoeing. However, none of these methods consistently result in a satisfactory outcome. (McClure 2004)

## Subjects:

Between April 2002 and August 2004, 40 sports horses with chronic proximal insertion desmopathies (23 in the hind limb, 17 in the front limb) have been treated with Radial Shock Wave Therapy (RSWT) The horses must have had clinical symptoms for at least 3 months and at least one failed conservative treatment approach prior to RSWT. Lameness was graded from 0 to 5 using a AAEP scale (American Association of Equine Practitioners)

#### Methods:

The horses were treated in 3 sessions (at intervals of one/two week, mean: 12 days) with 4000 shockwaves per session. Pressure of 3,5 bar (Energy flux density: 0,14 mJ/mm2 approx.) and 6 Hz of frequency. Device used: Swiss Dolor Clast (EMS-Switzerland).

The horses received sedation with Domosedan and Torbugesic.

The affected leg was lifted and the superficial and deep flexor tendon was pushed laterally and medially in order to be as close as possible to the origin of the proximal suspensory ligament. 2000 shockwaves were applied from each side (medial and lateral).

Evaluation was performed before the treatment, before 2nd RSWT, before 3rd RSWT, 30 days after last RSWT, 90 day after last RSWT: A special training program was elaborated for the time between the sessions and post shock wave therapy.

## Analyses:

The no parametric Wilcoxon test for dependent samples to compare means of AAEP lameness scale.

#### Results:

The horses showed a considerable lameness decrease 30 days after last RSWT (p<0.05), and 90 days after last RSWT (p<0.01).

90 days after last RSWT, 26 horses (65%) were free of lameness (return to full work) and 8 horses had a distinct lameness reduction. 6 horses showed no improvement.

Side effect and complications were not observed.

# ${\bf Conclusion:}$

RSWT is an effective treatment method for chronic insertion desmopathy of the proximal suspensory ligament in sports horses. Further randomized and controlled studies are necessary to underline the results of this investigation.

# Preliminary Results of Radial Extracorporeal Shockwave Therapy in Five Dogs With Cubarthrosis

**Authors**: M Müller, DVM\*; B Bockstahler, DVM\*; DVM, DECVS; M Skalicky<sup>+</sup> DTP, D Lorin-son\* **Institution**:

University of Veterinary Medicine, Project Group Motion Analysis in Dogs,

# Introduction:

Although RSWT has been used in small animals with orthopaedic disorders for some years only a few studies exist detailing this kind of treatment in dogs. At the present time the authors are unaware of any prospective study using ground reaction forces evaluated on a treadmill-system. The purpose of this study was to show results of RSWT in dogs with cubarthrosis. To document the effectiveness of RSWT ground reac-tion forces (GRF) measured on a treadmill-system were evaluated.

## Material and Method:

Five client-owned dogs of different breeds with cubarthrosis were included in this study. Age ranged from 6 to 11 years, bodyweight from 15.7 to 48 kilograms. Three dogs had bilateral and two dogs unilateral cubarthrosis. Radial Shock Wave Therapy was performed with the Swiss DolorClast Vet® (EMS Electro Medical Systems, Nyon, Switzerland). Treatment was given three times on a weekly basis using 1,000 radial shockwaves with a pressure of 2.0 bars were applied at the medial and lateral side of the affected elbow. Before first RSWT ground reaction forces were measured us-ing a treadmill with four force plates. Parameters chosen for evaluation were peak maxi-mal force (Fz), mean vertical force (Fm) and Impulse (Imp). Mean values of five valid steps were calculated and symmetry indices were calculated as described¹. Deviation of absolute symmetry was expressed as a percentage. Re-evaluation was performed be-fore subsequent treatments and one month after last RSWT. A paired t-test was performed to compare pre-treatment GRF values with values of each evaluation point, pi0.05 was considered as statistically significant.

# Results:

Percentage of deviation from symmetry before first RSWT was  $16.59 (\pm 9.89) \%$  for Fz,  $18.66 (\pm 5.60) \%$  for Fm and  $25.48 (\pm 9.01) \%$  for Impulse. No significant difference in values was found after the first RSWT. One month after last RSWT® all three values showed significant improved values compared to the basic GRF data: percentage of deviation of Fz was  $4.79 (\pm 4.20) \% (p=0.38)$ , of Fm  $7.59 (\pm 8.69)\% (p=0.34)$  and of Im-pulse  $9.55 (\pm 8.73)\% (p=0.001)$ .

## Discussion:

Our preliminary results show that dogs with cubarthrosis responded well to Radial Shock Wave Therapy. Although studies with more animals and long term controls are needed, we recommend Radial Shock Wave Therapy as a non-invasive treatment op-tion for dogs with degenerative joint diseases.

#### References:

<sup>1</sup> Budsberg SC, Jevens DJ, Brown J, et al. Evaluation of limb symmetry indices, using ground reaction forces. AmJVetRes 1993;54:10:1569-1575

<sup>\*</sup>Department of companion animals.

<sup>&</sup>lt;sup>+</sup>Department of natural science, Vienna, Austria

# Ultrasonographic Evaluation of Extracorporeal Shock Wave Therapy on Collagenase Induced Superficial Digital Flexor Tendonitis

Authors: Kevin D. Kersh, DVM; Scott R. McClure, DVM, PhD; David Van Sickle, DVM, PhD; Richard B. Evans, PhD

Institution: From the Departments of Orthopedic Research Laboratory, College of Veterinary Medicine, Iowa State University, Ames, IA 50010-1250 and the Department of Basic Medical Sciences (Van Sickle), School of Veterinary Medicine, Purdue University, West Lafayette, IN.

Injuries involving the superficial digital flexor tendon (SDFT) are common in performance horses of many disciplines. Many treatment modalities have been used to facilitate healing of these lesions, but there are currently no treatments that stimulate healing to proceed in a timely manner on a consistent basis. The methods that have been employed include prolonged periods of inactivity, controlled exercise programs, anti-inflammatory therapy, intra-lesional injections, peri-tendinous injection of counter-irritants, sclerosing agents, tendon splitting, annular ligament desmotomy, superior check ligament desmotomy, and numerous other therapies. None of these consistently promote healing in a timely fashion to allow earlier return to normal function. The objective of this study was to use the collagenase model to induce lesions and then to assess the rate of healing and histologic characteristics of the healing of tendons treated with ESWT versus untreated lesions. The goal of the study is to determine if ESWT will speed healing and improve quality of healing of SDFT lesions

Six mature horses were used in a blinded prospective study with untreated contralateral limb controls. Bilateral forelimb SDFT lesions were induced in each horse with collagenase. Ultrasonographic images were captured digitally and image analysis software was used to measure: 1) Percent lesion at the maximum injury zone (MIZ) 2) the gray scale of the SDFT at the MIZ 3) the percent disruption of the longitudinal fibers at the MIZ. The data were also summed for the ten sites from 4-22 centimetres distal to the accessory carpal bone. Physical examinations were performed on 4 occasions during the study to evaluate heat, response to palpation, presence/character of swelling over the SDFT, and lameness score. Measurements of the external width of the SDFT, and thermographic images were also evaluated. At the completion of the study all tendons were evaluated histologically.

There was no significant group by time interactions for any of the 3 variables at the MIZ or the sums for each variable. There was a trend toward a decrease in the external width, and there was a significant difference between the thermographic appearances of treated versus control limbs. There was an increase in neovascularization, increased mitotic activity, and greater degree of cellular reaction in treated tendons compared to untreated control tendons. The histologic changes indicate that ESWT may afford beneficial changes at the cellular level. While it is recognized that these are evaluations based on experimentally induced lesions, there does appear to be a beneficial reaction that takes in tissues in response to ESWT.

# Radial Extracoporeal Shock Wave Therapy For Hip

Authors: B Bockstahler, DVM\*; M Müller, MVM\*; M Skalicky DTP; D Lorinson, DVM, DECVS\*.

#### Institution:

University of Veterinary medicine, Project Group Motion Analysis in Dogs,

\*Department of companion animals, Department of natural science, Vienna, Austria

#### Introduction:

Recently Radial Shock Wave Therapy (RSWT®) was introduced in small animal veterinary medicine, although only few studies have been published. RSWT is recommend for different orthopaedic conditions like osteoarthritis and tendinopathies. Although a lot of good results are emphasized, controlled clinical studies are rare. This clinical prospective study analysed the effect of radial shock wave therapy in dogs with coxarthrosis using a treadmill system with four force plates.

#### Materials and methods:

Thirteen dogs of different breeds with coxarthrosis have been included in this study. Radial shock waves were generated by the Swiss DolorClast Vet® (EMS Electro Medical Systems, Nyon, Switzerland) and three treatments on a weekly basis were performed in the hip joint-region. Ground reaction forces (GRF) were measured before each treatment and one week, one and three month after last RSWT. Symmetry indices (SI) were evaluated as described¹ for each dog using the following parameters: peak maximal force (Fz), mean vertical force (Fm) and impulse (Imp). After calculation of SI percentage devia-tion of absolute symmetry was described. The results were compared to the values of 10 healthy dogs. To compare values of healthy dogs and patients we used an unpaired t-test. To compare patients values during the course of the study we used a paired -test (pj0.05 was considered as statistically significant).

## Results:

A significant difference between values of healthy dogs and patients was found over the whole treatment period, except for Fz (one week) and Impulse (one week and one month). Comparison of patients pre-treatment values with the subsequent values showed no significant difference for Fz, whereas Fm and Impulse showed a significantly improvement at one week (Fz, Imp), one month (Imp) and three month (Fm, Imp).

## Discussion:

Our preliminary results with RSWT showed positive effects of ground reaction forces in dogs with coxarthrosis. Although values of healthy dogs were not reached, Radial Shock Wave Therapy seems to help reducing pain and discomfort during locomotion. Although studies using a greater number of dogs and longer evaluation periods are necessary, we recommend RSWT as an alternative treatment for dogs with degenerative joint diseases.

# References:

<sup>1</sup> Budsberg SC, Jevens DJ, Brown J, et al. Evaluation of limb symmetry indices, using ground reaction forces. Am J Vet Res 1993;54:10:1569-157

# The Evaluation of Extracorporeal Shockwave Therapy in Naturally Occurring Osteoarthritis of the Stifle Joint in Dogs

Authors: J. Dahlberg, G. Fitch, R.B. Evans, S.R. McClure, M. Conzemius

**Institution**: From the Orthopedic Research Laboratory,

College of Veterinary Medicine, Iowa State University,

Ames, Iowa 50011-1250, USA

Extracorporeal shockwave therapy (ESWT) has expanded from the original uses of human urinary calculi treatment to veterinary orthopaedic applications. This paper investigates the feasibility and efficacy of treating dogs with osteoarthritis of the stifle joint with ESWT. In this study, dogs with persistent stifle lameness despite previous surgical or medical treatment were either treated with ESWT or served as untreated controls. The most lame rear limb of each dog was determined by force platform analysis. Range of motion of the stifle joints was assessed by goniometry. Force platform gait analysis and goniometry were performed on both groups for four visits at 3-week intervals and a final exam 4 weeks later. Shock wave therapy was performed three times on treated dogs during each of the first three examinations. Placebo treatment consisting of clipping and wetting the hair was performed on control dogs. Vertical forces were evaluated for objective analysis of treatment response. For peak vertical force (PVF), four of seven treated dogs improved while only one of five of control dogs improved. The PVF for the within group analysis showed no significant change for the treated group, however, the control group has a significant decrease (p=0.05) in PVF consistent with an increase in lameness. The range of motion of the stifle joint improved in five of seven treated dogs and three of five controls. Dogs in the treated group had a trend toward increased range of motion (p=0.07) and a positive slope compared to dogs in the control group which did not have a significant change (p=0.78) and had a negative slope indicating the dogs were developing a decrease in ROM. The subjective data provided by client questionnaire did not show significant difference between groups.

# Reviewing The Biologic Effects: Radial And Focussed Shockwaves Induce New Bone Formation.

Authors: Maier M, Tischer T, Hausdorf J, Saisu T, Schmitz C;

**Institution**: Munich, Chiba, Maastricht

In recent years, extracorporeal shock wave application to the musculoskeletal system has been established in the therapy of non-unions. However, there is a controvers discussion whether both, focused and ballistic (radial) shock wave devices lead to comparable new bone formation. Maier et al. used focussed shock waves with energy flux densities between 0 mJ/mm2 (sham-treatment) and 1.2 mJ/mm2 were applied in vivo to the distal femoral region of rabbits (1,500 pulses at 1 Hz frequency each). To investigate new bone formation, animals were injected with oxytetracycline at the days 5 to 9 after shock wave application, and were sacrificed on day 10 after shock wave application. Application of shock waves with energy flux densities of 0.9 mJ/mm2 and 1.2 mJ/mm2 resulted in new periosteal bone formation and the presence of cortical fractures and periosteal detachment. After application of shock waves with energy flux density of 0.5 mJ/mm2, however, for the first time clearly detectable signs of new periosteal bone formation were observed without cortical fractures or periosteal detachment. In 2004 the study group of Haupt described new bone formation in a rabbit animal model following radial shock wave application of at least 2000 pulses with 3 bar or 4 bar. 60 days after the treatment new bone formation was found. The activity was osteoblasts was described to be high with extended osteoid formation. Haupt et al. concluded from their rabbit experiment that radial shockwaves might be used in future times for the treatment of e.g. non-unions or diseases with decreased bone turn-over such as parodontitis. This present reviews actual basic science studies dealing with the effects on bone following focused and radial shockwave application. It seems to be possible that radial shockwaves have comparable effects on healthy bone as focused shock waves in an rabbit animal model.

# Tibial Stress Fractures Treated with Shockwave Surgery: Five Years After.

Authors: Herrera Juan M. MD, Leal Carlos MD, Lopez Juan C. MD, Reyes Oscar E. MD

**Institution**: Department of Orthopaedics

Orthopaedic Research Laboratory - Bosque University

Bogota DC, Colombia

Tibial stress fractures represent 49% to 73% of all overuse bone injuries due to biomechanical fatigue or overload. The natural history of this fracture shows that it is symptomatic for several years without treatment. However, therapeutic protocols for this fracture are still controversial. Many options have been described ranging from conservative treatment to intramedullary nailing. Few cases are available in the literature, so there is not enough evidence to accept any of them as the standard choice, and the treatment will need individual decision making. Compression tibial fractures may become chronic because of a lag in vascular supply to the fracture. Chronicity is a response to hypovascularity, and hypovascularity leads to delayed union or no union. The current gold-standard treatment includes a progressive retraining that will place the athlete out of active competition for at least four months, and if there are persistent symptoms, it could be over a year. This same challenging situation has been seen in military recruits. Limitation of the activity causing the symptoms is the keystone to any treatment regimen. Either on athletes or military recruits, cardiovascular conditioning and flexibility should be maintained by non-weight-bearing alternative exercises. We have explored the benefits of ESWT in tibial stress fractures, based upon the known effects of shockwaves in bone. We believe that osteoinduction, due to the micro lesions on the trabeculae and the vascular effects on both periosteum and cancellous bone may accelerate the recovery process in athletes with this condition. All experimental reports suggest that top pressing of the marrow from the medullary canal, marrow hypoxia and subperiostial haemorrhages, may cause and stimulate new bone growth. Hypovascularity in stress fractures leads to chronicity. Thus, there could be two theoretical advantages of shockwaves in the treatment of stress fractures: one, shockwave therapy promotes vascularity at fracture site, and two, shockwave therapy enhances bone remodelling. ESWT produces micro-cracks in cortical bone that may lead to an enhanced remodelling process in bone. This enhanced remodelling process actually increases the surface area over which the load is applied. Thus, the intrinsic strength of bone as a material is increased at the end of the remodelling process, decreasing the risk for new stress fractures. To determine if Extracorporeal Shock Wave Therapy enhances osseous remodelling and decreases the time of recovery in stress fractures, we performed a case series study in fourteen patients. We presented our first report in the 6th ISMST international congress in Winterthur 2002, showing the faster recovery in our study group. Now we want to present the follow up after five years follow up of the same group, as well as the results of our protocol in new subjects. In this series there were seven women and seven men, all of them 18 years old, first year cadets, with identical bilateral stress fractures located at the union of the middle and distal thirds of the tibia. The onset of the symptoms was 8 weeks before they were included in the study, and the diagnosis was made over clinical history, Tc-99 Bone scans, ultrasound tests and X-Ray positive to stress fractures. Two thousand 0.7 milli-Joule Shockwaves were applied to the more symptomatic Tibia and eight days later the shock wave dose was repeated. All patients went into a progressive retraining program. We controlled nutrition intake, activity, and the progressive retraining standard program for the management of stress fractures. The rate of success was measured by the presence of pain before, through, or after the training practice. All patients were free of pain during the retraining program on their shockwave treated tibia. All of them presented persistent pain during the progressive retraining program on the untreated Tibia. Treated tibias were pain free after the retraining program. Untreated tibias were painful after that time, and were the cause of incapacities. All patients were satisfied with the treatment, and are prone to repeat it in the untreated tibias. Treated tibias were significantly faster to recover than untreated tibias after three weeks of retraining and physical therapy. Results after five years showed that all of our patients recovered with no reincidence of the symptoms, and finished their military career without any athletic limitation. Our protocol is currently used in athletes in Venezuela and Cuba, and our results have been reproduced with similar results. We believe this is a safe procedure that can be recommended for athletes with tibial stress fractures in order to recover their physical activity in a shorter period of time.

## Osteonecrosis And ESWT

Authors: Coco Valeria<sup>1</sup>, Buselli Paolo<sup>2</sup>, Bosco Vincenzo<sup>3</sup>, Saggini Raoul<sup>4</sup>

### Institution:

<sup>1</sup>P.O.AciReale, ASL3 Catania,

<sup>2</sup>A.O.della Provincia di Lodi,

<sup>3</sup>Clinica Villa Maria Bologna,

<sup>4</sup>Cattedra di Medicina Fisica e Riabilitativa Università G. d'Annunzio Chieti - Italy

### Introduction:

Osteonecrosis is a pathology characterized by a bone circulatory disorder leading to its necrosis, it can affect various joints, but hip, knee, talus are mostly affected. There are spontaneous and secondary types; the first ones usually take most advantages from the conservative treatment. The circulatory disorder, being the underlying condition of this pathology, leads through oedema and intra-osseous pressure rise to ischemia and then to necrosis. The ESWT, thanks to its pain-releasing, neo-angiogenesys effect, can be suggested as an effective conservative treatment of this pathology.

Materials and Methods: Seventeen subjects have been selected aged on average 51 years (range 36-66); the diagnosis was osteonecrosis of the femoral head (No. 13), of the femoral condyle (No. 2), of the talus (No. 2). All of them reported pain since at least 6 months. Pain has been evaluated by means of the VAS scale in all patients and by means of the Fisher algometer in those patients suffering from osteonecrosis of the femoral condyle and of the talus. Restriction of the functional activities has been evaluated by means of the Algofunctional Index of Lequesne.

Patients had also undergone radiographic as well as MRI examination.

The treatment suggested is one ESWT session performed with an electro-hydraulic unit H.M.T. administering a number of SW with an output varying according to the joint type (femoral condyle  $1600 \text{ SW} - 0.15 \text{ mJ/mm}^2$ ; talus  $1500 \text{ SW} - 0.13 \text{mJ/mm}^2$ ; femoral head  $4000 \text{ SW} - 0.25 \text{mJ/mm}^2$ ). After treatment, according to injury type and degree, a period of 4 to 8 weeks of walking activity with no weight bearing on the treated side and a rehabilitation treatment to keep articular mobility and muscular tone-trophism were suggested to the patient.

One month after treatment a clinical examination was performed and in case of unsatisfactory response treatment was repeated in the same way.

Follow-up of the cases treated included an examination 1, 3, 6 months after the last ESWT session. The examination at 6 months also included a new MRI.

### Results:

The evaluation of the VAS scale showed on average values equal to 6,8 before treatment and 4,5 after 1 month, 4,3 after 3 months, 4,2 after 6 months.

The evaluation with the Fisher algometer showed on average values of 1,5 before treatment and 3,7 after 1 month, 5,4 after 3 months, 4,1 after 6 months.

The functional activities evaluated with the Algofunctional Index of Lequesne showed on average values equal to 7,1 before treatment and 5,2 after 1 month, 4,2 after 3 months, 4,1 after 6 months.

The MRI showed a positive evolution of the picture in 6 cases and stability of the imaging picture in 7 cases, whereas the evolution was negative in the remaining cases.

In 35% of the cases the MRI showed a reduction of the edema coupled with partial recovery of the cartilage as well as of the subchondral bone previously depleted.

During the treatments performed, no case reported significant undesired effects.

### Conclusions:

The data obtained in the population treated show a good clinical result in the follow-up at 3 and 6 months. The pain evaluation shows a substantial reduction; the Algofunctional Index of Lequesne shows a 45% increase

The effectiveness of the treatment with ESWT proves to be interesting for this kind of pathology, especially due to the scanty possible alternative therapies, although a limited number of subjects does not apparently report a significant improvement. Patients suffering from osteonecrosis of the femoral condyle and of the talus reported the most satisfactory results. The advantages of the SW Therapy prove to be especially interesting in the treatment of osteonecrosis with regard to the patient's compliance, to the reduced need of surgical treatment, to the absence of side effects, to the early outcome of positive response, to the reduced number of treatments necessary.

## Extracorporeal Shock Wave Treatment For Osteonecrosis Of The Femoral Head

Authors: CJ Wang, FS Wang, KD Yang, LH Weng and CC Huang

**Institution**: Chang Gung Memorial Hospital at Kaohsiung,

123, Ta Pei Road, Niao Sung Hsiang, Kaohsiung 833, Taiwan

### Purpose:

A prospective clinical study was performed to evaluate the efficacy of shock wave treatment for osteonecrosis of the femoral head.

### Patients and Methods:

This study consisted of 22 patients with 29 hips in the study group and 5 patients with 5 hips in the control group. The study group included 18 males and 4 females with an average age of 43 years. The average duration of symptoms was 4.9 months and the average follow-up time was 20 months. Each hip was treated with 4000 impulses of high-energy shock waves at 28 Kv. The control group received sham treatment without shock waves. Clinical assessments included pain scores and Harris hip scores. Radiographs and magnetic resonance images (MRI) were used to evaluate the size of the lesion, congruency of the femoral head and bone marrow edema of the hip joint.

### Results:

The study group showed significant improvement in pain scores (p ; 0.001) and Harris hip scores (p = 0.001) after shock wave treatment, whereas the changes in the control group were statistically not significant (p ; 0.05). The overall clinical outcomes of the study group were 76.2% improved, 19.1% unchanged and 4.7% worsened in patients with stage II lesions; and 62.5% improved, 12.5% unchanged and 25% worsened in patients with stage III lesions. All cases in the control group showed unchanged results. The complications are mild and negligible. MRI showed significant reduction in bone marrow oedema of the affected hip after shock wave treatment (P < 0.000) despite non-significant changes in the size of the lesion and the congruency of the femoral head.

## Conclusion:

High-energy shock wave treatment appeared to be effective in pain relief and improvement of hip function for osteonecrosis of the femoral head in short-term follow-up. The results are more successful in patients with stage II than stage III lesions. Despite satisfactory early results, the results of long-term follow-up are needed to further verify the efficacy of this novel treatment.

## ESWT For AVN of The Femoral Head-5-Years Results

Authors: R. Schleberger

**Institution**: Germany

Between the years 1995 and 2002 67 femoral head necroses have been treated by electrohydraulically generated shock waves. Most of them have been rated irreversible necroses through their ARCO stadium ¿ 2. Aims of treatment have been painless weight bearing and survival of the genuine hip joint for 5 years or more. The 5 year survivorship of the genuine joint rates more than 90 percent all over, recovery of every day weight bearing could be observed in over 95% of the patients. Early progressive changes had been observed in 5 hips, repetitive treatment could stop progression in three hips.

Functional improvement had been measured by a VAS-Score questionnaire and presented an average improvement of 5 points in a 11 parts VAS-Scale (range 0-10). Improvement of function of hip joints in all ARCO stadiums will be presented according to the image controls and the morphological changes.

Extracorporeal Shock Wave Therapy (ESWT): How to plan and treat a patient with non-union in long bones fractures. Effectiveness of ESWT (Extracorporeal Shock Wave Therapy) in pseudoarthrosis and delayed union

Authors: Alessandro Lettera MD, Davide Rozzati MD, Francesco Cravero MD, Alessandro Littera MD, Francesca Travaglini MD, Giuseppe Sessa MD,

Alessandro Carriero MD, Paola Fazio T.S.R.M.

Institution: Istituto Universitario di Radiodiagnostica

Ospedale Maggiore della Carità

Corso Mazzini 18 - 28100 NOVARA, Italy

### Introduction:

Extracorporeal shock wave therapy is now accepted as an addictional therapy, with low risks and invasivity, in the pseudoarthrosis and delayed union of long bones treatment. Our objective is to define and explain how patients with non healed long bones fractures can be prescribed and perform ESWT treatment. Our study also investigated the effectiveness of ESWT in the treatment of 30 patients with history of non unites fractures of long bones or pseudoarthrosis.

### Materials and methods:

Patients with delaying in healing and consolidation of long bone fracture can be sent from the orthopaedic specialist to a radiology center to be treated by mean of ESWT.

The first step in our treatments with ESWT is to define the patient's exclusion criteria, such as pregnancy, heart disease, coagulopaty, epiphiseal plate within the shock wave fiel and brain or spine within the shock wave field, and inclusion criteria, non-union of long bones fractures defined as a failure to show bony union six months after initial close or open treatment. We select the treatment area (target) by mean of fluoroscopic or ultrasonographic guidance and we plan the number of treatments, the shock wave impulses for each treatment, the energy flux density and the proper generator of shock waves to use. Shock wave treatment is provided with a "REFLECTRON" (HMT, Kreuzlingen, Switzerland) ESWT System.

After the treatments, and a proper rest, we do an x-ray control, to define the progress of bone union.

In our Institute from 03/03/2004 to 31/10/2004 thirty patients, 10 female and 20 male (range 15-68 years) were treated. 15 patients had pseudoarthrosis and 15 delayed union of long bones. The treatment procedure was 3000 shocks with 240 shocks/min frequency for every treatment. Every patient had one treatment a week for 4 total treatments (one month).

A valuation schedule to define the upcoming of bony union was done for every patient.

In our study we didn't require immobilization, anesthesiologic support or hospitalisation.

### Results:

The study was successful in 8 patients.

Pseudoarthrosis was successfully treated in 2 patients.

Delayed union of long bones was successfully treated in 6 patients.

### Discussion:

Results in our study revealed that ESWT can be considered as first choice in the treatment of delayed union for long bones and pseudoarthrosis.

The femur seems to be the most responsive bone.

## Treatment of nonunions with ESWT using Orthima-Dyrex

Authors: Paulo F. Kertzman

**Institution**: São Paulo Brasil

This paper is about the treatment of non-union after orthopaedic surgery with, at least, one year of evaluation and an biologic problem and not an poor fixation. We use and Orthima-Direx device and make the therapy on ambulatory, without use of anethesia and no inetranation

We localize the point of application using x-ray with an metal point over the skin or we make an measurement between the focus and one bone mark.

The treatment is done with 2000 shock waves ( 300 level 1 low energy, 300 level 2 medium energy, 400 level 3 high energy and 1000 level 4 high energy) and we repeat after 3 and 6 weeks. Between 2003 and 2004 we treat 8 patients with non-union. One radius, one ulna, one scaphoids, one humerus and 4 femur.

We have the consolidation of the non-union after 3 months of the last session in 7 patients.

The only one femur that does not consolidate was in fact an por fixation and we necessity to make a new surgery last month .

We conclude that its possible to treat non-unions without anesthesia and internation with good results.

# Extracorporeal Shockwave Therapy for Bone Pathologies

Authors: Santos Paulo Roberto, Souza Ana Claudia

**Institution**: Hospital Santa Rita - São Paulo - Brazil

### Introduction:

The aim of this study was to evaluate the effect of shockwave treatment in non-unions and delayed healing fractures, stress fractures and hip necrosis, with an electro hydraulic high energy device (Ossatron-HMT) at the Hospital Santa Rita,  $S\tilde{a}o$  Paulo - Brazil.

### Method:

Since July 2002 until December 2004, 18 patients (8 female and 10 male) with average age 35 years (min=20, max=82 years) were submitted to shockwave therapy in different bone indications: Ten patients with non-unions or delayed healing fractures, of which one bilateral tibia non-union, (three patients underwent conservative treatment, eight had surgery prior to shockwave therapy, one non union was operated on once, three-twice and four- more than three times). Seven patients with hip necrosis (four- Arco Stage I, two- Arco Stage II and one- Arco StageIII), 1 patient with bilateral tibia stress fracture.

### Pathologies patients sex age average:

non-union - delayed healing fracture 10 2 F / 8 M 20 - 82 44 hip necrosis 7 5 F / 2 M 18 - 68 41 stress fracture 1 1 F 19 19

All cases were treated with  $26-28 \mathrm{Kv}$  and 3000-4000 pulses per treatment session. General anaesthesia was performed and fluoroscopy was used to localize the focus of the application. To evaluate bony consolidation of the non union and stress fracture conventional X-Ray and CT was used In the hip-necrosis the ARCO-classification was applied and MRI and X-Ray were used to assess the results .

### Results:

In six patients with non-unions, the healing was achieved. Three patients showed no consolidation and two patients are in follow up . One patient with a bilateral hip necrosis showed complete recovery of the disease , 3 showed improvement in pain and function although the MRI-images showed little changes in the damaged area and no significant modifications in size. One patient Stage III showed no modifications and one patient is still in follow up . One patient with bilateral stress fracture showed improvement in pain and function.

### Conclusion:

In this study the patients with non-unions, delayed healing fractures, stress fracture and hip necrosis showed a positive effect after being treated with shockwave therapy.

# Shockwave Surgery and Autologous Growth Factors Combined Therapy for Non Unions and Pseudoarthrosis

Authors: Leal Carlos MD, Lopez Juan C. MD, Herrera Juan M. MD, Reyes Oscar E. MD

**Institution**: Department of Orthopaedics

Orthopaedic Research Laboratory - Bosque University,

Bogota DC, Colombia

Bone healing in non unions and pseudoarthrosis has been a challenge for the orthopaedic surgeon since the beginning of times. Improved surgical techniques, better biomaterials and hardware, as well as the use of appropriate grafting and tissue banking has made the revision process for a non united fracture less often and more predictable. However, surgical procedures in non unions and pseudoartrosis always involve large operations that significantly increase pre and postoperative risk factors, and also represent a longer and more difficult recovery period and rehabilitation process. Many non invasive techniques have been implemented to enhance the process of bone healing in difficult circumstances. Extracorporeal shockwave stimulation of bone has proved that enhancement of the production of endogenous growth factors, free radicals and NO's is possible, and results in bone healing in unfriendly soil. These effects have been studied in both molecular biology and clinical scenarios and ESWT is currently one of the most important tools in the orthopaedic arsenal of the 21'st century. By means of stimulating bone with focalized high energy ultrasound in the form of repetitive shockwaves, today we are able to enhance the healing process by causing neo-vascularization, periosteal stimulation and cell differentiation that result on bone callus in areas that would otherwise need surgical intervention and grafting. This procedure is non invasive, and has proven to be able to replace surgical procedures in stable non unions with no serious associated complications reported in more than 15 years of worldwide application. However, shockwave application in bone requires usually high energy generators that cause pain during the procedure, and in many occasions it must be done under general anaesthesia in an operating room. The cost of these devices is high for many countries, and difficult to introduce in the therapeutic arsenal of many hospitals. Being a non invasive procedure, rehabilitation protocols are shorter and recovery time reduced, but healing time, as seen in X-Rays, CT Scans or MRI's, is probably similar to large surgical interventions. In order to find a system that would reach the same minimally invasive goals as ESWT, using less expensive devices, we have tried Radial Shockwaves in combination with the injection of Platelet Autologus Growth Factors (AGF's). Both Orthopaedic and Maxillo Facial Surgeons have used AGF's for many years to reach the same goals as Shockwave Surgery. AGF's can be easily obtained from the alpha granules of platelets from the own patient's blood. It can be prepared in the form of a gel obtained from the Puffy Coat portion of centrifuged blood, which can be mixed to auto or allografts during a surgical procedure. We have developed a protocol to apply Radial Shockwaves with energies of 0.3mJ/mm2, in order to stimulate vascularization and periosteal reaction in the area. We have used them only in non unions lying in bones not deeper than 1.5 inches, like tibia, ulna, distal femur and humerus. We give 4000 radial Shockwaves in the surrounding area, and under fluoroscopy we apply10 cc of AGF's in different points of the fracture soft callus. In selected cases, where there is a defect larger than 2 cm<sup>2</sup>, we mix the AGF's with lyophilised 300 micron bone allografts that act as an osteoconductor. All this procedure is done in a surgical room with no anesthesia and under aseptic surgical conditions. We have done 12 patients to date with stable postoperative non unions, in which the surgical procedure would have been a large incision that would involve hardware removal and replacement, bone drilling and grafting. Some of our patients also had thin skin after free grafts or vascular grafts from their original interventions that would indicate extra care for surgical approaches or higher energy ESWT. We have treated 5 tibias, 3 humerus, 2 distal femurs and 2 ulnas. All of them have healed promptly, with dramatic x-ray changes after 6 weeks. We have no complications related to the procedure and all patients and referring doctors are highly satisfied with the results. We believe that the use of radial shockwaves is not enough to create adequate bone healing by themselves, both because of the lower energy and the loss of flux density as it goes deeper into the tissues. The use of single AGF's is also a good addition to surgical procedures where the trauma caused by the surgery itself will cause revascularization and cell migration to the area where the growth factors would cause some effect. However, used percoutaneusly alone, the AGF's would act only as a seed in a dry soil, not being able to help in the process of bone healing. We have very impressive results so far, and this has been an interesting finding that must be reported to the scientific community, as we have not found any previous report of any form of ESWT & AGF combined therapy. Of course we need to go further in the research of which one is the primary therapeutic element, so we are currently working on an experimental model in dogs, analysing in four groups the effects of single ESWT treatment, single AGF treatment, ESWT & AGF combined, and a control group. We will present in June 2005 in the ISMST meeting in Vienna our clinical results as a case- series study, and the preliminary results of our experimental study in animals. This new approach to non unions could make the treatment even easier than high energy ESWT or other surgical alternatives.

# Extracorporeal Shock Wave Therapy in the treatment of delayed union and nonunion.

Authors: M.C. Vulpiani, M. Vetrano, F. Conforti, D. Trischitta, A. Ferretti

**Institution**: St. Andrea Hospital, University "La Sapienza" Rome, Italy

The pathologies of healing of bone fractures (delayed union and non-union) remain one of the major complications after skeletal trauma despite progress reached by surgical techniques and conservative approaches. Extracorporeal shock wave therapy (ESWT) has become a common treatment for orthopaedic disorders in the last decade. Many experimental and clinical studies have confirmed a positive effect of shock waves on fracture healing.

The purpose of this study was to examine the effect of ESWT on the treatment of delayed union and pseudarthrosis. Ninety-three patients were enrolled in this study. There were 52 males and 41 females with an average age of 42.6 years (range 15-73 years). 34 patients had a diagnosis of delayed union (mean, 4.9 months) and 59 were non-unions (mean, 16.7 months; range 6-84 months).

The results of treatment were assessed clinically and fracture healing was assessed with plain radiographs, CT, MRI and three-phase bone scintigraphy. High-energy shock wave treatment was applied using two different electromagnetic shock wave generators, Minilith® SL-1 (43 patients) and Modulith® SLK (50 patients), both developed by STORZ MEDICAL AG. The shock waves were applied in 3-5 sessions with 2500-6000 impulses at 0,25-0,4 mJ/mm2 energy flux density for Minilith® SL-1 and at 0,25-0,84 mJ/mm2 for Modulith® SLK. After treatment patients with fractures without ostheosynthesis were immobilized with various plaster casts or orthotic devices until an osseous reaction was proven. Follow up assessments were done at short, medium and long term.

The Student T Test was used for statistical analysis of data.

The assessment of fracture healing showed total consolidation in 69 patients (74%), partial consolidation in 11 patients (12%) and no apparent changes in 13 patients (14%).

The analysis of our results showed similar results in delayed unions (79%) and non-unions (71%). As foreseeable, differentiation was noted in cases of hypertrophic and oligotrophic pseudarthroses which showed significantly better results than those relating to atrophic non-unions.

Although our results appear to be more successful with long bones rather than short bones, they cannot be considered statistically relevant. With respect to devices used, it is not possible at this time to evaluate the performance of the two devices on the basis of preliminary results. Evaluation will be possible at a later date.

The extracorporeal shock wave therapy to be a safe and effective alternative treatment for delayed union and pseudarthrosis.

# Extracorporeal Shockwave Therapy for Non-Unions and delayed Unions

Authors: W. Schaden, A. Fischer, A. Sailler, A. Menschik, N. Haffner

Institution: Trauma Centre Meidling, Vienna, Austria

### Introduction:

Since December 1998, more than 1,200 non-unions were treated with shockwave therapy in the Trauma Centre Meidling with an electro hybraulical device (Ossatron, HMT). To compare different technologies from April 2004 till January 2005, 149 Patients with non-unions or delayed unions were treated with an electro magnetical device (Modulith, Storz Medical). Till February 2005, the results of 62 patients are available.

### Material and Methods:

The patients consisted of 25 (40%) female and 37 (60%) male with a mean age of 44,5 years (14-84). The mean age of the non-unions was 18,1 months. 31 (50%) were considered as delayed unions (3 to 6 months from the trauma or the last surgery concerning the bone) and 31 (50%) were older the 6 months (non-unions). All treatments were performed under general or regional anaesthesia. Analogue energy flux densities and number of pulses to the electro hydraulical device were used. If necessary immobilisation with plaster cast or splints were applied.

#### Results:

Out of 62 treated non-unions 48 (77%) achieved bony healing within 3 to 6 months after shockwave therapy. Compared to 593 (79%) bony fusions out of 755 treated non-unions with an electro hydraulical device no significant difference was observed.

Besides local swelling, peterheal bleedings no adverse effects were reported in both collectives

# Extracorporeal Shock-Wave Therapy in Chronic Stable Angina Pectoris

Authors: J.-P. Schmid

Institution: Swiss Cardiovascular Centre Bern,

Cardiovascular Prevention & Rehabilitation,

University Hospital (Inselspital), Bern, Switzerland

#### Introduction:

Extracorporeal shock wave therapy (ESWT) has generated great interest in cardiology since the first report of enhanced neovascularization by shock wave application at the tendon-bone junction in a dog model. Ischemic heart disease is the single leading cause of death in the industrialized countries and chronic stable angina pectoris is the most common manifestation of this disease. The treatment of choice is coronary revascularization, either by percutaneous coronary intervention or aorto-coronary bypass surgery. A substantial number of patients continue to experience precordial ischemic pain, either due to a lack of revascularization options or progression of the underlying disease. Alternative methods in the treatment of chronic angina are therefore warranted.

#### Methods:

In patients with chronic stable angina, the myocardial region of exercise induced ischemia is defined by myocardial scintigraphy. By means of ultrasound guidance, the focus of the shock wave generator can by directed to the region to be treated. In general, 200 shots with an energy of 0.09 mJ/mm2 are delivered per spot. According to the area at risk, between 9 and 40 spots are chosen to scan the whole ischemic region at each session. The treatment is delivered in 9 sessions, 3 sessions grouped in 3 to 5 days, with a time interval of 4 weeks between the second and third 3 sessions.

#### Results:

The treatment is well tolerated by the patients and no increase in cardiac enzymes or arrhythmias have been noted. Canadian Cardiologic Society functional class and exercise capacity improved as well as the quality of life score of the Seattle Angina Questionnaire after a follow-up of 6 months. The amelioration of the clinical status after treatment correlated with improved myocardial scintigraphic perfusion images.

### **Conclusions:**

In patients with chronic refractory angina ESWT is safe and well tolerated. It improves symptoms, exercise capacity and myocardial perfusion. The mechanisms by which shock waves promote perfusion are still unknown, but nonenzymatic nitric oxide synthesis and upregulation of VEGF mRNA expression might be some hints in favour of formation of new capillary networks.

# Extracorporeal Shockwave Therapy for Adult Osteochondrosis Dissecans of the Femoral Condyle

Authors: S. Marx, R. Thiele

**Institution**: IZS- Berlin International Centre for Shockwave Therapy

Since extrakorporeal shockwave therapy started to conquer the orthopaedics it determined new indications to be treated.

Aim of this report is to show the effct of ESWT on the adult Osteochondritis Dissecans of the femoral condyle.

As seen in earlier studies the shockwave application shows effect on bone-growth, on vascularization and on the cartilage tissue.

The mechanism of effectiveness is still under research but changes that take place in the body are described. High energy shock waves show a neosynthesis of bone, neovascularization and micro fractures that are induced by effects like cavitation, enhancement of higher production of TGF-\$1, VEGF, NOS and other factors. The Osteochondritis dissecans should therefore profit from these effects.

The study was performed with the Ossatron by HMT on a number of 71 patients. The patients included have suffered from Osteochondritis Dissecans Stadium I and II in MRI. All wanted to get a therapy except for surgery which was in their eyes, the last possibility. The patients were scored by a subjective score, a Visual Analogue Scale, the Larson-Score and the Brückl-Score.

Further the patients received MRI- examinations to show the development of the affected area. It will still be shown to be the best course of treatment as the number of shocks and intensity of energy-flux-density to get the best results in revitalization of the osteochondral damage for this study was only performed in a prefixed schedule. The results of this study will be revealed in the lecture.

As extracorporeal shockwave therapy seems to be a treatment with minimal side effects, it is understandable that we look out for new indications to be treated with shockwaves.

The Osteochondritis Dissecans is only to be treated effectively by surgical intervention and the results presented in publications are not encouraging for patients and doctors as the disease will lead to an osteoarthritis of the joint. The conservative treatment is based on the hope for a spontaneous healing supported by the reduction of physical strain for long period.

The extracorporeal shockwave therapy therefore might be a casual therapy for an still unsolved indication and further investigations on the mechanism of effectiveness will lead us to better statements to indications that will gain from this method. In our experience we later have case reports about the effectiveness of the shockwave therapy even in states of the Osteochondritis so as state three. This may lead us to the possibility of treating osteoarthritis successfully by shockwaves. We even found very good results in the treatment of acute posttraumatic osteochondral lesions (controlled by arthroscopy).

# Antibacterial effects of extracorporeal shock waves

Authors: L. Gerdesmeyer, H. Gollwitzer, C. Horn, C van Eiff

Institution: Technical University Munich

Dept. of Orthopedic Surgery and Sportstraumatology

Ismaninger Str. 22., D-81675 München

Despite considerable knowledge about effects of extracorporeal shock wave therapy (ESWT) on eukaryotic tissues, only little data are available concerning their effect on prokaryotic micro organisms. The objective of the present study was to determine the bactericidal activity as a function of energy flux density and shock wave impulse number. Standardised suspensions of Staphylococcus aureus ATCC 25923 and other clinical relevant species were exposed to different impulse numbers of shock waves with an energy flux density (ED) up to 0.96 mJ mm-2 (2 Hz). Subsequently, viable bacteria were quantified by culture and compared with an untreated control. After applying 4000 impulses, a significant bactericidal effect was observed with a threshold ED of 0.59 mJ mm-2 (P ; 0.05). A threshold impulse number of more than 1000 impulses was necessary to reduce bacterial growth (P ; 0.05). Further elevation of energy and impulse number exponentially increased bacterial killing. ESWT proved to exert significant antibacterial effect in an energy-dependent manner. Certain types of difficult-to-treat infections could offer new applications for ESWT.

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Authors: Maier M., Meurer T.

54. Radial Shockwaves in The Treatment of Chronic Gluteal trigger points as a common source of pseudosciatic pain and their therapy with radial shockwaves.

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55. Extracorporeal Shockwave Therapy In Myofascial Pain Syndrome.

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56. Heat-shock proteins induced by extracorporeal shockwaves as a further cellular defence mechanism against external stress argents

Authors: Dr.med.H.Neuland, Prof.Dr.H.J.Duchstein, Prof. Dr. M.Menge

57. Significance of reactive oxygen- and nitrogen - compounds as muscular pain modulators with reference to triggerpoint shock wave therapy

Authors: Neuland Helmut, Duchstein Hans-Joachim

58. Extracorporeal shock wave therapy induces degeneration and subsequent regeneration of nerve fibers innervating from DRG neurons in rat.

Authors: Ryo Murata, Seiji Ohtori, Nobuyasu Ochiai, Norimasa Takahashi, Kenji Takahashi\*, Takashi Saisu, Yuichi Wada, Hideshige Moriya

- 59. Second Application of Low-energy Shock Waves Has a Cumulative Effect on Free Nerve Endings Authors: N. Takahashi, T. Saisu, S. Ohtori, K. Takahashi, R. Murata, N. Ochiai, H. Moriya, Y. Wada
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- 61. A Trial of Shockwave-mediated plasmid DNA transfection Authors: Ryo Murata, Seiji Ohtori, Nobuyasu Ochiai, Keiji Takahashi, Takashi Saisu, Yuichi Wada, Hideshige Moriya
- 62. Evaluation of Extracorporeal Shock Wave (ESWT) Therapy in Experimental Induced Equine Osteoarthritis
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- 86. The Employment of E.S.W.T. in Avascular Necrosis in Growing Patients Authors: S. Russo, B. Corrado, M. Tullio, S. de Rosa, V. La Mantia, E. Astarita, E. M. Corrado



# Extracorporeal Shockwave Therapy for Chronic Skin Lesions

Authors: W. Schaden, C. Kölpl, A. Valentin, M. Pusch, R. Thiele\*

Institution: Trauma Center Meidling, Vienna, Austria

\* Zentrum für extracorporale Stosswellentherapie, Berlin

### Introduction:

Treating infected non-unions with soft tissue problems with ESWT we observed that there was also a positive effect on the skin. In most of the patients an extremely rapid healing of the wounds was observed. After successful animal trials performed at the department of plastic and reconstructive surgery of the University of Innsbruck we started our pilot trial.

#### Material and Methods:

Since September 2004, 102 patients with 104 chronic skin lesions were treated by means of ESWT. A special therapy head to defocus the shockwaves was constructed. All therapies were performed without any kind of anesthesia as an outpatient treatment. We used the same form of dressing after ESWT that was applied before, the treatment. Depending on the surface of the defect different number of pulses were applied. The patients were treated in 1 up to 6 sessions depending to their tendency of regeneration and epithelialization.

### Reason for skin lesion:

Posttraumatic 44 Venous ulcer 25 Arterial ulcer 15 Postoperative 10 Decubital Ulcer 5 Burning wounds 5 Total 104

## Results:

Out of the 104 patients 77 (74%) showed complete healing, 11 (10%) had more than 50% of epithelialization and 7 (7%) had less than 50%. 9 (10%) patients were lost of follow up. The treatment was tolerated by all patients without any kind of anesthesia. No adverse effects have been observed. In none of the cases an increase of symptoms was reported. After further pilot studies evaluating the most efficient treatment parameters, prospective randomized trials have to be performed to proof safety ness and efficacy of shockwave therapy in this new medical field.

# Randomized placebo controlled trial to determine the placebo effect size in orthopaedic

Authors: L. Gerdesmeyer, H. Vester, M. Henne

**Institution**: Technical University Munich

Dept. of Orthopedic Surgery and Sportstraumatology

Ismaninger Str. 22, D-81675 München

### Introduction:

The aim of the trial was to detect the placebo effect size in orthopaedic

#### Methods:

First step was a complete literature search to find out relevant parameters. 2nd step was to complete a feasibility study to verify published data. In the 3rd step we designed the trial in accordance to GCP E6 and E4 guidelines with power calculation, sample size calculation, etc.. 106 patients, suffering from chronic shoulder or heel pain received shame extracorporeal shock wave treatment after written informed consent. Randomly 52 patients was told to get the real therapy and 53 to get the shame treatment. The primary criteria was the subjective outcome on the visual analogue scale, the secondary criteria the Roles and Maudsley score. The primary end point was 1 month after treatment

### Results:

Both groups showed a decrease on the VAS. Patients who know to be in the placebo-group decreased with 6% from 6.7 to 6.3 [95% CI: 0,4 .. 11,1]. Patients who believed to be in the "real" group decrease with 21% [95% CI:13,3 .. 27,7] from 7.0 to 5.5. The same effect was also shown in the Roles and Maudsley Score. Retrospective analysis showed effective randomisation and blinding technique.

## Discussion and Conclusion:

The placebo effect is very important in orthopaedic treatment methods. The effect size reaches clinical relevance and must be discussed and controlled in every clinical study

# A Case Study: Calcific Popliteal Tendinits and it's effective treatment using Low energy shockwaves

Author: D.K. Jones

**Institution**: The London Lithotripter Centre

The patient was an international level 400m hurdler complaining of pain during flexion in the postero lateral aspect of the knee.

Ultrasound imaging prior and during localisation whilst performing ESWT treatment demonstrated a 3mm calcific deposit within the popliteus tendon insertion to the lateral femoral condyle.

The Lithotripter of choice was a Storz Modulith SLK incorporating a 7.5Mhz inline.

The protocol was to perform three ESWT sessions, 1 month apart, employing an energy flux density ranging between 0.07 and .026mJ/mm2.

Visual Analogue scores were recorded prior to the first and after the third treatment session.

No Analgesia was prescribed.

6 months after the first ESWT session complete dissolution of the calcific deposit was recorded on ultrasound imaging and the pain associated with the condition presented was now completely resolved allowing the athlete to train and compete at the highest level once again. This is a minimally invasive procedure with no long term side effects recorded by ourselves or the patient.

## Shockwave Therapy for Hip bursitis: retrospective study

Authors: A. Souza, P. Rockett, P. Santos

Institution: Ortosom, Porto Alegre, Brazil

Cortrel, Rio de Janeiro, Brazil Orthomaster, São Paulo, Brasil

### Aim:

The aim of this study was to evaluate the efficacy and the safety of extracorporeal shock wave therapy for the treatment of Hip Burisitis in three Brazilian Orthopaedics Clinics.

### Material and Methods:

In a multi-center, retrospective study, the effect of shockwave therapy was investigated in 32 patients with Hip Bursitis treated in the period of 21 months from June 2002 to February 2004. There were 25 women and 7 men with an average age of 63 (range, 41-79) 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, previous corticosteroid injection, neurological abnormality, gout, malignant diseases, blood coagulation disorders. Each patient was treated with 1200 impulses of shock wave, a 35 mm focus depth, and with an energy flux density of no more than 0.14 mJ/mm after local anaesthesia. One treatment was performed on 30 patients and 2 patients underwent a second 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.

### Results:

The study showed the efficacy and safety of ESWT were excellent in 34.4%, good in 53.1%, acceptable in 12.5%, and poor in 12.5%, 180 days after ESWT

# Shock waves as therapeutic possibility in Reflex Sympathetic Distrophy

Authors: Gigliotti S., Corrado B., Caputo R., Zincarelli C.

Institution: University of Naples "Federico II" - Department of Orthopaedics and Traumatology

Algodystrophy, Reflex Sympathetic Dystrophy, Bone Marrow Edema, Transient Osteoporosis and Complex Regional Pain Syndrome are probably different terms of the same pathology due to a vascular disturbance of bone: pathogenetic mechanisms are not totally clear but a disorder of the sympathetic regulation of micro vessels is involved certainly. The evolution is not foreseeable: many cases have a spontaneous resolution within six months but some cases are the onset of a necrotic lesion. Authors show some cases of R.S.D. of the hip and of the leg treated with shock waves and they emphasize the importance of correct criteria of inclusion (only cases in stage I according to the M.R.I. classification of Grimm: diffuse edema of bone with low signal in T1 and high signal in T2). Their protocol of treatment consists in two sessions of shock waves in the opposite direction with interval of two days, 3000 shots and 0,30-0,40 mj/mm2 of energy flux density. In all 50 cases Authors have recorded a reduction of pain within one month and a complete recovery of M.R.I. signal within three months. Authors analyze possible mechanisms of action of shock waves more supporting the reset of sympathetic disorder of micro circle and the effects of nitric oxide.

# Therapy With ESWT Associated With Physiokinesitherapy in The Treatment of The Post-Surgical Stiff Knee

Authors: P.Buselli<sup>1</sup>, V. Coco<sup>2</sup>, V.Bosco<sup>3</sup>, R. Saggini<sup>4</sup>

Institution: <sup>1</sup> A.O. della Provincia di Lodi,

- <sup>2</sup> P.O.AciReale, ASL3 Catania, <sup>3</sup> Clinica Villa Maria Bologna,
- <sup>4</sup> Cattedra di Medicina Fisica e Riabilitativa Università G.d'Annunzio Chieti ITALY

### Introduction:

Various authors have described the possible onset of an articular stiffness associated with tendinosis and fibroutization of the ligamentous structures, in many cases accompanied by ossification processes of the synovial and of the tendinous capsular formations as well as of the periarticular soft tissues.

The treatment with ESWT allowed to obtain good results in different calcific and degenerative pathologies of the tendinous structures, also including the ossific myositis. Therefore, this method has been suggested to patients before a possible surgical treatment.

#### Materials and Methods:

Five subjects have been treated (4 females - 1 male, aged on average  $51.2 \pm 12.7$ ) suffering from knee stiffness after one or more surgical operations associated with a patellectomy. The time elapsing from the latest surgical operation varies from 4 to 9 months. The reduction of range of motion was sometimes accompanied by pain symptoms.

The subjects have been treated with SW (with a shock wave unit of the spark gap electro-hydraulic type: OSSATRON OSA 140, HMT) with 2000 SW at 16kV (equal to 0,154mJ/mm2); treatment was repeated after two weeks.

After each treatment, the patients received a physiokinesitherapeutic treatment with passive (also forced) and active mobilization; 3 cases were able to perform exercises in a swimming pool with water temperature at  $38^{\circ}$ C.

### Results:

The initial mobility evaluation of the knee flexion-extension movement showed a mean ROM of 38,0° (± 13,5). After the first SW administration a recovery of the mobility was reported already during the first 48 hours and went on in the following days; such response led to repeating the treatment two weeks after the first one. Two weeks after the second treatment the patients' articular range of flexion-extension has been newly evaluated showing a mean ROM of 73,0 ( $^{\circ}(\pm 14.4)$ ) with an average increase of 92,1% (p < 0.001). Three months after the second ESWT session a further evaluation of the articular function has been made showing a mean ROM of 79.0 ( $^{\circ}(\pm 16.4)$ ) with an average increase of 107.9%. The pain symptom shows an improvement not to be related to the functional recovery. Variation of the x-ray picture shows an unstable evolution and this proves to be related neither to the functional recovery nor to a reduction of the pain symptoms.

#### **Conclusions:**

The clinical cases described are a very limited sample but the result obtained allows to view the suggested therapeutic protocol with great interest.

In the end, we can state that ESWT associated with adequate physiokinesitherapy has led to significant results.

The costs as well as the risks taken by the health care centre and by the patients proved to be substantially smaller than a possible surgical therapy.

# Therapy With ESWT Associated With Physiokinesitherapy in The Treatment of The Stiff Hip in P.O.A. Post-Coma

Authors: Buselli Paolo<sup>1</sup>, Coco Valeria<sup>2</sup>, Bosco Vincenzo<sup>3</sup>, Saggini Raoul<sup>4</sup>

Institution: <sup>1</sup> A.O.della Provincia di Lodi,

- P.O.AciReale, ASL3 Catania,
   Clinica Villa Maria Bologna,
- <sup>4</sup> Cattedra di Medicina Fisica e Riabilitativa Università G.d'Annunzio Chieti ITALY

### Introduction:

The articular stiffness of the hip linked to the P.O.A. onset is quite a frequent pathology in subjects who have suffered from coma. It is a disabling condition, often appearing in progressive form.

The treatment with ESWT has been suggested in the past for this specific pathology by Morosini, De Pretto, Bosco, proving good results. The cases described hereafter have to be considered as special ones, since the major clinical focalisation refers to the psoas muscle with severe disorder not only of the flexion-extension of the hip but also of the intra-extrarotation and a stiffness of the up-and-over movement of the pelvis. Therefore, the ESWT therapy has been suggested to these patients before a possible surgical treatment.

Materials and Methods: Three subjects have been treated (3 females, aged on average 28) suffering from hip stiffness after a coma episode; bilateral in 2 cases, one of these showing a complex P.O.A. both medially and laterally, monolateral in 1 case. The time elapsing from coma resolution goes from 5 to 8 months. The subjects have been treated with SW (with a shock wave unit of the spark gap electro-hydraulic type: OSSATRON OSA 140, HMT) with 3000 SW at 16kV (equal to 0,164 mJ/mm2); treatment was repeated after two weeks. After each treatment, the patients received a physiokinesitherapeutic treament with passive (also forced) and active mobilization.

### Results:

The initial evaluation of the hip flexion-extension movement showed a mean ROM of  $58,0^{\circ}$  ( $\pm$  20,5), whereas the intra-extrarotation showed a mean ROM of  $27,0^{\circ}$  ( $\pm$  5,7). Two weeks after ending the therapeutical cycle, the clinical evaluation showed a mean ROM of  $80,0^{\circ}$  ( $\pm$  16,0) in the flexion-extension and  $37,0^{\circ}$  ( $\pm$  8,4) in the internal-external-rotation. After three months a further clinical evaluation has been made showing a mean ROM of  $84,0^{\circ}$  ( $\pm$  19,2) with an average increase of 62,1% (p < 0,0005) in the flexion-extension and of  $39,0^{\circ}$  ( $\pm$ 9,6) in the internal-external-rotation with an average increase of 44,0% (p < 0,005). The x-ray picture doesn't show any significant evolution and this especially proves to be neither constant nor related to a functional recovery.

### Conclusions:

The clinical cases described are a very limited sample but the result obtained allows to view the suggested therapeutic protocol with great interest. The costs as well as the risks taken by the health care centre and by the patients proved to be substantially smaller that a possible surgical therapy. The ESWT proves to be a non invasive treatment, not especially expensive and without side effects when administered by experts.

## Treatment of Back Pain with Shock Wave Therapy

Authors: R. Akopyan, MD; M. Jeshurun, MD; Akopyan N.

Institution: The "Reability" Medical Institute, Ramat-Hasharon, Israel

For several years both ESWT and RSWT have proven to be effective in the treatment of a wide range of orthopedic pathologies.

Back pain is one of the most common medical problems in the U.S.A. It affects most people at least once in their lifetime.

Nevertheless, there is yet minimal experience regarding back pain treatment with Extracorporeal Shock Wave Therapy.

We currently present our experience in treating this application with ESWT (Medispec Ltd.'s OrthospecTM) and RSWT (Medispec Ltd.'s Orthopedic LithospecTM).

18 patients with back pain were treated in 22 treatment "cases" with ESWT, RSWT, or the combination of both treatments.

Out of 18 patients 12 were males and 6 females, with the average age of 51.2 years (21-84 years). Spinal pathologies were divided as follows: 11 -Cervical Spine out of which 7 were of cervical spine purely, and 4 - treatments of both cervical and lumbar spine; 11 treatments were of lumbar Spine, out of which - 7 were of lumbar spine purely and 4 - a combination of lumbar and cervical spines treatments.

Out of these 11 Lumbar treatments - 3 patients were treated by ESWT, 4 were treated by RSWT and 4 were treated by a combination of ESWT and RSWT. Out of 11 cervical treatment 3 were treated with ESWT, 4 with RSWT and 4 by a combination of ESWT and RSWT. All treatments were combined with Manual Therapy.

The treatment parameters for ESWT were as follows: Treatment intensity: 4-7, Treatment frequency: 150 shocks/min.; the total number of shock waves: 1000-5000, and the number of treatment sessions: 3-5.

The average treatment parameters for RSWT were as follows: Maximal treatment intensity, Treatment frequency: 20 Hz, and an average of 3.54 treatment sessions.

All patients have shown remarkable improvement both in pain intensity and in everyday function. Five patients are currently proceeding with treatment in spite of their clinical improvement. One patient with cervical pain who has improved returned with recurrent pain and is currently under treatment, and one patient with Spina Bifida and HLA B27 has returned with back pain at a different location.

No anaesthesia was needed prior to or during treatment and no imaging was required. Treatment was well tolerated, with no adverse events reported.

Thus, Shock wave treatment seems to be both safe and effective in the treatment of back pain.

# Radial Shockwaves in The Treatment of Chronic Muscular Pain of The Back: Clinical Application And First Clinical Results.

Authors: Maier M., Meurer T.

Institution: Oberammergau, Germany

Radial shockwaves are in clinical use for the treatment of chronic muscular pain of the back. This kind of therapy is named "trigger point shock wave application".

In the present pilot study 16 patients are included until today. All of them presented with chronic muscular back pain and with positive trigger points in the muscles of the back. All patients received 5 to 7 sessions of radial shock waves (2000 - 3000 pulses a session, 2,0 bar, 6 to 8 Hz). No local anaesthesia was used. Ultrasound jelly was used as coupling medium. Pain intensity was determined before, 6 weeks and 12 weeks after radial shock wave application using the Visual Analog Scale (VAS) from 0 points (minimum pain) to 10 points (maximum pain). At both time points following the treatment the value of the VAS improved compared to the measurement before treatment. No major side effects were observed.

Following the present pilot study "trigger point shock wave application" seems to achieve good clinical results in patients with chronic muscular pain of the back. However, the number of patients is low, the follow-up period is short and the patients population is inhomogeneous. Therefore, more detailed clinical studies must be carried out until the general benefit of radial shock waves for chronic muscular pain of the back might be recommended in general. Furthermore it is important to analyse possible side effects systematically.

Radial Shockwaves in The Treatment of Chronic Gluteal trigger points as a common source of pseudosciatic pain and their therapy with radial shockwaves.

Author: M. Gleitz

Institution: Orthopeadic office, 3 rue des Capucins, L-1313 Luxembourg

### **Introduction**:

Patients with chronic low back pain often complain about irradiation in their legs although they have no objective neurologic deficit. These irradiations are called "pseudosciatic" and mostly explained by the muscle triggerpoint theory of Travell & Simons. Pseudosciatic pain is due to trigger points in the gluteal muscles. The triggerpoint theory further includes the possibility of secondary insertion tendonitis due to an increase of intramuscular tension over longer periods.

In this clinical study the frequency and localisation of musculotendinous pathologies amongst chronic low back pain patients were examined and the results of a radial shockwave therapy described.

### Material and method:

In a group of 184 patients with chronic pseudosciatic pain (>12 months) the gluteal muscles and their insertion at the ilium and the greater trochanter were examined by palpation and the correlation to the duration of pain calculated (1 examiner).

The triggerpoint areas in the gluteal muscles were treated with radial shockwaves (Masterpuls, Storz) during 6-8 sessions and the result of therapy documented over 6 months.

#### Results:

92% of all patients with chronic pseudosciatic pain showed trigger points in the gluteal muscles and described a typical referred pain in the lower extremities during high pressure on these areas. Amongst these 184 patients 61% showed muscular trigger points only (average pain duration 1.8 years, VAS 7.3), whereas additional insertion tendopathies were found in 31% of the patients (average pain duration 3.7 years, VAS 7.6). The difference in pain duration was statistically significant (p<0.01), whereas the intensity of pain was not.

The treatment with radial shockwaves resulted in a significant reduction of pain after 6 months in the subgroup of pure muscular triggerpoints in 84% of patients (VAS 1.9) and a relief of the referred pain in 69%. In the subgroup with additional insertion tendopathies only 49% of patients profited from the trigger shockwave therapy (VAS 3.4) and described a relief of the pseudosciatic pain in 35%.

### Conclusion:

Muscular gluteal trigger points are a common source of pseudosciatic low back pain and are a risk factor for secondary insertion tendopathies. Whereas muscular trigger points respond well to the radial shockwave therapy, insertion tendopathies do not improve equally. Under practical considerations we recommend an early shockwave treatment of muscular trigger points in patients with pseudosciatic low back pain.

# Extracorporeal Shockwave Therapy In Myofascial Pain Syndrome

Author: H. Müller-Ehrenberg, MD

Institution: Orthopädische Privatpraxis

Dr.med. Hannes Müller-Ehrenberg

Tibusplatz 6

48143 M $\ddot{u}$ nster, Germany

Myofascial Pain Syndrome is one of the most common causes of acute and chronic pain of the musculo-skeletal system. It is characterized by myofascial trigger points (MTrPs), which are hyperirritable spots in a palpable tense band of skeletal muscle. MTrPs are caused by a dysfunction from involved motor endplates, which is followed by a segmental shortening of groups of sarcomeres.

Diagnostic approach is based on the criteria defined by J.Travell and D.Simons: while palpating the hyperirretable MTrP a characteristic referred pain and familiar pain (recognition) is elicited. Effective diagnosis and treatment requires clinical experience and diagnostic skill, especially palpation ability. Exact pressure or impulse with minimum irritation or even damage of the collateral tissue is needed to identify and release MTrPs.

The focussed extracorporeal shockwave therapy (ESWT) is, on the contrary to the radial ESWT, able to apply an exact mechanical impulse on a small spot to release MTrPs.

Moreover the focussed ESWT was also able to reproduce, while treating a MTrP, the referred and also the familiar pain of the patient.

In a pilot study 40 patients with various musculoskeletal pain have been examined and treated by an experienced medical doctor (Triggerpunkt-Therapeut -IMTT®) and identified MTrPs were treated by focussed ESWT (Piezoson 100 plus, Fa. Wolf). In more than 90% of the cases the characteristic referred pain and familiar pain (recognition) has been elicited by the focussed ESWT, when precisely the MTrP was hit by the exact impulse. This study revealed that the focussed ESWT is able to improve the diagnosis of MTrPs and also to treat musculoskeletal pain successfully.

Conclusion: In clinical routine there was so far no imaging method or laboratory test of MTrPs. Diagnosis depended entirely on history and physical examination. The use of the focussed ESWT detects MTrps accurately and will lead us more often to recognize muscle-tissue being the cause of most of musculoskeletal pain.

# Heat-shock proteins induced by extracorporeal shockwaves as a further cellular defence mechanism against external stress argents

Authors: Dr.med.H.Neuland, Prof.Dr.H.J.Duchstein, Prof. Dr. M.Menge

Institution: ZES Kronberg, Pharm.Institut Uni Hamburg

Marienkrankenhaus Ludwigshafen

The human organism provides in addition to the enzymatic-oxidative system a further defence mechanism through the so-called stress proteins against reactive oxygenous and nitrogenous species (RONS). Part of this defense mechanism is the group of heat-shock proteins (HSP's), which can be formed quickly and substantial quantities as a cellular response to external physical or chemical stress.

So far, HSP's are found in nearly all pro- and eukaryotic cells. They are divided into groups according to their molecular weight in kilo Dalton.

Cellular stress-inducing agents of muscles and tendons are hyperthermia, ischaemia, denaturation of proteins caused by various chemical and physical effects and bodily strain.

Through mechanical irritations of muscles and tendons we were able to bring about the formation of heat-shock proteins in muscular and tendineous tissue. As mechanical stress argent we used extracorporeal shockwaves.

Subsequently, fine-needle biopsis were carried out at certain time intervals. Using the western blotting technique, we were able, to prove the formation of heat-shock proteins and their mRNA with monoclonal HSP-antibodies.

It is worth noting, that the frequency and intensity of stimulation appear to play a crucial role in the formation of heat-shock proteins.

# Significance of reactive oxygen- and nitrogen - compounds as muscular pain modulators with reference to triggerpoint shock wave therapy

Authors: Neuland Helmut, Duchstein Hans-Joachim

Institution: ZES Kronberg, 61476 Kronberg, Germany

Pharm.chemisches Institut Universität Hamburg

Hamburg Germany

One of the effects of the impact of various complex, signal emitting stress situations is the formation of free radicals. In the past, free radicals were primarily thought of a causing so-called oxidative stress. More recently it was discovered that they also play a significant role as signal and modulator molecules, particularly with regard to the activation of cellular defense mechanisms against various stress factors acting on the cell itself. The changes of the cellular redox system through oxidation and nitrolysation of other molecules or parts thereof are at the origin of the crucial role as signal and modulator molecules.

These changes are brought about through RONS (reactiv4 oxygenous and nitrogenous species). The formation of nitrogen oxide (NO) plays an important role in the occurrence of muscle pain. Nitrogen oxide blocks, through interaction with thiolat ions(cystein fragments), the receptors NMDA (N-methyl d-asparate) and NKI (nedrokinin I).

Neutrotransmitters like exitatory eninoacids (e.g.glutamate) and neuropeptides such as aomatostatin, substance and calcitonin-gene-related peptides are thereby deactivated. Through this mechanism the virtuous circle of continuous sensibilisation of muscular nociceptors and the related continuation of a local edema, accompanied by the release of bradikinin, is interrupted. We obtained evidence of the presence of nitrogen oxide in vitro through ERP(electron paramagnetic resonance) spectroscopy.

In vivo we were able to obtain evidence by using an NO-analyzing agent where a reaction takes place between NO and ozone resulting in chemiluminescence.

As mechanical stress agent we used extracorporeal shock waves.

# Extracorporeal shock wave therapy induces degeneration and subsequent regeneration of nerve fibers innervating from DRG neurons in rat.

**Authors**: Ryo Murata\*, Seiji Ohtori\*, Nobuyasu Ochiai\*, Norimasa Takahashi\*, Kenji Takahashi\*, Takashi Saisu\*\*, Yuichi Wada\*\*\*, Hideshige Moriya\*

Institution:: \*: Department of Orthopaedic Surgery, Graduate School of Medicine, Chiba University, Chiba, Japan

- \*\*: Division of Orthopaedic Surgery, Chiba Children's Hospital, Chiba, Japan
- \*\*\*: Department of Orthopaedic Surgery, Teikyo University Ichihara Hospital, Ichihara, Chiba, Japan

### Introduction:

Extracorporeal shock wave therapy (ESWT) has been applied to the management of various painful orthopaedic disorders. However, only a few reports have described the mechanism of the analgesic effect from this therapy. In this study, we investigated the analgesic effect of ESWT by immunohistological evaluation of dorsal root ganglion (DRG) neuron of rat.

### Methods:

Activating transcription factor 3 (ATF3) is regarded as a marker of nerve injury, and growth-associated phosphoprotein (GAP43) is used as a marker of nerve regeneration. We examined ATF3 and GAP43 expression profiles in rat DRG neurons after ESWT.

Shock waves were applied to the skin of both hind paws in 28 rats, and 4 naive rats were used as controls. After 1, 2, 4, 7, 14, and 28 days, rats were sacrificed and the bilateral L4 and L5 DRGs were evaluated immunohistochemically.

#### Results:

The average number of ATF3-immunoreactive neurons significantly increased in the treated rats at each time point, and 77.0% of those neurons also exhibited immunoreactivity for GAP-43. Among the ATF3-immunoreactive neurons, 76.8% were large diameter cells (>30&\pmu956;m).

## Discussion:

We showed that ESWT caused neuronal damage as represented by ATF3-immunoreactive neurons. Axonal regeneration was also confirmed by the expression of ATF3/GAP43 double-immunoreactive neurons. The significant increase in the number of ATF3-immunoreactive neurons observed after ESWT was sustained for at least 28 days. This result, however, does not assure the long-term analgesic effect of ESWT. The regeneration of nerve fibres which indicated by ATF3/GAP-43 double immunoreactivity began within 24 hours of ESWT, and 77.0% of ATF3-IR neurons were also reactive for GAP-43. This finding may relate to the temporary analgesic effect of ESWT in clinical subjects in whom repeated treatments are often necessary. With regard to the size distribution of ATF3-immunoreactive neurons, 23.2% were small and 76.8% were large, respectively. Large-diameter fibres from large neurons may be more sensitive to ESWT than small-diameter fibres from small neurons. The degeneration of nerve fibres originating from small ATF3-immunoreactive neurons may cause alleviation of pain because these fibres are mainly small-diameter fibres, which are involved in nociception and temperature perception. The degeneration of large-diameter fibres indicated by the expression of large ATF3-immunoreactive neurons may also relate to the analgesic effect of ESWT from the evidence that these fibres play a crucial role in some types of painful condition such as allodinia.

# Second Application of Low-energy Shock Waves Has a Cumulative Effect on Free Nerve Endings

**Authors**: N. Takahashi<sup>1</sup>, T. Saisu<sup>2</sup>, S. Ohtori<sup>3</sup>, K. Takahashi<sup>4</sup>, R. Murata<sup>3</sup>, N. Ochiai<sup>3</sup>, H. Moriya<sup>3</sup>, Y. Wada<sup>4</sup>

#### Institution:

- <sup>1</sup>:Department of Orthopaedics, University of California, San Diego, San Diego, US.
- <sup>2</sup>:Chiba Children's Hospital, Chiba, Japan.
- <sup>3</sup>:Department of Orthopaedic Surgery, Graduate School of Medicine, Chiba University, Chiba, Japan.
- <sup>4</sup>:Department of Orthopedic Surgery, Teikyo University School of Medicine Ichihara Hospital, Ichihara, Japan.

The aim of this study is to evaluate whether the repeated shock wave application provides a cumulative effect regarding the degeneration of cutaneous nerve fibres, comparing with the degeneration effects associated with the single application. We used 36 male rats. Four rats were study controls. Shock waves were applied to the left first globular foot pad of the remaining 32 rats. After 14 days, 16 of these rats received a second, identical shock-wave application. The foot pads of the rat hind paws were then resected on days 7, 14, 28 and 42 after final shock wave application. Foot pad sections were processed immunohistochemically using antibodies to protein gene product (PGP) 9.5 and calcitonin gene-related peptide (CGRP). We compared the number of epidermal nerve fibres between rats receiving one application of shock waves and rats receiving two applications. During the first four weeks, there was nearly complete degeneration of epidermal nerve fibres in both groups. By the end of six weeks, re-innervation of the epidermis had begun in the single application group. Re-innervation occurred significantly more slowly in the repeated application group than in the single application group. These data show that a second application has a cumulative effect on nerve fibres. The results of the present study suggest that multiple applications of low-energy shock waves could provide longer-lasting antinociceptive effect, comparing with a single application.

# Extracorporeal Shock Wave May Enhance Skin Flap Survival in an Animal Model.

Authors: Meirer R, Kamelger FS, Huemer GM, Wanner S, Piza-Katzer H.

**Institution**: Department of Plastic and Reconstructive Surgery,

University Hospital of Innsbruck, Leopold-Franzens University,

Anichstrasse 35, A-6020 Innsbruck, Austria.

Several methods have been used in an attempt to increase blood supply and tissue perfusion in ischemic tissues. The authors investigated the effect of extracorporeal shock wave (ESW) treatment on compromised skin flaps. For this purpose, the epigastric skin flap model in rats, based solely on the right inferior epigastric vessels was used.

Twenty male Sprague-Dawley rats were divided into two groups (ESW-group, Control group) of 10 rats each. The ESW-group was administered 2500 impulses at 0.15 mJ/mm(2) immediately after surgery, whereas, the control group received no treatment. Flap viability was evaluated on day 7 after the operation. Standardised digital pictures of the flaps were taken and transferred to the computer, and necrotic zones relative to total flap surface area were measured and expressed as percentages.

Overall, there was a significant reduction in the surface area of the necrotic zones of the flaps in the ESW group compared to the control group (ESW group: 2.2+/-1.9% versus control: 17.4+/-4.4% (p < 0.01). In this study, the authors demonstrated that treatment with ESW enhanced epigastric skin flap survival, as confirmed by the significant reduction of necrotic flap zones. ESW treatment seems to represent a feasible and cost effective method to improve blood supply in ischemic tissue.

## A Trial of Shockwave-mediated plasmid DNA transfection

**Authors**: Ryo Murata\*, Seiji Ohtori\*, Nobuyasu Ochiai\*, Keiji Takahashi\*, Takashi Saisu\*\*, Yuichi Wada\*\*\*, Hideshige Moriya\*

## Institution:

- \*: Department of Orthopaedic Surgery, Graduate School of Medicine, Chiba University, Chiba, Japan
- \*\*: Division of Orthopaedic Surgery, Chiba Children's Hospital, Chiba, Japan
- \*\*\*: Department of Orthopaedic Surgery, Teikyo University Ichihara Hospital, Ichihara, Chiba, Japan

### Introduction:

Viral vectors have been shown to be effective for gene transfer with high efficacy rate. However, for the therapeutic application it requires a number of improvements including the issues of safety, immunogenicity. Non-viral gene transfer systems are safe and easy to apply, but low efficacy rate remains unsolved. Among these methods ultrasound-mediated plasmid DNA transfection with microbubble agent is reported to be useful and reveal a certain level of efficiency. In considering an ideal gene therapy for orthopaedic disorders, to modify non-viral plasmid DNA transfection would be desirable. Thus we tried to develop shockwave-mediated plasmid DNA transfection.

## Methods:

Male rats (200-300g) were used for the experiment. Previously conditioned luciferase plasmid DNA solution and pEGFP plasmid DNA solution were injected directly into the pretibial muscle of the rat hindlimb under general anaesthesia. After that low-energy extracorporeal shock waves were exposed to the identical area. Two days later they were sacrificed and the muscles were harvested. GFP expression was observed by fluorescence microscope and luciferase activity was quantitatively measured by a luciferase assay system to evaluate efficacy rate of gene transfection. The advantageous effect of a microbubble agent (Optison) was also evaluated.

#### Results:

GFP expression and luciferase activity were significantly enhanced when the specimens were exposed to shock waves with Optison. Plasmid DNA injection without Optison or shock wave application was failed to increase transfection efficiency. Complication was not occurred except for minor subcutaneous hemorrhage of the exposed site.

## Discussion:

We showed that the shockwave-mediated plasmid DNA transfection was achieved with a microbubble agent. The cavitation effect, which is augmented by this agent, may cause transient hole formation on the neighbour cell surface. Plasmid DNA may be transferred into the target cell through this hole. This phenomenon called as Sonopolation may explain the mechanism of our method. The efficacy rate of gene transfection is not as high as other methods such as adenoviral vectors. Although it needs so many improvements before application for the clinical use, this safe and easy method may provide a possibility of gene therapy for various orthopaedic disorders.

# Evaluation of Extracorporeal Shock Wave (ESWT) - Therapy in Experimental Induced Equine Osteoarthritis

Authors: C.W. Mc Ilwraith, D.D. Frisbie, C.E. Kawcak

**Institution**: Equine Orthopaedic Research Center

Colorado State University, 2503 Bay Farm Road

Ft. Collins, CO 80523

There is some experimental evidence and anecdotal clinical impression of extracorporeal Shock Wave Therapy (ESWT) for the treatment of osteoarthritis (OA)<sup>1,2,3</sup>. The study was a blinded, experimentally controlled, randomized block design that used 24 horses in an established model of OA<sup>4</sup>. On day 0 of the study, arthroscopic surgery was performed on both middle carpal joints of horses and OA induced in one middle carpal joint. On day 14, horses were divided into three treatment groups, sham control, positive control (intramuscular PSGAG), and ESWT treated. The sham control group was treated similarly to the ESWT treated group in all respects except that bubble wrap was applied to the probe end to absorb all of the energy. The ESWT group received treatment on days 14 and 28 using a VersaTron® 12 mm probe. 2000 Shock Wave level were given on day 14 and 1500 Shock Waves on E6 level on day 28. Energy was delivered mainly to the middle carpal joint capsule attachment, but some delivered to the area of fragmentation. At day 14, horses began a strenuous treadmill exercise program.

Significant improvement in clinical lameness was noted at the first evaluation time point post-treatment (14 days) in the ESWT-treated horses compared with both the sham and positive control. The subsequent improvement was also noted at days 42, 56, and 70. Both the positive control and the ESWT horses had significant improvement in synovial fluid TP levels within 14 days of treatment, indicating less synovitis compared with sham control horses. Improvement with both Adequan® and ESWT treatment was also noted in the amount of glycosaminoglycan (GAG) released into the bloodstream 14 days post-treatment.

In conclusion, treatment with ESWT reduced the clinical signs of pain measured by lameness evaluations (this pain was even reduced 42 days after the last treatment, which was the longest time point measured). There was no significant improvement in response to flexion, implying that improvement in lameness was not caused by local desensitization of the region, or more specifically the joint capsule. Currently synovial fluid protein, another parameter of synovitis, was reduced with ESWT. There was no difference in articular cartilage parameters suggesting that ESWT had a greater effect on the soft tissue surrounding the joints compared with the articular cartilage.

### References and Footnotes:

Presenting Authors Email: wayne.mcilwraith@colostate.edu

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# Effects of Extracorporeal Shock Waves on Chondrocytes From Osteoarthritic Human Subjects

Authors: B. Moretti, F. Iannone, M. Corrado, P.A. Iasella, V. Patella

Institution: Ūniversità di Bari - Istituto di Clinica Ortopedica Federico II, Italy

## Objective:

A key role in the pathophysiology of articular cartilage is played by cell/extra-cellular matrix (ECM) interactions, which are mediated by cell surface integrins. In a physiologic setting, integrins modulate cell/ECM signaling, essential for regulating growth and differentiation and maintaining cartilage homeostasis. During OA, abnormal integrin expression alters cell/ECM signaling and modifies chondrocyte synthesis, with the following imbalance of destructive cytokines over regulatory factors. IL-1, TNF-alpha and other pro-catabolic cytokines activate the enzymatic degradation of cartilage matrix and are not counterbalanced by adequate synthesis of inhibitors(IGF, TGFb, IL-10).

We investigated the effects of extracorporeal shock waves on the expression of IL-10, TNFa ,b1 integrins (CD29) on chondrocytes from osteoarthritic human subjects.

#### Methods:

Articular cartilage was obtained from 9 patients with osteoarthritis (OA) undergoing surgical knee replacement. Chondrocytes were isolated by enzymatic digestion from articular cartilage. Chondrocytes of Group A were treated with ESWT with an electromagnetic lithotripter (MINILITH SL1 by STORZ MEDICAL) by selecting two different energy levels (0,055 - 0,17 mJ/mm2) and two total impulses (500, 1000) for each level. The Control Group (B) received no shock wave treatment but was maintained with the device off for the same time.

The cells from each group (A, B) were cultivated (37°C, 5% CO2) for 48 hour. The biological activity and viability were evaluated at 24 and 48 hours after treatment. Cytokines expression were carried out by flow-cytometry.

## Result:

Significant reduction in IL-10 and TNFa expression were found in Group A as compared to controls; this effect was seen in cultures receiving the highest energy treatments. No significant differences were found in b1 integrins (CD29) expression.

### Conclusion:

Our preliminary investigation revealed that extracorporeal shock wave treatment at lowest energy level does not cause cytotoxicity to human chondrocytes.

On the other hand, the lowest level appeared to significantly reduce the catabolic parameter. Further evaluation of the effect of ESWT on chondrocytes is indicated.

# Wnt3 and Wnt5 Proteins Mediate Shock Wave-Promoted Osteogenic Differentiation of Mesenchymal Stem Cells

Authors: KD Yang, CJ Wang, FS Wang, YT Huang, YC Sun

Institution: Departments of Medical Research and Orthopedic Surgery, Kaohsiung Chang Gung Memorial Hospital, Kaohsiung 833, TAIWAN

Osteogenesis has been implicated in recapitulation of embryonic skeletal development. The Wnt family of growth factors are important regulators of skeletogenesis. In animal studies, we have reported that shock waves (SW) can promote osteogenic differentiation of mesenchymal stem cells through TGF-beta-, BMP- and VEGF-mediated signal transduction. Here, we further found that SW promotion of osteogenic differentiation of bone marrow stromal cells mediated by the Wnt and beta-catenin-dependent pathway. SW treatment (0.16 mJ/mm2, 1 Hz, 500 impulses) promoted cell proliferation, alkaline phosphatase activity and mineralized nodule formation of primary human bone marrow stromal cells. Real-time PCR results showed that SW increased Wnt3a and Wnt5a, but not Wnt7a mRNA expression of cell cultures. Inhibition of Wnt3a and Wnt5a signalling by Wnt3a and Wnt5a neutralizing antibodies reduced the promoting effect of SW on osteogenic differentiation of stromal cells. Further studies demonstrated that SW significantly promoted cytosolic beta-catenin accumulation and nuclear osteogenic transcription factor Cbfa1/Runx2 activation. Wnt3a and Wnt5a neutralizing antibodies reduced SW-enhanced cytosolic beta-catenin and nuclear Runx2 activation. Mesenchymal cells responded to recombinant Wnt3a and Wnt5a protein by increasing cytosolic beta-catenin expression, nuclear Runx2 activation and bone nodule formation. Moreover, serum harvested from patients with non-union receiving SW treatment increased alkaline phosphatase activities and bone nodule formation of mesenchymal cells that were blocked by Wnt3a and Wnt5a neutralizing antibodies Taken together, we have shown that SW increased Wnt3a and Wnt5a synthesis followed by cytosolic beta-catenin accumulation and nuclear Cbfa1/Runx2 activation, resulting in an increase of osteogenic differentiation of mesenchymal cells.

## Insights Into The Molecular Mechanisms of Shockwave Mediated Analgesia

Authors: Maier M., Tischer T., Hausdorf J., Saisu T., Schmitz C.

**Institution**: Munich, Chiba, Maastricht

The biologic action of shock wave application on the muskuloskeletal system is understood poorly. To prove the hypothesis that alterations of tissue concentrations of substance P and prostaglandin E2 are involved in biologic actions - such as pain and analgesia - of shock waves, shock waves with energy flux density of 0.9 mJ/mm2 (1500 pulses at 1/second) were applied in vivo to the distal femur of rabbits. The concentrations of substance P and prostaglandin E2 eluted from the periosteum of the femur were measured. Compared with the untreated contralateral hindlimbs, substance P release from the periosteum from the femur was increased 6 hours and 24 hours after extracorporeal shock wave application, but was decreased 6 weeks after extracorporeal shock wave application. Remarkably, there was a close relationship between the time course of substance P release found here, and the well-known clinical time course of initial pain occurence and subsequent pain relief after shock wave application to tendon diseases. Accordingly, substance P might be involved in the biologic action of extracorporeal shock wave application on tissue of the musculoskeletal system.

# Deep Partial Thickness Burn Injury And The Effect of ESWT: an Experimental Investigation in Rats.

Authors: Kamelger FS, Djedovic G, Meirer R, Piza-Katzer H.

**Institution**: Department of Plastic and Reconstructive Surgery,

University Hospital of Innsbruck, Leopold-Franzens University,

Anichstrasse 35, A-6020 Innsbruck, Austria.

Extracorporal shock wave therapy enhances tissue vascularisation and neoangiogenesis. Recent animal studies in our lab showed an improved tissue regeneration using ESWT. Deep partial thickness burns most of the time require skin grafting. This surgical intervention frequently causes a functional as well as aesthetical dissatisfying outcome. The aim of this study was to demonstrate the effect of ESWT on skin regeneration in second degree burns. Two standardised deep partial thickness burns were applied to the back of 30 male Wistar rats, respectively. Immediately after the burn, ESWT was performed in rats (N=30; Group 1). The second group did not receive any treatment (N=30; Group 2). At day 5, 10 and 15 five rats of each group were analysed. The degree of re-epithelization was documented using digital photography and histology. Statistical analysis was performed. ESWT enhanced the percentage of wound closure over time (group 1) as compared to the group 2 (p;0.05). The re-epithelialization rate could be improved significantly at days 5 and 15 (p;0.05). Extracorporal shock wave therapy improves skin regeneration of deep partial thickness burns in rats, as confirmed by a significant reduction of wound areas and a significant increase of re-epithelialization. In this study we could show impressively the potential of this technology in skin applications.

# Cellular Response of Primary Human Line Cultures in Petri's Capsule to Application of Shock Waves

Authors: B. Corrado, S. Russo, R. Campese, L. Vallefuoco\*, F. Di Meglio\*, S. Montagnani\*

### Institution:

Department of Surgery, Orthopedics, Traumatology and Rehabilitation,

\* Department of Biomorphologic and Functional Sciences

"Federico II" University of Naples (ITALY)

One of the greater controversies concerning the action mechanisms of Shock Waves is represented by their biological effect on the alive tissues and especially on cells. The comprehension of such effects could be a remarkable step in the knowledge of this technique in order to improve the clinical application and to overhaul the current therapeutic protocols, especially concerning dosages and application fields.

To such purpose the authors have treated a high number of samples of primary line cells: osteoblasts, fibroblasts, cardiac stem cells, hemopoietic stem cells etc. The treatment has been carried out in a Petri's capsule with 800 Shock Waves at an energy level between 0.030 and 0.10 mJ/mm2. The cell cultures have been exposed to a single application of Shock Waves and then observed and evaluated in various appearances (modifications of mitotic index, percentage of cellular survival, activation/deactivation of enzymatic chains and metabolic activities) during the following weeks, always comparing the results with the ones in no treated cellular cultures. The authors report the results achieved and discuss widely about their clinical involves.

# Extracorporeal Shock Waves Induce Production of Bone Growth Factors in Osteoblasts

**Authors**: J. Hausdorf<sup>1</sup>, M. Maier<sup>2</sup>, M. Delius<sup>3</sup>

### Institution:

- <sup>1</sup> Orthopaedic Department, Ludwig-Maximilians-University Munich
- <sup>2</sup> Rheumaklinik Oberammergau
- <sup>3</sup> Institute for Surgical Research, Ludwig-Maximilians-University Munich

The molecular events following shock wave treatment of bone are too a large extent unknown. Nevertheless patients with osteonecrosis and non unions are already treated partly successfully with extracorporeal shock waves. In our study we isolated osteoblasts from bone pieces of patients undergoing knee or hip replacement surgery, subjected the cultured cells to shock waves and investigated the supernatants for bFGF, TGFbeta1 and VEGF.

After collagenase treatment cells were cultivated and characterised using FACS analysis. 95% of the cells were CD 44+ and CD 34-, CD14-, CD3- and CD 4-. After conditioning with an osteogenic medium containing Dexamethasone, Ascorbate and Beta-Glycerolphosphate cells showed a homogenous mineralisation-pattern in the v. Kossa staining.

These cells were subjected to 250 or 500 shock waves at 25 kv using an experimental electrohydraulic lithotripter (Dornier XL 1). After shock wave treatment cell viability was determined and cells were seeded at 100000 cells in 12 well plates. After 24, 48 and 72 h the cell number was determined and the supernatant was frozen. The levels of the bone and vascular growth factors bFGF, TGFbeta1 and VEGF were examined using ELISA. A control group was treated in the same way without receiving shock waves.

After 24 h there was a significant increase in bFGF levels ( $P_i0.05$ ) with significant correlation ( $P_i0.05$ ) to the number of impulses. TGFbeta1 showed an time dependent increase with a peak at 48 h which was not significantly different from the control group. VEGF showed also a tendency to be shock wave induced but with no significance.

For the first time it was shown that bFGF as an important growth factor in new bone formation is produced by human osteoblasts treated with shock waves.

This may be one piece in the cascade of new bone formation following shock wave treatment and may lead to a more specific application of shock waves in orthopaedic surgery.

## Osteochondral repopulation with help of intermittent extracorporal shockwaves and simultaneous intra-articular application of Hyaluronan. Biomechanical and biochemical basics

Authors: H.G.Neuland, H.J.Duchstein

Institution: ZES Kronberg - Chem.pharmazeutisches Institut Universität Hamburg

Through the effect of mechanical stress on hyalin cartilage tissue an induction of special physical-mechanical signals is achieved, which are able to initiate specific inter- and intracellular biochemical reactions within the chondrocyts or their precursor cells (fibroblasts or stem-cells). Furthermore, they activate special growth factors and they are able to suppress or induce special enzymes, which are important for the osteochondral metabolism. By the way, the hyalin cartilage is hypo cellular, avascular, aneural and alymphatic. That means that every single cartilage cell has much higher regenerative power than other tissue cells, because the chondrocyts are self-sufficient with regard to their environment.

The extra cellular matrix (ECM) of the cartilage contains various protein fibres interwoven in a hydrated gel composed of a network of glycosaminglycan (GAG) chains.

Hyaluronan is the simplest of the GAG's. Whereas other GAG's are synthesized inside the cell and released by excytosis, hyaluronan is spun out directly from the cell surface by enzyme complex embedded in the plasma membrane. Hyaluronan synthesises from the basal side of an epithelium, for example, often to create a cell-free space into which cells subsequently migrate. Furthermore Hyaluronan is an important constituent of joint fluid, where it serves as a lubricant.

This both facts are the basic idea for our pilot study:

- The induction of the repopulation of chondrocyts by activation of the precursor-cells ( fibroblast and stem cells).
- The setting-up of new intercellular space for the new developed chondrocyts by hyaluronan.

# First results of pilot study: osteochondral repopulation induced by extracorporal shockwaves and intra-articular Hyaluraninjection - Evaluation of 118 patients

Authors: H.G.Neuland, A.Lang, V.Böhler, M. Kraemer, St.Mathieu, D.Khorram-Sefat, M.Menge, R.Rädel

Institution: ZES Kronberg, Radiologie Krankenhaus Sachsenhausen-Frankfurt

Marienkrankenhaus Ludwigshafen, KVB Klinik Königstein,

Centre hospitalaire Wissembourg (France), Orth.Praxen Mettlach, Herne, Heilbronn

The study referred mainly to knee-lesions: Gonarthrosis, osteochondrosis disecans, acute chondral lesions. The examination were divided into four groups:

- 1. Diagnostic and if necessary surgal arthroscopy, ESWT, Hyaluronan injection
- 2. Only ESWT and Hyaluronan injection
- 3. Only ESWT
- 4. Only Hyaluronan injection

From the outset the study was accompanied by clinical examinations. Follow-up examinations were done four times at three-month intervals.

Examination of the sensitivity to pain by VAS (visual analogue scale) and the functional maximum load by Lysholm and HSS (hospital of special surgery) score were carried at the beginning, three, six and twelve month respectively after, if required, two years.

All groups started with MRI- examination. Control took place after six and twelve month. Previous clinical results: 31 patients Outerbridge - stadium I, all after therapy without complains during a time interval between 3 and 16 months. 25 of this group are sportsmen with state of diagnostic arthroscopy, complains and minimal 1 year with therapy resistance complains, including the end of their sportive activity. All of them do sports again.

43 patients Outerbridge - stadium II, 70% after the rapy without complains during the period of treatment from 3 to 24 months. The rest of 30% only complains after long stress, mainly content.

27 patients - Outerbridge stadium III, significant improvement 65%, mainly improvement of stress pains and prolongation of the walking range.

25% of the patients improvement, but remaining complains; a second attempt of therapy is planned. 10% no change of findings.

First results of 18 patients with rhizarthrosis: 8 patients stadium I and III all of them without sequelae 4 patients stadium III borderline complains

4 patients stadium IV no improvement

Treatment of patients with posttraumatic cartilage lesions in lower extremities with intermittent extracorporal shockwaves and intra-articular application of hyaluronic acid

Authors: P.Kraemer, H.G.Neuland

#### Institution:

Centre Hospitalaire, Wissembourg (France) ZES Kronberg (Germany)

Starting in October 2003 patients with posttraumatic cartilage lesions of varying severity have been treated with intra-articular injection of hyaluronic acid and intermittent extracorporal shockwaves at the surgery ward of the hospital at Wissembourg, France.

The period of discomfort of patients treated so far ranged from one to five years. In addition to the clinical examination at the beginning of the treatement, subjectiv registrations of complaints using VAS (visual analogue scale) and of mobile functions using the Lysholm score and HSS (hospital of special surgery) score were carried out.

The status of an admitted patient objectively registered through MRT examination with a standard procedure of cartilage description of medium size and larger joints in sagital and coronal cross-section.

T1-assessed spin-echo pulse sequence (SE)

T2-assesses turbospin-echo pulse sequence with fat suppression (TSE)

T1-assesses fat-suppressed gradient echo sequence (GE) with 3D-data acquisition (cartilage sequence).

The intra-articular hyaluronic acid injection was done five times at weekly interwals with a native molecular hyaluronic acid drug (e.g.Hyalubrix). The subsequent intermittent shockwave treatments were carried out at 2-finger distance focused on the center of cartilage lesion. Length of treatment: 2000 impulses with 400 impulses each per location of treatment, pressure maximum 20 - 40 MPa, frequency 1-2 Hz.

Clinic control examinations with VAS, Lysholm- and HSS-score six weeks and subsequently 3,6 and 12 month after the beginning of treatment.

Results of MRI - controls after 3,6 and 12 month will be reported in due course.

# Efficacy of Extracorporeal Shock-wave Therapy in Knee Osteoarthritis (animal study)

Authors: N.Ochiai\*, S.Ohtori\*, T.Saiasu\*\*, K.Takahashi\*, N.Takahashi\*, R.Murata\*, Y.Wada\*\*\*, H.Moriya\*

### Institution:

- \*Department of orthopedic Surgery, Chiba university, School of medicine,
- \*\*Division of Orthopedic Surgery, Chiba children's Hospital
- \*\*\*Department of orthopedic Surgery, Teikyou Ichihara Hospital

### Introduction:

There have been several reports on the use of extracorporeal shock waves in the treatment of pseudarthrosis, calcifying tendinitis, and tendinopathies of the elbow. However, there was no study for the treatment of knee osteoarthritis (OA).

**Purpose**: To investigate the effect of shock wave application for knee OA, we analyzed changes in calcitonin gene-related peptide (CGRP)-immunoreactive (ir) dorsal root ganglion (DRG) neurons.

### Material and method:

We made knee OA rat using the method of transecting anterior cruciate ligament, medial meniscus and medial collateral ligament. We divided into 3 groups. 1) Non-treated group (6 knees) 2) Knee OA group (6 knees) 3) shock wave group (6 knees). Fuorogold (neurotracer) were injected into the medial knee joint 10 days before perfusion fixation using 4% paraformaldehyde. In the shock wave group, shock wave (1000 shots, 4Hz, 0.08mJ/mm2) applied to the medial knee joint 10 days after injection of fluorogold and perfusion fixation was performed 4 days after application of shock waves. We statistically analyzed the number of CGRP-ir fluorogold-labeled neurons among non-treated group, knee OA group and shock wave group.

### Result:

In the non-treated group, fluorogold-labeled dorsal root ganglion neurons innervating the medial knee joint were distributed in the L1 to L6 dorsal root ganglia. There were statistically significance between the non-treated group and knee OA group, and between knee OA group and shock wave group. Shock wave application reduced CGRP-ir neurons in DRG.

## Discussion and conclusion:

We previously reported that application of shock wave to rat skin reduced the CGRP expression in DRG neurons and degeneration of free nerve endings. But these studies were applied shock wave to the normal condition. So we do not know whether the same condition occurs in the pathological condition. This study was applied shock wave to the pathological model and also confirmed the reduction of CGRP-ir neurons in DRG. These data shows that extracorporeal shock wave therapy may be useful for the treatment of knee OA.

## Clinical Efficacy of Extracorporeal Shock-wave Therapy in Knee Osteoarthritis

Authors: K. Takahashi, T. Saisu, N. Takahashi, R. Murata, N. Ochiai, Y. Wada, H. Moriya

**Institution**: Graduate School of medicine, Chiba University, Chiba, Japan

### Introduction:

A variety of non-operative treatments for osteoarthritis have been receiving considerable attention. The purpose of this study is to investigate the efficacy of extracorporeal shock-wave therapy (ESWT) in knee osteoarthritis preliminarily.

#### Methods:

ESWT were applied using Epos (Dornier Co., Germany) in 15 knees of 12 patients who had had an inadequate response to prior conventional conservative treatments for more than 6 months. The mean follow-up period was  $22.2~(\pm 20.6~\text{SD})$  weeks. We investigated the clinical efficacy of ESWT according to pain, function, X-ray and MRI findings. We used Japan Orthopaedics Association osteoarthritis score (JOAscore) and the Visual Analog Scale score (VASscore) for the clinical evaluation of knee osteoarthritis.

### Results:

Subjective symptoms improved in 11 of 15 knees (73.3%), and total score of JOA increased from 66.7 points to 84.7 during furrow up. Particularly, pain score significantly reduced. The analgesic effect of ESWT was observed from immediately after treatment and "night pain", "pain on walking" and "tenderness" reduced but tenderness was likely to remain finally. There was no deterioration of symptom and we didn't detect any complication by radiographic analysis.

### Discussion:

The efficacy of ESWT in enthesopathy such as tennis elbow or plantar fascilitis already has been known, while there was no report on the efficacy of ESWT in knee osteoarthritis. There are many reasons for pain in knee osteoarthrosis, but a pain related from the tendon and ligament insertion of the knee seemed to be relieved with shock waves. This is the first report, which shows the clinical efficacy of ESWT in knee osteoarthritis.

## Conclusion:

ESWT could be an alternative therapy in the treatment of knee osteoarthritis refractory to other therapies.

# Histological Findings in Human Osteoarthritis Treated With ESWT

Authors: M. Branes, L. Guiloff, L. Contrras

**Institution**: Clinica Aurico Salud, Clinica Providencia, Chile

## **Evaluating Instruments for Assessment of Elbow Function**

**Authors**: Leal Carlos MD, Cortes Michelle MD, Herrera Juan M. MD, Lopez Juan C. MD, Reyes Oscar E. MD

**Institution**: Department of Orthopaedics - Orthopaedic Research Laboratory - Bosque University, Bogota DC , Colombia

Any new therapeutic approach or development to medical conditions must be precisely validated by the scientific community before it can be safely recommended or used. In order to talk the same language, and to compare results in the same scales, there must be a consent of the instruments that measure the outcome of these treatments. The use of scoring systems has been widely accepted in the measurement of patient outcome in musculoskeletal disorders. However, the number of scoring systems, the variables they measure and their clinical and epidemiological validation as scientific instruments is currently a matter of great interest. We have seen reports of Shockwave Therapy for tennis elbow for nearly 15 years, but still many international scientific communities believe that there is not enough evidence to recommend this therapy. However, the literature does not support with solid evidence the surgical alternative to treat a rebel tennis elbow. In the past five years many orthopaedic research groups, including ours, have reported clinical case series and case-control studies showing the benefits of ESWT. However, clinical scales are either conflictive or non comparable, and there is a clear need to define proper scales in order to use reliable data that can be compared to report valid and reproducible results. Bosque University Orthopaedics started a prospective study that will compare the results of ESWT and surgery for tennis elbow. In the design process of the project we found different scales that we studied thoroughly to use as reliable instruments to compare these two procedures. A problem aroused: which scale should we use?. VAS is the most common one, and is an one-dimensional scale that allows the measurement of pain intensity with good reproducibility (Scudds 2001). The Disabilities of the Arm Shoulder and Hand questionnaire (DASH) is a long questionnaire that evaluates the upper limb as a whole. It has been validated and has excellent reproducibility (MacDermid 2000). Roles and Maudsley scale is the most frequent instrument found in ESWT papers. It was described in 1972 and is a fast way to compare results with easy questions. However it seems to be somehow simple, and evaluates only four stages in a subjective manner. Nirschl scale is more specific as it involves pain, range of motion and activities. However we did not find any validation studies of this scale in the literature. MacDermid published a scale that evaluates function and pain. But probably the most complete scale for elbow evaluation we found was reported by the American Shoulder and Elbow Surgeons in 1999, where J.W. King et al developed an instrument for elbow evaluation with specific sections for pain, function, treatment satisfaction and objective medical evaluation. We believe one of the most important issues in comparing ESWT with other treatment alternatives is the instruments and scales that we use in our protocols and publications. We propose that International societies like ISMST should create or validate the scales that can compare with solid criteria the outcome of patients in order to report our results with all the evidence needed in new therapeutic tools. In this presentation, we compare all elbow scales in the literature in order to discuss the best recommendation for our clinical researchers as an international consensus in Vienna 2005.

## ECSWT - U.S. Experiences/Studies

Author: Pettrone Frank

**Institution**: Arlington, Virginia

The U.S. FDA has approved 3 ECSWT devices for usage: 1) Healthtronics Ossitron (Oct. 2000) - Electrohydralic; 2) Dornier Epos Ultra (Jan. 2002); and Siemens/Sonocur (2004) Electromagnetic. A piezoelectric device is only in clinical trials.

The Ossitron and Epos are "high energy" single treatment devices. The siemens sonocor is a "low energy" multiple treatment device.

The Ossitrondevice is currently FDA approved for plantar fascitis and lateral epicondylitis. The Epos Ultra is approved for plantar fascitis only and the Sonocor is approved for lateral epicondylitis only.

The clinical studies of Ossitron (Healthtronics FDA study) and Dornier FDA will be presented. One study of 150 patients by Theodore and another by Wiel (96) patients for plantar fascitis with Epos will be reviewed. The studies for calcific tendonitis of the shoulder by Klimkiewicz (2005) and Gerdesmyer (2003) will be presented.

The two principal U.S. studies of successful Sonocor treatment of lateral epicondylitis of Dunham (2004) and Pettrone (2004) will be discussed.

# A review of basic and clinical researches on musculoskeletal shockwave therapy in Japan. Why it has not been approved?

**Authors**: T. Saisu\*, K. Takahashi\*\*, S. Ohtori\*\*, N. Takahashi\*\*, R. Murata\*\*, N. Ochiai\*\*, M. Kamegaya\*, Y. Wada\*\*\*, H. Moriya\*\*

## Institution:

- \*Division of Orthopaedic Surgery, Chiba Children's Hospital,
- \*\*Department of Orthopaedic Surgery, Chiba University and
- \*\*\*Department of Orthopaedic Surgery, Ichihara Hospital, Teikyo University, Chiba, Japan

Although musculoskeletal shockwave therapy has now spread all over the world, it has not still approved by the Ministry of Health, Labour and Welfare in Japan. Single blind clinical trial had finished in 1998, but the positive results did not accepted because of some accusations such as insufficiency of the protocol for control study, which had been permitted by the Ministry itself before beginning of the clinical study, and so on. After the FDA approval in 2000, some manufacturers applied to the Japanese government for approval of shockwave therapy using results of the FDA study. These applications had been under consideration until 2003, however, approval system in Japan completely changed in 2004, unfortunately. Japanese government newly established Pharmaceuticals and Medical Devices Agency for judging and all the process of judgment was restarted. In spite of these misfortune, musculoskeletal shockwave therapy have been developing in Japan since 1994, mainly in basic field. Purpose of this presentation is to introduce basic and clinical researches on musculoskeletal shockwave therapy uniquely developing in Japan.

# Reimbursement for ESWT for the Musculoskeletal Disorders in the United States

Authors: Pettrone Frank

**Institution**: Arlington, Virginia U.S.A.

ECSWT for musculoskeletal disorders has been available in the United States since October of 2000. Since that time, three ESWT systems have been approved by the FDA. Two for plantar fasciitis, one for lateral epicondylitis, and one for both lateral epicondylitis and plantar fasciitis. Generally, reimbursement for ESWT has been limited and varies greatly between regions of the country. Reference will be made to Sonocor, Ossatron, and Dornier Epos Ultra systems experiences.

Difficulties in obtaining reimbursement result from the following:

- 1. Inconsistency in the medical literature reguarding the effectiveness of ESWT
- 2. The lack of quality prospective, randomized, multi-centered, double-blinded clinical studies using similar technology with standardized treatment protocols and comparable endpoint assessments.
- 3. Reluctance of insurance carriers to provided payment for treatment of common musculoskeletal disorders, many of which spontaneously resolve.
- 4. The availability of only Category III CPT codes at the present time.
- 5. Erroneous CMS initial pricing.
- 6. Confusion about the differences in technology.

These difficulties have resulted in generally poor non-uniform payments limited to specific geographic areas and carriers. Medicare has coverage policies for specifically approved devices in approximately 19 states, but payment rates are so low to rarely cover costs. Private insurance carriers have very variable rates of reimbursement, often varying greatly within the same region. Workman's compensation is inconsistent. Present reimbursement discourages physicians from prescribing ESWT even if they think it is indicated. This situation will improve only if the above difficulties are addressed in a unified fashion by clinicians and ESWT device manufacturers.

# Comparison between Optically Controlled Adjustable and Non-adjustable Spark Gap System

Authors: C.C. Chang, L.K. Lu, Y.R. Pu, I. Manousakas, Y.C. Tong, F.M. Yu, S.M. Liang

**Institution**: Dept. of Urology, ESWL Laboratory, Institute of Aeronautics and Astronautics, National Cheng Kung University and Hospital, Tainan, Taiwan, R.O.C.

## Purpose:

Extracorporeal shock wave lithotripsy (ESWL) is the main treatment for patients with urinary stones. Meanwhile, ESWT is progressively developing. Nevertheless, the distance between the electrodes is fixed in conventional Electro-hydraulic Shock Wave generator. The shock wave power will decay during treatment. We have developed an optically controlled adjustable spark gap system to deal with the above problem. The system was tested in this experiment.

### Materials and Methods:

Two experiments were performed to evaluate the efficiency between the adjustable and non-adjustable system:1. Stone fragment ratio, 2. Stone fragment weight ratio.

#### Results:

In the first experiment, the stone fragment ratio was 100% fragmented by  $713\pm21$  shocks by the adjustable electrode. The ratio was  $77.2\%\pm4.8$  by 1500 shocks for the non-adjustable electrode. In the 2nd experiment, the weight ratio were  $40.1\pm5.1\%$  for the adjustable electrode and  $12.2\pm5.3\%$  for the non-adjustable electrode.

#### Conclusion:

The results showed that the optically adjustable electrode is better than the non-adjustable electrode in the performance and efficiency. The former one could save more treatments and send out more stable shock wave in both of ESWL and ESWT.

# Improvement of pain tolerance using a new electrode adjustment in eletrohydraulic equipments

Authors: M. Meyer, E. Thober, BF. Meyer

Institution: Centro de Ondas de Impacto(COI)

Porto Alegre, Brazil

Sociedade Brasileira de Terapia por Ondas de Choque(SBTOC)

Recents studies have demonstrated beneficial effects of Extracorporeal Shock Wave Therapy (ESWT) that consists of a sonic pulse or a focal kinetic energy, in the treatment of chronic diseases of tendons. The equipments utilized have differents energy generators: piezzoelectric, electromagnetic and electro-hydraulic. The aim of this study was to evaluate the pain tolerance during ESWT applications comparing the electrode adjustment based in manufacturer guidance with a new modified procedure that consists a lesser visual distance between the metallic tips.

Patients were included if they were 18 years or older, had symptoms for at least 6 months, and/or had failed at conservative treatment. Patients were excluded if they had ESWT contra-indication and/or received local corticosteroid injection in the previous month. We followed the Visual Analog Scale (VAS). The equipment utilized was ORTHIMA (Direx), that operate with an electro-hydraulic generator. The applications consisted of 20 impulses with each adjustment, alternatively, using the same energy of  $0.35 \text{mJ/mm}^2$ . We performed the tests before the treatments. The VAS was applied immediately after each test. The focus was the site of maximum reproduction of local pain at digitopressure. We did not use any kind of anaesthesia. We evaluated 20 patients. Bilateral disease in 3 cases, with a total of 23 foots. The VAS score was 2.3 with the new adjustment vs. 6.8 with the manufacturer orientation. Our results suggest that the electrode adjustment might be an important factor that increase the tolerability of ESWT and decrease the risks and the costs by the abolition of necessity of anaesthesia.

## Shockwave Therapy for Achilles tendonopathy: retrospective study

Authors: P. Rockett, A. Souza, P. Santos

### Institution:

Ortosom, Porto Alegre, Brazil Cortrel, Rio de Janeiro, Brazil Orthomaster, São Paulo, Brazil

#### Aim:

The aim of this study was to evaluate the efficacy and the safety of extracorporeal shock wave therapy for the treatment of Achilles tendonopathy in three Brazilian Orthopaedics Clinics.

## Material and Methods:

In a multi-center, retrospective study, the effect of shockwave therapy was investigated in 73 patients with Achilles tendon calcifying (or not) tendinosys treated in the period of 25 months from May 2002 to May 2004.

There were 28 women and 45 men with an average age of 60 (range, 34-87) 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, previous corticosteroid injection, neurological abnormality, gout, malignant diseases, blood coagulation disorders and previous Achilles tendon rupture. Each patient was treated with 1000 impulses of shock wave, a 05 mm focus depth, and with an energy flux density of no more than 0.13 mJ/mm after local anaesthesia.

One treatment was performed on 65 patients, 6 patients underwent a second treatment and 2 patients 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.

### Results:

The study showed the efficacy and safety of ESWT were excellent in 17.8%, good in 46.6%, acceptable in 21.9%, and poor in 13.7%, 180 days after ESWT.

# Overuse Achilles tendinopathy: ESWT vs placebo. An 18 months follow up study

Authors: F. Astore, V. Sansone, L. Spotorno

**Institution**: Departement of Orthopaedics,

Università degli Studi di Milano, IRCCS Humanitas,

Rozzano (Milan), Italy

The purpose of this study is to evaluate if Extracorporeal Shock Wave Therapy (ESWT) be considered potentially useful for overuse Achilles tendinopathy resistant to prolonged conventional non-operative treatment.

## Methods:

A prospective, double-blind clinical trial was performed to compare the outcomes of a standard treatment with ESWT with 2000 impulses of ESWT with energy flux density of 0.25 mJ/mm2 in the pain

## ESWT as a treatment for chronic insertional Achilles tendinosis

Author: J. Furia

Institution: Bucknell University, SUN Orthopedics and Sports Medicine - Lewisburg, PA USA

## Purpose:

The purpose of this study was to determine the efficacy of high energy extracorporeal shockwave therapy (ESWT) for the treatment of adults with chronic insertional Achilles tendinosis and to determine if use of a local anaesthesia field block has an adverse effect on outcome.

Type of Study: Retrospective case-control.

## Methods:

Between June 1 2003 and January 31 2004, 68 patients with chronic insertional Achilles tendinosis were enrolled in this study. Each patient had failed to respond to a minimum of six months of traditional non-operative treatments. Thirty-five patients were treated with a single dose of high energy shock wave therapy (ESWT group). Thirty-three patients were treated with additional forms of traditional non-operative measures (control group). All procedures were performed by a physician using either a local anaesthesia field block (12 patients) or an anesthesia other than local (23 patients). Each of the ESWT patients received a total of 3000 shocks for a total energy flux density of 604mJ/mm2. T-tests and analysis of variance (ANOVA) were used to test for differences in visual analog scores (VAS) between the ESWT and control groups.

#### Results

Four weeks post treatment, the mean visual analog score (VAS) for the control and ESWT groups were 8.2 (range, 6-10; SD=1.1) and 4.2 (range, 1-10; SD=2.4) respectively (t=8.7, P < .001). Twelve weeks post treatment, the mean VAS for the control and ESWT groups were 7.2 (range, 5-9; SD=1.3) and 2.9 (range, 1-10; SD=2.1) respectively (t=10.1, P ; .001). Fifty-two weeks post treatment, the mean VAS for the control and ESWT groups were 7.0 (range, 4-9; SD=1.2) and 2.8 (range, 1-10; SD=2.2) respectively (t=9.7, P ; .001). Using the Roles and Maudsley scale, 2 of the control patients (6.1%) and 6 of the ESWT patients (17.1%) were assigned an excellent result and 11 of the control patients (33.3%) and 23 of the ESWT patients (65.7%) had a good result at the final endpoint. ANOVA testing at 52 weeks post treatment revealed that the mean improvement in VAS score for the local anaesthesia subgroup was significantly less than the corresponding gain in the anaesthesia other than local subgroup ( F=16.77 verses F=53.95, P<.001). There were no significant complications.

## Conclusions:

ESWT is a safe and effective treatment for chronic insertional Achilles tendinosis. Local field block anaesthesia appears to decrease the effectiveness of this procedure.

## ESWT - A Prospective Double Blind Study on Mortons Neuroma

Authors: J. Furia

Institution: Weil Foot & Ankle Institute, Des Plaines, Illinois, USA

Introduction:

Two years ago at the Annual ISMST Meeting in Orlando, we presented a pilot study showing successful treatment of Morton's Neuroma in 27 out of 30 patients with ESWT. We have subsequently conducted a prospective placebo controlled double blind study on this treatment.

## Purpose:

The aim of the study was to evaluate the effect of extracorporeal shock wave therapy on painful Mortons Neuroma.

## Patient, Material, Methods:

25 patients with painful Morton's Neuroma of greater than 6 on a VAS that failed to respond to conservative care were eligible to participate.

Patients were anaesthetized with intravenous sedation and an infiltrative local block to the area was performed. Computer randomization then determined whether the treatment would be active or sham. For the active group treatment was performed utilizing an Ossatron by Healthtronics. The foot was treated with 2000 pulses at 21 Kv from directly inferior to the Morton's Neuroma. The sham foot received no treatment. 14 patients were randomized to the active group and 11 patients were placed in the Sham group.

Patients were evaluated at 1 week, 6 weeks and 12 weeks by a blinded investigator.

End point evaluation parameters were reduction in VAS and Roles and Maudsley quality of life assessment.

### Results:

The treated foot improved 70% of the time while the Sham foot improved 52% of the time. 79% of the treated feet improved by >50%, while 25% of the Sham feet improved by >50%. 75% of the treated feet attained a VAS of <3, while only 25% of the Sham group achieved <3 on a VAS. Only 8% of the treated patients had no improvement while 50% of the Sham group had no improvement.

Conclusion: ESWT can be considered a viable treatment alternative to painful Morton's Neuroma. It does not have complications associated with surgery and allows patients to ambulate immediately and return to activities of daily life without a prolonged recovery.

# Shock Waves for Pain Releif After Carpal Tunnel Release: THE Pathophysiological Basis of a New Clinical Application in "PILLAR PAIN" Disease

Authors: M.C. d'Agostino, S. Russo (\*), A. Lazzerini, M. Rubini, D. Smarrelli, D. De Spirito.

### Institution:

Hand Surgery Unit, Humanitas Clinical Institute, Milan (Italy);

(\*)Orthopedics and Traumatology Department, Federico II University, Naples (Italy).

Carpal tunnel release is a safe, simply and rapid procedure in hand surgery; in spite of this, 20% of the patients can suffer for a long time from scar discomfort (redness, pain and swelling) (sometimes described as "pillar pain").

Until now, no therapy has been described in the literature to be effective in rapid pillar pain relief, especially as its aetiology is still uncertain.

Only recently, some clinical evidences, as well as some anatomical and experimental studies suggest the possibility that this condition is due to a prolonged neurogenic inflammation, sustained by neuropeptides (especially Substance P).

As it is well known that Extracorporeal Shock Wave Therapy is effective in suppression of inflammatory processes, as well as that it can modulate Substance P, we treated a series of 25 patients, suffering from pillar pain after carpal tunnel release (from almost two months) (3 treatments, weekly, at very low energy of 0.03 mmJ/mm<sup>2</sup>, 2500 - 3000 shots/session), under in - line ultrasound examination (Modulith SLK - Storz Medical).

Patients were selected on the basis of some clinical data (subcutaneous painful swelling in the interthenar area, scar redness, thenar and/or hypothenar discomfort, pain) and by NMR findings (oedema in carpal tunnel granulation tissue, mild perineural oedema, rare bone marrow oedema). Pain was subjectively recorded by Visual Analogic Scale (VAS), before and after ESWT. Only for few patients it was possible to perform NMR also after ESWT.

Clinical results were very surprising and encouraging: 50% of pain relief already after first ESWT treatment, in about half of the patients; temporary pain increased within the first week of treatment in very few cases; completely pain relief within 25 days in almost all patients; rapid scar redness resolution in almost all patients; strict correlation between pathological NMR findings and clinical data (both pre - and post - ESWT).

Absolutely not local nor general side effects were observed during and after ESWT treatment.

The authors will expose in detail the data above reported, and discuss the theoretical and pathophysiological basis of this new safe application of ESWT in hand surgery.

## The Employment of E.S.W.T. in Avascular Necrosis in Growing Patients

Authors: S. Russo, B. Corrado, M. Tullio, S. de Rosa, V. La Mantia, E. Astarita, E. M. Corrado

**Institution**: Department of Surgery, Orthopedics, Traumatology and Rehabilitation

"Federico II" University of Naples (ITALY)

The presence of fertile cartilage nearby the treating area is commonly considered an absolute contraindication to the use of E.S.W.T. because of the possibility of inducing an asymmetric stimulation of the growing cartilage with a consequent angular deviation during limb growing phase. Instead the authors retain such contraindication just a relative one as several factors play a role, like the energy level and the number shots, the focus size and its relative stability, the absolute immobility of target limb, the complete absence of pain, the specific pathology for which treatment is demanded, etc.

Paying attention to such aspects, the authors have retained to use E.S.W.T. in treating osteonecrosis of several nature in growing patients.

They review their casuistry discussing the pathologic and natural prognostic meaning as well as the method and the results in a follow-up from 4 to 7 years.