

# ISMST

International Society for Medical Shockwave Treatment



## 13th International Congress of the ISMST

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# Abstracts

## **(1) Home training, local corticosteroid injection, or radial shock wave therapy for greater trochanter pain syndrome**

**Jan D. Rompe, Neil Segal, Angelo Cacchio, John Furia, Antonio Morral, Nicola Maffulli**

Department of Orthopaedics & Rehabilitation, University of Iowa, Iowa City, IA, USA

Department of Physical medicine and Rehabilitation, "La Sapienza" School of Medicine, Rome, Italy

SUN Orthopaedics, Lewisburg, PA, USA

Centre de Fisioteràpia Salut i Esport (Sta. Perpètua), EUIFN Blanquerna, Barcelona, Spain

Centre for Sports and Exercise Medicine, Barts and the London School of Medicine and Dentistry, London, Great Britain

**Introduction:** There are no controlled studies testing the efficacy of various nonoperative strategies for treatment of greater trochanter pain syndrome. The null hypothesis was that local corticosteroid injection, home training, and repetitive low-energy shock wave therapy produce equivalent outcomes 4 months from baseline.

**Methods:** Two hundred twenty-nine patients with refractory unilateral greater trochanter pain syndrome were assigned sequentially to a home training program, a single local corticosteroid injection (25 mg prednisolone), or a repetitive low-energy radial shock wave treatment. Subjects underwent outcome assessments at baseline and at 1, 4, and 15 months. Primary outcome measures were degree of recovery, measured on a 6-point Likert scale (subjects with rating completely recovered or much improved were rated as treatment success), and severity of pain over the past week (0-10 points) at 4-month follow-up.

**Results:** One month from baseline, results after corticosteroid injection (success rate, 75%; pain rating, 2.2 points) were significantly better than those after home training (7%; 5.9 points) or shock wave therapy (13%; 5.6 points). Regarding treatment success at 4 months, radial shock wave therapy led to significantly better results (68%; 3.1 points) than did home training (41%; 5.2 points) and corticosteroid injection (51%; 4.5 points). The null hypothesis was rejected. Fifteen months from baseline, radial shock wave therapy (74%; 2.4 points) and home training (80%; 2.7 points) were significantly more successful than was corticosteroid injection (48%; 5.3 points).

**Discussion:** The significant short-term superiority of a single corticosteroid injection over home training and shock wave therapy declined after 1 month. Both corticosteroid injection and home training were significantly less successful than was shock wave therapy at 4-month follow-up. Corticosteroid injection was significantly less successful than was home

training or shock wave therapy at 15-month follow-up.

**Conclusion:** The role of corticosteroid injection for greater trochanter pain syndrome needs to be reconsidered. Subjects should be properly informed about the advantages and disadvantages of the treatment options, including the economic burden.

**Device and producing company:** EMS Dolorclast

## **(2)No effect of extracorporeal shockwave therapy in jumping athletes with patellar tendinopathy; a randomized controlled trial**

**Johannes Zwerver (1), Inge van den Akker-Scheek (1), Fred Hartgens (2), Henk van de Worp (1), Evert Verhagen (3),**

**Ron Diercks (1)**

**1 Center for Sports Medicine, University Center for Sport, Exercise and Health, University Medical Center Groningen, Hanzeplein 1, 9700 RB Groningen, The Netherlands**

**2 Maastricht University Medical Center, Research school CAPHRI, Departments of Epidemiology and Surgery, PO Box 616, 6200 MD Maastricht, The Netherlands**

**3 Department of Public and Occupational Health, The EMGO Institute for Health and Care Research, VU University Medical Center, Van der Boechorststraat 7, 1081 BT Amsterdam, The Netherlands**

**Introduction:** Patellar tendinopathy is a major problem for many athletes, especially those involved in jumping activities. Despite its frequency and negative impact on athletic careers, no evidence-based guidelines for management of this overuse injury exist. Extracorporeal shockwave therapy (ESWT) appears to be a promising treatment in patients with chronic patellar tendinopathy. ESWT is most often applied after other conservative treatments have failed. However, its effectiveness as primary therapy has not been studied in athletes who keep playing sports despite having patellar tendon pain. The aim of this study was to determine the effectiveness of ESWT in athletes with patellar tendinopathy who are still in training and competition.

**Methods:** The TOPGAME-study (acronym of Tendinopathy Of Patella Groningen Amsterdam Maastricht ESWT) is a multicenter two armed randomized controlled trial with blinded participants and outcome assessors. Volleyball, handball and basketball players with symptoms of patellar tendinopathy for a minimum of 3 to a maximum duration of 12 months who were still able to train and compete were included. After establishing a clinical diagnosis they were randomly allocated to either an ESWT (treatment) or placebo group. The ESWT group received 3 patient guided piezoelectric focused medium energy density ESWT treatments

without local anesthesia at a weekly interval in the first half of the competition. The placebo group received sham-ESWT treatment using the same equipment and procedure. No restrictions with regard to sport participation and concurrent medical treatment were given. The follow-up measurements took place 1, 12 and 22 weeks after the final ESWT or placebo treatment, when athletes were still in competition. Primary outcome measure was the VISA-P score, a symptom based questionnaire specifically designed for patellar tendinopathy. During the follow-up period participants also registered pain, symptoms, sports participation, side effects of treatment and additional medical consumption in an internet based diary. Results: Out of 113 athletes who volunteered, 62 met the inclusion criteria and were randomized to either the ESWT (n = 31) or placebo group (n = 31). Duration of symptoms was comparable in both groups,  $7.3 \pm 3.6$  and  $8.1 \pm 3.8$  months respectively. The mean VISA-P scores before and at 1, 12 and 22 weeks after treatment are summarized in table 1. There was a significant effect for time (p Discussion: There was no effect of this ESWT treatment protocol on the course of symptomatic patellar tendinopathy in jumping athletes who continued to train and compete during and after the treatment period. Device and producing company: Piezowave, Wolf

### **(3)ESWT treatment protocols for jumper's knee: a worldwide survey**

**Henk Van der Worp, Hans Zwerver, Inge van den Akker-Scheek**

Center for Sports Medicine, University Center for Sport, Exercise and Health, University Medical Center Groningen, Hanzeplein 1, 9700 RB Groningen, The Netherlands

Introduction: A recent review by the authors concluded that ESWT (Extracorporeal Shockwave Therapy) is a promising treatment for jumper's knee (patellar tendinopathy). It was also concluded that based on the current knowledge it is impossible to recommend a specific treatment protocol. This raises the question of what treatment protocols are used in practice to treat jumper's knee with ESWT.

Methods: A cross-sectional study using an online-questionnaire among ISMST-members concerning the treatment of jumper's knee with ESWT. The questionnaire consisted sections about 1) respondent characteristics, 2) used shockwave device 3) treatment protocol and 4) treatment results. Descriptive statistics of the results of the questionnaire will be obtained.

Results: The survey is currently taking place. Results are expected in March/April 2010 and will be analyzed before the ISMST-congress takes place. Preliminary results of a similar questionnaire within the Netherlands showed a lot of variation between therapists in ESWT treatment protocols for jumper's knee.

**Discussion:** The results of the questionnaire will be compared with existing literature.

**Conclusion:** No conclusions can be drawn yet.

#### **(4) Shockwave treatment for chronic patellar tendinopathy of the knee**

**Re-Wen Wu, Ching-Jen Wang, Jih-Yang Ko**

Department of Orthopedic Surgery, Chang Gung Memorial Hospital /  
Kaohsiung Medical Center, 123 Ta-Pei Road, Niao Sung Hsing, Kaohsiung,  
Taiwan 833

**Introduction:** Patellar tendinopathy (Jumper's knee) is a common orthopedic problem characterized by pain and inflammation below, and less commonly above the patella. The etiologies of patellar tendinopathy are multi-factorial including overuse injuries, trauma and surgery.

**Methods:** 50 patients (54 knees) were included in this study. The source of shockwave was from an OssaTron (Sanuwave). In study group, each knee received 1500 impulses of shockwave at 14 Kv under no anesthesia. The location was focused with the laser control guide of the device and the depth by ultrasound guide.

**Results:** There were 27 patients (30 knees) in study group and 23 patients (24 knees) in control group. There were significant improvements of VAS pain scores, VISA scores, ROM of knee and functional improvement in study group.

**Discussion:** Chronic patellar tendinopathy manifested as mucoid and chondroid degeneration and formation of plump tenocytes and increased fibroblastic and myofibroblastic cells and absent inflammatory cells. The exact mechanism of extracorporeal shockwave remains unknown. In this study, ultrasonographic examinations showed significant increase in the vascularity of the patellar tendon and a trend of decrease of the tendon thickness after shockwave treatment. Therefore, it is reasonable to believe that extracorporeal shockwave relieved pain by hyper-stimulation analgesia, improvement in blood supply and promotion of tissue regeneration in chronic patellar tendinopathy.

**Conclusion:** Extracorporeal shockwave is more effective than conventional conservative treatments for patients with chronic patellar tendinopathy. Shockwave treatment is effective and safe for chronic patellar tendinopathy with negligible complications.

**Device and producing company:** OssaTron (Sanuwave, Inc.)

#### **(5) Efficiency of shockwave treatment for pain reduction in the shoulder**

**Erich Georgi 1, Thomas Georgi 2**

**Institution: 1 Trauma Hospital of Graz, Austria; 2 Medical University of Graz, Austria**

**Introduction: From 2006 – 2009, shockwave therapy was performed in the Trauma Hospital of Graz on patients with pain in the shoulder. Patient complaints were pain when raising the arm higher than 60° and pain during the night with trouble of continuous sleep. The aim of this study was to evaluate the rate of success and to detect any hints for predictable success of this treatment.**

**Methods: Patients suffering from tendinitis of the rotator cuff tendon (n=42) with or without calcification were treated. 86% patients (n=36) were available for follow up. Shockwaves were applied using an Orthowave 180 shockwave machine. Each patient received 2000 - 2500 impulses under general anesthesia.**

**Results: Post treatment evaluation included measurement of ROM and additional assessment of the patients condition. Therefore we created four categories ranging from success to impairment. 64% showed complete success with pain relief ranging from immediate to 4 months after treatment. 11% of patients continued to have painful restrictions but nightly pain attacks disappeared. No improvement could be achieved in 25%. These patients ultimately underwent surgery after additional treatment. Impairment of the situation was not observed in any subject.**

**Discussion: Although we received a high rate of success (75%), we could not find any parameters which can predict the success of the treatment.**

**Conclusion: In summery, the collected data on this topic explicitly proves that shockwave therapy can substitute surgery. Due to pain relief, the quality of life can be improved.**

**Device and producing company: Orthowave 180, MTS Europe**

## **(6)Increasing the efficieny of RSWT, by optimizing the differential diagnostic strategy by means of a standardized orthopaedic assessment form.**

**Steven L.H. De Coninck**

**Institution: European Teaching Group of Orthopaedic Medicine (ETGOM)  
Lepelemstraat 4, B 8421 De Haan**

**Introduction: The efficient use of RSWT automatically implies we first reach an accurate and valid diagnosis. The more focused the diagnosis, the better we can incorporate RSWT locally. This might be the biggest problem facing therapists. It is not always easy to reach a valid and useful diagnosis with patients who suffer from soft tissue lesions of the musculoskeletal system. By relying on medical imaging, we have to take into account a serious number of false positive and false negative images. Therefore it is probably more reliable to focus on a relevant functional examination first. For that purpose, ETGOM developed standardized Orthopaedic Assessment Forms (OAF) for different joints. In this article I would like to put emphasis on the diagnostic implications of the shoulder examination procedure and the**

**differential diagnosis between various inert and contractile lesions.**

**Methods:** The OAF needs to be practical in use and has to give an immediate and clear overview of the positive findings in the total examination process. Each OAF has a standardized structure and consists of several basic sections:

- Specific and general history
- Inspection
- Basic and accessory functional examination
- Palpation
- Clinical reasoning strategy
- Treatment strategy

Depending on the specific answers the patient gives during the history and the overview of different positive and negative tests one can reach a conclusion in a more reliable and efficient way. This optimizes the indication-area for RSWT.

In the abstract the clinical implications of each section are explored. In the oral powerpoint presentation we focus on the specific differential diagnosis between inert and contractile lesions and its implications for RSWT.

**Results:** This OAF allows one to reach a more objective and accurate diagnosis, automatically increasing the therapeutic strategy. It also stimulates standardization in the diagnostic process.

**Discussion:** One needs to have a basic knowledge of examination and clinical reasoning procedures in orthopaedic medicine in order to fully appreciate the advantage of using an OAF.

**Conclusion:** According to a study of Pellechia et al., the shoulder examination procedure is very reliable (kappa factor 0.87). In order to complete the total assessment procedure one needs only about 10 minutes. This I call the “ten minute investment of the first session”. This procedure will not only allow us to make e.g. the clinical distinction between contractile and inert lesions, but we will also be able to further differentiate the diagnosis such as if it is a contractile and/or inert lesion, which structure are we talking about, where in this structure lies the lesion ? This clinical reasoning process is a valuable extra tool to optimize the indication area and thus efficiency of our RSWT treatment strategy.

**Device and producing company:** Shockmaster 500 - Gymna-Uniphy

## **(7)Effect of extracorporeal shock wave therapy on postoperative rotator cuff tendon healing--Preliminary results of a prospective study**

**Sergio Russo (1), S. Russo (1), A. Cozzolino (1), G. Della Rotonda (1), E. Astarita (1), A. Carretta (1), M. Ciccarelli†, R. Russo†**

(1) Orthopaedic Department of the University Hospital “Federico II” of Naples, Italy

**(†) Orthopaedic Department of the “Pellegrini” Hospital of Naples, Italy**  
**Introduction:** Rotator cuff tendon re-tears are frequent and caused by a lack of cellular response to the surgical repair linked to the healing process and to the quality of tissue, more than to the repair technique. Several solutions were proposed to stimulate the tendon healing to reduce rotator cuff repair failure.

**The effects of ESWT on rotator cuff tendinopathy have been largely discussed. Different studies show its effects on the improvement of tendon healing process. The aim of this study is to evaluate the clinical and structural effects of ESWT on patients who have undergone a rotator cuff tendon repair.**

**Methods:** Patients were recruited at the time of surgery according to specific inclusion criteria. The surgical procedure was performed with a variable number of double loaded suture anchors according to the size of the lesion (min 1, max 4). After the surgical procedure, patients were immobilized for 6 weeks in abduction-neutral rotation or in adduction-internal rotation. 1 week after surgery patients started the treatment: 4 applications with power between 0.15mJ/mm<sup>2</sup> and 0.3mJ/mm<sup>2</sup>. Total number of impulses: 12000 for a total of applied energy ranging between 60 and 90 J. A Duolith (Storz) device was used.

**Results:** The clinical results have been evaluated with a Constant score performed the day before surgery, at 1, 3 and 6 month and at one year. Structural results were evaluated by ultrasound.

**Discussion:** Patients treated with ESWT showed an improved clinical outcome after the surgical repair.

**Conclusion:** The initial clinical data seem to confirm a better outcome with respect to the control group values.

**Device and producing company:** Storz Medical A.G.

## **(8)Monitoring cavitations during shockwave therapy**

**Michael Chang 1, Marla Paun 2, Tom Matula 2**

**Institution:** 1 Physical Medicine Institute, Bellevue, WA 98005, USA

**2 Applied Physics Lab, University of Washington , Seattle, WA 98195, USA**

**Introduction:** Shear stress and cavitations are physical effects induced by positive and negative shockwave pressures, respectively. Cavitations are known cause of tissue injury in shockwave lithotripsy (SWL). In shockwave therapy (SWT), cavitations may play an important role in bringing desirable biological responses, such as angiogenesis, disintegrating dystrophic calcifications or disrupting bacteria biofilms. Therefore, monitoring and controlling of in-vivo cavitations are important to SWT outcomes.

**Methods:** Real-time cavitations were searched/recorded using B-mode cine loops and continuous video capture with ultrasonographic device, HD 11XE. L12-3 or C5-2 transducer, which generally orientated perpendicular/transverse to SWT axis, was used for recording. SWT include OssaTron for Achilles tendinosis/enthesopathy and hip heterotopic ossifications; D-Actor for plantar fasciitis, tennis elbow, Achilles



tendinosis/enthesopathy, and shoulder supraspinatus/subscapularis tendinosis/enthesopathy.

**Results:** Cavitations are usually observed after few thousand shocks and can be anywhere within shockwave fields, but tend to scatter around soft tissue-bone surface. Appearance of cavitations is especially consistent using high-energy focused shockwave device, OssaTron. Cavitations are much less obvious using low-energy unfocused shockwave device, D-Actor. Cavitations are usually less obvious in tendon/ligament than in muscle. Higher shockwave PRF (4 or 5 Hz) at later stage of SWT usually show more persistent and wider spread cavitations.

**Discussion:** Cavitations are likely first observed within part of the tissue where there is abundant fluid, such as in renal pelvis (urine) or within vessels (blood). Cavitations may interact with subsequent shockwaves and cause blood vessel wall damage, which results in leaking/pooling of blood in local interstitial space. This hematoma may seed more persistent and wider spread tissue cavitations.

**Conclusion:** Prevalence of cavitations seems to depend on characteristics/location of the tissue, shockwave device (pressure waveforms), PRF and stage of the SWT. Device and producing company: OssaTron (SanuWave), D-Actor 100 (Storz Medical), HD 11XE (Philips HealthCare)

## **(9)Changes in connexine expression of cardiomyocytes after in vitro shock wave treatment**

**Johannes Holfeld 1, Barbara Kapeller 2, Can Tepeköylü 1, Fabian Hack 1, Barbara Thometich 2, Julia Dumfarth 1, Daniel Zimpfer 1, Wolfgang Schaden 3, Michael Grimm 1, Karin Macfelda 2**

**Institution:** 1 Dept. of Cardiothoracic Surgery, Medical University of Vienna, Austria

**2 Core Unit for Biomedical Research, Medical University of Vienna, Austria**

**3 AUVA Trauma Center Meidling, Vienna, Austria**

**Introduction:** Recently shock wave therapy (SWT) at low energy levels is well known to effect tissue regeneration in ischemic myocardium. However, the underlying mechanism remains largely unknown.

**Methods:** Primary cell cultures of endothelial cells and fibroblasts were established from native rat hearts. Additionally H9C2-cardiomyocytes (American Type Culture Collection) were used. A thermostatically controlled water bath was designed to avoid distracting physical effects. Adherent cells in common cell culture flasks fully filled with culture medium were dunked into the water bath. Unfocused SWT at an energy flux density of 0.15 mJ/mm<sup>2</sup> were applied with an frequency of 5 Hz. Non-treated cells were used as controls. Several analyses of immunohistochemistry and molecular

biology were performed.

**Results:** SWT causes significant changes in expression of connexines Cx40, Cx43 and Cx45 in cardiomyocytes. The expression of connexines is largely disproportionate in differentiated and normal cells. Changes in metabolic and electrical coupling of cardiomyocytes may cause considerable effects onto the myocardium.

**Discussion:** Gap junctions are water-filled pores formed by the docking of two hemi-channels (connexons), contributed by each of the adjoining cells. Gap junctions are responsible for direct exchange of small hydrophilic molecules and ions between neighboring cells. Therein metabolites and messengers such as sodium, potassium, calcium, cAMP/cGMP, ADP/ATP and inositol 1,4,5-triphosphate are included. This results in metabolic and electrical coupling of cells. Cx40, Cx43 and Cx45 are expressed between cardiomyocytes. Changes in their expression cause alteration of cell communication.

**Conclusion:** SWT causes significant changes in connexine expression of cardiomyocytes. The expression of connexines is largely disproportionate in differentiated and normal cells. This alteration of cell communication may at least be part of the tissue regenerative effect mediated by SWT in ischemic myocardium.

**Device and producing company:** DermaGold CP-155 (Tissue Regeneration Technologies, LLC, Woodstock, USA manufactured by MTS Europe GmbH, Konstanz, Germany)

## **(10)Growth promoting effect of ESWT on primary cultured human tenocytes**

**Maria Chiara Vulpiani, Mario Vetrano, Vincenzo Visco, Federica D'Alessandro, Maria Rosaria Torrisi, Andrea Ferretti**

Physical Medicine and Rehabilitation Unit, Department of Experimental Medicine and Pathology, Orthopaedic Unit and Kirk Kilgour Sports Injury Center, Sapienza University School of Medicine, Sant'Andrea Hospital, Rome, Italy

**Introduction:** Extracorporeal Shock-Wave Therapy (ESWT) is currently used to treat musculoskeletal disorders and ESWT stimulation has been previously analyzed on cell lines or animal culture systems.

**Methods:** In order to investigate the effects of exposure to a range of energy levels (0.08, 0.14 and 0.17 mJ/mm<sup>2</sup>) and impulses (500 and 1000) of ESWT - which are known to provide clinical benefits, we have used primary cultures of human tenocytes (HT) harvested from tendon of semitendinosus muscle during arthroscopic Anterior Cruciate Ligament reconstruction. According to the results obtained by the MTT (tetrazolium) colorimetric assay, we have selected the dose of 0.14 mJ/mm<sup>2</sup> at the amount of 1000 impulses, which represents a good compromise between the in vitro cell viability (>80%) and the clinical benefits.

**Results:** The cytoskeleton organization analyzed by staining for the intermediate filament component vimentin and the overall cell morphology were not affected by different doses and times of culture (24 and 48 hours after treatment) utilized in our model. Furthermore, immunofluorescence microscopy for the proliferation marker Ki67 showed a significant (p

**Discussion:** This effect can be important during tendon healing and repair, when active proliferation is required.

**Conclusion:** We believe our results are the first to demonstrate a growth promoting effect of ESWT on primary cultured human tenocytes, at the dose selected for both experimental and clinical efficacy.

**Device and producing company:** Modulith® SLK, Storz Medical AG

## **(11)Bactericidal effect of extracorporeal shock waves on an in vitro biofilm implant infection model**

**Scott McClure (1), Matthew M. Madron (1), Ronald Griffith (2), Chong Wong (3)**

**Institution:** Iowa State University, Ames, IA:

**1) Department of Veterinary Clinical Sciences,**

**2) Dpt. of Veterinary Microbiology and Preventative Medicine**

**3) Dpt. of Diagnostic and Production Animal Medicine, College of Veterinary Medicine and the Department of Statistics, College of Liberal Arts and Sciences**

**Introduction:** It has been shown that shockwaves can be bactericidal to organisms in suspension. We hypothesize that shockwaves will be bactericidal to *Escherichia coli* and *Staphylococcus epidermidis* organisms in biofilm on cortical bone screws.

**Methods:** Screws were monocultured with either *E. coli* or *S. epidermidis* for to form a biofilm. The screws with biofilm were treated with shockwaves at an EFD of 0.15 mJ/mm<sup>2</sup> for 250, 500, 1000 or 2000 pulses. The 2000 pulse groups were also treated with the screws parallel or perpendicular to the shockwave. Untreated controls and shockwave treated screws were sonicated to disrupt any remaining biofilm then bacterial plate counts performed. Plate count data were log transformed and a mixed effects model with treatment as a fixed effect and run as a random effect was used. Pairwise comparisons were performed with Tukey-Cramer's adjustment.

**Results:** There was a significant increase in plate counts from nonsonicated to sonicated (P = 0.0091). There as a significant (P = 0.0445) increase in plate counts between the sonicated *Staph.* biofilms and the 2000 pulse perpendicular treated *Staph.* biofilms.

**Discussion:** We did see a significant increase in bacterial counts following sonication, so it is confirmed the bacteria were free from the biofilm for counting. While there was no bactericidal effect, it would appear that the shock waves did further disrupt the biofilm because plate counts increased. Direct bactericidal effects of shockwaves on biofilms will require further evaluations with higher energy levels.

**Conclusion:** In this model, shockwaves were not bactericidal.  
**Device and producing company:** Equitron, PulseVet, Alpharetta Georgia

## **(12) Extracorporeal pulse activation on the mitochondrial function and nitric oxide release in LPS-treated chondrocytes**

**Roger Lyon (1), XueCheng Liu (1), JiangZ An (2), Joseph Schwab (1)**

**Institution:** 1) Dept. orthopaedic Surgery, Children's Hospital of Wisconsin, 2) Children's Research Institution, Medical College of Wisconsin

**Introduction:** The efficacy and mechanism of the extracorporeal pulse activation treatment (EPAT) on the in-vitro chondrocytes remain unclear. Our current study is 1) to investigate how different dosages of EPAT affect the oxygen consumption and viability for lipopolysaccharides (LPS) treated chondrocytes, 2) to compare biological responses between EPAT treated and non-EPAT treated in-vitro LPS-treated chondrocytes.

**Methods:** Human chondrocyte cell line was maintained in an incubator at 37°C and 5% CO<sub>2</sub>. The chondrocytes were cultured in 24-well culture plates containing LPS (200 µg/ml) at a density of 1.3 x 10<sup>5</sup> cells/well under nutrition deprived culture condition (no serum). Cells were divided into two groups for the EPAT treatment (Duolith SD1®, CuraMedix Inc., MA). The EPAT group consisted of three subgroups in which cells received low (0.1 mJ/mm<sup>2</sup>, 4.0Hz, and 2000 impulse), middle (0.25 mJ/mm<sup>2</sup>) and high doses (0.55 mJ/mm<sup>2</sup>), respectively. The cells in the Control group did not receive EPAT. After 24 hours EPAT, mitochondrial O<sub>2</sub> consumption, cell viability, and cytokine IL-1β were measured.

**Results:** The Control group presented with larger areas having apparent chondrocyte apoptosis. Following EPAT, both low and middle power subgroups displayed significant improvements of cell viability, while cell morphology deteriorated in the high EPAT subgroup. EPAT significantly decreased oxygen consumption in all three EPAT subgroups (P

**Discussion:** Middle dose EPAT significantly decreased cell apoptosis, and oxygen consumption, indicative of an improved physiological impact on mitochondrial respiratory chain (MRC) activity.

**Conclusion:** EPAT may provide a new approach to treating chondral defects such as osteochondritis dissecans and inflammatory joint conditions.

**Device and producing company:** Duolith SD1®, CuraMedix Inc., MA

## **(13) The effects of extracorporeal shockwave on subchondral bone and articular cartilage of the knee in rats**

**Ching-Jen Wang, Lin-Hsiu Weng, Yi-Chih Sun, Jih-Yang Ko,**

## **Ya-Ju Yang, Feng-Sheng Wang**

**Department of Orthopedic Surgery**

**Chang Gung Memorial Hospital / Kaohsiung Medical Center**

**123 Ta-Pei Road, Niao Sung Hsing**

**Kaohsiung, Taiwan 833**

**Introduction:** This study evaluated the effects of extracorporeal shockwave technology (ESWT) on subchondral bone and articular cartilage of the knee in rats.

**Methods:** Thirty-six male Sprague-Dawley rats were randomly divided into three groups, the control, ACLT (anterior cruciate ligament transected) and ACLT plus ESWT groups. The control group received neither surgery nor shockwave. The ACLT group underwent ACL resection of the knee. The ACLT plus ESWT group underwent ACL excision and received ESWT after surgery. The evaluations included radiograph, bone mineral density, blood and urine assessments, bone strength, histomorphological examination and immunohistochemical analysis.

**Results:** The ACLT group showed significant increases in cartilage degradation (CTX-II, COMP, Mankin score and Safranin O stain); decreases in angiogenesis (vWF and VEGF), osteogenesis (BMP-2, osteocalcin), bone mass and bone strength as compared to the control group and the ACLT plus ESWT group (P

**Discussion:** Subchondral bone remodeling plays an important role in the pathogenesis of OA. Both pharmaco-therapy with alendronate and physical shockwave are shown disease-modifying effects in OA knee in rats. These findings suggest a new insight that the management of OA should initially focus on the subchondral bone rather than the articular cartilage.

**Conclusion:** ESWT shows chondroprotective effect in ACLT knee model in rats.

**Device and producing company:** OssaTron orthotripter (High Medical Technology, Kruealigen, Switzerland. Sanuwave, Alpharetta, GA, U.S.A.)

## **(14) In vitro shock wave treatment – How to apply shock waves onto cells**

**Johannes Holfeld 1, Fabian Hack 1, Can Tepeköylü 1,  
Julia Dumfarth 1, Daniel Zimpfer 1, Wolfgang Schaden 2,  
Michael Grimm 1**

**Institution:** 1 Dept. of Cardiothoracic Surgery, Medical University of Vienna, Austria

**2 AUVA Trauma Center Meidling, Vienna, Austria**

**Introduction:** Literature reveals very diverse methods of in vitro shock wave treatment (IVSWT). Most research groups use different methods of applying shock waves onto cells. Some of them are associated with distinct limitations, especially distracting physical effects. In particular, reflections

can cause negative pressure onto the cells and interference with upcoming waves.

**Methods:** The proposed in-vitro model consists of a plexiglass built water bath. It is filled with degassed water to avoid cavitation, a heater at the bottom with a temperature sensor connected to a control unit enables regulation of temperature for imitation of in-vivo conditions. The distance between the target tube and the shock wave applicator can be varied. An absorber is mounted to the back of the water bath to avoid reflection.

**Results:** The IVSWT water bath is a recommendable and useful tool for applying shock waves onto cells. It thereby avoids distracting physical effects that may change the shock waves functionality. The proposed model enables perfect reproducibility to in vitro results.

**Discussion:** The distinct difference in the impedance of culture medium and the ambient air causes reflection of shock waves when applied to cell cultures. Reflection itself causes negative pressure onto the cells and is also disturbing upcoming waves by interference.

**Conclusion:** Since results of equal cells treated in different ways are not comparable, establishing a standardized model for future in-vitro trials is needed. The proposed model of a thermostatically controlled water bath may enhance intergroup communication, which could help everyone working on IVSWT to learn more about the shock waves' mechanism by being able to compare the results.

**Device and producing company:** IVSWT water bath produced by Hohenegger Technical Products (office@ing-hohenegger.at)

## **(15) Long-term ultrasonographic evaluation of the effectiveness of extracorporeal pulse activated treatment (EPAT) on chronic recalcitrant plantar fasciitis**

**Robert Gordon, Charles Wong, Eric Crawford**

**Introduction:** Plantar fasciitis is the most common etiology of inferior heel pain, and is estimated to account for eleven to fifteen percent of all foot symptoms requiring professional care. Most patients (90%) recover naturally over time or with conservative treatment which may include ice, non-steroidal anti-inflammatory drugs (NSAIDs), ultrasound treatment, or massage. Surgical treatment, typically endoscopic plantar fasciotomy, is often recommended for individuals resistive to conservative treatment, but evidence of the effectiveness of these invasive techniques are largely unfavourable. Clinical trials have now demonstrated the effectiveness of EPAT on chronic recalcitrant plantar fasciitis as an alternative to surgery. The vast majority of the available literature have thus far relied upon subjective outcome measures (pain score) which are low in validity, reliability and responsiveness. The purpose of this study is, 1) to show the effectiveness of EPAT in treating plantar fasciitis using ultrasonographic measurement as an objective outcome measure, and 2) to observe the long-term effect of EPAT.

**Methods:** Patients were recruited retrospectively at a university-affiliated orthopaedic practice. Inclusion into the study required a medical diagnosis of chronic recalcitrant plantar fasciitis for at least one year, having failed traditional treatment modalities including orthotics, physiotherapy, NSAIDs and local steroid injections. Patients who had undergone surgery of the heel were excluded. A minimum washout period of six months was applied to any patient who had received NSAIDs or local steroid injections. Patients must have also had baseline ultrasonographic analyses of both heels before shockwave therapy was administered. A follow-up ultrasound was requested of all patients after at least one year post-treatment. Informed consent was obtained from each patient, and ethical approval was granted by the William Osler Health Centre Research Ethics Board.

Ultrasonographic analyses of both heels were performed by a blinded ultrasound technician to measure the thickness of the plantar fascia at the [site of measurement]. Where available, patient-assessed pain evaluation on a visual analogue scale from 0 to 10 with 10 being the greatest possible pain, and 0 being no pain) was also obtained. Patients were not informed of their previous self-ratings in subsequent ratings.

Patients then received standard EPAT treatment of three sessions at one week intervals (2000 pulses, 2.6 barr). Treatment was patient-guide, targeting the point of maximal tenderness. Anaesthetic was not administered.

**Results:** Fifty-five feet (41 patients) were found to have met the inclusion criteria. All 55 feet had ultrasound-measured plantar fascia thickness prior to treatment and at follow-up (at least 12 months post-treatment). The average pre-treatment thickness pre-treatment was  $7.37 \pm 1.88$  mm, and post-treatment was  $6.20 \pm 1.42$ . This represents an average change of  $-1.17 \pm 1.44$  mm ( $p < 0.001$ ). Average length of follow-up was  $27.5 \pm 11.8$  months, ranging from 12 to 54 months. No association was found between change in plantar fascia thickness and length of follow-up. For all unilaterally afflicted patients, plantar fascia thickness actually increased slightly, on average (from  $5.20 \pm 1.46$  mm to  $5.47 \pm 1.65$  mm); however, this change was not statistically significant ( $P = 0.183$ ). Of the total patient group, 34 feet had VAS pain intensity ratings both before and after treatment. Pain score "at rest" decreased from  $7.0 \pm 2.9$  mm to  $0.7 \pm 1.5$  mm ( $P < 0.001$ ). Pain score "in activity" decreased from  $8.5 \pm 1.9$  mm to  $1.4 \pm 2.0$  mm ( $P < 0.001$ ). Overall, clinical success (60% decrease in pain) was achieved for 90.9 % and 85.3% of patients, with regard to pain intensity at rest and in activity, respectively. No association was found between change in plantar fascia thickness and change in pain intensity at rest or with activity. A median split was performed with respect to pre-treatment ultrasound measured plantar fascia thickness.

**Discussion:** There have been excellent blinded randomised controlled studies showing the effectiveness of radial shockwave on the treatment of plantar fasciitis. The ultrasonographic assessment as shown by Wall et al also demonstrated that a plantar fascial thickness greater than 4.5 mm is

indicative of plantar fasciitis.

The results of this study indicate two parameters. That after a minimum of 1 yr follow-up the plantar fascia thickness decreases in size towards a more normal measurement. Moreover 90.9% of patients had at least a 60% decrease in pain with rest and 85.3% with activity. The average length of follow up was 27 months.

EPAT can be safely recommended for the treatment of plantar fasciitis whereby both the thickness of the plantar fascia decreases and pain scores are significantly reduced over time.

Conclusion: EPAT significantly reduces the objective measurement of plantar fascia thickness in symptomatic patients and improves pain in patients affected with plantar fasciitis.

Name of device and producing company: Storz Medical Instruments

## **(16) Successful treatment of chronic plantar fasciitis with two sessions of radial extracorporeal shock wave Therapy (RSWT®)**

**Mahmoud Ibrahim, Robert Donatelli, Christoph Schmitz, Madeleine Hellman, Frederick Buxbaum**

Institution: Rocky Mountain University of Health Professions, USA

Introduction: Radial extracorporeal shock wave therapy (RSWT®) has been previously demonstrated as an efficient treatment option for chronic plantar fasciitis (PF) when administered in three sessions, each two weeks apart. The present study tested the hypothesis that chronic PF can also be treated with RSWT when only two treatment sessions are performed one week apart.

Methods: A total of n=50 patients with unilateral, chronic PF were randomly assigned to either RSWT (n=25) or placebo treatment (n=25). RSWT was applied in two sessions one week apart (2,000 impulses per session). Placebo treatment was performed with a clasp on the heel. Endpoints were changes in the Visual Analog Scale (VAS) score and the modified Roles & Maudsley score from baseline to four weeks, 12 weeks and 24 weeks followup.

Results: Mean VAS scores were reduced after RSWT from  $8.52 \pm 0.34$  (mean  $\pm$  SEM) at baseline to  $0.64 \pm 1.52$  at 4 weeks,  $1.08 \pm 0.28$  at 12 weeks and  $0.52 \pm 0.14$  at 24 weeks after treatment. Similar changes were found for mean RM scores after RSWT but were not observed after placebo treatment.

Statistical analysis demonstrated that RSWT resulted in significantly reduced mean VAS scores and mean RM scores at all followup intervals compared to placebo treatment (each with p

Discussion: The results of the present study demonstrate that RSWT for chronic PF resulted in profound and lasting reduction in pain as well as improvement of the patients' quality of life, with short-term treatment success of 92% and long-term treatment success of 100% compared to only



4% short-term and 16% long-term treatment success in the group of patients treated with placebo.

Conclusion: RSWT is efficient in the treatment of chronic PF even when only two sessions with 2,000 impulses each are performed one week apart. Device and producing company: EMS Swiss Dolorclast® (EMS Electro Medical Systems Corporation; Dallas, TX, USA)

## **(17)ESWT for the treatment of plantar fasciitis: A nine-year follow-up**

**Lowell Weil Jr, Kelly Ann Malinoski, Lowell Scott Weil, Sr.,**

**Anthony Borrelli, Wendy Benton-Weil**

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

Introduction: ESWT for the treatment of plantar fasciitis is a well accepted treatment alternative world wide. ESWT has been studied and early and midterm results have shown successful with a variety of orthopedic disorders including plantar fasciitis. However, there have been very few long term studies that have assessed how patients have done beyond their first several years post treatment. We present patient satisfaction eight years subsequent to having been treated for plantar fasciitis with ESWT at the Weil Foot & Ankle Institute.

Methods: The number of patients with plantar fasciitis treated with ESWT in 2001-2002 was identified using retrospective chart review (N=197).

### **Data Collection**

A 10-item paper pencil retrospective survey was mailed to each patient and was used to document level of function, pain, patient satisfaction, level of improvement, time necessary to resume regular activities, and complications.

### **Statistical Analysis**

Descriptive statistics were used to examine the distribution for all key variables. For categorical variables (i.e., level of satisfaction, level of function, and etc.), frequency counts were calculated. For continuous variables (i.e., level of improvement, level of pain), measures of central tendency and dispersion were calculated. Additional analyses included cross tabulation and correlations of key variables to further understand the data. SAS version 9.1 was used for all analyses.

Results: Of the 197 patients identified for inclusion in the study, 75 patients returned the survey (38.1%).

### **SATISFACTION**

65 patients (87.84%) reported moderate to high satisfaction with ESWT. Of those patients, 58 reported high satisfaction. For those patients, the percentage of improvement in heel pain was 96.4% (SD=6.16) with an average pain rating of 0.77 (SD=1.10) after the procedure.

### **ACTIVITY**

Of the 63 patients (87.50%) able to return to regular activities after ESWT,

the amount of time was 3.44 weeks and average pain rating after the procedure was 1.21.

#### **PAIN**

There was a significant negative correlation between percentage of improvement in heel pain and average pain rating after the procedure ( $r = -0.801$ ,  $p$  rupture reported).

Discussion: ESWT has been shown to be highly effective in treating numerous musculoskeletal conditions, including chronic plantar fasciitis, in patients as early as three months following treatment. To date, there have been no studies evaluating these patients beyond five years.

Conclusion: We have evaluated a limited number of patients, retrospectively, who were an average of nine-years post-ESWT treatment of plantar fasciitis. Our early results have continued to be beneficial and satisfying to the great majority of patients

Device and producing company: Orbasone; Orthometrix

### **(18)The effectiveness of radial extracorporeal shock wave therapy for patients with chronic plantar fasciitis: Randomized controlled trial**

**Ahmed Zaky Hussein, Mahmoud Ibrahim, Robert Donatelli**

Health Check Centers, Brooklyn, NY, USA

Introduction: Plantar fasciitis is a common cause of heel pain, affecting 10% of the general population. Extracorporeal shock wave therapy (ESWT) has been recommended as treatment for chronic plantar fasciitis in patients unresponsive to conservative treatment. The primary goal of this study was to determine the effectiveness of radial extracorporeal shock wave therapy compared with placebo in the treatment of chronic plantar fasciitis.

Methods: A randomized, blinded, controlled study with two groups of subjects each was proposed. 104 patients (104 heels), including 52 patients (52 heels) in the shockwave treatment group and 52 patients (52 heels) in the control group. All patients had been suffering from plantar fasciitis for at least 6 months. Pre-treatment measurements included a visual analog pain scale (VAS) and the modified Roles and Maudsley scale. In the shockwave group, Therapy was applied twice within a one week interval, 2000 impulses at an air pressure of 3.5 bars and frequency of 8 Hz were given at each sitting. The patients in the placebo group received treatment with the clasp on the heel. ESWT was performed without local anaesthesia. At the fourth week, the subjects again completed a VAS and the modified Roles and Maudsley score (R&M).

Results: At 4 weeks, there was a mean VAS decrease of 6.56 (79.7%) for the experimental group; there was a mean decrease of 2.94 (32.5%) for the control group. There was a statistically significant ANOVA group by time interaction indicating that the experimental group had a greater decrease in

pain when compared to the control group p ease in quality of life when compared with the control group p

**Discussion:** Extracorporeal shock wave therapy has a statistically significant decrease in pain scores than placebo for patients with plantar fasciitis. Extracorporeal shock wave therapy has a statistically significant increase in functional outcome (better quality of life) than placebo on patients with plantar fasciitis.

**Conclusion:** Radial Shock wave therapy is effective and safe for the treatment of chronic plantar fasciitis.

**Device and producing company:** EMS

## **(19)Plantar stretching vs. radial SWT for acute plantar fasciopathy**

**Jan D., Rompe, Angelo Cacchio, Joachim Haist, Volker Reiners, John Furia, Christoph Schmitz, Lowell Weil Jr., Nicola Maffulli** OrthoTrauma Evaluation Center, Mainz,

**Introduction:** To evaluate the effectiveness of repetitive plantar fascia-specific stretching (PFSS) or of repetitive low-energy radial shock wave therapy (RSWT) for patients with a previously untreated monolateral plantar fasciopathy (PF) of up to six-week duration.

**Methods:** 102 patients with an acute PF were randomly assigned to perform an eight-week PFSS program (Group I, n=54) or to receive repetitive low-energy RSWT without local anesthesia, given weekly for three weeks (Group II, n=48). All patients completed the pain subscale of the Foot Function Index and a subject-relevant outcome questionnaire (SROM) including generic and condition-specific outcome measures related to pain, function, and satisfaction with treatment outcome. Patients were evaluated at baseline, and at two, four, and fifteen months from baseline. Calculations were based on intention-to-treat.

**Results:** No difference (age gender, duration or symptoms) was found between the groups at baseline (all  $p > 0.1$ ). At two months, and at four months from baseline, the pain subscale scores of the Foot function Index showed significantly better results for the patients managed with PFSS, with respect to all seven items, including worst pain ( $p= 0.002$ ), pain at first steps in the morning ( $p= 0.004$ ), and walking barefoot ( $p= 0.001$ ). Analysis of the response rates to the SROM questionnaire also revealed significant differences in favor of Group I, with respect to pain, activity limitations, and patient satisfaction at two and four months from baseline ( $p > 0.001$ ). At 15 months from baseline, there was no significant between-group difference.

**Discussion:** A program of non-weight-bearing stretching exercises specific to the plantar fascia is superior to repetitive low-energy radial shock wave therapy for the treatment of acute symptoms of proximal plantar fasciopathy.

**Conclusion:** Radial SWT is ineffective in acute PF.Germany

Device and producing company: StorzMedical Duolith SD1

## **(20) Focused shock wave therapy in chronic plantar heel pain--A randomized placebo controlled trial**

**Ludger Gerdesmeyer, Hans W Gollwitzer, Amol Saxena, Louis Galli, Lawrence Didomenico, Richard T Bouche**

MedBaltic, Dept. Orthopaedic Surgery & Traumatology, Kiel, Germany

**Introduction:** To determine the long time efficacy of extracorporeal shock wave therapy on chronic plantar heel pain a prospective randomized multi center trial was performed.

**Methods:** A total of 250 patients were enrolled and assigned to ESWT or identical placebo. 2000 treatment-impulses were applied at 0.25 mJ/mm<sup>2</sup> without local anesthesia. 3 ESWT sessions were done with 2 weeks in between. The primary Criteria were: Heel pain when taking the first steps and during daily activities. Second criteria were local pain on pressure, Roles and Maudsley-Score and SF-36. The end point was 12 months after last ESWT. The study was performed in accordance to GCP guidelines.

**Results:** 12 month after ESWT success was observed in all criteria's. The rate difference in all items after ESWT were statistically significant better in favor of the ESWT treatment. Regarding the change of pain score after ESWT the VAS composite score decrease from 8.3 at baseline down to 2.7 after ESWT, compared to 5.31 after identical placebo after 3 month. 12 month after ESWT th VAS score dropped down to 0.8. The percent change was '69% after ESWT and '34% after placebo. The same outcome was found in all secondary criteria as well. The a priori ordered hypotheses of the final statistical analysis plan was statistically significant (P

**Discussion:** The long term results show further improvement up to 12 month. Placebo improved as well and but the difference remains significant in favor to the active group. Bio feed back localizing technique seems to be effective.

**Conclusion:** The focused shock wave therapy is effective and safe in treatment of chronic heel pain. Excellent outcome was found after 3 and 12 month. The effect size reached clinical relevance without relevant side effects.

Device and producing company: Storz Duolith

## **(21) Retrospective ESWT studies**

**Dornier Epos Ultra- a group submission**

**David Harris Zuckerman, Denise Ashcraft(USA)**

**Introduction:** This is a retrospective study of over 800 tendopathy cases involving the upper and lower extremity.

**Methods:** Use of the dornier epos ultra for plantar fasciosis, Achilles tendinosis, Tennis Elbow

**Results:** Results showed that the use of ESWT with the dornier epos ultra

was safe and effective method for tendopathy treatment.

Discussion: Outcomes were discussed using direct patient surveys.

Conclusion: ESWT is safe and effective treatment modality for upper and lower extremity tendon pathology. Device and producing company: Dornier Epos

## **(22) Topaz, radiofrequency Coblation for the treatment of chronic plantar fasciitis;**

### **A randomized, double blind study**

**Lowell Scott Weil, Sr, Lowell Weil, Jr, Robert Fridman, Wendy Benton-Weil, Anthony Borrelli, Gregory Amarantos (USA)**

Institution: Weil Foot & Ankle Institute

**Introduction:** The use of plasma ablation microtenotomy is becoming well established for treating chronic tendinopathy in the elbow and shoulder. Recently, this technology has been applied to the treatment of chronic foot and ankle pathology as well, including plantar fasciosis, Achilles and posterior tibial tendinosis. The purpose of this study was to evaluate the effectiveness of plasma RF-based fasciotomy for relieving pain associated with recalcitrant plantar fasciosis and, secondarily, to determine whether additional benefits, such as reduced incidence of postoperative complications and improved function, were observed compared to conventional surgical fasciotomy.

**Methods:** Patients with chronic, refractory plantar fasciosis treated unsuccessfully using conservative care measures and whose next step was surgery were approached to participate in the study. Random assignment into surgical group (fasciotomy or microtenotomy) took place during the surgery; both patients and the physicians conducting the follow-up examinations were blinded to treatment. The intention is to follow patients for up to 2 years post-procedure; this is an interim analysis conducted at 6 months. Clinical evaluation measures included ankle-hindfoot index score, visual analogue scale (VAS) pain score, SF-36 quality of life assessment, Roles and Maudsley score, and patient satisfaction.

**Results:** Pain associated with the surgical incision was the most important and commonly observed significant clinical event. Both surgical groups demonstrated significantly improved AHL and Roles and Maudsley scores and significantly reduced pain scores. Function and pain scores did not differ significantly between treatment groups. Quality of life (SF-36) scores were also statistically similar for both surgical groups; both groups demonstrated significantly improved quality of life scores post-operatively. The proportion of patients satisfied with each surgical procedure at 3 and 6 months post-operatively was 80%.

**Conclusion:** Micro-fasciotomy performed using plasma ablation appears to provide equally successful clinical results as plantar fasciotomy. As an added benefit, this procedure is fascia sparing and therefore may be associated with less long-term morbidity.

Device and producing company: Arthrocare Sports Medicine

### **(23) Recruitment of endothelial progenitor cells after direct epicardial shock wave treatment of ischemic heart failure in rats**

**Johannes Holfeld 1, Daniel Zimpfer 1, Raphael Rosenhek 2, Anita Thomas 3, Patrick Paulus 3, Julia Dumfarth 1, Seyedhossein Aharinejad 3, Wolfgang Schaden 4, Michael Grimm 1**

**Institution: 1 Dept. of Cardiothoracic Surgery, Medical University of Vienna, Austria**

**2 Dept. of Cardiology, Medical University of Vienna, Austria**

**3 Laboratory for Cardiovascular Research, Medical University of Vienna, Austria**

**4 AUVA Trauma Center Meidling, Vienna, Austria**

**Introduction: Shock wave therapy (SWT) reportedly improves ventricular function by enhancing angiogenesis in ischemic myocardium. We hypothesized that recruitment of Endothelial Progenitor Cells (EPC) may therein be involved.**

**Methods: Adult Sprague Dawley rats were subdivided in 3 groups: sham-operated (sham), infarcted myocardium with epicardial SWT (SWT group) and infarcted myocardium without epicardial SWT (control). Four weeks following myocardial infarction (MI), SWT (100 impulses at 0.15 mJ/m<sup>2</sup>) was applied directly to the infarcted region in the SWT-group, control animals were left untreated. Cardiac function was evaluated using echocardiography. Angiogenesis was evaluated by analysis of several RNA and protein expressions.**

**Results: Fourteen weeks after epicardial SWT, left ventricular function improved in the SWT-group as compared to 4 weeks after MI and as compared to the controls. Quantitative histology revealed more vital cells and more endothelial cells in the SWT group.**

**SDF-1 and its receptor CXCR-4 were both upregulated in the treatment group as shown by immunohistochemistry. FACS analysis of peripheral blood showed significantly more circulating EPCs in the treatment group.**

**Discussion: It is well known that SWT causes neo-vascularization. The chemoattractant SDF-1 is responsible for recruitment and homing of EPCs. We found high numbers of circulating EPCs in peripheral blood of the treatment group after direct epicardial SWT. At the same time SDF-1 and its**

receptor CXCR-4 were upregulated in the myocardium. These findings indicate that one of the main mechanisms of SWT may be recruitment of vessel forming cells.

**Conclusion:** Direct epicardial shock wave therapy induces neo-vascularisation in an experimental model of ischemic heart failure in rats. Thereby high numbers of circulating endothelial progenitor cells can be found in peripheral blood. Therefore, one of SWT's main mechanism may be recruitment of vessel forming cells.

**Device and producing company:** CardioGold® CG050 (CRT - Cardiac Regeneration Technologies, Woodstock, USA / manufactured by MTS-Europe GmbH, Konstanz, Germany)

## **(24) Comparison of the effects of human mesenchymal stem cells cultured into osteoblasts by extracorporeal shock waves and dexamethasone**

**Baijing An, Xing Gengyan**

**Institution:** Department of Orthopedics General Hospital of Chinese Peoples' Armed Polices Forces, Beijing 100039, China

**Introduction:** To observe the effects of extracorporeal shock waves therapy (ESWT) and dexamethasone on the differentiation of human mesenchymal stem cells (hMSCs)

**Methods:** Bone marrow was collected and isolated the hMSCs from ten healthy volunteers and then cultured the hMSCs with 10% FBS. The hMSCs were then inducted into osteoblast. The cells induced were compared with ALP quantitative assay, ALP staining, alizarin red staining and RT-PCR of the osteogenic gene expression

**Results:** In cell differentiation, the two groups have significant differences in ALP quantitative assay, ALP staining, alizarin red staining and osteogenic gene expression. ESWT is superior to dexamethasone.

**Discussion:** ESWT through a variety of cytokines and mechanical stimulation to promote stem cells to differentiate into osteoblasts, which have more advantages than the dexamethasone.

**Conclusion:** ESWT and dexamethasone were compared and the ESWT is more favorable to promote osteoblastic differentiation of hMSCs.

## **(25) Differentiation of mesenchymal stem cells by extracorporeal shock waves**

**Joerg Hausdorf, Susanne Mayer, Tolga Goeren, Birte Sievers, Volkmar Jansson**

**Institution:** Orthopaedic Department, Ludwig-Maximilians-University, Munich, Germany

**Introduction:** The delayed healing or nonunion of bone is a common problem as it occurs in 5 - 10 % of all fractures. Hypertrophic non-unions

need only to be stabilized and they will usually unite. But the treatment of the aseptic, atrophic nonunion is a clinically relevant problem, because of its biological inactivity. The current treatment is accompanied by an extended surgical procedure including resection of necrotic bone and bone grafting and therefore causing a large amount of stress, hospitalization and a prolonged work disability for the patient. Extracorporeal Shockwave Therapy (ESWT) is a possible non-invasive treatment, as recent clinical trials show. In basic research the application of extracorporeal shock waves has been shown to enhance new bone formation in healthy bone. Target cells are fibroblasts, osteoblasts and mesenchymal stem cells in the bone marrow. Therefore we investigated whether extracorporeal shock waves may differentiate mesenchymal stem cells into an osteoblastic lineage. **Methods:** Mesenchymal stem cells were cultured and treated by shock waves with 15 and 25 kV. Supernatant was investigated by ELISA for bone markers. Also expression of bone markers like cbfa1, collagen1 and ALP was examined by lightcycler. Histology was performed by a v. Kossa staining.

**Results:** In the group of 15 kV marked elevations in the expression of bone markers cbfa1, collagen1 and ALP were found. Histology showed a positive v. Kossa stain for the treated cells. ELISA did show only slight changes in the production of bone markers.

**Discussion:** The results reveal new insights in the mechanism of bone healing by extracorporeal shock waves. Until now, many authors have shown the production of bone growth factors by osteoblasts or fibroblasts, whether this leads to a differentiation or direct mechanical effects on the stem cells has to be clarified in the future.

**Conclusion:** Extracorporeal shock wave treatment of mesenchymal stem cells shows in vitro signs of a differentiation into an osteoblastic lineage. This may contribute to the healing of non unions.

Device and producing company: XL 1, Dornier

## **(26)Stem and progenitor cells in shock wave science**

**Holfeld J.**

**Introduction:**

Low energy shock waves are well known to induce tissue regenerative effects. Clinical findings in the treatment of several kinds of skin lesions suggest that there is not only wound healing but some kind of repair process involved. In some cases, tissue integrity and functionality could be completely restored. Besides the involvement of interleukins, growth factors and a suppression of the acute pro-inflammatory response (leading to a repair mechanism that is close to fetal wound repair), there is some evidence in the literature that even recruitment of progenitor cells may be involved. This and findings of wound healing with hardly any or even without scar tissue suggest that the shock wave induced effects may, in fact, be closer to fetal regeneration than to adult wound repair.



#### **Discussion:**

At least in part the tissue regenerative effect of shock waves may be explained by recruitment of progenitor cells. This has already been shown in some basic research studies, including our own findings of endothelial progenitor cells (EPCs) migrating into infarcted myocardium after direct epicardial shock wave treatment in rats. Release of a chemoattractant for recruitment and homing of stem/ progenitor cells in the treated tissue was found.

Findings of other groups show that pre-treatment with ESWT of ischemic limbs enhances migration of systemically injected EPCs into the target area. ESWT therefore seems to be a potent adjunct to all kinds of cell therapies. However, the question remains whether subsequent injection of stem or progenitor cells following ESWT is necessary.

Numerous studies showed the potential of ESWT on stem and progenitor cells in vitro. Findings include the promotion of differentiation as well as an increase of proliferation of the cultured cells.

An important point of interest therefore remains whether progenitor cells can be recruited and stem cells can be positively influenced by shock waves. ESWT may have a systemic effect when treating these cell types at their origin, e.g. bone marrow. If this hypothesis would work, ESWT would no longer be limited to the area of injury or disease. For example, treating bone marrow to heal stroke as released stem/ progenitor cells would migrate to the brain and could be a major target of future research.

Contact: johannes.holfeld@meduniwien.ac.at

**Friday, June 25**

#### **(27) Shockwave therapy response on ParaOstheoArthropathies**

**Paolo Buselli 1, Sara Messina 2, Valeria Coco 3, Vincenzo  
Bosco 4**

1 Spinal Unit Department, Hospital of Valtellina and Valchiavenna, Sondrio, Italy

2 Department of Physical Medicine and Rehabilitation, IRCCS Policlinico San Matteo, University of Pavia, Pavia, Italy

3 Physical Medicine and Rehabilitation Center, Acireale, Catania, Italy

4 Casa di Cura Madre Fortunata Toniolo, Bologna, Italy

**Introduction:** ParaOstheoArthropathies (POA) are frequent in post-coma or spinal injury. The incidences are around 10%. POA reduce Range of Motion (ROM), patient autonomy and increase medical complications.

**Methods:** From April 1997 to December 2009, 41 patients with 45 POA suffering from Heterotopic Ossification (HO) at the hip were treated with

**shock-wave (ESWT) therapy and an associated intensive rehabilitation program immediately after ESWT.**

**Results: 45 POA were evaluated one and three months after the treatment. For the patients treated less than 12 months after the injury, with biochemical signs of active process, we noted an improvement of the ROM in 87,5 % of cases; in patients treated more than 18 months after the injury, without biochemical signs of active process, we noted an improvement of the ROM in only 49% of cases. Only a partial reduction of the ossification was observed in the X-ray images, 3 months after treatment, despite patients showing signs of functional improvement after therapy.**

**Discussion: The different response between precocious and belated treatment is probably related to the evolution of connective tissues in HO. The particular X-ray response on the ossified tissue depends on the specific osteogenic characteristic of HO compared to tendinopathy calcification with different histological structure.**

**Conclusion: According to our results, we propose treating POA as soon as ROM reduction and associated X-ray imaging becomes evident. These encouraging results push us to continue these treatments, associated to rehabilitation, and will allow us to clarify better the therapeutic approach and the tissue response in POA.**

**Device and producing company: Ossatron OSA 140, Evotron - HMT s.r.l.**

## **(28) Shockwave therapy for mature heterotopic ossifications – A case report**

**Michael Chang 1, Tom Matula 2**

**Institution: 1 Physical Medicine Institute, Bellevue, WA 98005, USA**

**2 Applied Physics Lab, University of Washington, Seattle, WA 98195, USA**

**Introduction: Heterotopic ossification (HO) is the formation of lamellar bone in soft tissue, commonly seen among patients with burns, orthopedic fractures/procedures, brain/spinal cord injuries, muscle contusions and rare hereditary disorders. Patients with HO often experience functional disability due to joint limitations. Reduction of HO preventively and for treatment has been attempted, but with limited success. Encouraging recent HO outcomes using shockwave therapy (SWT) have been presented but with unclear mechanisms.**

**Methods: 46 yo male recovered from traumatic brain injury 4 years earlier but functionally limited by hip and elbow contracture due to mature heterotopic ossifications. 3D fine-cut CT angiography and dynamic ultrasonography were investigated for SWT planning. Etidronate was started at 1mg/Kg/d before, during and after two separate SWT sessions for each joint. Using fluoroscopic/ultrasonographic guidance to focus on the HO, shockwave energy of OssaTron was ramped to 20 kV (1Hz), then 20-21 kV (4 Hz) for the elbow (7-8000); to 24-26 kV (1Hz), then 24-26 kV (4Hz) for the hip (7000). Vascular and nervous systems across shockwave focus were closely monitored.**

**Results:** SWT for HO was well tolerated. 35 and 55-degree flexion/extension range of motion were gained in hip and elbow, respectively. Functional improvements noted in gait, standing and upper limb use.

**Discussion:** Physical mechanisms such as spallation, cavitation, squeezing, super-focusing, fatigue and layer separation have all been proposed for shockwave lithotripsy. These mechanisms may well apply to HO. Biological responses, such as controlled inflammation, neovascularization, and modification of soft tissue matrix may also contribute to favorable outcomes.

**Conclusion:** SWT provides a safe and efficacious therapeutic option for mature HO.

**Device and producing company:** OssaTron (SanuWave)

## **(29) Shock waves in the treatment of post-traumatic myositis ossificans**

**Sara Messina (1), Paolo Buselli (2), Valeria Coco (3), Angela Notarnicola (4), Biagio Moretti (4)**

**Institution:**

**1) Department of Physical Medicine and Rehabilitation, IRCCS Policlinico San Matteo, University of Pavia, Italy**

**2) Department of Spinal Unit, Hospital of Valtellina and Valchiavenna, Sondrio, Italy**

**3) Physical Medicine and Rehabilitation Center, Acireale, Catania, Italy**

**4) Department of Clinical Methodology and Surgical Techniques, Orthopedics Section, Faculty of Medicine and Surgery of University of Bari, Italy**

**Introduction:** Myositis Ossificans traumatica (MO) occurs after blunt trauma to muscle tissue. Patients experience tenderness and swelling at the site of injury and symptoms are generally unresponsive to one week of rest. The traditional therapeutic approach relies on a variety of treatments, such as physical therapy but evidence of their proven clinical efficacy is lacking. The aim of this clinical study is to assess the efficacy of extracorporeal shock wave therapy (ESWT) in the treatment of MO.

**Methods:** We illustrate a case series of 24 sportsmen with post-traumatic MO. After treatments with rest, ice, pharmacological therapies and daily physiotherapy, without any improvement, we administered three sessions of ESWT. Evaluations were made before treatment and 1, 2, 3, 6 and 12

months after treatment, and consisted of clinical and functional assessment and X-ray evaluation.

**Results:** Only a partial reduction of the ossification was observed in the X-ray images but all the patients showed signs of functional improvement immediately after therapy. Two months after the therapy, a normal range of motion and no signs of weakness were observed. Three months after treatment, 87.5% of patients resumed regular sports activities.

**Discussion:** Our clinical findings demonstrate that ESWT treatment improved the trophic changes of the damaged muscle tissue and induced a statistically significant functional recovery. The results of the current clinical experience reveal that when ESWT were associated to physiotherapy, the management of MO became efficacious.

**Conclusion:** Our results indicate that ESWT offers an interesting therapeutic opportunity for restoring the physiologic conditions of muscle extensibility in post-traumatic MO, associated to traditional rehabilitation.

**Device and producing company:** Ossatron OSA 140, Evotron - HMT s.r.l.

### **(30) Extracorporeal shock wave therapy in osteonecrosis of the talus**

**Geng-Yan Xing, Zhan Shi**

Department of Orthopedics, The General Hospital of the Chinese People's Armed Police Forces, Beijing, China

**Introduction:** Osteonecrosis of the talus is an often tragic and devastating bone disease. It has always been a surgical challenge because the talus is hidden by its anatomic location and lead to complications. Consequently, there is interest in developing an effective nonsurgical technique for treating osteonecrosis of the talus.

**Methods:** We treated six patients with three sessions of 2000 impulses of shockwaves each, at 0.14~0.16 mJ/mm of energy flux density with two days intervals between treatment using EMS Swiss Dolorclast ESWT generator (produced by EMS company Switzerland) and followed them up for two years. They were examined clinically and radiographically, and the clinical data were obtained at the time of presentation and at the most recent follow-up examination.

**Results:** Our results showed improvement in pain, function over a six-month period. At one year after ESWT, their symptoms were markedly relieved and no complications were observed. The MRI also showed that the low-signal-intensity segment in the talar dome was reduced and the articular surface was clearer than before.

**Discussion:** Shock waves induce hyperstimulation analgesia by increasing the threshold of pain and promote bone-healing as a result of microfracture. It is reasonable to believe that physical shockwaves provide analgesic effect and may alter the pathophysiology of osteonecrosis of the talus by altering the vascularity of the affected parts of the talus and improvement in blood supply and restoration of talus affected by osteonecrosis processes. **Conclusion:** We suggest that this favorable result may be due to the beneficial effects of ESWT.

**Device and producing company:** Swiss DolorClast, EMS

### **(31) Extracorporeal shock wave therapy combined with autograft of bone mesenchymal stem cells treatment of osteonecrosis of the femoral head**

**Geng-Yan Xing, Zhan Shi**

**Department of Orthopedics, The General Hospital of the Chinese People's Armed Police Forces, Beijing, China**

**Introduction:** Extracorporeal shockwave treatment has been shown effective in early osteonecrosis of the femoral head (ONFH). Since osteonecrosis may be a disease of mesenchymal cells or bone cells, the possibility has been raised that bone marrow containing osteogenic precursors implanted into a necrotic lesion of the femoral head may be of benefit in the treatment of this condition. The purpose of this study was to evaluate the effects of ESWT combined with autograft of bone mesenchymal stem cells (BMSCs) for ONFH.

**Methods:** We studied 92 patients (108 hips) with stage-I or II osteonecrosis of the femoral head, according to the system of the ARCO. The hips were allocated to a program of either ESWT (the control group) or ESWT and implantation of BMSCs (the BMSCs group). Each subject received three-sessions of ESWT. The primary outcomes studied were safety, clinical symptoms, and disease progression.

**Results:** After 12 months, significant improvement in the mean Harris hip score and decreases on the proportion of MRI low signal region were noted at both groups. When compared with the control group, BMSCs group was found to have better results, especially in stage II. Moreover, five hips in the control group had deteriorated to stage III, whereas only one hip in the BMSCs group had progressed to this stage.

**Discussion:** This method decreased the pain and other joint symptoms caused by the osteonecrosis and delayed the progression of the disease preventing collapse during the 12 month follow-up period. Long-term results are needed to confirm the efficacy of this novel treatment for ONFH. **Conclusion:** ESWT combined with autograft of BMSCs appears to be a safe and effective treatment for early stages of ONFH.

**Device and producing company:** HKSW-O (produced by Shenzhen Huikang China)

## **(32) Shock wave therapy verses intramedullary screw fixation for nonunion of the proximal fifth metatarsal metaphyseal diaphyseal (Jones) fracture**

**John Patrick Furia 1, Paul J. Juliano 2, Allison M. Wade 2, Wolfgang Schaden 3, Rainer Mittermayr 4**

**Institution: 1. SUN Orthopedics and Sports Medicine, 2. Chief Foot and Ankle Division, Dep. of Orthopedics, 3 AUVA Trauma Center Meidling, Austria, 4 Ludwig Boltzmann Institute for Experimental and Clinical Traumatology, 1090 Vienna, Austria**

**Introduction:** The current “gold standard” for treatment of chronic fracture nonunion of the fifth metatarsal metaphyseal diaphyseal region is intramedullary screw fixation (ISF). Complications with this procedure, however, are not uncommon. Shock wave therapy (SWT) can be an effective treatment for fracture nonunions. The purpose of this study was to evaluate the safety and efficacy of SWT as a treatment for fracture nonunions of the fifth metatarsal metaphyseal diaphyseal region.

**Methods:** Twenty-three patients with a fracture nonunion of the fifth metatarsal metaphyseal diaphyseal region received high-energy SWT (SWT Group; 2000 to 4000 shocks; energy flux density per pulse, 0.35mJ/mm<sup>2</sup>). Twenty patients with a fracture nonunion of the fifth metatarsal metaphyseal diaphyseal region were treated with ISF. Evaluation was by determination of the number of fractures healed at 3 and 6 months post-treatment and by incidence of complications.

**Results:** 20/23 nonunions in the SWT group and 18/20 nonunions in the ISF group were healed 3 months post-treatment. 21/23 nonunions in the SWT group and 18/20 nonunions in the ISF group were healed 6 months post-treatment. There was one complication in the SWT group ( one case of post-treatment petechiae) and 11 complications in the ISF group ( 1 refracture, 1 cellulitis, and 9 cases of symptomatic hardware).

**Discussion:** The present study evaluated the effects of SWT on a series of patients with a nonunion of a proximal fifth metatarsal metaphyseal diaphyseal fracture who had not responded to nonoperative management. The outcome for the entire population was evaluated and compared to a group of similar patients treated with ISF. Unlike prior studies, and one of the strengths of this trial, the patient groups were homogenous.

Eight-seven percent (20/23) of the SWT fractures and 90% (18/20) of the ISF fractures were healed 3 months post-treatment; 91% (21/23) of the SWT fractures and 90% (18/20) of the ISF fractures were healed 6 months post-treatment. SWT was well tolerated and yielded only one complication. ISF yielded 11 complications including 9 cases of symptomatic hardware that required a second surgical procedure and one refracture that required additional immobilization.

**Conclusion:** Both ISF and SWT are effective treatments for fracture nonunions of the fifth metatarsal metaphyseal diaphyseal region. ISF is

associated with complications that frequently result in additional surgery.  
Device and producing company: OssaTron® device (High Medical Technologies, Lengwil, Switzerland); Orthowave 280® device (MTS, Konstanz, Germany)

### **(33) Focused low energy ESWT for treatment of bony spur and pain condition in disabled double amputee athlete**

**Hannes Mueller-Ehrenberg, Helmut G. Neuland**

Orthopedic Practice Muenster, Germany

**Introduction:** Painful condition due to bony spur and trigger points after a calf amputation is not a rare complication. Very often a surgical revisionary operation is offered, to remove the bony spur, but success not consistent.

**Methods:** A disabled athlete double amputee ( Sport class T44) with bony spur at the amputation was treated four times at the bony structure and the trigger points in the remaining calf muscle

**Results:** After four sessions of focused low energy ESWT the patient was back to full training and qualified for The World Championships, where he ( 6 months later ) won 1 Gold and 2 Silver medals.

**Discussion:** The successful treatment of bony structures such as pseudarthrosis by ESWT is well known. This case report shows that painful conditions due to a bony spur can be treated successfully with ESWT.

**Conclusion:** Focused low energy ESWT is a good alternative for treating bony spurs and pain conditions after amputation in disabled athletes.

Device and producing company: Piezoston 100 plus, Wolf

### **(34) Shockwave therapy in the management of complex regional pain syndrome in medial femoral condyle of the knee**

**Biagio Moretti, Angela Notarnicola, Lorenzo Moretti, Antonio Panella, Silvio Patella**

**Institution:** Faculty of Medicine and Surgery, University of Bari, General Hospital, Piazza G. Cesare, 11, 70124, Bari, Italy

**Introduction:** The aim of this prospective study was to assess the efficacy of shockwave (SW) therapy in the management of complex regional pain syndrome (CRPS).

**Methods:** In this study, 30 patients (pts) who were affected by CRPS of the medial femoral condyle and unresponsive to previous standard physiotherapeutic and pharmacological treatment underwent 3 SW sessions at 72-hour intervals, each consisting of 4000 shocks emitted by a MiniLith SL1 Storz electromagnetic generator. An Energy Flux Density (EFD) of 0.035 or 0.09 mJ/mm<sup>2</sup> was used, depending on how well the patient endured the pain during the treatment.

**Results:** Satisfactory results were observed in 76.7% of the cases (23 pts) at the 2-month follow-up (FU) visit, and in 80% (24 pts) at the 6-month FU visit.  
**Discussion:** The CRPS is triggered by pain following trauma, which leads to capillary vasospasm causing edema of the spongy bone due to the lymph stasis and localized osteopenia that results from the reduced blood flow. It is recognized that SW treatment is able to bring about immediate pain relief due to desensitization of the local nociceptive fibers and the release of substance P. The early clinical efficacy in the treatment of osteonecrosis of the head of the femur is largely dependent on this effect.  
**Conclusion:** The therapeutic effects of SW were caused by decreasing pain. The significant improvements we obtained bear witness to the potential value of SW therapy in the management of CRPS.

### **(35) Watching a Walt Disney video before shock wave therapy reduces procedure related pain: A randomized controlled trial**

**Antonio Morral (1), Jan D. Rompe (2), Reme Ruiz (1), Lluís Costa (1), Mariano Fernández-Fairen (1), Bibiana Torrent (1)**

1 Salut i Esport Rehabilitation Center. Santa Perpètua de Mogoda. Barcelona. Spain,

Facultat de Ciències de la Salut Blanquerna, Universitat Ramon Llull, Barcelona, Spain

2 OrthoTrauma Evaluation Center. Mainz. Germany (Switzerland)

**Introduction:** Shock wave therapy is an effective, safe and non-invasive therapeutic option for some chronic tendinopathies. Shock wave therapy is designed as a local anesthetic-free procedure. However, it is sometimes perceived as an uncomfortable and painful procedure by the patients. Pain experience is related significantly to the context of the treatment (prior information, consequences, hope, fear, distraction, trust, setting, treatment purpose, etc ...)

The aim of this study was to evaluate the efficacy of adding metaphoric information (Walt Disney video) to our usual pre-procedural information in alleviating procedure related pain.

**Methods:** There were 40 patients with chronic tendinopathies, of which 22 were men and 18 women. The ages ranged from 26 to 65 years, with a mean age of 52 years. The pathology distribution was: 24 patients with plantar fasciopathy, 5 with lateral epicondylopathy, 4 with greater trochanter pain syndrome, 3 with shoulder impingement syndrome, 2 with achilles tendinopathy, and 2 with patellar tendinopathy. The 40 patients were divided in two groups using a computerized random-number generator. A video group of 20 patients that watched the video and a Non-Video Group of 20



patients that did not. All patients received the same prior information about the pathology and effect of shock wave therapy. But one group received the information with video support and another group without. The video was a 9 minute musical segment taken from Fantasia (Firebird. Fantasia 2000 Walt Disney. Music: Igor Stravinsky.) The video was a metaphoric representation of pain and tissues regeneration with shock wave therapy.

Procedure variables: Device used: Swiss DolorClast (EMS-Switzerland). Number of impulses: 2000. Frequency: 8 Hz. Energy flux density: the maximum tolerated by the patient; between 0.10mJ/mm<sup>2</sup> and 0.18mJ/mm<sup>2</sup>. (2-4 bar).

The patients rated pain associated with the procedure according to a 100-mm visual analog scale (VAS). Pain was assessed by a blinded evaluator. The evaluation was performed immediately after procedure. The t-test for independent samples was used for statistical analyses. In terms of baseline characteristics, there were no statistically significant differences between the two groups

Results: There were significant differences between the video and non-video group. The mean VAS score was 42 mm (SD: 2,1) in video group versus 68 mm (SD: 1,6) in non-video group. ( $p = 0.015$  mJ/mm<sup>2</sup> (SD: 0,03) in the video group versus 0.12 mJ/mm<sup>2</sup> (SD: 0,03) in non- video group. ( $p = 0.001$ ).

Discussion: Local anesthetics inhibit the release of substance P and CGRP from the nociceptive nerve endings. It could be for this reason that local anesthesia applied prior to treatment reduced the efficiency of shock wave therapy. Pain is a complex experience and it is not only the activation of nociceptive neurons. Sensory information from the peripheral neurons needs to be evaluated by the central nervous system. The evaluation of sensory information is extremely comprehensive. It involves complex memory, reasoning and emotional processes. The context and central mechanisms can influence pain perception. Two questions emerge:

1. Can these central mechanisms influence the release of neuropeptides from primary sensory nerve terminals?
2. Would it affect the clinical results either positively or negatively?

Basic research & further large randomized controlled studies are necessary to support the results of our clinical trial.

Conclusion: Watching a Walt Disney video before shock wave therapy is a simple, inexpensive and effective way of reducing the pain associated with a shock wave application. We propose the use of metaphoric information about pain and tissue regeneration prior to using shock wave therapy to reduce the pain associated with a shock wave application.

Device and producing company: Swiss DolorClast (EMS-

## **(36)Neurophysiological monitoring during shockwave therapy for elbow heterotopic ossifications**

## **Michael Chang, Tom Matula**

**Institution: Physical Medicine Institute, Bellevue, WA 98005, USA**

**Introduction: There's increasing concern over potential neurological injury during shockwave therapy (SWT), especially if neurovascular bundles are close to target tissues. A clinical case is presented for neurophysiological monitoring during two SWT sessions for elbow heterotopic ossifications (HO).**

**Methods: Peripheral nerves/vasculatures near the HO were traced using electrodiagnostic inching and ultrasonographic/duplex techniques. Using fluoroscopic/ultrasonographic guidance to target the HO, shockwave energy of OssaTron was ramped to 20 kV (1Hz), then to 20-21 kV (4Hz) for cumulative 7-8000 shocks. Real-time eletromyography (EMG) were monitored with electrodes on abductor digiti minimi/first dorsal interosseous (ulnar), abductor pollicis brevis (median) and extensor indicis (radial) muscles. With nerves stimulated supra-maximally proximal to SWT region, compound muscle action potential (CMAP) of ulnar, median and radial nerves were closely monitored before SWT, and at each 2000 shock. Results: Increased EMG response to shockwaves noted as SWT proceed. In one occasion, there's transient loss of median CMAP, which recovered after SWT focus readjusted. Noticeable CMAP amplitude reduction and latency increase during SWT, indicating conduction block across SWT region. Full recovery of CMAP amplitude/latency noted after SWT.**

**Discussion: Increases of EMG responses to shockwaves probably due to cavitations that interact/respond to shockwaves, resulting in evoked nerve action potential. Transient CMAP loss and delay in nerve conduction across nerve segments exposed to shockwaves probably result from alterations of local blood perfusion to nerves.**

**Conclusion: Shockwaves may evoke nerve action potential probably through its interaction with cavitations. This interaction becomes more apparent when tissue cavitations increase. Transient conduction block across nerve segments exposed to shockwaves recovers quickly after SWT. Device and producing company: OssaTron (SanuWave), Sierra Wave (Cadwell Laboratory)**

## **(37)Correlation between total energy emitted and efficacy of ESWT**

**Maria Cristina Ottone (1), Filippo Fagnani (2), Emanuela Roli**

**1 ASL AL-Distretto di Tortona - Via Milazzo,1 - Tortona, Italia**

**2 Alliance Medical Group - Via Alunno,23 – Milano, Italy**

**Introduction: We aim to verify the efficacy of total energy emitted comparing the results of different number of sessions and different pulses per session.**

**Methods: The treatment was carried out using Piezoson 300 from Wolf, a focused piezoelectric generator with three different focal dimensions and we used large focus and low energy density (0,06 mJ/mm<sup>2</sup>) with a total**

energy of 6,8 J.

This study includes 200 patients:

Group A: 150 patients, 4 applications, 2000 shock waves/session

Group B: 50 patients, 3 applications, 2700 shock waves/session

Results: The follow-up is ongoing and we will present the results during the meeting. Discussion: Last year we compared different protocols varying the focus dimension and energy density with a stable value of total Joules emitted: we obtained the same results in both groups, confirming a strong link between the efficacy of ESWT and the total energy emitted. Now we want to verify the results using the same total energy distributed in three sessions: if the results are similar it is possible to further confirm that the most important factor in shock waves therapy is the total energy emitted. Conclusion: If the results will confirm the efficacy of treatment using the same total energy, but with a reduction of sessions, it means that we can have the same efficacy with a shorter treatment and this is important because it is less expensive: more patients are treated and less working days are lost. We are currently evaluating the patients in order to obtain final data to draw final conclusions that will be presented at the Congress. Device and producing company: Piezoson 300 - WOLF

### **(39)Mathematical modeling of shockwave therapy for osteomyelitis**

**Kevin Seals (1), James Bryers (1), Michael Chang (2)**

1 Dept of Bioengineering, University of Washington, Seattle, Washington, USA

2 Physical Medicine Institute, Bellevue, Washington, USA

Introduction: Mathematical modeling has been widely used in science and engineering to investigate and optimize complex problems. Chronic osteomyelitis, usually associated with complex bony/hardware geometry, persists despite aggressive current clinical treatments. Evidences suggest shockwaves have the potential to treat osteomyelitis, likely through biofilm disruption and regional neovascularization. Mathematical modeling of shockwave propagation within osteomyelitis may help to optimize shockwave therapy. Methods: COMSOL Multiphysics is used to construct an acoustic model with Gaussian explosion at source F1. An ellipsoidal reflector of OssaTron focuses the shockwave to F2, where a tibia/fibula (separated by 3.5 cm) osteomyelitis model is placed. Anatomical features of osteomyelitis such as sequestra and drainage sinuses are introduced to these models. The distribution of pressure, von Mises stress, and shear stress are characterized as a function of time.

Results: Pressure traces suggest that sequestra should be placed on the F1/F2 axis, and multiple sequestra in the shockwave propagation pathway can be treated without a reduction of the therapeutic effect. Optimal treatment of osteomyelitis in the tibia is seen to occur when the tibia/fibula axis is perpendicular to the F1/F2 axis. The rotational orientation of an

asymmetrical sequestrum does not seem to influence the treatment. Discussion: Shockwave interactions with bony anatomy/hardware near the osteomyelitis may significantly impact treatment outcomes. Modeling provides unique insights into shockwave propagation/focus within such a complex target environment. Conclusion: Modeling can be used to investigate shockwave propagation within osteomyelitis. Models that incorporate images for osteomyelitis can be constructed to develop optimal patient-specific ESWT protocols.

Device and producing company: OssaTron, SanuWave

**(40)Extracorporeal cardiac shockwave therapy in severe coronary artery disease unsuitable for percutaneous coronary intervention (PCI) and coronary artery bypass surgery(CABG)--A single center experience.**

**Morgan Mao-Young Fu, Ching-Jen Wang, Hon-Kan Yip, Chiung-Jen Wu, Chu-Yuan Fang, Sarah Chua, Chun-Jen Chen, Su-Ming Chen, Wen-Hou Leu,**

Institution: Chang Gung Memorial Hospital, Kaohsiung Medical Center, 123, Ta-Pei Road, Niao-Sung Hsiang, Kaohsiung Hsien, Taiwan,

Introduction: To test the effectiveness and feasibility of extracorporeal cardiac shockwave(SW) therapy in patients(pts) with severe coronary artery disease (CAD) unsuitable for revascularization.

Methods: Extracorporeal SW is performed with the application of 100 shocks/spot at 0.09mJ/mm<sup>2</sup> energy flux density for 3-6 spots each time, with three times per week at each series for three series at 1, 5, 9 weeks. The location and depth of SW application are based on thallium scan findings guided by echocardiography. The following parameters will be evaluated including symptoms of angina and needs of nitroglycerine use. The exercise tolerance and dipyridamole thallium 201 myocardial perfusion scan and echocardiography will be followed up after 6 months of initial therapy.

Results: This study included 27 pts, 18 males and 9 females with mean age of 70 + 9 (50-89) yrs old. 14 pts had DM, 7 had CVA, 7 had previous CABG, 15 had old MI. 25 pts had triple vessel disease and 2 had two vessel disease. Each patient received 1200 to 5200 shocks (3881 + 935) respectively during the whole course of therapy. One patient did not complete the study due to recurrent CVA. Among the remaining 26 pts, 11 pts could perform treadmill exercise test, the maximal exercise duration increased from 248 to 319 second (P=0.007). 21 of 26 (80%) pts showed improvement of reversible ischemia by follow up thallium scan. Two patients received coronary angiography and coronary artery showed new neovascularization after SW therapy.

Discussion: Extracorporeal cardiac SW therapy can ameliorate myocardial ischemia detected by thallium 201 myocardial perfusion scan and improve

symptoms of angina.

**Conclusion: Extracorporeal cardiac SW is feasible and effective in patients with CAD unsuitable for PCI and CABG.**

**Device and producing company: Medispec LTD, Israel**

### **(41) Extracorporeal shock wave therapy (ESWT) for chronic pelvic pain syndrome (CPPS) in a randomized placebo-controlled double-blind study: One year follow up results**

**Reinhold P. Zimmermann (1), Alin Cumanas (2), Florin Miclea (2), Gunter Janetschek (1)**

**1 Dept. of Urology, Medical School, Paracelsus Medical University, Muellner Hauptstr. 48, 5020 Salzburg, Austria**

**2 Dept. of Urology, Medical School, University of Timisoara, Timisoara, Romania**

**AG, Switzerland**

**Introduction: ESWT has been shown to be an effective treatment for CPPS but effects are considered to be transitory. This investigation reports a prospective, randomized 1-year follow up.**

**Methods: 60 patients with CPPS (NIH classification IIIb) were treated by ESWT (focused shock wave, once weekly, perineal approach, Duolith, Storz Medical AG, Switzerland). For placebo treatment SW application was stopped within the transducer by membrane interposition. Pain was evaluated by visual analogous scale (VAS, 0-10), micturition by international prostate symptom score (IPSS, 0-35), specific complaints by NIH chronic prostatitis symptom index (NIH-CPSI, 0-43) and erectile function by the IIEF (international index of erectile function).**

**For the active-placebo relationship the Mann-Whitney Rank Sum Test was used ( $p = 0.05$ ). Differences before/after ESWT were evaluated using the Wilcoxon Signed Rank Test ( $p = 0.05$ ). Statistical analysis were done using SigmaStat 3.5 (Systat Software Inc, San Jose, CA, USA).**

**Results: The 1 year follow up (FU) was completed in 44 of 60 patients. In the 1 year FU, all parameters were still significantly improved in the active group. Side effects were excluded. VAS showed the clearest improvement (50% after 1 year).**

**Discussion: The long term FU proved ESWT as safe and effective. Pain and complaints were reduced permanently. Side effects were not seen. ESWT represents an optimal outpatient treatment option with attractive relation of costs/benefit in particular for private offices.**

**Conclusion: ESWT is now established as one of the very few CPPS therapy options whose efficacy has been proven by placebo control in long term FU and**

**nder economic aspects. Device and producing company: Duolith, Storz Medical**

## **(42) Shockwave therapy in treatment of chronic bacterial prostatitis**

**Boris A. Garilevich, Anton Rotov, Alexandr Levkovsky**

Institution: Central Clinical Aviation Hospital, Moscow, Russia

Introduction: The antibacterial therapy of patients with chronic bacterial prostatitis (CBP) seems difficult because the epithelium of the prostate is a barrier for the diffusion of antibiotics from the blood plasma into the nidus of the inflammation and the prostate secretion.

Methods: The experiment showed the influence of shockwaves on *Escherichia coli* in vitro and the level of the concentration of gentamicin in the tissues of the prostate against the background of shockwave influence. The active group in the clinical study was 28 patients, who received shockwave therapy according to the technique developed by us. The control group was 25 patients, to whom shockwave therapy was not applied.

Results: After the influence of shockwaves on *Escherichia coli*, their concentration was  $25.4 \pm 1.5 \times 10^7$  in 1 ml, while the control group showed  $54.6 \pm 1.7 \times 10^7$  in 1 ml, which testifies the reduction of the intensity of their reproduction.

In the experiment where gentamicin was applied to animals with shockwave influence, its concentration in the tissue of the prostate grew up to 2,000 mgr/gr, while the control group showed 25 to 30 mgr/gr.

The basic group of the patients showed the average term of the elimination of the agent from the prostate gland was  $7.8 \pm 1.2$  days, while the control group showed the sanitation of the prostate gland occurred 14.2 days (p

Discussion: Bacteriostatic action of shockwaves and elevation of local bioavailability of the antibiotic show reduction of the terms of the prostate sanitation among the patients with CBP.

Conclusion: Shockwave therapy promotes the elevation of efficiency in treating CBP.

Device and producing company: Compact

## **(43) Extracorporeal shockwaves in tissue specific regeneration of paw pad in canine –Clinical observations**

**Erling Pedersen**

Nordic-HealthClinics

Los Boliches, Spain and Denmark

Introduction: Left metacarpal paw pad injury to Chow-Chow female causing inflammation. No results with conservative medical intervention. Outcome: the dog chewed off the pad completely causing a non-healing wound lasting four years.

Treatment objectives: increase the local blood flow and activate “dormant” stem cells/progenitor cells in the pad tissue.

**Methods:** Extracorporeal shockwaves were administered six times over a period of three months using the #1 focal head of the Storz DuolithTT. 1st – 5th treatment 2 - 3.6 Joules total used per treatment at settings of 0.2 to 0.25 mJ/mm<sup>2</sup> at 1.5Hz. 6th: 1.38 Joule administered at 0.3 mJ/mm<sup>2</sup> Shockwaves were administered in specific angles at the proximal muscular tissues and into the wound.

**Results:** Treatments: 1st: bleeding resumed for a few days. The color of the tissue changed from deep red to pinkish. 2nd: cellular activity was noted at the perimeter; membrane over the tissue developing. 3rd – 4th: pad tissue grew rapidly from the perimeter. 5th: paw pad tissue had grown to cover 90% of wound. 6th: 100% completion of paw pad.

**Discussion:** Visual re-growth of an anatomical structure that would normally not regenerate to its full form and function, without activation of stem cells.

**Conclusion:** ESWT is a valid treatment for non-healing wounds. Further scientific work must be made to clearly identify the underlying histological processes and the roles of the blood vessels imbedded in adjacent tissues. Elastographic ultrasound scanning of compromised soft tissues and vessels would enhance the visual understanding.

#### **(44)Effects of shock wave therapy in the skin of patients with progressive systemic sclerosis: A pilot study**

**Ernesto Amelio, Elisa Tinazzi, Claudio Guerra, Claudio Lunardi**

**Institution:** Shock Wave Unit - Azienda Ospedaliera Universitaria Integrata di Verona - Largo L.A. Scuro,10 37134 Verona AG

**Introduction:** Vasculopathy, immunological abnormalities, and excessive tissue fibrosis are key elements in the pathogenesis of progressive systemic sclerosis (SSc). Extracorporeal shock waves (ESW) have anti-inflammatory and regenerative effects on different tissues. We hypothesized that ESW can reduce endothelial cell damage and skin fibrosis in patients with SSc.

**Methods:** We enrolled 30 patients affected by SSc, 29 females and 1 male. Rodnan Skin Score (RSS) and Visuo-Analogical Scale (VAS) for skin wellness were performed before and immediately after ESW therapy (ESWT) and at 7, 30, 60, and 90 days after the treatment.

Sonographic examination of the patients' arms was performed before and 7, 30, 60, 90 days after treatment. Blood samples were obtained before and 30 and 60 days after treatment to measure serological levels of von Willebrand factor, vascular endothelial growth factor, intracellular adhesion molecule-1, monocyte chemotactic protein-1. The number of endothelial progenitor cells (EPCs) and circulating endothelial cells (CECs) were determined at the same time points.

**Results:** After ESWT we observed a rapid and persistent reduction of RSS and decrease of VAS. There was no difference in skin thickness before and after ESWT; however, we observed a more regular skin structure and an

improvement in skin vascularization 90 days after treatment. EPCs and CECs increased 60 and 90 days after treatment, while serological biomarkers showed no variation before and after therapy.

**Discussion:** The present study demonstrates that, in patients affected by SSc, skin application of ESW causes a rapid and persistent improvement of clinical parameters (RSS and VAS for skin wellness) and a late increase in skin vascularization and in number of EPCs and CECs.

**Conclusion:** The results of our study suggest that ESWT is a novel and efficacious treatment that can be added to the pharmacological therapy in order to decrease endothelial cell damage and skin fibrosis in patients affected by SSc. This treatment is well tolerated and can be repeated without side effects; in the majority of cases it determines a rapid improvement of skin elasticity and skin wellness, even if the effects tend to reduce during the time.

**Device and producing company:** Duolith SD1 - Storz Medical

## **(45)Blood perfusion and molecular changes in diabetic foot ulcers: Extracorporeal shockwave vs. hyperbaric oxygen therapy**

**Ching-Jen Wang, Yur-Ren Kuo, Re-Wen Wu, June-Ming Chen, Rue-Tsuan Liu, Feng-Sheng Wang**

Department of Orthopedic Surgery, Chang Gung Memorial Hospital / Kaohsiung Medical Center, 123 Ta-Pei Road, Niao Sung Hsing, Kaohsiung, Taiwan 833

**Introduction:** Extracorporeal shockwave technology (ESWT) may be more effective than hyperbaric oxygen therapy (HBOT) in diabetic foot ulcers.

**Methods:** The ESWT group consisted of 38 patients who received ESWT. The HBOT group consisted of 45 patients who received HBO.

The evaluations included clinical assessment, blood flow perfusion scan and biopsy of the ulcers before and after treatment. The biopsy specimens were subjected to histopathological examination and immunohistochemical analysis.

**Results:** The ESWT group showed significantly better clinical results than the HBOT group. Blood flow perfusion rates were significantly improved after ESWT as compared to HBOT. The ESWT group showed significant increases in cell concentration, cell proliferation and reduced cell apoptosis than the HBOT group. Immuno-assays revealed significantly higher vWF, VEGF, eNOS, PCNA and EGF, and a decrease in TUNEL expression in the ESWT group, whereas the changes in the HBOT group were not significant.

**Discussion:** Managements of chronic diabetic foot ulcers require multi-disciplinary approaches including surgery in selected cases. Many adjunctive therapies are designed for the care of chronic diabetic foot ulcers including HBOT. Many studies have reported beneficial effects of



**HBOT, but none have showed universal success. The results of this study showed that ESWT is more effective than HBOT in chronic diabetic foot ulcers.**

**Conclusion: ESWT showed significant increases in neo-angiogenesis, and improvements in blood flow perfusion and tissue regeneration relative to HBOT in chronic diabetic foot ulcers.**

**Device and producing company: dermaPACE device (SANUWAVE, Alpharetta, GA, USA)**

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