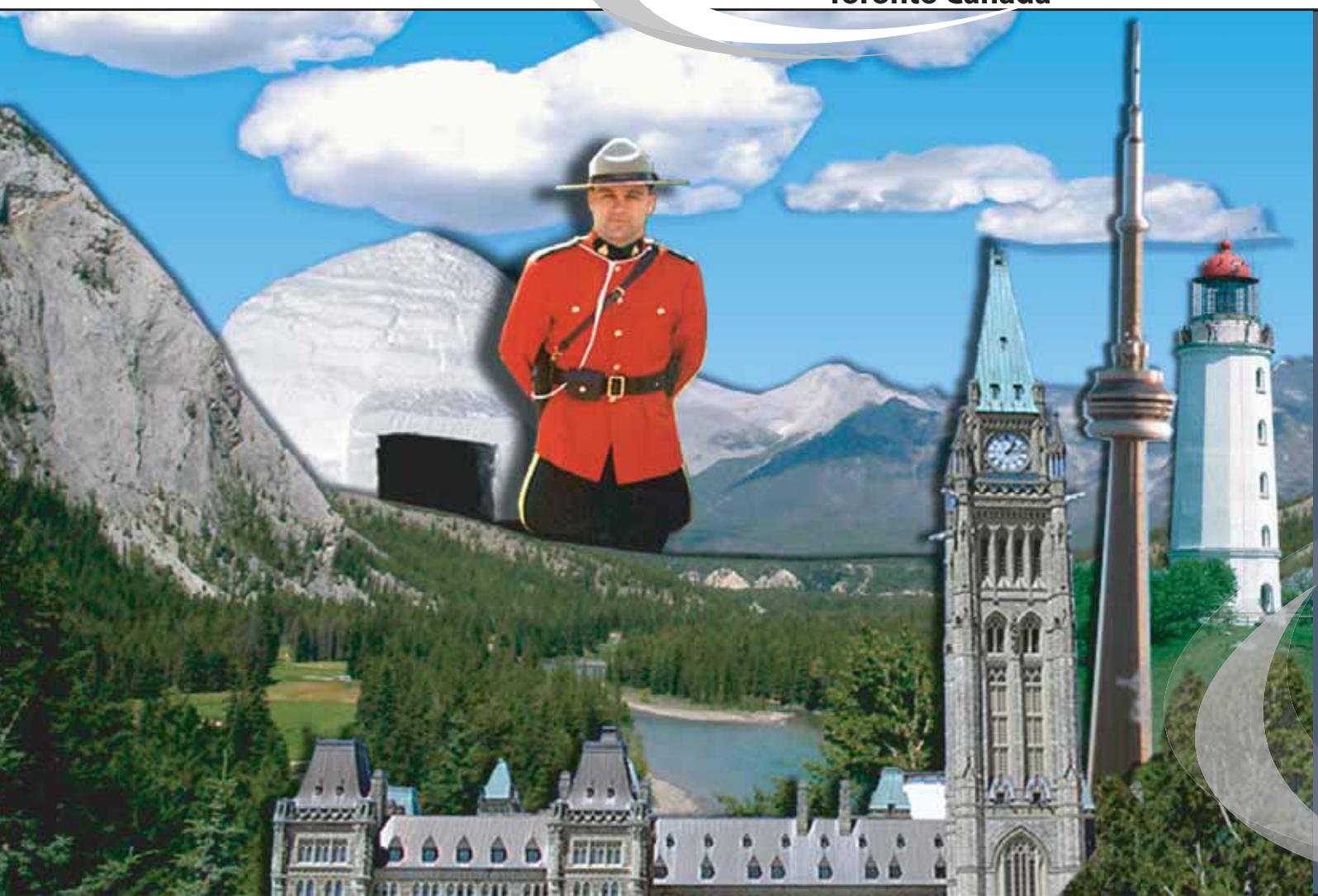




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Abstract

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1. Modelling of an electrohydraulic shock wave device - implications for optimal device operation

Michael Chang

Dept of Rehabilitation Medicine Box 356490 School of Medicine University of Washington Seattle, Washington 98195, USA

Device and producing company: OssaTron (HMT, SanuWave)

Introduction: Mathematical modelling is commonly used in science and engineering to gain insights into complex systems. Finite element analysis is used to model an electrohydraulic shock wave (SW) device to learn characteristics of this type of device.

Methods: COMSOL-Multiphysics is used to model an electrohydraulic SW device (OssaTron). Properties of de-gas water are used for modelling. Gaussian explosion shocks at F1 with various frequency contents are studied.

Results: Electrohydraulic SW device with semi-ellipsoid reflectors produced about 50% of the reflected shock wave intensity at F2 compare with the source (F1). Depending on the device and frequency contents of the SW, the primary divergent SW, which arrives at the F2 earlier than the reflected one, may have some therapeutic implications. SWs with higher frequency contents (shorter rise time) tend to have more focused F2 (-6dB). The F2 volumes tend to be oval in shape with the axial length longer than the lateral length. There's asymmetry in the axial length with the proximal portion longer than the distal one.

Discussion: Reflected SW rises gradually along the axial axis but declines quickly laterally. Higher frequency contents within the shock wave produce more focused F2 volume.

Conclusion: Intensity of the reflected SW at F2 amounts to about 50% of the source for an electrohydraulic device using a semi-ellipsoid reflector. Higher frequency contents within the shock wave produce more focused F2. Because of the narrower lateral axis of the F2 volume, aiming system is thus recommended. Moving the target tissue closer to F1 by deflating the coupling membrane is generally acceptable.

2. Shock wave energy deposition near model bone

Tom Matula, Juan Tu, Kirstin Fagnan, Michael Bailey, Randy LeVeque

Applied Physics Laboratory, University of Washington, Seattle, WA, USA

Applied Math Department, University of Washington, Seattle, WA, USA

Applied Physics Laboratory, University of Washington, Seattle, WA, USA

Applied Math Department, University of Washington, Seattle, WA, USA

Device and producing company: Dornier, Epos Ultra; Storz, Masterpuls

Introduction: The characterization of shock waves at the focal zone is well understood for some shock wave devices. For these devices the focal volume is shaped liked a small cigar. However, it should not be a surprise that the presence of bone will dramatically alter the shape of the focal zone. For a flat surface, reflected energy is simple to predict. For actual bone with more complicated geometries, the focal zone is much more difficult to predict. In particular, energy deposition needs to be better understood under these conditions. Our objective is to better understand energy deposition in the presence of musculoskeletal structures.

Methods: A disarticulated model plastic talus bone was used for in-vitro studies.

Electrohydraulic shock waves generated cavitation near the surface, the bubbles being imaged

with a high speed camera. Comparisons were made with numerical simulations of shock wave interactions with the model talus.

Results: Measurements of cavitation and pressure fields show that the presence of bone deflects shock wave energy. Simulations agree qualitatively with the data. Our interpretation of deflected energy deposition also agrees qualitatively with our observations of cavitation observed off-focus during in-vivo clinical ESWT.

Discussion: Modeling the interaction of the shock wave with bone yields important information about shock wave deflection. The degree of deflection, and ultimate deposition of energy, will depend on the relative orientation of the shock wave and bone structure.

Conclusion: It is important to better understand ESWT energy deposition. These studies should lead to improvements in designing standardized protocols. (Research partially supported by NIH DK43881).

3. Cavitation fields induced by shock wave propagation in polyacrylamide gel and ex-vivo porcine tissue

Michael Chang (1), Anh Truong (2), Daniel Santosa (3), Shahram Vaezy (4)

1) Dept of Rehabilitation Medicine/Mechanical Engineering, University of Washington, Seattle, Washington, USA

2) School of Medicine, University of Washington, Seattle, Washington, USA

3) Dept of Chemical Engineering, University of Washington, Seattle, Washington, USA

4) Dept of Bioengineering, University of Washington, Seattle, Washington, USA

Device and producing company: OssaTron (HMT, SanuWave) D-Actor 100 (Storz Medical)

Introduction: Extracorporeal shock wave therapy (ESWT) is the application of acoustic waves to biological tissue in the treatment of disease. These high-pressure acoustic waves deposit energy mainly at high acoustic impedance gradients through shear forces and cavitations. When this energy is released in biological tissues, the shock waves create cavitation bubbles, produce free radicals, and yield extremely high localized temperature. Cavitations are generated from the tensile portion of the shock wave (SW). It has been shown tissue cavitations can be induced by tensile pressure as low as -1 MPa. When cavitations collapse near an interface they create micro-jets pointing towards the interface and have been shown to erode kidney stones, disturb cell membrane and injure blood vessels. Therefore, roles of cavitations on a variety of SW's therapeutic efficacies as well as potential tissue injury need to be fully explored.

Methods: Cavitation fields generated by an electrohydraulic SW device (OssaTron - HMT, SanuWave) were compared with an unfocused pressure wave device (D-Actor 100 - Storz) in polyacrylamide gel blocks, with and without an embedded marble (2cm diameter, marble-gel interface at 4.5 cm depth), and in ex-vivo porcine thighs. Cavitation fields were monitored sequentially during the application using B-mode ultrasound with MicroMaxx (Sonosite).

Results: In polyacrylamide gel, OssaTron produced a deep (~2 cm) oval-shape cavitation field. Increases in SW energy density resulted in increases in both size and intensity of the cavitation field. Saturation of cavitation field was appreciated around 500 shocks. Increasing disruptions of the marble-gel interface from both shear stresses and cavitations were distinct with increasing number of shocks and energy density. D-Actor produced a superficial radially-diverging cavitation field, which increases in intensity with increasing number of pulses and application pressures. Saturation of cavitation field was also appreciated around

500 pulses. Minimal disruptions of the marble-gel interface from both shear stresses and cavitations were observed. In ex-vivo porcine thighs, using highest possible energy levels, both OssaTron and D-Actor did not produce any measurable cavitation field up to 3000 pulses cumulatively.

Discussion: Cavitation fields with different characteristics can be generated using either a focused SW device or an unfocused pressure wave device. Presence of cavitation bubbles may greatly diffract subsequent SW propagation. Ex-vivo porcine thighs are highly resistant in producing cavitation.

Conclusion: Both shear stresses and cavitations are important physical effects from SW application. Cavitations may induce therapeutic as well as damaging biological responses therefore need to be carefully controlled in ESWT. Characteristics of cavitation fields are tissue-, anatomy-, device-, and operation-dependent. There is obvious dynamic interaction between induced cavitations with SW applications that may greatly affect ESWT outcomes. Treatment of deep target tissue requires focused SW delivery of desired therapeutic dosages.

4. Acoustic and cavitation fields of three shock wave therapy devices

Robin O. Cleveland (1), Parag V. Chitnis (1), Scott R. McClure (2)

1) Dept. Of Aerosp. and Mech. Eng, Boston University, Boston, MA, USA

2) Dept of Vet. Clin. Sciences, Iowa State Univ. Ames, IA, USA

Device and producing company: OssaTron / Sanuwave, Evotron / Sanuwave, Swiss Dolorclast Vet / EMS

Introduction: There are a large number of different shock wave devices on the market. We report on measurements of three shock wave therapy (SWT) devices: two electrohydraulic devices (Sanuwave OssaTron, Sanuwave Evotron) and a ballistic device (EMS Swiss Dolorclast Vet).

Methods: Acoustic measurements were made using a fiber-optic probe hydrophone and a PVDF hydrophone. Cavitation was detected by passively listening to acoustic emissions. High-speed photography was used to image both the shock waves and cavitation activity.

Results: The electrohydraulic devices both generated focused shock waves with peak pressures 40 MPa (OssaTron) and 20 MPa (Evotron). The ballistic device produced a unfocused wave with 8 MPa peak and no shock front. Cavitation was measured using the characteristic time (cavitation inception to bubble collapse) which were 460 μ s (OssaTron), 400 μ s (Dolorclast) and 160 μ s (Evotron). The high-speed camera images show that cavitation activity for the electrohydraulic devices was located at the geometrical focus whereas for the ballistic device it was restricted to the surface of the applicator.

Discussion: The electrohydraulic devices measured produced focused shock waves. The smaller Evotron did not result in strong cavitation. The ballistic device did not produce a shock wave and analysis of the physics indicated that it was not possible for a shock wave to evolve. The Dolorclast has a "Focus" applicator but measurements and analysis indicated that it did not produce a focused field.

Conclusion: These data indicate that the SWT devices studied here vary in acoustic and cavitation output, and therefore mechanisms by which they generate therapeutic effects may be different.

5. Vulnerability of the spinal cord to injury from extracorporeal shock waves. An experimental study in rabbits

Tao-Chen Lee, Yu-Lin Yang, Ching-Jen Wang

Department of Neurosurgery and Orthopaedic Surgery, Kaohsiung Chang Gung Memorial Hospital, Kaohsiung, and Chang Gung University, Taoyuan, Taiwan

Device and producing company: None

Introduction: This experiment studied the vulnerability of spinal cord injury to extracorporeal shock wave treatment (ESWT).

Methods: In this experiment, twelve rabbits were used and divided into 3 groups (with 4 in each group). All the animals underwent a preceding lumbar laminectomy at L4 one week before ESWT. In group 1, 2000 impulses of high dose (0.62 mJ/mm² energy flux density) shockwave energy were applied to the spinal cord at the laminectomy site. In group 2, 2000 impulses of low dose (0.18 mJ/mm² energy flux density) shockwave energy were applied to the same site as group 1. Group 3 did not receive ESWT and served as control.

Results: None of the rabbits in the study groups (groups 1 and 2) showed weakness or paralysis of the hind limbs throughout the entire post-ESWT period. The spinal cord at L4 level of all the animals were harvested at the 13th day after laminectomy. On gross morphology, the cord from the study groups and the control group showed normal surface appearance. On microscopic examination, the cord from the control group showed normal findings, while the cord from the study groups showed variable degree of myelin damage and neuronal loss.

Discussion: These microscopic findings appeared dose dependent. In the cord of the low energy group (group 2), the neuronal loss was insignificant compared to the control group.

Conclusion: ESWT produced variable degree of microscopic changes of the treated cords, but no neurological symptoms. The neuronal injury was dose dependent and mild in the low energy group.

6. Application of extracorporeal shock wave treatment to enhance spinal fusion: a rabbit experiment

Tao-Chen Lee, Ching-Jen Wang

Department of Neurosurgery and Orthopedic Surgery, Kaohsiung Chang Gung Memorial Hospital, Kaohsiung and Chang Gung University College of Medicine Taoyang; Taiwan

Device and producing company: None

Introduction: Besides the applications in urolithiasis, extracorporeal shock wave treatment (ESWT) has been further utilized for the treatment of many orthopedic disorders. Some studies demonstrated that ESWT causes subperiosteal callus formation by creating small fractures on the cortex (decortication). Others showed that ESWT stimulates expression of growth factors that in turn improve blood supply and cell proliferation and eventual tissue regeneration. To our knowledge, no study has reported the effect of ESWT on spinal fusion.

Methods: Fifteen rabbits of 12 months old were used in this study. Spinal fusion was performed with decortication of bilateral L5 and L6 transverse processes, and placement of the bone chips onto the ipsilateral L5–6 intertransverse space. The right L5 and L6 transverse processes of all animals were treated with 1000 impulses of ESWT at 14 KV (equivalent to 0.18 mJ/mm²) at 3 and 6 weeks after surgery. The left transverse processes did not receive ESWT, and served as controls. Radiographic examinations of the spines were performed at 3, 6, and 12 weeks. Computed tomography (CT) was performed at 12 weeks. The rabbits were

sacrificed at 12 weeks, and the spinal segments were harvested for histomorphological examination.

Results: None of the rabbits developed neurological deficit throughout the course of this study. Radiographs of the tested rabbits taken at different post-ESWT stages demonstrated repairing effect of ESWT on the fusion gap of the treated (right) sides. Statistical analysis of the image studies indicated that 11 of 15 (73%) rabbits showed superior fusion mass on the ESWT (right) side than that of control (left) side ($p < 0.001$). The remaining 4 (27%) rabbits showed no discernable fusion difference between the ESWT side and the control side.

Histomorphological examination showed good new bone formation in 9 fusion masses. All of these cases were noted on the ESWT (right) sides. Statistical analysis showed that ESWT sides had better new bone formation than the control sides ($p = 0.001$).

Discussion: Our previous studies demonstrated that high-energy ESWT (0.47 mJ/mm^2 of EFD) may injure the femoral artery. Another recent study found that low-energy ESWT (0.18 mJ/mm^2 of EFD) causes no neurological symptoms (unpublished data). As ESWT of 0.12 to 0.16 mJ/mm^2 EFD induces bone formation, we therefore determined to utilize a safe and effective dose of 14 KV (equivalent to 0.18 mJ/mm^2 EFD) to induce new bone growth.

Conclusion: The results of this study demonstrated that ESWT is effective in promoting spinal fusion in rabbits.

7. Modulation of physeal growth using extra corporeal Shock wave lithotripsy in a rabbit model

Roger Lyon (1), XueCheng Liu (1), Kiran Sekhar (3), Heidi Meyer (3), Beth Trost (2)

1) Dept. of Orthopaedic Surgery,

2) Dept of Pathology, Children's Hospital of WI,

3) Medical College of WI

Device and producing company: OssaTron (SanuWave, Marietta, GA)

Introduction: Extracorporeal shockwave lithotripsy (ESWL) has the potential to provide a non-invasive modulation of physeal growth. The purpose of this investigation is two-fold: 1) to investigate the effects of 3 different dosages of ESWL on the rabbit physis as compared to the control group; 2) to analyze the histological and radiographic change.

Methods: Thirty female NZW rabbits of 3 weeks of age were used for this experiment. The OssaTron (SanuWave) was used to administer each physis. Each of the three groups received a different treatment of low (0.2 mJ/mm^2), medium (0.6 mJ/mm^2), and high (1.0 mJ/mm^2) dosages. Each rabbit received one administration of 6000 shocks on the right leg.

Radiological studies were analyzed quantitatively to monitor growth monthly. At 10 and 18 weeks, five rabbits from each group will be sacrificed and prepared for histological studies.

Results: There was no significant difference between right and left femur length in X-rays at 2, 10, 14 and 18 weeks (Wilcoxon, $P > 0.05$). Percentage change of right femur vs. left femur showed the greatest discrepancy in lower power group at 2 weeks, but delayed until 10 weeks in both intermediate and high power group. Both intermediate and high power group demonstrated histological changes in the treated side.

Discussion: Though there was no significant change of femur length in X-rays, there were obvious different trends in the bone growth progress between the treated groups and the untreated groups.

Conclusion: ESWL with more than 0.6 mJ/mm^2 power may be able to alter growth in children with growth deformities.

8. Extracorporeal shockwaves manifest themselves as biological mechanotransduction

Helmut Garrelt Neuland (1), Annette Schmidt, Yvonne Delhaase, Wilhelm Bloch (2), Hans Joachim Duchstein (3)

1) ZES - Kronberg

2) German Sports University Cologne

3) Pharmaceutic Institut University Hamburg

Device and producing company: No special apparatus was used

Introduction: The impact of extracorporeal shockwaves (ESWs) on living tissue results in the conversion of mechanical stimuli into biochemical and/or molecular-biological signals.

These signals in turn induce a certain flow of information. Subsequent signals are viewed as a biological information unit that brings about certain biological changes in the cell for which the signals are meant. These sequences are referred to as mechanotransduction. The tissue structures mainly involved in mechanotransduction are part of the extracellular matrix that transfers information via so-called adhesion molecules, as connecting links to the cytoskeleton. The signals are transmitted to the cell nucleus via the constituent components of the cytoskeleton, thereby inducing gene transcription and expression. In case of destruction of the cytoskeleton, mechanotransduction is rendered impossible. Relevant for the mechanotransduction are the frequency, amplitude, intensity and duration of the extracorporeal stimuli which determine - as if by code - the concentration of certain second messengers and thus turn on the gene expression.

9. Activation of protein kinase B (Akt1/PKB α) in porcine cartilage after application of radial extracorporeal shock waves

Jutta Ninck (1), Peter Lewandowski (2), Jens Dargel (1 + 3), Rüdiger Schmidt-Wiethoff (1 + 4), Wilhelm Bloch (5)

1) Department of Biomechanics and Orthopaedics German Sport University Cologne Carl-Diem-Weg 6, 50933 Cologne, Germany

2) not working at an institution

3) St. Vinzenz Hospital Merheimer Straße 221-223 50733 Cologne, Germany

Department of Biomechanics and Orthopaedics German Sport University Cologne Carl-Diem-Weg 6, 50933 Cologne, Germany

4) Dreifaltigkeits-Krankenhaus Köln Aachener Straße 445-449 50933 Cologne, Germany
Department of Biomechanics and Orthopaedics German Sport University Cologne Carl-Diem-Weg 6, 50933 Cologne, Germany

5) Department of Molecular and Cellular Sport Medicine German Sport University Cologne Carl-Diem-Weg 6, 50933 Cologne, Germany

Device and producing company: Swiss Dolorclast, EMS, Switzerland

Introduction: Mechanotransduction is a biological process of converting mechanical stimuli into biochemical signals which are further assimilated into specific cellular responses.

Protein Kinase B (Act/PKB) is a Ser/Thr protein kinase which is known to be a typical downstream signaling protein regulating cell growth, apoptosis and metabolism. The aim of

this study was the investigation of initial adaptation processes in signaling pathways of porcine cartilage after mechanical stimulation via radial extracorporeal shockwaves (rESW).

Methods: The shoulder joints of two groups of 5 and 6 animals, respectively, were treated with rESW at a different pressure initially post mortem (2000 impulses, 8Hz, 250kPa (group 1) and 400kPa (group 2); Swiss Dolorclast, EMS). The left foreleg served as intervention side, the right one as control. Six specimens were harvested on each side at specific points in time after the application (0, 2, 5, 10, 20 and 40 minutes). Protein Kinase B was detected using immunohistochemical stainings with Anti-phospho-Akt1/PKB α (Thr308). The staining of each cartilage zone was graded microscopically by a score of 0–3.

Results: The analysis revealed an activation of Akt1/PKB α in chondrocytes with different intensity depending upon the cartilage zone and, to some extent, with regard to the point in time of harvest and the application of shock waves.

Discussion: There is reason to believe that mechanotransduction is one of the mechanisms of action explaining the effects of (r)ESW. Yet in order to ascertain these first observations and to detect further specific changes in signaling pathways the number of subjects needs to be increased.

10. The Akt signaling pathway is activated in porcine patello-femoral joint cartilage after cyclic compression

Annette Schmidt, Michael Offermann, Jens Dargel, Gert-Peter Brüggemann, Wilhelm Bloch, Anja Niehoff

Department of Molecular and Cellular Sport Medicine, German Sport University Cologne, Germany and Institute of Biomechanics and Orthopaedics, German Sport University Cologne, Germany

Device and producing company: German Sport University Cologne

Introduction: Protein kinase B (Akt) dependent signaling pathways induced by mechanical loading have been identified in a variety of tissues. However, there is no evidence for a potential regulation of Akt in cartilage mechanotransduction. This study was conducted in order to determine whether or not Akt in chondrocytes is regulated by mechanical loading. In addition, the time course of Akt activation was characterized in response to cyclic compression and the frequency of the load applied.

Methods: Patello-femoral joints of fifteen 3-month-old pigs (42 ± 2 kg) were loaded in compression at 500 N for 150 s either dynamically at 12 Hz ($n = 5$) or 1 Hz ($n = 5$) or statically ($n = 5$) using a custom-designed loading frame. Left-side knees served as intervention, right-side as unloaded control. Cartilage samples were harvested at different times after mechanical loading. Immunohistochemistry on cartilage specimens was carried out to detect phospho-Akt and staining pattern was semi-quantitatively analyzed. A paired t-test was used (SPSS, $p < 0.05$) to determine significant differences between loaded and unloaded cartilage samples.

Results: A downregulation of Akt phosphorylation was seen in cartilage 300 s after mechanical loading, whereas Akt phosphorylation remained unchanged in unloaded specimens. In addition, regulation of Akt appeared to change with the frequency of loading, presenting different patterns in Akt phosphorylation with static and dynamic loading. Variations in Akt phosphorylation were detected in different zones of cartilage.

Discussion: Akt signaling in porcine patello-femoral joint cartilage is dependent upon frequency of loading and the time interval between loading and cartilage harvest.

Conclusion: We conclude that Akt might play a role in cartilage mechanotransduction.

11. Extracorporeal shock waves accelerate consolidation of distraction osteogenesis of mandible in a rat model

Jui-Pin Lai, Feng-Sheng Wang, Ching-Jen Wang, Yur-Ren Kuo

Department of Plastic and Reconstructive Surgery, Chang Gung Memorial Hospital-Kaohsiung Medical Center, Kaohsiung, Taiwan

Device and producing company: Ossatron (Sanuwave, USA)

Introduction: Long-duration of bony consolidation was found in the distraction osteogenesis in treatment of craniofacial skeleton hypoplasia. This study investigated whether extracorporeal shock wave (ESW) treatment could accelerate the bony consolidation in a rodent mandible distraction model.

Methods: An "L"-shape osteotomy in unilateral hemi-mandible of the Sprague-Dawley rat was performed. An internal distracter was applied to create a 7-mm distraction gap of lengthened mandible. One hundred and twenty rats were divided into 3 groups. Group I, as a control group, received no treatment. Group II received 500 impulses of ESW treatment at 0.14mJ/mm² postoperatively. Group III received 500 impulses of ESW at 0.21mJ/mm² postoperatively. Tissue samples for histological studies were harvested once a week for 6 weeks after ESW treatment. The bone mineral density (BMD) and three-point bending test were used to evaluate and analyze the mechanical strength of distracted mandible.

Results: Histological analysis revealed shock wave therapy in group II has significantly accelerated skeletal healing process. Bone mass analyzed by BMD and bending strength of new bone in group II revealed a significant increase compared to group III and control group at 4 weeks after distraction. The immunohistochemical study indicated vascular endothelial growth factor (VEGF), proliferating cell nuclear antigen (PCNA), and bone morphogenic protein (BMP)-2 expressions had significantly increased in group II post-ESW treatment compared to group III and the control group.

Discussion: The regional vascular supply plays an important factor in osteogenesis. The healing process in the craniofacial skeleton was superior to long bone because of a greater vascular plexus and soft issue envelope. Recent studies demonstrated that ESW treatment in long bone union application showed a significantly higher number of neo-vessels and angiogenesis-related markers including eNOS, VEGF and PCNA, as compared to group without ESW treatment. In our animal study, shock waves accelerated regenerated bone maturation after mandible distraction. The IHC staining of distraction zone of mandible revealed that the optimal dose of ESW treatment has significantly increased in VEGF and PCNA expressions, compared to the control and high-energy ESW. This indicated that ESW increases the neovascularization and cell proliferation during the healing process of mandible distraction.

Conclusion: Optimal dosage of ESW has a positive effect of accelerating the facial skeleton consolidation after mandibular distraction. The bio-mechanisms are through up-regulation of neovascularization, cell proliferation, and increasing cortical consolidation.

12. No influence of sedation on the clinical outcome of radial extracorporeal shock wave-treatment of the proximal suspensory desmopathy in sports horses Antonio Morral (1), Jordi Grau (2), Laura Tibau (2), Laura Mata (2), Lluís Costa (1), Marta Prades (3), Toni Ramon (3)

1) EUIF Blanquerna. Universitat Ramon Llull

2) Clínica Equina Jordi Grau.

3) Facultat de Veterinària. Universitat Autònoma de Barcelona. Spain.

Device and producing company: Swiss Dolor Clast (EMS-Switzerland).

Introduction: Extracorporeal shock wave therapy (ESWT) is being used to treat desmopathies and tendinopathies in horses (Kersh 2006). Radial extracorporeal shock wave therapy (rESWT) is a useful treatment modality for chronic or recurrent proximal suspensory desmopathy when combined with controlled exercise (Crowe 2004). The rESWT cause pain/nociception while being administered. Usually, horses receive this treatment under sedation (light-moderate). Sedation is recommended so the horse remains still so the treatment is applied accurately, targeted to the specific treatment location, and if fractious, the veterinarian is protected. Our clinical experience has shown that a total dose 0.5 ml Domosedan™ and 0,5-1.0 ml Torbugesic™ affords effective, safe sedation in horses above 200 kg bodyweight. In humans, the influence of local anesthesia on the clinical outcome of ESWT is in discussion. The results of ESWT on plantar heel spur without local anaesthesia has been significantly better than with local anesthesia (Auersperg 2002, Rompe 2004, Labek 2005). The aim of this study was to evaluate the influence of sedation on the clinical outcome of rESWT of the proximal suspensory desmopathy in sports horses.

Methods: 18 sports horses were recruited based on the following criteria: 1.- Proximal suspensory desmopathy in the front limb with lameness for at least three months. 2.- Docile horse. Not aggressive/rebellious horse. 3.- Sex: female o castrated male. Lameness was graded from 0 to 5 using a AAEP scale (American Association of Equine Practitioners) The horses were randomly assigned to two groups: Group A (n=9): rESWT with sedation. The intravenously administration of a sedative combination of 0.1 ml Domosedan™/100 kg (equivalent to 12 microg. detomidine hydrochloride/kg) and 0.1 ml Torbugesic™/ 100 kg (equivalent to 10 microg. butorphanol tartrate/kg) Group B (n=9): rESWT without sedation The 18 horses were treated 3 times at 2-week intervals with 4000 shockwaves per session. Pressure of 3,5 bar (Energy flux density: 0,14 mJ/mm² approx.) and 8 Hz of frequency. Device used: Swiss Dolor Clast (EMS-Switzerland). The affected leg was lifted and the superficial and deep flexor tendon was pushed laterally and medially in order to be as close as possible to the origin of the proximal suspensory ligament. 2000 shockwaves were applied from each side (medial and lateral). Evaluation of lameness was performed before the treatment, 30 days after last rESWT and 90 day after last rESWT: A special training program was elaborated for the time between the sessions and post shock wave therapy. Analyses: The differences between groups were carried out using U of Mann-Whitney test. Some factors that had no effect, such as age, sex and duration of lameness, were checked out using multivariate logistic regression analysis. The statistical analysis was carried out without knowledge of the treatments used (rESWT with sedation or rESWT without sedation)

Results: There were no statistically significant differences between the two groups. (P>0.05). In the group A (rESWT with sedation): 90 days after last rESWT, 6 horses were free of lameness (return to full work), 2 horses had a distinct lameness reduction and 1 horse showed

no improvement. In the group B (rESWT without sedation): 90 days after last rESWT, 5 horses were free of lameness (return to full work) and 4 horses had a distinct lameness reduction. In both groups, side effects and complications were not observed.

Discussion: In humans, the simultaneous application of local anesthesia interferes with clinical outcome. In humans, is important to feel pain during the ESWT?

Conclusion: In horses, the sedation applied before treatment no reduced the efficacy of rESWT. The decision to sedate to a horse before apply rESWT should be the security of the horse and of the veterinary one. Further studies of significantly larger groups of horses are necessary to underline the results of this investigation.

13. RSWT or splitting for the treatment of overuse tendon and ligament injuries in sport horses: Early results

Michelle Cortés, Juan J. Ramirez, Santiago Hernandez, Carlos Leal

Ortho Wave Colombia Ltda. Veterinary Division Calle 134 No. 7B-83 Office 122 Bogotá Colombia

Device and producing company: Storz Medical D-Actor 100

Introduction: The aim of this study was to compare the results of Radial Shockwave Therapy (RSWT) and splitting for the treatment of suspensory desmitis and digital flexor tendonitis in sport horses.

Methods: We performed a prospective study between October 2006 and March 2007. Twenty sport horses with clinical and ultrasonographic evidence of tendon or ligament injuries were treated with either RSWT or splitting. Both treatments were undertaken under sedation with the horse in standing position. RSWT was applied in a single session with a total of 3500 pulses at 1.5 to 3.5 bar using the Storz Medical D-Actor-100 device. If the lameness and the lesion grading were consistent with a severe condition, we injected Autologous Growth Factors within the injury area and/or performed a second RSWT session. Splitting was achieved with a syringe using the usual technique.

Results: Fourteen horses had suspensory desmitis and 6 had digital flexor tendonitis. The mean degree of lameness was 2.6 out of 5. Both groups showed a lameness decrease of 2 points at first month after treatment and a complete clinical recovery in 90% of horses at the third month of follow-up. Ultrasonographic exams showed a gradual decrease in lesion grading until the attainment of scars with good fiber alignment.

Discussion: RSWT and splitting are equally effective treatments for tendon and ligament injuries. Nevertheless, RSWT is preferred because it is a noninvasive option that avoids the risk of infection and does not depend on surgeon's skills.

Conclusion: RSWT is as effective as splitting for tendon and ligament injuries treatment in sport horses.

14. Extracorporeal shockwave therapy in the treatment of distal limb lacerations

Scott McClure, Dean Morgan

ISU-CVM; 50011-1250 Ames, Iowa, USA

Device and producing company: Equitron; Sanuwave

Introduction: The objective of this study was to determine if ESWT affects the rate of epithelialization and contraction of wounds on the metacarpus.

Methods: In 6 horses a 4-cm diameter defect including skin, subcutis, and periosteum was created on the metacarpi bilaterally. The wounds were digitally photographed, the circumference of the limb was measured, and the quantity of granulation tissue scored. The metacarpi were radiographed on days 14, 28, and 56. ESWT was initiated on day 7 on 1 randomly selected metacarpus and repeated weekly until the wound was healed. The photographs were analyzed to determine wound size, contraction and epithelialization. The area of bone lysis or proliferation was measured on each radiograph. Swelling was expressed in terms of percentage increase of the circumference. Parametric survival analysis was used to compare the days to wound healing. A matched pairs t-test was used to compare the data **between healed wounds.**

Results: The wounds treated with ESWT healed in a mean 76 days compared to a mean of 90 days for the untreated controls, resulting in a $P = 0.051$. The healed treated and control wounds had similar areas of epithelialization ($P = 0.48$) and percentages contraction ($P = 0.96$). The percent circumference of the limb was similar between treated and control wounds ($P = 0.99$) and there was no difference in the sum score for granulation tissue between treated and control wounds ($P = 0.52$). There were no radiographic differences between treated and control wounds.

Discussion: The epithelialization and contraction were similar between treated and control limbs which indicated the wounds healed in similar fashion.

Conclusion: This study indicates that ESWT may speed the rate of healing of distal limb wounds.

**15. ESWT in calcific tendonitis of the rotator cuff: 100 patients treated with the same piezoelectric generator but different focal dimensions
Maria Cristina Ottone, Orazio Barresi, Filippo Fagnani (bioengineer)**

Servizio Assistenza Sanitaria Territoriale (SAST) A.S.L. 20 Tortona - Piazza Cavallotti - Tortona ITALIA

Alliance Medical Group - Via Alunno,23 - Milano ITALIA

Device and producing company: Piezason 300, Wolf

Introduction: Through our work we want to evaluate the effect of ESWT using different focal dimensions but the same protocol (number of shock waves and density energy as mJ/mm^2) and using the same piezoelectric therapy unit.

Methods: Piezason 300 has an in-line ultrasound location system and a focused piezoelectric generator with the option of choosing between 3 different focal dimensions: in particular we used the smallest focus (F1) and the largest focus (F3). We had 2 groups of patients treated in subsequent periods: each patient received 4 applications (2000 shock waves/session, the frequency was 6 Hz). GROUP A: 50 patients, Focus - F1, Displayed level - 9/10, $0.16\text{-}0.18 \text{ mJ}/\text{mm}^2$; GROUP B: 50 patients, Focus F3, Displayed level - 12, $0.10 \text{ mJ}/\text{mm}^2$.

Results: With F1 it was possible to reach the desired density, but it was not possible to reach the desired value with F3 (level 14/15 of internal scale) due to the average of pain threshold. With F3 we reached level 12. Although the energy density reached with F3 is lower than with F1, the final results are similar in both groups.

Discussion: This is the first analysis made comparing focal dimensions, delivered energy levels and focal density energy levels utilizing the same shock wave therapy unit with the option of using different focal dimensions. The results are similar, so it is logical to ask: which is more important with respect to the clinical results; the energy level delivered (mJ) or the density of the energy level (mJ/mm²). Probably the effect of the shock wave is due to the combination of the effect of the spike of pressure of a single shock wave and the energy produced.

Conclusion: The investigation of this correlation between physical data of the shock wave (mJ, mJ/mm², MPa and focal dimension) and the direct effects on pathology is the "purpose" of this experimental study at present. These studies are designed to compare the treatments using different focal dimensions and different energy densities (mJ/mm²) at the same energy delivered (mJ).

16. Tendinosis calcarea of the shoulder: Treatment by extracorporeal shockwaves

Paulo Roberto Pires Rockett (1), Ana Cláudia de Souza (2), Paulo Roberto Dias dos Santos (3)

1) Ortosom - Praça Dom Feliciano, 78/801 - Porto Alegre - RS – Brazil

2) Cortrel - Ataulfo de Paiva, 734 - Rio de Janeiro - RJ – Brazil

3) Orthomaster - Av. Pacaembú, 1028 - São Paulo - SP - Brazil

Device and producing company: Reflectron- HMT

Introduction: To evaluate the safety and effectiveness ESWT in the treatment of tendinosis calcarea of the shoulder in three Brazilian orthopedic centers.

Methods: From April 2001 to February 2006, 187 cases with chronic tendinosis calcarea of the shoulder were treated. The age of the patients was between 25 and 79 years (average = 55 years). There were 177 patients, 10 with bilateral treatment; 93 women and 84 men. Inclusion criteria: pain for at least 6 months, three months of unsuccessful conservative treatment and failed surgical procedure. The exclusion criteria were: inflammatory arthritis, corticosteroid injection within the previous 6 weeks, neurological abnormality, gout, malignant diseases and coagulation disorders. The treatments were performed with an electrohydraulic device (REFLECTRON®). One treatment was performed on 162 cases, 21 underwent a second treatment and 4 cases underwent a third treatment. The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score and Visual Analogue Scale analysis 45, 90 and 180 days after the end of the therapy.

Results: The study showed the efficacy of ESWT was excellent in 28.34%, good in 36.9%, acceptable in 12.84%, and poor in 21.92%, 180 days after ESWT.

Discussion: ESWT must be considered as an alternative in the treatment of tendinosis calcarea of the shoulder which has been resistant to conventional procedures.

Conclusion: ESWT has the advantages of being non-invasive: no significant complications, lower operating costs, and eliminating the substantial potential risks of traditional surgical procedures.

17. Shockwave therapy for the treatment of the tendinosis with subacromial impingement of the shoulder

Ana Cláudia Souza (1), Flavia Arkader (1), Paulo Rockett (2), Paulo Santos (3)

1) Cortrel (Rio de Janeiro /RJ)

2) Ortosom (Porto Alegre /RS)

3) Orthomaster (São Paulo/SP) Brazil

E-mail: anaclaudia@cortrel.com.br, willyarkader@hotmail.com, rockett@ortosom.com.br, prds@uol.com.br

Device and producing company: Reflectron (HMT)

Introduction: Overuse or repetitive stress of the upper extremity in the overhead position may be a cause of rotator cuff tendinosis. Poor vascularity and primary degenerative changes also may contribute to the development of the lesion. The studies of basic research have demonstrated that the application of ESWT produces a biological response in the tissues, including the induction of neo-vascularization associated with the increase of angiogenic growth factors. Based on this new concept of “tissue regeneration,” the aim of this study was to evaluate the effectiveness and the safety of ESWT in the treatment of the tendinosis of the shoulder in three Brazilian orthopedic centers.

Methods: From May 2002 to February 2006, 70 cases with tendinosis of the shoulder were treated - 65 patients, 5 with bilateral treatment; 24 women and 41 men. The age of the patients was between 19 and 83 years (average age = 53 years). The treatments were performed with an electrohydraulic device (REFLECTRON®). One treatment was performed on 64 cases, 4 underwent a second treatment and 2 cases underwent a third treatment (minimum interval of 90 days). The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score and subjective outcome on Visual Analogue Scale (VAS) analysis 45, 90 and 180 days after the end of the therapy.

Results: The study showed the efficacy and safety of ESWT were excellent in 31.4%, good in 42.9%, acceptable in 8.6%, and poor in 17.1%), 180 days after ESWT.

Discussion: Based in this new concept of “tissue regeneration,” ESWT must be considered as an alternative in the treatment of the tendinosis of the shoulder which has been resistant to conventional procedures.

Conclusion: ESWT must be considered as an alternative in the treatment of tendinosis of the shoulder before operative intervention. ESWT has the advantages of being non-invasive: no significant complications, lower operating costs, and eliminating the substantial potential risks of traditional surgical procedures.

18. Prognostic value of CT evaluation of calcifications for extracorporeal shock wave therapy (ESWT) in calcifying tendinitis of the rotator cuff

Davide Volpe, Peter A.Mattei, Nicola Volpe, Paolo Pastore, Giuseppe Sessa, Alessandro Carriero

Radiology Department, Maggiore della Carita Hospital, Eastern Piedmont University, Novara, Italy

Device and producing company: Reflectron (HMT, Kreuzlingen, Switzerland)

Introduction: The aim of this study was to evaluate the prognostic value of computer tomography (CT) characterization of calcifications, as well as patient characteristics, in predicting positive outcome of extracorporeal shock wave therapy (ESWT) in calcifying tendinitis of the rotator cuff.

Methods: Twenty symptomatic patients with calcified tendinitis of the shoulder were enrolled. After giving their informed consent, all patients underwent CT (GE Lightspeed, Milwaukee) in order to characterize the calcifications in terms of volume, Hounsfield (HU) density and position. They then received three treatments of 500 pulses (240 pulses/min at an energy range of 0.11-0.12 mJ/mm² using a Reflectron (HMT). The treatments were separated by a 14-day period and the follow-up CT was performed 12 weeks after the third treatment. Patients were asked to complete a VAS scale to evaluate pain prior to each treatment and during the follow-up visit. The pre-treatment CT was used to target the pulses.

Results: All patients had a reduction in pain (decreased VAS score) and a significant reduction in the size of the calcification. The majority of the patients also showed a significant reduction in calcification density (HU). Preliminary analyses indicated that patient characteristics were not correlated with outcome while the initial density of the calcification was directly correlated with the percentage reduction in volume.

Discussion: Factors which can be used to effectively determine the benefits patients will receive should reduce unnecessary suffering and increase effectiveness of their overall treatment program, compensating or the increased radiation exposure.

Conclusion: CT evaluation prior to ESWT is a useful tool for predicting which patients will have a reduction of the calcification, but not in cases where the aim of the therapy is an analgesic effect.

19. Shock wave and greater trochanteric bursitis **Eli Peled, Zinman Chaim, Levin Daniel, Hana Kaufman, Norman Doron**

Orthopaedic B' Department, Rambam Medical Center and the Bruce Rappaport Faculty of Medicine, Technion - Israel Institute of Technology, Haifa, Israel

Device and producing company: Orthospec, Medispec Ltd.

Introduction: Extracorporeal Shock Wave Therapy (ESWT) has become a useful adjunct for the treatment of various musculoskeletal inflammatory conditions. The purpose of the study is prospective assessment of the efficacy of ESWT for the treatment of recalcitrant greater trochanteric bursitis (GTB).

Methods: Prospective evaluation and follow-up of fourteen patients with persistent GTB, two of them with bilateral problems. All the patients failed to respond to conventional treatment with oral NSAID's, physiotherapy, US and more than one steroid injection to the greater trochanter region. All patients underwent a complete physical examination. A Comprehensive VAS Score (grading from 0-10) was obtained prior to therapy and at follow-up. ESWT was applied in six consecutive courses each consisting of 1500 impulses of 0.32mJ/mm² to the lateral side of the greater trochanter region.

Results: Mean age of 60.6 years, 11.6 mean SD (range 38 to 81 years). Mean duration of symptoms 14.2 (from 8.1 to 37 months). Mean VAS dropped from 7.9 (0.9) to 1.6 (0.8) (p<0.0001). There were no side effects except minimal local discomfort during the treatment sessions.

Conclusion: ESWT is an effective treatment for recalcitrant GTB, with minimal side effects.

20. Shockwave therapy for the treatment of the trochanteric bursitis with tendinosis of the gluteus **Ana Cláudia Souza (1), Flavia Arkader (1), Paulo Rockett (2), Paulo Santos (3)**

1) Cortrel (Rio de Janeiro /RJ)

2) Ortosom (Porto Alegre /RS)

3) Orthomaster (São Paulo/SP) Brazil

E-mail: anaclaudia@cortrel.com.br, willyarkader@hotmail.com, rockett@ortosom.com.br, prds@uol.com.br

Device and producing company: REFLECTRON - HMT- SWITECH MEDICAL

Introduction: Trochanteric bursitis has potential risk factors which include local trauma, overuse activities, and leg length discrepancies. These factors are thought to lead to increased tension of the gluteus maximus on the iliotibial band producing bursal inflammation and tears or tendinosis of the gluteus medius, present on magnetic resonance imaging (MRI) in over 63% of patients clinically diagnosed. The studies of basic research have demonstrated that the application of ESWT produces a biological response in the tissues, including the induction of neo-vascularization at the tendon–bone interface associated with the increase of angiogenic growth factors. The aim of this study was to evaluate the effectiveness and the safety of ESWT in the treatment of trochanteric bursitis with tendinosis of the gluteus in three Brazilian orthopedic center.

Methods: From June 2002 to February 2006, 56 cases with chronic trochanteric bursitis were treated - 50 patients, 6 with bilateral treatment; 41 women and 9 men. The age of the patients was between 27 and 95 years (average age = 61 years). The treatments were performed with an electrohydraulic device (REFLECTRON®). One treatment was performed on 52 cases and 4 underwent a second treatment (minimum interval of 90 days). The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score and subjective outcome on Visual Analog Scale (VAS) analysis 45, 90 and 180 days after the end of the therapy.

Results: The study showed the efficacy and safety of ESWT were excellent in 41.1%, good in 48.2%, acceptable in 3.6%, and poor in 7.1%, 180 days after ESWT.

Discussion: Based in this new concept of “tissue regeneration,” ESWT must be considered as an alternative in the treatment of chronic trochanteric bursitis which has been resistant to conventional procedures.

Conclusion: ESWT must be considered as an alternative in the treatment of chronic trochanteric bursitis. ESWT has the advantages of being non-invasive: no significant complications, lower operating costs, and eliminating the substantial potential risks of traditional surgical procedures.

21. Controversial results in treatment of epicondylitis up to now. Reasons? **Andreas Lang, Helmut Neuland**

Praxis für Chirurgie/Unfallchirurgie, Hagenbacher Str.2, D-74177 Bad Friedrichshall. ZES, Westerbachstr.23F, D-61476 Kronberg

Device and producing company: PiezoWave (Wolf), Piezoson 100plus (Wolf), Therapiequelle FB 10G4

Methods: Treatment of the epiphyseal zones of muscle-insertion, where chondroid-like tissue is found (M.extensor carpi radialis, M.extensor digitorum communis). One thousand impulses/session, ED+ 0.22mJ/mm², depth 10-20mm, frequency max. 4 Hz.

Results: We have achieved up to 90% success when the above mentioned regions are treated. Successful treatment results only at primary tendinitis.

Discussion: If the wrong zones are treated with too high energy levels the results of treating lateral and medial epicondylitis of the humerus are not satisfactory.

Conclusion: Only primary tendinitis can be treated with ESWT. The results are good if the epiphyseal zones of muscle-insertion are treated with the correct energy level, frequency, number of impulses and penetration depth.

22. Shockwave therapy for the lateral epicondylitis of the elbow

Ana Claudia Souza (1), Flavia Arkader (1), Paulo Rockett (2), Paulo Santos (3)

1) Cortrel (Rio de Janeiro /RJ)

2) Ortosom (Porto Alegre /RS)

3) Orthomaster (São Paulo/SP) Brazil

E-mail: anaclaudia@cortrel.com.br, willyarkader@hotmail.com, rockett@ortosom.com.br, prds@uol.com.br

Device and producing company: REFLECTRON - HMT -SwiTech Medical

Introduction: Lateral epicondylitis is a difficult and prolonged disease for which several modalities of conservative treatment do not seem to modify the illness' natural progression. The studies of basic research have demonstrated that the application of ESWT produces a biological response in the tissues, including the induction of neo-vascularization associated with the increase of angiogenic growth factors. The aim of this study was to evaluate the effectiveness and the safety of ESWT in the treatment of the lateral epicondylitis of the elbow in three Brazilian orthopedic centers.

Methods: From March 2001 to February 2006, 105 cases with chronic Lateral Epicondylitis were treated - 100 patients, 5 with bilateral treatment; 42 women and 58 men. The age of the patients was between 33 and 74 years (average age = 51 years). The treatments were performed with an electrohydraulic device (REFLECTRON®). One treatment was performed on 92 cases, 12 underwent a second treatment and 1 case underwent a third treatment (minimum interval of 90 days). The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score and subjective outcome on Visual Analog Scale (VAS) analysis 45, 90 and 180 days after the end of the therapy.

Results: The study showed the efficacy and safety of ESWT were excellent in 41.0%, good in 31.4%, acceptable in 10.5%, and poor in 17.1%, 180 days after ESWT.

Discussion: Based in this new concept of "tissue regeneration," ESWT must be considered as an alternative in the treatment of chronic lateral epicondylitis of the elbow which has been resistant to conventional procedures.

Conclusion: ESWT must be considered as an alternative in the treatment of chronic lateral epicondylitis. ESWT has the advantages of being non-invasive: no significant complications, lower operating costs, and eliminating the substantial potential risks of traditional surgical procedures.

23. Extracorporeal shockwave for chronic patellar tendinopathy

Ching-Jen Wang, Jih-Yang Ko, Yi-Sheng Chan, Lin-Hsiu Weng, Shan-Lin Hsu

Department of Orthopedic Surgery Chang Gung Memorial Hospital Chang Gung University College of Medicine Kaohsiung, Taiwan

Device and producing company: OssaTron orthotripter from HMT (Kreuzlingen, Switzerland)

Introduction: The effect of shockwaves (ESWT) on chronic patellar tendinopathy is not well documented. This prospective clinical study evaluated the efficacy and safety of ESWT for chronic patellar tendinopathy.

Methods: This study consisted of 27 patients (30 knees) in the study group and 23 patients (24 knees) in the control group. Both groups showed similar demographic characteristics. In the study group, patients were treated with 1500 impulses of ESWT at 14 KV (= 0.18 mJ/mm² energy flux density) to the affected knee in a single session. Patients in the control group were treated with conservative treatments including NSAIDs, physiotherapy, exercise program and a knee strap. The evaluations included pain score, Victorian Institute of Sports Assessment (VISA) score and ultrasonographic examination.

Results: At 2- to 3-year follow-up, the overall results were 43% excellent, 47% good, 10% fair and 0% poor for the study group; and 0% excellent, 50% good, 25% fair and 25% poor for the control group (P < 0.001). Recurrence was 13% for study group versus 55% for control group (P = 0.014). Ultrasonographic examination showed a significant increase in the vascularity of the patellar tendon and a trend of reduction in the patellar tendon thickness after shockwave treatment as compared with conservative treatments. The complications are negligible.

Discussion: The results of conservative treatment are inconsistent and pain frequently recurs. This study showed that shockwave treatment produced superior results than conservative treatments for chronic patellar tendinopathy.

Conclusion: Extracorporeal shockwaves appear to be more effective than conservative treatment in chronic patellar tendinopathy.

24. Extracorporeal shockwave treatment of osteonecrosis of the femoral head in systemic lupus erythematosus

Ching-Jen Wang, Po-Chun Lin

Department of Orthopedic Surgery, Chang Gung Memorial Hospital, Chang Gung University College of Medicine, Taiwan

Device and producing company: OssaTron orthotripter (HMT, Kreuzlingen, Switzerland)

Introduction: Patients with systemic lupus erythematosus (SLE) often developed osteonecrosis of the femoral head (ONFH) due to corticosteroid administration. Shockwave treatment was shown effective in ONFH. This article reported a case of SLE with ONFH successfully treated with shockwaves.

Methods: A 19-year old-female was treated for SLE for 2 years with dexamethasone. Her medical history was complicated by thrombocytopenia. She was functionally disabled and unable to attend school regularly due to bilateral hip necrosis, stage III on x-rays and MRI. She received shockwave treatment to both hips in 2002. The source of shockwaves was from

an OssaTron (Sanuwave). A total of 4000 impulses were delivered to the affected femoral head.

Results: The last examination at 5 years showed that both hips had no pain during activities of daily living. She was able to attend school regularly. MR images showed substantial reduction in bone marrow edema and no further collapse of the lesion.

Discussion: Mont et al recommended that core decompression should not be performed in SLE patients with stage III ONFH because THA is inevitable in 14 months. In our case, no further collapse of the lesions was noted 5 years after shockwave treatment despite the existence of stage III lesions preoperatively. Shockwaves may provide an analgesic effect, alter the vascularity of the femoral head, improve blood supply and restore the hip.

Conclusion: Shockwaves may have the potential to curtail the progression of osteonecrosis and to delay the need for THA in very young patients who have contracted SLE.

25. ESWT in Kienbock`s disease: A case report **Carlos Leal, Juan C. Lopez, Oscar E. Reyes, Elkin Meyer**

Bosque University Orthopedics Ortho Wave Colombia Calle 134 # 7b-83, Office 1016
Bogota DC, Colombia

Device and producing company: Orthima - Direx Medical Systems

Introduction: Kienbock`s disease is caused by avascular necrosis of the lunate. It is related to ulnar variance and other congenital and vascular conditions. Early stages can be detected in young patients and treated with ESWT, based upon previous experiences in hip and talus avascular necrosis.

Methods: A 14-year-old male squash player diagnosed with right hand Kienbock`s, treated eight months with conventional methods (immobilization, medication, physical therapy and bracing) experienced persistent pain and was scheduled for radial shortening surgery. Instead, we treated the patient with 4000 dorsal radial shockwaves under fluoroscopy (one session, 0.3Mj/mm²), brace for 3 weeks, PT for 6 weeks.

Results: VAS pain scale, Evans Functional Score, and MRI Nakamura score improved significantly. Patient returned to competitive sports after 6 weeks, and won an international competition 6 months after.

Discussion: ESWT was the final treatment for this patient. He did not require surgery and recovered radiologically and clinically in 6 weeks. Two years after the treatment no further pain has been reported.

Conclusion: ESWT can be a treatment option in early stages of Kienbock`s disease, with similar results as those obtained in hip or talus AVN. Further comparative and case controlled studies are needed, but the pilot results are encouraging.

26. Treatment of osteonecrosis of the femoral head: Comparison of extracorporeal shockwaves versus shockwaves plus Alendronate **Ching-Jen Wang (1), Feng-Sheng Wang (2), Kuender D. Yang (2), Chung-Cheng Huang (3), Mel Shiuann- Sheng Lee (4), Yi-Sheng Chan (4), Jun-Wen Wang (1), Jih-Yang Ko (1)**

1) The Departments of Orthopedic Surgery

2) Medical Research

3) Diagnostic Radiology, Chang Gung Memorial Hospital-Kaohsiung Medical Center,

4) The Department of Orthopedic Surgery of Chang Gung Memorial Hospital-Lin-Kou Medical Center, Chang Gung University School of Medicine, Taiwan

Device and producing company: OssaTron Orthotripter from HMT, Kreuzlingen, Switzerland

Introduction: This prospective study compared the results of shockwaves plus alendronate (Group A) with that of shockwaves without alendronate (Group B) in the treatment of early ONFH.

Methods: Group A consisted of 25 patients with 30 hips with an average age of 38.6 ± 12.6 years, and group B consisted of 20 patients with 27 hips with an average age of 34.9 ± 10.8 years. Patients in group A received 6000 shockwave impulses at 28 KV ($= 0.62 \text{ mJ/mm}^2$) to the affected hip in a single session, but did not receive alendronate. Patients in group B received shockwaves plus alendronate (70 mg per week for one year). The evaluations included clinical assessments, radiographs and MR images of the affected hip.

Results: The overall clinical outcomes were improved in 83%, unchanged in 7% and worsened in 10% for group A; and improved in 74%, unchanged in 15% and worsened in 11% for group B. Total hip replacement was performed in 10% of group A and 11% of group B ($P = 0.891$). On MR images, regression of the lesion was noted in 47% of group A versus 55.6% of group B ($P = 0.791$).

Discussion: Shockwaves may promote blood supply to the femoral head with neovascularization. Alendronate may improve the bone quality by inhibiting osteoclast activity. The results of the current study failed to show the synergistic effects of alendronate and shockwaves in ONFH.

Conclusion: Shockwaves are effective with or without the concomitant use of alendronate. The use of alendronate over shockwaves in early ONFH appears superfluous in the short-term.

27. ESWT on benign bone conditions

Manuel R. Brañes, Leonardo J. Guiloff, Julian A. Brañes

Fundacion Medica San Cristobal, Santiago de Chile.

Device and producing company: ORTHOSPEC / MEDISPEC.

Introduction: In our experience with more than 900 patients treated with ESWT during the last six years, 7% (63) of which had bone pathologies, 3 presented with cases of benign bone conditions. According to results of using ESWT on bone, we decided to apply this option, looking for the osteogenetic/remodeling capabilities described for the method.

Methods: Clinical cases: 1) Male, 20 yo., professional athlete (motorcyclist) with long standing pain in right shoulder. X-rays showed heterotopic bone inside the bicipital groove; 2) Male, 13 yo., pain in left patella during daily life activities. X-rays and MRI showed a bipartite patella; 3) Male, 14 yo., with pain in distal left femur during normal activities. X-rays, Bone Scintigraphy and CT-scan displayed a large monostotic/solitaire Non-Ossifying Fibroma. Adolescent patients and parents consented to SW-treatment (single session, 5000 to 6000 pulses, 0.33 mJ/mm^2 , Orthospec device). Follow-up consisted of monthly reviews and restriction of activities.

Results: Bipartite Patella and Non-Ossifying Fibroma went into initial resolution within a period of 6 to 8 months, and resolved completely in about 14 months. The heterotopic bone cases showed initial dissolution in 12 weeks according to monthly echography and complete

fade-out in 24 weeks. All patients became rapidly asymptomatic after treatment. Follow up from 6 months to three years indicates no change in their resolution or clinical condition.

Discussion: The cases of incomplete bone development resulted in complete repair/remodeling. The heterotopic bone resulted in reabsorption. Possible explanations will be discussed in the oral presentation.

Conclusion: Antagonistic bone reactions were induced by SW in these special benign bone conditions. Further studies are needed for future clinical relevance.

28. ESWT as treatment in adult delayed & non-union fractures: Considerations about failures

Leonardo J. Guiloff, Manuel R. Brañes, Julian A. Brañes

Fundacion Medica San Cristobal, Clinica Davila, Santiago de Chile.

Device and producing company: ORTHOSPEC / MEDISPEC. COMPACT ALPHA / DORNIER.

Introduction: 1% to 3% of all fractures fail to consolidate. ESWT shows remarkable results for treating this pathology. Failure analysis should improve our success rate.

Methods: From November 1999 to February 2006, 31 adult patients with 26 non-unions (7 scaphoids, 7 humeri, 5 femurs, 4 tibia, 1 metatarsal, 1 pubis, 1 pelvis) and 5 delayed union (2 humeri, 1 femur, 1 metatarsal, 1 tibia), diagnosed by x-rays, MRI and/or CT scan were treated (19 - Orthospec, 0.33mJ/mm², 5000 to 12,000 pulses administered in 1 to 3 sessions; 12 - Compact Alpha, single session, 4000 shots, 0.5-0.7 mJ/mm²). Appropriate bone stabilization was assessed accurately pre- and post- ESWT, through individual analysis. Failures were determined when: a) clinical /radiological non-healing was present one year after treatment; b) patient opted to receive surgery during the first year of follow-up.

Results: Success was achieved in 21 (68%) of patients (all delayed unions went into resolution), with 10 failures (32%). In cases failing ESWT and needing surgical intervention histological analysis has been performed. These indicated some information of the working mechanism of ESWT and the reasons for failures.

Discussion: Carpal scaphoid non-unions represent 40% of the failures in this study. This study includes 24 B3 cases and 2 A3 cases (ISMST Classification), so the vascular aspect was a relevant factor in the failures. One tibia failure was considered a recalcitrant non-union (the condition having existed for more than 10 years).

Conclusion: 1. Before ESWT we must assess the vascular status of bones and their environment. 2. Carpal Scaphoid requires special consideration. 3. Long standing non-unions merit special analysis.

29. Extracorporeal shockwave therapy for non-unions and delayed healing fractures

Andrea Valentin, A. Fischer, A. Menschik, N. Haffner, W. Schaden

Trauma Centre Meidling, Vienna, Austria

Kundratstrasse 37, 1120 Vienna, Austria

Device and producing company: Orthowave 280c, MTS, Konstanz, Germany

Introduction: The objective of every fracture treatment is to reunite the fracture fragments in an anatomical position and completely restore the function of the injured section of the

skeleton as quickly as possible. Despite today's sophisticated technologies and good primary treatment, 1-3% of all bone fractures develop into pseudarthrosis. Surgical treatment with debridement of the pseudoarthrotic tissue, cleaning of the fragment edges, insertion of autologous spongiosa and stabilization with osteosynthesis material is considered the "gold standard" for the treatment of pseudarthrosis. However, these surgical procedures are extremely traumatic for the patient, costly, time-consuming, and associated with a high rate of complications. Therefore after successful pilot studies, the Trauma Centre Meidling began, in December 1998, to treat non-unions with shockwave therapy on a regular basis. Since August 2004 we have used the Orthowave 280, MTS, Konstanz, Germany for such treatments and have analyzed the results.

Methods: Treatment was basically envisaged as a single treatment. Depending on the region to be treated, shockwave therapy was administered under general, regional or local anesthesia. Thus far 232 patients have been treated, and the results of 174 patients with complete follow-up are available to date (April 2007). The patients were referred from 26 different hospitals, and consisted of 67 females (39%) and 107 males (61%). The mean age was 50.6 years with a range from 20-87 years. The average delay between the injury or the last operation and the shockwave therapy was 20.9 months (131 / 75% patients had more than 6 months delayed healing; 43 / 25% patients had between 3 and 6 months delayed healing). Seven of the non-unions were infected. Depending on the localization, between 2,000 and 4,000 pulses were applied (1,000 pulses per treatment location). We used an energy flow density (EFD) of 0.41ml/mm² for all bone treatments. For evaluation, the bony consolidation of the fracture/non-union on plain radiography or CT was judged.

Following shockwave therapy the pseudarthrosis was immobilized like a fresh fracture. This was usually done with a plaster cast or plastic splint; in 2 patients with especially mobile tibia non-unions, an external fixator was used. Fixation is not necessary when the pseudarthrosis has been treated with appropriate osteosynthesis material and this material exhibits no signs of loosening upon clinical or radiological examination. It can be assumed that the healing process is initially accompanied by neovascularization; for this reason, we try to prevent micro movements of the non-union during the first 3-4 weeks after treatment to preclude tearing of the new capillaries. It may be necessary in some cases for the patients to avoid full weight bearing on the affected extremity during this period. The patient's cooperation must be elicited by a detailed briefing since most patients are asymptomatic directly after the treatment, owing to the analgesic effects of the shockwaves, and want to put their full weight on the affected extremity again.

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

In cases where bony remodelling of the non-union could not be demonstrated after 3 to 6 months, patients were given the option of surgical repair. Numerous patients, especially those who had undergone multiple operations previously, refused this option. This led to a relatively high number (14%) of repeated treatments. In exceptional cases (2), a third treatment was carried out. The group of patients undergoing repeat ESWT included patients for whom a complicated pseudarthrosis operation was contraindicated for internal reasons or could have been carried out only at considerable risk to the patient.

Results: Osseous union was achieved in 142 (82%) of the pseudarthroses. No complications occurred other than the adverse reactions that have already been observed following shockwave therapy (i.e. localized swelling, petechial bleeding, hematoma).

Discussion: Even though the mechanism of action of shockwave therapy has not yet been fully explored, we are convinced that ESWT is an effective, inexpensive and time-saving therapeutic modality with an almost zero rate of complications.

Conclusion: Therefore, in Austria, ESWT is considered the first choice therapy for non-unions and delayed unions that do not require surgical realignment.

30. Extracorporeal shockwaves show regenerative effect in osteonecrosis of the femoral head **Ching-Jen Wang (1), Feng-Sheng Wang (1), Hsuan-Ying Huang (2)**

1) Department of Orthopedic Surgery

2) Department of Pathology Chang Gung Memorial Hospital-Kaohsiung Medical Center
Chang Gung University School of Medicine Taiwan

Device and producing company: Ossatron (SANUWAVE, USA)

Introduction: Extracorporeal shockwave treatment was shown effective in early osteonecrosis of the femoral head (ONFH). However, the effect of shockwave in ONFH is poorly understood. This study investigated the regenerative effect of shockwaves in ONFH.

Methods: This study consisted of 14 femoral heads removed from 14 patients undergoing total hip surgery. The study group included 7 patients with 7 hips that received shockwave treatment prior to surgery, whereas, the control group included 7 patients with 7 hips that did not receive shockwave treatment. Both groups showed similar demographic characteristics. The investigations included histomorphological examination for tissue distributions and immunohistochemical analyses for angiogenesis-related growth indicators including VEGF, CD 31, VCAM, and PCNA.

Results: In histomorphological examination, the study group showed significantly more viable bone and less necrotic bone, and more cell activity and phagocytosis than the control group ($P < 0.05$). In immunohistochemical analysis, the study group showed significantly higher expressions of VEGF ($P = 0.0012$), CD31 ($P = 0.0023$), and PCNA ($P = 0.0011$) and less VCAM ($P = 0.0013$) than the control group.

Discussion: In early ONFH, core decompression is performed with the rationale of decreasing the intra-osseous pressure and regeneration of the femoral head. Reparative effects of the femoral head were also reported after hyperbaric oxygen therapy, oral alendronate and shockwave therapy. The current study demonstrated that shockwaves promoted new vessel formation and cell proliferation similar to that observed in animal experiments.

Conclusion: Application of extracorporeal shockwaves results in a regenerative effect in hips with ONFH.

31. ESWT and bacteria: A critical review **Kevin Frederick Seals, Morgan Wise, Michael Chang**

University of Washington Medical Center 1959 N.E. Pacific Seattle, WA 98195 United States

Device and producing company: No device required

Introduction: ESWT has been implicated in the killing of bacteria. While many datasets suggest it possesses antibacterial properties, some suggest this is not the case. Our institution recently performed a review of, to our knowledge, all research on the subject. We have summarized our findings in a critical review paper, discussing the sources of contradictions in the literature and integrating the available data into general conclusions.

Methods: Most articles were found in online collections of scholarly work. Through regular meetings spanning approximately one year, we examined the available literature. This culminated in a formal review text.

Results: We present what is currently known about the importance of the following in the ESWT-bacteria interaction: energy density, pulse number, cavitation, thermal effects, UV light, and DNA augmentation. We also analyze fundamental bacteria research where it is relevant to the bacterial ESWT response.

Discussion: The main interest of our paper is developing a mechanistic understanding of how SWs kill bacteria. A number of possible mechanisms exist, including the destruction of bacteria by basic mechanical forces, cavitation microjets, localized thermal effects, and SW-generated free radicals. Another possibility, which receives little recognition in the literature, is the disruption of bacterial biofilms. We describe the current understanding of each possibility, critically examine previous research, and consider practical experimental designs capable of differentiating between the proposed mechanisms.

Conclusion: While we are fairly certain that SWs induce a bactericidal effect, the mechanism is unclear, and additional research is crucial.

32. Effects of unfocused extracorporeal shock waves on Gram positive and Gram negative bacteria

John Novak, Meera Govindaswami, Karen Novak, Jeffrey Ebersole, Wolfgang Schaden, Neil House

Center for Oral Health Research, College of Dentistry, University of Kentucky, Lexington, KY 40536, USA

Trauma Center Meidling, Vienna, Austria

Tissue Regeneration Technologies, Woodstock, GA 30188, USA

Device and producing company: Dermagold®, MTS (Konstanz, Germany)

Introduction: Extracorporeal shock wave therapy (ESWT) has been used for a multitude of applications in modern medicine. Although there is information on the effects of focused ESWT on eukaryotic and prokaryotic systems, there are currently no published studies on the effects of unfocused ESWT on either.

Methods: This study was designed to determine the effect of electro-hydraulic, unfocused ESWT on Gram-positive and Gram-negative, aerobic and anaerobic bacteria *Porphyromonas gingivalis* 381, *Porphyromonas gingivalis* W83, *Fusobacterium nucleatum* ATCC 49256, *Actinomyces naeslundii* ATCC 49340, *Streptococcus mutans* ATCC 25175 and *Staphylococcus aureus* ATCC 12600. Monoculture suspensions were treated with 100 to 500 pulses of ESWT at energy flux densities (EFD) of 0.12 mJ/mm², 0.22 mJ/mm² and 0.3 mJ/mm². Following treatment, aliquots were plated for viability determination and compared with untreated controls.

Results: ESWT showed a significant antibacterial effect for *S. mutans* and an unencapsulated strain of *P. gingivalis* following as little as 100 pulses at 0.3 mJ/mm² ($p < 0.001$). In addition, a significant disruption of bacterial aggregates was observed at lower EFDs. No significant reduction in viability was observed for all other bacteria at EFDs and pulses tested ($p > 0.05$).

Discussion: Unfocused ESWT appears to be able to disrupt bacterial aggregates and kill specific aerobic and anaerobic bacteria. This may be beneficial as adjunctive therapy for the treatment of bacterial biofilms in specific conditions.

Conclusion: ESWT appears to be antibacterial for selected Gram positive and Gram negative aerobic and anaerobic bacteria associated with human disease.

**33. Shockwave treatment for resistant bacterial infections-experience with two challenging cases
Richard Coombs, M. Hafez, M. Petrou, M. Hanna, S. Maher, K. Seehra, J. Ramsay**

Department of Musculoskeletal Surgery, Division of Surgery, Oncology, Reproduction and Anaesthetics, Faculty of Medicine, Imperial College London, Charing Cross Hospital, Fulham Palace Road (Great Britain)

Serious infections should be extremely rare in the well run orthopaedic unit. Implant surgery is normally covered with prophylactic antibiotics. If infection does occur, staged treatment with radical surgical excision of infected material is normally recommended. Any implants need to be removed together with infected fibrous tissue to reduce the chance of residual glycoalyx. Antibiotic impregnated beads and bone grafts will help to eradicate the problem in the vast majority of cases.

Occasional patients are unsuitable for surgery or may reject the surgical option.

We reported two challenging patients treated with shockwave treatment with a good initial result eradicating chronic infection.

Patient 1:

A female patient D.O.B 08/06/1958, an Afrocarribean patient from Grenada presented in 1995 with a tumour of her left knee. A biopsy confirmed a chondrosarcoma. A massive tumour prosthesis was inserted after resection of the distal femur. Twelve years later there is no sign of tumour recurrence.

This patient was working as a nurse. At the age of thirty she noted increasing headaches, nausea and dizziness and was found to be suffering from severe hypertension secondary to chronic renal disease. The patient has now been treated with dialysis for 9 years.

In 2001 she developed a chronic infection in her prosthesis affecting the tibial component with three sinuses discharging from the anterior aspect of the tibia. It was thought that implant exchange would be difficult to arrange without a substantial risk of amputation. This patient has now been considered for renal transplantation but the relevant team will not consider her for such surgery in the presence of chronic sepsis.

This patient has had four sessions of shockwave treatment combined with sinography on two occasions. At the present time the sinuses have now healed and the wounds are dry for the first time for five years.

Patient 2:

A patient with ankylosing spondylitis presented in 1990. He required bilateral total hip joint replacement. He made satisfactory progress from this operative procedure but ultimately required a major revision surgical procedure to his right hip with a long stem implant.

He has also suffered from gross lymphoedema of both legs with chronic low grade superficial infections. In April 2005 he stumbled and suffered a periprosthetic fracture below the left total hip joint replacement. Major revision surgery was performed with the insertion of a Huckstep cross screwed intramedullary component. The patient subsequently developed superficial soft tissue inflammation with a low grade cellulitis and infection.

He required antibiotic treatment but developed a major metabolic disturbance with renal failure requiring peritoneal dialysis. A bacteraemia occurred and led to an infection of his right total hip. He developed a fluctuant abscess and more than 500ml of pus were aspirated from the wound on two occasions. His general condition precluded major revision surgery. He was treated with 5 sessions of shockwave treatment to the lateral aspect of the right thigh. The deep abscess fibrosed and the infection resolved and has not recurred two years later.

34. An experimental study to optimise the bactericidal effects of shockwave treatment

Moustafa Hafez, R. Coombs, M. Petrou, M. Hanna, S. Maher, K. Seehra, J. Ramsay

Department of Musculoskeletal Surgery, Division of Surgery, Oncology, Reproduction and Anaesthetics, Faculty of Medicine, Imperial College London, Charing Cross Hospital, Fulham Palace Road (Great Britain)

The pioneering studies of Dr Gerdesmeyer led us to try shockwave treatment in two challenging patients. With a successful outcome in these clinical cases it was felt appropriate to repeat the studies and to attempt to define the parameters for a successful bactericidal effect.

For the experimental programme bacterial solutions have been exposed to shockwaves.

Experimental methods: In this study we have used a Lithotripter Modulith SLX-F2 from STORZ. The Bacterial Solutions were *S aureus* (American Tissue Culture Collection, ATCC 25923).

Conclusion: Shockwave treatment has the potential to provide a differential effect killing bacteria without harming adjacent normal tissues. This explains the potential to heal superficial infected ulcers. It is also has the potential to be effective against deep infection avoiding the need for aggressive surgical intervention.

35. Extracorporeal shock wave therapy induces alveolar bone regeneration in experimental periodontitis.

Sabapathi Sathishkumar (1), Meka Archana (2), Dolph Dawson (3), Neil House (4), Wolfgang Schaden (5), Michael Novak (3), Jeffrey Ebersole (3), Kesavalu Lakshmya (2)

1) Department of Physiology, University of Kentucky, Lexington, KY 40536, USA

2) Department of Periodontology, College of Dentistry, University of Florida, Gainesville, FL 32610, USA

3) Center for Oral Health Research, College of Dentistry, University of Kentucky, Lexington, KY 40536, USA

4) Tissue Regenerative Technologies, Woodstock, GA, USA

5) Trauma Center Meidling, Vienna, Austria

Device and producing company: DermaGold®, MTS, Konstanz, Germany.

Introduction: Periodontal inflammation with alveolar bone resorption is one of the hallmarks of periodontal disease, elicited in response to several periodontal pathogens including *Porphyromonas gingivalis*. We hypothesized that extracorporeal shock wave therapy (ESWT) could promote the regeneration of alveolar bone following *P. gingivalis*-induced gingival inflammatory reactions leading to periodontal disease in a rat model.

Methods: Rats were infected with *P. gingivalis* for 10 weeks, which caused measurable alveolar bone resorption. The infected rats were then treated with a single episode of 100, 300, or 1000 impulses of shock waves generated with a DermaGold® on both cheeks at energy levels 0.1 mJ/mm². Maxillary and mandibular alveolar bone levels were determined at 3, 6, and 12 weeks by radiography following ESWT and compared to untreated controls.

Results: PCR evaluation of the oral microbial samples demonstrated that 85-100% of the rats were infected with *P. gingivalis* during the experimental periodontal disease period. *P.*

gingivalis infected rats treated with ESWT at 300 and 1000 impulses demonstrated significantly improved maxillary and mandibular alveolar bone levels at 3 weeks than those demonstrated by untreated controls, which remained for at least 6 weeks in most rats.

Discussion: ESWT has been shown to regulate/activate several genes (TGF- β 1, IGF-1, BMP-2) linked to bone formation in rats. Thus, both resident cells and infiltrating inflammatory/immune cells in gingival and periodontal tissues might also reflect functional alterations from ESWT.

Conclusion: The results demonstrated effective regeneration of alveolar bone in P. gingivalis infected rats by ESWT and suggested that ESWT may be a useful adjunct in the regeneration of periodontal tissues following periodontal disease.

36. Microcirculatory response to shockwave therapy in acute model – preliminary report **Lukasz Krokowicz, Mariusz Mielniczuk, Maria Siemionow**

Cleveland Clinic 9500 Euclid Ave. 44195 Cleveland, Ohio USA

Device and producing company: EvoTron, SanuWave

Introduction: Regardless of clinical application the exact mechanism of Extracorporeal Shock Wave Therapy (ESWT) remains unknown. The aim of this study was to evaluate influence of ESWT on microcirculation in cremaster muscle flap model and its role in neovascularization and angiogenesis.

Methods: Cremaster muscles were dissected in 22 Lewis rats divided into 3 groups: 1) Non-ischemic baseline controls (n=10); 2) ESWT with 500 impulses (n=6) and 3) ESWT with 200 impulses (n=6) immediately before dissection. Microcirculatory hemodynamic parameters (vessel diameters, functional capillary index, RBC velocity number of rolling, sticking and transmigrating leukocytes in postcapillary venule) were recorded at 1, 2, 3, and 4 hours after ESWT. Tissue Oxygen Partial Pressure (Licox) was measured to check ESWT's influence on tissue oxygenation. Histological evaluation was performed to observe microscopical changes.

Results: In group 2 we noticed an increased level of functional capillary density (13%) during the first two hours of recordings when compared to the control group. Increased number of rolling, sticking and transmigrated leukocytes (30%) in group 2 was recorded in contrast to group 1. Licox oxygen showed no significant difference between the control group and groups 2 and 3 (18-20mm Hg versus 18.03 \pm 1.8mm Hg). Histological evaluation demonstrated no damage to small vessels and capillaries after ESWT nor any increase in inflammatory infiltrates.

Discussion: Our study showed that following ESWT increased capillary perfusion and leukocyte activation is observed.

Conclusion: Our results proved that 500 impulses of ESWT does not have negative impact on microcirculation. ESWT may have future application in clinical situations due its role in modification of inflammatory responses and stimulation of capillary perfusion. Further studies are currently underway to evaluate cytokines level and neovascularization factors.

37. Effects of unfocused shock waves stimulation on human microvascular endothelial cell line HMEC-1
M. Cristina d'Agostino, Cristina Bonora, Emanuele Ungaro, Valerio Sansone

Orthopaedic Department of the University of Milan (Milan, Italy)

Instituto Clinico Humanitas IRCCS (Milan, Italy)

Device and producing company: Dermagold, MTS - Europe

Introduction: Unfocused Shock Waves (uSW) can induce soft tissue regeneration, mainly due to neoangiogenesis, the mechanisms of which are partly unknown. The aim of our study was to investigate the effects of uSW on human microvascular endothelial cell line HMEC-1.

Methods: Cell cultures were stimulated with uSW (Dermagold, MTS) according to different protocols. Cell viability was assessed spectrophotometrically by XTT assay; for angiogenesis experiments, cells were grown in 24-well plates on Matrigel matrix, and vessels-like structures were quantified by counting the capillary connections under an inverted microscope.

Results: Most relevant results were obtained at lower energies and 200 pulses. Results of 24-h XTT assay showed enhanced metabolic activity in treated cultures, compared to controls (Treated/Controls Optical Density ratio was 1.8). Results from 24h-angiogenesis assay showed more capillary connections in uSW treated cultures than controls (31.40 ± 2.064 vs. 17.00 ± 3.286 ; $p < 0.05$).

Discussion: In the literature, endothelial cell damage has been described after lithotripsy. Our data (enhanced metabolic activity and increased in vitro angiogenesis after uSW stimulation of HMEC-1 cell line), while encouraging a suitable use of this in vitro model, suggest some intriguing speculation about mechano-induced tissue healing and angiogenesis.

Conclusion: A preliminary report on the potential metabolic enhancement and mitogenic effect on human microvascular endothelial cells, induced by unfocused Shock Wave (uSW) stimulation is presented. On this basis, the mechanism of neoangiogenesis in vivo and the role of endothelium as the main target of shock waves in living tissues may be postulated.

38. The first non-invasive way for inducing migration in mesenchymal stem cells (MSC)
Annette Schmidt, Yvonne Delhasse, Caroline Steingen, Helmut Neuland, Wilhelm Bloch

Department for Molecular and Cellular Sport Medicine, Department for Molecular and Cellular Sport Medicine, German Sport University, Germany and Center for Extracorporeal Shock Waves Kronberg, Germany

Device and producing company: German Sport University

Introduction: Stem cells have long been discussed as a useful tool for treating various dysfunctions. Different ways are described for placing stem cells into the area of need. Unfortunately, up to now there has been no non-invasive method which is able to attract stem cells to a targeted place. Here we demonstrate for the first time that it is possible to direct stem cells without invasion.

Methods: For this purpose MSC of human origin were obtained from bone marrow of patients undergoing hip joint surgery, isolated and cultured as described before (Schmidt A. et al.; Stem Cells 2006). Isolated MSC were treated with shock waves using the Piezoson 100 (Wolf Inc.). After treating MSC the migratory activity was analyzed using Boyden chambers.

Results: After shock wave treatment the migratory activity was increased significantly, up to three-fold as compared to the control. Also cell growth highly increased after shock wave treatment. During a wound and healing assay the MSC behave completely different after shock wave treatment compared to control. We also obtained interesting results by comparing the effect of two shock wave applicators (FP4 / F10G4) on the migration behaviour of MSC.

Discussion: Taken together shock waves might be the first approach to mobilize stem cells without invasion and induce increased cell growth. The strong effects on the behaviour of MSC indicate that these cells can also be sensitized against mechanic influences like shock waves.

Conclusion: These mechanic sensitizers can therefore be used to induce a directed migration in MSC and might be a powerful tool for goal-orientated placement of stem cells.

39. Shock wave treatment enhances osteogenesis of mesenchymal stem cells from the blood or Wharton jelly of human umbilical cord

Kuender D. Yang (1), Chi-Chin Chiu (1), Wan-Ching Chang (1), Chien-Ming Sheng (1), Chia-Yo Ou (2), Feng-Sheng Wang (3) , Ching-Jen Wang (3)

1) Department of Pediatrics

2) Department of Obstetrics

3) Department of Orthopedics,

Chang Gung Memorial Hospital – Kaohsiung Medical Center, Kaohsiung, Taiwan

Device and producing company: OssaTron

Introduction: Mesenchymal stem cells (MSCs) which present in bone marrow and human umbilical cord (HUC) can generate bone, muscle, cartilage and even neurons. We investigated whether mesenchymal tissue could derive from the MSCs of HUC blood or Wharton jelly, and whether shock wave (SW) treatment could enhance osteogenesis from MSCs of HUC.

Methods: MSCs isolated from the blood or Wharton jelly of HUC were treated with and without shock waves (SWs) at 0.16 mJ/mm² and set for in vitro culture or in vivo injection to a fracture site of severe combined immunodeficiency (SCID) mice for experiments.

Results: Shockwave (SW) treatment at 0.16 mJ/mm² for 200 impulses significantly enhanced CFU-Stroma (17.8± 3.2 v.s. 32.7 ± 4.9, p<0.01) formations. The SW enhancement of CFU-Stroma formations were associated with TGF β but not IL-3 or GM-CSF induction, which was suppressed by addition of superoxide dismutase suggesting redox reaction is involved in the SW-enhanced osteogenesis. Studies with MSCs from Wharton jelly of HUC also showed that MSCs from Wharton jelly could differentiate into bone nodules in in vitro culture which was enhanced by SW treatment. Further in vivo studies demonstrated that injection of the MSCs harvested from HUC with and without SW treatment into the segmental defect of severe combined immunodeficiency (SCID) mice induced obvious bone callus formation. The ones with shock wave treatment revealed a significantly larger callus formation than those without shock wave treatment. The callus formation revealed human HLA antigen and bone morphogenic protein 2 expression, indicating the bone formation originating in HUC.

Discussion: Results from this study suggest that physical SW treatment and its related biological responses may be useful in promoting osteogenesis of mesenchymal cells from HUC.

Conclusion: A combination of SW and stem cell therapy may be useful for bone and tendon reconstruction.

40. Heat shock proteins, extracorporeal shockwaves and wound healing process

Helmut Garrelt Neuland (1), Andreas Lang (3), Paul Kraemer (2)

1) ZES - Kronberg, Germany

2) Hôpital Central de Wissembourg, France

3) Surgery office Bad Reichenhall, Germany

Device and producing company: Apparatus: Piezoson 100, Fa. Wolf, Knittlingen, Germany

Introduction: The human organism provides, in addition to the enzymatic-oxidative protective system, a further defense mechanism through the formation of so-called stress proteins. Part of this defense mechanism is the group of so-called heat shock proteins (HSP), which can be formed quickly and in substantial quantities as a cellular response to external physical or chemical stress. So far, HSP are found in nearly all eukaryotic cells. They are divided into groups according to their molecular weight. The number given to any particular group is a rough indication of the molecular weight in kilodaltons. HSP60 and HSP70 concentration and presence in the blood serum of patients and in wound liquid and tissue seem to be able to serve as indicator not only for the wound healing process, but also as a yardstick for the antiulcerative effect of using extracorporeal shockwaves to support wound healing.

Methods: Detection of HSP60 - Elisa kits; HSP70 - Western blot. Group I Patients with retarded healing traumatic wounds: a. usual treatment; b. treatment supported by ESW. Group II Patients with chronic-septic wounds: a. usual treatment; b. treatment supported by ESW

Results: Group Ia: HSP60 and 70 concentration decreased continuously until wound healing. Group Ib: HSP60 concentration increased continuously in wound liquid and tissue; HSP70: the same observation but not as marked. The process of wound healing in group Ib proceeded noticeably. Group IIa: HSP concentration in wound liquid and tissue remained nearly the same until the end of the wound healing process. Group IIb: extraordinary increase of the HSP60 expression in wound liquid and tissue; also HSP70 increased more than in group Ib.

Discussion: Despite of the small collective of patients one can say that the expression of heatshock proteins - especially HSP60 - induced by extracorporeal shockwaves within the wounded tissue significantly accelerate the healing process.

Conclusion: The results of these experiments provide part of the explanation for the impact of the ESWT on dermal injuries.

41. Reactive oxygen and nitrogen species and mechanotransduction during shockwave application

Hans-Juergen Duchstein (1), Helmut Neuland (2)

1) Institute of Pharmacy, University of Hamburg 20146 Hamburg Germany

2) Centre for Shockwave Therapy 61476 Kronberg, Germany

Device and producing company: University of Hamburg

Introduction: It was supposed that during shockwave application reactive oxygen and nitrogen species play an important role.

Methods: Reactive nitrogen species like the NO-radical were measured by an ozone induced chemiluminescence. Reactive oxygen species were measured by ultra weak chemiluminescence.

Results: It was shown that NO was produced during shockwave application by measuring the NO signal through the skin. Reactive oxygen species, which we cannot discriminate now, were induced by shockwave application and were identified by ultra weak chemiluminescence.

Discussion: We have shown under other circumstances that an extrinsic stress like UV-light, ozone or cigarette smoke can induce the generation of reactive oxygen and nitrogen species. We believe that application of shockwaves are nothing more than another kind of extrinsic stress and can induce mechanotransduction and the production of reactive species.

Conclusion: The generation of reactive oxygen and nitrogen species may play a role in the mechanotransduction pathway.

42. Nitric oxide mediates osteogenic factors in shockwave-promoted bone healing of long bone non-union

Ching-Jen Wang (1), Feng-Sheng Wang (2), Kuender D. Yang (2), Chung-Cheng Huang (3), Hsuan-Ying Huang (4)

1) Department of Orthopedic Surgery,

2) Department of Medical Research,

3) Department of Diagnostic Radiology

4) Department of Pathology, Chang Gung University School of Medicine Chang Gung Memorial Hospital-Kaohsiung Medical Center Taiwan

Device and producing company: Ossatron (SANUWAVE, USA)

Introduction: The mechanism of shockwaves in treating non-unions remains unknown. Many studies demonstrated that nitric oxide (NO) may play an important role in mediating shockwave-stimulated bone healing. This study investigated the biological role of NO in mediating shockwave-promoted osteogenic signals in long bone non-unions.

Methods: Thirty-three patients with 34 non-unions of long bones were included in this study. There were 18 men (19 non-unions) and 15 women (15 non-unions) with an average age of 36.5 years. Each non-union bone was treated with 6000 shockwave impulses at 28 KV (= 0.62 mJ/mm² energy flux density) applied in 2 planes with equal dosage on each plane. The source of shockwaves is an Ossatron (Sanuwave) device. Evaluations included clinical assessments and radiographs of the affected bone. Ten milliliters of peripheral blood were

obtained before treatment and at 1, 3, 6 and 12 months after treatment for measurements of NO levels and osteogenic markers including TGF- β 1, VEGF and BMP-2.

Results: The union rate was 15% (4 of 27) at 3 months and 69% (18 of 26 cases) at 6 months. At 6 months, 18 unions and 8 non-unions were confirmed. The serum levels of NO, TGF- β 1, VEGF and BMP-2 between unions and non-unions were analyzed. Statistically significant differences in serum NO level, TGF- β 1, VEGF and BMP-2 were noted between patients with bony union and patients with non-union at 1 month ($p < 0.05$). It demonstrated NO modulation of systemic osteogenic factors in shockwave-promoted bone healing in long bone non-union.

Discussion: Recent studies showed that shockwaves induce NO to promote proliferation and differentiation of human osteoblasts. The results of this study demonstrated that shockwave-promoted bone healing was associated with significant elevations of systemic NO, TGF- β 1 and VEGF and a trend of increase in BMP-2.

Conclusion: Extracorporeal shockwaves are effective in promoting bone healing in non-union of long bones. Nitric oxide (NO) appears to play an important biological role in mediating osteogenic signals in shockwave-promoted bone regeneration in long bone non-union.

43. Shockwave induces up-regulation of endogenous VEGF-R2 during early hindlimb ischemia-reperfusion injury

Martina Hofmann, Rainer Mittermayr, Tatjana Morton, Sabine Pfeifer, Heinz Redl, Wolfgang Schaden, Martijn van Griensven

Ludwig Boltzmann Institute for Experimental and Clinical Traumatology Research Center of the AUVA, Vienna, Austria Austrian Cluster for Tissue Regeneration Donaueschingenstrasse 13 1200 Vienna - Austria

Device and producing company: OW180

Introduction: Different strategies have been developed to reduce ischemia/reperfusion injury. Shockwave therapy has been gaining increasing interest, not only for lithotripsy, but also in wound healing. This study investigates the *in vivo* expression of VEGF-R2 during early murine hindlimb ischemia/reperfusion and its alteration by shockwave application.

Methods: Transgenic FVB/N-Tg (Vegfr2-luc) Xen mice ($n=12$ /group) were used for non-invasive, real-time assessment of the VEGF-R2 (Flk-1/KDR) expression. Ischemia was induced by a tension controlled (250g) hindlimb tourniquet and was verified by laser Doppler imaging (LDI, Moor Instruments Inc.) technique. Ischemia was maintained for 2 hours with subsequent reperfusion for 24 hours. Control animals received no treatment, whereas the animals of the shockwave group received 50 percutaneous impulses on the ischemic hindlimb 15 minutes prior to reperfusion. The contra-lateral leg was used as an internal control. At different time-points LDI was done to check hindlimb perfusion; bioluminescence detection was done to observe VEGF-R2 expression (VivoVision® IVIS®, Xenogen).

Results: Applying the tourniquet resulted in reproducible ischemia, as verified by a reduction of leg perfusion to approximately 10% in all groups. Ischemia was maintained for the entire 2 hours. Furthermore, restoration of blood flow was seen to 85% of baseline in the control group after 24 hours of reperfusion. Increased perfusion levels were observed in the shockwave group (108%). Edema was found in all groups in the injured hindlimb. In the control group, VEGF-R2 expression was increased in the ischemic hindlimb only after 24 hours of reperfusion. The shockwave group showed significantly increased VEGF-R2

expression levels after 4 hours compared to the control group. The 24h levels exceeded the control group as well.

Discussion: This ischemia/reperfusion model in transgenic mice enables in vivo observation of the VEGF-R2 expression, a key receptor in angiogenesis. VEGF-R2 is up-regulated in the reperfusion period after severe ischemic conditions.

Conclusion: Shockwave application results in a substantial increase in endogenous VEGF-R2 expression indicating enhanced angiogenesis.

44. Shock wave therapy in peripheral nerve repair Gabriel Halat (1), H. Redl (1), T. Hausner (1,2), S. Zandieh (1), R. Hopf (1), W. Schaden (1), R. Schmidhammer (1)

1) Ludwig Boltzmann Institute for Traumatology and Austrian Cluster for Tissue Regeneration, Vienna, Austria

2) Lorenz Böhler Trauma Center AUVA, Vienna, Austria

Device and producing company: OW 180, MTS Europe (Konstanz, Germany)

Introduction: De-focused low energy extracorporeal shock wave therapy has been used in various clinical and experimental models. Reports showed a significant increase of angiogenesis following shock wave application. The aim of our study was to investigate the effects of shock wave therapy on peripheral nerve regeneration, applied after a nerve grafting procedure.

Methods: Seventy-two Sprague Dawley rats underwent mid-thigh sciatic nerve transection at two different levels creating an 8mm nerve graft. The nerve graft was rotated 180 degrees and epineurial coaptation was performed immediately. All animals were randomly assigned to three experimental groups: Group 1 - Shock wave therapy (300 impulses, 3 Hz) was applied through the closed wound over the graft using an ultrasound gel as a conductive and protective layer immediately after wound closure; Group 2 - Shock wave therapy was applied 2 days after surgery (assessments were carried out 1 week, 3 weeks, and 3 months after surgery); Group 3 - Control (nerve graft without shock wave therapy). Serial functional tests (BBB locomotor rating scale, Inclined plane test, Toe spread test, Sensory- and Proprioceptive placing tests) were performed at weekly intervals during the period between the 3rd and 12th week after the grafting procedure. At weeks 3 and 12, electrophysiological assessment was commenced. Additionally, at weeks 1, 3 and 12 histological samples were examined. Neural collagenic connective tissue and the number of vessels were evaluated.

Results: The shock wave groups showed a significantly better functional recovery. The sensory function in the shock wave groups reached their maximum (1.0 out of 1.2 mean points) 8 weeks after surgery. In the control group, sensory performance reached a maximum (0.7 out of 1.2 mean points) 12 weeks after surgery. The motor performance showed a significant improvement in all shock wave groups at all intervals. In all shock wave treated groups the histological examination indicated an increase of the vessel count and a slight decrease of neural collagenic connective tissue within the nerve graft at all intervals, corroborated to the control group. Moreover, electrophysiologic assessment illustrated the positive effect of the therapy on the regeneration of the sciatic nerve.

Discussion: It seems that improvement of angiogenesis may result in enhanced functional recovery. Further research for better understanding is necessary.

Conclusion: In a rat sciatic nerve graft repair model, shock wave therapy improves functional recovery, probably due to an increase of neural angiogenesis.

45. A study of the biological factors and wound healing of a skin flap model

Henry Vasconez, Stephanie Edelmann (2), Betsy F. Fink (1), Sreenatha Kirakodu (3), Robert E.H. Ferguson (1), Karen F. Novak(3), M. John Novak (3), Wolfgang Schaden, C. William Balke (2)

1) University of Kentucky Chandler Medical Center Division of Plastic and Reconstructive Surgery

2) Department of Internal Medicine

3) College of Dentistry³ Lexington, KY USA

Device and producing company: ESWT (VetWave 140®, MTS)

Introduction: This animal study was performed to assess the effectiveness of extracorporeal shock wave (ESWT) treatment to promote cell differentiation with neovascularization, thus minimizing the measurable area of necrosis and enhancing epigastric skin flap survival. In addition, we measured the expression level of the mRNAs of the growth factors known to play a major role during normal wound healing angiogenesis using Real-Time PCR. In particular, we studied the expression of basic fibroblast growth factor (bFGF), transforming growth factor beta, (TGF-β), platelet derived growth factor (PDGF), epidermal growth factor (EGF) and vascular endothelial cell growth factor (VEGF) at several time points following the skin flap surgery. We studied the localized changes in expression as well as systemic changes that were initiated by the treatment with ESWT.

Methods: Experimental Design: This study was approved by our Institutional Animal Care and Use Committee. This study was conducted in two phases. Sprague-Dawley rats with a weight range of 400-500g were used for both phases. Phase I The rats were randomized into two groups of eight: a control group and an ESWT group. Immediately following surgery, while the animals were anesthetized, the flap area was treated with Level 1 (500 pulses at 0.15 mJ/mm²) in the ESWT group. The control group underwent the same surgery but did not receive ESWT. On Day 7 post-op, the animals were euthanized and clinical measurements of healing were collected post-mortem. The control group underwent the same surgery but did not receive ESWT. Phase II The rats were randomized into two groups of eight: a control group and an ESWT group. Immediately following surgery, while the animals were still anesthetized, the flap area was treated with Level 1 (500 pulses at 0.15 mJ/mm²) in the ESWT group. Two rats from each group were euthanized at 12 hours, 24 hours, 48 hours and 72 hours. The necrotic area plus 2-3 mm of adjacent healthy tissue was obtained post-mortem and stored in liquid nitrogen for growth factor and stem cell marker analysis.

Results: When the area of necrosis was analyzed using the PictZar imaging software, we found that the area of skin flap necrosis for the control group (n=8) was an average of 11.7 cm². In the treatment group (n=8) necrosis of the same flaps were an average of 3.8 cm². Statistical analysis using the Mann Whitney t-test showed significance at P=0.0006. The expression of EGF, PDGF and VEGF was detectable at 12, 24, 48 and 72 hours in the control and shockwave treated animal on both, the treated and the untreated side of the flap. This was true when the expression was compared to actin as well as compared to GAPDH.

Discussion: The results of our animal study showed that the treatment of skin flaps with unfocused ESWT had a significant beneficial effect on survival and viability of the skin flaps. Additionally this effect appears similar with unfocused as compared to focused shockwaves. The area of necrosis on the skin flap was significantly smaller in the treated group compared to the untreated group without apparent side effects. (p=0.0006) The second phase of the

study demonstrated local and systemic effects of various growth factors, which could prove to be of invaluable help in wound healing. Some of the groups who experimented with injection of growth factor or with gene therapy using growth factors remarked that, because growth factors expression is orchestrated in a specific way, it would be necessary to inject several factors over a specific time frame in order to mimic what is naturally happening in the body

Conclusion: The range of applications of shockwave therapy is as yet undefined and is an area of active interest and research. Further work in the field of wound healing may result in establishing a painless, noninvasive, modality of therapy for wounds that have been up to now recalcitrant to other forms of established treatment.

46. Shockwave therapy is protective against ischemia induced tissue necrosis irrespective of application time

Rainer Mittermayr (1,2) Joachim Hartinger, Martina Hofmann, Tatjana Morton, Martijn van Griensven, Wolfgang Schaden, Heinz Redl (1)

1) Ludwig Boltzmann Institute for experimental and clinical Traumatology – Research Center of the AUVA, Vienna, Austria Austrian Cluster for Tissue Regeneration, Vienna, Austria

2) Trauma Hospital Meidling, Vienna, Austria

Device and producing company: Dermagold, MTS

Introduction: Tissue necrosis following hypoxic/ischemic events is critical in many surgical disciplines. Recently, interest in shockwave therapy has grown in many clinical and experimental fields. However, primarily only positive empirical clinical data exist with rare data on underlying mechanisms. The aim of this study was to evaluate if shockwave application is effective either as an elective, post-surgical or follow-up therapy alternative in reducing/avoiding tissue necrosis following ischemic insult.

Methods: In the ischemic area of a rodent epigastric flap, 300 shockwave impulses (electromagnetic generation; 0.1mJ/mm²) were applied to different time points (24h pre-OP, post-OP, 24h post-OP). The parameters of effectiveness included planimetry (necrosis, shrinkage) and flap perfusion (assessed by 2-D laser Doppler imaging) over a 7-day follow-up period.

Results: In comparison to the control group (no treatment) all shockwave treated groups showed substantially reduced tissue necrosis regardless of whether the shockwaves were applied prior, post or 24 hours post induction of ischemia. There was no difference within the shockwave groups. Flap perfusion was also enhanced in comparison to the control group, dependent on what time the shockwaves were applied. Perfusion values increased from the time the flaps were treated with shockwaves and were comparable within the shockwave groups on the 7th postoperative day.

Discussion: Shockwave therapy on ischemia-challenged flaps shows clear protective effect in reducing tissue necrosis. This was independent of the time at which the shockwaves were applied. In addition, flap perfusion was enhanced after shockwave treatment.

Conclusion: Reduction of tissue necrosis with consecutive increased perfusion due to the up-regulation of angiogenesis related receptors (e.g. VEGF-R2) as well as the alteration of the nitric oxide homeostasis might be of pivotal importance.

47. Extracorporeal shock wave therapy suppresses the acute early proinflammatory immune response to a

severe cutaneous burn injury

Thomas A. Davis, Alexander Stojadinovic, Khairul Amare, Mihret Anam, Shruti Naik, George E. Peoples, Douglas Tadaki, Eric A. Elster

Regenerative Medicine Dept, Combat Casualty Care, Naval Medical Research Center, Silver Spring, MD

Combat Wound Initiative, Department of Surgery at the Walter Reed Army Medical Center, Washington, DC

Combat Wound Initiative, Department of Surgery at the Brooke Army Medical Center, Fort Sam Houston, TX

Combat Wound Initiative, Department of Surgery at the National Naval Medical Center, Bethesda, MD

Department of Surgery, Uniformed Services University, Bethesda, MD.

Device and producing company: TRT LLC

Introduction: Extracorporeal shock wave therapy (ESWT) promotes the healing of chronic wounds; however, the mechanism is unclear. We investigated the role of ESWT treatment on the early proinflammatory response in a murine model of acute full-thickness burn wound.

Methods: A panel of 184 candidate genes known to be involved in acute inflammation and wound healing was screened.

Results: We demonstrate that ESWT of burn wounds at 1 hr post-wounding significantly blunts polymorphonuclear neutrophil (PMN) and macrophage infiltration into the wound site. ESWT potently attenuates both chemokine expression, acute proinflammatory cytokine expression and extracellular matrix proteolytic activity at the wound margin.

Discussion: These findings suggest that ESWT may optimize the cellular and molecular wound landscape to progress through normal inflammatory and proliferative phases of healing unimpeded, thereby limiting the development of a chronic non-healing wound.

Conclusion: Physical energy in the form of ESWT results in a biologic effect in which wound healing may be fostered.

48. Achilles tendinopathy: Treatment by extracorporeal shockwaves

Paulo Roberto Pires Rockett (1), Ana Cláudia de Souza (2), Paulo Roberto Dias dos Santos (3)

1) Ortosom - Praça Dom Feliciano, 78/801 - Porto Alegre - RS – Brazil

2) Cortrel - Ataulfo de Paiva, 734 - Rio de Janeiro - RJ – Brazil

3) Orthomaster - Av. Pacaembú, 1028 - São Paulo - SP - Brazil

Device and producing company: Reflectron - HMT

Introduction: To evaluate the safety and effectiveness ESWT in the treatment of Achilles tendinopathy in three Brazilian orthopedic centers.

Methods: From May 2002 to February 2006, 118 cases with chronic Achilles tendinopathy were treated. The age of the patients was between 33 and 87 years (average age = 56 years). There were 104 patients, 14 with bilateral treatment; 37 women and 67 men. Inclusion criteria: pain for at least 6 months, three months of unsuccessful conservative treatment and failed surgical procedure. The exclusion criteria were: inflammatory arthritis, corticosteroid injection within the previous 6 weeks, neurological abnormality, gout, malignant diseases, blood coagulation disorders and Achilles rupture. The treatments were performed with an

electrohydraulic device (REFLECTRON®). One treatment was performed on 105 cases, 9 underwent a second treatment and 4 cases underwent a third treatment. The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score and Visual Analogue Scale analysis 45, 90 and 180 days after the end of the therapy.

Results: The study showed the efficacy of ESWT was excellent in 26.27%, good in 44.92%, acceptable in 16.95%, and poor in 11.86%, 180 days after ESWT.

Discussion: ESWT must be considered as an alternative in the treatment of Achilles tendinopathy which has been resistant to conventional procedures.

Conclusion: ESWT has the advantages of being non-invasive: no significant complications, lower operating costs, and eliminating the substantial potential risks of traditional surgical procedures.

49. The effectiveness of ESW for patients who failed surgical release of the plantar fascia

John A. Ogden, J. Jaakkola, SS. Williams, JG. Keating, TM. Ganey

Introduction: Patients who fail to respond to open or endoscopic plantar fascial release have limited (if any) additional treatment options. ESW is a potential treatment.

Methods: Twenty-nine patients who had continuing unacceptable levels of pain following surgical release of the plantar fascia were treated with multidirectional focused electrohydraulic shock waves. Visual analogue scores were recorded at baseline and three months after treatment for three pain parameters. At least a fifty percent reduction in the score for each category was required for success in that category, and at least 2 of 3 pain categories had to be a success for patient satisfaction.

Results: Outcome results were excellent in 7 patients, good in 12 patients, fair in 3 patients and poor in 7 patients. Patient satisfaction was evident in 19 patients (65.5%).

Conclusion: Electrohydraulic focused shock waves may offer patients who have failed surgery an option to alleviate continuing heel pain. However, the results are not as successful as they are in patients who have never undergone surgical release.

50. Plantar fasciitis: Treatment by extracorporeal shockwaves

Paulo Roberto Pires Rockett (1), Ana Cláudia de Souza (2), Paulo Roberto Dias dos Santos (3)

1) Ortosom - Praça Dom Feliciano, 78/801 - Porto Alegre - RS – Brazil

2) Cortrel - Ataulfo de Paiva, 734 - Rio de Janeiro - RJ – Brazil

3) Orthomaster - Av. Pacaembú, 1028 - São Paulo - SP - Brazil

Device and producing company: Reflectron- HMT

Introduction: To evaluate the safety and effectiveness ESWT in the treatment of plantar fasciitis in three Brazilian orthopedics centers.

Methods: From March 2001 to February 2006, 181 cases with chronic plantar fasciitis were treated. The age of the patients was between 25 and 90 years (average age = 54 years). There were 164 patients, 17 with bilateral treatment; 87 women and 77 men. Inclusion criteria: pain for at least 6 months, three months of unsuccessful conservative treatment and failed surgical procedure. The exclusion criteria were: inflammatory arthritis, corticosteroid injection within the previous 6 weeks, neurological abnormality, gout, malignant diseases, and blood

coagulation disorders. The treatments were performed with an electrohydraulic device (REFLECTRON®). One treatment was performed on 163 cases, 14 underwent a second treatment and 4 cases underwent a third treatment. The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score and Visual Analogue Scale analysis 45, 90 and 180 days after the end of the therapy.

Results: The study showed the efficacy of ESWT was excellent in 44.19%, good in 28.18%, acceptable in 10.5%, and poor in 17.13%, 180 days after ESWT.

Discussion: ESWT must be considered as an alternative in the treatment of plantar fasciitis which has been resistant to conventional procedures.

Conclusion: ESWT has the advantages of being non-invasive: no significant complications, lower operating costs, and eliminating the substantial potential risks as described in the literature of the traditional surgical procedures.

51. Fasciitis plantaris - comparison between 3 devices Paulo Kertzman, Jose Eid

São Paulo Brazil

Device and producing company: Epos Dornier, Orthima Direx, Dolorclast EMS

Introduction: During the last 6 years we have the opportunity to use 3 different devices for treatment of chronic fasciitis plantaris and this paper is about our results on 212 feet.

Methods: We had treated all patients without anaesthesia, the point of application is the medial insertion of the fascia on the heel and the direction of the waves was plantar. All patients received 3 sessions with 2000 shock waves with low and medium energy with one week interval.

Results: The evaluation was done with one, 3 and 6 months after the conclusion of the treatment. We use clinical aspect like pain when stand, walk and palpation the medial side of the heel . All of the 3 devices offer good and comparable results with 70 to 75% of good results .

Discussion: Unfortunately we work only in a private clinic with no possibility to develop a placebo group . We used Dornier from 2000 to 2002, Direx from 2002 to 2004 and EMS from 2004 to 2006.

Conclusion: ESWT is effective for treatment of chronic plantar fasciitis independently of the device.

52. ESW for plantar fasciitis in patients with type 2 diabetes

**John A. Ogden, SS. Williams, JG. Keating, R. Thiele,
TM. Ganey**

Introduction: Patients with Type 2 diabetes often exhibit plantar fasciopathy that fails to respond to conservative therapies. Increased weight may be a significant factor. Repeated injections and surgical release are associated with increased risks of infection and poor incisional healing. Alternative non-invasive treatment with shock waves should be considered.

Methods: Patients with plantar fasciopathy and Type 2 diabetes were evaluated. There could be no open wounds or recent history of such. There could be no significant neuropathy. Patients underwent multidirectional focused electrohydraulic shock wave treatment to the involved heel or heels. Visual analogue scoring was done in three pain categories at baseline and three months after treatment.

Results: Forty-seven patients (51 heels) were treated with shock waves. The composite pain score decreased from 8.3 to 2.9. The results were excellent in 15 heels; good in 19 heels; fair in 9 heels; and poor in 8 heels. Fifteen patients (16 heels) had complete pain relief. The overall satisfaction rate was 67%. No patient developed any neurovascular or cutaneous complications.

Conclusion: Shock waves should be considered as a reasonable treatment alternative in patients with concomitant plantar fasciopathy and Type 2 diabetes, with the stipulation there be no open wounds at the heel and no significant neuropathy. Overall satisfaction is less compared to non-diabetic patients treated with shock waves.

53. ESWT in the treatment of acute plantar fasciitis in high level basketball players

**Claudio Tedeschi, Bianchini Dinetta, Camurri
Giovanni Battista**

Arcispedale " Santa Maria Nuova" Via Risorgimento 78 42100 Reggio Emilia, Italy
Device and producing company: Piezozon 300

Introduction: We want to report our experience about the efficacy of ESWT in the treatment of acute plantar fasciitis in high level basketball players.

Methods: We have treated 22 basketball players with acute plantar fasciitis in the playing seasons from 2001 to 2005. They were divided into two groups, double blind random criteria: 13 were treated with ESWT and nine with ultrasound.

Results: They were evaluated with VAS and are "back in the game."

Discussion: We anticipated the athletes' recovery from 7 to 15 days.

Conclusion: The experience was positive. Treatment was fast and painless, and no side effects were reported.

54. Study to determine the effectiveness of rESWT for chronic plantar heel pain regarding the short- and long-term outcomes

**Ludger Gerdesmeyer, Lowell Weil jr, Lowell Weil sr,
Carol Frey, Keith Fedder, Barry Scurran, John
Stienstra, Johannes Vester, Mark Henne, Martin
Russlies, Markus Maier**

MARE clinic Kiel; Dept. of Orthopedic Surgery and Sportstraumatology; Eckernförder Strasse 22; D-24119 Kiel, Germany

Device and producing company: Swiss Dolorclast, EMS medical

Introduction: RCT are needed to prove efficacy of treatment options. If rESWT showed significantly better outcomes at short-term follow-up (FU), long-time FU has to be analyzed as well

Methods: A total of 254 patients were enrolled. All patients had been suffering from painful heel syndrome for at least 6 months. RESWT was performed without local anesthesia. Two thousand impulses were applied with the working pressure of 0.4 MPa (4 bar). Subjects received 3 shock wave treatments of 2000 therapeutical shock wave impulses each. The primary criteria were: heel pain when taking the first steps of the day (VAS) and heel pain while doing daily activities (VAS). Second criteria were also defined. The endpoints were 3

and 12 months after rESWT. Efficacy was analyzed by comparing the success rates between the treatment and placebo groups and was defined as a 60% reduction in VAS pain scores. The study was performed in accordance to GCP guidelines.

Results: With regard to the demographic criteria, groups are well comparable. At 3 months after rESWT treatment, overall therapeutic success was observed in 75 out of 123 ESWT patients and in 49 out of 116 placebo patients. The rate difference was statistically significantly better in favor of the rESWT treatment. The VAS composite score showed similarly significantly better outcomes. Thus, the difference between the groups (in favor of the ESWT group) at the primary endpoint (visit 7) was enlarged during the follow-up II period. Regarding the percent change of VAS pain reduction on the composite score 12 months after rESWT (end of the follow-up II period), the reduction in the ESWT group was 84.8%, whereas the placebo group showed a 43.2% reduction. The difference at the end of the follow-up II period is 41.6% in favor of the ESWT treatment. Thus, the group difference in favor of the ESWT group at the primary endpoint (visit 7) was also further enlarged during the follow-up II period. The same outcome was found in the secondary criteria as well. The a priori ordered hypotheses of the final statistical analysis plan were statistically significant ($P < 0.025$ one-sided). All effect sizes (Mann-Whitney) denote more than small superiority of the ESWT group. Only minor side effects, such as petechial bleeding, swelling and discomfort during treatment, were detected.

Discussion: RESWT is effective in treating chronic plantar heel pain after long-term FU. Another RCT is needed to compare focussed and unfocussed ESWT.

Conclusion: Radial shock wave therapy is effective and safe for the treatment of chronic heel pain. The data showed high homogeneity and all analyses confirmed a more favourable outcome with radial shock wave therapy, the effects of which are clinically relevant. The significant difference between the groups increased with the length of the follow-up interval. No significant side effects were reported, but some minor side effects could occur.

55. Shock wave treatment for plantar fasciopathy: a meta-analysis of the current literature

John A. Ogden, W. Schaden, R. Thiele

Introduction: The last six years have been associated with an increasing number of Level 1 studies (blinded, placebo-controlled) for recalcitrant plantar fasciopathy. These types of studies are significant to the evaluation of the effectiveness and safety of extracorporeal shock waves for treatment. Three devices have been approved by the Food and Drug Administration specifically for plantar fasciopathy.

Methods: A search was made using several databases (principally PubMed) matching shock waves and plantar fasciopathy. A more generalized search was made utilizing the term "shock waves". We then analyzed the published studies for level of evidence, type of device, and outcomes.

Results: Sixty-one articles fit the combined criteria of plantar fasciopathy or plantar fasciitis treated by shock waves. Four different devices were used (the fourth was approved for tennis elbow rather than plantar fasciitis). The shock waves were administered electrohydraulically or electromagnetically. Eleven studies fit a level one study with adequate blinding (single or double) and placebo controls. Ten of these studies, involving over 1000 treated patients and a similar number of placebo patients reported a positive effect from the treatments. One study, which has caused some controversy concerning methodology, reported no effect from shock waves compared to the placebo group.

Conclusion: Evidence-based medicine with these aforementioned studies supports the efficacy and safety of extracorporeal shock waves for the treatment of plantar fasciopathy. Patients have the right to have this methodology offered to them as a compensable treatment alternative when other conservative therapies have failed. The method is superior to invasive surgery, allowing rapid return to activities of daily living and work.

56. Use of shock waves in complementary therapy of dermatomyositis (DMS)

Sergio Russo, C. Servodio Iammarrone, B. Corrado, E. Astarita, F. Servodio Iammarrone, E.M. Corrado

Orthopaedic Department University of Naples Federico II Via Pansini 5 Naples 80131 Italy
Device and producing company: Minilith SL1, Storz Medical A.G

Introduction: Dermatomyositis is a chronic and uncommon disease that generally involves muscles and skin. Various data confirm its self-immunological pathogenesis, and its symptoms are common to other chronic rheumatic disease. Vasculitic phenomena involving capillaries, venules and arterioles are frequent. Their gravity is generally correlated to the possibility of serious necrotic hemorrhagic complications. The skin alterations are characterized by a maculo-papular rash that, especially on the back of the hands, has the tendency to develop in white atrophic areas. The muscular involvement, principally proximal, in its early symptoms, can be expressed by muscle pain with increasing asthenia and atrophy, generally due to reduced physical activity. Joint stiffness and severe joint pain represent the final evolution. Presently therapy is principally based on corticosteroids and rehabilitation. Shock waves (SWs) could represent a valid aid in the therapy of this disease.

Methods: An electromagnetic device was used both with a focalized and a non-focalized source: 5 single sessions over one week (5 applications), power 0.4 mJ/mm², 1600/1200 or 600 shocks in function of the specific treated muscle.

Results: The AA shows the results obtained both using focalized and non-focalized SWs.

Discussion: The Authors discuss the experiences developed using a combination of SWs, rehabilitation and drugs.

Conclusion: Shock wave therapy can represent a valid therapeutic help to improve joint movement, to reduce muscle contractures and pain, and to reduce corticosteroid doses.

57. Extracorporeal shockwave therapy in the treatment of the osteochondropathy of tibial bone roughness

Viktor Vyacheslavovich Titov, Andrew Litvinenko

The Medical Centre SportMedService LLC.

119048, Russia, Moscow, Luzhniki, 24/9, office 311

Device and producing company: Swiss DolorClast, EMS

Introduction: The prevalence of Osgood-Shlatter disease among teenagers is as high as 20% and on the increase. Previous methods of treatment are not always effective, and the term of treatment can be as long as 6-12 months. The purpose of this study is to develop a scheme of treatment using ESWT, to improve results of treatment.

Methods: There were 2 groups of patients (103 persons) included in the research. The basic group (51 persons) consisted of patients who were treated with ESWT on a Swiss DolorClast, the course of treatment included 5 procedures; the interval between procedures was from 5 to 7 days. Treatment involved 2000-3000 impulses with frequency of 4-7 Hz and peak pressure 1.8-2.5 Bar during each procedure. The perifocal zone of the tibial bone roughness was

exposed as well as some area of the forefront of the tibial bone. Treatment in the control group (52 persons) was administered with Physico-Therapeutic Treatment, Nonsteroidal Resolvent, immobilization, and termination of stress. The results of treatment are studied for 3 to 12 months. The results were evaluated by means of the modified visual analog scale (VAS) on Coleman; the range of as from 0 to 10 where the minimal parameter corresponded to the best result.

Results: The length of treatment in the basic group was 4-6 weeks; in the control group up to 12 weeks. In the basic group, excellent results were achieved in 27 patients, good results in 19, and satisfactory results in 6. In the control group excellent results were achieved in 11 patients, good results in 13, and satisfactory results in 28.

Discussion: The results prove a role of stressing periosteopathy of the forefront of the tibial bone in disease development.

Conclusion: 1. The proposed scheme of treatment produces maximal excellent and good results in as little time as possible. 2. The carrying out of procedures is probably on a background of the minimal decrease of exercise stress.

58. Radial shock wave therapy as an aid to physiotherapy

Zila Atanelov, D. Hoch, Y. Birenbaum, M. Gelferson, G. Yarkoni

The Physiotherapy Dept. of Leumit Medical Care, Ashdod, Israel

Device and producing company: Radialspec™, Medispec Ltd.

Introduction: Radial waves (RW) are currently used for orthopedic treatment. The Radialspec™ is a device for RW treatment, used by our department for about a year. Goals: Proving the effectiveness of RW in the treatment of multiple orthopedic pathologies.

Methods: Sixty-five patients were treated with the Radialspec™. Their clinical diagnosis, disease's acuteness status, treatment parameters, pain intensity, and functional level were documented. Follow-up was conducted following treatment.

Results: Clinical diagnoses were: 31% Shoulder pathologies, 31% Epicondylitis, 22% Plantar Fascial pathologies, and 16% "other" pathologies. Twenty-nine percent of the patients' pathologies were "chronic", 12% "sub-acute" and 6% were "acute on chronic". The average number of waves per treatment was: 4001.5.

Eighty-five percent of patients were treated at low intensity (10Hz) and 15% at high intensity (20Hz). Sixty-eight percent of patients were treated at low energy (80 mJ) and 32% at high energy (115 mJ). Patient's average number of treatments was: 5.6. The average change in pain intensity at treatment's completion (1-10 scale) was 3.75 points. Eighty percent of the patients showed improvement in pain. Sixty-three percent demonstrated functional improvement.

Follow-up was achieved in 60% of the patients. Average follow-up duration was 4.12 months. Follow-up demonstrates long-term improvement in 79% of the patients. Comparing their follow-up condition to their treatment completion status – 44% had stable results, 33% improved and 23% deteriorated.

Discussion: Long term improvement is achievable in about 80% of our patients. Some of them were previously treated unsuccessfully with conventional physiotherapy techniques.

Conclusion: RW Therapy is effective, safe and has added value to current conventional physiotherapy treatments with poor past response.

59. Results of the combined treatment with radial and focussed shockwaves in patients with chronic cervical pain

Markus Gleitz

Medical office, Luxembourg

Device and producing company: Duolith (Storz)

Introduction: Radial shockwaves have already received acknowledgement in the treatment of myofascial pain. Recently the focussed shockwaves that have been used for the treatment of tendons have been increasingly used in the treatment of muscular trigger points. By being able to regularly provoke the characteristic referred pain of muscular trigger points with focused shockwaves one can presume this treatment will have more advantages.

Methods: To evaluate the efficiency of the different shockwaves, a prospective randomized study was executed on 150 patients with chronic cervical pain (> 6 months, VAS > 6) during an observation interval of 3 months. Three comparable groups of 50 patients each were treated 6 times with shockwaves: Group 1 (RSW) was treated with the radial shockwaves (8000 impulses/session, 1.8-3.5 bar). Group 2 (FSW-RSW) received a combined treatment starting with focussed shockwaves (1200 impulses/session, 0.05-0.35 mJ/mm²) and then continuing during the same session with radial shockwaves (4000 impulses). Group 3 (FSW) was treated only with focused shockwaves (2100 impulses/session). As clinical parameters we measured the mobility of the cervical spine (CROM) and the pain level (VAS) before and after the treatment and 3 months later.

Results: Group 1 (RSW) achieved an increase of +20° in rotation, +17° in ante-retro flexion and +16° in lateroflexion after treatment and 3 months later. The pain level was reduced from VAS 7.2 to 2.1. Group 2 (FSW-RSW) showed a slightly larger increase in mobility than group 1 (but was not statistically significant). The reduction of pain was the greatest (VAS 1.7, p<0.05) and appeared earlier than in the other 2 groups. Group 3 (FSW) gained less mobility (+13° in rotation, + 10° in ante-retro flexion, + 11° in latero flexion, p<0.05) but achieved the same pain reduction as group 1.

Discussion: The combined treatment of focused and radial shockwaves (group 2) achieved better results than the monotherapies in groups 1 and 3. The big advantage of this combined treatment seems to be the amount and speed of pain reduction. The smaller gain in mobility after treatment with only focused shockwaves could be explained by the fact that the treatment area of focused shockwaves is too limited and that the flexibility of muscles can also be increased by treating painless muscle areas as we do with unfocused radial shockwaves.

Conclusion: Myofascial pain syndromes should be treated with the combination of focused and radial shockwaves.

60. Extracorporeal shockwave therapy (ESWT) in near-the-bone soft tissue pain

Yong-Gon Ko, Jung-Hoon Ahn, Kwang-Hee Won

Yonsesarang Orthopedic Hospital 49-3 Yeokgokdong Wonmigu Bucheon, Korea

Device and producing company: SIEMENS SONOCUR Basic

Introduction: Extracorporeal shock wave therapy (ESWT) is now employed worldwide for the treatment of musculoskeletal complaints. Although ESWT has become increasingly popular there is still controversial debate as to its appropriate usage and efficacy. The

purpose of this study was to evaluate efficacy of low energy shockwave therapy in wide range and short term change of near-the-bone soft tissue pain.

Methods: A total of 939 patients (256 Shoulders 91 Elbow, 31 Plantar Fasciitis, 296 Knee, 139 Myofascial Syndrome, 60 Ankle and Achillodynia, 35 Wrist, 31 Hip) were treated from August 2006 to January 2007. The patients underwent treatment on three spots per session, once a week for 3 weeks, and received 2000 impulses of the energy density 0.04-0.12mmJ / mm² (total 3 sessions 18000 impulses).

Results: The patients treated with ESWT have clinically and statistically significant ($p < 0.005$) improvement in function and an important reduction of pain. On the average 80% of the patients had excellent and good results (81% of Shoulder, 80% of Elbow, 84% of Plantar Fasciitis, 78% of Knee, 87% of Myofascial Syndrome, 87% Ankle and Achillodynia, 72% of Wrist, 74% of Hip). Twenty percent of the patients had no improvement but no complications were noted in this study.

Discussion: A large number of musculoskeletal disorders show benefit from extracorporeal shock wave application in the treatment of patients with no response to regular therapy.

Conclusion: These results suggest that extracorporeal therapy is an effective and non-invasive therapeutic strategy for near-the-bone soft tissue pain.

61. Improvements in ESWT: comparing two different clinical protocols in treatment of soft tissue **Paolo Buselli (1), Sara Messina (1), Valeria Coco (2)**

1) Azienda Ospedaliera di Lodi, Str. Provinciale 19, 26866 Sant'Angelo Lodigiano (LO), Italy

2) Azienda Ospedaliera di Acireale, Via Caronia, 95024 Acireale (CT), Italy

Device and producing company: EVOTRON, OSSATRON OSA 140, HMT

Introduction: Improvements in Shockwave Therapy and its more widespread use have led to a number of questions being raised in our clinical practice. At the Vienna Congress, there was a suggestion to reduce both the number and power of shocks in bone therapy. In a similar way, we have changed our protocol in the treatment of soft tissue.

Methods: Patients with rotator cuff tendonitis with calcific deposit were considered and two different groups were identified: a) patients treated prior to 2004 with the following protocol - 2 or 3 ESWT sessions (1500 shocks per session) at a 3- or 4-week interval; b) patients treated after 2005 with the following protocol - 2 or 3 ESWT sessions (600 shocks per session) at a 2-week interval. Patients were evaluated with Constant and Murley Scale, Visual Analog Scale, and with pain response on Fisher's Algometer. Evaluations were performed prior to treatment and then 1 month, 3 months, and 6 months after treatment.

Results: We present here the results of our clinical data review comparing the previous protocol with the new protocol. The data indicates no statistical difference between the two groups.

Discussion: The two groups show similar results. However, the new protocol with the 2-week interval resulted in being less expensive, easier to organize, and more satisfactory from the patients' point of view. We should consider ESWT as a major breakthrough in the treatment of chronic inflammatory disease and we now have the possibility to eliminate the biomechanical causes of the pathology.

Conclusion: We have now adopted the new protocol but we consider it vitally important to investigate the biological response of ESWT more thoroughly.

62. Electronic Case Report Form for Multi-centre Standardized Data Collection during ESWT
Sara Messina (1), Paolo Buselli (1), Valeria Coco (2), Raoul Saggini (3)

1) Azienda Ospedaliera di Lodi, Str. Provinciale 19, 26866 Sant'Angelo Lodigiano (LO), Italy
2) Azienda Ospedaliera Acireale, Via Caronia, 95024 Acireale (CT), Italy
3) Università di Chieti, V.le Abruzzo 322, 66103 Chieti Scalo, Italy

Device and producing company: EVOTRON, REFLECTRON, OSSATRON OSA 140, HMT

Introduction: During Shockwave Therapy, systematic collection of clinical and therapeutic data is essential for the positive and pro-active development of an evidence-based medicine.

Methods: For this reason, an electronic Case Report Form (CRF) was introduced as a clinical practice support for multi-centre standardized data collection in order to facilitate scientific evaluation and convenient statistical processing of recorded information. The following issues were examined: 1) effective Information Technology support; 2) administrative, bureaucratic, and privacy issues; 3) reliable clinical evaluation; and 4) efficient data control and statistical analysis.

Results: Here we report on technical solutions and preliminary data recorded in the first 6 months after we started to use the above-mentioned support in our clinical activities.

Discussion: It is a useful instrument which is easy to learn. The data collection protocol (with the Constant and Murley Scale, the Visual Analog Scale, and the measurement of pain response with Fisher Algometer) has been quick and reliable. The electronic CRF allows us to use recorded data with Excel for every statistical process.

Conclusion: The electronic CRF began 6 months ago and since then 6 other SWT centers have been recording data in the same way. We have proposed improvements in multi-centre data collection for research on the effects of SWT.

63. Focused and defocused ESWT. The comparison of the results in the treatment of heelspurs
Sergej Marx, Richard Thiele

Internationales Stoßwellenzentrum Berlin, IZS Berlin

Device and producing company: MTS: Orthowave 180, HMT EvoTron

Introduction: In the former time only shockwave devices with focused and radio therapy heads were used in the orthopedic field. Since ca. 2 years defocused shockwave therapy head was used for wound and skin treatment. This was the reason to use therapy head for the heelspur treatments as well.

Methods: Between 1/2002 and 10/2005 there were treated 179 patients with heelspurs. Follow up: 6, 12, 18 and 124 weeks. The devices: HMT EvoTron and MTS Orthowave 180, Focus head: 1200 shocks, 0,12 - 0,14 mJ/mm², local anaesthesia 5Hz. Between 11/2005 and 12/2006 95 heelspur patients were treated with Orthowave 180 defocused therapy head, 1200 shocks 0,14 mJ/mm², no local anaesthesia, 5 Hz.

Results: Group 1: 20 weeks after the 1. treatment (in some cases 2 and 3 treatments), VHS 69 %, Roles and Maudsley score 67 % excellent and good, 33 % acceptable and poor Group 2: Defocused therapy head, 24 weeks, VHS 74% Roles and Maudsley score, 75,8 % excellent and good, 24,2 % acceptable and poor (drop out: group 1 45 patients, group 2 21 patients)

Discussion: better results in group 2, because of the defocused therapy head or of no use of local anaesthesia?

Conclusion: ESWT with defocused therapy heads seems to be a good matter to treat orthopedic indications. Now it is necessary to make valid studies to proof the effectiveness of this kind of treatment

64. Extracorporeal shock wave therapy and its effects on the nervous system – A critical review of current literature

Morgan Mackenzie Wise, Kevin Seals, Michael Chang

University of Washington Department of Rehabilitation Medicine 1959 NE Pacific Street Box 356490 Seattle, WA 98195-6490

Device and producing company: None

Introduction: Extracorporeal Shock Wave Therapy (ESWT) is a versatile treatment modality used over the past 25 years to disintegrate nephrolithiasis, and has recently been shown to have multiple clinical applications in human musculoskeletal systems. Although initially painful, ESWT evokes a subsequent analgesic response and thus must interact with the nervous system. However, there has been little research into the mechanism, and results are often contradictory.

Methods: We have compiled an extensive review of the current ESWT-NS research via electronic journal databases in an attempt to better understand how SWs affect the nervous system. Our goal was to analyze the relationship between the contradictory papers and offer explanations, general conclusions and future directions with relation to the individual papers and ESWT-NS interactions as a whole.

Results: Our review offers an overview of the nervous system as it relates to ESWT, followed by an in-depth analysis of past and current research within the peripheral and central nervous systems. This analysis encompasses neuropeptide release, neuronal morphology, the endogenous opioid system, hyperstimulation analgesia, and the gate control theory.

Discussion: Ultimately the complexity of the nervous system makes analysis and methodology difficult. As a result, most papers have inconclusive findings and therefore much of ESWT-mediated pain regulation is left to speculation, making a complete understanding of ESWT-induced analgesia difficult.

Conclusion: The neurochemicals implicated in nociception, the pathways pain travels, and regulation of these pathways must be studied in vivo to further elucidate the mechanism by which this therapeutic treatment modality confers its analgesic effect.

65. Treatment of shock wave therapy in traumatic skin lesion – Case report

Paulo Roberto Pires Rockett, Mara Bernardete Lui

Ortosom Praça Dom Feliciano, 78/801 Porto Alegre - RS Brazil

Device and producing company: Reflectron - HMT

Introduction: Studies in vitro and in vivo confirmed that high energy shock waves have antibacterial effects, probably acting on biofilms produced by bacteria. The aim of this study was to evaluate results of the application of ESWT on the traumatic skin lesion of a patient who was expected to undergo arthroscopy on his right knee 5 days after an accident.

Methods: Male patient, 41 years, with an ankle sprain resulting in a peroneal fracture and macerated tissue after an iron gate felt over his right leg and foot. One day after the accident,

a Shock Wave treatment was performed on the macerated tissue injury which presented first signs of inflammatory reaction. The objective of the treatment was to avoid infection and repair the tissue because the patient would undergo an arthroscopy 5 days after the accident. Shock wave treatment was given over five sessions (one per week), with an electro-hydraulic device (Reflectron – HMT) with a special non-focused coupler. Treatment was ambulatory, with no anesthesia.

Results: Clinical evaluation and photographic documentation showed that there was pain relief, increase of granulation tissue, diameter reduction and complete healing of lesion. On the day of the surgery, the injury was considered to present no risks of infection.

Discussion: ESWT enabled a safe surgical procedure abbreviating the patient's recovery.

Conclusion: Shock Wave Therapy proved to be effective and safe in treating traumatic skin injury. Complementary studies will be required to evaluate the extension of this therapy on skin lesions.

66. Extracorporeal shockwave therapy for chronic skin ulcers in diabetics patients

Paulo Roberto Santos, Marco Guedes, Lindomar Guimarães, Claudia Arantes, Judith Mesquita, Paulo Rockett, Ana C Souza, Mara Guimarães

Lar Escola São Francisco – UNIFESP Centro Marian Weiss - São Paulo – Brazil

Device and producing company: Reflectron -HMT

Introduction: The aim of this study was to evaluate the efficacy and safety of extra- corporeal shock wave therapy for the treatment of chronic skin ulcers in diabetes type II patients.

Methods: The study consisted of diabetic patients with chronic skin ulcers at their extremities, in lower limbs. The ulcers had existed for a minimum of 3 months and were categorized as chronic disease; and they had been resistant to conservative therapy for at least 3 months. This study included 20 patients, 11 male and 9 female, age 40 and older. In October 2005, we began to treat some patients with chronic skin lesions using a Reflectron (HMT) device with a special therapy head. Treatments were applied in intervals of 2 weeks and different numbers of pulses were used according to the size of the wound. All patients were treated without anesthesia, and for dressing only physiologic serum was used to clean the wound after shock wave treatment.

Results: This study showed promising results with complete or partial healing of the wound in most of the patients. Treatment was safe and well tolerated. Prospective randomized trials have to be performed to show the safety, efficacy and stability of the results of shockwave therapy for treating chronic skin ulcers in diabetic patients.

Discussion: In this study we found that ESWT is a safe and well tolerated method of treatment for chronic diabetic skin ulcers. In 20 patients with chronic diabetic skin ulcers in lowers extremities more than 50% experienced completed healing and others experienced improvement.

Conclusion: In this study we found that ESWT is a safe and well tolerated method of treatment for chronic diabetic skin ulcers. In 20 patients with chronic diabetic skin ulcers in lowers extremities more than 50% experienced completed healing and others experienced improvement.

67. Non-focussed ESWT & skin ulceration in complex neurological disabilities

Keith Andrews, Anna M. Larking

Institute of Neuropalliative Rehabilitation Royal Hospital for Neuro-disability West Hill Putney London SW15 3SW UK

Device and producing company: Orthowave 180c with unfocussed head. MTS Europe GmbH

Introduction: Skin Ulceration in complex neurological disabilities is often slow to heal in spite of good nursing care. ESWT offers an opportunity for improving healing rates.

Methods: A blind cross-over study with washout-out period (2 weeks) between unfocussed ESWT and fake ESWT (both weekly for 4 weeks) was used to assess 15 patients with skin lesions secondary to chronic neurological disabilities (late stage multiple sclerosis and brain damage). Nearly all of the patients had cognitive impairment which complicated nursing care.

Results: Several patterns emerged. The ulceration of those with multiple sclerosis either did not heal or took a long time to heal. Some patients showed improvement during the fake-ESWT phase and this was usually rapid. Sinuses did not respond or responded very slowly to unfocussed ESWT.

Discussion: A cross-over study was used to evaluate the response to good nursing care, the Hawthorne and Pygmalion effects or the possibility that concomitant effects (such as the ultrasound gel) might confound the effect of ESWT. When healing occurs in chronic ulceration it is delayed but more rapid than the normal healing pattern. It is still unclear as to the frequency, the 'dosage' or the length of treatment period for optimal benefits from ESWT treatment. Treatment of sinuses may require a focussed head for optimal benefit.

Conclusion: 1. A cross-over study design is essential to identify the effects of recovery associated with good nursing care. 2. The optimal 'dose', frequency and treatment period are yet to be identified. 3. Different types of ulceration require different forms of ESWT.

68. Shockwaves induce cellular responses in diabetic skin ulcers

Ching-Jen Wang (1), Feng-Sheng Wang (2)

1) Department of Orthopedic Surgery,

2) Department of Medical Research,

Chang Gung Memorial Hospital, Chang Gung University College of Medicine, Taiwan

Device and producing company: Orthowave 180, MTS, Konstanz, Germany

Introduction: Extracorporeal shockwaves were recently used for treatment of chronic diabetic skin ulcers. The preliminary data showed cell apoptosis in diabetic wounds before treatment and the reversal of cell apoptosis after shockwave treatment. This study was to evaluate the cellular responses in chronic diabetic skin ulcers before and after shockwave treatment.

Methods: There are 17 patients with 20 diabetic skin lesions in this study. The energy level of the shockwaves is between 0.03 mJ/mm² to 0.04 mJ/mm² energy flux density, and the focal size is up to 20 mm in diameter. The protocol of shockwave application consists of 300 shocks + 100 shocks/cm² of the size of the ulcer to be performed bi-weekly for a total of three sessions. Clinical assessments included size and depth of the lesion, epithelialization, local sepsis, arteriopathy and denervation before and after treatment. Biopsies of the lesions were obtained before treatment and at 6 weeks after treatment. The specimens are subjected to histomorphological examination for tissue distributions, cell concentration, the types of cells

with intact or disrupted cell membrane and the vascularity, and immunohistochemical analysis for detection of proliferation cell antigen (PCNA) to reflect cell replication, terminal deoxynucleotidyl transferase-mediated dUTP nick end-labelling (TUNEL) for cell apoptosis.

Results: Overall, 25% are healed, 50% improved and 25% are unchanged. Cell apoptosis was noted before treatment. After treatment, there was more active cell proliferation and less cell apoptosis.

Discussion: Shockwave treatment showed 75% satisfactory results in diabetic skin lesions. Reversal of cell apoptosis and enhancement in cell proliferation were observed after shockwave treatment.

Conclusion: Shockwaves appear effective in treating diabetic skin lesions. The cellular responses included the reversal of cell apoptosis and tissue regeneration.

69. Accelerated wound recovery in the treatment of burns using defocused shockwave therapy (ESWT) Richard Thiele (1), Christian Ottomann (2), Bernd Hartmann (2)

1) IZS Berlin (Internationales Stoßwellenzentrum)

2) Unfallkrankenhaus Berlin

Device and producing company: Dermagold of TRT (Tissue Regeneration Technologies, Konstanz)

Introduction: Musculoskeletal shockwave therapy increases blood flow in tissues and results in neoangiogenesis. In a study carried out on animals, enhanced tissue regeneration was observed in skin grafts. The aim of the planned clinical study is to demonstrate reduced recovery time and/or enhanced wound healing, specifically superficial and deep thermal lesions, as well as autogenous skin donor sites.

Methods: This will be a single-site, prospective, randomized and non-binding clinical study. Musculoskeletal shockwave therapy is to be administered within the first 24 hours post-trauma as part of the first aid care to be followed by a standardized dressing regime as a part of the burn treatment. The patients are to be divided into three groups according to the degree of the burns, i.e. OP planning.

Group A (superficial second degree burns or scald wound surfaces) – beginning January 1, 2007, 50 patients who meet the entry criteria and are not placed in Group B or Group C are to be selected. The patients, afflicted with second degree thermal lesions (burns and scalds), do not require transplants on the areas to be investigated and are expected to have a scar-free recovery within 14 days. Re-epithelization is to be attained through conventional treatment. Twenty-five patients from the group are randomly selected for ESWT treatment.

Group B (deep second degree burns or scald wound surfaces) – beginning January 1, 2007, 50 patients who meet the entry criteria and are not placed in Group A or Group C are to be selected. The patients are afflicted with second degree thermal lesions. Recovery under conventional therapy is expected to take more than two weeks and a conventional method of treatment is to be administered. Afterwards, depending on the size of the remaining defect it will be determined whether a surgical procedure is necessary. The total recovery time will be assessed. The application of ESWT is to be given to 25 randomly chosen patients.

Group C (autogenous skin donor sites) – beginning January 1, 2007, 50 patients who meet the entry criteria and are not placed in Group A or Group B are to be selected. Due to the necessity of a skin graft, autogenous skin will be removed from this group of patients. The autogenous skin tissue will be removed by machine using a strength of 0.2mm to 0.3 mm. ESWT is to be administered afterwards. Recovery to complete re-epithelization (primary

aim) will be determined visually in the course of dressing changes and photographed. The application of ESWT is to be given to 25 randomly chosen patients. The study is projected to last for one year. The use of a diffused shockwave head is to be administered tangentially on the burn wounds. Shockwaves with an energy level of 0.1-0.14 mJ/m² is to be administered in the study. All participating patients, i.e. patients given ESWT as well as those of the control group (Groups 1 to 3) will receive identical dressings made of perforated silicon film together with a hydrogel (Mepitel together with Lavaseptgel or Octenidigel), Suprathel dressing or Aquacell film bandage.

Results: Expected findings: A significantly shortened period for the re-epithelization of the thermal lesions (Group A), autogenous skin donor sites are removed for grafting (Group C), and enhanced recovery of the deep dermal lesions (Group B) with a reduction of necessary surgical surfaces is expected in those receiving musculoskeletal shockwave therapy.

70. Extracorporeal shockwave therapy for chronic skin lesions

Michael Pusch, C. Kölbl, A. Valentin, W. Schaden

Trauma Centre Meidling,
Kundratstrasse 37, 1120 Vienna, Austria

Device and producing company: Dermagold®, MTS, Konstanz, Germany

Introduction: In treating infected non-unions connected with chronic skin lesions with ESWT, we observed a significant impact on wound healing. In most of the patients, extremely rapid healing of the wounds was observed. After successful animal trials, performed at the Department of Plastic and Reconstructive Surgery of the University of Innsbruck and the University of Kentucky, we continued our feasibility trial. We used the new parabolic therapy head which delivers almost flat shockwaves.

Methods: Since late 2004 we have treated 261 patients with chronic skin lesions by means of ESWT with the DermaGold® / MTS, Konstanz, Germany. All therapies were performed without any kind of anesthesia as an outpatient treatment. Depending on the surface of the defect, different numbers of pulses were applied. The patients were treated in an average of 3 sessions (1-10) depending to their tendency for regeneration and epithelialization.

Results: Of the 261 patients with skin lesions, 190 (72.8%) showed complete healing; 7 (2.7%) had more than 50% epithelialization; 16 (6.1%) had less than 50% epithelialization; 7 (2.7%) showed no improvement of the lesion; and 41 (15.7%) were lost to follow up. The treatment was tolerated by all patients without any kind of anesthesia. No adverse effects have been observed. In none of the cases was an increase of symptoms reported.

Discussion: After this successful pilot study evaluating the most efficient treatment parameters was completed, a prospective randomized trial to confirm our results commenced in April at Walter Reed Army Medical Center (WRAMC) in Washington, DC.

71. Shock wave therapy to improve wound healing after vein harvesting for CABG

Margit Vögele-Kadletz, Julia Dumfarth, Daniel Zimpfer, Johannes Holfeld, Florian Sihorsch, Wolfgang Schaden, Ernst Wolner, Michael Grimm

University of Vienna, Dept. of Cardiothoracic Surgery Trauma Hospital Mediling
Device and producing company: Derma Gold, TRT/MTS Konstanz, Germany

Introduction: Wound healing disorders after vein harvesting for CABG are an evident clinical problem. Extracorporeal shock wave therapy (SWT) has been shown to improve wound healing in patients with diabetic and vascular ulcers. It remains uncertain if prophylactic application of SWT can improve wound healing after vein harvesting.

Methods: In order to study the effect of prophylactic SWT we performed a prospective randomized trial. Eighty patients undergoing isolated CABG were randomised to either prophylactic SWT (n=40) or no treatment as control (n=40). SWT was applied after wound closure at the end of the operation under sterile conditions. A total of 25 impulses (0.1mJ/mm²; 5Hz) were applied per centimetre wound length. Wound healing was evaluated using the ASEPSIS Score on postoperative days 3-7. Patient demographics, operative data and postoperative adverse events were monitored.

Results: The groups were comparable with regard to patient demographics, operative data and postoperative adverse events. Wound length (SWT: 41±13 vs control: 37±11) was comparable between the two groups (p=0.110) as well. The asepsis score showed improved wound healing in the SWT group (SWT: 5.1 ± 5.6 vs. control: 9.7 ± 8.1, p=0.009). We observed no difference in use of antibiotics or length of hospital stay. No adverse events were observed in the treatment group.

Conclusion: As shown in this prospective randomized study, prophylactic application of low energy extracorporeal shock wave therapy improves wound healing after vein harvesting for CABG.

72. Combat wound initiative summary

Eric A. Elster, Thomas A. Davis, Alexander Stojadinovic

Regenerative Medicine Dept, Combat Casualty Care, Naval Medical Research Center, Silver Spring, MD

Combat Wound Initiative, Department of Surgery at the Walter Reed Army Medical Center, Washington, DC

Combat Wound Initiative, Department of Surgery at the National Naval Medical Center, Bethesda, MD

Department of Surgery, Uniformed Services University, Bethesda, MD.

Device and producing company: TRT LLC

Introduction: Improvised explosive devices have brought about a high incidence of multiple penetrating wounds to the extremities with extensive soft tissue and bone destruction. The increased severity and complexity of these often-survivable war wounds pose formidable surgical treatment challenges. The primary aims of combat casualty care are preservation of life, limb, and function to allow safe and rapid return to functional existence and military duty. The Combat Wound Initiative is a unique inter-service and civilian partnership

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including Walter Reed Army Medical Center, National Naval Medical Center, Brooke Army Medical Center, Memorial Medical Center – Conemaugh Health Systems, and Hadassah University Medical Center Mount Scopus – Jerusalem.

Methods: This collaborative multi-disciplinary program will provide state-of-the-art wound care through targeted clinical and translational research incorporating advanced technology and treatment, informatics, tissue banking and research.

Results: The Combat Wound Initiative is a collaborative program of leading surgeons and scientists integrating clinical research and basic science to assess and develop further promising technologies and treatments to advance wound healing. The significance of this unrivalled collaborative research effort is to establish a definitive clinical care and research initiative to advance combat and civilian trauma casualty care.

Discussion: The Combat Wound Initiative has completed a Phase II Clinical Trial evaluating the role of shock wave therapy for complicated acute and chronic non-healing wounds, demonstrating the feasibility and safety of this treatment paradigm. The study has been accepted for publication in the Journal of Surgical Research and has been presented at the Annual Wound Healing: Science and Industry meeting as well as the Annual Academic Surgical Congress. This study serves as the basis for a military and civilian collaborative randomized clinical trial, which will provide the first critical analysis of the potential role of shock wave therapy in improved treatment and clinical outcomes of extremity injuries sustained in Operation Iraqi Freedom and Operation Enduring Freedom. On-going small animal research studies are defining previously unrecognized molecular mechanisms of shock wave therapy applied to severe burns.

Conclusion: The Combat Wound Initiative serves as a starting point for a programmatic approach to acute wound healing.

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