



**June 9<sup>th</sup> – 11<sup>th</sup> 2011**

Congress Venue:  
Atlantic Hotel Kiel, Germany

**Topics**

Bone pathologies  
Non-Unions  
Sports Traumatology  
Calcific tendonitis  
Impingement  
Heel pain  
Tennis elbow  
Technical Innovation  
Industry exhibition  
Chronic Wound Healing  
Skin lesions  
Triggerpoint treatment  
Myofascial treatment  
Avascular necrosis  
Up-Date Shockwave Treatment  
Instructional hands-on courses  
DIGEST/ISMST Certification course

[www.shockwavetherapy.org](http://www.shockwavetherapy.org)

# Abstracts



## Wednesday, June 8th, 2011

15.00 – 17.00 **Early registration  
at the Atlantic Hotel Kiel**

16.00 – 19.00 **Managing Board Meeting**

## Thursday, June 9th, 2011

as of 07.30 **Registration**

08.30 – 17.30 **Industrial Exhibition**

09.00 – 09.30 **Opening Ceremony  
with Words of welcome:**

Prof. Dr. Ludger Gerdesmeyer,  
President of the ISMST

Vinzenz Auersperg,  
General Secretary of the ISMST

09.30 – 10.40 **Basic Research I**

Chairman: Rainer Mittermayr, John Furia

09.30 – 09.40 **(1) Potential Roles of Cavitation in  
Tissue Angiogenesis - Observations from  
Cavitation Monitoring during  
Shockwave Therapy**

(Michael Chang)

*Device and producing company:  
OssaTron (SanuWave)*

*D-Actor (Storz Medical AG Switzerland)*

09.40 – 09.50 **(2) Energy transmission  
with radial pressure waves**  
(Pavel Novak)

*Device and producing company:  
Storz Medical AG Switzerland*

09.50 – 10.00 **(3) Investigation of the correlation  
between shockwave induced mechanical  
stress and biological response**

(Matias de la Fuente, Yifei Long, Marc Hein,  
Anna Röhl, Michael Becker, Klaus Radermacher)

*Device and producing company:  
Piezon 100 plus, Richard Wolf*

10.00 – 10.10 **(4) Shoulder Rotator Cuff Responses  
to Extracorporeal Shockwave Therapy  
(ESWT), Morphological and  
Immunohistochemical Analysis**

(Julian Andres Branes, Leonardo Guiloff,  
Leonardo Arellano, Manuel Branes)

*Device and producing company:  
Orthospec/Medispec*

*Storz Medical AG Switzerland*

10.10 – 10.25 **(5) Extracorporeal Shockwave Therapy  
minimizes necrosis and promotes tissue  
revascularization by stimulating  
angiogenesis in an ischemic epigastric  
flap model**

(Rainer Mittermayr, Joachim Hartinger,  
Alexandra Meinl, Sabine Pfeiffer,  
Vlado Antonic, Alexander Stojadinovic,  
Wolfgang Schaden, Heinz Redl)

*Device and producing company:  
orthowave 180C, mts*

10.25 – 10.40 **(6) Possible Working Mechanism  
of ESWT-Mechanotransduction**

(Wolfgang Schaden, Rainer Mittermayr)

10.40 – 11.00 **Discussion**

11.00 – 11.30 **Coffee break**

11.30 – 12.15 **ESWT for knee pathologies**

Chairman: Richard Thiele

11.30 - 11.40 **(7) TOPGAME study: In-depth analysis**

(Johannes Zwerver, Fred Hartgens,  
Evert Verhagen, Henk van der Worp,  
Inge van den Akker-Scheek, Ron Diercks)

*Device and producing company:  
Piezowave, Richard Wolf GmbH*

11.40 – 11.50 **(8) The TOPSHOCK study:  
Effectiveness of radial Shockwave Therapy  
compared to focused Shockwave Therapy  
for treating patellar tendinopathy.  
Design of a randomised controlled trial**

(Henk van der Worp, Johannes Zwerver,  
Ron Diercks, Inge van den Akker -Scheek)

*Device and producing company:  
Duolith SD1,*

*Storz Medical AG Switzerland*

11.50 – 12.00 **(9) Low Energy Extracorporeal  
Shock Therapy as a Treatment for  
Chronic Patellar Tendinopathy**

(John Patrick Furia, Jan Dirk Rompe,  
Angelo Cacchio, Nicola Maffulli)

*Device and producing company:*

*DolorClast, EMS*

12.00 – 12.15 **Discussion**

12.15 – 14.00 **Lunch at the congress hotel**

14.00 – 15.00 **ESWT for foot pathologies**

Chairman: Amol Saxena, Vinzenz Auersperg

**14.00 – 14.10 (10) Focused ESWT is a new modality to treat accessory Navicular Problems**

(Ayman Elwy Balabel, Faisal Al-Kandary, Sahar Othman)

*Device and producing company:*

*Piezoson 300, Wolf*

**14.10 – 14.20 (11) Comparison of Focused ESWT with Radial ESWT in Treatment of Chronic Plantar Fasciopathy with Heel Spur**

(Ayman Elwy Balabel, Faisal Al-Kandary)

Device and producing company:

Piezoson 300, Wolf

Swiss Dolorclast, EMS

**14.20 – 14.30 (12) ESWT in Chronic Proximal Plantar Fasciitis, 9 years of experience**

(José Eid)

*Device and producing company:*

*Swiss Dolor Clast, EMS*

*Epos Ultra, Dornier*

**14.30 – 14.40 (13) Extracorporeal Pulsed-activated Therapy (“EPAT”) for Achilles Tendinopathy: A Prospective Study**

(Amol Saxena, Sona Ramdath, Patrick O'Halloran, Ludger Gerdesmeyer, Hans Gollwitzer)

*Device and producing company:*

*Storz Medical AG Switzerland D-Actor 200*

**14.40 – 14.50 (14) Evidence in plantar fasciitis treatment**

(Vinzenz Auersperg)

**14.50 – 15.00 Discussion**

**15.00 – 15.30 Coffee break**

**15.30 – 17.00 Basic Research II**

Chairman:

Maria Cristina D'Agostino, Manuel Branes

**15.30 – 15.40 (15) Prospects of Shockwave Therapy application**

(Boris Garilevich, Anton Rotov, Alexandr Levkovsky, Marina Garilevich)

*Device and producing company:*

*„Bioslim“, Scientific Medical Company*

*„Rumelit“*

**15.40 – 15.50 (16) High Energy Shock Waves and 5-Aminolevulinic Acid for Sonodynamic Therapy: Effects on SK-N-BE and SH-SY5Y Neuroblastoma Cell Lines**

(Roberto Frairia, Loredana Serpe, Roberto Canaparo, Gian Paolo Zara, Mario Eandi, Laura Berta)

*Device and producing company:*

*Piezoson 100, Richard Wolf*

**15.50 – 16.00 (17) Influence of Shockwave Therapy on Fibroblasts - Special Meaning for Skin Remodeling**

(Kerstin Neumann, Hans-Jürgen Duchstein, Helmut Neuland)

*Device and producing company:*

*Piezowave, Wolf GmbH;*

*Piezoson 100 plus, PiezoWave,*

*Richard Wolf;*

*Orthowave 180c CP-155,*

*Tissue Regeneration Technologies and MTS*

**16.00 – 16.10 (18) Recruitment of endothelial progenitor cells and functional improvement in chronic hind limb ischemia by extracorporeal Shockwave Therapy in rats**

(Can Tepeköylü, Feng-Shen Wang, Wolfgang Schaden, Michael Grimm, Ching-Jen Wang, Johannes Holfeld)

*Device and producing company:*

*Dermapace, Sanuwave*

**16.10 – 16.20 (19) New Insights into Morphology of Cardiac Tissue Regeneration after direct Epicardial Shockwave Treatment**

(Johannes Holfeld, Daniel Zimpfer, Can Tepeköylü, Anita Thomas, Patrick Paulus, Seyedhossein Aharinejad, Wolfgang Schaden, Michael Grimm)

*Device and producing company:*

*Cardiogold, CRT AG*

*(produced by MTS Europe GmbH)*

**16.20 – 16.30 (20) Bone morphogenetic protein-2 expression in spinal fusion masses enhanced by extracorporeal Shockwave Treatment: a rabbit experiment**

(Tao-Chen Lee, Ching-Jen Wang)

*Device and producing company:*

*OssaTron,*

*HMT High Medical Technologies GmbH*

**16.30 – 17.00 Discussion**

**17.00 – 18.00 AGM of the ISMST**

**19.00 ISMST Congress Dinner**

Pier Restaurant

Atlantic Hotel Kiel

Raiffeisenstraße 2

24103 Kiel

Phone: +49 (431) 374 99 562

[www.atlantic-hotels.de](http://www.atlantic-hotels.de)



Friday, June 10th, 2011

**as of 07.30 Registration**

**08.30 – 17.30 Industrial Exhibition**

**07.30 – 09.30 Instructional Course part 1**

**09.50 – 10.35 ESWT and Bone Pathologies I**

Chairman:  
Wolfgang Schaden, Paulo Kertzman

**09.50 – 10.00 (21) Experience in the treatment of pseudoarthrosis by applying platelet-rich plasma in association with focused Shockwave stimulation**

(Paolo Buselli, L. Di Palma, R. Compagnoni, S. Messina, A. Branca)

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

**10.00 – 10.10 (22) ESWT in Treatment of Osteitis Pubis in Professional and Amateur Athletes**

(Ana Claudia Souza, Alexander Montenegro)

*Device and producing company:*  
REFLECTRON – HMT

**10.10 – 10.20 (23) ESWT for Osteonecrosis of femoral head – a retrospective study**

(Shrenik Shah)

*Device and producing company:*  
Stonolith-Israel, EPOS-Dornier

**10.20 – 10.35 Discussion**

**10.35 – 11.00 Coffee break**

**11.00 – 12.30 ESWT and Bone Pathologies II**

Chairman: Carlos Leal, Richard Coombs

**11.00 – 11.15 (24) Keynote lecture: Pseudarthrosis – treatment option and golden standard**

(Andres Seekamp)

**11.15 – 11.25 (25) Shockwaves in hand & foot surgery - retrospective analysis of results with different devices**

(Frank Bätje)

*Device and producing company:*  
Storz Duolith SD1,  
Storz Medical AG Switzerland  
Modulith SLK

**11.25 – 11.35 (26) ESWT in foot navicular stress fracture of a high performance**

(Sergio Abello, Carlos Leal)

*Device and producing company:*  
ORTHOGOLD 100 – TRT (USA)  
and MTS (Germany)

**11.35 – 11.45 (27) Extracorporeal Shockwave Therapy (ESWT) in the treatment of bone pseudoarthrosis: Verona experience**

(Claudio Guerra, Ernesto Amelio)

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

**11.45 – 11.55 (28) Quality Control of ESWT in the treatment of Non-Union fractures**

(Wolfgang Schaden, Andreas Fischer, Ender Karadas, Rainer Mittermayr)

*Device and producing company:*  
Ossatron, HMT, Orthowave 280, TRT and MTS

**11.55 – 12.05 (29) ESWT for Non-Union Fractures - Economic Aspects**

(Wolfgang Schaden, Rainer Mittermayr, Ender Karada, Heinz Kuderna)

*Device and producing company:*  
Orthowave 280, TRT (USA)  
and MTS (Germany)

**12.05 – 12.15 (30) ESWT for Non-Union Fractures – Evidence Based Medicine**

(Heinz Kuderna, Rainer Mittermayr, Wolfgang Schaden)

*Device and producing company: n.a.*

**12.15 – 12.30 Discussion**

**13:00 – 14.00 Press Conference**

**12.30 – 14.00 Lunch at the congress hotel**

**14.00 – 15.30 ESWT and Pain Management**

Chairman:  
Jan Dirk Rompe, Roberto Frairia, Markus Gleitz

**14.00 – 14.20 (31) Keynote lecture: Pain perception and mechanism of chronification in musculo-skeletal disorders**

(Ralf Baron)

**14.20 – 14.30 (32) Shockwave or Surgery – ESWT as an alternative to operative procedures in the treatment of musculoskeletal pain**

(Hannes Müller-Ehrenberg)

*Device and producing company: Piezowave, WOLF*

**14.30 – 14.40 (33) Long term effectiveness of ESWT in reducing pain and improving function in patients suffering from somatic diseases**

(Raoul Saggini, Alexandra Di Stefano, Mario Valeri, Emanuela Panelli, Angela Marri, Valentina Galati, Laura Scarcello, Rosa Grazia Bellomo)

*Device and producing company:*  
Evotron Electrohydraulic Spark Gap,  
HMT, Kreuzlingen.

**14.40 – 14.50 (34) Shockwaves in the treatment of paraosteopathies: A case report on painful paraosteopathy in a 3-year old girl**

(Sara Messina, Paolo Buselli, Vincenzo Bosco)

*Device and producing company:  
Modulith SLK – Storz Medical AG Switzerland*

**14.50 – 15.00 (34) Low energy focused Shockwave Therapy of adductor related groin pain in football players**

(Laura Berta, Roberto Frairia, Marina Berta)

*Device and producing company:  
Minilith SL1, Storz Medical AG Switzerland,  
Tägerwilen, Switzerland*

**15.00 – 15.10 (35) ESWT for athletic injuries during competition**

(Paulo Kertzman, Mauro Moreira)

*Device and producing company:  
Dolorclast, EMS*

**15.10 – 15.30 Discussion**

**15.30 – 16.00 Coffee break**

**16.00 – 17.30 ESWT and Skin Treatment**

Chairman:  
Alexander Stojadinovic, Richard Thiele

**16.00 – 16.20 (37) Keynote lecture: Treatment of Chronic Wounds - State of the Art**

(Karsten Knobloch)

**16.20 – 16.30 (38) Shockwave Therapy for Lipodystrophy improvement**

(Olga Krikunova)

*Device and producing company:  
Duolith, Storz Medical AG Switzerland*

**16.30 – 16.40 (39) Defocused ESWT for Chronic Skin Lesions - Treatment Interval Does Not Seem to Influence Healing Outcome**

(Rainer Mittermayr, M. Pusch, Ch. Schwab, W. Schaden)

*Device and producing company:  
Dermagold, Activator, MTS/TRT*

**16.40 – 16.50 (40) Placebo controlled, prospectively randomized, double-blinded study for the investigation of the effectiveness and safety of acoustic wave therapy (AWT®) for cellulite treatment**

(Katharina Russe-Wilflingseder, Elisabeth Russe, Monika Drmic, Johannes C. Vester, Gerd Haller, Pavel Novak, Alexander Krotz)

*Device and producing company:  
D-ACTOR® 200 by  
Storz Medical AG Switzerland*

**16.50 – 17.00 (41) Cellulite and Extracorporeal Shockwave Therapy (CelluShock-2009) - Randomized Trial**

(Karsten Knobloch, Beatrice Joest, Robert Krämer, Peter M. Vogt)

*Device and producing company:  
Duolith, STOR*

**17.00 – 17.10 (42) Prospective Trials of ESWT for Soft Tissue Indications**

Alexander Stojadinovic, Christian Ottomann, Bernd Hartmann, (Richard Thiele, Philip T. Lavin, Wolfgang Schaden)

*Device and producing company:  
OW180C DermaGold™, MTS Europe*

**17.10 – 17.20 Discussion**

**17.30 – 18.15 Industrial Meetin**

**18:30 Bording for Sea Site Cruise**

Hotel Atlantic to the Royal Yacht Club Kiel

**19.30 Ocean Site Evening**

Royal Yacht Club Kiel  
Hindenburg Ufer 70  
24105 Kiel  
Tel.: +49 (431) 8813-0  
<http://www.hotel-kyc.de>

Saturday, June 11th, 2011

**as of 07.30 Registration**

**08.30 – 17.30 Industrial Exhibition**

**07.30 – 09.30 Instructional Course part 2**

**10.00 – 11.20 ESWT for Shoulder pathologies**

Chairman: Jörg Hausdorf, Jose Eid

**10.00 – 10.20 (43) Keynote lecture: Standard of care for shoulder Impingement Surgery**

(Markus Loew)

**10.20 – 10.30 (44) Treatment of Frozen Shoulder with Focused ESWT**

(Ayman Elwy Balabel, Faisal Al-Kandary, Sahar Othman)

*Device and producing company:  
Piezason 300, Wolf*

**10.30 – 10.40 (45) The potential role of Shockwaves on shoulder tendons healing after surgery**

(Sergio Russo, A. Cozzolino, E. Astarita, A. Petteruti, R. Russo)

*Device and producing company:  
Duolith, Storz Medical AG Switzerland*

**10.40 – 10.50 (46) Evidence and necessity of focus control in ESWT of calcifying Tendinopathies of the Shoulder**

(Sergej Thiele, Richard Thiele)

**10.50 - 11.05 (47) ESWT for calcifying tendonitis Evidence Based Medicine**

(Ludger Gerdesmeyer)

**11.05 – 11.20 Discussion**

**11.20 – 12.00 Coffee break**

**12.00 – 13.45 Miscellaneous**

Chairman:

Sergio Russo, Ana Claudia de Souza

**12.00 – 12.10 (48) Ultrasound Elastography, a Novel Method for the Diagnosis of Trigger Points and a Tool to Evaluate the the Efficacy of Shockwaves in the Treatment of Myofascial Pain Syndroms**

(Wolfgang Bauermeister)

*Device and producing company:  
Swiss DoloClast, EMS; Piezoston 100,  
Wolf: ARIES, Dornier MedTech;  
Ultrasonix Tablet, Ultrasonix*

**12.10 – 12.20 (49) Shockwave-acupuncture: A method with excellent results in arthritis and asthma treatment**

(Heinrich Everke)

*Device and producing company:  
MP 50 - Storz Medical Company, Switzerland*

**12.20 – 12.30 (50) The use of computerized clinical files in Shockwave Therapy surgery: Our experience in Tortona**

(Maria Cristina Ottone, Francesca Maria Roldi)

*Device and producing company:  
Piezoston 300, Wolf*

**12.30 – 12.40 (51) A novel approach to ESWT for Achilles tendinopathy, guided and evaluated by means of Ultrasound Tissue Characterization (UTC)**

(Hans T. M. van Schie, Willem den Boer, Bert Verhoeven)

*Device and producing company:  
ESWT: ActiVitor ACV02,  
SwiTech Medical, 8280 Kreuzlingen,  
Switzerland, UTC: UTC Imaging,  
6171 GD Stein, the Netherlands*

**12.40 – 12.50 (52) safety and efficacy of ESWT in plantar heel pain – outcome of the STORZ FDA Study**

(Hans Gollwitzer, Amol Saxena, Louis Gally, Brian Fullem, Richard T. Bouché, David Caminear, Ludger Gerdesmeyer)

*Device and producing company:  
Storz, Duolith*

**12.50 – 13.00 (53) The Importance of Total Energy Emitted in the Results of ESWT**

(Maria Cristina Ottone, Filippo Fagnani, Emanuela Maria Roldi)

*Device and producing company:  
Piezoston 300, Wolf*

**13.00 – 13.10 (54) Effects of Extracorporeal Shockwave Therapy on Spasticity in Cerebral Palsy (CP): Our Experience (pilot study)**

(Maria Cristina d'Agostino, V. Gasparroni, A. M. Lopez Lopez, S. Respizzi, B. Bernardini, N. M. Portinaro)

*Device and producing company:  
Orthowave, TRT (USA) and MTS (Germany)*

**13.10 – 3.20 (55) Effects of ESWT in Osteitis**

(Hans Gollwitzer)

*Device and producing company: n.a.*

**13.20 – 13.30 (56) Shockwave Treatment for Orthopaedic Infections**

(Richard Coombs, Moustafa Hafez, Milad Hanna, Nikki Horwood, Vipin Asopa)

*Device and producing company: n.a.*

**13.30 – 13.45 (57) Differentiation of mesenchymal stem cells by extracorporeal shock waves**

(Jörg Hausdorf, Susanne Mayer, Birte Sievers, Tolga Goeren, Volkmar Jansson)

*Device and producing company:  
XL 1, Dornier*

**13.45 – 14.00 Discussion**

**14.00 – 14.30 Closing ceremony**

Closing addresses by  
Prof. Dr. Ludger Gerdesmeyer

Invitation to the 15th Congress of the ISMST in Cartagena, Colombia by the incoming president, Prof. Dr. Carlos Leal

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## **1. Potential Roles of Cavitation in Tissue Angiogenesis - Observations from Cavitation Monitoring during Shockwave Therapy**

Michael Chang

Institution: Physical Medicine Institute, WA, USA

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

**Introduction:** Cavitation may play an important role in Shockwave Therapy (SWT) bringing desirable biological responses, such as angiogenesis/regeneration, thrombolysis, or disrupting bacteria biofilms. Therefore, designing SWT protocol including cavitation control is important to achieve desirable clinical outcomes.

**Methods:** Real-time cavitation was monitored using B-mode ultrasonography during SWT for various chronic musculoskeletal conditions using either the OssaTron or D-Actor.

**Results:** Occurrence of cavitation highly depends on shockwave applications as well as characteristics of the target tissue. Presence of cavitation is usually more obvious with SWT using a high-energy focused shockwave device than a low-energy unfocused pressure wave device. Cavitation is more easily seen in tissues with high fluid or vascular contents. Cavitation tends to scatter around soft tissue-bone interfaces or wherever there is high negative pressure. With high shockwave intensity, fast application rate and high cumulative pulses, persistent and wide spread cavitation within target tissue may be observed.

**Discussion:** Cavitation often first occurs within blood vessels. There is apparent dynamic interaction between cavitation and shockwaves, exerting unique stress/stimulation on vascular cells. The stress may also disrupt vessel walls introducing intra-vascular contents into interstitial space, seeding wider spread cavitation. These events may participate in important bio-mechanisms for tissue angiogenesis. If excessive cavitation occurs, tissue/organ injury may result.

**Conclusion:** Shockwaves exert their unique influence on vasculatures through both production of cavitation and interaction with the cavitation. Cavitation may prove to be one of the most important factors that should be carefully controlled to achieve safety and efficacy for future clinical applications of SWT in medicine. Further investigation into cavitation control in various clinical settings is needed.

## **2. Energy transmission with radial pressure waves**

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Device and producing company: Masterpuls MP200, Storz Medical AG

**Introduction:** Radial pressure waves are typically generated pneumatically when a projectile, accelerated by compressed air, hits a stationary transmitter. Pressure waves are usually referred to either as EPAT (Extracorporeal Pulse Activation Therapy), or as RSWT (Radial Shockwave Therapy). The "classification" as shock waves is (along with marketing issues) based on the fact that both wave types are mechanical pulses and their therapeutic effect is similar for many indications. As a result, the same physical parameters for their description (MPa, mJ/mm<sup>2</sup>) as well as the same measurement methods are used for radial pressure waves as for focused shock waves. This approach leads to misinterpretation, because radial pressure waves have significantly different physical properties (pulse amplitude, pulse shape, frequency range) than focused shock waves.

**Methods:** Low frequency pressure waves cannot be measured in a water bath like shock or ultrasound waves can. They can only be measured by calibrated force transducer within a tissue phantom.

**Results:** The measurements confirm that the energy transmitted into the tissue by low frequency pressure waves is significantly higher than the energy transmitted by the ultrasound pulse (which is generated in parallel) and has much lower penetration depth and energy.

**Discussion:** Considering pressure waves as shock waves results in incorrect observations and is not consistent with observed biological effects. Observed therapeutic effects are due to the low frequency pressure waves.

**Conclusion:** The attempt to consider and quantify the pressure waves as shock waves results in misinterpretation of the observed effects. It prevents recognizing and optimizing the true benefits achievable by pulse activation therapy (EPAT).

### 3. Investigation of the correlation between shockwave induced mechanical stress and biological response

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3 Department of Cardiology, RWTH Aachen University Hospital, Germany

Device and producing company: Piezoston 100 plus, Richard Wolf

Introduction: Physical reasons for the destructive characteristics of shockwaves have been studied over the last few decades. However, the cause for the therapeutic characteristics remains unclear. Depending on the shockwave device used (method of shock-wave generation) and the device settings, different mechanical stimuli act on the target tissue. Therefore it is difficult both to compare studies of different authors and to set treatment-specific shockwave parameters.

Methods: A simulation model of non-linear shockwave propagation has been implemented as well as two simplified models for shockwave treatment – one for cell culture flasks and one for isolated rat hearts. During simulation the normal and shear strain and stress caused by the shockwave can be calculated at each time point.

Results: Non-linear shockwave propagation in water can be validated by comparing it to measurement data at the surface of the shockwave device as well as in the focal area.

Preliminary results of the simulation of mechanical stress at isolated rat hearts show a correlation between the local distribution of the maximum stress and the histological findings.

Discussion: Information regarding the correlation between the mechanical strain/stress caused by the shock wave and the biological response could make new target-oriented treatments possible. The mechanical stress model implemented so far represents the basis for our ongoing experimental evaluation and optimization of the simulation.

Conclusion: Shockwave simulation may be a means to better understand the cause-effect relation of shockwaves and biological responses. To achieve this, the model must be further validated and then correlated to verified biological findings.

### 4. Shoulder Rotator Cuff Responses to Extracorporeal Shockwave Therapy (ESWT) Morphological and Immunohistochemical Analysis

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2 Board ISMST

3 Faculty of Medicine, University of Chile

4 Faculty of Sciences, University of Chile

Device and producing company: Orthospec/Medispec, Storz Medical Duolith SD1

Introduction: Recent reports have indicated that application of extracorporeal Shockwave Therapy induces improvement in tissue repair capabilities with subsequent healing, based on augmented neo-vascularization and better blood supply for treated tissues. The present study aimed to elicit the human rotator cuff tissue responses to extracorporeal Shockwave Therapy.

Methods: From January 2006 to June 2009, thirty-one patients suffering shoulder rotator cuff tendinopathy with complete tears diagnosed by echography, were examined and offered the opportunity to receive extracorporeal shockwave treatment pre-operatively. Ten patients (Group A) accepted the treatment (single session, no anesthesia, 4000 pulses, energy flux density 0.3mJ/mm<sup>2</sup>) delaying their surgical procedures by 8 to 10 weeks. Twenty-one patients refused this option (Group B) and underwent surgery according to schedule. Morphological studies included histological analysis using Haematoxylin-Eosin, Alcian Blue and Masson Tri-Chrome stains, focused on matrix & cellular characteristics according to Riley Classification. Vascular Volume Areas (VVA) of the tendons were determined using semi-quantitative analysis (10x10 grilles onto micro-photograph 10x). Immunohistochemical analysis included CD14, CD34, PCNA, and D2-40 (lymphatic) markers. Image analysis was performed using Image Pro-Plus 6.2 software (Media Cybernetics Inc). Numerical data obtained from image software was processed with Stata 11.1 Software, using variance analysis for repeated measures.

Confidence interval for each marker was set at 95% considering comparison between tendinopathies type III (Riley) for A and B groups (largest populations).



Results: According to Riley Classification for Group A, 9 cases were type III and 1 was type IV; in Group B 13 cases were type III and 8 were type IV. Semi-quantitative analysis for vascular volume area for tendinopathies type III indicated an average value of 18.47% for Group A and 7.03% for Group B. Type IV tendinopathies in the untreated group had VVAs equivalent to 1.6%. Immunohistochemical analysis showed significant results for CD34, PCNA and D2-40 in Group A compared to Group B.

Discussion: Normal Vascular Volume Area (VVA) for human tendons is 2% to 3%. Histologically remarkable features indicate higher neovascularization for treated tendon tissues that show less gradation of tendinopathy; this finding indicates that matrix condition at the moment of shockwave treatment is a critical step. Immunohistochemical results also corroborate this finding, showing significant expression of markers for type III tendinopathy treated tissues. Augmented PCNA and CD34 expression for SW group, suggest that SW-induced neovascularization is associated with activated cellularity for mitosis and effective tissue repair. Lymphatic marker (D2-40) indicates that SWs induce a neo-lymph angiogenesis into tendon tissues, which could explain the modulation of calcium resorption observed for SW-treated calcified tendinopathies.

Conclusion: Extracorporeal Shockwave Therapy induces higher neovascularization in low-degree shoulder rotator cuff tendinopathies with complete tears, and immunohistochemical results suggest an improvement of healing capabilities for tendon treated tissues. Also SW-induced neo-lymph angiogenesis is a significant finding that deserves specific research and should be considered for repair of treated tissues.

## **5. Extracorporeal Shockwave Therapy minimizes necrosis and promotes tissue revascularization by stimulating angiogenesis in an ischemic epigastric flap model**

Rainer Mittermayr(1,2), Joachim Hartinger(1), Alexandra Meinel(1), Sabine Pfeiffer(1), Vlado Antonic(3,5), Alexander Stojadinovic (3,4, 5), Wolfgang Schaden(2), Heinz Redl(1)

No abstract available.

## **6. Possible Working Mechanism of ESWT – Mechanotransduction**

Wolfgang Schaden, Rainer Mittermayr

No abstract available.

## 7. **TOPGAME study: In-depth analysis**

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Device and producing company: Piezowave, Wolf GmbH

Introduction: A recent RCT (the TOPGAME study) found no effect of ESWT on patellar tendinopathy in competing jumping athletes. To improve knowledge of ESWT treatment for patellar tendinopathy, it is interesting to compare responders to the treatment to non-responders to see if there are differences between these two groups.

Methods: The results of the athletes who received ESWT treatment within the TOPGAME study were further analyzed. Athletes were divided into 2 groups: responders (n=13) and non-responders (n=17). The course of symptoms as measured with the VISA-P questionnaire for the responders was compared to that of the non-responders. Furthermore, baseline characteristics of responders and non-responders were compared.

Results: Only 1 week after treatment there was a significant difference (14 vs. 3 points improvement on VISA-P) between responders and non-responders. When looking at previous treatments, significantly more responders (77%) than non-responders (41%) had tried to reduce load prior to the study to improve symptoms.

Discussion: One week after treatment there were already differences between responders and non-responders. This is remarkable since positive effects of ESWT are expected to appear over a longer period. Athletes that reduced load prior to treatment were more likely to recover. However, these results should be interpreted with caution as the subject samples are small.

Conclusion: ESWT may be effective for patellar tendinopathy for certain athletes under certain circumstances.

## 8. **The TOPSHOCK study: Effectiveness of radial Shockwave Therapy compared to focused Shockwave Therapy for treating patellar tendinopathy. Design of a randomised controlled trial**

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Device and producing company: Duolith SD1, Storz Medical

Introduction: Most studies that investigated the effectiveness of Shockwave Therapy as treatment for patellar tendinopathy used focused Shockwave Therapy. Studies using radial Shockwave Therapy are scarce. The design of a study that directly compares the effectiveness of focused Shockwave Therapy and radial Shockwave Therapy as treatment for patellar tendinopathy is presented.

Methods: The TOPSHOCK study (Tendinopathy Of Patella SHOCKwave) is a two-armed randomized controlled trial in which the effectiveness of focused Shockwave Therapy and radial Shockwave Therapy are directly compared. Outcome assessors and patients are blinded as to which treatment is given. Patients undergo three sessions of either focused Shockwave Therapy or radial Shockwave Therapy at 1-week intervals, both in combination with eccentric decline squat training. Follow-up measurements are scheduled 1, 4, 7 and 12 weeks after the final treatment. The main outcome measure is the Dutch VISA-P questionnaire, which reports pain, function, and sports participation in subjects with patellar tendinopathy. Patients will also record their sports activities, pain during and after these activities, and concurrent medical treatment on a weekly basis in a web-based diary. Results will be analyzed according to the intention-to-treat principle.

Results: Are expected in spring 2012.

Discussion: The TOPSHOCK study is the first randomized controlled trial that directly compares the effectiveness of focused Shockwave Therapy and radial Shockwave Therapy, both in combination with eccentric decline squat training, for treating patellar tendinopathy.

## 9. Low Energy Extracorporeal Shock Therapy as a Treatment for Chronic Patellar Tendinopathy

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Device and producing company: DolorClast, EMS

**Introduction:** The pathologic changes seen in chronic patellar tendinopathy are similar to those of other overuse injuries of tendons. Extracorporeal Shockwave Therapy (SWT) is an effective treatment for many tendinopathic conditions.

**Methods:** Thirty-three patients with chronic patellar tendinopathy received low-energy SWT (2000 shocks; 4 bars of pressure, total energy flux density, 360 mJ/mm<sup>2</sup>). Thirty-three patients with chronic patellar tendinopathy were treated with additional forms of non-operative therapy (control group). Evaluation was by change in visual analog score (VAS), Victoria Institute Sport Assessment Score (VISA), and by Roles and Maudsley (RM) score.

**Results:** Mean pre-treatment VAS scores for the control and SWT groups were 7.5 and 7.8, respectively. One month, 3 months, and 12 months after treatment, mean VAS for control and SWT groups were 6.7 and 4.3 (pp001), and 54.9 and 74.5 (p the number of excellent, good, fair, and poor results for SWT and control groups were 8 and 3 (psis showed that the percentage of patients with excellent ("1") or good ("2") RM scores (successful results) 12 months after treatment was greater in the SWT group compared to the control group.

**Discussion:** Traditional treatment of chronic patellar tendinopathy is generally lengthy, associated with frequent recurrences, and in many cases, results in an unacceptable degree of improvement. This study demonstrates that low energy, radial SWT is safe and effective, that it can be used to treat patients with chronic patellar tendinopathy, and that satisfactory improvement is maintained for at least one year.

**Conclusion:** SWT is an effective treatment for chronic patellar tendinopathy.

## 10. Focused ESWT is a New Modality to Treat Accessory Navicular Problems

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Device and producing company: Piezoston 300, Wolf

Introduction: The navicular bone one of the small bones on the mid-foot. The bone is located at the instep in the arch at the middle of the foot. One of the larger tendons of the foot, called the posterior tibial tendon, attaches to the navicular bone before continuing under the foot and into the forefoot. This tendon is a tough band of tissue that helps hold up the arch of the foot. If an accessory navicular or os tibiale externum exists it is located in the instep where the posterior tibial tendon attaches to the real navicular bone. This is rare condition which generally occurs in less than 200,000 people in the US.

- Trauma, such as a foot or ankle sprain
- Chronic irritation from shoes or other footwear rubbing against the extra bone
- Excessive activity or overuse

Methods: We performed the treatment as an outpatient procedure without anesthesia. The treatment consisted of 3 Focused ESWT sessions (3000 pulses, 0.7mJ/mm<sup>2</sup>, frequency 4, intensity level 7-8). We treated 8 patients with Accessory Navicular problems (6 women, 2 men: age 37-54 years) and a pain VAS rating of 8-9. They had x-rays when initially diagnosed and had tried different types of treatment (NSAID's, physiotherapy and exercises, custom made orthotics), but all conservative treatment had failed. The last option was surgical intervention. An exercise program to strengthen muscles of the foot and use of foot orthotic were advised.

Results: We found that 6 (75%) of the patients showed significant clinical improvement, and when compared to initial assessment the pain VAS had decreased to 3-4. One patient (12.5%) was slightly better and one (12.5%) showed no change.

Discussion: F ESWT is typically not used for treatment of Accessory Navicular bone, but in our opinion, it is new modality for very specific cases. More clinical experience is necessary to make further conclusions.

Conclusion: Focused ESWT is an effective treatment that produces significant relief of pain in Accessory Navicular Problems and must be considered an advantageous alternative to surgery. F ESWT is non-not invasive and has no side effects. It is much less costly then surgical procedures and avoids the potential risks and complications associated with surgery.

## 11. Comparison of Focused ESWT with Radial ESWT in Treatment of Chronic Plantar Fasciopathy with Heel Spur

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Device and producing company: Piezoston 300, Wolf; Swiss Dolorclast,

EMS Introduction: Plantar fasciitis is a common painful condition affecting 10% of the general population. The terms "plantar fasciitis" and "heel spur" are often confusing for patients and clinicians. Plantar fasciitis refers to the syndrome of inflammation of the band of tissues that runs from the heel along the arch of the foot, whereas a heel spur is a hook of bone that can form on the heel bone (calcaneus). About 80% of patients with plantar fasciitis have been noted to have a heel spur that can be seen on X-ray. ESWT is a proven treatment for this condition when it has existed for more than 3-6 months and is not responding to conservative treatment.

Methods: We performed a retrospective control study on an outpatient basis without anesthesia on two groups of subjects. The study involved 108 outpatient procedures without anesthesia (60 females & 48 males; age 40-55 years) on patients with plantar fasciitis with a calcaneus spur. All patients had been suffering from plantar fasciitis for more than 6 months and had conservative treatment (physiotherapy, stretching exercises, local injection, hydrocortisone). Pretreatment measurements on the Visual Analog Scale were 8-9, but these were no significant improvement. Group I (n= 54) was treated by Focused ESWT, each patient received 3 applications of 2500 shocks, frequency 4, intensity level 10 Hz (high energy 0.7 mJ/mm<sup>2</sup>) at week intervals, Group II (n=54) was treated by Radial ESWT, each patient received 3 application of 2500 shocks, frequency 8 Hz, air pressure 3.5 bars. Full instruction and education regarding ESWT treatment were



given to both groups. They were advised to start stretching exercises for the plantar fascia 2 weeks after the last treatment session and that exercises should continue for 6 weeks. Then they could resume their normal activities.

Results: Follow up after 6 Months

Group I (F ESWT): 87% were complaint free and VAS decreased to 3-4, 7.4% were significantly better, 3.7% were slightly better and 1.9% were unchanged.

Group II (R ESWT): 85.1% were complaint free, 5.6% were significantly better, 3.7% were slightly better, and 5.6 % were unchanged

There were no device related problems, systemic or local complications for either device.

Discussion: Both Focused & Radial ESWT produced significant clinical improvements and relief of pain for plantar fasciitis. Significant decrease in length of spur (in X-ray) was also reported for those treated by Focused ESWT.

Conclusion: This study provides some evidence for focused extracorporeal shock wave treatment being superior to radial extracorporeal Shockwave Therapy for chronic plantar fasciitis with heel spur. However more research is required on this subject, and there are methodological limitations that prevent specific device comparisons.

## 12. ESWT in Chronic Proximal Plantar Fasciitis – 9 years of experience

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Device and producing company: Swiss Dolor Clast - EMS; Epos Ultra - Dornier

Introduction: Compare the efficacy of ESWT in Proximal Plantar Fasciitis between two different generators with similar levels of energy and number of sessions.

Methods: Between January 1999 and January 2008 we performed 717 sessions of ESWT in 239 patients.

Criteria for inclusion and exclusion are well known and based in ISMST protocol.

An electromagnetic generator (EMSE) was used on 90 patients between 1999 to 2005, and an electropneumatic device was used on 149 patients between 2004 to 2008. Exclusion criteria included the inability to follow up. We excluded 48 patients (35 in the EMSE group and 13 in the electropneumatic group) therefore this study was completed on 191 patients. The age variation was between 20 and 80 years (average: 52.8 years), 115 patients were female (59.8%), 76 were male (40.2%), and there was no significant prevalence between right (55%) and left (45%) sides.

Method: The electromagnetic generator was a Dornier Epos ultra (frequency of 7.5 Mhz), where the therapy head was positioned on the medial side tangential to the point of pain. The electropneumatic device was an EMS Swiss DolorClast that was applied directly on the painful point. The energy applied with the EMSE and Electropneumatic devices was 0.22 mJ/mm<sup>2</sup> and 0.18 mJ/mm<sup>2</sup>, respectively. We applied 2000 SWs without anesthesia at intervals of 10 days regardless of the device.

Results: The criterion was the Visual Analogue Scale, with follow up of 6 weeks, 12 weeks, 6 months, and 12 months. The efficacy was 85.2 % for the electromagnetic device and 84% for the electropneumatic device. There was moderate and transitory pain during the treatment. No patients presented with hematoma or petechia after application of ESWT. There are no complications or side effects with this method.

Discussion: The results show good to excellent efficacy with both devices, using the same energy levels and number of SWs. Although the discussion of focal or radial device exists, it seems that there are only differences in the physical principles; the biological and clinical response seems to be the same.

Conclusion: ESWT is an effective treatment method for CPPF. The therapy head, whether positioned in-line or tangentially, shows the same results as when SWs are applied directly to the point of pain.

ESWT should be considered a real method of choice.

This study shows relevant clinical evidence independent of the type of SW generator.

### 13. Extracorporeal Pulsed-activated Therapy (“EPAT”) for Achilles Tendinopathy: A Prospective Study

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2 Univ of Kiel, Kiel Germany

3 Technical University, Munich Germany

Device and producing company: Storz D-Actor 200

Introduction: Achilles tendinopathy is common, and extracorporeal Shockwave Therapy has become a popular treatment for this condition even though previous research has not provided conclusive results regarding its efficacy in cases of Achilles tendinopathy. The aim of this prospective cohort study was to evaluate a standardized protocol.

Methods: Three weekly shockwave treatments without anesthesia, were given to patients with Achilles tendinopathy, as quantified by the Roles and Maudsley score.

Results: A total of 74 tendons in 58 patients were assessed at baseline and at least 1-year post treatment, including 32 (43.24%) paratendinoses, 23 (31.08%) proximal tendinoses, and 19 (25.68%) insertional tendinoses. The average age of the participants was  $48.6 \pm 12.9$  years, and patients in the paratendinosis group were statistically significantly younger than those in the proximal and insertional tendinosis groups ( $p = .02$  and  $.04$ , respectively). Overall, 58 (78.38%) tendons had improved by at least 1-year post treatment; including 75% in the paratendinosis, 78.26% in the proximal tendinosis, and 84.21% in the insertional tendinosis groups, and no adverse effects were observed. The Roles and Maudsley score improved from a mean of  $3.2 \pm 0.6$  to  $1.8 \pm 1.1$  ( $p$

Discussion: We showed good improvement with no side-effects.

Conclusion: EPAT therapy serves as a safe, viable and effective option for the treatment of Achilles tendinopathy.

### 14. Evidence in plantar fasciitis treatment

Vinzenz Auersperg

No abstract available.

### 15. Prospects of Shockwave Therapy application

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Device and producing company: „Biostim“, Scientific Medical Company „Rumelit“

Introduction: To extend the range of Shockwave Therapy (SWT) application it is necessary to conduct new research on the biological effects of shock waves on organs and tissues.

Methods: We studied the influence of shock waves on kidney tissue simulating acute and chronic pyelonephritis, as well as on skin wound healing and on fractures of long cortical bones. The experiments were conducted using a “Biostim” device (Russia).

Results: While simulating acute pyelonephritis, the use of SWT reduced inflammation up until complete recovery on the 21st day of the experiment. We registered massive leukocyte infiltrates all over the surface of the organ within the same period in the control group. In the case of chronic pyelonephritis SWT had a significant positive effect on the decrease of inflammation. The experiments with artificial skin wounds showed that with the use of SWT the wound was healed 5-7 days earlier than in the control group. Histological examinations of the healed wound in the basic group showed the epidermis was properly formed with the normal order of layers. In the control group there was rough fibrous connective tissue which spread over wide areas. Under the influence of SWT on bone fractures, a callus was formed 9.6±0.1 days earlier than it was registered in the group treated according to traditional methods.

Discussion: The research results showed it is possible to purposefully influence the activity of reparative and metabolic processes, including internal diseases, by means of SWT.

Conclusion: SWT can be used to treat and rehabilitate patients with different diseases. It is possible to extend the area of this application.

## 16. High Energy Shock Waves and 5-Aminolevulinic Acid for Sonodynamic Therapy: Effects on SK-N-BE and SH-SY5Y Neuroblastoma Cell Lines

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Device and producing company: Piezoson 100, Richard Wolf

**Introduction:** An appealing form of treatment for solid tumors is sonodynamic therapy based on the ability of ultrasound to generate acoustic cavitation and to activate a tumor-localizing sonosensitizer agent (such as porphyrin compounds) like 5-aminolevulinic acid (ALA). High Energy Shock Waves (HESW), generated by a piezoelectric device, are able to induce acoustic cavitation, which results in a concentration of energy sufficient to generate a sonoluminescent emission, which is able to cause electronic excitation of porphyrins by energy transfer and to initiate a photochemical process resulting in cytotoxic reactive oxygen species (ROS). For this reason, we have investigated the ability of HESW to activate ALA in human neuroblastoma SK-N-BE and SH-SY5Y cell lines.

**Methods:** SK-N-BE and SH-SY5Y cells were exposed to ALA (50-300 µg/ml) for 24 h and then to HESWs (0.22-0.43 mJ/mm<sup>2</sup>; 500-1000 pulses): viable cell growth was determined at days 1, 3 and 7 after HESW treatment. Cell cytotoxicity was measured with WST-1 proliferation assay and cell death was evaluated by flow cytometric analysis. The relationship between sonodynamic treatment and production of ROS was evaluated by flow cytometric analysis with dichlorofluorescein diacetate. Furthermore, mRNA expression of different genes involved in apoptosis through ROS production was evaluated by quantitative SYBR Green real time RT-PCR, and fluorescence microscopic examination was carried out to highlight ROS production and cell death.

**Results:** Sonodynamic treatment was able to induce a significant decrease in cell growth compared to untreated cells at 72 h in both SK-N-BE and SH-SY5Y cells: up to 35% and 50%, respectively. Exposure of ALA pre-incubated cells to HESW significantly increased ROS production with different onset and extent in SK-N-BE and SH-SY5Y cells, and the apoptotic rate was significantly increased at 24 h in both cell lines.

**Discussion:** We have identified different treatment schedules of ALA and HESW to produce the best cytotoxic rate in the two cell lines studied. These findings are in agreement with our previous reports, indicating that shock waves have a sudden effect in enhancing cytotoxic activities of compounds defined as sonosensitizers in different cell lines.

**Conclusion:** Our results show that HESW are able to activate porphyrin compounds in neuroblastoma cell lines by acoustic cavitation obtaining significant in vitro cytotoxicity through ROS production.

### 17. Influence of Shock-Wave-Therapy on Fibroblasts - Special Meaning for Skin Remodeling

Kerstin Neumann, Hans-Jürgen Duchstein, Helmut Neuland

Institution:

University of Hamburg - Faculty of Pharmacy

Bundesstraße 45 – 20146 Hamburg – Germany

Device and producing company: Piezowave, Wolf GmbH; Piezoson 100 plus, PiezoWave, Richard Wolf; Orthowave 180c CP-155, Tissue Regeneration Technologies and MTS

Introduction: Shock waves are effective in the treatment of poor healing wounds. It has been shown that even necrotic tissue improves. Fibroblasts play a crucial role in the integrity and function of the skin. Examining the influence of shock waves on these cells may help to understand the underlying mechanism.

Methods: Normal human dermal fibroblasts were treated with shock waves generated by piezoelectric or electro-hydraulic devices. Treatment was carried out using the IVSWT Water Bath 2.0.

Viability and proliferation were determined. Isolated mRNA was used for studying the genetic expression of collagen, elastin, fibronectin and hyaluronan synthase. To verify these results the secreted amount of collagen, elastin and hyaluronan was measured in the supernatant.

Results: Migration increased significant immediately after treatment. Proliferation was enhanced for cells surviving shock waves over the time of 5 days. Genetic expression and secretion in the named pathways were influenced, too.

Discussion: Different energies, number of pulses and distances were tested for optimal results and viability of the cells. Using different parameters some effects can be enhanced for disadvantage of others. Energy level and number of pulses vary depending on the device.

Conclusion: Enhanced migration is one of the most notable early effects of shock wave treatment. Synthesis and secretion of important substances of the skin are also influenced by shock waves.

### 18. Recruitment of endothelial progenitor cells and functional improvement in chronic hind limb ischemia by extracorporeal Shockwave Therapy in rats

Can Tepeköylü(1), Feng-Shen Wang(2), Wolfgang Schaden(1), Michael Grimm(1),  
Ching-Jen Wang(2), Johannes Holfeld(1)

Institution:

1 Dept. of Cardiac Surgery, Innsbruck Medical University, Austria

2 Center of Excellence in Extracorporeal Shockwave Technology,  
Chang Gung Memorial Hospital / Kaohsiung Medical Center, Taiwan

Device and producing company: Dermapace, Sanuwave

Introduction: Shockwave Therapy (SWT) of ischemic skeletal muscle was shown to enhance the recruitment of intravenously injected endothelial progenitor cells (EPC) in rats. In a previous trial we showed that direct epicardial SWT induces angiogenesis in ischemic heart failure in rats without injection of EPC's. We therefore hypothesized that SWT causes recruitment of autologous EPC's in hind limb ischemia.

Methods: 5-week-old rats were subdivided in 3 groups: sham (n=18), ischemic muscle with SWT (SWT group, n=18) and without SWT (control, n=18). Hind limb ischemia was induced by ligation of the femoral artery. Three weeks later SWT (300 impulses at 0.1 mJ/ mm<sup>2</sup>) was applied on the adductor muscle; controls were left untreated. Blood flow was measured by laser Doppler imaging. Muscle samples were analyzed by RT-PCR for angiogenetic factors and chemoattractants for EPC recruitment. FACS analysis of the peripheral blood was performed for CD31 and CD34 positive cells. Functional improvement was evaluated by walking analysis.

Results: Six weeks after SWT there was increased blood flow within the ischemic muscle and functional improvement. PCNA analysis revealed increased proliferation in the SWT group. SDF-1 and VEGF were both up-regulated in the treatment group, indicating the recruitment of EPC's. FACS analysis of peripheral blood showed high numbers of CD31 / CD34 positive cells in the treatment group.

Discussion: This study showed that Shockwave Therapy of ischemic tissue induces recruitment of endothelial progenitor cells. We believe that they may originate from bone marrow and will have to prove this hypothesis in a future trial.

Conclusion: Shockwave Therapy may develop into a feasible alternative to (stem) cell therapy in regenerative medicine, in particular for ischemic heart disease.



## 19. New Insights into Morphology of Cardiac Tissue Regeneration after direct Epicardial Shock Wave Treatment

Johannes Holfeld, Daniel Zimpfer, Can Tepeköylü, Anita Thomas, Patrick Paulus, Seyedhossein Aharinejad, Wolfgang Schaden, Michael Grimm

Institution:

Department of Cardiac Surgery, Innsbruck Medical University

Device and producing company: Cardiogold, CRT AG (produced by MTS Europe GmbH)

Introduction: Recently we observed cardiac regeneration in rats after direct epicardial Shockwave Therapy as shown by a marked increase of left ventricular ejection fraction. However, the underlying mechanism remains largely unknown.

Methods: Sprague Dawley rats were subdivided into 3 groups: sham-operated (sham), infarcted myocardium with direct epicardial SWT (SWT group) and infarcted myocardium without SWT (control). Four weeks following myocardial infarction (MI), SWT (100 impulses at 0.38 mJ/m<sup>2</sup>) was applied directly to the anterior wall in the SWT group. Cardiac function was evaluated using echocardiography. Angiogenesis was evaluated by analysis of several RNA and protein expressions. Morphological changes were measured by quantitative morphometry in immunohistochemically stained sections.

Results: Fourteen weeks after SWT, left ventricular ejection fraction (LVEF) improved in the SWT group as compared to 4 weeks after MI (37±8%, p=0.021) and as compared to the controls (21±4%, pDESWT), decreasing to a normal level at 14 weeks after treatment in the anterior wall of treatment groups.

Amount of collagen was decreased in treatment groups, in particular in areas surrounding the infarction scar, whereas muscle tissue was clearly recovered in these border zones.

Discussion: Improvement of cardiac function in ischemic heart disease highly depends on the recovery of hibernating myocardium in the infarction border zone. Direct epicardial Shockwave Therapy induces tissue regeneration of the border zone as shown by reduced collagen and an increase of muscle.

Conclusion: Passive movement of the scar tissue by recovered myocardial contractility of border zones converts dyskinetic into akinetic motion of the anterior wall thereby being the morphological correlate to increased cardiac output.

## 20. Bone morphogenetic protein-2 expression in spinal fusion masses enhanced by extracorporeal shock wave treatment: a rabbit experiment

Tao-Chen Lee, Ching-Jen Wang

Institution:

Dept. of Neurosurgery and Dept. of Orthopedic Surgery, Chang Gung Memorial Hospital, Kaohsiung Medical Center, Chang Gung University College of Medicine, Taiwan

Device and producing company: OssaTron, HMT High Medical Technologies, GmbH

Introduction: Extracorporeal shock waves (ESW) are introduced to enhance spinal fusion. This study was conducted to assess the effect of ESW on bone morphogenetic protein-2 (BMP-2) expression in a spinal fusion experiment.

Methods: Twelve rabbits underwent fusion at bilateral L5–6 intertransverse spaces. They were evenly divided into two groups. In the study group, bilateral L5 and L6 transverse processes were treated with 1,000 pulses of ESW at 14 kV at 12 weeks. In the control group, the rabbits did not receive ESW treatment. All rabbits were sacrificed at 16 weeks, and their lumbar spines were harvested for radiographic and molecular biological study.

Results: In the study group (n=6), the radiographs showed good fusion in all six rabbits, while in the control group (n=6) good fusion was found only in three rabbits (50%). Although more rabbits in the study group had a good fusion result, the inter-group difference was not statistically significant (p=0.182). In the molecular biological examination, the mean value of the normalized expression of BMP-2 mRNA in the fusion masses of the study group was 90±8.4 while that of the control group was 77.33±6.74. Statistical analysis showed the study group had a significantly higher BMP-2 mRNA expression in the fusion masses than the control group (p=0.018).

Discussion: There has been evidence that ESW treatment promotes expression of BMP in treated long bones. These findings inspired us to study whether ESW treatment stimulates expression of BMP in spinal fusion masses. According to our previous experiment, we found that low energy ESW treatment is effective in enhancing spinal fusion. The major theme of the current study was to assess the over expression of BMP-2.

Conclusion: The current study showed that ESW treatment enhances BMP-2 mRNA expression in spinal fusion masses.

## 21. Experience in the treatment of pseudoarthrosis by applying platelet-rich plasma in association with focused shock wave stimulation

Paolo Buselli(1), L. Di Palma(2), R. Compagnoni(2), S. Messina(3), A. Branca(2)

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2 Hospital of Valtellina and Valchiavenna, Orthopedic Surgery Dept., Sondrio, Italy

3 School of Specialties in Physical Medicine and Rehabilitation, University of Pavia, Italy

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

Introduction: Pseudoarthrosis can be defined as a fracture that does not heal 6-8 months after the traumatic event which caused it. Over the years different therapies have been proposed to stimulate bone consolidation in these cases. Among them, Extracorporeal Shock Waves (ESW) and the use of growth factors through inoculation of Platelet-Rich Plasma (PRP) prove to be extremely interesting.

Methods: From October 2003 through August 2009, 30 patients suffering from pseudoarthrosis were treated. According to the protocol being used, PRP was administered at fracture level, followed by a single session of ESW. Between January and June 2010 the patients treated were evaluated again by means of a clinical and radiographic assay.

Results: Seventeen of the 30 patients treated were evaluated again. The average length of follow-up was 27 months (range: 6-72 months). Twelve patients achieved fracture healing with total functional recovery, 3 achieved fracture healing with residual functional limitation; in two cases there was no fracture healing.

Discussion: The two methods, taken individually, show good clinical efficacy in the literature. By combining the two methods, it seems there is a greater increase in the biological stimulation of the tissues treated. The operational aspects seem to be positively manageable when supported by a good multidisciplinary organization.

Conclusion: The two methods show:

- good clinical efficacy when combining the two therapies;
- low risk of complications;
- reduced costs.

## 22. ESWT in Treatment of Osteitis Pubis in Professional and Amateur Athletes

Ana Claudia Souza, Alexander Montenegro

Institution:

Cortrel-Clinica Ortopedica Leblon

Departamento Médico do Clube de Regatas Vasco da Gama

Device and producing company: REFLECTRON – HMT

Introduction: Osteitis Pubis often presents with nonspecific symptoms and difficult characterization, causing a delay in accurate diagnosis. Treatment can take several months or longer to completely take effect. The Aim of this study is demonstrate the results, efficacy, and safety of ESWT in the treatment of Osteitis Pubis in professional and amateur athletes.

Methods: From February 2004 to November 2009, were treated nine cases of chronic Osteitis Pubis resistant to conservative treatments. Of these, eight were followed up and one abandoned the follow-up. We used a single application of 3000 pulses, 0.12 mJ/mm<sup>2</sup> of energy flux density under regional anesthesia (ilioinguinal and iliohypogastric nerves) in an outpatient clinic. A kinesiotherapy protocol was applied after treatment. We used MRI and radiological evaluation at the end of follow-up, beyond the scale and visual analog pain (VAS), and return to activities in the analysis of results.

There were no significant complications.

Results: Seven athletes became asymptomatic after treatment.

One patient did not improve.

Discussion: Even after several conservative or surgical treatments, many athletes still present with disabling pain complaints enabling them practicing sport. ESWT is a noninvasive treatment and its biomechanical effects produce a biological response, including the induction of neovascularization and bone repair, caused by increased production of growth factors. Based on this new concept of "tissue regeneration", new indications for the use of ESWT have been reported and studied.

Conclusion: ESWT should be considered as an alternative in the treatment of chronic Osteitis Pubis in athletes. It is noninvasive, which is not considered doping, has no complications, is less expensive than surgery, does not have the risk of surgical procedures, and reduces the time an athlete is absent from training and competitive activities.

### **23. ESWT for Osteonecrosis of femoral head – a retrospective study**

Shrenik Shah

Institution:

Shrey Hospitals, Navrangpura, Ahmedabad, India

Bodyline Hospitals, Ahmedabad, India

Device and producing company: Stonelith-Israel, EPOS-Dornier

Introduction: Management of ARCO stage I to III of Osteonecrosis of Femoral Head (ONFH) is still controversial as the results are variable and unpredictable. The patients of ONFH present late in India. Very few are detected in ARCO stage I, however it is still beneficial to treat them with ESWT even in stage II/III, as the results are encouraging.

Methods: From 1998 through 2010, 55 patients (86 hips), 46 male and 9 female with an average age of 38 years were treated with ESWT and followed up long term. The patients were effected as follows: 31 bilateral, 7 left, and 17 right. All of them underwent ESWT under spinal anesthesia with an average of 3500 to 4000 shocks for each femoral head at 24-25 kv voltage/ 4-5 intensity, under IITV image guidance.

All patients were followed up at regular intervals of 6 weeks, 3, 6, and 12 months and then yearly.

Nine patients underwent subsequent THR.

Results: The outcome was measured with Harris Hip Score and radiologically monitored.

Four patients were lost to follow up.

The HHS which was 50.9 pre-ESWT, improved to 81.9 post-ESWT.

The result was rated as excellent in 22, good in 10, fair in 6, and poor in 16 patients.

Discussion: X-rays and MRI did not help in evaluating ONFH.

Conclusion: ESWT causes neovascularization and osteoneogenesis supplying enough strength and congruity to the head of the femur to enable sitting cross-legged, squatting and walking without significant pain or disability.

### **24. Keynote lecture: Pseudarthrosis - treatment option and golden standard**

Andreas Seekamp

No abstract available.

## 25. Shockwaves in hand & foot surgery - retrospective analysis of results with different devices

Frank Bätje

Institution:

Allgemeinmedizinische Privatpraxis Lavesstraße 6; Hannover, Germany

Device and producing company: Storz Duolith SD1, Storz Modulith SLK

Introduction: Superficial localization of bone-fractures and problems of patient positioning present treatment difficulties with clinical Shockwave Therapy devices that have radiological target detection in combination with computer-assisted target bearing. We present the results of Shockwave Therapy with devices with and without integrated imaging.

Methods: Delayed and non-union fractures and arthrodesis of the hands and feet were treated with or/and without electronic navigation aids; clinical and radiological follow-ups were performed to assess treatment success rates.

Results: In 100 cases of delayed unions and non-unions of the hand and tarsal, metacarpal and metatarsal bones, 75% healed. In delayed and non-healing ankle arthrodesis and both the carpometacarpal and tarsometatarsal regions, 60% healed.

Discussion: In bone healing disorders shockwaves should be administered under direct imaging and using computer-assisted navigation. Specific locations however, require manual target localization and navigation via bio-feedback. Because both treatments seem to produce similar results, ESWT guidelines should allow for flexibility in treatment methods.

Conclusion: Delayed and non-union fractures in superficial localized bones can be treated with appropriate Shockwave Therapy equipment as successfully as with hospital lithotripters.

## 26. ESWT in foot navicular stress fracture of a high performance

Sergio Abello, Carlos Leal

Institution:

ORTOMECA Feet Center, FENWAY Medical ESWT Center, Bogota, Colombia

Device and producing company: ORTHOGOLD 100 – TRT (USA) and MTS (Germany)

Introduction: We present the case of a 16-year-old competitive Olympic female gymnast with a history of foot problems. After athletic training she experienced pain on the medial side of her right foot and was initially diagnosed with Posterior Tibial Tendon Tendinitis after normal X-rays. She received physical therapy and medication for 3 months with no results. She came to our foot and ankle clinic and after a physical evaluation we suspected a deeper bone or joint pathology and ordered an MRI. The results clearly indicated a navicular bone stress fracture.

Methods: We proceeded to treat the patient with ESWT, using a single session under sedation of 2000 pulses at 0.25 mJ/mm<sup>2</sup> focused waves and a frequency of 4 Hz. The procedure was done under X-ray fluoroscopy from dorsal to plantar with an Orthogold 100 device and a OE050 focused applicator. After the procedure, the patient was in a cast for 6 weeks. After removing the cast, the patient underwent physical therapy and muscle balance rehabilitation.

Results: Both pain and motion improved, and the control MRI showed complete healing of the lesion.

Discussion: Even though this is a case report, we found ESWT to be the crucial variable for recovery in this patient's final outcome. With no complications related to the procedure, it was an excellent option for this high performance athlete, enabling full recovery of her symptoms after two months of treatment.

Conclusion: We are able to recommend ESWT in these rare cases of foot stress fractures.

## 27. Extracorporeal Shockwave Therapy (ESWT) in the treatment of bone pseudoarthrosis: Verona experience

Claudio Guerra, Ernesto Amelio

Institution:

Shock Wave Unit - Hand Surgery - Surgical Dept. – University Hospital - AOUI Verona - Italy

Device and producing company: SLK, Storz Medical AG

Introduction: ESWT induced osteoneogenesis in animal models with intact and fractured bones. Based on these findings,

shock waves were used for the treatment of bone pseudoarthrosis in humans. Here we report our experience in Verona treating bone pseudoarthrosis by means of ESWT.

Methods: Between 1997 and 2009 a total of 674 bone pseudoarthrosis were treated, with a minimum follow up of 6 months. Most consisted of long bone pseudoarthrosis.

The electromagnetic coil lithotripter (Modulith SLK by Storz Medical AG) used included in-line radiographic targeting and the Lithotrack system. The protocol usually consisted of one cycle of 3-4 sessions depending on the intrinsic characteristics of pseudoarthrosis.

Typically no general or local anesthesia was required. All pseudoarthrosis, if not surgically stabilized or well fixed, were immobilized with a brace.

Results: Bony union was achieved in 78.6% of patients. Failures were experienced more often in atrophic pseudoarthrosis. Some bones (humerus and carpal scaphoid) proved to be less sensitive to shock waves than others.

No serious complications were observed.

Discussion: The success rate of ESWT is very high and is comparable to results obtained with surgical procedures. It is a non-invasive method, and surgery can still be performed if Shockwave Therapy fails. Moreover the mass of data analyzed furnishes information concerning more exact indications and new prognostic factors.

Conclusion: These considerations led to consider ESWT as a therapeutic method not only characterized by a high success rate, but also that is well tolerated and accepted by patients because of its non-invasiveness and absence of complications. Also considering its low cost compared to surgery, we can say that ESWT should be proposed as the first approach to bone pseudoarthrosis.

## **28. Quality Control of ESWT in the treatment of Non-Union fractures**

Wolfgang Schaden(1), Andreas Fischer(2), Ender Karadas(2), Rainer Mittermayr(1)

Institution:

1 AUVA Trauma Centre Meidling, Vienna, Austria + shockwavetherapy-vienna.com

2 AUVA Trauma Centre Meidling, Vienna, Austria

Device and producing company: Ossatron, HMT, Orthowave 280, TRT and MTS

Introduction: Since December 1998 delayed and non-union fractures have been treated with ESWT on a regular basis in the AUVA Trauma Centre Meidling. Up to December 2009 a total of 1611 patients were treated and 70 parameters were documented for each patient. The data set includes demographic data, medical history, treatment parameters, side effects, and follow-up treatment as well as 3 and 6-month results. Since 153 (9.5%) patients were lost to follow-up, data for only 1458 patients is available.

Methods: Because the data were collected in a linked access database some important correlations can be made immediately. The database will be demonstrated during the presentation and the audience will have the opportunity to ask questions concerning age of the patients, age of the non-unions, treatment parameters, etc. in correlation to the outcome (3 and 6-month results).

For example,

Question: "What was the healing rate in patients over 80 years of age that received ESWT for their non-unions?"

Answer: n = 50 (14 male/34 female); mean age: 83.8 (range: 80-93); 47 fractures / 3 osteotomies; metaphyseal = 27 / diaphyseal = 23; healing rate after 3 months: 32 (64%); after 6 months: 42 (84%).

Results: The overall healing rate was 77% (1120). Only minor side effect, such as temporary superficial haematoma, petechial bleedings and reddening of the skin, were observed. None of them had a clinical impact and disappeared after 3 to 5 days without treatment.

Discussion: The quality control facilitated by collecting these data enabled us to optimize treatment parameters. The treatments were performed by a total of 25 trauma surgeons and there were no significant differences in the outcomes between the physicians.

Conclusion: These results prove that ESWT for the treatment of delayed and non-healing fractures is not only efficient and safe but has practically no learning curve and is easily reproducible.

## 29. ESWT for Non-Union Fractures - Economic Aspects

Wolfgang Schaden(1), Rainer Mittermayr(1), Ender Karadas(2), Heinz Kuderna(2)

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1 AUVA Trauma Centre Meidling, Vienna, Austria + shockwavetherapy-vienna.com

2 AUVA Trauma Centre Meidling, Vienna, Austria

Device and producing company: Orthowave 280, TRT (USA) and MTS (Germany)

Introduction: Incidence of non-unions in Austria:

Between 2005 and 2009 a total of 224,749 fractures were documented in all 7 AUVA Trauma Centres in Austria. During the same time period, 5,706 non-unions were registered. This indicates that 2.53% of fractures develop into a non-union. Throughout Austria 400,000 fractures are reported annually, thus approximately 10,000 non-unions per year are to be expected.

Methods:

Traditional Therapy:

Data from health insurance companies show that surgical treatment of non-unions is successful in 68% of patients after one surgical procedure, in 23% after two and in 7% after three. While the remaining 2% of non-unions end in amputation.

Shockwave therapy:

Based upon our experience, 70% of non-unions are suitable for ESWT (i.e. 7,000 patients per year).

Results: The estimated cost of one surgical procedure for a non-union is at least €0,000., thus surgical treatment of all non-unions in Austria burdens the health care system by approximately €00 MIO per year. If the 7,000 suitable patients were offered ESWT, 75% could expect bony healing. Calculated at €1,000 per ESWT treatment, the total cost to heal 5,250 patients (75% of 7,000) would be €5.25 MIO. The remaining 25% would require surgical treatment at a total cost of €5 MIO.

Discussion: Based upon these estimates, more than 66 MIO € per year could be saved in Austria by treating all suitable non-unions with ESWT. This is in addition to the cost savings from shorter rehabilitation time and less sick leave, which are not included in this calculation.

Conclusion: As recently published peer reviewed articles prove, ESWT is as efficient as surgery but with less complications and shorter rehabilitation time; therefore it is perplexing why less than 1% of non-unions in Europe receive this treatment option.

## 30. ESWT for Non-Union Fractures – Evidence Based Medicine

Heinz Kuderna, Rainer Mittermayr, Wolfgang Schaden

Institution: AUVA Trauma Centre Meidling, Vienna, Austria

Device and producing company: Not applicable

Introduction: Since the first publication (Valchanov et al, 1991) concerning the clinical use of shockwaves for the treatment of non-union fractures more than 50 animal trials, 25 in vitro trials and almost 50 clinical trials have been published in peer reviewed journals. All of them focused on the osteoinductive/regenerative effect of ESWT.

Methods: The first level Ib study concerning non-union treatment was presented at the end of 2009 by Cacchio et al.1. In that publication 3 study groups each with 42 patients suffering from a long bone non-union are presented. Two groups received ESWT and the third received “state of the art” surgery.

Results: X-ray did not show any significant differences after 6, 12 and 24 months between the three study groups. After two years the ESWT groups showed 94% and 92% of bony healing compared to 95% in the surgical group. Regarding pain and function, after 3- and 6-month follow-up both ESWT groups showed significantly better results than the surgical group. Side effects were observed in 27% of those within the ESWT groups (temporary superficial haematoma and petechial bleeding without clinical impact) compared to 30% in the surgical group (2 superficial infections, 1 deep infection, 1 temporary paresis, 9 patients suffering pain at the donor site). Similar results are reported by Furia et al.2, Stojadinovic et al.3 and Schaden et al.4

Discussion: Due to the present evidence ESWT must be recommended as therapy of first choice for the treatment of those non-unions not requiring surgical correction due to malalignment.

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### **31. Keynote lecture: Pain perception and mechanism of chronification in musculoskeletal disorders**

Baron

No abstract available.

### **32. Shockwave or Surgery – ESWT as an alternative to operative procedures in the treatment of musculoskeletal pain**

Hannes Müller-Ehrenberg

Institution:

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Device and producing company: Piezowave, WOLF

**Introduction:** Over the last three decades studies and clinical trials have revealed new indications for the use of focused Shockwave Therapy (ESWT). It has been found that many diseases of the musculoskeletal system can be treated successfully with non-invasive Shockwave Therapy rather than undergoing surgery. Exact application of focused ESWT has also shown to help in the diagnosis of pain conditions such as myofascial pain syndrome.

**Methods:** Review of literature, case report

**Results:** Lesions of the musculo-skeletal system and pain conditions have often been treated by orthopaedic doctors and mostly with surgical methods.

In the past, the use of ESWT in orthopaedics was more focused on the treatment of bony and calcified structures like heel spurs and calcified tendonitis of the shoulder. In these cases ESWT has shown good results eliminating the need for surgical treatment. Over years of clinical use of Shockwave Therapy, new indications for ESWT have been established and become the treatment of first choice especially for treating tendinopathies and enthesopathic changes such as Achilles tendonitis and tennis elbow.

Recently the understanding of focused shock waves as an exact mechanical energy that can deliver its specific impulse into deeper tissue layers, has given us a diagnostic tool for musculoskeletal pain. Especially with regard to the diagnosis of myofascial trigger points (mTrP), the ability to exactly reproduce the patient's pain with the stimulus of a focused shock wave has helped for a more precise diagnosis and a more specific treatment.

**Discussion:** Many pain conditions that have been difficult to treat, like unspecific back pain or chronic pelvic pain syndrome (CPPS), are now treatable using focused ESWT and do not require a surgical procedure.

Focused ESWT as a diagnostic tool can also identify some "neuropathic-like pain" often caused by mTrP, such as foot pain that imitates the symptoms of Morton's neuroma. In many of these cases exact diagnosis and treatment with focused ESWT has cured the pain condition and enabled the patient to avoid surgery.

**Conclusion:** ESWT is a successful method to treat orthopaedic pain conditions, and should also be used as a diagnostic tool to identify the structures that cause pain before seeking an invasive surgical treatment.

### **33. Long term effectiveness of ESWT in reducing pain and improving function in patients suffering from somatic diseases**

Raoul Saggini, Alexandra Di Stefano, Mario Valeri, Emanuela Panelli, Angela Marri, Valentina Galati,

Laura Scarcello. Rosa Grazia Bellomo

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Device and producing company: Evotron Electrohydraulic Spark Gap, HMT, Kreuzlingen.

Introduction: Over the last few years, extracorporeal Shockwave Therapy (ESWT) has been proposed as an elective treatment in somatic diseases with encouraging short-term results.

This study explored the long-term effectiveness of ESWT in reducing pain and improving function in patients suffering from deep somatic diseases (Rotator cuff syndrome, Epicondylitis, Epitrochleitis, Rear friction elbow syndrome, Heel spur, Plantar fasciitis, Achilles tendon tendinopathy, Friction back ankle syndrome, Patellar tendon tendinopathy, Rectum-adductoria syndrome, and Femoral head osteonecrosis) and superficial somatic diseases (chronic ulcers).

Methods: The aim of our study was to evaluate changes in pain and function after a rehabilitation program consisting of 3 treatments with focused ESWT (1 session per week) and physiotherapy.

We conducted a telephone interview with a sample of 562 patients who completed the rehabilitation program with ESWT between 2005 and 2009.

Patients with orthopedic disease of shoulder, foot, knee, hip and elbow, a VAS score greater than 4 at the first evaluation, and between 18 and 70 years of age were included.

Evotron Spark Gap Electrohydraulic equipment with focused therapeutic probe with a 5 mm focal depth and average energy equal to 0.132 mJ/mm<sup>2</sup> was used; 800 pulses per session were administered.

No patient underwent local anesthesia.

We also evaluated changes in pain and wound area in patients with chronic ulcers after a therapeutic program consisting of 7 sessions of ESWT with a specialized probe (1 session per week).

Results: Follow-up control showed a reduction of overall mean VAS (T<sub>0</sub>=7.5, T<sub>1</sub>=1.6) and VAS in each disease (Rotator cuff syndrome: T<sub>0</sub>=7, T<sub>1</sub>=1.9; Epicondylitis: T<sub>0</sub>=7.4, T<sub>1</sub>=0.9; Epitrochleitis: T<sub>0</sub>=7.5, T<sub>1</sub>=1; Rear friction elbow syndrome: T<sub>0</sub>=6, T<sub>1</sub>=2; Heel spur: T<sub>0</sub>=7.6, T<sub>1</sub>=0.35; Plantar fasciitis: T<sub>0</sub>=7.5, T<sub>1</sub>=2; Achilles tendon tendinopathy: T<sub>0</sub>=8.2, T<sub>1</sub>=1.1; Friction back ankle syndrome; Patellar tendon tendinopathy: T<sub>0</sub>=7.6, T<sub>1</sub>=1.8; Rectum-adductoria syndrome: T<sub>0</sub>=8.1, T<sub>1</sub>=2.5; femoral head osteonecrosis: T<sub>0</sub>=8, T<sub>1</sub>=1).

79% of patients report no pain today.

86% of patients describe a significant improvement in ADL functional ability.

There was also a significant reduction in drug consumption, especially during the first 3 years after treatment, and a reduction in need for surgery (5% of patients).

In patients suffering from chronic ulcers, there was a 79% reduction of the lesion and VAS reduction (T<sub>0</sub>=5.9, T<sub>1</sub>=1.3) at the end of treatment as well as long-term continuation of results.

Conclusion: These findings show that the therapeutic effect of ESWT in most somatic diseases persists over time and significantly improves patients' quality of life.

#### **34. Shock Waves in the treatment of paraosteopathies: A case report on painful paraosteopathy in a 3-year old girl**

Sara Messina(1), Paolo Buselli(2), Vincenzo Bosco(3)

Institution:

1 School of Specialties in Physical Medicine and Rehabilitation, University of Pavia, Italy

2 Hospital "Istituti Ospitalieri di Cremona" Department of Specialist Rehabilitation, Cremona, Italy

3 Madre Fortunata Toniolo Hospital, Bologna, Italy

Device and producing company: Modulith SLK – STORZ

Introduction: Para-Osteo-Arthropathy (POA) is frequent in post-coma or spinal injuries, but often occurs in neurological pathologies, especially in hip articulation. It reduces the Range of Motion (ROM), provokes articular pain, reduces patient autonomy and increases medical complications.

The traditional therapeutic approach relies on a variety of treatments, such as physical therapy, but evidence of their proven clinical efficacy is lacking.

**Methods:** We illustrate a case report of a 3-year-old girl affected by infantile spastic quadriplegia. After daily physiotherapy treatments without improvement and with persistent pain, we administered one session of ESWT. Evaluations were made before treatment and 1, 3, and 6 months after treatment; they consisted of clinical and functional assessment and X-ray evaluation.

**Results:** Although only a partial reduction of the ossification was observed in the X-ray images, the patient showed signs of functional improvement immediately after therapy, especially a reduction of pain. Three and six months after treatment, hip articulation was still limited, but there was a little improvement in the ROM, and there was a significant reduction in pain.

Only partial reduction of the ossification was observed in the X-ray images 6 months after treatment, despite the clinical signs of improvement.

**Discussion:** The symptomatic improvement was significant. The particular X-ray response on the ossified tissue depends on the specific osteogenic characteristic of HO compared to calcification in tendinopathies with different histological structure.

**Conclusion:** Our results indicate that ESWT offers an interesting therapeutic opportunity to reduce the pain associated with POA and increase muscle extensibility.

#### **34. Low energy focused Shockwave Therapy of adductor related groin pain in football players**

Laura Berta(1), Roberto Frairia(1), Marina Berta(2)

Institution:

1 Dept. of Clinical Pathophysiology, Universita di Torino, Italy

2 Med & Sport 2000, Torino, Italy

Device and producing company: Minilith SL1, Storz Medical, Tägerwil, Switzerland

**Introduction:** Groin pain is a major challenge in sports medicine, and among football players it is a serious and very common ailment, which may end the player's career. Adductor-, iliopsoas-, and inguinal-related groin injuries are the most common causes of groin pain in athletes. We report our long-time experience with Extracorporeal Shock Wave (ESW) treatment of athletes with adductor-related groin pain who are still in training and/or in competition.

**Methods:** From March 1999 to June 2010, we treated 78 high performance male football players, aged 19-35 yrs, who had experienced groin pain for more than fifteen months. Magnetic resonance imaging was performed on each subject to confirm muscle strain or tears, and/or partial and complete tendon tears as well as to exclude stress fractures, osteonecrosis, osteochondrosis or neoplasia. Treatment schedule: 4-6 sessions, 2-3 days interval; 2000-2500 shocks each session; energy level (EFD): 0.030-0.055 mJ/mm<sup>2</sup>. Following ESW treatment, only stretching was prescribed.

**Results:** After 4 sessions, 66 out of 78 subjects (85%) experienced enough pain relief to resume training; after 6 sessions another 8 subjects (10%) reported partial resolution of pain while 4 subjects (5%) reported no improvement of symptoms. Twelve athletes (15%) with mild persistent pain during heavier workouts or after practicing sports at a competitive level, reached complete pain resolution and full recovery with 2 additional treatments.

**Discussion:** Sixty-six out of 78 subjects recovered completely and returned to the same level of competition with no relapses up to 36 months following treatment. Low-energy was chosen because: 1) treatment elicits little or no pain; 2) no side effects; 3) early functional recovery; 4) continued training is possible, albeit with a varied load; 5) maintenance of muscle strength and tone.

**Conclusion:** Protocols with very low energy allow treatment of painful adductor-related groin ailments even during top-level sports events. The high percentage of total resolution and the absence of recurrence for a significantly long period suggest ESW treatment as first-line therapy and/or as a complement to general and/or local medical treatment of adductor-related groin pain in sports medicine.

#### **35. ESWT for athletic injuries during competition**

Paulo Kertzman, Mauro Moreira

Institution:

Instituto Ortopedia Campo Belo Sao Paulo, Brasil

Device and producing company: Dolorclast, EMS

Introduction: At the Olympic Games in Athens and Beijing and at the Pan American Games on Rio de Janeiro some athletes were treated at the Medical Center with ESWT. We performed ESWT treatments during the Brazilian Athletics Meeting in 2009 on tendons and muscle injuries with the view to relieve pain and muscle contracture.

Methods: Most athletes experience pain during training and competitions. They use anti-inflammatory drugs and physiotherapy techniques daily along with ice, massage and stretching in order to relieve pain.

We offered ESWT as a new option for pain treatment. Initially only 3 subjects asked for ESWT but on the second day of competition 16 athletes chose ESWT treatment. We treated muscle contracture at the adductor, hamstring, soleus, gastrocnemius, lumbar and dorsal areas and tendons.

Results: All the subjects underwent traditional physiotherapeutic techniques as well as ESWT, and at the end of the competition all were satisfied and very thankful.

Discussion: We know that patients feel an immediate sensation of pain relief and muscle relaxation after ESWT treatment. However, we do not know why this happens. In these particular patients we employed ESWT as a pain treatment, not a definitive solution for pathologies.

Conclusion: ESWT is an option for pain treatment.

### **37. Keynote lecture: Treatment of Chronic Wounds - State of the Art**

Karsten Knobloch

No abstract available.

### **38. Shockwave Therapy for Lipodystrophy improvement**

Olga Krikunova

Institution:

Medical Center „Classicus“, Leningradskoe Ave., 116, Moscow, Russia

Device and producing company: Duolith, Storz

Introduction: It is necessary to conduct research on the effect of shock waves on adipose and connective tissues in order to estimate their effectiveness and to greater apply Shockwave Therapy (SWT) in lipodystrophy treatment.

Methods: We performed research on the influence of shock waves on hypodermic adipose tissue having lipodystrophy of I-III degrees. The experiments were conducted using the Duolith device (Storz, Switzerland).

Results: A group of 28 people (12 men and 16 women) with lipodystrophy of I-III degrees participated in this experiment. By the 21st day of therapy all patients registered increased density of the connective tissue (skin turgor and elasticity improved) and visual improvement in skin texture. The amount of adipose tissue in the thigh zone decreased by 10.25% - 11.5%.

Discussion: The research results showed it is possible to purposefully influence the activity of metabolic processes, including lipodystrophy of various origins.

Conclusion: The research results showed it is possible to purposefully influence the activity of metabolic processes, including lipodystrophy of various origins.

### **39. Defocused ESWT for Chronic Skin Lesions – Treatment Interval Does Not Seem to Influence Healing Outcome**

Rainer Mittermayr(1,2,3), M. Pusch(1,2), Ch. Schwab(1,2), W. Schaden (1,2)

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Austrian Cluster for Tissue Regeneration, Vienna, Austria

Device and producing company: Dermagold, Activator, MTS/TRT

**Introduction:** Chronic or delayed healing wounds are a significant burden to both the healthcare system and the patient, often requiring protracted, intensive and quality-of-life-altering treatment. Due to multiple factors (e.g. longer life span, higher rate of co-morbidities such as diabetes) the incidence of chronic wounds is increasing worldwide. We show in our open study that extracorporeal Shockwave Therapy has great potential in the treatment of non-healing wounds. Additionally, different treatment intervals were tested and results are presented.

**Methods:** In our open study patient enrolment is done during routine clinical work. Between August 2004 and April 2011 patients of both sexes with soft tissue wounds of different etiology persistent longer than 1 month were included. The primary outcome measure was rate of wound closure. Secondly, the different treatment intervals (1, 2, and 3 weeks) were analyzed and compared.

**Results:** As of April 2011, 590 patients were treated with unfocused extracorporeal shock waves (male: 59%, female: 41%) and were included in this analysis. Mean age was 57.3 years  $\pm$  21.1(SD). Wounds of the lower extremities were treated most often followed by the upper extremities. In total 70% of the wounds treated with defocused ESWT healed completely (2010: 71%). Wounds unresponsive to ESWT were observed in 8% of treated patients which was minimally higher than in 2010 (6%). The percentage of patients who were lost to follow-up was 17%, a slight increase compared to 2010 (16%). Wounds which received only one treatment (191 patients) completely healed in 64% of patients. In this sub-group we experienced the highest rate of patients who were lost to follow-up (26%). Wounds which did not heal after 1 treatment were observed in 7% of patients. The main reasons for discontinuing ESWT in the wounds which did not heal after 1 session were: treatment in other hospitals; surgery; and patient refusal (in 3 cases). All other patients had 2 or more (maximum 11) treatments. Wounds treated in one-week interval completely healed in 74% of patients. Similar results were found in patients which received ESWT every two weeks (72% completely healed) and every three weeks (69% completely healed). No substantial differences were observed in the number of patients who were lost to follow-up (around 12%) or in wounds unresponsive to ESWT (around 10%).

**Conclusion:** In our open study at Trauma Center Meidling we show consistently excellent results in treating sub-acute and chronic wounds with ESWT. The healing outcome seems to be independent of the treatment interval. Furthermore, the different intervals do not seem to have an influence on patient compliance.

#### **40. Placebo controlled, prospectively randomized, double-blinded study for the investigation of the effectiveness and safety of acoustic wave therapy (AWT®) for cellulite treatment**

Katharina Russe-Wilflingseder(1), Elisabeth Russe(1), Monika Drmic(1), Johannes C. Vester(2), Gerd Haller(3), Pavel Novak(3), Alexander Krotz(3)

Institution:

1 Plastische Chirurgie und Laserzentrum, Innsbruck, Austria

2 idv, Gauting, Germany, 3 Storz Medical, Tägerwilen, Switzerland

Device and producing company: D-ACTOR® 200 by Storz Medical AG, Switzerland

Introduction: Acoustic wave treatment (AWT®) is a new approach to improve the appearance of cellulite. Cellulite is a biologically caused modification of the female connective tissue and affects more than 90% of all women worldwide. In AWT® pulses penetrate the tissue, stimulating tissue metabolism and blood circulation. The objective of this study is to demonstrate the efficacy and safety of AWT® in the treatment of cellulite.

Methods: The study was designed as a placebo controlled, double-blinded, prospectively randomized clinical trial to assess the efficacy of AWT® by combining superficial and deeper penetrating radial waves within one treatment session. Fifteen females were included: 11 verum, 4 placebo; BMI 22.7 SD 1.7; age 42.5 SD 7.6. Patients were treated once a week for 7 weeks: a total of 8 treatments. Treatments were performed using the D-ACTOR® 200 by Storz Medical (Tägerwilen, Switzerland). Documentation and evaluation was done before treatment, 1 week after the 7th treatment and at weeks 4 and 12 after final treatment. Patient questionnaire, weight control, measurement of circumference of upper leg and standardized photography were evaluated. Results were documented using a specially designed 3D imaging system (SkinSCAN3D, 3D-Shape GmbH, Erlangen, Germany). Surface topography parameters served as an objective measure of cellulite and were used as primary efficacy criteria.

Results: Comparing verum vs. placebo group there was a statistically significant improvement of cellulite in the verum group but not in the placebo group between baseline and the 3-month follow up shown by 3D measurements in Sq  $p=0.028$  (improvement of waviness of skin surface of height and depth of dimples), Sz  $p=0.002$  (improvement of the depth of dimples) and Vvv+Vmp  $p=0.019$  (improvement of volume of the depressions and elevations). The overall result based on the Multivariate Wilcoxon Test indicates the substantial superiority (MW = 0.6706) of the verum group vs. placebo group and its statistical significant (PWei-Lachin = 0.0106, one-sided, exploratory interpretation). Patient questionnaires revealed improvement in number and depth of dimples, skin firmness and texture, but little or no change in shape of treated area or reduction of circumference of the upper leg. Patients' average rating of treatment success for the verum group showed constant improvement at all follow ups, but not for the placebo group.

Discussion: The double-blinded, randomized study verified the efficacy of superficial and deeper penetrating radial acoustic waves in treating cellulite. Primary efficacy criteria of treatment results was the measurement of surface topography parameters

because this is seen as objective measurement of cellulite. Only in the verum group was a statistically significant improvement of waviness of skin surface, depth and volume of dimples seen; there was no improvement in the placebo group. Treatments were free of side effects.

Conclusion: AWT/EPAT is safe and effective in treating cellulite. Patient acceptance is high.

#### 41. Cellulite and Extracorporeal Shockwave Therapy (CelluShock-2009) - a Randomized Trial

Karsten Knobloch, Beatrice Joest, Robert Krämer, Peter M. Vogt

Institution:

Plastic, Hand and Reconstructive Surgery, Hannover Medical School, Germany

Device and producing company: Duolith, STORZ

Introduction: We hypothesize that the combination of extracorporeal Shockwave Therapy and a daily gluteal muscle strength program is superior to a gluteal muscle strength program alone in cellulite.

Methods: Randomized-controlled trial. For allocation of participants a 1:1 ratio randomization was performed using opaque envelopes for the concealment of allocation. Reporting: according to CONSORT 2010. There were 53 eligible patients (females aged 18-65 years with documented cellulite 1°-4° according to the Nürnberger score). Mean age was 43 years, mean BMI was  $24.8 \pm 3.23 \text{ kg/m}^2$ . Analysis: Intention-to-treat. Primary outcome parameter: Photonumeric cellulite severity scale, (CSS, 0-15). Five key morphological features are determined and assessed in the validated Cellulite Severity Scale (CSS): 1) number of evident depressions, 2) depth of depressions, 3) morphological appearance of skin surface alterations, 4) grade of laxity, flaccidity or sagging skin, and 5) classification by Nürnberger and Müller. Intervention group A: Six sessions of extracorporeal focused shock waves for six sessions (STORZ Duolith, 2000 impulses,  $0.25 \text{ mJ/mm}^2$



every 1-2 weeks) at both gluteal and thigh regions plus specific gluteal strength exercise training. Control group B: Six sessions of sham extracorporeal focused shock wave for six sessions (2000 impulses, 0.01mJ/mm<sup>2</sup> every 1-2 weeks) at both gluteal and thigh regions plus specific gluteal strength exercise training. Follow-up: 12 weeks. Blinding was achieved for all participants enrolled in the trial, the photographer taking the digital images for the primary outcome measure, the two assessors of the outcome measures, all additional health care providers and for the analyst from the biometrical department. ClinicalTrials.gov identifier: NCT00947414

Results: The Cellulite Severity Scale (CSS) in the intervention group A was 10.9±3.8 before and 8.3±4.1 after ( $p=0.001$ , 2.53 improvement, 95% confidence interval 1.43 to 3.62). The Cellulite Severity Scale (CSS) in the control group B was 10.0±3.8 before and 10.1±3.8 after the strength exercise intervention ( $p=0.876$ , 95% confidence interval -1.1 to 0.97). The change of the Cellulite Severity Scale (CSS) in group A vs. B was significantly different ( $p=0.001$ , -24.3 effect size, 95% confidence interval -36.5 to -12.1). All five sub-items of the Cellulite Severity Scale (CSS) were significantly improved in the intervention group only.

Discussion: The combination of focused extracorporeal Shockwave Therapy (0.25mJ/mm<sup>2</sup>, 2000 impulses, six sessions) in combination with gluteal strength training was superior to gluteal strength training alone in moderate to severe cellulite in terms of the Cellulite Severity Score (CSS).

Conclusion: This randomized-controlled trial demonstrates the significant clinical effectiveness of focused extracorporeal Shockwave Therapy as an adjunct to gluteal strength training in females with cellulite.

## 42. Prospective Trials of ESWT for Soft Tissue Indications

Alexander Stojadinovic, Christian Ottomann, Bernd Hartmann, Richard Thiele, Philip T. Lavin, Wolfgang Schaden

Institution:

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Unfallkrankenhaus Berlin, Zentrum für Schwerbrandverletzte mit Plastischer Chirurgie, Berlin, Germany;

Internationales Zentrum für Stosswellentherapie, Berlin, Germany; Boston Biostatistics Research Foundation, Framingham, MA; AUVA-Trauma Center Meidling, Vienna, Austria

Device and producing company: OW180C DermaGold™ (manufactured by MTS Europe GmbH, a subsidiary of Tissue Regeneration Technologies, LLC, Woodstock, GA., which is a certified medical device in Europe (TÜV Rheinland CE 1275)

Introduction: The collaborative, multi-disciplinary Combat Wound Initiative (CWI) Program has partnered with leaders in wound care and research to provide state-of-the-art, complex wound care through targeted clinical and translational research, incorporating advanced technology and treatment, tissue banking, and bioinformatics. The CWI has advanced prospective non-randomized and prospective randomized trials (PRT) testing extracorporeal Shockwave Therapy (ESWT) for soft tissue indications to provide evidence basis to further advance wound care.

Methods: The CWI has partnered with leaders in the field of ESWT to conduct three clinical trials: (1) prospective single-arm trial testing feasibility and safety of low-energy, defocused ESWT for complex, non-healing, soft-tissue wounds – 208 patients treated with wound debridement, outpatient ESWT [100-1000 pulses/cm<sup>2</sup> at 0.1 mJ/mm<sup>2</sup>, q 1-2 wks over mean 3 treatments], and moist dressings; (2) PRT comparing standard topical therapy alone (non-adherent silicone mesh and antiseptic gel, n=15) to standard therapy with ESWT (100 pulses/cm<sup>2</sup> at 0.1 mJ/mm<sup>2</sup>, applied once to the donor site, immediately after skin harvest; n=13) to split thickness skin graft (STSG) donor site; (3) PRT comparing standard topical therapy alone (as above, n=22) to standard therapy with ESWT (100 impulses/cm<sup>2</sup> at 0.1 mJ/mm<sup>2</sup>, applied once to the burn wound, immediately after debridement, n=22) to superficial 2nd degree, IIa° burns.

Results: (1) complete wound epithelialization occurred in 75% of patients during mean follow-up period of 44 d; there was no ESWT-related toxicity, infection, or wound deterioration; (2) mean healing time was significantly more rapid in ESW-treated STSG donor sites than those treated with standard therapy alone ( $14 \pm 2$  vs.  $17 \pm 2$  days,  $p = 0.0001$ ); (3) in patients with superficial 2nd degree, IIa° burns, mean time to complete epithelialization was significantly accelerated in the ESW-treated group ( $10 \pm 2$  and  $13 \pm 2$  days).

Discussion: Low-energy, defocused ESWT is a safe and effective adjunct to standard therapy for accelerating skin graft donor site and superficial second degree burn re-epithelialization.

Conclusion: Extracorporeal Shockwave Therapy is a feasible, safe and effective method to enhance the healing of both split thickness skin graft donor sites and superficial 2nd degree (IIa°) burns.

## 43. Standard of care for calcifying tendonitis of the shoulder

Markus Loew

No abstract available.

#### 44. Treatment of Frozen Shoulder with Focused ESWT

Ayman Elwy Balabel, Faisal Al-Kandary, Sahar Othman

Institution:

Physiotherapy Department, Ahmadi Hospital, Kuwait Oil Company, Kuwait

Device and producing company: Piezoston 300, Wolf

Introduction: Frozen shoulder, also called adhesive capsulitis, is a chronic, inflammatory disorder of the shoulder and surrounding soft tissues. This condition is frequently caused by injury, leading to pain and lack of use. As the joint becomes progressively tighter and stiffer, simple movements such as raising the arm become difficult. If inflammation occurs within the capsule itself, the shoulder bones are unable to move within the joint. In some instances, the patient may be unable to move the shoulder at all. This condition rarely appears in people under age 40. An arthrogram may be needed to confirm the diagnosis. Treatment can include non-steroidal anti-inflammatory medications (NSAID's) and physical therapy. However, it may take up to a year to see improvement. Arthroscopic surgery and shoulder manipulation under anesthesia may be necessary in more severe cases.

Methods: The study includes 20 patients with frozen shoulder problems, age 40-58 years, pain VAS rating of 8-10 with pain so severe at night they had X-rays when initially diagnosed to exclude Type I ACJ arthritis. They underwent different types of conservative treatment (such as NSAID's, local injection with hydrocortisone, and physiotherapy and exercises) for more than 6-8 months with no significant improvement. We performed the treatment as an outpatient procedure without anesthesia in 3 Focused ESWT sessions (3000 pulses, 0.7- 11mJ/mm<sup>2</sup>, frequency 4, intensity level 8-10) at two-week intervals. Mobilizing and stretching exercises were performed 3 weeks after final treatment to reduce muscle contracture and regain elasticity of the capsule (structures and ligaments). Also ROM strengthening exercises were started gradually and progressively for 3 months to restore the rotator cuff.

Results: 6 Months

We found that 80% of the patients showed significant clinical improvement, pain had been reduced to VAS 3-4 and range of motion had significantly improved, while 20% of patients were slightly better.

Discussion: Focused Shockwave Therapy produces significant relief of pain, improves ROM and decreases physical incapacity produced by frozen shoulder.

Conclusion: F ESWT is effective, noninvasive, with no complications or side effects, therefore shock waves must be considered a valuable treatment option for frozen shoulder. Although this technique reduces the recovery time and increases the clinical success rate, physiotherapy remains the main treatment for this indication.

#### 45. The potential role of shock waves on shoulder tendons healing after surgery

Sergio Russo(1), A. Cozzolino(1), E. Astarita(1), A. Petteruti(1), R. Russo(2)

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1 University of Naples, Italy

2 Pellegrini Hospital Naples, Italy

Device and producing company: Duolith - Storz

Introduction: Rotator cuff tendon re-tears are frequent and caused by a lack of cellular response to the surgical repair. To reduce rotator cuff repair failure, many solutions, such as PRP, BMP, tendon graft, biologic patch and extracellular matrix scaffold, have been introduced with differing results. Several studies have already demonstrated, in animal models, the improvement of tendon healing and the angiogenetic effect of ESWT (extracorporeal Shockwave Therapy) applied after tendon surgical repair.

The aim of this study is to evaluate the clinical and structural effects of low energy ESWT applied to patients who have undergone rotator cuff tendon repair.

Methods: Twenty patients with a degenerative rotator cuff tear that was arthroscopically repaired started low energy ESWT three weeks after surgery. The clinical results were evaluated with a Constant score taken the day before surgery and 3, 6 and 12 months after surgery. The structural results were evaluated by ultrasound at 6 and 12 months. The one-year follow-up results are still incomplete and will not be reported here. Results observed in the study group were compared with an historical group of patients treated for the same pathology with similar characteristics.

Results: Patients treated with ESWT showed improved clinical outcome at 3 and 6 months after the surgical repair.

Discussion: Ultrasound examination showed no tear recurrence at 6 months. A minimum of 1 year follow-up should be evaluated to demonstrate the effectiveness of ESWT in reducing the re-tear rate of rotator cuff tendons.

Conclusion: The use of ESWT after the rotator cuff tendon surgical repair does not affect the clinical outcome.

#### **46. Evidence and necessity of targeting ESWT in the Treatment of calcifying Tendinopathies of the Shoulder**

Sergej Marx, Richard Thiele

No abstract available.

#### **47. ESWT for calcifying tendonitis – Evidence Based Medicine**

Ludger Gerdesmeyer

No abstract available.

#### **48. Ultrasound Elastography, a Novel Method for the Diagnosis of Trigger Points and a Tool to Evaluate the the Efficacy of Shockwaves in the Treatment of Myofascial Pain Syndroms**

Wolfgang Bauermeister

Institution: None

Device and producing company:

Swiss DoloClast, EMS; Piezoson 100, Wolf: ARIES, Dornier MedTech; Ultrasonix Tablet, Ultrasonix

Introduction: Trigger Points (TPs) are the pain generators in Myofascial Pain Syndrome (MPS). TPs cannot be visualized by X-Ray, MRI or conventional ultrasound. Ultrasound Elastography (USE) can visualize TPs as small areas of reduced strain.

Methods: TPs were diagnosed using USE and treated with radial, piezoelectric sharply focused and electromagnetic shockwaves with a focus channel. After the treatment a follow-up USE examination was done.

Results: Radial shockwaves exert effects on superficial TPs, but have little or no effect on deeper structures. Piezoelectric shockwaves reach small areas because of their particular focus. Shockwaves with a channel-like focus exert their effect in several tissue layers simultaneously.

Discussion: USE can visualize areas of reduced strain like prostate, breast or liver tumors. Shockwaves vary regarding their depths of penetration and focus characteristics and may have very different effects on TPs.

Conclusion: This study demonstrates the capability to visualize TPs with USE in a clinical setting as a routine procedure. USE is a valid tool to diagnose TPs in MPS and can help evaluate the effects and efficacy of different types of shockwaves. The focus geometry and depth of penetration of shockwaves can result in significantly different clinical outcomes and be the deciding factor in the treatment's success and failure.

#### **49. Shockwave-acupuncture: A method with excellent results in arthritis and asthma treatment**

Heinrich Everke

Institution: None

Device and producing company: MP 50 - Storz Medical Company, Switzerland

Introduction: The application of extracorporeal shockwaves to acupuncture points is a new method of stimulation, which became possible after the invention of smaller devices for the generation of ballistic shockwaves. Since 2002, when at my request, Storz Medical Company produced a special machine capable of producing shockwaves for small areas, I have been observing the effectiveness of this new method for the treatment of coxarthrosis, gonarthrosis, asthma, and other diseases in more than 1000 patients.

Methods: The effect of this new therapy on pain and mobility of joints in gonarthrosis and coxarthrosis and on lung function in asthma were observed. The documentation was based on subjective parameters such as pain intensity and objective parameters such as joint mobility and spirometric measurements.

Results: 72.8% of gonarthrosis patients had less pain. The mobility of the knee and hip joints improved by an average of 19.1 degrees. In both studies, the younger patients (under 65 years of age) achieved better results than the older patients.

With regard to asthma, the subjective recovery from tightness in the chest and difficulty in breathing as well as chronic dry cough improved markedly. Also, the use of inhalers was significantly reduced.

Conclusion: The results show that pressure pulses on small areas can trigger reactions in pressure receptors in skin and connective tissue that can reduce pain, improve mobility and circulation, and relax bronchial muscles. The list of indications for this new type of therapy may be extensive.

#### **50. The Use of Computerized Clinical Files in Shockwave Therapy Surgery: Our Experience in Tortona**

Maria Cristina Ottone, Francesca Maria Roldi

Institution: ASL AI - Distretto di Tortona , Tortona, Italia

Device and producing company: Piezason 300, Wolf

Introduction: Although paper clinical files are comprehensive, accurate and impossible to change without leaving evidence, they also make it difficult to analyze all the clinical data and to obtain complete statistical results.

Methods: It is necessary to have a computerized clinical file which is easy for the operator to use in terms of both compiling and processing data. The file must contain the personal and clinical data of every patient, as well as process the results of different steps of treatment (i.e. VAS and Constant Index). Because of its private nature it is also necessary that the data only be entered by the operator and by the processing center staff when saving the information.. With the support of the Data Elaboration Center (DEC) using the system called „Access“, a computerized clinical file has been developed with all these features.

Results: In Tortona we have been using these computerized clinical files since 2002. We used them for six months then reviewed the practical aspects and made some modifications in order to have clinical files which are always complete. After this modification process we input all the records for patients treated previously: our case history records are complete.

Discussion: This system is easy to use, allows the complete collection of clinical and personal data, including printed address labels (making it easy to look up a group of patients for long-term follow-up).

Conclusion: With this program it is fast and easy to find and process patient data. It is also useful for reminding the patient of previous treatment that he may not remember. Moreover the statistical analysis is helpful for evaluating results.

#### **51. A novel approach to ESWT for Achilles tendinopathy, guided and evaluated by means of Ultrasound Tissue Characterization (UTC)**

Hans T.M. van Schie(1), Willem den Boer(2), Bert Verhoeven(2)

Institution:

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Erasmus University Medical Center, Orthopaedic Research Laboratory, Rotterdam, the Netherlands  
2 Maxima Medical Center, Department Orthopaedics, Eindhoven, the Netherlands

Device and producing company:

ESWT: ActiVitor ACV02, SwiTech Medical, 8280 Kreuzlingen, Switzerland,

UTC: UTC Imaging, 6171 GD Stein, the Netherlands

**Introduction:** ESWT treatment might benefit from an “inward view” into diseased tendons. Ultrasonography suffers from poor reproducibility and allows only qualitative assessment. In contrast, ultrasound tissue characterization (UTC) was developed for tomographic visualization and quantification of ultra-structure.

**Methods:** Patients (n=53) suffering chronic (> 9 months) refractory Achilles tendinopathy were included. Inclusion consisted of clinical examination and UTC. UTC data collection is standardized with the ultrasound probe fixed in a motorized tracking device that collects images at even distances of 0.2 mm.

Tendons are visualized tomographically, and UTC algorithms facilitate discrimination of 4 echo-types:

- I. generated by intact, aligned tendon bundles;
- II. generated by discontinuous, waving tendon bundles;
- III. related to interfering echoes from mainly fibrillar tissue;
- IV. related to interfering echoes from mainly cells and fluid in amorphous tissue.

ESWT (ActiVitor ACV02, SwiTech Medical, Kreuzlingen, CH) is based on localization, volume and tissue characteristics of lesion: probe F005, pulses ranging from 600 to 1500 each treatment, EFD from 0.11 to 0.15 mJ/mm<sup>2</sup>. Evaluations and, if necessary, re-treatments were done at 8 weeks intervals; in most cases 3 to 4 times until patient satisfaction and improved ultra-structure was reached or until further treatment was abandoned due to lack of improvement.

**Results:** A. Overall success rate, the sum of clinical improvement, decrease of swelling and significant improvement of ultra-structure on UTC, was 78.9% after an average of 1.51 treatments.

B. Prognosis varied remarkably with localization and tissue characteristics: (1) mid-portion, diffuse, fibrosis and mid-portion partial ruptures had a good prognosis, (2) “recent” relapses had a good prognosis too but these lesions are frequently surrounded by chronic fibrosis, requiring adjusted dosage and a less progressive rehab-protocol, (3) mid-portion postero-medial degeneration (with fibro-myxoid or amorphous aspect on UTC), frequently combined with swollen and irregular paratenon, had a less favorable prognosis, (4) insertional changes had a fair/good prognosis, however, cases with partial ruptures and/or intra-tendinous calcification just proximal to the insertional region are far less favorable.

**Discussion:** At end-stage, an excellent relationship was observed between clinical improvement and UTC parameters, except in patients with amorphous tissue on UTC, frequently seen as fatty degeneration in older patients. But at 8 weeks after first treatment clinical improvement is frequently, but not always, accompanied by improvement of ultra-structure. In these cases, exercise levels based on UTC may prevent relapses (do not start exercise too early). This pilot study of relatively short duration revealed benefits of the UTC-guided protocol, offering opportunities for long-term evaluation of ESWT in multi-center randomized trials.

**Conclusion:** UTC appeared to be the most useful for ESWT of Achilles tendinopathy for prognostics, targeted application, objective evaluation and rehabilitation.

## **52. Safety and efficacy of ESWT in plantar heel pain – outcome of the STORZ FDA Study**

Hans Gollwitzer, Amol Saxena, Louis Gally, Brian Fullem, Richard T. Bouché, David Caminear, Ludger Gerdesmeyer

**Methods:** A prospective, multicenter, double-blind, randomized, placebo-controlled FDA trial was conducted among 250 subjects. Subjects were randomized to ESWT (0.25 mJ/mm<sup>2</sup>) or placebo intervention. Both groups received three interventions of 2000 impulses, each session one week apart. The primary outcome was the percentage change of heel pain quantified by VAS composite score, as well as the change of Roles and Maudsley score at 12 weeks after the last intervention compared to baseline. Secondary endpoints were defined as single success rates (more than 60% reduction in single VAS), overall success rate, physician’s judgment of effectiveness, patient’s satisfaction with outcome, patient’s willingness to recommend treatment, subject’s analgesic medication consumption at 12 weeks and success rates at 12 months.

**Results:** 246 patients (98.4%) were available for intention-to-treat analysis at 12-week follow-up. ESWT resulted in a 69.2% reduction of heel pain regarding the primary endpoint VAS composite score compared to baseline, compared to 34.5% for placebo (p=0.0027, one-sided). ESWT was also significantly superior to placebo for the Roles and Maudsley score (p=0.0020, one-sided). The combined overall result of the eight secondary criteria also showed statistical significance (P = 0.0015 one-sided). Sensitivity analyses supported superiority of ESWT, and clinical success of the intervention persisted at 12 months. No clinically relevant device-related adverse events were recorded.

**Conclusion:** The results of the present study provide confirmatory proof of effectiveness of three interventions of ESWT without local anaesthesia in the treatment of refractory painful heel syndrome, with clinically relevant changes in pain scales.

## **53. The Importance of Total Energy Emitted in the Results of ESWT**

Maria Cristina Ottone, Filippo Fagnani, Emanuela Maria Roldi

Institution: ASLAL - Distretto di Tortona - Via Milazzo,1 - Tortona, Italia

Device and producing company: Piezoson 300, Wolf

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

Methods: The treatment was carried out using a Piezoson 300 from WOLF, a focused piezoelectric generator with three different focal dimensions. We used the large focus and low energy density (0.06 mJ/mm<sup>2</sup>) with a total energy of 6.8 J. This study includes 250 patients:

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

Group B: 100 patients, 3 applications, 2700 shock waves/session

Results: The follow-up is ongoing and we will present the results during the meeting.

Discussion: Two years ago we compared different protocols varying the focus dimension and energy density with a stable value of total mJ emitted. We obtained the same results in both groups, confirming a strong link between the efficacy of ESWT and the total energy emitted. Now we want to verify the results using the same total energy distributed in three sessions. If the results are similar, it may further confirm that the most important factor in Shockwave Therapy is the total energy emitted.

Conclusion: If the results confirm the efficacy of treatment using the same total energy but with a reduction of sessions, it means that we can achieve the same efficacy with a shorter course of treatment. This is important because it is less expensive: more patients are treated and less working days are lost. We are currently evaluating the patients in order to obtain final data to draw final conclusions that will be presented at the Congress.

#### **54. Effects of Extracorporeal Shockwave Therapy on Spasticity in Cerebral Palsy (CP): Our Experience (pilot study)**

Maria Cristina d'Agostino(1), V. Gasparroni(2), A.M. Lopez Lopez(2), S. Respizzi(2), B. Bernardini(2), N.M. Portinaro(3)

Institution:

1 ESWT Unit, Orthopedic Rehabilitation Dept., Humanitas Clinical Institute, Milan, Italy

2 Neuro Rehabilitation Dept. Humanitas Clinical Institute, Milan, Italy

3 University of Milan and Pediatric Orthopaedic Dept. Humanitas Clinical Institute, Milan, Italy

Device and producing company: Orthowave, TRT (USA) and MTS (Germany)

Introduction: Spasticity, an abnormality of the tonic stretch reflex, commonly found in Cerebral Palsy (CP), interferes with the normal growth and functionality of the musculoskeletal system, thus leading to deformities, functional limitations, and disability. The principal aim of treatment is to reduce spasticity and retard secondary musculoskeletal alterations, thus avoiding or delaying the need for surgery. Extracorporeal Shockwave Therapy (ESWT) is widely known to be efficacious in the treatment of tendon and osseous diseases as well as in tissue healing. Moreover, evidence from the Literature suggests that ESWT can reduce muscle spasticity, although the mechanism of action is still under investigation and further evidence may be useful.

Methods: 24 spastic diplegic children (6-10 years old, Gross Motor Function Classification System I-II) were treated with 4 sessions of weekly focalized bilateral ESWT on calf muscles (Orthowave, 2000 pulses, EL 0.03 mJ/mm<sup>2</sup>). Participants were evaluated before (baseline), after intervention program (T1) and 3 months later (T2). Primary outcome measurements were ankle ROM, calf spasticity by MAS and Tardieu scales, and descriptive walking abilities by quantitative gait analysis. Secondary outcomes were individually defined by Goal Attainment scale (GAS).

Results: Statistically significant improvements were observed in ankle ROM and calf spasticity by MAS; walking abilities by gait analysis didn't show any significant modification in kinetic or kinematic pattern of the ankle. Significant improvement was reported in activity performance measured by GAS.

Discussion: These findings provide further clinical evidence in this new field of application in term of efficacy, safety and a painless treatment approach in CP tone reduction.

Conclusion: These findings also seem to suggest some hypothesis on possible mechanisms of action.

#### **55. Interactions of extracorporeal shock waves with pathogenic bacteria in vitro and in vivo**

Hans Gollwitzer, Carsten Horn, Ludger Gerdesmeyer



Institution:

Klinik für Orthopädie und Sportorthopädie, Klinikum rechts der Isar, TU München

The aim of the present study was to investigate interactions of extracorporeal shock wave therapy (ESWT) with pathogenic bacteria.

Direct effects of ESWT on bacterial growth were investigated with different pathogenic bacteria (*Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Enterococcus faecium*) in vitro. ESWT resulted in an energy-dependent reduction of bacterial viability, with significant inhibition of bacterial growth after increase of both energy flux density and impulse counts. Antibacterial effectiveness of ESWT proved dependent on treatment temperature and growth medium. ESWT performed on bacteria suspended in growth medium at 35°C showed significantly reduced antibacterial effectiveness compared to ESWT at 20°C in normal saline. Low-energy ESWT on bacteria in tryptic soy broth at 35°C even resulted in stimulation of bacterial growth. Additional experiments performed to reveal the antibacterial mechanisms of ESWT demonstrated energy-dependent increase of bacterial cell wall permeability, whereas damage of bacterial DNA was not observed. Synergistic effects of ESWT and additionally applied antibiotics could not be shown.

Furthermore, safety and effectiveness of ESWT was investigated in chronic osteomyelitis in the rabbit. Chronic bone infections were established in the tibia 12 New Zealand White rabbits with *S. aureus*. Two interventions of planar ESWT were applied at 4 and 5 weeks after establishment of infection. Non-treated animals served as control. A significant reduction of soft tissue abscesses and reduced histopathologic infection score were observed in the ESWT group at study endpoint at 8 weeks. Furthermore, ESWT proved safe without postinterventional bacteremia or sepsis. However, healing of the chronic bone infection did not occur.

## 56. Shockwave Treatment for Orthopaedic Infections

Richard Coombs, Moustafa Hafez, Milad Hanna,

Nikki Horwood, Vipin Asopa

Introduction: Initial experimental studies have been carried out to assess the potential for shockwave treatment eliminating bacterial infection. These studies have now been extended to include Gram-negative organisms.

Methods: Twelve standardised pieces of lamb meat 7 x 5 x 5 cm were cut from fresh ovine leg muscle. Each piece was partially sliced across approximately 2 cm from the top. A 2 cm cube of muscle was cut from the centre of each sample and was discarded. A radio-opaque lead marker was placed at the bottom of each cavity and 1 ml of sterile liquid 1.2% Agar maintained at 42 °C was added to fill the cube completely. The top of each sample was then closed by covering with the partially cut slice of meat.

Experimental samples were treated with shockwaves and were compared with untreated controls. All samples were diluted with brain heart infusion broth and counts of viable organisms were estimated after incubating the broth. Serial dilutions were used to assess the bacterial counts. The numbers of viable bacterial colonies were counted in the treated samples and were compared to the untreated controls.

Results: In an initial ten samples there was a statistically significant kill rate for *E. coli* bacteria. Some changes were noted in the muscle tissue in the treated samples. This situation does not reflect the clinical condition. Part of the damage may be related to heat necrosis which would be reduced in the living patient with normal muscle blood flow. In the clinical situation, petechial haemorrhages and minor haematomas have been reported in the literature following the treatment of soft tissue problems with shockwaves.

In our own clinical series of nearly 400 patients, we have so far not experienced this complication.

Further experiments will be carried out with *E. coli* bacteria inserted into an intraosseous position. In addition, experiments will be carried out to assess the minimum level of shockwave energy which is required to have a significant effect on bacteria in the in vitro situation.

Discussion: Initial studies have shown that shockwave treatment in an appropriate experimental model can kill up to 99% of bacteria. Additional studies have been carried out with Gram-positive organisms, specifically *Staphylococci* including MRSA and also fungi. These studies have now been extended to include Gram-negative organisms which are also killed by shockwaves in an experimental preparation using sheep muscle.

Conclusion: Shockwave treatment may be extremely helpful in treating superficial and deep orthopaedic infections.

## 57. Differentiation of mesenchymal stem cells by extracorporeal shock waves

Jörg Hausdorf, Susanne Mayer, Birte Sievers, Tolga Goeren, Volkmar Jansson

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

Device and producing company: XL 1, Dornier

Introduction: The delayed healing or nonunion of bone is a common problem as it occurs in 5 - 10 % of all fractures. Hypertrophic non-unions need only to be stabilized and they will usually unite. But the treatment of the aseptic, atrophic nonunion is a clinically relevant problem, because of its biological inactivity. The current treatment is accompanied by an extended surgical procedure including resection of necrotic bone and bone grafting and therefore causing a large amount of stress, hospitalization and a prolonged work disability for the patient. Extracorporeal Shockwave Therapy (ESWT) is a possible non-invasive treatment, as recent clinical trials show. In basic research the application of extracorporeal shock waves has been shown to enhance new bone formation in healthy bone. Target cells are fibroblasts, osteoblasts and mesenchymal stem cells in the bone marrow. Therefore we investigated whether extracorporeal shock waves may differentiate mesenchymal stem cells into an osteoblastic lineage.

Methods: Mesenchymal stem cells were cultured and treated by shock waves with 15 and 25 kV. Supernatant was investigated by ELISA for bone markers. Also expression of bone markers like cbfa1, collagen1 and ALP was examined by lightcycler. Histology was performed by a v. Kossa staining.

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

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

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

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