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Abstracts

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1. How cavitation evolves during ESWT treatment

Tom Matula, Jinfei Yu
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Device and producing company: Dornier Epos Ultra

Introduction: Cavitation may be important in ESWT treatment. However, the extent to which cavitation actually occurs in-vivo is unknown. The object of this study was to image and quantify cavitation during treatment.

Methods: A Dornier Epos Ultra with ultrasound guidance was used to treat patients for plantar fasciitis in a lateral-to-medial direction. Treatment was performed by the attending physician using their own protocol. The ultrasound images were recorded onto a laptop computer for post processing. Cavitation, when it occurs, manifests as a hyperechoic region. These regions were measured by quantifying the intensity and area of the hyperechoic regions.

Results: The results of this feasibility study suggest that cavitation can and does occur under some conditions. Cavitation activity can build over treatment time. After treatment, cavitation bubbles dissolve. The location of cavitation is not necessarily at the focus of the device.

Discussion: When cavitation occurs, the bubbles may not have enough time to dissolve before the next shock wave arrives. This leads to a growth in cavitation activity with each subsequent shock wave. Blood pooling due to damaged blood vessels may also contribute to increased cavitation activity. The location of cavitation 'hot-spots' depend on the presence of nearby bones, and possibly on vessel damage location. During treatment, it is possible that the cavitation field becomes too large, preventing the acoustic wave from passing through, reducing therapeutic benefit.

Conclusion: Cavitation was measured and quantified from ultrasound imaging. Optimal treatment protocols should take into account the possibility that cavitation will influence subsequent shock waves. (Acknowledgments: AKSM, APL, NIH #RO1AR053652).

2. Extracorporeal Pulse Activation Therapy (EPAT)

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Device and producing company: Duolith SD1, Storz Medical AG

Introduction: Within the last two decades the high energy shock waves used for stone disintegration proved their ability to stimulate healing processes in human tissue using much lower energy levels, especially in soft tissue pain management. Also the pulse characteristics changed when radial pressure wave systems were introduced.

Methods: The excursion of different transmitters (D-Actor, V-Actor) has been measured with laser vibrometer and/or laser distance transducer.

Results: The pressure waves generated with pneumatically driven hand pieces and their attached pulse transmitters are typically in the frequency range <10kHz resulting from the oscillation of the transmitter. Depending on the transmitter design and materials, there are also pressure waves in the frequency range of approximately 100-150kHz which are due to longitudinal vibrations within the transmitter's material.

Discussion: None of the pressure waves generated by the pneumatically driven hand pieces exhibit typical physical characteristics of shock waves. Still, multiple clinical studies proved that for many soft tissue indications the healing effects achieved are comparable to the results

achieved with shock waves. Thus the common, typical pulse form and not the shock wave characteristic might be responsible for the healing effect.
Conclusion: It should be accepted that shock wave characteristics are not the only source for multiple beneficial physiological effects. "Shock waves" applied for soft tissue treatments today have very low energy levels which have stimulating effects. There are no destruction effects (ESWL) and almost no negative side effects. Consequently, another term is suggested for more appropriate description and clear differentiation from (ESWT): "Extracorporeal Pulse Activation Therapy" (EPAT).

3. Shock wave therapy: What really matters

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Institutions:
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Device and producing company: Swiss Dolorclast, EMS Electro Medical Systems SA, Ch. de la Vuarpillière 31, 1260 Nyon, Switzerland
Introduction: A recent study in the literature (Cleveland et al., Ultrasound Med Biol 2007; 33: 1327-1335) suggested that the rise times of the waveforms produced by the EMS Swiss Dolorclast shock wave source (as well as of piezoelectric and electromagnetic shock wave sources from other providers operated at low settings) would be too long for the pulses to be considered shock waves, and this could explain the negative outcome of some clinical studies performed with these sources.
Methods: We performed a comprehensive literature survey about definitions of the term "shock wave" used in the biomedical field; and the potential significance of the leading positive phase of shock waves for their biomedical effects.
Results: Several definitions of the term "shock wave" are used in the biomedical field. Importantly, cavitation consequent to the negative phase of the wave propagation appears to be the most relevant effect of shock waves on tissue.
Discussion: Focussing mainly on the leading positive phase of shock waves in further basic research on applications of shock waves to the musculo-skeletal system might be misleading. It appears more effective to evaluate the actual contribution of the positive and negative phases of shock waves to their biomedical effects, and to develop innovative strategies to maximize the exposure of patients to the predominant factor.
Conclusion: The negative outcome of some clinical studies performed with the EMS Swiss Dolorclast shock wave source was most probably due to other reasons than the relatively long rise time of the leading positive phase of the shock waves generated with this source.

4. Possible mechanism of mechanotransduction induced by external stress like shockwave application

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Device and producing company: PiezoSon 100 Plus, Richard Wolf, Knittlingen, Germany
Introduction: We would like to introduce a mechanism of the mechanotransduction induced by different external stress applications.
Methods: NO was measured by chemiluminescence, reactive oxygen species by ultra weak chemiluminescence, chemical methods and ESR-spectroscopy.
Results: External stress produced NO and reactive oxygen species, which are measured through the skin.
Discussion: We discuss a common mechanism in mechanotransduction, which could be the answer to all stress applications.
Conclusion: This mechanism was compared with another, in which the appearance of either reactive nitrogen or oxygen species after physical training was found.

5. The development and state of the art treatment of ESWT

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Device and producing company: Various (experimental sources)
Introduction: Previous research addressing effects of extracorporeal shock waves on the musculoskeletal system mainly focused on connective tissue and bone. However, several clinical effects of shock waves could not be explained this way.
Methods: We and others performed a variety of experimental studies analyzing the peripheral nervous system after application of extracorporeal shock waves to the musculoskeletal system.
Results: These studies showed several effects of extracorporeal shock waves applied to the musculoskeletal system on the peripheral nervous system. Perhaps the most intriguing among these effects was the recent finding that application of shock waves with energy flux density of 0.9 mJ/mm2 on the ventral side of the distal femur of rabbits resulted in a selective, substantial loss of unmyelinated nerve fibres within the femoral nerve of the treated hind limb, whereas the sciatic nerve of the treated hind limb remained unaffected (Hausdorf et al., Neuroscience: in press).

Discussion: Collectively, these data indicate that alleviation of chronic pain by selective partial denervation may play an important role in the effects of clinical shock wave application to the musculoskeletal system.
Conclusion: The actual role of the peripheral nervous system in mediating effects of extracorporeal shock waves on the musculoskeletal system might have been underestimated so far and should be reconsidered in both experimental and clinical studies focusing on the application of extracorporeal shock waves to the musculoskeletal system.

6. Improving the effectiveness of shock wave therapy in plantar fasciitis: A comparative trial

Gabriele Verratti, Miguel Angel Guedez, Myriam Capasso

Institutions: Servicios medicos ortho shock, Caracas, Venezuela
Device and producing company: EMS and Dornier
This is a prospective comparative study evaluating the effectiveness of simultaneous application of shock wave therapy, physiotherapy and use of at night splint as a method of treatment of chronic plantar fasciitis unresponsive to conventional treatment methods for 6 months or longer. The paper includes 637 patients with a control group of 172 patients that received shock wave treatment alone. This study aims to demonstrate efficacy and time for the reduction of pain and thickness of the plantar fascia as well as the return of the patient to his daily routine by comparing shock wave therapy as a stand alone treatment and shock wave therapy systematically combined with other therapeutic methods. The authors will present the effectiveness and the recovery time comparing both groups as well as long-term outcomes.

7. ESWT in Plantar Fasciitis - 7 years of experience with two different devices

José Eid

Institutions: Clinica Ortopédica Brasil
Device and producing company: Epos Ultra – Dornier, Swiss DolorClast – EMS
Introduction: Comparison of the efficacy of ESWT in the treatment of plantar fasciitis using two different devices at similar levels of energy and the same number of sessions.
Methods: From January 1999 to August 2006 we performed 429 sessions of ESWT on 143 patients. We included 95 patients and excluded 48 due to the impossibility of follow up. The electromagnetic device was used on 51 patients between January 1999 and June 2005. The pneumatic device was used on 44 patients during the period of January 2004 to August 2006. Patient age was between 20 to 81 years; 49 female, 46 male; 50 right foot, 45 left foot, 9 bilateral. The point of application was guided with ultrasound of 7.5 MHz (Epos Ultra), and with the pneumatic device (Swiss DolorClast) we applied directly at the point of maximum pain. The energy applied was 0.22 mJ/mm2 and 0.18 mJ/mm2 with the Epos Ultra and DolorClast, respectively. We applied 2,000 shock waves over 3 weekly sessions with no anesthesia. The follow up was done using the VAS at 2, 6 and 12 months.
Results: The improvement of pain and function with the electromagnetic device was 52.4 % at 2 months post-treatment, 73.2 % at 6 months post-treatment and 85.2% at 12 months post-treatment. The improvement with the pneumatic device at 2-month follow-up was 55.2 %, at 6-month follow-up was 72.9% and at 12-month follow-up was 84%.

Discussion: Similar levels of energy and numbers of sessions demonstrated similar clinical results.
Conclusion: The effectiveness of ESWT is similar in both devices. ESWT should be the treatment of choice before surgical intervention.

8. Extracorporeal shockwave therapy in the treatment of plantar fasciitis: Report of 195 cases

Roberto Audain; Raul Chirinos, Yarila Alvarez
Institutions: Unidad de Traumatologia y Extracorporeal Shockwave: R&R Shockwave de Venezuela; Valencia Estado Carabobo Venezuela
Device and producing company: R&R Shockwave de Venezuela, Orthospec
Introduction: Plantar fasciitis is characterized by pain in the heel and pain in the plantar fascia insertion of the calcaneus. As enthesopathy; it includes the development of degenerative changes in the fascia and the periostium of the medium tubercle of the calcaneus. Treatment is very difficult and includes: NSAIDs, physio-therapy, orthotics and surgery, all of which have different results.
Methods: An experimental study conducted at the Unidad de Traumatologia y Extracorporeal Shockwave: R&R Shockwave Venezuela from February 2006 to February 2007: complete series of 154 patients with 195 heels. Patients received ESWT treatment with the ORTHOSPEC class IIA device; intensity: 0.04 and 0.16mJ/mm2; frequency: 120 to 196 impulses per minute. Initial clinical evaluation based on a visual analog scale (VAS) and the patient's satisfaction level. Clinical control: each group was evaluated every six weeks thoughout the twelve-month study.
Results: An experimental study conducted at the Unidad de Traumatologia y Extracorporeal Shockwave: R&R Shockwave Venezuela from February 2006 to February 2007: complete series of 154 patients with 195 heels. Patients received ESWT treatment with the ORTHOSPEC class IIA device; intensity: 0.04 and 0.16mJ/mm2; frequency: 120 to 196 impulses per minute. Initial clinical evaluation was based on a visual analog scale (VAS) and the patient's satisfaction level. Clinical control: each group was evaluated every six weeks throughout the twelve-month study.
Discussion: The differences between initial (VAS) and final (VAS) measurements differed in each group; the patients' satisfaction levels during the 12 months were very high.
Conclusion: The efficacy of this procedure makes it a safe and useful therapeutic option for this pathology

9. ESWT in Sever's Disease, an Exceptionally Good Indication

Roland Hamisultane
Institutions: ISMST (President 2008), SFOCAL (President), Grecho (groupement des rhumatologues echographistes) France
Device and producing company: Richard Wolf - Piezoson 100; Storz - Duolith
Introduction: Calcaneal apophysitis otherwise known as Sever's disease is a painful condition that occurs in the heel bone (calcaneaus) in patients generally between the ages of 10 to 15 years of age. Calcaneal apophysitis is a disease of the growth plate of the bone. The basis of treatment is to reduce repetitive trauma from such activities as football, running and jumping. The condition is normally self limiting, and a return to normal activities is usually

possible after a period of 2-3 months. In children it is a self-limiting condition that may interfere with walking and physical performance in sports, thus causing concern to the patient and parents. The only variable is how long it will take a given individual to return to normal activity. In very few cases, the child will have to be removed from all sporting activities due to the level of pain and loss of function. For talented young football players or athletes with hopes for a professional career in sport, ceasing activity can be disastrous. The purpose of this study was to determine the safety and efficacy of ESWT for Sever's disease.

Methods: We studied 9 young patients (high level athletes) with Sever's disease who had no resolution after common treatments and reducing activity for 2 months. In 7 boys and 1 girl ranging in age from 11 to 14 years, lateral radiographs of the heel were taken before and 1 month after the treatment. The radiographic aspect of the secondary nucleus of the calcaneus in children with heel pain remains controversial. The recent studies stated that the fragmentation of the calcaneal secondary nucleus was the most typical finding and also showed the disappearance of the areas of disintegration after treatment of the apophysitis. The patients were treated with 3 sessions of low energy SWT (1,000 shocks, 0.15 mJ/mm2) on the areas of x-ray disintegration (only if corresponding to the pain point).

Results: One month after the first session of ESWT all patients' lateral radiographs of the heel showed the complete disappearance of the areas of disintegration of the secondary nucleus of the calcaneus. Correlated with the complete decrease of pain and a return to normal activities.

Discussion: What treatment options are available? Sometimes, the passage of time may be all that is needed. It takes one to two years for the bone growth plates that make up the back of the heel to grow together and form one solid bone. At this point, pain and symptoms usually go away completely. In some cases of Sever's syndrome, the patient may need to stop sports activities for a short period. This brings the pain and inflammation under control. Typically patients do not need to avoid sports for a long period of time. The study shows ESWT postivively affects the growth plate, but must be reserved for severe cases.

Conclusion: ESWT is an effective treatment for Sever's disease, but the usually good prognosis of this disease indicates that ESWT must be reserved for exceptional and expert indications only.

10. The Effectiveness of Extracorporeal Shock Wave Therapy for Patients with Plantar Fasciitis who Satisfy a Clinical Prediction Rule

Mahmoud Ibrahim; Robert A. Donatelli, Madeleine Hellman, Frederick Buxbaum

Institutions: Rocky Mountain University of Health Professions, Provo, UT 84601, USA

Device and producing company: Swiss Dolorclast, EMS medical

Introduction: Plantar fasciitis is a common cause of heel pain, affecting 10% of the general population. Extracorporeal shock wave therapy has been recommended as treatment for chronic plantar fasciitis in patients unresponsive to conservative treatment. The efficacy of extracorporeal shock wave therapy in plantar fasciitis cannot be ascertained owing to the poor quality of methods in previous studies. The primary goal of this study was to determine the effectiveness of extracorporeal shock wave therapy compared with placebo in the treatment of chronic plantar fasciitis.

Methods: A prospective, randomized, blinded, controlled study with two groups of subjects was proposed. Fifty patients (50 heels), including 25 patients (25 heels) in the shockwave treatment group and 25 patients (25 heels) in the control group. All patients had been suffering from plantar fasciitis for at least 6 months. Pre-treatment measurements including a visual analog pain scale and the modified Roles and Maudsley scale were completed by the subjects. In the shockwave group, therapy was applied twice within a one-week interval (2 x 2,000 impulses at an air pressure of 3.5 bars and frequency of 8 Hz were given at each sitting). The patients in the placebo group received treatment with the clasp on the heel. ESWT was performed without local anesthesia. At 4 and 12 weeks the subjects again completed a VAS and the modified Roles and Maudsley score.
Results: Before treatment, the groups showed no significant differences in the scores for pain and function. At 12 weeks after treatment, the shockwave group showed significantly better pain and function scores as compared with the control group.. There were no systemic or local complications or device-related problems.
Discussion: Extracorporeal shock wave therapy has a statistically significant decrease in pain scores than placebo for patients with plantar fasciitis. Extracorporeal shock wave therapy has a statistically significant increase in functional outcome (better quality of life) than placebo on patients with plantar fasciitis.
Conclusion: Shock wave therapy is effective and safe for the treatment of chronic plantar fasciitis.

11. The effect of oral analgesics on pain tolerance during Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis (CPF): A double-blind randomized placebo-controlled trial.

Bernard Fabio Meyer, Erno Thober, Mauro Meyer

Institutions: Sociedade Brasileira de Terapia por Ondas de Choque (SBTOC)
Device and producing company: Orthima - Direx
Introduction: High-energy shockwave impulses appear to be more effective in the treatment of CPF than low-energy shockwaves. However, most patients report pain or discomfort during therapy application. A non-invasive and a low-cost analgesic therapy could be used as an alternative approach. The aim of this study was to evaluate the pain-alleviating effect of oral analgesics during application of ESWT for CPF.
Methods: A prospective study with 60 patients divided equally into four groups of fifteen each: A (PLACEBO); B (TRAMADOL 50 mg); C (ACETAMINOFEN 750 mg) and D (without medication). The first dose was administered 6 hours before and the second dose 30 minutes before the ESWT session. We used the Visual Analogue Scale (VAS) applied on the first clinical evaluation and after 500 impulses of ESWT. The equipment utilized was an electro-hydraulic generator. The applications consisted of 200 impulses of 0.08mJ/mm² followed by 1500 impulses of 0.35 mJ/mm².
Results: No significant difference existed between the groups at baseline. The preliminary results demonstrated no significant decrease of VAS scores during ESWT in groups A ($p=0.84$), B ($p=0.38$) and C ($p=0.79$). More pronounced decreases in VAS scores were observed in group B (6.72 ± 1.61 vs. 6.02 ± 1.63, $p=0.38$). Differently, no significant increase of VAS score during the application was observed in group D (6.74 ± 2.20 vs. 7.52 ± 1.78, $p=0.35$

Discussion: The increases of pain during ESWT session observed in the group without medication justify the search for a low-cost and non-invasive analgesic therapy.
Conclusion: The preliminary results suggest an analgesic effect of Tramadol. A larger patient population will be helpful to make a determination.

12. ESWT - large focus/low energy density versus small focus/high energy density using the same total energy delivered (mJ): evaluation of Results on calcific tendinitis of the shoulder.

Maria Cristina Ottone, Filippo Fagnani (bioengineer)

Institutions: Servizio Assistenza Sanitaria Territoriale (SAST) ASL Alessandria - distretto di Tortona - Piazza Cavallotti – Tortona, Italia; Alliance Medical Group - via Alunno,23 – Milano, Italia

Device and producing company: Piezoson 300 - WOLF
Introduction: We want to verify the importance of total energy delivered through the comparison of different protocols varying the focus dimension and energy density with a stable value of total mJ emitted
Methods: The treatments were carried out with Piezoson 300 from WOLF, a focused piezoelectric generator with three different focal dimensions. In this study we compared two groups of patients: each patient received 4 applications, 2000 shock waves/session. - First group: 37 patients treated with large focus and low energy density: 0,06 mJ/mm2 - second group results on more than 50 patients using small focus and high energy density: 0,18 mJ/mm2
Results: We are checking the patients and the results will be presented during the meeting
Discussion: Last year we tried to verify the results obtained using different focal dimensions, with the same energy density. We could not respect the established protocols because the pain of patient was too much when using a large focus with high energy density. The results obtained, with the first used protocols, suggested a deeper analysis about the importance of total energy delivered in ESWT versus energy density and focal dimension. The effect of shock waves is due to the combination of: the pressure peak (MPa), the energy density (mJ/mm2), the focal dimension and the total energy delivered (mJ). Therefore we continued the experimental study and we decided to compare the results obtained previously with a new group of patients treated with a large focus and low energy density at a specific level of total energy delivered.
Conclusion: Preliminary results seem to confirm a strong dependency between the efficacy of ESWT and the total energy emitted. We are waiting to be able to evaluate the completeness of data for a final conclusion to be presented at the Congress. It is necessary to study more patients because the aim is to compare the results of a large focus and low energy density with a small focus and middle density of energy : for this reason our study is again a project for the future.

13. Effect of radial extracorporeal shock wave therapy for trochanter pain syndrome.

Antonio Morral, Mariano Fernández-Fairen

Institutions: Salut i Esport Rehabilitation Center, Santa Perpetua de Mogoda, Instituto de Cirugía Ortopédica y Traumatología, Barcelona. EUIFN Blanquerna, Universitat Ramon Llull, Barcelona, Spain

Device and producing company: Swiss Dolor Clast, EMS

Introduction: Trochanteric pain syndrome or trochanteric bursitis is a common regional pain syndrome. It is characterized by chronic and intermittent aching pain over the lateral side of the hip and limitation of function. The prevalence is higher in females than males (rate 4:1), and the incidence is highest between the ages of 40 to 60, even though cases have been reported in all age groups. The etiology is not well known. Upon physical examination, the clinical signs are pain on resisted abduction and pain to the palpation of the greater trochanter. Treatment includes physical therapy methods, painkillers, and local steroid injection. The aim of this study was to evaluate the effect of radial extracorporeal shock wave therapy (rESWT) in trochanter pain syndrome. This study is a starting point for a future randomized clinical trial.

Methods: Between June 2005 and March 2007, 81 patients with trochanter syndrome were treated with rESWT, 15 of them with bilateral syndrome (total of 96 trochanter pain syndromes). These patients consisted of 14 men and 67 women, aged 29-69 years old (mean 56). The patients must have had clinical symptoms for at least 3 months before the treatment. The patients were treated in 3 sessions (at intervals of 1-2 weeks, mean 12 days) with 3,000 impulses per session. Device used: Swiss Dolor Clast (EMS-Switzerland). Energy flux density: 0.12-0.16 mJ/mm2. The pain center was detected by biofeedback. The intensity of pain was evaluated by a Visual Analogue Scale (VAS). The pain on palpation of the greater trochanter and pain during daily activity were evaluated in each examination. Evaluation was performed several times: immediately before treatment and on the week 4th, 26th and 52nd week after treatment. Analyses: The non-parametric Wilcoxon test for dependent samples has been used to compare means of VAS. At the end of follow-up, the patients were asked to assess their level of residual pain compared with pain before treatment, according to the Roles & Maudsley scale (RM scale).

Results: Patients showed a considerable pain level decrease four weeks after the treatment (to the palpation $p<0.05$ and during daily activity $p<0.05$), and pain levels decreased further in the following examinations (to the palpation $p<0.01$ and during daily activity $p<0.01$). Good and excellent results (grades 1 and 2 by RM scale) were obtained in 69 trochanter pain syndromes (72%). These side effects were observed: small superficial haematomas (76%), petechiae (32 %), swelling (52%) and pain (88%). All side effects were tolerated by all the patients and disappeared after 2-15 days.

Conclusion: rESWT is an effective treatment method for trochanter pain syndrome. Further randomized and controlled studies are necessary to underline the results of this investigation.

14. ESWT in the treatment of epicondylitis: What results in medium- to long-term? (Efficacy only in the short term or also in the medium- to long- term?)

Maria Cristina Ottone, Rino Feltri

Institutions: Seervizio Assistenza Sanitaria Territoriale (SAST) - ASL Alessandria - distretto di Tortona; Piazza Cavallotti- Tortona, ITALIA

Device and producing company: Piezoson 300 - WOLF

Introduction: The study of basic research has demonstrated that the application of ESWT produces a biological response in tissues. The aim of this study is to evaluate the effectiveness and safety of ESWT in the treatment of humeral epicondylitis two years after treatment.

Methods: We treated 50 patients with chronic epicondylitis and we checked them two years later.

Results: At two years from the start of the treatment we had the same positive results as we had had in the short term.

Discussion: The results of conservative treatment are inconsistent and pain frequently recurs. The efficacy of ESWT at short term is well known. With our study, we demonstrate more lasting efficacy.

Conclusion: When we consider the efficacy and safety of ESWT as a non-invasive treatment as well as its prolonged effectiveness, we can say that it is a low cost alternative method of treatment for chronic epicondylitis, without the risks of traditional surgical procedures.

15. Eccentric loading versus shock wave treatment for chronic insertional Achilles tendinopathy

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Institutions:

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2) SUN Orthopaedics, Lewisburg, USA

3) Dept. of Trauma and Orthopaedic Surgery, Keele, University School of Medicine, UK

Device and producing company: Swiss Dolorclast, EMS

Introduction: Nonoperative management of chronic tendinopathy of the Achilles tendon insertion is poorly studied. With demonstrated effectiveness of eccentric loading and of repetitive low-energy shock wave therapy in patients with midsubstance Achilles tendinopathy recently, this randomized controlled trial aimed at verifying effectiveness of both procedures exclusively in patients with insertional Achilles tendinopathy.

Methods: Fifty patients with chronic recalcitrant (> 6 months) insertional Achilles tendinopathy were enrolled in a randomized controlled study. All patients had been treated unsuccessfully for at least 3 months, including local injections and non-steroidal anti-inflammatory drugs and physiotherapy. A computerized random-number generator was used to draw up an allocation schedule. Twenty-five patients were allocated to Group 1 (eccentric loading), 25 patients were allocated to Group 2 (repetitive low-energy shock wave therapy). Analysis was on an intention-to-treat basis. Primary follow-up was at 4 months, afterwards patients were allowed to cross over. The last follow-up was at one year after completion of the initial treatment. The patients were assessed for pain, function and activity using a validated questionnaire (the VISA-A).

Results: At 4 months from baseline, the VISA-A score had increased in both groups, from 53 to 62 points in Group 1, and from 53 to 80 points in Group 2. The pain rating decreased in both groups, from 7 to 5 points in Group 1, and from 7 to 3 points in Group 2. Seven patients (28%) in Group 1, and sixteen patients (64%) in Group 2 reported that were "completely recovered" or "much improved". For all outcome measures, Group 1 and 2 differed significantly in favour of shock wave therapy. At 4 months, 18 of 25 patients from Group I opted to cross over, as did 9 of 25 patients from Group 2. The favorable results after shock wave therapy at 4 months were stable at 1-year follow-up.
Discussion: Eccentric loading as applied showed inferior results to low-energy shock wave therapy as applied in patients with chronic recalcitrant tendinopathy of the insertion of the Achilles tendon at 4 months of follow-up.
Conclusion: Further research is warranted to better define the indication of this treatment modality.

16. High Energy Extracorporeal Shock Wave Therapy as a Treatment for Non-Insertional Achilles Tendinopathy

John Patrick Furia

Institutions: SUN Orthopedics and Sports Medicine 900 Buffalo Road Lewisburg, PA USA
Device and producing company: Dornier Epos, Dornier Medical
Introduction: Prior studies have shown that single treatment, high energy extracorporeal shock wave therapy (SWT) is an effective treatment for chronic insertional Achilles tendinopathy. Multiple treatment, low energy SWT has been shown to be an effective treatment for non-insertional Achilles tendinopathy. The results of single treatment high energy SWT for chronic non-insertional Achilles tendinopathy are not determined. The purpose of this study was to determine the safety and efficacy of high energy SWT as a treatment for adults with chronic non-insertional Achilles tendinopathy.
Methods: Thirty-four patients with chronic non-insertional Achilles tendinopathy were treated with a single dose of high energy SWT (SWT Group, 3000 shocks, 0.21 mJ/mm2, total energy flux density of 604 mJ/mm2). Thirty-four patients with chronic non-insertional Achilles tendinopathy were not treated with SWT, but instead were treated with additional forms of non-operative therapy (control group). All SWT procedures were performed using regional anesthesia. Evaluation was by change in visual analog score (VAS) and by determination of the Roles and Maudsley functional score.
Results: One month, three months, and twelve months post treatment, the mean VAS for the control and SWT groups were 8.4 and 4.4 ($p<.001$), 6.5 and 2.9 ($p<.001$), and 5.6 and 2.2 ($p<.001$) respectively. Chi square analysis revealed that the percentage of patients with excellent or good Roles and Maudsley scores (i.e. successful results) twelve months post treatment was statistically greater in the SWT group compared to the control group ($p<.002$). Eighty-five percent of the SWT patients and 25 percent of the control patients were assigned an excellent or good result twelve months post treatment.
Discussion: Although extensively studied, the optimal treatment regime for non-insertional Achilles tendinopathy remains unclear. Spontaneous recovery after more than 6 months of symptoms is unlikely. The results from this study add to the growing number of favorable reports that substantiate the efficacy of SWT as an effective treatment for chronic non-insertional Achilles tendinopathy. The mean VAS for the SWT group was statistically improved at 1, 3, and 12 months after treatment compared with the control group. The

percentages of excellent or good results after the procedure for the SWT and control groups were 85% and 27% respectively, and there were no significant complications.
Conclusion: Single treatment, high energy SWT is an effective treatment for chronic non-insertional Achilles tendinopathy. Further prospective studies are needed to confirm this finding. Studies comparing high energy single treatment protocols with low energy multiple treatment protocols, and studies comparing various dosing intervals and energy flux densities are also needed to determine optimal treatment parameters.

17. Chronic Achilles tendon pain: tendon microcirculation and radial extracorporeal shock wave therapy (rESWT).

Antonio Ammendolia, T. Iona

Institutions: University of Catanzaro – Orthopaedic Clinic
Device and producing company: EMS Swiss DolorClast
I**ntroduction**: Achilles tendinopathy is a common cause of posterior heel pain and is often difficult to treat. This condition is more frequent in athletes, particularly runners and jumpers, but it can affect non-athletes as well. The origin and pathogenesis of the tendinopathy are unknown, however some intrinsic and extrinsic factors have been implicated (1,2). Intrinsic factors include abnormal range of motion of the subtalar joints such as those seen in hyperpronation syndrome or a leg length discrepancy. Extrinsic factors for athletes include training errors with subsequent excessive mechanical overload. Other possible extrinsic causes are advanced age, fatigue, and obesity (3,4,5,6,7,8). Recently, some clinical studies have demonstrated the association between increased tendon microvascularity and the symptomatic chronic Achilles tendinopathy. Using Doppler Ultrasonography, an increased vascular density in the Achilles tendon has been demonstrated that is clinically associated with chronic Achilles tendinopathy (9,10,11,12,13). Traditional non-operative treatment of chronic Achilles tendinopathy consists of rest and the administration of NSAIDS. Some studies have suggested different types of therapeutic interventions such as: steroid injection, sclerosing therapy, aprotinin injection, eccentric training, heel lifts and custom orthoses (14,15,16,17,18,19,20). Recently, extracorporeal shock wave therapy (ESWT) has been reported to be effective for the treatment of Achilles tendinopathy, but until now few studies have investigated the efficacy of ESWT for the treatment of chronic Achilles tendinopathy (21, 22, 23 and 24). The purpose of this study is to evaluate the correlation between increased tendon microvascularity and pain and to determine the efficacy of low energy radial ESWT for the treatment of chronic Achilles tendinopathy.
Methods: Twenty-four subjects were evaluated. Twelve athletes (group A – 9 males and 3 females) with an average age of 25.9 years were included. The athletes were runners of mid and long distance races. All twelve patients displayed evidence of chronic Achilles tendinopathy in painful phase and had undergone medical treatment and physical therapy for a minimum of 3 months without clinical improvement. For the control group, we selected 12 subjects (group B – 9 males and 3 females) with an average age of 25.6 years and morphologic characteristics similar to subjects of group A, but who were sedentary. All subjects were chosen for this study after obtaining informed consent and undergoing accurate clinical examination, excluding patients with associated pathologies that would prohibit them from receiving ESWT; coagulopathies, local infection, or tumors. The intensity of pain was registered using a VAS scale for pain with direct palpation of the tendon as well as pain during ambulation. In group B subjects no pain was reported. All 24 subjects underwent one

identical ultrasonographic evaluation with Color Doppler, provided by a single operator, using a Toshiba Power Vision 9000 scanner with a small parts 5-12 mHz tranducer. The twelve athletes with tendinopathy demonstrated a diffuse disomogeneous hypoechogenicity of the Achilles tendon with blood flow at the depth over 5 mm (mean 5.5 mm, range 4.5/6.5 mm). All 12 group B subjects demonstrated normal sonographic characteristics of the tendon. All 24 subjects underwent low energy (less than 3 bar) radial ESWT by the same operator, using a Swiss Dolorclast device by EMS. Treatment consisted of three sessions, one every 72 hours, during which subjects received 2,000 shocks each session, for a total of 6,000 shocks, using a flux of energy density averaging 2.2 bar. No local anesthetic was used and no patients required pain medication. A Color Doppler examination was performed one month and six months following the end of the treatment with ESWT and all subjects underwent clinical evaluation one month and six months after the end of the treatment. We also evaluated whether patients had pain under direct palpation or pain with ambulation. All subjects were asked to refrain from athletic activities and allowed only to walk normally during the treatment phase. A return to normal activities was allowed for all subjects one month after the end of the treatment.

Results: Doppler Ultrasonographic evaluation of subjects who underwent radial ESWT treatment demonstrated a reduction of the microvascularity present prior to treatment in group A subjects, with a disappearance of microvascularity in 58.3 % of group A subjects (7 out of 12) at one month and 83.3 % (10 out of 12) at six months. In group B subjects we noted no significant differences and no symptoms. Furthermore, at six months after the end of the treatment we registered a reduction of local pain on walking or running in 83.3% of the athletes of the group A ($P<0.0001$ – T test) (TAB. II). No significant complications were observed in either treatment group, except for a temporary increase in paratendon edema in three subjects of group A, which responded to local cryotherapy.

Discussion: Many studies have evaluated the association of increased microvascularity of the Achilles and patellar tendons and the associated clinical symptoms in patients with Achilles and patellar tendinopathy with Color Doppler. This test has proven to be highly specific (100%) and 50% specificity for the evaluation of altered microvascularity with tendinopathy (10,25). Ohberg (9) used Colored Power Doppler ultrasonography to demonstrate an increase of microvascularity in patients with Achilles tendinopathy. The same author also noted a reduction of pain in 8 of 12 subjects in whom he injected a sclerosing agent in the paratendon near the Achilles tendon insertion. In 2003 Silvestri observed a hypervascularity (paratendinosis) in patients with acute tenosynovitis, compared with normal subjects (26). Other authors have also demonstrated an increase of microvascularity in patients with Achilles tendinopathy, while in asymptomatic subjects no altered microvascularity was observed (12,13). Treatment of Achilles tendinopathy has included many types of treatment, but in some cases complications have occurred (17,18). Injection of steroids may reduce pain and microvascularity, but are associated with rupture of the tendon (17). Some studies have evaluated the effect of eccentric exercise on the pain and microvascularity of the Achilles tendon and have shown successful results in 83% of patient symptoms and alteration of the microvascularity in 17% of patients (16). Recently injection of aprotine, a proteinase inhibitor, has been proposed, but results have been unsatisfactory (18). Among treatment modalities of Achilles tendinopathy, ESWT has become for many authors a treatment of choice with satisfactory results in more than eighty percent of patients (22,24). We observed a similar improvement in 83% of patients without significant side effects. In our study we observed a decrease in tendon microvascularity in group A subjects within one month of treatment with radial ESWT. This was associated with a significant decrease ($P<0.0001$) in discomfort at rest and during ambulation (average VAS 1.04 at rest and 1.25

during ambulation), and allowed the majority of athletes to return to sports activity. No significant difference in pain was noted in group B subjects.
Conclusion: This study was designed to demonstrate the changes of the microvascularity of the Achilles tendon in patients with chronic Achilles pain, before and after treatment with radial extracorporeal shock wave therapy (rESWT). Twelve athletes with chronic Achilles pain (group A) were compared with twelve athletes free of Achilles pain (group B), all of whom were of a similar age, sex, and weight. Each group received the same treatment protocol with radial ESWT. Clinical evaluation was undertaken prior to treatment and at one month and six months after treatment was terminated. The microvascularity of all 24 subjects was evaluated with Color Doppler echography both prior to treatment with radial ESWT and at one month and six months following treatment. In group A we observed greater microvascularity of the tendon than in group B. This hypervascularity was noted to have decreased when patients were evaluated one month after the treatment with radial ESWT. Clinically, 80% of patients of group A experienced absence of pain and were able to return to sports activity at one month after the end of the treatment with radial ESWT. No significant clinically adverse effects were noted in any subjects who received radial ESWT.

18. Eccentric loading, shock wave treatment, or a wait-and-see policy for tendinopathy of the main body of tendo Achillis

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Device and producing company: Swiss Dolorclast, EMS
Introduction: Few randomized controlled trials compare different methods of management in chronic tendinopathy of the main body of tendo Achillis. Our purpose was to compare the effectiveness of 3 management strategies: Group 1, eccentric loading; Group 2, repetitive low-energy shock wave therapy (SWT); and Group 3, wait-and-see in patients with chronic tendinopathy of the main body of tendo Achillis in a randomized controlled trial.
Methods: Seventy-five patients with a chronic recalcitrant (>6 months) non-insertional Achilles tendinopathy were enrolled in a randomized controlled study. All patients had received unsuccessful management for >3 months, including at least: (1) peritendinous local injections, (2) nonsteroidal anti-inflammatory drugs, and (3) physiotherapy. A computerized random-number generator was used to draw up an allocation schedule. Analysis was on intention-to-treat basis.
Results: At 4 months from baseline, the Victorian Institute of Sport Assessment (VISA)-A score increased in all groups: from 51 to 76 points in Group 1 (eccentric loading); from 50 to 70 points in Group 2 (repetitive low-energy SWT); and from 48 to 55 points in Group 3 (wait-and-see). Pain rating decreased in all groups: from 7 to 4 points in Group 1; from 7 to 4 points in Group 2; and from 8 to 6 points in Group 3. Fifteen of 25 patients in Group 1 (60%), 13 of 25 patients in Group 2 (52%), and 6 of 25 patients in Group 3 (24%) reported a Likert scale of 1 or 2 points ("completely recovered" or "much improved"). For all outcome measures, Groups 1 and 2 did not differ significantly. For all outcome measures, Groups 1 and 2 showed significantly better results than group 3.

Discussion: At 4-month follow-up, eccentric loading and low-energy SWT showed comparable results.
Conclusion: The wait-and-see strategy was ineffective for the management of chronic recalcitrant tendinopathy of the main body of the Achilles tendon.

19. The Influence of Mechanotransduction (ESW) on the Reaction of Membrane Ion Channels by means of Patch Clump Technique

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Device and producing company: Piezoson 100 and Piezowave (Richard Wolf GmbH, Knittlingen Germany)
Introduction: Ion channels aqueous pores across the liquid bilayer and allow inorganic ions of appropriate size and charge to cross the membrane down their electrochemical gradients at rates about 1,000 times greater than those achieved by any known carrier. These channels are "gated" and usually open transiently in response to a specific pertuberation (ESW) in the membrane, such as a change in membrane potential (voltage gated channels) or the binding of a neurotransmitter (transmitter gated channels). Ion channels work together in complex ways to control the behavior of electrically excitable cells.
Methods: Unlike traditional voltage clamp recordings, the patch clamp recording uses a single electrode to voltage clamp a cell. This allows the researcher to keep the voltage constant while observing changes in current. For our experiments we used rat muscles for patch clump measurement for a single voltage-gated Na+ channel after mechanical stress (ESW).
Results: The best density of energy to open voltage-gated Na+-channels in the plasma membrane of muscle cells by a local depolarisation is between 0.04 and 0.22mJ/mm².
Discussion: This experiments shows at the beginning of the influence of ESWT on living tissue we have the mechanotransduction with the change of mechanical energy to electric and chemical energy.
Conclusion: For a good application of ESWT the knowledge of the physico-chemical pathways is very important.

20. Extracorporeal Shockwaves, Cell and Pain

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2) ZES, Kronberg, Germany

Device and producing company: Piezoson 100plus (Wolf, Germany)
Introduction: For a useful, promising and convincing ESW-treatment it is essential to determine optimal energy density, frequency and number of impulses. We used the analgesic effect of ESW to define the best parameters for a maximal analgesia.

Methods: Seventy-one patients with painful points at the musculoskeletal system, aged from 16 to 78. Special group of 21 patients with gonarthritis. 1,000 impulses/session, depth depending on indication, 4 Hz, Level 1-6(0.04- 0.22 mJ/mm²). VAS before, immediately after, 24 hours after treatment.
Results: VAS before treatment 3.40- 5.39(depending on the group). VAS directly after treatment 2.64-3.24. Twenty-four hours after treatment 0-4.46.
Discussion: ESW has an analgesic effect, but only in low energy state corresponding to the irritation of the myelinated A- delta fibres. That leads to the inhibition of the pain transmission via non-myelinated C-fibres. The analgesia is not persistent as long as painful stimuli can not be stopped.
Conclusion: ESW of low energy levels between 0.04- 0.22mmJ/mm² cause an analgesic effect.

21. High Energy Shock Waves and 5-aminolevulinic acid: effects on a rat colon cancer cell line

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Device and producing company: Piezoson 100, Wolf
Introduction: In a previous study we demonstrated the ability of high energy shock waves (HESW), generated by a piezoelectric device, to activate natural porphyrin precursor 5-aminolevulinic acid (ALA), the most common photodynamic sensitizer, on a human colon cancer cell line, HT-29. Therefore, in order to progress our investigation to a syngeneic model of colon cancer, first we studied in vitro the cytotoxic effect of the combination of ALA and HESW, on DHD/K12/TRb rat colon cancer cells.
Methods: Cytotoxicity was investigated by cell growth curves. DHD/K12/TRb cells were exposed to ALA (50 microg/ml) for 24 h and then to HESW treatment (E1, EFD = 0.22 mJ/mm2, 1,000 impulses; and E2, EFD = 0.88 mJ/mm2, 500 impulses), and viable cell growth was determined by trypan blue die exclusion assay at days 1, 3 and 7 after HESW treatment. Cell death was investigated by flow cytometry analysis. DHD/K12/TRb cells were exposed to ALA (50 microg/ml) for 24 h and then to HESW treatment (E1 and E2), and stained with annexin-V-fluorescin (A-V-FITC)/propidium iodide (PI) at 24 h after HESW treatment. Viable cells were defined to be A-V-FITC and PI negative.
Results: ALA exposed to HESW resulted in a significant reduction of in vitro cancer cell proliferation at day 3 with respect to cells exposed to ALA ($p<0.01$) or HESW ($p<0.001$) alone. An enhancement of necrotic and apoptotic cells was observed after the combined treatment with ALA and HESW E1 (3.1 and 6.4 fold increase vs. ALA alone) or E2 (3.4 and 5.3 fold increase vs. ALA alone).
Discussion: 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: In conclusion, HESW may be proposed for the sonodynamic treatment of colon and liver cancer in in vivo animal model.

22. High energy shock waves (HESW) enhance 5-aminolevulinic acid and paclitaxel cytotoxity in anaplastic thyreoid cancer cells.

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Device and producing company: Piezoson 100; Richard Wolf, Knittlingen, Germany

Introduction: The use of paclitaxel for the treatment of anaplastic thyroid cancer (ATC) is under clinical investigation; it determines about 50% response rate, but it is not able to alter the fatal outcome of patients with this aggressive carcinoma. High energy shock waves (HESW) have been shown to cause a transient increase in the permeability of cell membranes thus allowing higher intracellular drug concentrations. 5-Aminolevulinic acid (ALA), a precursor of the endogenous photosensitizer protoporphyrin IX, is used in the photodynamic therapy (PDT) of cancer. HESW are under evaluation for their use as activator in ALA-PDT. The aim of the present study was to investigate the effect of HESW produced by a piezoelectric generator on anaplastic thyroid cancer cells' viability and sensitivity to paclitaxel and ALA.

Methods: Two different anaplastic thyroid cancer cell lines (ARO and CAL-62 cells) treated sequentially with ALA and paclitaxel were exposed to HESW. After treatment, cell viability and apoptosis induction were evaluated.

Results: Combined exposure to ALA, paclitaxel and shock waves resulted in a significant enhancement of cytotoxicity and induction of apoptosis in thyroid cancer cells with respect to cells treated with paclitaxel alone.

Discussion: HESW enhances cytotoxicity of paclitaxel and activates ALA-PDT, inducing cell damage. Moreover, the combined treatment with ALA, HESW and paclitaxel results in a further increase of cell death.

Conclusion: These data suggest the possibility to use HESW and ALA in combination with paclitaxel as a new promising therapy in the treatment of anaplastic thyroid cancer.

23. New RSWT protocols validation in inflamed tendon

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Device and producing company: Radial Shock Wave Therapy (RSWT) by a Swiss DolorClast from EMS

Introduction: The diversity of tendon injury could limit the use of RSWT. Our aim was to validate new RSWT protocols adapted to the type and location of tendonitis.

Methods: Patients suffering from pathologic tendonopathies were treated with RSWT and followed prospectively for six months. Selection criteria included prior radiology, only one therapy (IB), and the scrupulous respect of established protocols. Tendon tears were excluded. Pain killers without local injection were permitted if present before RSWT. Three protocols (P1, P2A, and P2B) were established. P1 was used for undamaged painful tendon of the shoulder and elbow. P2A was designed for tendon injury in the shoulder and infra-patella. P2B was used for hip, Achilles and sole tendonitis. Device parameters were adapted to both the protocol and patient tolerance. Each patient signed a written informed consent, and the study was approved by the local ethical committee.
Results: Out of 244 inflamed or injured tendons initially selected, 119 were excluded. In the remaining 125 pathologic tendons (100 patients) analysed, a five-month follow-up evaluation showed patient satisfaction of 100% for Achilles (7 tendons), 91% for plantar fascia injuries (18 patients, 22 locations), 89% for hip involvement (30 patients, 55 tendons), 88% for shoulder problems (15 patients, 17 tendons), and 58% for the 19 tendons located in the lateral elbow.
Discussion: No discussion
Conclusion: Our RSWT protocols could be validated for the hip, shoulders, plantar fascias, and Achilles tendonitis.

24. Extracorporeal Shockwave for Chronic Tendinopathies – Data Analysis.

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Device and producing company: REFLECTRON – HMT
Introduction: We investigate the success of ESWT on patients who underwent treatment for Plantar Fasciitis, Achilles Tendinopathies and calcified lesions of the shoulder. Based on a sample of patients from a retrospective study we are able to provide the probability, with its associated uncertainty, of a patient recovering after 180 days of the treatment.
Methods: We analyzed a sample of 486 patients with chronic tendinopathies treated between March 2001 and February 2006 for Plantar Fasciitis, Calcifying Tendinosis of the shoulder or Achilles tendinopathies. The subjects were evaluated by means of a clinical evaluation according to the Roles and Maudsley Score and the Visual Analogue Scale. We fitted a logistic regression model that considers the effect of gender, side of application, age, and pathologies from the follow up after 45, 90, and 180 days of the completion of treatment.
Results: We clearly notice an increasing pattern on the proportion of patients who move to categories 1 and 2 by the end of the 180 days. Our model point that the estimated odds ratio (OR) with respect to the side (right or left) the patient was treated for is not significant; whereas, women seem to have a higher probability of recovering as compared to men (OR=0.53).

Discussion: Given the profile of a new patient, we can estimate his probability, with its associated uncertainty, of being in category 1 ("excellent") after the end of the treatment.
Conclusion: Our statistical model provides evidence that the use of ESWT in Chronic Tendinopathies seems to significantly improve the condition of a patient after the treatment.

25. The practicalities of the application of the complex enthesopathy theory in orthopaedics

Viktor Vyacheslavovich Titov, Andrew Litvinenko

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Device and producing company: Swiss DolorClast, EMS, Switzerland.
Introduction: The effectiveness of extracorporeal shock-wave therapy for treatment of musculoskeletal system diseases is recognized worldwide. As is well known, the effectiveness of SWT treatment methods average 80%, however the algorithm of treatment which we use allows us to attain positive results in 96-98% of cases.
Methods: Our research was conducted with the Swiss DolorClast (Classic). We began our procedures with the necessary diagnostics, including only exploratory, USI or R-graphical research, but also the using the device on a feed-back principle.
Results: It is known that the causes of chronic diseases of the musculoskeletal system connected with the bands overpressure are the changes in the form of calcinosis and fibrosis. Moreover the same changes are certainly present in the "contiguous" bands of that anatomical area also. In this way the algesic impulse will be associated with such a band in which these changes are more expressed. Therefore, for every chronic disease of the musculoskeletal system there needs to be an examination of the complex of ligaments, tendons and myogeloses.
Discussion: In our practice we use the term "Complex enthesopathy" to refer to all ligamentoses, tendinoses and myogeloses of one anatomical area (complex enthesopathy of the 1st order) or of some contiguous anatomical areas (complex enthesopathy of the 2nd order). Consequently, when diagnosing and treating a disease, it is necessary to pay attention to the condition of the entire ligamentous apparatus of that area, not only to the "painful" band.
Conclusion: Our new approach to the diagnosis and treatment of musculoskeletal system diseases allows us to attain good and excellent results in 96-98% of cases.

26. Evaluation with ultrasound and color doppler of the results of ESWT for the control of hypervascular areas in Non-Insertional Achilles tendinosis. Power Doppler: new tool for ESWT

Roland Hamisultane

Institutions: ISMST (President 2008), SFOCAL(President), Grecho (groupement des rhumatologues echographistes), Antibes (France)
Device and producing company: Dornier Epos, Dornier Medical; Logic 5, GE
Introduction: There is considerable controversy regarding the origin of pain in chronic tendinosis. Even though tendon biopsies have shown an absence of inflammatory cell

infiltration, recent studies indicate that the pain is closely related to the presence of hypervascularization of the tendon. The preliminary study indicates that the effectiveness of ESWT on the neovessels correlates with reduced pain. The purpose of this study was to confirm the preliminary result and to determine if ultrasound with Power Doppler could be a new tool for determining the appropriate level of ESWT energy for the treatment.

Methods: We studied patients with Achilles tendinosis. Tendon hypervascularization was rated as: none (0), mild (1), moderate (2), or intense (3), based on Power Doppler ultrasound findings. The effect on pain during Achilles tendon loading activity was evaluated using a visual analogue scale (VAS). In this study 24 Achilles tendons in 23 patients with pain symptoms from the mid-portion of the Achilles tendon were included in the investigation; 18 chronic tendinoses (pain more than 3 months) and 6 recent tendinoses. At follow-up, all patients answered a questionnaire assessing their satisfaction with the result of their treatment, the level of present tendon loading activity, and tendon related symptoms. Clinical and ultrasound follow-up was done three to six weeks after three sonographically-guided shock wave treatments. We compare whether these results indicate an effect on the neovessels similar to that of Eccentric training or US- and CD-guided injections of the sclerosing agent Polidocanol.

Results: Neovascularization was found inside and outside the ventral side of the region with structural tendon changes in all tendons with chronic painful mid-portion Achilles tendinosis. Only one mild case of neovascularization was found in the recent tendinosis group. Before treatment, the mean VAS-score evaluating the amount of pain during Achilles tendon loading activity was 65 . At the six-week follow up, 22 of 24 patients were satisfied with the treatment, mean VAS score had decreased to 14, and in the majority of the tendons all neovessels had decreased. In the 2 patients that not were satisfied with the treatment (remaining tendon pain), multiple neovessels remained. In the chronic group, the mean VAS-score before treatment was 64 and decreased to 18. In the recent tedinosis group VAS-score initially was 68 and decreased to 10, all patients were satisfied, and in one case mild neovascularization appeared for a short time during the treatment.

Discussion: Treatment subjects received three sessions of ESWT of 2,000 shocks each at maximum energy level 4 (0.17 mJ/mm2). Because the patients receive neither sedation nor anesthesia, the energy level was determined by the maximum pain induced by ESWT that could be tolerated by each patient. In the recent group the mean energy level was 2 (low energy) and in the chonic group the mean level was 4 (mid and high energy). Better results were found in the recent group (VAS divided by 7), which indicate ESWT is effective for early tendinosis. In one case in the recent group, mild neovascularization was found for a short time during the treatment, which could indicate that the mechanism of ESWT on neovessels is different than that of polidocanol injections (biologic effect and no direct destruction). Good results were found in the chronic group (VAS divided by 3.5) correlating with the decrease of neovascularization.

Conclusion: This study indicates that the effect of ESWT on the neovessels correlates well with reduced pain. This effect maybe different than the destruction of neovessels by polidocanol injection (biological effect for tendon repair in the Wang model). Ultrasound with Power Doppler could be a tool to determine the level of energy (low energy for tendinosis within neovessels and high energy for hypervascular tendinosis), but additional randomized controlled trials are needed.

27. Ten-year results of high-energy extracorporeal shock wave therapy (electro-hydraulic) of tendinosis calcarea of the shoulder

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Institutions: Centre of High-energy Shock Wave Therapy Herne, Germany
Device and producing company: none
Introduction: In 1996 and 1997 we treated 76 patients with 84 cases of tendinosis calcarea of the shoulder. Each case followed the same procedure, combining a CT scan with exact detection of the calcification including the necessary rotation of the arm and treatment with ESWT directly after. This study was made to evaluate the percentage of re-calcification (which was found in 5% of the cases) and the need for operative treatment like arthroscopy of the shoulder within 1 year after ESWT (which was performed on only 4 patients). Full resorption of the calcification was found in nearly 90% of all treated shoulders. In conclusion, we think electro-hydraulic high-energy extracorporeal shock wave therapy is a highly reliable treatment in patients with tendinosis calcarea of the shoulder.

28. Falsities and false diagnosis in shock wave therapy

Ulrich Dreisilker, Rolf Rädel

Institutions: DKRS-Stoßwellenzentrum Bochum Wattenscheid
Device and producing company: Storz Medical - Duolith; HMT - Ossatron / Evotron
Introduction: The proper approach is very important to assure correct diagnosis of fasciitis plantaris, epycondylitis radialis and tendinosis calcarea.
Methods: We performed a control and review of patients failing ESWT by rechecking our diagnoses.
Results: A three-year control and follow up study clarified the symptoms which imitated a standard diagnosis of fasciitis plantaris, epycondylitis radialis or tendinosis calcarea. According to our control, in many cases ESWT was not indicated and therefore was destined to fail. For example, 67 heels were treated for fasciitis plantaris but later diagnoses indicated the following: 3 fractures of the ankle, 8 varicose and lymphatic edemas with compression of the tibial nerve, 6 ganglions, 7 patients with hyperuricemia, and 18 patients with Triggerpoints at the triceps surae muscle. Of the 56 patients originally diagnosed with radial epicondylitis, later determinations indicated 3 had compressions r. recurrens n. radialis, 6 had compressions in the supinator slit, 3 had scalenus slit and 18 had trigger points. Out of 76 patients originally diagnosed with tendinosis calcarea only 17 were patients with calcifying tendinopathy; 14 had supraspinatus tendinopathy without calcification and the remaining 46 patients had a rotator cuff lesion.
Discussion: Our results clearly demonstrate that it is very important to review the diagnosis of these standard indications, both before and after the treatment.
Conclusion: An accurate diagnosis is essential for the successful use and promotion of ESWT.

29. ESWT as an option when surgery fails

Paulo Facciolla Kertzman, Jose Eid

Institutions: Clinica Campo Belo e Clinica Brasil
Device and producing company: Dolorclast, EMS
Introduction: Treatment with ESWT for tendinopathies is a well-known treatment option with good results reported in a large number of publications. We treated some cases after failed open or arthroscopic procedures.
Methods: We treated two cases with recalcitrant plantar fasciitis after open surgery, two after open repair of Achilles tendon rupture, two patellar tendons after open procedures and three cases of lateral epicondylitis after arthroscopic surgery. All patients underwent three sessions with 2000 shocks at 0.3 mJ/mm2 within a week interval.
Results: With the exception of one patellar tendon, in all cases, after 3 months pain was reduced and the patients could return to their daily activities.
Discussion: The treatment with ESW in our clinic is very effective for chronic tendinopathies and is offered to the patients before any surgical procedure.
Conclusion: ESWT is an option for patients with tendinopathies after failed surgery.

30. Flow analysis of out-patient activity: one-year report. Reflections on shock-wave therapy indications.

Paolo Buselli, Sara Messina

Institutions: Azienda Ospedaliera di Lodi Rehabilitation Department Strada Provinciale 19 S.Angelo Lodigiano (LO) Italy
Device and producing company: Ossatron OSA 140, HMT s.r.l.
Introduction: Shock-wave therapy (ESWT), as used for various recently introduced treatments carried out in specialist centres, is often misinterpreted. This could be due to a certain lack of awareness by general practitioners or specialists on this type of therapy or simply due to an incorrect diagnosis or the decision to treat similar pathologies with less expensive and more available therapies. We have recently performed a systematic review of our clinical cases evaluated over a one-year period in our ESWT out-patient clinic.
Methods: We reported all referrals to the ESWT service to the Azienda Ospedaliera of Lodi in 2007; for each medical examination we recorded the diagnosis, previous treatment, the appropriateness of the request and the patient's clinical situation at the time of the visit, and therapy decided on.
Results: Soft tissue pathologies make up more than 90% of ESWT requests; shoulder tendinopathy being the most frequent complaint, followed by plantar fasciitis and elbow lateral epicondylitis. ESWT was used on only half of the patients examined.
Discussion: We noted that ESWT was all too often proposed as initial treatment and, in a large number of cases, we found discrepancies with the patient's real clinical situation. ESWT was used on far fewer cases than initially brought to our attention.
Conclusion: According to our data, we have discovered a serious lack of information on the real indications of ESWT among GPs and even among many specialists. As a result, in order avoid possible legal issues, physicians who perform ESWT should be extremely careful about treating patients who may have been diagnosed incorrectly.

31. Our experience using the Dornier Epos Ultra High Energy Protocol one year follow-up

David H. Zuckerman, Denise Ashcraft

Institutions: Excellence Shockwave Therapy, 13 West Ave., PO Box 145, Woodstown, New Jersey USA

Device and producing company: Dornier Epos Ultra

Introduction: The study will detail our experience using high energy ESWT to treat plantar fasciitis, Achilles tendonitis, and tennis elbow. This group of patients was treated in 2005. One-year follow-up surveys were mailed to all patients that were treated by Excellence Shockwave Therapy physicians. Results were evaluated and are ready to be reported.

Methods: All patients were treated with single session high energy ESWT under local and/or regional anesthesia. All patients were treated in an office setting. Patients were given a second ESWT treatment after the 4-6 month mark if indicated

Results: Average VAS Pre-ESWT was 8.32. At one–year follow-up, average VAS was 1.53 as reported by Patient R/M - 88.31%.

Discussion: We will discuss reasons for success and reasons for failure and how we prevent and/or reduce failures. ESWT is an excellent treatment method however proper selection and patient education play a major part in higher successful outcomes.

Conclusion: Patient selection with proper evaluation is very important. Post-ESWT care and use of additional ESWT treatments can make the difference between success and failure of the procedure.

32. Focused or Radial Shockwave Therapy?

Nick Boden, Thomas Ong

Institutions: Chiropractic Physician KL Integrated Healthcare Centre Sdn Bhd Suite A-5-2 Megan Avenue II 12 Jalan Yap Kwan Seng KL 50450

Device and producing company: HMT (Evotron); EMS (Swiss DolorClast)

Introduction: Much discussion surrounds patient tolerance, effectiveness and cost per treatment of focused and radial ESWT. We analysed our results of using: (i) a combination of focused and radial ESWT, (ii) focused ESWT alone and (iii) r-ESWT alone, in the treatment of pain related to AVN of the left hip in a 45-year-old Chinese male.

Methods: During the first treatment regimen, the patient received 4 combination treatments and 1 rESWT treatment over 8 weeks. The patient then had 2 months rest before receiving a second treatment regimen consisting of 1 combination treatment, 1 Focused ESWT only treatment and 3 rESWT only treatments over 8 weeks.

Results: After the first treatment regimen a 20% decrease in pain was noted (pain rating scale) as well as a 20% increase in ROM. After the second treatment regimen a further 30% decrease in pain and 30% increase in ROM were noted. Pain during Evotron treatment (focused ESWT) was 8 out of 10 and during Dolorclast treatment (rESWT) was 4 out of 10. Results were maintained at 15-month telephonic follow up.

Discussion: Both types of treatments appeared to help the patient, with rESWT being much better tolerated. Cost per treatment did not differ between the two machines. A larger study group with a more structured protocol would be useful to explore further.

Conclusion: ESWT appears to be effective in the treatment of pain associated with AVN of the hip, and there appears to be little difference between the effectiveness of the two devices used in the study although there was more tolerance to the rESWT device.

33. Avascular osteonecrosis in young patients: Long distance follow up of treatment with shock waves

Sergio Russo, Emanuele Astarita, Umberto Russo, Vincenzo Scarpato, Clemente Servodio Iammarrone

Institutions: University of Naples Federico II Department of Surgery, Orthopaedics, Traumatology and Emergency via S.Pansini 5 Naples - ITALY
Device and producing company: Modulith SLK, Storz Medical A.G.
Introduction: The use of shock waves (SW) in young patients affected with bone osteonecrosis is not uniformly accepted. This is because there is the possibility of damaging the growth nucleus thereby causing a secondary deformity. With this study the AA show the results obtained in young patients treated with shock waves: follow up between 5 and 11 years. Specific precautions were used to avoid secondary deformity.
Methods: A lithotripter with a very small focus dimension (diameter 0.5cm) was used (Modulith SLK from Storz A.G.), with a pressure field convergence angle of 60° and focal distance of up to 16 cm. Careful targeting was obtained by using Rx-ray and the "window" was checked by in-line eco system. Every treatment session consisted of 4 applications (3,000 shots with maximum energy power of 0.1/0.4mJ/mm2. There was a minimum of 2 and maximum of 4 sessions.
Results: The results show good vascular response, pain disappearance and good range of recovered articulate movements in the absence of deformity.
Discussion: The shock wave effect on bone vascularization has been shown in various research. The goal of this paper is to open discussion about whether or not to treat young patients with this technique. The results show absence of deformity of the treated area. This is due to the use of low energy power, a small focal point, very careful aiming to avoid crossing the growth nucleuses. For these reasons it is very important to eliminate all movement of the young patient during treatment in order to avoid pain during the treatment.
Conclusion: The authors conclude this technique represents a safe method of treatment but it is necessary to adhere to all the required conditions.

34. Extracorporeal Shockwave in Hip Necrosis: Are combined therapies more effective than ESWT alone?

Ching-Jen Wang, Feng-Sheng Wang, Jih-Yang Ko, Hsuan-Ying Huang, Chung-Jen Chen, Yi-Chih Sun, Ya-Ju Yang

Institutions: Chang Gung University College of Medicine, Chang Gung Memorial Hospital Kaohsiung Medical Center Kaohsiung, Taiwan
Device and producing company: OssaTron orthotripter (Sanuwave, Alpharetta, GA, USA)
Introduction: Extracorporeal shockwave therapy (ESWT), hyperbaric oxygen therapy (HBO) and alendronate were reported effective in early osteonecrosis of the femoral head (ONFH). Some studies reported that ESWT works better than the gold standard core decompression. This study investigated whether combined therapies are more effective than ESWT alone in early ONFH.

Methods: Three comparison studies were conducted including: (1) ESWT vs. core decompression; (2) ESWT vs. combined ESWT and alendronate; and (3) ESWT vs. cocktail therapy (ESWT + HBO + alendronate). The evaluations included pain score, Harris hip score, radiograph and MR imaging. The primary end-point is the need for total hip replacement (THR).
Results: 23 patients (29 hips) treated with ESWT were compared with 25 patients (28 hips) treated with core decompression. The results showed better overall outcomes after ESWT than core decompression. THR was performed in 10% of ESWT group and 29% of surgical group. 25 patients (30 hips) treated with ESWT were compared to 23 patients (30 hips) treated with combined ESWT and oral alendronate. Comparable clinical results were noted in both groups at 2-year follow-up. THR was performed in 10% of ESWT group and 10% of combined group (P = 1.000). Another study compared 28 patients (50 hips) treated with cocktail therapy (ESWT + HBO + alendronate) with 35 patients (48 hips) treated with ESWT. The clinical results of both groups are comparable at two-year follow-up. THR was performed in 10% of cocktail group and 10.4% of ESWT group (P = 0.946).
Discussion: It is surmised that combined therapies of 2 or 3 modalities may work better than single ESWT alone in early ONFH. However, the results of this current study failed to demonstrate the synergistic effects from combined therapies.
Conclusion: ESWT is effective with or without the concomitant application of HBO and alendronate in early ONFH.

35. Extracorporeal shock waves in Kienböck disease: Clinical experience and scientific speculations

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Device and producing company: Modulith SLK, Storz Medical
Introduction: A gold standard therapy for avascular osteonecrosis of hamate has not yet been described in the Literature; in the latest stages, surgery is the only treatment. On the basis of positive results in the treatment of osteonecrosis of other bones, we decided to treat Kienbock disease with Extracorporeal Shock Waves (ESW).
Methods: From January 2003 to March 2008, 11 patients, suffering from Kienbock disease, were submitted to ESW treatment (Modulith SLK, Storz). The protocol consisted of repeated single sessions (4,000 – 5,000 shots at 0.35 – 0.45 mJ/mm2) under local anesthesia.
Results: Almost all patients showed a rapid improvement of pain, even after the first session, with the possibility of returning to daily and working activities. NMR controls did not correlate with the improvements in clinical symptoms: we observed only bone marrow edema resolution (especially in early stages), without a significant improvement of osteonecrosis.
Discussion: These clinical results seem to confirm the possibility of successfully treating Kienbock disease, although without significant imaging improvement of the osteonecrotic site. These positive results are confirmed by recent data, which describes the possibility to counteract osteonecrosis degeneration, as well as to induce Vascular Endothelial Growth Factor production in subchondral bone, through the use of ESW. Moreover, the possibility of

obtaining bone marrow edema resolution, already confirmed by previous data, opens interesting therapeutical perspectives.
Conclusion: It is recognized in the Literature that earlier diagnosis and treatment of Kienbock disease can avoid more invasive and destructive surgery. ESW treatment could be considered a valid therapeutical option, especially in the early stages, for slowing or reducing the progression of osteonecrosis, thus avoiding or delaying surgery and consequent sequelae.

36. Twenty-one years ago the first patent was filed for treating bone pathologies using high energy shock waves.

Peter Marinov Mihaylov, V. Valchanov (died in 2001), Heriberto Bickman

Institutions: University Hospital of the City Luanda, Angola
Device and producing company: Osteostar – Siemens
Introduction: Twenty-one years ago the authors patented a method and apparatus for treatment of bone pathology with high-energy shock waves. The authors, Mihaylov and Valchanov, began experimenting on the impact of shockwaves on bones at the beginning of 1986. Their idea was derived from the method of lithotripsy for treating kidney-stones in the distal part of the ureter with Dornier's HM-3 lithotripter.
Methods: The experiments were performed on corpse bones and in vivo on rabbits and dogs. As a result, the authors decided to begin treatment of pseudoarthrosis with retarded consolidation with shockwaves instead of the method by Judet (1965). Their idea was to destroy the eburnated edges of the pseudoarthrosis and, at the same time, keep intact the periosteum. That way, by preserving the osteogenic material in the periosteum, rapid vascularization and consolidation of the bone is achieved.
Results: In the period from June 1986 to October 1986 the first patients, with a diagnosis of pseudoarthrosis were treated. A modified version of Dornier's HM-3 lithotripter was used. After the excellent results achieved with ten patients, the authors decided to widen the usage of ESWOR Extracorporeal shockwave osteorestoration.
Discussion: A new specialized device for orthopedic services, called the "Osteorestorer", was designed in collaboration with Prof. Patrashkov and engineers, Manolov and Kerin.
Conclusion: The prototype was constructed in "Electron" Varna, Bulgaria at the beginning of 1987. The method and apparatus have been registered on 19.05.1987 by Patent Office of Republic of Bulgaria with N79804, patented USA N4979501 with priority-date 19.05.1987 and pretences for 9 medical applications. Another apparatus was designed in collaboration with Siemens, called the "Osteostar". The treatment was applied to over 380 patients on almost every long bone in the human body at Sofia's Military Medical Academy.

37. Our Experience with Shockwave Therapy

Fernando Dujo Rodriguez

Institutions: Fraternidad Muprespa, occupational accidents mutual. Hospital Central Paseo De La Habana Nº 83-85 Madrid
Device and producing company: OrthoGold 280 (USA) / Orthowave 280c (Outside USA), Tissue Regeneration Technologies (TRT), USA (manufactured by MTS Europe GmbH, Germany)

Introduction: We studied the application of high energy shockwaves as an alternative to other treatments, using shockwaves as complementary treatment when orthopaedic and surgical treatments have failed in traumatology.
Methods: The patients were divided into different groups according to their pathology: (i) bone pathologies and (ii) insertion tendinopathies with or without calcifications. As we are dealing with patients in the labour sector, this implies typical characteristics, especially with regard to being refractory concerning pain.
Results: We achieved bony healing in 99% of patients who had had non-unions for up to two years and 90% in pseudoarthrosis of more than two years duration. We achieved 100% improvement in patients with delayed healing fractures and calcifications. ESWT was successful in 60% of patients with insertion tendinopathies.
Discussion: We treated patients in no more than 4 sessions, one every two weeks, when the application was done under anaesthesia; and we treated patients with eight sessions, one per week, when the application was done without anesthesia.
Conclusion: For our institution, high energy shockwave therapy is the treatment of choice in delayed healing fractures and pseudoarthroses of less than two years duration; ESWT is used in established pseudoarthroses (older than two years) and in patients with calcifications. It also can be used as a first attempt to treat insertion tendinopathies.

38. ESWT in Delayed Union of the Ulna

Dimitar Ivanov Raykov

Institutions: Varna University of Medicine, Dept. of Orthopaedics and Traumatology - "St. Anna Hospital" 55 Drinov str., Varna - 9001, Bulgaria
Device and producing company: STONELITH V5
Introduction: Extracorporeal shock wave therapy (ESWT) is proven to be effective in delayed bone unions or pseudoarthrosis after fractures of the long bones. The aim of this study is to present our experience with high energy extracorporeal shock wave therapy (ESWT) in complicated ulnar diaphysial fractures. The treatment is provided by an ordinary urologic electrohydraulic lithotripter.
Methods: The study group consists of 8 patients with delayed union of the ulna. Six of them had closed fractures and 2 of them had open fractures. All of them underwent prior surgical procedures – open reduction and plate fixation, early removal because of infection with a late picture delayed union or non-union.
Results: By applying ESWT in appropriate doses – one procedure of 14-16KV and 3,000 shocks - we observed early X-ray evidence of bone consolidation in 4 patients on the 45th day. We repeated the procedure in the other 4 and assessed bone consolidation in 3 of them after another 45 days. The 8th patient did not achieve bone union and underwent re-operation.
Discussion: The study shows a success rate of 87.5% in bone healing of the ulna with delayed unions, without any risks following surgical intervention.
Conclusion: ESWT is an effective method in cases of complicated ulnar fractures, even when performed with ordinary and popular urolithotripter devices. It confirms the benefit of shock waves and makes this method more applicable for daily traumatology.

39. Delayed union and non-union in pediatric patients treated with ESWT.

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Device and producing company: ORTHOSPEC / MEDISPEC

Introduction: Pediatric patients with bone repair disturbances following corrective osteotomy represent a considerable burden to surgeons and significant delays to surgical schedule processes for each case. Many times these patients exhibit intrinsic bone repair damage, therefore all medical decisions concerning them require expertise.

Methods: From January 2002 to December 2007 we treated 8 children (3 male, 5 female; average age - 12 years, age range: 4 to 16 years) after failed limb lengthening surgeries. For 5 Delayed Union cases and 3 definite Non-Unions, the main bone diagnosis was: Proximal Femoral Focal Deficiency (PFFD, 3), Pyogenic Hip Arthritis with failed femur-ischial support (2), Idiopathic Short Stature (ISS, 1), Achondroplasia (1) and Tibiae Pseudo-Arthosis in Neurofibromatosis (NF1, 1). Seven cases received a single session of SW (Orthospec - 5000 impacts-0.33mJ/mm2-40MPa). One case (PFFD, rosary osteotomy into 5 fragments with infected non-union) was treated with three similar sessions over a period of 10 weeks. Immobilization was indicated or maintained on all cases until bone repair.

Results: Seven cases achieved resolution (average time - 12 weeks) and one case (achondroplasia) failed, maintaining her non-union status longer than 20 weeks and requiring a massive bone graft.

Discussion: In literature, intrinsic bone repair disturbances are described only for NF1 and Achondroplasia patients. For this last condition, SW failure occurred mainly because we intended to solve a massive lateral defect of the lengthened femur. In this case, despite several previous surgical procedures , including one infected multi-focal non-union and pseudo-arthosis in Neurofibromatosis, we observed significant bone repair induced by shockwave treatment.

Conclusion: SW might be the most important post-operative tool for those pediatric patients with post-surgical complications related to bone consolidation. The adequate response of tibiae pseudo-arthosis in NF1 to shockwaves needs further studies. In this sense, a novel protein specifically associated to osteoblast during osteogenesis (Osteocrin) seems to be a good marker of normal or abnormal bone repair and has been selected as a "bone molecular target" in our experimental studies with SW.

40. Extracorporeal Shockwave Therapy for Non-Unions and Delayed Healing Fractures

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

Institutions: Trauma Centre Meidling, Vienna, Austria

Device and producing company: OrthoGold 280 (USA) / Orthowave 280c (Outside USA), Tissue Regeneration Technologies (TRT), USA manufactured by MTS Europe GmbH, Germany

Introduction: The objective of every fracture treatment is to reunite the fracture fragments in an anatomical position and completely restore the function of the injured section of the skeleton as quickly as possible. Despite today's sophisticated technologies and good primary treatment, 1-3% of all bone fractures develop into pseudarthrosis. Surgical treatment with debridement of the pseudoarthrotic tissue, cleaning of the fragment edges, insertion of autologous spongiosa and stabilization with osteosynthesis material is considered the "gold standard" for the treatment of pseudarthrosis. However, these surgical procedures are extremely traumatic for the patient, costly, time-consuming, and are associated with a high rate of complications. Therefore after successful pilot studies, in December 1998 the Trauma Centre Meidling started to treat non-unions regularly with shockwave therapy. Different devices were used and success rates between 63% and 75% were generated. Since August 2005 we have used the Orthowave 280c, Tissue Regeneration Technologies (manufactured by MTS Europe GmbH, Konstanz, Germany).

Methods: From the start of the study, more than 50 patient-specific data items were stored in a database developed especially to permit the combination of a broad range of parameters. This database structure serves as the basis for quality assurance measures and enables the researchers to determine the optimal treatment parameters and other important criteria. This database containing documentation of the treatment of pseudarthrosis with ESWT is made available to all interested parties free of charge; it can be ordered from the authors. Treatment was basically envisaged as a single treatment. Depending on the region to be treated, shockwave therapy was administered under general, regional or local anaesthesia. Thus far, 527 patients have been treated. As of March 2008, results of 349 patients with complete follow up are available. The patients, referred from 45 different hospitals, consisted of 114 females (33%) and 235 males (67%). The mean age was 49.0 years with a range from 16-91years. The average delay between the injury or the last operation and the shockwave therapy was 11.7 months (in 241 / 69% patients more than 6 months, in 108 / 31% patients between 3 and 6 months / delayed healing). Eighteen of the non-unions were infected. Depending on the localization, between 2,000 and 4,000 pulses were applied (1,000 pulses per treatment location). We used an energy flow density (EFD) of 0.35 mJ/mm2 for all bone treatments. For evaluation, the bony consolidation of the fracture/non-union was observed on plain radiography or CT. Following shockwave therapy the pseudarthrosis is immobilized like a fresh fracture. This is usually carried out with a plaster cast or plastic splint; in 3 patients with especially mobile tibia non-unions, an external fixator was used. Fixation is not necessary when the pseudarthrosis has been treated with appropriate osteosynthesis material and this material exhibits no signs of loosening upon clinical or radiological examination. It can be assumed that the healing process is initially accompanied by neovascularization; for this reason, we try to prevent micro movements of the non-union during the first 3-4 weeks after treatment to preclude tearing of the new capillaries. It may be necessary, in some cases, for the patients to avoid full weight bearing on the affected extremity during this period. The

patient's cooperation must be elicited by a detailed briefing since most patients are asymptomatic directly after the treatment, owing to the analgesic effects of the shockwaves, and want to put their full weight on the affected extremity again. A pseudarthrosis gap with a width greater than 5 mm shows a poor prognosis. In cases where bony remodelling of the non-union could not be demonstrated after 3 to 6 months, patients were given the option of surgical repair. Numerous patients, especially those who had undergone multiple operations previously, refused this offer. This led to a relatively high number (15.9%) of repeated treatments. In exceptional cases (9), more than two treatments were carried out. The group of patients undergoing repeat ESWT included patients for whom a complicated pseudarthrosis operation was contraindicated for internal reasons or could have been carried out only at considerable risk to the patient.

Results: Osseous union was achieved in 282 (81%) of the pseudarthroses. No complications occurred other than the adverse reactions that have already been observed following shockwave therapy (i.e. local swelling, petecheal bleeding and haematoma). Even though the mechanism of action of shockwave therapy has not yet been fully explored, we are convinced that ESWT is an effective, inexpensive and time-saving therapeutic modality with an almost zero rate of complications. Therefore in Austria, ESWT is considered as the therapy of first choice for non-unions and delayed unions that do not require surgical realignment.

41. Shock Wave Treatment for Non-Unions - Verona Experience

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Institutions: Shock wave unit – and surgery dept., University Hospital of Verona, Italy.

Device and producing company: Modulith SLK, Storz Medical AG

Introduction: We will present our personal experience matured in the treatment of non-unions with extracorporeal shock therapy at the Shock Wave Unit of the University Hospital of Verona (Italy). The evaluation of the results obtained during ten years of treatments provides important data regarding the indications, the protocols of therapy, the prognostic factors and the percentage of successes attended.

Methods: Our series includes 581 cases of non-union of different bony segments. The introduced data refer to the period between 1997 and 2007 and is related to 482 evaluated cases. The bony segments were: humerus - 30, radius - 70, ulna - 54, carpal scaphoid - 80, hand - 48, clavicle - 7, femur - 64, tibia - 96, fibula - 6, foot - 27.

Results: Follow up is between a minimum of six months and a maximum of ten years. The shock wave therapy protocol, including number of applications, energy intensity and number of impulses, depends on factors such as duration, localization and seriousness of the non-union.

Discussion: The percentage of successful treatments has risen considerably over time with notable factor being the type and the localization of the non-union. The therapy has shown a total absence of collateral effects for the reported protocols.

Conclusion: The analysis of the results obtained during ten years of treatments offers useful information to the expert practitioner in the choice of therapy to undertake for treatment of the non-union. The Authors give an interpretation of the reasons for the failed treatments with regard to some bones districts.

42. The first experience of shock wave application in the treatment of chronic prostatitis

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Device and producing company: Compact, Dornier

Introduction: The unique biological properties of shock waves (SW) allow us, for the first time, to apply them to the prostate in patients with chronic prostatitis (CP).

Methods: We performed a prospective study of the results of treating 68 patients with CP using shock wave therapy (SWT) based on technique we developed (basic group) versus traditional physiotherapeutic cure (control group).

Results: We found that the action of SWT produced a quick and apparently anesthetic effect, which occurred after 1 or 2 procedures. In the basic group, the maximum systolic flow in prostate vessels increased 81 % (on average), while in the control group the increase was 47 % ($p < 0.001$). The maximum speed of urination increased to/by? 36 % (on average), while in the control group it increased only 19 % ($p < 0.001$). High efficacy of the method was proved in the cases of fibrous forms of CP. No apparent side effects of the SWT including spermograms were observed.

Discussion: The parameters of the SWT that we developed allow SW application to the prostate because of the anesthetic and anti-inflammatory effect, increase of the blood supply and activation of the metabolic processes, and decrease of fibrosclerotic changes.

Conclusion: SWT with the parameters we developed is an effective and safe method in the treatment of CP including difficult forms of CP which are resistant to other kinds of physiotherapeutic action.

43. Evaluation of the therapeutic efficacy of shock wave treatment in patients affected by rhizoarthrosis

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

Introduction: The thumb is the main digit on which the complexity of human prehension depends. Instability of the carpometacarpal (CMC) joint is connected to an aberrant motion and is associated with loss of stability, deformity and pain. The evolution of this pathology involves the presence of marked adduction at CMC joint with eventual subluxation. Physical therapy showed no efficacy in this kind of disorder.

Methods: We enrolled 20 patients affected by rhizoarthrosis of the 1st or 2nd degree according to Nalebuff classification, and we performed two sessions of shock wave therapy (ESWT) over a 3-week interval. Patients were evaluated with the Visual Analogical Scale, with pain response on Fisher's Algometer, with the pinch test and palmar test prior to treatment and then 1 month, 3 months, and 6 months after treatment.

Results: Our results indicate a statistically significant reduction of pain and an improved range of motion. This improvement was maintained at the 3 month follow-up evaluation, but at 6 months we noted a decrease in the clinical condition.

Discussion: Despite the fact that ESWT is not indicated for osteoarthritis diseases, it would seem to be an interesting approach for patients affected by rhizoarthrosis at the early stages; it

was well tolerated and no adverse events were noted. Furthermore, this kind of treatment can delay and sometimes prevent surgical intervention, which in any case has often poor results which did not always resolve clinical and functional problems.
Conclusion: According to our experience, patients treated with ESWT showed good clinical and functional results with a better capacity to perform their own activity for a medium-term period of time. Further double-blind studies are needed in order to provide more in-depth analysis of the effects of ESWT on this disease.

44. Shockwave treatment for deep orthopaedic infections-an experimental model.

Mustafa Hafez, Coombs R, Petrou M, Hanna M, Maher S, Asopa V and Ramsay J

Institutions: Imperial College London, Charing Cross Hospital, Department of Musculoskeletal Surgery

Introduction: Deep orthopaedic infection is normally treated by major revision surgery. A proportion of patients are not suitable for operation. Shockwave treatment for deep sepsis is a potentially valuable alternative.
Methods: Experiments with Multi resistant Staphylococcus aureus have been carried out using beef muscle. The microorganisms were sandwiched between different concentrations of sterile agar before the shockwave treatment. Each specimen was localised with X-ray.
The initial experiments were carried out with a low energy of 235 SMLI. Further experiments were carried out with high energy of 400SMLI.
Results: The low energy shock waves failed to kill the bacteria.
Once the energy was increased to 400 SMLI a statistically significant kill rate was observed for the Multi resistant bacteria.
This was in vitro model in which additional biological factors were not active. In the biological situation, shockwaves may promote angiogenesis, can stimulate the immune system and may also lead to differentiation of stem cells.

45. Shockwave treatment for aseptic loosening of prostheses

Richard Coombs, Moustafa Hafez , Michael Petrou , Milad Hanna ,Maher Shah ,Vipen Asopa, Johnson Ramsay

Institutions: Imperial College London, Charing Cross Hospital, Department of Musculoskeletal Surgery

Methods: Shockwave treatment has proven helpful for deep infections of implants in patients who are not suitable for operative intervention. We have experience of a patient who had undergone a massive replacement of the left distal femur for a tumour. Five years later she developed a bacteremic infection of the implant with chronic sinuses leaking pus from the tibial component.
Despite vigorous treatment with appropriate antibiotics, the sepsis continued for five years. Surgical revision was considered but the patient could not accept the inevitable significant risk of an above knee amputation.

The patient developed renal failure and required regular dialysis. She was referred for a renal transplant but could not be accepted on the programme with a chronic infection which could jeopardise the outcome.
Shockwave treatment was provided and four sessions led to the ultimate complete healing of the infected sinuses.
Since developing the sepsis, the patient had experienced extreme difficulty in mobilising because the tibial component appeared to be loose within the bone. As the sinuses healed, the patient found that she could bear weight on her leg for the first time for several years.
A beneficial side effect of shockwave treatment appeared to be consolidation of the implant within the bone. Shockwave treatment is proposed as a potential valuable treatment for aseptic loosening of hip and knee replacements.
National Joint Registries now provide objective information on the incidence of early complications. Aseptic loosening is the most common reason for early revision of hip prostheses. In the British National Joint Registry aseptic loosening accounts for more than 60% of cases requiring revision within the first three years of implantation. This has comprised a total of more than 8,000 patients over a three year period.
Discussion: We are at present seeking funding for an appropriate animal experimental model to establish the efficacy of shockwave treatment consolidating implants within bone. There is concern that shockwave treatment could delaminate the hydroxyapatite coating of uncemented prostheses. In addition shockwave treatment could fragment bone cement. Push out tests and histological examinations are required before clinical trials of such treatment can be advocated.

46. Efficacy and research of extracorporeal shock wave therapy in the treatment of main postural muscles (Comparison of MET and ESWT)

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Device and producing company: Duolith (Storz Medical)

Introduction: MET (Muscle Energy Techniques) has been reported to be effective for reducing pain intensity and disability in subjects suffering with low back pain (LBP).

Methods: We applied combined ESWT (focussed and non-focussed shock waves) to 26 patients with acute LBP (less than 12 weeks duration) for about 4 weeks (4-7 sessions). Patients were diagnosed and included with a segmental flexion restriction (extended, ipsilaterally rotated and side-bent - ERS dysfunction). They were excluded if they had radiating pain, motor weakness, absent reflexes, previous back surgery, or chronic pain of more than 12 weeks duration. Patients assigned into the matched MET control group received a specific MET program for lumbal dysfunction. Both groups were given a home exercise program. All patients were seen twice a week for 4 weeks. All patients then performed a strengthening exercise program supervised by an instructor of our rehabilitation center who was blinded to the treatment allocation.

Results: Those patients treated with ESWT (according to the anatomy trains of MYERS) showed a significantly higher change in the Disability Index scores. The spinal ROM (side lying passive ROM) was higher in the ESWT group than in the matched control patients.

Discussion: This study supports the use and effectiveness of ESWT on spinal pain to increase spinal ROM and improve clinical indicators of pain and disability.

Conclusion: Further investigation of duration of these effects and the clinical benefit to symptomatic individuals is needed.

47. Combined EPAT/Focussed Shock Wave Therapy and Trigger Points in Sports Medicine

Ulrich Piontkowski, Silvia Sommer

Institutions: SWC Bietigheim Steinheimer Strasse 7-9 D- 74321 Bietigheim-Bissingen

Device and producing company: Duolith SD 1, STORZ MEDICAL

Introduction: Using D-Actor technology (pressure pulse therapy - low energy) combined with focussed shock wave therapy (high energy) we have been treating myofascial trigger points according to the model of Anatomy Trains (Myers) for about 5 years.

Methods: We performed a preliminary study from 07/2004 to 12/2007 in 412 patients (runners), ages 24 - 41, to soften the impact of their feet and the associated muscle chains. Clinical and radiographic parameters, VAS and patient satisfaction level were evaluated. Follow up was performed every 8 weeks for a total period of six months. Descriptive and interferential statistical analysis were performed, based on Pearson`s coefficients of correlation and Chi square analysis.

Results: The study shows the efficacy and safety of EPAT and shock wave technologies were: excellent in 22.1%, good in 47%, acceptable in 20.1% and poor in 10.8 % of patients six months after first treatment.
Discussion: A limited numbers of sessions (3-4) is useful to reduce pain, but careful monitoring of the response is required prior a second or third (or fourth session). (Elimination of end-plated dysfunction - hypoxia normalization in trigger points - dissolution of contraction nodes - stimulation of metabolism in affected muscle fibers.)
Conclusion: The mobile combined EPAT/Shock Wave Therapy is effective and safe in chronic and acute lesions in Sports medicine, especially in running sports.

48. Requirements for Research in ESWT Management of Spasticity

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Device and producing company: DERMAGOLD, Tissue Regeneration Technolgies (TRT) (Outside USA - ORTHOWAVE 180c), MTS Europe GmbH
PIEZOWAVE, WOLF
Introduction: Spasticity following brain injury is usually permanent and if unmanaged results in contractures or fixed deformities. There have been suggestions that ESWT can help decrease in muscle tone in spasticity. Because spasticity occurs in a wide range of muscles from the small muscles of the hand to large muscles of the legs it is uncertain as to the techniques required, the optimal equipment design, the muscle groups with the greatest potential for treatment and the study design. This pilot study of two types of ESWT machines on a range of severe spasticity in neurological conditions aimed to answer some of these questions.
Methods: An uncontrolled trial of ESWT was tried on ten patients with severe spasticity. Two ESWT machines were tried – Orthowave 180 - with both focussed (6 areas) and unfocussed (12 areas) heads and a Wolf Peizo Wave machine (3 areas). Patients included in this pilot study were those patients on rehabilitation wards in a hospital specialising in severe forms of neurological disorders. The patients all had acute onset brain damage due to trauma, anoxia or subarachnoid haemorrhage. The contracted limb was treated at the muscle tendon origins and insertions and also over the muscle belly. Measurement of range of movement was taken using the Neutral Zero Method, a standardised method of measurement of range of movement from a defined neutral point using a goniometer. This gave three measurement components: the range of flexion; the extension; and the level at which the deformity was fixed as a starting point. This assessment was carried out for passive movement of the joints and also the range for active movement by the patient.
Results: The treatment approach, both in time and area treated, needed to change throughout each session depending on the degree of muscle relaxation during the session, especially in the presence of deformities. The two ESWT devices used had both advantages and disadvantages: The Orthowave therapy head was heavy to hold, especially for long periods, but easily moulded to the accessible skin surface of a contracted hand whereas the Piezowave head was more difficult to easily access some of the joints in a contracted limb. The high noise level of the Orthowave increased the spasticity in some patients and made it impossible to carry out in the presence of other patients thus limiting the treatment environment. Since it started up at a higher energy level than was required for treatment and

the level could only be reduced by firing unnecessary shockwaves this added to the noise level without benefiting the patient. The Peizowave was a very quiet machine to work with. The Orthowave therapy head was easy to use and clean between patient treatments, whereas the Piezowave had to be dismantled after each patient for thorough cleaning. The Orthowave was not easy to push from one ward to another, whereas the Peizowave, a much smaller machine, was stored and moved around the hospital on a large dressings trolley.
Discussion: Since physiotherapy could not be discontinued on ethical grounds it is suggested that the most appropriate study is a randomised cross-over study of physiotherapy + placebo ESWT vs. physiotherapy + ESWT. The nature of spasticity is such that external factors such as sudden changes in temperature and noise increase the muscle tone. The sudden impact noise level is therefore an important factor limiting treatment with ESWT. This study suggests that the optimal requirements of an ESWT machine for treating spasticity are: small head, flexibility for access to a wide range of joints, quiet, ease of cleaning (or availability of disposable covers) and ease of mobility.
Conclusion: A randomised controlled trial of physiotherapy vs. physiotherapy + ESWT is recommended. The optimal ESWT machine for treating spasticity needs to be quiet, have a small head, be flexibile to enable access to a wide range of joints, be easily cleaned (or have disposable covers) and be easily mobile.

49. Radial extracorporeal shock wave therapy (rESWT) in the treatment of spasticity in cerebral palsy: a preliminary report.

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Institutions: Associació de Paràlisi Cerebral (ASPACE). Centre Pilot Arcàngel Sant Gabriel. Barcelona EUIFN Blanquerna. Universitat Ramon Llull. Barcelona. Spain
Device and producing company: Swiss Dolor Clast, EMS
Introduction: Spasticity is a disorder of excess muscle tone associated with central nervous system disease. Cerebral palsy (CP) is a central nervous system deficit resulting from a non-progressive lesion in the developing brain. Although the brain lesions are static, the movement disorders that arise are not unchanging and are characterized by atypical muscle tone, posture and movement. The spastic motor type is the most common form of CP and its conventional therapeutic management may include splinting/casting, passive stretching, facilitation of posture and movement, spasticity-reducing medication, botulinum toxin and surgery (Wasiak 2004). ESWT reduces hypertonia of the wrist and finger muscles in patients affected by stroke (Manganotti 2005). The aim of this initial experience was to evaluate the effect of radial extracorporeal shock wave therapy (rESWT) in the treatment of spasticity in patients with cerebral palsy.
Methods: In April 2008, 3 patients with spastic cerebral palsy, 2 men (34 and 48 years old) and 1 woman (42 years old), were treated with rESWT. The patients were treated in 1 session only. The muscle groups were the following: biceps, wrist flexors and triceps surae in all patients and the thenar eminence in a sole patient. Number of impulses: 2,000 in each muscle group. Device used: Swiss Dolor Clast (EMS-Switzerland). Energy flux density: 0.10mJ/mm2. Spasticity was evaluated by the Aschworth Scale from 0 to 4 (0 = no spasticity to 4 = severe spasticity) in each muscle group. Passive elongation of the triceps surae was also

measured with a goniometer. Evaluation was performed immediately before treatment and immediately after, on the next day and 4 weeks after treatment.
Results: All the patients reduced spasticity immediately after treatment and in all muscle groups. On the Aschworth Scale there was an average reduction of 3 to 1(+). Passive elongation of the triceps surae increased by 5 degrees. The following day, spasticity returned to initial values in the upper extremity. Gains achieved in the lower extremity continued to the following day and one month later. These side effects were observed: small superficial hematoma (1 biceps), and petechiae (1 biceps). All side effects were tolerated by all the patients and disappeared after 1-7 days. At the end of follow-up, all the patients were asked to assess if they would repeat the experience and all of them said yes.
Conclusion: rESWT reduces spasticity of the triceps surae immediately and a month after treatment. rESWT reduces spasticity of biceps, wrist flexors and thenar eminence immediately after treatment, but the benefits are not retained the following day. Further randomized and controlled studies are necessary to underline the results of this initial experience.

50. Treatment of Heterotopic Ossifications Using Shock Waves: An In Vitro Study

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Device and producing company: OssaTron & EvoTron, SanuWave Inc
Introduction: Heterotopic ossification (HO) is a common clinical problem often associated with aging, trauma, immobilization, renal failure and rheumatological diseases. HO within the cardiovascular system can severely impair cardiac function as well as reduce arterial compliance, accelerating atherosclerosis. HO in joints often causes pain, swelling and contractures leading to severe disability. Current HO treatment is to wait until it matures, then surgically remove the HO. Common surgical complications are blood loss, infection and HO recurrence. We study shock wave treatment mechanisms for HO with an in vitro model.
Methods: Mineralized macroporous nanofibrous fibrin scaffolds were fabricated using sphere-templating and leaching methods. The scaffolds were incubated in calcium phosphate solution containing CaCl2-2H2O, NaHCO3, NaCl and K2HPO4 at 37°C. The fibrin scaffolds with precipitation of calcium phosphate crystals were treated with electrohydraulic shock waves (OssaTron, EvoTron). The calcium in scaffolds was solubilized in HCl and measured using cresophthalein complexone at absorbance 575 nm.
Results: Scaffold calcium contents decreased from 45.4 ± 3.6 (untreated) to 20.9 ± 18.1 (OssaTron, 0.71 mJ/mm2, 1 Hz, x200) and 27.53 ± 23.47 ug Ca/mg dry weight (EvoTron, 0.46 mJ/mm2, 1 Hz, x200). Scanning electron microscopy of the scaffolds after the shock wave treatment shows separation of calcifications from the fibrin matrix.
Discussion: High variations observed in treatment efficacy could be due to scaffold or shock wave variability (cavitation & shear stress control, scaffold movement, stability of electrohydraulic shock waves, etc).
Conclusion: Shock waves can effectively separate calcifications from soft tissue. Future research on HO treatment in an in vivo model is worthwhile.

51. Effect of ESWL on Osteochondritis Dissecans of the Knee in a Rabbit Model

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Institutions: Dept. of Orthopaedic Surgery, Children's Hospital of WI; *Dept. of Pathology, Froedtert Hospital, Medical College of WI

Device and producing company: OssaTron (Sanuwave, GA)

Introduction: Treatment of severe osteochondritis dissecans (OCD) often includes surgical interventions (i.e. a multiple drilling, excision, or debridement). Still, only 35% of them had a good to excellent result in a 4 to 15-year follow up1. The goal of this study was to determine the effects of ESWL on OCD lesions in the medial femoral epicondylar cartilage of New Zealand White (NZW) rabbits.

Methods: Twenty skeletally immature (8 week old) female NZW rabbits had a 4 mm plug of the osteochondral surface harvested on the medial femoral epicondylar of each knee. A piece of Surgerosis ™ was placed into the cavity then the plug was replaced. Two weeks post OCD model, each rabbit was sedated and their right knee was treated with OssaTron (4,000 impulses at a setting of 4 Hz and 18kV - SANUWAVE, GA). The left knee was sham control. Histological and radiographic evaluation was done up until 10 weeks post treatment.

Results: Histologically, there is significantly more mature bone formation and a healing articular cartilage of the plug margin on the treated side, resulting in pronounced differences of the healing scale (0.71 vs. 3.24) and density of the cartilage (60.2 vs. 48.8) ($p<0.05$). Radiographically, a better bony union on the plug margin was noticed before 5 weeks post ESWL, showing a significant increase of bony density (153.4 vs.138.2) ($p=0.002$).

Discussion: ESWL accelerated the healing rate and improved the quality of cartilage and subchondral bone in the OCD rabbit model.

Conclusion: ESWL shows promise in accelerating osteochondral defect healing in this rabbit OCD model.

52. The importance of a standardized model for shock wave in-vitro trials - a proposal plus preliminary results of cardiac cells

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Device and producing company: DermaGold (Tissue Regeneration Technologies, TRT, Woodstock, USA manufactured by MTS Europe GmbH, Konstanz, Germany)

Introduction: Literature reveals very diverse methods of applying shock waves onto cell cultures. Since results of equal cells treated in different ways are not comparable, establishing a standardized model for future in-vitro trials would be useful.

Methods: Primary cell cultures of endothelial cells and fibroblasts were established from native rat hearts. Additionally H9C2-cardiomyocytes (American Tissue Culture Collection) were used. All cell types were cultured using DMEM medium supplement with different nutrients and growth factors. A thermostatically controlled water bath was designed to avoid distracting physical effects, in particular, reflections. Adherent cells in common cell culture flasks filled with culture medium were dunked into the water bath. Various energy flux densities of unfocused SWT were applied in different distances to the cells. Number of cells and their vitality then were analysed over a period of 7 days.
Results: The water bath is a good method to avoid reflections and negative pressure of the shock waves. SWT stimulates every cardiac cell type to a different extent. Each cell type reacts at a different timepoint after treatment. The distance between the applicator and the cells, as well as the energy flux density have a strong influence on the cells' behaviour.
Conclusion: SWT stimulates growth of cardiac cells. The thermostatically controlled water bath is a useful and recommendable tool for further shock wave in-vitro trials.

53. ESWT down regulates the pathologic mechanisms causing cartilage damage in osteoarthritis

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Institutions: Department of Clinical Methodology and Surgical Technique, Orthopaedics Section, University of Bari, Bari, Italy DiMIMP – Rheumatology Unit, University of Bari
Device and producing company: Minilith-SL1, Storz Medical
Introduction: This study proposed to investigate the effects of ESWT on the metabolism of healthy and osteoarthritic (OA) human chondrocytes (HD).
Methods: Human articular cartilage was obtained from 9 patients with OA, undergoing joint replacement and from 3 young healthy donors HD with traumatic fracture. After isolation, chondrocytes underwent ESW treatment (electromagnetic generator system, Minilith-SL1, Storz Medical) at different numbers of impulses, energy levels and fluxes. Chondrocytes were cultured in 24-well plate in DMEM supplemented with 10% FCS for 48 hours and then beta-1-integrin surface expression and intracellular IL-10 and TNF-alfa levels were evaluated by flow-cytometry.
Results: At baseline, osteoarthritic chondrocytes expressed significantly lower levels of beta-1-integrin and higher levels of IL-10 and TNF-alfa. Following ESW application, while beta-1-integrin expression intracellularremain unchanged, a significant decrease of IL-10 and TNF-alfa levels was observed both in osteoarthritic and healthy chondrocytes. IL-10 levels decreased at all numbers of impulses and energy levels, while a significant reduction of TNF-alfa was mainly found at middle energy levels.
Discussion: It has been reported that ESW may be useful for treating OA in dogs, and veterinarians have also begun to use ESW to treat OA in horses.
Conclusion: Our study confirmed that osteoarthritic chondrocytes express low beta-1-integrin and high TNF-alfa and IL-10 levels. ESW treatment application down-regulates the intracellular levels of TNF-alfa and IL-10 by chondrocytes, suggesting that ESW might restore TNF-alfa and IL-10 production by osteoarthritic chondrocytes at normal levels, thus potentially interfering with the pathologic mechanisms causing cartilage damage in OA and representing the theoretical rationale for using ESW as therapy for OA.

54. Osteoblast repair action induced by ESWT

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Institutions: Department of Clinical Methodology and Surgical Technique, Orthopedics Medical School, University of Bari, Italy; Department of Human of Anatomy and Histology, Medical School, University of Bari, Italy

Device and producing company: MINILITH-SL1, STORZ MEDICAL

Introduction: Osteoclastogenesis is regulated by signaling system between pro-apoptotic (Bax-CyclinE2-Cdk2) and necrosis factor families (RANKL-RANK-OPG).

Methods: Murine osteoblast cultures were subjected to shockwaves at low energy intensities (0.05mJ/mm2) and 500 impulses, whereas control cells received no treatment. We evaluated cell viability quantifying the expressions of Bax and Opg by PCR.

Results: We found an immediate negative effect on cell viability, that occurs with an increase of Bax protein expression, after 3 hours of treatment. After a longer time lapse a stimulatory effect on cell proliferation, as reflected by the increase of a G1-S-phase marker, was observed. In the 24, 48 and 72 hours following ESWT, we found a stronger association of Cyclin E2 and Cdk2, forming active cyclin E-Cdk2 kinase, compared to untreated cells. We explored the molecular mechanism for the ESW induction of osteogenesis: by Real-Time-PCR an enhancement of Runx2 mRNA, evident 48 hours after treatment, was found. A link between physical ESW and Runx2 activation has already been demonstrated. ESW-induced O2 production, followed by tyrosine-kinase mediated ERK activation and Runx2 activation, resulted in osteogenic cell growth and maturation. We analyzed the cytokines RANK-L and OPG osteoblast expression, involved in regulation of osteoclastogenesis. A decrease in RANK-L /OPG ratio was found, perhaps leading to a reduced osteoclastogenesis.

Discussion: ESWT is used in orthopaedic treatments to induce bone repair, but its mechanism of action needs further investigation.

Conclusion: Shockwaves have repair action on bone which can been explained by the regulation on osteoclastogenesis by apoptoic pathway of BAX and OPG.

55. Focused Extracorporeal Shock Waves Influence Migration, Proliferation and Growth of Human Mesenchymal Stem Cells

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Device and producing company: PiezoSon 100 Plus, Richard Wolf, Knittlingen, Germany

Introduction: Mechanotransduction leads to transformation of mechanical sensations into cellular impulses. The routes of these impulses are time-dependent in different supporting connective tissue. These routes induce a certain flow direction of information. There are arising follow-up signals, which are considered as biological information units, leading to very specific signals and thus to equally specific biological transformation within the celullar structure. The adherence to precise methods of application by means of mechanical stimulus is of utmost importance. For the first time we were able to prove that mechanical activation of

stem cells is possible with the help of extracorporeal shock waves, hereby establishing further therapy methods.
Methods: The needed mesenchymal stem cells were aspirated from the femur bone-marrow, filtered and centrifugated. The enriched cells were subjected by microscopic assessment of morphology (Flow cytometry, CFU-assay, differentiation assay). The differentiation potential of MSCs was controlled by culturing the cells under conditions that were favourable for adipogenic, osteogenic and chondrogenic differentiation. Shock waves were applied to adherent MSCs. In order to imitate natural application in in vivo culture dishes were completely filled with media and covered with freshly prepared pork skin. Ultrasound gel was placed on top of the pork skin to ensure best adjustment to the shock wave system. We controlled the migration, growth and proliferation under shock wave influence.
Results: We could show that shock waves increase the migratory activity of MSCs when used under distinct conditions. They increase significantly MSC growth in the first passage after treatment and they increase also MSC proliferation.
Discussion: The strong effects of shock waves on MSCs indicate that these cells can be influenced by mechanical stimuli.
Conclusion: The results of shock wave treatment depend on number of applications, frequency and density of energy; they might be the first approach to mobilize stem cells non-invasively.

56. Comparative study between the effects and mode of application of focused and radial shock wave treatment on the behaviour of human mesenchymal stem cells (MSC)

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3) EMS, Elektro Medical Systems, Am Schatzbogen 86, 81829 München

Device and producing company: Swiss DolorClast (EMS), Piezoson 100 (Richard Wolf)
Introduction: Recent studies demonstrate the successful use of shock wave therapies for improvement of tissue repair and regeneration; processes where stem and progenitor cells are involved e.g. wound healing and bone repair. Human adult bone marrow derived mesenchymal stem cells (MSC) have the capability to differentiate into various mesenchymal tissues and rebuild these e.g. bone tissues, muscles, cartilage tissues or tendons. Therefore the question arises as to whether shock waves can influence stem cells involved in tissue regeneration. MSC dependent regeneration can by improved by enhancement of migration, increase of proliferation and reduction of apoptosis. Due to the fact that two different kinds of shock waves (focused and radial) improve stem cell dependent regenerative processes, it seems appropriate to investigate the influence of both kinds of shock waves on MSC.
Methods: The first experiment with treatment conditions where the shock waves are reflected by culture dishes shows a dose dependent increase of MSC migration by shock wave treatment. We established a new experimental cell culture setup for shock wave treatment under absorbing conditions to better simulate in vivo circumstances. We tested the effect of

different intensities of shock waves on cell vitality and we are performing different assays on MSC to investigate migration, proliferation and apoptosis under different conditions (impulses, frequency and intensities of energy) with both kinds of shock waves.
Results: We developed methods for in vitro treatments of MSC with both kinds of shock waves with guarantee of cell vitality, which allow investigations of both kinds of shock wave treatments.
Conclusion: The present results indicate that MSC can be dose dependently influenced by shock waves.

57. Shockwave therapy on human fat-derived stem cells

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Institutions:
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2) Austrian Cluster for Tissue Regeneration, Austria
3) Trauma Center Meidling, Vienna, Austria

Device and producing company: DermaGold, Tissue Regeneration Technologies (TRT), USA manufactured by MTS Europe GmbH, Germany
Introduction: The field of application for shockwave therapy has widened over the last few years. Electro-hydraulic shock wave technology has been used successfully for improved healing of chronic wounds. Little is known about the mechanism of action of shockwave therapy. In this study we treated isolated and cultured human adipose-derived stem cells to find out more about the influence of shockwave therapy on cells in vitro.
Methods: Human adipose-derived stem cells were seeded 24 hours before shockwave treatment into 6-well plates and covered with DMEM/HAM'sF12 medium containing 2% FCS. Thirty or 50 pulses with a frequency of 1 Hz and an energy flux density of 0.1 mJ/mm2 (DermaGold, MTS Europe GmbH, Germany) were applied on the bottom of the cell culture plates. At certain time points, photographs for evaluation of the cell morphology were taken. On days 2, 7 and 14, cells were collected and RNA expression levels of different markers were analysed.
Results: Macroscopically, human adipose-derived stem cells contracted their cytoskeleton to be only half the size directly after shockwave treatment. By day 2, cells had fully recovered their original size. Interestingly, shockwave therapy did not improve cell proliferation within 14 days. However, an upregulation of specific osteogenic expression genes in treated cells could be observed. Collagen 1 alpha 1 and the bone sialo protein showed significantly higher RNA expression levels in both treated groups compared to the control group (without shockwave therapy). Vimentin, desmin and alpha smooth muscle actin were also up-regulated in treated human adipose-derived stem cells.
Conclusion: In conclusion, shockwave therapy on isolated and cultured human adipose-derived stem cells does not influence cell proliferation but seems to induce or accelerate osteogenic differentiation in these cells.

58. The effect of ESWT on matrix structure, tenocyte metabolism and gene expression in non-injured tendinous structures

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Device and producing company: HMT Equitron, High Medical Technologies, Lengwil, Switzerland

Introduction: Although ESWT is frequently used for the treatment of tendinopathies, little is known about the mechanism of action and the actual effects on tendon tissue. In this study the effects of ESWT on non-injured equine tendon were investigated.

Methods: Different tendinous structures were exposed to ESWT in ponies either 6 weeks or 3 hours before euthanasia. The contralateral tendons were used as untreated controls. The tendons were analysed biochemically and histologically. Gene expression was determined using rtPCR and tenocyte metabolism was studied by the incorporation of radioactively labelled 3H and 35S in explants.

Results: There was a significant increase in GAG and protein metabolism 3 hours after ESWT, but after 6 weeks metabolic activity was decreased. Biochemically, the level of degraded collagen was increased 3 hours after treatment. Histologically disorganisation of the collagen network was apparent 3 hours after ESWT, which was less severe but still visible after 6 weeks. Gene expression levels of COL1 and MMP1 were elevated 6 weeks after ESWT.

Discussion: ESWT causes a transient stimulation of tendon metabolism and an upregulation of the expression of the major constituent COL1. Both factors might contribute to the healing process in injured tendons. The disorganisation of the collagen network and the increase in MMP expression appear less desirable, but could, however, be indicative for early matrix remodelling.

Conclusion: It is concluded that exposure of non-injured tendinous tissue to ESWT is not as un-eventful as expected and that exercise of recently treated patients should be limited to prevent tissue structure from being further affected.

59. Surface-Enhanced Raman Scattering (SERS) as a new tool for the study of Tendinopathic Human Rotator Cuff.

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4) University of Windsor, Materials & Surface Science Group, N9B3P4 Ontario, Canada.

Device and producing company: MEDISPEC / ORTHOSPEC

Introduction: Symptomatic Tendinopathic Rotator Cuff is the main cause of medical consultation for shoulder pain or upper girdle disabilities, and their biochemical features are present long before the clinical settings. It is then possible, during the natural history of this condition, to observe progressive derangement of the Rotator Cuff, ending in its rupture. Histological(1) and immunohistochemical studies do not completely characterize the different phases of the disease or tissue damage. However, SERS as an analytical tool can help to bring to light more specific and complementary features improving tissue analysis at different stages. The SERS Technique has several advantages which allow the study of biological materials in physiological and physiopathological conditions for direct comparison(2). A far less sensitive technique, FT-Raman Spectroscopy, has been used in an attempt to classify the degenerative grade of lesions of supraespinatus rotator cuff tendons(3).

Methods: In this first communication we report preliminary studies including 1016 SERS spectra of 52 biopsies of tendinopathic tissues. The SERS spectra were obtained using Ag and Au nanostructures formed in colloidal solutions(4).

Results: The spectra analysis allowed the identification of aminoacids, collagens, elastin, lipids and carbohydrates. Spectral differences, in particular from collagen signals, were observed depending on the spatial location excited within the tissue.

Discussion: The spectral mapping seems to suggest that collagen structure is sensitive to the pathology. Related research efforts include FT_Raman Spectroscopy following a tendinopathic tendon treated with shockwaves.

Conclusion: References. (1)Brañes M., Guiloff L., Brañes J., Contreras L. ISMST News Letter vol 3, May 2007, pp:9-10. (2)Kneipp J., Kneipp H., Kneipp K. Surface-Enhanced Raman Spectroscopy-Based Optical labels deliver Chemical Information from Live Cells. Chapter 13 in New Approaches in BioMedical Spectroscopy. Eds. Kneipp K., Aroca R., Kneipp H., Wentrup-Byrne E. ACS Symposium Series 963, American Chemical Society, Washington DC, 2007. (3)Palma Fogazza B., C. Da Silva C., Pentead S.G., Meneses C.S., Martin A.A., Da Silva Marthino H. Proc SPIE, 6445 (2007)64450S. (4)Aroca R. Surface-Enhanced Vibrational Spectroscopy, 2006, John Wiley & Sons Ltda.Inc., Chichester, England. (5) Wang C-J., Wang F-S., Yang K.D. ISMST News Letter vol 1, 2005, pp:5-11.

60. Biomechanical Testing of Spinal Fusion Segments Enhanced by Extracorporeal Shock Wave Treatment: A Rabbit Experiment.

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Device and producing company: 1. OssaTron machine (HMT) (High Medical Technologies, GmbH, Kreuzlingen, Switzerland); 2. Qtest10 (a material testing machine) (MTS Systems Co., Minneapolis, MN, USA)

Introduction: Extracorporeal shock wave treatment (ESWT) has been proven effective in enhancing spinal fusion in a preliminary animal study. However, biomechanical tests were not performed.

Methods: All 12 rabbits in this study underwent decortication at the bilateral L5 and L6 transverse processes. Bone chips were bitten off and placed onto the intertransverse space. The rabbits were divided into two groups, a study group (n=6) and control group (n=6). In the study group, the bilateral L5 and L6 transverse processes were treated with 1,000 impulses of ESWT at 14 KV (equivalent to 0.18 mJ/mm²) at 12 and 18 weeks after surgery. The control group rabbits did not undergo ESWT. A series of radiographic examinations on each rabbit were performed subsequently. All rabbits were sacrificed at 21 weeks, and their spines were harvested for biomechanical tests.

Results: Radiographic examination showed 5 of 6 rabbits in the study group had callus formation in the fusion masses. Biomechanical tests of fusion segments showed that mean flexion stiffness (with internal control) of the study group was 2.11±0.46, while that of the control group was 1.17±0.19. Mean extension stiffness (with internal control) of the study group was 1.70±0.39, while that of the control group was 1.23±0.29. Statistical analysis showed that fusion segments in the study group had significantly better flexion and extension stiffness than those in the control group ($P<0.05$).

Discussion: In this animal study, radiographic examinations showed that ESWT stimulated new bone growth. Biomechanical tests showed that ESWT significantly increased flexion and extension stiffness of spinal fusion segments.

Conclusion: Biomechanical tests showed that ESWT significantly increased flexion and extension stiffness of spinal fusion segments.

61. Treatment of Heart Failure with Physical Methods

Johannes Mueller, Karin Macfelda

Institutions: Berlin Heart, Berlin, Germany; Medical University of Vienna, Vienna Austria

Device and producing company: There is no device involved.

Introduction: The efficacy of the application of physical methods as treatment for different diseases is widely underestimated because of a lack of knowledge of the mode of action on the molecular level. It is known, for example, that the application of shock waves as well as the application of electrical current has an influence on the collagen synthesis in bones. Furthermore, unloading of hearts with mechanical pumps leads to an improvement of heart function merely from the physical effect of mechanical unloading. We investigated the effect of electrical microcurrent on the extracelluar matrix of rats in heart failure. We hypothesized

that electrical microcurrent changes the collagen composition of the myocardium with favorable effects on the heart's function.
Methods: Mircocurrent (MC) was applied over a period of up to 31 days after surgical implantation of two electrodes covering the right and left myocardium of five spontaneous hypertensive rats (SHR). Thereafter, the myocardium was analyzed and compared to the myocardium from five healthy wild type rats and five SHR without previous MC application. Gene expression (quantitative PCR) was measured for MMP 2, 3, 8, 9, 13, 14, 16; TIMP 1, 2, 3, 4; connexin 40, 43, 45 and collagen I and III.
Results: Compared to the myocardium of the healthy rats, the myocardium of SHR without MC application showed a significantly higher level of MMP 3, significant lower level of MMP 8, 14, 16 and an unchanged level of MMP 2 and 13. The TIMPs and connexins were only marginally altered. Collagen I showed an upregulation of 40%. After MC application, MMP 2, 3, 9, 13, 14 and 16 were significantly up-regulated, MMP 8 remained unchanged, and most importantly, collagen I up-regulated by a factor of 2.5. All other analyzed parameters were not altered significantly by MC application.
Discussion: Despite the fact that it is still unknown how the MC works, MC generates a potential difference which facilitates molecules and electrolytes to move along the potential gradient. Furthermore, MC influences the membrane potential with the effect of a modified exchange of molecules between the inner and outer space of cells.
Conclusion: MC application up-regulates MMPs as well as collagen I on the gene expression level and normalizes the extracellular matrix of hearts in a progressed state of failure. MC application initializes a process towards healing of the diseased myocardium.

62. Epicardial Shock Wave Therapy Induces Neoangiogenesis and Improves Left Ventricular Function After Myocardial Infarction in Pigs in Vivo

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Institutions: Dept. of Cardiothoracic Surgery, Medical University Vienna
Device and producing company: CardioGold® CG050 (CRT Cardiac Regeneration Technologies, a subsidiary of TRT, Woodstock, GA, USA / manufactured by MTS-Europe GmbH, Konstanz, Germany)
Introduction: Therapeutic options of ischemic heart failure are limited. Shock wave therapy (SWT) reportedly induces VEGF overexpression in ischemic myocardium. We hypothesized that epicardial SWT improves ventricular function in an experimental model of ischemic heart failure by inducing neoangiogenesis.
Methods: Pigs were subdivided in 3 groups: unharmed myocardium with epicardial SWT (healthy control, n=2), infarcted myocardium with epicardial SWT (SWT-group, n=6) and infarcted myocardium without epicardial SWT (control, n=2). Four weeks following myocardial infarction (MI), epicardial SWT (300 impulses at 0.15 mJ/m²) was applied directly to the infarcted area in the healthy control and the SWT-group; controls were left untreated. Cardiac function was evaluated using echocardiography before MI, 4 weeks after MI and 4 weeks after SWT. Angiogenesis was evaluated 4 weeks after treatment by

immunohistology with vonWillebrand Factor antibody, which was morphometried with Lucia software.
Results: Compared to healthy controls (68±0.7%), left ventricular ejection fraction decreased in the SWT (43±2.5%, p<0.001) and control group (41±4.2%, p=0.012) 4 weeks after MI. After epicardial SWT, ejection fraction improved in the SWT-group as compared to 4 weeks after MI (62±9.1%, p=0.006), no improvement was observed in the control group (46±5%, p=0.126). As compared to healthy controls (69±1.4%) ejection fraction normalized in the SWT-group 4 weeks after SWT (p=0.358), it remained decreased in the control group **(p=0.031). No adverse effects were observed.**
Discussion: Epicardial SWT improves left ventricular function after myocardial infarction in pigs.
Conclusion: Epicardial SWT therefore seems to be an effective and safe therapeutic strategy for the treatment of ischemic heart disease.

63. Direct epicardial shock wave therapy improves left ventricular function in an experimental model of ischemic heart failure

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Device and producing company: CardioGold® CG050 (Cardiac Regeneration Technologies, Woodstock, USA, a subsidiary of Tissue Regeneration Technologies (TRT) / manufactured by MTS-Europe GmbH, Konstanz, Germany)
Introduction: Prognosis of ischemic heart failure is poor and therapeutic options are limited. Shock wave therapy (SWT) reportedly induces VEGF overexpression in ischemic skin flaps and ischemic myocardium. Here, we hypothesized that epicardial SWT improves ventricular function by enhancing angiogenesis in an experimental model of ischemic heart failure in rats.
Methods: Adult Sprague Dawley rats were subdivided into 3 groups: sham-operated (sham), infarcted myocardium with epicardial SWT (SWT group) and infarcted myocardium without epicardial SWT (control). Four weeks following myocardial infarction (MI), epicardial SWT (100 impulses at 0.38 mJ/m²) was applied directly to the infarcted region in the SWT-group, control animals were untreated. Cardiac function was evaluated using echocardiography before MI, 4 weeks after MI and 12 weeks after SWT. Angiogenesis was evaluated 12 weeks after treatment in serial sections stained with von Willebrand Factor antibody, which were digitalized and morphometried.
Results: As compared to sham group (50±4%), left ventricular function decreased in the SWT (21±9%, p<0.001) and control (18±4%, p<0.001) group 4 weeks after MI. Fourteen weeks after epicardial SWT, left ventricular function 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%, p<0.001). Quantitative histology revealed more vital cells (384±84 cells/field in SWT vs. 288±56 in controls, p=0.02) and enhanced angiogenesis (7.1±3.3 vessels/field in SWT vs. 3.2±1.8 in controls, p=0.016) in the SWT group.
Conclusion: Direct epicardial shock wave therapy improves left ventricular function and induces neoangiogenesis in an experimental model of ischemic heart failure in rats.

64. How many shockwaves are enough? Dose-response relationship in ischemic challenged tissue.

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Device and producing company: DermaGold, Tissue Regeneration Technologies (TRT), USA manufactured by MTS Europe GmbH, Germany

Introduction: Recently, we showed beneficial effects of extracorporeal shock wave therapy (ESWT) on ischemic challenged tissue. We were able to show that ESWT improved flap outcome irrespective of application time (elective treatment 24h preoperatively, 1h postoperatively or treating manifest ischemic tissue 24h postoperatively). In the current study we investigated flap outcome in respond to various total amounts of impulses.

Methods: In the ischemic area of a rodent epigastric flap, different amounts of total shock wave impulses were applied (30, 300, and 1,000) which corresponds to 1.4, 14, and 47 pulses/cm2, respectively. Parameter of effectiveness included planimetry (necrosis, shrinkage), flap perfusion (assessed by 2-D laser Doppler imaging), and immuno-histochemistry over a 7 day follow-up period.

Results: All shock wave treated groups showed substantial reduced tissue necrosis compared to control. Looking at the total amount of pulses within treatment groups, animals receiving 300 impulses showed the best results (less necrosis). Neither lower nor higher amounts (30 and 1,000, respectively) further improved flap outcome. No significant differences were found in the perfusion and immuno-histochemical parameters.

Conclusion: ESWT in soft tissue complications such as ischemia has clear beneficial effects. A dose response relationship was found in reducing tissue necrosis.

65. Pulsed Acoustic Cellular Technology Protecting Microcirculation due to Neovascularization and Wound Healing in Ischemic Muscle Flap Model

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Device and producing company: dermaPACE, SanuWave

Introduction: Tissue ischemia affects restoration of circulation to damaged tissues and has a direct effect on wound healing. Pulsed Acoustic Cellular Expression (PACE) is a novel technology which supports tissue neovascularization in muscle flap microcirculation.

Methods: Forty cremaster muscle flaps were evaluated under intravital microscopy system in 4 experimental groups (10 animals each): 1) Non-ischemic controls, 2) 5 hrs

ischemia, 3) pre-ischemic (5 hrs) PACE treatment, 4) post-ischemic (5 hrs) PACE treatment. Microcirculatory hemodynamics of capillary perfusion and leukocyte-endothelial interaction were recorded 5 hrs after ischemia. Mechanism of leukocyte stimulation was assessed by immunohistochemistry by expression of cell adhesion molecules: E-selectin, ICAM-1 and VCAM-1 and proangigenic factors: VEGF and von Willebrand factor (vWF).
Results: Pre-ischemic PACE therapy decreased number of rolling and sticking leukocytes and this correlated with down-regulation of ELAM-1 and ICAM-1 and lack of VCAM-1 expression compared to 5 hrs ischemic controls. Post-ischemic PACE treatment showed increase in functional capillary density and decreased activation of rolling and sticking leukocytes. Application of PACE treatment 5 hrs after ischemia resulted in down-regulation of ELAM-1 and VCAM-1 and in up-regulation of VEGF and vWF expression on vessel endothelium compared to 5 hrs ischemic control.
Discussion: Pre-ischemic and post-ischemic PACE treatment resulted in down-regulation of adhesion molecules (ELAM-1 and VCAM-1) expression and correlated with reduced number of sticking leukocytes at microcirculatory level. Post-ischemic PACE treatment induced expression of pro-angiogenic factors of VEGF and vWF which correlated with increased capillary density and confirms potential for neoangiogenesis.
Conclusion: This study confirmed protective effect of PACE treatment after ischemia-reperfusion injury in muscle flaps.

66. Radial extracorporeal shock wave therapy (rESWT) in wound healing – a prospective randomized Placebo-controlled animal trial

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Institutions: MARE Clinic Kiel
Device and producing company: EMS swiss Dolorclast
Introduction: Shock waves were initially used to treat wound healing disorders. First results showed good outcomes. Radial shock waves were not applied in wound healing until now.
Methods: In an epigastric skin flap model the effect of radial extracorporeal shock waves was investigated in rats (Male Sprague Dawley rats weighing 300 to 350 g). A total of 25 subjects randomly received assigned treatment. All subjects underwent surgery to create a specific skin flap with reduced perfusion due to ligation of the epigastric artery and vein. After surgery the subjects were assigned into 3 groups. The first group received 300 shock waves with an ED of 0.13 mJ and 2 Hz, the second group received 600 shock waves with an ED of 0.13 mJ and 4 Hz, the third group received a placebo. To quantify the effect, planimetry and laser Doppler imaging (LDI) were performed 7 days after intervention and compared to baseline.
Results: Baseline showed homogeneity regarding all criteria. Seven days after treatment rats receiving a total of 600 SW at 0.13 mJ showed significantly better outcomes compared to placebo and rats receiving 300 SW at 0.13 mJ. These significantly better outcomes after 600 SW at 0.13 mJ were found in both criteria (Planimetry and LDI). The group receiving 300 SW at 0.13 mJ showed slightly better outcomes but they were not significant compared to placebo. Only minor side effects such as petechial bleeding and edema were observed.
Discussion: These findings demonstrate positive effects in a rat model. The clinical effect size remains unknown and needs to be determined.

Conclusion: rESWT is an effective and safe method to treat wound healing with impaired perfusion conditions after surgery. The effect size reaches clinical relevance. These initial findings have to be verified in further studies. Clinical feasibility trials could start to calculate the clinical effect size of radial shock waves in perfusion-related wound healing disorders.

67. Shock wave Therapy in peripheral nerve repair: Investigation in a rat sciatic nerve repair model

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Device and producing company: DERMAGOLD (USA), Tissue Regeneration Technologies (TRT)
ORTHOWAVE 180c (Outside USA), MTS Europe GmbH

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

Methods: 72 Sprague Dawley rats underwent mid-thigh sciatic nerve transection at two different levels creating an 8mm nerve graft. The nerve graft was now rotated 180 degrees and epineurial coaptation was performed immediately. All animals were randomly assigned to two experimental groups: Group 1: Shock wave therapy (300 impulses, 3 Hz) was applied over the graft using an ultrasound gel as a conductive and protective layer immediately after wound closure. Group 2: (sham control) Nerve graft without shock wave therapy. Serial functional tests (BBB locomotor rating scale, Inclined plane test, Toe spread test, Sensory- and Proprioceptive placing tests as well as Catwalk© locomotion assessment device) were performed in weekly intervals within the period between the 1st and the 12th week after the grafting procedure. Electrophysiological studies were carried out 3, 6 and 12 weeks after surgery. Histologic and immuno-histochemical evaluation of neural collagenic connective tissue, axonal sprouting, axonal diameter and axonal count as well as angiogenesis was performed 1, 3 and 12 weeks after surgery.

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

Discussion: It seems that improvement of angiogenesis and increase of the axonal sprouting rate may result in enhanced functional recovery. Further research for better understanding is necessary.
Conclusion: The results of this nerve transection and repair study in the rat shows that SW treatment immediately after surgery is effective. There is improvement of functional recovery. This may be due to an increased neural angiogenesis, decreased neural collagenisation and improved axonal sprouting.

68. Effects of extracorporeal shock waves on skin fibrosis and on biomarkers of patients with Progressive Systemic Sclerosis

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Device and producing company: Duolith, Storz Medical AG
Introduction: Progressive systemic sclerosis (SSc) is a rare systemic autoimmune disease characterized by vascular endothelial dysfunction with intimal proliferation and luminal narrowing of capillaries and small arteries, by immunological abnormalities, such as the presence of autoantibodies to intracellular and cell-surface antigens, and by excessive extracellular matrix accumulation leading to fibrosis of the skin and internal organs. The main clinical features are Raynaud's phenomenon, a transient ischemia of the fingers and internal organs followed by the major characteristics of the disease: skin fibrosis and digital ulcerations. The aim of this work is to test the effectiveness of shock waves on skin manifestations.
Methods: We enrolled 22 patients affected by SSc, one male and 21 female, after written consent. Rodnan skin score and sonographic examination of the patients' arms and hands were performed before and immediately after the first shock wave treatment. The same examinations were carried out at 7 and 30 days after the end of the therapy. We obtained blood samples at the same time points to determine whether shock waves could modulate serological levels of vascular endothelial growth factor (VEGF), von Willebrand factor (vWF), endothelin I, and adhesion molecules such as ICAM-1 and VCAM-1. We have also determined the number of circulating endothelial cells and their progenitors with the aim to evaluate the possible role of the treatment in the induction of endothelial repair. In a few patients the levels of blood NO were also determined at particular time points during the treatment. We treated the volar and the dorsal face of the forearm and of the hand, using a defocalized shock wave device, performing 3 sessions in two weeks.
Results: We will introduce the results and our observations.
Discussion: The method is effective, not painful and well accepted by the patients. We have not recorded any complications.
Conclusion: These preliminary data lead us to believe that shock waves can be a new non-invasive weapon for treating SSc, mainly for its cutaneous indications. Further studies with a greater number of patients will better enable us to determine its potentialities.

69. ESWT in Chronic Decubitus Ulceration in Complex Neurological Disability

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Introduction: Skin ulceration in complex neurological disabilities is often chronic causing pain, risk of septicaemia and limitation of activities leading to a decreased quality of life. Chronic ulcers are also expensive in terms of nursing time and financial cost of treatment. We have previously described provisional findings of a study of ESWT on chronic ulceration. This paper presents the final findings of the study.

Methods: A randomised double-blind cross-over study, with washout period, of ESWT and a placebo ESWT was used. All patients in a large long-stay hospital specialising in chronic neurological conditions were eligible for inclusion in the study. Patients were randomised into treatment with ESWT first or with the placebo ESWT head first. Treatment periods were weekly for four weeks. There was a two week washout period between the two forms of 'treatment'. After six weeks the treatment methods crossed over. The machine used was the Orthowave 180c with two heads – one active and one inactive. The machine fired for both the ESWT and the placebo treatments thus the noise was the same for both treatment groups. The area and depth of the ulceration was recorded by tracing the outline of the ulcer onto an acetate sheet and measuring the area using a computerised grid system (Visitrak™ [Smith & Nephew]). For each observation the average of three measurements were taken.

Results: Fifteen ulcers (in 13 patients) were included in the study; eight were on the buttocks/sacrum/trochanter and seven were on the feet/ankles. Where there was some healing prior to the study (5) there was no evidence that the ESWT increased the rate of healing. Where there was small surface area ulceration but with a sinus present (3) there was no evidence of healing; but for those with static chronic ulcers all showed improved healing after the start of ESWT. Where the placebo head was used first there was no healing until after the ESWT treatment started. After the research period those with sinuses were treated using a different technique of ESWT and there was some evidence that healing began to occur though this needs further study under research conditions. Some patients showed a deterioration in the size of the ulceration on starting ESWT. These were patients with undermined ulcers with vulnerable ischemic skin. There was then improved healing – thus the ESWT assisted debridement of the ulcers.

Discussion: It is uncertain why there was no effect of ESWT on those ulcers already showing healing, and this needs further study. The non-healing of the sinuses was probably due to the technique being used, and this needs further research. The main finding was that those ulcers that had not been healing prior to the study all improved, with some healing completely. Considering that some of these ulcers had been present for many months, or even years, this indicates that ESWT has a potential place in the treatment of chronic ulceration in people with complex neurological disabilities.

Conclusion: We were unable to demonstrate any benefit of ESWT on ulcers that were already healing or where there was a sinus present. In the latter case this was probably due to

the technique being used. ESWT had a significant effect on healing of those ulcers that had not been showing any healing prior to the study.

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

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

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

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

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

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

71. Clinical Experience with ESWT in Sub Acute and Chronic Wounds

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Device and producing company: DermaGold (USA) / Orthowave 180 (Outside USA), Tissue Regeneration Technologies (TRT) manufactured by MTS Europe GmbH

Introduction: Sub-acute or chronic wounds of different aetiology represent a major problem not only for the patient but also for the social system. The Trauma Centre Meidling started treating wounds non-respondent to standard care with ESWT in August 2004. An update from the clinical ESWT experience between 2004 and 2007 is given.
Methods: Patient study enrollment was done during routine clinical work between August 2004 and December 2007. Patients of both sexes with soft tissue wounds of different aetiology persistent longer than 1 month were included. The primary outcome measure was rate of wound closure. Secondary different correlation analyses (e.g. defect size, age, aetiology) were also done.
Results: As of December 2007, 350 patients had been treated with unfocused extracorporeal shock waves (male: 56%, female: 44%), primarily in an outpatient clinical setting. Mean age was 50.4 (SD 18.0) in males and 71.7 (SD 16.2) in females. Main wound location was the lower extremity, followed by the upper extremity. Aetiologically, wound healing disturbances (38.8%) and post-traumatic necrosis (28.9%) were most common. The overall complete healing rate was 69.2%. In addition, 5% of patients showed a healing rate greater than 50% and 2.1% of the patients a healing rate lower than 50% of initial wound size. The percentage of wounds that remained unchanged during ESWT (=non-healed) was 5.9%. The percentage of patients who missed follow-up was 23.7%. A correlation between greater wound size and non-healing wounds was found in the aetiology of disturbed wound healing, whereas in the venous ulcers this was not found. A correlation was also found between age of the patient and therapy responsiveness.
Conclusion: ESWT for sub-acute and chronic wounds that are partly non-responsive to standard of care, shows clearly beneficial effects in terms of entire wound closure.

72. ESWT to improve the outcome of complex non-healing leg and foot ulcers

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Device and producing company: Activitor, Switech (Kreuzlingen, Switzerland)
Introduction: Unfocused, low energy Extracorporeal Shock Wave Therapy (ESWT) has been shown to be a feasible treatment option in acute and chronic non-healing wounds with complete healing rates of up to 75%. We report our preliminary experience with soft-focused low energy (SFLE) ESWT in complex non-healing leg and foot ulcer patients.
Methods: Retrospective analysis of 22 patients (mean age 73+-13.6 years) with 30 complex non-healing (mean 104 weeks; max 1,382 weeks) leg or foot ulcers treated by SFLE ESWT from July 2007 to February 2008. Etiologies were: arterial (n=11), venous (n=5), mixed arterio-venous (n=4) and other (n=9) such as rheumatic, postoperative, posttraumatic and of unknown etiology. Seven of 30 wounds were infected, 11 of 30 associated with diabetes and 5 of 30 with immunosuppressive therapy. Twenty-nine of 30 wounds were chronic and non-healing despite adequate local therapy and treatment of underlying disease. One diabetic patient suffered from subacute Osteomyelitis. The device (Activitor, Switech, Kreuzlingen, Switzerland) was used at an energy level of 0.09 mJ/mm2, 4 pulses/sec. Chosen treatment dose was 100 pulses/cm2. Accordingly, 300 to 3,000 pulses were applied based on wound size initially weekly, then every one to three weeks according to the clinical response.

Thorough debridement was carried out either before or after SFLE USWT and the wounds were treated after the principles of phase adapted moist wound healing.
Results: Nineteen of 22 patients (26 of 30 wounds) completed all proposed sessions. Three patients (13.6%; 4 of 30 wounds) withdrew because of pain, inflammatory reaction of periwound tissue or unknown reasons, respectively. Of the remaining 26 wounds, 7 (29%) were completely healed, 14 (58%) improved and 5 (13%) were non-responding to SFLE ESWT. Possible reasons for non-responding were: 2 skin cancers (1 proved, 1 unproved due to patient denial of biopsy), 1 gadolinium associated nephrogenic dermatofibrosis, 1 lymphedema, and 1 infection of Achilles tendon. Average wound size in the 21 (87%) responding wounds decreased from 4.2 +- 5.07 cm2 to 1.6 +- 3.09 cm2.
Discussion: Healing was induced in 21 of 26 (87%) non-healing wounds after treatment with SFLE ESWT.
Conclusion: SFLE ESWT is a valuable treatment tool for complex non-healing wounds with a high responder rate. However, RCTs are needed to definitely prove its efficacy.

73. Accelerated Healing of IIa-Burns Under the Influence of ESWT

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Device and producing company: DermaGold (USA), Tissue Regeneration Technologies (TRT)
Orthowave 180c (Outside USA), MTS Europe GmbH
Introduction: Introduction: Musculoskeletal shockwave therapy increases blood flow in tissues and results in neoangiogenesis. In a study carried out on animals, enhanced tissue regeneration was observed in adipocutaneous flaps. The aim of our conducted clinical study was to demonstrate reduced duration of healing after shockwave therapy on IIa° burn wounds.
Methods: Material and Methods: We carried out a prospective, randomized non-blinded clinical study. Musculoskeletal shockwave therapy was applied within 24 hours post-trauma. Shockwaves with an energy level of 0.1-0.14 mJ/mm² were used. Fifty patients with superficial second degree thermal lesions (burns and scalds) were selected, twenty-five patients from this group received ESWT treatment, twenty-five patients served as the control group. All participating patients, i.e. patients given ESWT as well as those of the control group, received identical dressings made of perforated silicon layer (Mepitel®) in combination with polyhexanid. Main objective criterion was the time to complete reepithelization, secondary objective criterion was the incidence of side effects.
Results: Results: The group treated with ESWT resulted in a significantly shortened time of reepithelization (minus 2.48 days) compared to the control group. No side effects were observed.
Discussion: The presently available publications discussing the positive effects of ESWT, especially on skin/soft tissue, underscore the results of our own study, in which a highly significant shortened period of reepithelization of skin donor sites via ESWT could be verified. Because ESWT is still in its early stages as a treatment for chronic wounds and skin lesions, the actual mechanism is purely hypothetical.

Conclusion: Conclusion: Extracorporeal shock wave therapy is a new treatment option in terms of a supplementary method in the therapy of superficial second degree burn wounds (IIa°).

74. ESWT-induced healing of diabetic foot ulcers

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Device and producing company: MINILITH-SL1, STORZ MEDICAL

Introduction: ESWT became a standard treatment for common orthopedic conditions based on its therapeutic potential to locally induce increases in circulation and growth factors. Our study aim is to determine the role of shock waves in the management of chronic wounds.

Methods: We selected 25 diabetic patients with non-healing foot ulcer and prospectively we randomized them into 2 groups; treated and not treated with ESWT. The study lasted 20 weeks. Every 72 hours we applied a protocol of three applications of shockwaves by an electromagnetic generator (Storz Minilith SL-1), 100 impulses/cm2 with flux energy of 0.03 mJ/mm2. The two groups were compared by means of reepithelization index and the percentage of recovery. All patients received debridement and then were inserted into either group A (ESWT: 13 patients) or group B (control: 12 patients).

Results: In group A the reepithelization index was 2.9 mm2/day, (range 2 - 3.5); complete healing occured in 46% of patients and reepithelization above 50% occurred in 38.5% of patients. In group B the index was 1.3 mm2 /day (range 1 - 1.5), complete recovery occurred in 33% of patients and reepithelization above 50% occurred in 16.5%.

Discussion: The rationale of this study is to prove the influence of shockwaves on skin lesions, as reported by Schaden and Meirer. In an ongoing study we apply shockwaves on fibroblast cultures in vitro to value the cellular response in relationship to the clinical results.

Conclusion: Topical shockwave application promotes healing and accelerates recovery time of diabetic foot skin ulcers.

75. Blood flow perfusion and molecular response after ESWT in chronic skin ulcers

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Device and producing company: DermaGold (USA), Tissue Regeneration Technologies (TRT)

Orthowave 180 (Outside USA), MTS Europe GmbH

Introduction: This prospective study evaluated the efficacy of extracorporeal shockwave treatment (ESWT) in chronic skin ulcers and compared with hyperbaric oxygen therapy (HBO), and investigated the antibacterial and regeneration effects.

Methods: 105 patients with 112 chronic skin ulcers were randomly divided into two groups. There were 60 patients with 67 ulcers in the ESWT group and 45 patients with 45

ulcers in the HBO group. Both groups showed similar demographic characteristics. Patients in ESWT group received shockwave treatment, whereas patients in HBO group received HBO therapy. Blood flow perfusion culture and sensitivity and biopsy were performed before and after treatment. The evaluations included clinical assessment, blood flow perfusion scan bacteriological study, histomorphological examination, and immunohistochemical analysis.
Results: The overall results showed: completely healed in 39%, improved in 51% and unchanged in 10% for the ESWT group; and 18% completely healed, 51% improved and 31% unchanged for HBO group (P = 0.007). ESWT group showed significantly better blood flow perfusion and considerably more active cell proliferation and concentration than HBO. On immunohistochemical analysis, ESWT group showed significant increases of eNOS, VEGF and PCNA expressions and decreases of TUNEL expression over the HBO group. The culture results revealed significant decreases in bacteria growth after treatment, but no difference was noted between the two groups.
Discussion: ESWT is more effective than HBO in treating chronic diabetic skin ulcers. ESWT significantly improves blood flow perfusion associated with increased angiogenesis, increases cell proliferation and decreases cell apoptosis.
Conclusion: ESWT is effective for treating chronic diabetic ulcers. The application of ESWT results in increased angiogenesis with improved blood flow perfusion molecular responses and tissue regeneration in chronic skin ulcers.