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**Shock Waves:
the new frontiers**

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Abstracts

Is it possible to treat non-unions with radial shock wave therapy?

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Institution:

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Device and producing company: Swiss Dolorclast®, EMS

Introduction: The treatment of delayed unions or non-unions with focused ESWT is a common option for these difficult pathologies. The use of Radial ESWT is indicated for soft tissues tendinopathies. We treated some superficial bones with delayed unions with radial shock waves due to economic constraints.

Methods: We performed the treatment as an outpatient procedure without anaesthesia, using X-rays for targeting. We performed 3 sessions with 3000 pulses at 0.2 mJ/mm². We treated 2 tibias, 2 metatarsal bones, one distal femur and 2 scaphoids.

Results: After 6 months we observed bony consolidation in six out of seven cases.

Discussion: Radial ESWT is typically not used for bone injuries, but in our opinion, it is a new indication for some very specific cases. More clinical experience is necessary to draw further conclusions.

Conclusion: Radial ESWT is effective for treatment of superficial bone delayed unions.

Eccentric loading plus radial shock wave therapy in the treatment of chronic patellar tendinopathy Javier Crupnik

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Device and producing company: Swiss Dolorclast®, EMS

Introduction: Tendon diseases constitute an increasingly important problem in medicine and sport rehabilitation fields. When speaking specifically about patellar tendon pathology, Blazina and colleagues in 1973 first used the term “jumper's knee” to describe patellar insertional tendinopathy, a condition that affects approximately 20% of athletes for whom jumping is the most important sport drill. Although the majority of conventional treatments produce poor results, many are offered to patients with this pathology. Nevertheless some treatment methods are based on basic evidence and have been investigated with randomized controlled trials (RCT). Low-energy shock wave therapy (rESWT) and eccentric loading (EE) recently have demonstrated therapeutic effectiveness. The aim of this study is to analyze the results obtained with the combined application of both procedures (rESWT + EE) in patients with chronic patellar tendinopathy.

Methods: Thirty patients with chronic patellar tendinopathy for more than four months and who showed poor or no results from conservative treatment, which could include physiotherapy, prescription of NSAIDS or the injection of corticosteroids, were evaluated in the areas of pain, function and activity according to the VISA, Score Grading Patellar Tendinosis (Victorian Institute of Sport Assessment, Australia), using the non-parametric test of Wilcoxon dependent samples for evaluation. All the patients received 3 weekly sessions, of 2000 impulses, with an intensity of 2.5-3.5 bar (energy flux density = 0.1-0.16 mJ/mm²) and a frequency of 8 Hz. In addition to this, patients were fully informed about the protocol of eccentric training based on the study of Jonsson and Alfredson (Br. J. Sports Med. 2005; 39; 847-850).

Results: Four months after the initial evaluation, the VISA score demonstrated an increase from 52 to 82. Twenty-three of the 30 (76%) patients reported excellent or good results according to the Roles and Maudsley Scale. The return to sport activity for this group was an average of 51.3 days.

Conclusion: The combination of radial shock wave therapy (rESWT) and eccentric loading (EE) demonstrated improvement in function and activity, as well as diminution of pain, signifying it as a good alternative for conservative treatments on chronic patellar tendinopathy. Future randomized controlled studies are necessary to confirm the results of this investigation.

The Effectiveness of Extracorporeal Radial Shock Wave Therapy for Patients with Plantar Fasciitis

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Introduction: Plantar fasciitis is a common cause of heel pain, affecting 10% of the general population. Extracorporeal shock wave therapy (ESWT) has been recommended as treatment for chronic plantar fasciitis in patients unresponsive to conservative treatment. The primary goal of this study was to determine the effectiveness of 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 each was proposed. The study involved 104 patients (104 heels), including 52 patients (52 heels) in the shockwave treatment group and 52 patients (52 heels) in the control group. All patients had been suffering from plantar fasciitis for at least 6 months. Pre-treatment measurements included a visual analog pain scale (VAS) and the modified Roles and Maudsley scale (R&M). In the shock wave group, therapy was applied once a week for two weeks (2 x 2000 impulses) at an air pressure of 3.5 bars and frequency of 8 Hz at each session. The patients in the placebo group received treatment with the clasp on the heel. ESWT was performed without local anaesthesia. At the fourth week the subjects again completed a VAS and R&M.

Results: At 4 weeks, there was a mean VAS decrease of 6.56 (79.7%) for the experimental group; there was a mean decrease of 2.94 (32.5%) for the control group. There was a statistically significant ANOVA group by time interaction indicating the experimental group had a greater decrease in pain when compared to the control group p and an increase in quality of life when compared with the control group p.

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

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

Wound Healing - Influence of focused and radial shock wave treatment on the behaviour of human mesenchymal stem cells Yvonne Delhasse, H. G. Neuland (2), W. Bloch (1)

Institutions:

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Device and producing company: Swiss DolorClast®, EMS, Piezoston 100

Introduction: Recent studies demonstrate the successful use of shock wave therapies for improvement of wound healing disorders. Mesenchymal stem cells seem to be involved in tissue regeneration such as occur in wound healing. Therefore the question arises as to whether shock waves can influence mechanisms involved in stem cell dependent regeneration. MSC dependent regeneration can be improved by inducement migration, proliferation and apoptosis. Migration is of particular importance with regard to MSC's reaching the target location. Due to the fact that two different kinds of shock waves (focused and radial) improve mesenchymal stem cell dependent regenerative processes such as wound healing, it seems appropriate to investigate the influence of both kinds of shock waves on MSC's.

Methods: We established a new experimental cell culture setup for shock wave treatment under more absorbing conditions to better simulate in vivo circumstances. We tested the effects of different intensities of energy, frequency and total number of shocks on MSC's to investigate changes in cytoskeleton ((F-Actin) by phalloidin staining) and migration (by Boyden chamber assay) for both kinds of shock waves.

Results: We developed methods for in vitro treatments of MSC's with both kinds of shock waves that guarantee cell vitality and allow investigation of both kinds of shock wave treatments. We can show significant results in influence of migration and reorganisation of cytoskeleton (F-Actin) dose dependency with both kinds of shock wave treatments. Different shock wave systems show a different range of efficiency in our investigations. Treatments with densities of energy of 0.077 mJ/mm² with a focused shock wave system show significant increase in the migration and reorganisation of F-Actin fibers without actin accumulation. We detected converse results at treatments with higher energy levels of 0.122 mJ/mm² in migration and reorganisation of cytoskeleton. Small spots of actin

accumulation were visible at higher doses of 0.122 mJ/mm². Treatments with 0.122 mJ/mm² had a lower rate of migration in Boyden Chamber Assay but a higher rate of reorganisation of cytoskeleton compared to control. Radial shock wave treatment shows a significant increase in migration by densities of energy of 0.50 bar but no significant increase effects of the reorganisation of cytoskeleton.

Discussion: The present results indicate that MSC's can be influenced depending on the dose of shock wave treatments. We can verify explicit influences on migration of MSC's with both kind of shock waves, but with different ranges of efficacy. The results also provide evidence for a distinct dose-dependent influence of shock waves for cytoskeletal organisation with signs of cytoskeletal disruption at higher doses leading to an inverse migratory effect.

Conclusion: We can show the importance of correct dosing for treatment especially for focused shock waves.

Focused and Radial Shock Wave Treatment Influence Human Mesenchymal Stem Cells

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Device and producing company: Piezoson 100 and Swiss Dolorclast®, EMS, Switzerland

Introduction: Focused and radial shock waves can influence mesenchymal stem cells.

Therefore it can be speculated that shock waves can influence tissue repair and regeneration in this way.

Methods: By special experimental studies we can demonstrate that migration, cytoskeleton, proliferation and apoptosis of MSC`s can be influenced.

Results: The present results show that MSC`s dose and frequently dependently influenced by different kind of shock waves.

Discussion: The question was whether the radial or the focused shock wave application had different effects on MSC`s.

Conclusion: The dose range for a pro-migration effect seems small for focused compared to radial shock waves. A pro-proliferation effect is only seen for focused shock waves.

Effect of Radial Extracorporeal Shock Wave Therapy for Overuse Injury in Athletes Ruyun Yan

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Device and producing company: Swiss Dolor Clast®, EMS

Introduction: Overuse injury is a common cause of athletes' complaints about pain and is often difficult to treat. Traditional non-operative treatment consists of rest and the administration of NSAIDs. Some studies have suggested different types of therapeutic interventions such as steroid injection, sclerosing therapy and aprotinin injection. Recently, extracorporeal shock wave therapy (ESWT) has been reported to be effective for the treatment of sports injuries. The purpose of this study was to evaluate the efficacy of radial extracorporeal shock wave therapy (rESWT) in the treatment of athletes with overuse injury.

Methods: Sixty-nine athletes with overuse injury were treated with rESWT (13 epicondylitis of the elbow, 8 plantar fasciitis, 15 chronic Achilles tendinopathy, 21 jumper's knee and 12 tendinitis of the rotator cuff), 43 males and 26 females, aged between 20 and 35 years (mean age: 23 years). All patients must have undergone clinical diagnosis and had been treated unsuccessfully for at least 3 months, including local injections and non-steroidal antiinflammatory drugs and physiotherapy. The evaluation consisted of assessments of pain (Visual Analogue Scale, VAS) and functional impairment. The patients were treated in 3-5 sessions (at intervals of 5-7 days, mean 6 days) with 1,500-2,500 impulses per session. Device used was the Swiss Dolor Clast (EMS, Switzerland) and the energy flux density was 0.06-0.12 mJ/mm². The patients received no anesthesia, the energy level was determined by the maximum pain induced by ESWT that could be tolerated by each patient. The pain on palpation of the injury point and pain during daily activity were evaluated at each examination. Evaluation was performed at 0, 1, and 2 weeks and 1, 2, and 4 months postinitiation of therapy. At the end of follow-up, the patients were asked to assess their level of residual pain compared with pain before treatment.

Results: We obtained satisfactory results in 86.5% of cases (67.2% had excellent results and 19.3% showed good results), with an average time of approximately 4 weeks for resuming sport. Patients showed a considerable pain level decrease 1-2 weeks after the treatment (to the palpation $p < 0.05$ and during daily activity $p < 0.05$) and a further decrease in the subsequent examinations (to the palpation $p < 0.01$ and during daily activity $p < 0.01$). No obvious side effects were observed.

Conclusion: The outcome of the described rESWT treatment appears to be satisfactory and confirms its role in the treatment of athletes with overuse injury.

Low Energy Extracorporeal Shock Wave for Chronic Greater Trochanteric Pain Syndrome (GTPS)

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Device and producing company: Swiss DolorClast®, EMS

Introduction: Lateral hip pain is a frustrating condition encountered regularly by primary care physicians and orthopedists. The aim of this study was to determine whether low-energy SWT is a safe and effective management modality for chronic GTPS.

Methods: Thirty-three patients with chronic GTPS received low-energy SWT (SWT Group; 2000 shocks; 4 bars of pressure which is equal to 0.18 mJ/mm², total energy - 360 mJ/mm²). Thirty-three patients with chronic GTPS were not treated with SWT, but received additional forms of non-operative therapy (control group). All SWT procedures were performed without anesthesia. Evaluation was by change in visual analog score (VAS), Harris Hip Score (HHS) and by Roles and Maudsley score.

Results: Mean pre-treatment VAS scores for the control and SWT groups were 8.5 and 8.5, respectively. One month, 3 months, and 12 months after treatment, the mean VAS for the control and SWT groups were 7.6 and 5.1 (p₁ (p and 57.6 and 79.9 (p_{final} follow-up, the number of excellent, good, fair, and poor results for the SWT and control groups were 10 and 0 (p_{he} percentage of patients with excellent ("1") or good ("2") Roles and Maudsley scores (i.e. successful results) 12 months after treatment was statistically greater in the SWT group compared to the control group.

Discussion: The present study evaluated the effects of SWT on a consecutive series of patients with GTPS who had not responded to nonoperative management. The outcome for the entire population was evaluated and compared to a well matched control group. The mean VAS and HHS for the SWT group were statistically improved at 1, 3, and 12 months after treatment compared with the control group. The percentages of excellent or good results 12 months post-treatment for the SWT and control groups were 79% and 36%, respectively. There were no significant complications, and no patient required additional shock wave therapy. The results from this study add to the growing number of favourable reports that substantiate the efficacy of SWT as an effective treatment for chronic tendinopathies.

Conclusion: SWT is an effective treatment for GTPS.

ESWT for AVN of the talus

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Device and producing company: Swiss DolorClast®, EMS

Introduction: The talus is predisposed to AVN or bone death due to ischemia owing to its unique structure characteristic extraosseous arterial sources and variable intraosseous blood

supply. Neither surgical operation nor conservative treatments are very effective.

Methods: We used an EMS DolorClast®, a radial extracorporeal shock wave therapy machine (made in Switzerland) to treat the patient with an energy flux density of 0.12 ~ 0.16 mJ/mm². The impact points were chosen dependent on the pain location, 200 shocks at each

point. Five treatments were performed.

Results: One year later the symptoms were markedly relieved and no complications were observed. The MRI also changed significantly. It showed that the low-signal-intensity segment in the talar dome was reduced and the articular surface was clearer than before.

Discussion: Shock waves can increase the pain threshold. Shock waves might generate micro-fractures to promote bone healing and the formation of new local microcirculation due to angiogenesis. Shock waves traveling through different tissues can generate mechanical stress at the interfaces with the effect of tensile and pressure stress on the cells. Tensile stress

can cause the release of growth factors promoting microcirculation.

Conclusion: Extracorporeal shock wave treatment provided beneficial effects for this problem. This novel treatment modality resulted in significant pain relief and functional improvement.

rESWT in the Treatment of Spasticity in Cerebral Palsy: Randomized, Placebo-Controlled Clinical Trial

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Device and producing company: Swiss DolorClast®, EMS-Switzerland

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 nonprogressive lesion in the developing brain. Although the brain lesions are static, the movement disorders that arise are not and they are characterized by atypical muscle tone, posture and movement. 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. ESWT reduces hypertonia of the wrist and finger muscles in patients affected by stroke (Manganotti 2005). The aim of this study was to evaluate the efficacy and safety of radial extracorporeal shock wave therapy (rESWT) in the treatment of spasticity in patients with cerebral palsy.

Methods: This study is a randomized, placebo-controlled clinical trial that included 15 patients with spastic cerebral palsy; 12 men and 3 women, aged 10-46 years (mean age, 31). The 15 patients presented 40 spastic muscles (6 biceps brachii, 6 wrist flexors, 5 hip adductors, 10 gastrocnemius, 10 soleus and 3 hamstrings). The 40 spastic muscles were divided in three groups using a computerized random-number generator. Group I (14 muscles) received rESWT in spastic muscle. Group II (13 muscles) received rESWT in spastic muscle + rESWT in antagonist muscle. Group III (13 muscles) received placebo via application of a sham rESWT with sound in spastic muscle. Device used was the Swiss Dolor Clast (EMS, Switzerland). The patients were treated in 3 sessions at intervals of one week. Number of impulses was 2000 in each spastic muscle (4000 in Group II). Energy flux density was 0.10mJ/mm² (2 bar). Spasticity was evaluated by the Ashworth Scale from 0 to 4 (0: no spasticity to 4: severe spasticity) on the upper extremity muscles. Spasticity was evaluated with a goniometer (passive elongation) on lower extremity muscles. Outcomes were assessed by a blinded evaluator. Evaluation was performed immediately before treatment and at one and two months after treatment. The non-parametric Mann-Whitney U

test for independent samples was used for statistical analyses.

Results: There were no significant differences between Group I (rESWT in spastic muscle) and Group II (rESWT in spastic muscle + rESWT in antagonist muscle). However, with regard to the spastic muscles from upper limbs there were significant differences ($p=0.05$) between Group I (rESWT) and Group III (placebo). With regard to the spastic muscles of lower limbs there were significant differences ($p=0.044$) between Group I (rESWT) and Group III (placebo) as well as significant differences ($p=0.043$) between Group II (rESWT in spastic muscle + rESWT in antagonist muscle) and Group III (placebo). Observed side effects were 3 small superficial hematomas, 3 petechiae and 3 patients expressed light pain during the therapy. All side effects were tolerated by all the patients and disappeared after 1-7 days. All the patients finished the study. At the end of follow-up, all the patients were asked to assess if they would repeat the experience and all of them answered affirmatively.

Discussion: The study presents interesting insights on the usefulness of rESWT in treating patients with cerebral palsy to reduce spastic muscle tone. The mechanism of shock wave therapy on spastic muscles is still unknown. Basic research & larger randomized controlled studies are necessary to support the results of this clinical trial.

Conclusion: rESWT is more effective than placebo in decreasing spasticity of patients with cerebral palsy. Positive outcomes are maintained at least 2 months after treatment.

Side effects of Extracorporeal Shock Waves

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Device and producing company: Various devices, all FDA approved

Introduction: Extracorporeal shock waves have been widely used for decades. Several randomised multi centre trials have shown efficacy but some without clinical relevance with regard to outcome criterion. Two FDA trials were re-analysed for adverse events.

Methods: A total of 504 patients were randomly assigned to receive extracorporeal shock wave therapy or identical placebo intervention. ESWT was indicated if they fit standard inclusion criteria. Within 3 sessions at 1 week intervals, 6000 shock waves were applied to treat chronic plantar heel pain. All treatments were performed without any local anaesthesia. Main time endpoint was defined as 12 weeks after final ESWT.

Results: Twelve weeks after last intervention several adverse events were documented. In the active group, 117 adverse events were documented as device related and 35 AE were scored as not device related after ESWT. If identical placebo ESWT were performed 19 relevant device related adverse events and 39 not device related AE occurred. No device related severe adverse events such as tendon rupture or neural pathological finding were reported.

Discussion: After standard ESWT of plantar heel pain adverse events occurred, some of which have shown clinical relevance. Although needed, no long term follow up was performed. Neither were systemic adverse events screened with regard to endocrine pathologies despite the fact that they occurred when ESWT was applied to kidney stones.

Conclusion: ESWT has shown to have a good efficacy/adverse events ratio but thorough knowledge of musculoskeletal disorders indicated for ESWT and treatment of ESWT-induced side effects is essential.

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