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Extracorporeal Shockwave Therapy for Chronic Skin Lesions

Authors: W. Schaden, C. Kölbl, A. Valentin, M. Pusch, R. Thiele*

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Introduction:

Treating infected non-unions with soft tissue problems with ESWT we observed that there was also a positive effect on the skin. In most of the patients an extremely rapid healing of the wounds was observed. After successful animal trials performed at the department of plastic and reconstructive surgery of the University of Innsbruck we started our pilot trial.

Material and Methods:

Since September 2004, 102 patients with 104 chronic skin lesions were treated by means of ESWT. A special therapy head to defocus the shockwaves was constructed. All therapies were performed without any kind of anesthesia as an outpatient treatment. We used the same form of dressing after ESWT that was applied before the treatment. Depending on the surface of the defect different number of pulses were applied. The patients were treated in 1 up to 6 sessions depending to their tendency of regeneration and epithelialization.

Reason for skin lesion:

Posttraumatic 44
Venous ulcer 25
Arterial ulcer 15
Postoperative 10
Decubital Ulcer 5
Burning wounds 5
Total 104

Results:

Out of the 104 patients 77 (74%) showed complete healing, 11 (10%) had more than 50% of epithelialization and 7 (7%) had less than 50%. 9 (10%) patients were lost of follow up. The treatment was tolerated by all patients without any kind of anesthesia. No adverse effects have been observed. In none of the cases an increase of symptoms was reported. After further pilot studies evaluating the most efficient treatment parameters, prospective randomized trials have to be performed to proof safety ness and efficacy of shockwave therapy in this new medical field.

Randomized placebo controlled trial to determine the placebo effect size in orthopaedic

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Introduction:

The aim of the trial was to detect the placebo effect size in orthopaedic

Methods:

First step was a complete literature search to find out relevant parameters. 2nd step was to complete a feasibility study to verify published data. In the 3rd step we designed the trial in accordance to GCP E6 and E4 guidelines with power calculation, sample size calculation, etc.. 106 patients, suffering from chronic shoulder or heel pain received sham extracorporeal shock wave treatment after written informed consent. Randomly 52 patients was told to get the real therapy and 53 to get the sham treatment. The primary criteria was the subjective outcome on the visual analogue scale, the secondary criteria the Roles and Maudsley score. The primary end point was 1 month after treatment

Results:

Both groups showed a decrease on the VAS. Patients who know to be in the placebo-group decreased with 6% from 6.7 to 6.3 [95% CI: 0,4 .. 11,1]. Patients who believed to be in the “real” group decrease with 21% [95% CI:13,3 .. 27,7] from 7.0 to 5.5. The same effect was also shown in the Roles and Maudsley Score. Retrospective analysis showed effective randomisation and blinding technique.

Discussion and Conclusion:

The placebo effect is very important in orthopaedic treatment methods. The effect size reaches clinical relevance and must be discussed and controlled in every clinical study

A Case Study: Calcific Popliteal Tendinitis and its effective treatment using Low energy shockwaves

Author: D.K. Jones

Institution: The London Lithotripter Centre

The patient was an international level 400m hurdler complaining of pain during flexion in the postero lateral aspect of the knee.

Ultrasound imaging prior and during localisation whilst performing ESWT treatment demonstrated a 3mm calcific deposit within the popliteus tendon insertion to the lateral femoral condyle.

The Lithotripter of choice was a Storz Modulith SLK incorporating a 7.5Mhz inline.

The protocol was to perform three ESWT sessions, 1 month apart, employing an energy flux density ranging between 0.07 and .026mJ/mm².

Visual Analogue scores were recorded prior to the first and after the third treatment session.

No Analgesia was prescribed.

6 months after the first ESWT session complete dissolution of the calcific deposit was recorded on ultrasound imaging and the pain associated with the condition presented was now completely resolved allowing the athlete to train and compete at the highest level once again. This is a minimally invasive procedure with no long term side effects recorded by ourselves or the patient.

Shockwave Therapy for Hip bursitis : retrospective study

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Aim:

The aim of this study was to evaluate the efficacy and the safety of extracorporeal shock wave therapy for the treatment of Hip Bursitis in three Brazilian Orthopaedics Clinics.

Material and Methods:

In a multi-center, retrospective study, the effect of shockwave therapy was investigated in 32 patients with Hip Bursitis treated in the period of 21 months from June 2002 to February 2004. There were 25 women and 7 men with an average age of 63 (range, 41-79) years. The criteria for inclusion were at least three months of unsuccessful conservative therapy or six months of pain. Criteria for exclusion were inflammatory arthritis, previous corticosteroid injection, neurological abnormality, gout, malignant diseases, blood coagulation disorders. Each patient was treated with 1200 impulses of shock wave, a 35 mm focus depth, and with an energy flux density of no more than 0.14 mJ/mm after local anaesthesia. One treatment was performed on 30 patients and 2 patients underwent a second treatment. The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score and subjective outcome on Visual Analogue Scale (VAS) analysis 45, 90 and 180 days after the end of the therapy.

Results:

The study showed the efficacy and safety of ESWT were excellent in 34.4%, good in 53.1%, acceptable in 12.5%, and poor in 12.5%, 180 days after ESWT

Shock waves as therapeutic possibility in Reflex Sympathetic Dystrophy

Authors: Gigliotti S., Corrado B., Caputo R., Zincarelli C.

Institution: University of Naples "Federico II" - Department of Orthopaedics and Traumatology

Algodystrophy, Reflex Sympathetic Dystrophy, Bone Marrow Edema, Transient Osteoporosis and Complex Regional Pain Syndrome are probably different terms of the same pathology due to a vascular disturbance of bone : pathogenetic mechanisms are not totally clear but a disorder of the sympathetic regulation of micro vessels is involved certainly. The evolution is not foreseeable: many cases have a spontaneous resolution within six months but some cases are the onset of a necrotic lesion. Authors show some cases of R.S.D. of the hip and of the leg treated with shock waves and they emphasize the importance of correct criteria of inclusion (only cases in stage I according to the M.R.I. classification of Grimm: diffuse edema of bone with low signal in T1 and high signal in T2). Their protocol of treatment consists in two sessions of shock waves in the opposite direction with interval of two days, 3000 shots and 0,30-0,40 mj/mm² of energy flux density. In all 50 cases Authors have recorded a reduction of pain within one month and a complete recovery of M.R.I. signal within three months. Authors analyze possible mechanisms of action of shock waves more supporting the reset of sympathetic disorder of micro circle and the effects of nitric oxide.

Therapy With ESWT Associated With Physiokinesitherapy in The Treatment of The Post-Surgical Stiff Knee

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Introduction:

Various authors have described the possible onset of an articular stiffness associated with tendinosis and fibrotization of the ligamentous structures, in many cases accompanied by ossification processes of the synovial and of the tendinous capsular formations as well as of the periarticular soft tissues.

The treatment with ESWT allowed to obtain good results in different calcific and degenerative pathologies of the tendinous structures, also including the ossific myositis. Therefore, this method has been suggested to patients before a possible surgical treatment.

Materials and Methods:

Five subjects have been treated (4 females - 1 male, aged on average $51,2 \pm 12,7$) suffering from knee stiffness after one or more surgical operations associated with a patellectomy. The time elapsing from the latest surgical operation varies from 4 to 9 months. The reduction of range of motion was sometimes accompanied by pain symptoms.

The subjects have been treated with SW (with a shock wave unit of the spark gap electro-hydraulic type: OSSATRON OSA 140, HMT) with 2000 SW at 16kV (equal to $0,154\text{mJ}/\text{mm}^2$); treatment was repeated after two weeks.

After each treatment, the patients received a physiokinesitherapeutic treatment with passive (also forced) and active mobilization; 3 cases were able to perform exercises in a swimming pool with water temperature at 38°C .

Results:

The initial mobility evaluation of the knee flexion-extension movement showed a mean ROM of $38,0^\circ (\pm 13,5)$. After the first SW administration a recovery of the mobility was reported already during the first 48 hours and went on in the following days; such response led to repeating the treatment two weeks after the first one. Two weeks after the second treatment the patients' articular range of flexion-extension has been newly evaluated showing a mean ROM of $73,0^\circ (\pm 14,4)$ with an average increase of 92,1% ($p < 0,001$). Three months after the second ESWT session a further evaluation of the articular function has been made showing a mean ROM of $79,0^\circ (\pm 16,4)$ with an average increase of 107,9%. The pain symptom shows an improvement not to be related to the functional recovery. Variation of the x-ray picture shows an unstable evolution and this proves to be related neither to the functional recovery nor to a reduction of the pain symptoms.

Conclusions:

The clinical cases described are a very limited sample but the result obtained allows to view the suggested therapeutic protocol with great interest.

In the end, we can state that ESWT associated with adequate physiokinesitherapy has led to significant results.

The costs as well as the risks taken by the health care centre and by the patients proved to be substantially smaller than a possible surgical therapy.

Therapy With ESWT Associated With Physiokinesitherapy in The Treatment of The Stiff Hip in P.O.A. Post-Coma

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Introduction:

The articular stiffness of the hip linked to the P.O.A. onset is quite a frequent pathology in subjects who have suffered from coma. It is a disabling condition, often appearing in progressive form.

The treatment with ESWT has been suggested in the past for this specific pathology by Morosini, De Pretto, Bosco, proving good results. The cases described hereafter have to be considered as special ones, since the major clinical focalisation refers to the psoas muscle with severe disorder not only of the flexion-extension of the hip but also of the intra-extrarotation and a stiffness of the up-and-over movement of the pelvis. Therefore, the ESWT therapy has been suggested to these patients before a possible surgical treatment.

Materials and Methods: Three subjects have been treated (3 females, aged on average 28) suffering from hip stiffness after a coma episode; bilateral in 2 cases, one of these showing a complex P.O.A. both medially and laterally, monolateral in 1 case. The time elapsing from coma resolution goes from 5 to 8 months.

The subjects have been treated with SW (with a shock wave unit of the spark gap electro-hydraulic type: OSSATRON OSA 140, HMT) with 3000 SW at 16kV (equal to 0,164 mJ/mm²); treatment was repeated after two weeks. After each treatment, the patients received a physiokinesitherapeutic treatment with passive (also forced) and active mobilization.

Results:

The initial evaluation of the hip flexion-extension movement showed a mean ROM of 58,0° ($\pm 20,5$), whereas the intra-extrarotation showed a mean ROM of 27,0° ($\pm 5,7$). Two weeks after ending the therapeutical cycle, the clinical evaluation showed a mean ROM of 80,0° ($\pm 16,0$) in the flexion-extension and 37,0° ($\pm 8,4$) in the internal-external-rotation. After three months a further clinical evaluation has been made showing a mean ROM of 84,0° ($\pm 19,2$) with an average increase of 62,1% ($p < 0,0005$) in the flexion-extension and of 39,0° ($\pm 9,6$) in the internal-external-rotation with an average increase of 44,0% ($p < 0,005$). The x-ray picture doesn't show any significant evolution and this especially proves to be neither constant nor related to a functional recovery.

Conclusions:

The clinical cases described are a very limited sample but the result obtained allows to view the suggested therapeutic protocol with great interest. The costs as well as the risks taken by the health care centre and by the patients proved to be substantially smaller than a possible surgical therapy. The ESWT proves to be a non invasive treatment, not especially expensive and without side effects when administered by experts.

Treatment of Back Pain with Shock Wave Therapy

Authors: R. Akopyan, MD; M. Jeshurun, MD; Akopyan N.

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For several years both ESWT and RSWT have proven to be effective in the treatment of a wide range of orthopedic pathologies.

Back pain is one of the most common medical problems in the U.S.A. It affects most people at least once in their lifetime.

Nevertheless, there is yet minimal experience regarding back pain treatment with Extracorporeal Shock Wave Therapy.

We currently present our experience in treating this application with ESWT (Medispec Ltd.’s Orthospec™) and RSWT (Medispec Ltd.’s Orthopedic Lithospec™).

18 patients with back pain were treated in 22 treatment “cases” with ESWT, RSWT, or the combination of both treatments.

Out of 18 patients 12 were males and 6 females, with the average age of 51.2 years (21-84 years). Spinal pathologies were divided as follows: 11 -Cervical Spine out of which 7 were of cervical spine purely, and 4 - treatments of both cervical and lumbar spine; 11 treatments were of lumbar Spine, out of which - 7 were of lumbar spine purely and 4 - a combination of lumbar and cervical spines treatments.

Out of these 11 Lumbar treatments - 3 patients were treated by ESWT, 4 were treated by RSWT and 4 were treated by a combination of ESWT and RSWT. Out of 11 cervical treatment 3 were treated with ESWT, 4 with RSWT and 4 by a combination of ESWT and RSWT. All treatments were combined with Manual Therapy.

The treatment parameters for ESWT were as follows: Treatment intensity: 4-7, Treatment frequency: 150 shocks/min.; the total number of shock waves: 1000-5000, and the number of treatment sessions: 3-5.

The average treatment parameters for RSWT were as follows: Maximal treatment intensity, Treatment frequency: 20 Hz, and an average of 3.54 treatment sessions.

All patients have shown remarkable improvement both in pain intensity and in everyday function. Five patients are currently proceeding with treatment in spite of their clinical improvement. One patient with cervical pain who has improved returned with recurrent pain and is currently under treatment, and one patient with Spina Bifida and HLA B27 has returned with back pain at a different location.

No anaesthesia was needed prior to or during treatment and no imaging was required. Treatment was well tolerated, with no adverse events reported.

Thus, Shock wave treatment seems to be both safe and effective in the treatment of back pain.

Radial Shockwaves in The Treatment of Chronic Muscular Pain of The Back: Clinical Application And First Clinical Results.

Authors: Maier M., Meurer T.

Institution: Oberammergau, Germany

Radial shockwaves are in clinical use for the treatment of chronic muscular pain of the back. This kind of therapy is named “trigger point shock wave application”.

In the present pilot study 16 patients are included until today. All of them presented with chronic muscular back pain and with positive trigger points in the muscles of the back. All patients received 5 to 7 sessions of radial shock waves (2000 - 3000 pulses a session, 2,0 bar, 6 to 8 Hz). No local anaesthesia was used. Ultrasound jelly was used as coupling medium. Pain intensity was determined before, 6 weeks and 12 weeks after radial shock wave application using the Visual Analog Scale (VAS) from 0 points (minimum pain) to 10 points (maximum pain). At both time points following the treatment the value of the VAS improved compared to the measurement before treatment. No major side effects were observed.

Following the present pilot study “trigger point shock wave application” seems to achieve good clinical results in patients with chronic muscular pain of the back. However, the number of patients is low, the follow-up period is short and the patients population is inhomogeneous. Therefore, more detailed clinical studies must be carried out until the general benefit of radial shock waves for chronic muscular pain of the back might be recommended in general. Furthermore it is important to analyse possible side effects systematically.

Radial Shockwaves in The Treatment of Chronic Gluteal trigger points as a common source of pseudosciatic pain and their therapy with radial shockwaves.

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Introduction:

Patients with chronic low back pain often complain about irradiation in their legs although they have no objective neurologic deficit. These irradiations are called “pseudosciatic” and mostly explained by the muscle triggerpoint theory of Travell & Simons. Pseudosciatic pain is due to trigger points in the gluteal muscles. The triggerpoint theory further includes the possibility of secondary insertion tendonitis due to an increase of intramuscular tension over longer periods.

In this clinical study the frequency and localisation of musculotendinous pathologies amongst chronic low back pain patients were examined and the results of a radial shockwave therapy described.

Material and method:

In a group of 184 patients with chronic pseudosciatic pain (>12 months) the gluteal muscles and their insertion at the ilium and the greater trochanter were examined by palpation and the correlation to the duration of pain calculated (1 examiner).

The triggerpoint areas in the gluteal muscles were treated with radial shockwaves (Masterpuls, Storz) during 6-8 sessions and the result of therapy documented over 6 months.

Results:

92% of all patients with chronic pseudosciatic pain showed trigger points in the gluteal muscles and described a typical referred pain in the lower extremities during high pressure on these areas. Amongst these 184 patients 61% showed muscular trigger points only (average pain duration 1.8 years, VAS 7.3), whereas additional insertion tendopathies were found in 31% of the patients (average pain duration 3.7 years, VAS 7.6). The difference in pain duration was statistically significant ($p < 0.01$), whereas the intensity of pain was not.

The treatment with radial shockwaves resulted in a significant reduction of pain after 6 months in the subgroup of pure muscular triggerpoints in 84% of patients (VAS 1.9) and a relief of the referred pain in 69%. In the subgroup with additional insertion tendopathies only 49% of patients profited from the trigger shockwave therapy (VAS 3.4) and described a relief of the pseudosciatic pain in 35%.

Conclusion:

Muscular gluteal trigger points are a common source of pseudosciatic low back pain and are a risk factor for secondary insertion tendopathies. Whereas muscular trigger points respond well to the radial shockwave therapy, insertion tendopathies do not improve equally. Under practical considerations we recommend an early shockwave treatment of muscular trigger points in patients with pseudosciatic low back pain.

Extracorporeal Shockwave Therapy In Myofascial Pain Syndrome

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Myofascial Pain Syndrome is one of the most common causes of acute and chronic pain of the musculoskeletal system. It is characterized by myofascial trigger points (MTrPs), which are hyperirritable spots in a palpable tense band of skeletal muscle. MTrPs are caused by a dysfunction from involved motor endplates, which is followed by a segmental shortening of groups of sarcomeres.

Diagnostic approach is based on the criteria defined by J.Travell and D.Simons: while palpating the hyperirritable MTrP a characteristic referred pain and familiar pain (recognition) is elicited. Effective diagnosis and treatment requires clinical experience and diagnostic skill, especially palpation ability. Exact pressure or impulse with minimum irritation or even damage of the collateral tissue is needed to identify and release MTrPs.

The focussed extracorporeal shockwave therapy (ESWT) is, on the contrary to the radial ESWT, able to apply an exact mechanical impulse on a small spot to release MTrPs.

Moreover the focussed ESWT was also able to reproduce, while treating a MTrP, the referred and also the familiar pain of the patient.

In a pilot study 40 patients with various musculoskeletal pain have been examined and treated by an experienced medical doctor (Triggerpunkt-Therapeut -IMTT®) and identified MTrPs were treated by focussed ESWT (Piezoston 100 plus, Fa. Wolf). In more than 90% of the cases the characteristic referred pain and familiar pain (recognition) has been elicited by the focussed ESWT, when precisely the MTrP was hit by the exact impulse. This study revealed that the focussed ESWT is able to improve the diagnosis of MTrPs and also to treat musculoskeletal pain successfully.

Conclusion: In clinical routine there was so far no imaging method or laboratory test of MTrPs. Diagnosis depended entirely on history and physical examination. The use of the focussed ESWT detects MTrPs accurately and will lead us more often to recognize muscle-tissue being the cause of most of musculoskeletal pain.

Heat-shock proteins induced by extracorporeal shockwaves as a further cellular defence mechanism against external stress argents

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The human organism provides in addition to the enzymatic-oxidative system a further defence mechanism through the so-called stress proteins against reactive oxygenous and nitrogenous species (RONS). Part of this defense mechanism is the group of heat-shock proteins (HSP's), which can be formed quickly and substantial quantities as a cellular response to external physical or chemical stress.

So far, HSP's are found in nearly all pro- and eukaryotic cells. They are divided into groups according to their molecular weight in kilo Dalton.

Cellular stress-inducing agents of muscles and tendons are hyperthermia, ischaemia, denaturation of proteins caused by various chemical and physical effects and bodily strain.

Through mechanical irritations of muscles and tendons we were able to bring about the formation of heat-shock proteins in muscular and tendineous tissue. As mechanical stress argent we used extracorporeal shockwaves.

Subsequently, fine-needle biopsy were carried out at certain time intervals. Using the western blotting technique, we were able, to prove the formation of heat-shock proteins and their mRNA with monoclonal HSP-antibodies.

It is worth noting, that the frequency and intensity of stimulation appear to play a crucial role in the formation of heat-shock proteins.

Significance of reactive oxygen- and nitrogen - compounds as muscular pain modulators with reference to triggerpoint shock wave therapy

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One of the effects of the impact of various complex, signal emitting stress situations is the formation of free radicals. In the past, free radicals were primarily thought of as causing so-called oxidative stress. More recently it was discovered that they also play a significant role as signal and modulator molecules, particularly with regard to the activation of cellular defense mechanisms against various stress factors acting on the cell itself. The changes of the cellular redox system through oxidation and nitrolysis of other molecules or parts thereof are at the origin of the crucial role as signal and modulator molecules.

These changes are brought about through RONS (reactive oxygenous and nitrogenous species). The formation of nitrogen oxide (NO) plays an important role in the occurrence of muscle pain. Nitrogen oxide blocks, through interaction with thiolate ions (cysteine fragments), the receptors NMDA (N-methyl D-aspartate) and NK1 (neurokinin I).

Neurotransmitters like excitatory amino acids (e.g. glutamate) and neuropeptides such as somatostatin, substance P and calcitonin gene-related peptide are thereby deactivated. Through this mechanism the virtuous circle of continuous sensitization of muscular nociceptors and the related continuation of a local edema, accompanied by the release of bradykinin, is interrupted. We obtained evidence of the presence of nitrogen oxide in vitro through EPR (electron paramagnetic resonance) spectroscopy.

In vivo we were able to obtain evidence by using an NO-analyzing agent where a reaction takes place between NO and ozone resulting in chemiluminescence.

As mechanical stress agent we used extracorporeal shock waves.

Extracorporeal shock wave therapy induces degeneration and subsequent regeneration of nerve fibers innervating from DRG neurons in rat.

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Introduction:

Extracorporeal shock wave therapy (ESWT) has been applied to the management of various painful orthopaedic disorders. However, only a few reports have described the mechanism of the analgesic effect from this therapy. In this study, we investigated the analgesic effect of ESWT by immunohistological evaluation of dorsal root ganglion (DRG) neuron of rat.

Methods:

Activating transcription factor 3 (ATF3) is regarded as a marker of nerve injury, and growth-associated phosphoprotein (GAP43) is used as a marker of nerve regeneration. We examined ATF3 and GAP43 expression profiles in rat DRG neurons after ESWT.

Shock waves were applied to the skin of both hind paws in 28 rats, and 4 naive rats were used as controls. After 1, 2, 4, 7, 14, and 28 days, rats were sacrificed and the bilateral L4 and L5 DRGs were evaluated immunohistochemically.

Results:

The average number of ATF3-immunoreactive neurons significantly increased in the treated rats at each time point, and 77.0% of those neurons also exhibited immunoreactivity for GAP-43. Among the ATF3-immunoreactive neurons, 76.8% were large diameter cells ($>30\mu\text{m}$).

Discussion:

We showed that ESWT caused neuronal damage as represented by ATF3-immunoreactive neurons. Axonal regeneration was also confirmed by the expression of ATF3/GAP43 double-immunoreactive neurons. The significant increase in the number of ATF3-immunoreactive neurons observed after ESWT was sustained for at least 28 days. This result, however, does not assure the long-term analgesic effect of ESWT. The regeneration of nerve fibres which indicated by ATF3/GAP-43 double immunoreactivity began within 24 hours of ESWT, and 77.0% of ATF3-IR neurons were also reactive for GAP-43. This finding may relate to the temporary analgesic effect of ESWT in clinical subjects in whom repeated treatments are often necessary. With regard to the size distribution of ATF3-immunoreactive neurons, 23.2% were small and 76.8% were large, respectively. Large-diameter fibres from large neurons may be more sensitive to ESWT than small-diameter fibres from small neurons. The degeneration of nerve fibres originating from small ATF3-immunoreactive neurons may cause alleviation of pain because these fibres are mainly small-diameter fibres, which are involved in nociception and temperature perception. The degeneration of large-diameter fibres indicated by the expression of large ATF3-immunoreactive neurons may also relate to the analgesic effect of ESWT from the evidence that these fibres play a crucial role in some types of painful condition such as allodynia.

Second Application of Low-energy Shock Waves Has a Cumulative Effect on Free Nerve Endings

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The aim of this study is to evaluate whether the repeated shock wave application provides a cumulative effect regarding the degeneration of cutaneous nerve fibres, comparing with the degeneration effects associated with the single application. We used 36 male rats. Four rats were study controls. Shock waves were applied to the left first globular foot pad of the remaining 32 rats. After 14 days, 16 of these rats received a second, identical shock-wave application. The foot pads of the rat hind paws were then resected on days 7, 14, 28 and 42 after final shock wave application. Foot pad sections were processed immunohistochemically using antibodies to protein gene product (PGP) 9.5 and calcitonin gene-related peptide (CGRP). We compared the number of epidermal nerve fibres between rats receiving one application of shock waves and rats receiving two applications. During the first four weeks, there was nearly complete degeneration of epidermal nerve fibres in both groups. By the end of six weeks, re-innervation of the epidermis had begun in the single application group. Re-innervation occurred significantly more slowly in the repeated application group than in the single application group. These data show that a second application has a cumulative effect on nerve fibres. The results of the present study suggest that multiple applications of low-energy shock waves could provide longer-lasting antinociceptive effect, comparing with a single application.

Extracorporeal Shock Wave May Enhance Skin Flap Survival in an Animal Model.

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Several methods have been used in an attempt to increase blood supply and tissue perfusion in ischemic tissues. The authors investigated the effect of extracorporeal shock wave (ESW) treatment on compromised skin flaps. For this purpose, the epigastric skin flap model in rats, based solely on the right inferior epigastric vessels was used.

Twenty male Sprague-Dawley rats were divided into two groups (ESW-group, Control group) of 10 rats each. The ESW-group was administered 2500 impulses at 0.15 mJ/mm² immediately after surgery, whereas, the control group received no treatment. Flap viability was evaluated on day 7 after the operation. Standardised digital pictures of the flaps were taken and transferred to the computer, and necrotic zones relative to total flap surface area were measured and expressed as percentages.

Overall, there was a significant reduction in the surface area of the necrotic zones of the flaps in the ESW group compared to the control group (ESW group: 2.2+/-1.9% versus control: 17.4+/-4.4% (p < 0.01).

In this study, the authors demonstrated that treatment with ESW enhanced epigastric skin flap survival, as confirmed by the significant reduction of necrotic flap zones. ESW treatment seems to represent a feasible and cost effective method to improve blood supply in ischemic tissue.

A Trial of Shockwave-mediated plasmid DNA transfection

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Introduction:

Viral vectors have been shown to be effective for gene transfer with high efficacy rate. However, for the therapeutic application it requires a number of improvements including the issues of safety, immunogenicity. Non-viral gene transfer systems are safe and easy to apply, but low efficacy rate remains unsolved. Among these methods ultrasound-mediated plasmid DNA transfection with microbubble agent is reported to be useful and reveal a certain level of efficiency. In considering an ideal gene therapy for orthopaedic disorders, to modify non-viral plasmid DNA transfection would be desirable. Thus we tried to develop shockwave-mediated plasmid DNA transfection.

Methods:

Male rats (200-300g) were used for the experiment. Previously conditioned luciferase plasmid DNA solution and pEGFP plasmid DNA solution were injected directly into the pretibial muscle of the rat hindlimb under general anaesthesia. After that low-energy extracorporeal shock waves were exposed to the identical area. Two days later they were sacrificed and the muscles were harvested. GFP expression was observed by fluorescence microscope and luciferase activity was quantitatively measured by a luciferase assay system to evaluate efficacy rate of gene transfection. The advantageous effect of a microbubble agent (Optison) was also evaluated.

Results:

GFP expression and luciferase activity were significantly enhanced when the specimens were exposed to shock waves with Optison. Plasmid DNA injection without Optison or shock wave application was failed to increase transfection efficiency. Complication was not occurred except for minor subcutaneous hemorrhage of the exposed site.

Discussion:

We showed that the shockwave-mediated plasmid DNA transfection was achieved with a microbubble agent. The cavitation effect, which is augmented by this agent, may cause transient hole formation on the neighbour cell surface. Plasmid DNA may be transferred into the target cell through this hole. This phenomenon called as Sonoporation may explain the mechanism of our method. The efficacy rate of gene transfection is not as high as other methods such as adenoviral vectors. Although it needs so many improvements before application for the clinical use, this safe and easy method may provide a possibility of gene therapy for various orthopaedic disorders.

Evaluation of Extracorporeal Shock Wave (ESWT) - Therapy in Experimental Induced Equine Osteoarthritis

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There is some experimental evidence and anecdotal clinical impression of extracorporeal Shock Wave Therapy (ESWT) for the treatment of osteoarthritis (OA)^{1,2,3}. The study was a blinded, experimentally controlled, randomized block design that used 24 horses in an established model of OA⁴. On day 0 of the study, arthroscopic surgery was performed on both middle carpal joints of horses and OA induced in one middle carpal joint. On day 14, horses were divided into three treatment groups, sham control, positive control (intramuscular PSGAG), and ESWT treated. The sham control group was treated similarly to the ESWT treated group in all respects except that bubble wrap was applied to the probe end to absorb all of the energy. The ESWT group received treatment on days 14 and 28 using a VersaTron® 12 mm probe. 2000 Shock Wave level were given on day 14 and 1500 Shock Waves on E6 level on day 28. Energy was delivered mainly to the middle carpal joint capsule attachment, but some delivered to the area of fragmentation. At day 14, horses began a strenuous treadmill exercise program.

Significant improvement in clinical lameness was noted at the first evaluation time point post-treatment (14 days) in the ESWT-treated horses compared with both the sham and positive control. The subsequent improvement was also noted at days 42, 56, and 70. Both the positive control and the ESWT horses had significant improvement in synovial fluid TP levels within 14 days of treatment, indicating less synovitis compared with sham control horses. Improvement with both Adequan® and ESWT treatment was also noted in the amount of glycosaminoglycan (GAG) released into the bloodstream 14 days post-treatment.

In conclusion, treatment with ESWT reduced the clinical signs of pain measured by lameness evaluations (this pain was even reduced 42 days after the last treatment, which was the longest time point measured). There was no significant improvement in response to flexion, implying that improvement in lameness was not caused by local desensitization of the region, or more specifically the joint capsule. Currently synovial fluid protein, another parameter of synovitis, was reduced with ESWT. There was no difference in articular cartilage parameters suggesting that ESWT had a greater effect on the soft tissue surrounding the joints compared with the articular cartilage.

References and Footnotes:

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⁴ Frisbie DD, Kawcak CE, Trotter GW, et al. *The effects of triamcinolone acetate on an in vivo equine osteochondral fragment exercise model*. Equine Vet J 1997; 29:349-359.

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Effects of Extracorporeal Shock Waves on Chondrocytes From Osteoarthritic Human Subjects

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Objective:

A key role in the pathophysiology of articular cartilage is played by cell/extra-cellular matrix (ECM) interactions, which are mediated by cell surface integrins. In a physiologic setting, integrins modulate cell/ECM signaling, essential for regulating growth and differentiation and maintaining cartilage homeostasis. During OA, abnormal integrin expression alters cell/ECM signaling and modifies chondrocyte synthesis, with the following imbalance of destructive cytokines over regulatory factors. IL-1, TNF-alpha and other pro-catabolic cytokines activate the enzymatic degradation of cartilage matrix and are not counterbalanced by adequate synthesis of inhibitors (IGF, TGFb, IL-10).

We investigated the effects of extracorporeal shock waves on the expression of IL-10, TNFa, b1 integrins (CD29) on chondrocytes from osteoarthritic human subjects.

Methods:

Articular cartilage was obtained from 9 patients with osteoarthritis (OA) undergoing surgical knee replacement. Chondrocytes were isolated by enzymatic digestion from articular cartilage. Chondrocytes of Group A were treated with ESWT with an electromagnetic lithotripter (MINILITH SL1 by STORZ MEDICAL) by selecting two different energy levels (0,055 - 0,17 mJ/mm²) and two total impulses (500, 1000) for each level. The Control Group (B) received no shock wave treatment but was maintained with the device off for the same time.

The cells from each group (A, B) were cultivated (37°C, 5% CO₂) for 48 hours. The biological activity and viability were evaluated at 24 and 48 hours after treatment. Cytokines expression were carried out by flow-cytometry.

Result:

Significant reduction in IL-10 and TNFa expression were found in Group A as compared to controls; this effect was seen in cultures receiving the highest energy treatments. No significant differences were found in b1 integrins (CD29) expression.

Conclusion:

Our preliminary investigation revealed that extracorporeal shock wave treatment at lowest energy level does not cause cytotoxicity to human chondrocytes.

On the other hand, the lowest level appeared to significantly reduce the catabolic parameter. Further evaluation of the effect of ESWT on chondrocytes is indicated.

Wnt3 and Wnt5 Proteins Mediate Shock Wave-Promoted Osteogenic Differentiation of Mesenchymal Stem Cells

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Osteogenesis has been implicated in recapitulation of embryonic skeletal development. The Wnt family of growth factors are important regulators of skeletogenesis. In animal studies, we have reported that shock waves (SW) can promote osteogenic differentiation of mesenchymal stem cells through TGF-beta-, BMP- and VEGF-mediated signal transduction. Here, we further found that SW promotion of osteogenic differentiation of bone marrow stromal cells mediated by the Wnt and beta-catenin-dependent pathway. SW treatment (0.16 mJ/mm², 1 Hz, 500 impulses) promoted cell proliferation, alkaline phosphatase activity and mineralized nodule formation of primary human bone marrow stromal cells. Real-time PCR results showed that SW increased Wnt3a and Wnt5a, but not Wnt7a mRNA expression of cell cultures. Inhibition of Wnt3a and Wnt5a signalling by Wnt3a and Wnt5a neutralizing antibodies reduced the promoting effect of SW on osteogenic differentiation of stromal cells. Further studies demonstrated that SW significantly promoted cytosolic beta-catenin accumulation and nuclear osteogenic transcription factor Cbfa1/Runx2 activation. Wnt3a and Wnt5a neutralizing antibodies reduced SW-enhanced cytosolic beta-catenin and nuclear Runx2 activation. Mesenchymal cells responded to recombinant Wnt3a and Wnt5a protein by increasing cytosolic beta-catenin expression, nuclear Runx2 activation and bone nodule formation. Moreover, serum harvested from patients with non-union receiving SW treatment increased alkaline phosphatase activities and bone nodule formation of mesenchymal cells that were blocked by Wnt3a and Wnt5a neutralizing antibodies. Taken together, we have shown that SW increased Wnt3a and Wnt5a synthesis followed by cytosolic beta-catenin accumulation and nuclear Cbfa1/Runx2 activation, resulting in an increase of osteogenic differentiation of mesenchymal cells.

Insights Into The Molecular Mechanisms of Shockwave Mediated Analgesia

Authors: Maier M., Tischer T., Hausdorf J., Saisu T., Schmitz C.

Institution: Munich, Chiba, Maastricht

The biologic action of shock wave application on the musculoskeletal system is understood poorly. To prove the hypothesis that alterations of tissue concentrations of substance P and prostaglandin E2 are involved in biologic actions - such as pain and analgesia - of shock waves, shock waves with energy flux density of 0.9 mJ/mm² (1500 pulses at 1/second) were applied in vivo to the distal femur of rabbits. The concentrations of substance P and prostaglandin E2 eluted from the periosteum of the femur were measured. Compared with the untreated contralateral hindlimbs, substance P release from the periosteum from the femur was increased 6 hours and 24 hours after extracorporeal shock wave application, but was decreased 6 weeks after extracorporeal shock wave application. Remarkably, there was a close relationship between the time course of substance P release found here, and the well-known clinical time course of initial pain occurrence and subsequent pain relief after shock wave application to tendon diseases. Accordingly, substance P might be involved in the biologic action of extracorporeal shock wave application on tissue of the musculoskeletal system.

Deep Partial Thickness Burn Injury And The Effect of ESWT: an Experimental Investigation in Rats.

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Extracorporeal shock wave therapy enhances tissue vascularisation and neoangiogenesis. Recent animal studies in our lab showed an improved tissue regeneration using ESWT. Deep partial thickness burns most of the time require skin grafting. This surgical intervention frequently causes a functional as well as aesthetical dissatisfying outcome. The aim of this study was to demonstrate the effect of ESWT on skin regeneration in second degree burns. Two standardised deep partial thickness burns were applied to the back of 30 male Wistar rats, respectively. Immediately after the burn, ESWT was performed in rats (N=30; Group 1). The second group did not receive any treatment (N=30; Group 2). At day 5, 10 and 15 five rats of each group were analysed. The degree of re-epithelization was documented using digital photography and histology. Statistical analysis was performed. ESWT enhanced the percentage of wound closure over time (group 1) as compared to the group 2 ($p < 0.05$). The re-epithelialization rate could be improved significantly at days 5 and 15 ($p < 0.05$). Extracorporeal shock wave therapy improves skin regeneration of deep partial thickness burns in rats, as confirmed by a significant reduction of wound areas and a significant increase of re-epithelialization. In this study we could show impressively the potential of this technology in skin applications.

Cellular Response of Primary Human Line Cultures in Petri's Capsule to Application of Shock Waves

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One of the greater controversies concerning the action mechanisms of Shock Waves is represented by their biological effect on the alive tissues and especially on cells. The comprehension of such effects could be a remarkable step in the knowledge of this technique in order to improve the clinical application and to overhaul the current therapeutic protocols, especially concerning dosages and application fields.

To such purpose the authors have treated a high number of samples of primary line cells: osteoblasts, fibroblasts, cardiac stem cells, hemopoietic stem cells etc. The treatment has been carried out in a Petri's capsule with 800 Shock Waves at an energy level between 0.030 and 0.10 mJ/mm². The cell cultures have been exposed to a single application of Shock Waves and then observed and evaluated in various appearances (modifications of mitotic index, percentage of cellular survival, activation/deactivation of enzymatic chains and metabolic activities) during the following weeks, always comparing the results with the ones in no treated cellular cultures. The authors report the results achieved and discuss widely about their clinical involves.

Extracorporeal Shock Waves Induce Production of Bone Growth Factors in Osteoblasts

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The molecular events following shock wave treatment of bone are to a large extent unknown. Nevertheless patients with osteonecrosis and non unions are already treated partly successfully with extracorporeal shock waves. In our study we isolated osteoblasts from bone pieces of patients undergoing knee or hip replacement surgery, subjected the cultured cells to shock waves and investigated the supernatants for bFGF, TGFbeta1 and VEGF.

After collagenase treatment cells were cultivated and characterised using FACS analysis. 95% of the cells were CD 44+ and CD 34-, CD14-, CD3- and CD 4-. After conditioning with an osteogenic medium containing Dexamethasone, Ascorbate and Beta-Glycerolphosphate cells showed a homogenous mineralisation-pattern in the v. Kossa staining.

These cells were subjected to 250 or 500 shock waves at 25 kv using an experimental electrohydraulic lithotripter (Dornier XL 1). After shock wave treatment cell viability was determined and cells were seeded at 100000 cells in 12 well plates. After 24, 48 and 72 h the cell number was determined and the supernatant was frozen. The levels of the bone and vascular growth factors bFGF, TGFbeta1 and VEGF were examined using ELISA. A control group was treated in the same way without receiving shock waves.

After 24 h there was a significant increase in bFGF levels ($P < 0.05$) with significant correlation ($P < 0.05$) to the number of impulses. TGFbeta1 showed an time dependent increase with a peak at 48 h which was not significantly different from the control group. VEGF showed also a tendency to be shock wave induced but with no significance.

For the first time it was shown that bFGF as an important growth factor in new bone formation is produced by human osteoblasts treated with shock waves.

This may be one piece in the cascade of new bone formation following shock wave treatment and may lead to a more specific application of shock waves in orthopaedic surgery.

Osteochondral repopulation with help of intermittent extracorporal shockwaves and simultaneous intra-articular application of Hyaluronan. Biomechanical and biochemical basics

Authors: H.G.Neuland, H.J.Duchstein

Institution: ZES Kronberg - Chem.pharmazeutisches Institut Universität Hamburg

Through the effect of mechanical stress on hyalin cartilage tissue an induction of special physical-mechanical signals is achieved, which are able to initiate specific inter- and intracellular biochemical reactions within the chondrocyts or their precursor cells (fibroblasts or stem-cells). Furthermore, they activate special growth factors and they are able to suppress or induce special enzymes, which are important for the osteochondral metabolism. By the way, the hyalin cartilage is hypo cellular, avascular, aneural and alymphatic. That means that every single cartilage cell has much higher regenerative power than other tissue cells, because the chondrocyts are self-sufficient with regard to their environment.

The extra cellular matrix (ECM) of the cartilage contains various protein fibres interwoven in a hydrated gel composed of a network of glycosaminglycan (GAG) chains.

Hyaluronan is the simplest of the GAG's. Whereas other GAG's are synthesized inside the cell and released by excytosis, hyaluronan is spun out directly from the cell surface by enzyme complex embedded in the plasma membrane. Hyaluronan synthesises from the basal side of an epithelium, for example, often to create a cell-free space into which cells subsequently migrate. Furthermore Hyaluronan is an important constituent of joint fluid, where it serves as a lubricant.

This both facts are the basic idea for our pilot study:

- The induction of the repopulation of chondrocyts by activation of the precursor-cells (fibroblast and stem cells).
- The setting-up of new intercellular space for the new developed chondrocyts by hyaluronan.

First results of pilot study: osteochondral repopulation induced by extracorporeal shockwaves and intra-articular Hyaluraninjection - Evaluation of 118 patients

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The study referred mainly to knee-lesions: Gonarthrosis, osteochondrosis disecans, acute chondral lesions. The examination were divided into four groups:

1. Diagnostic and if necessary surgical arthroscopy, ESWT, Hyaluronan injection
2. Only ESWT and Hyaluronan injection
3. Only ESWT
4. Only Hyaluronan injection

From the outset the study was accompanied by clinical examinations. Follow-up examinations were done four times at three-month intervals.

Examination of the sensitivity to pain by VAS (visual analogue scale) and the functional maximum load by Lysholm and HSS (hospital of special surgery) score were carried at the beginning, three, six and twelve month respectively after, if required, two years.

All groups started with MRI- examination. Control took place after six and twelve month. Previous clinical results: 31 patients Outerbridge - stadium I, all after therapy without complains during a time interval between 3 and 16 months. 25 of this group are sportsmen with state of diagnostic arthroscopy, complains and minimal 1 year with therapy resistance complains, including the end of their sportive activity. All of them do sports again.

43 patients Outerbridge - stadium II, 70% after therapy without complains during the period of treatment from 3 to 24 months. The rest of 30% only complains after long stress, mainly content.

27 patients - Outerbridge stadium III, significant improvement 65%, mainly improvement of stress pains and prolongation of the walking range.

25% of the patients improvement, but remaining complains; a second attempt of therapy is planned.

10% no change of findings.

First results of 18 patients with rhizarthrosis: 8 patients stadium I and III all of them without sequelae

4 patients stadium III borderline complains

4 patients stadium IV no improvement

Treatment of patients with posttraumatic cartilage lesions in lower extremities with intermittent extracorporeal shockwaves and intra-articular application of hyaluronic acid

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Institution:

Centre Hospitalaire, Wissembourg (France)
ZES Kronberg (Germany)

Starting in October 2003 patients with posttraumatic cartilage lesions of varying severity have been treated with intra-articular injection of hyaluronic acid and intermittent extracorporeal shockwaves at the surgery ward of the hospital at Wissembourg, France.

The period of discomfort of patients treated so far ranged from one to five years. In addition to the clinical examination at the beginning of the treatment, subjectiv registrations of complaints using VAS (visual analogue scale) and of mobile functions using the Lysholm score and HSS (hospital of special surgery) score were carried out.

The status of an admitted patient objectively registered through MRT examination with a standard procedure of cartilage description of medium size and larger joints in sagital and coronal cross-section.

T1-assessed spin-echo pulse sequence (SE)

T2-assesses turbospin-echo pulse sequence with fat suppression (TSE)

T1-assesses fat-suppressed gradient echo sequence (GE) with 3D-data acquisition (cartilage sequence).

The intra-articular hyaluronic acid injection was done five times at weekly intervals with a native molecular hyaluronic acid drug (e.g.Hyalubrix). The subsequent intermittent shockwave treatments were carried out at 2-finger distance focused on the center of cartilage lesion. Length of treatment: 2000 impulses with 400 impulses each per location of treatment, pressure maximum 20 - 40 MPa, frequency 1-2 Hz.

Clinic control examinations with VAS, Lysholm- and HSS-score six weeks and subsequently 3,6 and 12 month after the beginning of treatment.

Results of MRI - controls after 3,6 and 12 month will be reported in due course.

Efficacy of Extracorporeal Shock-wave Therapy in Knee Osteoarthritis (animal study)

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Introduction:

There have been several reports on the use of extracorporeal shock waves in the treatment of pseudarthrosis, calcifying tendinitis, and tendinopathies of the elbow. However, there was no study for the treatment of knee osteoarthritis (OA).

Purpose: To investigate the effect of shock wave application for knee OA, we analyzed changes in calcitonin gene-related peptide (CGRP)-immunoreactive (ir) dorsal root ganglion (DRG) neurons.

Material and method:

We made knee OA rat using the method of transecting anterior cruciate ligament, medial meniscus and medial collateral ligament. We divided into 3 groups. 1) Non-treated group (6 knees) 2) Knee OA group (6 knees) 3) shock wave group (6 knees). Fluorogold (neurotracer) were injected into the medial knee joint 10 days before perfusion fixation using 4% paraformaldehyde. In the shock wave group, shock wave (1000 shots, 4Hz, 0.08mJ/mm²) applied to the medial knee joint 10 days after injection of fluorogold and perfusion fixation was performed 4 days after application of shock waves. We statistically analyzed the number of CGRP-ir fluorogold-labeled neurons among non-treated group, knee OA group and shock wave group.

Result:

In the non-treated group, fluorogold-labeled dorsal root ganglion neurons innervating the medial knee joint were distributed in the L1 to L6 dorsal root ganglia. There were statistically significance between the non-treated group and knee OA group, and between knee OA group and shock wave group. Shock wave application reduced CGRP-ir neurons in DRG.

Discussion and conclusion:

We previously reported that application of shock wave to rat skin reduced the CGRP expression in DRG neurons and degeneration of free nerve endings. But these studies were applied shock wave to the normal condition. So we do not know whether the same condition occurs in the pathological condition. This study was applied shock wave to the pathological model and also confirmed the reduction of CGRP-ir neurons in DRG. These data shows that extracorporeal shock wave therapy may be useful for the treatment of knee OA.

Clinical Efficacy of Extracorporeal Shock-wave Therapy in Knee Osteoarthritis

Authors: K. Takahashi, T. Saisu, N. Takahashi, R. Murata, N. Ochiai, Y. Wada, H. Moriya

Institution: Graduate School of medicine, Chiba University, Chiba, Japan

Introduction:

A variety of non-operative treatments for osteoarthritis have been receiving considerable attention. The purpose of this study is to investigate the efficacy of extracorporeal shock-wave therapy (ESWT) in knee osteoarthritis preliminarily.

Methods:

ESWT were applied using Epos (Dornier Co., Germany) in 15 knees of 12 patients who had had an inadequate response to prior conventional conservative treatments for more than 6 months. The mean follow-up period was 22.2 (± 20.6 SD) weeks. We investigated the clinical efficacy of ESWT according to pain, function, X-ray and MRI findings. We used Japan Orthopaedics Association osteoarthritis score (JOA score) and the Visual Analog Scale score (VAS score) for the clinical evaluation of knee osteoarthritis.

Results:

Subjective symptoms improved in 11 of 15 knees (73.3%), and total score of JOA increased from 66.7 points to 84.7 during follow up. Particularly, pain score significantly reduced. The analgesic effect of ESWT was observed from immediately after treatment and “night pain”, “pain on walking” and “tenderness” reduced but tenderness was likely to remain finally. There was no deterioration of symptom and we didn’t detect any complication by radiographic analysis.

Discussion:

The efficacy of ESWT in enthesopathy such as tennis elbow or plantar fasciitis already has been known, while there was no report on the efficacy of ESWT in knee osteoarthritis. There are many reasons for pain in knee osteoarthritis, but a pain related from the tendon and ligament insertion of the knee seemed to be relieved with shock waves. This is the first report, which shows the clinical efficacy of ESWT in knee osteoarthritis.

Conclusion:

ESWT could be an alternative therapy in the treatment of knee osteoarthritis refractory to other therapies.

Histological Findings in Human Osteoarthritis Treated With ESWT

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Institution: Clinica Aurico Salud, Clinica Providencia, Chile

Evaluating Instruments for Assessment of Elbow Function

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Any new therapeutic approach or development to medical conditions must be precisely validated by the scientific community before it can be safely recommended or used. In order to talk the same language, and to compare results in the same scales, there must be a consent of the instruments that measure the outcome of these treatments. The use of scoring systems has been widely accepted in the measurement of patient outcome in musculoskeletal disorders. However, the number of scoring systems, the variables they measure and their clinical and epidemiological validation as scientific instruments is currently a matter of great interest. We have seen reports of Shockwave Therapy for tennis elbow for nearly 15 years, but still many international scientific communities believe that there is not enough evidence to recommend this therapy. However, the literature does not support with solid evidence the surgical alternative to treat a rebel tennis elbow. In the past five years many orthopaedic research groups, including ours, have reported clinical case series and case-control studies showing the benefits of ESWT. However, clinical scales are either conflictive or non comparable, and there is a clear need to define proper scales in order to use reliable data that can be compared to report valid and reproducible results. Bosque University Orthopaedics started a prospective study that will compare the results of ESWT and surgery for tennis elbow. In the design process of the project we found different scales that we studied thoroughly to use as reliable instruments to compare these two procedures. A problem aroused: which scale should we use?. VAS is the most common one, and is an one-dimensional scale that allows the measurement of pain intensity with good reproducibility (Scudds 2001). The Disabilities of the Arm Shoulder and Hand questionnaire (DASH) is a long questionnaire that evaluates the upper limb as a whole. It has been validated and has excellent reproducibility (MacDermid 2000). Roles and Maudsley scale is the most frequent instrument found in ESWT papers. It was described in 1972 and is a fast way to compare results with easy questions. However it seems to be somehow simple, and evaluates only four stages in a subjective manner. Nirschl scale is more specific as it involves pain, range of motion and activities. However we did not find any validation studies of this scale in the literature. MacDermid published a scale that evaluates function and pain. But probably the most complete scale for elbow evaluation we found was reported by the American Shoulder and Elbow Surgeons in 1999, where J.W. King et al developed an instrument for elbow evaluation with specific sections for pain, function, treatment satisfaction and objective medical evaluation. We believe one of the most important issues in comparing ESWT with other treatment alternatives is the instruments and scales that we use in our protocols and publications. We propose that International societies like ISMST should create or validate the scales that can compare with solid criteria the outcome of patients in order to report our results with all the evidence needed in new therapeutic tools. In this presentation, we compare all elbow scales in the literature in order to discuss the best recommendation for our clinical researchers as an international consensus in Vienna 2005.

ECSWT - U.S. Experiences/Studies

Author: Pettrone Frank

Institution: Arlington, Virginia

The U.S. FDA has approved 3 ECSWT devices for usage: 1) Healthtronics Ossitron (Oct. 2000) - Electrohydraulic; 2) Dornier Epos Ultra (Jan. 2002); and Siemens/Sonocur (2004) Electromagnetic. A piezoelectric device is only in clinical trials.

The Ossitron and Epos are “high energy” single treatment devices. The siemens sonocor is a “low energy” multiple treatment device.

The Ossitron device is currently FDA approved for plantar fasciitis and lateral epicondylitis. The Epos Ultra is approved for plantar fasciitis only and the Sonocor is approved for lateral epicondylitis only.

The clinical studies of Ossitron (Healthtronics FDA study) and Dornier FDA will be presented. One study of 150 patients by Theodore and another by Wiel (96) patients for plantar fasciitis with Epos will be reviewed. The studies for calcific tendonitis of the shoulder by Klimkiewicz (2005) and Gerdesmyer (2003) will be presented.

The two principal U.S. studies of successful Sonocor treatment of lateral epicondylitis of Dunham (2004) and Pettrone (2004) will be discussed.

A review of basic and clinical researches on musculoskeletal shockwave therapy in Japan. Why it has not been approved?

Authors: T. Saisu*, K. Takahashi**, S. Ohtori**, N. Takahashi**, R. Murata**, N. Ochiai**, M. Kamegaya*, Y. Wada***, H. Moriya**

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Although musculoskeletal shockwave therapy has now spread all over the world, it has not still approved by the Ministry of Health, Labour and Welfare in Japan. Single blind clinical trial had finished in 1998, but the positive results did not accepted because of some accusations such as insufficiency of the protocol for control study, which had been permitted by the Ministry itself before beginning of the clinical study, and so on. After the FDA approval in 2000, some manufacturers applied to the Japanese government for approval of shockwave therapy using results of the FDA study. These applications had been under consideration until 2003, however, approval system in Japan completely changed in 2004, unfortunately. Japanese government newly established Pharmaceuticals and Medical Devices Agency for judging and all the process of judgment was restarted. In spite of these misfortune, musculoskeletal shockwave therapy have been developing in Japan since 1994, mainly in basic field. Purpose of this presentation is to introduce basic and clinical researches on musculoskeletal shockwave therapy uniquely developing in Japan.

Reimbursement for ESWT for the Musculoskeletal Disorders in the United States

Authors: Pettrone Frank

Institution: Arlington, Virginia U.S.A.

ECSWT for musculoskeletal disorders has been available in the United States since October of 2000. Since that time, three ESWT systems have been approved by the FDA. Two for plantar fasciitis, one for lateral epicondylitis, and one for both lateral epicondylitis and plantar fasciitis. Generally, reimbursement for ESWT has been limited and varies greatly between regions of the country. Reference will be made to Sonacor, Ossatron, and Dornier Epos Ultra systems experiences.

Difficulties in obtaining reimbursement result from the following:

1. Inconsistency in the medical literature regarding the effectiveness of ESWT
2. The lack of quality prospective, randomized, multi-centered, double-blinded clinical studies using similar technology with standardized treatment protocols and comparable endpoint assessments.
3. Reluctance of insurance carriers to provided payment for treatment of common musculoskeletal disorders, many of which spontaneously resolve.
4. The availability of only Category III CPT codes at the present time.
5. Erroneous CMS initial pricing.
6. Confusion about the differences in technology.

These difficulties have resulted in generally poor non-uniform payments limited to specific geographic areas and carriers. Medicare has coverage policies for specifically approved devices in approximately 19 states, but payment rates are so low to rarely cover costs. Private insurance carriers have very variable rates of reimbursement, often varying greatly within the same region. Workman's compensation is inconsistent. Present reimbursement discourages physicians from prescribing ESWT even if they think it is indicated. This situation will improve only if the above difficulties are addressed in a unified fashion by clinicians and ESWT device manufacturers.

Comparison between Optically Controlled Adjustable and Non-adjustable Spark Gap System

Authors: C.C. Chang, L.K. Lu, Y.R. Pu, I. Manousakas, Y.C. Tong, F.M. Yu, S.M. Liang

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Purpose:

Extracorporeal shock wave lithotripsy (ESWL) is the main treatment for patients with urinary stones. Meanwhile, ESWT is progressively developing. Nevertheless, the distance between the electrodes is fixed in conventional Electro-hydraulic Shock Wave generator. The shock wave power will decay during treatment. We have developed an optically controlled adjustable spark gap system to deal with the above problem. The system was tested in this experiment.

Materials and Methods:

Two experiments were performed to evaluate the efficiency between the adjustable and non-adjustable system: 1. Stone fragment ratio, 2. Stone fragment weight ratio.

Results:

In the first experiment, the stone fragment ratio was 100% fragmented by 713 ± 21 shocks by the adjustable electrode. The ratio was $77.2\% \pm 4.8$ by 1500 shocks for the non-adjustable electrode. In the 2nd experiment, the weight ratio were $40.1 \pm 5.1\%$ for the adjustable electrode and $12.2 \pm 5.3\%$ for the non-adjustable electrode.

Conclusion:

The results showed that the optically adjustable electrode is better than the non-adjustable electrode in the performance and efficiency. The former one could save more treatments and send out more stable shock wave in both of ESWL and ESWT.

Improvement of pain tolerance using a new electrode adjustment in eletrohydraulic equipments

Authors: M. Meyer, E. Thober, BF. Meyer

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Sociedade Brasileira de Terapia por Ondas de Choque(SBTOC)

Recent studies have demonstrated beneficial effects of Extracorporeal Shock Wave Therapy (ESWT) that consists of a sonic pulse or a focal kinetic energy, in the treatment of chronic diseases of tendons. The equipments utilized have different energy generators: piezoelectric, electromagnetic and electro-hydraulic. The aim of this study was to evaluate the pain tolerance during ESWT applications comparing the electrode adjustment based in manufacturer guidance with a new modified procedure that consists a lesser visual distance between the metallic tips.

Patients were included if they were 18 years or older, had symptoms for at least 6 months, and/or had failed at conservative treatment. Patients were excluded if they had ESWT contra-indication and/or received local corticosteroid injection in the previous month. We followed the Visual Analog Scale (VAS). The equipment utilized was ORTHIMA (Direx), that operate with an electro-hydraulic generator. The applications consisted of 20 impulses with each adjustment, alternatively, using the same energy of $0.35\text{mJ}/\text{mm}^2$. We performed the tests before the treatments. The VAS was applied immediately after each test. The focus was the site of maximum reproduction of local pain at digitopressure. We did not use any kind of anaesthesia. We evaluated 20 patients. Bilateral disease in 3 cases, with a total of 23 feet. The VAS score was 2.3 with the new adjustment vs. 6.8 with the manufacturer orientation. Our results suggest that the electrode adjustment might be an important factor that increase the tolerability of ESWT and decrease the risks and the costs by the abolition of necessity of anaesthesia.

Shockwave Therapy for Achilles tendonopathy : retrospective study

Authors: P. Rockett, A. Souza, P. Santos

Institution:

Ortosom, Porto Alegre, Brazil

Cortrel, Rio de Janeiro, Brazil

Orthomaster, São Paulo, Brazil

Aim:

The aim of this study was to evaluate the efficacy and the safety of extracorporeal shock wave therapy for the treatment of Achilles tendonopathy in three Brazilian Orthopaedics Clinics.

Material and Methods:

In a multi-center, retrospective study, the effect of shockwave therapy was investigated in 73 patients with Achilles tendon calcifying (or not) tendinosys treated in the period of 25 months from May 2002 to May 2004.

There were 28 women and 45 men with an average age of 60 (range, 34-87) years.

The criteria for inclusion were at least three months of unsuccessful conservative therapy or six months of pain. Criteria for exclusion were inflammatory arthritis, previous corticosteroid injection, neurological abnormality, gout, malignant diseases, blood coagulation disorders and previous Achilles tendon rupture.

Each patient was treated with 1000 impulses of shock wave, a 05 mm focus depth, and with an energy flux density of no more than 0.13 mJ/mm after local anaesthesia.

One treatment was performed on 65 patients, 6 patients underwent a second treatment and 2 patients underwent a third treatment.

The subjects were evaluated by means of a clinical evaluation according to Roles and Maudsley score and subjective outcome on Visual Analogue Scale (VAS) analysis 45, 90 and 180 days after the end of the therapy.

Results:

The study showed the efficacy and safety of ESWT were excellent in 17.8%, good in 46.6%, acceptable in 21.9%, and poor in 13.7%, 180 days after ESWT.

Overuse Achilles tendinopathy: ESWT vs placebo. An 18 months follow up study

Authors: F. Astore, V. Sansone, L. Spotorno

Institution: Departement of Orthopaedics,
Università degli Studi di Milano, IRCCS Humanitas,
Rozzano (Milan), Italy

The purpose of this study is to evaluate if Extracorporeal Shock Wave Therapy (ESWT) be considered potentially useful for overuse Achilles tendinopathy resistant to prolonged conventional non-operative treatment.

Methods:

A prospective, double-blind clinical trial was performed to compare the outcomes of a standard treatment with ESWT with 2000 impulses of ESWT with energy flux density of 0.25 mJ/mm² in the pain

ESWT as a treatment for chronic insertional Achilles tendinosis

Author: J. Furia

Institution: Bucknell University, SUN Orthopedics and Sports Medicine - Lewisburg, PA USA

Purpose:

The purpose of this study was to determine the efficacy of high energy extracorporeal shockwave therapy (ESWT) for the treatment of adults with chronic insertional Achilles tendinosis and to determine if use of a local anaesthesia field block has an adverse effect on outcome.

Type of Study: Retrospective case-control.

Methods:

Between June 1 2003 and January 31 2004, 68 patients with chronic insertional Achilles tendinosis were enrolled in this study. Each patient had failed to respond to a minimum of six months of traditional non-operative treatments. Thirty-five patients were treated with a single dose of high energy shock wave therapy (ESWT group). Thirty-three patients were treated with additional forms of traditional non-operative measures (control group). All procedures were performed by a physician using either a local anaesthesia field block (12 patients) or an anesthesia other than local (23 patients). Each of the ESWT patients received a total of 3000 shocks for a total energy flux density of 604mJ/mm². T-tests and analysis of variance (ANOVA) were used to test for differences in visual analog scores (VAS) between the ESWT and control groups.

Results:

Four weeks post treatment, the mean visual analog score (VAS) for the control and ESWT groups were 8.2 (range, 6-10; SD=1.1) and 4.2 (range, 1-10; SD=2.4) respectively ($t=8.7$, $P < .001$). Twelve weeks post treatment, the mean VAS for the control and ESWT groups were 7.2 (range, 5-9; SD=1.3) and 2.9 (range, 1-10; SD=2.1) respectively ($t=10.1$, $P < .001$). Fifty-two weeks post treatment, the mean VAS for the control and ESWT groups were 7.0 (range, 4-9; SD=1.2) and 2.8 (range, 1-10; SD=2.2) respectively ($t=9.7$, $P < .001$). Using the Roles and Maudsley scale, 2 of the control patients (6.1%) and 6 of the ESWT patients (17.1%) were assigned an excellent result and 11 of the control patients (33.3%) and 23 of the ESWT patients (65.7%) had a good result at the final endpoint. ANOVA testing at 52 weeks post treatment revealed that the mean improvement in VAS score for the local anaesthesia subgroup was significantly less than the corresponding gain in the anaesthesia other than local subgroup ($F=16.77$ verses $F=53.95$, $P < .001$). There were no significant complications.

Conclusions:

ESWT is a safe and effective treatment for chronic insertional Achilles tendinosis. Local field block anaesthesia appears to decrease the effectiveness of this procedure.

ESWT - A Prospective Double Blind Study on Mortons Neuroma

Authors: J. Furia

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

Introduction:

Two years ago at the Annual ISMST Meeting in Orlando, we presented a pilot study showing successful treatment of Morton's Neuroma in 27 out of 30 patients with ESWT. We have subsequently conducted a prospective placebo controlled double blind study on this treatment.

Purpose:

The aim of the study was to evaluate the effect of extracorporeal shock wave therapy on painful Mortons Neuroma.

Patient, Material, Methods:

25 patients with painful Morton's Neuroma of greater than 6 on a VAS that failed to respond to conservative care were eligible to participate.

Patients were anaesthetized with intravenous sedation and an infiltrative local block to the area was performed. Computer randomization then determined whether the treatment would be active or sham. For the active group treatment was performed utilizing an Ossatron by Healthtronics. The foot was treated with 2000 pulses at 21 Kv from directly inferior to the Morton's Neuroma. The sham foot received no treatment. 14 patients were randomized to the active group and 11 patients were placed in the Sham group.

Patients were evaluated at 1 week, 6 weeks and 12 weeks by a blinded investigator.

End point evaluation parameters were reduction in VAS and Roles and Maudsley quality of life assessment.

Results:

The treated foot improved 70% of the time while the Sham foot improved 52% of the time. 79% of the treated feet improved by >50%, while 25% of the Sham feet improved by >50%. 75% of the treated feet attained a VAS of <3, while only 25% of the Sham group achieved <3 on a VAS. Only 8% of the treated patients had no improvement while 50% of the Sham group had no improvement.

Conclusion: ESWT can be considered a viable treatment alternative to painful Morton's Neuroma. It does not have complications associated with surgery and allows patients to ambulate immediately and return to activities of daily life without a prolonged recovery.

Shock Waves for Pain Relief After Carpal Tunnel Release: THE Pathophysiological Basis of a New Clinical Application in “PILLAR PAIN” Disease

Authors: M.C. d’Agostino, S. Russo (*), A. Lazzerini, M. Rubini, D. Smarrelli, D. De Spirito.

Institution:

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Carpal tunnel release is a safe, simply and rapid procedure in hand surgery; in spite of this, 20% of the patients can suffer for a long time from scar discomfort (redness, pain and swelling) (sometimes described as “pillar pain”).

Until now, no therapy has been described in the literature to be effective in rapid pillar pain relief, especially as its aetiology is still uncertain.

Only recently, some clinical evidences, as well as some anatomical and experimental studies suggest the possibility that this condition is due to a prolonged neurogenic inflammation, sustained by neuropeptides (especially Substance P).

As it is well known that Extracorporeal Shock Wave Therapy is effective in suppression of inflammatory processes, as well as that it can modulate Substance P, we treated a series of 25 patients, suffering from pillar pain after carpal tunnel release (from almost two months) (3 treatments, weekly, at very low energy of 0.03 mmJ/mm^2 , 2500 - 3000 shots/session), under in - line ultrasound examination (Modulith SLK - Storz Medical).

Patients were selected on the basis of some clinical data (subcutaneous painful swelling in the interthenar area, scar redness, thenar and/or hypothenar discomfort, pain) and by NMR findings (oedema in carpal tunnel granulation tissue, mild perineural oedema, rare bone marrow oedema). Pain was subjectively recorded by Visual Analogic Scale (VAS), before and after ESWT. Only for few patients it was possible to perform NMR also after ESWT.

Clinical results were very surprising and encouraging: 50% of pain relief already after first ESWT treatment, in about half of the patients; temporary pain increased within the first week of treatment in very few cases; completely pain relief within 25 days in almost all patients; rapid scar redness resolution in almost all patients; strict correlation between pathological NMR findings and clinical data (both pre - and post - ESWT).

Absolutely not local nor general side effects were observed during and after ESWT treatment.

The authors will expose in detail the data above reported, and discuss the theoretical and pathophysiological basis of this new safe application of ESWT in hand surgery.

The Employment of E.S.W.T. in Avascular Necrosis in Growing Patients

Authors: S. Russo, B. Corrado, M. Tullio, S. de Rosa, V. La Mantia, E. Astarita, E. M. Corrado

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The presence of fertile cartilage nearby the treating area is commonly considered an absolute contraindication to the use of E.S.W.T. because of the possibility of inducing an asymmetric stimulation of the growing cartilage with a consequent angular deviation during limb growing phase. Instead the authors retain such contraindication just a relative one as several factors play a role, like the energy level and the number shots, the focus size and its relative stability, the absolute immobility of target limb, the complete absence of pain, the specific pathology for which treatment is demanded, etc.

Paying attention to such aspects, the authors have retained to use E.S.W.T. in treating osteonecrosis of several nature in growing patients.

They review their casuistry discussing the pathologic and natural prognostic meaning as well as the method and the results in a follow-up from 4 to 7 years.