

# Radial Shock Wave Therapy For Chronic Heel Pain

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## **Purpose of the study:**

Evaluation of the effect of Unfocused or Radial Shock Wave Therapy (RSWT) on chronic plantar heel pain.

## **Materials and Methods:**

Since July 2002, a prospective study was conducted including 74 heels in 63 patients with a minimum of 6 months of pain. All patients had a definite indication for open surgery after at least two unsuccessful different conservative treatment approaches. Informed consent of the patients was gained. There were 24 females and 39 males with an average age of 50 (17-79).

History and physical examination were recorded in detail. The patients were asked to determine the effect of RSWT by a visual analogue scale (VAS) for walking, at rest and at night. The walking distance, onset of pain and return to daily activities or sports were registered as well as objective findings. All patients received 2000 shockwaves at a frequency of 5Hz and a work pressure of 2, 5 Bars, without local anaesthesia, in 3 weekly sessions. After each session, patients were given non-narcotic analgesic and an ice pack. All the patients tolerated the treatment well, and the majority were able to retake daily activities again. There were neither systemic nor local complications after treatment. No patient showed any kind of deterioration.

Two independent orthopaedic surgeons did the follow up. At 12-month follow-up, and using the VAS a reference, the pressure-elicited pain decreased from 6,9 to 2 ( $p<0,05$ ), the pain in sports decreased from 6,8 to 2,1 ( $p<0,05$ ). Night complaints improved from a VAS score of 2,6 to 1,4 ( $p<0,05$ ). Pain at daily activities also improved from 4,8 to 1,8 ( $p<0,05$ ). Before the RSWT, only 17 patients were pain-free after walking more than 1000 meters. After the treatment, 38 patients were able to walk more than 1000 m without pain.

## **Conclusions:**

The Unfocused or Radial Shock Wave Therapy (RSWT) is an attractive non-invasive and highly economical alternative for open surgery. The cost of the device is far cheaper than focused extracorporeal machines (ESWT). The results are very satisfactory and reduce the need for surgery in a high percentage of patients.

# Economic Randomization of ESWT With Dolorclast And Ossatron Results

**Author: Rob Gordon  
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**Purpose:**

To determine the efficiency of the Ossatron to the Dolorclast in the treatment of plantar fasciitis.

**Introduction:**

The efficiency of the Ossatron has been shown to be effective for the treatment of plantar fasciitis. A pilot study was determined to see the effectiveness of the Dolorclast machine in treating plantar fasciitis.

**Materials and Methods:**

Prospective Patients were asked to choose treatment by either the Dolorclast or Ossatron by economic reasons.

**Results:**

Both the Ossatron and Dolorclast improved pain relief for plantar fasciitis.

**Conclusion:**

Economics and perceived gold standard play a role in the treatment of plantar fasciitis. Both the Ossatron and Dolorclast appear to improve symptoms of plantar fasciitis.

## Radial Extracorporeal Shock Wave Therapy (rESWT) in Chronic Plantar Heel Pain - a RCT

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### **Aim:**

The study has to determine the effectiveness of rESWT for chronic plantar heel pain.

### **Materials and methods:**

A total of eight study centers enrolled 254 patients in this study, 252 patients were randomized, 251 patients received assigned treatment (129 active-ESWT, 122 Placebo-ESWT). All patients were suffering from painful heel syndrome for at least 6 months, all of them previously get unsuccessful conservative treatments. Basically the radial extracorporeal shock wave therapy was performed without local anesthesia. 2000 treatment-impulses were applied with the working pressure of 0.4 MPa (4 bar). Subjects received 3 shock wave treatments with 2000 therapeutical shock wave impulses each. Between each treatment, a treatment-free interval of 2 weeks was observed.

The primary Criteria were: Heel pain when taking the first steps of the day (VAS) and Heel pain while doing daily activities (VAS). Second criteria were defined as: Pain on pressure, measured with standardized pressure device (Dolormeter), Roles and Maudsley-Score, SF-36, physician's global judgment of effectiveness, subject's satisfaction with the outcome of the treatment, Subject's willingness to recommend treatment

The primary point in time for comparison of groups was three months after last treatment.

The patients of the ITT (intention-to-treat) population were defined in the final blind review report (individual listing) before blind was broken. A total of 125 ESWT patients (96.9% of all treated ESWT patients) and 118 placebo patients (96.7% of all treated placebo patients) were evaluated for the ITT analysis.

The size of the treatment effects were quantified using the Mann-Whitney superiority measure with associated confidence intervals. Efficacy was analysed by comparing the success rates between the treatment and placebo groups, with success being defined on a per patient basis for each of the two primary efficacy criteria as at least a 60% reduction in VAS pain scores from baseline to 3 month after ESWT.

The study was performed in accordance to GCP guidelines.

### **Results:**

With regard to the demographic criteria, sex, BMI, age and other baseline characteristics including the baseline efficacy criteria, groups are well comparable, all effect sizes are denoting only marginal group differences, all p-values are statistically not significant ( $p > 0.1$ ).

With regard to the primary criteria the analysis showed statistically significant results ( $P = 0.0059$ , one-sided, ESWT success rate 55.20% vs. placebo success rate 38.98%).

With regard to the secondary criteria the clinical relevant data criteria mental/physical health score of the SF36, the Roles and Maudsley Score, global judgment of effectiveness, therapy satisfaction and therapy recommendation all showed better outcome at the primary endpoint in favour to the ESWT group ( $P < 0.025$  one-sided) and all effect sizes (Mann-Whitney) denote more than small superiority of the ESWT group

The a priori ordered hypotheses of the final statistical analysis plan are statistically significant ( $P < 0.025$  one-sided): Composite score (sum score) of heel pain (VAS) when taking first steps of the day, heel pain (VAS) while doing daily activities and heel pain (VAS) after application of the Dolormeter ( $P = 0.0220$  one-sided,  $MW = 0.5753$ ,  $LB-CI = 0.5023$ ). Overall success rate with regard to heel pain defined as percentage decrease of heel pain larger than 60% from baseline at visit 7 for at least two of the three heel pain (VAS) measurements ( $P = 0.0020$  one-sided,  $MW = 0.5937$ ,  $LB-CI = 0.5314$ ).

The other criteria also demonstrate superiority of the ESWT group with p-values below the level of significance. All effect sizes (Mann-Whitney) denote more than small superiority of the ESWT group.

Only minor side effects as petechial bleeding, swelling and discomfort during treatment were detected.

#### Conclusion:

The radial shock wave therapy is effective and safe in treatment of chronic heel pain. The data showed high homogeneity, all other sensitivity analysis confirmed these findings in favour to radial shock wave therapy. The effect size reaches clinical relevance. No significant side effects were found but some minor findings could occur.

# Radial Shock Wave Therapy For Chronic Insertion Desmopathy of The Proximal Suspensory Ligament in Sports Horses

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## Introduction

Suspensory ligament desmopathy is a common disease causing primary and compensatory lameness in the sport horse. The disease can cause long-term lameness restricting the horse's ability to perform at the level of competition achieved prior to the onset of lameness. Current medical treatment options include confinement and rest, controlled exercise protocols, intralesional injections, corticosteroid therapy, anti-inflammatory therapy, bone marrow injection, and corrective shoeing. However, none of these methods consistently result in a satisfactory outcome.(McClure 2004)

## Subjects

Between April 2002 and August 2004, 40 sports horses with chronic proximal insertion desmopathies (23 in the hind limb, 17 in the front limb) have been treated with Radial Shock Wave Therapy (RSWT)

The horses must have had clinical symptoms for at least 3 months and at least one failed conservative treatment approach prior to RSWT. Lameness was graded from 0 to 5 using a AAEP scale (American Association of Equine Practitioners)

## Methods

The horses were treated in 3 sessions (at intervals of one/two week, mean: 12 days) with 4000 shockwaves per session. Pressure of 3,5 bar (Energy flux density: 0,14 mJ/mm<sup>2</sup> approx.) and 6 Hz of frequency.

Device used: Swiss Dolor Clast (EMS-Switzerland).

The horses received sedation with Domosedan and Torbugesic.

The affected leg was lifted and the superficial and deep flexor tendon was pushed laterally and medially in order to be as close as possible to the origin of the proximal suspensory ligament.

2000 shockwaves were applied from each side (medial and lateral).

Evaluation was performed before the treatment, before 2nd RSWT, before 3rd RSWT, 30 days after last RSWT, 90 day after last RSWT:

A special training program was elaborated for the time between the sessions and post shock wave therapy.

Analyses

The non-parametric Wilcoxon test for dependent samples to compare means of AAEP lameness scale.

## Results

The horses showed a considerable lameness decrease 30 days after last RSWT ( $p < 0,05$ ), and 90 days after last RSWT ( $p < 0,01$ ).

90 days after last RSWT, 26 horses (65%) were free of lameness (return to full work) and 8 horses had a distinct lameness reduction. 6 horses showed no improvement.

Side effect and complications were not observed

## Conclusion

RSWT is an effective treatment method for chronic insertion desmopathy of the proximal suspensory ligament in sports horses. Further randomized and controlled studies are necessary to underline the results of this investigation.

## Preliminary Results of Radial Extracorporeal Shockwave Therapy in Five Dogs With Cubarthritis

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### Introduction:

Although RSWT has been used in small animals with orthopaedic disorders for some years only a few studies exist detailing this kind of treatment in dogs. At the present time the authors are unaware of any prospective study using ground reaction forces evaluated on a treadmill-system. The purpose of this study was to show results of RSWT in dogs with cubarthritis. To document the effectiveness of RSWT ground reaction forces (GRF) measured on a treadmill-system were evaluated.

### Material and Method:

Five client-owned dogs of different breeds with cubarthritis were included in this study. Age ranged from 6 to 11 years, bodyweight from 15.7 to 48 kilograms. Three dogs had bilateral and two dogs unilateral cubarthritis. Radial Shock Wave Therapy was performed with the Swiss DolorClast Vet® (EMS Electro Medical Systems, Nyon, Switzerland). Treatment was given three times on a weekly basis using 1,000 radial Shockwaves with a pressure of 2.0 bars were applied at the medial and lateral side of the affected elbow. Before first RSWT ground reaction forces were measured using a treadmill with four force plates. Parameters chosen for evaluation were peak maximal force (Fz), mean vertical force (Fm) and Impulse (Imp). Mean values of five valid steps were calculated and symmetry indices were calculated as described (1). Deviation of absolute symmetry was expressed as a percentage. Re-evaluation was performed before subsequent treatments and one month after last RSWT. A paired t-test was performed to compare pre-treatment GRF values with values of each evaluation point,  $p < 0.05$  was considered as statistically significant.

### Results:

Percentage of deviation from symmetry before first RSWT was 16.59 ( $\pm 9.89$ ) % for Fz, 18.66 ( $\pm 5.60$ ) % for Fm and 25.48 ( $\pm 9.01$ ) % for Impulse. No significant difference in values was found after the first RSWT. One month after last RSWT® all three values showed significant improved values compared to the basic GRF data: percentage of deviation of Fz was 4.79 ( $\pm 4.20$ ) % ( $p=0.38$ ), of Fm 7.59 ( $\pm 8.69$ )% ( $p=0.34$ ) and of Impulse 9.55 ( $\pm 8.73$ )% ( $p=0.001$ ).

### Discussion:

Our preliminary results show that dogs with cubarthritis responded well to Radial Shock Wave Therapy. Although studies with more animals and long term controls are needed, we recommend Radial Shock Wave Therapy as a non-invasive treatment option for dogs with degenerative joint diseases.

### References:

1. Budsberg SC, Jevens DJ, Brown J, et al. Evaluation of limb symmetry indices, using ground reaction forces. *AmJVetRes* 1993;54:10:1569-1575

## Radial Extracorporeal Shock Wave Therapy For Hip

Authors: B. Bockstahler, DVM\*; M. Müller, MVM\*; M. Skalicky DTP\*\*, D. Lorinson, DVM, DECVS\*  
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### Introduction:

Recently Radial Shock Wave Therapy (RSWT®) was introduced in small animal veterinary medicine, although only few studies have been published. RSWT is recommended for different orthopaedic conditions like osteoarthritis and tendinopathies. Although a lot of good results are emphasized, controlled clinical studies are rare. This clinical prospective study analysed the effect of radial shock wave therapy in dogs with coxarthrosis using a treadmill system with four force plates.

### Materials and methods:

Thirteen dogs of different breeds with coxarthrosis have been included in this study. Radial shock waves were generated by the Swiss DolorClast Vet® (EMS Electro Medical Systems, Nyon, Switzerland) and three treatments on a weekly basis were performed in the hip joint-region. Ground reaction forces (GRF) were measured before each treatment and one week, one and three month after last RSWT. Symmetry indices (SI) were evaluated as described (1) for each dog using the following parameters: peak maximal force (Fz), mean vertical force (Fm) and impulse (Imp). After calculation of SI percentage deviation of absolute symmetry was described. The results were compared to the values of 10 healthy dogs. To compare values of healthy dogs and patients we used an unpaired t-test. To compare patients values during the course of the study we used a paired -test ( $p < 0.05$  was considered as statistically significant).

### Results:

A significant difference between values of healthy dogs and patients was found over the whole treatment period, except for Fz (one week) and Impulse (one week and one month). Comparison of patients pre-treatment values with the subsequent values showed no significant difference for Fz, whereas Fm and Impulse showed a significantly improvement at one week (Fz, Imp), one month (Imp) and three month (Fm, Imp).

### Discussion:

Our preliminary results with RSWT showed positive effects of ground reaction forces in dogs with coxarthrosis. Although values of healthy dogs were not reached, Radial Shock Wave Therapy seems to help reducing pain and discomfort during locomotion.

Although studies using a greater number of dogs and longer evaluation periods are necessary, we recommend RSWT as an alternative treatment for dogs with degenerative joint diseases.

### References:

1. Budsberg SC, Jevens DJ, Brown J, et al. Evaluation of limb symmetry indices, using ground reaction forces. *Am J Vet Res* 1993;54:10:1569-157

tibias, 3 humerus, 2 distal femurs and 2 ulnas. All of them have healed promptly, with dramatic x-ray changes after 6 weeks. We have no complications related to the procedure and all patients and referring doctors are highly satisfied with the results. We believe that the use of radial Shockwaves is not enough to create adequate bone healing by themselves, both because of the lower energy and the loss of flux density as it goes deeper into the tissues. The use of single AGF's is also a good addition to surgical procedures where the trauma caused by the surgery itself will cause revascularization and cell migration to the area where the growth factors would cause some effect. However, used percutaneously alone, the AGF's would act only as a seed in a dry soil, not being able to help in the process of bone healing. We have very impressive results so far, and this has been an interesting finding that must be reported to the scientific community, as we have not found any previous report of any form of ESWT & AGF combined therapy. Of course we need to go further in the research of which one is the primary therapeutic element, so we are currently working on an experimental model in dogs, analysing in four groups the effects of single ESWT treatment, single AGF treatment, ESWT & AGF combined, and a control group. We will present in June 2005 in the ISMST meeting in Vienna our clinical results as a case- series study, and the preliminary results of our experimental study in animals. This new approach to non unions could make the treatment even easier than high energy ESWT or other surgical alternatives.

## Reviewing The Biologic Effects: Radial And Focussed Shockwaves Induce New Bone Formation

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

In recent years, extracorporeal shock wave application to the musculoskeletal system has been established in the therapy of non-unions. However, there is a controverse discussion whether both focused and ballistic (radial) shock wave devices lead to comparable new bone formation. Maier et al. used focussed shock waves with energy flux densities between 0 mJ/mm<sup>2</sup> (sham-treatment) and 1.2 mJ/mm<sup>2</sup> were applied in vivo to the distal femoral region of rabbits (1,500 pulses at 1 Hz frequency each). To investigate new bone formation, animals were injected with oxytetracycline at the days 5 to 9 after shock wave application, and were sacrificed on day 10 after shock wave application. Application of shock waves with energy flux densities of 0.9 mJ/mm<sup>2</sup> and 1.2 mJ/mm<sup>2</sup> resulted in new periosteal bone formation and the presence of cortical fractures and periosteal detachment. After application of shock waves with energy flux density of 0.5 mJ/mm<sup>2</sup>, however, for the first time clearly detectable signs of new periosteal bone formation were observed without cortical fractures or periosteal detachment.

In 2004 the study group of Haupt described new bone formation in a rabbit animal model following radial shock wave application of at least 2000 pulses with 3 bar or 4 bar. 60 days after the treatment new bone formation was found. The activity was osteoblasts was described to be high with extended osteoid formation. Haupt et al. concluded from their rabbit experiment that radial shockwaves might be used in future times for the treatment of e.g. non-unions or diseases with decreased bone turn-over such as parodontitis.

This present reviews actual basic science studies dealing with the effects on bone following focused and radial shockwave application. It seems to be possible that radial shockwaves have comparable effects on healthy bone as focused shock waves in an rabbit animal model.