



**CLINICAL TRIALS PUBLISHED IN THE INTERNATIONAL
PEER-REVIEWED LITERATURE
WITH THE SWISS DOLORCLAST® METHOD**

Clinical trials published in the international peer-reviewed literature¹ demonstrating efficacy and safety of treatment with the Swiss Dolorclast[®] according to Evidence Based Medicine criteria²:

Plantar fasciopathy

Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: results of a confirmatory randomized placebo-controlled multicenter study.

Am J Sports Med 2008;36:2100-2109

Gerdesmeyer L, Frey C, Vester J, Maier M, Weil L Jr, Weil L Sr, Russlies M, Stienstra J, Scurran B, Fedder K, Diehl P, Lohrer H, Henne M, Gollwitzer H.

BACKGROUND: Radial extracorporeal shock wave therapy is an effective treatment for chronic plantar fasciitis that can be administered to outpatients without anesthesia but has not yet been evaluated in controlled trials. HYPOTHESIS: There is no difference in effectiveness between radial extracorporeal shock wave therapy and placebo in the treatment of chronic plantar fasciitis. STUDY DESIGN: Randomized, controlled trial; Level of evidence, 1. METHODS: Three interventions of radial extracorporeal shock wave therapy (0.16 mJ/mm²; 2000 impulses) compared with placebo were studied in 245 patients with chronic plantar fasciitis. Primary endpoints were changes in visual analog scale composite score from baseline to 12 weeks' follow-up, overall success rates, and success rates of the single visual analog scale scores (heel pain at first steps in the morning, during daily activities, during standardized pressure force). Secondary endpoints were single changes in visual analog scale scores, success rates, Roles and Maudsley score, SF-36, and patients' and investigators' global judgment of effectiveness 12 weeks and 12 months after extracorporeal shock wave therapy. RESULTS: Radial extracorporeal shock wave therapy proved significantly superior to placebo with a reduction of the visual analog scale composite score of 72.1% compared with 44.7% (P = .0220), and an overall success rate of 61.0% compared with 42.2% in the placebo group (P = .0020) at 12 weeks. Superiority was even more pronounced at 12 months, and all secondary outcome measures supported radial extracorporeal shock wave therapy to be significantly superior to placebo (P < .025, 1-sided). No relevant side effects were observed. CONCLUSION: Radial extracorporeal shock wave therapy significantly improves pain, function, and quality of life compared with placebo in patients with recalcitrant plantar fasciitis.

¹ As of March 10, 2014.

² The term *Evidence Based Medicine* refers to the demonstration of efficacy and safety of therapeutic interventions in prospective, randomized, controlled clinical trials. According to the U.S. Preventive Services Task Force (USPSTF), Level 1 evidence is reached when efficacy and safety is demonstrated in at least one properly designed randomized controlled trial. All clinical trials listed here fulfil the criteria of Level 1 Evidence, except of the studies by Furia et al. (2009) on greater trochanteric pain syndrome, Rompe et al. (2009) on medial tibial stress syndrome and Furia et al. (2013) on patellar tendinopathy. These studies reached Level 3 evidence (nonrandomized concurrent cohort comparisons between contemporaneous patients).

Successful treatment of chronic plantar fasciitis with two sessions of radial extracorporeal shock wave therapy

Ibrahim Ibrahim M, Donatelli R, Schmitz C, Hellman M, Buxbaum F

Foot Ankle Int 2010;31:391-397

BACKGROUND: Radial extracorporeal shock wave therapy (RSWT) has been previously demonstrated as an efficient treatment option for chronic plantar fasciitis (PF) when administered in three sessions. The present study tested the hypothesis that chronic PF can also be treated successfully with RSWT when only two treatment sessions are performed. **MATERIALS AND METHODS:** A total of n=50 patients with unilateral, chronic PF were randomly assigned to either RSWT (n=25) or placebo treatment (n=25). RSWT was applied in two sessions one week apart (2,000 impulses with energy flux density = 0.16 mJ/mm² per session). Placebo treatment was performed with a clasp on the heel. Endpoints were changes in the Visual Analog Scale (VAS) score and the modified Roles & Maudsley (RM) score from baseline to four weeks, 12 weeks and 24 weeks followup. **RESULTS:** Mean VAS scores were reduced after RSWT from 8.52 ± 0.34 (mean ± SEM) at baseline to 0.64 ± 1.52 at 4 weeks, 1.08 ± 0.28 at 12 weeks and 0.52 ± 0.14 at 24 weeks from baseline. Similar changes were found for mean RM scores after RSWT but were not observed after placebo treatment. Statistical analysis demonstrated that RSWT resulted in significantly reduced mean VAS scores and mean RM scores at all followup intervals compared to placebo treatment (each with p < 0.001). No serious adverse events of RSWT were observed. **CONCLUSION:** RSWT is efficient in the treatment of chronic PF even when only two sessions with 2,000 impulses each are performed one week apart. **LEVEL OF EVIDENCE:** Level 1 (prospective, randomized, double-blinded, controlled therapeutic study).

Achilles tendinopathy

Eccentric loading versus eccentric loading plus shock-wave treatment for midportion achilles tendinopathy: a randomized controlled trial.

Rompe JD, Furia J, Maffulli N.

Am J Sports Med 2009;37:463-470

BACKGROUND: Results of a previous randomized controlled trial have shown comparable effectiveness of a standardized eccentric loading training and of repetitive low-energy shock-wave treatment (SWT) in patients suffering from chronic midportion Achilles tendinopathy. No randomized controlled trials have tested whether a combined approach might lead to even better results. **PURPOSE:** To compare the effectiveness of 2 management strategies--group 1: eccentric loading and group 2: eccentric loading plus repetitive low-energy shock-wave therapy. **STUDY DESIGN:** Randomized controlled trial; Level of evidence, 1. **METHODS:** Sixty-eight patients with a chronic recalcitrant (>6 months) noninsertional Achilles tendinopathy were enrolled in a randomized controlled study. All patients had received unsuccessful management for >3 months, including at least (1) peritendinous local injections, (2) nonsteroidal anti-inflammatory drugs, and (3) physiotherapy. A computerized random-number generator was used to draw up an allocation schedule. Analysis was on an intention-to-treat basis. **RESULTS:** At 4 months from baseline, the VISA-A score increased in both groups, from 50 to 73 points in group 1 (eccentric loading) and from 51 to 87 points in group 2 (eccentric loading plus shock-wave treatment). Pain rating decreased in both groups, from 7 to 4 points in group 1 and from 7 to 2 points in group 2. Nineteen of 34 patients in group 1 (56%) and 28 of 34 patients in group 2 (82%) reported a Likert scale of 1 or 2 points ("completely recovered" or "much improved"). For all outcome measures, groups 1 and 2 differed significantly in favor of the combined approach at the 4-month follow-up. At 1 year from baseline, there was no difference any longer, with 15 failed patients of group 1 opting for having the combined therapy as cross-over and with 6 failed patients of group 2 having undergone surgery. **CONCLUSION:** At 4-month follow-up, eccentric loading alone was less effective when compared with a combination of eccentric loading and repetitive low-energy shock-wave treatment.

Eccentric loading compared with shock wave treatment for chronic insertional achilles tendinopathy. A randomized, controlled trial.

Rompe JD, Furia J, Maffulli N.

J Bone Joint Surg Am 2008;90:52-61

BACKGROUND: Nonoperative management of chronic tendinopathy of the Achilles tendon insertion has been poorly studied. With the recently demonstrated effectiveness of eccentric loading and of repetitive low-energy shock wave therapy in patients with midsubstance Achilles tendinopathy, the aim of the present randomized, controlled trial was to verify the effectiveness of both procedures exclusively in patients with insertional Achilles tendinopathy. **METHODS:** Fifty patients with chronic (six months or more) recalcitrant insertional Achilles tendinopathy were enrolled in a randomized, controlled study. All patients had received treatment, including local injections of an anesthetic and/or corticosteroids, a prescription of nonsteroidal anti-inflammatory drugs, and physiotherapy, without success for at least three months. A computerized random-number generator was used to draw up an allocation schedule. Twenty-five patients were allocated to receive eccentric loading (Group 1), and twenty-five patients were allocated to treatment with repetitive low-energy shock wave therapy (Group 2). Analysis was on an intention-to-treat basis. Primary follow-up was at four months, and afterward patients were allowed to cross over. The last follow-up evaluation was at one year after completion of the initial treatment. The patients were assessed for pain, function, and activity with use of a validated questionnaire (the Victorian Institute of Sport Assessment-Achilles [VISA-A] questionnaire). **RESULTS:** At four months from baseline, the mean VISA-A score had increased in both groups, from 53 to 63 points in Group 1 and from 53 to 80 points in Group 2. The mean pain rating decreased from 7 to 5 points in Group 1 and from 7 to 3 points in Group 2. Seven patients (28%) in Group 1 and sixteen patients (64%) in Group 2 reported that they were completely recovered or much improved. For all outcome measures, the group that received shock wave

therapy showed significantly more favorable results than the group treated with eccentric loading ($p = 0.002$ through $p = 0.04$). At four months, eighteen of the twenty-five patients from Group 1 had opted to cross over, as did eight of the twenty-five patients from Group 2. The favorable results after shock wave therapy at four months were stable at the one-year follow-up evaluation. **CONCLUSIONS:** Eccentric loading as applied in the present study showed inferior results to low-energy shock wave therapy as applied in patients with chronic recalcitrant tendinopathy of the insertion of the Achilles tendon at four months of follow-up. Further research is warranted to better define the indications for this treatment modality.

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

Rompe JD, Nafe B, Furia JP, Maffulli N

Am J Sports Med 2007;35:374-383

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

Medial tibial stress syndrome

Low-energy extracorporeal shock wave therapy as a treatment for medial tibial stress syndrome.

Rompe JD, Cacchio A, Furia JP, Maffulli N.

Am J Sports Med 2010;38:125-132

BACKGROUND: Medial tibial stress syndrome (MTSS) is a pain syndrome along the tibial origin of the tibialis posterior or soleus muscle. Extracorporeal shock wave therapy (SWT) is effective in numerous types of insertional pain syndromes. **HYPOTHESIS:** Shock wave therapy is an effective treatment for chronic MTSS. **STUDY DESIGN:** Case control study; Level of evidence, 3. **METHODS:** Forty-seven consecutive subjects with chronic recalcitrant MTSS underwent a standardized home training program, and received repetitive low-energy radial SWT (2000 shocks; 2.5 bars of pressure, which is equal to 0.1 mJ/mm²; total energy flux density, 200 mJ/mm²; no local anesthesia) (treatment group). Forty-seven subjects with chronic recalcitrant MTSS were not treated with SWT, but underwent a standardized home training program only (control group). Evaluation was by change in numeric rating scale. Degree of recovery was measured on a 6-point Likert scale (subjects with a rating of completely recovered or much improved were rated as treatment success). **RESULTS:** One month, 4 months, and 15 months from baseline, success rates for the control and treatment groups according to the Likert scale were 13% and 30% ($P < .001$), 30% and 64% ($P < .001$), and 37% and 76% ($P < .001$), respectively. One month, 4 months, and 15 months from baseline, the mean numeric rating scale for the control and treatment groups were 7.3 and 5.8 ($P < .001$), 6.9 and 3.8 ($P < .001$), and 5.3 and 2.7 ($P < .001$), respectively. At 15 months from baseline, 40 of the 47 subjects in the treatment group had been able to return to their preferred sport at their preinjury level, as had 22 of the 47 control subjects. **CONCLUSION:** Radial SWT as applied was an effective treatment for MTSS.

Patellar tendinopathy

A single application of low-energy radial extracorporeal shock wave therapy is effective for the management of chronic patellar tendinopathy.

Furia JP, Rompe JD, Cacchio A, Del Buono A, Maffulli N.

Knee Surg Sports Traumatol Arthrosc 2013;21:346-350

PURPOSE: Extracorporeal shock wave therapy (SWT) is effective for the management of chronic recalcitrant tendinopathy. The objective of the current study was to assess whether a standardized, single treatment SWT is effective for the management of chronic patellar tendinopathy

METHODS: Thirty-three patients with chronic patellar tendinopathy received low-energy SWT. Thirty-three patients with chronic patellar tendinopathy received other forms of non-operative therapy (control group). Evaluation was by change in Visual Analogue Scale (VAS), Victoria Institute of Sport Assessment score for patellar tendinopathy (VISA-P) score and by Roles and Maudsley Score.

RESULTS: Mean pre-treatment VAS scores for the control and SWT groups were 7.5 and 7.8, respectively. One month, 3 months, and 12 months after treatment, the mean VAS for the control and SWT groups were 6.7 and 4.3 ($p < 0.001$), 5.9 and 3.5 ($p < 0.001$), and 5.1 and 2.7 ($p < 0.001$), respectively. One month, 3 months, and 12 months after treatment, the mean VISA for the control and SWT groups were 50.7 and 65.5 ($p < 0.001$), 52.1 and 71 ($p < 0.001$), and 54.9 and 74.5 ($p < 0.001$), respectively. At final follow-up, the number of excellent, good, fair, and poor results for the SWT and control groups were 8 and 3 ($p < 0.001$), 17 and 10 ($p < 0.001$), 5 and 16 ($p < 0.001$), and 3 and 4 ($p < 0.001$), respectively. The percentage of patients with excellent ("1") or good ("2") Roles and Maudsley Scores (i.e. successful results) 12 months after treatment was statistically greater in the SWT group compared to the control group ($p < 0.001$).

CONCLUSION: A single application of radial SWT is an effective treatment for chronic patellar tendinopathy.

Knee osteoarthritis

(Note: the Swiss Dolorclast is currently not approved for this indication)

Efficacy of extracorporeal shockwave therapy for knee osteoarthritis: a randomized controlled trial.

Zhao Z, Jing R, Shi Z, Zhao B, Ai Q, Xing G

J Surg Res 2013;185:661-666

BACKGROUND: Extracorporeal shockwave therapy (ESWT) has been widely used for pain relief and treatment of musculoskeletal disorders. We aimed to assess ESWT for knee osteoarthritis (OA) over 12 wk by comparison with placebo treatment.

MATERIALS AND METHODS: We randomized 70 patients to receive placebo (n = 36) or ESWT (n = 34). For ESWT, patients received 4000 pulses of shockwave at 0.25 mJ/mm² weekly for 4 wk. In the placebo group, patients received shockwave at 0 mJ/mm² in the same area. The effect on OA was assessed by pain on a visual analog scale and disability on the Lequesne index, Western Ontario and McMaster University Osteoarthritis Index, and patient perception of the clinical severity of OA. Evaluation was performed at baseline and after 1, 4, and 12 wk.

RESULTS: We found no adverse events during and after ESWT. ESWT was more effective than placebo in reducing pain on movement at each period (P < 0.01). The mean visual analog scale score with ESWT was 3.83 at 12 wk versus 7.56 at baseline (P < 0.01). The Lequesne index and the Western Ontario and McMaster University Osteoarthritis Index score were reduced with ESWT. Moreover, patient perception of clinical severity of OA was significantly greater with ESWT than that with placebo (P < 0.01).

CONCLUSIONS: ESWT is effective in reducing pain and improving knee function, with better results than placebo during the 12-wk treatment. However, further pilot studies are needed to determine whether ESWT should be recommended at an early or later stage of OA or combined with conventional therapies.

Greater trochanteric pain syndrome

Home training, local corticosteroid injection, or radial shock wave therapy for greater trochanter pain syndrome.

Rompe JD, Segal NA, Cacchio A, Furia JP, Morral A, Maffulli N.

Am J Sports Med 2009;37:1981-1990

BACKGROUND: There are no controlled studies testing the efficacy of various nonoperative strategies for treatment of greater trochanter pain syndrome. **HYPOTHESIS:** The null hypothesis was that local corticosteroid injection, home training, and repetitive low-energy shock wave therapy produce equivalent outcomes 4 months from baseline. **STUDY DESIGN:** Randomized controlled clinical trial; Level of evidence, 2. **METHODS:** Two hundred twenty-nine patients with refractory unilateral greater trochanter pain syndrome were assigned sequentially to a home training program, a single local corticosteroid injection (25 mg prednisolone), or a repetitive low-energy radial shock wave treatment. Subjects underwent outcome assessments at baseline and at 1, 4, and 15 months. Primary outcome measures were degree of recovery, measured on a 6-point Likert scale (subjects with rating completely recovered or much improved were rated as treatment success), and severity of pain over the past week (0-10 points) at 4-month follow-up. **RESULTS:** One month from baseline, results after corticosteroid injection (success rate, 75%; pain rating, 2.2 points) were significantly better than those after home training (7%; 5.9 points) or shock wave therapy (13%; 5.6 points). Regarding treatment success at 4 months, radial shock wave therapy led to significantly better results (68%; 3.1 points) than did home training (41%; 5.2 points) and corticosteroid injection (51%; 4.5 points). The null hypothesis was rejected. Fifteen months from baseline, radial shock wave therapy (74%; 2.4 points) and home training (80%; 2.7 points) were significantly more successful than was corticosteroid injection (48%; 5.3 points). **CONCLUSION:** The role of corticosteroid injection for greater trochanter pain syndrome needs to be reconsidered. Subjects should be properly informed about the advantages and disadvantages of the treatment options, including the economic burden. The significant short-term superiority of a single corticosteroid injection over home training and shock wave therapy declined after 1 month. Both corticosteroid injection and home training were significantly less successful than was shock wave therapy at 4-month follow-up. Corticosteroid injection was significantly less successful than was home training or shock wave therapy at 15-month follow-up.

Low-energy extracorporeal shock wave therapy as a treatment for greater trochanteric pain syndrome.

Furia JP, Rompe JD, Maffulli N.

Am J Sports Med 2009;37:1806-1813

BACKGROUND: Greater trochanteric pain syndrome is often a manifestation of underlying gluteal tendinopathy. Extracorporeal shock wave therapy is effective in numerous types of tendinopathies. **HYPOTHESIS:** Shock wave therapy is an effective treatment for chronic greater trochanteric pain syndrome. **STUDY DESIGN:** Case control study; Level of evidence, 3. **METHODS:** Thirty-three patients with chronic greater trochanteric pain syndrome received low-energy shock wave therapy (2000 shocks; 4 bars of pressure, equal to 0.18 mJ/mm²); total energy flux density, 360 mJ/mm²). Thirty-three patients with chronic greater trochanteric pain syndrome were not treated with shock wave therapy but received additional forms of nonoperative therapy (control). All shock wave therapy procedures were performed without anesthesia. Evaluation was by change in visual analog score, Harris hip score, and Roles and Maudsley score. **RESULTS:** Mean pretreatment visual analog scores for the control and shock wave therapy groups were 8.5 and 8.5, respectively. One, 3, and 12 months after treatment, the mean visual analog score for the control and shock wave therapy groups were 7.6 and 5.1 ($P < .001$), 7 and 3.7 ($P < .001$), and 6.3 and 2.7 ($P < .001$), respectively. One, 3, and 12 months after treatment, mean Harris hip scores for the control and shock wave therapy groups were 54.4 and 69.8 ($P < .001$), 56.9 and 74.8 ($P < .001$), and 57.6 and 79.9 ($P < .001$), respectively. At final follow-up, the number of excellent, good, fair, and poor results for the shock wave therapy and control groups were 10 and 0 ($P < .001$), 16 and 12 ($P < .001$), 4 and 13 ($P < .001$), and 3 and 8 ($P < .001$), respectively. Chi-square analysis showed the



percentage of patients with excellent (1) or good (2) Roles and Maudsley scores (ie, successful results) 12 months after treatment was statistically greater in the shock wave therapy than in the control group ($P < .001$). CONCLUSION: Shock wave therapy is an effective treatment for greater trochanteric pain syndrome.

Tennis elbow

The use of a mobile lithotripter in the treatment of tennis elbow and plantar fasciitis.

Mehra A, Zaman T, Jenkin AI.

Surgeon 2003;1:290-292

OBJECTIVE: To evaluate the use of the mobile lithotripter in the treatment of tennis elbow and plantar fasciitis.

METHOD: A prospective single blind randomised trial was performed on 24 patients with tennis elbow and 23 patients with plantar fasciitis, with a mean duration of symptoms of 11 months. All patients had failed one or more method of treatment--conservative, topical non-steroidal anti-inflammatory drugs (NSAID), steroid injection and/or surgery. The patients were divided into treatment and placebo groups. The placebo group received treatment with a clasp on the elbow/heel to stop penetration of shock waves. A baseline pain score was obtained using the Million Visual Analogue scale (0-10). The affected area was infiltrated with 3-5mls of 1% lignocaine. The treatment consisted of 2000 shock waves at 2.5 bars of air pressure with a frequency of 8-10Hz. A total of three treatments were given at an interval of two weeks, each lasting for three to four minutes.

RESULTS: In the treatment groups, a final pain score at six months post treatment showed significant improvement (three or more points) in 78% of patients with tennis elbow and 93% of patients with plantar fasciitis. In the placebo groups, significant improvement was seen in one patient (9%) with tennis elbow. The other patients in the placebo groups did not show significant improvement. This was statistically significant (chi square test) for both conditions.

CONCLUSION: The mobile lithotripter is an effective way of treating tennis elbow and plantar fasciitis but warrants further larger studies.

Effectiveness of initial extracorporeal shock wave therapy on the newly diagnosed lateral or medial epicondylitis

Lee SS, Kang S, Park NK, Lee CW, Song HS, Sohn MK, Cho KH, Kim JH.

Ann Rehabil Med 2012;;36:681-687

OBJECTIVE: To evaluate the effectiveness of initial extracorporeal shock wave therapy (ESWT) for patients newly diagnosed with lateral or medial epicondylitis, compared to local steroid injection.

METHOD: An analysis was conducted of twenty-two patients who were newly confirmed as lateral or medial epicondylitis through medical history and physical examination. The ESWT group (n=12) was treated once a week for 3 weeks using low energy (0.06-0.12 mJ/mm²), 2,000 shocks), while the local steroid injection group (n=10) was treated once with triamcinolone 10 mg mixed with 1% lidocaine solution. Nirschl score and 100 point score were assessed before and after the treatments of 1st, 2nd, 4th and 8th week. And Roles and Maudsley score was assessed one and eight weeks after the treatments.

RESULTS: Both groups showed significant improvement in Nirschl score and 100 point score during the entire period. The local steroid injection group improved more in Nirschl score at the first week and in 100 point score at the first 2 weeks, compared to those of the ESWT group. But the proportion of excellent and good grades of Roles and Maudsley score in the ESWT group increased more than that of local steroid injection group by the final 8th week.

CONCLUSION: The ESWT group improved as much as the local steroid injection group as treatment for medial and lateral epicondylitis. Therefore, ESWT can be a useful treatment option in patients for whom local steroid injection is difficult.

Subacromial pain syndrome

Radial extracorporeal shockwave therapy compared with supervised exercises in patients with subacromial pain syndrome: a single blind randomised study.

Engebretsen K, Grotle M, Bautz-Holter E, Sandvik L, Juel NG, Ekeberg OM, Brox JI.

Brit Med J 2009;339:b3360. doi: 10.1136/bmj.b3360

OBJECTIVE: To compare the effectiveness of radial extracorporeal shockwave treatment with that of supervised exercises in patients with shoulder pain. **DESIGN:** Single blind randomised study. **SETTING:** Outpatient clinic of physical medicine and rehabilitation department in Oslo, Norway. **PARTICIPANTS:** 104 patients with subacromial shoulder pain lasting at least three months. **INTERVENTIONS:** Radial extracorporeal shockwave treatment: one session weekly for four to six weeks. Supervised exercises: two 45 minute sessions weekly for up to 12 weeks. Primary outcome measure Shoulder pain and disability index. **RESULTS:** A treatment effect in favour of supervised exercises at 6, 12, and 18 weeks was found. The adjusted treatment effect was -8.4 (95% confidence interval -16.5 to -0.6) points. A significantly higher proportion of patients in the group treated with supervised exercises improved-odds ratio 3.2 (1.3 to 7.8). More patients in the shockwave treatment group had additional treatment between 12 and 18 weeks-odds ratio 5.5 (1.3 to 26.4). **CONCLUSION:** Supervised exercises were more effective than radial extracorporeal shockwave treatment for short term improvement in patients with subacromial shoulder pain. **TRIAL REGISTRATION:** Clinical trials NCT00653081.

Primary long bicipital tenosynovitis

(Note: the Swiss Dolorclast is currently not approved for this indication)

Radial extracorporeal pressure pulse therapy for the primary long bicipital tenosynovitis a prospective randomized controlled study.

Liu S, Zhai L, Shi Z, Jing R, Zhao B, Xing G.

Ultrasound Med Biol 2012;38:727-735

Long bicipital tenosynovitis is regarded as one of the common causes of shoulder pain and dysfunction. The traditional therapeutic approach includes a variety of conservative treatments, but these treatments are not substantiated, owing to the lack of proven clinical efficacy. Radial extracorporeal shock wave therapy (rESWT) uses a pneumatically generated and radially propagating low-energy pressure pulse and has been clinically shown to be a new alternative form of treating refractory soft tissue inflammation. While treating patients suffering from long bicipital tenosynovitis, a randomized, controlled trial was conducted to analyze the effects of radial shock wave therapy on pain and function. Seventy-nine adults with long bicipital tenosynovitis were randomized to receive either active (1500 pulses, 8 Hz, 3 bars) or sham treatment through four sessions that were held once a week. All of these adults were assessed before treatment and at time intervals of 1, 3 and 12 months since the completion of the treatment. The outcomes were measured through the visual analogue scale (VAS) and L'Insalata shoulder questionnaire. Mean VAS in the rESWT group showed significant and sustained reduction from 5.67 ± 1.32 at baseline to 2.58 ± 1.49 at one month, 1.83 ± 1.25 at three months and 1.43 ± 0.94 at 12 months from baseline, whereas the sham group's mean VAS was 6.04 ± 0.97 before treatment and stabilized at 5.57 ± 0.84 at 12 months. Similar trends were found for the function scores. Mean scores were increased after rESWT from 60.57 ± 6.91 at baseline to 79.85 ± 6.59 at 1 month and 83.44 ± 5.21 at 12 months from baseline. Both pain and function scores showed significant differences between the two groups ($p < 0.001$). The rESWT group consisted of "invalid conservative treatment subgroup" and "none conservative treatment subgroup." Both groups showed good recovery and prognosis. Therefore, we recommend rESWT in treating primary long bicipital tenosynovitis.

Spasticity in cerebral palsy

(Note: the Swiss Dolorclast is currently not approved for this indication)

Radial extracorporeal shock wave therapy (rESWT) in the treatment of spasticity in cerebral palsy: a randomized, placebo-controlled clinical trial.

Vidal X, Morral A, Costa L, Tur M.

NeuroRehabilitation 2011;29:413-419

AIM: The aim of this study was to evaluate the efficacy and safety of radial extracorporeal shock wave therapy (rESWT) in the treatment of spasticity in patients with cerebral palsy.

METHODS: Fifteen patients with spastic cerebral palsy, 12 men and 3 women, aged 10-46 years (mean age 31). The 15 patients presented 40 spastic muscles that were divided in three groups using a computerized random-number generator. The first group, received rESWT in spastic muscle. The second group received rESWT in spastic muscle + rESWT in antagonist muscle. The third group received placebo. Range of motion and Ashworth Scale were performed. This study is a randomized, placebo-controlled clinical trial. The patients were treated in 3 sessions at intervals of one week.

RESULTS: There are significant differences between groups treated with rESWT and group placebo. A significant decrease in the Ashworth Scale, an increase in the range of motion, were observed in all patients that were treated with rESWT. Positive results were maintained for at least 2 months after treatment.

INTERPRETATION: The treatment with rESWT is more effective than placebo in decreasing spasticity of patients with CP.



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