SWISS DOLORCLAST® METHOD

CLINICAL TRIALS PUBLISHED IN THE INTERNATIONAL PEER-REVIEWED LITERATURE

EMS

Clinical trials published in the international peer-reviewed literature[1] demonstrating efficacy and safety of treatment with the EMS Swiss DolorClast® according to Evidence Based Medicine criteria[2]:

Plantar fasciopathy

Comparison of different energy densities of extracorporeal shock wave therapy (ESWT) for the management of chronic heel pain.

Chow IH, Cheing GL.

Clin Rehabil 2007;21:131-141

OBJECTIVE: To compare the effectiveness of different energy densities of extracorporeal shock wave therapy (ESWT) for managing chronic heel pain.

DESIGN: A randomized clinical trial.

SETTING: Hospital-based practice.

SUBJECTS: Fifty-seven patients with chronic heel pain were recruited; eight patients withdrew from the study.

INTERVENTIONS: Subjects were randomized into three groups receiving: (1) a 'fixed' energy density, (2) 'maximum tolerable' energy density, or (3) control treatment once a week for three weeks.

OUTCOME MEASURES: Pain on palpation, pain on tension, maximum tolerable walking/standing duration and Foot Function Index were assessed before treatment in each treatment session and at the three-week follow-up.

RESULTS: By week 3, the 'maximum tolerable' energy density group experienced a 66% cumulative reduction in pain from tension, a 65% reduction on palpation and a 112% cumulative increase in maximum tolerable walking/standing duration. The 'fixed' energy density group experienced a 45% cumulative reduction in pain from tension, a 32% reduction in pain on palpation, and a 45% increase in walking/standing tolerance. The 'maximum tolerable' energy density group also showed a significantly greater reduction in Foot Function Index scores than the other two groups. Therapeutic effects were maintained at least up to the three-week follow-up period. The control group had no significant changes in any outcome measures across time periods.

CONCLUSION: The delivery of ESWT with a maximum tolerable energy density is a more effective treatment protocol than a fixed energy density in terms of relieving pain and restoring the functional activity of people suffering from chronic heel pain. The analgesic effects were maintained at least up to the three-week follow-up.

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[1] As of March 14, 2016.

[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. (2010) 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).

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.

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.

Am J Sports Med 2008;36:2100-2109

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/mm(2); 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.

Extracorporeal shock-wave therapy (ESWT) with a new generation pneumatic device in the treatment of heel pain. A double blind randomised controlled trial.[3]

Marks W, Jackiewicz A, Witkowski Z, Kot J, Deja W, Lasek J.

Acta Orthop Belg 2008;74:98-101

Although low-energy extracorporeal shock wave therapy (ESWT) is widely used to treat a variety of soft tissue disorders, no precise algorithm has been accepted in clinical management. Furthermore, the clinical use of a new generation pneumatic device has not yet been evaluated. We performed a double blind randomised controlled trial on a group of 25 patients with heel pain from chronic plantar fasciitis, to assess the efficacy of ESWT. The main outcome measure was the patients' subjective assessment of pain by means of a Visual Analog Scale (VAS) and the Roles and Maudsley Score before ESWT, early after treatment and six months later. There appeared to be a significant placebo effect with low-energy ESWT in patients with heel pain, and there was also lack of evidence for the efficacy of ESWT when compared to sham therapy.

[3] For a detailed discussion of the methodological shortcomings of this study see Schmitz C, Császár NB, Rompe JD, Chaves H, Furia JP. Treatment of chronic plantar fasciopathy with extracorporeal shock waves (review). *J Orthop Surg Res 2013;8:31*.

Comparison of radial shockwaves and conventional physiotherapy for treating plantar fasciitis.

Greve JM, Grecco MV, Santos-Silva PR.

Clinics 2009;64:97-103

OBJECTIVE: To compare radial shockwave treatment and conventional physiotherapy for plantar fasciitis.

MATERIALS AND METHODS: Thirty-two patients with plantar fasciitis were included in this study. They were randomly divided into two groups. Group 1 was composed of 16 patients who underwent 10 physiotherapy sessions each, consisting of ultrasound, kinesiotherapy and instruction for stretching exercises at home. Group 2 was composed of 16 patients who underwent three applications of radial shockwaves (once a week) and received instruction for stretching exercises at home. Pain and ability to function were evaluated before treatment, immediately afterwards, and three months later. The mean age of the patients was 47.3 +/- 10.3 years (range 25-68); 81% were female, 87% were overweight, 56% had bilateral impairment, and 75% used analgesics regularly.

RESULTS: Both treatments were effective for pain reduction and for improving the functional abilities of patients with plantar fasciitis. The effect of the shockwaves was apparent sooner than physiotherapy after the onset of treatment.

CONCLUSION: Shockwave treatment was no more effective than conventional physiotherapy treatment when evaluated three months after the end of treatment.

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 follow-up.

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 follow-up 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).

Plantar fascia-specific stretching versus radial shock-wave therapy as initial treatment of plantar fasciopathy.

Rompe JD, Cacchio A, Weil L Jr, Furia JP, Haist J, Reiners V, Schmitz C, Maffulli N.
J Bone Joint Surg Am 2010;92:2514-2522

BACKGROUND: Whether plantar fascia-specific stretching or shock-wave therapy is effective as an initial treatment for proximal plantar fasciopathy remains unclear. The aim of this study was to test the null hypothesis of no difference in the effectiveness of these two forms of treatment for patients who had unilateral plantar fasciopathy for a maximum duration of six weeks and which had not been treated previously.

METHODS: One hundred and two patients with acute plantar fasciopathy were randomly assigned to perform an eight-week plantar fascia-specific stretching program (Group I, n = 54) or to receive repetitive low-energy radial shock-wave therapy without local anesthesia, administered weekly for three weeks (Group II, n = 48). All patients completed the seven-item pain subscale of the validated Foot Function Index and a patient-relevant outcome questionnaire. Patients were evaluated at baseline and at two, four, and fifteen months after baseline. The primary outcome measures were a mean change in the Foot Function Index sum score at two months after baseline, a mean change in item 2 (pain during the first few steps of walking in the morning) on this index, and satisfaction with treatment.

RESULTS: No difference in mean age, sex, weight, or duration of symptoms was found between the groups at baseline. At two months after baseline, the Foot Function Index sum score showed significantly greater changes for the patients managed with plantar fascia-specific stretching than for those managed with shock-wave therapy ($p < 0.001$), as well as individually for item 2 ($p = 0.002$). Thirty-five patients (65%) in Group I versus fourteen patients (29%) in Group II were satisfied with the treatment ($p < 0.001$). These findings persisted at four months. At fifteen months after baseline, no significant between-group difference was measured.

CONCLUSIONS: A program of manual stretching exercises specific to the plantar fascia is superior to repetitive low-energy radial shock-wave therapy for the treatment of acute symptoms of proximal plantar fasciopathy.

Comparison of three different treatment protocols of low-energy radial extracorporeal shock wave therapy for management of chronic plantar fasciitis

Shaheen AAM

Ind J Physiother Occup Ther 2010;4:8-12

OBJECTIVE: The aim of this study was to compare the effectiveness of three different treatment protocols of low-energy radial extracorporeal shock wave therapy for management of chronic plantar fasciitis.

SUBJECTS: The study was double-blind randomized study. Forty five adult subjects were randomly divided into three equal groups (I, II & III).

METHODS: The treatment group (I) received 2000 impulses with 2.5 bars and frequency of 8Hz, group (II) received 3500 impulses with 3-3.5 bars and frequency of 8Hz while group (III) received 1000 impulses with 1.5 bars and frequency of 4.8 Hz. All groups received total 3 sessions given at weekly interval. Pain and function of foot were measured at baseline, after 3 weeks of treatment and after 6 weeks of follow up after the end of the treatment by visual analog scale and ankle-hind foot scale respectively.

RESULTS: The results revealed significant reduction of pain and improvement in function of the foot in all treated groups (I, II & III) ($P<.0.0001$), significant difference in pain and function scores between group I & III as well as between group II & III and negative correlation between pain and function of the foot ($r=-.44$) after 6 weeks follow up.

CONCLUSION: Radial extracorporeal shockwave therapy significantly improves pain and foot function. The delivery of low-energy radial extracorporeal shock wave therapy 3 sessions given at weekly interval with 2000 impulses, 2.5 bars and frequency of 8Hz is the most effective treatment protocol in terms of relieving pain and restoring the functional activity of people suffering from chronic plantar fasciitis.

One-year treatment follow-up of plantar fasciitis: radial shockwaves vs. conventional physiotherapy.

Grecco MV, Brech GC, Greve JM.

Clinics 2013;68:1089-1095

OBJECTIVE: To compare radial shockwave treatment with conventional physiotherapy for plantar fasciitis after 12 months of follow-up.

METHOD: This was a randomized, prospective, comparative clinical study. Forty patients with a diagnosis of plantar fasciitis were divided randomly into two treatment groups: group 1, with 20 patients who underwent ten physiotherapy sessions comprising ultrasound, kinesiotherapy and guidance for home-based stretching; and group 2, with 20 patients who underwent three applications of radial shockwaves, once a week, and guidance for home-based stretching. All patients were assessed regarding pain and functional abilities before treatment, immediately after and 12 months after treatment. The mean age was 49.6 ±11.8 years (range: 25-68 years), 85% were female, 88% were overweight, 63% were affected bilaterally, and 83% used analgesics regularly.

RESULTS: At the 12-month follow-up, both treatments were effective for improving pain and functional ability among the patients with plantar fasciitis. The improvement with shockwaves was faster.

CONCLUSION: Shockwave treatment was not more effective than conventional physiotherapy treatment 12 months after the end of the treatment.

Radial shock wave treatment alone is less efficient than radial shock wave treatment combined with tissue-specific plantar fascia-stretching in patients with chronic plantar heel pain.

Rompe JD, Furia J, Cacchio A, Schmitz C, Maffulli N.

Int J Surg 2015;24(Pt B):135-142

BACKGROUND: Whether shock wave therapy or shock wave therapy combined with plantar fascia-specific stretching is more efficient in treating chronic plantar heel pain remains unclear. The aim of the study was to test the null hypothesis of no difference of these two forms of management for patients who had unilateral plantar fasciopathy for a minimum duration of twelve months and which had failed at least three other forms of treatment.

METHODS: One hundred and fifty-two patients with chronic plantar fasciopathy were assigned to receive repetitive low-energy radial shock-wave therapy without local anesthesia, administered weekly for three weeks (Group 1, n = 73) or to receive the identical shock wave treatment and to perform an eight-week plantar fascia-specific stretching program (Group 2, n = 79). All patients completed the nine-item pain subscale of the validated Foot Function Index and a subject-relevant outcome questionnaire. Patients were evaluated at baseline, and at two, four, and twenty-four months after baseline. The primary outcome measures were a mean change in the Foot Function Index sum score at two months after baseline, a mean change in item 2 (pain during the first steps of walking in the morning) on this Index, and satisfaction with treatment.

RESULTS: No difference in mean age, sex, weight or duration of symptoms was found between the groups at baseline. At two months after baseline, the Foot Function Index sum score showed significantly greater changes for the patients managed with shock-wave therapy plus plantar fascia-specific stretching than those managed with shock-wave therapy alone ($p < 0.001$), as well as individually for item 2 ($p < 0.001$). Twenty-four patients in Group 1 (32%) versus forty-seven patients in Group 2 (59%) were satisfied with the treatment ($p < 0.001$). Significant differences persisted at four months, but not at twenty-four months.

CONCLUSIONS: A program of manual stretching exercises specific to the plantar fascia in combination with repetitive low-energy radial shock-wave therapy is more efficient than repetitive low-energy radial shock-wave therapy alone for the treatment of chronic symptoms of proximal plantar fasciopathy.

A comparison of the effectiveness of radial extracorporeal shock wave therapy and ultrasound therapy in the treatment of chronic plantar fasciitis: a randomized controlled trial.

Konjen N, Napnark T, Janchai S.

J Med Assoc Thai. 2015 Jan;98 Suppl 1:S49-56.

OBJECTIVE: To compare the effectiveness ofradial extracorporeal shock wave therapy (rSWET) and ultrasound therapy (US) in the treatment of chronic plantar fasciitis.
STUDY DESIGN: Randomized controlled trial.
SETTING: Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital.
MATERIAL AND METHOD: Thirty patients who were diagnosed with plantar fasciitis for at least 3 months and who had not responded to other forms of conservative treatment were recruited for this study. They were randomly divided into two groups of 15 patients. The rESWT group was treated with 1 session per week and the US group with 3 sessions per week, with both groups undergoing a total of 6 consecutive weeks of treatment. Visual analog scale (VAS) assessments were performed before and after treatment at 1, 3, 6, 12, and 24 weeks. The mobility subscale of the plantar fasciitis pain and disability scale (PFPS) was measured before and after treatment. Patient satisfaction was evaluated at the conclusion of the 6-week treatment protocol.
RESULTS: VAS pain intensity scores were significantly decreased in both groups ($p < 0.001$), when measured after treatment at 1, 3, 6, 12, and 24 weeks. The VAS pain scores for the rESWT group dropped significantly more than those of the US group ($p < 0.001$). At the end of treatment, the PFPS mobility subscale scores in both groups were significantly decreased ($p < 0.001$). Similar to the VAS pain score outcome, the PFPS mobility subscale score for the rESWT group decreased significantly more than that of the US group ($p < 0.001$). Patient satisfaction was significantly higher in the rESWT group, relative to the US group ($p = 0.025$).
CONCLUSION: In chronic plantar fasciitis treatment, both rESWT and US were found to be effective in reducing pain and increasing mobility; however, statistical analysis showed that rESWT is significantly more effective than US.

Long-term results of radial extracorporeal shock wave treatment for chronic plantar fasciopathy: A prospective, randomized, placebo-controlled trial with two years follow-up.

Ibrahim MI, Donatelli RA, Hellman M, Hussein AZ, Furia JP, Schmitz C.

J Orthop Res. 2016 Aug 27. doi: 10.1002/jor.23403. [Epub ahead of print]

BACKGROUND: Numerous randomized controlled trials (RCTs) demonstrated efficacy and safety of extracorporeal shock wave therapy (ESWT) for chronic plantar fasciopathy (cPF). However, only two such RCTs investigated a follow-up period of more than 1 year, both applying focused ESWT. Corresponding data for radial ESWT (rESWT) have not yet been reported. We therefore tested the hypothesis that rESWT is effective and safe for the management of cPF with long-term follow-up of 2 years.
MATERIAL AND METHOD: To this end $n = 50$ patients with cPF were randomly allocated to either two sessions of rESWT (one session per week; 2,000 shock waves with energy flux density of 0.16 mJ/mm^2 per session) ($n = 25$) or to placebo treatment ($n = 25$).
RESULTS: Evaluation was by change in Visual Analog Scale (VAS) score and Roles and Maudsley (RM) score. Mean pretreatment VAS scores for the rESWT and placebo groups were 8.5 and 8.9, respectively. 1, 3, 6, 12, and 24 months after treatment, the mean VAS scores for the rESWT and placebo groups were 0.6, 1.1, 0.5, 2.3, and 1.4 and 7.6, 7.7, 7.4, 6.9, and 5.6 ($p < 0.001$), respectively. Differences in mean RM scores were statistically significant between groups at 1, 3, 6, 12, and 24 months post treatment, but not at baseline. There were no significant complications.
CONCLUSION: These data indicate that rESWT is effective and safe for the management of cPF with long-term follow-up of 2 years.

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) non insertional Achilles tendinopathy were enrolled in a randomized controlled study. All patients had received unsuccessful management for >3 months, including at least (1) peritendinous local injections, (2) nonsteroidal anti-inflammatory drugs, and (3) physiotherapy. A computerized random-number generator was used to draw up an allocation schedule. Analysis was on 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: Non operative 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 mid-substance 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 I 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) non insertional Achilles tendinopathy were enrolled in a randomized controlled study. All patients had received unsuccessful management for >3 months, including at least (1) peritendinous local injections, (2) nonsteroidal anti-inflammatory drugs, and (3) physiotherapy. A computerized random-number generator was used to draw up an allocation schedule. Analysis was on intention-to-treat basis.
RESULTS: At 4 months from baseline, the Victorian Institute of Sport Assessment (VISA)-A score increased in all groups, from 51 to 76 points in group 1 (eccentric loading), from 50 to 70 points in group 2 (repetitive low-energy SWT), and from 48 to 55 points in group 3 (wait and see). Pain rating decreased in all groups, from 7 to 4 points in group 1, from 7 to 4 points in group 2, and from 8 to 6 points in group 3. Fifteen of 25 patients in group 1 (60%), 13 of 25 patients in group 2 (52%), and 6 of 25 patients in Group 3 (24%) reported a Likert scale of 1 or 2 points ("completely recovered" or "much improved"). For all outcome measures, groups 1 and 2 did not differ significantly. For all outcome measures, groups 1 and 2 showed significantly better results than group 3.
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 pre-injury 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

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/mm(2) weekly for 4 wk. In the placebo group, patients received shockwave at 0 mJ/mm(2) 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.

Radial extracorporeal shock wave therapy for disabling pain due to severe primary knee osteoarthritis.

Imamura M, Alamino S, Hsing WT, Alfieri FM, Schmitz C, Battistella LR

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OBJECTIVE: To assess the efficacy and safety of radial extracorporeal shock wave therapy (rESWT) for disabling pain due to primary knee osteoarthritis.

STUDY DESIGN: Randomized, placebo-controlled trial (level of evidence, 1).

SUBJECTS: A total of 105 women with disabling pain due to primary knee osteoarthritis lasting for a mean of 103 months (range 3-480 months).

METHODS: Patients received either rESWT (3 sessions, each one week apart, 2,000 rESWT impulses per session, positive energy flux density 0.10-0.16 mJ/mm2) or placebo treatment. Primary outcome measure was pain on movement 3 months after the final treatment session. Secondary outcomes were pain, stiffness and limitations in physical function on the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index and the level of tolerance to pressure over muscles, tendons, ligaments and skin at both the treated and the untreated side at 1 week and 3 months follow-up examinations.

RESULTS: Compared with placebo treatment, rESWT led to a statistically significant improvement only in mean WOMAC scores for pain and a few of the pressure measurements.

CONCLUSION: rESWT, as performed in the present study, is not efficient for treating patients with disabling pain due to primary knee osteoarthritis. Published data indicate that substantially higher energy flux densities are necessary for treatment success in this condition.

Chronic proximal hamstring tendinopathy

Shockwave therapy for the treatment of chronic proximal hamstring tendinopathy in professional athletes.

Cacchio A, Rompe JD, Furia JP, Susi P, Santilli V, De Paulis F.

Am J Sports Med 2011;39:146-153

BACKGROUND: Chronic proximal hamstring tendinopathy is an overuse syndrome that is usually managed by nonoperative methods. Shockwave therapy has proved to be effective in many tendinopathies.

HYPOTHESIS: Shockwave therapy may be more effective than other nonoperative treatments for chronic proximal hamstring tendinopathy.

STUDY DESIGN: Randomized controlled clinical study; Level of evidence, 1.

METHODS: Forty professional athletes with chronic proximal hamstring tendinopathy were enrolled between February 1, 2004, and September 30, 2006. Patients were randomly assigned to receive either shockwave therapy, consisting of 2500 impulses per session at a 0.18 mJ/mm² energy flux density without anesthesia, for 4 weeks (SWT group, n = 20), or traditional conservative treatment consisting of nonsteroidal anti-inflammatory drugs, physiotherapy, and an exercise program for hamstring muscles (TCT group, n = 20). Patients were evaluated before treatment, and 1 week and 3, 6, and 12 months after the end of treatment. The visual analog scale (VAS) score for pain and Nirschl phase rating scale (NPRS) were used as primary outcome measures.

RESULTS: The patients were observed for a mean of 10.7 months (range, 1-12 months). Six patients were lost to follow-up because they underwent a surgical intervention: 3 (all in TCT group) were lost at 3 months; 2 (1 in each group), at 6 months; and 1 (in the TCT group), at 12 months. Primary follow-up was at 3 months after the beginning of treatment. The VAS scores in the SWT and TCT groups were 7 points before treatment (P = .84), and 2 points and 5 points, respectively, 3 months after treatment (P < .001). The NPRS scores in the SWT and TCT groups were 5 points in either group before treatment (P = .48), and 2 points and 6 points, respectively, 3 months after treatment (P < .001). At 3 months after treatment, 17 of the 20 patients (85%) in the SWT group and 2 of the 20 patients (10%) in the TCT group achieved a reduction of at least 50% in pain (P < .001). There were no serious complications in the SWT group.

CONCLUSION: Shockwave therapy is a safe and effective treatment for patients with chronic proximal hamstring tendinopathy.

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 non-operative 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/mm(2); total energy flux density, 360 mJ/mm(2)). Thirty-three patients with chronic greater trochanteric pain syndrome were not treated with shock wave therapy but received additional forms of non-operative 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

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/mm(2), 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.

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.

Chronic distal biceps tendinopathy

Radial extracorporeal shock wave therapy is effective and safe in chronic distal biceps tendinopathy.

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

Clin J Sport Med. 2016 Nov 23. [Epub ahead of print]

OBJECTIVE: To assess the efficacy and safety of radial extracorporeal shock wave therapy (rESWT) for chronic distal biceps tendinopathy (cDBT).
STUDY DESIGN: Case-control study (level of evidence, 3).
SETTING: SUN Orthopaedics and Sports Medicine.
PATIENTS: Patients with a diagnosis of cDBT were recruited between January 2010 and February 2015.
INTERVENTIONS: Patients received a single session of rESWT (2000 shock waves with energy flux density of 0.18 mJ/mm) or other forms of nonoperative therapy.
MAIN OUTCOME MEASURES: Patients completed the visual analog scale (VAS), the modified QuickDASH (MQD) score, and the Roles and Maudsley (RM) score over a 12-month period.
RESULTS: Forty-eight patients completed the final review at 12 months and were included in the study. Subjects ranged in age from 30 to 64 years. Mean pretreatment VAS scores for the rESWT and control groups were 8.3 and 8.5, respectively. Three and 12 months after inclusion in the study, the mean VAS scores for the rESWT and control groups were 3.4 and 5.6 ($P < 0.001$) and 2.7 and 4.7 ($P < 0.001$), respectively. Twelve-month follow-up MQD-Sports and MQD-Work scores for the rESWT and control groups were 3.7 and 1.7 ($P < 0.001$) and 3.8 and 1.8 ($P < 0.001$), respectively. Differences in mean RM scores were statistically significant between groups at 3 months after the treatment. There were no significant complications.
CONCLUSIONS: Overall, rESWT is an effective and safe treatment for cDBT.
CLINICAL RELEVANCE: Radial ESWT as a novel, effective, and safe treatment for cDBT.

Primary long bicipital tenosynovitis

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

BACKGROUND: 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.
HYPOTHESIS: 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.
METHOD: 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.
RESULTS: 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.
CONCLUSION: Therefore, we recommend rESWT in treating primary long bicipital tenosynovitis.

Subacromial pain syndrome / Chronic rotator cuff tendinitis

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.

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.

Supervised exercises compared with radial extracorporeal shock-wave therapy for subacromial shoulder pain: 1-year results of a single-blind randomized controlled trial.

Engebretsen K, Grotle M, Bautz-Holter E, Ekeberg OM, Juel NG, Brox JI.
Phys Ther 2011;91:37-47

BACKGROUND: Evidence from a recent randomized controlled trial indicated that supervised exercises (SE) were more effective than radial extracorporeal shock-wave therapy (rESWT) for the treatment of subacromial shoulder pain in the short to medium term. Little knowledge exists about the long-term results of rESWT for subacromial pain.
OBJECTIVE: The aim of this study was to evaluate the results of rESWT and SE provided to patients with subacromial shoulder pain after 1 year.
DESIGN: This was a single-blind randomized controlled trial.
SETTING: The study was conducted in the outpatient clinic of the Physical Medicine and Rehabilitation Department at Oslo University Hospital, Ullevaal, Norway.
PATIENTS: One hundred four patients with subacromial shoulder pain lasting at least 3 months participated. Patients were randomly assigned to either an rESWT group (n=52) or an SE group (n=52).
INTERVENTION: The rESWT intervention consisted of one session weekly for 4 to 6 weeks. The SE intervention consisted of two 45-minute sessions per week for up to 12 weeks.
MEASUREMENTS: The primary outcome measure was the Shoulder Pain and Disability Index. Secondary outcome measures were questions regarding pain and function and work status.
RESULTS: After 1 year, an intention-to-treat analysis showed no significant differences between the 2 groups for the primary outcome measure (-7.6 points, 95% confidence interval=-16.6 to 0.5) and pain, function, and medication use. Twenty-nine participants (60%) in the SE group versus 24 participants (52%) in the rESWT group were categorized as clinically improved. Thirty-eight participants in the SE group were at work compared with 30 participants in the rESWT group (odds ratio=1.1, 95% confidence interval=1.0 to 1.2). Fewer patients in the SE group had received additional treatments between 18 weeks and 1 year.

LIMITATIONS: The lack of a placebo control group, the lack of a cost-benefit analysis, and the small sample size were limitations of the study.
CONCLUSION: No significant difference was found between the SE and rESWT groups at the 1-year follow-up. More participants in the SE group had returned to work.

Radial extracorporeal shock-wave therapy in patients with chronic rotator cuff tendinitis: a prospective randomised double-blind placebo-controlled multicentre trial.[4]

Kolk A1, Yang KG, Tamminga R, van der Hoeven H.

Bone Joint J 2013;95-B:1521-1526

OBJECTIVE: The aim of this study was to determine the effect of radial extracorporeal shock-wave therapy (rESWT) on patients with chronic tendinitis of the rotator cuff.
DESIGN AND METHOD: This was a randomised controlled trial in which 82 patients (mean age 47 years (24 to 67)) with chronic tendinitis diagnosed clinically were randomly allocated to a treatment group who received low-dose rESWT (three sessions at an interval 10 to 14 days, 2000 pulses, 0.11 mJ/mm^2, 8 Hz) or to a placebo group, with a follow-up of six months. The patients and the treating orthopaedic surgeon, who were both blinded to the treatment, evaluated the results. A total of 44 patients were allocated to the rESWT group and 38 patients to the placebo group.
RESULTS: A visual analogue scale (VAS) score for pain, a Constant-Murley (CMS) score and a simple shoulder test (SST) score significantly improved in both groups at three and six months compared with baseline (all $p \leq 0.012$). The mean VAS was similar in both groups at three ($p = 0.43$) and six months ($p = 0.262$). Also, the mean CMS and SST scores were similar in both groups at six months ($p = 0.815$ and $p = 0.834$, respectively).
CONCLUSION: It would thus seem that low-dose rESWT does not reduce pain or improve function in patients chronic rotator cuff tendinitis compared with placebo treatment.

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[4] A major shortcoming of this study was the application of insufficient energy that can adversely affect the outcome of radial extracorporeal shock wave therapy (for a detailed discussion see Schmitz C, Császár NB, Milz S, Schieker M, Maffulli N, Rompe JD, Furia JP. Efficacy and safety of extracorporeal shock wave therapy for orthopedic conditions: a systematic review on studies listed in the PEDro database. *Br Med Bull 2015;116:115-138*.

Spasticity in cerebral palsy

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

OBJECTIVE: 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.

A prospective case-control study of radial extracorporeal shock wave therapy for spastic plantar flexor muscles in very young children with cerebral palsy.

Wang T, Du L, Shan L, Dong H, Feng J, Kiessling MC, Angstman NB, Schmitz C, Jia F.

Medicine (Baltimore). 2016 May;95(19):e3649

OBJECTIVE: To assess the effects of radial extracorporeal shock wave therapy (rESWT) on plantar flexor muscle spasticity and gross motor function in very young patients with cerebral palsy (CP).

STUDY DESIGN: The design was case-control study (level of evidence 3).

SETTING: The setting was the Department of Pediatric Neurology and Neurorehabilitation, First Hospital of Jilin University, Changchun, China.

METHODS: Those with a diagnosis of CP and spastic plantar flexor muscles were recruited between April 2014 and April 2015.According to the parents' decision, patients received 1 ESWT session per week for 3 months, with 1500 radial shock waves per ESWT session and leg with positive energy flux density of 0.03 mJ/mm, combined with traditional conservative therapy (rESWT group) or traditional conservative therapy alone (control group).The Modified Ashworth Scale (MAS) (primary outcome measure) and passive range of motion (pROM) measurements were collected at baseline (BL), 1 month (M1), and 3 months (M3) after BL. The Gross Motor Function Measure (GMFM)-88 was collected at BL and M3.Sixty-six patients completed the final review at 3 months and were included in the study. Subjects ranged in age from 12 to 60 months (mean age 27.0±13.6 months; median age 22.0 months; 33.3% female).

RESULTS: For the rESWT group (n=34), mean MAS grades at BL, M1, and M3 were 2.6, 1.9, and 1.5 on the left side and 1.9, 1.7, and 1.2 on the right side. For the control group (n=32), mean MAS grades at BL, M1, and M3 were 2.5, 2.4, and 2.1 on the left side and 1.8, 1.8, and 1.5 on the right side. The within-subject effects time×side and time×treatment were statistically significant ($P<0.01$). Similar results were found for the improvement of mean pROM. GMFM-88 improved from BL to M3, but showed no statistically significant difference between the groups. There were no significant complications.

CONCLUSION: This study demonstrates that the combination of rESWT and traditional conservative therapy is more effective than traditional conservative therapy alone in the treatment of spasticity in very young patients with CP.

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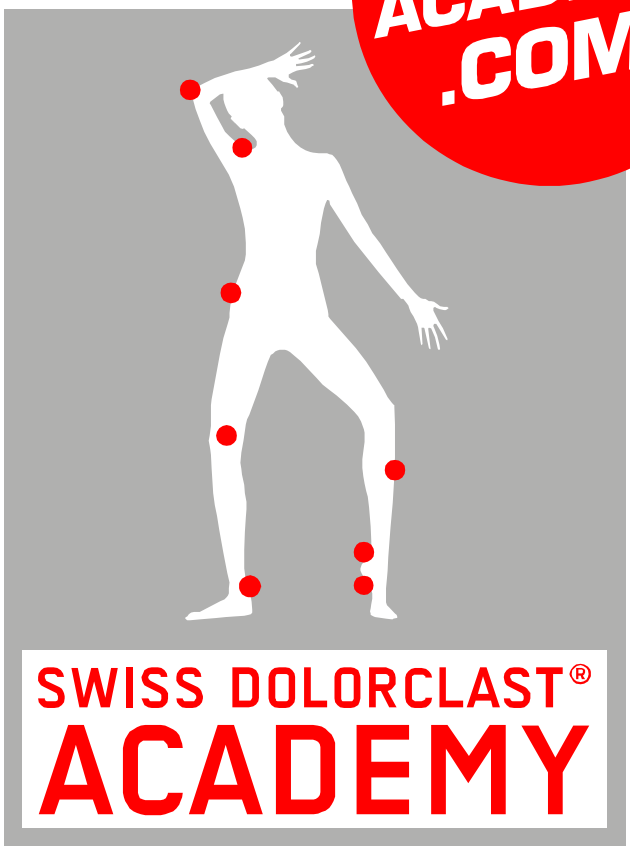

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