



**Clinical trials published in the international peer-reviewed literature<sup>1</sup> demonstrating efficacy and safety of treatment with the EMS Swiss Dolorclast<sup>®</sup> according to Evidence Based Medicine criteria<sup>2</sup>:**

### **Plantar fasciitis:**

**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/mm<sup>2</sup>; 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.

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<sup>1</sup> As of October 1, 2009

<sup>2</sup> 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 and Rompe et al. (2009) on medial tibial stress syndrome. 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: *in press*

**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/mm<sup>2</sup> 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:

### **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.**

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

*Am J Sports Med* 2009 Sep 23 [Epub ahead of print]

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/mm<sup>2</sup>; total energy flux density, 200 mJ/mm<sup>2</sup>; 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.

## 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/mm<sup>2</sup>; total energy flux density, 360 mJ/mm<sup>2</sup>). 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.

## **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 JJ. *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.