SWISS DOLORCLAST® CLASSIC → EXTRACORPOREAL SHOCK WAVE THERAPY







THE SWISS DOLORCLAST® DOLORCLAST® METHOD EXTRACORPOREAL SHOCK WAVE THERAPY FOR CHRONIC HEEL PAIN

- → NON-INVASIVE TREATMENT
- \rightarrow IN-OFFICE PROCEDURE ON OUTPATIENT
- \rightarrow NO ANESTHESIA, MEDICATION OR SURGICAL PROCEDURES
- \rightarrow PLUG AND TREAT
- → FAST AND EFFECTIVE PAIN RELIEF
- \rightarrow FDA APPROVED
- \rightarrow CLINICALLY PROVEN

FOR SUCCESSFUL PRACTICE

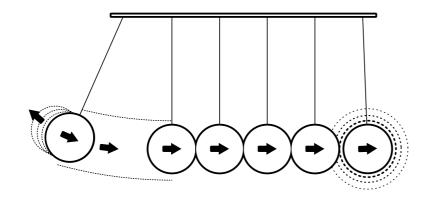


ENT URGICAL PROCEDURES

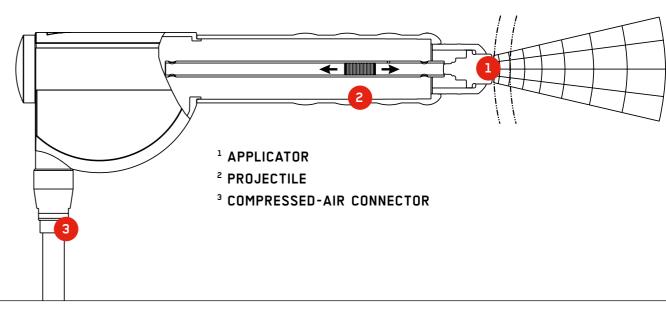
FOR RELIEF FROM HEEL PAIN -SHOCK WAVES **GENERATED BY HIGH PNEUMATIC** ENERGY →

A TEXTBOOK LAW OF PHYSICS

> Kinetic energy is converted into impact energy, as illustrated by Newton's Cradle



GENERATING PNEUMATIC ENERGY WITH SWISS PRECISION - FOR CONTROL AND RELIABILITY



→ PRECISE COMPRESSED-AIR IMPULSE ACCELERATES THE PROJECTILE IN THE HANDPIECE → THE IMPACT OF THE PROJECTILE ON THE APPLICATOR GENERATES THE SHOCK WAVE

→ THE SHOCK WAVE IS DELIVERED TO THE TISSUE

The advantage of radial shock waves is that they > generally produce an extensive analgesic area

> The unfocused propagation of shock waves encompasses the entire area where lies the pain

EXTRACORPOREAL SHOCK WAVE THERAPY WITH THE SWISS DOLORCLAST[®] METHOD →

PATENTED FOR SUCCESS

SWISS DOLORCLAST

TECHNOLOGY

THE SHOCK WAVE → SHOCK WAVE GENERATED BY SWISS DOLORCLAST® DEMONSTRATED BY CAVITATION

SECONDARY SHOCK WAVES OF THE CAVITATION BUBBLES→

AVITATION BUBBLI

lat. Capsicum annuum

RED CHILI PEPPERS - OR THE SECRET OF THE SOOTHING EFFECT OF MODERN SHOCK WAVE THERAPY WITH THE ORIGINAL SWISS DOLORCLAST[®] METHOD→

> Red chili peppers contain capsaicin. At first this substance overwhelms the so-called C nerve fibers responsible for transmitting pain but then desensitizes them for an extended period of time. Everybody knows the feeling – first, the mouth is on fire, then it feels completely numb

> Research has indicated that shock wave therapy works the same way.¹ When activated, the C nerve fibers release a specific substance (substance P) in the tissue as well as in the spinal cord. This substance is responsible for causing slight discomfort during and after shock wave treatment. However, with prolonged activation, C nerve fibers become incapable of releasing substance P and causing pain² for some time

> Less substance P in the tissue means to reduced pain. But there is more: less substance P also causes so-called neurogenic inflammation to decline³

> A decline in neurogenic inflammation may in turn soothe the pain – together with the release of growth factors and the activation of stem cells in the treated tissue⁴

¹ Maier et al., Clin Orthop Relat Res 2003; (406):237-245

 2 In addition, shock waves activate the so-called A\delta nerve fibers (sensory afferences from the periphery) via receptors in the tissue. According to the gate control theory of Melzack and Wall (Science 1965; 150:971–979) these activated A\delta f ibers then suppress the conduction of pain in the second-order neuron of the sensory pathway in the dorsal horn of the spinal cord.

³ The release of substance P, CGRP (calcitonin gene-related peptide) and other inflammation mediators from afferent nerve fibers is generally referred to as "neurogenic inflammation" (Richardson and Vasko, J Pharmacol Exp Ther 2002; 302:839–845). It is also linked to the pathogenesis of tendinopathies such as plantar fasciitis (Roetert et al., Clin Sports Med 1995; 14:47–57; LeMelle et al., Clin Podiatr Med Surg 1990; 7:385–389). Shock wave treatment causes a drop in substance P and CGRP in the tissue (Maier et al., 2003; Takahashi et al., Auton Neurosci 2003; 107:81–84).

⁴ Shock waves lead in the treated tissue to a stronger expression of growth factors such as BMP (bone morphogenetic protein), eNOS (endothelial nitric oxide synthase), VEGF (vascular endothelial growth factor) and PCNA (proliferating cell nuclear antigen) as well as to an activation of stem cells (Wang CJ, ISMST Newsletter 2006 Vol 1 Issue 1; Hofmann et al., J Trauma 2008; 65:1402–1410).



IS HEEL PAIN AFFECTING YOUR LIFE?→

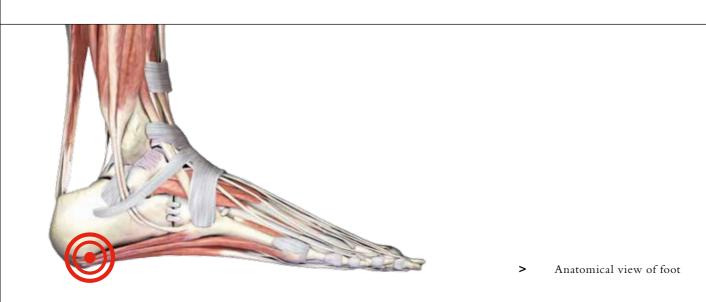
> Plantar fasciopathy (PF) is an acute or chronic, painful disorder of the plantar fascia that spans between the medial calcaneal tubercle and the proximal phalanges of the toes.

> It is the most common cause of plantar heel pain and accounts for approximately 11-15% of foot symptoms presented to physicians. The main clinical symptom is heel pain, particularly in the morning or after a resting. Often patients report improvement of pain after walking. Pain is usually located at the root of the plantar fascia, i.e., at the medial calcaneal tubercle. Passive dorsiflexion of the toes may aggravate the pain in some patients, particularly for those with chronic PF. Patients suffering from chronic PF may also present for heel pad swelling symptoms.

> Diagnosis is based on the clinical features of the disease. When in doubt, diagnostic imaging should be considered to rule out other causes of plantar heel pain or to establish the diagnosis of PF. Histologic examination of biopsy specimens from patients undergoing plantar fascia release surgery for chronic symptoms has shown that chronic PF is associated with degenerative changes in the fascia. Accordingly, the disease is better characterized as "fasciopathy" than "fasciitis", resembling the situation in found in overused tendon problems.

> In the United States, more than two million individuals are treated for PF on an annual basis. Up to 10% of the population will experience plantar heel pain during the course of a lifetime. Both athletes and the elderly commonly have PF.

> The treatment of PF should start with conservative treatment modalities including rest, physiotherapy, stretching, exercises, shoe inserts/orthotics, night splints, non-steroidal anti-inflammatory drugs, and local corticosteroid injections. Patients who do not respond to conservative treatment for a period of six months – between 10% and 20% of all patients – are recommended to undergo to radial shock wave therapy (RSWT[®]). Surgery should be considered for recalcitrant cases of PF.



SIMPLE TREATMENT →



1. Locating pain by palpation



3. Applying the contact gel

TREATMENT PROTOCOL →

- > 2000 impulses per session between 2.5 and 4 bar
- > No imaging necessary
- > No anesthesia required thanks to the analgesic effect of the treatment
- > No additional therapy, medication or surgery needed

BENEFITS FOR THE PRACTICIONER→

- > Short application time
- > High patient satisfaction
- > Low maintenance and operating costs





2. Marking the treatment area



4. Delivering the shock waves

fect of the treatment eded

FAST, GENTLE EFFECTIVE

THE EFFICACY AND SAFETY OF EXTRACORPOREAL SHOCK WAVE THERAPY FOR CHRONIC PLANTAR FASCIOPATHY WITH THE SWISS DOLORCLAST® HAS BEEN PROVEN ACCORDING TO THE PRINCIPLES OF EVIDENCE BASED MEDICINE (EBM) →

→ 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. HYPOTH-ESIS: 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.

LEVEL OF EVIDENCE: Level 1 (prospective, randomized, double-blinded, controlled therapeutic study).

\Rightarrow 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, single-blinded, controlled therapeutic study).

\rightarrow COMPARISON OF DIFFERENT ENERGY DENSITIES OF EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR THE MANAGEMENT OF CHR

Chow IH, Cheing GL. Clin Rehabil. 2007 Feb;21:131-411

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.

LEVEL OF EVIDENCE: Level 1 (prospective, randomized, controlled therapeutic study).

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.

SETTINGS →

1 Display desired impulse count per treatment

EMS

8

9

3

4

5

6

18

EMS

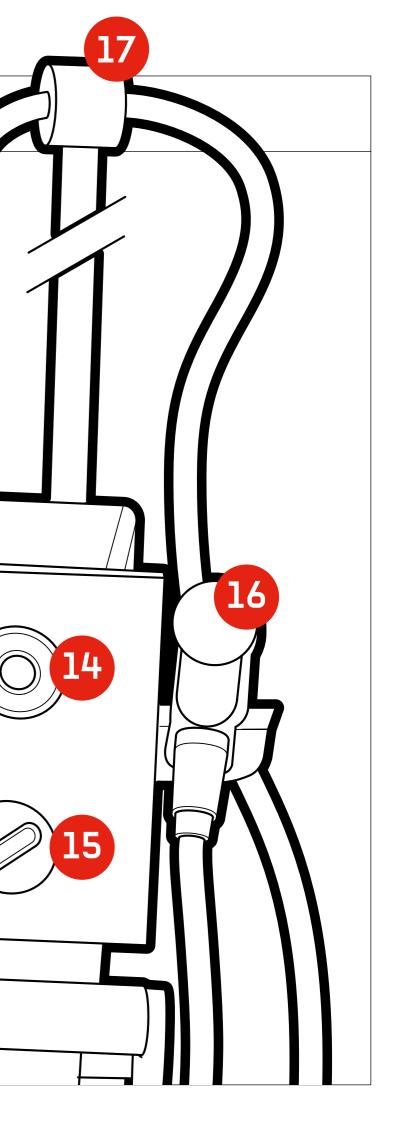
1

2

3

Swiss DolorClast*

- **2** Display current impulse count
- **3** Display operating frequency
- 4 Increase impulse count per treatment
- **5** Reduce impulse count per treatment
- **6** Increase operating frequency
- 7 Reduce operating frequency
- 8 "On/Off" with indicator light
- **9** Handpiece connection
- **10** "Select" to activate change in preset impulse count
- **11** "Validate" to confirm setting
- **12** Push button for single-impulse operation with indicator light
- **13** Push button for continuous impulse operation with indicator light
- **14** Manometer for operating pressure
- **15** Operating pressure control
- **16** Handpiece
- **17** Cable holder
- **18** Bottle holder (gel)



TESTIMONIALS →



HOWARD A. PENN, D.P.M. (LACKAWANNA, NY)

6.6 Extracorporeal Shockwave Therapy utilizing the EMS DolorClast[®] has become the standard of treatment for chronic plantar fasciitis in my practice for the past 6 years. This technology is a non-invasive, non- surgical modality which requires no anesthesia, no disability and offers patients an 85% success rate. The ability to improve people's lifestyle in a positive direction is well worth the investment! **?**

Howard A Penn, DPM, FACFAS



JOHN P. FURIA, MD (LEWISBURG, PA)

6 As someone who routinely utilizes ESWT to treat fasciopathies, tendinopathies and disorders of bone, I have experience with multiple shock wave generating devices.

Since 2007, however, my "go-to" ESWT device has been the EMS DolorClast[®].

Designed by Swiss engineers, the DolorClast is a compact, user-friendly, highly effective shock wave generator that is durable, portable, incredibly simple to set up and intuitive to use!

What used to be an elaborate ambulatory surgical center procedure is now safely and reliably performed with the DolorClast[®] in my office in just minutes! ??

John P. Furia, MD



DR. CHRISTOPH SCHMITZ, MD (MUNICH, GERMANY)

6 Modern shock wave therapy for the musculoskeletal system has successfully found its place in the treatment of top-level athletes.

As someone who has been treating athletes on-site during the Olympic Games since 2008, the Swiss DolorClast[®] Method is the treatment of choice for athletes suffering from different sporting disciplines with a wide range of disorders. In July 2012, as invited speaker at the 5th Edition of the Olympic Programme on Sport Medicine and Sport Physiotherapy hold at the Polyclinic in the London Olympic Village, I had the opportunity to meet the Olympic sports teams and treat a few of them.Thanks to the development of small, mobile Swiss DolorClast[®] shock wave units, the treatment can now be administered easily in competitions and during away-games.

This great method providing significant results is based essentially on (i) rapid treatment successes with minimum treatment risk, given proper and appropriate application, (ii) almost complete absence of adverse events, (iii) the non-invasive nature of the method and (iv) compatibility with anti-doping regulations. ??

Dr. Christoph Schmitz, MD





"I FEEL GOOD"

WWW.DOLORCLAST.US

EMS

ELECTRO MEDICAL SYSTEMS SA Chemin de la Vuarpillière 31 CH-1260 Nyon

Tel. +41 22 99 44 700 Fax +41 22 99 44 701 welcome@ems-ch.com www.ems-medical.com EMS CORPORATION 11886 Greenville Avenue #120 Dallas, TX 75243, USA

TOLL-FREE +1 800 367 0367 Tel. +1 972 690 83 82 Fax.+1 972 690 89 81 info@ems-medicalamerica.com www.dolorclast.us