Published in „Journal für Mineralstoffwechsel, Zeitschrift für Knochen- und Gelenkerkrankungen 11/2004“

Radial Extracorporeal Shockwave Therapy (rESWT) in Orthopaedics

L. Gerdesmeyer[1], H. Gollwitzer[1], P. Diehl[1], K. Wagner[2]

Radial extracorporeal shock wave therapy (rESWT) is widely used as an alternative treatment option in chronic tendinopathies. Good and excellent results were found in clinical trials which also did not report about clinical relevant side effects. Beside tennis elbow and chronic plantar fasciitis rESWT was effectively used in chronic calcific tendinitis of the shoulder and also in chronic patella syndrome. Recent studies showed also rESWT as a new treatment modality in Triggerpoint treatment. Good and excellent results were published in chronic head-, shoulder- and low back pain syndromes. Although good outcome in clinical studies were found there is still low evidence to use rESWT. In clinical practise rESWT seems to be useful and could be applicated in chronic recalcitrant cases but high-level randomized placebo-controlled clinical trials have to be done to proof efficacy of rESWT. Nevertheless randomized placebo controlled trials are lacking but have to be performed to proof the efficacy of rESWT on the basis of evidence-based medicine. Standard measurement of acoustic properties of radial shock waves showed energy flux densities up to 0,16 mJ/mm². ***J Miner Stoffwechs 2004; 11 (4): 36–39.***

Since the introduction of Extracorporeal Shockwave Therapy (ESWT) for the treatment of nephrolithiasis, the indication has been extended and the technical possibilities of ESWT have been considerably improved. Besides the classical indication of “kidney stones”, extra-corporeal shockwaves are also used in gall stones, pancreatic stones and salivary calculi [1-3]. In orthopedics ESWT is indicated in pseudarthrosis and enthesiopathies, such as epicondylitis, calcifying tendonitis and plantar fasciitis (heel spur).

The development of radial Extracorporeal Shockwave Therapy (rESWT) was started 10 years ago and was first constructed as the Swiss LithoClast®, a corresponding device for treating nephrolithiasis. Later on, the same technology was used to extend the range of indications to the orthopaedic field. In this respect, the Swiss DolorClast® has been used for about 5 years for treating soft-tissue painful disorders. The Swiss DolorClast® produces shockwaves up to an energy flux density of 0.16 mJ/mm^2 and a positive point pressure of 12 Mpa. Because of the nature of shockwave technology, radial shockwaves are used preferentially in treatment areas close to the applicator.

In comparison to other application techniques, finding the position with rESWT is achieved through a patient-oriented feedback process, so that ultrasound or X-ray locating devices can be dispensed with.

After the first reports on the experience with successful use of rESWT, the first prospective studies were initiated. In this case, good to very good clinical success was established both for tennis elbow as well as for plantar fasciitis. In individual cases, small petechial haemorrhages or superficial skin lesions were observed, which had no clinical relevance. The previously available data on rESWT is, however, currently unsuitable to substantiate efficacy with regards to evidence-based medicine criteria.

Principle of shockwave generation in rESWT

Different processes have been developed for the generation of shockwaves, of which predominantly four techniques are used clinically. All shockwave generation processes used in practice have the objective to link up the generated pressure impulse to the tissue with as little loss as possible. Various coupling media are used for this purpose. The devices used in medicine which generate pressure impulses make use of techniques which are to some extent fundamentally different (Schräbler 1999).

One of the newest but in the meantime very widely used processes is the mechanical generation of shockwaves. In this ballistic technique, a projectile is strongly accelerated by means of compressed air and then hits an applicator which is in contact with the skin with very high kinetic energy (Figure 1). By using a coupling agent, such as ultrasound gel or castor oil, this impact impulse which hits the applicator can then be transmitted into the tissue in the form of a shockwave. From there the shockwave spreads out as a spherical or ball-shaped wave, which propagates in a radiating fashion, so that the term “radial shockwave” is used here descriptively.

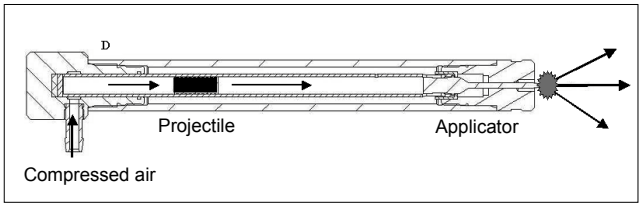


Figure 1: Schematic illustration of a ballistic shockwave source

From the [1]University Clinic for Orthopaedics and Sport Orthopaedics, Technical University of Munich and the [2]University Clinic for Anaesthesiology, Technical University, Munich

Address for correspondence: Dr. med. Ludger Gerdesmeyer, University Clinic for Orthopaedics and Sport Orthopaedics of the TU, Munich, Ismaninger Strasse 22, 81675 Munich, Germany, e-Mail:Gerdesmeyer@aol.com

Fundamentally, this type of device excels in that no build-up of the pressure wave takes place, so that there is no classical focal point in the sense of a shockwave which could be positioned in deeper tissue areas. In other words, compared to other devices used, no acoustic focus is formed with the ballistic generated shockwave. With this principle of generation, the applicator surface represents the geometric site of the highest pressure and the highest energy density. On account of the radial propagation, the pressure and energy density of the shockwave fall off continuously after it emerges from the applicator – similar to a focussed shockwave behind the acoustic focus – and this seems to make classical indications, such as pseudo-arthritis or calcifying tendonitis which are located in deeper tissue layers, appear at first as less suitable for treatment out of theoretical reasons (Wess 2001). On the other hand indications which are located closer to the surface are excellently accessible to a radial propagated shockwave. New and improved techniques in the meantime have led to a modification of the applicator system used as part of the ballistic shockwave technique. By means of special geometry and a change to the applicator, the ballistic generated shockwave can be influenced in such a way that higher concentrated zones can be focussed.

Whether these modifications mean that conditions which have so far only been treated by "classical" shockwaves, such as pseudo-arthritis or calcifying tendonitis, can also be treated with rESWT still has to be shown in clinical trials.

Clinical use of rESWT

In contrast to the focussed ESWT the positioning in rESWT is achieved through a patient-oriented biofeedback process. Whereas focussed shockwaves have to be positioned very exactly and checked with imaging processes such as X-rays or ultrasound due to the normally very small focus, this is not necessary with radial shockwave propagation in rESWT; the indications for rESWT are limited to those close to the surface. These include the classical indications such as tennis elbow, heel spur as well as other areas of application such as the treatment of chronic patella syndrome, anterior tibial syndrome or other conditions which can be assigned to enthesiopathies [1, 2].

At the beginning of treatment, the affected area is localised by provoking pressure pain. In this way, it is possible to provoke a so-called "memory pain". The area painful to pressure is marked on the skin and then covered with a contact medium [3]. As treatment is often found to be painful to start with, it is recommended to carry it out in small initial doses of 500 shockwaves. In this phase, pain adaptation takes place quickly so that as a rule there is no need for the use of a local anaesthetic. rESWT is thus designed as a local anaesthetic-free procedure. Papers by Auersperg et al. and Rompe et al. were able to show that dispensing with a local anaesthetic leads to better clinical results and they underline the advantage of rESWT [4, 5].

Clinical results

Most publications on rESWT are of more recent date. In the majority of cases, indications for treatment are reported in which the pathology is localized close to the applicator. Prospective studies have shown that rESWT can be used successfully in radial epicondylitis, plantar fasciitis or chronic patella syndrome [2, 6-9].

The success rates reported in these publications do not differ from those of other forms of application. In a more recent paper the use of rESWT for treating calcifying tendonitis of the shoulder was studied, whereby good results could also be achieved in the medium to long-term [10, 11]. One year after rESWT the Constant-Murley Score improved from 68 to 80 points. In 75% of patients, disintegration of calcium deposits could be achieved in most cases.

Besides the classical indications, rESWT is also being increasingly used for trigger point treatment [12, 13]. Various authors were able to determine clinical improvements of up to 80% in their prospective non-controlled clinical trials in the treatment of therapy-resistant disorders of the shoulder, head and lumbar part of the spine. So far, scientific proof of efficacy is still also missing in these indications, so that rESWT is to be considered as an experimental and individual therapeutic attempt at treatment [14].

Radial Extracorporeal Shockwave Therapy in plantar fasciitis – Results of a prospective study

Patients

A total of 95 cases with plantar fasciitis in 79 patients were treated with radial extracorporeal shockwaves in the period from 1st July, 2001 to 1st March, 2002. The average age was 56.4 years (24 – 81), the sex ratio (female:male) was 52:27. Before the first treatment, the weight and height of all patients were measured. The calculated Body Mass Index (BMI) at baseline was 27.1 (20.3 – 48.8) kg/m^2 and corresponded as such to grade 1 according to the WHO obesity classification.

The average duration of symptoms was 21 months. Radiological controls at the time of recruitment into the trial (baseline) showed a bony heel spur in 65 out of 95 heels with an average length of 3.7 (1 – 11) mm. The inclusion and exclusion criteria are summarized in Table 1.

Method

Radial Extracorporeal Shockwave Therapy (rESWT) was performed with the EMS Swiss Dolor Clast®. After localisation by biofeedback of the patient and marking the pain maximum, ultrasound gel was applied to the skin and the applicator couple was put into place (Figure 1). Three treatments of 2000 impulses each and 6 weeks apart were applied with an energy density of 0.12 mJ/mm^2 and a frequency of 8 Hertz and a pressure of 4 bar.

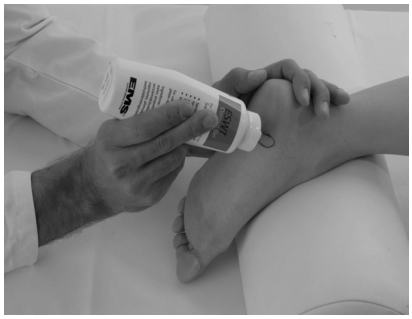
Table 1: Inclusion and exclusion criteria

Inclusion criteria
• Clinical relevant pain longer than 6 months
• Unsuccessful conservative treatment
• Clinically relevant heel spur pain
Exclusion criteria
• Age < 18 years
• Dysfunctions of the ankle joint and foot
• Local arthritis;
• Rheumatoid arthritis
• Pathological neurological and/or vascular result
• Tarsal tunnel syndrome
• Pregnancy
• Coagulation disorders
• Infections
• Tumour patients

The primary criterion was defined as the change of morning “warm-up” pain measured on the visual analogue scale (VAS, 0 = no pain, 10 = maximum pain). The secondary criterion was defined as changes in pain sensation during everyday exertion measured on the VAS. The main end-point was the follow-up examination 12 months after the last rESWT. Additional control examinations were carried out at 6 weeks, 3 and 6 months after the last rESWT. They served to document progress and to record possible side-effects.

The treatment area is localised by palpation.

Following localisation, the skin over the treatment area is marked.



The coupling surface is improved with EMS Swiss Dolor-Clast® coupling gel.

The 15 mm diameter applicator is passed over the treatment area with strong contact pressure in single or continuous impulse operation mode. The contact pressure should be as high as possible so that the patient is just able to withstand it.

Figure 2: Treatment of heel spur with rESWT

Furthermore, we analysed the outcome scored on the Roles and Maudsley Score for the subjective determination of patient activity. The survey of the target criteria and data reporting and evaluation were blinded by an investigator independent of the treating physician, the so-called “blinded observer”.

In order to test the primary hypothesis with regard to the main target criterion, the t-Test for 2 dependent samples was used; the statistical significance level was defined with $p < 0.05$. Statistical analysis of the secondary target criteria was performed descriptively using the Wilcoxon rank sum test.

Results

78 out of 79 patients could be examined at follow-up. Patients specified an average value of VAS from 6.0 ± 3.0 (“warm-up” pain) before the first treatment with radial extracorporeal shockwaves. After 3 treatment sessions

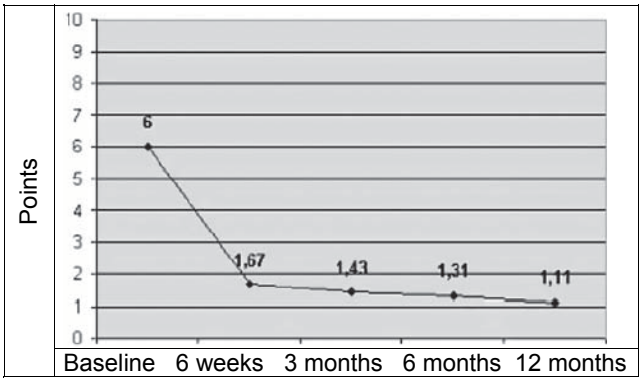


Figure 3: Change of the VAS (morning “warm-up” pain)

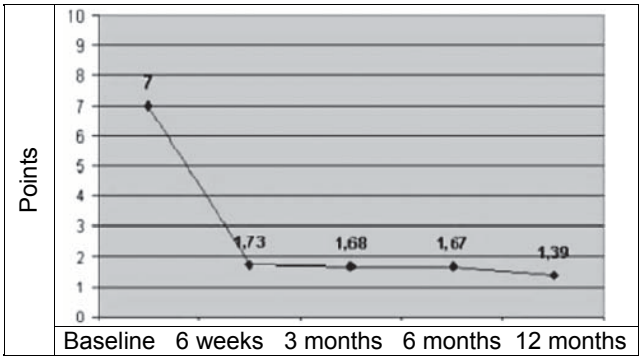


Figure 4: Change of the VAS (average pain during the day)

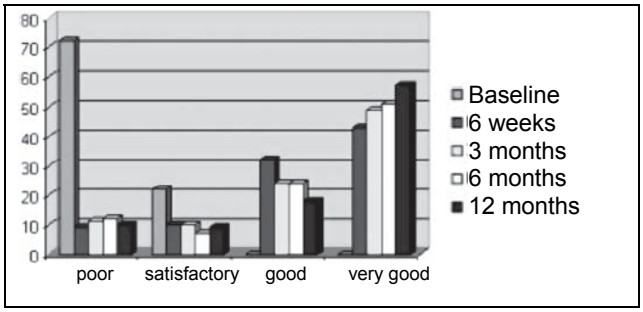


Figure 5: Change of the Roles and Maudsley Score

The VAS could be reduced to 1.67 ± 2.46 after 6 weeks, 1.43 ± 2.37 after 3 months, 1.31 ± 2.27 after 6 months and 1.11 ± 2.12 after 12 months (Fig. 3). These changes were statistically significant with $p < 0.01$ as well as clinically relevant.

Pain during daily activities shows a similar course: complaints decreased in the treated patients from initially 7.0 ± 2.0 to 1.73 ± 2.42 after 6 weeks, 1.68 ± 2.45 after 3 months, 1.67 ± 2.54 after 6 months and 1.39 ± 2.35 after 12 months (Fig.4). These changes were also statistically significant ($p < 0.01$).

The results of the Roles and Maudsley Scores were similar: whereas at the baseline examination 76.6 % were classified as poor and 23.4 % as satisfactory, there was a significant improvement during the further course of things. 6 weeks after final treatment, 34.0 % were classified as good and 45.7 % as very good (45.7 %). After 6 months there were already 24 good (25.5 %) and 51 very good results (54.3 %). At the main end-point 12 months after treatment, 57 heels were classified as very good (60.6 %), 18 good (19.1 %), 9 satisfactory (9.6%) and 10 poor (10.6 %).

In summary, it can be said that by using rESWT in heel spur 80 % of the patients show a good/very good result.

Discussion

Radial Extracorporeal Shockwave Therapy represents a further application possibility of ESWT. Technical innovations and device modifications have meant that in indications which are close to the skin such as tennis elbow or heel spur, additional location and positioning control checks for correct focussing can be dispensed with. In rESWT, application is carried out in a patient controlled bio-feedback process. Measurements which were performed according to the valid norm were able to show that a low to medium energy level up to 0.16 mJ/mm^2 can be achieved [15].

On the one hand, a high clinical success was reported in all published clinical studies, on the other hand no clinically relevant side-effects have been determined so far, so that the method of radial extra-corporeal shockwave therapy can be described as successful without clinical relevant side effects [1, 7-9, 12, 16, 17]. The success rate after rESWT is similar to that after focussed ESWT [18-20]. Apart from the typical indications, located close to the skin, rESWT should also be indicated in calcifying tendonitis. However, initial trials were able to show unexpectedly good results in this respect in non-controlled studies [11]. Whether these results can also be confirmed in a stricter clinical efficacy study, however, as is the case with focussed ESWT, still remains to be examined [21].

Apart from the classical indications for shockwave therapy, rESWT can also be used for trigger point treatment. Although the data so far is unsatisfactory, the available results of clinical studies do allow the founded suspicion that rESWT can also quite possibly be used here sensibly, too.

The results reported by various authors of the treatment of therapy resistant pain disorders of the shoulder, head and lumbar part of the spine show improvement rates of up to 80 %.

It has to be established for all indications that proof of efficacy of the rESWT method is still lacking so far, so that treatment should only be carried out under controlled conditions.

References:

1. Schoell J, Lohrer H, Arentz S. Sportinduzierte Krankheitsbilder. Behandlung der Achillodynie, Patellaspitzensyndrom und Tibiakantensyndrom mit radialen Stosswellen (rESWT). In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 120–42.
2. Lohrer H, Schoell J. Achillodynie und Patellaspitzensyndrom – Ergebnisse der Behandlung austherapierter, chronischer Fälle mit radialen Stosswellen. Sportverletz Sportschaden 2002; 16: 108–14.
3. Gerdesmeyer L, Henne M, Diehl P, Gollwitzer H, Goebel M. Klinische Anwendung des Swiss Dolorclast. In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 110–9.
4. Auersperg V, Labek G, Böhler N. Influence of simultaneous local anesthesia on the outcome of repetitive low-energy shock wave therapy for chronic plantar fasciitis. 5th ISMST Congress, Winterthur, 26.–28.6.2002.
5. Rompe JD, Auersperg V, Labek G, Gerdesmeyer L. Unterschiedliche Ergebnisse bei repetitiver niedrig energetischer ESWT der chronischen plantaren Fasciitis – ein Effekt der lokalen Anästhesie? In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 292–9.
6. Diesch R, Straub T, Peninger E, Froelich T, Schoell J, Lohrer H et al. rESWT beim Fersensporn – Fasciitis plantaris. In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 167–82.
7. Haupt G, Diesch R, Straub T, Penninger E, Froelich T, Schoell J et al. rESWT bei der Epikondylitis humeri lateralis. In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 183–97.
8. Henne M, Goebel M, Diehl P, Gerdesmeyer L. Painful heel – Anatomie, Klinik und Therapie. Ergebnisse nach radialer extrakorporaler Stosswellentherapie (rESWT). In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 211–27.
9. Henne M, Gerdesmeyer L. Kurz- und mittelfristige Ergebnisse bei der Behandlung der Epicondylitis humeri radialis mit rESWT. In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 228–39.
10. Magosch P, Lichtenberg S, Habermeyer P. Effizienz der radialen Stosswellentherapie bei der Tendinosis calcarea der Rotatorenmanschette – eine prospektive Studie. In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 143–66.
11. Magosch P, Lichtenberg S, Habermeyer P. Radial shock wave therapy in calcifying tendinitis of the rotator cuff – a prospective study. Z Orthop Ihre Grenzgeb 2003; 141: 629–36.
12. Bauermeister W. TST – Triggerpunkt Stosswellentherapie. Ergebnisse dreier prospektiver Studien. In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 319–27.
13. Dreisilker U, Raedel R, Piontkowski U. Triggerpunkte – ein komplexes Kankheitsgeschehen. In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 328–39.
14. Haake M, Gerdesmeyer L. Geschichte der extrakorporalen Stosswellentherapie. In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 8–18.
15. Stierle T. Methode Swiss Dolorclast. In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 100–9.
16. Gremion G, Farron A, Leyvraz P. rESWT bei der Tendinosis Calcarea. In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 198–210.
17. Van der Hoeven H, Tamminga R. rESWT bei chronischer Tendinopathie der Rotatorenmanschette. In: Gerdesmeyer L (Hrg). Extrakorporale Stosswellentherapie. Books on Demand, Norderstedt, 2004: 252–69.
18. Ogden JA, Alvarez R, Levitt R, Cross GL, Marlow M. Shock wave therapy for chronic proximal plantar fasciitis. Clin Orthop 2001; 387: 47–59.
19. Rompe JD, Hopf C, Nafe B, Burger R. Low-energy extracorporeal shock wave therapy for painful heel: a prospective controlled single-blind study. Arch Orthop Trauma Surg 1996; 115: 75–9.
20. Theodore GH. Shock wave therapy for treatment of plantar fasciitis. JAMA 2003; 289: 172–3.
21. Gerdesmeyer L, Wagenpfeil S, Haake M, Maier M, Loew M, Wortler K et al. Extracorporeal shock wave therapy for the treatment of chronic calcifying tendonitis of the rotator cuff: a randomized controlled trial. JAMA 2003; 290: 2573–80.