Radial Shock Wave Therapy in Calcifying tendinitis of the Rotator Cuff – A Prospective Study

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Abstract

Aim: The aim of the study was to evaluate the influence of radial shock wave therapy (RSWT) on the course of calcifying tendinitis of the rotator cuff.

Material and Methods: 35 patients with a mean age of 47.5 years suffering for an average of 28 months from calcifying tendinitis with a Gaertner type 2 calcific deposit with a mean size of 16.6 mm in typical location (true a.p. view) were treated by low energy RSWT three times. The acromio-humeral distance averaged 10.4 mm measured on the true a.p. view. All patients were followed up clinically and radiologically 4 weeks, 3, 6 and 12 months after the last treatment.

Results: The Constant score improved significantly ($p < 0.0001$) during the first 4 weeks after RSWT from a mean of 68.5 to a mean of 80.5 points and remained approximately constant at 3, 6 and 12 months follow-up. After 4 weeks, 25.7% of the patients had no pain and 54.3% reported pain relief. 80.8% of the patients were painfree and 19.2% reported pain relief 12 months after RSWT. Radiologically, no calcific deposit was visible in 17.6% 4 weeks after RSWT. There was disintegration in 20.5% and no change in the calcific deposit was apparent in 61.5%. At further follow-up we found complete resorption of the calcific deposit in 75% up to 12 months after RSWT and there was no change in 25%. Overall three patients (8.5%) had to undergo surgical treatment 3-7 months after RSWT.

Conclusion: Low-energy RSWT leads to significant pain relief and an improvement in shoulder function within the first 4 weeks. In view of the long history, the size and the spontaneous resorption rate of the calcific deposit, an inductive effect of RSWT on the resorption of the calcific deposit can be assumed.

Key words

Shoulder – rotator cuff – calcifying tendinitis – radial shock wave – conservative treatment

Introduction

Calcifying tendinitis is a frequent cause of shoulder complaints and is condition occurring in stages [25] that is treated differently depending on the stage and symptoms.

The duration of the spontaneous course of calcifying tendinitis differs individually and is reported to last from a few months to several years [17].
In 1992, Dahmen for the first time employed extracorporeal shock wave therapy (ESWT) to treat calcifying tendinitis [2]. Rompe classified extracorporeal shock wave therapy according to the energy flux density generated (Tab. 1). Electrohydraulic, piezoelectric and electromagnetic systems have been used up to now.

Since 2000, pneumatically generated low-to medium-energy radial shock wave therapy (RSWT) with a maximum energy flux density of 0.191 mJ/mm^2 in the focus at the tip of the shock wave applicator (hydrophone measurement) and a positive peak pressure of 123 bar has been employed. This should be distinguished from unfocussed pressure pulse therapy (Tab. 2).

Table 1 Classification of energy flux density according to Rompe	
Low-energy	energy density in the focus: 0.08 mJ/mm^2
Medium-energy	energy density in the focus: 0.28 mJ/mm^2
High-energy	energy density in the focus: 0.60 mJ/mm^2

The principle of the radial shock wave consists of extreme acceleration of a projectile that is propelled by means of compressed air, which encounters an applicator, through which the energy impulse is transmitted to the tissue.
In contrast to the principles of conventional shock wave generation, the focus is not at the site of the effect itself but in the tip of the applicator. The radial shock wave spreads radially from the tip of the applicator with a penetration depth of 3.5 cm without focusing the shock wave field in the tissue, as a result of which the pressure and the energy density decrease by the third power of the penetration depth in the tissue so that the pneumatically generated shock wave appears little suited for the treatment of calcifying tendinitis of the rotator cuff [7, 26]. The goal of radial shock wave treatment of calcifying tendinitis is therefore not to induce disintegration of the calcific deposit but rather to achieve pain relief.

In a mineralogical study of clinically symptomatic and radiologically dense, sharply demarcated calcification of the rotator cuff, Maier et al. [16] found a high variability in the proportion by weight of calcium and phosphorus. Patients with the highest relative proportions by weight of calcium and phosphorus in the calcific deposit had a history of unsuccessful ESWT so the authors assume that the capacity for disintegration of calcification of the rotator cuff by means of ESWT depends on its mineral content.

The aim of this prospective study was the evaluation of the influence of RWST as a conservative method of treatment on the natural course of chronic calcifying tendinitis (Gaertner type 2) of the rotator cuff of the shoulder for pain relief and its effects on the calcific deposit.

Material and methods

Between 2000 and 2002, 35 patients (23 male, 12 female) with an average age of 47.5 years (33-73) with chronic calcifying tendinitis were included in the prospective study. The right shoulder was affected by the disease in 22 patients and the left shoulder in 13 patients.

The inclusion criteria were unsuccessful conservative treatment with a minimum duration of symptoms of more than 6 months, a Gaertner type 2 calcific deposit [4] with a calcific deposit size II or III according to Bosworth [1] and an acromion type 1 or 2 according to Bigliani. Patients with osteoarthritis of the AC joint and of the glenohumeral joint and patients with concomitant rotator cuff rupture were excluded from the study.

Table 2 Differences between ESWT, RSWT and UPPT

	Technique	Positive tip pressure	Focus	Production of cavitations	Lithotripsy
ESWT	Electrohydraulic, electromagnetic, piezoelectric	100-1000 bar	Yes	Yes	Non-contact
RSWT	Pneumatic	123 bar	No	Yes	Non-contact
UDPT	Pneumatic	No	No	no	Contact

ESWT: extracorporeal shock wave treatment
RSWT: radial shockwave treatment
UPPT: unfocused pressure pulse treatment

Prior to the shock wave treatment, the diagnosis of calcifying tendinitis was confirmed by X-rays in three planes (true a.p., axial, y-view) along with clinical examination. In all patients, a rotator cuff rupture was excluded by MRI.

The average duration of symptoms was 28 months (6 – 120 months). The deposit was localized in the supraspinatus tendon (typical position) in 33 patients and in the infraspinatus tendon in two patients. 29 patients had a grade 2 calcific deposit and 6 patients had a grade 3 (greatest diameter) calcific deposit according to Bosworth (average 16.6 mm; 7 – 37 mm). 15 patients demonstrated an acromion type 1 on the y-view and 20 patients had a type 2 acromion according to Bigliani. The acromiohumeral distance averaged 10.4 mm (7 – 13 mm).

The radial low-energy shock wave therapy (Swiss DolorClast®, EMS Medical GmbH; EFD = 0.12 mJ/mm^2) was administered to the supine patient with the arm internally rotated 30 – 45° without local anaesthesia. The shock wave applicator was positioned over the area of maximum tenderness as reported by the patient. In each case 2000 impulses with a working pressure of 2.5 bar and a working frequency of 8 Hz were administered using moderate applicator pressure. All 35 patients received three RSWT treatments at intervals of 7 – 10 days.

Side effects such as skin irritation, petechiae, haematomas or swelling were not observed in any patient.

During the treatment, no physiotherapy was carried out and the patients were instructed to avoid overhead sports up to a week after the third shock wave treatment. After the first follow-up examination (4 weeks after the last shock wave application), additional physiotherapeutic treatment by means of manual therapy and warm packing commenced.
All of the patients (100%) were followed up clinically and radiologically 4 weeks, 3, 6 and 12 months after administration of the last RSWT. The subjective change in pain was classified from the patient's history into pain exacerbation, increase in pain, persistence of pain, relief of pain and freedom from pain. The functional results were recorded by means of unweighted Constant score. Power was measured using the Isobex at the level of the scapula with the arm abducted 90°. The standardised radiographic examination was carried out in all patients at each follow-up in 3 planes (true a.p.; axial; y-view).

Statistical analysis of the results was performed with StatView (Abacus Concepts, Inc., Berkeley, California). Student's t test for linked samples was used for the change in shoulder function, the X^2 test for the change in subjective pain symptoms and for the disintegration of the calcific deposit, and the Spearmans rank correlation was used for the association between the change in pain symptoms and the disintegration of the calcific deposit.

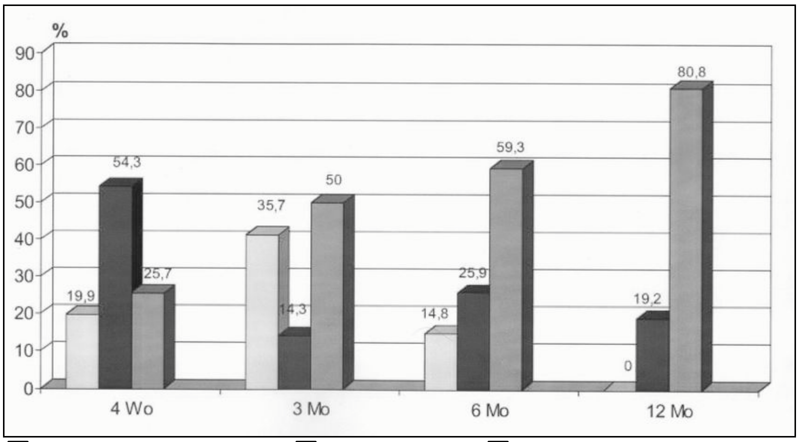
Results

Functionally, there was a significant ($p < 0.0001$) improvement in the Constant Score from an average of 68.5 points (bar ± 10 points, 46.2 – 80.6 points, max. 100 points) before the treatment to 80.5 points (bar ± 12.9 points, 58.3 – 96.1 points) 4 weeks after the treatment. When the individual categories of pain, activity of daily living, range of motion and power were considered, significant pain relief ($p = 0.0037$) was found 4 weeks after the treatment with an increase in points from an average of 6.9 points (bar ± 2.5 points, 1-12 points; max. 15 points) before the treatment to 10 points (bar ± 4.1 points, 0 - 15 points) after the treatment, a significant improvement ($p < 0.0001$) in daily activity from an average of 10.4 points (bar ± 3.7 points, 1-18 points; max. 20 points) to an average of 16 points (bar ± 5 points, 7 - 20 points) and a significant improvement ($p = 0.02$) in the range of motion from 36 points (bar ± 3.3 points, 26 - 40 points; max. 40 points) to an average of 38 points (bar ± 1.5 points, 36 - 40 points). An average increase in power of 1.3 kg was observed 4 weeks after the treatment ($p = 0.2$).

In the course of further follow-up, the Constant Score three months after the treatment remained almost constant with an average of 74.7 points compared to the Constant Score 4 weeks after RSWT (bar ± 14.5 points, 46.7 – 95.8 points; $p = 0.9$), an average of 78.9 points after 6 months compared to the Constant Score 3 months after the treatment (bar ± 15.8 points, 46.7 – 100 points; $p = 0.5$) and an average of 79.7 points a year after the RSWT compared to the 6-month result (bar ± 13.2 points, 62.2 – 100 points; $p = 0.9$).

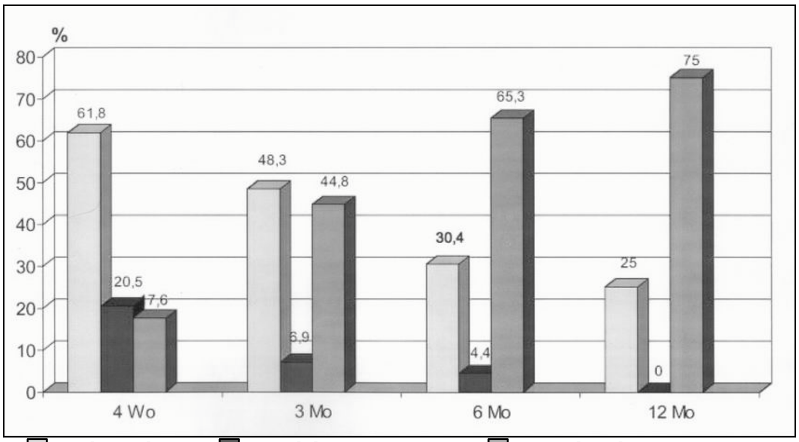
25.7% of the patients were painfree after 4 weeks, pain relief was achieved in 54.3%, 14.2% had unchanged pain symptoms and pain exacerbation occurred in 5.7%. Three months after the treatment there was a further significant improvement ($p < 0.0001$) in the pain symptoms (n = 35). 50% of the patients were painfree and 14.3% of the patients reported relief of pain, in 30.7% the pain symptoms were unchanged and in three patients the pain increased (10.7%). 6 months after RSWT (n = 34), a further significant reduction in pain ($p = 0.003$) could be observed. At the 6-month follow-up, 59.3% of the patients were painfree, 25.9% reported further pain relief and 14.8% of the patients were suffering from unchanged pain symptoms. Worsening of the pain symptoms did not occur in any patient. 12 months after the treatment (n = 32), there was freedom from pain in 80.8% and pain relief in 19.2%. No patient reported unchanged pain symptoms (fig. 1).

Fig. 1 Change in pain symptoms



Pain persistence/increase   Pain relief   Freedom from pain

Fig. 2 Change in the calcific deposit



Unchanged   Partial disintegration   Complete disintegration

Radiologically no calcific deposit could be seen in 17.6% of the patients 4 weeks after the treatment. Disintegration of the calcific deposit occurred in 20.5% with an alteration of the stage from Gaertner 2 to 3 in 4 cases and a reduction of the size of the calcific deposit within the same stage in three cases. In 61.8% of the patients, the calcific deposit was unchanged. Three months after RSWT, 44.8% of the patients no longer had a calcific deposit, disintegration of the deposit occurred in 6.9% with a reduction in the size of the deposit with the stage unchanged in three cases and in 48.3% of the patients there was no change in the calcific deposit.

After 6 months, 30.4% of the patients demonstrated an unchanged calcific deposit, in 4.4% of the patients (one patient) there was disintegration of the calcific deposit from Gaertner stage 2 to 3 without a change in diameter and 65.3% of the patients had no calcific deposit.

In the course of further follow-up, we found complete resorption of the deposit in 75% and an unchanged deposit in 25% after 12 months.

Compared to the initial findings, significant disintegration (in each case $p < 0.0001$) was observed at each follow-up up to 6 months. There was a further obvious change in the calcific deposit even 12 months after RSWT ($p = 0.0507$) (fig. 2).

At each follow-up, we found a correlation (Spearmans rank correlation) between the change in the pain and the change in the calcific deposit. 4 weeks after RSWT the correlation was 0.523 ($p = 0.0031$) and three months after RSWT we found a correlation of 0.71 ($p = 0.0002$). After 6 months the correlation was 0.959 ($p < 0.0001$) and after 12 months there was a correlation between the change in pain symptoms and the change in the calcific deposit of 0.83 ($p < 0.0001$).

Table 3 Literature comparison of results after shock wave treatment

Author	Mechanism	Energy flux density	Number of shock waves per treatment	Number of treatments	n	Max. FU (weeks)	Calcific deposit after Gaertner/size	Calcific deposit disintegration	Pain relief/freedom (%)	CS before treatment (P)	CS at follow-up (P)	p value group 1 vs. group 2
Rompe JD et al. [18]	(ESWT)	0.28 mJ/mm^2	1500	1	100	24	/> 10 mm	partial 53%, complete resorption 19%	67	43	78	
Rompe JD et al. [19]	electro-magnetic (ESWT)	0.06 mJ/mm^2	1500	1	50	24	1.2/>5 mm	partial 34%, complete resorption 16%		47	71	p < 0.01
	electro-magnetic (ESWT)	0.28 mJ/mm^2	1500	1	50	24	1.2/>5 mm	partial 42%, complete resorption 22%		53	88	
Seil R et al. [23]	(ESWT)	0.04-0.12 mJ/mm^2	5000	3	25	24	1.2	partial and complete resorption 32%		64.5	77.5	p < 0.05
	(ESWT)	>0.12 mJ/mm^2	5000	1	25	24	1.2	partial and complete resorption 48%		67.2	79.4	
Loew M et al. [13]	no treatment	0	0	0	20	12	1.2/>15 mm	partial and complete resorption 10%	5	44.5	47.8	
	electrohydraulic (ESWT)	0.1 mJ/mm^2	2000	1	20	12	1.2/>15 mm	partial and complete resorption 20%	30	39.4	51.6	
	electrohydraulic electro-magnetic (ESWT)	0.3 mJ/mm^2	2000	1	20	12	1.2/>15 mm	partial and complete resorption 55%	40	39	63.7	
	electrohydraulic electro-magnetic (ESWT)	0.3 mJ/mm^2	2000	2	20	12	1.2/>15 mm	partial and complete resorption 60%	47	43.5	68.5	
	electrohydraulic electro-magnetic (ESWT)	0.3 mJ/mm^2	2000	1	42	24	1.2/>15 mm	partial and complete resorption 47%	45	49.3	67.7	6 CS and pain: p > 0.05/calcium p = 0.04
	electrohydraulic electro-magnetic (ESWT)	0.3 mJ/mm^2	2000	2	49	24	1.2/>15 mm	partial and complete resorption 77%	53	44.4	69.6	
Henne M et al. [9]	pneumatic (RSWT)	0.191 mJ/mm^2	2000	3	62	12		partial and complete resorption 34%				
Own results	pneumatic (RSWT)	0.12 mJ/mm^2	2000	3	35	12	2/>15 mm	partial 6.9%, complete resorption 44.8%	64.3	68.5	74.7	
	pneumatic (RSWT)	0.12 mJ/mm^2	2000	3	35	24	2/>15 mm	complete resorption 65.3%	85.2	68.5	78.9	

n: number of patients; max. FU (weeks): maximum follow-up; CS: Constant score; CS at FU (P): Constant score at follow-up (points)

Within the first 4 weeks after the third shock wave treatment, an exacerbation of the calcifying tendinitis occurred in two patients with extremely painful deposit disintegration. The pain symptoms in this acute phase could only be controlled with local infiltration of a local anaesthetic with a steroid and oral opioid medication. In one of the two patients, the exacerbation occurred a week after the treatment. At the 4-week follow-up, clear pain relief was already reported and the calcific deposit (13 mm diameter before the treatment) was already resorbed. In one patient the exacerbation occurred 4 weeks after the last treatment. The patient attended for the 4-week follow-up with unchanged pain symptoms and an unchanged calcific deposit on X-ray (diameter 23 mm). Three days after the 4-week follow-up, painful resorption of the calcific deposit occurred, which was no longer detectable on the X-ray three months after the treatment. At this time, the patient was already completely painfree.

Overall, three patients (8.5%) with unchanged pain symptoms and unchanged calcific deposit on X-ray underwent arthroscopic extirpation of the calcific deposit 3, 7 and 8 months after RSWT.

Discussion

Dahmen was the first to use extracorporeal shock wave therapy in calcifying tendinitis of the shoulder [2]. Since then, there have been a few clinical studies of high-energy shock wave treatment of calcifying tendinitis of the rotator cuff, which have confirmed the pain-relieving effect with an improvement in shoulder function along with induction of disintegration of the calcific deposit [8].

A direct comparison of the study results with one another is hardly possible because of the use of different devices with different mechanisms and energy output and also different dosages. In the literature, success rates between 30 and 79% and radiological calcific deposit changes between 10 and 95% are described with various technologies and dosages and with follow-up of up to 18 months, [8].

Table 3 compares the results of extracorporeal shock wave therapy (ESWT) with our results using RSWT.

By varying the energy flux density (EFD 0.06 mJ/mm^2 and EFD 0.28 mJ/mm^2 respectively) with an otherwise identical treatment protocol, Rompe et al. investigated the influence of the energy flux density on the result of treatment of calcifying tendinitis. After 6 months, partial or complete calcific deposit disintegration was significantly more frequent in the group of patients treated with high energy at 64% compared to 50% in the low-energy group. Functionally there was a significantly higher Constant Score at 88 points in the high-energy group compared to 71 points in the patient group treated with low energy. However, the authors see the advantage of the low-energy shock wave treatment as the ability to do without plexus anaesthesia particularly in cardiac or pulmonary risk patients [19].

Loew et al. confirmed in a randomised prospective study with three different treatment protocols that the subjective, functional and radiological results after shock wave therapy are energy- and dose-dependent [13]. The subjective, functional and radiological results in the group that received a single low-energy treatment were a pain relief rate of 30%, a Constant score of 51.6 points and a calcific deposit disintegration rate of 20% three months after treatment and were much lower than the functional and radiological result of our study. Compared with the group of patients treated with low energy in the study by Rompe et al. [19], we observed more frequent pain relief or freedom from pain in 85.2% of patients with a slightly higher Constant score of 78.9 points and a higher calcific deposit disintegration rate of 69.7% 6 months after higher-dose RSWT (6000 impulses), which at least appears to confirm that the success of treatment is dose-dependent.

Seil et al. concluded from a prospective randomised study that the results of the single high-energy shock wave treatment were similar to several low-energy shock wave treatments [23].

Maier et al. [14] showed that the size of the calcific deposit and its morphology before the treatment do not influence the functional result of the low-energy shock wave treatment. They treated 65 shoulders 4 times with a low-energy shock wave using 2000 impulses and 2 Hz. After an average follow-up period of 18.2 months, there was a significant functional improvement in the treated shoulders with a Constant Score of 78%.

The success rate of 70% with ESWT contrasts with 60% with needling and 80% with operative treatment [8].

Ebenbichler et al. were able to achieve a radiological success rate of 64.5% 9 months after treatment using pulsed ultrasound treatment [3]. In a randomised double-blind study, they investigated the effect of pulsed ultrasound treatment 6 weeks and 9 months after treatment in patients with calcifying tendinitis of Gaertner type 1 or 2 and a calcific deposit diameter of more than 5 mm. After 6 weeks, no calcific deposit was visible radiologically significantly more often in 19% of treated patients than in 0% of the untreated control group. In the treated group, there was significantly greater relief of pain and improvement in daily activities than in the untreated group after 6 weeks. After 9 months there was further pain relief and functional improvement in both groups without a significant difference between the groups. Radiologically, no calcific deposit could be seen in 42% of the group treated with ultrasound and in 8% of the untreated group after 9 months. Differences between patients with a calcific deposit of Gaertner type 1 or 2 were not observed. There was significant pain relief and functional improvement in 34% of the untreated patients after 9 months. If the rate of resorption in patients with Gaertner type 1 and 2 calcific deposit without treatment is considered, a spontaneous cure rate of 8% after 9 months can be assumed. In a prospective study of 47 patients with type 1 or 2 calcifying tendinitis, Rupp et al. [20] found spontaneous partial resorption of 50% up to complete resorption in 32% of their patients within the first 6 months. Loew et al. [13] described a spontaneous resorption rate of 10% in 20 patients in their randomised study in patients with a Gaertner type 1 and 2 calcific deposit in the course of three months but without significant pain relief and functional improvement.

The weakness of our study is the absence of a control group. A possible placebo effect influencing the result of the study, as described for pulsed ultrasound treatment of calcifying tendinitis in the study by Ebenbichler et al. with 34% and for ESWT of supraspinatus tendinitis with 17% [22] – 45% [24] in the course of three months, is not revealed by our study. If the highest spontaneous resorption rate described hitherto by Rupp et al. of 32% after 6 months is assumed and their patient group is taken as a control group, we then achieve a resorption rate of 33.4% with RSWT.

Due to the radial spread of the RSWT, the pressure and energy density diminish with the third power of the penetration depth in the tissue. Haake et al. demand that the shock wave be focused at the site of action. They achieved significantly better results after ESWT with the shock wave focused in the region of the calcification compared to focusing the shock wave treatment on the greater tubercle [7]. Gerdesmeyer et al. [5] concluded from this that the pneumatically generated low-energy shock wave appeared little suited for the treatment of calcifying tendinitis of the shoulder as this is a pathological alteration in deeper layers. Since then, there have been experimental studies (Institute of Fluid Mechanics of Freiburg University, personal communication) which confirm the production of cavitation with the spread of the radial shock wave. The results of our prospective study appear to confirm this assumption, though the mechanical mechanism of action of the radial low-energy shock wave has not been elucidated with certainty. If the results of our study are compared with the results of low-energy electrohydraulically, electromagnetically or piezoelectrically generated shock waves, the technique by which the shock waves are generated appears to be irrelevant.

The apparent induction of calcific deposit disintegration by means of low-energy radial shock waves contradicts our expectations according to the state of knowledge of experimental studies. There have already been numerous experimental, animal and clinical studies of high- and medium-energy electromagnetically, electrohydraulically or piezoelectrically generated shock waves. However, the molecular mechanism of action of these methods is still largely unclear. Positive effects in different syndromes confirm the assumptions that different mechanisms of action are involved [18].

It has been shown in vitro that high-energy shock waves can induce nerve action potentials [21], and this enables substance P to be released from non-myelinated nerve fibres. Substance P can induce neurogenic inflammation [11], plasma extravasation [27] and stimulation of proliferation of various types of cell [6]. The initial rise in the concentration of substance P in the zone of the shock wave focusing with a subsequent prolonged reduction in concentration represents a possible explanation of the ESWT-induced initial pain stimulus with subsequent prolonged analgesia [15].

In biological tissues, a mechanical effect proportional to the magnitude of the impedance difference at the interfaces between different tissues is ascribed to the extracorporeal shock wave along with subordinate thermal and chemical effects [5, 12]. The mechanisms of the analgesic effect of the radial shock wave are still unclear.

Low-energy radial shock wave therapy already leads within the first 4 weeks and for up to 12 months to significant pain reduction and appears against expectations to induce resorption of the calcific deposit, while a significant improvement in shoulder function is achieved only within the first four weeks.

If the clinical and radiological results 6 and 12 months after a single high-energy shock wave treatment are compared with the results 6 and 12 months after three low-energy shock wave treatments of calcifying tendinitis, both treatment methods appear to achieve similar results, suggesting that the success of treatment is dose-dependent independent of the principle of shock wave generation.

Whether the hitherto unknown molecular and mechanical mechanisms of action of the low-energy ballistically generated shock wave is similar to high-energy shock waves generated electrohydraulically, electromagnetically or piezoelectrically remains to be clarified.

The clinical and radiological results of our study should be confirmed by means of further placebo-controlled randomised studies.

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