CLINICAL ORTHOPAEDICS AND RELATED RESEARCH
Number 397, pp. 323–331

SECTION II
ORIGINAL ARTICLES

Exact Focusing of Extracorporeal Shock Wave Therapy for Calcifying Tendinopathy

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A controlled prospective randomized study was designed to analyze the effect of extracorporeal shock wave therapy on calcifying tendinopathy of the shoulder focused on the calcified area or the origin of the supraspinatus tendon. Fifty patients were included in the study and were treated with a Storz Minilith Sl-1 shock wave generator. The first group of patients received 4000 impulses (positive energy flux density, 0.78 mJ/mm^2) in two treatment sessions after receiving local anesthesia at the origin of the supraspinatus tendon. Patients in the second group received extracorporeal shock wave therapy at the calcified area. Followups were done 12 weeks and 1 year after treatment by an independent observer. An increase of function and a reduction of pain occurred in both groups. Statistical analyses showed a significant superiority of extracorporeal shock wave application at the calcified area in the primary end point (Constant and Murley score). Therefore, exact fluoroscopic focusing of extracorporeal shock wave therapy at the calcific deposit for treatment of calcifying tendinopathy of the supraspinatus muscle is recommended. Based on these results, extracorporeal shock wave application should be focused fluoroscopically with appropriate shock wave generators.

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Received: March 1, 2001.

Revised: July 9, 2001; September 4, 2001.

Accepted: September 12, 2001.

Calcifying tendinopathy of the supraspinatus muscle is a common problem in orthopaedic practice.[14] The incidence of calcifications in the muscles of the rotator cuff varies from 2.5% to 20% in patients with asymptomatic shoulders and as much as 54% in patients with shoulder disorders.[2,10] The usual site is the tendon of the supraspinatus.[2] Calcifying tendinopathy may

be attributable to chronic degenerative changes in tendinous tissue with formation of metaplastic chondroid tissue.[25] Patients with calcifying tendinopathy usually are treated with physiotherapy, analgesics, and subacromial injection with steroids and local anesthetics.[24] Although the disease may be self-limiting,[10] chronic pain with time is possible and approximately 10% of patients may require surgery.[11]

Extracorporeal shock wave therapy for treatment of insertion tendinopathies first was used in Germany and Austria.[8,15] In the past year, extracorporeal shock wave therapy for therapy of heel spurs received Food and Drug Administration approval in the United States.[16] All major lithotripter manufacturers currently are planning or doing multicenter studies to obtain Food and Drug Administration approval for different indications. Extracorporeal shock wave therapy as a new method to treat calcifying tendinopathy first was described as a case report of six patients in 1992.[8] Clinical success is reported in 60% to 80% of patients from uncontrolled prospective trials.[13,19,21,22] Loew et al[17] showed the efficacy of high-energy extracorporeal shock wave therapy (2×2000 pulses; 0.3 mJ/mm^2) in a controlled prospective study, and had good clinical results in 58% of patients. Radiologic disintegration rates of the calcific deposit after extracorporeal shock wave therapy vary from 47% to 77%.[17,18]

In clinical practice, shock waves usually are aimed at the painful area at the insertion of the tendon, the biofeedback method, and not focused with radiographic or ultrasound guidance. This procedure is recommended by some authors[5,7] and by the producers of shock wave generators.[9] Although good success rates of extracorporeal shock wave therapy have been reported if the shock waves are focused using fluoroscopy,[18,21] the majority of patients are treated without fluoroscopic focusing.

The aim of the current study was to determine the influence of exact fluoroscopic focusing of extracorporeal shock wave therapy at the calcific deposit compared with aiming the shock waves at the insertion of the muscle on the clinical outcome in calcifying tendinopathy of the supraspinatus muscle.

MATERIAL AND METHODS

Protocol

This study was a prospective, blinded trial with a randomized two-sample parallel-group design. The primary end point (Constant and Murley score[6] during followup) was assessed by blinded independent observers. The sample size was 25 patients in each group. Inclusion and exclusion criteria are shown in Table 1. A radiograph of the affected shoulder (not older than 2 weeks) confirmed the diagnosis of calcifying tendinopathy with a deposit Stage I or II according to Gärtner[10] with at least 0.5 cm diameter. All patients in the first group were treated with extracorporeal shock waves in two ses-

TABLE 1. List of Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Symptomatic calcifying tendinopathy	Glenohumeral or acromioclavicular joint arthrosis
At least a 6-month duration of symptoms	Previous operations to the treated shoulder
Failed conservative treatment including a minimum of:	Acute bursitis of the shoulder
10 sessions of physiotherapy plus	Instability of the shoulder
2 subacromial injections plus	Local tumors or infections
6 sessions of physical therapy plus intake of NSAIDs	Neurologic disorders
No treatment in the past 4 weeks	Rotator cuff lesion
Free range of movement or at least 90° abduction and free rotation	Allergy to mepivacaine
	Age of patient younger than 18 years
	Pregnancy

NSAIDs = nonsteroidal antiinflammatory drugs

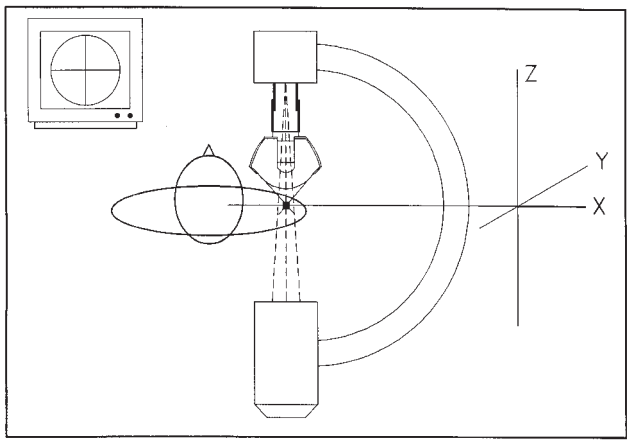

Fig 1. The patient was placed in the center of the C-arm of the mobile fluoroscopy unit. The calcific deposit then was positioned in the center of the C-arm. The water cushion of the shock wave generator was coupled to the shoulder anteriorly. (Reprinted with permission from Haake M, Deike B, Thon A, Schmitt J: Importance of accurately focusing extracorporeal shock waves in the treatment of calcifying tendinitis. Biomed Tech 45:69–74, 2001.)

sions (1-week interval[17]) with an adapted shock wave generator Storz Minilith SL-1 (Storz Medical AG, CH 8280 Kreuzlingen, Switzerland; Fig 1). Technical specifications of the device and the focusing procedure have been described previously.[12] Subacromial local anesthesia was given using 15 mL mepivacaine 1%. Two thousand impulses of a positive energy flux density of 0.35 mJ/mm^2 measured with a membrane hydrophone (equivalent to 0.78 mJ/mm^2 measured with a fiberoptic hydrophone; Table 2) at 120 impulses per minute were applied using fluoroscopic localization at the origin of the supraspinatus tendon (Fig 2A) and at intervals during treatment. Patients in the second group were treated with extracorporeal shock wave therapy combined with local anesthesia under the same conditions except the shock waves were aimed exactly at the calcific deposit (Fig 2B). The clinician checked the inclusion and exclusion criteria (Table 1) and obtained signed informed consent from all patients before the randomization. Before consenting, the patients were informed orally regarding the study and received an information sheet. All patients were evaluated

TABLE 2. List of Shock Wave Parameters of the Shock Wave Generator Storz Minilith SI-1 used in the Study

Parameter	Symbol	Energy Setting Level 7
Peak positive pressure	P_+ (MPa)	62.5 (PVDF 44.5)
Positive energy flux density	ED_+ (mJ/mm^2)	0.78 (PVDF 0.35)
Total energy flux density	ED (mJ/mm^2)	1.05
−6-dB focal extend in x, y, and z-direction	$f_{x(-6dB)}$ (mm)	2.8
	$f_{y(-6dB)}$ (mm)	2.8
	$f_{z(-6dB)}$ (mm)	24.5
5-MPa focal extend, lateral	$f_{x(5MPa)}$ (mm)	27
	$f_{y(5MPa)}$ (mm)	27
Positive energy of the −6-dB focus	$E_{+(-6dB)}$ (mJ)	5.8
Total energy of the −6-dB focus	$E_{+(-6dB)}$ (mJ)	5.8
Positive energy of the 5-MPa focus	$E_{+(5MPa)}$ (mJ)	11.3
Total energy of the 5-MPa focus	$E_{(5MPa)}$ (mJ)	62
Positive energy of the 5-mm focal area	$E_{+(5mm)}$ (mJ)	4.8
Total energy of the 5-mm focal area	$E_{(5mm)}$ (mJ)	15.2

All measurements were done with a fiberoptic-hydrophone; when available additional measurements with membrane hydrophone (PVDF) in brackets

PVDF = Poly-vinylidene-fluoride membrane hydrophone; dB = Decibel; ED = Total energy flux density; ED_+ = Positive energy flux density

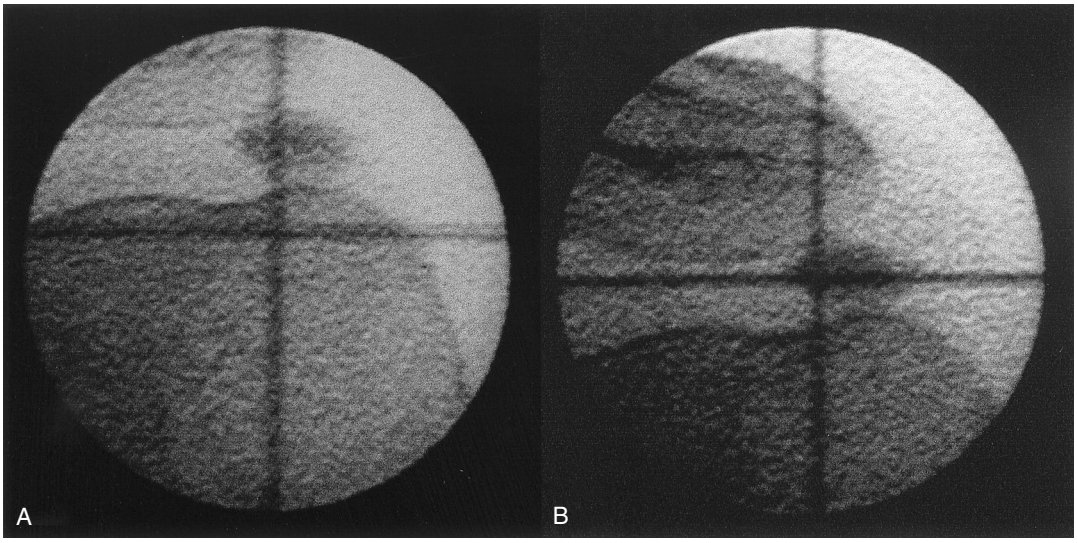

Fig 2A–B. A typical view from the monitor is shown. The overlying cross hairs indicate the focus of the acoustic lens aimed at (A) the insertion point of the supraspinatus tendon at the tuberculum majus and (B) at the calcific deposit.

using a questionnaire before randomization including the Constant and Murley score, subjective pain rate on a visual numeric rating scale from 0 (no pain) to 11 (maximum pain) for pain during activity and pain during rest. Rupture of the rotator cuff was excluded by ultrasound or magnetic resonance imaging (MRI). Twelve weeks and 1 year after treatment, the patient was reevaluated by an independent observer with the same questionnaire. The primary outcome measure of the study was the success rate 12 weeks after the last treatment, with success being defined as 80% of the normal value in the age-corrected Constant and Murley score. This outcome is considered clinically relevant. The target sample size was projected by an estimated duration of the treatment of 1 year. Comparative analyses were done on an intention-to-treat basis. No prospective rules were defined for stopping the study and no interim analysis was planned. The study protocol was approved by the ethics committee at the authors' institution.

Assignment

After being entered into the study, the patient was randomized using random permutated blocks. The treatment group assigned to the patient was written on the treatment protocol that was separated from the evaluation protocol used by the independent observer. The observer was not involved in the treatment of the patient nor knew to which group the patient was assigned.

Masking

The set-up in both groups was identical. The monitor of the mobile fluoroscopy unit was positioned outside the sight of the patient. Only the physician doing the intervention knew the treatment group.

Statistical Analysis

The SPSS 10.0 software program (Statistical Packet for the Social Sciences, SPSS Inc, Chicago, IL) was used for analysis of the study results. For statistical analysis of the differences between both groups, Student's t test for nonpaired samples was used ($\alpha \leq 0.05$). Before using the t test, the Kolmogorov-Smirnov test for normal distribution of the data and equal variances was done. Ninety-five percent confidence intervals were calculated for the differences between both groups with SPSS 10.0.

RESULTS

Participant Flow and Followup

Between September 1998 and December 1999, 50 patients were included in the study.

Thirty-five patients were women and 15 were men. In 24 patients, the right shoulder was affected, and in the other 26 patients, the left shoulder was affected. The mean age of the patients at the time of randomization was 50 years with a minimum of 29 years and a maximum of 68 years. The mean Constant and Murley score before treatment was 48.6 with a minimum of 21 and a maximum of 67. The pain during activity ranged from 5 to 11 with an average of 8.5, and the pain during rest ranged from 1 to 11 with an average of 7. A flow diagram showing the progress of patients throughout the trial is shown in Figure 3.[1] Twenty-five patients were randomized into the Calcific Deposit Group and 25 patients were randomized into the Tuberculum Majus Group. One patient in the Tuberculum Majus Group never returned after the initial visit. The other 49 patients received randomized treatment. No significant side-effects of the treatment were seen during or after treatment. In the Calcific Deposit Group, 24 of 25 patients participated in the 12-week followup, whereas 23 of 25 patients in the Tuberculum Majus Group were seen after 12 weeks. At the 1-year followup, 25 patients in the Calcific Deposit Group and 24 patients in the Tuberculum Majus Group were examined. Four patients in the Calcific Deposit Group and 16 patients in the Tuberculum Majus Group were not satisfied with the results 12 weeks after treatment. These patients were not demasked and not informed to which group they belonged. After 1 year, all patients in the Calcific Deposit Group were satisfied with the result, whereas 14 patients in the Tuberculum Majus Group were not satisfied. The patients in the Tuberculum Majus Group were informed about additional treatment options. No deviations from the study protocol occurred.

Table 3 shows the numerical results of the study as a comparison between groups. Figure 4 shows a plot of the 95% confidence interval of the Constant and Murley score results for both groups at the initial examination and 12 weeks and 1 year after intervention. The rate of complete resorption of the calcific deposit in each group 1 year after extracorporeal shock wave therapy is shown in Table 4 for 46 patients. A chi square test at a level of $\alpha < 0.05$ showed no significant difference in the resorption rate.

DISCUSSION

Extracorporeal shock wave therapy has been used in Germany and Austria for treatment of calcifying and noncalcifying tendinopathy of the shoulder since 1992. The number of applications in the orthopaedic area, with an estimated 60,000 to 100,000 patients annually in Germany, has exceeded the number of applications of lithotripsy in urology.[23]

Until now, a pain-triggered or laser-guided application to the insertion of a tendon without ultrasound or fluoroscopic imaging of the target area has been recommended for all indications including calcifying tendinopathy.[4,5,8] In clinical practice, the treatment of calcifying tendinopathy is done analogous to the treatment of other insertion tendinopathies such as tennis elbow using the biofeedback method.

Contrary to other indications,[15,23] Loew et al[17] showed the efficacy of high-energy extracorporeal shock wave therapy in a controlled prospective study for treatment of calcifying tendinopathy of the shoulder. Based on this study, the current authors examined the effect of different focusing sites of the shock waves and therefore used similar energy flux densities and the same treatment protocol for shock wave application.

Significantly better 1-year results (t test, $\alpha < 0.05$) were seen in all observed parameters if extracorporeal shock wave therapy was aimed exactly at the calcific deposit. After 12 weeks, all parameters except pain at rest showed a significant improvement compared with the other group (extracorporeal shock wave therapy focused on the insertion of the supraspinatus tendon).

The current clinical results of the patients in the Calcific Deposit Group are better than results reported by Loew et al.[17] The reason for this may be the more exact localization of the

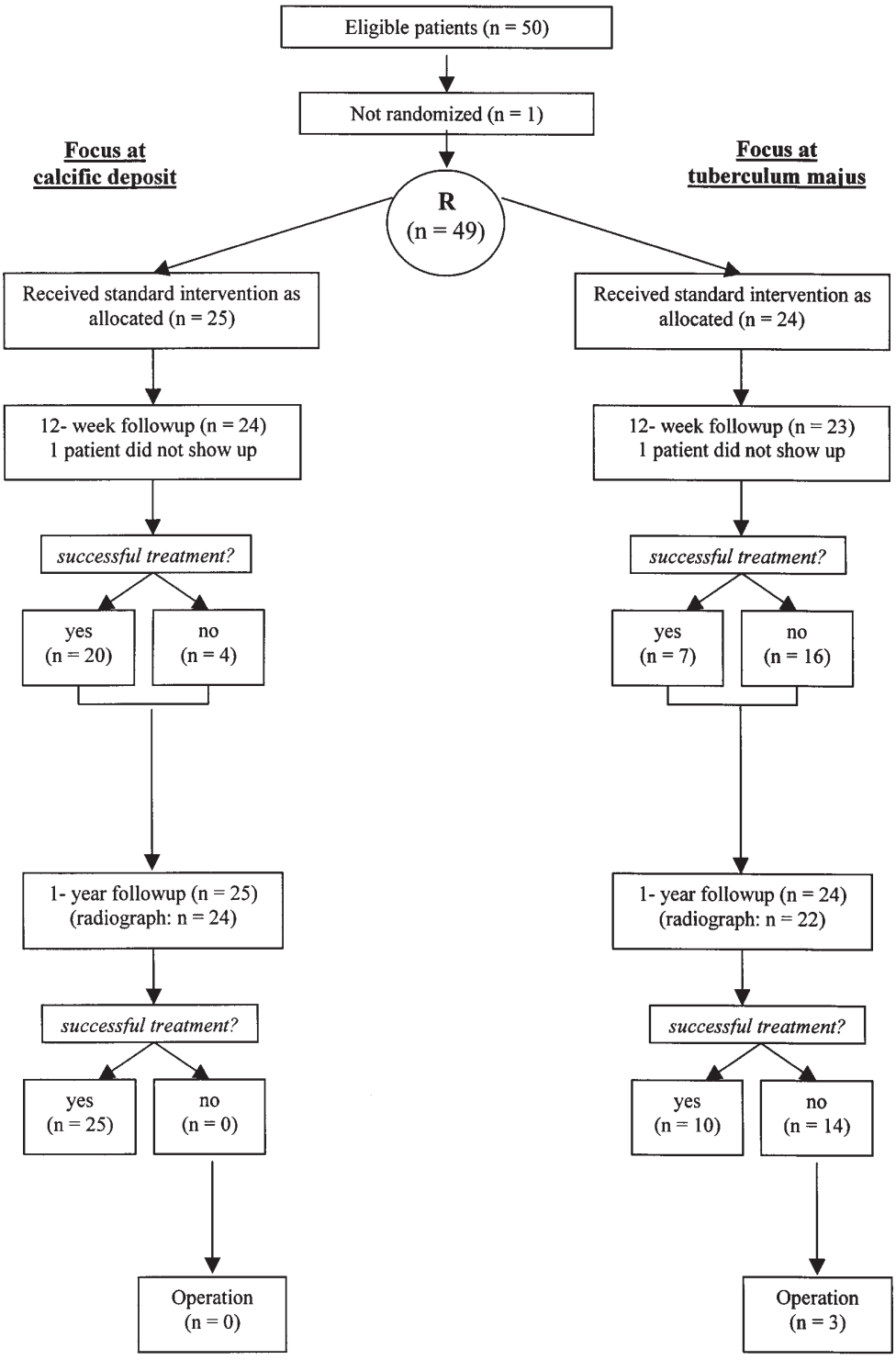

Fig 3. This flow diagram shows the progress of patients throughout the trial: One patient from each group did not return for the 12-week followup because of another disorder. Both patients were evaluated at the 1-year followup. One patient in the Tuberculum Majus Group withdrew his consent after randomization. No other deviations from the study protocol occurred.

TABLE 3. Mean Values (± standard deviation) of All Clinical Parameters Before and 12 Weeks and 1 Year After Intervention

	Focus on Deposit	Focus on Tuberculum Majus	95% Confidence Interval	Student's Test
Group / Parameter	*Calcific Deposit Group*	*Tuberculum Majus Group*	*(group difference)*	*significant*
Constant and Murley score (age-corrected)				
Before intervention	49.96 ± 10.87 (n = 25)	47.17 ± 11.53 (n = 24)	−3.64 to 9.23	
12 weeks	104.59 ± 23.12 (n = 24)	73.08 ± 29.44 (n = 23)	16.99 to 47.03	Yes
1 year	116.24 ± 16.23 (n = 25)	83.51 ± 26.40 (n = 24)	20.19 to 45.27	Yes
Number of successful treatments				
12 weeks	20 (n = 24)	7 (n = 23)	n/a	n/a
1 year	25 (n = 25)	10 (n = 24)	n/a	n/a
Subjective improvement (%)				
12 weeks	57.46 ± 32.18 (n = 24)	31.74 ± 35.60 (n = 23)	5.80 to 45.64	Yes
1 year	81.36 ± 19.08 (n = 25)	47.04 ± 36.50 (n = 24)	17.68 to 50.96	Yes
Pain during rest (NRS 0–11)				
Before intervention	7.08 ± 2.74 (n = 25)	7.17 ± 2.53 (n = 24)	−1.60 to 1.43	
12 weeks	3.21 ± 2.86 (v = 24)	4.74 ± 3.11 (n = 23)	−3.28 to 0.22	No
1 year	1.48 ± 0.92 (v = 25)	3.75 ± 2.91 (n = 24)	−3.50 to −1.04	Yes
Pain during activity (NRS 0–11)				
Before intervention	8.56 ± 1.58 (n = 25)	8.54 ± 1.91 (n = 24)	−0.99 t1.03	
12 weeks	3.79 ± 2.67 (n = 24)	6.65 ± 3.10 (n = 23)	−4.56 to −1.16	Yes
1 year	2.76 ± 1.92 (n = 25)	6.04 ± 2.87 (n = 24)	−4.68 to −1.88	Yes

Numbers in Columns 2 and 3 are mean ± standard deviation. Differences between the groups were evaluated using Student's t test; significant if $p < 0.05$. In all parameters except rest pain after 12 weeks, the differences between both groups are significant (t test, $\alpha < 0.05$).

NRS = Eleven-point numeric rating scale; n/a = Not available

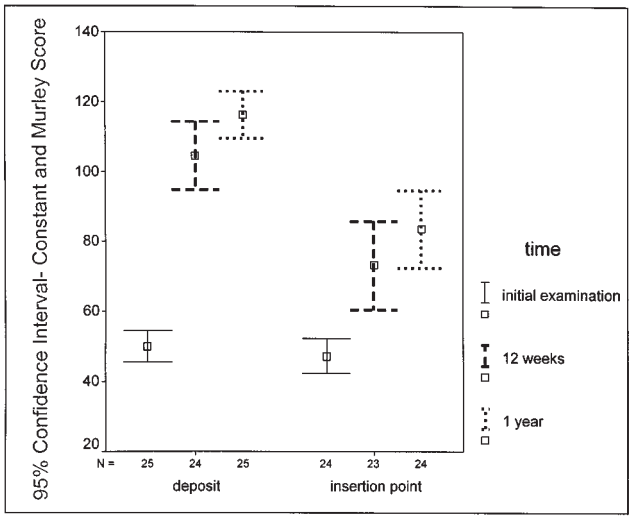

Fig 4. This plot shows the 95% confidence interval of the age-adjusted Constant and Murley score before intervention, 12 weeks (dashed lines), and 1 year (dotted lines) after intervention.

TABLE 4. Two-by-Two Cross Table for Complete Resorption of the Calcific Deposit 1 Year After Extracorporeal Shock Wave Therapy

Group	Resorption	No Resorption	Number
CD group	14	10	24
TM group	8	14	22
Number	22	24	46

A chi^2 test ($\alpha < 0.05$) showed no significant difference between both groups.

CD group = focus of shock waves at calcific deposit

TM group = focus of shock waves at tuberculum majus

calcific deposit from two angles before beginning the treatment and continuous observation during extracorporeal shock wave therapy every 200 to 300 pulses. The authors did not determine whether the in-line radiographic localization through the cylindrical source of the shock wave generator is more effective than off-line radiographic localization used by others.

Based on the current results, it seems important to keep the focal spot constantly at the calcific deposit during the entire treatment. In some cases, the patient's arm has to be rotated slightly or flexed, enabling the clinician to aim exactly at the deposit and not to affect other superimposed structures.

The mechanisms of the therapeutic effect of extracorporeal shock wave therapy for treatment of calcifying tendinopathy are uncertain. Although some authors favor the theory of a direct mechanical disintegrating effect on the deposit,[17] others prefer long-lasting hyperstimulation analgesia.[8,22] The current results do not support the disintegrating theory because there was no significant difference found in the resorption rate between both groups although the clinical results were statistically different. For patients in the group in which the extracorporeal shock waves were focused on the tuberculum majus, there was improvement in the Constant and Murley score and pain, which is comparable with the natural history of the disease.[10]

Although no severe side effects were found, it might be disadvantageous to hit other structures such as cartilage or bone with an unguided application of high-energy shock waves. The frequency with which hematomas occur seems to be dependent on the energy used, as seen when using a Dornier Compact lithotriptor.[3] By using MRI, no changes in muscular tissue in patients after extracorporeal shock were therapy of the shoulder were detected applying an energy flux density of 0.28 mJ/mm^2, but in one patient, a transient edema of the bone could be seen.[18] However, Maier et al[20] found changes in the MRI signal intensity of the tendinous insertion after extracorporeal shock wave therapy at the shoulder. These findings underline the importance of exact focusing.

The study results suggest that extracorporeal shock wave therapy with 2×2000 impulses of a positive energy flux density of 0.78 mJ/mm^2 ($= 0.35$ mJ/mm^2 measured with a membrane hydrophone) was highly effective for treatment of calcifying tendinopathy of the supraspinatus muscle when it was focused exactly using fluoroscopic control at the calcific deposit. It should not be used without exact focusing as a biofeedback procedure to the insertion of the muscle. Based on the results of the current study, shock wave generators should be built with the ability to focus the shock waves with fluoroscopic imaging.

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