Effectiveness of Radial Shock-Wave Therapy for Calcific Tendinitis of the Shoulder: Single-Blind, Randomized Clinical Study

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Research Report

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Background and Purpose. Radial shock-wave therapy (RSWT) is a pneumatically generated, low- to medium-energy type of shock-wave therapy. This single-blind, randomized, "less active similar therapy"-controlled study was performed to evaluate the effectiveness of RSWT for the management of calcific tendinitis of the shoulder. **Subjects.** Ninety patients with radiographically verified calcific tendinitis of the shoulder were tested. **Methods.** Subjects were randomly assigned to either a treatment group (n=45) or a control group (n=45). Pain and functional level were evaluated before and after treatment and at a 6-month follow-up. Radiographic modifications in calcifications were evaluated before and after treatment. **Results.** The treatment group displayed improvement in all of the parameters analyzed after treatment and at the 6-month follow-up. Calcifications disappeared completely in 86.6% of the subjects in the treatment group and partially in 13.4% of subjects; only 8.8% of the subjects in the control group displayed partially reduced calcifications, and none displayed a total disappearance. **Discussion and Conclusion.** The results suggest that the use of RSWT for the management of calcific tendinitis of the shoulder is safe and effective, leading to a significant reduction in pain and improvement of shoulder function after 4 weeks, without adverse effects. [Cacchio A, Paoloni M, Barile A, et al. Effectiveness of radial shock-wave therapy for calcific tendinitis of the shoulder: single-blind, randomized clinical study. *Phys Ther.* 2006;86:672–682.]

Key Words: *Calcific tendinitis, Lithotripsy, Radial shock-wave therapy, Rotator cuff, Shoulder.*

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Calcific tendinitis of the shoulder is a commonly observed problem[1] characterized by calcium phosphate crystal deposition in the rotator cuff tendons, typically occurring between the fourth and the fifth decades of life.[2–4] It most frequently affects the supraspinatus tendon near its insertion, followed by the infraspinatus, teres minor, and subscapularis tendons in descending order.[5] The etiology and pathogenesis of shoulder calcific tendinitis are still unclear. Hypovascularization and local degenerative and proliferative changes in tendinous tissue of the rotator cuff have been suggested as possible causes.[2,6,8] The incidence of calcific tendinitis varies, depending on different reports, from 2.7% to 63%.[1,9,10] This wide variability may be due to the use of different clinical and radiographic criteria,[11] because the incidence of the calcification may be overestimated when evaluated by radiographs rather than by clinical parameters.

The disorder leads to pain, particularly nocturnal discomfort, in about 50% of patients[1,12] and frequently to a considerable restriction of range of motion. The clinical presentation varies considerably, and symptoms may last for several days and then either disappear or become chronic,[1,13] which means that it has not yet been possible to clearly predict the natural history of the disease. For example, Bosworth[1] described the disappearance of calcifications in 9.3% of patients within 3 years of the initial diagnosis. According to Wagenhauser,[14] calcifications disappeared in 27.1% of patients after 10 years, and Gartner[15] reported that calcifications with sharp margins and a homogeneous or heterogeneous structure disappeared spontaneously in 33% of patients over a period of 3 years. The time required for a spontaneous disappearance of the calcifications, however, often is too long and unacceptable for the patient's quality of life.

Treatment of patients with calcific tendinitis is typically conservative and includes the use of nonsteroidal antiinflammatory drugs, subacromial injection with steroids, percutaneous needle aspiration,[16] transcutaneous electrical nerve stimulation,[17] and therapeutic exercise,[18] all of which have a limited effect[19]; the only intervention that has been shown to result in a clinical improvement is therapeutic ultrasound.[20,21] Open or arthroscopic surgical procedures have been proposed to relieve symptoms for patients with chronic pain, with good results.[3,22,23]

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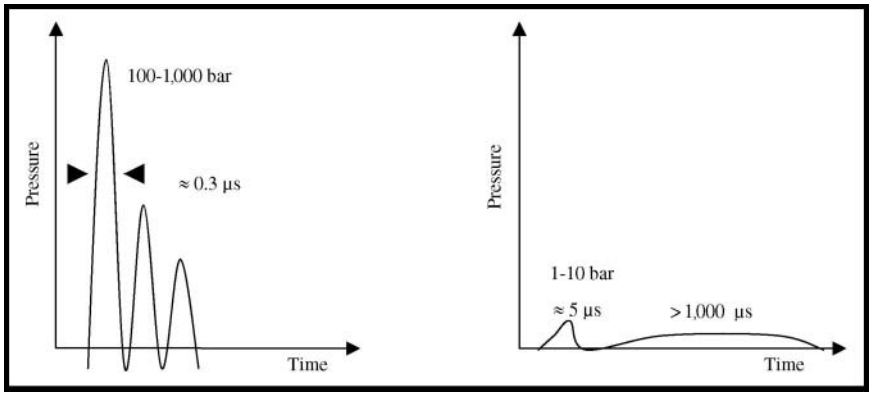

Figure 1.
Physical characteristics of extracorporeal shock-wave therapy (ESWT) (left) and radial shock-wave therapy (RSWT) (right).

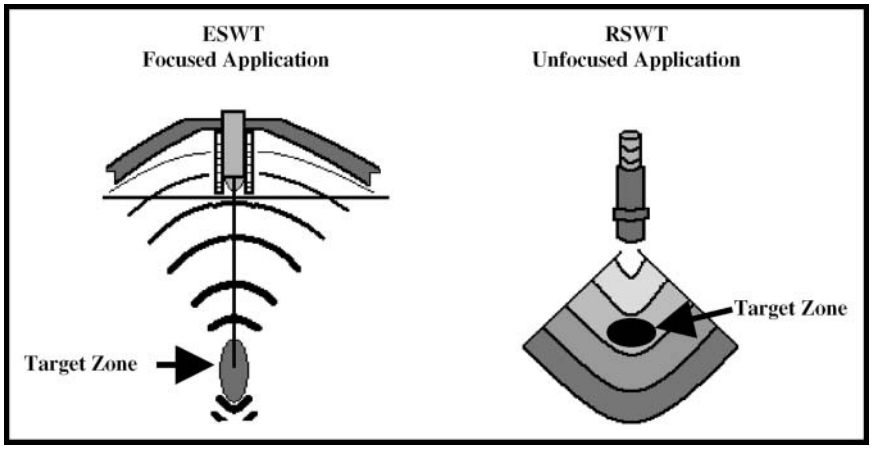

Figure 2.
Wave propagation of extracorporeal shock-wave therapy (ESWT) and radial shock-wave therapy (RSWT).

When conservative therapy has not been effective in relieving pain and other symptoms, extracorporeal shock-wave therapy (ESWT) has been used,[11,24–28] yielding results such as relief of pain[29–31] and improved function[25,29,31,32] that are sometimes as good as those achieved by means of surgical procedures.[28] However, recent randomized controlled trials have shown negative results with the use ESWT for the management of calcific tendinitis.[33,34]

A radial shock wave (RSW) is a low- to medium-energy shock wave that is pneumatically generated through the acceleration of a projectile inside the handpiece of the treatment device and then transmitted radially from the tip of the applicator to the target zone. The pressure and the energy density decrease by the third power of the penetration depth in the tissue. Radial shock waves show a lower peak pressure and a considerably longer rise time than extracorporeal shock waves (ESWs) (Fig. 1). In radial shock-wave therapy (RSWT), the focal point is not centered on the target zone, as occurs in ESWT, but on the tip of the applicator (Fig. 2). The energy at the focal point of the shock wave per impulse is called the "energy flux density" (EFD) and is recorded as joules per area. The effective total energy of a treatment is defined by the number and EFD of the single impulses and by the geometrical measurement of the focal point. Low-energy shock waves (EFD less than 0.1 mJ/mm^2) are generally differentiated from high-energy waves (EFD of 0.2–0.4 mJ/mm).[2,25]

Recent studies by Loew et al[25] and Rompe et al[27] compared high-energy shock-wave therapy with low-energy shock-wave therapy in the management of calcific tendinitis of the shoulder, and the results showed energy-dependent success.[25] It was assumed that low-energy and unfocused shock-wave therapy (eg, RSWT), although effective for achieving pain relief, could not be effective in disintegrating the calcific deposit of the rotator cuff.[35] Recent findings, however, have demonstrated that ultrasound treatment in patients with calcific tendinitis of the shoulder leads to calcific deposit demolition, and not only to relief of pain[21]; moreover, a considerable total level energy can be administered through RSWT by using an adequate number of impulses per treatment.

Potential benefits could derive from RSWT, compared with ESWT, because it is less painful and thus can be administered without anesthesia, thereby reducing the risks of treatment for patients. Furthermore, due to the radial emission of RSWT, the calcification, once located radiographically, is surely included inside the wave propagation area. Contrarily, when the shock wave is focused, as occurs in the ESWT, refocusing of the applicator is periodically necessary to be certain that the waves hit the calcification.[36] Moreover, no ultrasound guide is needed to perform therapeutic applications of RSWT.

Although RSWT has been successfully used since the late 1990s for the management of various orthopedic disorders such as epicondylitis of the elbow and chronic heel pain,[37,38] which represent 2 of the 3 musculoskeletal indications for ESWT (plantar fasciitis, lateral epicondylitis, and calcific tendinitis[39]), no randomized clinical study has yet been performed in the treatment of shoulder calcifications.

Table 1.
Failed Previous Conservative Interventions

Failed Interventions	Treatment Group (n=45)	Control Group (n=45)	Total (% of 90 Patients)
Anti-inflammatory drugs	42	40	82 (91.1%)
Ultrasound and exercise	13	16	29 (32.2%)
Laser therapy and exercise	10	8	18 (20.0%)
Transcutaneous electrical nerve stimulation and exercise	16	12	28 (31.1%)
Acupuncture	3	3	6 (6.7%)
Corticosteroid injection	39	33	72 (80.0%)

Table 2.
Baseline Characteristics of the Treatment and Control Groups[a]

Characteristics	Treatment Group	Control Group
Subjects (n)	45	45
Age (y)[b]	56.12±1.98	56.42±2.09
Duration (mo)[b]	14±4.95	13±5.03
Male/female (n)	27/18	28/17
Shoulder	45	45
Treatment side (right/left)	27/18	23/22
UCLA Shoulder Rating Scale score (range=0–35)[b]	10.25±2.08	10.14±1.96
VAS (range=0–10)[b]	7.96±0.88	7.72±1.03
Calcification size (mm)[b]	21.30±7.50	19.70±8.30
Type of calcification[c]		
I	11	13
II	34	32

[a] UCLA=University of California—Los Angeles, VAS=visual analog scale.
[b] Values are mean ± standard deviation.
[c] Gartner and Simons radiographic classification.[6]

The aim of our study was to evaluate the effectiveness of RSWT on pain relief, restoration of shoulder function, and resolution of calcific tendinitis of the shoulder, using a single-blind, randomized, "less active similar therapy"-controlled study. We considered functionality and pain as primary end points, because we initially did not expect a reduction in calcification, and we considered the radiographic disappearance of calcifications as a secondary end point.

Subjects and Method

Between November 2002 and December 2003, we conducted a single-center, single-blind, "less active similar therapy"-controlled study. Inclusion criteria were: calcific tendinitis of the shoulder, detected on standardized radiographs, with type I (homogenous and with well-defined borders) or type II (heterogeneous in structure with sharp outline or homogenous in structure with no defined border) calcifications according to the Gartner and Simons radiographic classification[6]; visual analog scale (VAS) score of ≥4 cm at the moment of the evaluation; presence of symptoms for at least 6 months; failure of previous conservative treatments (anti-inflammatory drugs, ultrasound and exercises, laser therapy and exercises, electrical stimulation and exercises, acupuncture, and steroid injection) (Tab. 1). Exclusion criteria were: rotator cuff tear, glenohumeral or acromioclavicular arthritis or acromioclavicular spur to rule out alternative explanations for the pain; pregnancy; implanted pacemaker; blood coagulation disorders or use of anticoagulant drugs; age of <18 years; inflammatory or neoplastic disorders; presence of type III (cloudy and transparent) calcifications according to the Gartner and Simons radiographic classification[6]; and conservative treatments administered in the last 4 weeks.

Presence of shoulder pathologies was clinically evaluated by an expert orthopedic physician, and, when suspected on the basis of the clinical findings, ultrasound and magnetic resonance imaging (MRI) examinations were performed. All subjects were verbally informed of the potential risks of treatment as well as of the possibility of unknowingly being included in the control group and receiving a "less active similar therapy." Written informed consent was obtained from all subjects, and the procedures followed were in accordance with the ethical standards of the Committee on Human Experimentation of "San Salvatore" Hospital of L'Aquila. Subjects who met the eligibility criteria were randomly assigned, by the use of a computer-based 1:1 randomization scheme and sealed envelopes, to either a treatment group or a control group (Tab. 2), so that each subject had an equal probability of being assigned to either group.

Ninety-five patients were enrolled and assessed for eligibility between November 2002 and December 2003; 2 patients did not meet the inclusion criteria, and 3 patients met the exclusion criteria (Fig. 3), showing a tear of the rotator cuff muscles with diagnostic ultrasound. Six patients whom the orthopedic physician believed had a rotator cuff tear received diagnostic ultrasound. In 3 of the 6 patients (the 3 patients who were excluded), positive findings for rotator cuff tear were found. In the remaining 3 patients, due to uncertain findings for rotator cuff tear using diagnostic ultrasound, an MRI examination revealed no rotator

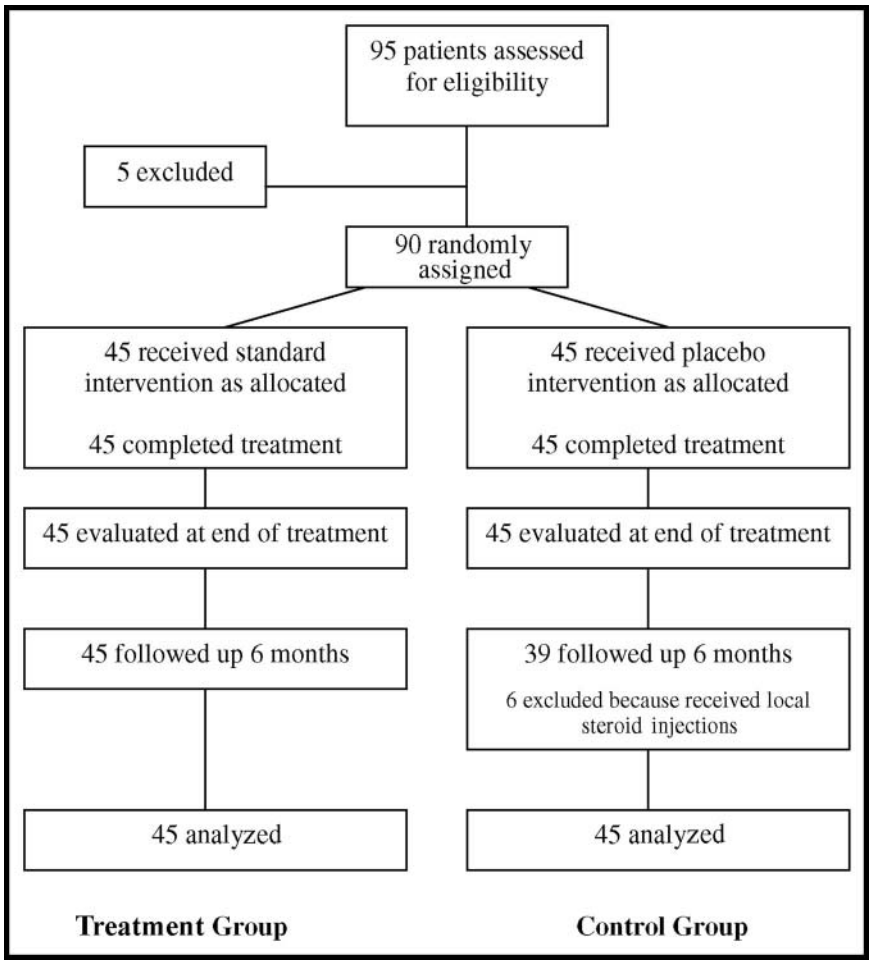

Figure 3.
Flow diagram of the study.

cuff tear, and thus these 3 patients were enrolled in the study. The remaining 90 patients (55 men and 35 women; mean age=56.2 years, SD=3.05, range=40–62) with radiographically verified calcific tendinitis of the shoulder and a mean duration of symptoms of 13 months (SD=6.43, range=6–26) were randomly assigned to either the treatment group or the control group. Calcifications were found in the supraspinatus tendon (87%) and the infraspinatus tendon (13%).

The baseline characteristics, which were similar and without statistically significant differences between groups, are shown in Table 2. All 90 subjects were re-examined after the treatment period. At the 6-month follow-up, all 45 patients in the treatment group were reappraised, and 6 subjects (13.4%) in the control group were excluded because they had received corticosteroid injection therapy between the end of treatment and follow-up. Nevertheless, based on the principle of intention-to-treat,[40] the data for these 6 subjects were included in the data analysis. At the 6-month follow-up, the blinding procedure was unmasked, and real RSWT was offered to the subjects in the control group.

Outcome Measures

The primary end points were a significant increase in the mean score of the University of California–Los Angeles (UCLA) Shoulder Rating Scale[41,42] and a significant decrease in the VAS score from before to after treatment and to the 6-month follow-up period. The UCLA Shoulder Rating Scale is a 35-point shoulder scale that combines scores for pain, function, active range of forward flexion, strength of forward flexion (manual muscle testing), and patient satisfaction. Pain and function are both scored from 1 to 10 points, with 1 being the worst score and 10 being the best score. Active range of forward flexion, strength of forward flexion, and patient satisfaction are scored from 0 to 5 points, with 0 being the worst score and 5 being the best score. The outcome score is defined as follows: 34 to 35 points, excellent; 29 to 33 points, good; 21 to 28 points, mild; and 20 points or less, poor. The single-administration reliability and the validity of UCLA Shoulder Rating Scale scores compared with Shoulder Pain and Disability Index (SPADI) scores have recently been tested.[43] The reliability of the UCLA Shoulder Rating Scale scores, estimated using the Cronbach alpha statistic, could not be assessed because of the typology of the pain and function subscales. Regarding the validity of the UCLA Shoulder Rating Scale scores, negative correlations were found between the SPADI disability subscale scores and the UCLA Shoulder Rating Scale function subscale scores ($r=-.64$) and between the SPADI pain subscale scores and the UCLA Shoulder Rating Scale pain subscale scores ($r=-.63$). To our knowledge, no other publications are available regarding responsiveness, error, and reliability for this scale, even though it has been used for patients with different shoulder conditions, including rotator cuff disease[41] and calcific tendinitis.[44]

Self-rated pain intensity at the moment of the evaluation was measured on a 10-cm horizontal VAS with 0 cm labeled "no pain" and 10 cm labeled "worst pain I have ever had." Subjects were asked to answer the question: "Referring to the worst pain you have experienced in your life, what is the relative level of your shoulder pain?"

The secondary end point was the radiographic disappearance of calcifications at the end of treatment. Success was defined as complete disappearance of calcification. An anteroposterior radiograph of the shoulder obtained in 45 degrees of external rotation and 45 degrees of internal rotation was taken for each subject under standardized conditions in terms of distance from radiographic film and exposure setting[45] in order to evaluate the presence, type, and size of calcifications, as well as their location within a specific tendon. Type of calcification was evaluated according to the Gartner and Simons classification.[6] A caliper that evaluated calcification length (in millimeters) was used for size measurement. The radiographic assessments were obtained before treatment; posttreatment assessment was performed 1 week after the end of treatment so as to be able to correlate the disappearance of the calcification with the therapy performed.

Table 3.
Mean (±SD) Values and Outcomes of the University of California—Los Angeles Shoulder Rating Scale in the Treatment and Control Groups

Mean (±SD) Values	Treatment Group (n=45)					Control Group (n=45)					*P*
Before treatment	10.25±2.08					10.14±1.96					.9144[a]
After treatment	33.12±2.94					11.28±2.82					.0056[b]
P	.00000002[c]					.1438[c]					
Follow-up	32.12±3.02					10.57±3.96					.0023[d]
P	.1151[e]					.3302[e]					
Outcomes[f]	**E**	**G**	**M**	**P**	**Total**	**E**	**G**	**M**	**P**	**Total**	
Before treatment				45	45				45	45	
After treatment	41	4			45			8	37	45	
Follow-up	39	5	1		45			3	36	39	

[a] Comparison between treatment and control groups before treatment.
[b] Comparison between treatment and control groups after treatment.
[c] Comparison between before and after treatment within each group.
[d] Comparison between treatment and control groups at 6-month follow-up.
[e] Comparison between after treatment and 6-month follow-up within each group.
[f] E=excellent (34–35 points), G=good (29–33 points), M=mild (21–28 points), P=poor (≤20 points).

Primary outcome measurements were performed by 2 experienced physicians. The secondary outcome measurements were assessed by an experienced radiologist. The subjects, the outcome assessors, and the radiologist were all blinded to the treatment performed.

Method of Treatment

A Physio Shock Wave Therapy device* consisting of a control unit, a handpiece with 3 different head applicators (8, 10, and 15 mm), and a medical air compressor was used. The compressor generates a pneumatic energy that is used to accelerate a projectile inside the handpiece. When the projectile strikes the applicator, a shock wave is generated and radially spreads from the tip of the applicator to the target zone.

Subjects were seated with the shoulder abducted at 45 degrees, the elbow flexed at 90 degrees, and the forearm resting on a flat surface, and the shock-wave applicator was placed in the direction of the calcifications. No local anesthetics or analgesic drugs were administered before or during the treatment and no therapeutic cointervention was administered in either the treatment group or the control group. Radial shock-wave therapy was administered in both groups by the same experienced physician (in accordance with Italian law, shock-wave therapy must be administered by a physician and not by a physical therapist).

The RSWT was administered using a 15-mm-head applicator. Each subject in the treatment group received 4 sessions at 1-week intervals, with 2,500 impulses per session (500 impulses with a pressure of 1.5 bar and a frequency of 4.5 Hz and 2,000 impulses with a pressure of 2.5 bar and a frequency of 10 Hz), an EFD of 0.10 mJ/mm^2, and a fixed impulse time of 2 milliseconds. The treatment area was prepared with a coupling gel (Aquasonic 100†) to minimize the loss of shock-wave energy at the interface between applicator tip and skin.

The same treatment procedure was followed for the subjects in the control group, except that the total number of impulses administered was only 25 (5 impulses with a pressure of 1.5 bar and a frequency of 4.5 Hz and 20 impulses with a pressure of 2.5 bar and a frequency of 10 Hz). Because we were not able to perform a simulated treatment, we had to give some shock-wave impulse to the control group to avoid possible blinding failure. Other researchers[46,47] also have used a "less active similar therapy," and the rationale for this technique is that the efficacy of shock-wave therapy seems to be dose-dependent.[25]

Data Analysis

Statistical analysis was performed using the SSP 2.5 statistical package (Smith's Statistical Package, version 2.75, 2004‡). All analyses of the primary and secondary

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† Parker Laboratories Inc, 286 Eldridge Rd, Fairfield, NJ 07004.
‡ Gary Smith, Pomona College, Claremont, Calif 91711 (http://www.economics.pomona.edu/StatSite/framepg.html).

Table 4.
Comparison of Single Items of the Unviersity of California–Los Angeles (UCLA) Shoulder Rating Scale Before and After Treatment With Radial Shock-Wave Therapy and at 6-Month Follow-up in the Treatment and Control Groups

UCLA Shoulder Rating Scale Item	Treatment Group (n=45)	Control Group (n=45)	*P*
Pain (range=1–10)			
Before treatment	1.39±0.97	1.04±1.03	.8966[a]
After treatment	7.90±1.09	2.85±2.03	.0044[b]
P	.00000001[c]	.0386[c]	
Follow-up[1]	7.95±0.92	2.64±1.14	.0023[d]
P	.8147[e]	.5471[e]	
Active range of forward flexion			
Before treatment	66.75±15.41	68.14±18.77	.2033[a]
After treatment	134.35±24.93	85.00±32.45	.0084[b]
P	.000002[c]	.0693[c]	
Follow-up	152.00±28.99	90.00±26.15	.0127[d]
P	.0026[e]	.4232[e]	
Strength of forward flexion (range=0–5)			
Before treatment	3.49±0.75	3.16±0.32	.6590[a]
After treatment	4.98±0.35	3.66±0.95	.0067[b]
P	.0000009[c]	0.1611[c]	
Follow-up	4.85±0.46	3.42±0.95	.0045[d]
P	.1352[e]	0.2340[e]	
Function (range=0–5)			
Before treatment	2.10±0.33	2.18±0.45	.4738[a]
After treatment	4.48±0.85	2.98±1.23	.0748[b]
P	.000001[c]	.2145[c]	
Follow-up	4.50±0.82	2.45±1.61	.0163[d]
P	.9098[e]	.0830[e]	
Patient satisfaction (range=0–5)			
Before treatment	0.80±0.50	0.84±0.45	.7494[a]
After treatment	4.80±1.02	1.70±1.90	.0017[b]
P	.0000001[c]	.0921[c]	
Follow-up	4.60±1.03	1.05±0.95	.0011[d]
P	.3572[e]	.0442[e]	

[a] Comparison between treatment and control groups before treatment.
[b] Comparison between treatment and control groups after treatment.
[c] Comparison between before and after treatment within each group.
[d] Comparison between treatment and control groups at 6-month follow-up.
[e] Comparison between after treatment and 6-month follow-up within each group.

outcomes were performed according to the principle of intention-to-treat. The intention-to-treat analysis was carried out according to a "worst-case scenario" analysis: subjects who did not complete the treatment or had not undergone the post-treatment or final follow-up assessments were assigned a poor outcome, corresponding to the final average change recorded in the per-protocol completer population in the control group.[40] A 2-sample *t* test was applied to compare the differences of the baseline data. A 2-way analysis of variance (ANOVA) with group (treatment versus control) as the between-subjects factor and time as the within-subjects factor was used to assess the presence of significant differences between the treatment and control groups and within each group before and after treatment and at the 6-month follow-up. A Tukey *post hoc* comparison was used to determine significant differences between mean values when a significant main effect and interaction were found. Two-sample paired and unpaired *t* tests were applied to compare the differences of average size of calcium deposits on radiographic examination before and after treatment and between the treatment and control groups, respectively. For all analyses, the level of significance was set at $P \leq .05$.

To allow a clinical translation of the statistical results, the number needed to treat (NNT)[48] was evaluated. The NNT is expressed in terms designed to help decide whether the intervention might be valuable in clinical practice.[48] For example, when comparing treatment X and treatment Y, an NNT score of 5 for treatment X indicates that, on average, after treating 5 patients, treatment X will have achieved one more positive outcome than if treatment Y had been used.[48] For the primary outcome, the NNT was calculated considering the "excellent" category (34–35 points on the UCLA Shoulder Rating Scale) as a positive outcome and the "good," "mild," and "poor" categories (below 34 points on the UCLA Shoulder Rating Scale) as negative outcomes. For the secondary outcome, number of disappearance of calcifications was used to calculate the NNT.

Results

Primary Outcome Measures

The ANOVA demonstrated a significant effect of treatment ($P<.0001$) and a significant treatment-time interaction ($P<.0001$). One week after the end of treatment and at the 6-month follow-up, statistically significant improvements in mean total scores (Tab. 3) and single-item scores (Tab. 4) on the UCLA Shoulder Rating Scale were observed in the treatment group. Statistically significant improvements in scores on the pain subscale of UCLA Shoulder Rating Scale also were observed in the control group. No statistically significant difference was found between the treatment and control groups for the function subscale of UCLA Shoulder Rating Scale at the

Table 5.
Visual Analog Scale (VAS) Scores Before and After Treatment and at 6-Month Follow-up in the Treatment and Control Groups

VAS Score	Treatment Group (n=45)	Control Group (n=45)	*P*
Before treatment	7.96±0.88	7.72±1.03	.9855[a]
After treatment	0.90±0.99	5.85±2.23	.0039[b]
P	.00000001[c]	.0418[c]	
Follow-up	0.95±0.99	6.84±2.41	.0010[d]
P	.8112[e]	.0462[e]	

[a] Comparison between treatment and control groups before treatment.
[b] Comparison between treatment and control groups after treatment.
[c] Comparison between before and after treatment within each group.
[d] Comparison between treatment and control groups at 6-month follow-up.
[e] Comparison between after treatment and 6-month follow-up within each group.

post-treatment assessment. However, statistically significant differences between groups were found at the 6-month follow-up. The NNT to reach an excellent UCLA Shoulder Rating Scale score was 1.09 one week after the last treatment session and 1.15 at the 6-month follow-up. Statistically significant VAS score reduction (Tab. 5) was observed both 1 week after the end of treatment and at the 6-month follow-up in the treatment group.

Secondary Outcome Measures

Radiographic assessment was performed 1 week after the end of treatment. Radiographic changes in the average size of calcifications are shown in Table 6. The average size of calcifications showed a significant decrease after treatment in the treatment group, whereas no change was seen in the control group. After treatment, calcifications disappeared in 39 subjects (86.6%) and were partially reabsorbed in 6 subjects (13.4%) in the treatment group (Fig. 4). Thirty-four (87.2%) of the 39 calcifications that totally disappeared were classified as type II and 5 calcifications (12.8%) were classified as type I according to the Gartner and Simons classification[6]; all 6 calcifications that partially disappeared were classified as type I. The NNT for complete disappearance of calcifications was 1.15 in the treatment group.

In the control group, no complete disappearance of calcifications was observed. Partial disappearance of calcifications was seen in 4 subjects (8.8%) in the treatment group, and no change in calcifications was seen in 41 subjects (91.2%) in the treatment group. All 4 calcifications that partially disappeared were type II in the Gartner and Simons classification.[6] Thirteen (31.7%) of the 41 unmodified calcifications were type I, while the remaining 28 unmodified calcifications (68.3%) were type II in the Gartner and Simons classification.[6]

Table 6.
Average Size of Diameter of Calcium Deposits (in Millimeters) Before and After Treatment on Radiographic Examination in the Treatment and Control Groups

	Treatment Group (n=45)	Control Group (n=45)	*P*
Before treatment	21.30±7.50	19.70±8.30	.9855[a]
After treatment	0.85±1.20	18.85±6.40	.0001[b]
P	.00000001[c]	.9918[c]	

[a] Comparison between treatment and control groups before treatment.
[b] Comparison between treatment and control groups after treatment.
[c] Comparison between before and after treatment within each group.

Adverse Effects

After shock-wave treatment, no clinically relevant side effects were seen in either group. Hematomas that lasted 4 to 6 days were observed in only 3 subjects (6.7%) in the treatment group, but the hematomas did not cause discomfort or pain in the subjects, and they received the remaining RSWT applications. No other adverse effects were noted.

Discussion

Extracorporeal shock-wave therapy has been used for the management of calcific tendinitis of the shoulder when conventional physical therapy was not effective in relieving pain and other symptoms,[11,24–28] showing results comparable to those obtained by means of surgical treatment.[28] Although RSWT has been used in the management of various orthopedic disorders,[35,36] no randomized clinical trial has yet been conducted to assess its effectiveness and safety in the management of calcific tendinitis of the shoulder.

Clinical and radiographic results of the current study showed that RSWT is effective in reducing pain, improving shoulder function, and removing calcifications. These results were maintained at the 6-month follow-up. Reduction in pain, as evaluated by VAS scores, was comparable to that observed in other studies in which ESWT was used.[11,29] Moreover, the functional improvement of the shoulder, as evaluated with the UCLA Shoulder Rating Scale, was comparable to that obtained by other researchers with the use of ESWT.[44]

Our study showed that RSWT is effective in dissolving calcifications, and this effect was unexpectedly better than the effect achieved with ESWT in a recent study by Rompe et al.[44] Rompe et al[44] observed a rate of calcification disappearance of 47% and of partial disappearance of 33%; in our study, calcifications completely disappeared in 86.6% of the subjects in the treatment group and partially disappeared in 13.4% of the subjects.

Differences between ESWT and RSWT in the way the shock waves are administered may contribute to these

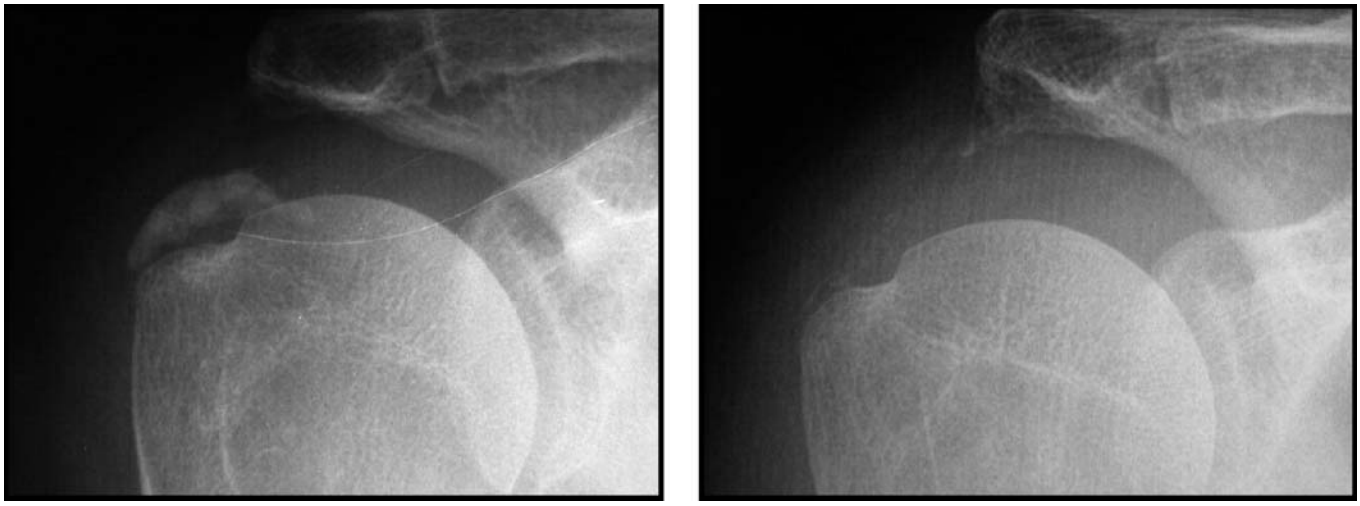

Figure 4.
Treatment using radial shock-wave therapy (RSWT) of the right shoulder of a 44-year-old man with a type II subacromial calficiation according to Gartner and Simons radiographic classification[6]: (left) before RSWT; (right) 4 weeks after RSWT, showing complete disappearance of calcification.

contrasting results. In RSWT, the calcification, once located radiographically, is surely included inside the wave propagation area. Contrarily, when the shock wave is focused, as occurs in ESWT, refocusing of the applicator periodically is necessary. Haake et al[36] achieved poor results when they used ESWT nonfluoroscopically focused on the calcified area to dissolve calcifications in the shoulder, suggesting that it is important to keep the focal spot constantly on the calcific deposit during the entire treatment. Our results suggest that when RSWT is administered, an exact focusing of the shock waves is not required to obtain the disappearance of the calcification due to their radial emission. In RSWT, the applicator was positioned on the posterior or anterior region of the shoulder, according to the radiographic calcification location, which could be on the infraspinatus tendon or on the supraspinatus tendon and, therefore, more posterior or more anterior, respectively. The number of impulses administered in RSWT was greater (2,500 impulses per session) in comparison with the standard number of impulses administered (1,000 impulses per session). In this way, a greater amount of EFD could be aimed at the target zone. More research, however, is needed to confirm this hypothesis.

As shown in the study by Rompe et al,[44] a complete disappearance of the calcium deposits was found more frequently in patients with type II calcifications according to the Gartner and Simons classification.[6] Rompe et al[28] investigated how differences in EFD can modify the ability of the shock wave to dissolve calcifications in the shoulder. In 2 groups of subjects treated with the same ESWT protocol, although with different EFDs (0.06 mJ/mm^2 versus 0.28 mJ/mm^2), the percentage of calcification disappearance was significantly higher in the high-EFD group (64%) than in the low-EFD group (50%) at the 6-month follow-up; Constant and Murley scores showed a greater effect in the high-EFD group than in the low-EFD group (88 points versus 71 points).

The use of Constant and Murley scores (minimum score of 0 and maximum score of 100, with higher scores reflecting increased function) is a standardized, highly reliable, clinical method of assessing shoulder function. The total score is obtained by adding the results of 4 subscales: subjective pain (15 points), function (20 points), objective clinician assessment of range of motion (40 points), and strength (25 points).

Our results suggest that, using RSWT (EFD=0.10 mJ/mm^2, comparable to low-EFD ESTW), 2,500 impulses per session for 4 sessions (total of 10,000 impulses) is more effective in comparison with 25 impulses per session for 4 sessions (total of 100 impulses) for the management of calcific tendinitis of the shoulder. A potential limitation of this study is the lack of a true placebo-control group, even though our results showed a significantly higher rate of success in all of the parameters evaluated in the treatment group and no adverse effects. Use of "less active same therapy," however, was needed to avoid a possible blinding failure.

Conclusion

Our results suggest that RSWT effectively reduces pain (improvement of VAS scores) and increases shoulder function (improvement of UCLA Shoulder Rating Scale scores) without device-related adverse effects. Moreover, the results seen after the treatment were maintained over the following 6 months. In contrast to the ESWT, RSWT may be used without an ultrasound guide with apparently no adverse effects on safety and efficacy. Moreover, RSWT was unexpectedly better than ESWT in dissolving calcifications of the shoulder. Further research is needed to directly compare RWST and ESWT.

References

1 Bosworth BM. Calcium deposits in the shoulder and subacromial bursitis: a survey of 12,122 shoulders. *JAMA.* 1941;116:2477–2482.

2 Uhthoff HK, Sarkar K. Calcifiyng tendinitis. In: Rockwood CA, Matsen FA III, eds. *The Shoulder.* Philadelphia, Pa: WB Saunders Co; 1990:774–790.

3 Ark JW, Flock TJ, Flatow EL, Bigliani LU. Arthroscopic treatment of calcific tendinitis of the shoulder. *Arthroscopy.* 1992;8:183–188.

4 Wainner RS, Hasz M. Management of acute calcific tendinitis of the shoulder. *J Orthop Sports Phys Ther.* 1998;27:231–237.

5 Uhthoff HK. Calcifying tendinitis. *Ann Chir Gynaecol.* 1996;85: 111–115.

6 Gartner J, Simons B. Analysis of calcific deposits in calcifying tendinitis. *Clin Orthop Relat Res.* 1990;254:111–120.

7 Hayes CW, Conway WF. Calcium hydroxyapatite depositing disease. *Radiographics.* 1990;10:1031–1048.

8 Moseley HF. The natural history and clinical syndromes produced by calcified deposits in the rotator cuff. *Surg Clin North Am.* 1963;43: 1489–1493.

9 Refior HJ, Krodel A, Melzer C. Examinations of the pathology of the rotator cuff. *Arch Orthop Trauma Surg.* 1987;106:301–308.

10 Milone FP, Copeland MM. Calcific tendinitis of the shoulder joint: presentation of 136 cases treated by irradiation. *Am J Roentgenol Ther.* 1961;85:901–913.

11 Gerdesmyer L, Wagenpfeil S, Haake M, et al. Extracorporeal shock wave therapy for the treatment of chronic calcifying tendonitis of the rotator cuff: a randomized controlled trial. *JAMA.* 2003;290: 2573–2580.

12 McKendry RJR, Uhthoff HK, Sakar K, Hyslop PS. Calcifying tendinitis of the shoulder: prognostic value of clinical, histologic, and radiologic features in 57 surgically treated cases. *J Rheumatol.* 1982;9: 75–80.

13 Uhthoff HK, Sakar K, Maynard JA. Calcifying tendinitis: a new concept of its pathogenesis. *Clin Orthop Relat Res.* 1976;118:164–168.

14 Wagenhauser JF. Die periarthropatie-syndrome. *Therapiewoche.* 1972;37:3187–3192.

15 Gartner J. Tendinosis calcarea: results of treatment with needling. *Z Orthop Ihre Grenzgeb.* 1993;131:461–469.

16 Parlier-Cuau C, Champsaur P, Nizard R, et al. Percutaneous treatments of painful shoulder. *Radiol Clin North Am.* 1998;36:589–596.

17 Kaada B. Treatment of peritendinitis of the shoulder by transcutaneous nerve stimulation. *Acupunct Electrother Res.* 1984;9:115–125.

18 Gimblett PA, Saville J, Ebrall P. A conservative management protocol for calcific tendinitis of the shoulder. *J Manipulative Physiol Ther.* 1999;22:622–627.

19 Green S, Buchbinder R, Glazier R, Forbes A. Systematic review of randomised controlled trials of interventions to painful shoulder: selection criteria, outcome assessment, and efficacy. *BMJ.* 1998;316: 354–360.

20 Philadelphia Panel Evidence-Based Clinical Practice Guidelines on Selected Rehabilitation Interventions for Shoulder Pain. *Phys Ther.* 2001;81:1719–1730.

21 Ebenbichler GR, Erdogmus CB, Resch KL, et al. Ultrasound therapy for calcific tendinitis of the shoulder. *N Engl J Med.* 1999;340: 1533–1538.

22 Rochwerger A, Franceschi JP, Viton JM, et al. Surgical management of calcific tendinitis of the shoulder: an analysis of 26 cases. *Clin Rheumatol.* 1999;18:313–316.

23 Jerosch J, Strauss JM, Schmiel S. Arthroscopic treatment of calcific tendinitis of the shoulder. *J Shoulder Elbow Surg.* 1998;7:30–37.

24 Loew M, Jurgowski W, Mau HC, Thomsen M. Treatment of calcifying tendinitis of rotator cuff by extracorporeal shock waves: a preliminary report. *J Shoulder Elbow Surg.* 1995;4:101–106.

25 Loew M, Daecke D, Kusnierczak D, et al. Shock-wave therapy is effective for chronic calcifying tendinitis of the shoulder. *J Bone J Surg Br.* 1999;81:863–867.

26 Wang C-J, Ko J-Y, Chen H-S. Treatment of calcifying tendinitis of the shoulder with shock wave therapy. *Clin Orthop Relat Res.* 2001;387: 83–89.

27 Rompe JD, Rumler F, Hopf C, et al. Extracorporeal shock wave therapy for calcifying tendinitis of the shoulder. *Clin Orthop Relat Res.* 1995;321:196–201.

28 Rompe JD, Burger R, Hopf C, Eysel P. Shoulder function after extracorporeal shock wave therapy for calcific tendinitis. *J Shoulder Elbow Surg.* 1998;7:505–509.

29 Cosentino R, De Stefano R, Selvi E, et al. Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulder: single blind study. *Ann Rheum Dis.* 2003;62:248–250.

30 Daeke W, Kusnierczak D, Loew M. Long-term effects of extracorporeal shock wave therapy in chronic calcific tendinitis of the shoulder. *J Shoulder Elbow Surg.* 2002;11:476–480.

31 Pan P-J, Chou C-L, Chiou H-J, et al. Extracorporeal shock wave therapy for chronic calcific tendinitis of the shoulders: a functional and sonographic study. *Arch Phys Med Rehabil.* 2003;84:988–993.

32 Wang CJ, Yang KD, Wang FS, et al. Shock wave therapy for calcific tendinitis of the shoulder. *Am J Sports Med.* 2003;31:425–430.

33 Schmitt J, Tosch A, Hunerkopf M, Haake M. Extracorporeal shockwave therapy (ESWT) as therapeutic option in supraspinatus tendon syndrome? One-year results of a placebo controlled study. *Orthopade.* 2002;31:652–657.

34 Speed CA, Richards C, Nichols D, et al. Extracorporeal shock-wave therapy for tendonitis of the rotator cuff: a double-blind, randomized, controlled trial. *J Bone Joint Surg Br.* 2002;84:509–512.

35 Gerdesmeyer L, Maier M, Haake M, Schmitz C. Physikalisch-technische Grundlagen der extrakorporalen Stoβwellentherapie (ESWT). *Orthopade.* 2002;31:610–617.

36 Haake M, Deike B, Thon A, Schmitt J. Exact focusing of the extracorporeal shock wave therapy for calcifying tendinopathy. *Clin Orthop Relat Res.* 2002;397:323–331.

37 Straub T, Penninger E, Froelich T, et al. Prospective, multicentric and placebo-controlled study on shockwave treatment of tennis elbow and plantar fasciitis. *Int J Sports Med.* 1999;20:S105–S106.

38 Lohrer H, Schoell J, Arentz S, et al. Effectiveness of radial shockwave therapy (RSWT) on tennis elbow and plantar fasciitis. In: *Proceedings of the Annual Meeting of the Canadian Academy of Sports Medicine; July 4–7, 2001; Calgary, Alberta, Canada.*

39 *Health Technology Assessment: Extracorporeal Shockwave Therapy for the Treatment of Musculoskeletal Disorders.* Olympia, Wash: Department of Labor and Industries; March 29, 2004.

40 Hollis S, Campbell F. What is meant by intention-to-treat analysis? Survey of a published randomised controlled trials. *BMJ.* 1999;319: 670–674.

41 Ellman H. Arthroscopic subacromial decompression: analysis of one- to three-years results. *Arthroscopy.* 1987;3:173–181.

42 Kay SP, Amstutz HC. Shoulder hemiarthroplasty at UCLA. *Clin Orthop Relat Res.* 1988;228:42–48.

43 Roddey TS, Olson SL, Cook KF, et al. Comparison of the University of California–Los Angeles Shoulder Scale and the Simple Shoulder Test with the Shoulder Pain and Disability Index: single-administration reliability and validity. *Phys Ther.* 2000;80:759–768.

44 Rompe JD, Zoellner J, Nafe B. Shock wave therapy versus conventional surgery in the treatment of calcifying tendinitis of the shoulder. *Clin Orthop Relat Res.* 2001;387:72–82.

45 Kilcoyne RF, Reddy PK, Lyons F, Rockwood CA Jr. Optimal plain film imaging of the shoulder impingement syndrome. *Am J Roentgenol.* 1989;153:795–797.

46 Pleiner J, Crevenna R, Langenberger H, et al. Extracorporeal shockwave treatment is effective in calcific tendonitis of the shoulder: a randomized controlled trial. *Wien Klin Wochenschr.* 2004;116:536–541.

47 Rompe JD, Hopf C, Küllmer K, et al. Analgesic effect of extracorporeal shock-wave therapy on chronic tennis elbow. *J Bone Joint Surg Br.* 1996;78:233–237.

48 Dalton GW, Keating JL. Number needed to treat: a statistic relevant for physical therapists. *Phys Ther.* 2000;80:1214–1219.

Effectiveness of Radial Shock-Wave Therapy for Calcific Tendinitis of the Shoulder: Single-Blind, Randomized Clinical Study

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